659656

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AUSTRALIA

PATENTS ACT 1990

PATENT REQUEST: STANDARD PATENT

I/We, the Applicant(s)/Nominated Person(s) specified below, request I/We be granted a patent for the invention disclosed in the accompanying standard complete specification.

[70,71] Applicant(s)/Nominated Person(s):

Cook Incorporated, of 925 South Curry Pike, Bloomington, Indiana, 47402, UNITED STATES OF AMERICA

[54] Invention Title:
Surgical Introducer Sheath

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Details of Basic Application(s):

[31] Appl'n No(s):	[33] Country:	[32] Application Date:
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Cook Incorporated

By:

Registered Patent Attorney

IRN: 216453

INSTR CODE: 54781

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NOTICE OF ENTITLEMENT

I, John Gordon Hinde, of Spruson & Ferguson, St Martins Tower, 31 Market Street, Sydney, New South Wales 2000, Australia, being the patent attorney for the Applicant/Nominated Person in respect of an application entitled:

Surgical Introducer Sheath

state the following:-

The Applicant/Nominated Person has entitlement from the actual inventor~~(s)~~ as follows:-

The Applicant/Nominated Person is the assignee of the actual inventor~~(s)~~.

The Applicant/Nominated Person is entitled to rely on the basic application~~(s)~~ listed on the Patent Request as follows:

The Applicant/Nominated Person is the assignee of the basic applicant~~(s)~~.

The basic application~~(s)~~ listed on the Patent Request is/~~are~~ the application~~(s)~~ first made in a Convention country in respect of the invention.

DATED this THIRTY FIRST day of JULY 1992

.....

John Gordon Hinde

IRN: 216452 INSTR CODE: 54781

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(19) AUSTRALIAN PATENT OFFICE (10) Acceptance No. 659656

(54) Title
SURGICAL INTRODUCER SHEATH

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(56) Prior Art Documents
US 4842590
US 4516972
US 3879516

(57) Claim

1. A flexible, kink-resistant introducer sheath, comprising:

an inner tube with a passageway extending longitudinally therethrough;

a resilient coil fitted around the outer surface of the inner tube with the coil exerting a compressive force on that outer surface; and

an outer tube whose inner surface is formed about and in contact with the turns of the coil and also in contact with the surface of the inner tube between the spaces of the turns.

12. A method of manufacturing an introducer sheath, said sheath comprising an inner tube with a passageway extending longitudinally therethrough, an outer tube, and a reinforcing coil of resilient material between the two tubes, wherein the method comprises the steps of fitting the coil around the inner tube in such a manner that the coil remains in contact with the outer surface of the inner tube, and exerts a compressive force thereon, and wherein the outer tube is heat treated to extend between the spaces of the coil and to contact the outer surface of the inner tube.

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COMPLETE SPECIFICATION

FOR A STANDARD PATENT

ORIGINAL

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Invention Title: Surgical Introducer Sheath

The following statement is a full description of this invention, including the best method of performing it known to me/us:-

SURGICAL INTRODUCER SHEATH

This invention relates to surgical introducer sheaths.

Introducer sheaths are well-known for percutaneous vascular access such as for introducing catheters and/or medication. These sheaths are of a thin-wall construction such as of polytetrafluoroethylene or fluorinated ethylene propylene, but tend to kink. Increasing the wall thickness only minimally improves the level of kink resistance. Sheaths used in hemofiltration and dialysis may become bent or pinched off due to repeated use or patient movement. A kinked sheath cannot be straightened while in a patient, and must be removed. An alternative site if available must then be used and could cause a life threatening situation.

Such sheaths can be easily kinked whilst various catheters are introduced therethrough during emergency procedures. Small diameter introducer sheaths are also typically bent and kinked under the time constraints of an emergency situation.

Introducer sheaths are described in US Patent Nos. 4,634,432; 4,657,772 and 4,705,511.

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

There is disclosed herein a flexible, kink-resistant introducer sheath, comprising:

an inner tube with a passageway extending longitudinally therethrough;

a resilient coil fitted around the outer surface of the inner tube with the coil exerting a compressive force on that outer surface; and

an outer tube whose inner surface is formed about and in contact with the turns of the coil and also in contact with the surface of the inner tube between the spaces of the turns.

There is further disclosed herein a method of manufacturing an introducer sheath, said sheath comprising an inner tube with a passageway extending longitudinally therethrough, an outer tube, and a reinforcing coil of resilient material between the two tubes, wherein the method comprises the steps of fitting the coil around the inner tube in such a manner that the coil remains in contact with the outer surface of the inner tube, and exerts a compressive force thereon, and wherein the outer tube is heat treated to extend between the spaces of the coil and to contact the outer surface of the inner tube.

In the preferred embodiment, the coil reinforces the wall to provide an extremely kink-resistant introducer sheath. A predetermined uniform spacing between the coils is preferable, although extremely wide spacing may weaken the wall and

create a rough surface and narrow spacing may not allow sufficient room for connecting the outer tube to the inner tube. In the preferred embodiment, the coil comprises a flat wire coil for further improving the strength of the introducer sheath.

The wall of the inner tube advantageously prevents the coil turns from extending into the inner tube passageway. As a result, the inner tube passageway has a uniform diameter for passing the largest possible diameter catheter therethrough. The protrusion of coil turns into the passageway would establish a varying diameter, which would limit the size of the catheter passable therethrough.

The heat formable polyamide material is advantageously

self-levelling for providing a smooth outer surface which also reduces the formation of blood clots thereon.

The inner diameter of the passageway about the distal ends of the inner and outer tubes is preferably uniform to again minimize the formation of blood clots on the inner surface of the inner tube.

Brief description of the drawings

FIG.1 depicts an embodiment introducer sheath;

FIG.2 is a partially sectioned view of FIG.1;

FIGs.3 and 4 are views illustrating manufacture of the sheath.

FIG.1 depicts an illustrative flexible, kink-resistant, introducer sheath 10 with a tapered dilator 11 extending longitudinally through the passageway of the sheath. As shown, the introducer sheath includes an outer tube 12 with a tapered distal end 13 and connector valve 14 attached about proximal end 15 of the sheath. Valve 14 includes a silicone disk (not shown) for preventing the backflow of fluids. The disk includes a slit for the insertion of dilator 11. By way of example, the dilator 11 has a 6.0 French 0.2cms (0.079") outside diameter. Connector 14 also includes side arm 16 to which polyvinyl tube 17 and male Luer lock connector 18 are connected for introducing and aspirating fluids therethrough. Dilator 11 includes tapered distal end 19 for accessing and dilating a vascular access site over a well-known and commercially available wire guide. The guide is inserted in the vessel with an introducer needle using, for example, the well-known percutaneous vascular access Seldinger technique. A well-known male Luer lock connector hub 20 is attached at the proximal end of the dilator for connection to syringes and other medical apparatus.

Depicted in FIG.2 is a partially sectioned view of introducer sheath 10 with dilator 11 removed from longitudinal passageway 21. The sheath comprises inner tube 22, flat wire reinforcing coil 23 compression fitted therearound, and outer tube 12 mechanically connected to roughened outer surface 26 of the inner tube through the spacings of the coil. Inner tube 22 is a 7.4cms length of a lubricous material tube such as polytetrafluoroethylene having a uniform inside diameter in the range of 0.2cms (0.0825") to 0.213cms (0.084") with

a wall thickness of 0.0038cms (0.0015") plus or minus 0.0013 cms (0.0005") before heating. The inner tube has a minimum inside dimension of 0.206 cms (0.081") after heating. The lubricous polytetrafluoroethylene material presents a slippery inner surface 25 for the easy insertion and withdrawal of the dilator as well as other catheters and medical apparatus. Inner surface 25 is also smooth and nonporous for minimizing the formation of blood clots and other thrombi thereon. Outer surface 26 of the inner tube is chemically etched to form a rough outer surface to which outer tube 12 is mechanically connected using a shrinking and formation process. The uniform inner diameter of inner tube 22 extends the entire length of passageway 21 for passing the largest possible diameter catheter therethrough. The wall of the inner tube prevents the turns of compression-fitted coil 23 from protruding into inner tube passageway 21.

Coil 23 comprises a plurality of spaced flat wire turns such as 27-31, which preferably have equal width spaces 32-35 therebetween. Coil 23 is 6.5cms in length with an outside diameter of 0.239cms (0.0942") plus or minus 0.005cms (0.002") formed from 0.0076cms (0.003") thick by 0.03cms (0.012") wide flat rectangular stainless steel wire wound preferably with a uniform space in the range of 0.013cms (0.005") to 0.038cms (0.015") between the turns of the coil. Wire coil 23 is compression fitted around the outer surface of inner tube 22 approximately 4mms from the distal end thereof and approximately 5mms from the proximal end thereof to maintain the spacing between the turns of the coil. The coil is compression fitted by collapsing inner tube 22 and inserting the wire coil thereover. Inner tube 22 is then compressed-air expanded to engage and compression fit the inner surface of the flat wire coil. A mandril inserted through the passageway of the inner tube further compresses the inner tube against the coil turns during the manufacture of the sheath as hereinafter described. The coil is preferably positioned away from the distal and proximal ends of the inner tube to permit tapering and flaring of the sheath without extending the coil turns through the polyamide material of the outer tube.

Outer tube 12 is 7.4cms in length with an inside diameter of 0.26cms (0.103") plus or minus 0.005cms (0.002") of a heat formable polyamide material such as nylon that is heat shrunk over coil 23, which in turn is compression fitted over inner tube 22. The wall thickness of the nylon tube is approximately 0.0165cms (0.0065") plus or minus 0.00254cms (0.001"). The outer tube is heated and compressed through the spaces between the coil turns with a heat shrink tube for mechanically connecting to rough outer surface 26 of the inner tube. As a result, the outside diameter of the outer tube is approximately 0.0559cms (0.022") greater than that of the inner tube. After the outer tube is heat shrunk on to the roughened surface of the inner tube, the shrink tube is removed therefrom, and a taper formed at the distal end of the sheath. As a result, the thickness of the sheath including the inner tube, coil and outer tube is approximately 0.0279cms (0.011"). The 4mms length about the distal end of the inner and outer tubes are cut to within a range of 0.0254cms (0.01") to 0.229cms (0.09") from the end of coil 23 depending on the inside diameter of the sheath. For a 6.0 French introducer sheath, approximately 0.0508cms (0.02") of outer tube 12 is externally tapered about the distal end to form contact surface area 38. Tapered distal end 13 is formed by cutting and slitting a 3mms length of nylon tubing having a 0.254cms (0.1") inside diameter and inserting it into a taper mould. The short length of tubing is heated, and the distal end of the sheath with a mandril inserted therethrough is inserted into the taper mould to thermally bond nylon tip material 24 to the outer tube and to form tapered distal end 13, as shown. As a result, the inside diameter of outer tube 12 and inner tube 22 about the distal end thereof assumes the uniform inner diameter of the inner tube. After the distal end is tapered, the outer tube extends approximately 0.3cms (0.12") beyond the distal end of the inner tube and 0.356cms (0.14") beyond the distal end of the flat wire coil. The distal end of inner tube 22 may vary along the length of the tapered distal end of the outer tube, but should not extend all the way to the distal end of the outer tube so as not to break the tapered surface of the outer tube. In this particular embodiment, nylon tip material 24 is of the

same durometer as that of outer tube 12. However, it is contemplated that the tip material may have a durometer other than that of the outer tube material. It is further contemplated that the tip material preferably has a harder durometer so as to further facilitate entry into the access site. It can, however, be softer if required. Proximal end 15 of the sheath is formed into a flared configuration such as inserting over a heated, tapered tip end and then cooled.

FIG.3 depicts a partially sectioned view of introducer sheath 10 with heat shrink tube 36 positioned over outer tube 12 and flat wire coil 23 with longitudinal space 39 therebetween. As previously described, flat wire coil 23 is compression fitted around inner tube 22. Prior to heating shrink tube 36 and forming outer tube 12, mandril 37 is inserted through passageway 21 to preferably maintain uniform spacing between the coil turns. As shown, heat shrink tube 36 is somewhat longer than nylon outer tube 12 and has an inside diameter in the range of 0.21cms (0.0825") to 0.213cms (0.084") with a wall thickness of approximately 0.0038cms (0.0015") plus or minus 0.0013cms (0.0005"). The heat shrink tube is preferably of a fluorinated ethylene propylene heat formable material. The nylon outer tube has a processing temperature range for the heat formation thereof in the range of 198°C to 278°C (356 to 500 degrees Fahrenheit).

FIG.4 depicts heat shrink tube 36 being oven heated to a temperature of 203°C (365 degrees Fahrenheit), which is in the processing temperature range of the nylon outer tube material. As the heat shrink tube shrinks, the heated nylon outer tube material 12 is compressed between coil turns 27-31 in spaces 32-35 to mechanically connect with roughened surface 26 of inner tube 22. The heat formable nylon material tube is also self-levelling, which provides a uniform outer diameter surface for the sheath. Heat shrink tube 36 is then split from the sheath. As previously described, distal end 13 is tapered, and proximal end 15 is flared.

It is contemplated that various other materials may be utilized for the inner, outer and heat shrink tubes. It is also contemplated that introducer sheaths with an inside diameter ranging in size from 5.5 to 14.0 French are readily producible. In summary, the

flexible, kink-resistant introducer sheath provides a thin-wall sheath that is extremely kink-resistant for long-term use applications. The flat wire coil construction of this introducer sheath is also extremely kink-resistant with small outside diameter dilators during introduction through an access site.

The claims defining the invention are as follows:

1. A flexible, kink-resistant introducer sheath, comprising:

an inner tube with a passageway extending longitudinally therethrough;

a resilient coil fitted around the outer surface of the inner tube with the coil exerting a compressive force on that outer surface; and

an outer tube whose inner surface is formed about and in contact with the turns of the coil and also in contact with the surface of the inner tube between the spaces of the turns.

2. The sheath of claim 1, wherein the coil has equally spaced turns.

3. The sheath of claim 1 or 2, wherein the turns are of flat wire.

4. The sheath of any one of claims 1 to 3, wherein the ends of the inner and outer tubes extend beyond the ends of the coil.

5. The sheath of claim 4, wherein the distal end of the outer tube extends beyond the distal end of the inner tube, and is tapered.

6. The sheath of claim 4 or claim 5, wherein tip material is bonded to the distal end of the outer tube, said tip material being adapted to facilitate sheath insertion.

7. The sheath of any one preceding claim, wherein the sheath has a uniform internal diameter.

8. The sheath of any one preceding claim, wherein the proximal end of the tube is flared.

9. The sheath of any one preceding claim, wherein the inner tube has a smooth inner surface.

10. The sheath of any one preceding claim, wherein the inner tube comprises a lubricous material such as polytetrafluoroethylene.

11. The sheath of any one preceding claim, wherein the outer tube comprises polyamide which optionally comprises nylon.

12. A method of manufacturing an introducer sheath, said sheath comprising an inner tube with a passageway extending longitudinally therethrough, an outer tube, and a reinforcing coil of resilient material between the two tubes, wherein the method comprises the steps of fitting the coil around the inner tube in such a manner that the coil remains in contact with the outer surface of the inner tube, and exerts a compressive force thereon, and wherein the outer tube is heat treated to extend between the spaces of the coil and to contact the outer surface of the inner tube.

13. The method of claim 12, wherein the inner tube has a roughened outer surface.

14. The method of claim 12 or claim 13, wherein the inner tube has a smooth inner surface.

15. The method of any one of claims 12 to 14, wherein the turns of the coil are of predetermined spacing.

16. The method of any one of claims 12 to 15, wherein a shrinkable tube is positioned around the outer tube in order to compress the outer tube between the spaces of said turns.

17. The method of any one of claims 12 to 16, wherein a mandrel is positioned inside the inner tube to maintain the shape of the sheath during manufacture.

18. A flexible, kink-resistant introducer sheath substantially as hereinbefore described with reference to the accompanying drawings.

19. A method of manufacturing an introducer sheath, said method being substantially as hereinbefore described with reference to the accompanying drawings.

DATED this Tenth Day of March 1995
Cook Incorporated

Patent Attorneys for the Applicant
SPRUSON & FERGUSON

Surgical Introducer Sheath

ABSTRACT

(with reference to FIG.2)

A flexible, kink-resistant, introducer sheath for percutaneous vascular access. The introducer sheath includes a flat wire coil with uniform spacing between the turns, which is compression fitted about an inner, lubricous material polytetrafluoroethylene tube. The introducer sheath further includes an outer tube of a heat formable polyamide material which is heat formed and compressed through the spaces between the turns of the wire coil to mechanically connect to the roughened outer surface of the inner tube. The distal end of the outer tube is tapered in a mould with additional polyamide outer tube material. The proximal end of the sheath is flared for connection to a connector fitting.

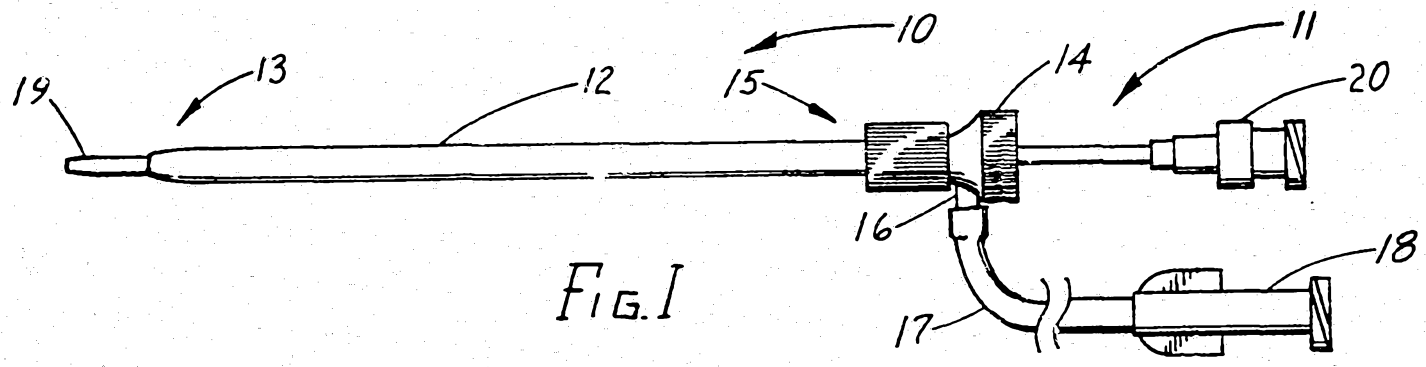

FIG. 1

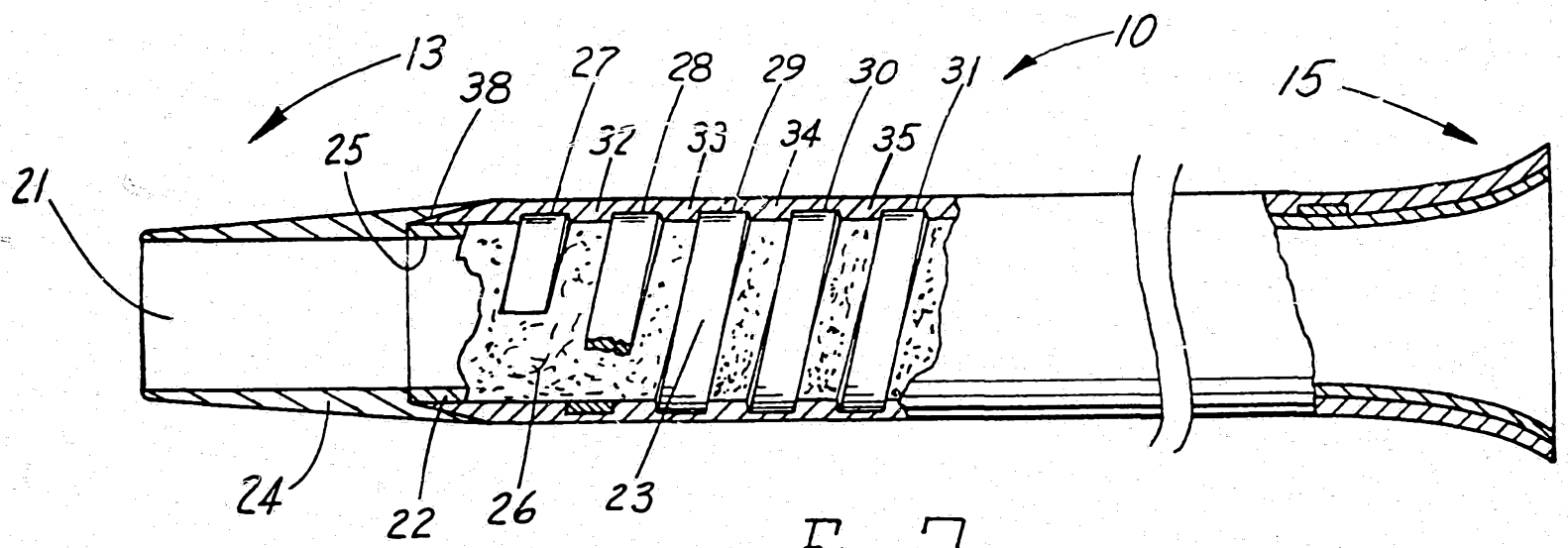

FIG. 2

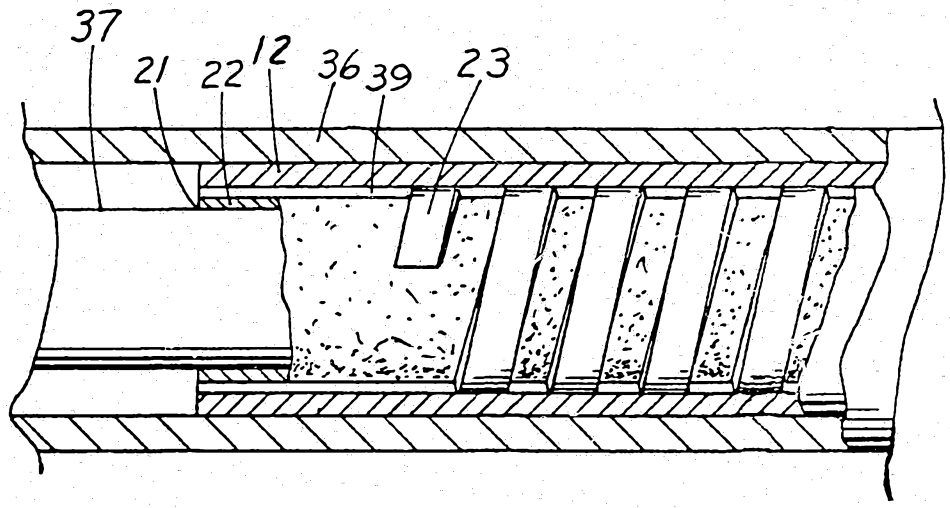

FIG. 3

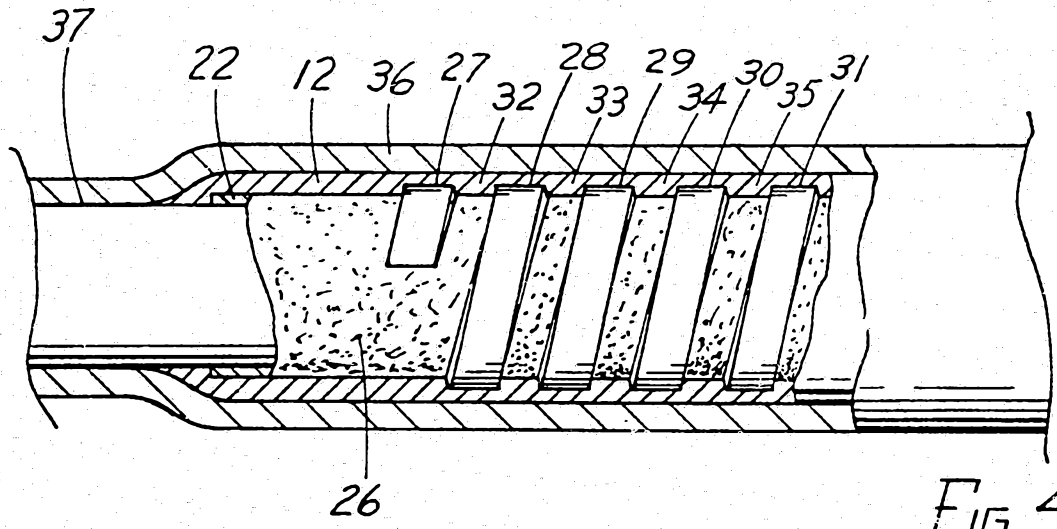

FIG. 4