(19)日本国特許庁(JP)　(12)公表特許公報(A)　(11)特許出願公表番号
特表2005-508202
(P2005-508202A)
(43)公表日　平成17年3月31日(2005.3.31)

(51)Int.Cl.[7]	F I			テーマコード（参考）
A61M 5/178	A61M	5/18		4C066
A61J 1/06	A61J	1/06	E	
A61J 1/20	A61J	1/06	F	
A61M 5/28	A61J	1/06	G	
	A61M	5/28		

審査請求 未請求　予備審査請求 有　（全 162 頁）　最終頁に続く

(21)出願番号　特願2002-571129(P2002-571129)
(86)(22)出願日　平成14年3月13日(2002.3.13)
(85)翻訳文提出日　平成15年9月16日(2003.9.16)
(86)国際出願番号　PCT/US2002/007712
(87)国際公開番号　WO2002/072171
(87)国際公開日　平成14年9月19日(2002.9.19)
(31)優先権主張番号　60/275,568
(32)優先日　平成13年3月13日(2001.3.13)
(33)優先権主張国　米国(US)

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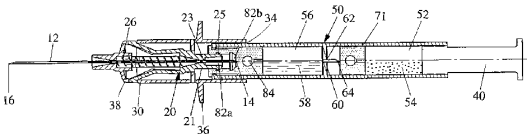
最終頁に続く

(54)【発明の名称】予充填式セーフティー希釈剤注入器

(57)【要約】
安全な有針装置（１０、１１０、２１０、３１０）であり、薬剤を混合して２個のチャンバを有するカートリッジ（５０、１５０、２５０、３５０）から注入するものが提供される。この装置は、外筒（３０、１３０、２３０、３３０）の前端を介して突出する針部材（１２、１１２、２１２、３１２）を含むものである。２個のチャンバを有するカートリッジ（５０、１５０、２５０、３５０）は、外筒（３０、１３０、２３０、３３０）に取り付けられ、チャンバに別々に格納される薬剤成分を含むものである。カートリッジの後端のプランジャ（４０、１４０、２４０）は、カートリッジに向けて進められ、別々の成分を混合して薬剤を準備するものである。カートリッジ（５０、１５０、２５０、３５０）が外筒（３０、１３０、２３０、３３０）内で前方に進められると、薬剤が針部材（１２、１１２、２１２、３１２）を介して患者に注入される。注入工程の完了時、カートリッジ（５０、１５０、２５０、３５０）は針リテイナに係合し、針部材の引き込みを作動させる。その後、この針部材は収納されて汚染された針部材を保護する。



【特許請求の範囲】
【請求項１】
医療用装置であって、前記医療用装置は、：
開口する手前側の端部及び先端側の端部を有する外筒と、；
第１の尖端を有し、前記第１の尖端が前記外筒から前方に突出する突出位置と、前記第１の尖端が封入されて前記第１の尖端との不慮の接触が防止される封入位置との間で移動可能な針部材と、；
前記針部材と液連通されるカートリッジであって、前記カートリッジは、：
第１の物質を含む第１のチャンバ、；
第２の物質を含む第２のチャンバ、；
前記第１のチャンバと第２のチャンバとの間の液体流通調整部、；及び
前記カートリッジ内でスライド可能に配置されたプランジャ、；
を有する前記カートリッジと、；
前記針部材を前記外筒に対して移動させる駆動力を提供し、前記第１の尖端を封入するための付勢要素と、；
前記針部材を前記突出位置でリリース可能に保持する針リテイナと、；
を有する前記医療用装置において、；
前記プランジャが前記第１のチャンバ内で軸方向に進められると、前記第１の物質が前記液体流通調整部を介して前記第２のチャンバに進められ、前記第１の物質は前記第２の物質と混合されて薬剤混合物が形成され、前記混合物が前記カートリッジから放出された後、前記プランジャ及び前記カートリッジの前記外筒に対する継続的な前進が前記針リテイナを作動させて前記針部材がリリースされ、これにより前記付勢要素が前記針部材を前記外筒に対して移動させて前記第１の尖端が封入される、
ことを特徴とする前記医療用装置。
【請求項２】
請求項１記載の前記医療用装置において、前記医療用装置は前記針部材に固定されたニードルキャリアを更に有するものである。
【請求項３】
請求項１記載の前記医療用装置において、前記針部材は第２の尖端を後端部に有するものである。
【請求項４】
請求項１記載の前記医療用装置において、前記針部材は前記プランジャにかけられる圧力が開放されると引き込まれるものである。
【請求項５】
請求項１記載の前記医療用装置において、前記医療用装置は、前記針部材が前記保護位置に移動するに従い、前記第１の尖針端が前記外筒の前記手前側を通過して継続的に後方に移動することを防止する１以上の止め部を更に有するものである。
【請求項６】
請求項１記載の前記医療用装置において、前記プランジャはエラストマー系のシールに結合されたプラスチック成形のプランジャロッドからなるものである。
【請求項７】
請求項１記載の前記医療用装置において、前記第１の物質が前記第１のチャンバから放出される間、前記プランジャは前記カートリッジに対して移動させることができるが、前記混合物が前記第２のチャンバから放出される間、前記プランジャは前記カートリッジに対して静止されているものである。
【請求項８】
請求項１記載の前記医療用装置において、前記第２の物質はパウダー材料である。
【請求項９】
請求項１記載の前記医療用装置において、前記第２の物質は液体材料である。
【請求項１０】

請求項１記載の前記医療用装置において、前記第２のチャンバの容量は、前記第１の物質と前記第２の物質を混合させた容量よりも大きいものである。
【請求項１１】
請求項１記載の前記医療用装置において、前記液体流通調整部は、；
開口を有する前記第１及び第２のチャンバの間の壁部と、；
前記開口を介して配置され、前記第１のチャンバに突出する尖端を有する中空突刺構成要素と、；
前記突刺構成要素を介する液体流通路と、；
を有する前記液体流通調整部において、；
前記カートリッジが前記外筒に向けて軸方向に移動させられると、前記プランジャは前記プランジャが前記突刺構成要素により破られるまで移動し、前記突刺構成要素の液体流通路と同軸上にある前記プランジャを通過する流路が形成され、第１の物質を前記プランジャを介して前記第２のチャンバに流通させるものである。
【請求項１２】
請求項１記載の前記医療用装置において、前記液体流通調整部は、；
開口を有する前記第１及び第２のチャンバの間のバリアと、；
前記開口を介して配置され、前記第１のチャンバに突出する尖端を有する中空突刺構成要素と、；
前記突刺構成要素を介する液体流通路と、；
前記第１のチャンバ内で軸方向に配置可能であり、前記突刺構成要素で突刺されることにより、前記第１及び第２のチャンバ間に液連通を提供する前記突刺可能な中間シールと、；
を有する前記液体流通調整部において、；
前記プランジャが前記外筒に向けて軸方向に移動させられると、前記突刺可能な中間シールは前記中間シールが前記突刺構成要素により破られるまで移動し、前記突刺構成要素の液体流通路と同軸上にある前記中間シールを通過する流路が形成され、第１の物質を前記中間シールを介して前記第２のチャンバに流通させるものである。
【請求項１３】
請求項１記載の前記医療用装置において、前記液体流通調整部は、：
前記カートリッジ内で軸方向に移動可能な前記第１及び第２のチャンバ間にある中間シールと、：
前記カートリッジの前記側壁に設けられた細長の液体流路と、；
を有する前記液体流通調整部において、；
前記プランジャが前記外筒に向けて軸方向に移動させられると、前記中間シールは前記液体流路と直線的に位置決めされ、前記中間シールと前記液体流路の前記内壁との間に流路が形成され、前記第１の物質を前記中間シール周辺から前記第２チャンバに流通させるものである。
【請求項１４】
請求項１記載の前記医療用装置において、前記カートリッジは略永久的に前記外筒に取り付けられるものである。
【請求項１５】
請求項１記載の前記医療用装置において、前記カートリッジは、前記カートリッジの前記先端側にビーズ状の環状リムを有し、前記外筒は前記外筒の手前側の端部で前記外筒の内側貫通孔から径方向内側に突出するリップを含み、前記リップは前記カートリッジの前記ビーズ状のリムに係合わさるようにされており、針部材収納後、前記カートリッジが前記外筒の後方から取り外されることを防止するものである。
【請求項１６】
請求項２記載の前記医療用装置において、前記付勢要素は、前記外筒の前記先端側の端部と前記針キャリアとの間に配置された圧縮バネを含むものである。
【請求項１７】

請求項２記載の前記医療用装置において、前記針リテイナは、前記針キャリアから径方向外側に突出し、前記外筒の壁面にある一対のウインドウにリリース可能に係合するよう構成された一対の前方歯（ｆｏｒｗａｒｄ　ｔｉｎｅｓ）を有するものである。

【請求項１８】

請求項２記載の前記医療用装置において、円筒形のスリーブは、前記注入工程の終わりにおける前記カートリッジの軸方向への前進が前記スリーブを前記外筒の前記先端側の端部に向けて移動させ前記針リテイナを作動させるように、通常前記カートリッジと軸方向に位置決めされている針キャリアの外周近傍で配置される前記カートリッジと略同様の外径を有するものである。

【請求項１９】

請求項３記載の前記医療用装置において、前記カートリッジは前記カートリッジの先端側の端部にフロントシールを更に有し、前記第２の尖端により突刺されて前記針部材と第２のチャンバとを液連通させるように構成されているものである。

【請求項２０】

請求項１９記載の前記医療用装置において、前記フロントシールに穴を開けるために必要な前記プランジャにかかる最小限の軸方向への駆動力は、前記後方チャンバで前記プランジャを軸方向に移動させるために必要な最小限の軸方向への駆動力よりも小さい又は等しいものである。

【請求項２１】

請求項１９記載の前記医療用装置において、前記フロントシールの前記先端側の端部は外側スレッドを含み、前記針キャリアの前記手前側の端部は前記フロントシールの前記ねじ込み形（ｔｈｒｅａｄｅｄ　ｅｎｄ）を受け入れるようにされたキャビティを含むものである。

【請求項２２】

医療用装置であって、前記医療用装置は、：

開口する手前側の端部、先端側の端部、及び外筒の長手軸方向に対して垂直方向に位置する前記外筒の壁部を貫く開口を有する外筒と、；

第１の尖端を有し、前記第１の尖端が前記外筒から前方に突出する突出位置と、前記第１の尖端が保護され前記第１の尖端との不慮の接触が防止される保護位置との間で移動可能な針部材と、；

前記針部材と液連通するカートリッジであって、前記カートリッジは、：

第１の物質を含む第１のチャンバ、；

第２の物質を含む第２のチャンバ、；

前記第１のチャンバと前記第２のチャンバとを結合させる液体流通調整部、；及び

前記カートリッジ内でスライド可能に配置されたプランジャ；

を有する前記カートリッジと、；

前記針部材を前記外筒に対して移動させることができ、前記第１の尖端を封入するための動力を提供する付勢要素と、；

前記外筒に着脱可能に結合された係止用クリップと、；

を有する前記医療用装置において、；

前記プランジャが前記第１のチャンバ内で軸方向に進められると、前記第１の物質は前記第１の物質が前記第２の物質と混合され薬剤混合物が形成される前記第２のチャンバに前記液体流通調整部を介して進められ、前記係止用クリップが前記外筒から外されると、前記プランジャと前記カートリッジは前記外筒に対して更に進められて前記第２のチャンバから前記混合物が放出され、その後、前記カートリッジが軸方向に進められると前記針リテイナは係合から外され、前記付勢要素が前記針部材を前記外筒に対して移動させて前記第１の尖端が封入されるものである。

【請求項２３】

請求項２２記載の前記医療用装置において、前記医療用装置は前記針部材に固定された針キャリアを更に有するものである。

【請求項２４】
請求項２２記載の前記医療用装置において、前記針部材は第２の尖端を前記針部材の後端に有するものである。
【請求項２５】
請求項２２記載の前記医療用装置において、前記針部材は前記プランジャにかけられる圧力が開放されると引き込まれるものである。
【請求項２６】
請求項２２記載の前記医療用装置において、前記カートリッジは前記カートリッジの前記先端側の端部にビーズ状の環状リムを有し、前記外筒は前記外筒の手前側の端部で前記外筒の内側貫通孔から径方向内側に突出するリップを含み、前記リップは前記カートリッジの前記ビーズ状のリムに係合わさるようにされ、針部材収納後、前記カートリッジが前記外筒の後方から取り外されることを防止するものである。
【請求項２７】
請求項２２記載の前記医療用装置において、前記医療用装置は、前記針部材が前記保護位置まで移動するに従い、前記第１の尖端が前記外筒の前記開口する手前側の端部を超えて継続的に後方移動することを防止する１以上の止め部を更に有するものである。
【請求項２８】
請求項２２記載の前記医療用装置において、前記プランジャは、エラストマー系シールに結合されたプラスチック成形のプランジャロッドからなるものである。
【請求項２９】
請求項２２記載の前記医療用装置において、前記第１の物質が前記第１のチャンバから放出されている間、前記プランジャは前記カートリッジに対して移動可能であり、前記混合物が前記第２のチャンバから放出される際、前記プランジャは前記カートリッジに対して静止するものである。
【請求項３０】
請求項２２記載の前記医療用装置において、前記係止用クリップは、前記内側エッジに沿う複数の歯を有する平坦なU形状のディスクを有し、前記クリップは前記外筒の前記スリットを介して前記外筒の長手軸に対して垂直方向に、前記カートリッジと前記針リテイナとの間でスライドし、これにより前記カートリッジと前記針リテイナが接触することを防止するものである。
【請求項３１】
請求項２２記載の前記医療用装置において、前記第２の物質はパウダー材料である。
【請求項３２】
請求項２２記載の前記医療用装置において、前記第２の物質は液体材料である。
【請求項３３】
請求項２２記載の前記医療用装置において、前記第２のチャンバの容量は、前記第１の物質と前記第２の物質が結合された容量よりも大きいものである。
【請求項３４】
請求項２２記載の前記医療用装置において、前記液体流通調整部は、；
開口を有する前記第１及び第２のチャンバの間のバリアと、；
前記開口を介して配置され、前記第１のチャンバに突出する尖端を有する中空突刺構成要素と、；
前記突刺構成要素を介する液体流通路と、；
前記第１のチャンバ内で軸方向に配置可能であり、前記突刺構成要素で突刺されることにより前記第１及び第２のチャンバ間に液連通を提供する前記穴開け可能な中間シールと、；
を有する前記液体流通調整部において、；
前記プランジャが前記外筒に向けて最初に軸方向に移動させられると、前記突刺可能な中間シールが移動して前記突刺構成要素と接触し、前記中間シールに穴が開けられ、前記突刺構成要素内の液体流通路の直線上にある中間シールを貫通する流路が形成され、前記第

１の物質を前記中間シールを介して前記第２のチャンバに流通させるものである。
【請求項３５】
請求項２２記載の医療用装置において、前記液体流通調整部は、；
前記カートリッジ内で軸方向に移動可能な前記第１及び第２のチャンバ間にある中間シールと、：
前記中間シールと前記カートリッジの先端側の端部との間にある前記カートリッジの前記側壁に設けられた細長の液体流路と、；
を有する前記液体流通調整部において、；
前記プランジャが前記外筒に向けて軸方向に移動させられると、前記中間シールは前記液体流路と直線的に位置決めされ、前記中間シールと前記液体流路の前記内壁との間に流路が形成され、前記第１の物質を前記中間シール周辺から前記第２チャンバに流通させるものである。
【請求項３６】
請求項２３記載の前記医療用装置において、前記付勢要素は前記外筒の前記先端側の端部と前記針キャリアとの間に配置された圧縮バネを含むものである。
【請求項３７】
請求項２３記載の前記医療用装置において、前記針リテイナは、前記外筒の壁面に設けられた一対のウインドウと、前記針キャリアから径方向外側に突出して前記外筒の壁面に設けられた一対のウインドウにリリース可能に係合するよう構成された一対の前方歯（ｆｏｒｗａｒｄ　ｔｉｎｅｓ）とを有するものである。
【請求項３８】
請求項２４記載の前記医療用装置において、前記カートリッジは、前記カートリッジの先端側の端部にフロントシールを更に有し、前記第２の尖端により突刺されて前記針部材と第２のチャンバとが液連通されるように構成されている。
【請求項３９】
請求項３８記載の前記医療用装置において、前記フロントシールに穴を開けるために必要な前記プランジャにかけられる最小限の軸方向への駆動力は、前記後方チャンバで前記プランジャを軸方向に移動させるために必要な最小限の軸方向への駆動力よりも小さい又は等しいものである。
【請求項４０】
医療用装置であって、前記医療用装置は、；
開口する手前側の端部及び先端側の端部を有する外筒と、；
第１の尖端を有し、前記第１の尖端が前記外筒から前方に突出する突出位置と、前記第１の尖端が保護され前記第１の尖端との不慮の接触が防止される保護位置との間で移動可能な針部材と、；
前記針部材と液連通するカートリッジであって、前記カートリッジは：
第１の物質を含む第１のチャンバ、；
第２の物質を含む第２のチャンバ、；
前記第１のチャンバと前記第２のチャンバとの間の液体流通調整部、；及び、
前記針部材を前記外筒に対して移動させることができ前記第１の尖端を保護する動力を提供する付勢要素と、；
を有する前記カートリッジと、；
前記針部材を前記突出位置でリリース可能に保持する針リテイナと、；
を有する前記医療用装置において、；
前記液体流通調整部は、使用前、前記第１及び第２の物質は隔離され続けるようにされており、注入前、前記第１及び第２の物質は混合されるようにされており、使用後、前記針部材は前記保護位置に移動させられるものである。
【請求項４１】
薬剤を注入する方法であって、前記注入工程は、：
第１の薬剤成分を含む第１のチャンバ、第２の薬剤成分を含む第２のチャンバ、及び針部

材を有する注入装置を提供する工程と；
前記第２の薬剤成分を前記第１のチャンバから前記第２のチャンバに送る工程と；
前記第１及び第２の成分を混合して薬剤混合物を形成する工程と；
前記薬剤混合物を前記チャンバから放出させる工程と；
前記薬剤液が放出された後、前記針部材を収納して前記針部材を接触から保護する工程と；
を有する前記薬剤を注入する方法。
【発明の詳細な説明】
【技術分野】
【０００１】
本出願は、２００１年３月１３日付けで出願された米国特許仮出願第６０／２７５，５６８号の優先権を主張するものであり、この引用により本願明細書に組み込まれたものとする。
【０００２】
本発明は医療用装置に関し、より具体的には、２個のチャンバに別々の薬剤成分を格納し、これらの成分を混合して最終的に患者へ投与するカートリッジを有する医療用装置に関する。
【背景技術】
【０００３】
予充填式のシリンジは、別々の薬剤成分を格納して混合するものである。これらシリンジの多くは、「混合用シリンジ」と称され、第１の成分を１つ目のコンパートメントに、希釈剤又は第２の成分を２つ目のコンパートメントに格納する。これらのシリンジは、シリンジが使用される直前まで２つの成分を別々に格納することができ、シリンジ使用時において成分をシリンジ内で混合して直接患者に投与することができる。
【０００４】
予充填式の混合用シリンジは、多様な薬剤にとって利点を有する。抗生物質、ビタミン及びホルモンのようないくつかの薬剤は、保管寿命を向上させるため成分毎にパッケージして保管しなければならない。これらの薬剤は、パウダー要素及び希釈剤、又は別々の一組の溶液として保管する必要がある。予充填式の混合用シリンジは、薬剤が投与される直前まで薬剤を成分毎に分けて格納することができる。加えて、予充填式の混合用シリンジは、薬剤成分の測量や希釈剤を別の容器から混合させる負担を取り除くものである。
【０００５】
これらの利点があるにも関わらず、従来の混合用シリンジは、注入に付随する不慮の針刺しからシリンジの使用者を保護するための、確実な安全機能を提供するものではなかった。具体的には、従来のシリンジアセンブリは、注入の完了に際し、自動的に保護することができる注入用針部材と一体的に機能する混合用シリンジを提供するものではなかった。
【発明の開示】
【課題を解決するための手段】
【０００６】
上記事情に鑑み、本発明は別々の成分を混合して薬剤を患者に注入するための予充填式の医療用装置を提供するものである。この装置は２個のチャンバを有する容器を含むものであって、使用後に自動的に引き込む針部材と結合したカートリッジ等である。収納後、汚染された針先は装置内に封入されて不慮の針刺しが防止される。
【０００７】
この装置は、針部材を囲み、ソケットを形成する通常開口している後端を有する中空の外筒を含む。薬剤成分を保持する２チャンバ式カートリッジは、ソケットに係合するようになっている。使用前、成分は別々に２個のカートリッジチャンバに格納される。使用中、カートリッジの後端に配置されたプランジャはカートリッジ内へと進められ、２つの成分が１つに混合される。そして、プランジャにかけられる圧力により、薬剤混合物は針部材を介して患者に投入される。

【０００８】
この注入用針部材は、突出位置と収納位置との間で移動可能である。突出位置において、針部材の先端は外筒から前方に突出する。収納位置において、先端は外筒内に封入される。針部材が突出位置にある場合、付勢要素は、この針部材を収納位置に向けて付勢する。針リテイナは、付勢要素の力に抗してこの針部材を突出位置でリリース可能に保持する。注入動作中、カートリッジが針リテイナとの係合から外れると、付勢要素は針部材を外筒に向けて後方に駆動する。
【発明を実施するための最良の形態】
【０００９】
図面全体、特に図１～１１を参照すると、注入装置１０は、患者に挿入される先尖端１６を有する針部材１２と共に示されている。図４に示されるように、注入装置１０は、第１のチャンバ５２及び第２のチャンバ５６を有する一体式のカートリッジ５０を有している。２個のチャンバ５２、５６には、注入前に混合されるべき薬剤成分が予め充填されている。カートリッジ５０はまた、カートリッジ内でスライド可能なプランジャ４０を含む。最初、プランジャ４０がカートリッジ５０内で前進させられると、薬剤成分が第１のチャンバ５２から第２のチャンバ５６に放出され、２種類の薬剤成分が混合される。成分が混合された後、更にプランジャが前進させられると、カートリッジが前方に駆動され薬剤が患者に注入される。注入工程が完了すると、医療専門家はプランジャから圧力を開放し、針部材１２を装置１０内に自動的に収納して汚染された針部材１２を不慮の接触から保護する。
【００１０】
注入装置１０は、両頭の針部材１２、略円筒形の外筒３０、圧縮バネ２６及び針部材をバネの付勢力に抗してリリース可能に保持する針リテイナ２０を含むものである。図４及び５に示されるように、針部材１２は手前側の尖端１４及び先端側の尖端１６を有する。バネ２６は針部材１２を囲み、外筒３０の先端側の内面に対して圧縮されている。バネ２６の後端は、針リテイナ２０の内部で支持され、針部材１２及び針リテイナ２０に後方に向けて付勢する。
【００１１】
針部材１２は、突出位置と収納位置の２個所の間で移動可能である。突出位置において、針部材１２は外筒３０の前端から前方に突出している。収納位置において、針部材１２は外筒３０内に引き込まれ、これにより針部材１２の尖端１６は外筒内に封入されて尖端との不慮の接触が防止される。針部材が突出位置にある場合、バネ２６は、針部材１２を収納位置に向けて後方に付勢する。針リテイナ２０は、バネ２６の付勢力に抗して針部材１２を突出位置でリリース可能に保持する。注入工程の間、図１０に示されるように、カートリッジ５０は針リテイナ２０と協働して針部材を外筒３０に収納させることができる。
【００１２】
図５～７を参照すると、カートリッジ５０は、第１の薬剤成分５４を保持する第１のチャンバ５２と、第２の薬剤成分５８を保持する第２のチャンバ５６を含むものである。チャンバ５２、５６は、オリフィス６２を含む中間壁６０により隔てられている。後方シール７０は、第１のチャンバ５２を密封し、成分同士が使用前に混合されることを防止する。後方シール７０が突刺されてプランジャ４０がカートリッジ５０内へと進められると、図６～７に示されるように、第１の成分５４が第２のチャンバ５６にオリフィス６２を介して流れ込み、第２の成分５８と混合されて薬剤５９が形成される。プランジャ４０とカートリッジ５０にかけられる更なる圧力が針部材１２を介して薬剤５９を患者に投入する。
【００１３】
図４～６を参照して、注入装置１０の構成要素をより詳細に説明する。外筒３０は略円筒形であり、外筒の先端側はテーパがかけられたノーズ３２を有する。このノーズ３２は、針部材１２が延伸される開口を有しており、これにより針部材の尖端１６を患者に挿入することができる。外筒３０の後端は開口しており、カートリッジ５０を受け入れるようにされた円筒形のソケット３４を形成する。２つの側方に延びるフランジ３６は、外筒の長

手軸を横断して外筒３０から外側方向に突設され、一対のフィンガーグリップが装置１０の操作用に形成されている。外筒３０は、一対の保持開口３８と一対のロックアウトウインドウ３９とを更に有し、下記のように針リテイナ２０と協働する。

【００１４】

図５に示されるように、ハブ２１は針リテイナ２０の後端から突出している。ハブ２１は、中央貫通孔２３を有する略円筒形の構成要素である。針部材１２は、ハブ２１の中央貫通孔２３内に配置され、これにより針部材１２の後端１４はハブから後方に突出し、針部材の前端１６はハブから前方に突出する。針部材１２は、いくつかの方法でハブ２１に取り付けることができる。例えば、針部材１２は、ＵＶ硬化粘着剤などの接着剤でハブ２１に取り付けることができる。或いは、針部材１２は、プラスチックから形成されるハブ２１内に成形することができる。ハブ２１の後端は、円周に引っかかりが設けられたコネクタ２５を有しており、更に下記のように、カートリッジ５０と協働してカートリッジとニードルハブ２１とを結合させる。

【００１５】

針リテイナ２０は外筒３０内で軸方向に移動可能であり、針部材の収納を容易にさせる。針リテイナ２０は、ポリカーボネートなどの硬い、高強度の樹脂から成形することができる。引き込み前、薬剤５９がカートリッジ５０から放出されている間、針リテイナ２０は所定の軸方向位置で維持される。注入後、針リテイナ２０と取り付けられた針部材１２は圧縮バネ２６により後方に移動させられる。

【００１６】

バネ２６は圧縮バネであり、ステンレススチール、処理済みのカーボンスチールワイヤ又はその他の適切な腐食性のないバネ金属から形成されてもよい。針リテイナが係合から外れる前のバネの残圧は十分な大きさがあり、針部材の収納を容易に完了させ、装置１０内で摺動する構成要素間の摩擦抵抗を上回るものである。

【００１７】

図６を参照すると、針リテイナ２０は、針リテイナ２０の先端側から径方向外側かつ前方に延びる一対の保持アーム２２を含むものである。動作中、針リテイナ２０は係止位置と非係止位置との間で移動可能である。係止位置において、保持アーム２２は外筒の壁の保持開口３８に係合し、外筒３０から前方に突出している針部材１２の先端１６と共に、針部材を所定の軸方向位置に固定する。より具体的には、係止位置において、保持アーム２２は外筒３０に係合し、バネ２６の後方への付勢力に抗してニードルハブ２１と針部材１２とを保持する。非係止位置において、保持アーム２２は、ニードルハブ２１と針部材１２とを後方に収納することができるように位置決めされる。より具体的には、非係止位置において、保持アーム２２は保持開口３８との係合から外され、バネ２６がニードルハブ２１と針部材１２とを後方に駆動することができるようにする。

【００１８】

上記のように、針リテイナ２０の保持アーム２２は、前方外側に向けて突出し、外筒３０の壁の保持開口３８と係合する。各アームの終端は保持用タブ２４を形成し、保持開口３８で突出するように構成されている。より具体的には、保持用タブ２４は、外筒３０の壁の各保持開口３８により形成されたリップに係合する。このようにして、保持用タブ２４は一対のラッチとして動作し、バネの後方への付勢力に抗してニードルハブ２１と針部材１２とを保持する。

【００１９】

再度図４及び図５を参照すると、カートリッジ５０は、ホウケイ酸塩などの薬品の品質を有するガラス、又はポリオレフィン若しくはポリエステルなどの硬い不活性プラスチックから成形されてもよい略円筒形の容器である。第１及び第２のチャンバを隔てる中間壁６０は、ポリオレフィン又はポリエステルなどの硬い不活性プラスチックから形成されてもよい。バリア又は中間壁６０は、カートリッジ５０の一部として成形することができ、若しくはカートリッジの内壁に接着させることができる。各チャンバは、装置１０の製造中、所定量の薬剤で満たされる。

【００２０】
前方チャンバ５６の前端は、ポリイソプレンなどのセルフシールの生体適合性エラストマーで成形することができるエラストマー系フロントシール８０により密封されている。フロントシール８０は略円筒形であり、複数の軸方向に離間した環状リブ８１を有する。リブ８１は、図２でより明確に示されているが、容器の内側で摩擦及び密閉係合して液体密封シールを提供し、これにより液体がカートリッジ５０から漏れることを防止する。また、フロントシール８０は前端を有し、針部材１２の後尖端１４により突刺可能である。突刺後、フロントシール８０の前端は針部材１２の周りを再び密閉し、液体がカートリッジ５０から漏れることを防止する。
【００２１】
図５及び６を参照すると、フロントシール８０は、ニードルハブ２１にある、引っかかりが設けられたコネクタ２５と協働するように構成されたソケット８２を有する。ソケット８２は、２つの径方向にリリーブ（ｒｅｌｉｅｖｅｄ）された凹部８２ａ及び８２ｂを含み、引っかかりが設けられたコネクタ２５と結合する。具体的には、引っかかりが設けられたコネクタ２５は、フロントシール８０に第１の位置及び第２の位置で係合する。
【００２２】
第１の位置において、引っかかりが設けられたコネクタ２５は、図５に示される第１の凹部８２ａに係合する。この位置で、カートリッジはハブに取り付けられるが、針部材の後端はフロントシール８０を突刺しない。プランジャ４０に圧力がかけられると、カートリッジはハブに対して前方に移動し、これによりバーブが第２の位置に移動する。第２の位置において、引っかかりが設けられたコネクタ２５は、図６に示されるように第２の凹部８２ｂに係合する。この位置で、針部材１２の後端はフロントシール８０を突刺する。
【００２３】
フロントシール８０は、その後端に中空のキャビティ８４を含むものである。このようにして、突刺可能な壁８６は、キャビティ８４と第２の凹部８２ｂとの間のフロントシール８０で形成される。図５に示されるように、使用前、カートリッジ５０は第１の位置に取り付けられ、これにより引っかかりが設けられたコネクタ２５は第１の凹部８２ａに係合する。この位置において、針部材１２は突刺可能な壁８６を貫通しない。図６に示されるように、ハブ２１が第１の位置から第２の位置に移動するに従い、針部材１２の後端１４は壁８６を突刺してキャビティ８４へと延びる。キャビティ８４は、カートリッジ５０の第２チャンバ５６内で開いており、これにより針部材１２が中空部分８４に突出する場合、針部材はカートリッジの内側と液連通する。針部材１２が突刺可能な壁８６を貫通した後、この壁は針部材の周囲を再び密閉して液体密閉シールを形成し、カートリッジ内の薬剤が針部材の周囲に漏れることを防止する。
【００２４】
注入装置１０を使用に向けて準備するため、医療専門家は、カートリッジ５０を針リテイナ２０に対して前方に移動させ、引っかかりが設けられたコネクタが第２の凹部８２ｂに係合するように、前方シール８０は引っかかりが設けられたコネクタ２５を覆って駆動される。同時に、針部材１２の手前側の尖端１４は、突刺可能な壁８６に穴を開け、図６に示されるように、これにより針部材は第２のチャンバと液連通される。
【００２５】
フロントシール８０とニードルハブ２１の結合は、一方向の係合であることが好ましい。すなわち、フロントシール８０が引っかかりが設けられたコネクタ２５に取り付けられている場合、カートリッジ５０を引っかかりが設けられたコネクタに対して前方に移動させることができるが、カートリッジを引っかかりが設けられたコネクタに対して後方に移動させることができない。このようにして、カートリッジ５０は外筒３０のニードルハブ２１から容易に取り外すことはできず、カートリッジは略永久的にニードルハブと外筒に取り付けられることになる。
【００２６】
一方向の結合は、引っかかりが設けられたコネクタ２５の後面テーパショルダ及び引っか

かりが設けられたコネクタの方形前面ショルダにより容易になされる。具体的には、引っかかりが設けられたコネクタ２５の後面ショルダは、第１と第２の半径方向の凹部８２ａ及び８２ｂ内のテーパ面と協働し、第１の凹部から第２の凹部までプラグが相対移動することを可能にさせる。第２の凹部８２ｂから第１の凹部８２ａに戻る逆移動は、逆移動を防止する引っかかりが設けられたコネクタ２５の方形前面ショルダによって阻止される。

【００２７】

図４を参照すると、引っかかりが設けられたコネクタ２５が、第１の半径方向の凹部８２ａに係合する第１の位置から、引っかかりが設けられたコネクタ２５が第２の半径方向の凹部８２ｂに係合する第２の位置まで移動する場合、フロントシール８０が液体の噴出を防止するように構成されている。具体的には、フロントシール８０はフレアヘッド８８（ｆｌａｒｅｄ　ｈｅａｄ）又は環状フランジをフロントシールの前端に含むものである。カートリッジ５０の開口末端はビーズ状のリム５１で終端処理され、フレアヘッド８８の後方エッジに対して合わさる。フレアヘッド８８の外径は、カートリッジ５０の開口末端の内径よりも大きく、これにより力が最初にプランジャ４０にかけられる時、フロントシール８０がカートリッジに後方移動することが防止される。加えて、フロントシール８０の外面とカートリッジ５０の内面との摩擦接触を克服するために要する力は、プラグ２５を第１の凹部８２ａから第２の凹部８２ｂまで移動させるのに要する力よりも大きい。従って、力が最初にプランジャ４０にかけられる時、フロントシール８０はカートリッジ５０に対して定位置にとどまるが、引っかかりが設けられたコネクタ２５は第２の位置に移動させられる。針部材１２が壁８６を突刺するとき、フロントシール８０のこの制約は、カートリッジ５０から液体がリリースされることを制限する。

【００２８】

注入装置１０の保管中、図５に示されるように、薬剤は２種類の別々の成分に分けられてカートリッジ５０に格納される。具体的には、薬剤の第１の成分５４は後方チャンバ５２に格納され、薬剤の第２の成分５８は前方チャンバ５６に格納される。２個のチャンバはオリフィス６２及びこのオリフィスに取り付けられた中空突刺部材６４を含む中間壁６０により隔てられている。オリフィス６２は、中間壁６０に軸方向に配置されている。加えて、小さな通気孔６３は中間壁６０の中心から外れたところに配置され、中間壁と中間シール７０との間のデッドスペースエリアから空気を通風する。突刺部材６４は、ステンレススチール又は処理済みのカーボンスチールワイヤなどの適切な非腐食性材料からなるいものであるのが好ましい。プランジャ４０がカートリッジ５０内で軸方向に移動すると、後方チャンバ５２の第１の成分５４は、突刺部材６４を介して前方チャンバ５６に進められ、第２の成分５８と混合される。

【００２９】

注入装置１０の使用前、第１及び第２のチャンバ間の液連通は、エラストマー系の中間シール７０によって防止される。なお、この中間シール７０は、ポリイソプレンなどのセルフシールの生体適合性エラストマーで成形されてもよい。図４～５に示されているように、まず、中間シール７０は、突刺部材６４と第１の成分５４の間で第１のチャンバ５２内に摺動可能に配置される。図２でより明確に示されているように、中間シール７０は略円筒形であり、複数の軸方向に離間した環状リブ７１を有する。リブ７１はカートリッジ５０の内壁に擦って入り込むように係合し、液体密封シールを提供する。この液体密封シールは、第１のチャンバの液体が突刺部材６４に流入することを防止する。また、中間シール７０は中間シールの前端に形成された中空部分７２を含むものであり、中間シールの後端で第１のチャンバ５２に対して開いている。中間シール７０の前端は、膜７８により閉じられており、突刺部材６４により突刺可能である。膜７８が突刺されると、第１及び第２のチャンバ間で液連通が確立され、薬剤の第１及び第２の成分を混合させることができる。

【００３０】

フロントシール８０や中間シール７０のように、プランジャ４０は略円筒形であり、好ましくは複数の軸方向に離間した環状リブ４１を有するものである。プランジャ４０は、ポ

リイソプレンなどのセルフシールの生体適合性エラストマーで成形されてもよい。或いは、プランジャ４０は、２つの部分から組み立てることができ、円筒形のエラストマー系シールを硬性プラスチックのプランジャロッドに取り付けることができる。リブ４１は、図２でより明確に示されているが、カートリッジ５０の内側に擦って入り込むように係合して液体密封シールを提供し、これにより液体がカートリッジの手前側から漏れることが防止される。

【００３１】

プランジャ４０は、親指パッド４２にかかる圧力に応じ、第１のチャンバ５２内で摺動可能である。プランジャ４０がカートリッジ５０に向けて軸方向に駆動されると、第１の成分５４は、第１チャンバ５２内の中間シール７０の後端に向けて押される。中間シール７０にかかるバックプレッシャが中間シールとカートリッジ５０の間の摩擦抵抗を上回ると、図６に示されているように、膜７８に穴が開くまで中間シールは突刺部材６４方向に駆動される。中間シールが進むに従い、中間シールと中間壁とのスペースの空気は中間壁の通気孔６３を介して通風される。その場合、突刺部材６４は、中空部分７２を介して貫通し、第１のチャンバ５２と第２のチャンバ５６を液連通する。

【００３２】

中間シール７０が突刺された後、プランジャ４０にかけられる圧力は、第１の成分５４を、第１及び第２の成分が最終的に混合され薬剤５９が形成される第２のチャンバ５６に突刺部材６４を介して移動させる。プランジャ４０は、図７に示されるように、親指パッド４２のフランジ部分がカートリッジ５０の手前側に接触するまで、第１のチャンバ５２に対して前方に移動させられる。親指パッド４２の外径は、カートリッジ５０の内径よりも大きく、これにより一旦親指パッドがカートリッジ５０の手前側に接触すると、プランジャ４０の更なる移動が防止される。プランジャ４０の前端と中間シール７０の後端との距離は、親指パッド４２のフランジ部分とカートリッジ５０の手前側との距離と等しいものであるのが好ましい。一旦親指パッド４２がカートリッジ５０の手前側に接触すると、プランジャはカートリッジ５０に対して固定される。この時点で、より詳しく後述されるように、外筒３０に対してカートリッジ５０が軸方向に移動することは抑制される。

【００３３】

注入装置１０は、２種類の成分を混合させる前、第２のチャンバの内容物の不慮の放出を防止する係止機能を含むものであるのが好ましい。図７に示される本実施形態において、外筒３０は係止用クリップ１００を外筒の壁面に保持し、薬剤成分の不慮の放出を防止する。外筒３０の壁面は、平面で形成され外筒の長手軸を横断する一対の径方向スロット１０４を含む。係止用クリップ１００がスロット１０４に挿通されると、クリップは、カートリッジ５０がフロントシール８０に対して不慮に前方に移動することを防ぎ、これにより薬剤成分が針部材１２を介して不慮に押されることは防止される。係止用クリップ１００は、アセチル又はポリカーボネートなどの弾力性があり高強度かつ高モジュラスな樹脂から形成され、外筒３０のスロット１０４にリリース可能に係合されるように構成されるものであるのが好ましい。

【００３４】

図１～３を参照すると、係止用クリップ１００は、弾力性を有し、たわませることができ、Ｕ形状を共に形成する一対のレッグ１０１を有する平面部材であるのが好ましい。係止用クリップ１００の開端はテーパがかけられたエッジ１０２を有しており、係止用クリップ１００が外筒３０の側壁に挿入されるに従い、レッグ１０１が外側に曲がる。加えて、係止用クリップ１００は、レッグ１０１の内側エッジに複数の歯１０３を有しており、径方向スロット１０４のエッジと係合するようにされている。

【００３５】

係止用クリップが外筒３０の側壁に挿入されるに従い、レッグ１０１は外側に曲がり、径方向スロット１０４のエッジを歯１０３にクリアにさせる。外側に曲げられている場合、レッグ１０１の弾力性は、レッグを元の位置に向けて径方向内側へ付勢する。一旦歯１０３がスロット１０４内に配置されると、レッグ１０１は元の位置に向けて径方向内側に曲

がり、外筒３０の針リテイナ２０の外側エッジにリリース可能に係合する。挿入位置において、係止用クリップ１００の閉端は、図１及び４に示されるように、外筒３０の外側にとどまる。

【００３６】

薬剤成分がカートリッジ内で混合された後、図８に示されるように、係止用クリップ１００が取り外されて薬剤５９の注入が可能になる。係止用クリップ１００は、外筒の長手軸を横断する方向にクリップの閉端を引くことによって外筒３０から取り外される。この方向は、図１において「Ａ」で示されている。このようにクリップを引くことで、レッグ１０１はスロット１０４から外側に曲がり、スロット１０４のエッジを歯１０３にクリアにさせる。

【００３７】

係止用クリップ１００が外筒３０から取り外された後、カートリッジを外筒に向けて前方に移動させることにより、薬剤５９が患者に注入される。親指パッド４２にかけられる圧力は、プランジャ４０とカートリッジ５０を外筒３０に対して前方に移動させる。フロントシール８０の第２の凹部８２ｂに取り付けられた引っかかりが設けられたコネクタ２５により、フロントシールは静止するが、図９に示されるように、カートリッジ５０は前方に移動する。フロントシール８０とフレアヘッド８８は、カートリッジ５０の内側と滑りばめを形成するように構成されており、カートリッジはフロントシールを覆って摺動する。カートリッジ５０が進められると、中間シール７０と中間壁６０はフロントシール８０に向けて移動する。これが第２のチャンバ５６内の薬量を減少させて薬剤が針部材に移動し注入を容易にさせる。注入完了後、図９に示されるように、中間壁６０はフロントシール８０の後端を支持する。

【００３８】

図９～１０を参照して、針部材１２の自動収納を説明する。カートリッジ５０は、薬剤５９が第２のチャンバ５６から完全に放出されるまで外筒３０の手前側に向けて軸方向に進められる。カートリッジ５０が進められるに従い、カートリッジのビーズ状の環状リム５１が針リテイナ２０の保持アーム２２と係合するように移動する。カートリッジが第２の位置で引っかかりが設けられたコネクタ２５に取り付けられる際、カートリッジ５０は、フロントシール８０の後端と中間壁６０との長さ距離が、カートリッジの環状リム５１と保持アーム２２との長さ距離に対応するように構成されるのが好ましい。このようにして、略全ての薬剤５９が装置１０から放出されると、カートリッジ５０のリム５１は保持アーム２２に係合する。

【００３９】

カートリッジ５０のリム５１が保持アーム２２に係合した後、図９に示されるように、カートリッジの継続的な軸方向への駆動は保持アームを径方向内側に曲げ、保持タブ２４が内側に移動させられる。内側位置において、保持タブ２４は外筒３０の保持開口３８との係合から外される。このようにして、カートリッジ５０は作動装置として動作し、カートリッジの軸方向への移動が針リテイナ２０を非係止位置に移動させる。非係止位置において、針リテイナ２０はもはや、バネ２６の力に抗した位置に係止されない。針リテイナ２０が非係止位置にあり、使用者がプランジャ４０にかかる圧力を放した後、針部材の手前側の尖端１６が外筒３０内に封入されるまでバネ２６は針部材１２を後方に押す。

【００４０】

図１０に示されるように、針部材１２が引き込まれる際、針部材、針リテイナ２０及びカートリッジ５０は後方に共に移動する。引き込み中、保持アーム２２は径方向外側に付勢されており、保持タブ２４は外筒の内壁に沿って駆動する。バネ２６の力は、ガイドアーム２８と外筒３０との間で生成される摩擦抵抗を上回るには十分に強いものである。

【００４１】

注入装置１０は、引き込み要素が後方に移動することを制限する機能を含むものであるのが好ましい。図２、４及び１０を参照すると、針リテイナ２０は、外筒３０の内壁に形成された一対のアラインメントチャネル又は溝３１と協働する一対のガイドアーム２８を含

む。ガイドアーム２８は、ポリカーボネートなどの硬性、弾力性がある高強度な樹脂から成形されてもよい。ガイドアーム２８は、針リテイナ２０から前方に延び、径方向外側に突出してアラインメント溝３１に係合する。

【００４２】

各ガイドアーム２８は、好ましくは外筒３０の長手軸と略平行で直線的な細長の後部を含む。各ガイドアーム２８の前部は、外筒３０の長手軸を横断するように外側に曲がり、アラインメント溝３１の１つに達する。針リテイナ２０が外筒内に配置される際、ガイドアーム２８は自然な状態から径方向内側に曲がる。この位置において、ガイドアームの弾力特性により、ガイドアーム２８は外筒３０の内壁に対して径方向外側に付勢される。

【００４３】

ガイドアーム２８の前端は、好ましくはアラインメント溝３１に含まれ、針部材の引き込み中、針部材と針リテイナ２０の回転を実質的に制限するものである。この係合は、ガイドアームがロックアウトウインドウ３９で位置決めされ、これによりガイドアームが引き込みの最後でロックアウトウインドウに留まることを確実にさせる。このようにして、針リテイナ２０は、針部材引き込み中、軸方向に移動することを制限される。引き込み中、ガイドアーム２８の前端と外筒３０の内壁との摩擦抵抗は、バネ２６の膨張力によって克服される。

【００４４】

図４に示されるように、各ガイドアーム２８の直線的な細長の後部は、外筒３０の内壁から径方向内側に離間しており、ガイドアームの直線部分と外筒との間に空間距離が作り出される。空間距離の最低限の径方向の厚さは、カートリッジ５０又はカートリッジリム５１の壁の厚さよりも大きいものであるのが好ましい。このようにして、カートリッジ５０が前方に進められ保持アーム２２が係合から外される時、カートリッジの前進はガイドアーム２８により妨げられることがない。

【００４５】

各アラインメント溝３１は、外筒３０の長手軸と略平行である。図４には、外筒の後端まで延びている溝３１が示されている。しかし、この溝は外筒の後端の手前で終端することが望ましい場合もある。各アラインメント溝３１の後部は、外筒３０の壁に形成されたロックアウトウインドウ３９に交差する。ロックアウトウインドウ３９は、図１０に示されるように、ガイドアーム２８の前端を受け入れるようにされている。具体的には、針部材の引き込み中、各ガイドアーム２８の前端が対応するロックアウトウインドウ３９で位置決めされると、ガイドアームの径方向外側への付勢力がアームを外側に移動させ、これにより前端はロックアウトウインドウで突出する。ガイドアーム２８とロックアウトウインドウ３９の係合は、リテイナ２２が更に軸方向に移動することを防止する。結果として、引き込み要素が前方又は後方に更に移動することが制限される。

【００４６】

注入装置１０は、変更又は外筒ソケット３４からカートリッジ５０を取り外すことを制限する機能を含むものであるのが好ましい。図１１を参照すると、本実施形態は、外筒３０のソケット３４の内壁から径方向内側に突出している環状リップ３５を含む。リップ３５は、カートリッジ５０のビーズ状のリム５１に対して係合わさるようにされており、カートリッジが外筒３０から容易に引き抜くことができないようにされている。結果として、引き込み要素、特に汚染された針部材へのアクセスが制限される。

【００４７】

図４～１０を参照して、注入装置１０の操作を説明する。使用前、針部材１２は突出位置に配置され、これにより針部材の先端側１６は、図４に示されるように、外筒３０から前方に突出する。装置１０は、すでに外筒３０と一体化されているカートリッジ５０と共に出荷され、引っかかりが設けられたコネクタ２５が第１の凹部８２ａに係合しているものが好ましい。或いは、カートリッジ５０が外筒３０と別個に出荷され、カートリッジは使用前に外筒に取り付けられるものであってもよい。

【００４８】

カートリッジ５０と外筒３０が組み立てられた状態で装置１０は垂直に保持され、これにより針部材１２の先端側１６は上を向く。使用者は、プランジャ４０の親指パッド４２を下向きにして使用者の親指を支持位置に置き、装置１０を保持する。加えて、使用者は指を各フィンガーグリップ３６に置き、装置１０の動作をコントロールする。フィンガーグリップ３６に固定された使用者の指で、通常のシリンジと同様に、使用者は親指パッド４２を少し押圧する。押圧は、カートリッジ５０を外筒に対して前方に移動させ、これにより針リテイナ２０の引っかかりが設けられたコネクタ２５がフロントシール８０の第２の凹部８２ｂに係合し、針部材１２が壁８６を突刺する。フロントシール８０が突刺されると、前方チャンバ５６内に閉じ込められた空気が針部材１２を介して通風される。

【００４９】

プランジャ４０の継続的な前進は、突刺構成要素６４が中間シールを突刺するまで、シール７０を突刺構成要素６４に向けて移動させ、前方と後方のチャンバ５２、５６との間に液連通を提供する。このとき、第１の成分５４が前方チャンバ５６に向けて移動させられてもよい。第１の成分５４が後方チャンバ５２から前方チャンバ５６に完全に放出され、プランジャの前端が中間シール７０の後端に接触するまで、圧力が親指パッド４２にかけられる。その後、使用者は、注入装置１０を振り、前方チャンバ５６内の第１及び第２の成分５４、５８を混合させる。

【００５０】

混合中、係止用クリップ１００は、カートリッジ５０が針リテイナ２０に向かって前方に移動することを防止する。カートリッジ５０にかかるこの制限は、針部材１２から薬剤５９が不慮に放出される可能性及び針部材の予定外の引き込みを制限する。一旦薬剤５９が十分に混合されると、使用者は係止用クリップ１００を外筒３０から取り外し、これによりカートリッジ５０を外筒内で前方に移動させることができる。このとき、親指パッド４２にかけられた最初の圧力がカートリッジを押し進め、余分な空気を第２のチャンバ５６から通風させる。

【００５１】

その後、針部材は患者に挿入され、プランジャ４０が押されて外筒３０に対してカートリッジ５０が軸方向に進められ、薬剤５９はカートリッジから患者に注入される。注入工程の終わりに、カートリッジ５０のビーズ状のリム５１は保持アーム２２に係合し、保持タブ２４が径方向内側に移動して係合が外され、針リテイナ２０が非係止位置に移動する。針リテイナ２２は非係止位置にあるが、針部材１２は使用者が親指パッド４２から圧力を開放するまで収納されない。このようにして、針部材が患者から抜かれるまで、使用者は親指パッド４２への圧力を維持することができる。その後、使用者は圧力を親指パッド４２から開放し、針部材はバネ２６により後方に移動させられる。或いは、使用者は圧力を親指パッド４２から開放するが、針部材１２は患者に挿入したままにすることができる。一旦親指パッド４２がリリースされると、バネ２６が針部材１２を後方に移動させ、針部材の汚染された先端側１６は外筒３０内に封入される。

【００５２】

図１２～１６全体を参照し、具体的には図１２～１３を参照すると、安全な希釈剤が予め充填された注入器の第２の実施形態が示されている。注入装置１１０は、図１～１１で示された第１の実施形態１０に関連して上述された構成要素と略同様の構成要素を含むものである。これらの構成要素は、両頭の針部材１１２、略円筒形の外筒１３０、圧縮バネ１２６、バネの付勢力に抗して針部材をリリース可能に保持する針リテイナ１２０、係止用クリップ２００を含むものである。針部材１１２、は手前側の尖端１１４及び先端側の尖端１１６を有する。バネ１２６は針部材１１２を囲み、外筒の前端で外筒１３０の内面を押す。バネ１２６の後端は、針リテイナ１２０の内側を支持して針部材１１２及び針リテイナを後方に付勢する。

【００５３】

上記実施形態とは対照的に、第２の実施形態は、第１の実施形態における上記のような中間壁や突刺可能なシールではなく、２種類の薬剤成分を隔てるための選択的に密閉可能な

バイパス液体流路１６０を有するカートリッジ１５０を利用するものである。使用前、カートリッジ１５０内の中間シール１７０は２種類の薬剤成分１５４、１５８を隔てる。使用前、中間シール１７０は、液体流路を提供するバイパス流路１６０に近接して前方に移動され、２種類の薬剤成分１５４、１５８を混合することができるようにされる。その後、混合された成分は患者に注入される。

【００５４】

図１２、１３を参照して、カートリッジ１５０の細部をより詳細に説明する。カートリッジは略円筒形の容器である。カートリッジの前端は突刺可能な前方シール１８０により密閉されている。カートリッジの後端は、ピストン１４３により密閉されており、カートリッジの内壁と液体密封シールを形成する。前方シール１８０とピストン１４３との中間で、中間シール１７０はカートリッジの内壁と液体密封シールを形成し、カートリッジを第１の成分１５８を受け入れる前方チャンバ１５６と第２の成分１５４を受け入れる後方チャンバ１５２の２個のチャンバに隔てる。

【００５５】

カートリッジ１５０は、カートリッジの側面から外側に突出した泡のような液体流路１６０を含む。液体流路１６０には、カートリッジの直径が中間シールの直径よりも大きい個所が形成されている。液体流路１６０は軸方向に細長のチャネルであり、中間シール１７０の軸方向の長さよりも長く、好ましくは中間シールとピストン１４３が結合した長さよりも短いものである。

【００５６】

液体流路１６０は泡のような突出物として示されているが、この液体流路はその他の構成で形成されてもよい。例えば、液体流路は、カートリッジ１５０の内壁に形成された凹部又は軸方向の溝であってもよく、この場合液体流路はカートリッジの外側表面から突出することはない。同様に、液体流路はカートリッジの内壁に形成された環状の凹部であってもよい。

【００５７】

図１２を参照すると、装置１１０は「格納」位置で示されている。この位置では、中間シール１７０は２種類の薬剤成分が混合されることを防止する。従って、密閉されたカートリッジ１５０は、所望の場合、薬剤成分の有効性を損なうことなく長期間保存することができる。保存位置において、中間シール１７０は液体流路１６０の後方に配置され、中間シールとカートリッジの内壁との間で中間シールの全周にわたり液体密封シールが形成される。

【００５８】

注入装置１１０の保存中、図１２～１３に示されるように、薬剤はカートリッジ１５０に格納された２種類の別々の成分に分けられる。具体的には、薬剤の第１の成分１５４は第１のチャンバ１５２に格納され、薬剤の第２の成分１５８は第２のチャンバ１５６に格納される。更に下記に示されるように、カートリッジが製造中に充填される場合、多少の空気が第２のチャンバ１５６内に残ることが好ましい。

【００５９】

プランジャ１４０はカートリッジ１５０の後端に摺動可能に配置される。プランジャ１４０は、プラスチック成形されたプランジャロッド１４１とエラストマー系ピストン１４３からなる。ピストン１４３は、液体密封シールをカートリッジの内壁と共に形成し、カートリッジ内で摺動させることができる。プランジャロッド１４１は、プランジャシール１４３に様々な方法で結合させることができる。本実施形態において、プランジャロッド１４１は外部ねじスレッド（ｅｘｔｅｒｎａｌ　ｓｃｒｅｗ　ｔｈｒｅａｄ）を有し、プランジャシール１４３内の内側スレッドと係合わさるように構成されており、プランジャロッドとシールはねじ締めすることができる。

【００６０】

図１４を参照して、第１の薬剤要素１５４の第２チャンバ１５６への移動について説明する。中間シール１７０は、液体流路１６０に合わさるまで軸方向に前進されられる。その

後、液体流路１６０はバイパス流路を提供し、これにより後方チャンバの成分を前方チャンバに注入することができる。前方チャンバは、好ましくは多少の空気（又は他の圧縮性の液体）を含んでいるので、前方チャンバの材料は圧縮されて中間シールが液体流路１６０に合わさるように前進させることができる。或いは、液体が後方チャンバから前方チャンバに移動した場合、前方チャンバは空気を前方チャンバから通風させる通気孔を含むものであってもよい。通気孔が含まれる場合、通気孔は密閉可能であり、混合された成分が注入中に漏れることを防ぐものであるのが好ましい。

【００６１】

具体的には、カートリッジ内で２つの成分を混合させるためにプランジャ１４０はカートリッジ１５０に向かって軸方向に進められ、第１の成分１５４は中間シール１７０の後端に対して第１のチャンバ内１５２で押される。中間シール１７０にかけられるバックプレッシャは、中間シールとカートリッジ１５０の摩擦抵抗を上回るものであり、中間シールはカートリッジ内で前方に移動させられる。一旦中間シール１７０が移動して液体流路１６０に係合すると、図１４に示されるように、流路が中間シールと液体流路の内壁との間に作られる。

【００６２】

液体流路１６０は十分に大きく、第１の物質１５４は中間シール周辺を流れ、第２の物質１５８と混合される第２のチャンバ１５６に流入することができる。一旦第１の成分が第２のチャンバ１５６に完全に移動すると、図１５に示されるように、プランジャシール１４３は中間シール１７０に隣接するまで進められる。中間シール１７０とピストン１４３が結合した軸方向の長さは、液体流路１６０の長さよりもわずかに長い。従って、中間シールとピストンは、液体流路を全長にわたり密閉する。これが第２のチャンバ１５６内の成分が混合中に逆流することを防止する。

【００６３】

成分の混合が完了した後、係止用クリップ２００は取り外されて薬剤が患者に注入できるようにされる。圧力がカートリッジ１５０に加えられ、薬剤が第２のチャンバ１５６から放出される。注入工程が完了すると、カートリッジ１５０は針リテイナ１２０を動作させる。その後、図１６に示されるように、カートリッジ１５０にかけられる圧力は開放されて針部材を収納することができる。

【００６４】

図１７～２３全体を参照し、具体的には図１７を参照すると、希釈剤が予め充填された安全な注入器の別の実施形態が一般に２１０で示されている。注入装置２１０は、両頭の針部材２１２、針部材を収納する略円筒形の外筒２３０及び略円筒形のカートリッジ２５０含む。外筒２３０は更に、圧縮バネ２２６及び針部材２１２をバネの付勢力に抗してリリース可能に保持する針リテイナ２２０を含む。針部材２１２は後尖端２１４及び先尖端２１６を有する。バネ２２６は、針部材２１２を囲み、外筒の前端で外筒２３０の内面に対して圧縮される。バネ２２６の後端は、針リテイナ２２０の内部で支持され、針部材２１２と針リテイナとを後方に付勢する。

【００６５】

この実施形態において、薬剤成分の移動及び混合は、カートリッジがニードルハブ２２１に取り付けられる前、カートリッジ２５０内で行われる。カートリッジ２５０は、混合中、針アセンブリに結合されていないため、成分の混合中、針部材が不慮に引き込まれるリスクがない。結果として、外筒は他の実施形態のように係止用クリップを含まない。

【００６６】

図１８～１９を参照すると、カートリッジ２５０と外筒２３０はパッケージで供給され、２つは分解される。カートリッジ２５０は略円筒形の容器であり、ホウケイ酸塩などの薬品の品質を有するのガラス又はポリオレフィン若しくはポリエステルなどの硬質の不活性プラスチックから成形されてもよい。カートリッジキャップ２５３はカートリッジ２５０の先端側に配置される。カートリッジ２５０は、図１２～１６で示されたカートリッジ１５０と同様の構成を有し、カートリッジの側方から外側に突出した泡のような液体流路２

６０を含む。中間シール２７０は、カートリッジ２５０内で摺動可能に配置され、カートリッジを第１のチャンバ２５２と第２のチャンバ２５６とに隔てる。カートリッジ２５０の各チャンバには、装置２１０の製造中、所定量の薬剤成分が充填される。具体的には、第１のチャンバ２５２には薬剤の第１の成分２５４が予め充填され、第２のチャンバ２５６には第２の成分２５８が予め充填される。

【００６７】

図２０を参照すると、プランジャ２４０は、カートリッジ２５０の手前側に摺動可能に配置されている。プランジャ２４０は、プラスチック成形されたプランジャロッド２４１及びエラストマー系プランジャシール２４３からなる。プランジャ２４０がカートリッジ２５０に向けて軸方向に進められる場合、第１の成分２５４は第１のチャンバ２５２で中間シール２７０の後端に対して押される。中間シール２７０にかかるバックプレッシャが中間シールとカートリッジ２５０の摩擦抵抗を上回るに従って、中間シールがカートリッジ内で前方に移動される。一旦中間シール２７０が液体流路２６０と直線的に配置されると、流路が中間シールと液体流路内壁との間に形成され、第１の物質２５４は中間シールの近傍を通り第２の物質と混合される第２のチャンバ２５６に流れることができる。

【００６８】

液体流路２６０は、第１の物質２５４が中間シールの近傍を通り第２の物質２５８と混合される第２のチャンバ２５６に流れるように十分な長さのものである。一旦第１の成分が第２のチャンバ２５６に完全に移動すると、図２１に示されるように、プランジャシール２４３が中間シール２７０に近接するまで進められる。中間シール２７０とプランジャシール２４３が結合された軸方向の長さは、液体流路２６０の最長よりもわずかに長いものであり、これにより中間シールとプランジャシールは液体流路を全長にわたり閉鎖させる。これは、薬剤の混合中、第２のチャンバ２５６の中身が逆流することを防止する。

【００６９】

再度図１８を参照すると、カートリッジ２５０は、エラストマー系フロントシール２８０をカートリッジの先端側で含む。フロントシール２８０は、ポリイソプレンなどのセルフシールの生体適合性エラストマーで成形されてもよい。フロントシール２８０は略円筒形であり、カートリッジ内に配置された幅広の円筒形後端２８２と、カートリッジの前端から前方に突出して直径が縮小された前端２８４とを有する。後端２８２は、カートリッジ２５０の内径と同様の外径を有する。加えて、後端２８２は、複数の軸方向に離間した環状リブ２８６を有し、摩擦摺動でカートリッジの内部に係合し、液体密封シールを提供してカートリッジから液体が漏れることを防止する。

【００７０】

フロントシール２８０の前端２８４は、外部スレッド２８８を外周に含む。また、先端側２８４は、浅い正面キャビティ２９０を含む。第２のチャンバ２５６と液連通している狭い穴２９２は、フロントシール２８０の手前側から延び、直径が縮小された先端側２８４内で終端する。正面キャビティ２９０と穴２９２の液連通は、突刺部材２９４で塞がれている。

【００７１】

図１９を参照すると、外筒２３０は略円筒形であり、先端側にテーパがかけられたノーズ２３２を有する。ノーズ２３２は、針部材２１２が挿通される開口を有している。加えて、ノーズ２３２は、針部材２１２が突出位置にある場合、ノーズにフィットして不慮の針刺しを防止する針カバー２１１を受け入れるように構成されている。外筒２３０の手前側は開いており、カートリッジ２５０を受け入れるようにされた円筒形ソケット２３４を形成する。カートリッジ２５０に取り付けられる前、外筒２３０の開口後端は円筒形の外筒キャップ２３３によって閉じられる。外筒は更に、針部材をリリース可能に保持するための針リテイナ２２０と協働する一対の保持開口２３８と、収納位置で針部材をロックするための係止用タブと協働する一対のロックアウトウインドウとを含む。

【００７２】

針リテイナ２２０は、略円筒形の本体２２１と、本体２２１から径方向前方に延びる一対

の保持アーム２２２とを含む。略円筒形の開口２９６は、針リテイナ本体２２１の手前側に配置される。開口２９６の内壁は、内側ねじスレッド２９８を含み、カートリッジ２５０内のフロントシール２８０の外側ねじスレッド２８８を受け入れるようにされている。

【００７３】

カートリッジキャップ２５３と外筒キャップ２３３は、カートリッジ２５０と外筒２３０から夫々取り外され、カートリッジと外筒を組み立てる準備が整う。カートリッジ２５０は、フロントシールの前端を外筒２３０の開口端を介して挿入し、カートリッジを時計回りに開口２９６にねじ込むことにより外筒２３０に結合される。図１７に示されるように、カートリッジ２５０が外筒２３０に取り付けられることで針部材の手前側の尖端２１４はキャビティ２９０を通って部材２９４を突刺し、これによりカートリッジの第２のチャンバが針部材２１２と液連通されるように、フロントシール２８０の正面キャビティ２９０は針部材２１２と同軸上にあることが好ましい。

【００７４】

図１７を参照すると、カートリッジ２５０は外筒２３０に結合され、カートリッジが外筒に向かって前方に進められることにより薬剤が患者に注入される。フロントシール２８０の手前側は、カートリッジ２５０の内側と滑りばめを形成するように構成されており、カートリッジが進む間、カートリッジはフロントシールを覆って摺動する。カートリッジ２５０が進められると、フロントシール２８０の後端は針リテイナ２２０を支持し、これによりカートリッジが進められる間、フロントシールの固定状態が維持される。同時に、第２のチャンバ２５６の後方で中間シール２７０はフロントシール２８０の方向に配置される。これが第２のチャンバ２５６内の薬剤量を減少させ、薬剤は針部材に移動し注入が容易にされる。注入の完了すると、図２２に示されるように、中間シール２７０はフロントシール２８０の後端で支持される。

【００７５】

上記実施形態のように、針部材２１２は、針リテイナ２２０を作動させることにより収納される。具体的には、針部材２１２は、保持アーム２２２が外筒壁の保持開口２３８との係合から外され、バネ２２６が針部材２１２を後方に押すことにより引き込まれる。針リテイナ２２０を作動させるために、圧力がカートリッジ２５０にかけられ、図２２に示されるように、カートリッジは針リテイナ本体２２１に進められる。進められている間、カートリッジ２５０の先端側は、針リテイナ本体２２１の先端側近傍に配置された円筒形のスリーブ３００に係合する。リリーススリーブ３００の内径及び外径は、好ましくはカートリッジ２５０の内径及び外径と等しいものであり、これによりカートリッジの先端側はスリーブの手前側と合わさる。カートリッジ２５０に係合する前、針リテイナに沿うリリーススリーブ３００の軸方向への移動は、針リテイナ本体２２１上の環状液体流路２２３内でスライドする内側フランジ３０２により制限される。カートリッジ２５０がスリーブ３００に係合した後、カートリッジの継続的な前進は、スリーブを軸方向前方に駆動させ保持アーム２２２に係合させる。図２３に示されるように、リリーススリーブ３００は、保持アームを径方向内側に曲げて保持開口２３８との係合を外させ、バネ２２６が針部材２１２を後方に押させることを可能にする。

【００７６】

上記のように、第３の実施形態は、最初の２つの実施形態で示されたような引っかかりによる結合ではなく、フロントシール２８０と針リテイナ２２０のスレッド結合を含むものである。スレッド結合の使用は針リテイナ２２０の全長を増大させることができる。すなわち、カートリッジ２５０の先端側と保持アーム２２２との距離を増大させることができるものである。この増大した長さを調節する１つの方法は、外筒２３０の長さを増大することである。しかし、リリーススリーブ３００と協働させて外筒２３０の長さを実質的に増大させる必要はない。リリーススリーブ３００がカートリッジ２５０の延長として作用することにより、増大した距離を補填する。これは、装置２１０の全長を増大させる必要性を取り除く。リリーススリーブ３００の長さは、フロントシール２８０と針リテイナ２２０のスレッド係合の長さよりもわずかに長いものであるのが好ましい。

【００７７】
図２４～２９全体を参照し、具体的には図２４～２５を参照すると、希釈剤が予め充填された安全な注入器の第４の実施形態が示されている。注入装置３１０は、両頭の針部材３１２、針部材を収納する略円筒形の外筒３３０及び外筒の手前側内に取り付けられた略円筒形のカートリッジアセンブリ３５０を含むものである。上記実施形態のように、外筒は更に、圧縮バネ３２６と、バネの付勢に抗して針部材３１２をリリース可能に保持する針リテイナ３２０とを含むものである。装置３１０はまた、Ｕ形状の係止用クリップ４００を外筒壁に含み、薬剤が装置３１０から不慮に放出されることを防止する。
【００７８】
カートリッジアセンブリ３５０は、費用効率の良いプラスチックをアセンブリに使用する利点を提供する２つの設計を有するものである。カートリッジアセンブリ３５０は、開口手前側を有するフロントシリンダ３５１と、フロントシリンダの手前側に伸縮自在に取り付けられた先端側開口を有する後方シリンダ３５３とを含むものである。フロントシリンダ３５１は、カートリッジアセンブリ３５０を第１のチャンバ３５２と第２のチャンバ３５６に隔てる内壁３６０を含む。第１のチャンバ３５２は薬剤の第１の成分３５４を所定量保持するものであり、第２のチャンバ３５６は薬剤の第２の成分３５８を所定量保持するものである。フロントシリンダ３５１の手前側は、突刺可能なエラストマー系フロントシール３８０により閉じられている。
【００７９】
多くの用途において、第２の成分３５８は、乾燥パウダー状の成分である。乾燥成分はガラス製の容器を必要とせず、成分の長期安定性を悪化させることなくプラスチック製の容器に格納することができる。ガラスよりもプラスチックから複雑な部分を成形した方がより費用効率が良いため、カートリッジアセンブリ３５０の複雑なガラス部分を最小限にすることが好ましい。この目的を達成するため、フロント及び後方シリンダ３５１、３５３を構成し、第１の成分３５４は後方シリンダ内に完全に格納され、第２の成分３５６はフロントシリンダ内に完全に格納される。この割り当てにより、フロントシリンダ３５１はより複雑な構造を含み、後方シリンダを単純なカップ形状の容器にすることが可能になる。従って、より複雑な前方シリンダは、乾燥した第２の成分３５８を第２のチャンバ３５６に格納するこれらの装置用に、費用効率の良いプラスチックから成形することができる。ガラスは、例え使用されるとしても、後方シリンダ３５３を成形するためにのみ使用されるのが好ましい。
【００８０】
上記のように、後方シリンダ３５３はフロントシリンダ３５１の手前側に伸縮自在に取り付けられる。後方シールの後方部分の外径は後方シリンダ３５３の内径と略等しく、後方シリンダの内側に摩擦係合して液体密封シールを提供するものである。後方シリンダ３５３は、後方シリンダの手前側にかかる圧力に応じて後方シール３４０を覆って軸方向に摺動するようにされている。
【００８１】
外筒３３０は後方シリンダ３５３の外径を調節するために十分な大きさの内径を有する。結果として、図２５に示されるように、フロントシリンダ３５１の外壁は空隙によって外筒３３０の内壁から隔てられている。フロントシリンダ３５１は、フロントシリンダの外壁にある一対の対向する長手軸リブ３５５によって、より大きい外筒３３０と同心関係で維持されている。長手軸リブは図２４に示されている。
【００８２】
エラストマー系の後方シール３４０はフロントシリンダ３５１と後方シリンダ３５３の間に配置されている。後方シール３４０はフロントシリンダ３５１の開口手前側に一部に配置された小径端部３４２を含む。また、後方シール３４０は後方シリンダ３５３内に配置されたフランジ形３４４を含む。小径端部３４２とフランジ形３４４は、それぞれフロントシリンダ３５２及び後方シリンダ３５４の内側と摩擦摺動して係合する。この係合は液体密封シールを両シリンダの内側で提供する一方、後方シール３４０をどちらかのシリン

ダに対して移動させるものである。フロントシリンダ３５１に対する後方シール３４０の前進は、フロントシリンダの手前側で制限され、後方シールのフランジ部分に合わさって係合するように構成される。

【００８３】

上記のように、フロントシリンダ３５１は内壁３６０を含む。内壁３６０は、カートリッジの後方開口端に近接し、後方シール３４０を受け入れるソケットを形成する。内壁３６０は壁３６０の中央に設けられたオリフィス３６２を含む。中空の突刺部材３６４はオリフィスに取り付けられ、後方シール３４０に向けて後方に延びる。加えて、通気口（ｖｅｎｔ　ｏｐｅｎｉｎｇ）が内壁３６０に提供され、後方シリンダが進み後方シールが突刺される際、後方シール３４０と内壁の間で空気が通風されることが望ましい。

【００８４】

後方シール３４０の先端側は、突刺部材３６４により突刺されるように構成された膜３４８で密閉されている。後方シール３４０は、後方シールの手前側を介して第１のチャンバ３５２と液連通で結合された中空の中間部分３４６を含む。一旦膜３４８が突刺されると、第１及び第２のチャンバ３５２、３５６が液連通で結合されるように、液体流路が突刺部材３６４と後方シール３４０を介して形成される。後方シール３４０は、ポリイソプレンなどの高伸長のセルフシール式生体適合性エラストマーで成形されてもよい。

【００８５】

次に装置３１０の動作を説明する。わずかな絞り圧力が後方シリンダ３５３の手前側にかけられ、後方シリンダはフロントシリンダ３５１に向かって軸方向に進められる。これにより第１の成分３５４は、後方シール３４０と後方シリンダ３５３の密閉された手前側との間で押される。後方シリンダ３５３への継続的な圧力は、後方シール３４０にバックプレッシャをかけ、後方シールを突刺部材３６４に向けて前方に軸方向移動させる。このとき、膜３４８は突刺され、液体流路が第１及び第２のチャンバ３５２、３５６の間に形成される。

【００８６】

後方シリンダ３５３はフロントシリンダ３５１に対して前方に進められ、第１の成分３５４を第１のチャンバ３５２から第２のチャンバ３５６に放出させる。図２６に示されるように、一旦第１の成分３５４が完全に第１のチャンバ３５２から放出されると、後方シリンダの密閉された手前側が後方シールの手前側３４０に近接するまで、後方シリンダへの更なる圧力はフロントシリンダ３５０に対して後方シリンダを前方に進める。このとき、装置３１０を振ると、成分は第２のチャンバ３５６内で混合される。混合処理の間、カートリッジアセンブリ３５０の移動は係止用クリップ４００により防止され、薬剤が不慮に放出される恐れは最小限にされる。

【００８７】

要素が混合された後、係止用クリップ４００は取り外される。その後、カートリッジアセンブリは前方に移動させられ、針部材３１２の後端が前方シール３８０を突刺する。そして、空気が前方チャンバから通風される。更なる圧力がカートリッジアセンブリにかけられ、薬剤が第２のチャンバ３５６から針部材３１２を介して放出される。図２７に示されるように、注入工程の完了時、カートリッジアセンブリ３５０の手前側が針リテイナ３２０を作動させる。図２８及び２９に示されるように、その後、カートリッジアセンブリ３５０への圧力が開放されることにより、針部材３１２を収納することができる。

【００８８】

ある場合には、カートリッジは成分単位で格納されることが望ましい。すなわち、後方シリンダ３５３は前方シリンダ３５１から取り外されるものであってもよい。使用前、後方シリンダ３５３は前方シリンダ３５１に取り付けられ、一体化したアセンブリは上記のように利用される。この場合、個々の後方コンテナ３５３は、前端を覆う個々のキャップを含むものであってもよい。同様に、前方シリンダ３５１は、後端を覆うキャップを含むものであってもよい。取り外し可能な後方シリンダ３５３は、予め処理された様々な薬剤成分を格納し、使用前、様々なコンビネーションで容易に組み合わせられるものであっても

よい。
【００８９】
本明細書で使用する用語および表現は、記述目的のものであり、制限目的のものではない。ここに示し説明している機能と同等のいかなる機能を排他する用語および表現も、使用する意図はない。ただし、本発明の要旨を変更しない範囲で種々の変形が可能であることが当業者により認識される。例えば、上記の実施形態は、使用後、針部材を収納するために自動的にリリースさせる一対の径方向に移動可能なアームを有する針リテイナを含むものである。しかし、この装置は、使用後、針部材を自動的に収納しても、しなくてもよい異なる針リテイナを利用するものに変形されてもよい。従って、本発明は本明細書に記載した特定の実施態様に制限されるものではないが、本発明の要旨を変更しない範囲での変形や修正を含むものである。
【図面の簡単な説明】
【００９０】
発明の解決しようとする課題及び発明を実施するための最良の形態は、図面との関連で最もよく理解されるものである。
【図１】図１は、薬剤成分部分を格納する２個のチャンバ容器を有する予充填式のカートリッジ型注入器の斜視図である。
【図２】図２は、図１に示されたカートリッジ型注入器の分解斜視図である。
【図３】図３は、図２に示されたカートリッジ型注入器の係止用クリップの拡大図である。
【図４】図４は、図１に示されたカートリッジ型注入器であり線４－４に沿う断面図である。
【図５】図５は、図４に示されたカートリッジ型注入器であり線５－５に沿う断面図である。
【図６】図６は、図１に示されたカートリッジ型注入器の断面図であり、薬剤成分部分を混合する前の装置である。
【図７】図７は、図１に示されたカートリッジ型注入器の断面図であり、混合後に注入を防止するためにロックされたカートリッジを有する装置である。
【図８】図８は、図１に示されたカートリッジ型注入器の断面図であり、混合後に注入するためロックが解かれたカートリッジを有する装置である。
【図９】図９は、図１に示されたカートリッジ型注入器の断面図であり、注入後であり、針部材が引き込む直前の装置である。
【図１０】図１０は、図１に示されたカートリッジ型注入器の断面図であり、針部材引き込み後の装置である。
【図１１】図１１は、図１に示されたカートリッジ型注入器の拡大断片の断面図であり、針部材が引き込まれた後、カートリッジと外筒の開封防止の結合である。
【図１２】図１２は、引込可能な針部材を有し、２個のチャンバを有する予充填式のカートリッジ型注入器の第２の実施形態の断面図である。
【図１３】図１３は、図１２に示された装置であり線１３－１３に沿う断面図である。
【図１４】図１４は、図１２に示された装置の断面図であり、カートリッジ内で薬剤成分を混合し、チャンバ間で薬剤成分を移動させている最中の装置である。
【図１５】図１５は、図１２に示された装置の断面図であり、薬剤成分が混合された後の装置を示す。
【図１６】図１６は、図１２に示された装置の断面図であり、針部材収納後の装置を示す。
【図１７】図１７は、収納可能な針部材を有し、２個のチャンバを有する予充填式のカートリッジ型注入器の第３の実施形態の断面図である。
【図１８】図１８は、図１７に示された装置のカートリッジ部分の断面図である。
【図１９】図１９は、図１７に示された装置の断面図であり、カートリッジなしで使用前である。

【図２０】図２０は、図１８に示されたカートリッジの断面図であり、薬剤成分を混合している最中の装置である。
【図２１】図２１は、図１８に示された装置の断面図であり、薬剤成分を混合した後の装置である。
【図２２】図２２は、図１７に示された装置の断面図であり、注入完了時の装置である。
【図２３】図２３は、図１７に示された装置の断面図であり、針部材収納後の装置である。
【図２４】図２４は、収納可能な針部材を有し、２個のチャンバを有する予充填式のカートリッジ型注入器の第４の実施形態の拡大斜視図である。
【図２５】図２５は、図２４に示された装置の断面図である。
【図２６】図２６は、図２４に示された装置の断面図であり、薬剤成分を混合した後の装置である。
【図２７】図２７は、図２４に示された装置の断面図であり、注入完了時の装置である。
【図２８】図２８は、図２４に示された装置の断面図であり、針部材収納後の装置である。
【図２９】図２９は、図２４に示された装置の断面図であい、針部材収納後の装置である。

【図１】

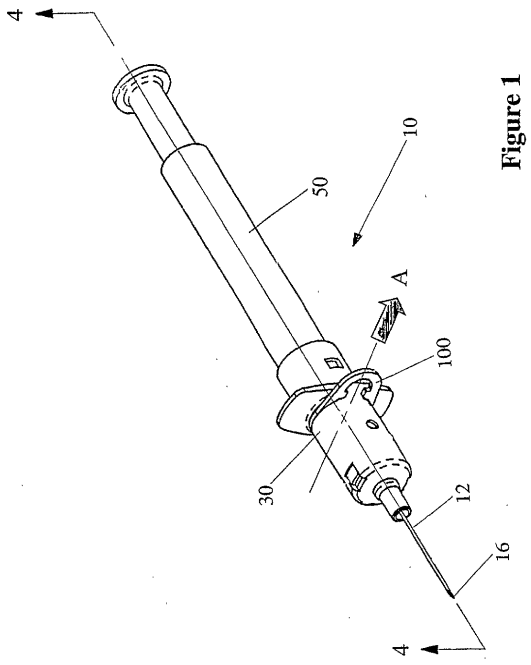


Figure 1

【図２】

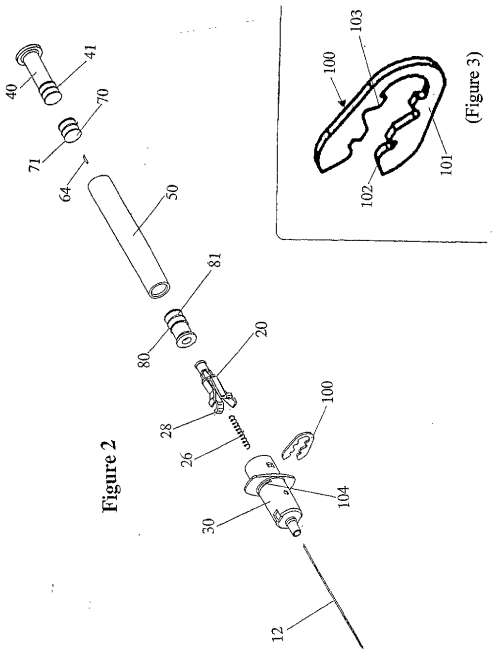
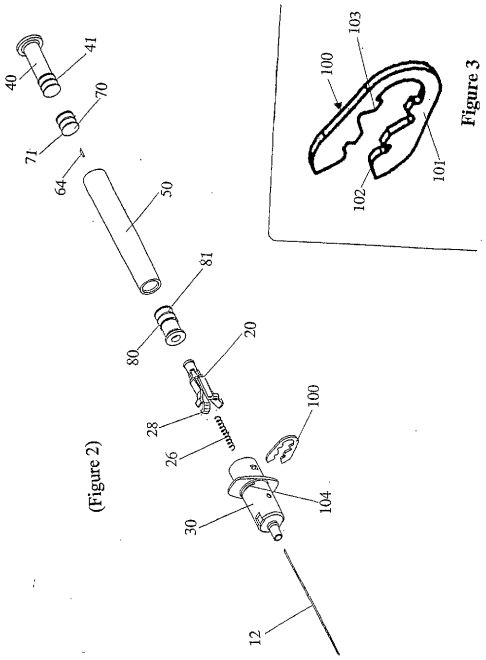


Figure 2

(Figure 3)

【図３】


40
41
70
71
64
50
81
80
20
28
26
30
104
100
12
(Figure 2)
103
100
102
101
Figure 3

【図４】

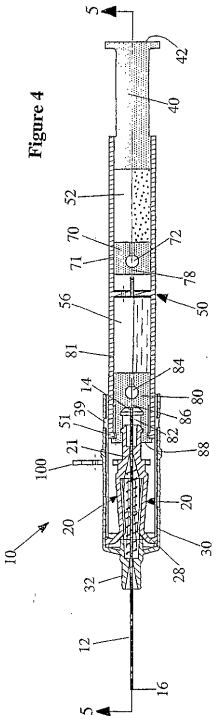


Figure 4
5
42
40
52
70
72
71
78
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56
81
84
14
80
51
39
86
82
21
88
100
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10
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32
12
16

【図５】

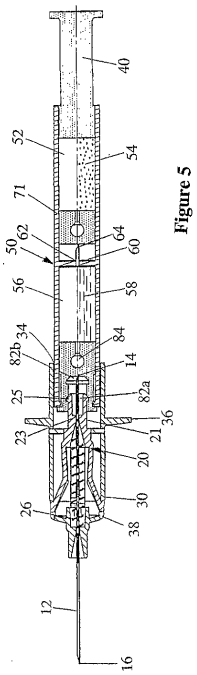
Figure 5
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52
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71
62
64
50
60
56
58
82b
34
84
14
25
82a
36
23
21
20
26
30
38
12
16

【図６】

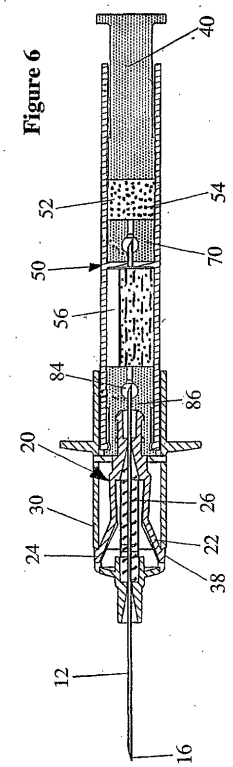
Figure 6
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52
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70
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56
84
86
20
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12
16

【図７】

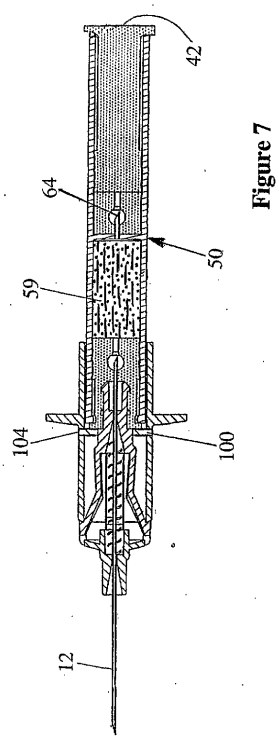


Figure 7

【図８】

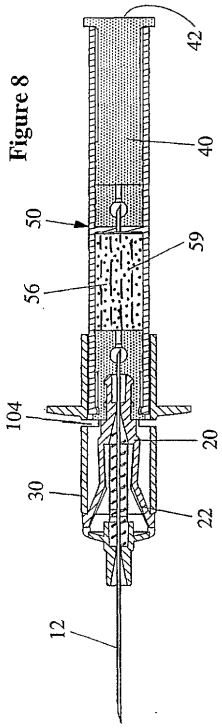


Figure 8

【図９】

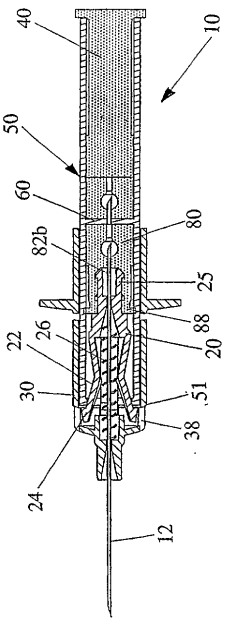


Figure 9

【図１０】

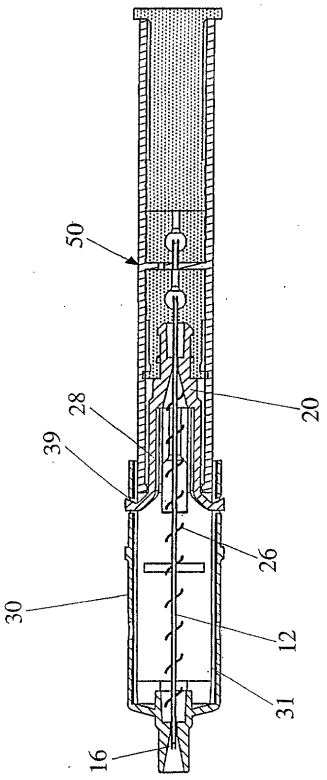
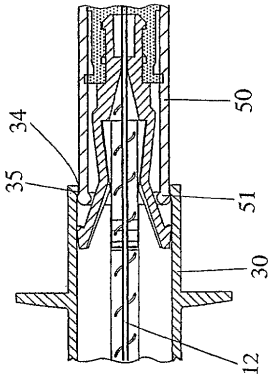


Figure 10

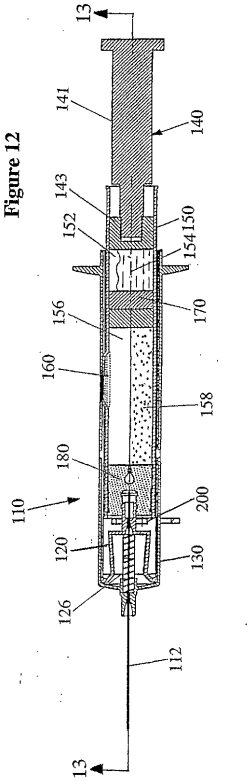
【図１１】

Figure 11



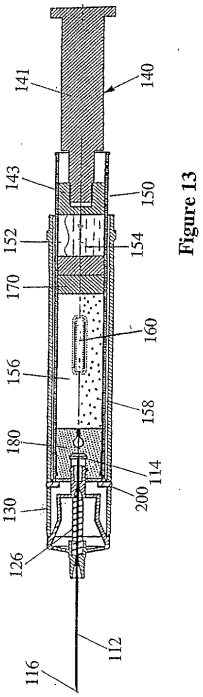
【図１２】

Figure 12



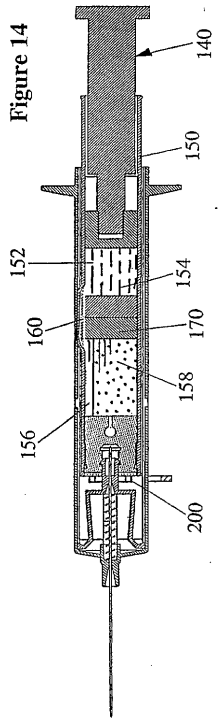
【図１３】

Figure 13



【図１４】

Figure 14



【図１５】

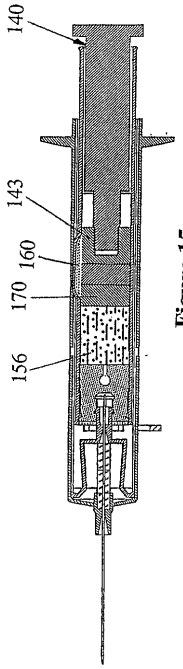


Figure 15

【図１６】

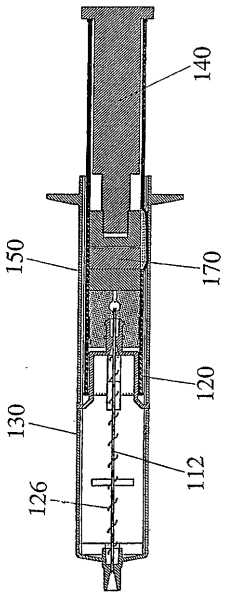


Figure 16

【図１７】

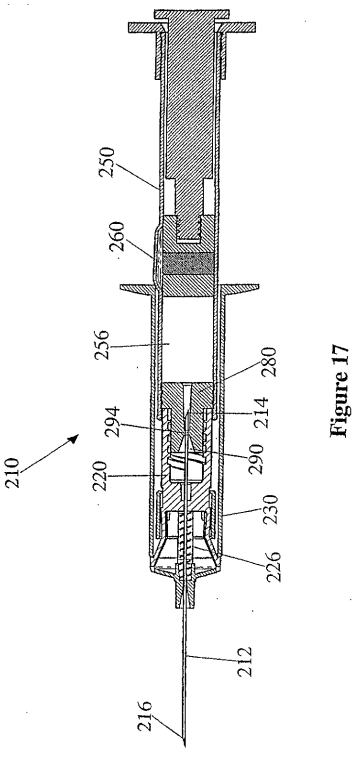


Figure 17

【図１８】

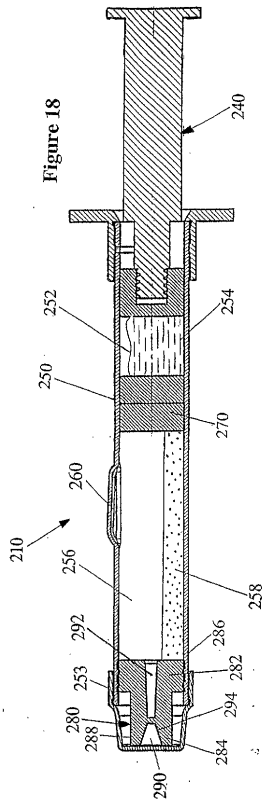


Figure 18

【図１９】

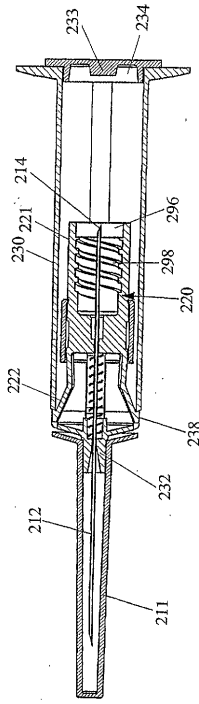


Figure 19

【図２０】

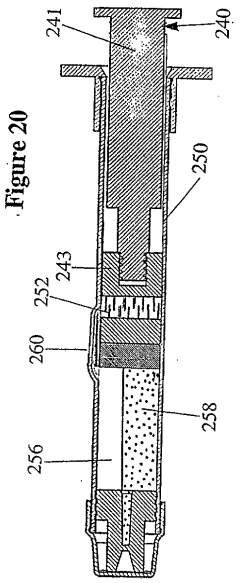


Figure 20

【図２１】

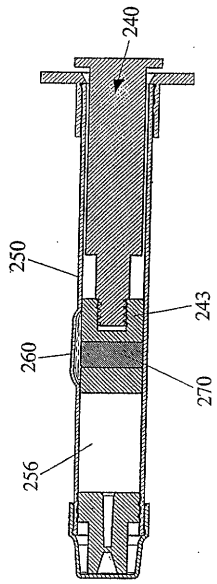


Figure 21

【図２２】

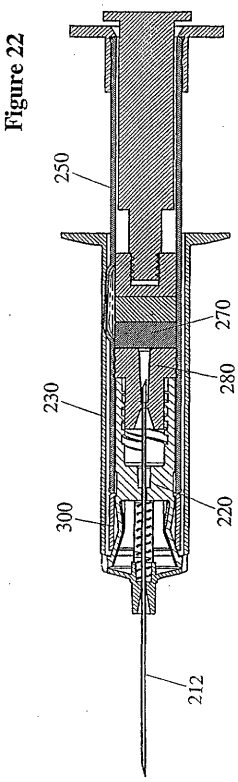


Figure 22

【図２３】

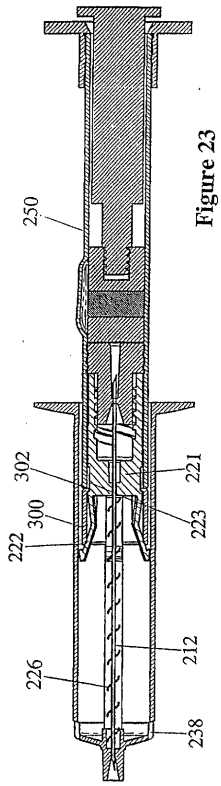


Figure 23

【図２４】

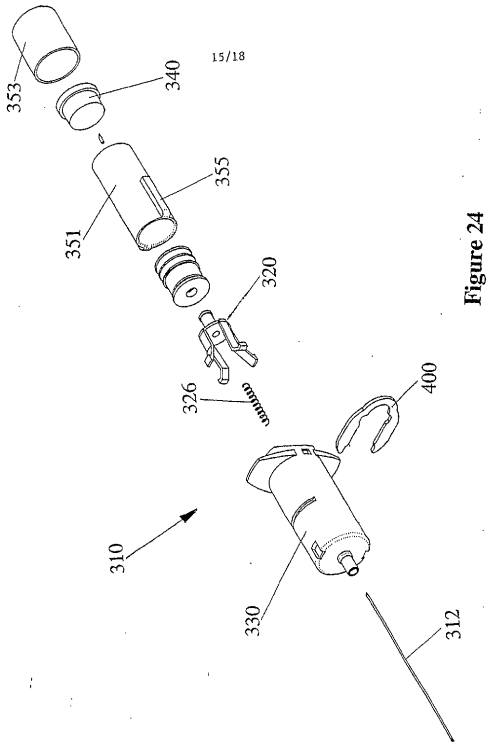


Figure 24

【図２５】

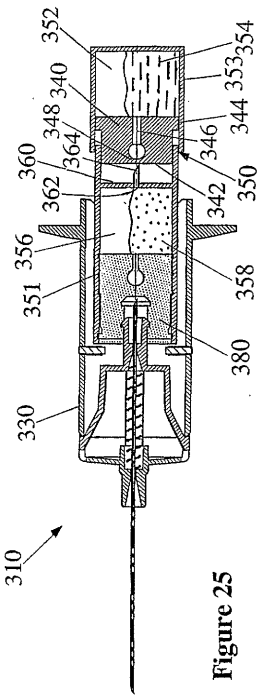


Figure 25

【図２６】

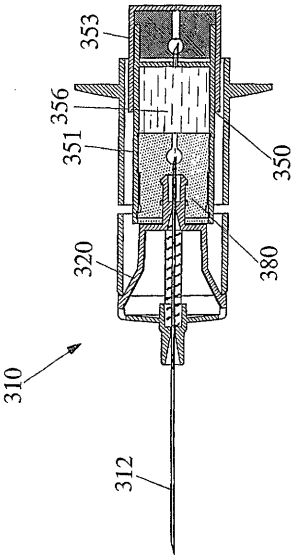


Figure 26

【図２７】

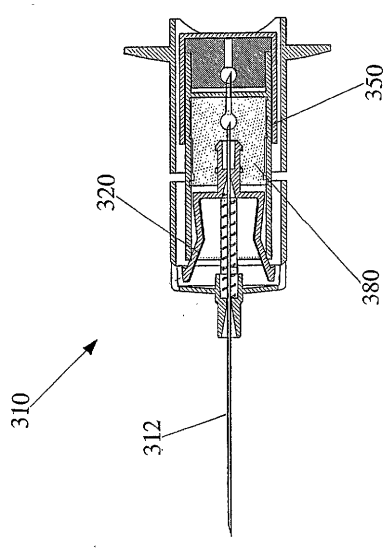


Figure 27

【図２８】

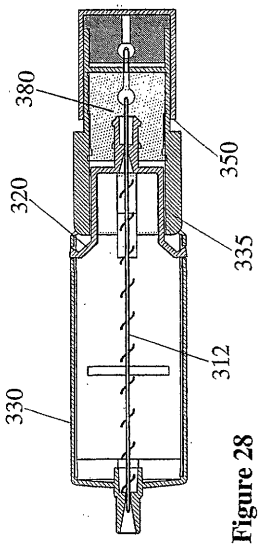


Figure 28

【図２９】

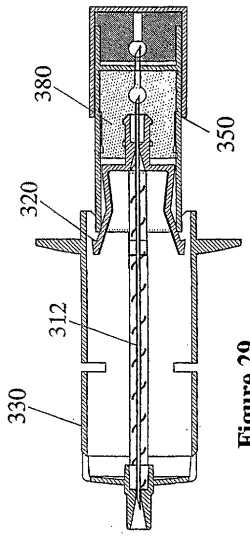


Figure 29

【国際公開パンフレット】

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
19 September 2002 (19.09.2002)

PCT

(10) International Publication Number
WO 02/072171 A2

(51) International Patent Classification[7]: A61M

(21) International Application Number: PCT/US02/07712

(22) International Filing Date: 13 March 2002 (13.03.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/275,568 13 March 2001 (13.03.2001) US

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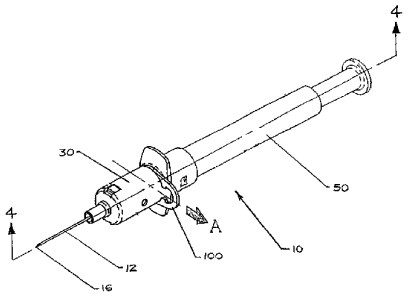
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: PRE-FILLED SAFETY DILUENT INJECTOR



(57) Abstract: A safety needle-bearing device (10, 110, 210, 310) for mixing and injecting medication from a two-chambered cartridge (50, 150, 250, 350) is provided. The device includes a needle (12, 112, 212, 312) that extends through the forward end of a barrel (30, 130, 230, 330). The two-chambered cartridge (50, 150, 250, 350) is attached to the barrel (30, 130, 230, 330) and contains components of a medication stored separately in the chambers. A plunger (40, 140, 240) in the rearward end of the cartridge can be advanced into the cartridge to combine the separate components and prepare the medication. As the cartridge (50, 150, 250, 350) is advanced forwardly into the barrel (30, 130, 230, 330), the medication is injected through the needle (12, 112, 212, 312) and into a patient. At the completion of the injection stroke, the cartridge (50, 150, 250, 350) engages a needle retainer to actuate needle retraction. The needle is subsequently retracted to shield the contaminated needle.

WO 02/072171 A2

WO 02/072171 A2

Published:
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

PRE-FILLED SAFETY DILUENT INJECTOR

PRIORITY CLAIM

This application claims priority to U.S. Provisional Application No. 60/275,568, filed March 13, 2001, which is hereby incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to medical devices and more particularly to medical devices having a cartridge with two chambers that store separate components of a medication and allow the components to be mixed and subsequently injected into a patient.

BACKGROUND

Pre-filled syringes store and allow for mixing of separate medicinal components. Many of these syringes, sometimes called "mixing syringes," store a first component in one compartment and a diluent or a second component in a second compartment. These syringes allow the two components to be stored separately until just before the syringe is used, at which time the components can be mixed within the syringe and immediately injected into a patient.

Pre-filled mixing syringes are advantageous for many types of pharmaceuticals. Some medications, like antibiotics, vitamins and hormones, must be packaged and stored in component parts to enhance shelf life. These medications may need to be stored as a powdered component and a diluent, or as a separate pair of solutions. Pre-filled mixing syringes allow medications to be stored in component parts right up until the medication is

injected. In addition, pre-filled mixing syringes eliminate the burden of measuring medicinal components and mixing diluents from separate containers.

Despite these advantages, prior mixing syringes have not offered reliable safety features to protect the syringe user from accidental needle sticks following injection. In particular, prior syringe assemblies have not provided a mixing syringe that operates integrally with an injection needle that can be automatically shielded upon completion of the injection.

SUMMARY OF THE INVENTION

With the foregoing in mind, the present invention provides a pre-filled medical device for mixing separate components of a medication and injecting the medication into a patient. The device includes a two-chambered container, such as a cartridge, connected to a needle that retracts automatically after use. After retraction, the contaminated needle tip is enclosed within the device to prevent inadvertent needle sticks.

The device includes a hollow barrel surrounding the needle and having a generally open rearward end that forms a socket. A two-chambered cartridge containing component parts of a medication is adapted to engage the socket. Prior to use, the components are stored separately in the two cartridge chambers. During use, a plunger disposed in the rearward end of the cartridge is advanced into the cartridge to combine the two components in one chamber for mixing. Subsequent pressure on the plunger advances the medicinal mixture through the needle into a patient.

The injection needle is operable between an extended position and a retracted position. In the extended position, the forward tip of the needle projects forwardly from the barrel. In the retracted position, the forward tip is enclosed within the barrel. When the needle is in the extended

position, a biasing element biases the needle toward the retracted position. A needle retainer releasably retains the needle in the extended position against the force of the biasing element. During the injection stroke, the cartridge disengages the needle retainer to allow the biasing element to propel the needle rearwardly into the barrel.

DESCRIPTION OF THE DRAWINGS

The foregoing summary as well as the following detailed description of the preferred embodiments will be best understood when read in conjunction with the following drawings, in which:

Fig. 1 is perspective view of a pre-filled cartridge injector having a two-chambered container that stores component parts of a medication;

Fig. 2 is an exploded perspective view of the cartridge injector shown in Fig. 1;

Fig. 3 is an enlarged view of a locking clip of the cartridge injector shown in Fig. 2;

Fig. 4 is a sectional view of the cartridge injector shown in Fig. 1 taken along the line 4-4;

Fig. 5 is a sectional view of the cartridge injector shown in Fig. 4 taken along the line 5-5;

Fig. 6 is a sectional view of the cartridge injector shown in Fig. 1, illustrating the device prior to mixing the component parts of the medication;

Fig. 7 is a sectional view of the cartridge injector shown in Fig. 1, illustrating

the device after mixing with the cartridge locked to impede injection;

Fig. 8 is a sectional view of the cartridge injector shown in Fig. 1, illustrating the device after mixing the cartridge unlocked to allow injection;

Fig. 9 is a sectional view of the cartridge injector shown in Fig. 1, illustrating the device, after injection, just prior to needle retraction;

Fig. 10 is a sectional view of the cartridge injector shown in Fig. 1, illustrating the device after needle retraction.

Fig. 11 is an enlarged fragmentary sectional view of the cartridge injector shown in Fig. 1, illustrating the tamper resistant connection between the cartridge and barrel after the needle is retracted.

Fig. 12 is a sectional view of a second embodiment of a two-chambered pre-filled cartridge injector having a retractable needle.

Fig. 13 is a sectional view of the device shown in Fig. 12 taken along the line 13-13.

Fig. 14 is a sectional view of the device shown in Fig. 12 illustrating the device during mixture of the medicinal components in the cartridge transfer of one component of medicine between chambers.

Fig. 15 is a sectional view of the device shown in Fig. 12 illustrating the device after mixture of the medicinal components.

Fig. 16 is a sectional view of the device shown in Fig. 12 illustrating the device after needle retraction.

Fig. 17 is a sectional view of a third embodiment of a two-chambered pre-filled cartridge injector having a retractable needle.

Fig. 18 is a sectional view of the cartridge portion of the device illustrated in Fig. 17.

Fig. 19 is a sectional view of the device shown in Fig. 17 illustrated without the cartridge, illustrated prior to use.

Fig. 20 is a sectional view of the cartridge in Fig. 18 illustrating the device during mixture of the medical components.

Fig. 21 is a sectional view of the device shown in Fig. 18 illustrating the device after mixture of the medical components.

Fig. 22 is a sectional view of the device shown in Fig. 17 illustrating the device at the completion of an injection.

Fig. 23 is a sectional view of the device shown in Fig. 17 illustrating the device after needle retraction.

Fig. 24 is an exploded perspective view of a fourth embodiment of a two-chambered pre-filled cartridge injector having a retractable needle.

Fig. 25 is a sectional view of the device illustrated in Fig. 24.

Fig. 26 is a sectional view of the device in Fig. 24 illustrating the device after mixture of the medical components.

Fig. 27 is a sectional view of the device shown in Fig. 24 illustrating the device at the completion of an injection.

Fig. 28 is a sectional view of the device shown in Fig. 24 illustrating the device after needle retraction.

Fig. 29 is a sectional view of the device shown in Fig. 24 illustrating the device after needle retraction.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the figures in general, and to Figs. 1-11 specifically, an injector device **10** is shown with a needle **12** having a sharpened distal tip **16** for insertion into a patient. As shown in Fig. 4, the injector device **10** has an attached cartridge **50** having a first chamber **52** and a second chamber **56**. The two chambers **52, 56** are pre-filled with component parts of a medication that are to be mixed prior to injection. The cartridge **50** also includes a plunger **40** that is slidable within the cartridge. Initially, advancing the plunger 40 in the cartridge 50 expels the medicinal component from the first chamber 52 into the second chamber 56 to mix the two medicinal components. After mixing the components, advancing the plunger drives the cartridge forwardly to inject the medicine into a patient. Upon completion of the injection stroke, the medical professional releases pressure from the plunger to allow automatic retraction of the needle **12** into the device **10** to protect the contaminated needle 12 from inadvertent contact.

The injector device **10** includes a double-ended needle **12**, a generally cylindrical barrel **30**, a compression spring **26** and a needle retainer **20** releasably retaining the needle against the bias of the spring. As shown in Figs. 4 and 5, the needle **12** has a sharpened proximal tip **14** and a sharpened distal tip **16.** The spring **26** circumscribes the needle **12** and is compressed against the interior of the barrel **30** at the barrel's distal end. The rearward end of the spring **26** bears against the interior of the needle retainer **20** to bias the needle **12** and needle retainer in the rearward direction.

The needle **12** is operable between two positions, an extended position and a retracted position. In the extended position, the needle **12** projects forwardly from the forward end of the barrel **30**. In the retracted position, the needle **12** is retracted into the barrel **30** so that the sharpened tip **16** of needle **12** is enclosed within the barrel to prevent inadvertent contact with the sharpened tip. When the needle is in the extended position, the spring **26** biases the needle **12** rearwardly toward the retracted position. The needle retainer **20** releasably retains the needle **12** in the extended position, against the bias of the spring **26**. During the injection stroke, the cartridge **50** cooperates with the needle retainer **20** to allow the needle to retract into the barrel **30**, as shown in Fig. 10.

Referring now to Figs. 5-7, the cartridge **50** includes a first chamber **52** containing a first medicinal component **54** and a second chamber **56** containing a second medicinal component **58**. The chambers **52, 56** are separated by a mid wall **60** containing an orifice **62.** A rear seal 70 seals the first chamber 52 to prevent the components from being mixed prior to use. When the rear seal 70 is pierced and the plunger **40** is advanced into the cartridge **50**, the first component **54** flows into the second chamber **56** through the orifice 62, where it combines with the second component **58** to form the medication **59**, as shown in Figs. 6-7. Subsequent pressure on the plunger **40** and cartridge **50** forces the medication **59** through the needle **12** and into the patient.

Referring now to Figs. 4-6, the elements of the injector device **10** will be described in greater detail. The barrel **30** is generally cylindrical and the distal end of the barrel has a tapered nose **32**. The nose **32** has an opening through which the needle **12** extends so that the sharpened tip **16** of the needle can be inserted into a patient. The rearward end of the barrel **30** is open, forming a cylindrical socket **34** adapted to receive the cartridge **50**. Two laterally extending flanges **36** project outwardly from the barrel **30**,

transverse the longitudinal axis of the barrel, forming a pair of finger grips for operating the device **10**. The barrel **30** further includes a pair of retaining apertures **38** and a pair of lockout windows **39** that cooperate with the needle retainer **20** as described further below.

As shown in Fig. 5, a hub **21** projects from the rearward end of the needle retainer **20**. The hub **21** is a generally cylindrical element having a central bore **23**. The needle **12** is disposed within the central bore **23** of the hub **21** so that the rearward end **14** of the needle **12** projects rearwardly from the hub and the forward end **16** of the needle projects forwardly from the hub. The needle **12** can be attached to the hub **21** in one of several ways. For example, the needle **12** can be attached to the hub **21** by an adhesive such as a UV curable adhesive. Alternatively, the needle **12** can be molded into the hub **21**, which is formed of plastic. The rearward end of the hub **21** includes a circumferentially barbed connector **25** configured to cooperate with the cartridge **50** to connect the cartridge to the needle hub 21 as discussed further below.

The needle retainer **20** is axially displaceable within barrel **30** to facilitate needle retraction. The needle retainer **20** can be molded out of a rigid, high strength resin, such as polycarbonate. Prior to retraction, the needle retainer **20** is maintained in a fixed axial position while the medication **59** is expelled from the cartridge **50**. After the injection, the needle retainer **20** and the attached needle **12** are displaced rearwardly by the compression spring **26**.

The spring **26** is a compression spring and may be formed of stainless steel, treated carbon steel wire or other suitable non-corrosive spring metal. The residual compression of the spring prior to disengagement of the needle retainer is of sufficient magnitude to facilitate complete needle retraction and overcome the frictional resistance between sliding components within the device **10**.

Referring now to Fig. 6, the needle retainer **20** includes a pair of retaining arms **22** that extend radially outwardly and forwardly from the distal end of the needle retainer **20**. During operation, the needle retainer **20** is operable between a locked position and an unlocked position. In the locked position, the retaining arms **22** engage the retaining apertures **38** in the barrel wall to maintain the needle in a fixed axial position with the forward tip **16** of needle **12** projecting forwardly from the barrel **30**. More specifically, in the locked position, the retaining arms **22** engage the barrel **30** to hold the needle hub **21** and needle **12** against the rearward bias of the spring **26**. In the unlocked position, the retaining arms **22** are positioned so as to allow the needle hub 21 and needle **12** to be retracted rearwardly. More specifically, in the unlocked position, the retaining arms **22** are disengaged from the retaining apertures **38**, allowing the spring 26 to propel the needle hub **21** and needle **12** rearwardly.

As discussed above, the retaining arms **22** on the needle retainer **20** project forwardly and outwardly into engagement with the retaining apertures **38** in the wall of the barrel **30**. The terminal end of each arm forms a retaining tab **24** that is configured to project into a retaining aperture **38**. More specifically, the retaining tabs **24** engage the lip formed by each retaining aperture **38** in the wall of the barrel **30**. In this way, the retaining tabs **24** operate as a pair of latches to retain the needle hub 21 and needle **12** against the rearward bias of the spring.

Referring again to Figs. 4 and 5, the cartridge **50** is a generally cylindrical vessel that may be molded out of pharmaceutical quality glass such as borosilicate, or a rigid inert plastic such as polyolefin or polyester. The midwall **60** that separates the first and second chambers may be formed of a rigid inert plastic such as polyolefin or polyester. The barrier or midwall **60** can be molded as part of the cartridge **50** or bonded to the inside wall of the cartridge. Each chamber is filled with a predetermined amount of a

medication during manufacturing of the device **10**.

The front end of the forward chamber **56** is sealed by an elastomeric front seal **80**, which may be molded in a self-sealing biocompatible elastomer such as polyisoprene. The front seal **80** is generally cylindrical, having a plurality of axially-spaced circumferential ribs **81**. The ribs **81**, which are more clearly shown in Fig. 2, frictionally and sealingly engage the interior of the container to provide a fluid tight seal, thereby preventing fluid from leaking from the cartridge **50**. The front seal **80** also has a front end that is pierceable by the rearward sharpened tip **14** of needle **12**. After being pierced, the front end of the front seal **80** reseals around the needle **12** to prevent fluid from leaking from the cartridge **50**.

Referring now to Figs. 5 and 6, the front seal **80** has a socket 82 configured to cooperate with the barbed connector 25 on the needle hub 21. The socket **82** includes two radially relieved recesses, **82a** and **82b**, that mate with the barbed connector **25**. Specifically, the barbed connector **25** matingly engages the front seal **80** in a first position and a second position.

In the first position, the barbed connector **25** engages the first recess **82a**, as shown in Fig. 5. In this position, the cartridge is attached to the hub, but the rearward end of the needle does not pierce the front seal 80. Applying pressure to the plunger **40** displaces the cartridge forwardly relative to the hub, thereby displacing the barb into to the second position. In the second position, the barbed connector **25** engages the second recess **82b**, as shown in Fig. 6. In this position, the rearward end of the needle **12** pierces the front seal 80.

The front seal **80** includes a hollowed cavity **84** at its rearward end. In this way, a pierceable wall **86** is formed in the front seal **80** between the cavity **84** and the second recess **82b**. As shown in Fig. 5 prior to use, the

cartridge 50 is mounted in the first position so that the barbed connector **25** engages the first recess **82a**. In this position, the needle **12** does not penetrate the pierceable wall **86**. As the **hub 21** is displaced from the first position to the second position, the rearward end **14** of the needle**12** pierces the wall **86** and extends into the cavity **84** as shown in Fig. 6. The cavity **84** opens into the interior of the second chamber **56** of cartridge **50** so that when the needle **12** projects into the hollowed section **84**, the needle is in fluid communication with the interior of the cartridge. After the needle **12** penetrates the pierceable wall **86**, the wall reseals around the needle to form a fluid-tight seal and prevent medication in the cartridge **50** from leaking around the needle.

To prepare the injection device **10** for use, the medical professional displaces the cartridge **50** forwardly relative to the needle retainer **20**, so that the forward seal **80** is driven over the barbed connector **25**, such that the barbed connector engages the second recess **82b**. At the same time, the proximal tip **14** of needle **12** pierces the pierceable wall **86**, so that the needle is in fluid communication with the second chamber, as shown in Fig. 6.

The connection between the front seal **80** and the needle hub **21** is preferably a one-way engagement. In other words, when the front seal **80** is mounted on the barbed connector **25**, the cartridge **50** can be displaced forwardly relative to the barbed connector, but the cartridge cannot be displaced rearwardly relative to the barbed connector. In this way, the cartridge **50** cannot be readily removed from the needle hub 21 in barrel **30**, such that the cartridge is substantially permanently attached to the needle hub and barrel.

The one-way connection is facilitated by the rearward-facing tapered shoulder of the barbed connector **25** and the square shaped forward-

facing shoulder of the barbed connector. In particular, the rearward-facing shoulder of the barbed connector **25** cooperates with tapered sides in the first and second radial recesses **82a** and **82b** to permit relative displacement of the plug from the first recess to the second recess. Reverse displacement from the second recess **82b** back to the first recess **82a** is resisted by the square shaped forward-facing shoulders on barbed connector **25**, which act to impede reverse displacement.

Referring now to Fig. 4, the front seal **80** is configured to prevent ejection of fluid when the barbed connector **25** is displaced from the first position, in which the barbed connector **25** engages the first radial recess **82a**, to the second position, in which the barbed connector engages the second radial recess **82b**. Specifically, the front seal **80** includes a flared head **88** or circumferential flange at the forward end of the front seal. The open distal end of the cartridge **50** terminates with a beaded rim **51** that seats against the rearward edge of the flared head **88**. The outside diameter of the flared head **88** is greater than the inside diameter of the open distal end of the cartridge **50**, thereby impeding rearward displacement of the front seal **80** into the cartridge when force is initially applied to the plunger **40**. In addition, the force required to overcome the frictional engagement between the outer circumference of the front seal **80** and the inner wall of the cartridge **50** is greater than the force required to displace the plug **25** from the first recess **82a** to the second recess **82b**. Accordingly, when force is initially applied to the plunger **40**, the front seal **80** remains in a fixed position relative to the cartridge **50**, while the barbed connector **25** is displaced into the second position. This restriction on the front seal **80** limits the release of fluid from the cartridge **50** when the needle **12** pierces the wall **86**.

During storage of the injection device **10**, the medication is divided into two separate components stored in the cartridge **50**, as shown in Fig. 5. Specifically, a first component **54** of the medicine is stored in the rear

chamber **52** and a second component **58** of the medicine is stored in the forward chamber **56**. The two chambers are separated by the mid-wall **60** containing an orifice **62** and a hollow piercing member **64** mounted in the orifice. The orifice **62** is located axially at the center of the midwall **60**. In addition, a small vent hole **63** is located just off center in the midwall **60** to vent the air from the dead space area between the mid wall and the mid seal 70. Preferably, the piercing member **64** is fabricated out of suitable non-corrosive material such as stainless steel or treated carbon steel wire. When the plunger **40** is axially advanced in the cartridge **50**, the first component **54** in the rear chamber **52** advances through the piercing member **64** and into the forward chamber **56** to combine with the second component **58**.

Prior to use of the injection device **10**, fluid communication between the first and second chambers is prevented by an elastomeric mid seal **70**, which may be molded in a self-sealing biocompatible elastomer such as polyisoprene. The mid seal **70** is initially slidably disposed in the first chamber **52** between the piercing member **64** and the first component **54**, as shown in Figs. 4-5. The mid seal **70** is generally cylindrical, having a plurality of axially-spaced circumferential ribs **71**, as shown more clearly in Fig. 2. The ribs **71** frictionally and sealingly engage the inner wall of the cartridge **50** to provide a fluid-tight seal. This fluid-tight seal prevents fluid in the first chamber from entering the piercing member **64**. The mid seal **70** also includes a hollowed section **72** formed in the forward end of the mid seal that opens to the first chamber **52** at the rearward end of the mid seal. The forward end of the mid seal **70** is closed by a membrane **78** that is pierceable by the piercing member **64**. Upon piercing the membrane **78**, fluid communication is established between the first and second chambers to allow the first and second components of the medication to be mixed.

Like the front seal **80** and mid seal **70**, the plunger **40** is generally cylindrical, preferably having a plurality of axially-spaced

circumferential ribs **41**. The plunger **40** may be molded in a self-sealing biocompatible elastomer such as polyisoprene. Alternatively, the plunger **40** could be a two-part assembly in which a cylindrical elastomeric seal is mounted to a rigid plastic plunger rod. The ribs **41**, which are more clearly shown in Fig. 2, frictionally and sealingly engage the interior of the cartridge **50** to provide a fluid tight seal, thereby preventing fluid from leaking from the proximal end of the cartridge.

The plunger **40** is slidable within the first chamber **52** in response to pressure applied to the thumb pad **42**. When the plunger **40** is axially advanced into the cartridge **50**, the first component **54** is compressed against the rearward end of the mid seal **70** in the first chamber **52**. As back pressure on the mid seal **70** overcomes the frictional resistance between the mid seal and the cartridge **50**, the mid seal is displaced into the piercing member **64** until the membrane **78** is pierced, as shown in Fig. 6. As the mid seal advances, air from the space between the mid seal and mid wall vents through the vent hole **63** in the mid wall. At such time, the piercing member **64** penetrates through the hollowed section **72** to connect the first chamber **52** and second chamber **56** in fluid communication.

After the mid seal **70** is pierced, pressure applied to the plunger **40** advances the first component **54** through the piercing member **64** and into the second chamber **56** where the first and second components are subsequently mixed to form the medication **59**. The plunger **40** is displaced forwardly relative to the first chamber **52** until the flanged portion of the thumb pad **42** contacts the proximal end of the cartridge **50**, as shown in Fig. 7. The outside diameter of the thumb pad **42** is larger than the inside diameter of the cartridge **50**, thereby preventing further displacement of the plunger **40** once the thumb pad contacts the proximal end of the cartridge **50**. Preferably, the distance between the forward end of the plunger **40** and the rearward end of the mid seal **70** is equal to the distance between the flanged portion of the

thumb pad **42** and the proximal end of the cartridge **50**. Once the thumb pad **42** contacts the proximal end of the cartridge **50**, the plunger is fixed relative to the cartridge **50**. At this point, axial advancement of the cartridge **50** relative to the barrel **30** is restricted, as described in more detail below.

Preferably, the injection device **10** includes a locking mechanism for preventing accidental release of the contents in the second chamber prior to mixing the two components. In the present embodiment shown in Fig. 7, the barrel **30** includes a locking clip **100** in the barrel wall to prevent accidental discharge of the medicinal components. The wall of the barrel **30** includes a pair of radial slots **104** formed in a plane that is transverse the longitudinal axis of the barrel. When the locking clip **100** is inserted through the slots **104**, the clip prevents inadvertent forward displacement of the cartridge **50** relative to the front seal **80**, thereby preventing accidental advancement of the medicinal components through the needle **12**. The locking clip **100** is preferably formed of a resilient high strength and high modulus resin, such as acetyl or polycarbonate, and is configured to releasably engage the slots **104** in the barrel **30**.

Referring to Figs. 1-3, the locking clip **100** is preferably a flat member having a pair of resiliently deflectable legs **101** that join to form a U-shape. The open end of the locking clip **100** has tapered edges **102** that allow the legs **101** to deflect outwardly as the locking clip **100** is inserted into the sidewall of the barrel **30**. In addition, the locking clip **100** has a plurality of teeth **103** on the inside edge of the legs **101** that are adapted to engage the edges of radial slots **104**.

As the locking clip is inserted into the sidewall of the barrel **30**, the legs **101** deflect outwardly to allow the teeth **103** to clear the edges of radial slots **104**. Upon being deflected outwardly, the resilience of legs **101** bias the legs radially inwardly toward their original position. Once the teeth

103 are disposed within the slots **104**, the legs **101** deflect radially inwardly toward their original position and releasably engage the outer edges of the needle retainer **20** in barrel **30**. In the inserted position, the closed end of the locking clip **100** remains outside the barrel **30**, as shown in Figs. 1 and 4.

After the medicinal components are mixed within the cartridge, the locking clip **100** is removed to permit injection of the medicine **59**, as shown in Fig. 8. The locking clip **100** is removed from the barrel **30** by pulling the closed end of the clip in a direction transverse to the longitudinal axis of the barrel. This direction is marked "A" in Fig. 1. By pulling the clip in this manner, the legs **101** are deflected outwardly from the slots **104** to allow the teeth **103** to clear the edges of slots **104**.

After the locking clip **100** is removed from the barrel **30**, the medication **59** is injected into the patient by advancing the cartridge forwardly into the barrel. Pressure applied to the thumb pad **42** causes the plunger **40** and cartridge **50** to move forwardly relative to the barrel **30**. With the barbed connector **25** mounted in the second recess **82b** in the front seal **80**, the front seal remains stationary while the cartridge **50** is advanced forwardly, as shown in Fig. 9. The front seal **80** and flared head **88** are configured to form a sliding fit with the interior of the cartridge **50** so that the cartridge can slide over the front seal. As the cartridge **50** is advanced, the mid seal **70** and the mid wall 60 are displaced toward the front seal **80**. This causes a reduction of volume in the second chamber **56**, whereby the medication is displaced into the needle to facilitate the injection. At the completion of the injection, the mid wall **60** bears against the rearward end of the front seal **80**, as shown in Fig. 9.

Referring now to Figs. 9-10, the automatic retraction of the needle **12** shall be described. The cartridge **50** is axially advanced to the

proximal end of the barrel **30** until the medication **59** is completely expelled from the second chamber **56**. As the cartridge **50** is advanced, the beaded circumferential rim **51** of the cartridge is displaced into engagement with the retaining arms **22** of needle retainer **20**. Preferably, the cartridge **50** is configured so that the longitudinal distance between the rearward end of the front seal **80** and the mid wall **60** corresponds to the longitudinal distance between the circumferential rim **51** of the cartridge and the retaining arms **22** when the cartridge is mounted on the barbed connector **25** in the second position. In this way, the rim **51** of the cartridge **50** engages the retaining arms **22** when substantially all of the medication **59** is expelled from the device **10**.

After the rim **51** of cartridge **50** engages the retaining arms **22**, continued axial advancement of the cartridge deflects the retaining arms radially inwardly so that the retaining tabs **24** are displaced inwardly, as shown in Fig. 9. In the inward position, the retaining tabs **24** are disengaged from the retaining apertures **38** of the barrel **30**. In this way, the cartridge **50** operates as an actuator, such that axial advancement of the cartridge displaces the needle retainer **20** into an unlocked position. In the unlocked position, the needle retainer **20** is no longer locked in place against the force of the spring **26**. After the needle retainer **20** is in the unlocked position and the user releases pressure on the plunger **40**, the spring **26** propels the needle **12** rearwardly until the sharpened distal tip **16** of the needle is enclosed within the barrel **30**.

As shown in Fig. 10, when the needle **12** is retracted, the needle, needle retainer **20** and cartridge **50** are displaced rearwardly together. During retraction, the retaining arms **22** are biased radially outwardly so that the retaining tabs **24** ride along the inside wall of the barrel. The force of the spring **26** is sufficiently strong to overcome the frictional resistance generated between the guide arms 28 and the barrel **30**.

Preferably, the injection device **10** includes a mechanism for limiting rearward displacement of the retracted elements. Referring now to Figs. 2, 4 and 10, the needle retainer **20** includes a pair of guide arms **28** that cooperate with a pair of alignment channels or grooves **31** formed in the interior wall of the barrel **30**. The guide arms **28** may be molded out of a rigid, resilient high strength resin, such as polycarbonate. The guide arms **28** extend forwardly from the needle retainer **20** and project radially outwardly into engagement with the alignment grooves **31**.

Each guide arm **28** includes a linear elongated rear portion which preferably is generally parallel to the longitudinal axis of barrel **30**. The forward portion of each guide arm **28** bends outwardly transverse to the longitudinal axis of the barrel **30** and extends into one of the alignment grooves **31**. When the needle retainer **20** is disposed within the barrel, the guide arms **28** are deflected radially inwardly from their natural state. In this position, the guide arms **28** are biased radially outwardly against the inner wall of the barrel **30** due to the resilient properties of the guide arms.

The forward ends of guide arms **28** are preferably contained within the alignment grooves **31** to substantially limit rotation of the needle and needle retainer **20** during needle retraction. This engagement ensures that the guide arms are aligned with the lockout windows 39 so that the guide arms snap into the lockout windows at the end of retraction. In this way, the needle retainer **20** is limited to axial displacement during needle retraction. During retraction, the frictional resistance between the forward ends of the guide arms **28** and the inside wall of the barrel **30** is overcome by the expansion force of the spring **26**.

As shown in Fig. 4, the linear elongated rear portion of each guide arm **28** is spaced radially inwardly from the inner wall of the barrel **30** to create a clearance space between the linear portion of the guide arms and

the barrel. Preferably, the minimum radial thickness of the clearance space is greater than the thickness of the wall of the cartridge **50** or the cartridge rim **51**. In this way, when the cartridge **50** is advanced forwardly to disengage the retaining arms **22**, advancement of the cartridge will not be impeded by the guide arms **28**.

Each alignment groove **31** is substantially parallel to the longitudinal axis of the barrel **30**. In Fig. 4, the groove 31 is shown extending to rearward end of the barrel. However, it may be desirable to terminate the groove forward of the rearward end of the barrel. The rearward portion of each alignment groove **31** intersects a lockout window **39** formed in the wall of the barrel **30**. The lockout windows **39** are adapted to receive the forward ends of the guide arms **28**, as shown in Fig. 10. In particular, as the front end of each guide arm **28** aligns with the corresponding lockout window **39** during needle retraction, the radially outward bias of the guide arm displaces the arm outwardly so that the forward end projects into the lockout window. The engagement between the guide arms **28** and lockout windows **39** prevent further axial movement of the retainer **22**. As a result, the retracted elements are limited from further displacement in the forward or rearward direction.

Preferably, the injection device **10** includes a mechanism to limit tampering or removal of the cartridge **50** from the barrel socket **34**. Referring now to Fig. 11, the present embodiment includes an annular lip **35** that projects radially inwardly from the inside wall of the socket **34** in barrel **30**. The lip **35** is adapted to seat against the beaded rim **51** on the cartridge **50** so that the cartridge can not be easily pulled out of the rear of the barrel **30**. As a result, access to the retracted elements, and the contaminated needle in particular, is limited.

Referring now to Figs. 4-10, the operation of the injection device

10 will be described. Prior to use, the needle **12** is disposed in an extended position so that the distal end **16** of the needle projects forwardly from the barrel **30**, as shown in Fig. 4. Preferably, the device **10** is shipped with the cartridge **50** already mounted in barrel **30** so that the barbed connector **25** is engaged in the first recess **82a**. Alternatively, the cartridge **50** may be shipped separately from the barrel **30**, so that the cartridge must be attached to the barrel prior to use.

With the cartridge **50** and barrel **30** assembled, the device **10** is held vertically so that the distal end **16** of needle **12** points upwardwardly. The user holds the device **10** by placing the user's thumb in a supporting position beneath the thumb pad **42** of plunger **40**. In addition, the user places a finger over each finger grip **36** to control the operation of the device **10.** With the user's fingers anchored over the finger grips **36**, the user applies a slight squeezing pressure on the thumb pad **42**, much like a conventional syringe. The squeezing pressure displaces the cartridge **50** forwardly relative to the barrel so that the barbed connector **25** on the needle retainer **20** engages the second recess **82b** in front seal **80** and the needle **12** pierces the wall **86**. As the front seal **80** is pierced, entrapped air in the forward chamber **56** is vented through needle **12**.

Continued advancement of the plunger 40 drives the seal 70 toward the piercing element 64 until the piercing element pieces the mid seal, thereby providing fluid communication between the forward and rearward chambers 52, 56. At this point, the first component **54** may be advanced into the forward chamber **56**. Pressure is applied on the thumb pad **42** until the first component **54** is completely expelled from the rearward chamber 52 into the forward chamber **56** and the forward end of the plunger meets the rearward end of the mid seal **70**. The user then shakes the injector device **10** to mix the first and second components **54**, **58** inside the forward chamber **56**.

During mixing, the locking clip **100** prevents the cartridge **50** from being advanced forwardly into the needle retainer **20**. This constraint on the cartridge **50** limits the potential for inadvertent discharge of the medication **59** from the needle **12** and premature needle retraction. Once the medication **59** is adequately mixed, the user removes the locking clip **100** from the barrel **30** so that the cartridge **50** can be advanced forwardly within the barrel. At this point, initial pressure applied to the thumb pad **42** advances the cartridge and vents excess air out of the second chamber **56**.

The needle is then inserted into a patient and the plunger **40** is depressed to axially advance the cartridge **50** relative to the barrel **30**, thereby injecting the medication **59** from the cartridge into the patient. At the end of the injection stroke, the beaded rim **51** on the cartridge **50** engages the retaining arms **22**, thereby displacing the retaining tabs **24** radially inwardly to disengage the needle retainer **20** into the unlocked position. Although the needle retainer **22** is in the unlocked position, the needle **12** does not retract until the user releases pressure from the thumb pad **42**. In this way, the user can retain pressure on the thumb pad **42** until after the needle is withdrawn from the patient. The user can then release pressure from the thumb pad **42** so that the needle is propelled rearwardly by the spring **26**. Alternatively, the user can release pressure from the thumb pad **42** while the needle **12** is still inserted in the patient. Once the thumb pad **42** is released, the spring **26** propels the needle **12** rearwardly so that the contaminated distal tip **16** of the needle is enclosed within the barrel **30**.

Referring now to Figs. 12-16 in general, and to Figs. 12-13 specifically, a second embodiment of a pre-filled safety diluent injector is shown. The injector device **110** includes elements that are substantially similar to the elements described above in connection with the first embodiment 10, illustrated in Figs. 1-11. These elements include: a double-ended needle **112**, a generally cylindrical barrel **130**, a compression spring

126, a needle retainer 120 releasably retaining the needle against the bias of the spring, a locking clip 200. The needle 112 has a sharpened proximal tip 114 and a sharpened distal tip 116. The spring 126 circumscribes the needle 112 and is compressed against the interior of the barrel 130 at the barrel's forward end. The rearward end of the spring 126 bears against the interior of the needle retainer 120 to bias the needle 112 and needle retainer in the rearward direction.

In contrast to the previous embodiment, the second embodiment utilizes a cartridge 150 having a selectively sealable by-pass fluid passage 160 to separate the two medicinal components, rather than a mid wall and a pierceable seal as described above with the first embodiment. Prior to use, a mid seal 170 within the cartridge 150 separates the two medicinal components 154, 158. Prior to use, the mid seal 170 is displaced forwardly adjacent the by-pass passage 160, which provides a fluid passage, allowing the two medicinal components 154, 158 to be mixed. The mixed components can then be injected into the patient.

Referring to Figs. 12, 13, the detail of the Cartridge 150 will be described in greater detail. The cartridge is a generally cylindrical container. The forward end of the cartridge is sealed by the pierceable forward seal 180. The rearward end of the cartridge is sealed by a piston 143 that forms a fluid-tight seal with the interior wall of the cartridge. Intermediate the forward seal 180 and the piston 143, a mid seal 170 forms a fluid-tight seal with the interior wall of the cartridge, separating the cartridge into two chambers, a forward chamber 156 for receiving a first component 158, and a rearward chamber 152 for receiving a second component 154.

The cartridge 150 includes a bubble-like fluid passage 160 that protrudes outwardly from the side of the cartridge. The fluid passage 160 forms an area in which the diameter of the cartridge is greater than the

diameter of the mid seal. The fluid passage **160** is an axially elongated channel having a length that is greater than the axial length of the mid seal **170**, and preferably, is shorter than the combined length of the mid seal and the piston **143**.

Although the fluid passage 160 is illustrated as a bubble-like protrusion, the fluid passage may be formed in other configurations. For instance, the fluid passage may be a recess or axial groove formed in the interior wall of the cartridge 150, so that the fluid passage does not protrude from the exterior surface of the cartridge. Similarly, the fluid passage may be an annular recess formed in the interior wall of the cartridge.

Referring to Fig. 12, the device **110** is illustrated in a "storage" position. In this position, the mid seal **170** prevents the two medicinal components from mixing. Therefore, the sealed cartridge **150** can be stored for an extended period, if desired, without compromising the efficacy of the medicinal components. In the stored position, the mid seal **170** is disposed rearwardly of the fluid passage **160** so a fluid-tight seal is formed between the mid seal and the interior wall of the cartridge, around the entire circumference of the mid seal.

During storage of the injection device **110**, the medication is divided into two separate components stored in the cartridge **150**, as shown in Figs. 12-13. Specifically, the first component **154** of the medicine is stored in the first chamber **152** and the second component **158** of the medicine is stored in the second chamber **156**. As discussed further below, preferably, when the cartridge is being filled during manufacture, a quantity of air remains within the second chamber **156**.

A plunger **140** is slidably disposed in the rearward end of the cartridge **150**. The plunger **140** is comprised of a plastic molded plunger rod

141 and an elastomeric piston **143**. The piston **143** forms a fluid-tight seal with the inner wall of the cartridge, and is slidably displaceable within the cartridge. The plunger rod **141** can be connected to the plunger seal **143** in a number of ways. In the present embodiment, the plunger rod **141** includes external screw threads that are configured to engage internal threads inside the plunger seal **143**, whereby the plunger rod and seal can be screwed together.

Referring now to Fig. 14, the transfer of the first medicine component **154** into the second chamber **156** shall be described. The mid seal **170** is advanced axially until it registers with the fluid passage **160**. The fluid passage **160** then provides a by-pass passage so that the component in the rearward chamber can be injected into the forward chamber. Since the forward chamber preferably includes a quantity of air (or other compressible fluid), the material in the forward chamber can be compressed to allow the mid seal to be advanced into registry with the fluid passage **160**. Alternatively, the forward chamber may include a vent for venting the air from the forward chamber when the fluid is transferred from the rearward chamber into the forward chamber. If a vent is included, preferably the vent is sealable to prevent leakage of the mixed components during injection.

Specifically, to mix the two components in the cartridge, the plunger **140** is axially advanced into the cartridge **150**, to compress the first component **154** against the rearward end of the mid seal **170** in the first chamber **152**. As back pressure on the mid seal **170** overcomes the frictional resistance between the mid seal and the cartridge **150**, the mid seal is displaced forwardly in the cartridge. Once the mid seal **170** is displaced into alignment with the fluid passage **160**, a passage is created between the mid seal and the inside wall of the fluid passage, as shown in Fig. 14.

The fluid passage **160** is sufficiently large to allow the first

substance **154** to flow around the mid seal and into the second chamber **156** where it is mixed with the second substance **158**. Once the first component is completely transferred to the second chamber **156**, the plunger seal **143** is advanced until it abuts the mid seal **170**, as shown in Fig. 15. The combined axial length of the mid seal **170** and piston **143** is slightly longer than the length of the fluid passage **160**. Therefore, the mid seal and piston seal off the entire length of the fluid passage. This prevents the contents of the second chamber **156** from backflowing during mixing of the components.

After mixing of the components is completed, the locking clip **200** is removed to allow injection of the medication into the patient. Pressure is applied to the cartridge **150** to discharge the medication from the second chamber **156**. At the completion of the injection stroke, the cartridge **150** actuates the needle retainer **120**. Pressure on the cartridge **150** is then released so that the needle can be retracted, as shown in Fig. 16.

Referring now to Figs. 17-23 in general, and to Fig. 17 specifically, another embodiment of a pre-filled safety diluent injector is designated generally 210. The injector device **210** includes a double-ended needle **212**, a generally cylindrical barrel **230** that houses the needle and a generally cylindrical cartridge **250**. The barrel **230** further includes a compression spring **226** and a needle retainer **220** releasably retaining the needle **212** against the bias of the spring. The needle **212** has a sharpened rearward tip **214** and a sharpened forward tip **216**. The spring **226** circumscribes the needle **212** and is compressed against the interior of the barrel **230** at the barrel's forward end. The rearward end of the spring **226** bears against the interior of the needle retainer **220** to bias the needle **212** and needle retainer in the rearward direction.

In this embodiment, the transferring and mixing of the medication components is done in the cartridge **250** prior to attaching the

cartridge to the needle hub 221. Since the cartridge **250** is not connected to the needle assembly during mixing, there is no risk of inadvertently retracting the needle during the mixture of the components. As a result, the barrel does not include a locking clip, as in the other embodiments.

Referring now to Figs. 18-19, the cartridge **250** and barrel **230** are packaged and distributed so that the two are disassembled. The cartridge **250** is a generally cylindrical vessel that may be molded out of pharmaceutical quality glass such as borosilicate or a rigid inert plastic such as polyolefin or polyester. A cartridge cap **253** is disposed over the distal end of the cartridge **250**. The cartridge **250** is configured similar to the cartridge 150 illustrated in Figs. 12 - 16, and includes a bubble-like fluid passage **260** that protrudes outwardly from the side of the cartridge. A mid seal **270** is slidably disposed in the cartridge **250** and divides the cartridge into a first chamber **252** and a second chamber **256**. Each chamber of cartridge **250** is filled with a predetermined amount of a component of medication during manufacturing of the device **210**. In particular, the first chamber **252** is prefilled with a first component **254** of the medication and the second chamber **256** is prefilled with a second component **258**.

Referring now to Fig. 20, a plunger **240** is slidably disposed in the proximal end of the cartridge **250**. The plunger **240** is comprised of a plastic molded plunger rod **241** and an elastomeric plunger seal **243**. When the plunger **240** is axially advanced into the cartridge **250**, the first component **254** is compressed against the rearward end of the mid seal **270** in the first chamber **252**. As back pressure on the mid seal **270** overcomes the frictional resistance between the mid seal and the cartridge **250**, the mid seal is displaced forwardly in the cartridge. Once the mid seal **270** is displaced into alignment with the fluid passage **260**, a passage is created between the mid seal and the inside wall of the fluid passage to allow the first substance **254** to flow around the mid seal and into the second chamber **256** where it is mixed

with the second substance **258**.

The fluid passage **260** is sufficiently long to allow the first substance **254** to flow around the mid seal and into the second chamber **256** where it is mixed with the second substance **258**. Once the first component is completely transferred to the second chamber **256**, the plunger seal **243** is advanced until it abuts the mid seal **270**, as shown in Fig. 21. The combined axial length of the mid seal **270** and plunger seal **243** is slightly longer than the maximum length of the fluid passage **260** so that the mid seal and plunger seal close off the entire length of the fluid passage. This prevents the contents of the second chamber **256** from backflowing during mixing of the components.

Referring again to Fig. 18, the cartridge **250** includes an elastomeric front seal **280** in the distal end of the cartridge. The front seal **280** may be molded of a self-sealing biocompatible elastomer such as polyisoprene. The front seal **280** is generally cylindrical with a wide cylindrical rearward end **282** disposed within the cartridge and a reduced diameter forward end **284** projecting forwardly from the forward end of the cartridge. The rearward end **282** has an outside diameter that is similar to the inside diameter of the cartridge **250**. In addition, the rearward end **282** has a plurality of axially-spaced circumferential ribs **286** that frictionally and sealingly engage the interior of the cartridge to provide a fluid tight seal and prevent fluid from leaking from the cartridge.

The forward end **284** of front seal **280** includes an external thread **288** about its circumference. The distal end **284** also contains a shallow frontal cavity **290**. A narrow bore **292** in fluid connection with the second chamber **256** extends from the proximal end of the front seal **280** and terminates within the reduced diameter distal end **284**. Fluid communication between the frontal cavity **290** and the bore **292** is obstructed by a pierceable

membrane **294**.

Referring now to Fig. 19, the barrel **230** is generally cylindrical and has a tapered nose **232** at its distal end. The nose **232** has an opening through which the needle **212** extends. In addition, the nose **232** is configured to receive a needle cover 211 that fits over the nose to prevent accidental needle sticks when the needle **212** is in an extended position. The proximal end of the barrel **230** is open, forming a cylindrical socket **234** adapted to receive the cartridge **250**. Prior to attachment with the cartridge **250**, the rearward open end of the barrel **230** is closed by a cylindrical barrel cap **233**. The barrel further includes a pair of retaining apertures **238** that cooperate with the needle retainer **220** to releasably retain the needle, and a pair of lockout windows that cooperate with locking tabs to lock the needle in the retracted position.

The needle retainer **220** includes a generally cylindrical body **221** and a pair of retaining arms **222** that extend radially forwardly from the body **221**. A generally cylindrical aperture **296** is disposed within the proximal end of the needle retainer body **221**. The inner wall of the aperture **296** includes internal screw threads **298** that are adapted to receive the external screw thread **288** of the front seal **280** in the cartridge **250**.

The cartridge cap **253** and barrel cap **233** are removed from the cartridge **250** and barrel **230**, respectively, to prepare the cartridge and barrel for assembly. The cartridge **250** is connected to the barrel **230** by inserting the forward end of the front seal through the open end of the barrel **230** and screwing the cartridge clockwise into the aperture **296**. The frontal cavity **290** in the front seal **280** is preferably coaxial with the needle **212**, such that attachment of the cartridge **250** to the barrel **230** causes the proximal needle tip **214** to enter the cavity **290** and pierce the membrane **294**, thereby connecting the second chamber of the cartridge in fluid communication with

the needle **212**, as shown in Fig. 17.

Referring to Fig. 17, the cartridge **250** is connected to the barrel **230**, the medication can be injected into the patient by advancing the cartridge forwardly into the barrel. The proximal end of the front seal **280** is configured to form a sliding fit with the interior of the cartridge **250** so that the cartridge slides over the front seal during advancement of the cartridge. As the cartridge **250** is advanced, the rearward end of the front seal **280** bears against the needle retainer **220**, thereby keeping the front seal stationary during advancement of the cartridge. At the same time, the mid seal **270** at the rear of the second chamber **256** is displaced toward the front seal **280.** This causes a reduction of volume in the second chamber **256**, whereby the medication is displaced into the needle to facilitate the injection. At the completion of the injection, the mid seal **270** bears against the rearward end of the front seal **280**, as shown in Fig. 22.

As in the previous embodiments, the needle **212** is retracted by actuating the needle retainer **220**. In particular, the needle **212** is retracted by disengaging the retaining arms **222** from the retaining apertures **238** in the barrel wall to allow the spring **226** to propel the needle **212** rearwardly. To actuate the needle retainer **220**, pressure is applied to the cartridge **250** to advance the cartridge over the needle retainer body **221**, as shown in Fig. 22. During advancement, the distal end of the cartridge **250** engages a cylindrical sleeve **300** that is disposed around the distal end of the needle retainer body **221**. The inside and outside diameters of the release sleeve **300** are preferably equal to the inside and outside diameters of the cartridge **250** so that the distal end of the cartridge mates with the proximal end of the sleeve. Prior to engagement with the cartridge **250**, axial movement of the release sleeve **300** along the needle retainer is limited by an internal flange **302** that slides within an annular fluid passage **223** on the needle retainer body **221**. After the cartridge **250** engages the sleeve **300** continued advancement of

the cartridge drives the sleeve axially forwardly into engagement with the retaining arms **222**. The release sleeve **300** deflects the retaining arms radially inwardly and out of engagement with the retaining apertures **238**, allowing the spring **226** to propel the needle **212** rearwardly, as shown in Fig. 23.

As described above, the third embodiment includes a threaded engagement between the front seal **280** and the needle retainer **220** rather than a barbed connection as described in the first two embodiments. Using a threaded connection can increase the overall length of the needle retainer **220**, which in turn increases the distance between the distal end of the cartridge **250** and the retaining arms **222**. One manner for accommodating this increased length is to increase the length of the barrel **230**. However, by incorporating the release sleeve **300**, the length of the barrel **230** need not be substantially increased. The release sleeve **300** compensates for the increased distance by acting as an extension of the cartridge **250**. This eliminates the need to increase the overall length of the device **210**. Preferably, the length of the release sleeve **300** is slightly longer than the length of the threaded engagement between the front seal **280** and the needle retainer **220**.

Referring now to Figs. 24-29 in general, and to Figs. 24-25 specifically, a fourth embodiment of a pre-filled safety diluent injector is shown. The injector device **310** includes a double-ended needle **312**, a generally cylindrical barrel **330** that houses the needle and a generally cylindrical cartridge assembly **350** mounted within the proximal end of the barrel. Like the previous embodiments, the barrel further includes a compression spring **326** and a needle retainer **320** releasably retaining the needle **312** against the bias of the spring. The device **310** also includes a U-shaped locking clip **400** in the barrel wall to prevent accidental discharge of medication from the device **310**.

The cartridge assembly **350** has a two-part design that offers the advantage of using cost-efficient plastic in the assembly. The cartridge assembly **350** includes a front cylinder **351** having an open proximal end and a rear cylinder **353** having an open distal end telescopically mounted to the proximal end of the front cylinder. The front cylinder **351** contains an internal wall **360** that divides the cartridge assembly **350** into a first chamber **352** and a second chamber **356**. The first chamber **352** contains a predetermined amount of a first component **354** of medication, and the second chamber **356** contains a predetermined amount of a second component **358** of medication. The proximal end of the front cylinder **351** is closed by a pierceable elastomeric front seal **380**.

In many applications, the second component **358** will be a dry powdered component. Dry components do not require a glass container and can be stored in plastic containers without jeopardizing long term stability of the component. Since it is more cost-efficient to mold complex parts out of plastic than glass, it is preferable to minimize the complexity of the glass portion of the cartridge assembly **350**. To this end, the front and rear cylinders **351**, **353** are configured so that the first component **354** is stored entirely within the rear cylinder and the second component **356** is stored entirely within the front cylinder. In this arrangement, the front cylinder **351** comprises a more complicated structure to allow the rear cylinder to be a simple cup-shaped container. Therefore, the more complex forward cylinder can be molded out of cost-efficient plastic for those devices that store a dry second component **358** in the second chamber **356**. Preferably, glass is only used, if at all, to mold the rear cylinder **353**.

As stated earlier, the rear cylinder **353** is telescopically mounted on the proximal end of the front cylinder **351**. The outside diameter of the rear portion of the rear seal is generally equal to the inside diameter of the rear cylinder **353** so as to frictionally engage the interior of the rear cylinder

and provide a fluid tight seal. The rear cylinder **353** is adapted to slide axially over the rear seal 340 in response to pressure applied to the proximal end of the rear cylinder.

The barrel **330** has an inside diameter large enough to accommodate the outside diameter of the rear cylinder **353**. As a result, the outside wall of the front cylinder **351** is separated from the interior wall of barrel **330** by a clearance space, as shown in Fig. 25. The front cylinder **351** is maintained in a concentric relationship with the much larger barrel **330** by a pair of opposing longitudinal ribs **355** on the outside wall of the front cylinder. The longitudinal ribs are illustrated in Fig. 24.

An elastomeric rear seal **340** is disposed between the front cylinder **351** and rear cylinder **353**. The rear seal **340** includes a reduced diameter end **342** partially disposed in the open proximal end of the front cylinder **351**. The rear seal **340** also includes a flanged end **344** disposed within the rear cylinder **353**. The reduced diameter end **342** and flanged end **344** frictionally and sealingly engage the interior of the front cylinder **352** and rear cylinder **354,** respectively. This engagement provides a fluid tight seal with the interior of both cylinders, while allowing the rear seal **340** to be displaced relative to either cylinder. Forward advancement of the rear seal **340** relative to the front cylinder **351** is limited by the proximal end of the front cylinder, which is configured to matingly engage the flanged portion of the rear seal.

As stated earlier, the front cylinder **351** contains an internal wall **360.** The internal wall **360** is adjacent the rearward open end of the cartridge, forming a socket for receiving the rear seal **340**. The internal wall **360** contains an orifice **362** mounted in the center of the wall **360**. A hollow piercing member **364** is mounted in the orifice and extends rearwardly toward the rear seal **340**. In addition, it may be desirable to provide a vent opening in

the internal wall **360** to vent the air between the rear seal **340** and the internal wall when the rear cylinder is advanced to pierce the rear seal.

The distal end of the rear seal **340** is closed by a membrane **348** that is configured to be pierced by piercing member **364**. The rear seal **340** includes a hollowed mid section **346** that is connected in fluid communication with the first chamber **352** through the proximal end of the rear seal. Once the membrane **348** is pierced, a fluid passage is created through the piercing member **364** and rear seal **340**, such that the first and second chambers, **352**, **356** are connected in fluid communication. The rear seal **340** may be molded in a high elongation self-sealing biocompatible elastomer, such as polyisoprene.

The operation of the device **310** will now be described. A slight squeezing pressure is applied to the proximal end of the rear cylinder **353** to axially advance the rear cylinder over the front cylinder **351**. This causes the first component **354** to become compressed between the rear seal **340** and the closed proximal end of the rear cylinder **353**. Continued pressure on the rear cylinder **353** creates back pressure on the rear seal **340** which axially displaces the rear seal forwardly into the piercing member **364**. At this time, the membrane **348** is pierced to create a fluid passage between the first and second chambers **352**, **356**.

The rear cylinder **353** is advanced forwardly relative to the front cylinder **351** to expel the first component **354** from the first chamber **352** into the second chamber **356**. Once the first component **354** is completely expelled from the first chamber **352**, additional pressure on the rear cylinder **353** advances the rear cylinder forwardly relative to the front cylinder **351** until the closed proximal end of the rear cylinder abuts the proximal end of the rear seal **340**, as shown in Fig. 26. At this point, the device **310** is shaken to mix the components within the second chamber **356**. During the mixing process,

displacement of the cartridge assembly **350** is prevented by the locking clip **400**, thereby minimizing the potential for accidental discharge of the medication.

After the components are mixed, the locking clip 400 is removed. The cartridge assembly is then displaced forwardly so that the rearward end of the needle 312 pierces the forward seal 380. The air is then vented from the forward chamber. Further pressure is applied to the cartridge assembly **350** to discharge the medication from the second chamber **356** and through the needle **312**. At the completion of the injection stroke, the proximal end of the cartridge assembly **350** actuates the needle retainer **320**, as shown in Fig. 27. Pressure on the cartridge assembly **350** is then released so that the needle **312** can be retracted, as shown in Figs. 28 and 29.

In some instances, it may be desirable to store the cartridge in its component parts. In other words, the rear cylinder 353 may be detached from the forward cylinder **351**. Prior to use, the rear cylinder **353** would be attached to the forward cylinder 351 and the combined assembly would be utilized as described above. In such instances, the separate rear container **353** may include a separate cap to cover its forward end. Similarly, the forward cylinder **351** may include a cap to cover its rearward end. The detachable rearward cylinder **353** may permit a variety of pre-measured medicinal components to be stored and readily combined in various combinations prior to use.

The terms and expressions which have been employed are used as terms of description and not of limitation. There is no intention in use of such terms and expressions of excluding any equivalents of the features shown and described or portions thereof. It is recognized, however, that various modifications of the embodiments described herein are possible within the scope and spirit of the invention. For instance, the embodiments

described above include a needle retainer having a pair of radially displaceable arms to automatically release the needle for retraction after use. However, the devices may be modified by utilizing different needle retainers that may or may not automatically retract the needle after use. Accordingly, the invention incorporates variations that fall within the scope of the following claims.

CLAIMS

1. A medical device, comprising:
a barrel having an open proximal end and a distal end;
a needle having a first sharpened tip and being operable between an extended position in which the first sharpened tip projects forwardly from the barrel and a shielded position in which the first sharpened tip is shielded to prevent inadvertent contact with the first sharpened tip;
a cartridge in fluid communication with the needle, comprising:
a first chamber containing a first substance;
a second chamber containing a second substance;
a fluid flow controller between the first chamber and the second chamber; and
a plunger slidably disposed within the cartridge;
a biasing element imparting a force capable of displacing the needle relative to the barrel to shield the first sharpened tip; and
a needle retainer releasably retaining the needle in the extended position;
wherein axially advancing the plunger within the first chamber advances the first substance through the fluid flow controller and into the second chamber where said first substance combines with the second substance to form a medicinal mixture, and continued advancement of the plunger and cartridge relative to the barrel after the mixture is expelled from the cartridge actuates the needle retainer to release the needle, whereupon the biasing element displaces the needle relative to the barrel to shield the first sharpened tip.

2. The medical device in claim 1 wherein the medical device further comprises a needle carrier fixed to the needle.

3. The medical device in claim 1 wherein the needle has a second sharpened tip at its rearward end.

4. The medical device in claim 1 wherein the needle is retracted upon release of pressure on the plunger.

5. The medical device in claim 1 wherein the medical device further comprises one or more stops that impede continued rearward displacement of the first sharpened needle tip beyond the proximal end of the barrel as the needle is moved to the shielded position.

6. The medical device in claim 1 wherein the plunger is comprised of a plastic molded plunger rod connected to an elastomeric seal.

7. The medical device in claim 1 wherein the plunger is displaceable relative to the cartridge while the first substance is expelled from the first chamber, and the plunger is stationary relative to the cartridge when the mixture is expelled from the second chamber.

8. The medical device in claim 1 wherein the second substance is a powdered material.

9. The medical device in claim 1 wherein the second substance is a liquid material.

10. The medical device in claim 1 wherein the volume of the second chamber is greater than the combined volume of the first substance and the second substance.

11. The medical device in claim 1 wherein the fluid flow controller comprises:
a wall between the first and second chambers having an opening;
a hollow piercing element disposed through the opening having a sharpened end extending into the first chamber; and
a fluid flow pathway through the piercing element;
wherein axially displacing the cartridge toward the barrel displaces the plunger until the plunger is ruptured by the piercing element,

creating a passage through the plunger which aligns with the fluid flow pathway in the piercing element to allow the first substance to pass through the plunger into the second chamber.

12. The medical device in claim 1 wherein the fluid flow controller comprises:
a barrier between the first and second chambers having an opening;
a hollow piercing element disposed through the opening having a sharpened end extending into the first chamber;
a fluid flow pathway through the piercing element; and
a pierceable mid seal axially displaceable within the first chamber that provides fluid communication between the first and second chambers upon being pierced by the piercing element;
wherein axially displacing the plunger toward the barrel displaces the pierceable mid seal until the mid seal is ruptured by the piercing element, creating a passage through the mid seal which aligns with the fluid flow pathway in the piercing element to allow the first substance to pass through the mid seal into the second chamber.

13. The medical device in claim 1 wherein the fluid flow controller comprises:
a mid seal between the first and second chambers that is axially displaceable within the cartridge; and
an elongated fluid passage in the side wall of the cartridge;
wherein axially displacing the plunger toward the barrel displaces the mid seal into alignment with the fluid passage, creating a passage between said mid seal and the inside wall of the fluid passage that allows the first substance to flow around the mid seal into the second chamber.

14. The medical device in claim 1 wherein the cartridge is substantially permanently attached to the barrel.

15. The medical device in claim **1** wherein the cartridge comprises a beaded circumferential rim on the distal end of the cartridge, and the barrel contains a lip projecting radially inwardly from the inner bore of the barrel at the barrel's proximal end, said lip adapted to engage the beaded rim of the cartridge to impede removal of the cartridge from the rear of the barrel after needle retraction.

16. The medical device in claim **2** wherein the biasing element comprises a compression spring disposed between the distal end of the barrel and the needle carrier.

17. The medical device in claim **2** wherein the needle retainer comprises a pair of forward tines extending radially outwardly from the needle carrier and configured to releasably engage a pair of windows in the barrel wall.

18. The medical device in claim **2** wherein a cylindrical sleeve having generally the same outside diameter as the cartridge is disposed around the circumference of the needle carrier in general axial alignment with the cartridge, such that axial advancement of the cartridge at the end of the injection stroke displaces the sleeve toward the distal end of the barrel to actuate the needle retainer.

19. The medical device in claim **3** wherein the cartridge further comprises a front seal at the distal end of the cartridge that is configured to be pierced by the second sharpened tip to connect the needle and second chamber in fluid communication.

20. The medical device in claim **19** wherein the minimum axial force on the plunger that is required to pierce the front seal is less than or equal to the minimum axial force required to axially displace the plunger in the rear chamber.

21. The medical device in claim **19** wherein the distal end of the front seal

includes an external thread and the proximal end of the needle carrier includes a cavity adapted to receive the threaded end of the front seal.

22. A medical device, comprising:

a barrel having an open proximal end, a distal end and an opening through the barrel wall oriented perpendicularly to the longitudinal axis of the barrel;

a needle having a first sharpened tip and being operable between an extended position in which the first sharpened tip projects forwardly from the barrel and a shielded position in which the first sharpened tip is shielded to prevent inadvertent contact with the first sharpened tip;

a cartridge in fluid communication with the needle, comprising:

a first chamber containing a first substance;

a second chamber containing a second substance;

a fluid flow controller connecting the first chamber and the second chamber; and

a plunger slidably disposed within the cartridge;

a biasing element imparting a force capable of displacing the needle relative to the barrel to shield the first sharpened tip;

a needle retainer releasably retaining the needle in the extended position; and

a locking clip detachably connected to the barrel;

wherein axially advancing the plunger within the first chamber advances the first substance through the fluid flow controller and into the second chamber where said first substance combines with the second substance to form a medicinal mixture, and removal of the locking clip from the barrel permits further advancement of the plunger and cartridge relative to the barrel to expel the mixture from the second chamber, whereafter axially advancing the cartridge disengages the needle retainer to allow the biasing element to displace the needle relative to the barrel to shield the first sharpened tip.

23. The medical device in claim **22** wherein the medical device further comprises a needle carrier fixed to the needle.

24. The medical device in claim **22** wherein the needle has a second sharpened tip at its rearward end.

25. The medical device in claim **22** wherein the needle is retracted upon release of pressure on the plunger.

26. The medical device in claim **22** wherein the cartridge comprises a beaded circumferential rim on the distal end of the cartridge, and the barrel contains a lip projecting radially inwardly from the inner bore of the barrel at the barrel's proximal end, said lip adapted to engage the beaded rim of the cartridge to impede removal of the cartridge from the rear of the barrel after needle retraction.

27. The medical device in claim **22** wherein the medical device further comprises one or more stops that impede continued rearward displacement of the first sharpened tip beyond the open proximal end of the barrel as the needle is moved to the shielded position.

28. The medical device in claim **22** wherein the plunger is comprised of a plastic molded plunger rod connected to an elastomeric seal.

29. The medical device in claim **22** wherein the plunger is displaceable relative to the cartridge while the first substance is expelled from the first chamber, and the plunger is stationary relative to the cartridge when the mixture is expelled from the second chamber.

30. The medical device in claim **22** wherein the locking clip comprises a flat U- shaped disk having a plurality of teeth along the inner edge, said clip being configured to slide through the slits in the barrel in a direction perpendicular to the longitudinal axis of the barrel and at a location between the cartridge and the needle retainer, thereby impeding

contact between the cartridge and the needle retainer.

31. The medical device in claim **22** wherein the second substance is a powdered material.

32. The medical device in claim **22** wherein the second substance is a liquid material.

33. The medical device in claim **22** wherein the volume of the second chamber is greater than the combined volume of the first substance and the second substance.

34. The medical device in claim **22** wherein the fluid flow controller comprises:
a barrier between the first and second chambers having an opening;
a hollow piercing element disposed through the opening having a sharpened end extending within the first chamber;
a fluid flow pathway through the piercing element; and
a pierceable mid seal axially displaceable within the first chamber that provides fluid communication between the first and second chambers upon being pierced by the piercing element;
wherein initial axial displacement of the plunger toward the barrel displaces the pierceable mid seal into contact with the piercing element, piercing the mid seal and creating a passage through the mid seal which aligns with the fluid flow pathway in the piercing element to allow the first substance to pass through the mid seal into the second chamber.

35. The medical device in claim **22** wherein the fluid flow controller comprises:
a mid seal between the first and second chambers that is axially displaceable within the cartridge; and
an elongated fluid passage in the side wall of the cartridge between the

mid seal and the distal end of the cartridge;

wherein axially displacing the plunger toward the barrel displaces the mid seal into alignment with the fluid passage, creating a passage between said mid seal and the inside wall of the fluid passage that allows the first substance to flow around the mid seal into the second chamber.

36. The medical device in claim **23** wherein the biasing element comprises a compression spring disposed between the distal end of the barrel and the needle carrier.

37. The medical device in claim **23** wherein the needle retainer comprises a pair of forward windows in the barrel wall and a pair of forward tines extending radially outwardly from the needle carrier and configured to releasably engage the forward windows.

38. The medical device in claim **24** wherein the cartridge further comprises a front seal at the distal end of the cartridge that is configured to be pierced by the second sharpened tip to connect the needle and second chamber in fluid communication.

39. The medical device in claim **38** wherein the minimum axial force on the plunger that is required to pierce the front seal is less than or equal to the minimum axial force required to axially displace the plunger in the rear chamber.

40. A medical device, comprising:

a barrel having an open proximal end and a distal end;

a needle having a first sharpened tip and being operable between an extended position in which the first sharpened tip projects forwardly from the barrel and a shielded position in which the first sharpened tip is shielded to prevent inadvertent contact with the first sharpened tip;

a cartridge in fluid communication with the needle, comprising:

a first chamber containing a first substance;
a second chamber containing a second substance;
a fluid flow controller between the first chamber and the second chamber; and
a biasing element imparting a force capable of displacing the needle relative to the barrel to shield the first sharpened tip; and
a needle retainer releasably retaining the needle in the extended position;
wherein the fluid flow controller is adapted to keep the first and second substances separate prior to use, and also adapted to allow mixing of the first and second substances prior to an injection, wherein after use the needle is disposed in the shielded position.

41. A method for injecting medicine, comprising the steps of:
providing an injection device having a first chamber containing a first medicinal component, a second chamber containing a second medicinal component, and a needle;
transferring the first medicinal component from the first chamber to the second chamber;
mixing the first and second components to form a medicinal mixture;
expelling the medicinal mixture from the chamber; and
retracting the needle after expelling the medicinal fluid to shield the needle against contact.

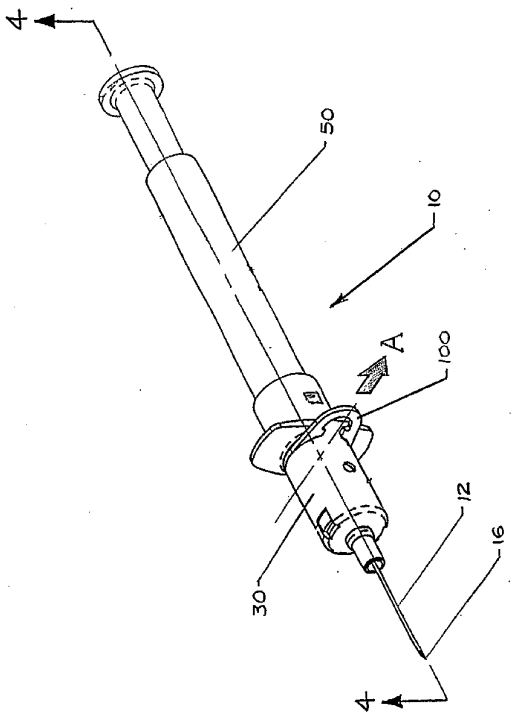

Figure 1

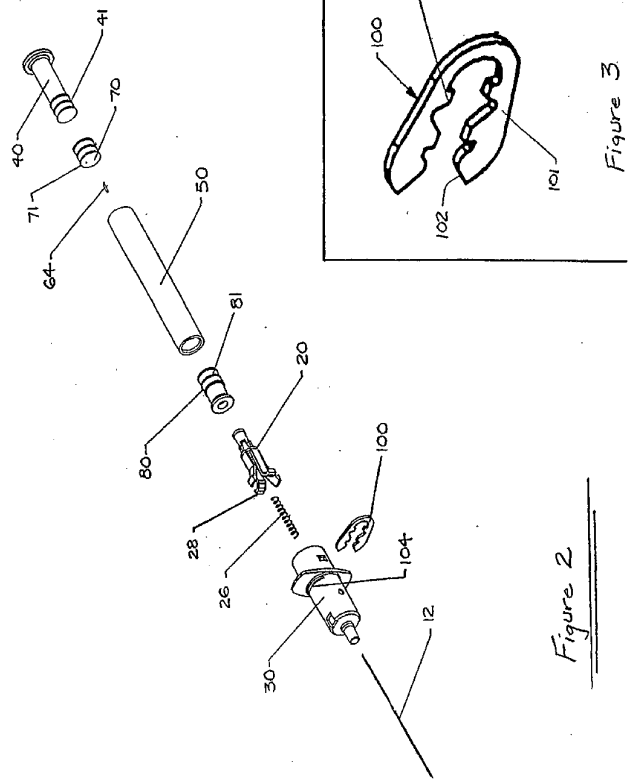

Figure 2

Figure 3

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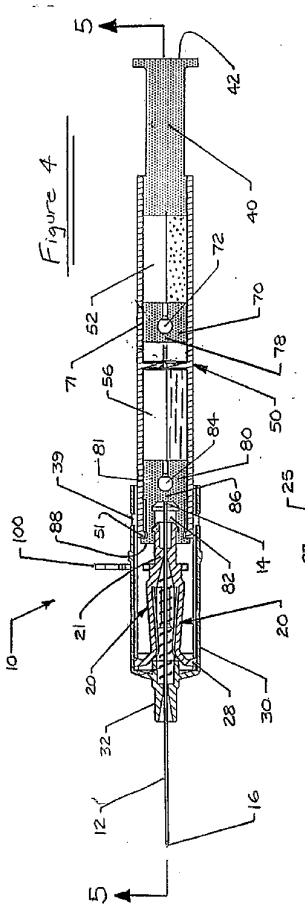


Figure 5

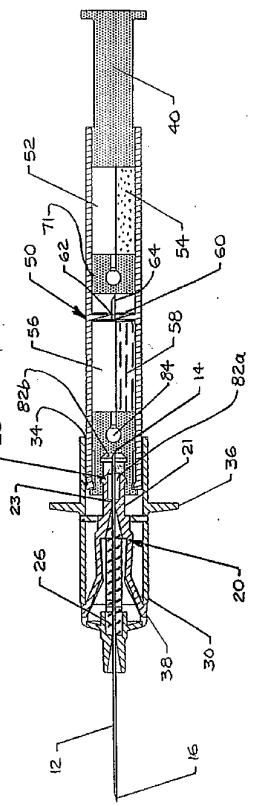
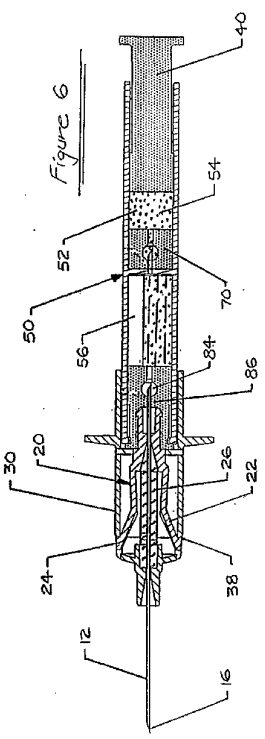


Figure 6



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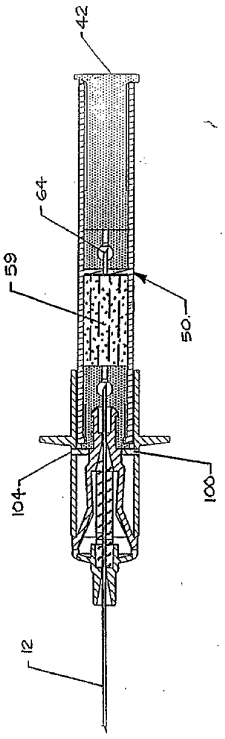
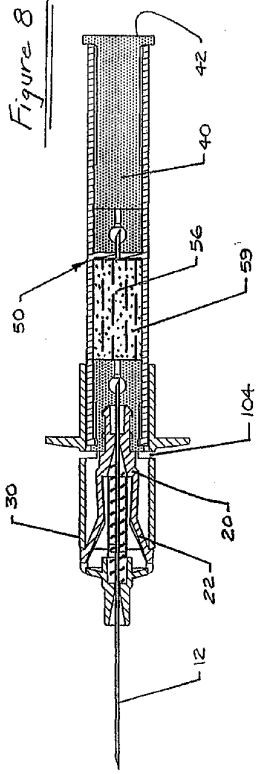


Figure 8



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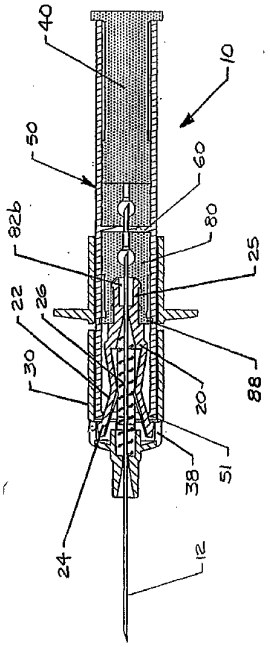

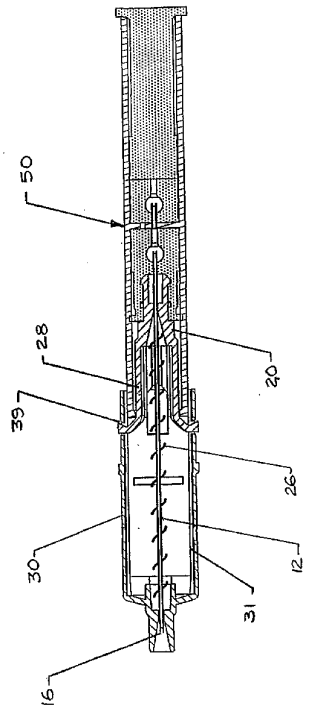

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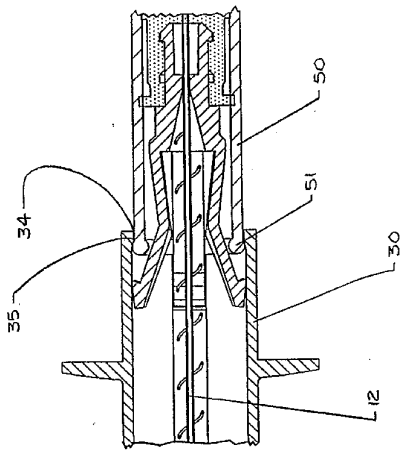


Figure 11

Figure 12

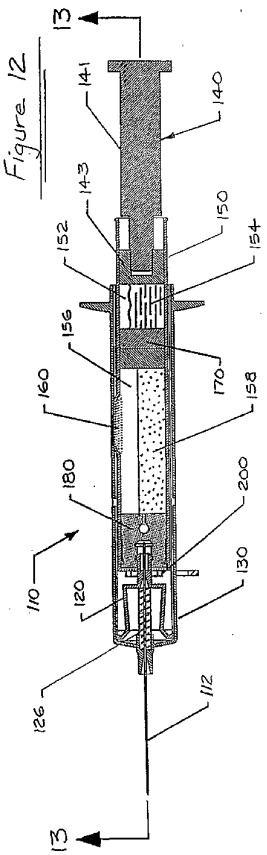
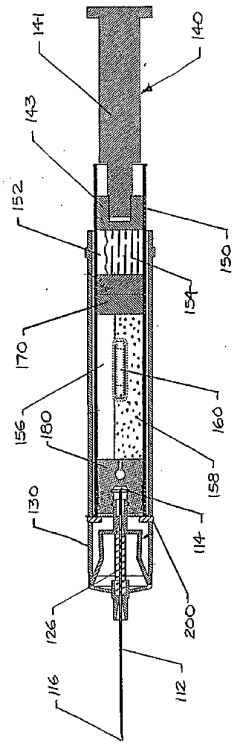


Figure 13



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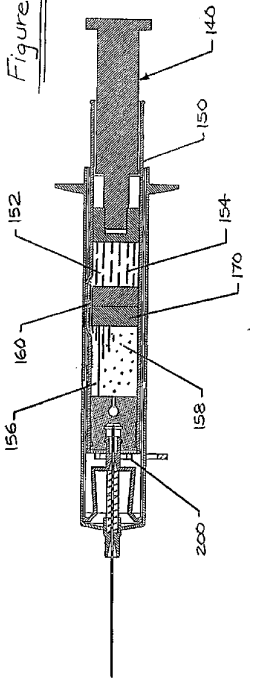

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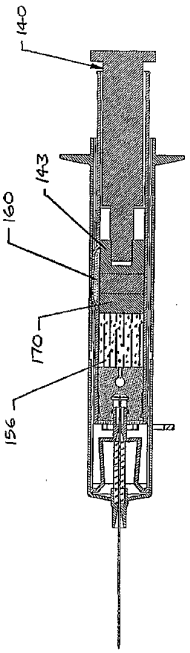

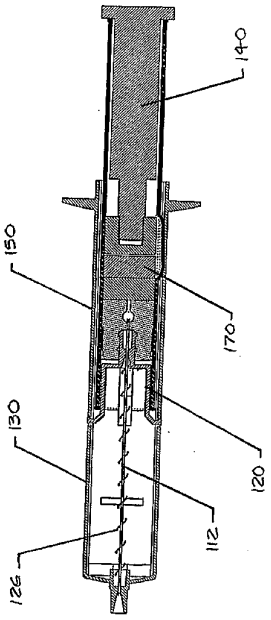

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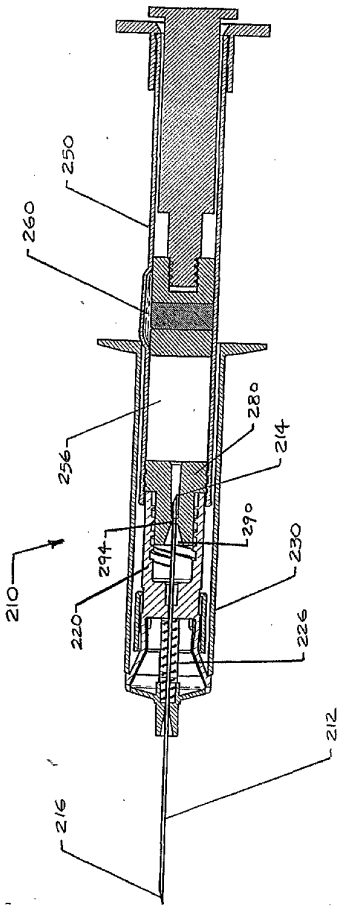
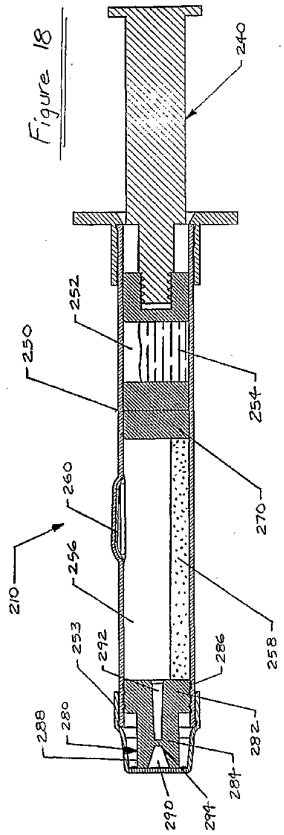
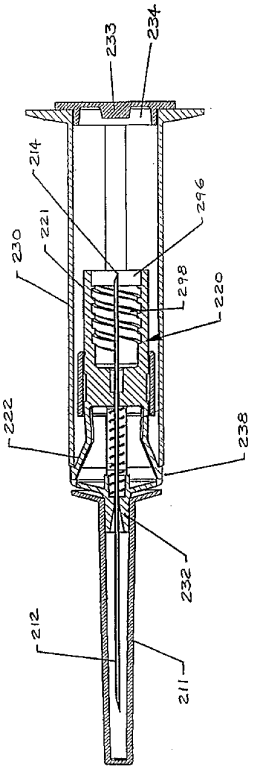


Figure 17

Figure 18





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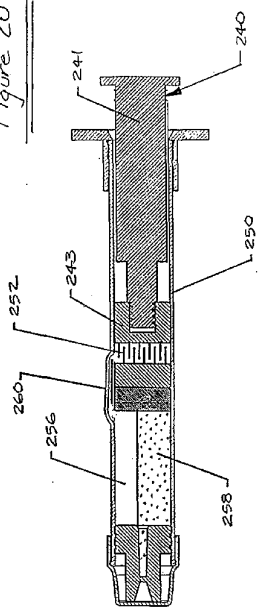

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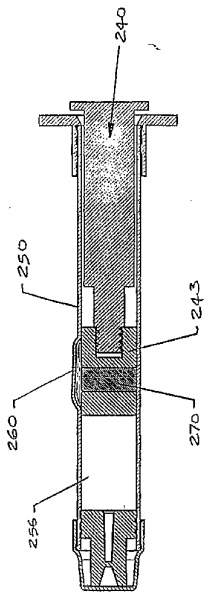

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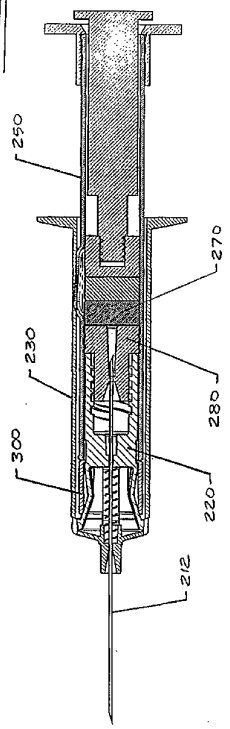
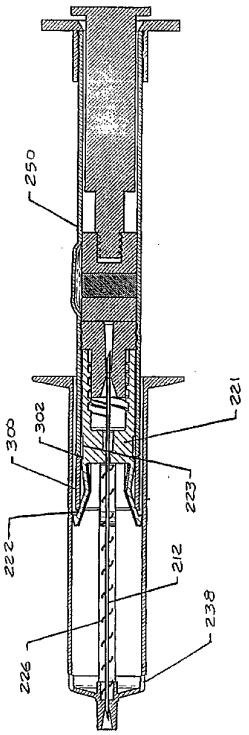
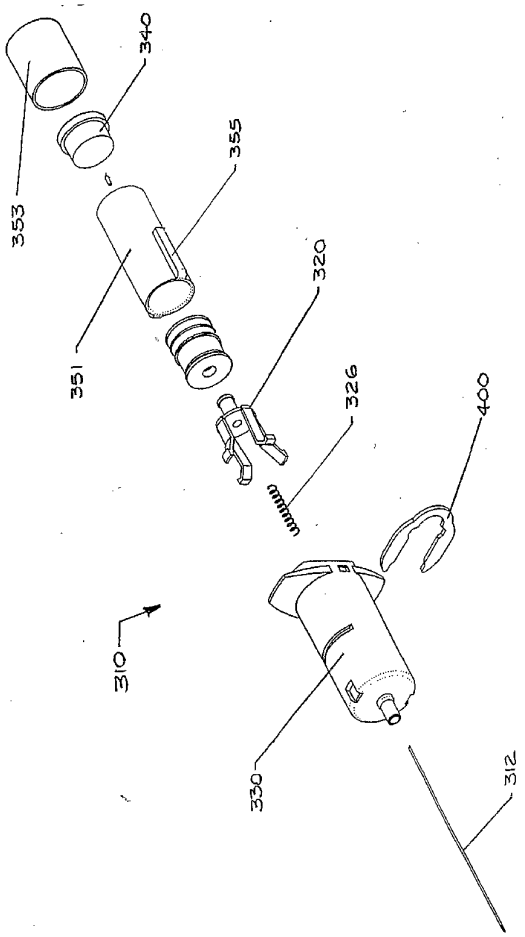


Figure 23





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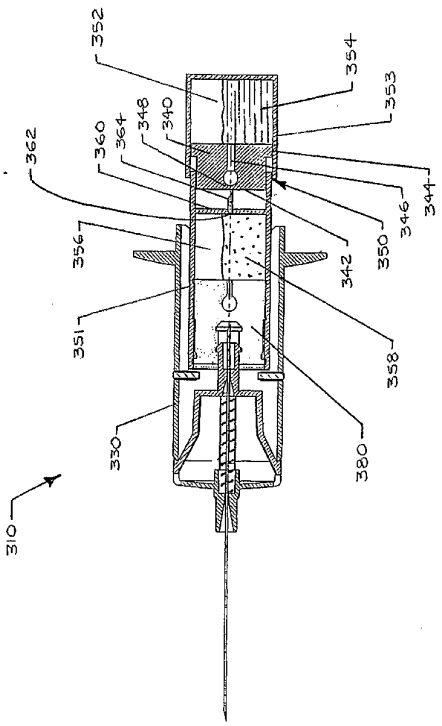
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Figure 25

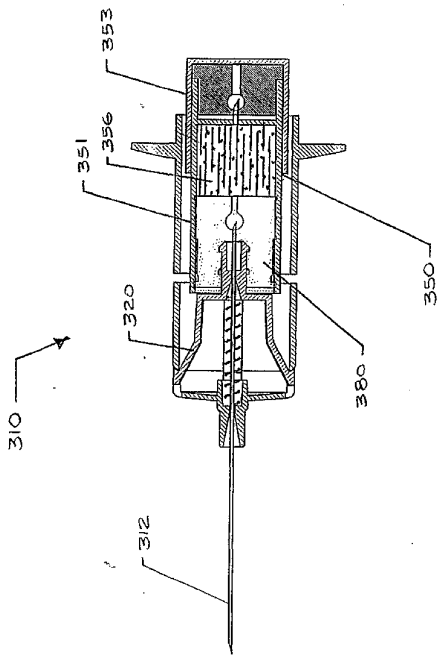

Figure 26

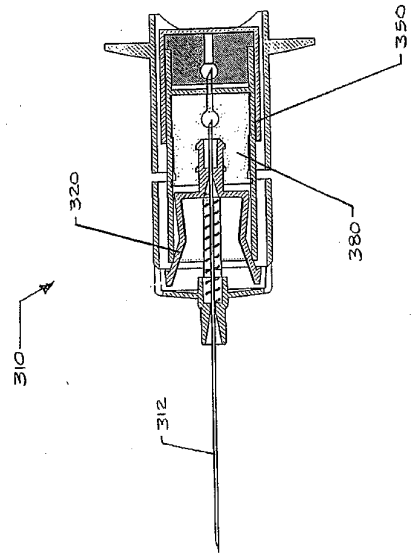

Figure 27

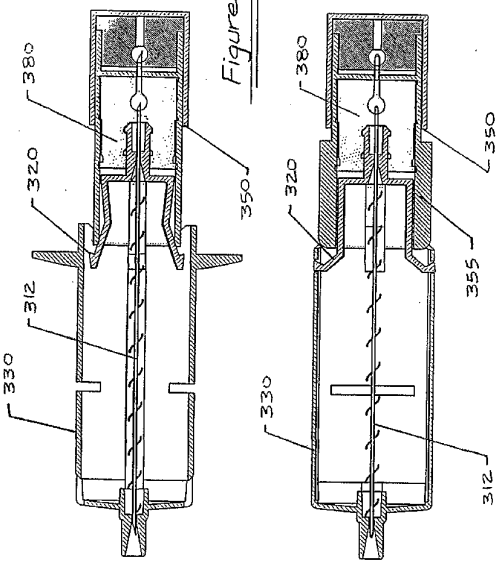

Figure 29

Figure 28

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(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

CORRECTED VERSION

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
19 September 2002 (19.09.2002)

PCT

(10) International Publication Number
WO 02/072171 A2

(51) International Patent Classification⁷: A61M

(21) International Application Number: PCT/US02/07712

(22) International Filing Date: 13 March 2002 (13.03.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/275,568 13 March 2001 (13.03.2001) US

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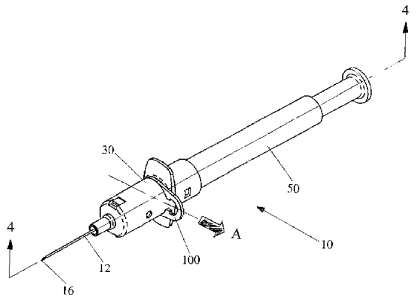
(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),

[Continued on next page]

(54) Title: PRE-FILLED SAFETY DILUENT INJECTOR



(57) Abstract: A safety needle-bearing device (10, 110, 210, 310) for mixing and injecting medication from a two-chambered cartridge (50, 150, 250, 350) is provided. The device includes a needle (12, 112, 212, 312) that extends through the forward end of a barrel (30, 130, 230, 330). The two-chambered cartridge (50, 150, 250, 350) is attached to the barrel (30, 130, 230, 330) and contains components of a medication stored separately in the chambers. A plunger (40, 140, 240) in the rearward end of the cartridge can be advanced into the cartridge to combine the separate components and prepare the medication. As the cartridge (50, 150, 250, 350) is advanced forwardly into the barrel (30, 130, 230, 330), the medication is injected through the needle (12, 112, 212, 312) and into a patient. At the completion of the injection stroke, the cartridge (50, 150, 250, 350) engages a needle retainer to actuate needle retraction. The needle is subsequently retracted to shield the contaminated needle.

WO 02/072171 A2

WO 02/072171 A2

Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
without international search report and to be republished upon receipt of that report

(48) Date of publication of this corrected version:
31 October 2002

(15) Information about Correction:
see PCT Gazette No. 44/2002 of 31 October 2002, Section II

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

PRE-FILLED SAFETY DILUENT INJECTOR

PRIORITY CLAIM

This application claims priority to U.S. Provisional Application No. 60/275,568, filed March 13, 2001, which is hereby incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to medical devices and more particularly to medical devices having a cartridge with two chambers that store separate components of a medication and allow the components to be mixed and subsequently injected into a patient.

BACKGROUND

Pre-filled syringes store and allow for mixing of separate medicinal components. Many of these syringes, sometimes called "mixing syringes," store a first component in one compartment and a diluent or a second component in a second compartment. These syringes allow the two components to be stored separately until just before the syringe is used, at which time the components can be mixed within the syringe and immediately injected into a patient.

Pre-filled mixing syringes are advantageous for many types of pharmaceuticals. Some medications, like antibiotics, vitamins and hormones, must be packaged and stored in component parts to enhance shelf life. These medications may need to be stored as a powdered component and a diluent, or as a separate pair of solutions. Pre-filled mixing syringes allow medications to be stored in component parts right up until the medication is

injected. In addition, pre-filled mixing syringes eliminate the burden of measuring medicinal components and mixing diluents from separate containers.

Despite these advantages, prior mixing syringes have not offered reliable safety features to protect the syringe user from accidental needle sticks following injection. In particular, prior syringe assemblies have not provided a mixing syringe that operates integrally with an injection needle that can be automatically shielded upon completion of the injection.

SUMMARY OF THE INVENTION

With the foregoing in mind, the present invention provides a pre-filled medical device for mixing separate components of a medication and injecting the medication into a patient. The device includes a two-chambered container, such as a cartridge, connected to a needle that retracts automatically after use. After retraction, the contaminated needle tip is enclosed within the device to prevent inadvertent needle sticks.

The device includes a hollow barrel surrounding the needle and having a generally open rearward end that forms a socket. A two-chambered cartridge containing component parts of a medication is adapted to engage the socket. Prior to use, the components are stored separately in the two cartridge chambers. During use, a plunger disposed in the rearward end of the cartridge is advanced into the cartridge to combine the two components in one chamber for mixing. Subsequent pressure on the plunger advances the medicinal mixture through the needle into a patient.

The injection needle is operable between an extended position and a retracted position. In the extended position, the forward tip of the needle projects forwardly from the barrel. In the retracted position, the forward tip is enclosed within the barrel. When the needle is in the extended

position, a biasing element biases the needle toward the retracted position. A needle retainer releasably retains the needle in the extended position against the force of the biasing element. During the injection stroke, the cartridge disengages the needle retainer to allow the biasing element to propel the needle rearwardly into the barrel.

DESCRIPTION OF THE DRAWINGS

The foregoing summary as well as the following detailed description of the preferred embodiments will be best understood when read in conjunction with the following drawings, in which:

Fig. 1 is perspective view of a pre-filled cartridge injector having a two-chambered container that stores component parts of a medication;

Fig. 2 is an exploded perspective view of the cartridge injector shown in Fig. 1;

Fig. 3 is an enlarged view of a locking clip of the cartridge injector shown in Fig. 2;

Fig. 4 is a sectional view of the cartridge injector shown in Fig. 1 taken along the line 4-4;

Fig. 5 is a sectional view of the cartridge injector shown in Fig. 4 taken along the line 5-5;

Fig. 6 is a sectional view of the cartridge injector shown in Fig. 1, illustrating the device prior to mixing the component parts of the medication;

Fig. 7 is a sectional view of the cartridge injector shown in Fig. 1, illustrating

the device after mixing with the cartridge locked to impede injection;

Fig. 8 is a sectional view of the cartridge injector shown in Fig. 1, illustrating the device after mixing the cartridge unlocked to allow injection;

Fig. 9 is a sectional view of the cartridge injector shown in Fig. 1, illustrating the device, after injection, just prior to needle retraction;

Fig. 10 is a sectional view of the cartridge injector shown in Fig. 1, illustrating the device after needle retraction.

Fig. 11 is an enlarged fragmentary sectional view of the cartridge injector shown in Fig. 1, illustrating the tamper resistant connection between the cartridge and barrel after the needle is retracted.

Fig. 12 is a sectional view of a second embodiment of a two-chambered pre-filled cartridge injector having a retractable needle.

Fig. 13 is a sectional view of the device shown in Fig. 12 taken along the line 13-13.

Fig. 14 is a sectional view of the device shown in Fig. 12 illustrating the device during mixture of the medicinal components in the cartridge transfer of one component of medicine between chambers.

Fig. 15 is a sectional view of the device shown in Fig. 12 illustrating the device after mixture of the medicinal components.

Fig. 16 is a sectional view of the device shown in Fig. 12 illustrating the device after needle retraction.

Fig. 17 is a sectional view of a third embodiment of a two-chambered pre-filled cartridge injector having a retractable needle.

Fig. 18 is a sectional view of the cartridge portion of the device illustrated in Fig. 17.

Fig. 19 is a sectional view of the device shown in Fig. 17 illustrated without the cartridge, illustrated prior to use.

Fig. 20 is a sectional view of the cartridge in Fig. 18 illustrating the device during mixture of the medical components.

Fig. 21 is a sectional view of the device shown in Fig. 18 illustrating the device after mixture of the medical components.

Fig. 22 is a sectional view of the device shown in Fig. 17 illustrating the device at the completion of an injection.

Fig. 23 is a sectional view of the device shown in Fig. 17 illustrating the device after needle retraction.

Fig. 24 is an exploded perspective view of a fourth embodiment of a two-chambered pre-filled cartridge injector having a retractable needle.

Fig. 25 is a sectional view of the device illustrated in Fig. 24.

Fig. 26 is a sectional view of the device in Fig. 24 illustrating the device after mixture of the medical components.

Fig. 27 is a sectional view of the device shown in Fig. 24 illustrating the device at the completion of an injection.

Fig. 28 is a sectional view of the device shown in Fig. 24 illustrating the device after needle retraction.

Fig. 29 is a sectional view of the device shown in Fig. 24 illustrating the device after needle retraction.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the figures in general, and to Figs. 1-11 specifically, an injector device **10** is shown with a needle **12** having a sharpened distal tip **16** for insertion into a patient. As shown in Fig. 4, the injector device **10** has an attached cartridge **50** having a first chamber **52** and a second chamber **56**. The two chambers **52, 56** are pre-filled with component parts of a medication that are to be mixed prior to injection. The cartridge **50** also includes a plunger **40** that is slidable within the cartridge. Initially, advancing the plunger 40 in the cartridge 50 expels the medicinal component from the first chamber 52 into the second chamber 56 to mix the two medicinal components. After mixing the components, advancing the plunger drives the cartridge forwardly to inject the medicine into a patient. Upon completion of the injection stroke, the medical professional releases pressure from the plunger to allow automatic retraction of the needle **12** into the device **10** to protect the contaminated needle 12 from inadvertent contact.

The injector device **10** includes a double-ended needle **12**, a generally cylindrical barrel **30**, a compression spring **26** and a needle retainer **20** releasably retaining the needle against the bias of the spring. As shown in Figs. 4 and 5, the needle **12** has a sharpened proximal tip **14** and a sharpened distal tip **16**. The spring **26** circumscribes the needle **12** and is compressed against the interior of the barrel **30** at the barrel's distal end. The rearward end of the spring **26** bears against the interior of the needle retainer **20** to bias the needle **12** and needle retainer in the rearward direction.

The needle **12** is operable between two positions, an extended position and a retracted position. In the extended position, the needle **12** projects forwardly from the forward end of the barrel **30**. In the retracted position, the needle **12** is retracted into the barrel **30** so that the sharpened tip **16** of needle **12** is enclosed within the barrel to prevent inadvertent contact with the sharpened tip. When the needle is in the extended position, the spring **26** biases the needle **12** rearwardly toward the retracted position. The needle retainer **20** releasably retains the needle **12** in the extended position, against the bias of the spring **26**. During the injection stroke, the cartridge **50** cooperates with the needle retainer **20** to allow the needle to retract into the barrel **30**, as shown in Fig. 10.

Referring now to Figs. 5-7, the cartridge **50** includes a first chamber **52** containing a first medicinal component **54** and a second chamber **56** containing a second medicinal component **58**. The chambers **52, 56** are separated by a mid wall **60** containing an orifice **62**. A rear seal 70 seals the first chamber 52 to prevent the components from being mixed prior to use. When the rear seal 70 is pierced and the plunger **40** is advanced into the cartridge **50**, the first component **54** flows into the second chamber **56** through the orifice 62, where it combines with the second component **58** to form the medication **59**, as shown in Figs. 6-7. Subsequent pressure on the plunger **40** and cartridge **50** forces the medication **59** through the needle **12** and into the patient.

Referring now to Figs. 4-6, the elements of the injector device **10** will be described in greater detail. The barrel **30** is generally cylindrical and the distal end of the barrel has a tapered nose **32**. The nose **32** has an opening through which the needle **12** extends so that the sharpened tip **16** of the needle can be inserted into a patient. The rearward end of the barrel **30** is open, forming a cylindrical socket **34** adapted to receive the cartridge **50**. Two laterally extending flanges **36** project outwardly from the barrel **30**,

transverse the longitudinal axis of the barrel, forming a pair of finger grips for operating the device **10**. The barrel **30** further includes a pair of retaining apertures **38** and a pair of lockout windows **39** that cooperate with the needle retainer **20** as described further below.

As shown in Fig. 5, a hub **21** projects from the rearward end of the needle retainer **20**. The hub **21** is a generally cylindrical element having a central bore **23**. The needle **12** is disposed within the central bore **23** of the hub **21** so that the rearward end **14** of the needle **12** projects rearwardly from the hub and the forward end **16** of the needle projects forwardly from the hub. The needle **12** can be attached to the hub **21** in one of several ways. For example, the needle **12** can be attached to the hub **21** by an adhesive such as a UV curable adhesive. Alternatively, the needle **12** can be molded into the hub **21**, which is formed of plastic. The rearward end of the hub **21** includes a circumferentially barbed connector **25** configured to cooperate with the cartridge **50** to connect the cartridge to the needle hub 21 as discussed further below.

The needle retainer **20** is axially displaceable within barrel **30** to facilitate needle retraction. The needle retainer **20** can be molded out of a rigid, high strength resin, such as polycarbonate. Prior to retraction, the needle retainer **20** is maintained in a fixed axial position while the medication **59** is expelled from the cartridge **50**. After the injection, the needle retainer **20** and the attached needle **12** are displaced rearwardly by the compression spring **26**.

The spring **26** is a compression spring and may be formed of stainless steel, treated carbon steel wire or other suitable non-corrosive spring metal. The residual compression of the spring prior to disengagement of the needle retainer is of sufficient magnitude to facilitate complete needle retraction and overcome the frictional resistance between sliding components within the device **10**.

Referring now to Fig. 6, the needle retainer **20** includes a pair of retaining arms **22** that extend radially outwardly and forwardly from the distal end of the needle retainer **20**. During operation, the needle retainer **20** is operable between a locked position and an unlocked position. In the locked position, the retaining arms **22** engage the retaining apertures **38** in the barrel wall to maintain the needle in a fixed axial position with the forward tip **16** of needle **12** projecting forwardly from the barrel **30**. More specifically, in the locked position, the retaining arms **22** engage the barrel **30** to hold the needle hub **21** and needle **12** against the rearward bias of the spring **26**. In the unlocked position, the retaining arms **22** are positioned so as to allow the needle hub 21 and needle **12** to be retracted rearwardly. More specifically, in the unlocked position, the retaining arms **22** are disengaged from the retaining apertures **38**, allowing the spring 26 to propel the needle hub **21** and needle **12** rearwardly.

As discussed above, the retaining arms **22** on the needle retainer **20** project forwardly and outwardly into engagement with the retaining apertures **38** in the wall of the barrel **30**. The terminal end of each arm forms a retaining tab **24** that is configured to project into a retaining aperture **38**. More specifically, the retaining tabs **24** engage the lip formed by each retaining aperture **38** in the wall of the barrel **30**. In this way, the retaining tabs **24** operate as a pair of latches to retain the needle hub 21 and needle **12** against the rearward bias of the spring.

Referring again to Figs. 4 and 5, the cartridge **50** is a generally cylindrical vessel that may be molded out of pharmaceutical quality glass such as borosilicate, or a rigid inert plastic such as polyolefin or polyester. The midwall **60** that separates the first and second chambers may be formed of a rigid inert plastic such as polyolefin or polyester. The barrier or midwall **60** can be molded as part of the cartridge **50** or bonded to the inside wall of the cartridge. Each chamber is filled with a predetermined amount of a

medication during manufacturing of the device **10**.

The front end of the forward chamber **56** is sealed by an elastomeric front seal **80**, which may be molded in a self-sealing biocompatible elastomer such as polyisoprene. The front seal **80** is generally cylindrical, having a plurality of axially-spaced circumferential ribs **81**. The ribs **81**, which are more clearly shown in Fig. 2, frictionally and sealingly engage the interior of the container to provide a fluid tight seal, thereby preventing fluid from leaking from the cartridge **50**. The front seal **80** also has a front end that is pierceable by the rearward sharpened tip **14** of needle **12**. After being pierced, the front end of the front seal **80** reseals around the needle **12** to prevent fluid from leaking from the cartridge **50**.

Referring now to Figs. 5 and 6, the front seal **80** has a socket 82 configured to cooperate with the barbed connector 25 on the needle hub 21. The socket **82** includes two radially relieved recesses, **82a** and **82b**, that mate with the barbed connector **25**. Specifically, the barbed connector **25** matingly engages the front seal **80** in a first position and a second position.

In the first position, the barbed connector **25** engages the first recess **82a**, as shown in Fig. 5. In this position, the cartridge is attached to the hub, but the rearward end of the needle does not pierce the front seal 80. Applying pressure to the plunger **40** displaces the cartridge forwardly relative to the hub, thereby displacing the barb into to the second position. In the second position, the barbed connector **25** engages the second recess **82b**, as shown in Fig. 6. In this position, the rearward end of the needle **12** pierces the front seal 80.

The front seal **80** includes a hollowed cavity **84** at its rearward end. In this way, a pierceable wall **86** is formed in the front seal **80** between the cavity **84** and the second recess **82b**. As shown in Fig. 5 prior to use, the

cartridge 50 is mounted in the first position so that the barbed connector **25** engages the first recess **82a**. In this position, the needle **12** does not penetrate the pierceable wall **86**. As the **hub 21** is displaced from the first position to the second position, the rearward end **14** of the needle**12** pierces the wall **86** and extends into the cavity **84** as shown in Fig. 6. The cavity **84** opens into the interior of the second chamber **56** of cartridge **50** so that when the needle **12** projects into the hollowed section **84**, the needle is in fluid communication with the interior of the cartridge. After the needle **12** penetrates the pierceable wall **86**, the wall reseals around the needle to form a fluid-tight seal and prevent medication in the cartridge **50** from leaking around the needle.

To prepare the injection device **10** for use, the medical professional displaces the cartridge **50** forwardly relative to the needle retainer **20**, so that the forward seal **80** is driven over the barbed connector **25**, such that the barbed connector engages the second recess **82b.** At the same time, the proximal tip **14** of needle **12** pierces the pierceable wall **86**, so that the needle is in fluid communication with the second chamber, as shown in Fig. 6.

The connection between the front seal **80** and the needle hub **21** is preferably a one-way engagement. In other words, when the front seal **80** is mounted on the barbed connector **25**, the cartridge **50** can be displaced forwardly relative to the barbed connector, but the cartridge cannot be displaced rearwardly relative to the barbed connector. In this way, the cartridge **50** cannot be readily removed from the needle hub 21 in barrel **30**, such that the cartridge is substantially permanently attached to the needle hub and barrel.

The one-way connection is facilitated by the rearward-facing tapered shoulder of the barbed connector **25** and the square shaped forward-

facing shoulder of the barbed connector. In particular, the rearward-facing shoulder of the barbed connector **25** cooperates with tapered sides in the first and second radial recesses **82a** and **82b** to permit relative displacement of the plug from the first recess to the second recess. Reverse displacement from the second recess **82b** back to the first recess **82a** is resisted by the square shaped forward-facing shoulders on barbed connector **25**, which act to impede reverse displacement.

Referring now to Fig. 4, the front seal **80** is configured to prevent ejection of fluid when the barbed connector **25** is displaced from the first position, in which the barbed connector **25** engages the first radial recess **82a**, to the second position, in which the barbed connector engages the second radial recess **82b**. Specifically, the front seal **80** includes a flared head **88** or circumferential flange at the forward end of the front seal. The open distal end of the cartridge **50** terminates with a beaded rim **51** that seats against the rearward edge of the flared head **88**. The outside diameter of the flared head **88** is greater than the inside diameter of the open distal end of the cartridge **50**, thereby impeding rearward displacement of the front seal **80** into the cartridge when force is initially applied to the plunger **40**. In addition, the force required to overcome the frictional engagement between the outer circumference of the front seal **80** and the inner wall of the cartridge **50** is greater than the force required to displace the plug **25** from the first recess **82a** to the second recess **82b**. Accordingly, when force is initially applied to the plunger **40**, the front seal **80** remains in a fixed position relative to the cartridge **50**, while the barbed connector **25** is displaced into the second position. This restriction on the front seal **80** limits the release of fluid from the cartridge **50** when the needle **12** pierces the wall **86**.

During storage of the injection device **10**, the medication is divided into two separate components stored in the cartridge **50**, as shown in Fig. 5. Specifically, a first component **54** of the medicine is stored in the rear

chamber **52** and a second component **58** of the medicine is stored in the forward chamber **56**. The two chambers are separated by the mid-wall **60** containing an orifice **62** and a hollow piercing member **64** mounted in the orifice. The orifice **62** is located axially at the center of the midwall **60**. In addition, a small vent hole **63** is located just off center in the midwall **60** to vent the air from the dead space area between the mid wall and the mid seal 70. Preferably, the piercing member **64** is fabricated out of suitable non-corrosive material such as stainless steel or treated carbon steel wire. When the plunger **40** is axially advanced in the cartridge **50**, the first component **54** in the rear chamber **52** advances through the piercing member **64** and into the forward chamber **56** to combine with the second component **58**.

Prior to use of the injection device **10**, fluid communication between the first and second chambers is prevented by an elastomeric mid seal **70**, which may be molded in a self-sealing biocompatible elastomer such as polyisoprene. The mid seal **70** is initially slidably disposed in the first chamber **52** between the piercing member **64** and the first component **54**, as shown in Figs. 4-5. The mid seal **70** is generally cylindrical, having a plurality of axially-spaced circumferential ribs **71**, as shown more clearly in Fig. 2. The ribs **71** frictionally and sealingly engage the inner wall of the cartridge **50** to provide a fluid-tight seal. This fluid-tight seal prevents fluid in the first chamber from entering the piercing member **64**. The mid seal **70** also includes a hollowed section **72** formed in the forward end of the mid seal that opens to the first chamber **52** at the rearward end of the mid seal. The forward end of the mid seal **70** is closed by a membrane **78** that is pierceable by the piercing member **64**. Upon piercing the membrane **78**, fluid communication is established between the first and second chambers to allow the first and second components of the medication to be mixed.

Like the front seal **80** and mid seal **70**, the plunger **40** is generally cylindrical, preferably having a plurality of axially-spaced

circumferential ribs **41**. The plunger **40** may be molded in a self-sealing biocompatible elastomer such as polyisoprene. Alternatively, the plunger **40** could be a two-part assembly in which a cylindrical elastomeric seal is mounted to a rigid plastic plunger rod. The ribs **41**, which are more clearly shown in Fig. 2, frictionally and sealingly engage the interior of the cartridge **50** to provide a fluid tight seal, thereby preventing fluid from leaking from the proximal end of the cartridge.

The plunger **40** is slidable within the first chamber **52** in response to pressure applied to the thumb pad **42**. When the plunger **40** is axially advanced into the cartridge **50**, the first component **54** is compressed against the rearward end of the mid seal **70** in the first chamber **52**. As back pressure on the mid seal **70** overcomes the frictional resistance between the mid seal and the cartridge **50**, the mid seal is displaced into the piercing member **64** until the membrane **78** is pierced, as shown in Fig. 6. As the mid seal advances, air from the space between the mid seal and mid wall vents through the vent hole **63** in the mid wall. At such time, the piercing member **64** penetrates through the hollowed section **72** to connect the first chamber **52** and second chamber **56** in fluid communication.

After the mid seal **70** is pierced, pressure applied to the plunger **40** advances the first component **54** through the piercing member **64** and into the second chamber **56** where the first and second components are subsequently mixed to form the medication **59**. The plunger **40** is displaced forwardly relative to the first chamber **52** until the flanged portion of the thumb pad **42** contacts the proximal end of the cartridge **50**, as shown in Fig. 7. The outside diameter of the thumb pad **42** is larger than the inside diameter of the cartridge **50**, thereby preventing further displacement of the plunger **40** once the thumb pad contacts the proximal end of the cartridge **50**. Preferably, the distance between the forward end of the plunger **40** and the rearward end of the mid seal **70** is equal to the distance between the flanged portion of the

thumb pad **42** and the proximal end of the cartridge **50**. Once the thumb pad **42** contacts the proximal end of the cartridge **50**, the plunger is fixed relative to the cartridge **50**. At this point, axial advancement of the cartridge **50** relative to the barrel **30** is restricted, as described in more detail below.

Preferably, the injection device **10** includes a locking mechanism for preventing accidental release of the contents in the second chamber prior to mixing the two components. In the present embodiment shown in Fig. 7, the barrel **30** includes a locking clip **100** in the barrel wall to prevent accidental discharge of the medicinal components. The wall of the barrel **30** includes a pair of radial slots **104** formed in a plane that is transverse the longitudinal axis of the barrel. When the locking clip **100** is inserted through the slots **104**, the clip prevents inadvertent forward displacement of the cartridge **50** relative to the front seal **80**, thereby preventing accidental advancement of the medicinal components through the needle **12**. The locking clip **100** is preferably formed of a resilient high strength and high modulus resin, such as acetyl or polycarbonate, and is configured to releasably engage the slots **104** in the barrel **30**.

Referring to Figs. 1-3, the locking clip **100** is preferably a flat member having a pair of resiliently deflectable legs **101** that join to form a U-shape. The open end of the locking clip **100** has tapered edges **102** that allow the legs **101** to deflect outwardly as the locking clip **100** is inserted into the sidewall of the barrel **30**. In addition, the locking clip **100** has a plurality of teeth **103** on the inside edge of the legs **101** that are adapted to engage the edges of radial slots **104**.

As the locking clip is inserted into the sidewall of the barrel **30**, the legs **101** deflect outwardly to allow the teeth **103** to clear the edges of radial slots **104**. Upon being deflected outwardly, the resilience of legs **101** bias the legs radially inwardly toward their original position. Once the teeth

103 are disposed within the slots **104**, the legs **101** deflect radially inwardly toward their original position and releasably engage the outer edges of the needle retainer **20** in barrel **30**. In the inserted position, the closed end of the locking clip **100** remains outside the barrel **30**, as shown in Figs. 1 and 4.

After the medicinal components are mixed within the cartridge, the locking clip **100** is removed to permit injection of the medicine **59**, as shown in Fig. 8. The locking clip **100** is removed from the barrel **30** by pulling the closed end of the clip in a direction transverse to the longitudinal axis of the barrel. This direction is marked "A" in Fig. 1. By pulling the clip in this manner, the legs **101** are deflected outwardly from the slots **104** to allow the teeth **103** to clear the edges of slots **104**.

After the locking clip **100** is removed from the barrel **30**, the medication **59** is injected into the patient by advancing the cartridge forwardly into the barrel. Pressure applied to the thumb pad **42** causes the plunger **40** and cartridge **50** to move forwardly relative to the barrel **30**. With the barbed connector **25** mounted in the second recess **82b** in the front seal **80**, the front seal remains stationary while the cartridge **50** is advanced forwardly, as shown in Fig. 9. The front seal **80** and flared head **88** are configured to form a sliding fit with the interior of the cartridge **50** so that the cartridge can slide over the front seal. As the cartridge **50** is advanced, the mid seal **70** and the mid wall 60 are displaced toward the front seal **80**. This causes a reduction of volume in the second chamber **56**, whereby the medication is displaced into the needle to facilitate the injection. At the completion of the injection, the mid wall **60** bears against the rearward end of the front seal **80**, as shown in Fig. 9.

Referring now to Figs. 9-10, the automatic retraction of the needle **12** shall be described. The cartridge **50** is axially advanced to the

proximal end of the barrel **30** until the medication **59** is completely expelled from the second chamber **56**. As the cartridge **50** is advanced, the beaded circumferential rim **51** of the cartridge is displaced into engagement with the retaining arms **22** of needle retainer **20**. Preferably, the cartridge **50** is configured so that the longitudinal distance between the rearward end of the front seal **80** and the mid wall **60** corresponds to the longitudinal distance between the circumferential rim **51** of the cartridge and the retaining arms **22** when the cartridge is mounted on the barbed connector **25** in the second position. In this way, the rim **51** of the cartridge **50** engages the retaining arms **22** when substantially all of the medication **59** is expelled from the device **10**.

After the rim **51** of cartridge **50** engages the retaining arms **22**, continued axial advancement of the cartridge deflects the retaining arms radially inwardly so that the retaining tabs **24** are displaced inwardly, as shown in Fig. 9. In the inward position, the retaining tabs **24** are disengaged from the retaining apertures **38** of the barrel **30**. In this way, the cartridge **50** operates as an actuator, such that axial advancement of the cartridge displaces the needle retainer **20** into an unlocked position. In the unlocked position, the needle retainer **20** is no longer locked in place against the force of the spring **26**. After the needle retainer **20** is in the unlocked position and the user releases pressure on the plunger **40**, the spring **26** propels the needle **12** rearwardly until the sharpened distal tip **16** of the needle is enclosed within the barrel **30**.

As shown in Fig. 10, when the needle **12** is retracted, the needle, needle retainer **20** and cartridge **50** are displaced rearwardly together. During retraction, the retaining arms **22** are biased radially outwardly so that the retaining tabs **24** ride along the inside wall of the barrel. The force of the spring **26** is sufficiently strong to overcome the frictional resistance generated between the guide arms 28 and the barrel **30**.

Preferably, the injection device **10** includes a mechanism for limiting rearward displacement of the retracted elements. Referring now to Figs. 2, 4 and 10, the needle retainer **20** includes a pair of guide arms **28** that cooperate with a pair of alignment channels or grooves **31** formed in the interior wall of the barrel **30**. The guide arms **28** may be molded out of a rigid, resilient high strength resin, such as polycarbonate. The guide arms **28** extend forwardly from the needle retainer **20** and project radially outwardly into engagement with the alignment grooves **31**.

Each guide arm **28** includes a linear elongated rear portion which preferably is generally parallel to the longitudinal axis of barrel **30**. The forward portion of each guide arm **28** bends outwardly transverse to the longitudinal axis of the barrel **30** and extends into one of the alignment grooves **31**. When the needle retainer **20** is disposed within the barrel, the guide arms **28** are deflected radially inwardly from their natural state. In this position, the guide arms **28** are biased radially outwardly against the inner wall of the barrel **30** due to the resilient properties of the guide arms.

The forward ends of guide arms **28** are preferably contained within the alignment grooves **31** to substantially limit rotation of the needle and needle retainer **20** during needle retraction. This engagement ensures that the guide arms are aligned with the lockout windows 39 so that the guide arms snap into the lockout windows at the end of retraction. In this way, the needle retainer **20** is limited to axial displacement during needle retraction. During retraction, the frictional resistance between the forward ends of the guide arms **28** and the inside wall of the barrel **30** is overcome by the expansion force of the spring **26**.

As shown in Fig. 4, the linear elongated rear portion of each guide arm **28** is spaced radially inwardly from the inner wall of the barrel **30** to create a clearance space between the linear portion of the guide arms and

the barrel. Preferably, the minimum radial thickness of the clearance space is greater than the thickness of the wall of the cartridge **50** or the cartridge rim **51**. In this way, when the cartridge **50** is advanced forwardly to disengage the retaining arms **22**, advancement of the cartridge will not be impeded by the guide arms **28**.

Each alignment groove **31** is substantially parallel to the longitudinal axis of the barrel **30**. In Fig. 4, the groove 31 is shown extending to rearward end of the barrel. However, it may be desirable to terminate the groove forward of the rearward end of the barrel. The rearward portion of each alignment groove **31** intersects a lockout window **39** formed in the wall of the barrel **30**. The lockout windows **39** are adapted to receive the forward ends of the guide arms **28**, as shown in Fig. 10. In particular, as the front end of each guide arm **28** aligns with the corresponding lockout window **39** during needle retraction, the radially outward bias of the guide arm displaces the arm outwardly so that the forward end projects into the lockout window. The engagement between the guide arms **28** and lockout windows **39** prevent further axial movement of the retainer **22**. As a result, the retracted elements are limited from further displacement in the forward or rearward direction.

Preferably, the injection device **10** includes a mechanism to limit tampering or removal of the cartridge **50** from the barrel socket **34**. Referring now to Fig. 11, the present embodiment includes an annular lip **35** that projects radially inwardly from the inside wall of the socket **34** in barrel **30**. The lip **35** is adapted to seat against the beaded rim **51** on the cartridge **50** so that the cartridge can not be easily pulled out of the rear of the barrel **30**. As a result, access to the retracted elements, and the contaminated needle in particular, is limited.

Referring now to Figs. 4-10, the operation of the injection device

10 will be described. Prior to use, the needle **12** is disposed in an extended position so that the distal end **16** of the needle projects forwardly from the barrel **30**, as shown in Fig. 4. Preferably, the device **10** is shipped with the cartridge **50** already mounted in barrel **30** so that the barbed connector **25** is engaged in the first recess **82a**. Alternatively, the cartridge **50** may be shipped separately from the barrel **30**, so that the cartridge must be attached to the barrel prior to use.

With the cartridge **50** and barrel **30** assembled, the device **10** is held vertically so that the distal end **16** of needle **12** points upwardwardly. The user holds the device **10** by placing the user's thumb in a supporting position beneath the thumb pad **42** of plunger **40**. In addition, the user places a finger over each finger grip **36** to control the operation of the device **10**. With the user's fingers anchored over the finger grips **36**, the user applies a slight squeezing pressure on the thumb pad **42**, much like a conventional syringe. The squeezing pressure displaces the cartridge **50** forwardly relative to the barrel so that the barbed connector **25** on the needle retainer **20** engages the second recess **82b** in front seal **80** and the needle **12** pierces the wall **86**. As the front seal **80** is pierced, entrapped air in the forward chamber **56** is vented through needle **12**.

Continued advancement of the plunger 40 drives the seal 70 toward the piercing element 64 until the piercing element pieces the mid seal, thereby providing fluid communication between the forward and rearward chambers 52, 56. At this point, the first component **54** may be advanced into the forward chamber **56**. Pressure is applied on the thumb pad **42** until the first component **54** is completely expelled from the rearward chamber 52 into the forward chamber **56** and the forward end of the plunger meets the rearward end of the mid seal **70**. The user then shakes the injector device **10** to mix the first and second components **54**, **58** inside the forward chamber **56**.

During mixing, the locking clip **100** prevents the cartridge **50** from being advanced forwardly into the needle retainer **20**. This constraint on the cartridge **50** limits the potential for inadvertent discharge of the medication **59** from the needle **12** and premature needle retraction. Once the medication **59** is adequately mixed, the user removes the locking clip **100** from the barrel **30** so that the cartridge **50** can be advanced forwardly within the barrel. At this point, initial pressure applied to the thumb pad **42** advances the cartridge and vents excess air out of the second chamber **56**.

The needle is then inserted into a patient and the plunger **40** is depressed to axially advance the cartridge **50** relative to the barrel **30**, thereby injecting the medication **59** from the cartridge into the patient. At the end of the injection stroke, the beaded rim **51** on the cartridge **50** engages the retaining arms **22**, thereby displacing the retaining tabs **24** radially inwardly to disengage the needle retainer **20** into the unlocked position. Although the needle retainer **22** is in the unlocked position, the needle **12** does not retract until the user releases pressure from the thumb pad **42**. In this way, the user can retain pressure on the thumb pad **42** until after the needle is withdrawn from the patient. The user can then release pressure from the thumb pad **42** so that the needle is propelled rearwardly by the spring **26**. Alternatively, the user can release pressure from the thumb pad **42** while the needle **12** is still inserted in the patient. Once the thumb pad **42** is released, the spring **26** propels the needle **12** rearwardly so that the contaminated distal tip **16** of the needle is enclosed within the barrel **30**.

Referring now to Figs. 12-16 in general, and to Figs. 12-13 specifically, a second embodiment of a pre-filled safety diluent injector is shown. The injector device **110** includes elements that are substantially similar to the elements described above in connection with the first embodiment 10, illustrated in Figs. 1-11. These elements include: a double-ended needle **112**, a generally cylindrical barrel **130**, a compression spring

126, a needle retainer **120** releasably retaining the needle against the bias of the spring, a locking clip **200**. The needle **112** has a sharpened proximal tip **114** and a sharpened distal tip **116.** The spring **126** circumscribes the needle **112** and is compressed against the interior of the barrel **130** at the barrel's forward end. The rearward end of the spring **126** bears against the interior of the needle retainer **120** to bias the needle **112** and needle retainer in the rearward direction.

In contrast to the previous embodiment, the second embodiment utilizes a cartridge 150 having a selectively sealable by-pass fluid passage **160** to separate the two medicinal components, rather than a mid wall and a pierceable seal as described above with the first embodiment. Prior to use, a mid seal **170** within the cartridge **150** separates the two medicinal components 154, 158. Prior to use, the mid seal **170** is displaced forwardly adjacent the by-pass passage **160**, which provides a fluid passage, allowing the two medicinal components **154, 158** to be mixed. The mixed components can then be injected into the patient.

Referring to Figs. 12, 13, the detail of the Cartridge 150 will be described in greater detail. The cartridge is a generally cylindrical container. The forward end of the cartridge is sealed by the pierceable forward seal **180**. The rearward end of the cartridge is sealed by a piston **143** that forms a fluid-tight seal with the interior wall of the cartridge. Intermediate the forward seal **180** and the piston **143**, a mid seal **170** forms a fluid-tight seal with the interior wall of the cartridge, separating the cartridge into two chambers, a forward chamber **156** for receiving a first component **158**, and a rearward chamber **152** for receiving a second component **154**.

The cartridge **150** includes a bubble-like fluid passage **160** that protrudes outwardly from the side of the cartridge. The fluid passage **160** forms an area in which the diameter of the cartridge is greater than the

diameter of the mid seal. The fluid passage **160** is an axially elongated channel having a length that is greater than the axial length of the mid seal **170**, and preferably, is shorter than the combined length of the mid seal and the piston **143**.

Although the fluid passage 160 is illustrated as a bubble-like protrusion, the fluid passage may be formed in other configurations. For instance, the fluid passage may be a recess or axial groove formed in the interior wall of the cartridge 150, so that the fluid passage does not protrude from the exterior surface of the cartridge. Similarly, the fluid passage may be an annular recess formed in the interior wall of the cartridge.

Referring to Fig. 12, the device **110** is illustrated in a "storage" position. In this position, the mid seal **170** prevents the two medicinal components from mixing. Therefore, the sealed cartridge **150** can be stored for an extended period, if desired, without compromising the efficacy of the medicinal components. In the stored position, the mid seal **170** is disposed rearwardly of the fluid passage **160** so a fluid-tight seal is formed between the mid seal and the interior wall of the cartridge, around the entire circumference of the mid seal.

During storage of the injection device **110**, the medication is divided into two separate components stored in the cartridge **150**, as shown in Figs. 12-13. Specifically, the first component **154** of the medicine is stored in the first chamber **152** and the second component **158** of the medicine is stored in the second chamber **156**. As discussed further below, preferably, when the cartridge is being filled during manufacture, a quantity of air remains within the second chamber **156**.

A plunger **140** is slidably disposed in the rearward end of the cartridge **150**. The plunger **140** is comprised of a plastic molded plunger rod

141 and an elastomeric piston **143**. The piston **143** forms a fluid-tight seal with the inner wall of the cartridge, and is slidably displaceable within the cartridge. The plunger rod **141** can be connected to the plunger seal **143** in a number of ways. In the present embodiment, the plunger rod **141** includes external screw threads that are configured to engage internal threads inside the plunger seal **143**, whereby the plunger rod and seal can be screwed together.

Referring now to Fig. 14, the transfer of the first medicine component **154** into the second chamber **156** shall be described. The mid seal **170** is advanced axially until it registers with the fluid passage **160**. The fluid passage **160** then provides a by-pass passage so that the component in the rearward chamber can be injected into the forward chamber. Since the forward chamber preferably includes a quantity of air (or other compressible fluid), the material in the forward chamber can be compressed to allow the mid seal to be advanced into registry with the fluid passage **160**. Alternatively, the forward chamber may include a vent for venting the air from the forward chamber when the fluid is transferred from the rearward chamber into the forward chamber. If a vent is included, preferably the vent is sealable to prevent leakage of the mixed components during injection.

Specifically, to mix the two components in the cartridge, the plunger **140** is axially advanced into the cartridge **150**, to compress the first component **154** against the rearward end of the mid seal **170** in the first chamber **152**. As back pressure on the mid seal **170** overcomes the frictional resistance between the mid seal and the cartridge **150**, the mid seal is displaced forwardly in the cartridge. Once the mid seal **170** is displaced into alignment with the fluid passage **160**, a passage is created between the mid seal and the inside wall of the fluid passage, as shown in Fig. 14.

The fluid passage **160** is sufficiently large to allow the first

substance **154** to flow around the mid seal and into the second chamber **156** where it is mixed with the second substance **158**. Once the first component is completely transferred to the second chamber **156**, the plunger seal **143** is advanced until it abuts the mid seal **170**, as shown in Fig. 15. The combined axial length of the mid seal **170** and piston **143** is slightly longer than the length of the fluid passage **160**. Therefore, the mid seal and piston seal off the entire length of the fluid passage. This prevents the contents of the second chamber **156** from backflowing during mixing of the components.

After mixing of the components is completed, the locking clip **200** is removed to allow injection of the medication into the patient. Pressure is applied to the cartridge **150** to discharge the medication from the second chamber **156**. At the completion of the injection stroke, the cartridge **150** actuates the needle retainer **120**. Pressure on the cartridge **150** is then released so that the needle can be retracted, as shown in Fig. 16.

Referring now to Figs. 17-23 in general, and to Fig. 17 specifically, another embodiment of a pre-filled safety diluent injector is designated generally 210. The injector device **210** includes a double-ended needle **212**, a generally cylindrical barrel **230** that houses the needle and a generally cylindrical cartridge **250**. The barrel **230** further includes a compression spring **226** and a needle retainer **220** releasably retaining the needle **212** against the bias of the spring. The needle **212** has a sharpened rearward tip **214** and a sharpened forward tip **216**. The spring **226** circumscribes the needle **212** and is compressed against the interior of the barrel **230** at the barrel's forward end. The rearward end of the spring **226** bears against the interior of the needle retainer **220** to bias the needle **212** and needle retainer in the rearward direction.

In this embodiment, the transferring and mixing of the medication components is done in the cartridge **250** prior to attaching the

cartridge to the needle hub 221. Since the cartridge **250** is not connected to the needle assembly during mixing, there is no risk of inadvertently retracting the needle during the mixture of the components. As a result, the barrel does not include a locking clip, as in the other embodiments.

Referring now to Figs. 18-19, the cartridge **250** and barrel **230** are packaged and distributed so that the two are disassembled. The cartridge **250** is a generally cylindrical vessel that may be molded out of pharmaceutical quality glass such as borosilicate or a rigid inert plastic such as polyolefin or polyester. A cartridge cap **253** is disposed over the distal end of the cartridge **250**. The cartridge **250** is configured similar to the cartridge 150 illustrated in Figs. 12 - 16, and includes a bubble-like fluid passage **260** that protrudes outwardly from the side of the cartridge. A mid seal **270** is slidably disposed in the cartridge **250** and divides the cartridge into a first chamber **252** and a second chamber **256**. Each chamber of cartridge **250** is filled with a predetermined amount of a component of medication during manufacturing of the device **210**. In particular, the first chamber **252** is prefilled with a first component **254** of the medication and the second chamber **256** is prefilled with a second component **258**.

Referring now to Fig. 20, a plunger **240** is slidably disposed in the proximal end of the cartridge **250**. The plunger **240** is comprised of a plastic molded plunger rod **241** and an elastomeric plunger seal **243**. When the plunger **240** is axially advanced into the cartridge **250**, the first component **254** is compressed against the rearward end of the mid seal **270** in the first chamber **252**. As back pressure on the mid seal **270** overcomes the frictional resistance between the mid seal and the cartridge **250**, the mid seal is displaced forwardly in the cartridge. Once the mid seal **270** is displaced into alignment with the fluid passage **260**, a passage is created between the mid seal and the inside wall of the fluid passage to allow the first substance **254** to flow around the mid seal and into the second chamber **256** where it is mixed

with the second substance **258**.

The fluid passage **260** is sufficiently long to allow the first substance **254** to flow around the mid seal and into the second chamber **256** where it is mixed with the second substance **258**. Once the first component is completely transferred to the second chamber **256**, the plunger seal **243** is advanced until it abuts the mid seal **270**, as shown in Fig. 21. The combined axial length of the mid seal **270** and plunger seal **243** is slightly longer than the maximum length of the fluid passage **260** so that the mid seal and plunger seal close off the entire length of the fluid passage. This prevents the contents of the second chamber **256** from backflowing during mixing of the components.

Referring again to Fig. 18, the cartridge **250** includes an elastomeric front seal **280** in the distal end of the cartridge. The front seal **280** may be molded of a self-sealing biocompatible elastomer such as polyisoprene. The front seal **280** is generally cylindrical with a wide cylindrical rearward end **282** disposed within the cartridge and a reduced diameter forward end **284** projecting forwardly from the forward end of the cartridge. The rearward end **282** has an outside diameter that is similar to the inside diameter of the cartridge **250**. In addition, the rearward end **282** has a plurality of axially-spaced circumferential ribs **286** that frictionally and sealingly engage the interior of the cartridge to provide a fluid tight seal and prevent fluid from leaking from the cartridge.

The forward end **284** of front seal **280** includes an external thread **288** about its circumference. The distal end **284** also contains a shallow frontal cavity **290**. A narrow bore **292** in fluid connection with the second chamber **256** extends from the proximal end of the front seal **280** and terminates within the reduced diameter distal end **284**. Fluid communication between the frontal cavity **290** and the bore **292** is obstructed by a pierceable

membrane **294**.

Referring now to Fig. 19, the barrel **230** is generally cylindrical and has a tapered nose **232** at its distal end. The nose **232** has an opening through which the needle **212** extends. In addition, the nose **232** is configured to receive a needle cover 211 that fits over the nose to prevent accidental needle sticks when the needle **212** is in an extended position. The proximal end of the barrel **230** is open, forming a cylindrical socket **234** adapted to receive the cartridge **250**. Prior to attachment with the cartridge **250**, the rearward open end of the barrel **230** is closed by a cylindrical barrel cap **233**. The barrel further includes a pair of retaining apertures **238** that cooperate with the needle retainer **220** to releasably retain the needle, and a pair of lockout windows that cooperate with locking tabs to lock the needle in the retracted position.

The needle retainer **220** includes a generally cylindrical body **221** and a pair of retaining arms **222** that extend radially forwardly from the body **221**. A generally cylindrical aperture **296** is disposed within the proximal end of the needle retainer body **221**. The inner wall of the aperture **296** includes internal screw threads **298** that are adapted to receive the external screw thread **288** of the front seal **280** in the cartridge **250**.

The cartridge cap **253** and barrel cap **233** are removed from the cartridge **250** and barrel **230**, respectively, to prepare the cartridge and barrel for assembly. The cartridge **250** is connected to the barrel **230** by inserting the forward end of the front seal through the open end of the barrel **230** and screwing the cartridge clockwise into the aperture **296**. The frontal cavity **290** in the front seal **280** is preferably coaxial with the needle **212**, such that attachment of the cartridge **250** to the barrel **230** causes the proximal needle tip **214** to enter the cavity **290** and pierce the membrane **294**, thereby connecting the second chamber of the cartridge in fluid communication with

the needle **212**, as shown in Fig. 17.

Referring to Fig. 17, the cartridge **250** is connected to the barrel **230**, the medication can be injected into the patient by advancing the cartridge forwardly into the barrel. The proximal end of the front seal **280** is configured to form a sliding fit with the interior of the cartridge **250** so that the cartridge slides over the front seal during advancement of the cartridge. As the cartridge **250** is advanced, the rearward end of the front seal **280** bears against the needle retainer **220**, thereby keeping the front seal stationary during advancement of the cartridge. At the same time, the mid seal **270** at the rear of the second chamber **256** is displaced toward the front seal **280**. This causes a reduction of volume in the second chamber **256**, whereby the medication is displaced into the needle to facilitate the injection. At the completion of the injection, the mid seal **270** bears against the rearward end of the front seal **280**, as shown in Fig. 22.

As in the previous embodiments, the needle **212** is retracted by actuating the needle retainer **220**. In particular, the needle **212** is retracted by disengaging the retaining arms **222** from the retaining apertures **238** in the barrel wall to allow the spring **226** to propel the needle **212** rearwardly. To actuate the needle retainer **220**, pressure is applied to the cartridge **250** to advance the cartridge over the needle retainer body **221**, as shown in Fig. 22. During advancement, the distal end of the cartridge **250** engages a cylindrical sleeve **300** that is disposed around the distal end of the needle retainer body **221**. The inside and outside diameters of the release sleeve **300** are preferably equal to the inside and outside diameters of the cartridge **250** so that the distal end of the cartridge mates with the proximal end of the sleeve. Prior to engagement with the cartridge **250**, axial movement of the release sleeve **300** along the needle retainer is limited by an internal flange **302** that slides within an annular fluid passage **223** on the needle retainer body **221**. After the cartridge **250** engages the sleeve **300** continued advancement of

the cartridge drives the sleeve axially forwardly into engagement with the retaining arms **222**. The release sleeve **300** deflects the retaining arms radially inwardly and out of engagement with the retaining apertures **238**, allowing the spring **226** to propel the needle **212** rearwardly, as shown in Fig. 23.

As described above, the third embodiment includes a threaded engagement between the front seal **280** and the needle retainer **220** rather than a barbed connection as described in the first two embodiments. Using a threaded connection can increase the overall length of the needle retainer **220**, which in turn increases the distance between the distal end of the cartridge **250** and the retaining arms **222**. One manner for accommodating this increased length is to increase the length of the barrel **230**. However, by incorporating the release sleeve **300**, the length of the barrel **230** need not be substantially increased. The release sleeve **300** compensates for the increased distance by acting as an extension of the cartridge **250**. This eliminates the need to increase the overall length of the device **210**. Preferably, the length of the release sleeve **300** is slightly longer than the length of the threaded engagement between the front seal **280** and the needle retainer **220**.

Referring now to Figs. 24-29 in general, and to Figs. 24-25 specifically, a fourth embodiment of a pre-filled safety diluent injector is shown. The injector device **310** includes a double-ended needle **312**, a generally cylindrical barrel **330** that houses the needle and a generally cylindrical cartridge assembly **350** mounted within the proximal end of the barrel. Like the previous embodiments, the barrel further includes a compression spring **326** and a needle retainer **320** releasably retaining the needle **312** against the bias of the spring. The device **310** also includes a U-shaped locking clip **400** in the barrel wall to prevent accidental discharge of medication from the device **310**.

The cartridge assembly **350** has a two-part design that offers the advantage of using cost-efficient plastic in the assembly. The cartridge assembly **350** includes a front cylinder **351** having an open proximal end and a rear cylinder **353** having an open distal end telescopically mounted to the proximal end of the front cylinder. The front cylinder **351** contains an internal wall **360** that divides the cartridge assembly **350** into a first chamber **352** and a second chamber **356**. The first chamber **352** contains a predetermined amount of a first component **354** of medication, and the second chamber **356** contains a predetermined amount of a second component **358** of medication. The proximal end of the front cylinder **351** is closed by a pierceable elastomeric front seal **380**.

In many applications, the second component **358** will be a dry powdered component. Dry components do not require a glass container and can be stored in plastic containers without jeopardizing long term stability of the component. Since it is more cost-efficient to mold complex parts out of plastic than glass, it is preferable to minimize the complexity of the glass portion of the cartridge assembly **350**. To this end, the front and rear cylinders **351**, **353** are configured so that the first component **354** is stored entirely within the rear cylinder and the second component **356** is stored entirely within the front cylinder. In this arrangement, the front cylinder **351** comprises a more complicated structure to allow the rear cylinder to be a simple cup-shaped container. Therefore, the more complex forward cylinder can be molded out of cost-efficient plastic for those devices that store a dry second component **358** in the second chamber **356**. Preferably, glass is only used, if at all, to mold the rear cylinder **353**.

As stated earlier, the rear cylinder **353** is telescopically mounted on the proximal end of the front cylinder **351**. The outside diameter of the rear portion of the rear seal is generally equal to the inside diameter of the rear cylinder **353** so as to frictionally engage the interior of the rear cylinder

and provide a fluid tight seal. The rear cylinder **353** is adapted to slide axially over the rear seal 340 in response to pressure applied to the proximal end of the rear cylinder.

The barrel **330** has an inside diameter large enough to accommodate the outside diameter of the rear cylinder **353**. As a result, the outside wall of the front cylinder **351** is separated from the interior wall of barrel **330** by a clearance space, as shown in Fig. 25. The front cylinder **351** is maintained in a concentric relationship with the much larger barrel **330** by a pair of opposing longitudinal ribs **355** on the outside wall of the front cylinder. The longitudinal ribs are illustrated in Fig. 24.

An elastomeric rear seal **340** is disposed between the front cylinder **351** and rear cylinder **353**. The rear seal **340** includes a reduced diameter end **342** partially disposed in the open proximal end of the front cylinder **351**. The rear seal **340** also includes a flanged end **344** disposed within the rear cylinder **353**. The reduced diameter end **342** and flanged end **344** frictionally and sealingly engage the interior of the front cylinder **352** and rear cylinder **354**, respectively. This engagement provides a fluid tight seal with the interior of both cylinders, while allowing the rear seal **340** to be displaced relative to either cylinder. Forward advancement of the rear seal **340** relative to the front cylinder **351** is limited by the proximal end of the front cylinder, which is configured to matingly engage the flanged portion of the rear seal.

As stated earlier, the front cylinder **351** contains an internal wall **360**. The internal wall **360** is adjacent the rearward open end of the cartridge, forming a socket for receiving the rear seal **340**. The internal wall **360** contains an orifice **362** mounted in the center of the wall **360**. A hollow piercing member **364** is mounted in the orifice and extends rearwardly toward the rear seal **340**. In addition, it may be desirable to provide a vent opening in

the internal wall **360** to vent the air between the rear seal **340** and the internal wall when the rear cylinder is advanced to pierce the rear seal.

The distal end of the rear seal **340** is closed by a membrane **348** that is configured to be pierced by piercing member **364**. The rear seal **340** includes a hollowed mid section **346** that is connected in fluid communication with the first chamber **352** through the proximal end of the rear seal. Once the membrane **348** is pierced, a fluid passage is created through the piercing member **364** and rear seal **340**, such that the first and second chambers, **352**, **356** are connected in fluid communication. The rear seal **340** may be molded in a high elongation self-sealing biocompatible elastomer, such as polyisoprene.

The operation of the device **310** will now be described. A slight squeezing pressure is applied to the proximal end of the rear cylinder **353** to axially advance the rear cylinder over the front cylinder **351**. This causes the first component **354** to become compressed between the rear seal **340** and the closed proximal end of the rear cylinder **353**. Continued pressure on the rear cylinder **353** creates back pressure on the rear seal **340** which axially displaces the rear seal forwardly into the piercing member **364**. At this time, the membrane **348** is pierced to create a fluid passage between the first and second chambers **352**, **356**.

The rear cylinder **353** is advanced forwardly relative to the front cylinder **351** to expel the first component **354** from the first chamber **352** into the second chamber **356**. Once the first component **354** is completely expelled from the first chamber **352**, additional pressure on the rear cylinder **353** advances the rear cylinder forwardly relative to the front cylinder **351** until the closed proximal end of the rear cylinder abuts the proximal end of the rear seal **340**, as shown in Fig. 26. At this point, the device **310** is shaken to mix the components within the second chamber **356**. During the mixing process,

displacement of the cartridge assembly **350** is prevented by the locking clip **400**, thereby minimizing the potential for accidental discharge of the medication.

After the components are mixed, the locking clip 400 is removed. The cartridge assembly is then displaced forwardly so that the rearward end of the needle 312 pierces the forward seal 380. The air is then vented from the forward chamber. Further pressure is applied to the cartridge assembly **350** to discharge the medication from the second chamber **356** and through the needle **312**. At the completion of the injection stroke, the proximal end of the cartridge assembly **350** actuates the needle retainer **320**, as shown in Fig. 27. Pressure on the cartridge assembly **350** is then released so that the needle **312** can be retracted, as shown in Figs. 28 and 29.

In some instances, it may be desirable to store the cartridge in its component parts. In other words, the rear cylinder 353 may be detached from the forward cylinder **351**. Prior to use, the rear cylinder **353** would be attached to the forward cylinder 351 and the combined assembly would be utilized as described above. In such instances, the separate rear container **353** may include a separate cap to cover its forward end. Similarly, the forward cylinder **351** may include a cap to cover its rearward end. The detachable rearward cylinder **353** may permit a variety of pre-measured medicinal components to be stored and readily combined in various combinations prior to use.

The terms and expressions which have been employed are used as terms of description and not of limitation. There is no intention in use of such terms and expressions of excluding any equivalents of the features shown and described or portions thereof. It is recognized, however, that various modifications of the embodiments described herein are possible within the scope and spirit of the invention. For instance, the embodiments

described above include a needle retainer having a pair of radially displaceable arms to automatically release the needle for retraction after use. However, the devices may be modified by utilizing different needle retainers that may or may not automatically retract the needle after use. Accordingly, the invention incorporates variations that fall within the scope of the following claims.

CLAIMS

1. A medical device, comprising:
a barrel having an open proximal end and a distal end;
a needle having a first sharpened tip and being operable between an extended position in which the first sharpened tip projects forwardly from the barrel and a shielded position in which the first sharpened tip is shielded to prevent inadvertent contact with the first sharpened tip;
a cartridge in fluid communication with the needle, comprising:
a first chamber containing a first substance;
a second chamber containing a second substance;
a fluid flow controller between the first chamber and the second chamber; and
a plunger slidably disposed within the cartridge;
a biasing element imparting a force capable of displacing the needle relative to the barrel to shield the first sharpened tip; and
a needle retainer releasably retaining the needle in the extended position;
wherein axially advancing the plunger within the first chamber advances the first substance through the fluid flow controller and into the second chamber where said first substance combines with the second substance to form a medicinal mixture, and continued advancement of the plunger and cartridge relative to the barrel after the mixture is expelled from the cartridge actuates the needle retainer to release the needle, whereupon the biasing element displaces the needle relative to the barrel to shield the first sharpened tip.

2. The medical device in claim 1 wherein the medical device further comprises a needle carrier fixed to the needle.

3. The medical device in claim 1 wherein the needle has a second sharpened tip at its rearward end.

4. The medical device in claim **1** wherein the needle is retracted upon release of pressure on the plunger.

5. The medical device in claim **1** wherein the medical device further comprises one or more stops that impede continued rearward displacement of the first sharpened needle tip beyond the proximal end of the barrel as the needle is moved to the shielded position.

6. The medical device in claim **1** wherein the plunger is comprised of a plastic molded plunger rod connected to an elastomeric seal.

7. The medical device in claim **1** wherein the plunger is displaceable relative to the cartridge while the first substance is expelled from the first chamber, and the plunger is stationary relative to the cartridge when the mixture is expelled from the second chamber.

8. The medical device in claim **1** wherein the second substance is a powdered material.

9. The medical device in claim **1** wherein the second substance is a liquid material.

10. The medical device in claim **1** wherein the volume of the second chamber is greater than the combined volume of the first substance and the second substance.

11. The medical device in claim **1** wherein the fluid flow controller comprises:
a wall between the first and second chambers having an opening;
a hollow piercing element disposed through the opening having a sharpened end extending into the first chamber; and
a fluid flow pathway through the piercing element;
wherein axially displacing the cartridge toward the barrel displaces the plunger until the plunger is ruptured by the piercing element,

creating a passage through the plunger which aligns with the fluid flow pathway in the piercing element to allow the first substance to pass through the plunger into the second chamber.

12. The medical device in claim 1 wherein the fluid flow controller comprises:
a barrier between the first and second chambers having an opening;
a hollow piercing element disposed through the opening having a sharpened end extending into the first chamber;
a fluid flow pathway through the piercing element; and
a pierceable mid seal axially displaceable within the first chamber that provides fluid communication between the first and second chambers upon being pierced by the piercing element;
wherein axially displacing the plunger toward the barrel displaces the pierceable mid seal until the mid seal is ruptured by the piercing element, creating a passage through the mid seal which aligns with the fluid flow pathway in the piercing element to allow the first substance to pass through the mid seal into the second chamber.

13. The medical device in claim 1 wherein the fluid flow controller comprises:
a mid seal between the first and second chambers that is axially displaceable within the cartridge; and
an elongated fluid passage in the side wall of the cartridge;
wherein axially displacing the plunger toward the barrel displaces the mid seal into alignment with the fluid passage, creating a passage between said mid seal and the inside wall of the fluid passage that allows the first substance to flow around the mid seal into the second chamber.

14. The medical device in claim 1 wherein the cartridge is substantially permanently attached to the barrel.

15. The medical device in claim **1** wherein the cartridge comprises a beaded circumferential rim on the distal end of the cartridge, and the barrel contains a lip projecting radially inwardly from the inner bore of the barrel at the barrel's proximal end, said lip adapted to engage the beaded rim of the cartridge to impede removal of the cartridge from the rear of the barrel after needle retraction.

16. The medical device in claim **2** wherein the biasing element comprises a compression spring disposed between the distal end of the barrel and the needle carrier.

17. The medical device in claim **2** wherein the needle retainer comprises a pair of forward tines extending radially outwardly from the needle carrier and configured to releasably engage a pair of windows in the barrel wall.

18. The medical device in claim **2** wherein a cylindrical sleeve having generally the same outside diameter as the cartridge is disposed around the circumference of the needle carrier in general axial alignment with the cartridge, such that axial advancement of the cartridge at the end of the injection stroke displaces the sleeve toward the distal end of the barrel to actuate the needle retainer.

19. The medical device in claim **3** wherein the cartridge further comprises a front seal at the distal end of the cartridge that is configured to be pierced by the second sharpened tip to connect the needle and second chamber in fluid communication.

20. The medical device in claim **19** wherein the minimum axial force on the plunger that is required to pierce the front seal is less than or equal to the minimum axial force required to axially displace the plunger in the rear chamber.

21. The medical device in claim **19** wherein the distal end of the front seal

includes an external thread and the proximal end of the needle carrier includes a cavity adapted to receive the threaded end of the front seal.

22. A medical device, comprising:

a barrel having an open proximal end, a distal end and an opening through the barrel wall oriented perpendicularly to the longitudinal axis of the barrel;

a needle having a first sharpened tip and being operable between an extended position in which the first sharpened tip projects forwardly from the barrel and a shielded position in which the first sharpened tip is shielded to prevent inadvertent contact with the first sharpened tip;

a cartridge in fluid communication with the needle, comprising:

a first chamber containing a first substance;

a second chamber containing a second substance;

a fluid flow controller connecting the first chamber and the second chamber; and

a plunger slidably disposed within the cartridge;

a biasing element imparting a force capable of displacing the needle relative to the barrel to shield the first sharpened tip;

a needle retainer releasably retaining the needle in the extended position; and

a locking clip detachably connected to the barrel;

wherein axially advancing the plunger within the first chamber advances the first substance through the fluid flow controller and into the second chamber where said first substance combines with the second substance to form a medicinal mixture, and removal of the locking clip from the barrel permits further advancement of the plunger and cartridge relative to the barrel to expel the mixture from the second chamber, whereafter axially advancing the cartridge disengages the needle retainer to allow the biasing element to displace the needle relative to the barrel to shield the first sharpened tip.

23. The medical device in claim **22** wherein the medical device further comprises a needle carrier fixed to the needle.

24. The medical device in claim **22** wherein the needle has a second sharpened tip at its rearward end.

25. The medical device in claim **22** wherein the needle is retracted upon release of pressure on the plunger.

26. The medical device in claim **22** wherein the cartridge comprises a beaded circumferential rim on the distal end of the cartridge, and the barrel contains a lip projecting radially inwardly from the inner bore of the barrel at the barrel's proximal end, said lip adapted to engage the beaded rim of the cartridge to impede removal of the cartridge from the rear of the barrel after needle retraction.

27. The medical device in claim **22** wherein the medical device further comprises one or more stops that impede continued rearward displacement of the first sharpened tip beyond the open proximal end of the barrel as the needle is moved to the shielded position.

28. The medical device in claim **22** wherein the plunger is comprised of a plastic molded plunger rod connected to an elastomeric seal.

29. The medical device in claim **22** wherein the plunger is displaceable relative to the cartridge while the first substance is expelled from the first chamber, and the plunger is stationary relative to the cartridge when the mixture is expelled from the second chamber.

30. The medical device in claim **22** wherein the locking clip comprises a flat U- shaped disk having a plurality of teeth along the inner edge, said clip being configured to slide through the slits in the barrel in a direction perpendicular to the longitudinal axis of the barrel and at a location between the cartridge and the needle retainer, thereby impeding

contact between the cartridge and the needle retainer.

31. The medical device in claim **22** wherein the second substance is a powdered material.

32. The medical device in claim **22** wherein the second substance is a liquid material.

33. The medical device in claim **22** wherein the volume of the second chamber is greater than the combined volume of the first substance and the second substance.

34. The medical device in claim **22** wherein the fluid flow controller comprises:
a barrier between the first and second chambers having an opening;
a hollow piercing element disposed through the opening having a sharpened end extending within the first chamber;
a fluid flow pathway through the piercing element; and
a pierceable mid seal axially displaceable within the first chamber that provides fluid communication between the first and second chambers upon being pierced by the piercing element;
wherein initial axial displacement of the plunger toward the barrel displaces the pierceable mid seal into contact with the piercing element, piercing the mid seal and creating a passage through the mid seal which aligns with the fluid flow pathway in the piercing element to allow the first substance to pass through the mid seal into the second chamber.

35. The medical device in claim **22** wherein the fluid flow controller comprises:
a mid seal between the first and second chambers that is axially displaceable within the cartridge; and
an elongated fluid passage in the side wall of the cartridge between the

mid seal and the distal end of the cartridge;

wherein axially displacing the plunger toward the barrel displaces the mid seal into alignment with the fluid passage, creating a passage between said mid seal and the inside wall of the fluid passage that allows the first substance to flow around the mid seal into the second chamber.

36. The medical device in claim **23** wherein the biasing element comprises a compression spring disposed between the distal end of the barrel and the needle carrier.

37. The medical device in claim **23** wherein the needle retainer comprises a pair of forward windows in the barrel wall and a pair of forward tines extending radially outwardly from the needle carrier and configured to releasably engage the forward windows.

38. The medical device in claim **24** wherein the cartridge further comprises a front seal at the distal end of the cartridge that is configured to be pierced by the second sharpened tip to connect the needle and second chamber in fluid communication.

39. The medical device in claim **38** wherein the minimum axial force on the plunger that is required to pierce the front seal is less than or equal to the minimum axial force required to axially displace the plunger in the rear chamber.

40. A medical device, comprising:

a barrel having an open proximal end and a distal end;

a needle having a first sharpened tip and being operable between an extended position in which the first sharpened tip projects forwardly from the barrel and a shielded position in which the first sharpened tip is shielded to prevent inadvertent contact with the first sharpened tip;

a cartridge in fluid communication with the needle, comprising:

a first chamber containing a first substance;
a second chamber containing a second substance;
a fluid flow controller between the first chamber and the second chamber; and
a biasing element imparting a force capable of displacing the needle relative to the barrel to shield the first sharpened tip; and
a needle retainer releasably retaining the needle in the extended position;
wherein the fluid flow controller is adapted to keep the first and second substances separate prior to use, and also adapted to allow mixing of the first and second substances prior to an injection, wherein after use the needle is disposed in the shielded position.

41. A method for injecting medicine, comprising the steps of:
providing an injection device having a first chamber containing a first medicinal component, a second chamber containing a second medicinal component, and a needle;
transferring the first medicinal component from the first chamber to the second chamber;
mixing the first and second components to form a medicinal mixture;
expelling the medicinal mixture from the chamber; and
retracting the needle after expelling the medicinal fluid to shield the needle against contact.

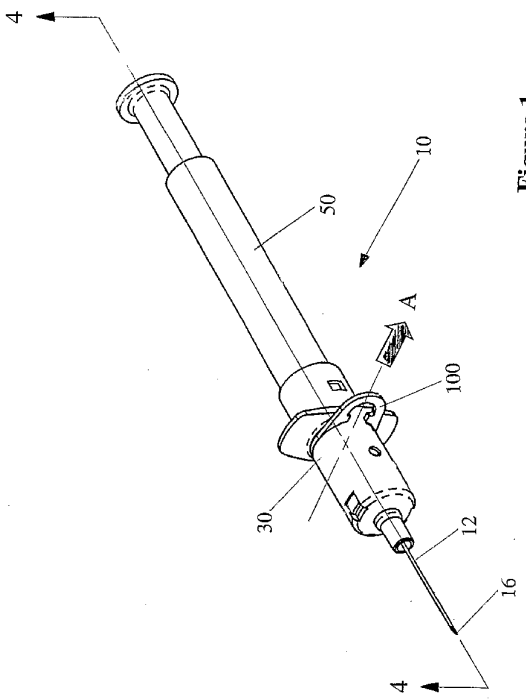
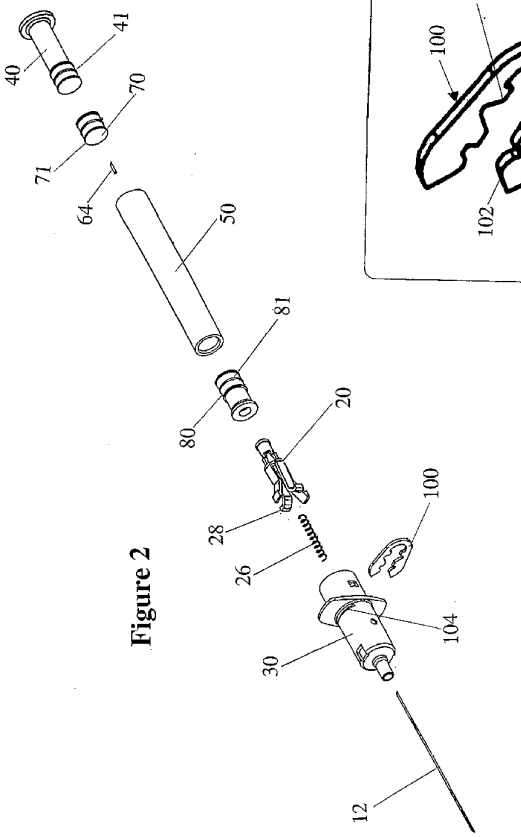


Figure 1



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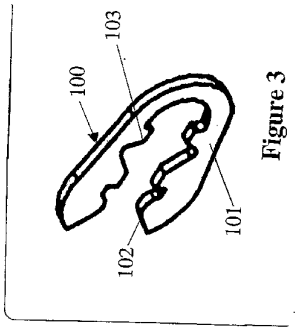

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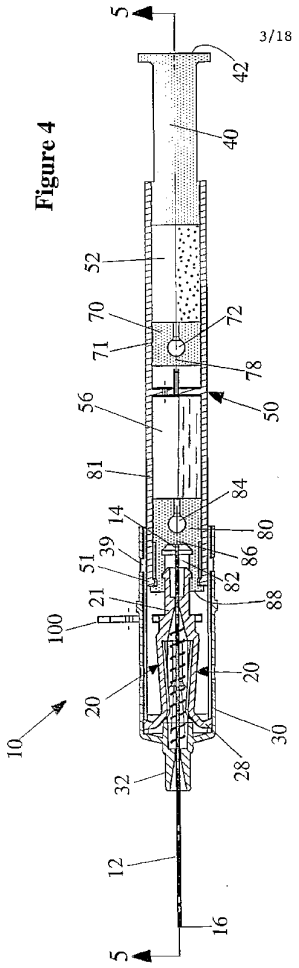

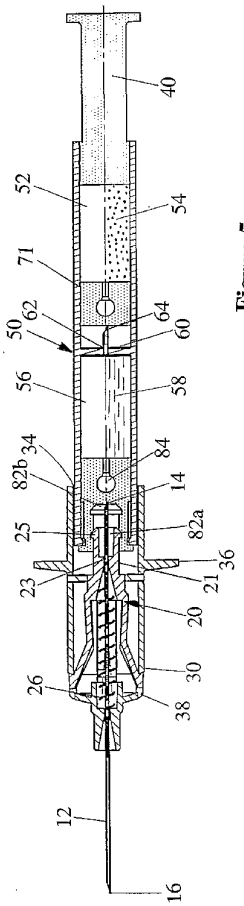

Figure 5

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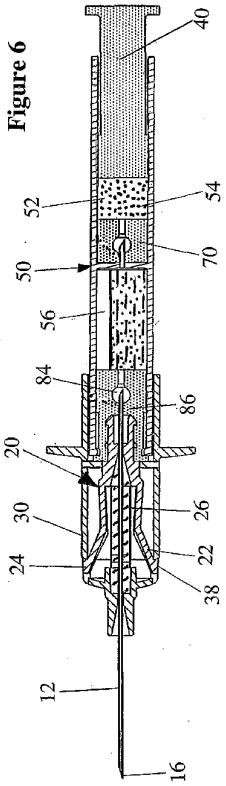

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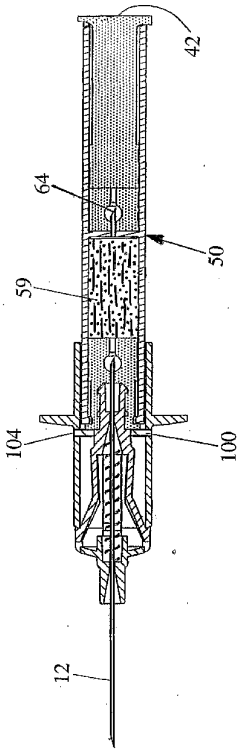

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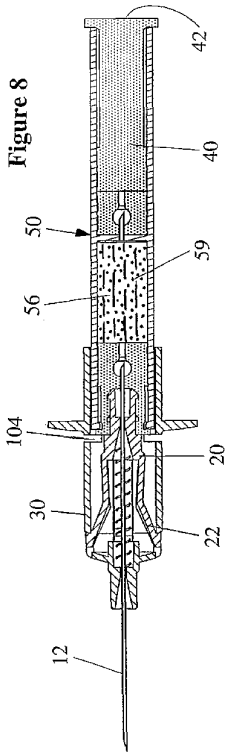

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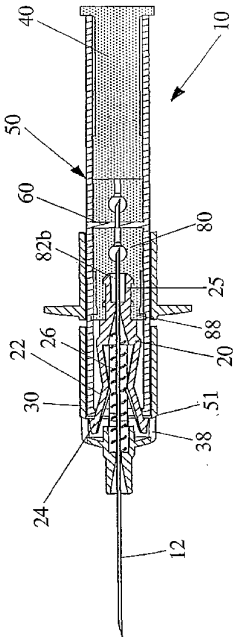


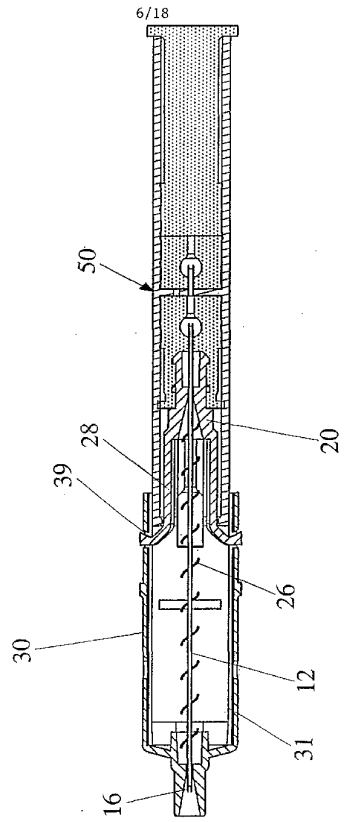
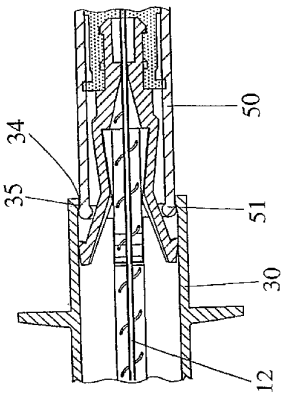


Figure 10

Figure 11



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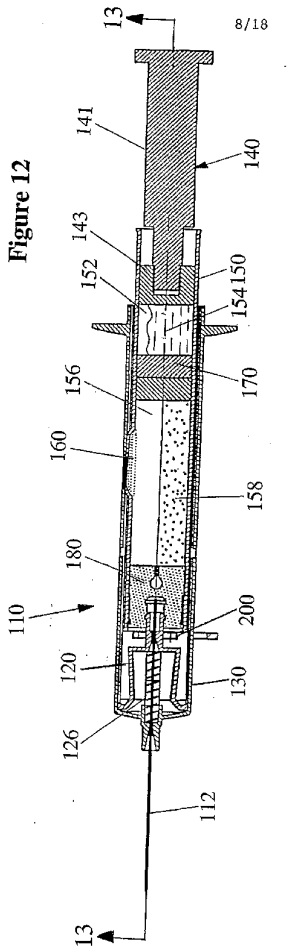


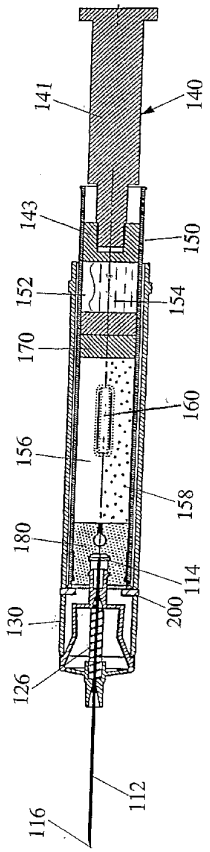
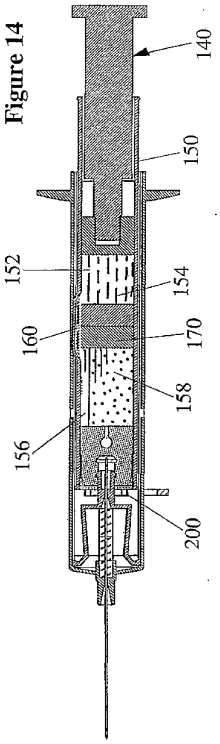


Figure 13

Figure 14



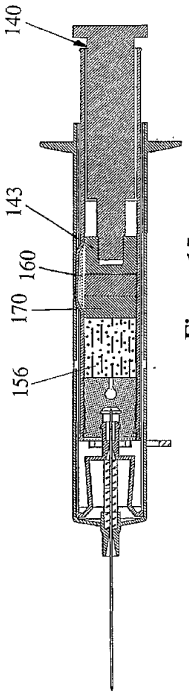
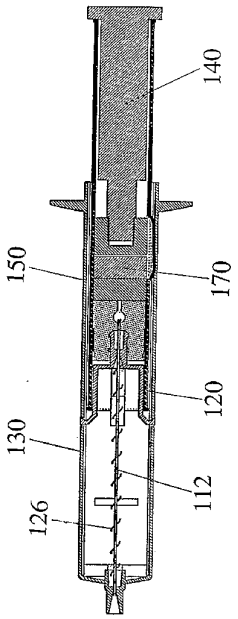


Figure 15

Figure 16



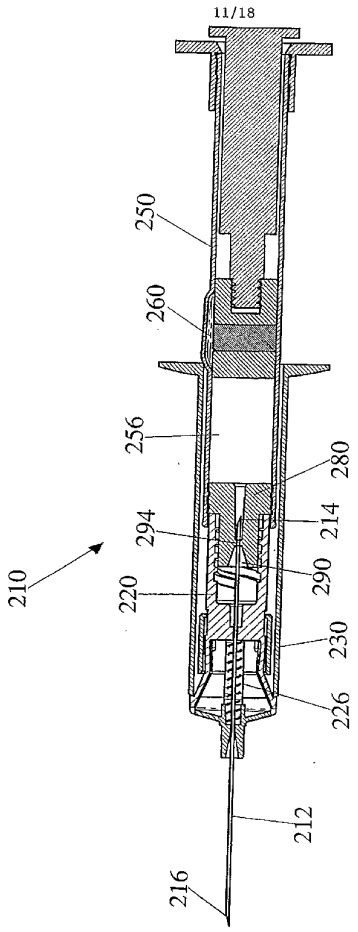


Figure 17

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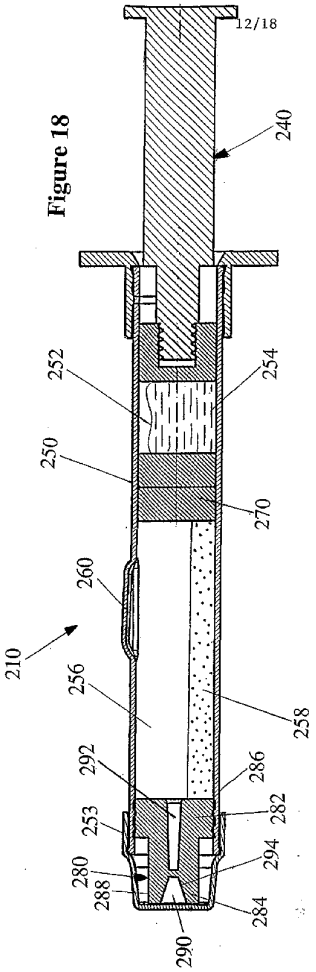

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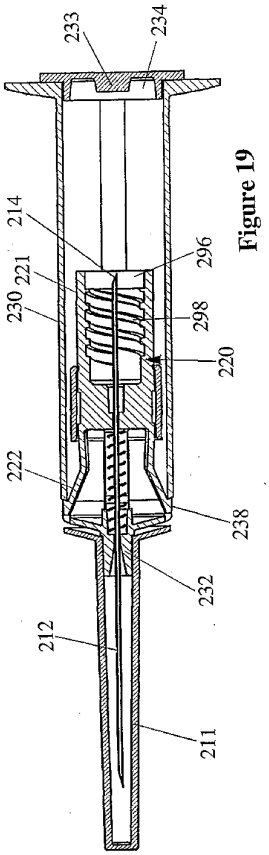

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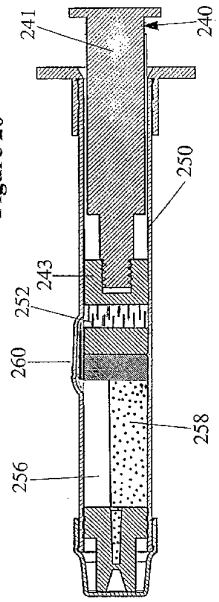

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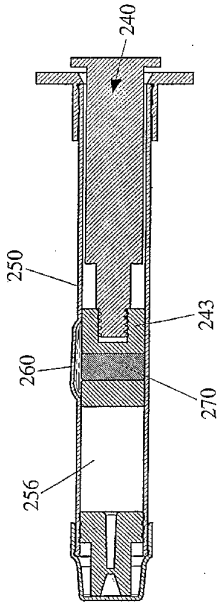
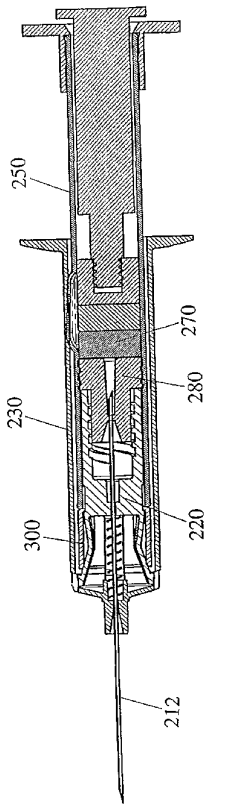


Figure 22



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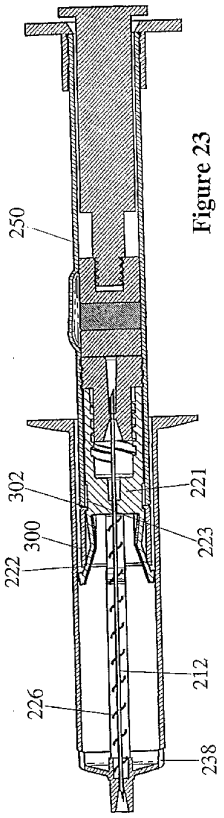


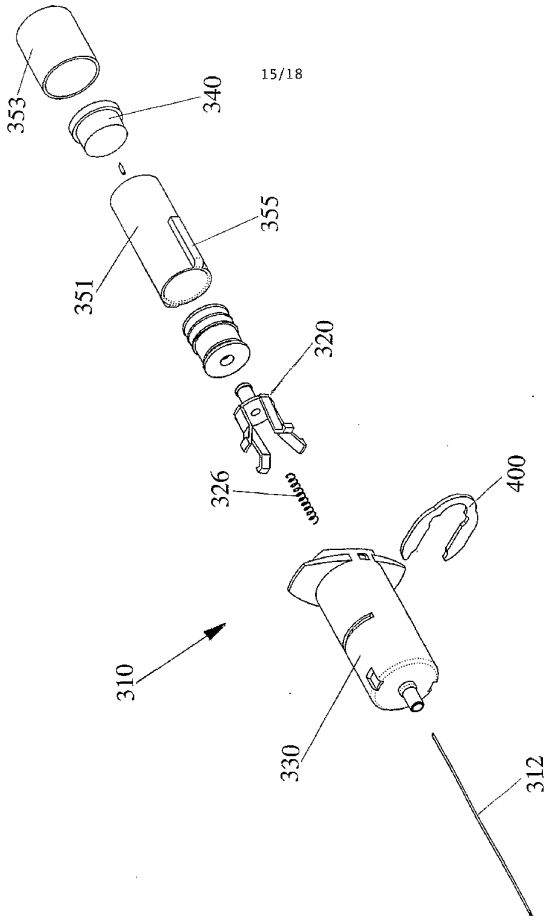


Figure 24

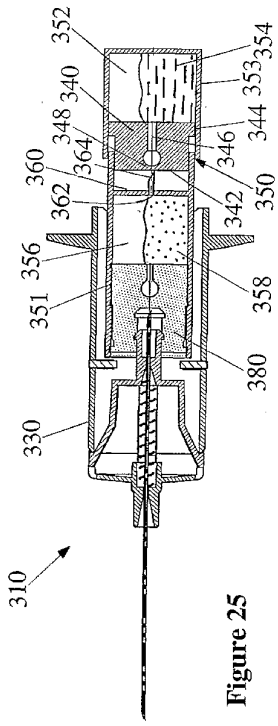


Figure 25

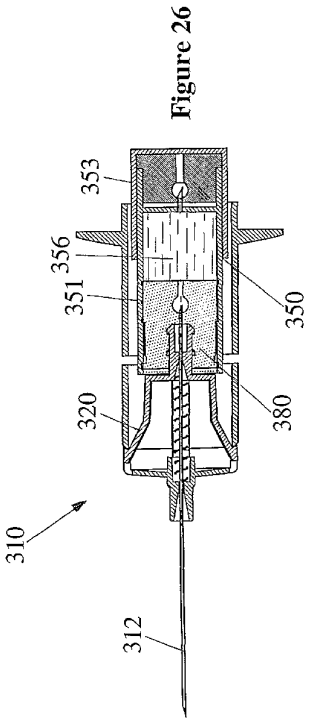
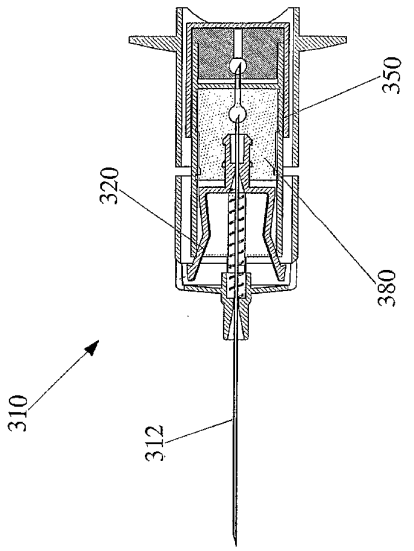


Figure 26



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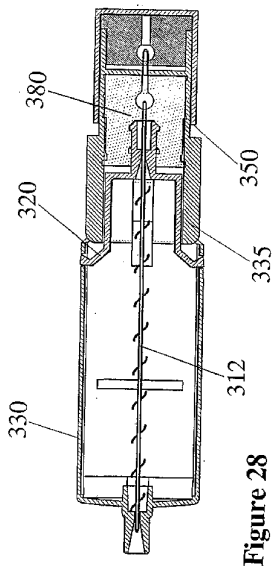

Figure 28

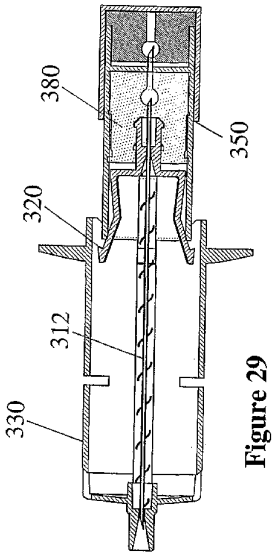

Figure 29

【国際公開パンフレット（コレクトバージョン）】

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
19 September 2002 (19.09.2002)

PCT

(10) International Publication Number
WO 02/072171 A3

(51) International Patent Classification⁷: A61M 37/00

(21) International Application Number: PCT/US02/07712

(22) International Filing Date: 13 March 2002 (13.03.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/275,568 13 March 2001 (13.03.2001) US

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(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

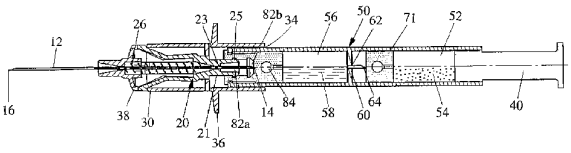
Published:
— *with international search report*

(88) Date of publication of the international search report:
30 October 2003

(15) Information about Correction:
Previous Correction:
see PCT Gazette No. 44/2002 of 31 October 2002, Section II

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: PRE-FILLED SAFETY DILUENT INJECTOR



(57) Abstract: A safety needle-bearing device (10, 110, 210, 310) for mixing and injecting medication from a two-chambered cartridge (50, 150, 250, 350) is provided. The device includes a needle (12, 112, 212, 312) that extends through the forward end of a barrel (30, 130, 230, 330). The two-chambered cartridge (50, 150, 250, 350) is attached to the barrel (30, 130, 230, 330) and contains components of a medication stored separately in the chambers. A plunger (40, 140, 240) in the rearward end of the cartridge can be advanced into the cartridge to combine the separate components and prepare the medication. As the cartridge (50, 150, 250, 350) is advanced forwardly into the barrel (30, 130, 230, 330), the medication is injected through the needle (12, 112, 212, 312) and into a patient. At the completion of the injection stroke, the cartridge (50, 150, 250, 350) engages a needle retainer to actuate needle retraction. The needle is subsequently retracted to shield the contaminated needle.

WO 02/072171 A3

【国際調査報告】

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/07712

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) :A61M 37/00
US CL :604/82, 87
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbols)
U.S. : 604/82-91, 282, 244

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EAST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,637,087 A (O'NEIL et al.) 10 June 1997, see abstract and Figures 1, 4 & 5.	1-3, 5-15, 18-24, 26, 28, 29, 31-35, 38-41
X	US 5,281,198 A (HABER et al.) 25 January 1994, see abstract and Figures 3-6.	1-3, 5-15, 18-24, 26, 28, 29, 31-35, 38-41
X	US 5,531,683 A (KRIESEL et al.) 02 July 1996, see Figure 25.	40 & 41.

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 JULY 2002	25 SEP 2002

Name and mailing address of the ISA/US	Authorized officer
Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	ANHTUAN T. NGUYEN Diane Smith
Facsimile No. (703) 305-3230	Telephone No. 703-308-2154

Form PCT/ISA/210 (second sheet) (July 1998)★

フロントページの続き

(51)Int.Cl.[7]	ＦＩ	テーマコード（参考）
	Ａ６１Ｊ　3/00　３１４Ｃ	

(81)指定国　AP(GH,GM,KE,LS,MW,MZ,SD,SL,SZ,TZ,UG,ZM,ZW),EA(AM,AZ,BY,KG,KZ,MD,RU,TJ,TM),EP(AT,BE,CH,CY,DE,DK,ES,FI,FR,GB,GR,IE,IT,LU,MC,NL,PT,SE,TR),OA(BF,BJ,CF,CG,CI,CM,GA,GN,GQ,GW,ML,MR,NE,SN,TD,TG),AE,AG,AL,AM,AT,AU,AZ,BA,BB,BG,BR,BY,BZ,CA,CH,CN,CO,CR,CU,CZ,DE,DK,DM,DZ,EC,EE,ES,FI,GB,GD,GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KP,KR,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,MN,MW,MX,MZ,NO,NZ,OM,PH,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TN,TR,TT,TZ,UA,UG,US,UZ,VN,YU,ZA,ZM,ZW

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Ｆターム(参考)　4C066 AA09 BB01 CC01 DD07 GG05 GG11 JJ07 JJ08 LL24 LL25
NN04 NN07