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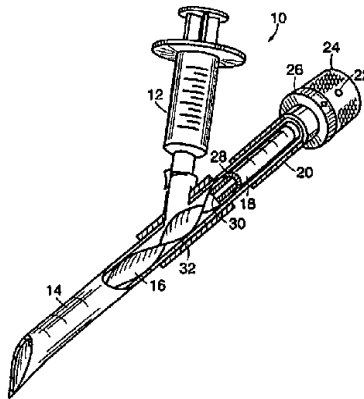
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(54) Title: DEVICE AND METHOD FOR DELIVERING FIBER INTO A BODY



(57) Abstract

A device, and related method, for introducing fiber material into a body includes a tubular member with a lumen extending to an opening in a distal end portion of the tubular member and a mechanism in the tubular member for passing the fiber material through the lumen and the opening and into the body. The mechanism can be a helical member rotatable within the tubular member to convey the fiber material through at least a portion of the lumen, out of the opening, and into the body, and the fiber material can be particles in a carrier that are injected into the lumen by a syringe coupled to the tubular member. The mechanism alternatively can be a sleeve slidable within the tubular member to force the fiber material through at least a portion of the lumen, out of the opening, and into the body, and the fiber material can be a suture or thread that is fed into a distal portion of the tubular member where it collects until it is forced out of the opening by the sleeve. The mechanism also can be a push rod slidable within the tubular member to push the fiber material through at least a portion of the lumen, out of the opening, and into the body, and the fiber material can be one or more pellets.

DEVICE AND METHOD FOR DELIVERING FIBER INTO A BODY

Cross-Reference to Related Application

This specification incorporates by reference the disclosure of U.S. provisional
5 patent application serial number 60/060,842 which was filed on October 2, 1997.

Technical Field

This invention relates to a device for delivering material into the body and a
method of using such a device. More particularly, the present invention relates to feeding
10 a fiber or particles through a tubular member, such as a needle.

Background Information

Many different types of medical and surgical treatments require a mass of material
to be implanted into the body. For example, in one type of procedure for treating urinary
15 incontinence, material is delivered to radial sites about the urethra to bulk tissue around the
urethra. In other procedures, materials, such as bulking materials, are implanted in the
body to treat aneurysms and arteriovenous malformations (AVMs), for example.

One type of bulking material currently approved by the FDA is a mixture of a
phosphate carrier and either collagen or fat. However, this type of material is absorbed in
20 the body within about one year and sometimes needs to be reinjected into a patient
periodically. Other materials, such as TEFLON and silicone, have been tested, but some
of these materials may be capable of migrating to vital organs of the body, such as the
brain or the lungs, and thereby harm a patient.

The reference to any prior art in this specification is not, and should not be taken
25 as, an acknowledgment or any form of suggestion that that prior art forms part of the
common general knowledge in Australia.

Summary of the Invention

The invention relates to the use of fiber materials, such as threads and sutures, in
30 bulking tissue. These fiber materials provide a permanent bulking, and are not absorbed in
or by the body. The fiber materials can be made of the same substances used to form



surgical sutures and wound care products that have a long, successful, and safe history when used for patient implantation.

The present invention provides a device for introducing fiber material into a body, comprising:

5 a tubular member having a lumen extending to an axial opening in a distal end portion of the tubular member; and

a helical member rotatable within the tubular member to convey the fiber material through at least one portion of the lumen, out of the opening and into the body.

The present invention also provides a method for introducing fiber material into a
10 body, comprising:

providing a device including (i) a tubular member having a lumen extending to an axial opening in a distal end portion of the tubular member and (ii) a helical member rotatable within the tubular member for passing the fiber material through the lumen and the opening and into the body;

15 introducing the tubular member into the body; and

rotating the helical member within the tubular member to pass the fiber material through the opening in the distal end portion of the tubular member into the body.

In treating urinary incontinence, devices and methods according to embodiments of the invention may be used to deliver the fiber material to radial sites about the urethra, and
20 the fiber material provides bulking of tissue around the urethra to enable the patient to be continent permanently. That is, placing the fiber material at radial sites about the urethra forces coaptation of this valve and thus enables the patient to be continent permanently.

In one embodiment, the invention involves a device for introducing fiber material into a body, comprising a tubular member having a lumen extending to an opening in a
25 distal end portion of the tubular member. The device also comprises a mechanism in the tubular member for passing the fiber material through the lumen and the opening and into the body.

In another embodiment, the invention relates to a device which comprises a tubular member having a lumen extending to an opening in a distal end portion of the tubular
30 member, and a helical member within the tubular member for conveying the fiber material through at least a portion of the lumen, out of the opening, and into the body. A syringe



can be coupled to the tubular member in communication with the lumen, and the syringe can provide the fiber material into the lumen of the tubular member. The fiber material can comprise particles in a carrier such as a gel or liquid carrier.

In yet another embodiment, the invention features a device which comprises a tubular member having lumen extending to an opening in a distal end portion of the tubular member, and a sleeve slidable within the tubular member for forcing the fiber material through at least a portion of the lumen, out of the opening, and into the body. A driving roller can feed the fiber material into a distal portion of the tubular member until the fiber material accumulates inside the distal portion, and then the sleeve can be moved to force the accumulated fiber material out of the opening in the distal end portion of the tubular member and into the body. The fiber material can comprise a suture or a thread.

In still another embodiment, the invention involves a device which comprises a tubular member having a lumen extending to an opening in a distal end portion of the tubular member, and a push rod slidable within the tubular member for pushing the fiber material through at least a portion of the lumen, out of the opening, and into the body. The fiber material can comprise one or more pellets.

In yet still another embodiment, the invention relates to a method of introducing fiber material into a body. The method comprises providing a device including (i) a tubular member having a lumen extending to an opening in a distal end portion of the tubular member and (ii) a mechanism in the tubular member for passing the fiber material through the lumen and the opening into the body. The method further comprises introducing the tubular member of the device into the body, and operating the mechanism in the tubular member of the device to pass the fiber material through the opening in the distal end portion of the tubular member and into the body.

The foregoing and other features and advantages of the invention will become more apparent from the following description, by way of example only, and from the claims.

Brief Description of the Drawings

In the drawings, like reference characters generally refer to the same parts throughout the different views. Also, the drawings are not necessarily to scale, emphasis instead generally being placed upon illustrating the principles of the invention.



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FIG. 1 is a perspective view of a material delivery device in accordance with a first embodiment of the invention with portions of the device removed to reveal internal components of the device.

FIG. 2 is a perspective view of a second embodiment of the device.

5 FIG. 3 is a cross sectional view of the device of FIG. 2.

FIG. 4 is a cross sectional view of particular components of the device of FIG. 2.

FIG. 5a is a top view of a housing of the device of FIG. 2.

FIG. 5b is a cross sectional view of the housing of FIG. 5a.

FIG. 5c is a cross sectional view of the housing of FIG. 5a.

10 FIG. 6a is a rear view of a pivot arm shown in FIG. 2.

FIG. 6b is a side view of the pivot arm of FIG. 6a.

FIG. 7a is a front view of a coupler shown in FIG. 3.

FIG. 7b is a side view of the coupler of FIG. 7a.

FIG. 7c is a top view of the coupler of FIG. 7a.

15 FIG. 8a is a side view of a roller mount shown in FIG. 3.

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- FIG. 8b is a front view of the roller mount of FIG. 8a.
- FIG. 8c is a top view of the roller mount of FIG. 8a.
- FIG. 9a is a bottom view of an advancing lever shown in FIG. 2.
- FIG. 9b is a side view of the advancing lever of FIG. 9a.
- 5 FIG. 10a is a cross sectional view of a drive roller shown in FIGS. 3 and 4.
- FIG. 10b is a front view of the drive roller of FIG. 10a.
- FIG. 11a is a cross sectional view of a driving knob shown in FIG. 2.
- FIG. 11b is a side view of the driving knob of FIG. 11a.
- FIG. 12a is a cross sectional view of a drive mechanism cover shown in FIG. 2.
- 10 FIG. 12b is a side view of the drive mechanism cover of FIG. 12a.
- FIG. 13a is a perspective view of a third embodiment of the device.
- FIGS. 13b and 13c are cross sectional views of the device of FIG. 13a.
- FIG. 14a is a top view of a housing shown in FIG. 13a.
- FIGS. 14b and 14c are cross sectional views of the housing of FIG. 14a.
- 15 FIG. 14d is a rear view of the housing of FIG. 14a.
- FIG. 15a is a bottom view of an advancing lever shown in FIG. 13a.
- FIG. 15b is a side view of the advancing lever of FIG. 13a.
- FIG. 16a is a rear view of a pivot arm shown in FIG. 13a.
- FIG. 16b is a side view of the pivot arm of FIG. 16a.
- 20 FIG. 17a is a front view of a coupler shown in FIG. 13a.
- FIG. 17b is a side view of the coupler of FIG. 17a.
- FIG. 17c is a top view of the coupler of FIG. 17a.
- FIG. 18 shows three layers of fiber wound on a mandrel to form a fiber pellet for loading
in one of the devices.
- 25 FIG. 19 shows two layers of fiber wound on a mandrel to form a fiber pellet for loading
in one of the devices.
- FIG. 20 shows structure for winding the fiber on the mandrel to form a pellet.
- FIG. 21 shows a way in which a fiber pellet is loaded in one of the devices.
- FIG. 22 shows a way in which the fiber pellet is loaded in the devices.
- 30 FIG. 23 is a view of a push rod advancing apparatus for use with a fourth embodiment of
the invention.
- FIG. 24 is a side view of a needle for mounting to the device of FIG. 23.

FIG. 25 is a view of tubular cartridge loaded with a fiber pellet.

FIG. 26 is a view showing how the fiber pellet in the cartridge of FIG. 25 is loaded in the needle of FIG. 24.

FIG. 27 is a view showing the needle of FIG. 24 mounted to the advancing
5 apparatus of FIG. 23 to deliver the fiber pellet.

FIG. 28 is a perspective view of a fifth embodiment of the device.

Description of the Preferred Embodiments

A preferred embodiment of the invention is directed to a device for delivering a
10 fiber through a tubular member, such as a hypodermic needle. As used herein, the term
fiber or fiber material includes one or more fiber strands, suture material, or thread
material, for example. The fiber is preferably made of material comprising polypropylene,
nylon, polyester, silk, and/or cross linked polysaccharide, such as calcium alginate. For
example, the fiber is preferably polypropylene suture, polyester suture, calcium alginate
15 thread, or silk suture. In addition, the fiber alternatively includes polyester, polypropylene,
silk, and/or calcium alginate fibrous material having a length or diameter of about 100
microns to about 200 microns.

Preferably, the device is capable of delivering the fiber material to radial sites about
the urethra. The fiber material provides bulking of tissue around the urethra, thus enabling
20 the patient to be permanently continent.

Preferably, the device does not use a carrier, such as saline solution or phosphate
solution to carry the fiber and to open the tissue planes. The device is preferably capable
of directing the fiber into the body with a sufficient force to maintain long-term bulking of
tissue.

25 FIG. 1 shows a first embodiment of a device 10 for delivering the fiber. The device
10 includes a syringe 12 coupled to a tubular member 14 via a Y-shaped luer adapter 32.
The syringe 12 includes a slidable plunger and a barrel filled with the fiber. Alternatively,
the barrel of the syringe 12 contains other materials or particles for delivery into the body
and for bulking of tissue. When the plunger of the syringe 12 is pressed, the material in
the barrel of the syringe 12 passes into the tubular member 14. The tubular member 14 is
30 preferably a needle or tube having a gauge of about 16 and a length of about 10 inches.



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Optionally, the tubular member 14 is joined to the adapter 32 with an adhesive.

As shown in Fig. 1, a helical member 16 is provided in a lumen of the tubular member 14. The helical member 16 is shaped like an impeller, corkscrew, or auger.

Rotation of a driving

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knob 24 rotates the helical member 16 in the lumen of the tubular member 14 so that the helical member 16 conveys bulking material (fiber) along the length of the tubular member 14 and through an opening in a distal portion of the tubular member 14.

5 A brazed connection 30 joins the helical member 16 to a mandrel 18, and the mandrel 18 is connected to the driving knob 24 via a set screw 22. A tubular housing 20 for the mandrel 18 has a distal end connected to a leg of the adapter 32. A driving lock 26 threaded on a proximal portion of the tubular housing 20 is rotatable to prevent (or provide resistance to) rotation of the driving knob 24. An o-ring seal 28 maintains a seal between the tubular housing 20 and the rotatable mandrel 18.

10 To use the device 10, the tubular member 14 is inserted in the body. The plunger of the syringe 12 is pressed to pass material from the syringe 12 to the tubular member 14. The driving knob 24 is rotated to rotate the helical member 16 and thereby convey the material through both the tubular member 14 and the opening in the tubular member 14.

15 The barrel of the syringe 12 may be filled with many different types of materials, such as suture material, flat textured yarn material, ground suture material, or ground fabric polyester material. Preferably, the syringe 12 contains a paste or compound like substance, such as particles in a gel or liquid carrier. In the alternative, the syringe 12 contains a mixture of chopped suture and compound.

20 FIGS. 2-4, 5a, 5b, 5c, 6a, 6b, 7a, 7b, 7c, 8a, 8b, 8c, 9a, 9b, 10a, 10b, 11a, 11b, 12a, and 12b show a second embodiment of a device 100 for delivering fiber in the body. As shown in FIGS. 2-4, 5a, 5b, and 5c, the device 100 includes a housing 110 and a tubular member 14a coupled to the housing 110 at a proximal end of the tubular member 14a. Preferably, the tubular member 14a is a needle or tube connected directly to the housing 110. Alternatively, the tubular member 14a is releasably coupled to the housing 110 via an adapter (not shown).

25 A hollow guide 132 shown in FIGS. 3 and 4 is connected to a proximal end portion of the housing 110 and extends into a proximal end of the tubular member 14a. The fiber F is capable of passing through the hollow guide 132. As shown in FIGS. 3, 4, 10a, and 10b, a rotatable driving roller 120 is provided for feeding the fiber F through the hollow guide 132. The driving roller 120 is rotatably mounted in a roller mount 124 shown in FIGS. 3, 8a, 8b, and 8c, and extends into the lumen of the hollow guide 132 via a slot in the hollow guide 132, as shown in FIG. 4.

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A driving knob 116, shown in FIGS. 2, 11a, and 11b, is coupled to the driving roller 120 so that rotation of the driving knob 116 rotates the driving roller 120. A drive mechanism cover 118 shown in FIGS. 2, 12a and 12b is mounted to the housing 110 to cover an opening in the housing 110 for accommodating the driving roller 120 and roller mount 124.

5 The device 100 also includes an adjustable tension screw 128 shown in FIGS. 2 and 3 for adjusting the distance between the outer surface of the driving roller 120 and an inner surface of the hollow guide 132. Adjustment of the tension screw 128 controls the degree of slippage between the outer surface of the driving roller 120 and the fiber F. This allows the device 110 to accommodate a number of different sizes of fiber F. Preferably, the outer surface of the driving
10 roller 120 is designed to reduce slippage of the fiber F.

As shown in FIG. 3, an axially movable sleeve 130 is positioned between an outer surface of the hollow guide 132 and an inner surface of a proximal portion of the tubular member 14a, and between an outer surface of the hollow guide 132 and a distal portion of the housing 110. A coupler 126 shown in FIGS. 3, 4, 7a, 7b, and 7c is connected to a proximal end of the movable
15 sleeve 126.

As shown in FIGS. 2, 3, 9a, and 9b, the device 100 also includes an advancing lever 112 having an end portion pivotally connected to the housing 110. A pivot arm 114 shown in FIGS. 2-4, 6a, and 6b has a first end pivotally connected to the advancing lever 112 and a second end pivotally connected to the coupler 126.

20 Pivoting of the advancing lever 112 with respect to the housing 110 transmits motion to the pivot arm 114 and coupler 126 to move the sleeve 130 about its axis. In other words, pivoting of the advancing lever 112 slides sleeve 130 distally or proximally in the tubular member 14a depending upon the direction of pivoting of the advancing lever 112. With reference to FIG. 3, counter clockwise pivoting of the advancing lever 112 with respect to the
25 housing 110 moves the sleeve 130 distally, and clockwise pivoting of the advancing lever 112 moves the sleeve 130 proximally. Preferably, a spring 122 shown in FIGS. 2 and 3 has one end connected to the advancing lever 112 and another end connected to the pivot arm 114 to bias the advancing lever 112 in the clockwise direction after the lever 112 pivots in the counter clockwise direction.

30 To use the embodiment of FIGS. 2-4, the tubular member 14a is inserted into the body. The fiber material F is passed into an opening in a proximal end of the guiding member 132. The driving roller 116 is rotated to rotate the driving roller 120 and thereby feed fiber F through

the guiding member 132 and into the lumen of the tubular member 14a. When the fiber F encounters body tissue at the opening of the distal portion of the tubular member 14a, the fiber F bunches up inside the distal portion of the tubular member 14a. After a sufficient amount of fiber F accumulates in the distal portion of the tubular member 14a, an operator pivots the
5 advancing lever 112 counter clockwise toward the housing 110 to move the sleeve 130 in the distal direction. The distal end of the sleeve 130 moves against the bunched fiber in the tubular member 14a to force this fiber mass from the distal opening of the tubular member 14a and into a body.

When an operator releases the advancing lever 112, the spring 122 biases the lever 112
10 away from the housing 110 and thereby moves the sleeve 130 in the proximal direction to its original position. During movement of the sleeve 130 in the proximal direction, the outer surface of the driving roller 120 maintains contact with the fiber F to resist proximal movement of fiber F in the device 110.

Preferably, the inner diameter of the tubular member 14a is large enough to allow a
15 sufficient amount of the fiber material to bunch together. In addition, a space for the fiber F could be created using a balloon or some mechanical device. The device 110 also preferably includes structure (not shown) for cutting the fiber F to separate the bunch of fiber from the rest of the fiber. The fiber F can be a suture or a thread.

FIGS. 13a, 13b, 13c, 14a, 14b, 14c, 14d, 15a, 15b, 16a, 16b, 16c, 17a, and 17b show a
20 third embodiment of a device 200 for introducing fiber in the body. As shown in FIGS. 13a, 13b, 13c, 14a, 14b, 14c, and 14d, the device 200 includes a housing 210 having a passage extending along its length. A tubular member 14b shown in FIGS. 13a and 13b has a proximal end connected to a distal end of the housing 210. Preferably, the tubular member 14b is a tube or needle releasably coupled to the housing 210.

As shown in FIG. 13a, an inner lumen of the tubular member 14b is preferably loaded
25 with one or more pellets P of fiber, described below. Preferably, the tubular member 14b contains a plurality of pellets P, for example, ten.

An axially movable push rod 220 shown in FIG. 13b extends in the longitudinal passage
of the housing 210 and in the tubular member 14b. Similar to the embodiment of FIG. 2, the
30 device 200 includes an advancing lever 212 (shown in FIGS. 13a, 13b, 15a, and 15b) pivotally connected to the housing 210, a coupler 216 (shown in FIGS. 17a, 17b, and 17c) connected to the push rod 220, a pivot arm 214 (shown in FIGS. 13a, 13b, 16a, and 16b) having one end pivotally

connected to the advancing lever 212 and another end pivotally connected to the coupler 216, and a spring 218.

To use the device 200, the housing 210 is connected to the tubular member 14b loaded with one or more fiber pellets P and the tubular member 14b is inserted in the body. When the
5 advancing lever 212 is pivoted toward the housing 210, the push rod 220 moves in the distal direction in the housing 210 and tubular member 14b. The distal end of the push rod 220 pushes one or more of the pellets P through an opening in a distal end of the tubular member 14b and into the body. Thereafter, the spring 218 returns the advancing lever 212 and push rod 220 to their original positions.

10 Optionally, the device 200 has unidirectional engagement mechanism (described below) and clutch mechanism (described below) for resisting proximal movement of the push rod when the advancing lever 212 returns to its original position. With such an arrangement, each depression of the advancing lever 212 moves the push rod 220 further in the distal direction so that more of the pellets P may be dispensed through the opening in the tubular member 14b.

15 FIG. 20 shows how the fiber pellet P is formed. A mandrel 310 is inserted into a pin vise 340 and an end portion of fiber F extending from a fiber spool 320 is secured to the pin vise 340. The pin vise 340 is rotated to wrap the fiber F helically around the mandrel 310. When a single layer of fiber F builds up on the mandrel 310, other layers are optionally wound on the initial layer. FIG. 18 shows an example of a fiber pellet P having 3 layers of helically wound fiber, and
20 FIG. 19 shows an example of a fiber pellet P having 2 layers of helically wound fiber. For example, the pellet P is preferably about 1 inch to about 2 inches in length and made of nylon suture material.

After the fiber pellet P is formed, the pellet P is loaded in a tubular member of a device for introducing the pellet P. FIG. 21 shows one example of how the pellet P is loaded in a tubular
25 member 14c, such as a tube or needle. The pellet P is inserted in a lumen of the tubular member 14c and the mandrel 310 is removed from the pellet P. Optionally, additional pellets P are inserted in the tubular member 14c in the same manner.

FIG. 22 shows another example of how a pellet P is loaded in a tubular member 14d, such as a tube or needle. Initially, one or more pellets P are loaded in a cartridge 440 in the same way
30 that the pellet P is inserted in the tubular member 14c shown in FIG. 21. Then the cartridge 440 is coupled to an adapter 410 on the proximal end of the tubular member 14d. A pushing member 450 is then used to push the pellet(s) P from the cartridge 440 into the tubular member 14d.

FIGS. 23-27 show another device for delivering fiber into a body. As shown in FIG. 23, this embodiment includes a syringe 510 having a plunger 512 slidable in a barrel 514. A threaded luer adapter 518 is provided at the distal end of the barrel 514. A push rod 516 extends from a distal end of the plunger 512 and through a distal opening in the barrel 514. Movement of the plunger 512 in the barrel 514 moves the push rod 516 axially.

A tubular member 14e shown in FIGS. 24, 26, and 27 has a threaded luer adapter 520 capable of being connected to the luer adapter 518 on the syringe barrel 514, as shown in FIG. 27. Preferably, tubular member 14e is a tube or needle, and the luer adapter 520 on the tubular member 14e is capable of being connected to a cystoscope for use in imaging the urethra.

As shown in FIG. 27, the tubular member 14e is preferably loaded with one or more of the fiber pellets P. The tubular member 14e is preferably loaded with the fiber pellet(s) P in the same way in which the tubular member 14d shown in FIG. 22 is loaded with pellet(s) P. In other words, one or more of the pellets P are pushed into the tubular member 14e from a cartridge 440 shown in FIGS. 25 and 26 by a pushing member 450.

After one or more pellets P are loaded in the tubular member 14e and the tubular member 14e is connected to the barrel 514, the tubular member 14e is inserted in the body. An operator moves the plunger 512 in the distal direction to extend the push rod 516 in the tubular member 14e. The distal end of the push rod 516 pushes one or more of the pellets P from a distal end of the tubular member 14e and into the body via an opening in the tubular member 14e.

If more pellets P need to be loaded into the tubular member 14e during a procedure, the syringe barrel 514 is removed from the tubular member 14e, optionally while the tubular member 14e is still inserted in the body. Thereafter, the pellets P are loaded with the structure shown in FIG. 26.

For example, the distance from the distal end of the tubular member 14e needle to its connector 520 is 14 inches, and the length of the push rod 516 is 15 inches.

FIG. 28 shows another device 600 for introducing fiber into the body. The device 600 includes a housing 610 and a tubular member 14f connected to the housing 600. Preferably, the tubular member 14f is a needle or tube releasably connected of the housing 610. In addition, the tubular member 14f is preferably loaded with a plurality of the pellets P.

A slide 620 is movable in a proximal end portion of the housing 610. A push rod 630 extends through a passage in the slide 620 and into the tubular member 14f. The slide 620 has a unidirectional engagement mechanism 636 including a pair of pivoting cams 632. The

unidirectional engagement mechanism 636 engages an outer surface of the push rod 630 when the slide 620 is moved in the distal direction, and disengages from the push rod 630 when the slide 620 moves in the proximal direction. In other words, the mechanism 636 may function in a manner similar to a cleat used on a sail boat.

5 The device 600 also includes a return spring 650 and one-way clutch mechanism 640 having a clutch spring 642 and clutch pad 644. The return spring 650 forces the slide 620 in the proximal direction after the slide 620 moves in the distal direction. The one-way clutch mechanism 640 allows distal movement of the push rod 630 and resists proximal movement of the push rod 630. Movement of the slide 620 in the distal direction overcomes a biasing force of
10 the clutch spring 642 and moves the clutch pad 644 out of engagement with the push rod 630. Proximal movement of the slide 620 allows the clutch spring 642 to place the clutch pad 644 into engagement with the push rod 630.

To use the device 600, fiber pellets P are loaded in the tubular member 14f and the tubular member 14f is connected to the housing 610. The tubular member 14f is inserted in the
15 body and the slide 620 is moved in the distal direction with respect to the housing 610. The unidirectional engagement mechanism 636 engages an outer surface of the push rod 630 and the one-way clutch mechanism 640 is placed out of engagement with the push rod 630. This allows the push rod 630 to move in the distal direction along with the slide 620. The distal end of the push rod 630 pushes one or more fiber pellets P through the opening in the tubular member 14f.

20 When the slide 620 is released, the return spring 650 moves the slide 620 proximally back to its original position. The unidirectional engagement mechanism 636 releases its engagement with an outer surface of the push rod 630 and the one-way clutch mechanism 640 engages with the push rod 630. This resists movement of the push rod 630 in the proximal direction.

25 Repeated distal movement and release of the slide 620 advances the push rod 630 further toward the distal end of tubular member 14f and thereby allows for continued dispensing of fiber pellets P from the tubular member 14f without the need to reload the device 600.

30 Preferably, each of the devices mentioned above is used to dispense fiber or fiber pellets for bulking tissue. For example, these devices are preferably used to provide tissue bulking for treating incontinence.

Variations, modifications, and other implementations of what is described herein will occur to those of ordinary skill in the art without departing from the spirit and the scope of the

invention as claimed. Accordingly, the invention is to be defined not by the preceding illustrative description but instead by the spirit and scope of the following claims.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and
5 "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

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THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A device for introducing fiber material into a body, comprising:
a tubular member having a lumen extending to an axial opening in a distal end
5 portion of the tubular member; and
a helical member rotatable within the tubular member to convey the fiber material
through at least one portion of the lumen, out of the opening and into the body.
2. The device of claim 1 further comprising a syringe coupled to the tubular member
10 for delivering the fiber material into the lumen of the tubular member.
3. The device of claim 2 further comprising fiber material.
4. A method for introducing fiber material into a body, comprising:
15 providing a device including (i) a tubular member having a lumen extending to an
axial opening in a distal end portion of the tubular member and (ii) a helical member
rotatable within the tubular member for passing the fiber material through the lumen and
the opening and into the body;
introducing the tubular member into the body; and
20 rotating the helical member within the tubular member to pass the fiber material
through the opening in the distal end portion of the tubular member into the body.
5. The device of claim 3 wherein the fiber material comprises particles in a carrier.
- 25 6. The method of claim 4, further comprising the step of cutting the fiber material as it
passes through the opening in the distal end portion of the tubular member into the body.
7. A device for introducing a fiber material into a body substantially as hereinbefore
described with reference to the accompanying drawings.



8. A method for introducing fiber material into a body substantially as hereinbefore described with reference to the accompanying drawings.

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DATED this 28th day of March 2001

Boston Scientific Limited

10 By its Patent Attorneys
DAVIES COLLISON CAVE

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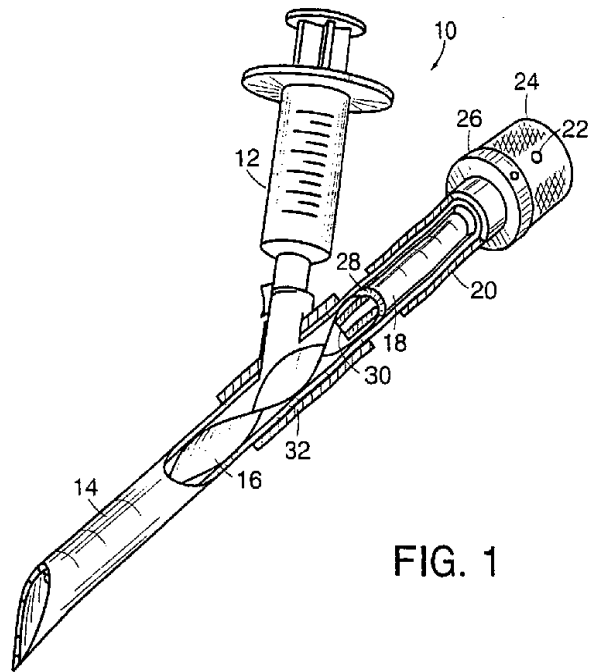


FIG. 1

2/13

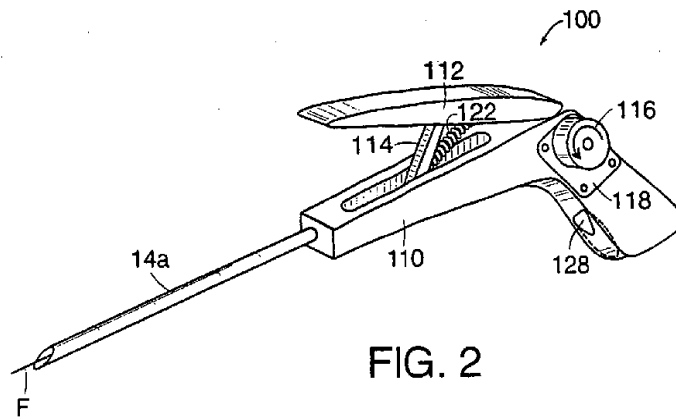


FIG. 2

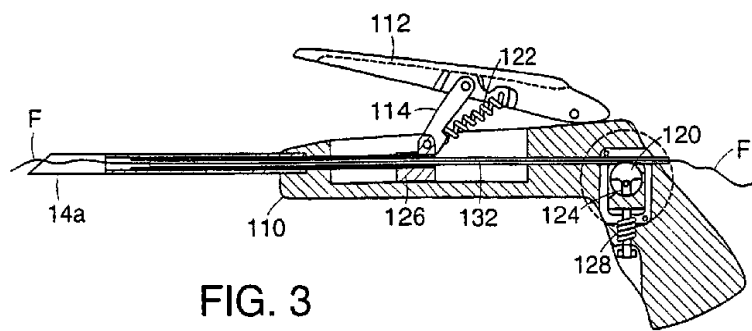


FIG. 3

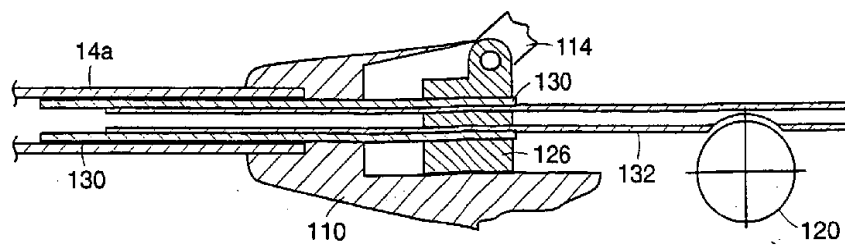


FIG. 4

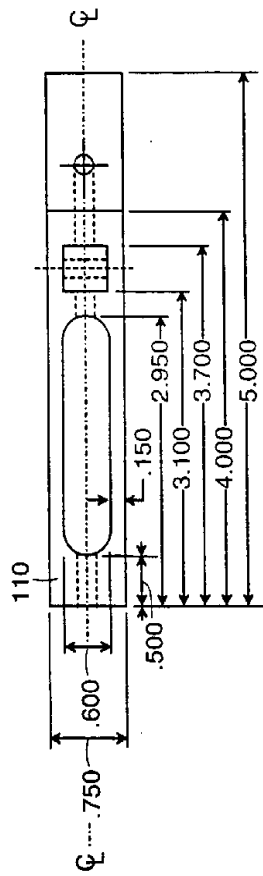


FIG. 5a

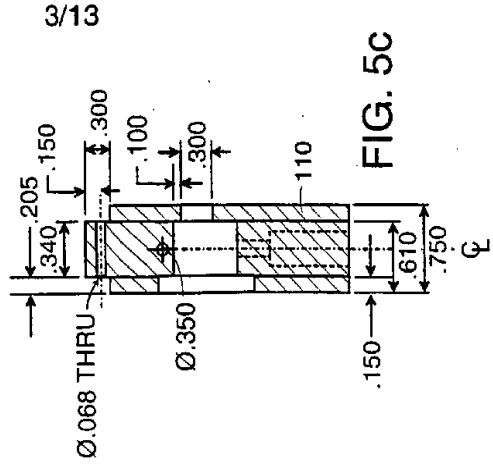


FIG. 5c

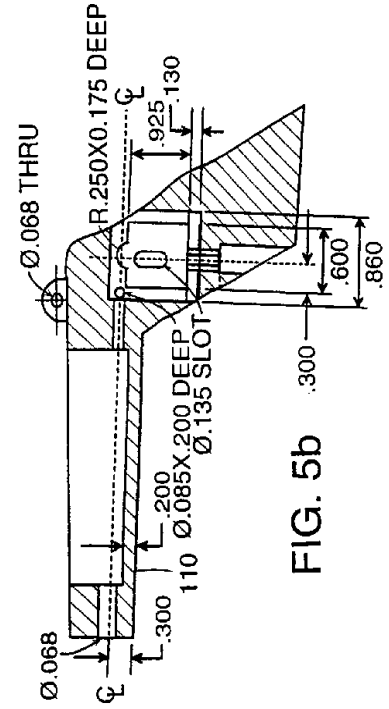


FIG. 5b

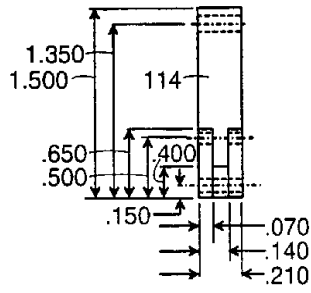


FIG. 6a

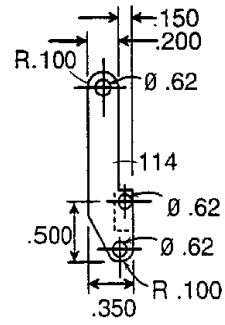


FIG. 6b

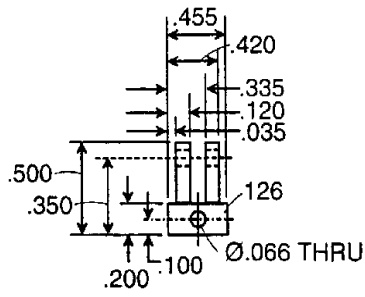


FIG. 7a

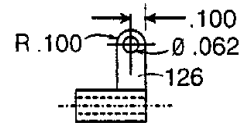


FIG. 7b

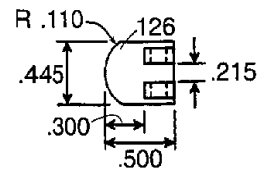


FIG. 7c

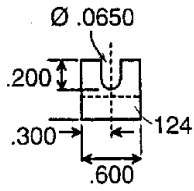


FIG. 8a

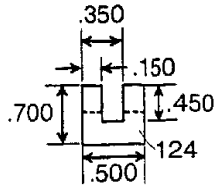


FIG. 8b

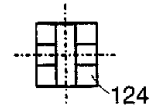


FIG. 8c

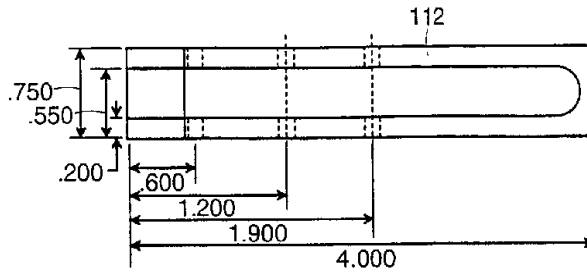


FIG. 9a

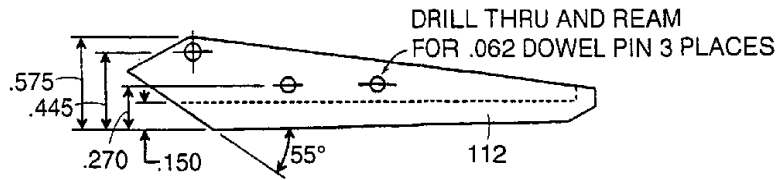


FIG. 9b

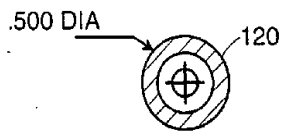


FIG. 10a

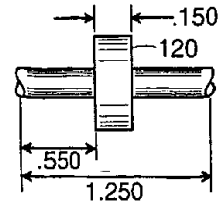


FIG. 10b

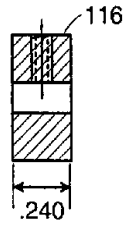


FIG. 11a

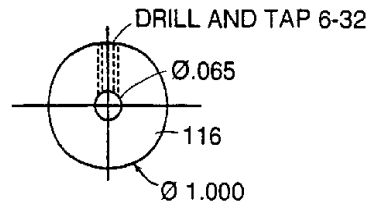


FIG. 11b

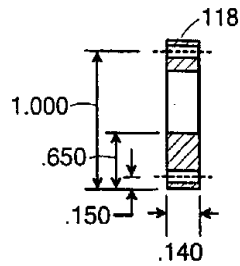


FIG. 12a

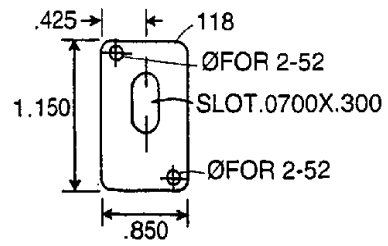


FIG. 12b

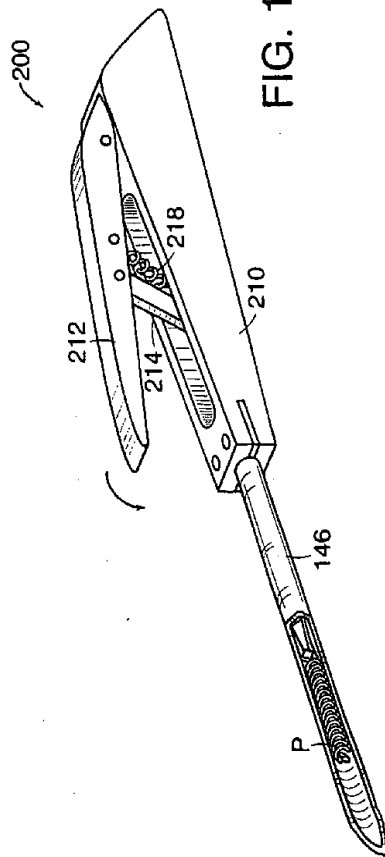


FIG. 13a

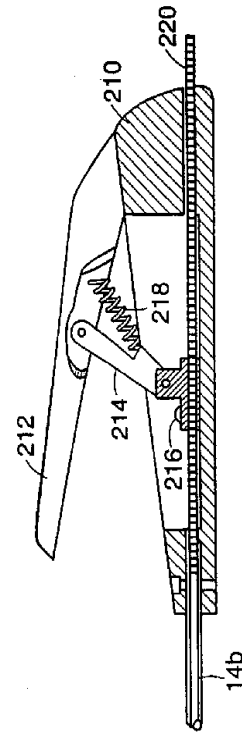


FIG. 13b

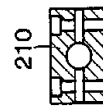


FIG. 13c

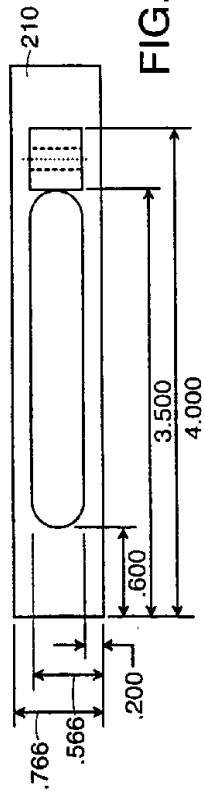
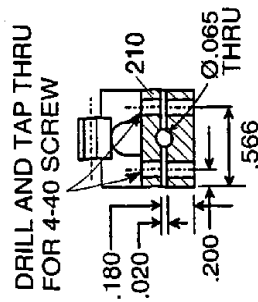


FIG. 14a



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FIG. 14c

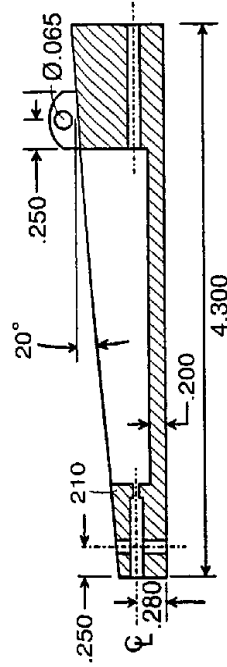


FIG. 14b

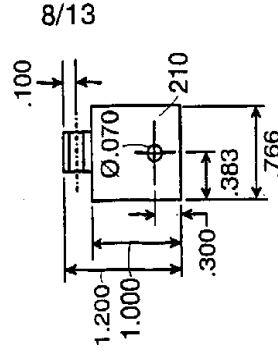
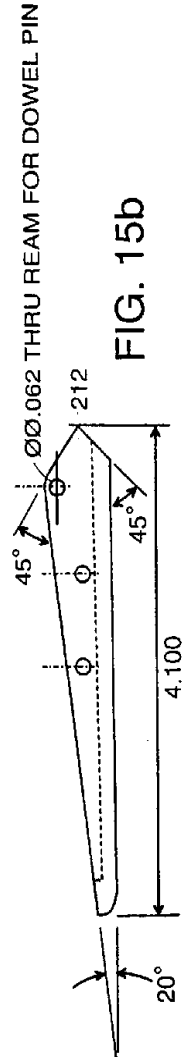
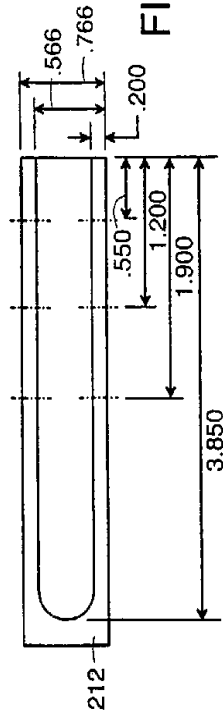


FIG. 14d



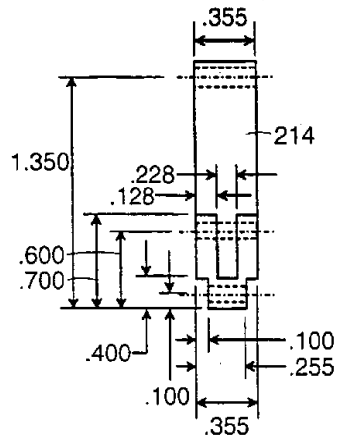


FIG. 16a

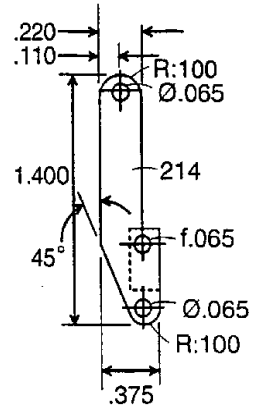


FIG. 16b

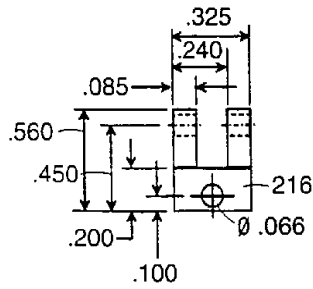


FIG. 17a

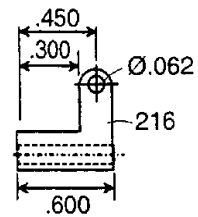


FIG. 17b

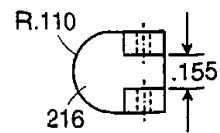
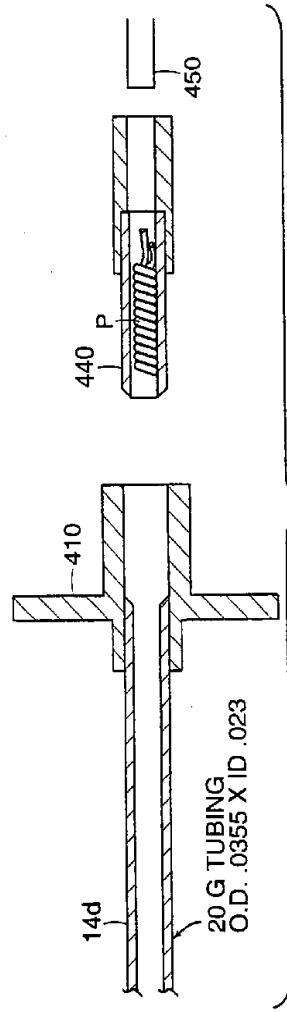
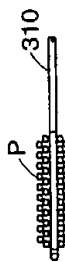
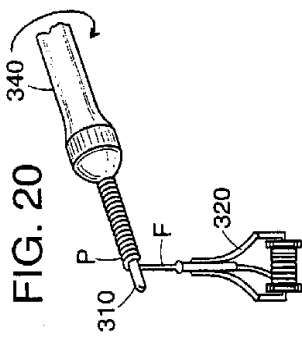
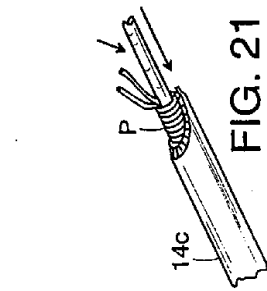


FIG. 17c



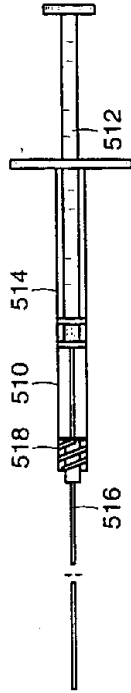


FIG. 23



FIG. 24



FIG. 25



FIG. 26

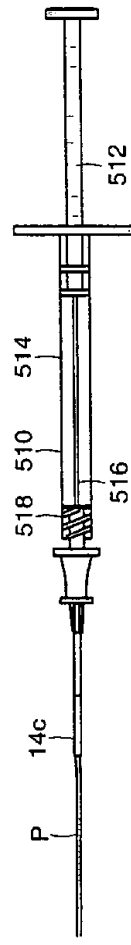


FIG. 27

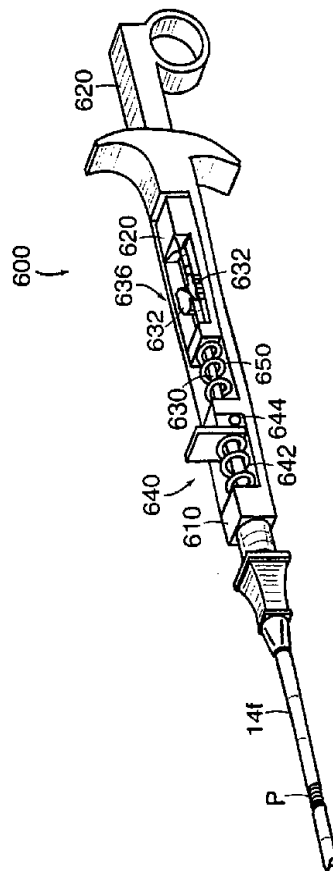


FIG. 28