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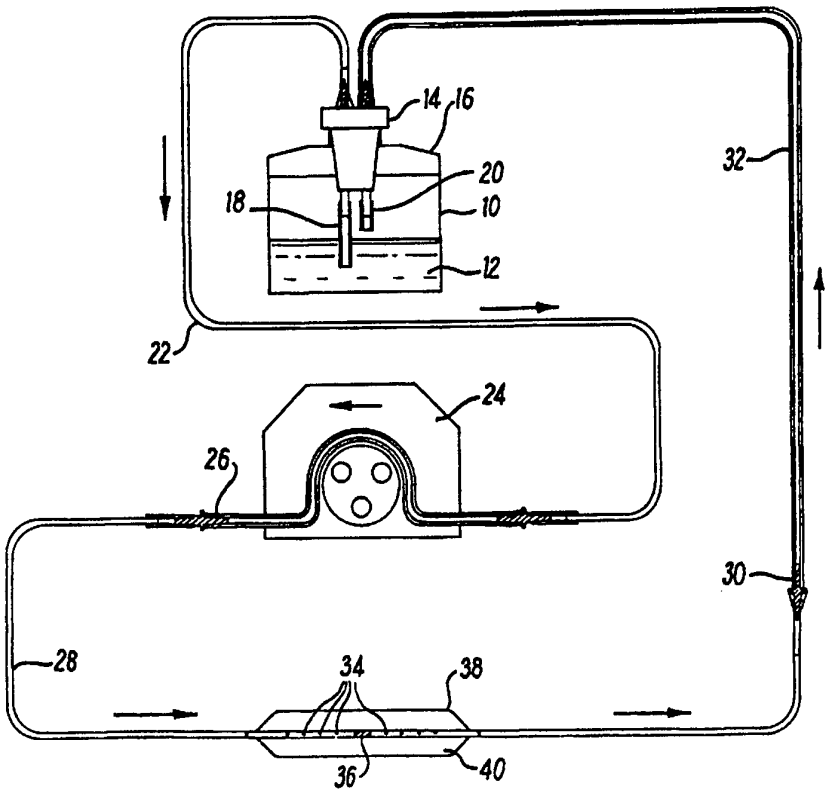
(57) Abstract

Apparatus is provided for the localised heating of internal body tissue to prevent unwanted freezing of healthy tissue adjacent to a site of cryogenic surgery. The apparatus has a bag locatable adjacent the tissue which provides for the entry of liquid at a required temperature, circulation of liquid through the bag in a heat transfer relation with a wall thereof, and removal of the liquid. In one embodiment the bag is provided around an outer wall of a catheter and in fluid communication with catheter contents.



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Surgical Apparatus

The present invention concerns surgical apparatus, and relates in particular to an apparatus for providing localised heating within a patient's body adjacent to a site at which cryosurgery is to take place.

Currently available cryosurgical apparatus permits the treatment of tumours within a patient's body by localised freezing whereby to destroy cancerous tissue in situ. Surgery is carried out by the insertion into the centre of a tumour of a probe having a tip region which is cooled cryogenically and which is adapted to permit rapid heat transfer across its walls so that the tissue surrounding the probe tip becomes frozen as heat is given up to the cryogen.

Surgery of the kind described requires precautions to be taken to ensure that healthy tissue surrounding the site of the operation is not also damaged. For example, in the treatment of male prostate cancer there is a risk of damage both to the urethra and to the rectum. Breach of the rectal wall gives rise to an additional source of infection or other complications. The present invention seeks to mitigate or obviate these problems.

According to the invention there is provided apparatus for the localised heating of body tissue adjacent to a site of cryosurgery, the apparatus comprising a membranous bag adapted to be located adjacent the required tissue and adapted to permit heat transfer through a wall thereof, means providing for entry of liquid at a predetermined temperature to the bag, means providing for removal of the liquid from the bag, and means for causing the liquid to move through the bag in a heat transfer relation with the wall thereof.

In a first embodiment of the invention the liquid entry and removal means may be provided by opposed ends of a catheter The bag may be sealed around an outer wall of the catheter to provide a chamber of substantially annular cross-section.

The invention may also provide apparatus in the form of a catheter having a single passageway therethrough, a plurality of through apertures arranged in a spaced series in an outer wall thereof, means for obstructing the passageway between two adjacent ones of the apertures, and a membrane adapted to permit heat transfer therethrough and providing a wall of a sealed chamber around the catheter outer wall to enclose the apertures. whereby a liquid at a predetermined temperature passed into a first section of the catheter

can flow into the chamber through the apertures upstream of the obstruction to effect heat transfer and then pass back into a second section of the catheter through the apertures downstream of the obstruction.

The obstructing means may comprise a tie or clip. Preferably the apparatus includes means facilitating positioning of the apparatus in a required position. Preferably the obstructing means comprises a marker visible under ultrasound analysis.

In a second embodiment of the invention the apparatus is preferably adapted to provide for entry of liquid to a location within the bag spaced from an outlet for removal of the liquid whereby to facilitate circulation of liquid throughout the bag.

The bag may take the form of a sheath which can locate around a suitable core. The core may be a diagnostic or imaging device such as an ultrasound probe.

According to the invention there is further provided surgical apparatus comprising a cryosurgical instrument having a tip region which is cooled cryogenically and which is adapted to permit rapid heat transfer across its walls to freeze tissue surrounding

the tip, and apparatus for the localised heating of body tissue as described in any of the preceding six paragraphs.

According to the invention there is further provided a method of providing localised heating of body tissue comprising the steps of providing a bag having a wall adapted to permit heat transfer therethrough, positioning the bag adjacent to the tissue to be heated, and circulating to and from the bag a supply of a liquid at a predetermined temperature whereby to cause warming of tissue adjacent to the bag by transfer of heat thereto from the liquid

The liquid may be sterile saline.

According to the invention there is further provided a method of providing localised heating of body tissue during cryogenic surgery on the male prostate gland which method comprising providing apparatus according to the first embodiment as hereinbefore described and locating said apparatus within the urethra, providing apparatus according to the second embodiment as hereinbefore described and locating said apparatus within the rectum, and circulating to and from each apparatus liquid at a predetermined temperature whereby to cause warming of urethral and rectal tissue

by transfer of heat thereto from the liquid.

Preferably the core of the apparatus of the second embodiment is an ultrasound probe, which probe is used to assist in location of the apparatus of the first embodiment by virtue of an appropriate marker included therewithin.

The invention will be further described for the purposes of illustration only with reference to the accompanying drawing in which:-

Fig. 1 is a schematic diagram of an apparatus according to a first embodiment of the invention;

Fig. 2 is a side view of an apparatus according to a second embodiment of the invention;

Fig. 3 is an end view of the apparatus of Fig. 2;

Fig. 4 is a view corresponding to Fig. 2 of a modified arrangement of the apparatus;

Fig. 5 is an enlarged end view of a ring of the Fig. 4 apparatus; and

Fig. 6 is a section on line A-A of Fig. 5.

Fig 1 shows an apparatus for the localised heating of body tissue adjacent to a site for cryosurgery. A sterile storage vessel 10 contains a supply of sterile saline solution 12 which is maintained at a predetermined temperature by means not shown. A

stopper 14 mounted in a lid 16 of the container 10 houses a supply tube 18 and a return tube 20 for the saline solution 12. The tube 18 is connected to tubing 22 forming the supply part of a supply and return circuit for the solution. A peristaltic pump 24 is provided at a suitable location within the circuit to enable saline solution 12 to be pumped therearound. Downstream of the pump 24 a suitable connector 26 connects into the circuit one end of a catheter 28 which has previously been introduced into the patient's body as will be further described hereinafter. The catheter 28 has a single passageway therethrough for the saline solution 12. The second end of the catheter 28 is connected via an appropriate connector 30 to suitable tubing 32 forming the return part of the circuit, which tubing is connected to the return tube 20.

A portion of the catheter 28 intermediate the first and second ends is provided with a series of spaced through apertures 34. An obstruction 36 in the form of a suitable tie or clip closes the catheter passageway between two adjacent ones of the apertures 34. The obstruction 36 is adapted to be visible under ultrasound analysis. A membranous tube 38 is secured at each end to an outer wall of the catheter 28 to form an annular bag 40 around the catheter 28 The membrane 38 is so positioned and secured to the catheter 28 as to

enclose the apertures 34 within the bag 40. The membrane 38 provides a thin, flexible wall of the bag 40 across which heat transfer may readily occur.

The apparatus shown in the drawing may be used in internal cryosurgery. For example, prostate cancer may be treated by freezing the tumour by the insertion therein of the tip of a suitable instrument which is frozen cryogenically in accordance with known techniques. In such an operation considerable control of the freezing is required to avoid damaging healthy tissue surrounding the site of the operation. Even with considerable precautions there is a danger of damage, in particular to the urethra. Accordingly, before the freezing commences the catheter 28 and bag 40 are introduced into the patient's urethra so that the bag 40 lies adjacent the proposed surgical site. Correct positioning of the bag 40 is ensured by monitoring the location of the ultrasound-visible marker 36. The respective ends of the catheter 28 lie outside the patient's body, and are connected in circuit with the container 10 and pump 24 as shown in the drawing Warmed sterile saline solution 12 is circulated into the urethra via the tubing 22 and the catheter 28. On reaching the obstruction 36, the saline solution is forced to flow through the apertures 34 upstream of the obstruction 36 and thus into the bag 40. The membrane

wall 38 of the bag 40 is thin and flexible and provides a large surface area across which heat exchange may occur from the warmed saline 12 to the urethra and surrounding body tissue (not shown). In this way, sufficient warmth is supplied to prevent these tissues from freezing despite the close proximity of the ice produced by the cryosurgical instrument.

After heat exchange has occurred, the saline 12 flows back into the catheter 28 through the apertures 34 located downstream of the obstruction 36. It then flows from the other end of the catheter 28 to the tubing 32 and is thus returned to the container 10.

The apparatus described may conveniently be provided in combination with known cryosurgical systems. For example the container 10 can be provided in a single unit together with means for retaining a supply of cryogen such as liquid nitrogen, and associated control instrumentation, valve arrangements and connection points for both the saline supply circuit of the apparatus of the invention and a cryogen supply circuit of the cryosurgical equipment.

There is thus described an arrangement which has excellent heat transfer properties at the required location by virtue of the extremely thin flexible wall

of the membrane. The provision of the membranous bag permits a large volume of warmed liquid to be used to effect heat transfer whilst using a standard diameter catheter, since the entire cross-sectional area of the catheter can be used for supply of liquid, the liquid being removed via a subsequent length of catheter. There is no need for the catheter wall itself to have suitable heat transfer properties, and it will further be appreciated that heating is carried out only where required, so that body tissue is not redundantly or undesirably heated.

Referring to Figs. 2 and 3, there is shown an apparatus 42 adapted to provide rectal warming during cryosurgery. The apparatus 42 may be connected for use in a circuit similar to that shown in Fig. 1 and containing a sterile storage vessel 10 for a supply of saline solution 12, a peristaltic pump 24 and appropriate supply and return tubing 22, 32.

The apparatus 42 comprises an inlet tube 44 which is connected to the supply side of a saline solution circulation circuit as just described by a suitable tube fitting 46.

The tube 44 provides an inlet for a supply of saline solution at a predetermined temperature to a

hollow cylindrical bag 45 which is formed of a thin and flexible membranous material adapted to permit rapid heat transfer across the walls thereof. An outlet tube 54 provides for removal of saline solution from the bag 45. The latter is formed as a double walled sheath, with an open end 52 being sealed around the inlet and outlet tubes 44, 54, and walls of the bag material being point welded together at the closed end of the sheath to restrict relative movement of the walls. The inlet tube 44 extends into the bag 45 to adjacent the closed end of the sheath, while the outlet tube 54 extends into the bag 45 adjacent the open end 52 of the sheath, whereby to facilitate circulation of the warm liquid throughout the bag 45 in heat exchange relationship with its surroundings.

Fig. 4 shows a modified version of the Fig. 2 apparatus, in which like components have been given the reference numerals used in Fig. 2. As will be seen from the drawing, in the Fig. 4 apparatus the bag 45 is sealed around the inlet and outlet tubes 44, 54 by means of a ring 56 (illustrated on an enlarged scale in Figs. 5 and 6). The ring 56 comprises a short tube 60 having an outwardly directed radial flange 62 at one end thereof. The flange 62 is drilled parallel to the tube axis to provide two diametrically opposite through apertures 58 to permit inlet and outlet pipes 44, 54 to pass therethrough. Appropriate retaining devices 60A,

60B secure respective walls of the bag 45 to the ring 56, to form a double walled sheath.

The apparatus may be used to provide localised warming of the rectum during cryogenic ablation of prostate cancer The apparatus may be inserted by means of a suitable tool previously placed in the interior space 64 of the sheath. Warmed saline passes into the bag 45 via the inlet pipe 44 and exchanges its heat with surrounding tissue through the membrane wall thus preventing such tissue from freezing when in the vicinity of an ice ball formed by the cryosurgical instrument being used by the surgeon. Saline is removed from the apparatus through the outlet pipe 54.

When the apparatus is inserted, an insertion tool may be removed. The space 64 can conveniently then receive a diagnostic or imaging device, and in particular an ultrasound probe (not shown). Where the rectal warming apparatus of Figs. 2 to 6 is to be employed during prostate surgery in conjunction with the urethral warming apparatus of Fig. 1, an ultrasound probe may advantageously be used to monitor the position of the urethral warming apparatus, for example by locating the tie 36 as hereinbefore described.

Whilst endeavouring in the foregoing Specification

to draw attention to those features of the invention believed to be of particular importance it should be understood that the Applicant claims protection in respect of any patentable feature or combination of features hereinbefore referred to and/or shown in the drawings whether or not particular emphasis has been placed thereon.

Claims:-

1. Apparatus for preventing freezing of body tissue adjacent to a site of cryosurgery, the apparatus comprising a membranous bag adapted to be located at least partially within the body and adjacent the required tissue and adapted to permit heat transfer through a wall thereof, means providing for entry of liquid at a predetermined temperature to the bag, means providing for removal of the liquid from the bag, and means for causing the liquid to move through the bag in a heat transfer relation with the wall thereof whereby to prevent freezing of adjacent body tissue.

2. Apparatus according to Claim 1, wherein the liquid entry and removal means are provided by opposed ends of a catheter.

3. Apparatus according to Claim 2, wherein the bag is sealed around an outer wall of the catheter to provide a chamber of substantially annular cross-section.

4. Apparatus for the localised heating of body tissue adjacent to a site of cryosurgery, the apparatus comprising a catheter having a single passageway therethrough, a plurality of through apertures arranged in a spaced series in an outer wall thereof, means for obstructing the passageway between two adjacent ones of

the apertures, and a membrane adapted to permit heat transfer therethrough and providing a wall of a sealed chamber around the catheter outer wall to enclose the apertures, whereby a liquid at a predetermined temperature passed into a first section of the catheter can flow into the chamber through the apertures upstream of the obstruction to effect heat transfer and then pass back into a second section of the catheter through the apertures downstream of the obstruction.

5. Apparatus according to Claim 4, wherein the obstructing means comprises a tie or clip.

6. Apparatus according to any of the preceding Claims, and including means facilitating positioning of the apparatus in a required position.

7. Apparatus according to Claim 6 when dependent on Claim 5, wherein the obstructing means comprises a marker visible under ultrasound analysis.

8. Apparatus according to Claim 1 adapted to provide for entry of liquid to a location within the bag spaced from an outlet for removal of the liquid whereby to facilitate circulation of liquid throughout the bag.

9. Apparatus according to Claim 1 or Claim 8, wherein

15. A method of providing localised heating of body tissue during cryogenic surgery on the male prostate gland which method comprising providing apparatus according to any of Claims, 1 to 7 and locating said apparatus within the urethra, providing apparatus according to any of Claims 1, 2 or 8 to 11 and locating said apparatus within the rectum, and circulating to and from each apparatus liquid at a predetermined temperature whereby to cause warming of urethral and rectal tissue by transfer of heat thereto from the liquid.

16. A method according to Claim 15 when dependent on Claim 10, wherein the core of the second said apparatus is an ultrasound probe, which probe is used to assist in location of the first said apparatus by virtue of an appropriate marker included therewithin.

17. Apparatus substantially as hereinbefore described with reference to Fig. 1 of the accompanying drawings.

18. Apparatus substantially as hereinbefore described with reference to Figs. 2 to 6 of the accompanying drawings.

19. A method substantially as hereinbefore described with reference to the accompanying drawings.

15. A method of providing localised heating of body tissue during cryogenic surgery on the male prostate gland which method comprising providing apparatus according to any of Claims, 1 to 7 and locating said apparatus within the urethra, providing apparatus according to any of Claims 1, 2 or 8 to 11 and locating said apparatus within the rectum, and circulating to and from each apparatus liquid at a predetermined temperature whereby to cause warming of urethral and rectal tissue by transfer of heat thereto from the liquid.

16. A method according to Claim 15 when dependent on Claim 10, wherein the core of the second said apparatus is an ultrasound probe, which probe is used to assist in location of the first said apparatus by virtue of an appropriate marker included therewithin.

17. Apparatus substantially as hereinbefore described with reference to Fig. 1 of the accompanying drawings.

18. Apparatus substantially as hereinbefore described with reference to Figs. 2 to 6 of the accompanying drawings.

19. A method substantially as hereinbefore described with reference to the accompanying drawings.

20. Any novel subject matter or combination including novel subject matter disclosed, whether or not within the scope of or relating to the same invention as any of the preceding Claims.

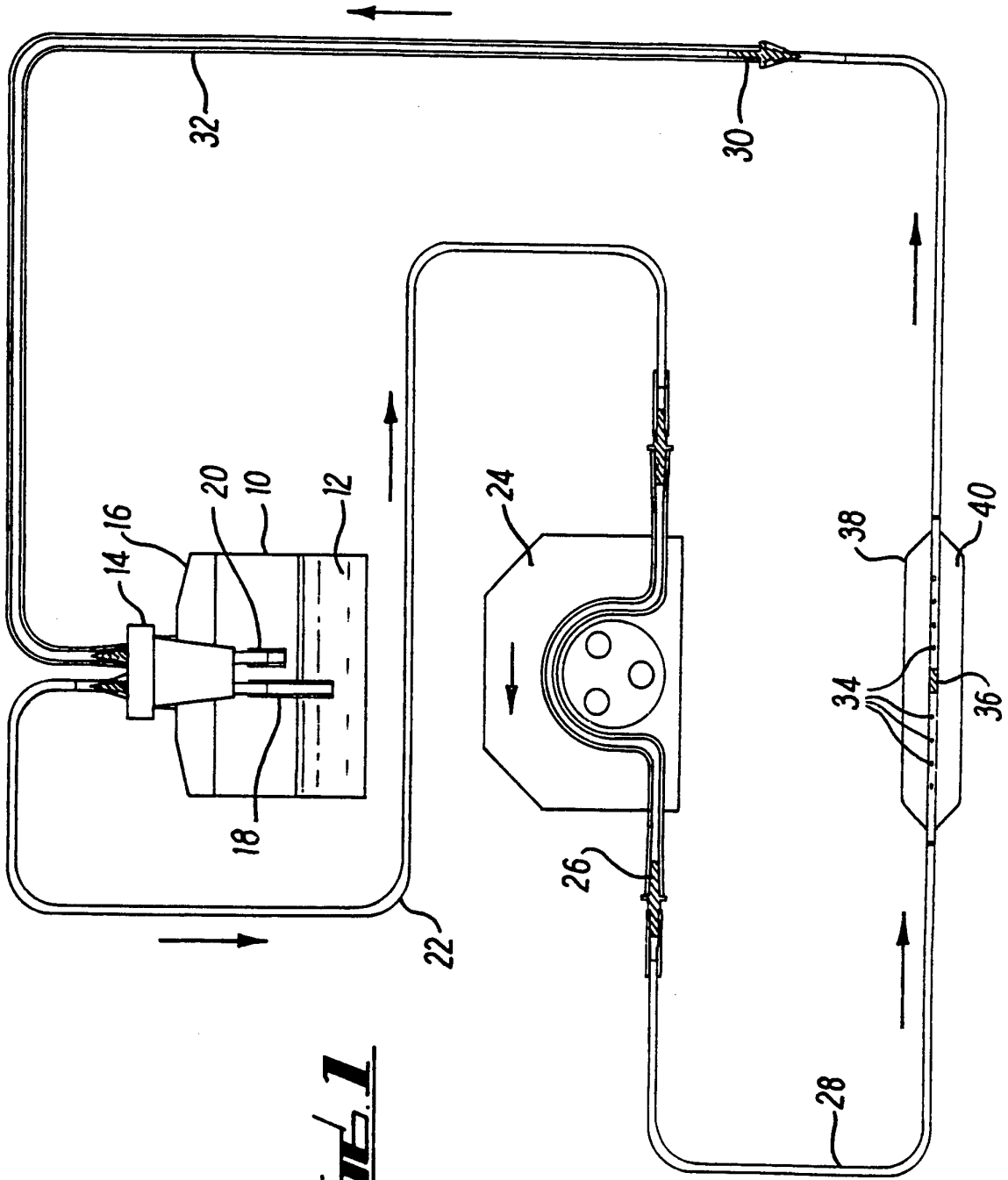


FIG. 1

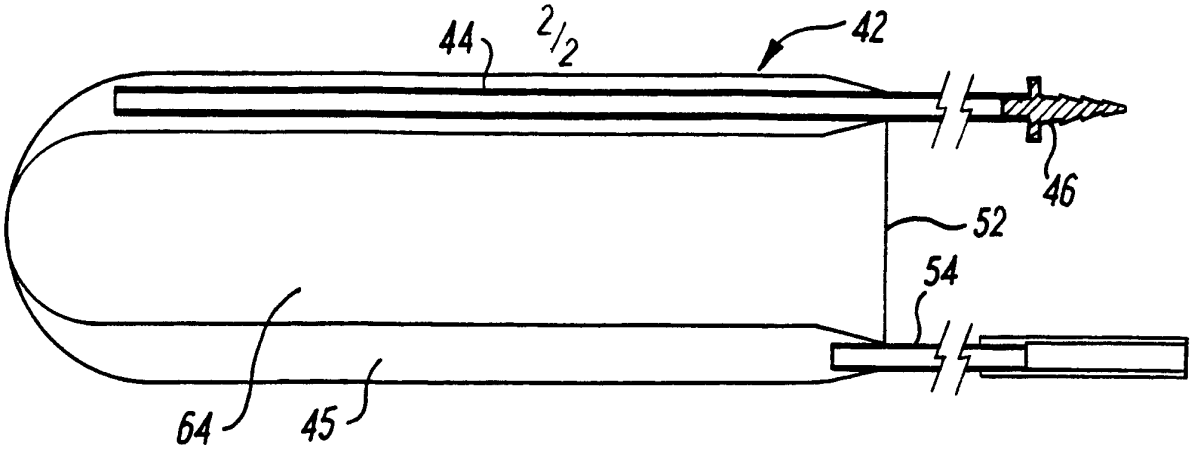


FIG. 2

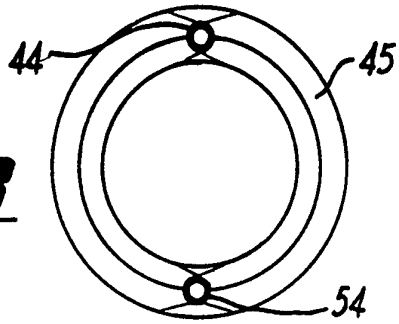
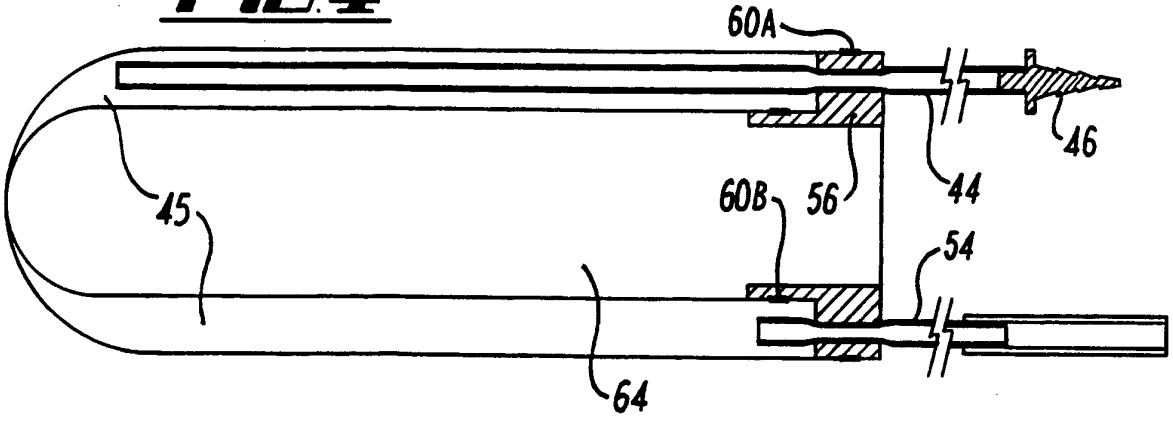


FIG. 3

FIG. 4



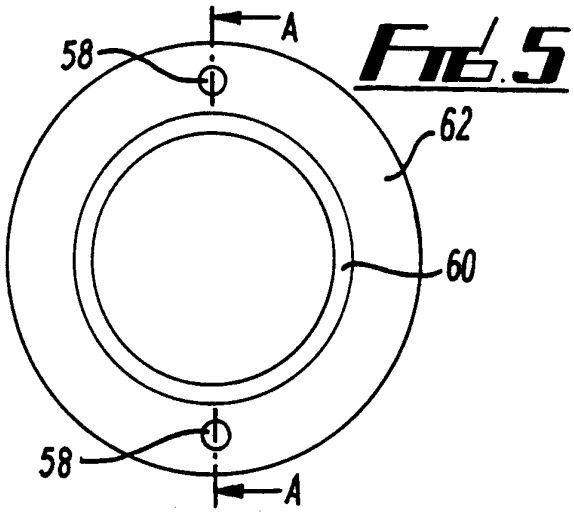


FIG. 5

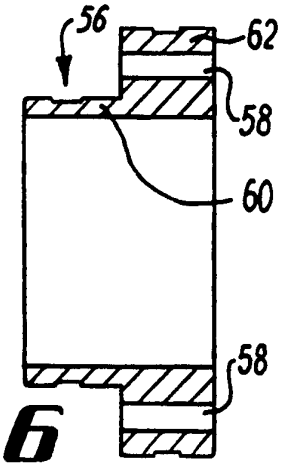


FIG. 6