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(54) Title of the Invention: **Anal insertion device**
Abstract Title: **Degradable enema device**

(57) An insertion nozzle 1 for an anal irrigation system comprising a positioning member and at least one exit aperture separated by a hollow shaft 3, wherein the structure of the device is weakened upon immersion in a toilet bowl such that the device can be flushed. The nozzle may comprise a water soluble material. The nozzle may comprise polyvinyl alcohol.

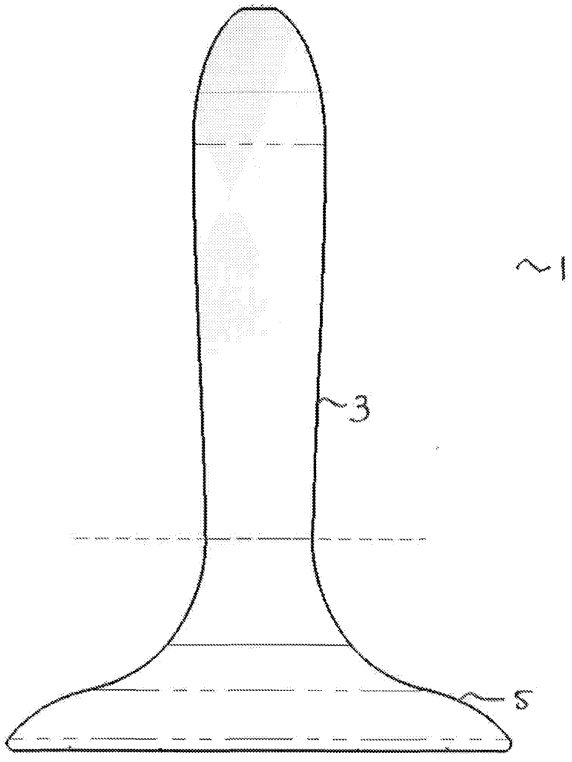

Fig. 1a

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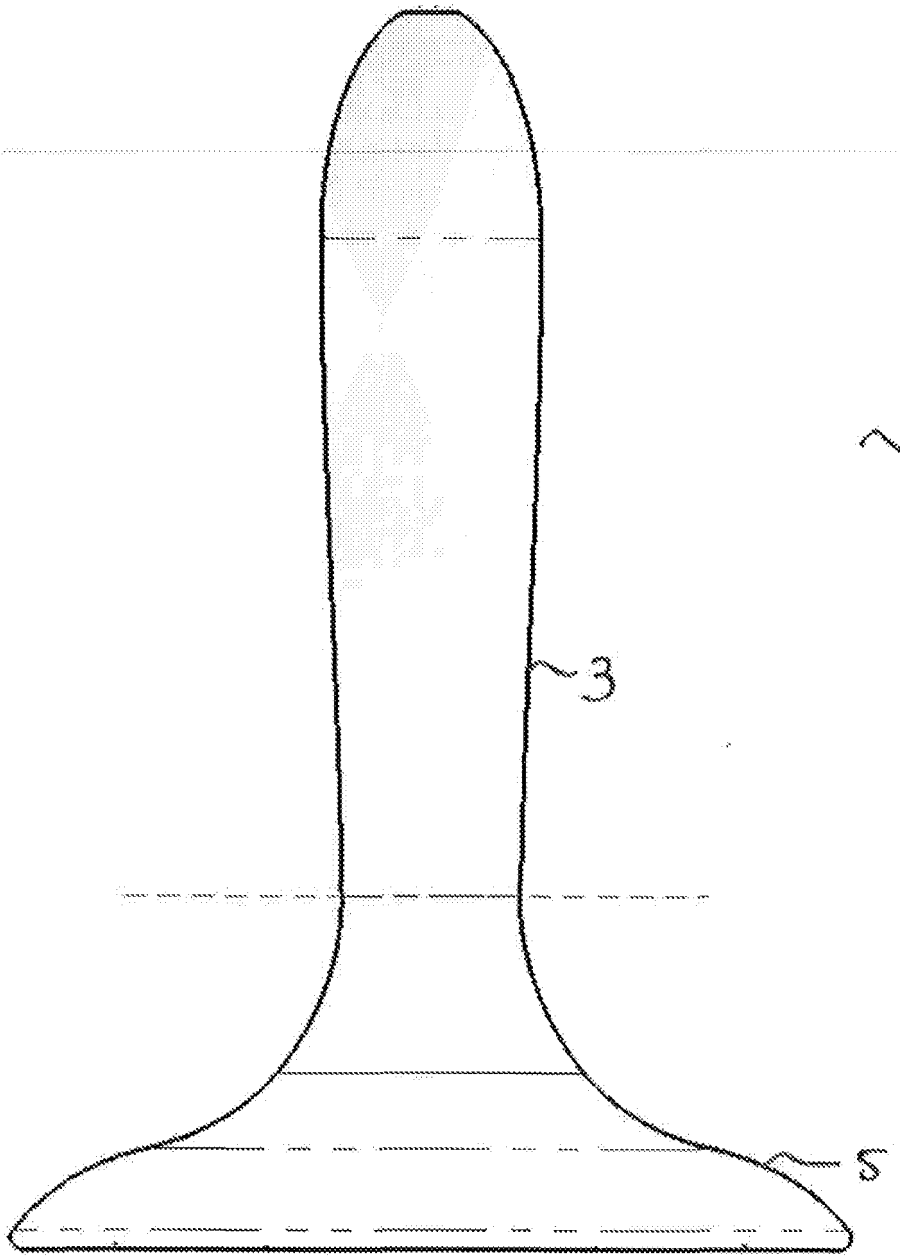

Fig. 1a

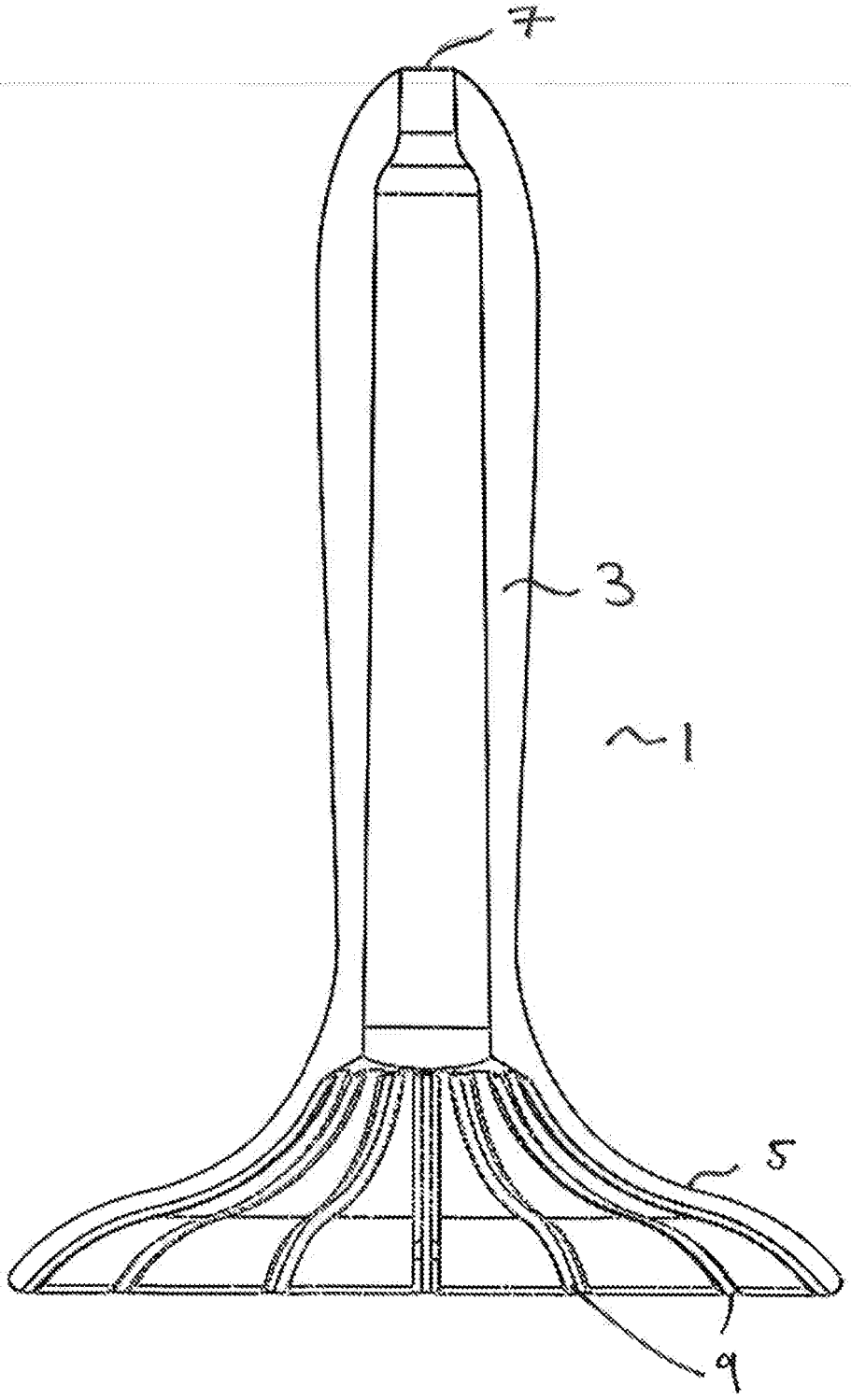

Fig. 1b

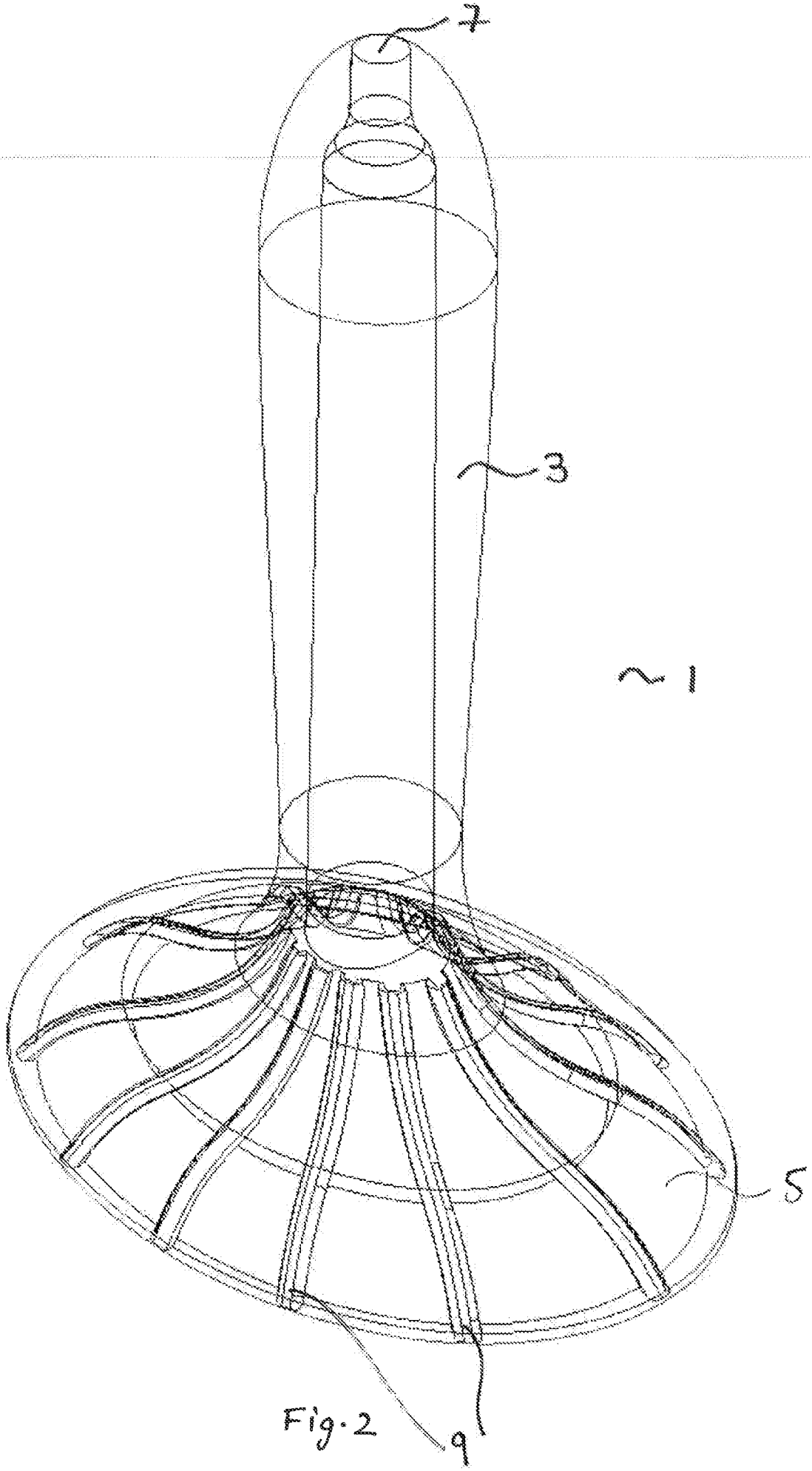

Fig. 2

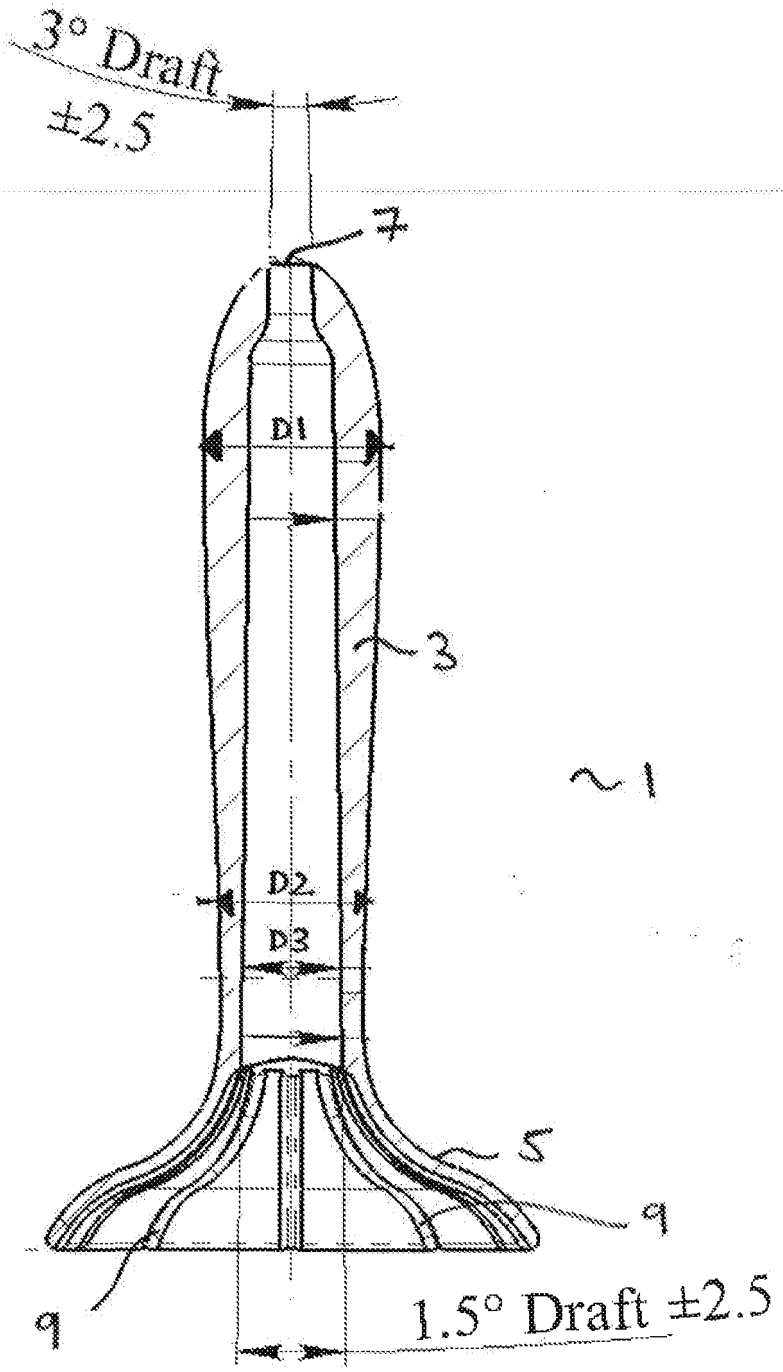

Fig. 3

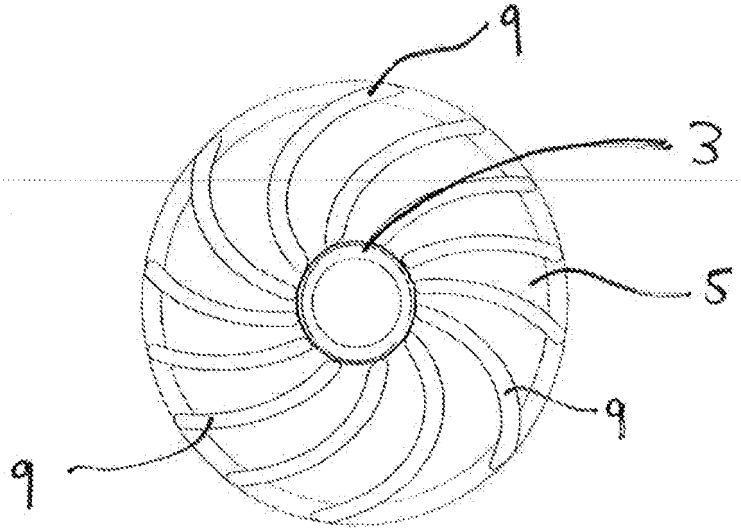

Fig. 4

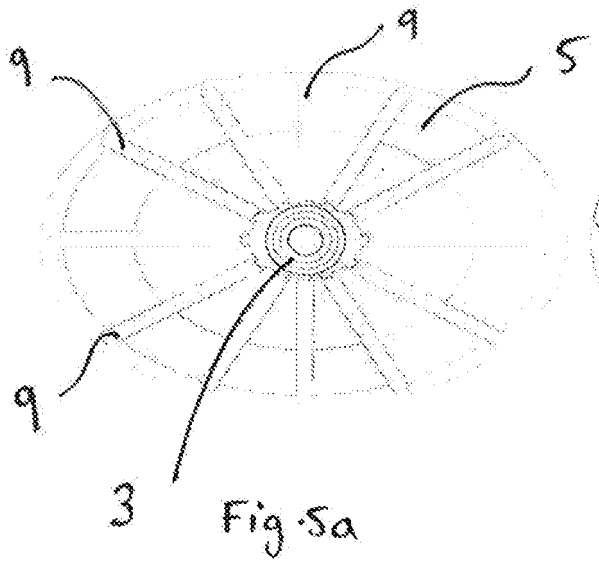

Fig. 5a

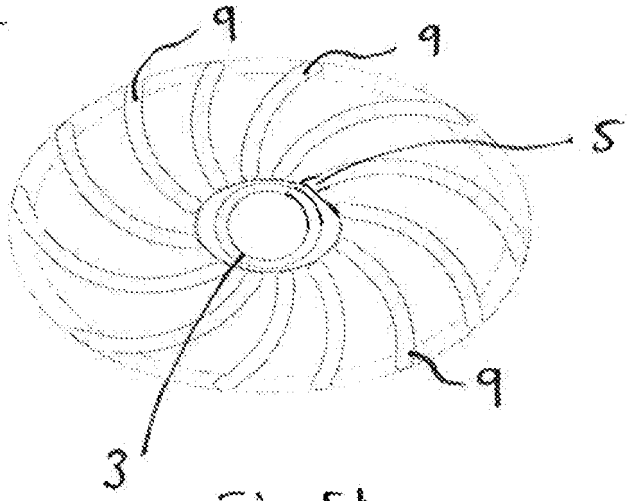

Fig. 5b

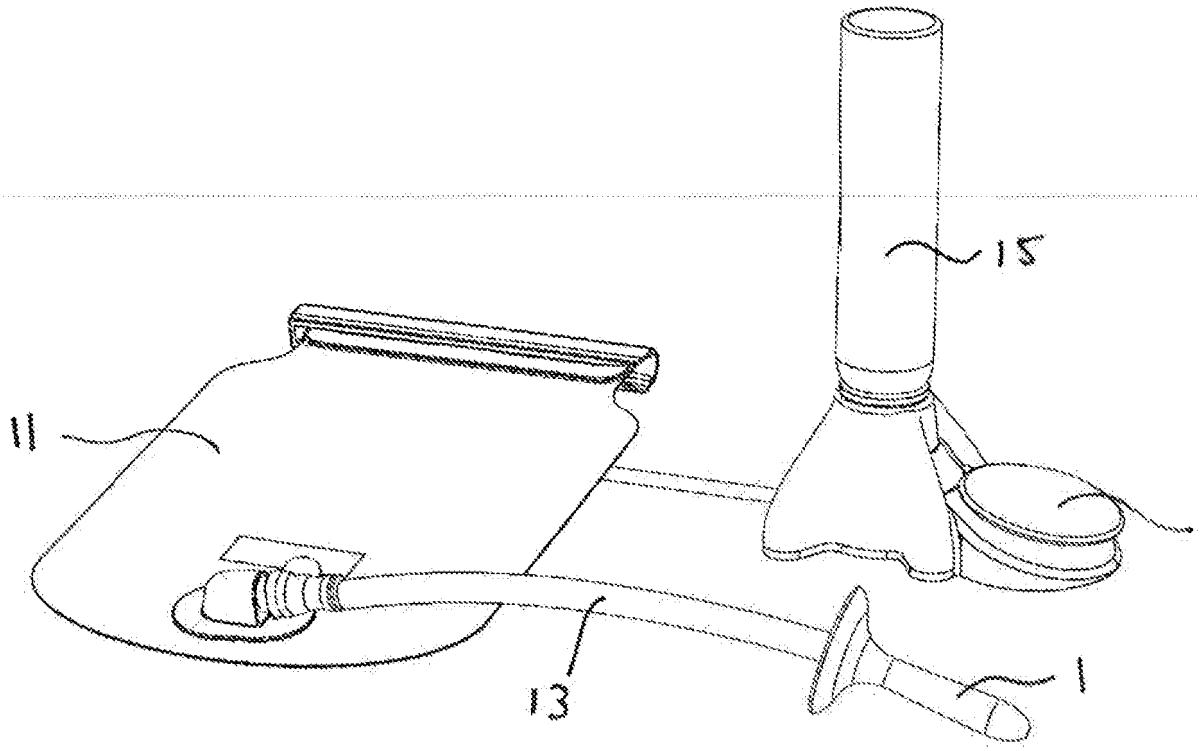

Fig. 6

Anal Insertion Device

The present invention relates to an anal irrigation system and an insertion device for use in anal irrigation.

Background

Anal irrigation is used to prevent constipation and also where a user is incontinent. This method is used when a user does not have bowel control, for example, when a user has a spinal cord injury. The use of anal irrigation is necessary for both the health and the quality of life of the user. The primary application of the present invention is to assist people with faecal incontinence and/or chronic constipation. The present invention alleviates symptoms of bowel dysfunction by reducing the time spent on the toilet and increases a user's quality of life. The invention offers significant advantages to those suffering from neurological disorders or brain tumours; those with spinal cord injury, or suffering from spina bifida; Alzheimer's disease, multiple sclerosis, Parkinson's disease, or apoplexies. The invention also has applications to users with reduced tissue elasticity, common in elderly people or after multiple births; to users with sensory disorders, which can occur after surgery; and also to users with psychological or psychiatric disorders.

Existing anal irrigation devices and methods include those disclosed in patent publications WO 05032617 and EP 1434611. An anal catheter is inserted into the rectum through the anus and retained by a balloon, which acts as a fixation device. The balloon is inflated against the bowel wall. A liquid, such as water or a saline solution, is then pumped from a reservoir into the rectum through the anal catheter. A hand pump is used to pump air into the reservoir to force liquid to flow from the reservoir into the anal catheter and into the user. The balloon fixation device is then removed, which allows the bowel to evacuate with the flow of water triggering peristalsis.

The insertion/fixation device used in anal irrigation can be a single-use device, which needs to be disposed of after use. A new fixation device is

then used for each anal irrigation treatment. EP1011754 discloses the use of a polyurethane foam fixation member, which is compressible and resilient to retain the device in use, with gauze attached to assist removal from the rectum after use. US5578017 discloses a flexible plastic nozzle fixation member, which has self-adhesive securing means for attachment to a user. Single-use fixation devices need to be safely and hygienically disposed of after removal. For example, the device is wrapped up and disposed of in a waste bin. This can often be inconvenient, messy and embarrassing for a user, especially when the users of such devices have limited manual dexterity. Alternatively, the fixation device can be re-usable. This requires the device to be thoroughly washed and stored hygienically between use, which increases the time and inconvenience involved in the treatment.

The present invention sets out to provide an anal irrigation system, which alleviates the problems described above by providing an internal fixation device that is convenient and hygienic to use, which allows a user to easily and safely carry out their daily routine.

Summary of the Invention

In one aspect, the invention provides an insertion device for an anal irrigation system comprising a positioning member and at least one exit aperture separated by a hollow shaft, wherein the structure of the device is weakened upon immersion in a toilet bowl to become less buoyant such that the device can be flushed away.

The internal fixation device of the present invention is suitable to be flushed down a toilet in its entirety. A flushable insertion device allows for convenient and hygienic disposal after anal irrigation. Adantageously, a user is not required to wash or wrap the device for re-use or disposal and the device can be easily disposed of by users with limited manual dexterity.

Preferably, the insertion device comprises a water soluble material.

More preferably, the insertion device comprises a polyvinyl alcohol material.

It has been found that polyvinyl alcohol of the required grade ensures that the insertion device remains insoluble and stable when stored and when it is inserted into the rectum, whilst the device is water softenable and biodegradable over a longer period of time.

Preferably, the insertion device is self-lubricating when wet.

Advantageously, an insertion device that is self-lubricating allows for easier insertion of the device into the rectum and prevents unintended expulsion of the device.

Preferably, the hollow shaft comprises two or more exit apertures.

Multiple exit apertures ensure that water can still pass through and exit the insertion device, in the event that one of the apertures was to be blocked.

Preferably, the insertion device has a length of about 70mm.

Preferably, the hollow shaft has a length of between about 50mm and about 90mm.

More preferably, the hollow shaft has a length of about 51mm.

Preferably, the hollow shaft has an outer diameter of between about 7.5mm and about 15mm.

Preferably, the hollow shaft has an inner diameter of between about 4.5mm and about 9.5mm.

Within this specification, the term "about" is interpreted to mean optionally ±20%, preferably optionally ±10%, more preferably optionally ±5%.

Preferably, the wall thickness of the hollow shaft varies along its length.

More preferably, the wall thickness of the hollow shaft is greater adjacent to the or each exit aperture than adjacent to the positioning member.

Preferably, the wall thickness of the hollow shaft is between about 0.5mm and about 5.0mm adjacent to the positioning member and between about 0.7mm and about 5.7mm adjacent to the or each exit aperture.

More preferably, the wall thickness of the hollow shaft is about 1.5mm adjacent to the positioning member and about 3.2mm adjacent to the or each exit aperture.

Preferably, the outer wall of the hollow shaft is tapered from the or each exit aperture towards the positioning member at an angle of between about 0.5 and about 5.5 degrees from the vertical axis of the hollow shaft.

More preferably, the outer wall of the hollow shaft is tapered at an angle of about 3.0 degrees from the vertical axis of the hollow shaft.

A thicker wall around the exit aperture of the hollow shaft ensures that the area of the shaft that is in contact with water for the greatest amount of time is stable and will remain secure and intact during the period of use of the device.

Preferably, the internal wall of the hollow shaft is tapered from the positioning member towards the or each exit aperture at an angle of between about 0.5 and about 4.0 degrees from the vertical axis of the hollow shaft.

More preferably, the internal wall of the hollow shaft is tapered from the positioning member towards the or each exit aperture at an angle of about 1.5 degrees towards the vertical axis of the hollow shaft.

The insertion device is preferably manufactured by injection moulding and the tapering of the internal wall of the insertion device allows for easier removal of the insertion device from the mould.

Preferably, the positioning member comprises a substantially hemispherical collar.

A hemispherical collar allows a user to safely and conveniently hold the device for insertion and use and also assists with the correct positioning of the device by preventing over-insertion and the potential for internal damage of a user.

Preferably, the positioning member has a substantially elliptical or oval base.

Optionally, the positioning member has a substantially circular base.

Preferably, the internal surface of the positioning member comprises one or more channels.

Optionally, the internal surface of the positioning member comprises one or more protrusions.

More preferably, the internal surface of the positioning member comprises two or more channels.

Channels or protrusion(s) on the internal surface of the positioning member increase the surface area of the insertion device, which comes into contact with water when the device is immersed in a toilet bowl. This has the advantage of increasing the speed at which the device breaks down and can be flushed away.

Preferably, each channel is equally spaced around the inner surface of the positioning member.

More preferably, the channels are spaced apart from each other by a distance of at least about 10mm.

Preferably, the or each channel is curved.

Optionally, the or each protrusion is curved.

Curved channels or protrusions provide the advantage that they strengthen the device whilst it is stored and when it is in use.

Preferably, the hollow shaft of the insertion device comprises at least one annular recess around its inner surface.

Optionally, the hollow shaft of the insertion device comprises at least one annular protrusion around its inner surface.

An annular recess or protrusion on the inner surface of the hollow shaft provides the advantage of a secure "click-fit" with a corresponding protrusion or recess around the tip of a water conduit, which is inserted into the insertion device for use in anal irrigation. This ensures that that the water conduit is correctly fitted and provides the advantage of giving reassurance to the user that the insertion device is safe and ready to use.

Detailed Description

For the purposes of clarity and a concise description, features are described herein as part of the same or separate embodiments; however it will be appreciated that the scope of the invention may include embodiments having combinations of all or some of the features described.

The invention will now be described by way of example with reference to the accompanying diagrammatic drawings, in which:-

Figure 1a is a front view of an insertion device constructed in accordance with a first embodiment of the present invention;

Figure 1b is a front view of an insertion device constructed in accordance with a second embodiment of the present invention;

Figure 2 is a perspective schematic view of the insertion device of Figure 1b showing both the external and internal features of the device;

Figure 3 is a front schematic view of the insertion device of Figure 1b showing the external and internal features of the device;

Figure 4 is a view from below of the insertion device of Figure 1b;

Figures 5a and 5b are views from below of an alternative embodiment of the insertion device shown in Figure 1b; and

Figure 6 is a perspective view of an anal irrigation system incorporating the insertion device of the present invention, as shown in Figures 1 to 5;

Referring to Figure 1, the insertion device 1 of the present invention is an approximately frustoconical device comprising a substantially tubular insertion shaft 3 integrally formed with an positioning collar 5. The device 1 is injection moulded and formed from a water soluble material, such as a polyvinyl alcohol material (PVOH). The grade of PVOH used ensures that the device 1 remains insoluble when it is stored in sealed packaging and when it is inserted into the rectum during use. However, over a longer period of time, the material is water-softenable and biodegradable. The material used is self-lubricating when wet and slightly adhesive or "tacky" when drying. In use, this assists in insertion of the device and reduces any unintended expulsion of the device.

As shown in Figures 1a and 2, the insertion device 1 of the present invention is a catheter, shaped to interact with the anal sphincter to encourage retention of the device 1. The device 1 comprises a substantially cylindrical, hollow shaft 3 extending from a positioning collar 5 at its base to an aperture 7 at its tip. The positioning collar 5 forms a funnel-shape with the hollow shaft 3. In alternative embodiments, the hollow shaft has multiple apertures at its tip and/or spaced around its surface. In the event that one or more apertures were to be blocked, additional apertures would ensure that water could still escape from the insertion device to allow anal irrigation. The positioning collar 5 assists with insertion into the anal sphincter and prevents over-insertion of the device 1.

The length of the device 1 is between 50 and 90mm. In a preferred embodiment the overall length of the device 1 is 70mm and the length of the hollow shaft 3 is 51mm. Referring to Figure 3, the hollow shaft has an outer diameter (D2, D1) of between 10 and 12.5mm and an inner diameter (D3) of 7mm. The inner diameter (D3) is sized according to the water conduit that is to be inserted into the shaft 3 in use. The wall thickness of the shaft 3 varies along its length between 1.5mm adjacent to the positioning collar 5 to 3.2mm at the tip, adjacent to the aperture 7 and furthest from the positioning collar 5. The thicker end of the shaft 3 is furthest from the collar 5 and, in use, is in contact with water for a greater amount of time. The increased wall thickness ensures that the device 1 is stable enough to remain secure and intact during use.

As discussed in the following Examples, the thickness of the shaft wall is configured to ensure a sufficient thickness for the device to be stable during use whilst minimising the amount of material from which the device is made to ensure that the device will dissolve after use.

As shown in Figure 3, the internal wall of the hollow shaft 3 is tapered at an angle of 1.5 degrees towards the vertical axis from the positioning collar 5 towards the aperture 7 of the device 1. The tapering of the internal wall allows for ease of removal of the insertion device 1 from the

mould into which it is injected and formed. The tapering of the internal hollow of the shaft 3 also allows for uniform pressure to be applied to the water conduit inserted into the device during use. The outer wall of the shaft 3 is tapered at an angle of 3.0 degrees to the vertical axis from the aperture 7 of the device 1 towards the positioning collar 5.

In a first embodiment of the invention, as shown in Figure 1b, the positioning collar 5 has a circular base with a diameter of between about 20 and about 70 mm. In a preferred embodiment of the invention, shown in Figure 1a and Figure 2, the positioning collar 5 has an elliptical or oval cross section with a major diameter of about 47 mm and a minor diameter of about 35 mm. The positioning collar is curved and it slopes at an angle of between about *0.5* and about 5 degrees to the longitudinal, vertical axis of the shaft 3 of the device 1. The angle of the slope, ensures that the device 1 can easily be inserted and removed.

As shown in Figures 4, 5a, and 5b, the internal surface of the positioning collar 5 comprises a series of ridges or cut-outs 9 extending along the internal surface of the positioning collar 5 between its base and the hollow shaft 3. Figure 4 shows an positioning collar 5 with a circular base and curved ridges 9 between the base of the shaft 3 and the base of the positioning collar 5. Figures 5a and 5b show an positioning collar 5 with an elliptical base. Figure 5a shows straight ridges 11 between the base of the shaft 3 and the base of the positioning collar 5; Figure 5b shows curved ridges 9 between the base of the shaft 3 and the base of the positioning collar 5. In alternative embodiments of the device, protrusions extend along the internal surface of the positioning collar.

In a preferred embodiment shown in Figure 5a, a series of ridges/channels 9 are equally spaced around the inner surface of the positioning collar 5 with a distance of at least 10mm between each ridge at the base of the insertion device 1. On immersion in water, these external ridges 9 increase the surface area of the device 1 that comes into contact with water. The ridges 9 fold inwardly towards each other on immersion and decrease the time taken for the device 1 to dissolve. They also assist in

the flushing of the device 1 because they allow the catheter to break down into easily flushable strips. In an alternative embodiment, as shown in Figure 5, the ridges 9 are curved to strengthen the device 1 during storage and use.

In use, the insertion device 1 is sufficiently rigid to allow a user to insert the device securely and comfortably into the rectum. As shown in Figure 6, the insertion device 1 is connected to a reservoir of fluid 11, such as water, by a length of tubing, referred to as the water conduit 13. The water conduit 13 is inserted into the hollow shaft of the insertion device 1 and is held securely in place. The water conduit 13 is inserted substantially along the full length of the hollow shaft, which assists in maintaining stability of the device 1 once inserted. In one embodiment, the insertion device 1 and the water conduit 13 have a "click-fit", wherein an annular protrusion around the tip of the water conduit 13 mates with a corresponding annular recess around the hollow shaft 3 of the insertion device 1. The water conduit 13 is inserted until the protrusion mates with the recess and a "click" sound indicates that the conduit 13 is held in place. It is also envisaged that a "click-fit" between the water conduit and the insertion device could be achieved wherein an annular recess around the tip of the water conduit mates with a corresponding annular protrusion inside the hollow shaft of the insertion device. In an alternative embodiment, a lever is used to assist in sliding the water conduit into the insertion device without the user contacting the water conduit. When the water conduit is sufficiently inserted into the hollow shaft of the insertion device the lever is removed.

As shown in Figure 6, the water reservoir 11 is connected to a pump 15. The pump 15 can be pneumatic, electric, battery-powered or a manual device. In use the insertion device 1 acts as an irrigation nozzle, which is inserted into the rectum and will remain in position whilst the pump 15 is used to pump air into the reservoir 11. It is envisaged that the insertion device 1 will remain stable for between 5 and 30 minutes when inserted into the rectum. The pump 15 is operated by a lever switch or pedal 17 and forces water to flow from the reservoir 11 through the water conduit

13, through the anal insertion device 1 and out of the or each aperture 7 therein, into the user. The insertion device 1 is then removed from the rectum, allowing the bowels to evacuate as the presence of water triggers peristalsis.

After use, the insertion device 1 is placed into a toilet bowl and will become weakened on immersion in water to gradually dissolve so that the device can be flushed away.

The invention will now be described with reference to the following examples.

Example 1

1. Summary

To determine the solubility, and therefore suitability, of injection moulded PVOH as a material for "flushable" anal irrigation components using standardised test methods.

2. Test Method

300ml of water was poured into a beaker and cooled to 2.3deg in the lab's fridge. The beaker was set up with an automatic agitator to ensure constant water flow around the test material.

2g of the moulded PVOH was placed in the beaker and observed over a period of 4 hours.

The 2g in 300ml ratio of PVOH to water was representative the entire cone in a toilet bowl. The sample would be deemed suitable for flushing if it could fit through a 10mm mesh sieve after 4 hours.

3. Results

After 4 hours only 0.15g of the initial 2g PVOH remained intact.

The sample had dissolved into several small pieces.

It was observed that the water temperature rose by around 10deg through the experiment.

4. Conclusion

After 4 hours submerged in active water, any remaining parts were easily small and flexible enough to pass through a 10mm mesh as required.

They would have comfortably passed through a 5mm mesh.

The flow of water around the material greatly affects its dispersal within the water and as such it was considered that any material left in still water will require more time to dissolve.

Two 30mm x 10mm samples were left in static water for 7 hours and dissolved by around 70%.

Example 2

1. Summary

To determine the solubility, and therefore suitability, of injection moulded PVOH as a material for "flushable" A.I. components using standardised test methods.

This is a continuation of the initial experiment (described in Example 1).

The objective of this test was to measure the time taken for smaller, thinner samples to dissolve within a warmer, larger volume of water.

2. Test Method

500ml of room temperature (24.6°) water was poured into a beaker. The beaker was set up on an automatic agitator to ensure constant water flow.

3 samples were put in the beaker;

1x thin large sample (0.65mm thick and 0.4g)

1x medium sample (1.1mm thick and 0.7g)

1x thick small sample (2.2mm 0.13g)

The samples were observed until they dissolved entirely.

3. Results

After 25mins the thin sample had totally dissolved and the thicker samples were becoming thinner and more pliable.

After 40mins the only remaining PVOH was a 5mm section of the thicker sample part.

After 50mins only a 3mm part remained and after 1 hour all of the sample material had dissolved into the water.

4. Conclusion

All 3 samples dissolved entirely within 1 hour of being put into the beaker, with the thinner (larger) sample dissolving in just 25mins.

The increased reaction speed compared to the initial experiment (described in Example 1) was considered to be due to the smaller sample size, the larger volume of water and the increased temperature of the water (from around 4°C to 24.6°C).

The rate of dissolving is well within the guidelines set out for "flushable" items. As such, an anal irrigation cone made from the tested PVOH to the correct design should dissolve in a toilet bowel and sewage system.

Example 3

1. Summary

The purpose of this experiment was to compare 4 different injection moulded PVOH formulations and determine if they are "flushable" using standardised test methods and the "test protocol to determine the flushability of disposable products" as defined by various Water Board Authorities and Local Government Council Authorities.

Additional parameters have been recorded to facilitate a qualitative and quantitative materials selection process. Additional properties of interest include:

Solubility
Flexibility/Rigidity
Colour
Lubrication
Adhesion

2. Test Method

Prototype injection mouldings of the insertion device were produced using 4 different formulations of PVOH.

In turn each of these formulations were put in a beaker of room temperature water and agitated using an automatic stirrer.

The breakup/absorption rates were recorded after 1 hour, the solution was poured through a 10mm sieve after 4 hours and the time taken for each sample to dissolve entirely was tabulated.

The experiment was repeated to validate results.

The flexibility of each formulation was also compared. This qualitative test was achieved by applying forces across the flange and along the length of the shaft to visually determine the relative flexibility of each (un-wetted) component. A grade of 1, 2 or 3 was then given to the formulation to show the relative rigidity of each sample.

Lubrication and adhesion were initially tested by adding a drop of water to a sample of each material and rubbing the surface to compare coefficients of friction. As the samples dried, surface contact was made again and the adhesive properties of each surface was compared.

3. Results

Sample No.	Material Name	Visual Properties	Relative rigidity 1= Soft 3= Stiff	Size/Appearance after 1hr in water	Pass through 10mm sieve after 4 hours	Time taken to fully dissolve
1	TBA	Translucent	3	55mm (see pic)	Yes	4hr
2	C22/C74	White Lighter	1	63mm (see pic)	Yes	4hr 42min
3	F11.3	Yellow Darker	1	45mm (see pic)	Yes	2hr 21min
4	IM5xx	Yellow	2	45mm (see pic)	Yes	2hr 26min

4. Conclusion

The fundamental purpose of this experiment was to determine if any of the different PVOH formulations could be used to produce a flushable product.

The results show that when injection moulded into this form, each of the different formulations dissolved at a rate greater than that required for an official flushability certification. As such all of the parts tested could be considered suitable for flushing into the sewerage system.

Due to each formulation being considered flushable we now focus on other factors to assist in the materials selection process.

Colour and translucency are important factors which will impact on both product aesthetics and users' perception of the dissolving PVOH.

The material leaching from a white device will be more visible than material leaching from a translucent device.

It is equally important that the part looks like a quality medical device and should appear clean and fit for purpose.

Softness is another important factor. An insertion device with a degree of flexibility could be perceived as being easier to insert and less dangerous than a stiffer alternative. It is very important for safety reasons that the part bends rather than cracks if over-stressed.

The preferred embodiment of the device is self lubricating. The process of lubrication is an integral part of priming the water conduit and once "wetted" the device is insertable into the anus without requiring any additional lubrication.

The adhesive properties of the insertion devices' drying surfaces assists retention during use and may also reduce leakage.

Initial tests have indicated that lubrication and adhesion values are similar throughout the range.

The above described embodiments have been given by way of example only, and the skilled reader will naturally appreciate that many variations could be made thereto without departing from the scope of the claims.

Claims

1. An insertion device for an anal irrigation system comprising a positioning member and at least one exit aperture separated by a hollow shaft, wherein the structure of the device is weakened upon immersion in a toilet bowl such that the device can be flushed away.

2. An insertion device according to claim 1, wherein the insertion device comprises a water soluble material.

3. An insertion device according to claim 1 or any proceeding claim, wherein the insertion device comprises a polyvinyl alcohol material.

4. An insertion device according to claim 1 or any proceeding claim, wherein the insertion device is self-lubricating when wet.

5. An insertion device according to claim 1 or any proceeding claim, wherein the hollow shaft comprises two or more exit apertures.

6. An insertion device according to claim 1 or any proceeding claim, wherein the insertion device has a length of about 70mm.

7. An insertion device according to claim 1 or any proceeding claim, wherein the hollow shaft has a length of between about 50mm and about 90mm.

8. An insertion device according to claim 1 or any proceeding claim, wherein the hollow shaft has a length of about 51mm.

9. An insertion device according to claim 1 or any proceeding claim, wherein the hollow shaft has an outer diameter of between about 7.5mm and about 15mm.

10. An insertion device according to claim 1 or any proceeding claim, wherein the hollow shaft has an inner diameter of between about 4.5mm and about 9.5mm.

11. An insertion device according to claim 1 or any proceeding claim, wherein the wall thickness of the hollow shaft varies along its length.

12. An insertion device according to claim 1 or any proceeding claim, wherein the wall thickness of the hollow shaft is greater adjacent to the or each exit aperture than adjacent to the positioning member.

13. An insertion device according to claim 1 or any proceeding claim, wherein the wall thickness of the hollow shaft is between about 0.5mm and about 5.0mm adjacent to the positioning member and between about 0.7mm and about 5.7mm adjacent to the or each exit aperture.

14. An insertion device according to claim 1 or any proceeding claim, wherein the wall thickness of the hollow shaft is about 1.5mm adjacent to the positioning member and about 3.2mm adjacent to the or each exit aperture.

15. An insertion device according to claim 1 or any proceeding claim, wherein the outer wall of the hollow shaft is tapered from the or each exit aperture towards the positioning member at an angle of between about 0.5 and about 5.5 degrees from the vertical axis of the hollow shaft.

16. An insertion device according to claim 1 or any proceeding claim, wherein the outer wall of the hollow shaft is tapered at an angle of about 3.0 degrees from the vertical axis of the hollow shaft.

17. An insertion device according to claim 1 or any proceeding claim, wherein the internal wall of the hollow shaft is tapered from the positioning member towards the or each exit aperture at an angle of between about 0.5 and about 4.0 degrees from the vertical axis of the hollow shaft.

18. An insertion device according to claim 1 or any proceeding claim, wherein the internal wall of the hollow shaft is tapered from the positioning member towards the or each exit aperture at an angle of about 1.5 degrees towards the vertical axis of the hollow shaft.

19. An insertion device according to claim 1 or any proceeding claim, wherein the positioning member comprises a substantially hemispherical collar.

20. An insertion device according to claim 1 or any proceeding claim, wherein the positioning member has a substantially elliptical or oval base.

21. An insertion device according to claim 1 or any proceeding claim, wherein the internal surface of the positioning member comprises one or more channels, optionally wherein the internal surface of the positioning member comprises one or more protrusions.

22. An insertion device according to claim 1 or any proceeding claim, wherein the internal surface of the positioning member comprises two or more channels, optionally wherein each channel is equally spaced around the inner surface of the positioning member.

23. An insertion device according to any one of claims 21 or 22, wherein the or each channel is curved, and / or wherein the or each protrusion is curved.

24. An insertion device according to claim 1 or any proceeding claim, wherein the hollow shaft of the insertion device comprises at least one annular recess around its inner surface.

25. An insertion device according to claim 1 or any proceeding claim, wherein the hollow shaft of the insertion device comprises at least one annular protrusion around its inner surface.

26. An insertion device substantially as described herein with reference to the accompanying drawings and/or description.

Application No:	GB1120401.3	**Examiner:**	Dr Matthew Parker
Claims searched:	1-26	**Date of search:**	8 March 2012

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
X	1-25	JP2000033119 A (GUREITOCHIREN), see abstract

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^{X} :

Worldwide search of patent documents classified in the following areas of the IPC

A61M

The following online and other databases have been used in the preparation of this search report

EPODOC, WPI

International Classification:

Subclass	Subgroup	Valid From
A61M	0003/02	01/01/2006