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(54) Title: TUBE ASSEMBLIES AND INSULATING SLEEVES

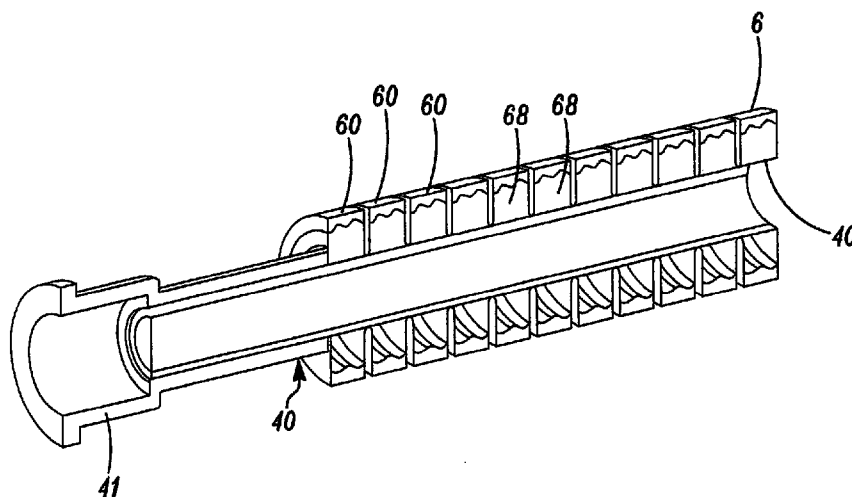


FIG. 3

(57) Abstract: Tubing (40) extending from the patient end of a heat exchanger (2) is insulated by an outer sleeve (6) extending along most of the length of the tubing. The sleeve (6) is moulded of a transparent flexible plastics with a series of separate, isolated annular air pockets (68) or channels each formed by a pair of radially-extending side walls (61) and an outer wall (63). The side walls (61) of adjacent channels are flexibly joined at their inner ends so that the walls can hinge at the join (62) when the tubing (40) and its outer sleeve (6) are bent. Adjacent side walls (61) are naturally angled away from one another at an angle of about 45° but are bent towards one another when the sleeve (6) is axially compressed by assembly on the tubing (40) and held between opposite end fittings (41) and (42) on the tubing.



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TUBE ASSEMBLIES AND INSULATING SLEEVES

This invention relates to tube assemblies of the kind having a length of transparent flexible tubing arranged to be supplied at one end with infusion liquid and having a coupling at its opposite end for connection with an infusion catheter or needle.

Patients usually receive some form of intravenous fluids during or after surgery, such as saline, blood or liquid drugs. It is well established that the patient usually benefits considerably if such fluids are not supplied at room temperature or at a refrigerated storage temperature but are instead warmed close to body temperature (around 37°C). There are various ways in which the fluid can be warmed. For example, the fluid container could be placed in a warmed water bath before use, an electrical heating element could be placed in contact with the fluid container or the path from the container to the patient. Alternatively, the flow path from the container to the patient could act as a heat exchanger, having an outer jacket with one or more lumens through which warmed fluid is circulated around the outside of the infusion fluid flow path along the tubing. Such an arrangement is sold by Smiths Medical under the Hotline® trade mark (Hotline is a registered trade mark of Smiths Medical). The problem with all these arrangements is the difficulty of preventing heat loss from the tubing after the fluid has been warmed. Even where the tubing itself is warmed by an outer jacket it is not possible for this to extend up to the patient because of the bulk and weight of the warming jacket. Instead, most warming systems include an extension tube connected via a coupling at one end to the outlet of the fluid warmer and connected at its opposite end via a coupling to the hub of the IV catheter or needle. This extension kit is not heated so there is heat loss from the infusion fluid along its length, causing a drop in temperature along its length. Although it would be possible to insulate the extension kit to some extent by means of a neoprene or foam sleeve this has various disadvantages in that it would prevent the clinician seeing the fluid flow along the extension tubing, thereby preventing the clinician confirming flow, checking for blood flash-back or checking for air bubbles. There is an additional problem in that the insulating sleeve would prevent the use of conventional slide clamps used to close the tubing.

It is an object of the present invention to provide an alternative tube assembly and insulating sleeve.

According to one aspect of the present invention there is provided a tube assembly of the above-specified kind, characterised in that the assembly includes a thermally-insulating outer sleeve extending externally along the major part of the length of the tubing, that the sleeve is moulded of a transparent flexible plastics material and has multiple annular channels along its length, that each channel has an outer wall of circular section together forming the outer surface of the assembly and supported by two generally radially-extending side walls projecting inwardly from opposite edges of the outer wall, that the inner end of the side walls extend close to or in contact with the outer surface of the tubing, and that the inner end of side walls of adjacent channels are joined with one another to form a flexible joint enabling adjacent side walls to hinge towards or away from one another as the assembly is bent, with the channels providing individual air pockets separate from one another along the length of the outer sleeve.

The assembly preferably includes an end fitting at opposite ends of the tubing, the end fittings being contacted by opposite ends of the outer sleeve. The assembly may include a slide clamp for closing the tubing. The slide clamp is preferably in the form of a plate with a tapering elongate aperture large enough at one end to be positioned along the length of the outer sleeve and being slidable along the length of the aperture between the side walls of adjacent channels so as to compress both the outer sleeve in the valley between the side walls and the underlying tubing to prevent fluid flow along the tubing. The outer wall is preferably substantially flat across its width on its outer surface. The outer sleeve in its natural state where it is not compressed axially preferably has its adjacent side walls inclined at an angle of about 45° to one another.

According to another aspect of the present invention there is provided an outer sleeve for an assembly according to the above one aspect of the present invention.

According to a third aspect of the present invention there is provided an outer sleeve for thermally insulating the outside of a part at least of the length of medical tubing,

characterised in that the sleeve is moulded of a transparent flexible plastics material and has multiple annular channels along its length, that each channel has an outer wall of circular section together forming the outer surface of the assembly and supported by two generally radially-extending side walls projecting inwardly from opposite edges of the outer wall, that the inner ends of adjacent side walls extend close to or in contact with the outer surface of the tubing, and are joined with one another to form a flexible joint enabling adjacent side walls to hinge towards or away from one another as the assembly is bent, with the channels providing individual air pockets separate from one another along the length of the sleeve, and that the sleeve in its natural state before assembly on the medical tubing is axially uncompressed with the adjacent side walls being inclined at an angle to one another.

According to a fourth aspect of the present invention there is provided an assembly including an outer sleeve according to the above third aspect of the present invention assembled to extend along a length of medical tubing, characterised in that the outer sleeve is held in axial compression on the medical tubing between end fittings at opposite ends of the tubing.

A fluid warming system including a tube assembly according to the present invention will now be described with reference to the accompanying drawings, in which:

- Figure 1 illustrates the fluid warming system schematically;
- Figure 2 is a perspective view of a conventional tube extension;
- Figure 3 is a perspective, cut-away view to an enlarged scale of a part of the tube assembly of the present invention;
- Figure 4 is a cross-sectional view of a part of the tube sleeve as moulded;
- Figure 5 is a cross-sectional view of tube sleeve assembled on the infusion tube;

Figure 6 is a perspective view showing a part of the tube assembly with a slide clamp in an open state;

Figure 7 is a perspective view showing a part of the tube assembly with the slide clamp in a closed state; and

Figure 8 is an enlarged cross-sectional side elevation view through a part of the tube assembly illustrating heat transfer.

Figure 1 shows an infusion fluid warming system including a source of infusion fluid, such as a saline bag 1 suspended above the patient on a pole (not shown). The outlet 10 of the bag 1 is connected to the inlet 20 of a heat exchanger 2 having a central lumen through which the infusion liquid flows and two outer lumens (not visible) of C-shape in section surrounding the central lumen and connected together to provide a path for warming liquid flowed through the heat exchanger. The warming liquid is warmed and pumped through the heat exchanger 2 by an electrical warming unit 3 mounted adjacent the upper end of the heat exchanger and connected with the upper end of the heat exchanger 2 via tubing 30. At its lower end the heat exchanger 2 has an outlet 21 through which the warmed infusion liquid flows out of the exchanger. The heat exchanger 2 may be of a conventional kind sold by Smiths Medical under the Hotline® mark and described in US5063994 and US5097898, although a detailed understanding of the heat exchanger is not needed for an understanding of the present invention. Alternative arrangements for heating the infusion liquid could be used, such as those employing an electrical heating element in thermal contact with the infusion liquid flow path, such as described in US6641556. The source of infusion fluid need not be a suspended bag but could be of any conventional kind, such as an infusion pump.

Because of the bulk and weight of conventional heat exchangers when filled with the liquid heat exchange medium it is usual not to connect the outlet of the heat exchanger directly with the infusion catheter or needle but instead to use an extension kit 4 of the kind shown in Figure 2. This includes a length of flexible, transparent plastic tubing 40 having end fittings in the form of luer connectors 41 and 42 at opposite ends and a simple slide clamp 43 in the form of a plate 44 with a tapering aperture 45 through which the tubing is

threaded. In its normal position with the tubing 40 extending through the larger end of the aperture 45, the tubing is open to allow free flow of liquid along it. If the clamp 43 is slid along its length across the tubing 40, so that the tubing is forced into the narrow end of the aperture 45, this compresses and clamps closed the tubing to prevent flow. In use, one of the connectors 41 is coupled to the outlet 21 of the heat exchanger 2 and the other connector 42 is coupled to a connector or hub 50 at the rear or machine end of the infusion catheter or needle 5, such as an IV infusion catheter or needle.

As so far described the fluid warming system is conventional.

The system of the present invention differs from conventional systems by the addition of a thermally-insulating outer sleeve 6 extending along the extension kit 4 as shown in Figures 3 to 7. The sleeve 6 is moulded from a transparent plastics material, such as silicone, with an undulating profile formed by a linked series of hollow annular hoops or channels 60 of substantially square section. The hoops 60 are formed by radially-extending walls 61 joined to adjacent walls at their inner ends to provide flexible joins 62 enabling the walls to hinge outwardly and inwardly towards and away from one another. The outer edge of the walls 61 of each hoop 60 is linked by and supports an integral annular band, outer wall or roof 63 presenting an outer flat surface 64 across its width and an undulating inner surface 65 having a central convex projection 66 bordered by shallow concave recesses 67 along opposite sides. The external diameter of the sleeve 6 is about 2.0 to 2.5 times the external diameter of the extension tubing 40 and the length "l" of each hoop 60 is about 0.5 to 0.7 times the external diameter of the extension tubing. The wall thickness of the sleeve 6 varies, being thicker in the region of the roof 63 than in the region of the walls 61 so that the roof is stiffer and maintains a flat external profile. The internal diameter of the sleeve 6 at the joins 62 between the walls 61 is equal to or slightly greater than the external diameter of the extension tubing 40 so that the sleeve can move freely along the tubing. The sleeve 6 is moulded in the form shown in Figure 4 with the walls 61 projecting inwardly from the rooves 63 and inclined outwardly at the joins 62 at an angle θ of about 45° . The natural state of the sleeve 6 (where it is not axially compressed) is, therefore, with the walls 61 at this angle and the sleeve extended in length. When the sleeve 6 is loaded onto the tubing 40 it is axially compressed, as shown in Figure 5, so that the angle between adjacent walls 61 closes

resiliently and they lie parallel in contact or closely adjacent with one another. The length of the sleeve 6 as moulded exceeds the length of the tubing 40 on which it is to be fitted but when slid along the tubing and compressed axially between the end connectors 41 and 42 its compressed length is such that the opposite ends of the sleeve resiliently engage the connectors as shown in Figure 3.

Figure 8 shows that the annular shape of the channels or hoops 60 produces multiple separate annular air pockets 68 between the sleeve 6 and the extension tubing 40 that are isolated from one another. The volume of these multiple discrete air pockets 68 is less than would be produced by, for example a helically-corrugated sleeve with a single continuous air pocket along its length. The result of this is that thermal convection losses from the warm extension tubing 40 can be very low compared with arrangements with a single large air pocket enabling the establishment of convective flow patterns. By arranging for the walls 61 of adjacent hoops 60 to lie close to one another in use it ensures that the maximum proportion of the length of the extension tubing 40 is insulated by the full depth of air in the air pockets and that the area through which heat could leak out is minimised. The increased thickness of the roof 63 of each channel 60 further helps reduce heat loss from the sleeve 6. An alternative sleeve with an undulating, sinewave, profile, by contrast, would have air pockets that vary in thickness along their length and regions where the air pockets would be relatively thin and allow a greater heat loss.

The transparent nature of the insulating sleeve 6 enables the extension tube 40 to be viewed through the sleeve so that liquid flowing along the tube can be seen. This enables the clinician to identify any air bubbles, blood flash-back or interruption to flow. The annular, hooped configuration of the insulating sleeve 6 enables adjacent walls 61 to open and close and the inner joins 62 between the walls to slide freely along the extension tube 40. This ensures that the extension tube 40 is completely flexible so that it can be positioned freely without loading the IV site.

The annular configuration of the sleeve 6 also enables a slide clamp 7 similar to the conventional clamp 43 (Fig 2) to be used, as shown in Figures 6 and 7. The slide clamp 7 comprises a rigid rectangular plastics plate 70 with a tapering aperture 71 that differs from

conventional clamps only in that the width of aperture 71 is wider than usual, being able to receive the external diameter of the insulating sleeve 6 freely at its wider end. The clamp 7 is used in the manner shown in Figures 6 and 7 by positioning the clamp in a gap between adjacent hoops 60 and then sliding the clamp along its length to move the extension tubing 40 and the sleeve 6 to the narrow end of the aperture 71. The flexible nature of the sleeve 6 enables the underlying tube 40 to be clamped easily in this way.

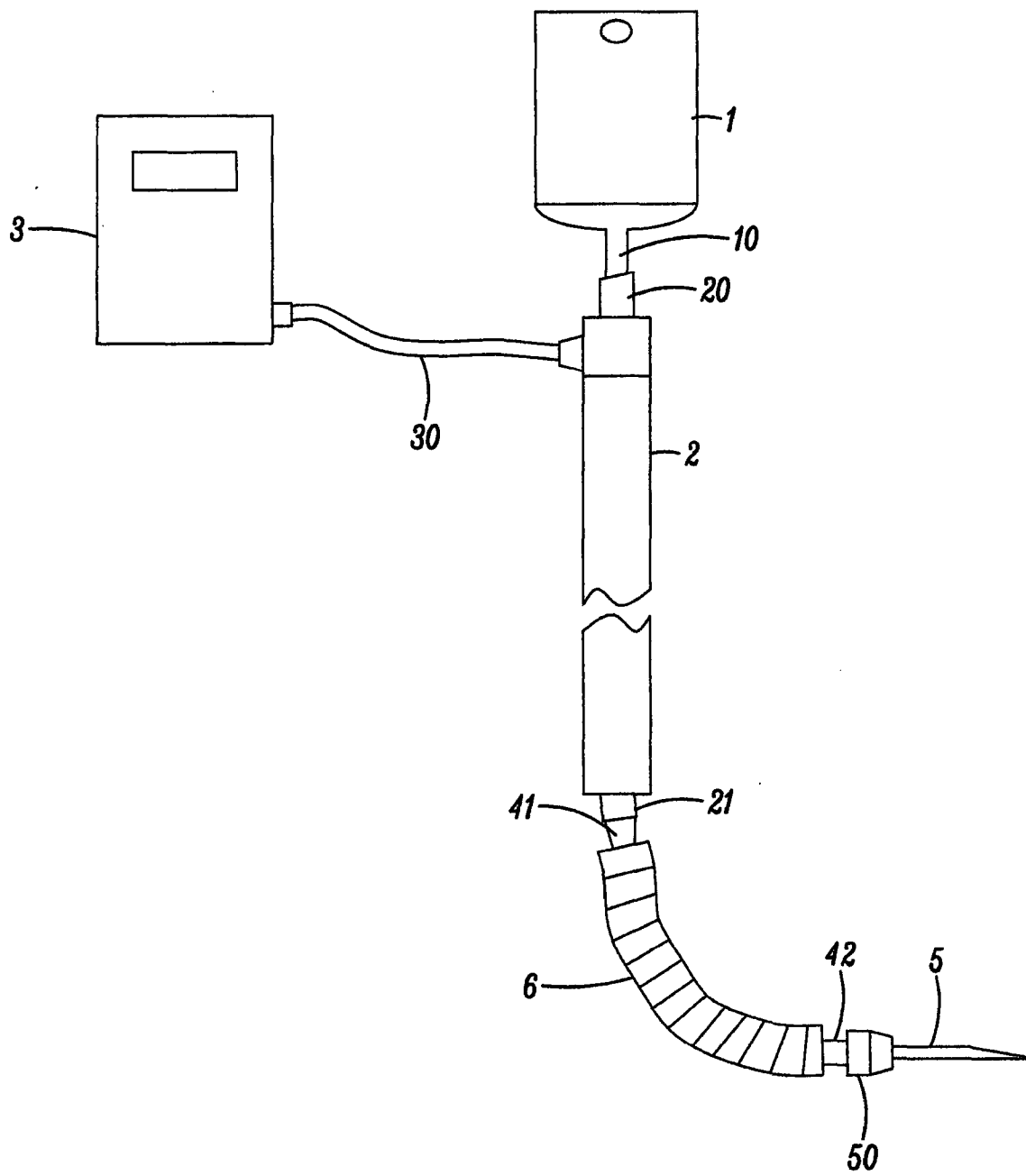
Instead of a separate extension tube, the heat exchanger could have an integral small bore extension tube or tail that would also benefit from an insulating sleeve of the present invention.

The insulating sleeve could be made of various different materials and have different dimensions. The sleeve could have alternative profiles providing separate air pockets, for example, the roof of each hoop need not be flat but could be curved. The present invention could also be used where a cooled fluid is infused to a patient since it would reduce warming of the fluid caused by exposure to an environment at room temperature.

CLAIMS

1. A tube assembly having a length of transparent flexible tubing (40) arranged to be supplied at one end with infusion liquid and having a coupling (42) at its opposite end for connection with an infusion catheter or needle (5), characterised in that the assembly includes a thermally-insulating outer sleeve (6) extending externally along the major part of the length of the tubing (40), that the sleeve (6) is moulded of a transparent flexible plastics material and has multiple annular channels (60) along its length, that each channel (60) has an outer wall (63) of circular section together forming the outer surface of the assembly and supported by two generally radially-extending side walls (61) projecting inwardly from opposite edges of the outer wall (63), that the inner end of the side walls (61) extend close to or in contact with the outer surface of the tubing (40), and that the inner end of side walls (61) of adjacent channels (60) are joined with one another to form a flexible join (62) enabling adjacent side walls to hinge towards or away from one another as the assembly is bent, with the channels (60) providing individual air pockets separate from one another along the length of the outer sleeve (60).
2. An assembly according to Claim 1, characterised in that the assembly includes an end fitting (41, 42) at opposite ends of the tubing, and that the end fittings are contacted by opposite ends of the outer sleeve (6)
3. An assembly according to Claim 1 or 2, characterised in that the assembly includes a slide clamp (7) for closing the tubing (40).
4. An assembly according to Claim 3, characterised in that the slide clamp (7) is in the form of a plate (70) with a tapering elongate aperture (71) large enough at one end to be positioned along the length of the outer sleeve (6) and being slidable along the length of the aperture (71) between the side walls (61) of adjacent channels (60) so as to compress both the outer sleeve in the valley between the side walls and the underlying tubing (40) to prevent fluid flow along the tubing.

5. An assembly according to any one of the preceding claims, characterised in that the outer wall (63) is substantially flat across its width on its outer surface.
6. An assembly according to any one of the preceding claims, characterised in that the outer sleeve (6) in its natural state where it is not compressed axially has its adjacent side walls (61) inclined at an angle (θ) of about 45° to one another.
7. An outer sleeve (6) for an assembly according to any one of the preceding claims.
8. An outer sleeve (6) for thermally insulating the outside of a part at least of the length of medical tubing (40), characterised in that the sleeve is moulded of a transparent flexible plastics material and has multiple annular channels (60) along its length, that each channel (60) has an outer wall (63) of circular section together forming the outer surface of the assembly and supported by two generally radially-extending side walls (61) projecting inwardly from opposite edges of the outer wall (63), that the inner ends of adjacent side walls extend close to or in contact with the outer surface of the tubing, and are joined with one another to form a flexible join (62) enabling adjacent side walls (61) to hinge towards or away from one another as the assembly is bent, with the channels providing individual air pockets (60) separate from one another along the length of the sleeve (6), and that the sleeve in its natural state before assembly on the medical tubing (40) is axially uncompressed with the adjacent side walls (61) being inclined at an angle to one another.
9. An assembly including an outer sleeve (6) according to Claim 8 assembled to extend along a length of medical tubing (40), characterised in that the outer sleeve (6) is held in axial compression on the medical tubing (40) between end fittings (41 and 42) at opposite ends of the tubing.

1/4*FIG. 1*

2/4

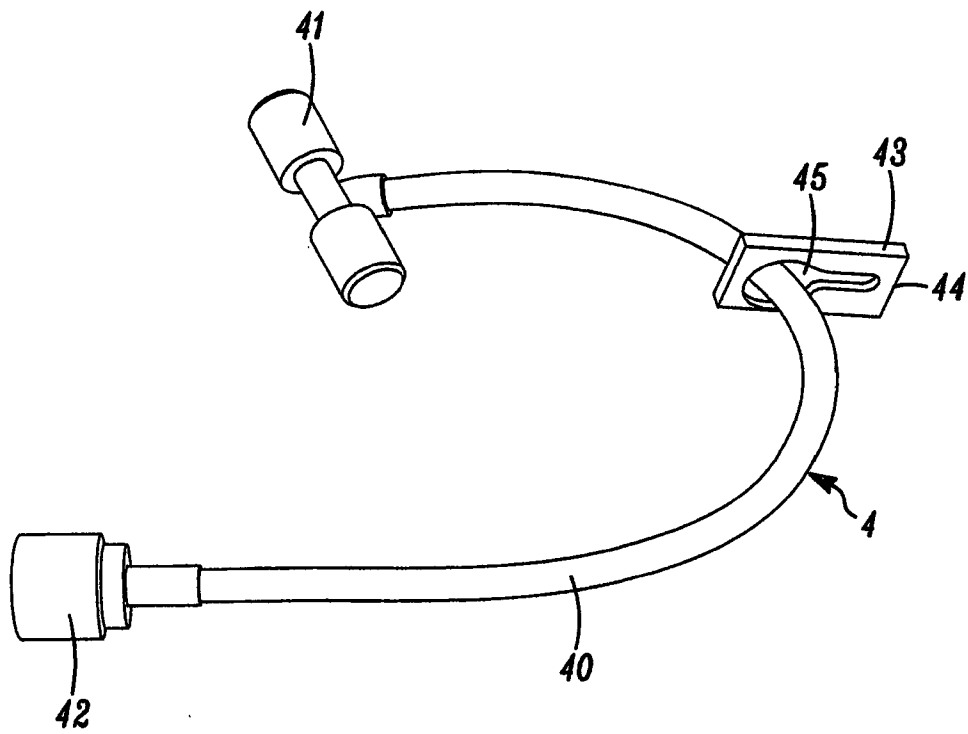


FIG. 2

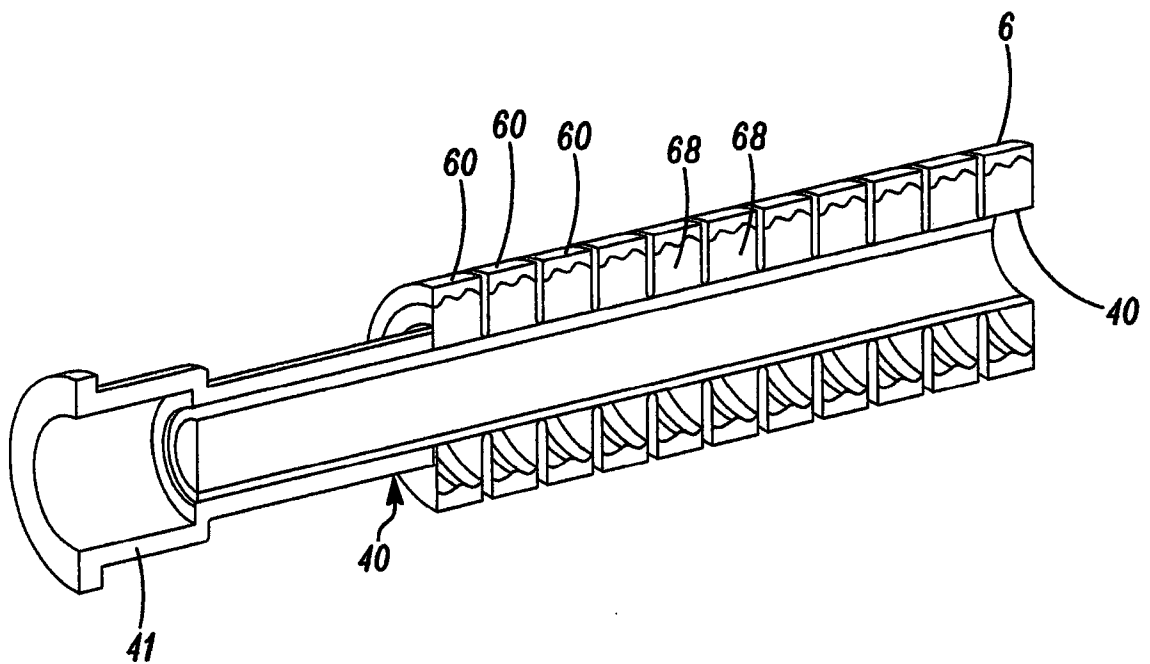


FIG. 3

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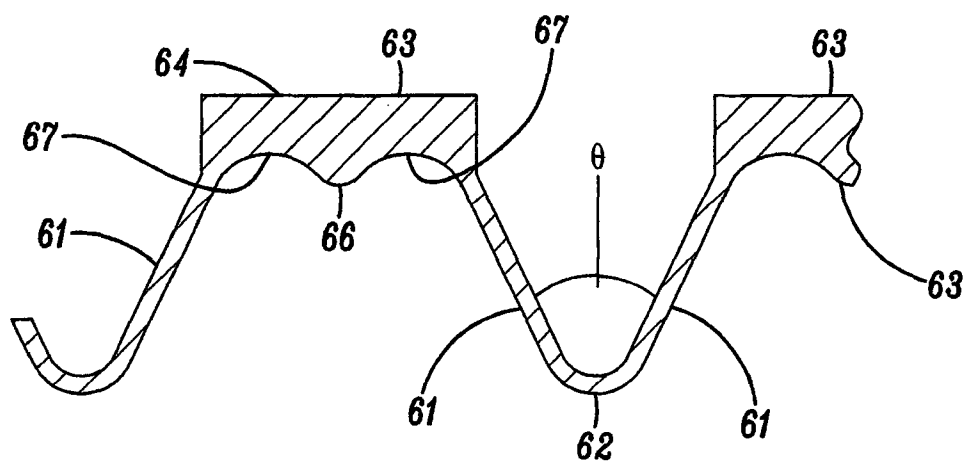


FIG. 4

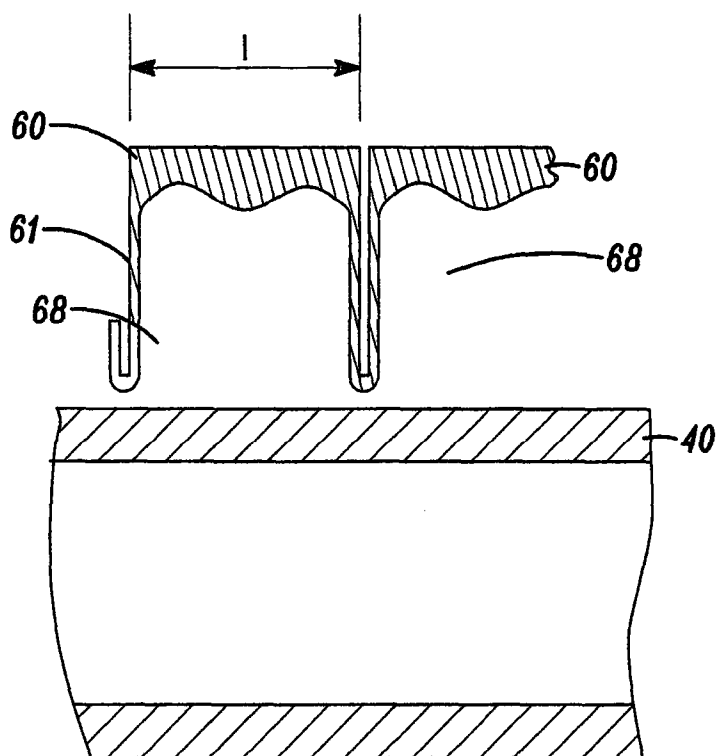


FIG. 5

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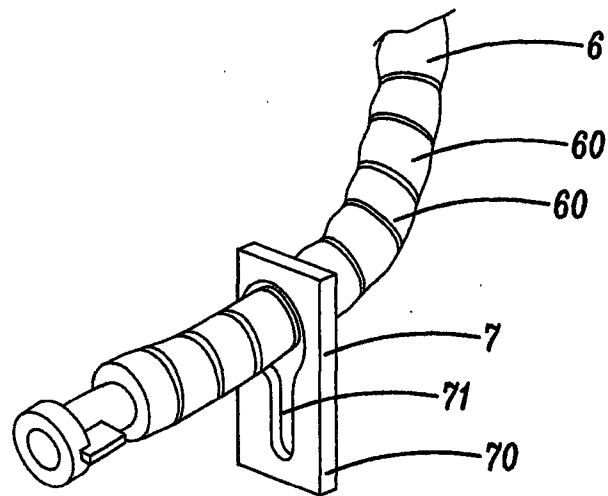


FIG. 6

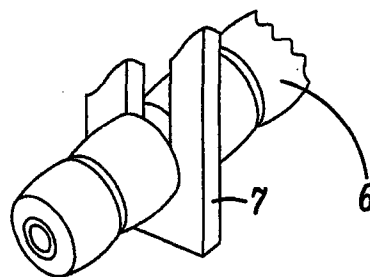


FIG. 7

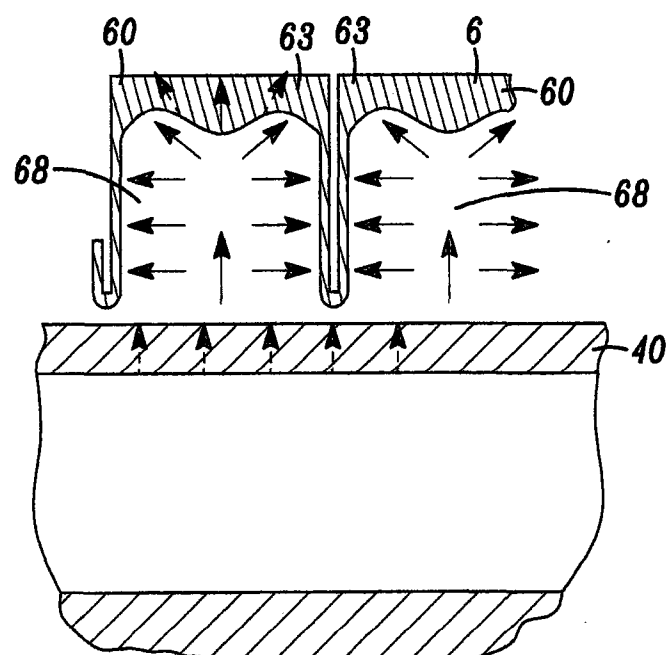


FIG. 8

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2018/000102

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M39/08 A61M5/162
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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A	DE 103 24 116 A1 (BARKEY VOLKER [DE]) 5 January 2005 (2005-01-05) figures 1-2	1
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Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

29 August 2018

Date of mailing of the international search report

10/09/2018

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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