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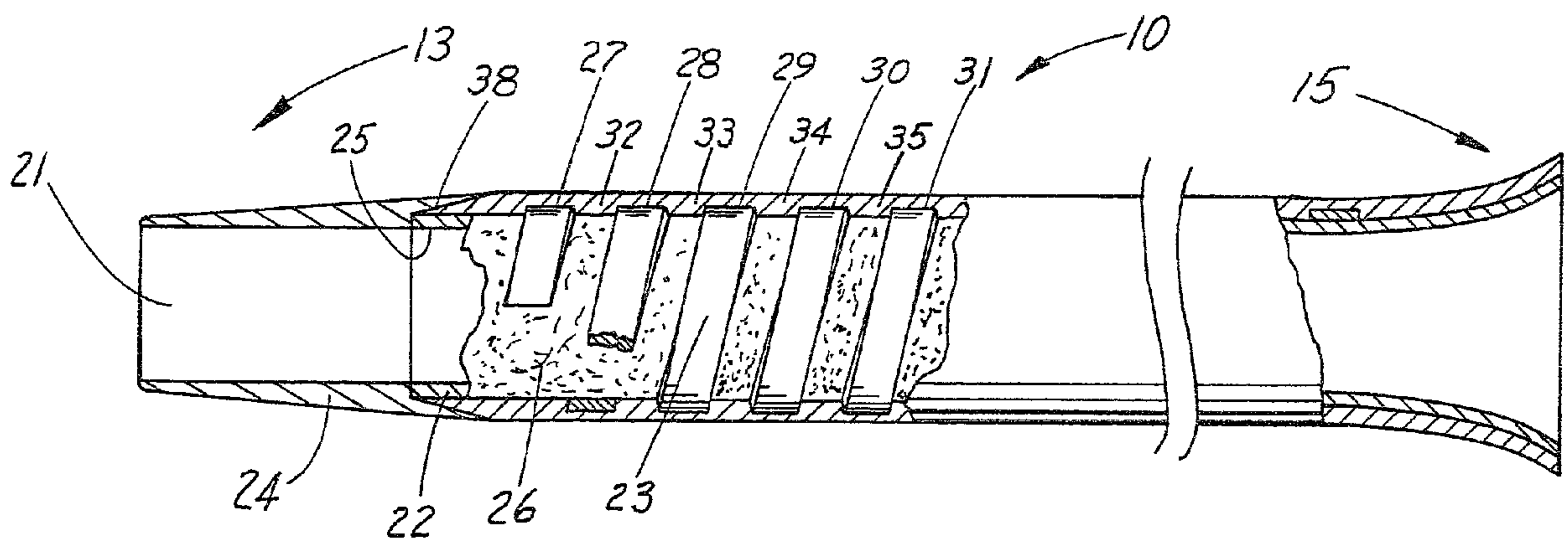
(54) Titre : GAINE EXTERIEURE, SOUPLE RESISTANT AU GAUCHISSEMENT
(54) Title: A FLEXIBLE, KINK-RESISTANT, INTRODUCER SHEATH



(57) Abrégé/Abstract:
A flexible, kink-resistant, introduces 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 polytetrafluorethylene 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 mold with additional polyamide outer tube material. The proximal end of the sheath is flared for connection to a connector fitting.

Abstract of the Disclosure

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 polytetrafluorethylene 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 mold with additional polyamide outer tube material. The proximal end of the sheath is flared for connection to a connector fitting.

A Flexible, Kink-Resistant, Introducer Sheath

Technical Field

This invention relates generally to sheaths for maintaining vascular access and for introducing catheters and medication therethrough and, in particular, to a flexible, kink-resistant, introducer sheath.

Background of the Invention

Introducer sheaths are well-known for percutaneous vascular access and typically comprise polytetrafluoroethylene or fluorinated ethylene propylene. These sheaths are of a thin-wall construction, but tend to kink. Increasing the thickness of the sheath wall minimally improves the level of kink resistance, which is still unacceptable. Sheaths used in hemofiltration and dialysis, in particular, are prone to kinking since they remain positioned in a patient's body for a long time. While positioned in a patient, the sheath may be bent or pinched off and, as a result, kinked due to repeated use or patient movement. A kinked sheath is unusable and cannot be straightened while positioned in the body of a patient. Consequently, the sheath must be removed, leaving an enlarged, bleeding opening, which typically cannot be reused. Vascular access is then attempted at an alternative site, and the procedure is restarted. Restarting the procedure causes a time delay, which may be life threatening. In some cases, an alternative site is not available for introducing another sheath.

Another problem with thin-wall sheaths is that an emergency room physician will typically kink an introducer sheath while inserting various catheters therethrough during emergency procedures. Small diameter introducer sheaths are also typically bent and kinked under the time constraints of an emergency situation. As a result, a new sheath must be introduced at the same or another access site.

Another introducer sheath is described in U.S. Patent Nos. 4,634,432; 4,657,772; and 4,705,511. This introducer sheath utilizes a helical coil spring and a cylindrical wall formed by dipping the spring in a protective coating composition, which completely surrounds the spring. The coating composition comprises a thermoplastic polymer material dissolved in a solvent solution. Although this introducer sheath appears to be more kink-resistant and flexible than a polytetrafluoroethylene sheath, the cylindrical wall is approximately twice as thick as that of the polytetrafluoroethylene sheath with the same inside diameter. The increased outside diameter of this introducer sheath significantly increases the size of the access site, which further accentuates the problem of bleeding.

Summary of the Invention

The foregoing problems are solved and a technical advance is achieved in an illustrative flexible, kink-resistant, introducer sheath comprising a coil having a plurality of uniformly spaced turns positioned between an inner and an outer tube. The outer tube is connected to the inner tube through the uniform spacing of the coil turns. As a result, the coil reinforces the wall to provide an extremely kink-resistant introducer sheath. A predetermined uniform spacing between the coils is important since extremely wide spacing weakens the wall and creates a rough surface. Narrow spacing does 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. In contrast, the protrusion of coil turns into the passageway establishes a varying diameter, which limits the size of the catheter passable therethrough. The inner tube also comprises a lubricous material such as polytetrafluoroethylene, which presents a slippery surface for easy insertion of a catheter therethrough. Furthermore, the inner tube includes a smooth inner surface for resisting the formation of blood clots thereon. The inner tube also advantageously includes a rough outer surface for improving the connection of the outer tube thereto through the uniform spacing of the coil turns.

The outer tube advantageously comprises a heat formable polyamide material such as nylon for mechanically connecting with the rough outer surface of the inner tube. The sheath further comprises a heat shrinkable tube positioned around the outer tube for compressing the outer tube between the uniform spacing of the compression-fitted coil turns and mechanically connecting the outer tube to the rough surface of the inner tube when heated. The heat formable polyamide material is also advantageously self-leveling for providing a smooth outer surface which also reduces the formation of blood clots thereon.

The distal ends of the inner and outer tubes extend beyond the distal end of the coil. The distal end of the outer tube is tapered and extends beyond the distal end of the inner tube to advantageously prevent the inner tube from presenting a rough edge or surface, which may cause injury to the vessel wall. The inner diameter of the passageway about the distal ends of the inner and outer tubes is uniform to again minimize the formation of blood clots on the inner surface of the inner tube.

The proximal ends of the inner and outer tubes also extend beyond the proximal end of the coil and are flared for attachment to a connector.

In accordance with one aspect of the present invention there is provided a flexible, kink-resistant, introducer sheath, comprising: an inner tube having a passageway extending longitudinally therethrough; a coil having a plurality of turns positioned longitudinally and compression fitted around said inner tube, said turns having a predetermined spacing therebetween; and an outer tube positioned longitudinally around said coil and said inner tube and connected to said inner tube through the spaces between said turns.

In accordance with another aspect of the present invention there is provided a method of manufacturing a percutaneous introducer sheath, said method comprising the step of securing a reinforcing coil within tubular material(s), said tubular material(s) defining a passageway extending longitudinally therethrough; characterised in that the said sheath comprises an inner tube and an outer tube; and in that the method further comprises the steps of compression fitting the coil around the inner tube and heat treating the outer tube to extend between the spaces of the coil and to bond to the inner tube.

Brief Description of the Drawings

FIG. 1 depicts an illustrative flexible, kink-resistant, introducer sheath of the present invention;

FIG. 2 depicts a partially sectioned view of the introducer sheath of FIG. 1;

FIG. 3 depicts a partially sectioned view of the introducer sheath of the present invention with a heat shrink tube prior to being heated; and

FIG. 4 depicts a partially sectioned view of the introducer sheath of FIG. 3 with the heat shrink tube heated and the outer tube resultingly formed.

Detailed Description

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. Well-known connector valve 14 includes a silicone disk (not shown) for preventing the backflow of fluids therethrough. The disk includes a slit for the insertion of dilator 11. By way of example, the dilator 11 has a 6.0 French (.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 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 7.4 cm length of a lubricous material tube such as polytetrafluoroethylene having a uniform inside diameter in the range of .0825" to .0840" with a wall thickness of .0015" plus or minus .0005" before heating. The inner tube has a minimum inside dimension of .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 in a well-known manner for forming a rough outer surface to which outer tube 12 is mechanically connected using a well-known heat 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 flat wire turns, for example, 27-31, with uniform spacing including equal width spaces 32-35 therebetween. Coil 23 is 6.5 cm in length with an outside diameter of .0942" plus or minus .0020" formed from .003" thick by .012" wide flat rectangular stainless steel wire wound with a uniform space in the range of .005" to .015" between the turns of the coil. Wire coil 23 is compression fitted around the outer surface of inner tube 22 approximately 4 mm from the distal end thereof and approximately 5 mm from the proximal end thereof to maintain the uniform 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 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 7.4 cm in length with an inside diameter of .103" plus or minus .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 .0065" plus or minus .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 .022" greater than that of the inner tube. After the outer tube is heat shrunk onto 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 .011". The 4 mm length about the distal end of the inner and outer tubes are cut to within a range of .010" to .090" from the end of coil 23 depending on the inside diameter of the sheath. For a 6.0 French introducer sheath, approximately .020" of outer tube 12 is externally tapered about the distal end in a well-known manner to form contact surface area 38. Tapered distal end 13 is formed by cutting and slitting a 3 mm length of nylon tubing having a .100" inside diameter and inserting it into a well-known taper mold. The short length of tubing is heated, and the distal end of the sheath with a mandril inserted therethrough is inserted into the taper mold 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 .120" beyond the distal end of the inner tube and .140" 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 may have a harder durometer so as to further facilitate entry into the access site. Proximal end 15 of the sheath is formed into a flared configuration in a well-known manner 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 further maintain the 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 .0825" to .0840" with a wall thickness of approximately .0015" plus or minus .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 356 to 500 degrees

Fahrenheit.

FIG. 4 depicts heat shrink tube 36 being oven heated to a temperature of 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 uniform spaces 32-35 to mechanically connect with roughened surface 26 of inner tube 22. The heat formable nylon material tube is also self-leveling, 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 to be understood that the above-described flexible, kink-resistant, introducer sheath is merely an illustrative embodiment of the principles of this invention and that other introducer sheaths may be devised by those skilled in the art without departing from the spirit and scope of this invention. 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.

CLAIMS:

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

an inner tube having a passageway extending longitudinally therethrough;

a coil having a plurality of turns positioned longitudinally and compression fitted around said inner tube, said turns having a predetermined spacing therebetween; and

an outer tube positioned longitudinally around said coil and said inner tube and connected to said inner tube through the spaces between said turns.

2. The sheath of claim 1 wherein said passageway of said inner tube has a uniform diameter.

3. The sheath of claim 2 wherein said inner tube comprises a lubricous material.

4. The sheath of claim 3 wherein said lubricous material comprises polytetrafluoroethylene.

5. The sheath of claim 3 wherein said inner tube includes a smooth inner surface.

6. The sheath of claim 4 wherein said outer tube comprises polyamide.

7. The sheath of claim 6 wherein said polyamide comprises nylon.

8. The sheath of claim 1 wherein said inner tube includes a rough outer surface.

9. The sheath of claim 1 wherein said coil is compression fitted around said inner tube by winding said coil around said inner tube.

10. The sheath of claim 1 wherein said coil comprises flat wire.

11. The sheath of claim 1 wherein said inner tube includes a rough outer surface and wherein said outer tube comprises a heat formable material mechanically connected to said rough outer surface of said inner tube.

12. The sheath of claim 11 further comprising a heat shrinkable tube positioned around said outer tube for compressing said outer tube between the spaces of said coil and mechanically connecting said outer tube to said rough

surface of said inner tube when heated.

13. The sheath of claim 1 wherein each of said inner and outer tubes and said coil includes an end and wherein the end of said inner and outer tube extends beyond the end of said coil.

14. The sheath of claim 13 wherein the end of said outer tube ends beyond the end of said inner tube and is tapered.

15. The sheath of claim 14 wherein the passageway about the ends of said inner and outer tubes has a uniform inner diameter.

16. The sheath of claim 14 further comprising tip material bonded to the distal end of said outer tube.

17. The sheath of claim 16 wherein the ends of said inner and outer tubes are flared.

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

an inner tube having a smooth inner surface, a rough outer surface, and a uniform diameter passageway extending longitudinally therethrough;

a flat wire coil having a plurality of turns positioned longitudinally and compression fitted around said inner tube, said turns having a predetermined spacing therebetween; and

an outer tube positioned longitudinally and heat shrunk between the spaces of said coil and around said coil and around said inner tube and mechanically connected to said rough outer surface of said inner tube.

19. The sheath of claim 18 further comprising a heat shrink tube positioned around said outer tube.

20. A percutaneous introducer sheath, comprising:

a lubricous material tube having a smooth inner surface defining a uniform passageway extending longitudinally therethrough, and an etched outer surface;

a flat wire coil having a plurality of turns positioned longitudinally and compression fitted around said lubricous material tube and proximally from an end of said lubricous material tube, said turns having a predetermined spacing therebetween;

a heat deformable polyamide material tube heat shrunk between the spaces of said coil and mechanically connected with said etched outer surface of said lubricous material tube through the spaces between said turns and having a smooth outer surface and tip material bonded thereto to form a tapered distal end extending distally beyond said end of said lubricous material tube; and

a fluorinated ethylene propylene material tube heat shrunk around said heat deformable tube.

21. A flexible, kink-resistant, introducer sheath comprising tubular material with a reinforcing coil therein, said tubular material having a passageway extending longitudinally therethrough, characterised in that the tubular material comprises an inner tube and an outer tube, in that the coil has spaced turns compression fitted around the inner tube, and in that the inner surface of outer tube is formed about and in contact with the coil and also in contact with the inner tube between the spaces of the said turns.

22. The sheath of claim 21, characterised in that the coil has equally spaced turns.

23. The sheath of claim 21 or 22, characterised in that the turns are of flat wire.

24. The sheath of claim 21, characterised in that the ends of the inner and outer tubes extend beyond the ends of the coil.

25. The sheath of claim 24, characterised in that the distal end of the outer tube extends beyond the distal end of the inner tube, and is tapered.

26. The sheath of claim 21 or 22, characterised in that the sheath has a uniform internal diameter.

27. The sheath of claim 21 or 22, characterised in that the inner tube comprises a lubricous material such as polytetrafluoroethylene, and the outer tube comprises polyamide which may comprise nylon.

28. A method of manufacturing a percutaneous introducer sheath, said method comprising the step of securing a reinforcing coil within tubular material(s), said tubular material(s) defining a passageway extending longitudinally therethrough; characterised in that the said sheath comprises an inner tube and an outer tube; and in that the method further comprises the steps of compression fitting the coil around the inner tube and heat treating the outer tube to extend between the spaces of the coil and to bond to the inner tube.

29. The method of claim 28, characterised in that the method further comprises the step of roughening the outer surface of the inner tube.

30. The method of claim 28 or 29, characterised in that the method further comprises the step of compressing the outer tube between the spaces of the turns of the coil.

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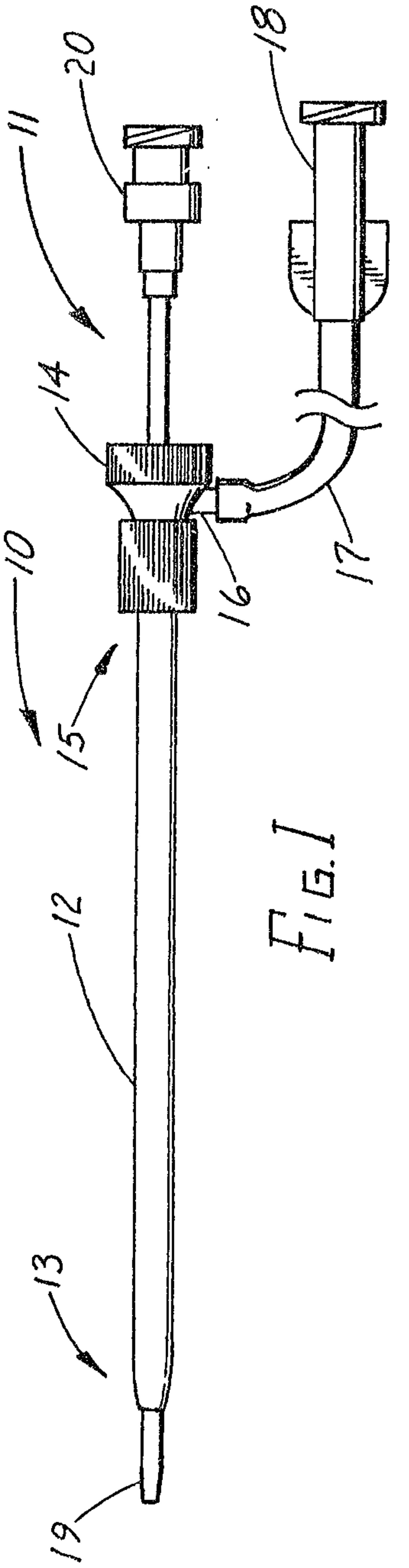

FIG. 1

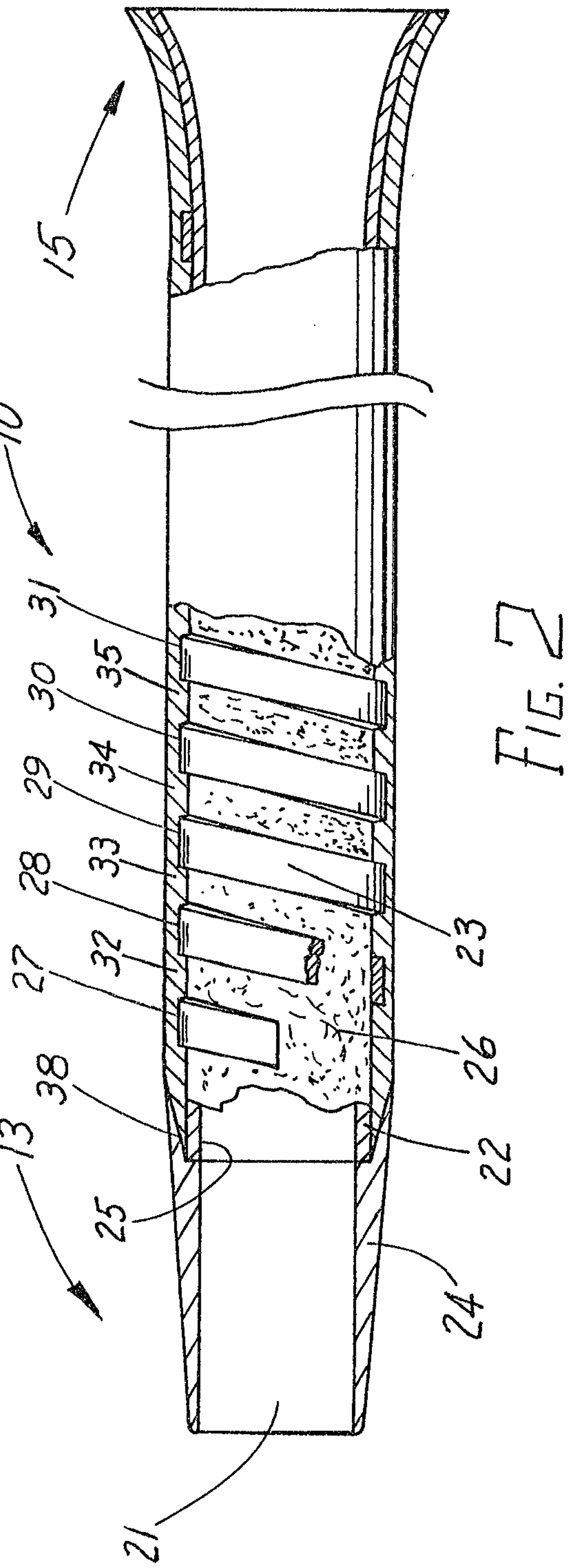

FIG. 2

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FIG. 3

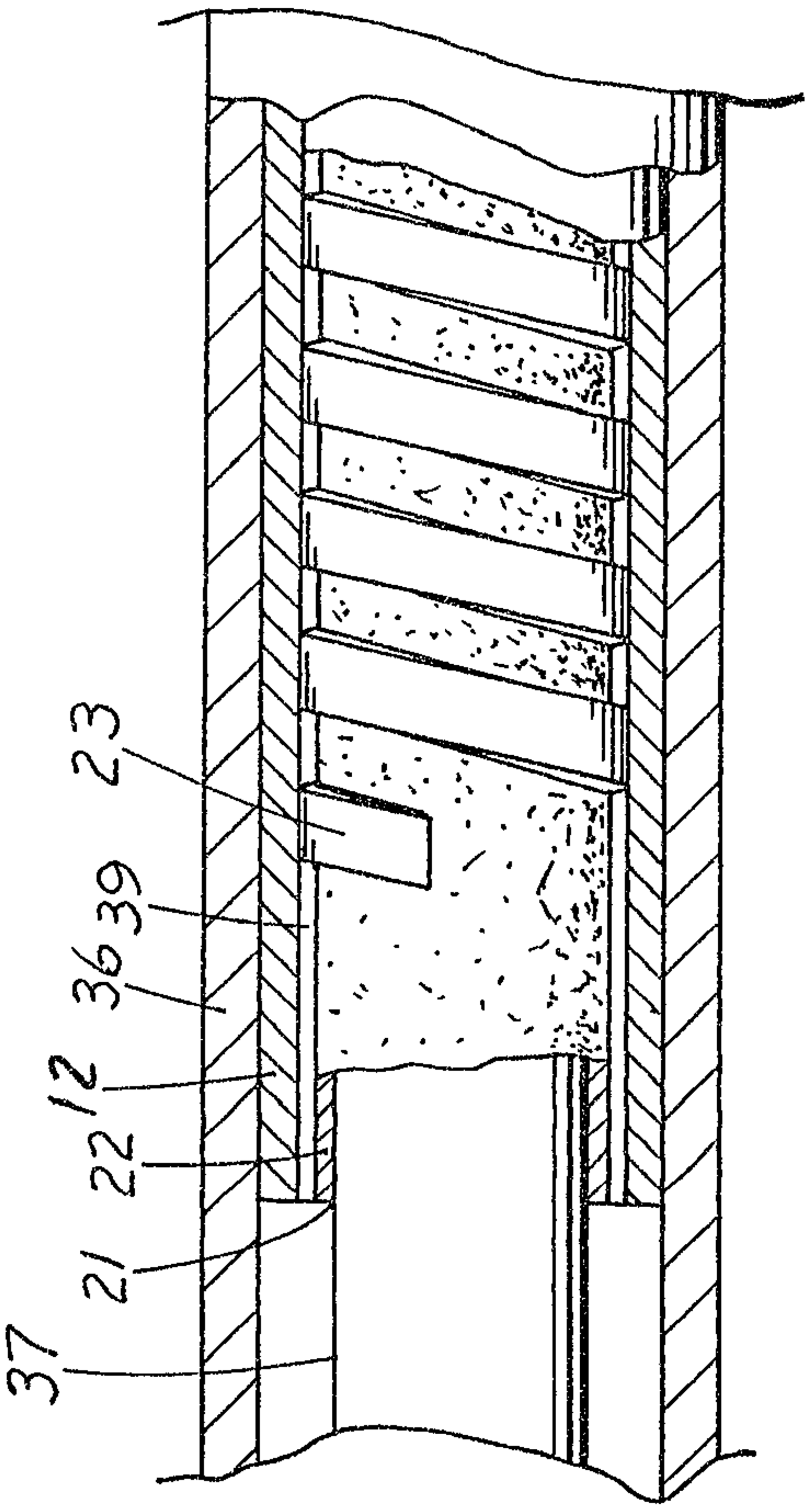
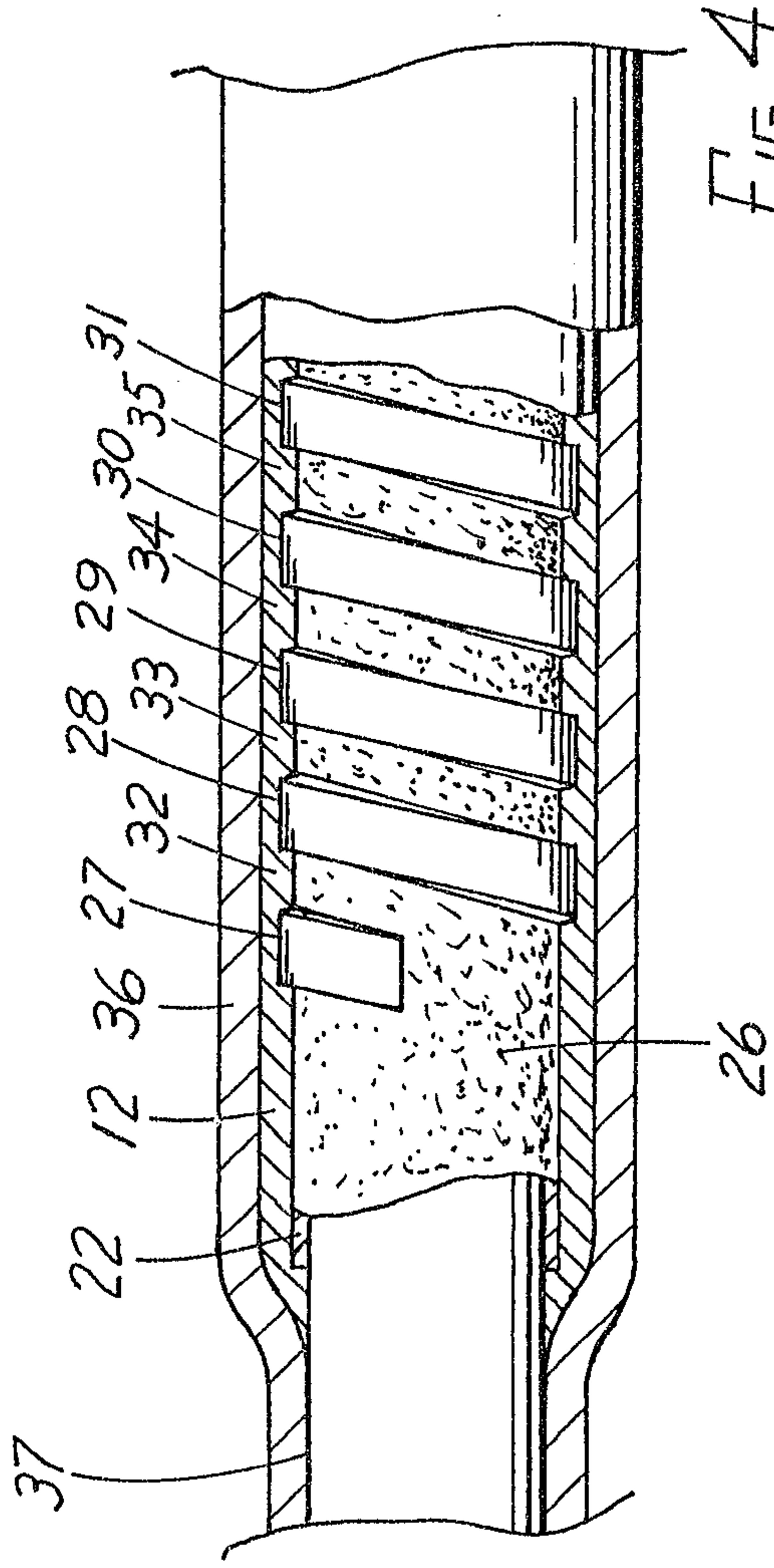


FIG. 4



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