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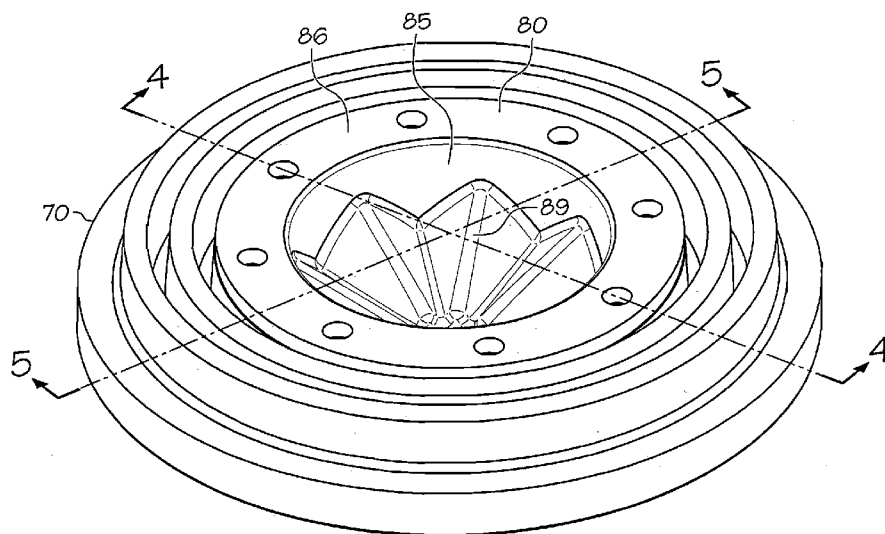
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ning of each regular issue of the PCT Gazette.

(54) Title: PLEATED TROCAR SEAL



(57) Abstract: A trocar seal comprising an elastomeric membrane having an opening adapted to receive a surgical instrument. The membrane is configured with a plurality of pleats circumscribing the opening and extending laterally from opening. The pleats comprise a plurality of pleat walls increasing in height as the pleats extend laterally from the opening. In one embodiment, the pleats are conically arranged.

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## PLEATED TROCAR SEAL

### BACKGROUND

The present invention relates in general to endoscopic surgical procedures, and in particular, to trocars used in such procedures.

The use of endoscopic procedures in surgery has become widely accepted. The term “endoscopic” refers to all types of minimally invasive surgical procedures including laparoscopic and arthroscopic procedures. Endoscopic surgery has numerous advantages compared to traditional open surgical procedures, including reduced trauma, faster recovery, reduced risk of infection, and reduced scarring.

Numerous endoscopic instruments have been developed that allow the surgeon to perform complex surgical procedures with minimal incisions into the skin and tissue surrounding a particular body cavity or anatomical region. In order to introduce the endoscopic instrumentation into the body cavity, a device known as a “trocar” is often used to puncture and/or cannulate the wall of the body cavity. Trocars are widely known in the art and typically comprise an obturator and a cannula. The obturator typically includes a sharply pointed or appropriately structured tip that facilitates penetration of the body cavity wall. The cannula provides a channel or opening through the body cavity wall through which endoscopic instruments may be introduced and removed by the surgeon.

Endoscopic surgery is often performed with an insufflatory fluid present within the body cavity, such as carbon dioxide or saline, to provide adequate space to perform the intended surgical procedures. The insufflated cavity is generally under pressure and is sometimes referred to as being in a state of pneumoperitoneum. It is common for a sealing arrangement or seal assembly to be used in association with the trocar to maintain pneumoperitoneum. The seals will generally prevent the insufflatory fluid from escaping while an endoscopic instrument is positioned in the trocar cannula.

No one has previously made or used a trocar or seal in accordance with the present invention.

## BRIEF DESCRIPTION OF DRAWINGS

While the specification concludes with claims which particularly point out and distinctly claim the invention, it is believed the invention will be better understood from the following description taken in conjunction with the accompanying drawings illustrating some non-limiting examples of the invention. Unless otherwise indicated, the figures are drawn to scale and like reference numerals identify the same elements.

Fig. 1 depicts a cross-sectional view of a trocar;

Fig. 2 depicts an exploded view of the trocar of Fig. 1;

Fig. 3 depicts a perspective view of an instrument seal and bellows;

Fig. 4 depicts a cross-sectional view from Fig. 3; and

Fig. 5 depicts another cross-sectional view from Fig. 3.

## DETAILED DESCRIPTION

Fig. 1 depicts a cross-sectional view of a trocar (10). During typical use the distal end (14) will be inserted through the body wall into the cavity, and the proximal end (12) will be positioned outside the patient. A cannula (16) opens through the distal end (14) and is in fluid communication with a seal housing (18). The size of the cannula (16) can vary widely, but in the present example the inside diameter is about 12.9 mm. A valve (20), shown here as a stopcock, permits the surgeon to selectively introduce or relieve pressurized insufflation fluid through the trocar (10) to the body cavity. Optionally, the trocar (10) may include an obturator (not shown).

The seal housing (18) contains a seal arrangement comprising a closure valve (40) and an instrument seal (80) that work together to maintain pneumoperitoneum. In this example, the closure valve (40) is a single-silted "duck bill" valve; however, other types of closure valves may also be used, including flapper valves, multi-silted duck bill valves, and the like. When an endoscopic instrument is passed through the proximal end (12) through the closure valve (40), the valve will open but will generally not provide a complete seal against the instrument. When the instrument is removed from the trocar (10), the closure valve (40) closes and substantially prevents insufflation fluid from escaping through the trocar (10). The instrument seal (80) seals against the instrument to prevent insufflation fluid from escaping through the trocar (10); however, the instrument seal (80) generally will not maintain pneumoperitoneum unless an instrument is positioned in the trocar (10). In this example, the instrument seal (80) "floats"

1 within the valve housing (18) such that the seal (80) can move laterally relative the trocar (10)  
2 centerline.

3 Fig. 2 depicts an exploded view of the trocar (10) and helps illustrate the assembly of the  
4 component parts. The lower body (30) includes an elongate tube portion (32), which defines the  
5 cannula (16), and a housing portion (34). The upper body (110) attaches to the housing portion  
6 (34), which together provide a housing wall to define the seal housing (18). The closure valve  
7 (40) is positioned and seated in the housing portion (34). The retainer ring (50) is positioned and  
8 seated against the closure valve (40) and sandwiches a flange on the closure valve (40) against  
9 the housing portion (34) to provide a seal at that location. These components can be made from a  
10 variety of different materials. For instance, in the present example the lower body (30), retainer  
11 ring (50), and upper housing (110) are formed from relatively rigid plastic such as polycarbonate,  
12 and the closure valve (40) is formed from a relatively soft elastomer such as polyisoprene;  
13 however, other materials could also be used.

14 The instrument seal assembly (120) is sandwiched between the retainer ring (50) and the  
15 upper body (110) to provide a seal at that location. The instrument seal assembly (120) includes  
16 an anchor (60), bellows (70), instrument seal (80), protectors (90), and retainer (100). The posts  
17 on the retainer (100) align with the corresponding holes on the other components of the assembly  
18 (120). The bellows (70), instrument seal (80), and protectors (90) are sandwiched between the  
19 retainer (100) and the anchor (60). An interference fit between the retainer (100) posts and  
20 anchor (60) holes keep the assembly (120) in compression. The protectors (90) comprise four  
21 sequentially overlapping plates to protect the instrument seal (80) from perforating or tearing due  
22 to surgical instruments. The components of the instrument seal assembly (120) can be made from  
23 a variety of different materials with a range of different material properties. For instance, in the  
24 present example the anchor (60) and retainer (100) are formed from relatively rigid plastic such  
25 as polycarbonate, the bellows (70) and instrument seal (80) are formed from a relatively soft  
26 elastomer such as polyisoprene, and the protectors (90) are formed from a pliant but semi-rigid  
27 plastic such as pellathane; however, other materials could also be used.

28 Figs 3-5 illustrate the bellows (70) and instrument seal (80). The bellows (70) are an  
29 elastomeric membrane comprising a circular lateral flange (74), a circular medial flange (76),  
30 and circumferential pleats (72) positioned between the flanges (74, 76). The pleats (72) provide  
31 lateral pliancy so the assembly (120) can float. The medial flange (76) includes a plurality of

1 holes (77) that align with the retainer (100) posts. The lateral flange engages the housing wall  
2 creating a seal at that location.

3 The instrument seal (80) is an elastomeric membrane having lips (82) defining an  
4 opening (81) adapted to receive and sealingly engage an endoscopic surgical instrument. The  
5 size of the opening (81) in its relaxed state may vary widely, but in the present example the  
6 inside diameter is between 3.8 and 4.0 mm. The instrument seal (80) of the present example is  
7 sufficiently elastic that the opening (81) can expand to sealingly engage instruments having  
8 diameters of up to 12.9 mm. A plurality of pleats (89) circumscribe the opening (81) and extend  
9 laterally from opening (81). As shown in this example, the instrument seal (80) comprises eight  
10 linear pleats (89); however, greater or fewer or non-linear pleats could also be used. In this  
11 embodiment, the pleats (89) are conically arranged. A wall section (85) circumscribes and is  
12 connected to the pleats (89). As shown here, the inside diameter of the wall section (85) is  
13 between 17.7 and 17.9 mm. A radial flange (86) extends laterally from the wall section (85) and  
14 includes a plurality of holes (87) that align with the retainer (100) posts.

15 Each pleat (89) comprises a pleat wall extending between the pleat peak (84) and pleat  
16 valley (83). The height of the pleat walls can be measured along the wall surface from the peak  
17 (84) to the valley (83). As shown here, the pleat walls each have a variably height that tapers  
18 medially. Accordingly, the pleat walls increase in height as the pleats extend laterally from the  
19 opening (81). Among other advantages, the pleats (89) help to reduce hoop stresses when an  
20 instrument is positioned in the opening (81), thus reducing friction between the instrument and  
21 the trocar (10). Reduced hoop stresses facilitate a thicker wall thickness to be used while  
22 providing similar or reduced drag forces than non-pleated lip seal designs, thus increasing seal  
23 durability.

24 Optionally, the geometry of the pleats (89) can be designed to minimize or eliminate  
25 hoop stress in the pleated portion of the seal (80) when an instrument is introduced. In one  
26 embodiment, this geometric relationship conforms to the following equation:

$$27 \quad h \geq \frac{\pi}{P} \sqrt{r^2 + r_i^2 - r_{id}^2}$$

28 where:

29  $h$  = pleat wall height as a function of radius

30  $r$  = radius

1  $r_i$  = radius of largest instrument designed for insertion through seal

2  $r_{id}$  = radius at inside diameter of pleat section of seal

3  $P$  = number of pleats

4 A pleat design will substantially conform to the this equation if it complies with the  
5 essence of this equation, even if the pleat geometry varies insignificantly. For example,  
6 geometric variances to accommodate molding or other manufacturing considerations would  
7 substantially conform to this equation. As another example, a pleat design that satisfies the  
8 equation at all locations excepts for minor variances at the inside or outer diameters of the pleat  
9 section of the seal would nevertheless substantially conform to the equation.

10 As shown in the figures, the pleats (89) form a generally frustoconical shape bounded by  
11 the wall section (85) and the lip (82). In this example, the slope of the frustoconical shape is  
12 greater on the proximal side than the distal side, with both the proximal and distal surfaces  
13 sloping distally toward the opening (81). Alternatively, both surfaces could slope proximally. In  
14 another variation, the proximal surface could slope distally and the distal surface could slope  
15 proximally. In yet another variation, one of the surfaces could slope while the other could be  
16 planar. It is also contemplated that both the surfaces could have the same slope or both could be  
17 planar.

18 The lip (82) in this example has a cylindrical portion, which when intersected with the  
19 pleats (89) results in a crown-shaped surface with proximally pointing tips corresponding to each  
20 peak (84). Similarly, the wall section (85) in this example has a cylindrical portion, which when  
21 intersected with the pleats (89) results in an upside crown-shaped surface with distally pointing  
22 tips corresponding to each valley (83). Naturally, the lip (82) and/or wall section (85) could be  
23 non-cylindrical, such as having a straight or curved taper.

24 The lateral flange (74) is compressed between the retainer ring (50) and the upper body  
25 (110) to provide a seal against the housing wall. The medial flange (76) and radial flange (86) are  
26 compressed between the anchor (60) and the retainer (100) to provide a seal. When an instrument  
27 is positioned and sealed in the opening (81), pneumoperitoneum can be maintained. While the  
28 bellows (70) and instrument seal (80) are shown in this example as separate parts, it is  
29 contemplated that the bellows (70) and instrument seal (80) can be formed as a unitary part.

30 Preferably, the trocars will be processed before surgery. First, a new or used trocar is  
31 obtained and if necessary cleaned. The trocar can then be sterilized. In one sterilization

1 technique, the trocar is placed in a closed and sealed container, such as a plastic or TYVEK bag.  
2 The container and trocar are then placed in a field of radiation that can penetrate the container,  
3 such as gamma radiation, x-rays, or high-energy electrons. The radiation kills bacteria on the  
4 trocar and in the container. The sterilized trocar can then be stored in the sterile container. The  
5 sealed container keeps the trocar sterile until it is opened in the medical facility.

6 Having shown and described various embodiments and examples of the present  
7 invention, further adaptations of the methods and apparatuses described herein can be  
8 accomplished by appropriate modifications by one of ordinary skill in the art without departing  
9 from the scope of the present invention. Several of such potential modifications have been  
10 mentioned, and others will be apparent to those skilled in the art. For instance, the specific  
11 dimensioned described above will be understood to be nonlimiting examples. Accordingly, the  
12 scope of the present invention should be considered in terms of the following claims and is  
13 understood not to be limited to the details of structure, materials, or acts shown and described in  
14 the specification and drawings.  
15

## CLAIMS

1. A seal for endoscopic instruments, comprising an elastomeric membrane having an opening adapted to receive a surgical instrument, said membrane being configured with a plurality of pleats circumscribing the opening and extending laterally from opening, said pleats comprising a plurality of pleat walls increasing in height as the pleats extend laterally from the opening.
2. The seal of claim 1, wherein the pleats are conically arranged.
3. The seal of claim 1, further comprising a wall section circumscribing and connected to the pleats.
4. The seal of claim 3, wherein the wall section is cylindrical.
5. The seal of claim 3, further comprising a radial flange extending laterally from the wall section.
6. The seal of claim 3, further comprising bellows circumscribing and connected to the wall section.
7. The seal of claim 1, further comprising a lip defining the opening.
8. The seal of claim 1, wherein the pleat height substantially conforms to the following equation:

$$h \geq \frac{\pi}{P} \sqrt{r^2 + r_i^2 - r_{id}^2}$$

where:

$h$  = pleat wall height as a function of radius

$r$  = radius

$r_i$  = radius of largest instrument designed for insertion through seal



$r_{id}$  = radius at inside diameter of pleat section of seal

$P$  = number of pleats

9. The seal of claim 1, comprising only eight pleats.
10. A trocar comprising the seal of claim 1.
11. A method for processing a trocar for surgery, comprising:
  - a) obtaining the trocar of claim 10;
  - b) sterilizing the trocar;
  - c) storing the trocar in a sterile container.
12. A trocar, comprising:
  - a) a seal housing;
  - b) a cannula extending distally from the seal housing;
  - c) a closure valve aligned with the cannula and positioned in the seal housing; and
  - d) an instrument seal aligned with the cannula and positioned in the seal housing, the instrument seal comprising an opening dimensioned to sealingly engage surgical instruments and a plurality of conically arranged pleats extending radially about the opening.
13. The trocar of claim 12, further comprising shield plates positioned in the concave portion of the conically arranged pleats.
14. A method for processing a trocar for surgery, comprising:
  - a) obtaining the trocar of claim 12;
  - b) sterilizing the trocar;
  - c) storing the trocar in a sterile container.
15. A trocar seal comprising:

- 1 a) a lip defining and an opening, said lip being adapted to sealingly engage a  
2 endoscopic surgical instrument; and  
3 b) a plurality of conically arranged linear pleats circumscribing the lip and extending  
4 radially away from lip, said pleats comprising a plurality of medially tapering  
5 walls.

6  
7 16. A trocar comprising the seal of claim 15 positioned in a seal housing.

8  
9 17. A method for processing a trocar for surgery, comprising:

- 10 a) obtaining the trocar of claim 16;  
11 b) sterilizing the trocar; and  
12 c) storing the trocar in a sterile container.

13  
14 18 The trocar seal of claim 15, further comprising a wall section circumscribing the pleats.

15  
16 19. The trocar seal of claim 18, further comprising bellows circumscribing the wall section.

17  
18 20. The trocar seal of claim 18, wherein the wall section has a cylindrical portion.  
19

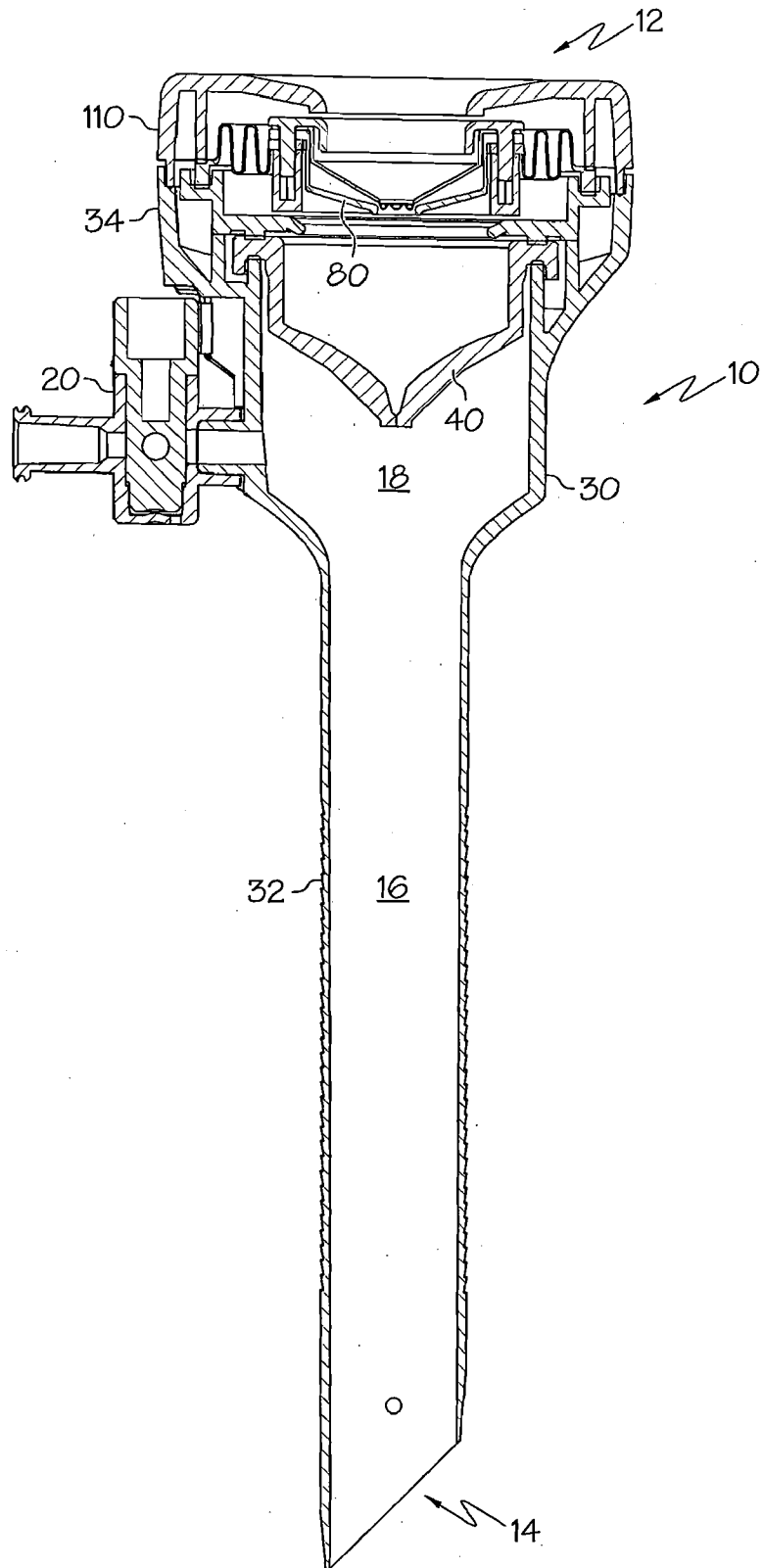


FIG. 1

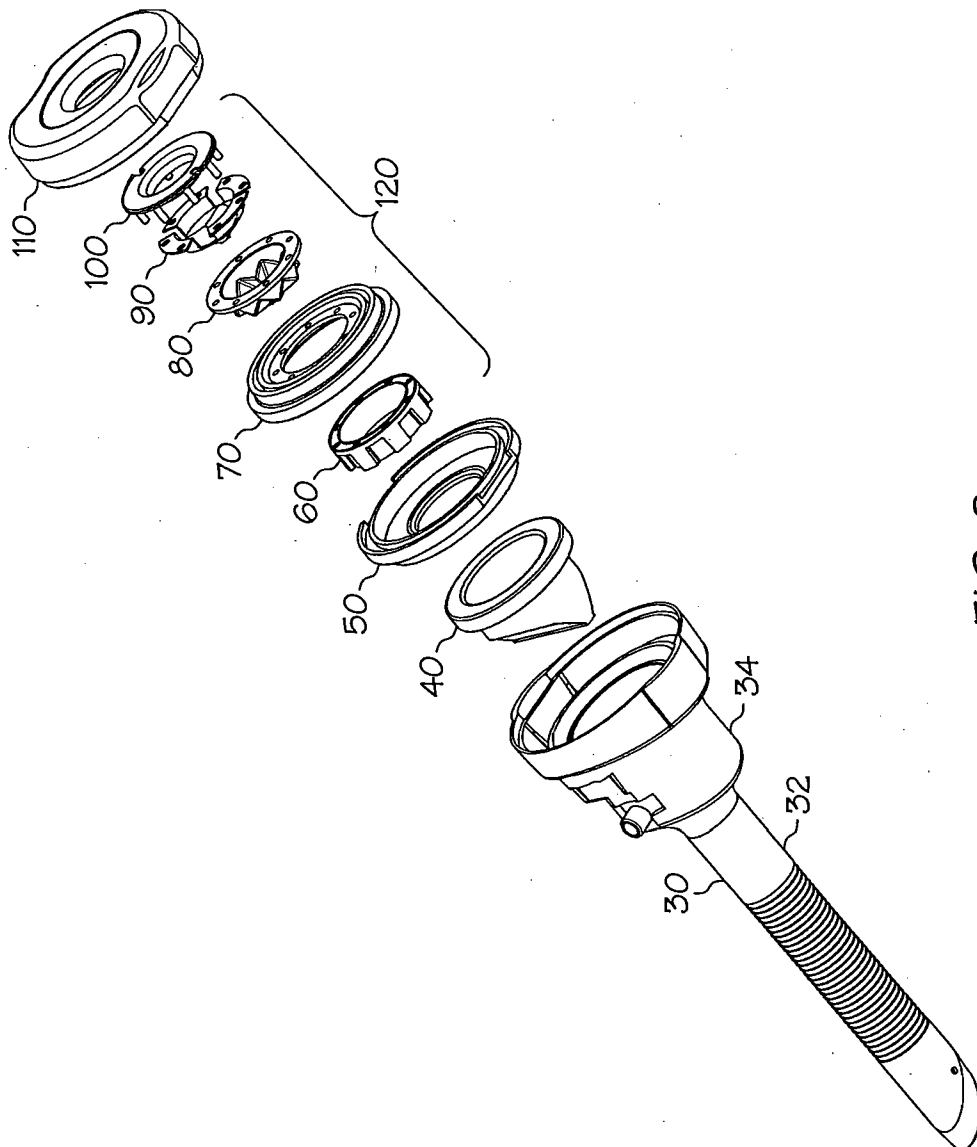


FIG. 2

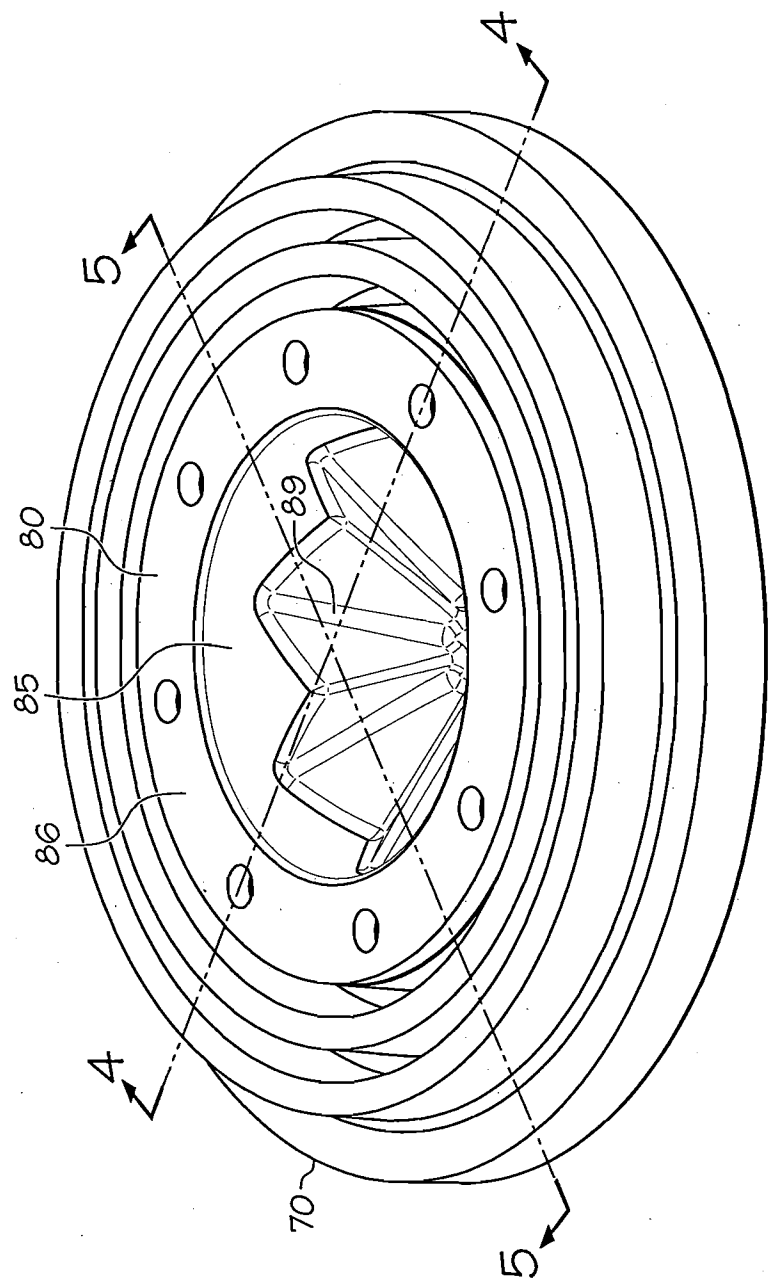


FIG. 3

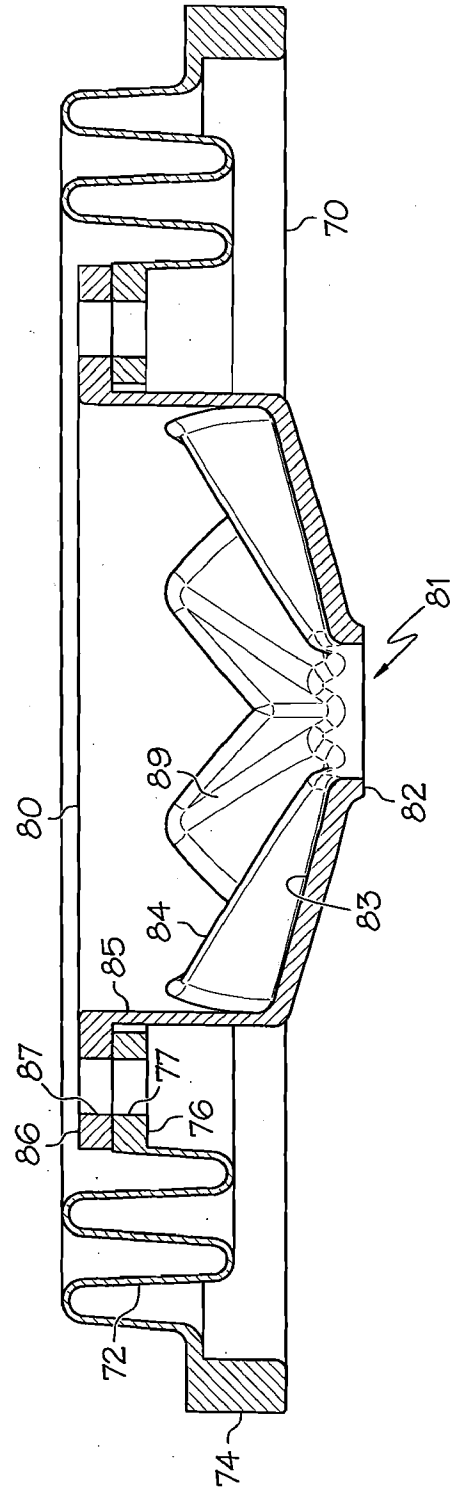
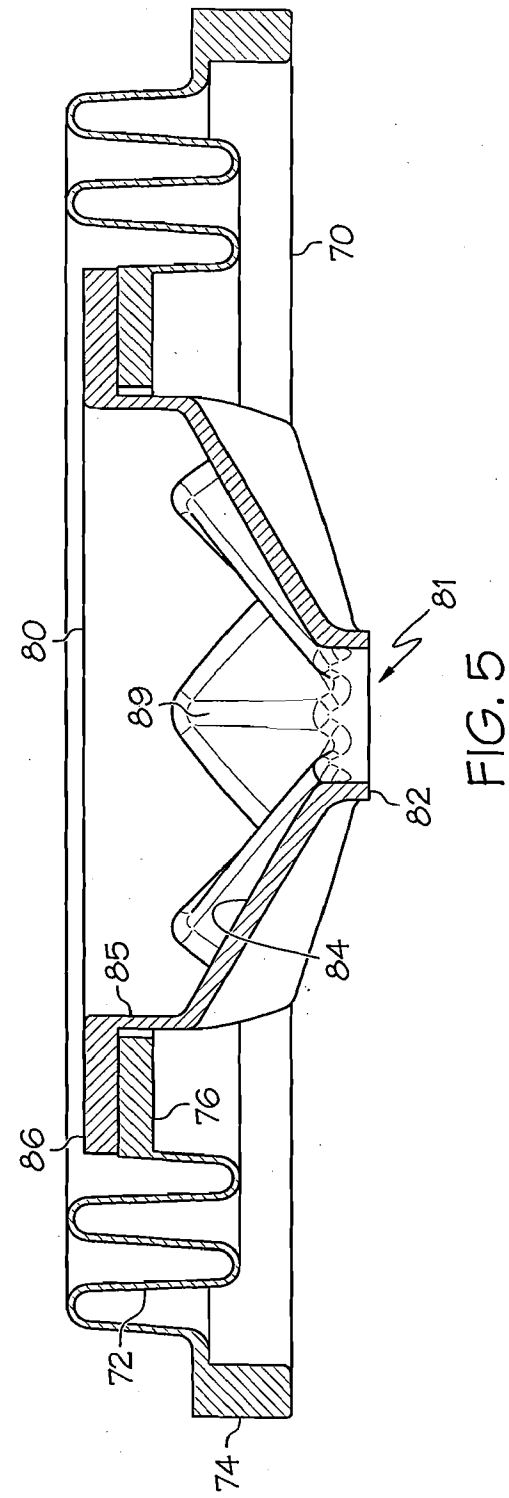


FIG. 4



## INTERNATIONAL SEARCH REPORT

International application No

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A. CLASSIFICATION OF SUBJECT MATTER  
INV. A61B17/34

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Minimum documentation searched (classification system followed by classification symbols)

A61B

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 practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/288634 A1 (O'HEERON PETER T [US] ET AL) 29 December 2005 (2005-12-29) paragraph [0011] - paragraph [0013]; figures 4,5 paragraph [0029]	1-20
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Further documents are listed in the continuation of Box C.



See patent family annex.

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# INTERNATIONAL SEARCH REPORT

Information on patent family members

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