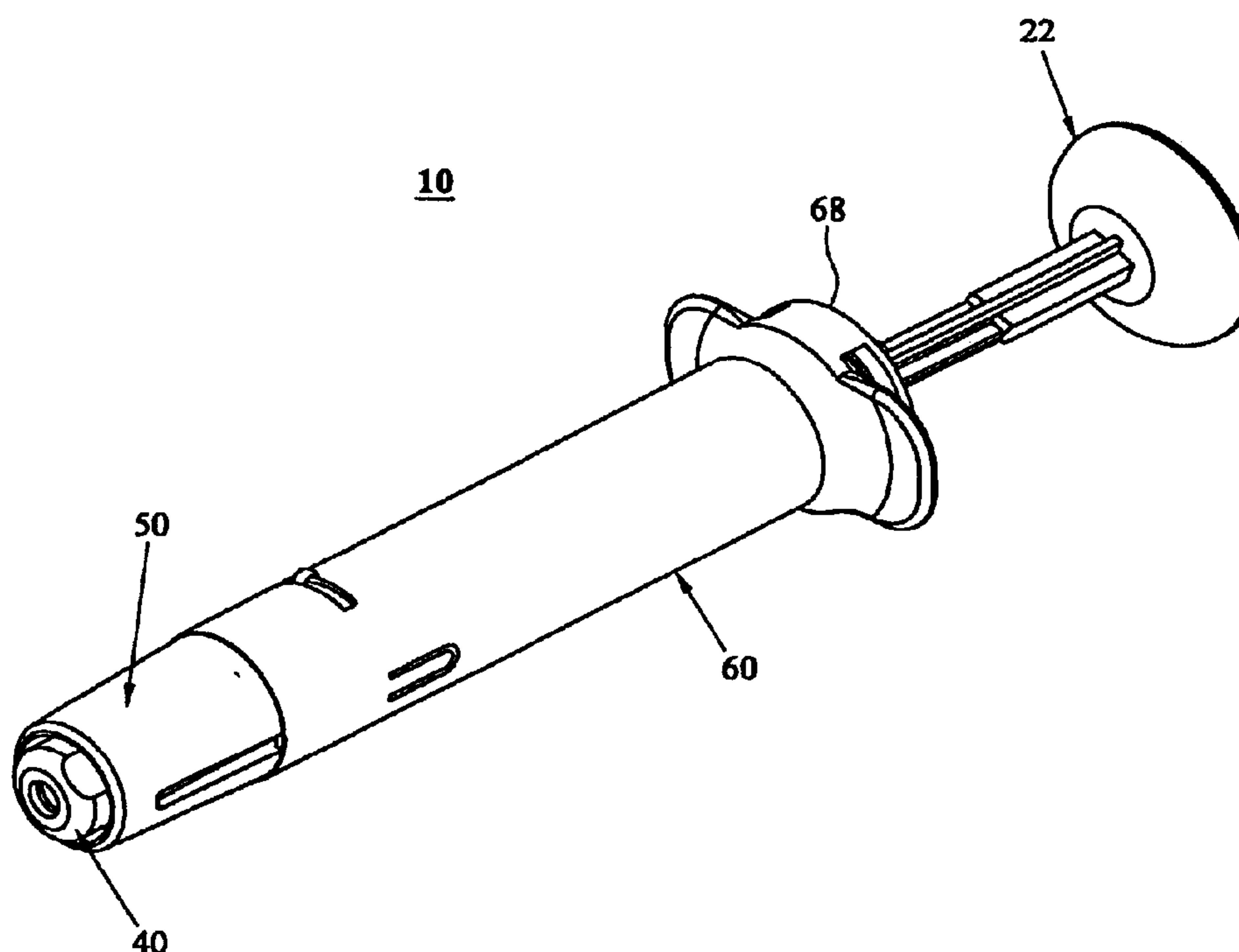




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(54) Title: PATIENT-CONTACT ACTIVATED NEEDLE STICK SAFETY DEVICE



(57) Abrégé/Abstract:

A device that is used in conjunction with a needle-based medication injection device (e.g. a prefilled syringe) that prevents needle stick injuries after the medication has been injected into a patient. The used needle is shielded by a cylindrical needle guard that surrounds and extends beyond the needle tip. In a preferred embodiment, before the needle is inserted into the patient, the needle guard projects forward to substantially hide visibility of the needle for safety and to reduce patient anxiety.

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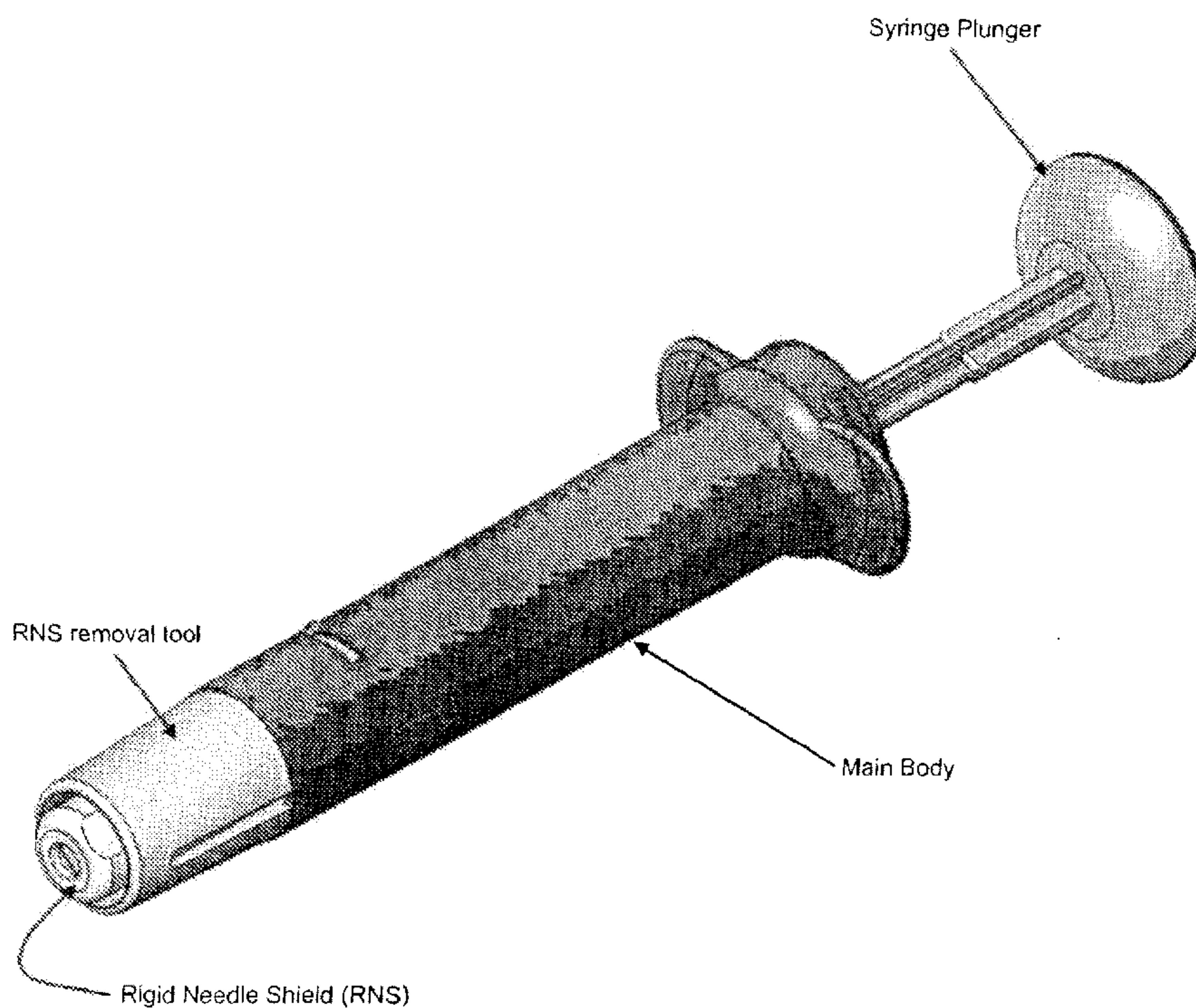
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[Continued on next page]

(54) Title: PATIENT-CONTACT ACTIVATED NEEDLE STICK SAFETY DEVICE

**Figure 1** Fully Assembled Device

(57) Abstract: A device that is used in conjunction with a needle-based medication injection device (e.g. a prefilled syringe) that prevents needle stick injuries after the medication has been injected into a patient. The used needle is shielded by a cylindrical needle guard that surrounds and extends beyond the needle tip. In a preferred embodiment, before the needle is inserted into the patient, the needle guard projects forward to substantially hide visibility of the needle for safety and to reduce patient anxiety.

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PATIENT-CONTACT ACTIVATED NEEDLE STICK SAFETY DEVICE**GENERAL DESCRIPTION OF INVENTION**

The following describes a device that is used in conjunction with a needle-based medication injection device (e.g. a prefilled syringe) that prevents needle stick injuries after the medication has been injected into a patient. The used needle is shielded by a cylindrical needle guard that surrounds and extends beyond the needle tip. In a preferred embodiment, before the needle is inserted into the patient, the needle guard projects forward to substantially hide visibility of the needle to reduce patient anxiety. The elements of the design and how they function are described below.

The glass syringe and rubber stopper have for years provided an ideal drug storage closure having unique properties of impermeability to oxygen, low extractables, biocompatibility, durability, etc. However they are both formed by processes that do not lend themselves to tight geometrical tolerances. For instance, the syringe flange is formed when a glass tube is heated to a soft state and the edges pressed over to form an edge. Typical tolerances for the inside length of a syringe or the length of a stopper are both +/- 0.5 mm. The finger flange thickness has a similar tolerance. Furthermore, tight tolerances were not originally needed by these devices because they were not used mechanically with other devices. Existing passive anti-needle stick safety devices for prefilled syringes must mount to the syringe but not interfere excessively with the force required to move the plunger rod during injection nor prevent the full travel of the plunger rod. The safety mechanism necessarily must be triggered toward the end of administration of the drug (near the end of the plunger rod travel). However, since virtually all safety devices locate the syringe against the safety device at a point under the syringe finger flange, a stackup of worst-case tolerances can put the required plunger rod travel variance at +/- 1.5 mm when considering just the tolerances of the inside length of the syringe, syringe flange thickness, and stopper length (syringe manufacturers reference the syringe length from the proximal end of the syringe, not the distal underside of the finger flange). To accommodate this 3 mm range of plunger rod position variance is very difficult for safety devices and it is a deliberate aim of the present invention to reduce and or eliminate any dependence of the safety device on the syringe and stopper tolerances. This is accomplished by having the safety device triggering mechanism independent of the syringe geometry. The present device is triggered when the Needle Guard Body is displaced proximally as the needle is inserted into the patient. The triggering point is

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broadly placed between point C in Figure 4 and the angled step down feature proximal to point C. As long as the Needle Guard Body is pushed such that the Main Body Protrusion makes it to anywhere between point C and the angled step down, the device will lockout and this is almost completely independent of the syringe or stopper geometry.

5 The present safety device also makes the needle shielding completely contemporaneous with needle removal, reducing the possibility of needle stick injuries when, for instance, a patient suddenly jerks or flinches causing the needle to be come out of the patient before the plunger rod had fully traveled and activated the safety mechanism as would be the case with existing passive safety devices.

10 Some embodiments disclosed herein relate to a needle stick safety device for a pre-filled syringe that prevents needle stick injuries comprising a main body for receiving a syringe, the main body including a protrusion, a needle shield removal tool positionable over a needle shield for removal of the needle shield prior to injecting medication into a patient and removably coupled to the main body, and a needle guard slidable with respect to the main
15 body and biased in the distal direction by a compression spring, the needle guard including a groove for receiving the protrusion from the main body, the needle guard is retainable in a first position against the bias of the spring by the needle shield removal tool and moveable under the bias of the spring to a second position covering the needle when the needle shield removal tool is removed to remove the needle shield, wherein the needle guard is moveable to
20 a third position against the bias of the spring as the needle guard is pressed against a patient's skin to expose the needle and insert the needle into the patient to inject medicine and moveable to a fourth position under the bias of the spring to cover the needle as the needle is withdrawn from the patient.

 Some embodiments disclosed herein relate to a needle stick safety device for a
25 pre-filled syringe that prevents needle stick injuries comprising a main body for receiving a syringe, the main body including a protrusion, and a needle guard slidable with respect to the main body and biased in the distal direction by a compression spring, the needle guard including a groove for receiving the protrusion from the main body, the needle guard is retainable under the bias of the spring in a first position covering the needle, wherein the

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needle guard is moveable to a second position against the bias of the spring as the needle guard is pressed against a patient's skin to expose the needle and insert the needle into the patient to inject medicine and moveable to a third position under the bias of the spring to cover the needle as the needle is withdrawn from the patient.

5

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates the fully assembled device;

Figure 2 illustrates the fully assembled device quarter section view;

Figure 3 illustrates the exploded view of various components of the device;

10 Figure 4 illustrates the needle guard body grooves showing a position of the main body protrusions during the steps of operating the device;

Figure 5 illustrates rigid needle shield (RNS) removal;

Figure 6 illustrates the device ready for medication dispensing;

Figure 7 illustrates medication dispensing steps;

Figure 8 is a cross section after an injection of medication;

15 Figure 9 illustrates removal of the device and needle from the injection site;

Figure 10 illustrates the final safety configuration;

Figure 11 illustrates the main body window position prior to the removal of the RNS and RNS Removal Tool;

20 Figure 12 provides an illustration after the RNS has been removed and the needle guard body has moved forward;

Figure 13 is a detailed showing of the RNS removal tool improvement;

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Figure 14 illustrates the RNS removal tool radial CAM mechanism to engage RNS;

Figure 15 illustrates the RNS removal tool axial CAM mechanism;

Figure 16 shows the RNS removal tool retention tool, nominal orientation
5 allowing syringe assembly; and

Figure 17 shows the removal tool retention barb engaging proximal end of the RNS.

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DETAILED DESCRIPTION**Figure 1 Fully Assembled Device**

The fully assembled device 10 is shown in Figure 1. The assembly comprises of a Main Body 60 with a Plunger 22 emanating proximally from the proximal end 68. Inside the device 10 is a prefilled syringe 20 with an attached needle 24 and a cover over the needle called a Rigid Needle Shield (RNS) 40 that protects the needle and maintains a sterile barrier for the medication injection pathways. At the distal end of the assembly is the RNS Removal Tool 50, which is a removable covering over the RNS 40 that facilitates its removal just before injecting medication into the patient. The plunger 22 is attached to the syringe stopper 26. At the distal end of the assembly inside the Main Body 60 is the Needle Guard Body 80, which is a tube that is concentric and interior to the Main Body 60 (see Figures 3, 5, and 6).

Figure 2 Fully Assembled Device Quarter Section View

The Needle Guard Body 80 is axially slide-able with respect to the rest of the Main Body 60 and is biased in a distal direction by a compression spring 61 acting at its proximal end 82. Initially, the Needle Guard Body 80 is held in a proximal position by the RNS Removal Tool 50. The RNS Removal Tool 50 is held in this position against the force of the spring by Retention Barbs 54 that project outwardly at the proximal end 55 of the RNS Removal Tool 50 and that mate with corresponding Retention Windows 62 in the wall 63 of the Main Body 60 of the device 10.

Immediately before injecting medication into a patient, the RNS 40 is removed by squeezing the RNS Removal Tool 50, which collapses along two slits 52 that run along the side of the tool 50 starting at its proximal end 55. The collapsed configuration of the tool 50 allows the Retention Barbs 54 at the proximal end 55 to disengage from the corresponding Retention Windows 62 in the Main Body 60 of the device 10. Inwardly projecting RNS Barbs 54 at the proximal inside surface of the RNS Removal Tool 50 grasp the proximal edge 42 of the RNS 40, which in combination with the compressive force transmitted by the collapsed RNS Removal Tool 50 walls allows it to pull the RNS 40 from the distal end of the syringe 20 when the user pulls it in a distal direction.

Figure 3 Component Nomenclature-Exploded View

As the RNS Removal Tool 50 is withdrawn from the end of the device 10, the Needle Guard Body 80 slides forward to an intermediate stop point B governed by the interference between one or more inwardly projecting Protrusions 64 from the Main Body 60 and

corresponding grooves 90 in the outer surface of the Needle Guard Body 80 (see Figure 4). The outer side of one Protrusion 64 on the Main Body 60 is shown in Figure 3. They are positioned at the end of cut-out sections that provide flexibility to the Protrusions 64. The Protrusions 64 interfere with the Needle Guard Body grooves 90 by projecting into the groove space and controlling the movement of the Needle Guard Body 80 against the distally directed force of the spring 61 and the proximally directed reaction force from the patient's skin. Prior to removal of the RNS 40, the Protrusion 64 is in position A of the Needle Guard Body groove 50 as shown in Figure 4. After the RNS 40 is removed, the Needle Guard Body 80 moves distally in response to the spring force, so that the Protrusion 64 is at position B. As the needle 24 is inserted into the patient, the patient's skin pushes the Needle Guard Body 80 proximally against the spring force, such that the groove-protrusion 90-64 interface moves from position B to position C. Toward the distal end of this groove section 90, the groove depth steps down to a deeper portion along an edge 92 that is angled to the axis of the needle guard body 80. After injection is complete and the device 10 is pulled away from the patient, the Needle Guard Body 80 moves distally from position C such that the Protrusions 64 encounter the stepped angled edge groove 94 under the force of the spring 61. The angled stepped surface 92 causes the Needle Guard Body 80 to rotate with respect to the Main Body 60 and to enter a final groove 96 toward position D, wherein the Protrusion 64 drops into a further deepening of the groove 98 such that the protrusion 64 is substantially captured. This engagement prevents relative motion of the Needle Guard Body 80 with respect to the Main Body 60

At this point the Needle Guard Body 80 has projected distally around the needle 64 to the extent that it protects the caregiver and others from inadvertently being stuck by the needle tip 25. The Needle Guard Body 80 is held in this needle-shielding position by interference of the Protrusions 64 in the groove recess 98 at position D so that the Needle Guard Body 80 can not be pushed proximally with respect to the Main Body 60.

The sequence of steps to operate the device is described in Figures 5 through 10. The RNS Removal Tool 50 is squeezed and pulled distally to remove the RNS 40 as shown in Figure 5. As shown in Figure 5, to disengage the Retention Barbs 54 from the Barb Retention Windows 62 and grip the proximal end of the RNS 40, the user presses downward from both sides on the RNS removal tool 50. As a result of this, the Needle Guard Body 80 moves distally to the position shown in Figure 6. A composite of 3 steps to inject medication is shown in Figure 7. In Step 1 the device 10 is pushed against the patient's injection site 100. In Step 2, as the device 10 is pushed against the injection site 100, the Needle Guard Body 80 moves proximally and slides into the Main Body 60 allowing the needle to enter into the

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injection site 100. In Step 3, the Plunger Rod 22 is pushed forward to dispel the medication into the injection site 100. Figure 8 shows a cross-section of the device 10 with the needle guard 80 fully retracted and after the plunger 22 has been fully depressed. In Figure 9, the device 10 is being withdrawn from the injection site while the spring 61 pushes the Needle Guard Body 80 distally. As the device 10 is fully withdrawn from the injection site 100, the Needle Guard Body 80 fully extends forward as shown in Figure 10. At this point the Main Body Protrusions 64 have entered position D in the groove 98 of the Needle Guard Body 80 shown in Figure 4 and locked the Needle Guard Body 80 from further motion with respect to the Main Body 60 to prevent any needle sticks.

To facilitate movement of the Main Body 60 and its Protrusions 64 with respect to the Grooves 90 of the Needle Guard Body 80, one or both components can be made using a plastic resin with ample lubrication (e.g. high content of mold release). Alternatively, dissimilar plastic resins exhibiting a low mutual coefficient of friction can be used for the components.

It is to be understood that there exist alternative arrangements of components that would still fall within the scope of what is described and claimed within this application. For instance, the Needle Guard Body 80 could be positioned on the outside of the main body with interior-facing grooves and outwardly facing protrusions on the main body 80.

Light Protected Embodiment

An alternative embodiment for the safety device is presented for use with light-sensitive drugs that require only minimal exposure to light. In this embodiment, the Patient-Contact Activated Needle Stick Safety Device components are made of opaque materials (e.g. plastic resins with pigments, tinted glass, etc.) that effectively block light from reaching the drug in the medication delivery device. However, drug injection instructions normally require the caregiver to inspect the drug to check that it is not cloudy, etc. prior to giving the injection. To achieve this, the Main Body 60 and Needle Guard Body 80 of the device 10 each have diametrically opposed windows that are positioned with respect to each other such that they are not aligned until the RNS Removal Tool 50 and RNS 40 have been removed. After removal, when the diametrically opposed windows on the two components align, they form a line of sight through the device 10, which enables the caregiver to inspect the drug volume. The RNS 40, RNS Removal Tool 50, and Plunger rod 22 components would also be made of opaque materials to prevent light exposure at the ends of the device 10. A covering (not shown) over the proximal end of the syringe with a hole for the plunger rod could also be created to provide additional light protection.

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In Figure 11, prior to the removal of the RNS 40 and RNS Removal Tool 50, the Main Body Window 65 is blocked internally by the outer surface of the opaque Needle Guard Body 80. In Figure 12, after the RNS 40 has been removed and the Needle Guard Body 80 has moved forward, the window 65 of the main Body 60 is aligned the window 85 of the opaque Needle Guard Body 80 allowing visibility into the syringe 20. A similar window is provided on diametric opposite side of device 10.

The Rigid Needle Shield 40 not only protects the needle 24 from being bent or its tip 25 from being damaged but it also forms one of the sterile barriers for the drug closure system. It must perform these functions before, during, and after sterilization and is therefore a complicated component that receives a tremendous amount of testing during drug development and approval process. Since it has potential contact with the drug inside the syringe 20, it becomes part of the specific drug closure system that receives regulatory approval and is therefore difficult to change after approval. They have become industry standard devices produced by specialized third party manufacturers. Nevertheless, they have limitations and deficiencies, namely that they can become difficult to remove from the syringe 20 after sterilization and storage, often requiring greater than 20N of force to remove, which on a part so small (approximately 0.25 inches in diameter, 1 inch long) makes it difficult for healthcare workers to remove due to the small grasping area. Patients that perform self-administration, especially those with limited manual dexterity or strength (e.g. arthritic or multiple sclerosis patients) will find it extremely difficult to remove. Therefore, an added improvement of the present device 10 is to facilitate the RNS 40 removal. This is accomplished by the RNS Removal Tool 50, which in addition to presenting a bigger surface area with which the user can grab, it also features some CAM mechanisms to provide a mechanical leverage to removing the RNS 40. As shown in Figures 13, 14, and 16 the RNS Removal Tool Retention Barbs 54 reside inside the Main Body Barb Retention Window 62 before the RNS 40 is removed. The lateral sides of this Barb 54 and or the corresponding edges of the Main Body Barb Retention Window 62 are angled such that as the RNS removal tool 50 is rotated, the barbs 54 push against the edge of the window 62 and are deflected radially inward as shown in Figures 14 and 15. The Axial Cam Follower 56 on the RNS Removal Tool 50, as shown in Figure 14, has not yet acted against the Main Body Axial Cam Profile 66.

This mechanical advantage provides a strong radial squeeze so that the removal tool 50 further engages the proximal edge 42 of the RNS 40 as shown in Figure 17. This engagement cannot pre-exist sufficiently since the syringe 20 and RNS 40 must assemble into the device 10, from the proximal to distal end of device 10, with minimal resistance or disturbance to the

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RNS 40 seal as shown in Figure 16. After the proximal end 42 of the RNS 40 is engaged by the RNS Removal Tool 50, the Axial Cam Follower 56 engages a sloped surface 67 of the Main Body Axial Cam Profile 66 as shown in Figures 15 and 17, which places a mechanically advantaged axial force on the RNS Removal Tool 50 in a distal direction, creating a distal axial displacement and forming a gap between the Main Body 60 and the RNA Removal Tool 50. Because the proximal end of the RNS 40 is engaged, the RNS Removal Tool 50 pushes the RNS 40 off of the syringe 20 and needle 24 with much less effort on the part of the user than would normally be required.

Although this description has used a Rigid Needle Shield 40 as an example, soft needle shields, which do not have a hard plastic outer shell, could equally be used in this application with minor changes to account for different geometry.

A further improvement to the device could be a distal end cap on the RNS Removal Tool 50 and a proximal inwardly projecting lip that together would help contain the RNS 40 after it had been removed from the syringe 20, preventing it from falling to the floor, etc.

The RNS Removal Tool 50 can also have large cut-through arrows 51 indicating the direction of rotation to the end user. It could also have large wings extending radially outward to provide greater rotational mechanical advantage for the end user.

For patients that have limited hand strength, holding the device against the skin while the needle 24 is in the injection site, requires maintaining a force against the spring that pushes against the Needle Guard Body 80 (position C in Figure 4). A further improvement to the device would be to lessen this force by increasing the angle of the deeper groove section 94 that starts proximally to point C in Figure 4 and deflects the Main Body Protrusion 64 over to the straight groove section 96 that ends at D. In Figure 4, this angle is shown at about 45 degrees. An angle of perhaps 60 degrees would place a greater axial component of force against the spring force at some reduction of the lateral force.

Of course, an angle of 90 degrees would hold the Needle Guard Body 80 completely against the force of the spring 61 if the Main Body Protrusion 64 could stay down in the deeper section of the groove 94, but there would be no lateral deflection to get the Main Body Protrusion 64 over to point D where the device 10 locks out into the desired safety configuration.

Depending on the coefficient of friction between the Main Body Protrusion 64 and the Needle Guard Body 80, the angle can be optimized to reduce the holding force for the patient, but still allow the Main Body Protrusion 64 to lockout at point D of Figure 4.

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CLAIMS:

1. A needle stick safety device for a pre-filled syringe that prevents needle stick injuries comprising

a main body for receiving a syringe, the main body including a protrusion,

5 a needle shield removal tool positionable over a needle shield for removal of the needle shield prior to injecting medication into a patient and removably coupled to the main body, and

a needle guard slidable with respect to the main body and biased in the distal direction by a compression spring, the needle guard including a groove for receiving the protrusion from the main body, the needle guard is retainable in a first position against the bias of the spring by the needle shield removal tool and moveable under the bias of the spring to a second position covering the needle when the needle shield removal tool is removed to remove the needle shield, wherein the needle guard is moveable to a third position against the bias of the spring as the needle guard is pressed against a patient's skin to expose the needle and insert the needle into the patient to inject medicine and moveable to a fourth position under the bias of the spring to cover the needle as the needle is withdrawn from the patient.

2. The device of claim 1 wherein the protrusion is moveable within the groove from a first groove position to a second groove position as the needle guard moves from the first to the second position.

20 3. The device of claim 2 wherein the protrusion is moveable within the groove from the second groove position to a third groove position as the needle guard moves from the second to the third position.

4. The device of claim 3 wherein the third groove position is at a lower groove elevation relative to the surface of the needle guard than the second groove position.

25 5. The device of claim 4 wherein the groove having a groove edge preventing movement of the protrusion within the groove from the third position to the second position.

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6. The device of claim 5 wherein the protrusion is moveable within the groove from the third groove position to a fourth groove position as the needle guard moves from the third to the fourth position.
7. The device of claim 6 wherein the fourth groove position is at a lower groove
5 elevation relative to the surface of the needle guard than the third groove position.
8. The device of claim 7 wherein movement of the protrusion along the groove edge from the third groove position to the fourth groove position cause rotation of the needle guard about a longitudinal axis of the needle guard.
9. The device of claim 1 wherein the main body including barb retention
10 windows for engaging barbs on the needle shield removal tool.
10. The device of claim 9 wherein the barbs on the needle shield removal tool including internally directed lips for engaging the needle shield for removal of the needle shield.
11. The device of claim 1 wherein the needle shield removal tool including one or
15 more axial slits.
12. The device of claim 1 wherein the main body including an axial cam and the needle shield removal tool including a cam follower for engaging the axial cam.
13. The device of claim 12 wherein rotation of the needle shield removal tool causes the cam follower to engage a slope edge of the axial cam causing the needle shield
20 removal tool to move axially in the distal direction.
14. The device of claim 13 wherein rotation of the needle shield removal tool causes the barbs on the needle shield removal tool to engage the edge of the barb retention windows causing compression of the end of the needle shield removal tool.
15. The device of claim 1 wherein the needle shield removal tool including radial
25 and axial cam mechanisms.

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16. The device of claim 1 wherein the main body and the needle guard are opaque and include first and second diametrically opposed windows that are alignable when the needle guard moves to the second position.

17. A needle stick safety device for a pre-filled syringe that prevents needle stick
5 injuries comprising

a main body for receiving a syringe, the main body including a protrusion, and

a needle guard slidable with respect to the main body and biased in the distal direction by a compression spring, the needle guard including a groove for receiving the protrusion from the main body, the needle guard is retainable under the bias of the spring in a
10 first position covering the needle, wherein the needle guard is moveable to a second position against the bias of the spring as the needle guard is pressed against a patient's skin to expose the needle and insert the needle into the patient to inject medicine and moveable to a third position under the bias of the spring to cover the needle as the needle is withdrawn from the patient.

15 18. The device of claim 17 wherein the protrusion is moveable within the groove from a first groove position to a second groove position as the needle guard moves from the first to the second position.

19. The device of claim 18 wherein the protrusion is moveable within the groove from the second groove position to a third groove position as the needle guard moves from the
20 second to the third position.

20. The device of claim 19 wherein the second groove position is at a lower groove elevation relative to the surface of the needle guard than the first groove position.

21. The device of claim 20 wherein the groove having a groove edge preventing movement of the protrusion within the groove from the second position to the first position.

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22. The device of claim 21 wherein the protrusion is moveable within the groove from the second groove position to a third groove position as the needle guard moves from the second to the third position.

23. The device of claim 22 wherein the third groove position is at a lower groove
5 elevation relative to the surface of the needle guard than the second groove position.

24. The device of claim 23 wherein movement of the protrusion along the groove edge from the second groove position to the third groove position causes rotation of the needle guard about a longitudinal axis of the needle guard.

25. The device of claim 22 wherein the third groove position is a groove recess and
10 wherein the protrusion and groove recess cooperate to retain needle guard in the third position covering the needle.

26. The device of claim 17 wherein the main body including barb retention windows for engaging barbs on a needle shield removal tool.

27. The device of claim 26 wherein the barbs on the needle shield removal tool
15 including internally directed lips for engaging a needle shield for removal of the needle shield.

28. The device of claim 26 wherein the needle shield removal tool including one or more axial slits.

29. The device of claim 26 wherein the main body including an axial cam and the needle shield removal tool including a cam follower for engaging the axial cam.

20 30. The device of claim 29 wherein rotation of the needle shield removal tool causes the cam follower to engage a slope edge of the axial cam causing the needle shield removal tool to move axially in the distal direction.

31. The device of claim 30 wherein rotation of the needle shield removal tool causes the barbs on the needle shield removal tool to engage the edge of the barb retention
25 windows causing compression of the end of the needle shield removal tool.

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32. The device of claim 26 wherein the needle shield removal tool including radial and axial cam mechanisms.

33. The device of claim 17 wherein the main body and the needle guard are opaque and include first and second diametrically opposed windows that are alignable when the
5 needle guard moves to the second position.

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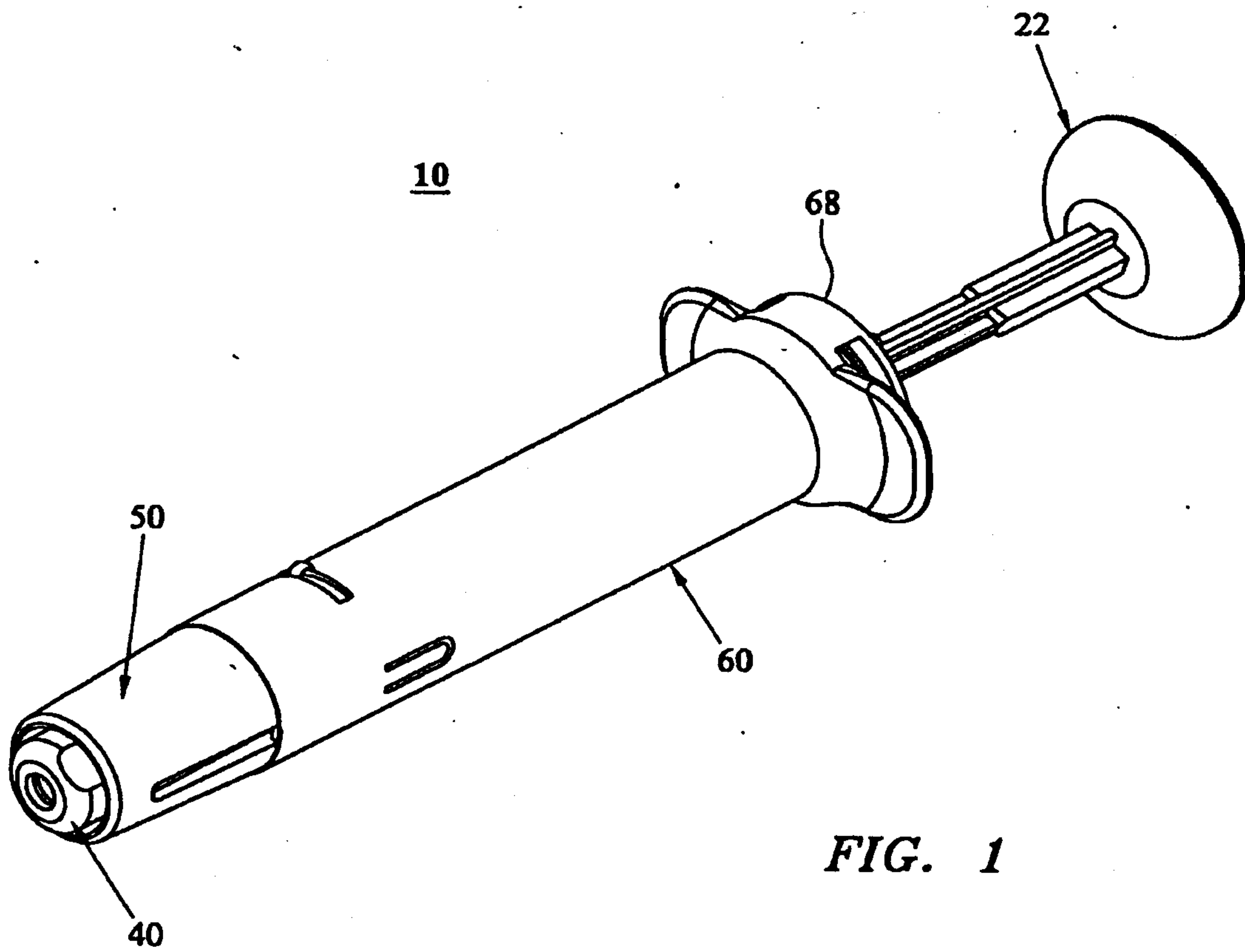
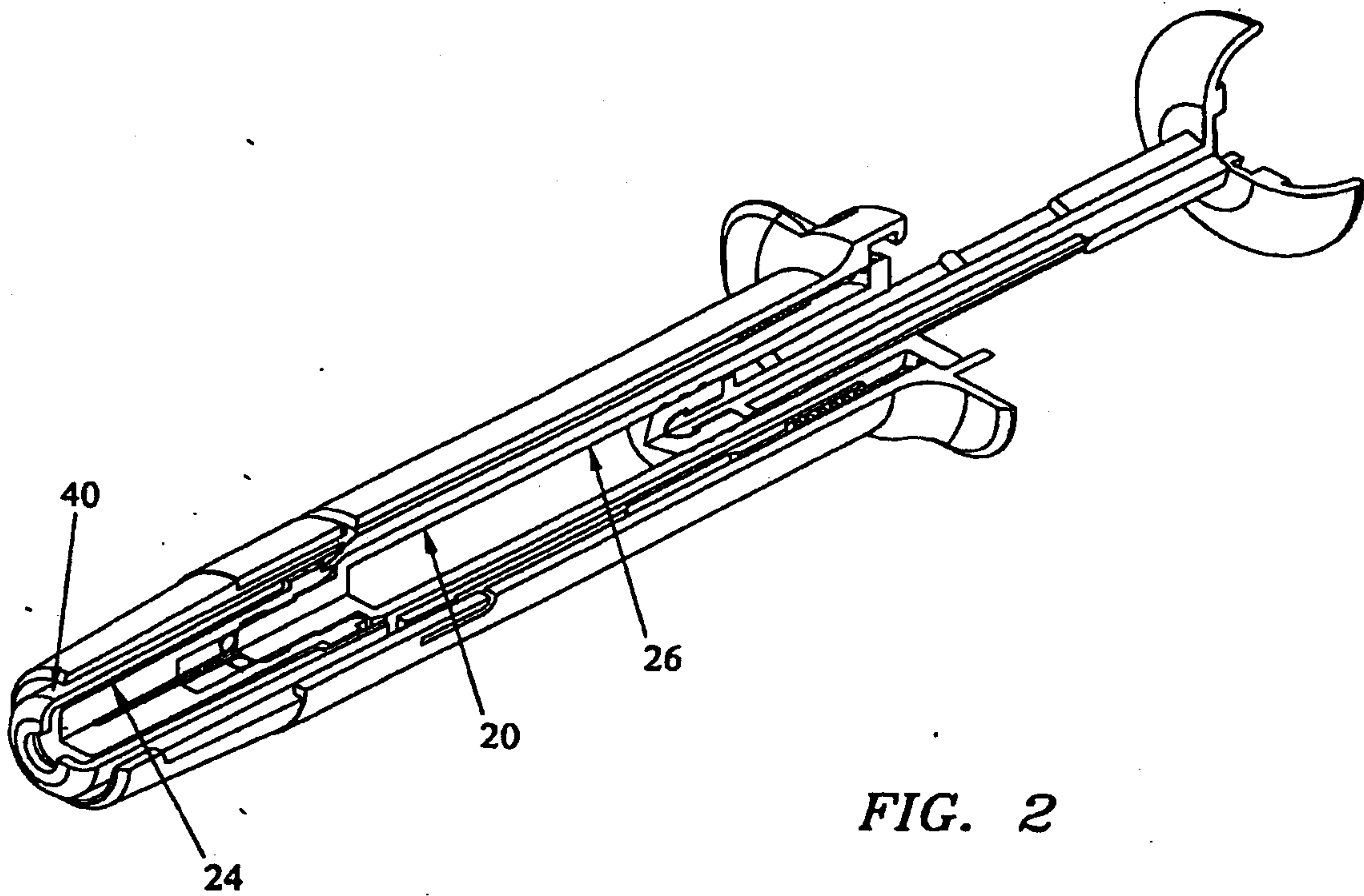


FIG. 1

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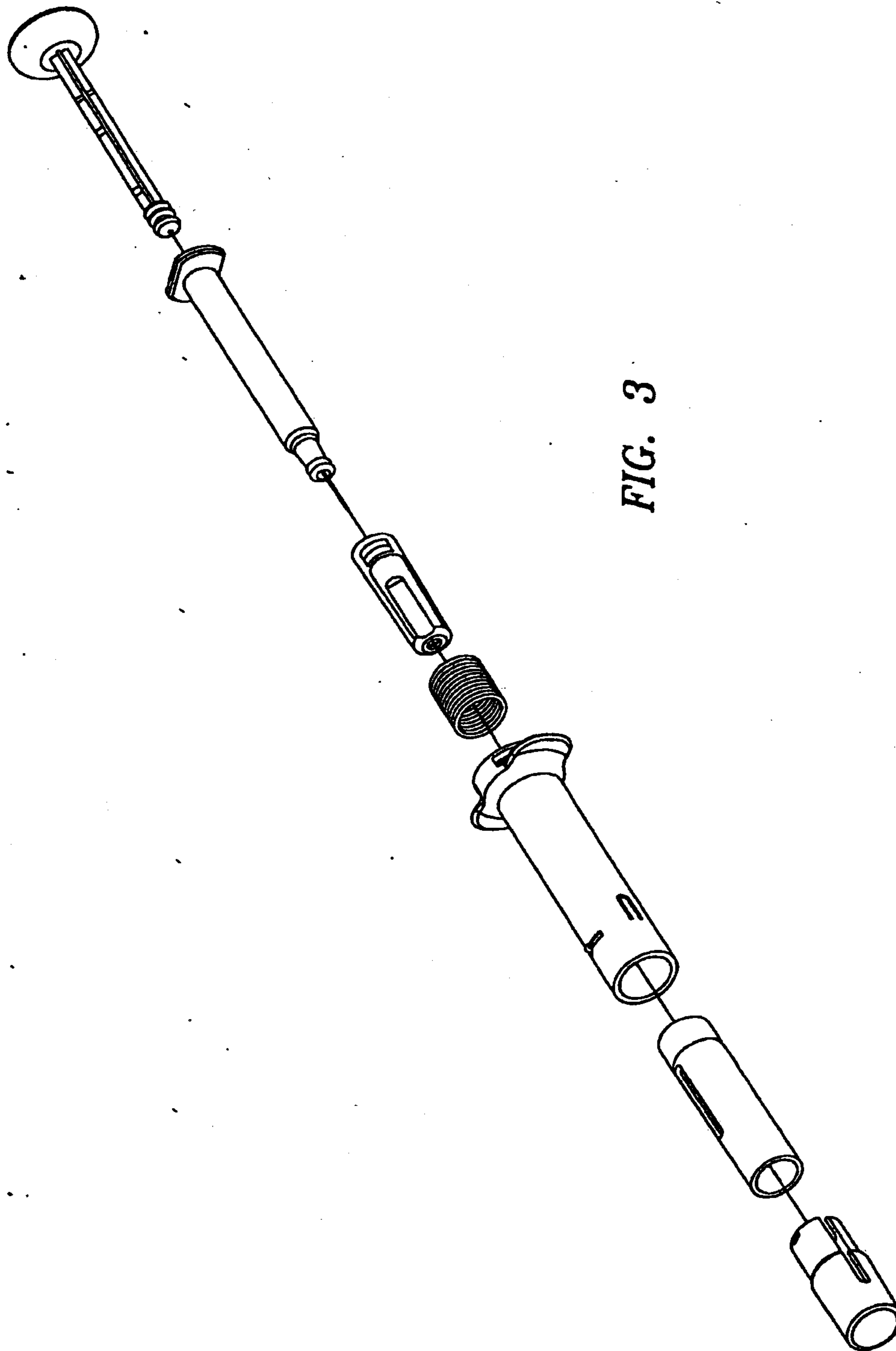
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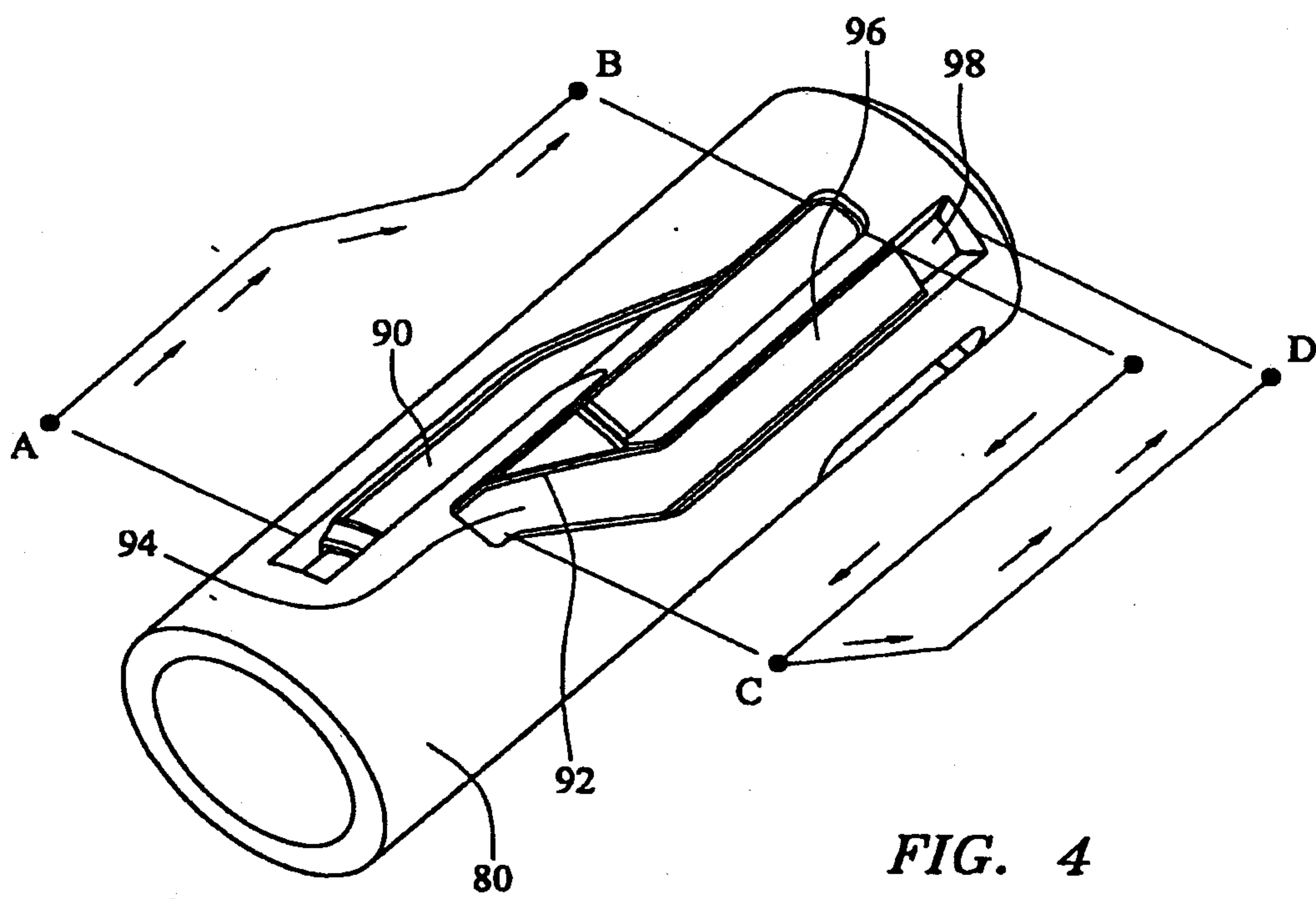
FIG. 3



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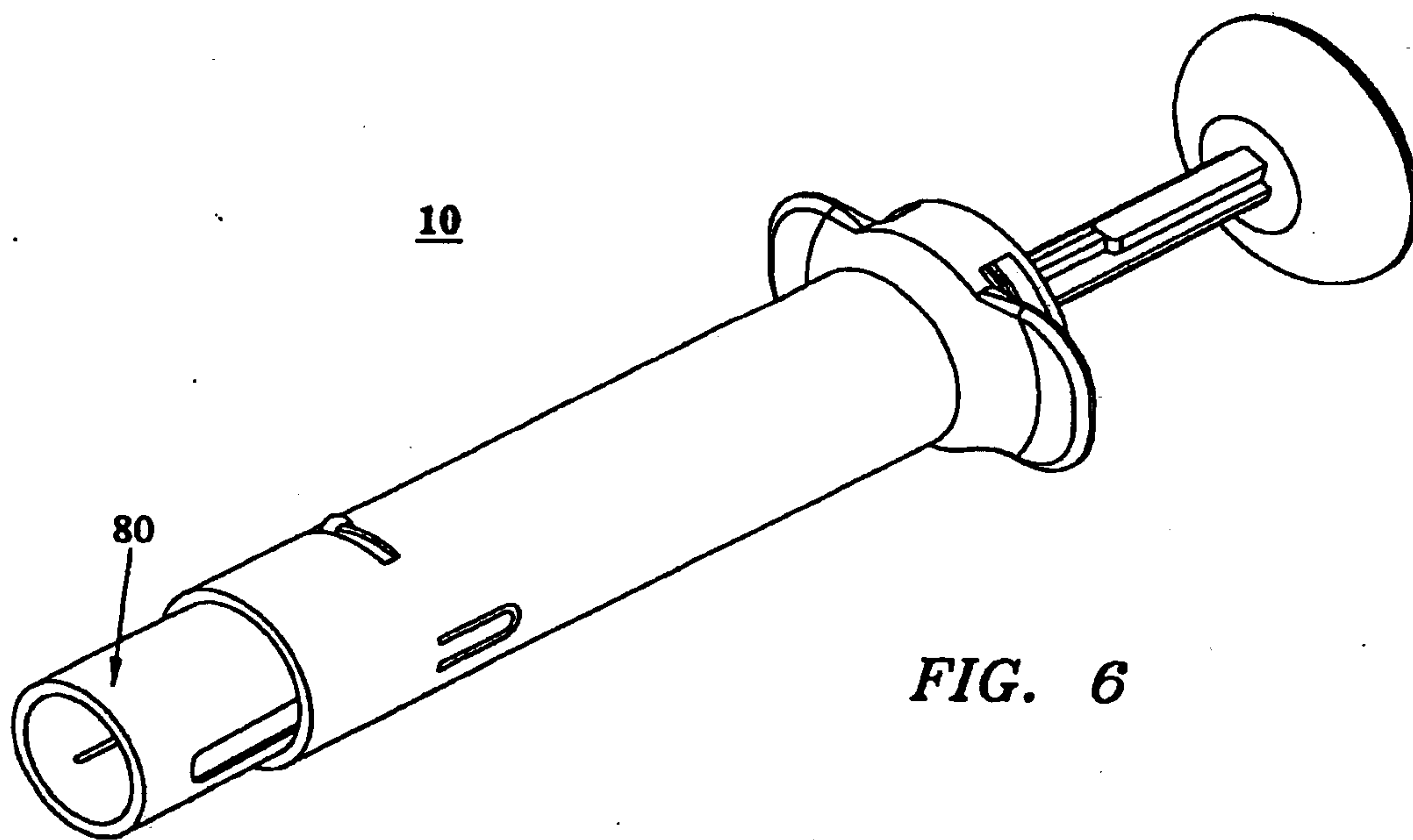
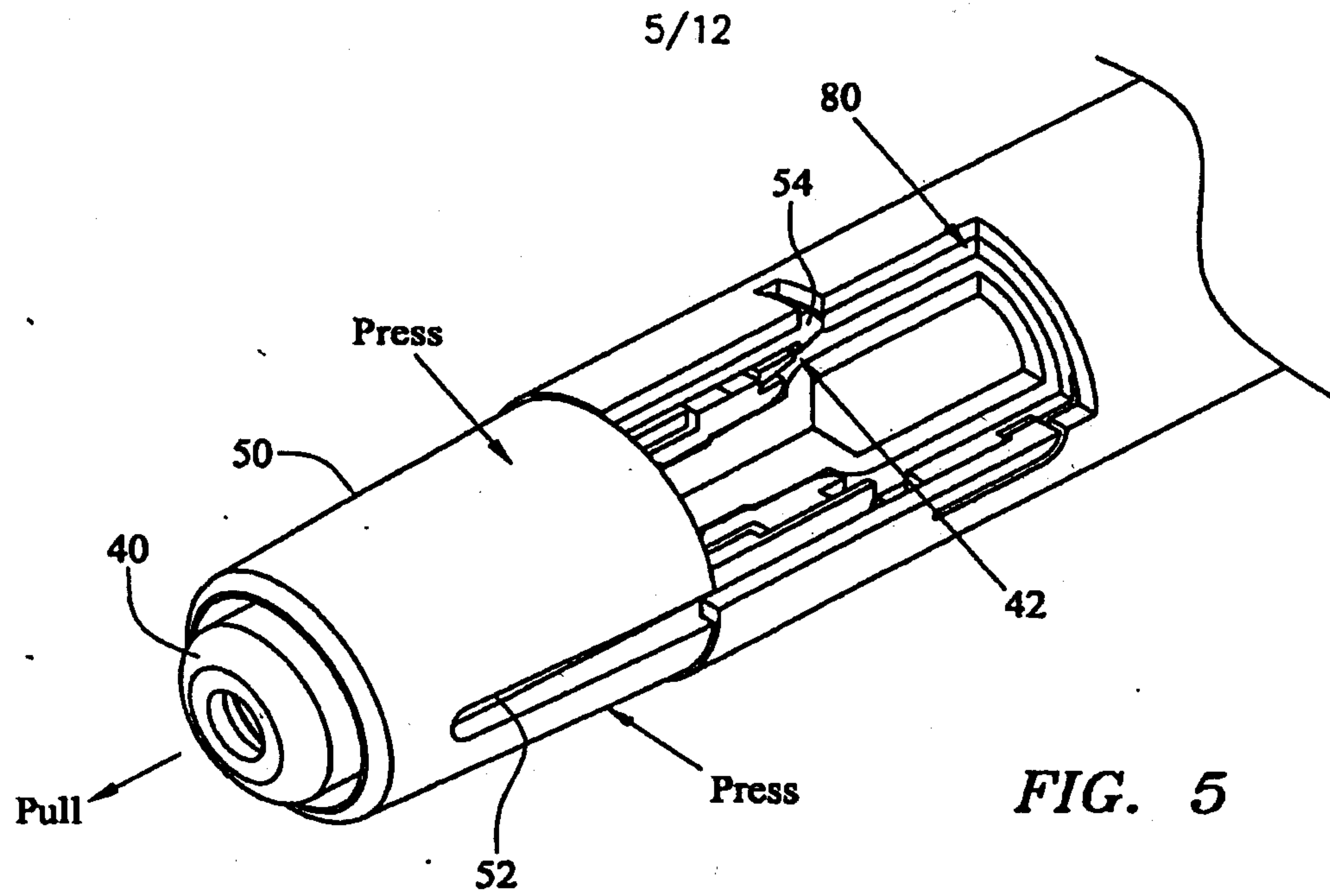
IPEA/US

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AMENDED SHEET

IPEAUS



AMENDED SHEET

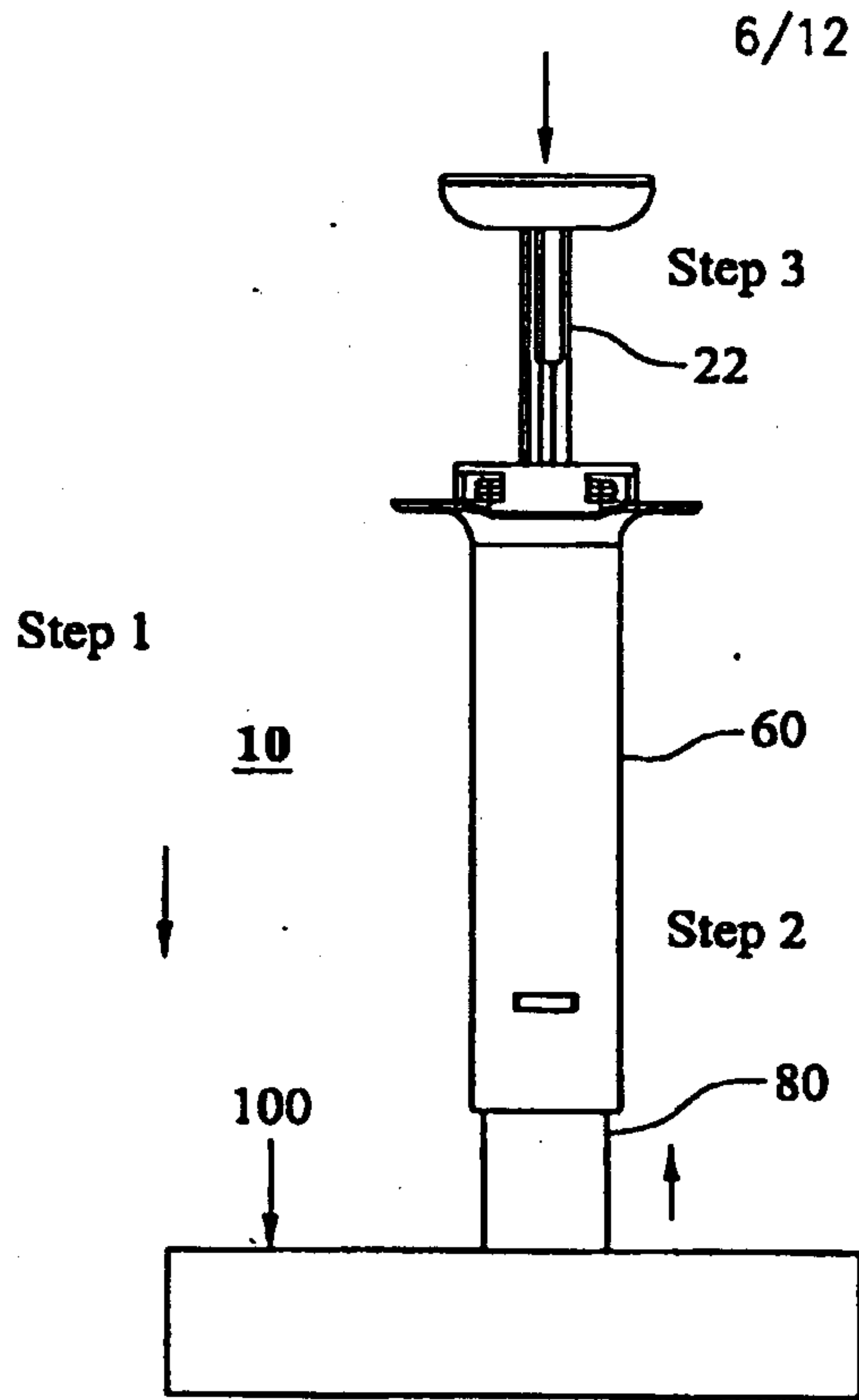


FIG. 7

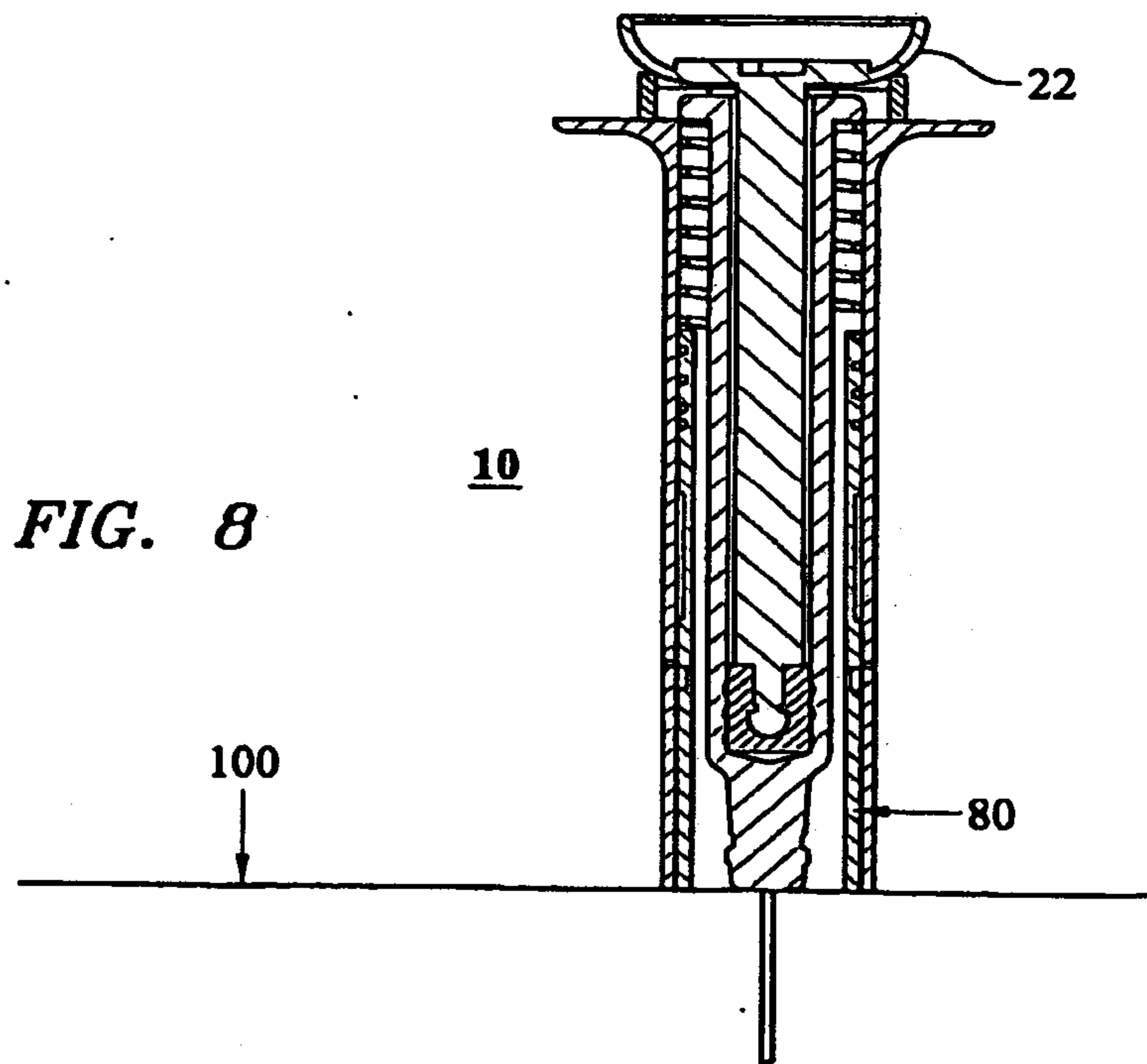


FIG. 8

AMENDED SHEET

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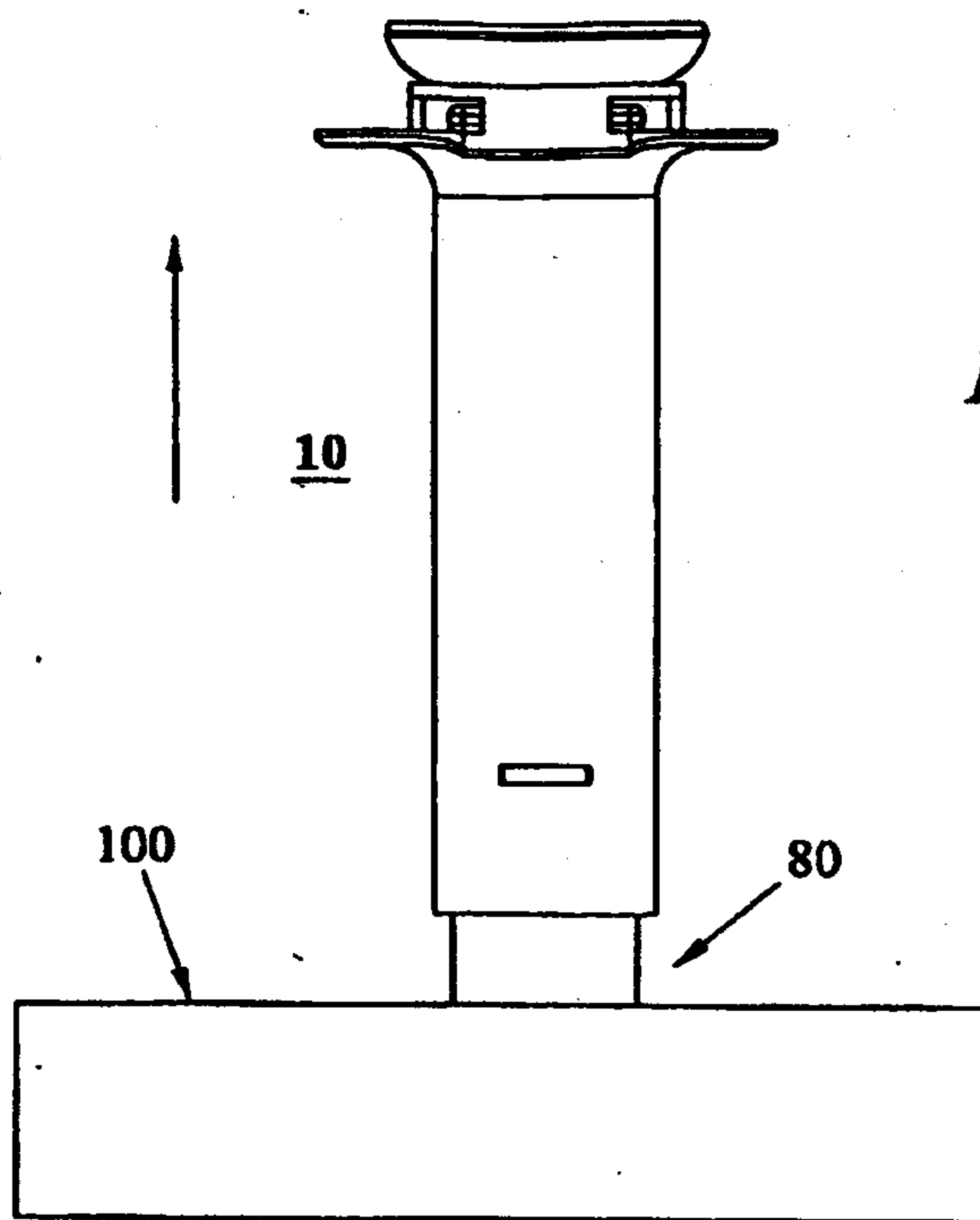


FIG. 9

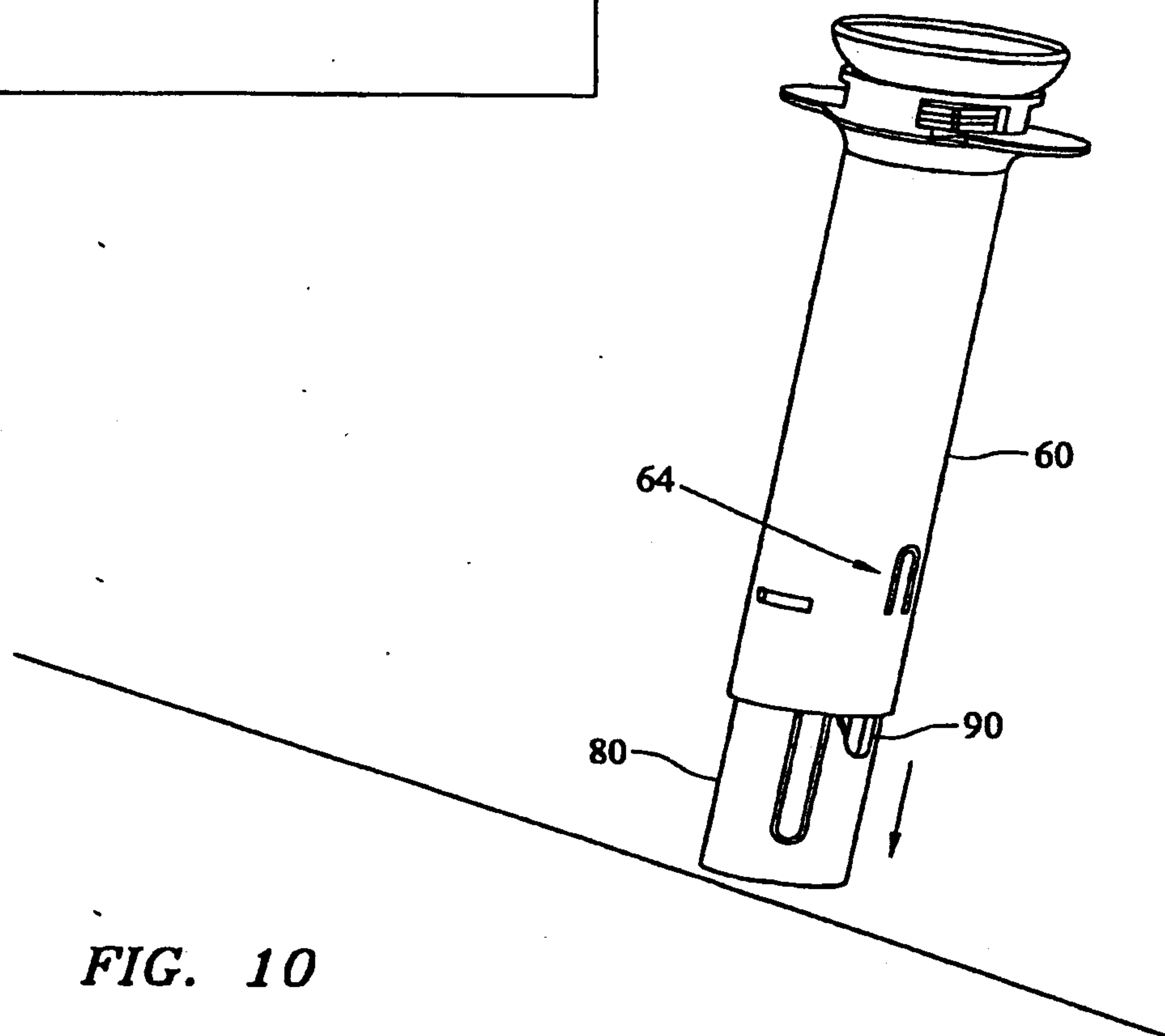


FIG. 10

AMENDED SHEET

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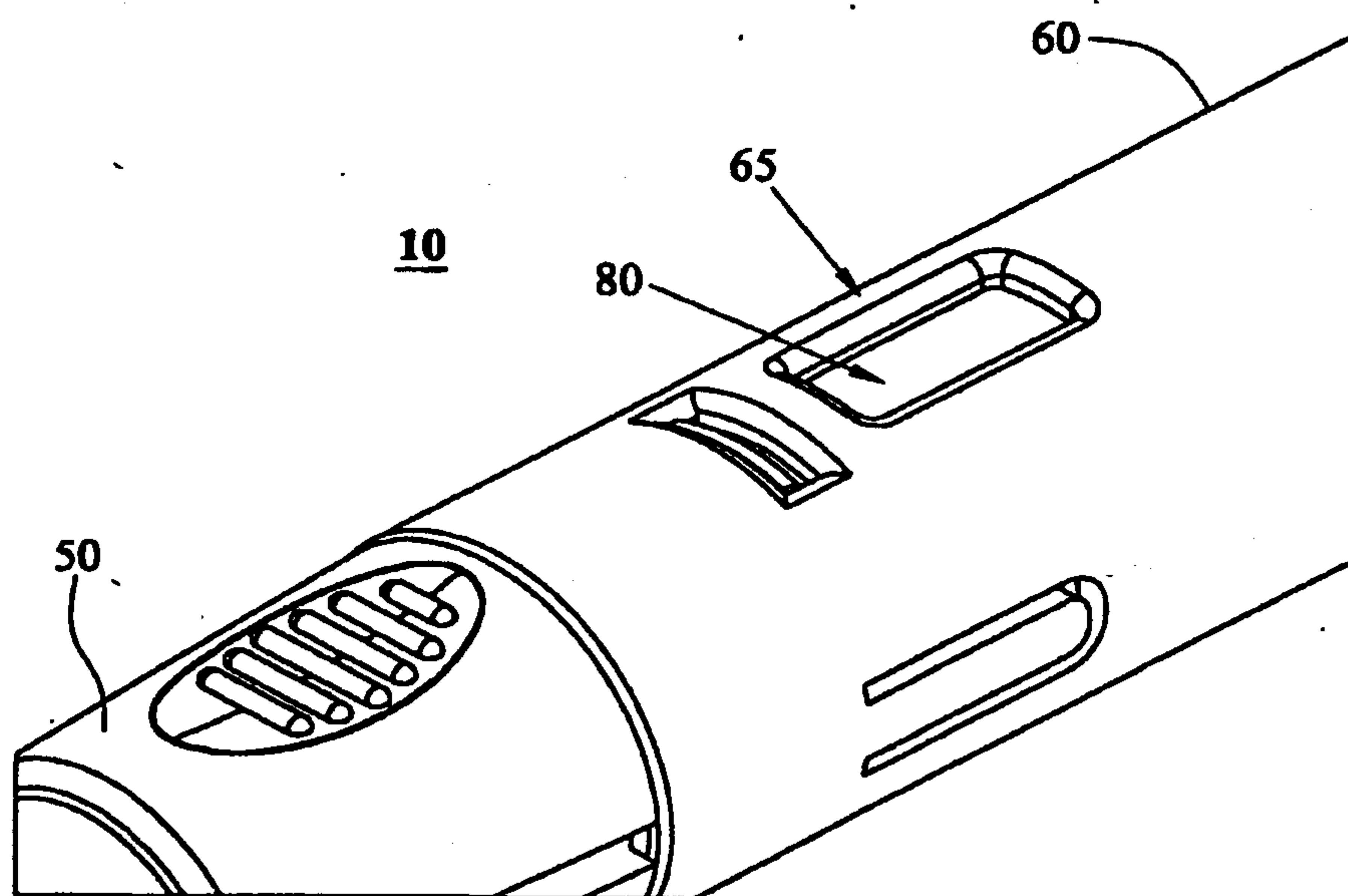


FIG. 11

AMENDED SHEET

IPEA/US

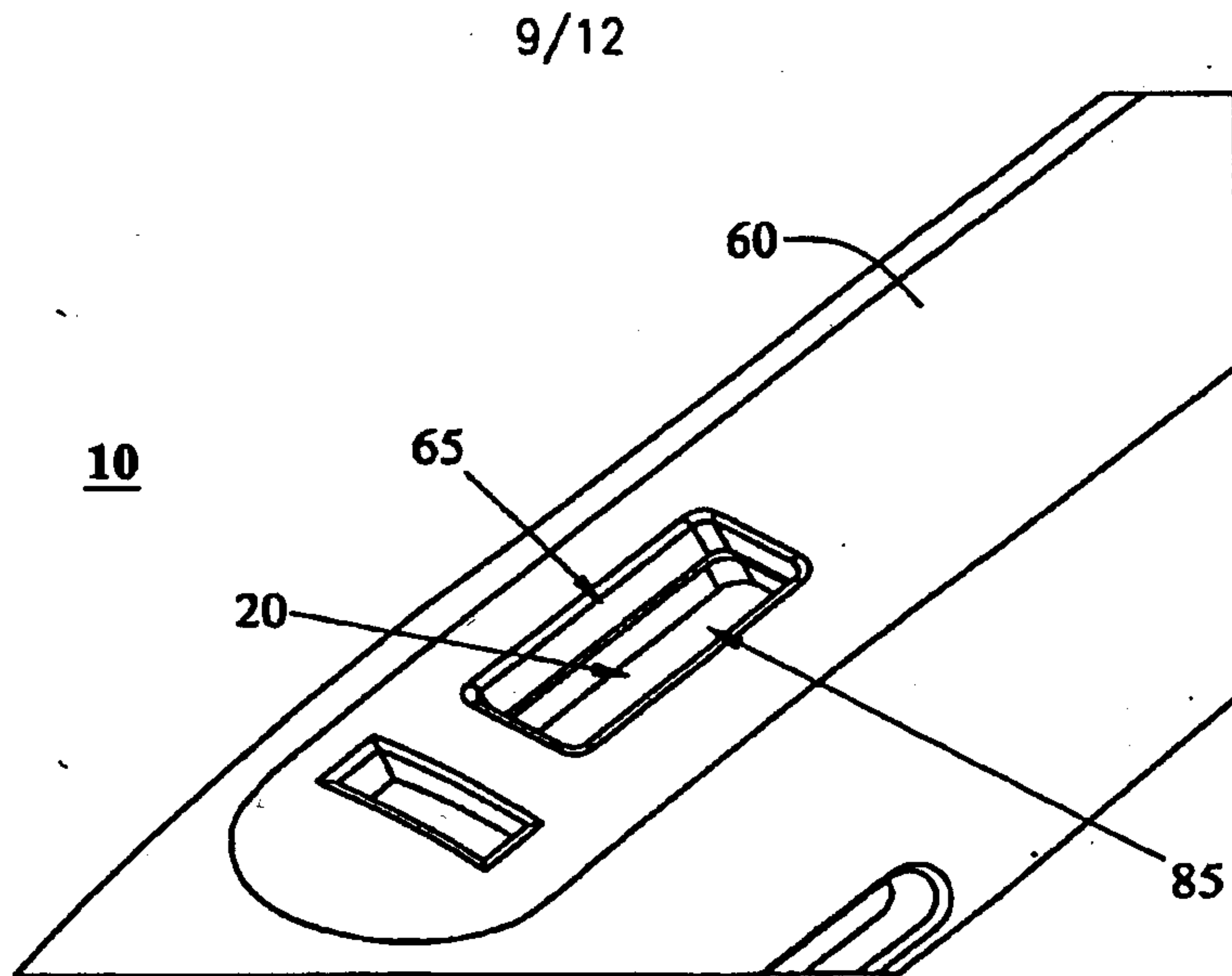


FIG. 12

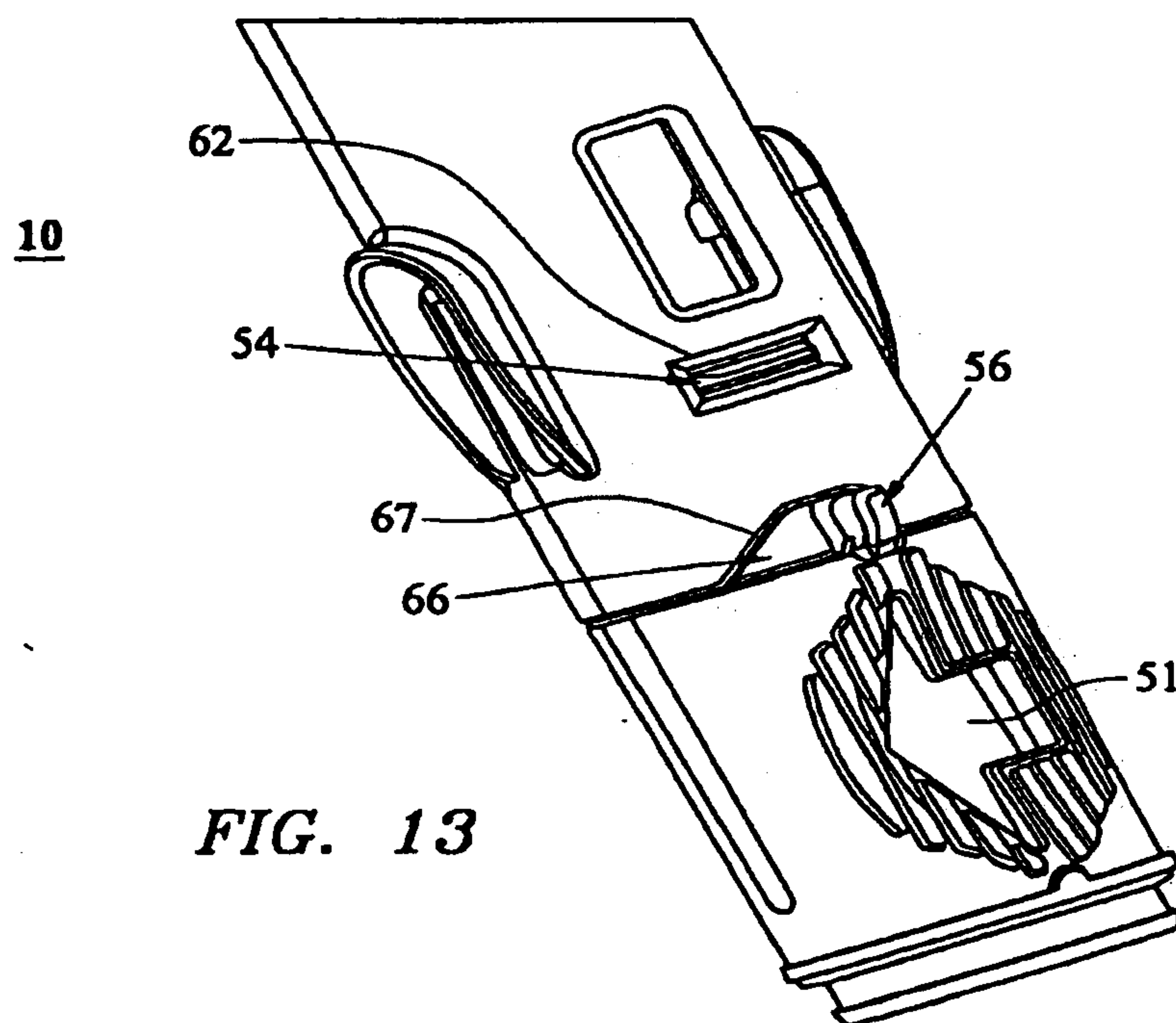


FIG. 13

AMENDED SHEET

IPEAUS

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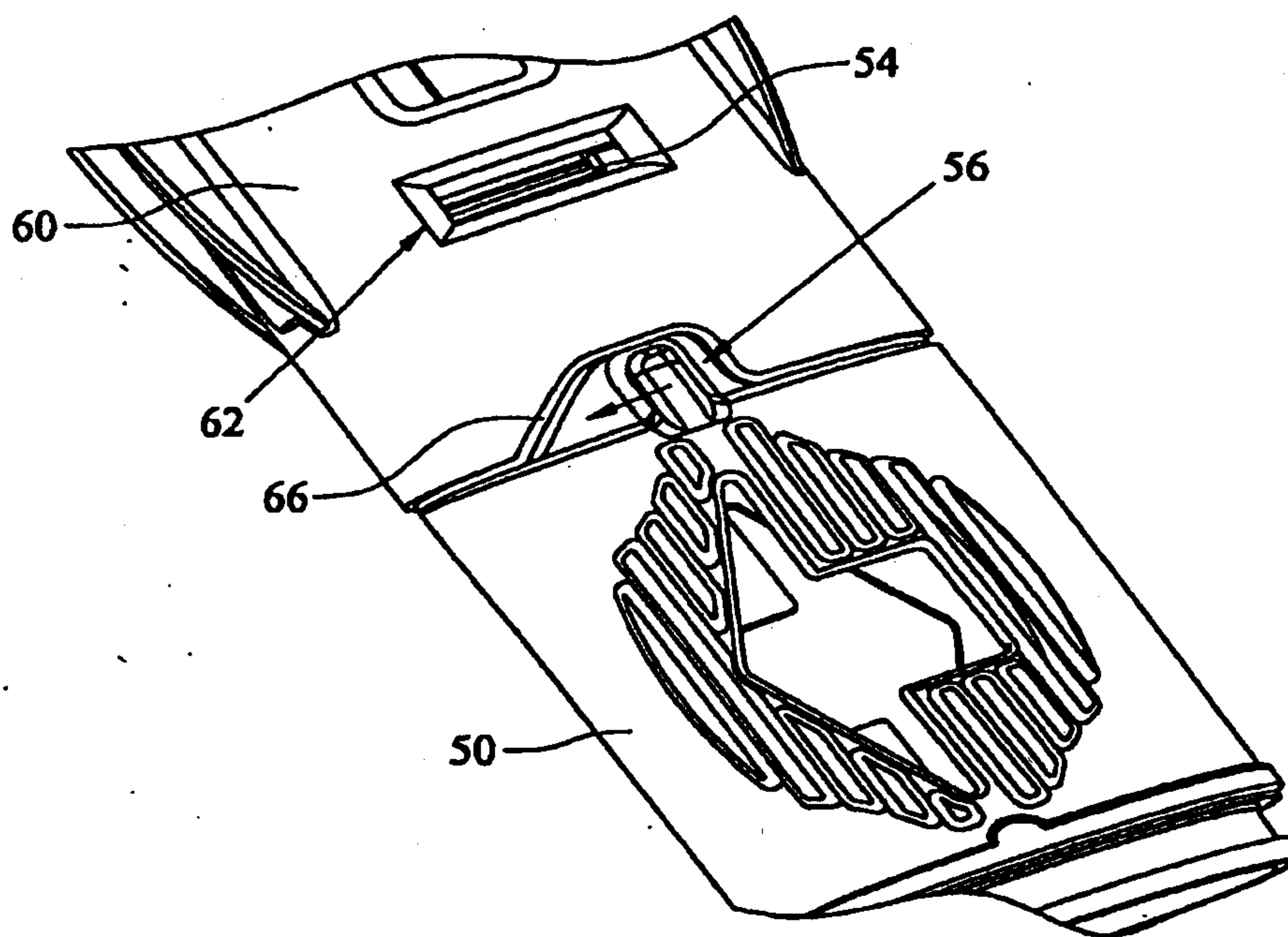


FIG. 14

AMENDED SHEET

IPEAUS

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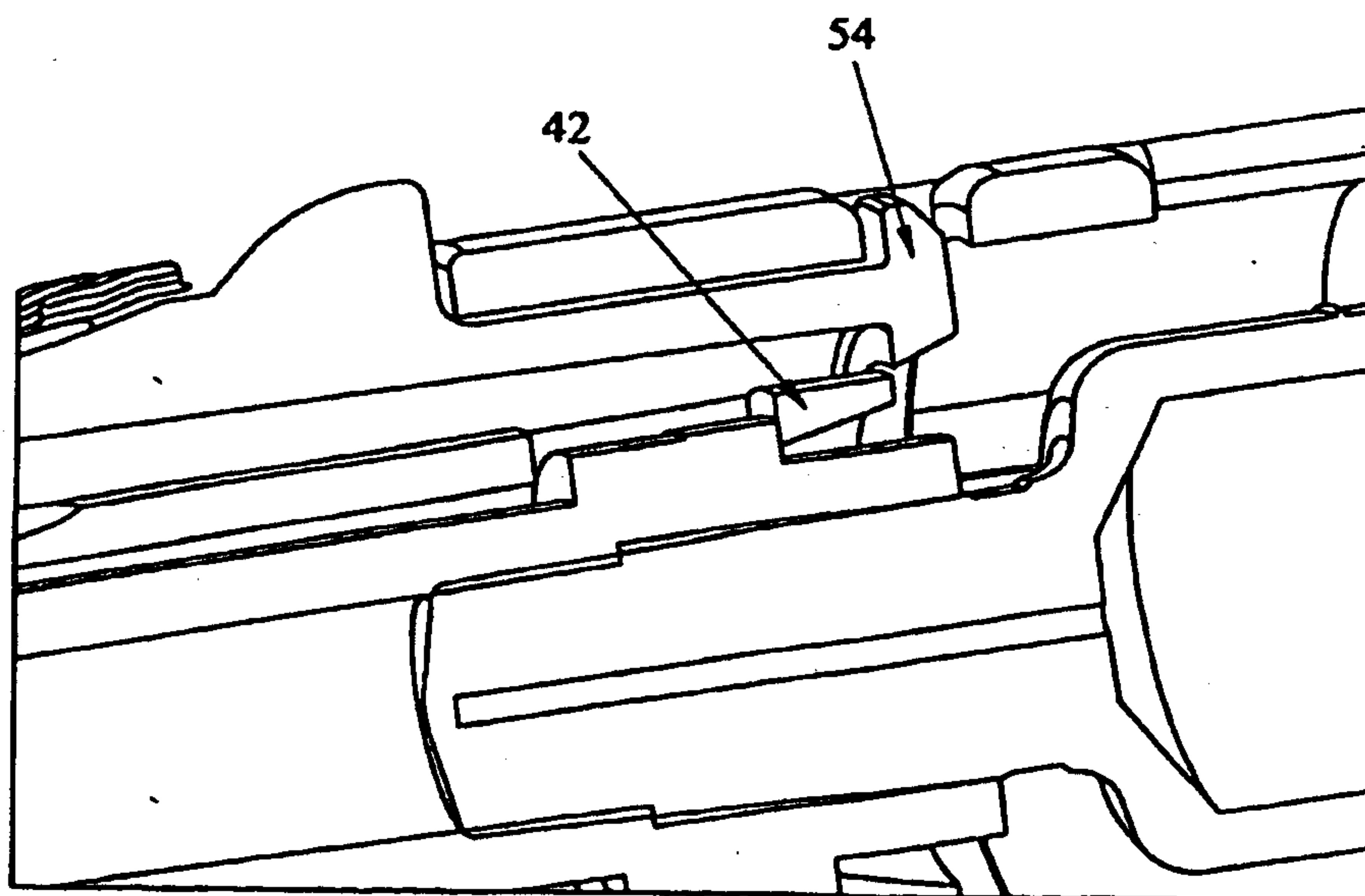
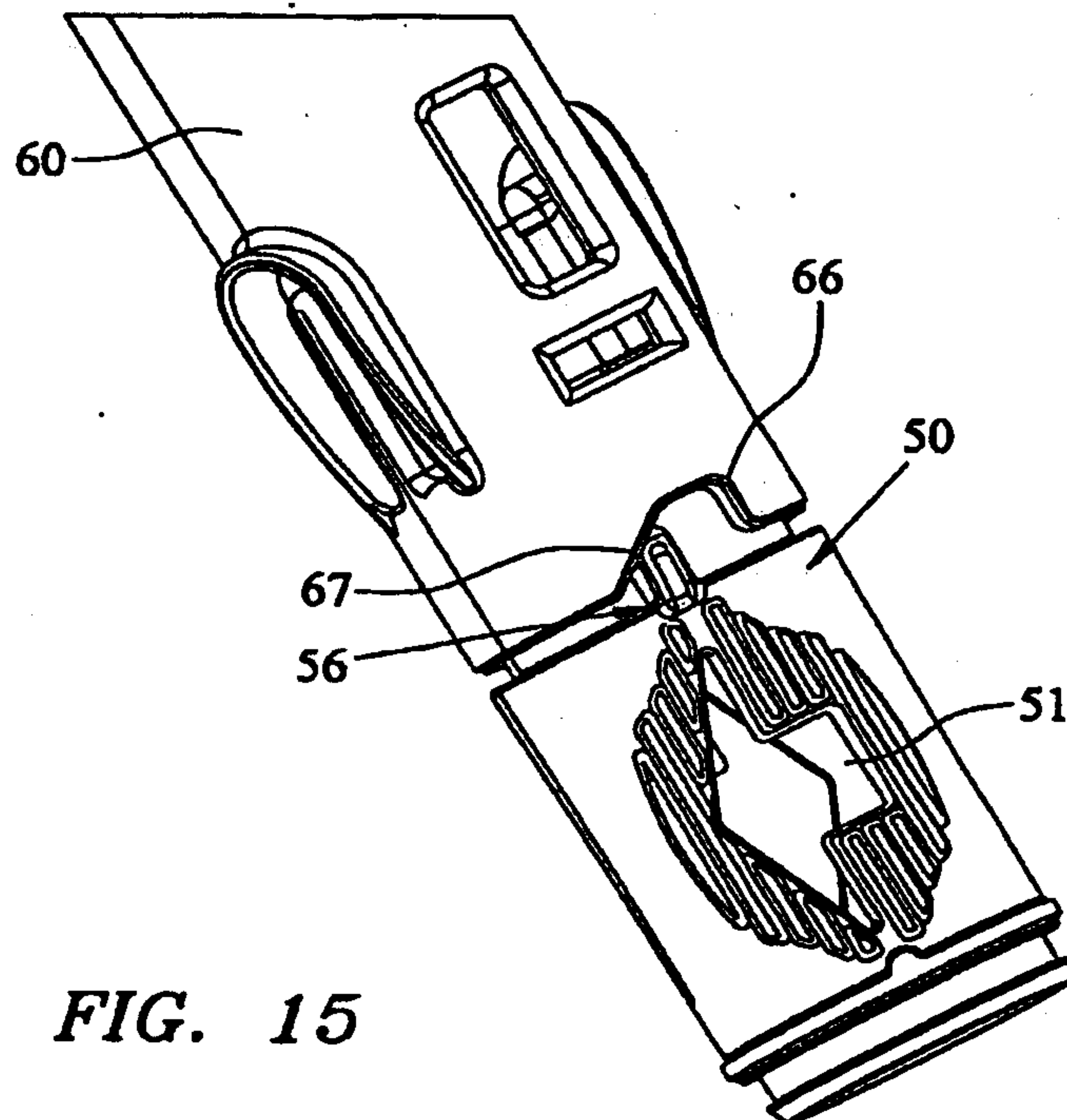


FIG. 16

AMENDED SHEET

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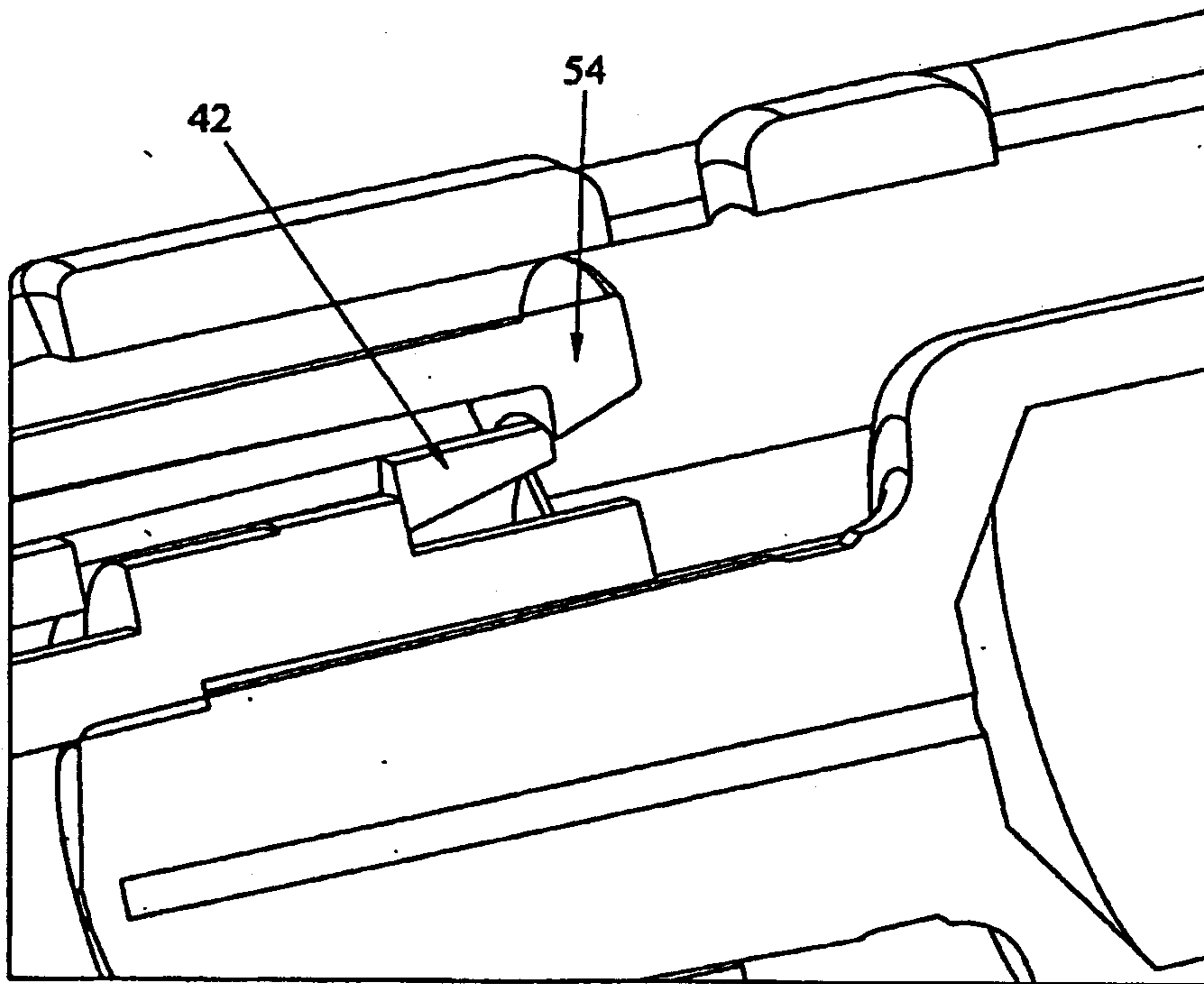


FIG. 17

AMENDED SHEET

