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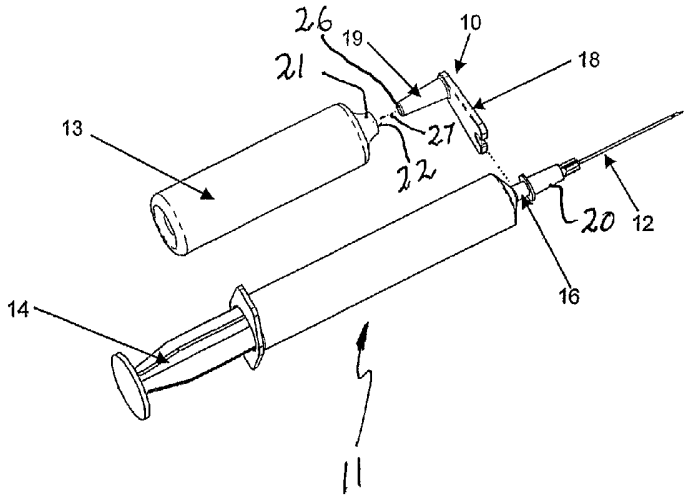
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: A MEDICATION CLIP



(57) Abstract: A clip (10) to releasably engage an ampoule (13) and syringe (11). The clip (10) includes an ampoule engaging portion (19) and a syringe engaging portion in the form of a recess (17). The ampoule engaging portion (19) is formed of resilient material so that upon insertion in the neck (21) of the ampoule (13) the portion (19) is compressed so as to aid in engagement with the ampoule (13).

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A MEDICATION CLIP

Field of the Invention

The present invention relates to devices used in the medical field and in particular to devices for preventing or reducing medication errors such as Preventable Adverse Drug Reaction Events (ADE's).

Background of the Invention

Medication errors are frequent events in hospitals and in emergency care situations and often have tragic consequences. Such errors include administration of the wrong drug, drug overdoses, and overlooked drug interactions and allergies. They occur for many reasons, including illegible handwritten prescriptions and decimal point errors.

According to a 1999 Institute of Medicine (IOM) report, medication errors alone contribute to 7,000 deaths annually.

Medication errors result in approximately 250,000 non-fatal injuries each year (Harvard Medical Practice Study). More than one million serious medication errors occur every year in U.S. hospitals.

Preventable injuries caused by bad reactions to drugs increased hospital costs by US$4,700 per admission (Journal of the American Medical Association) in the United States and more than NZ$2,000 in New Zealand. Furthermore, this figure excludes other important costs of medication errors, such as malpractice insurance premiums and losses in worker productivity.

Computer Information systems have been developed that claim to reduce medication errors significantly. Computer physician order entry (CPOE) systems are electronic prescribing systems that intercept errors when they most commonly occur – at the time medications are ordered. With CPOE, physicians enter orders into a computer rather than on paper. Orders are integrated with patient information, including laboratory and prescription data. The order is then automatically checked for potential errors or problems.

A 1998 study showed a 55 percent decrease in serious medication errors, and a 1999 study showed an 86 percent decrease in serious medication errors through implementation of an automated drug-entry system (JAMA).

Fewer than 2 percent of U.S. hospitals have computer physician order entry (CPOE), an electronic prescribing system that intercepts errors, and require its use by physicians (AMIA).

However, the CPOE systems do not prevent ADE's which are caused by poor identification of syringes in which medication has already been drawn-up. Prepared dosages, already drawn up into syringes are used often in medical emergency situations and also in timetabled events such as surgery, where trays of medication needed over the course of the surgery are prepared before the surgery begins and are laid out on trays.

Of all medications, intravenous medications are one of the most difficult medications to identify once they have been drawn up into a syringe. Almost all intravenous medications appear as a clear liquid when viewed through a syringe sidewall with virtually no way of distinguishing between medications once drawn up.

One available prior art device is described in United States Patent Application No. 20020083564. This clip consists of a single piece of durable yet flexible molded plastic with two semicircular c-shaped rings placed side by side a short distance apart. Their respective openings face upward with the bases attached by an adjoining bridge. A syringe and vial can be easily placed in a beginning position by placing them parallel to the openings of the c-shaped rings. When gentle pressure is applied, the rings flex slightly outward around the circumference of the syringe or vial. The vial or syringe are in the final position when they have been pressed into the base of both c-shaped rings with the curved portions of the rings and endpoints holding them firmly into place.

The device described in that document has not found widespread use in the medical profession. Indeed, other methods used for drug syringe identification are hand written adhesive labels using adhesive tape to fasten the ampoule to the body portion of the syringe. The Queensland Ambulance Service Clinical Practice Manual instructs its members to use adhesive tape to attach the used glass ampoule to the syringe.

Both of these methods have the common disadvantage that the measurement indicators (dose markers) in the syringe body are often obscured, affecting the user's ability to read the dosage that has been drawn up into the prepared syringe.

The other main disadvantage with using adhesive tape to attach a use ampoule to the syringe body portion is that the broken ampoule pose a risk of sharps injury to a user not taking absolute care when handling the syringe with the broken ampoule attached.

Object of the Invention

It is the object of the present invention to overcome or substantially ameliorate at least one of the above disadvantages.

Summary of the Invention

There is disclosed herein a clip to secure a syringe to a medication ampoule, said ampoule having a neck surrounding a neck passage, said clip including:

a base;

an ampoule engaging portion projecting from the base, said ampoule engaging portion being a projection to be received within said passage and resiliently compressed by said neck so as to be resiliently urged into engagement with the neck to attach the ampoule to the clip; and

a syringe engaging portion to releasably attach the syringe to the clip.

Preferably, said syringe engaging portion is a recess in said base within which a portion of the syringe is to be located so as to be releasably retained therein.

Preferably, said recess is located between a pair of resilient arms, the arms being resiliently urged apart to provide for location of the syringe in the recess.

Preferably, said recess is open in a direction away from said projection.

Preferably, said base has a first end adjacent which said projection is located, and a second end spaced from said first end, said second end having said recess.

Preferably, said base has a longitudinal axis, with said projection and recess being located on said longitudinal axis.

Preferably, said base has a longitudinal axis and said recess faces perpendicularly away from said longitudinal axis.

Preferably, said projection has a plurality of barbs to aid the projection to securely but releasably engage the neck.

Preferably, said projection is bifurcated longitudinally so as to provide two elongated arms that are resiliently deformed to move toward each other by engagement with the neck.

Preferably, said projection is provided by a plurality of elongated arms that are resiliently urged together by the neck.

Preferably, said syringe engaging portion is an arcuate socket within which a portion of the syringe is to be located.

Preferably, said socket is resiliently deformed by the syringe so as to be urged into contact with the syringe to aid in retaining the syringe releasably attached to the clip.

Preferably, said projection is a first projection, and said clip includes at least one further ampoule engaging projection.

Preferably, said recess is located between two projections of the clip.

Preferably, said clip includes a plurality of arms that engage externally of the neck.

Preferably, said arms are resiliently deformed when engaged with the neck so as to be urged into contact therewith to aid in releasably attaching the ampoule to the clip.

Preferably, said base is generally planar, and said projection extends generally normal to said base.

Brief Description of the Drawings

Preferred forms of the present invention will now be described by way of example with reference to the accompanying drawings wherein:

Figure 1 is a schematic side elevation of a syringe and ampoule releasably attached by a clip;

Figure 2 is a schematic top plan view of the syringe, ampoule and clip of Figure 1;

Figure 3 is a schematic end elevation of the syringe, ampoule and clip of Figure 1;

Figure 4 is a schematic end elevation of the syringe, ampoule and clip of Figure 1 with the syringe removed from the clip;

Figure 5 is a schematic parts exploded isometric view of the syringe, ampoule and clip of Figure 1;

Figure 6 is a schematic parts exploded isometric view of a modification of the clip of Figure 1 together with a syringe and two ampoules; and

Figures 7 to 12 are schematic isometric views of modifications of the clip of Figure 1.

Detailed Description of the Preferred Embodiments

In the accompanying drawings there is schematically depicted a clip 10 that is used to secure an ampoule 13 to a syringe 11. The syringe 11 includes a hollow cylindrical body 15 terminating at its forward end with a tip 16. The tip 16 frictionally engages the needle base 20 so that the needle 20 is secured thereto. A plunger 14 is slidably located in the body 15 and is movable relative thereto to draw liquid into the body 15 and to expel liquid through the needle 12. Typically in use, the syringe 11 would be operated to withdraw liquid from within the ampoule 11, and then inject the liquid.

Typically the clip 10 would be discarded.

The ampoule 13 may be formed of glass or plastics and would include a neck 21 surrounding a neck opening 22 through which liquid passes with respect to the interior of the ampoule 13. Extending inwardly from the opening 22 through the neck 21 is a neck passage.

Typically the clip 10 is disposable and is integrally formed from molded plastics material, and more particularly from resiliently plastics material.

The clip 10 includes a base 18 that is elongated so as to have a longitudinal axis 23. The base 18 has opposite end portions 24 and 25, with the end portion 25 being provided with an ampoule engaging portion 19. In this embodiment the portion 19 is a frusto-conical projection that tapers from the base 18 to its end extremity 26. The portion 19 has a longitudinal axis 27 that is generally normal to the axis 23 so that the portion 19 extends generally normal to the base 18. In that regard the base 18 is generally planar in construction.

In operation of the clip 10, the portion 19 is inserted in the neck passage of the ampoule 13 so that the portion 19 is compressed by the neck 21 to thereby securely and

preferably frictionally engage the internal surfaces of the neck 21 to releasably attach the ampoule 13 to the clip 10. By being resiliently compressed the portion 19 is urged into engagement with the neck 21.

The end portion 25 is provided with a recess 17 within which the tip 16 of the syringe 11 is received. The recess 17 is located between a pair of resilient arms 28 that are resiliently deflected apart to enable insertion of the tip 18 in the recess 17. Thereafter the arms 18 retain the tip 16 releasably secured in the recess 17 so that the syringe 11 is releasably attached to the clip 10. The arms 17 by being resiliently deformed are urged into engagement with the syringe 11.

Preferably the recess 17 openly projects away from the portion 19.

Preferably the extremity of each arm 28 is provided with a lip or projection that aids in retaining the tip 16 in the recess 17.

In the embodiment of Figure 6, the clip 10 is provided with a pair of ampoule engaging portions 19 to aid in releasably attaching two ampoules 13 to the syringe 11. In this embodiment, the portions 19 are located at opposite end portions 24 of the base 18, with the recess 17 located therebetween. In this embodiment, the recess 17 extends away from the longitudinal axis 23. Also in this embodiment, the recess 17 has a tapered entrance passage 29.

In the embodiment of Figure 7, the portion 19 although frusto-conical in overall configuration is bifurcated so as to have a central longitudinal slot 30 located between a pair of arms 31. The arms 31 are joined at the extremity 26. In the embodiment of Figure 8, the arms 31 are not joined at the extremity 26. More particularly in use of the clip 10 of Figure 8, the arms 31 are resiliently deflected together when inserted in the neck 21.

In the embodiment of Figure 9, a plurality of resilient arms 32 are provided and extend from the base 18. The arms 32 converge away from the base 18 and terminate with ramp portions 33 that diverge and aid the arms 32 in engaging the external surfaces of an ampoule. For example, the ampoule may have a lip adjacent the neck thereof so that the arms 32 aid in retaining the ampoule 13 releasably attached to the clip 10.

In the embodiment of Figure 10, the portion 19 includes a plurality of resilient arms 34 that are resiliently deformed to move together when inserted in the neck 21. This embodiment also has the arms 32.

In Figure 11, a modification of the clip 10 of Figure 7 is illustrated. In this embodiment, the clip 10 has a socket 35 having a longitudinal axis 36 generally normal to the longitudinal axis 23. The socket 35 is generally arcuate in transverse cross-section and has a side wall 37 that extends generally parallel to the axis 36. The socket 35 is shaped to receive the body 15 and is resiliently urged into contact with the body 15 to aid in releasably attaching the syringe 11 to the clip 10.

In the embodiment of Figure 12, the clip of Figure 9 is modified to include the socket 35 of Figure 11.

A preferred procedure for the use of the above medication clip 10 according may be as follows:

1. Select appropriate size syringe 11. (1ml, 2ml, 5ml, 10ml, 20ml, 50ml).
2. Select and attach drawing up needle 12/syringe cannula to syringe 11.
3. Apply medication clip 10 to base of tip 16 of syringe 11.
4. Select Drug ampoule/s or vial/s.
5. Draw drug and/or mixing solution in to syringe 11 and connect ampoule/s and vial/s directly onto medication clip 10. *(Ensuring that ampoule/s and vial/s remains attached to syringe for drug and expiry date confirmation by authorising Medical Officer/Administering Officer).*
6. Do not tape ampoule/s onto syringe 11 with medication clip 10. *(This practice obscures the Drug name and expiry details which must at all times be legible for correct drug administration/cross checking).*
7. When administration complete discard complete unit in appropriate sharps container.

CLAIMS:

1. A clip to secure a syringe to a medication ampoule, said ampoule having a neck surrounding a neck passage, said clip including:

a base;

an ampoule engaging portion projecting from the base, said ampoule engaging portion being a projection to be received within said passage and resiliently compressed by said neck to thereby engage the neck to attach the ampoule to the clip; and

a syringe engaging portion to releasably attach the syringe to the clip.

2. The clip of claim 1, wherein said syringe engaging portion is a recess in said base within which a portion of the syringe is to be located so as to be releasably retained therein.

3. The clip of claim 2, wherein said recess is located between a pair of resilient arms, the arms being resiliently urged apart to provide for location of the syringe in the recess.

4. The clip of claim 2 or 3, wherein said recess is open in a direction away from said projection.

5. The clip of claim 4, wherein said base has a first end adjacent which said projection is located, and a second end spaced from said first end, said second end having said recess.

6. The clip of claim 2, wherein said base has a longitudinal axis, with said projection and recess being located on said longitudinal axis.

7. The clip of claim 2, wherein said base has a longitudinal axis and said recess faces perpendicularly away from said longitudinal axis.

8. The clip of anyone of claims 1 to 7, wherein said projection has a plurality of barbs to aid the projection to securely but releasably engage the neck.

9. The clip of anyone of claims 1 to 8, wherein said projection is bifurcated longitudinally so as to provide two elongated arms that are resiliently urged toward each other by engagement with the neck.

10. The clip of anyone of claims 1 to 8, wherein said projection is provided by a plurality of elongated arms that are resiliently urged together by the neck.

11. The clip of claim 1, wherein said syringe engaging portion is an arcuate socket within which a portion of the syringe is to be located.

12. The clip of claim 11, wherein said socket is resiliently deformed by the syringe so as to be urged into contact with the syringe to aid in retaining the syringe releasably attached to the clip.

13. The clip of claim 1, wherein said projection is the first projection, and said clip includes at least one further projection.

14. The clip of claim 12, wherein said recess is located between two projections of the clip.

15. The clip of anyone of claims 1 to 14, wherein said clip includes a plurality of arms that engage externally of the neck.

16. The clip of claim 15, wherein said arms are resiliently deformed when engaged with the neck so as to be urged into contact therewith to aid in releasably attaching the ampoule to the clip.

17. The clip of anyone of claims 1 to 16, wherein said base is generally planar, and said projection extends generally normal to said base.

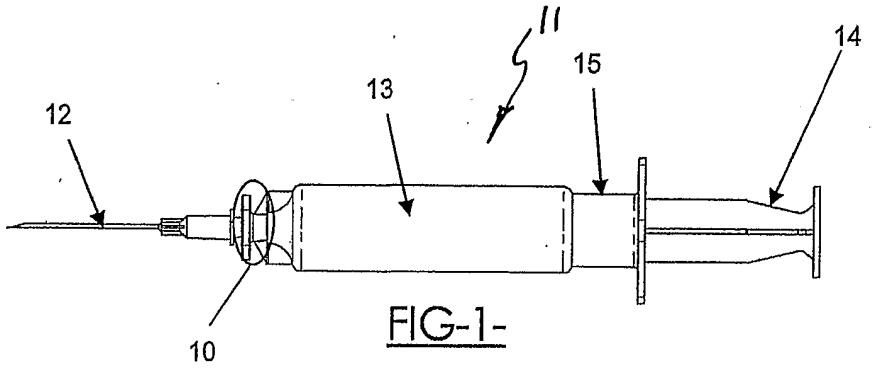

FIG-1-

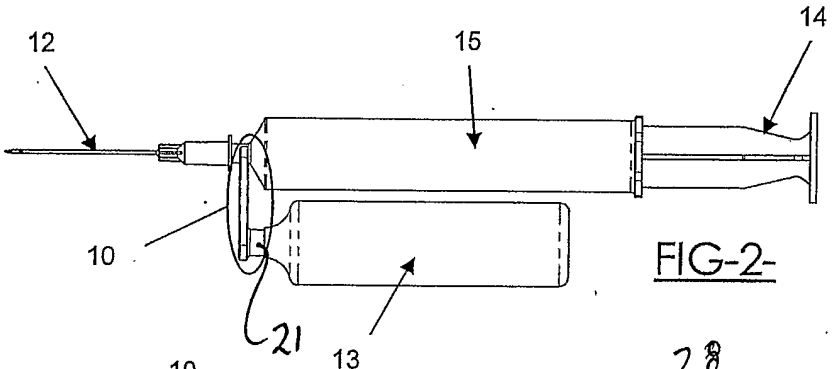

FIG-2-

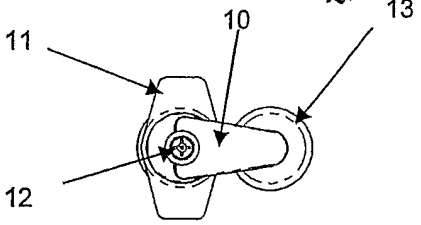

FIG-3-

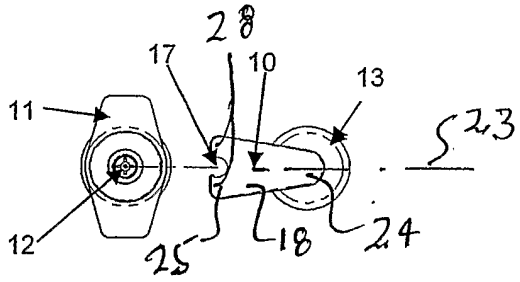

FIG 4

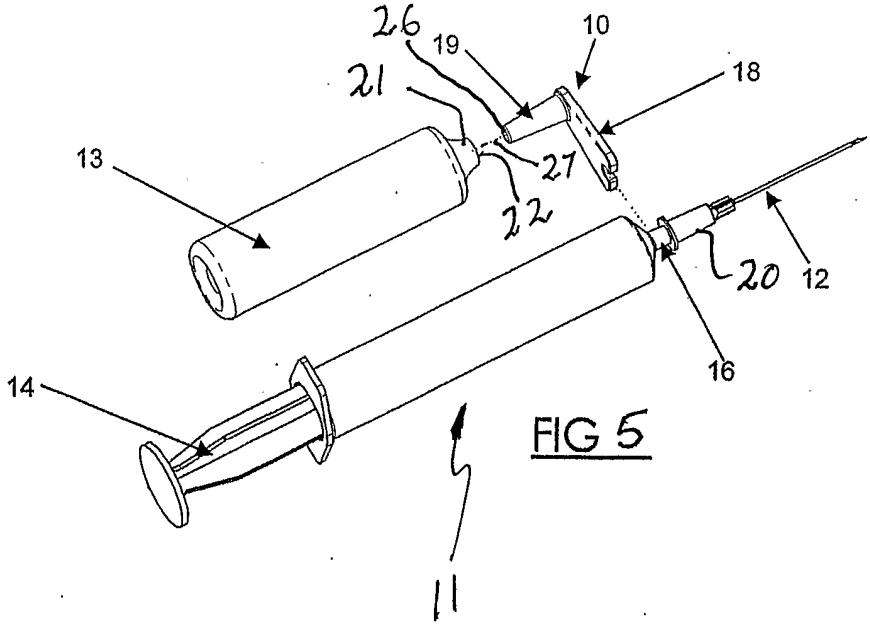

FIG 5

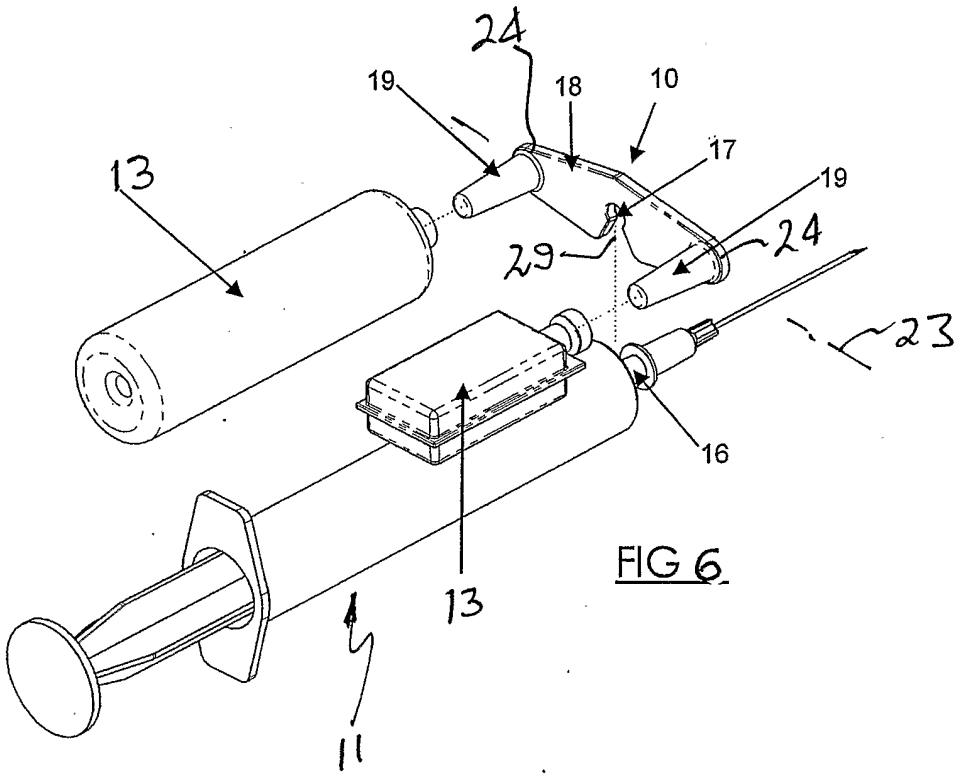

FIG 6

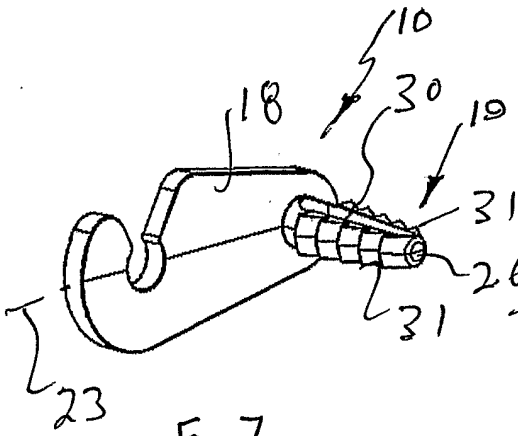

Fig 7

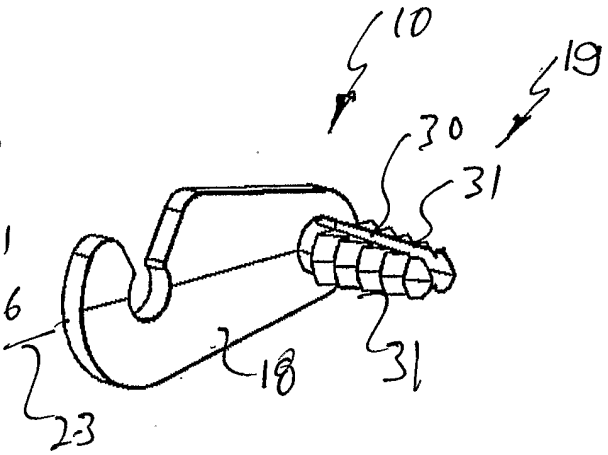

Fig 8

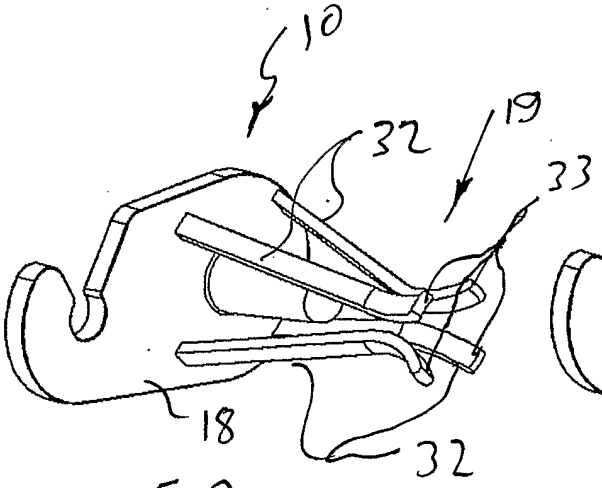

Fig 9

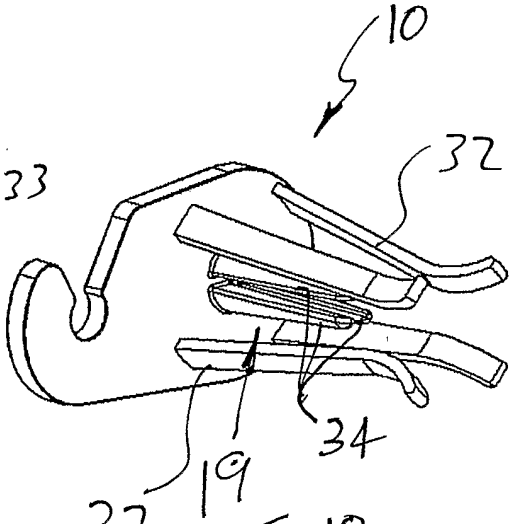

Fig 10

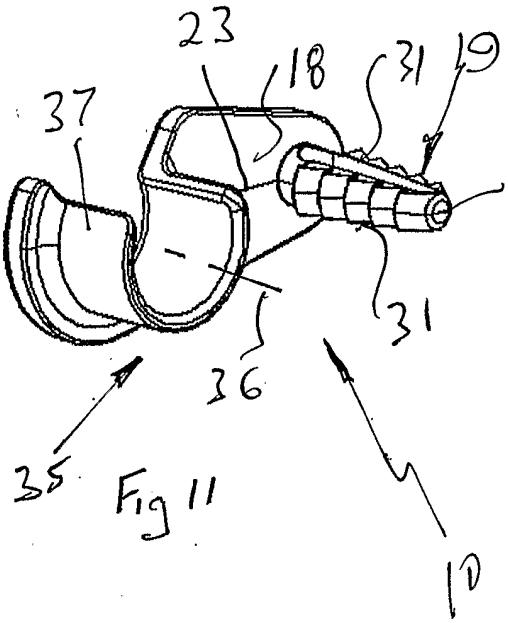

Fig 11

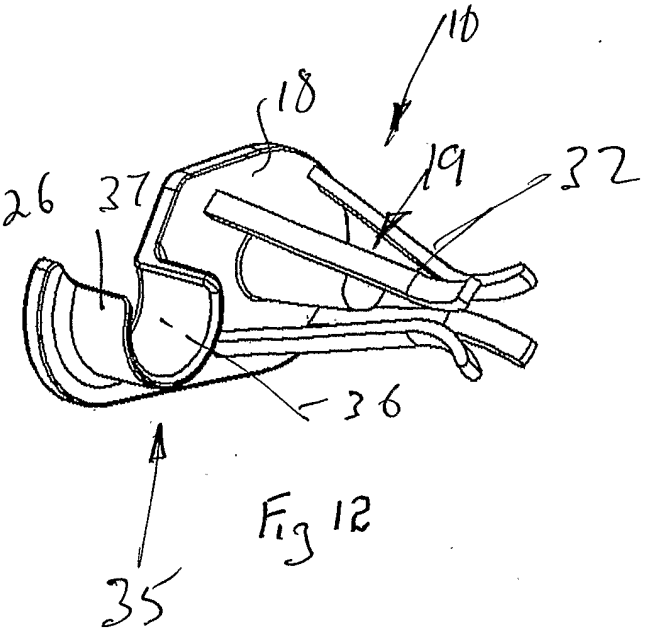

Fig 12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2005/001642

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: A61M 5/31, G09F 3/16

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)

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)
DWPI - IPC: A61M, A44B, G09F and Keywords: (syringe, ampule, clip, identif+) and like terms

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 20020083564 A1 (JAMES) 4 July 2002 WHOLE DOCUMENT	1-17
X	US 5290261 A (SMITH, JR et al.) 1 March 1994 WHOLE DOCUMENT	1-17
P, X	WO 2005011781 A1 (LIVERSIDGE) 10 February 2005 WHOLE DOCUMENT	1-17
X	US 2627269 A (McGREGOR) 3 February 1953 WHOLE DOCUMENT	1-17

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

* Special categories of cited documents:

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
3 November 2005	11 NOV 2005
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer **MATTHEW FORWARD** Telephone No : (02) 6283 2606

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2005/001642

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report	Patent Family Member
WO 2005011781	
US 2002083564	
US 5290261	
US 2627269	

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX