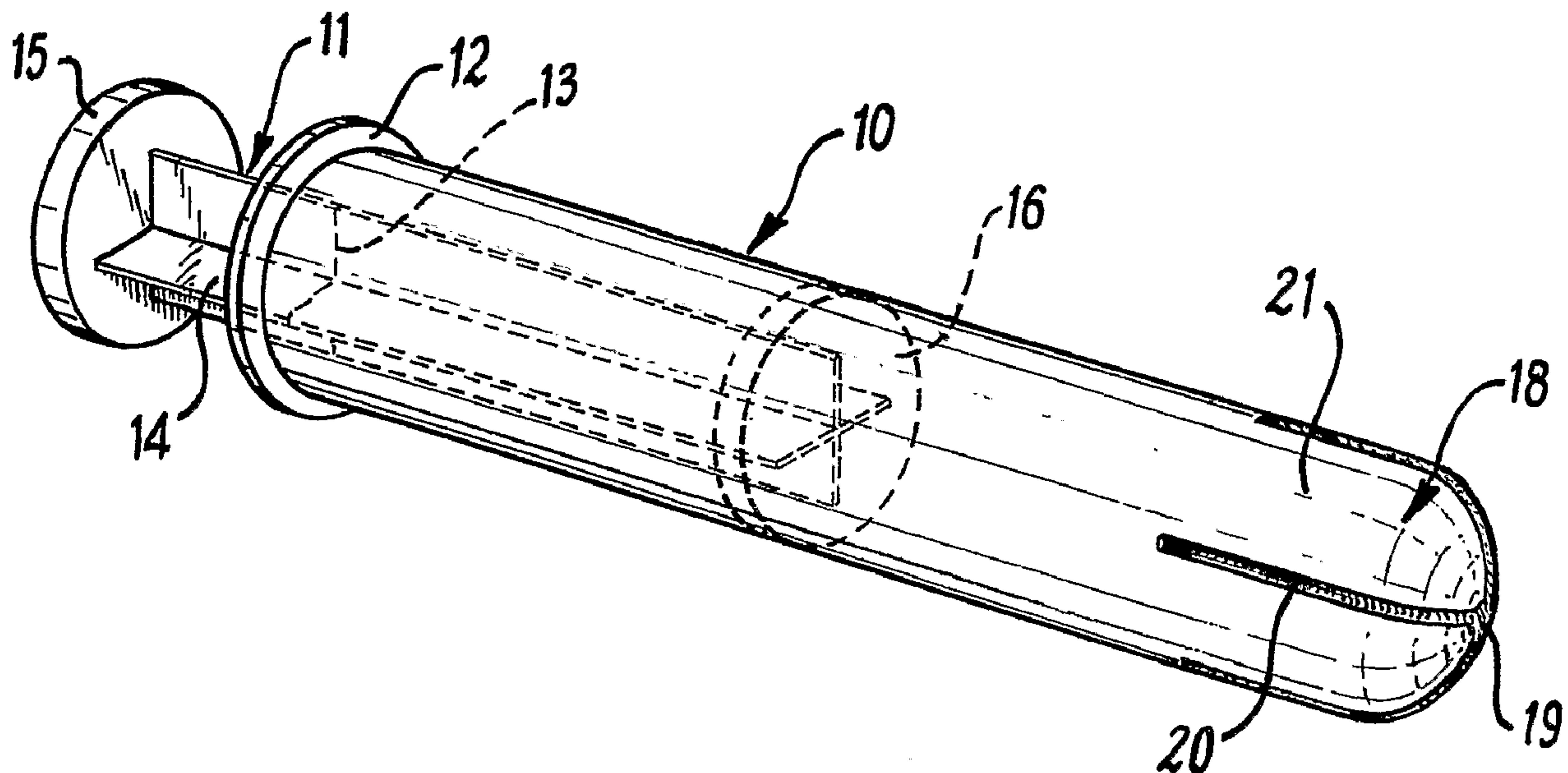




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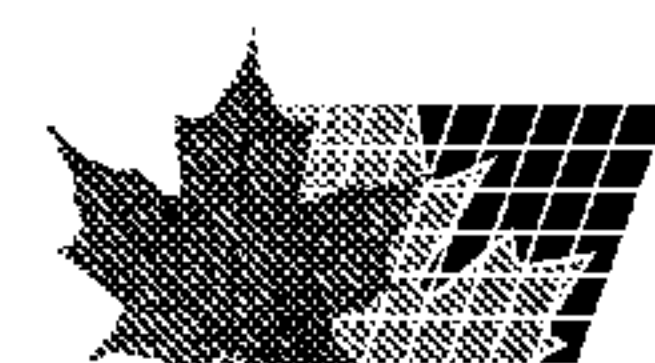
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A tool for application of a haemostat to a site of bleeding comprises a cylindrical barrel (10), a plunger (11) slidable in the barrel, the barrel (10) having an outlet end (18). The outlet end (18) may be configured as a cone or rounded end with a central aperture (19) and longitudinal slots (20) in a cruciform arrangement, or may be left open. The barrel may have a slot (39) alignable with a slot (37) in an inner member for insertion of a haemostat body (40) in the barrel. The barrel and plunger may be separable for insertion of the body into an open end of the barrel.



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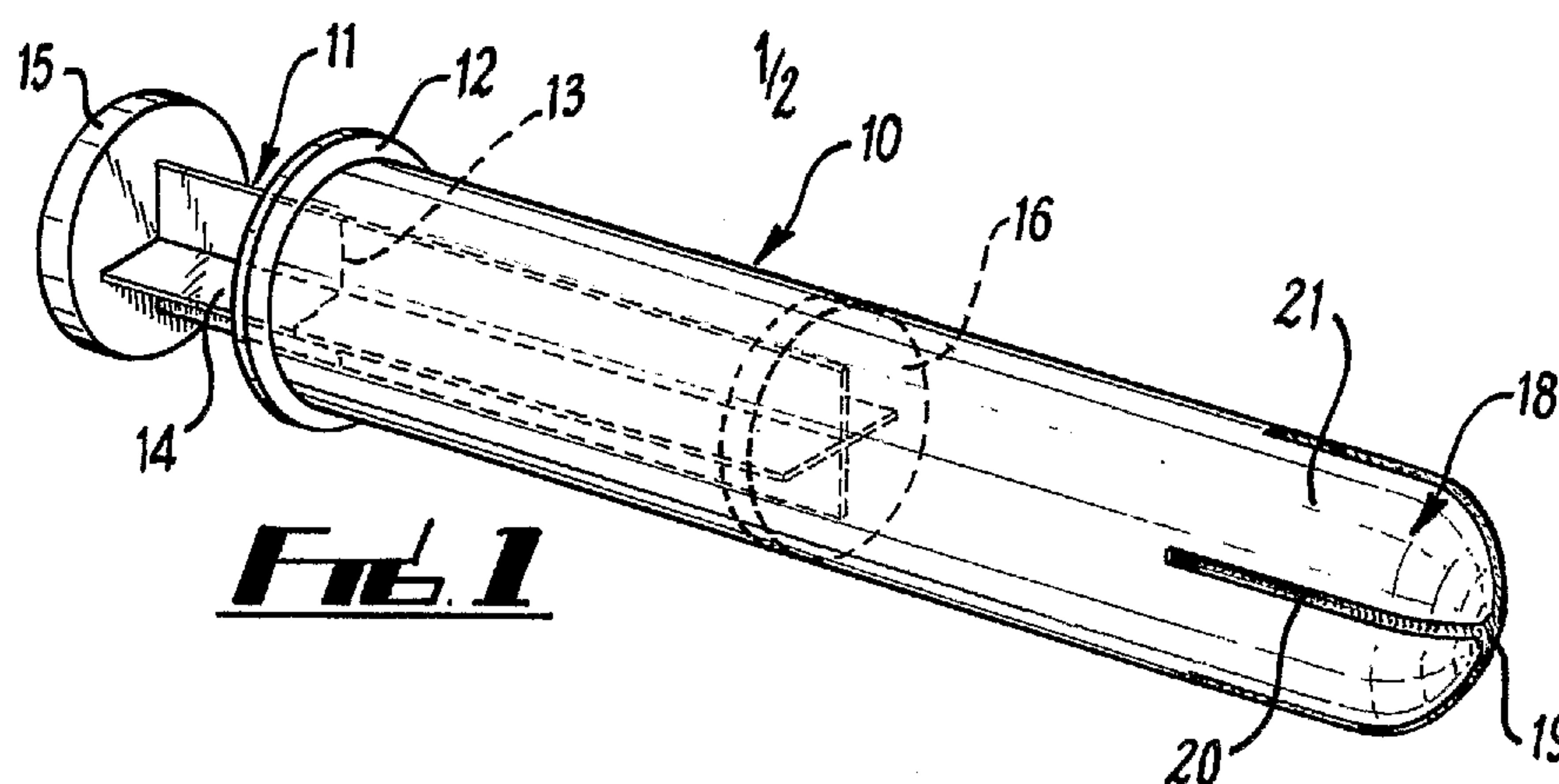
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(57) Abstract: A tool for application of a haemostat to a site of bleeding comprises a cylindrical barrel (10), a plunger (11) slidable in the barrel, the barrel (10) having an outlet end (18). The outlet end (18) may be configured as a cone or rounded end with a central aperture (19) and longitudinal slots (20) in a cruciform arrangement, or may be left open. The barrel may have a slot (39) alignable with a slot (37) in an inner member for insertion of a haemostat body (40) in the barrel. The barrel and plunger may be separable for insertion of the body into an open end of the barrel.

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Haemostat Application

This invention relates to the field of application of haemostats to sites of bleeding, in order to control, reduce or end bleeding, particularly internal blood loss.

In particular, the invention relates to a device for the insertion of a haemostat
5 to a deep site of bleeding.

Haemostats are used in medical treatment to staunch bleeding wounds due to injury, or surgical incisions. They act by physical or chemical means to reduce or eliminate blood loss e.g. by absorption of liquid, or by promoting clotting or coagulation or both. The haemostat itself may be in the form of a powder, or fibrous
10 material for example, including dry foam, freeze dried foam, or a fibrous nonwoven, a gel or the like. An absorbent material may be used as a support for a chemically active material distributed through the absorbent material.

At present, such haemostat preparations are applied using dressings for surface tissue wounds, or by specially adapted forceps or tongs, the latter having relatively
15 long limbs to assist in placing *haemostats in deep tissues*.

Such existing methods are effective with wounds which are sufficiently wide to allow manipulation with such tools but small aperture deep wounds, such as may be produced by gunshot or stabbing cause difficulty, and may require to be surgically widened to allow placement of the haemostat.

20 It is an object of the invention to provide a tool which can be used to locate haemostats in their correct place in deep or narrow or other wounds or incisions which are difficult of access.

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In accordance with the invention, a tool for application of a haemostat comprises a barrel for holding a quantity of haemostat, an outlet, and a plunger operable to expel the haemostat from the barrel.

The tool for application of a haemostat may in one embodiment comprise a
5 barrel having an inner sleeve and an outer sleeve, a loading aperture in each of the sleeves, the sleeves being relatively rotatable whereby the apertures may alternatively be placed in alignment or out of alignment, one with the other; a plunger which can be moved axially of the barrel between a withdrawn position and a fully inserted position, and an outlet at an end of the barrel opposite to the plunger, said outlet being
10 of at least minimally smaller diameter than the internal diameter of the barrel, to provide an abutment to limit full insertion of the plunger.

The loading apertures when aligned preferably admit to a chamber within the barrel, for placement of a haemostat therein when the plunger is fully withdrawn. The haemostat preparation may be provided in the form of a cartridge or pellet of a size
15 and configuration to fit into the chamber, and may be provided in a bag or casing which is preferably of soluble material.

The haemostat may alternatively be in the form of a cylindrical plug or fibrous material. This can contain granules of any chemically or pharmaceutically active composition, in the quantities prescribed, which may form a minor part of the
20 haemostat by weight. The material of the fibrous plug may be inactive, or have at least physical haemostatic action, e.g. as an absorbent.

The outlet may be defined by an internal rim about the respective end of the barrel which is sufficient to provide a step to retain the plunger against being pushed beyond the respective end of the barrel.

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The loading apertures may comprise elongate slots one in each of the inner and outer sleeves. The inner sleeve may be fixed with respect to an end member which has an aperture for sliding of the plunger, and the shank of the plunger may be of any suitable shape such as cruciform, or cylindrical. The outlet may alternatively
5 be formed as for example a rounded, tapering or conical nozzle, with an opening of reduced diameter with respect to the diameter of the barrel and optionally with longitudinal slots in a cruciform array. This may be of particular utility for the placement of a particulate, powdered, or pelletized haemostat preparation, whilst a wider outlet aperture such as suggested above, may be of particular utility for location
10 of haemostatic preparations provided in the form of bagged doses, or as fibrous plugs or wads. Such nozzles may be interchangeable to provide orifices of differing size and shape, may be fittable over the full width end of the barrel. The longitudinal slots in the outlet end or cone may extend back beyond any tapered section of the end so that the end can open out in the manner of the petals of a flower.

15 To penetrate into wounds having small or very small entry sizes, e.g. stab wounds or gunshot pellet wounds, the barrel of the tool preferably has a diameter of 2.0cm or less, preferably 1.5cm or less, more preferably 1.0cm or less, most preferably 0.5cm or less.

Preferred embodiments of tool for haemostat application according to the
20 invention will now be described, by way of example, with reference to the accompanying drawings, wherein:-

Fig. 1 is a perspective view of a first embodiment of applicator tool according to the invention;

Fig. 2 is a longitudinal cross-sectional view of the applicator tool of Fig. 1;

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Fig. 3 is a longitudinal cross-sectional view similar to Fig. 2 of a modified version of the applicator tool;

Fig. 4 is a fragmentary perspective view of an alternative nozzle outlet;

Fig. 5 is a perspective view of a further embodiment of applicator tool according to the invention;

Fig. 6 is a longitudinal cross-sectional view of the applicator tool of Fig. 5; and

Fig. 7 is a longitudinal cross-sectional view of a simplified applicator tool according to the invention.

10 The applicator tool shown in Figs. 1 and 2 comprises a cylindrical barrel 10, and a plunger 11 which is inserted slidably into the barrel 10 from a first end of the barrel. The first end of the barrel is closed by a disc 12 which has a guide aperture 13, of a cruciform shape to match a cruciform cross-sectional shaft 14 of the plunger 11. The free end of the plunger 11 is formed with a disc or knob 15, whilst the end of the
15 plunger 11 located in the barrel 10 forms a disc shaped piston 16, dimensioned to slidably contact the inner surface of the barrel 10. This piston 16 prevents withdrawal of the plunger 11 from the barrel 10 when fully extended, and serves to propel a dose of e.g. haemostatic material from the discharge end of the barrel 10.

The discharge end of the barrel 10 is constituted by the end 17 of the barrel
20 opposite the first end of the barrel which is closed by disc 12. The discharge end 17 is formed as a torpedo shaped end 18 with an end orifice 19, and longitudinal slots 20 which divide the rounded end cap into tapering segments 21. The material of these segments is a flexible plastic, so that the segments may dilate like the petals of a

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flower to expand the orifice 19 if relatively large bodies such as 25 in Fig. 3 of material are expelled.

A quantity of material may be loaded into the barrel 10 in the manner of a syringe, by withdrawing the plunger 11 and allowing the material to be drawn in by
5 suction. This is suitable for use with powders, liquids, or fluent gels. To load more solid or fibrous material say in the form of pellets or wads, the flexible segments 21 may be opened out, and the material pushed into the barrel by the user's gloved fingers, or by a suitable tool such as a spatula.

The tool is operated to discharge the material at the required site simply by
10 pressing the plunger into the barrel, so that the piston 16 will push the material out through the orifice 19.

The Fig. 3 embodiment differs from that of Figs. 1 and 2, in that the plunger 11 is configured as a cylinder 22, enclosing a chamber 23 which is accessible through an opening 24 in the wall of the cylinder. The chamber is used to store one or more
15 charges of haemostat material 25, which may be ready made up into bags sachets wads or plugs of material. The bags may be of water or body fluid soluble or dispersible material, and contain the haemostatic material, whilst wads or plugs may be of compacted granular material, or of fibrous material which is either inert or has a haemostatic effect itself, and may carry medically active material dispensed
20 therethrough, as granular material or as an impregnating fluid.

The bags, sachets wads or plugs 25 may be loaded into the barrel 10 in the same way as in the first embodiment, as the discharge end 17 is configured in the same way as in Figs. 1 and 2, and corresponding parts have the same reference numerals as in the foregoing.

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Fig. 4 shows an alternative configuration for the discharge end of the tool, which comprises a conical end cap 26, which has a similar end orifice 27 and similar longitudinal slots 28.

A further embodiment of tool for application of haemostats or other medical or pharmaceutical devices or doses to a site, is shown in Figs. 5 and 6. The tool comprises a barrel 30 and a plunger 31. The barrel is configured as a cylinder, and has a first end which is closed by a disc 32 having a cruciform aperture for sliding engagement of a cruciform shank 33 of the plunger 32. The free end of the plunger 32 is formed with an end disc or knob 34, and the inner end, contained within the barrel 30, carries a circular disc 35 which acts as a piston.

The barrel 30 comprises an inner, fixed cylindrical wall 36, having a slot 37 extending therealong. The barrel 30 is further provided with an outer cylindrical sleeve 38 which can be rotated by twisting the sleeve relative to the inner wall 36. The sleeve 38 has a slot 39 extending therealong which is congruent with the slot 37 in the wall 36 and can be aligned with the latter or closed relative thereto, by rotation of the sleeve. The sleeve 38 can be rotated by simple hand pressure, but an annular part thereof may be textured or provided with ribs or knurling to provide a finger grip.

The slots 37, 39 may be aligned to provide an opening through which a charge 40 of haemostat material may be inserted into the barrel 30. This may be provided in a soluble bag, as a wad or plug of fibrous, or gel material etc. The opening is closed simply by rotating the sleeve 38 until the aperture slots are no longer aligned.

The end 41 of the barrel 30 opposite to the plunger 31 provides a discharge opening 42 which is surrounded by a rim 43 which provides an abutment to prevent excess travel of the piston 35, so that the opening 42 is only slightly smaller in

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diameter than the internal diameter of the barrel 30. This is particularly suitable for discharge of bags or plugs of material of diameter comparable to that of the barrel.

The outlet configuration may be varied by fitting appropriate cones over the end of the barrel, and the discharge opening structure described in relation to this embodiment may be the basic structure, for the Fig. 1 - 2 or Fig. 3 embodiment also, and be adaptable for discharge of powders, particles or gels for example by fitting appropriate nozzle cones such as described in relation to the foregoing embodiments. These cones may vary as to outlet size and shape, for example for extruding a plastic gel or paste into the required site.

Figure 7 illustrates a simplified haemostat applicator which is capable of being used as a disposable one-slot applicator or very simple mass producible item. The applicator is formed from a plastics material, and comprises a tubular barrel 50 having an open end 51 with a flange 52, and a discharge end 53 with a dilatable slotted end cone 54. The applicator also comprises a hollow plastics plunger, comprising a shaft 55 comprising a hollow tube 56 with a closed inner end 57, and an end flange 58 which is used to aid pressure. In use a charge 59 of haemostatic material is inserted into the open end 51 of the barrel 50, and pushed down towards the discharge end 53 using the plunger 55, which is inserted into the open end 51 after the charge 59. To carry out treatment, the barrel 50 is then inserted into the wound to penetrate to the site of bleeding, and the charge 59 of haemostatic material is implanted by pushing the plunger 55 completely home, till flange 58 abuts flange 52.

The pressure expels the charge 59 from the discharge end 53 causing the segments of the cone 54 to dilate into the broken line positions 54a, to allow the charge to be expelled from the end of the barrel 50.

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The tools described may be made suitable for disassembly for sterilization and re-use or may be disposable after one use.

The barrel, plunger and any other parts may be made from suitable inert plastics materials, and may be provided, ready charged with a specific haemostat
5 material or combination materials, sealed to maintain sterility until use. The material is preferably transparent.

As the tool is of relatively small diameter, it can be inserted into wounds or incisions of small diameter, and implant the haemostat into relatively deep bleeding sites without need for the wound to be widened surgically.

10 The haemostat may be adapted to expand after placement at the required site, and release from the confines of the tube. The degree of expansion, by volume, or by linear measure, may be greater than 10%, preferably more than 33%, and ideally between 50 and 100%, although excessive expansion might damage body tissues.

A preferred material for the barrel and plunger is a polyolefine such as
15 polypropylene, or high, medium, or low-density polyethylene, or a polyester. Advantageously a biodegradable plastic may be used, so that if the tool is discarded in the field for instance, it will biodegrade.

The tool could be formed with a rounded tip to allow easier access to a small site such as a bullet entry wound.

20 The tool may be used as part of an automated system to be dispensed at the touch of a button, for example using air under pressure.

The tool, particularly the outer surface of the barrel, may have a lubricated self-lubricating, or low friction surface or coating to ease insertion and reduce pain produced by abrasion during insertion.

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The barrel may be calibrated so that the user can judge the amount of material applied and thus judge the size of an internal cavity which cannot be seen.

The tool is suitable to be carried by paramedics, and by military casualty treatment teams, for use in applying immediate treatment to injuries, and combat
5 wounds, and may also be used in casualty wards and surgically for treatment e.g. of bleeding in 'keyhole' incisions.

The barrel of the syringe may be made of a material which is dissoluble in body fluids such as blood plasma etc and is left in place without being withdrawn, and may be dissolved in situ. This may make the applicator more effective, easier or
10 faster to use, or be necessary if a soluble bag or some of a haemostatic powder adheres to the rim of the barrel when the latter is wetted.

Where the barrel is filled with loose unbagged powder, this may be retained in place with a soluble haemostatic discardable or removable plug.

The tool may be adaptable for other medical purposes such as the placement
15 of suppositories or the like in target locations.

Claims

1. A tool for application of a haemostat comprising a barrel for holding a quantity of a haemostat, an outlet, and a plunger operable to expel the haemostat from the barrel, wherein
5 the outlet is formed as a rounded, tapering or conical nozzle with an opening of reduced diameter with respect to the diameter of the barrel, and wherein the nozzle is formed with longitudinal slots in a cruciform array converging on the opening.
2. A tool according to claim 1, wherein the barrel has an inner sleeve and an outer
10 sleeve, a loading aperture in each of the sleeves, the sleeves being relatively rotatable whereby the apertures may alternatively be placed in alignment or out of alignment one with the other; wherein the plunger can be moved axially of the barrel between a withdrawn position and a fully inserted position, and the outlet is located at one end of the barrel opposite to the plunger, said outlet being of at least minimally smaller diameter than the
15 internal diameter of the barrel, to provide an abutment to limit full insertion of the plunger.
3. A tool according to claim 2, wherein the loading apertures when aligned admit to a chamber within the barrel, for placement of a haemostat therein when the plunger is fully withdrawn.
- 20 4. A tool according to claim 2 or claim 3, wherein the outlet is defined by an internal rim about the respective end of the barrel which provides a step to retain the plunger against being pushed beyond the respective end of the barrel.
- 25 5. A tool according to any one of claims 2-4, wherein the loading apertures comprise elongate slots one in each of the inner and outer sleeves, the inner sleeve being fixed with respect to an end member which has an aperture for sliding of the plunger.
6. A tool according to any one of claims 1-5, wherein the outer surface of the barrel has
30 a coating of self-lubricating or low friction material.
7. A tool according to any one of claims 1-6, wherein the barrel is calibrated so that the user can judge the amount of material applied.

8. A tool according to any one of claims 1-7, wherein the barrel is made of a material which is dissoluble in body fluids such as blood plasma.
9. A tool according to claim 1, wherein an open ended barrel is provided with a withdrawable plunger, which can be inserted into the open end, after a charge of haemostatic material, the barrel having a discharge end opposite said open end.
10. A tool according to claim 9, wherein the discharge end includes a cone with longitudinal slots which provide flaps which can be dilated to allow egress of a body of haemostatic material.
11. A tool according to any one of claims 1-10, wherein the barrel has a diameter of 2 cm or less.
12. A tool according to claim 11 wherein the barrel has a diameter of 1.5 cm or less.
13. A tool according to claim 12 wherein the barrel has a diameter of 1.0 cm or less.
14. A tool according to claim 13 wherein the barrel has a diameter of 0.5 cm or less.

