PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 5/315, F16J 15/32 — A1

(11) International Publication Number: **WO 99/44659**

(43) International Publication Date: 10 September 1999 (10.09.99)

(21) International Application Number: PCT/US99/03837

(22) International Filing Date: 23 February 1999 (23.02.99)

(30) Priority Data:
09/033,264 2 March 1998 (02.03.98) US

(71) Applicant: MEDRAD, INC. [US/US]; One Medrad Drive, Indianola, PA 15051 (US).

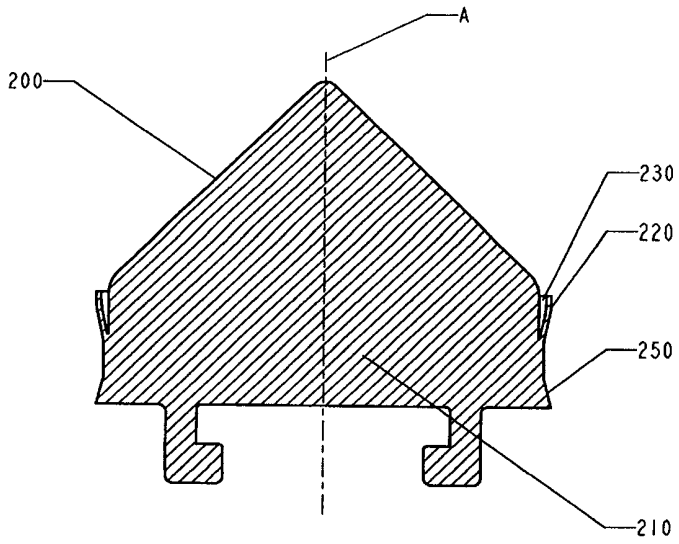
(72) Inventors: DEDOLA, Salvatore, J.; 321 Lynn Ann Drive, New Kensington, PA 15068 (US). HITCHINS, Mark, W.; 329 Chestnut Street, Sewickley, PA 15143 (US).

(74) Agents: BRADLEY, Gregory, L.; Medrad, Inc., One Medrad Drive, Indianola, PA 15051 (US) et al.

(81) Designated States: JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: SYRINGES AND PLUNGERS FOR USE THEREIN



(57) Abstract

The present invention provides a plunger for use in a syringe and a syringe comprising such a plunger. The plunger includes a pressure member extending around the circumference of a generally cylindrical body of the plunger. The pressure member is in substantially sealing contact with the plunger body. The pressure member is sufficiently flexible to be forced radially outwardly to exert force upon the inner wall of the syringe as a result of increased fluid pressure upon forward motion of the plunger. The pressure member thereby forms a substantially sealing engagement with the inner wall of the syringe. In one embodiment, the pressure member comprises a flange attached at a rearward portion of the flange to a body of the plunger. The flange extends forward and radially outward to form a circumferential channel between the flange and the body of the plunger. In another embodiment, the pressure member comprises a resilient O–ring seated in a seating formed around the circumference of the body of the plunger. The seating comprises a ramp portion having a forward radius that is smaller than a rearward radius thereof.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

SYRINGES AND PLUNGERS FOR USE THEREIN

Field of the Invention

The present invention relates to syringes and plungers for use therein, and more particularly, to syringes and plungers for use therein in which lubricant need not be applied between the syringe and the plunger.

Background of the Invention

In many medical procedures, such as drug delivery, it is desirable to inject a fluid into a patient. Likewise, numerous types of contrast media (often referred to simply as contrast) are injected into a patient for many diagnostic and therapeutic imaging procedures. For example, contrast media are used in diagnostic procedures such as X-ray procedures (including, for example, angiography, venography and urography), CT scanning, magnetic resonance imaging (MRI), and ultrasonic imaging. Contrast media are also used during therapeutic procedures, including, for example, angioplasty and other interventional radiological procedures. Regardless of the type of procedure, any fluid injected into the patient must be sterile and contain a minimum of pyrogens.

Typically, a fluid is injected into a patient using a manual or powered syringe. Such syringes typically comprise a reciprocally slidable plunger disposed within a cylindrical syringe body.

A number of injector-actuated syringes and powered injectors for use in angiography, computed tomography and NMR/MRI have been developed. In general, syringe plungers for use with such powered injectors require an elastomeric cover which forms a sealing engagement with the inner wall of the syringe barrel. To reduce friction and provide an adequate seal, the syringe barrel, the plunger and the elastomeric plunger cover are typically lubricated during manufacture with, for example, a silicone oil lubricant. U.S. Patent Nos. 4,628,969 and 4,718,463 describe such lubrication.

The requirement of application of a silicone lubricant oil adds a step in the manufacturing process. Moreover, there is a risk that small amounts of silicone oil can be injected into the patient.

It is desirable to develop a syringe and a plunger for use therein in which an adequate seal is formed therebetween without the need for applying lubrication between the syringe and plunger.

Summary of the Invention

The present invention provides a syringe and a plunger for use therein for injecting a fluid into a patient. In one aspect of the invention, the plunger comprises a pressure member extending around the circumference of a generally cylindrical body of the plunger. The pressure member is in substantially sealing contact with the plunger body. The pressure member is sufficiently flexible to be forced radially outwardly to exert force upon the inner wall of the syringe in response to increased fluid pressure upon forward motion of the plunger (that is, during an injection procedure). The pressure member thereby forms a substantially sealing engagement with the inner wall of the syringe.

In one embodiment, the pressure member comprises a flange attached at a rearward portion thereof to a body of the plunger. The flange extends forward and radially outward to form a circumferential channel between the flange and the body of the plunger. The flange flexes radially outwardly to form a substantially sealing engagement with the inner wall of the syringe in response to increasing fluid pressure within the channel upon forward motion of the plunger.

In another embodiment, the pressure member comprises a resilient O-ring in sealing contact with the body of the plunger. The O-ring is also preferably in sealing engagement with the inner wall of the syringe. The O-ring is seated in a seating formed around the circumference of the body of the plunger. The seating comprises a ramp portion having a forward radius that is smaller than a rearward radius thereof. The ramp portion

thus extends radially outward toward the rear thereof. As the plunger is moved forward, frictional contact with the inner wall of the syringe and increasing fluid pressure force the O-ring to move rearward along the ramp portion of the seating. The increasing radius of the ramp portion causes the O-ring to exert greater force upon the inner wall of the syringe, thereby ensuring a substantially sealing engagement between the O-ring and the inner wall.

The pressure members of the present invention, as compared to conventional designs, maintain a substantially sealing contact with the inner wall of the syringe while reducing frictional forces associated with movement of the plunger within the syringe. Moreover, the pressure members of the present invention maintain substantially sealing contact with the inner wall of the syringe even as the syringe expands under increased pressure (that is, increased fluid pressure during injection).

Brief Description of the Drawings

Figure 1 illustrates a cross-sectional view of a syringe having one embodiment of a plunger of the present invention slidably disposed therein.

Figure 2A illustrates a cross-sectional view of the plunger of Figure 1.

Figure 2B illustrates an enlarged cross-sectional view of the encircled portion of Figure 2A.

Figure 3A illustrates a top perspective view of the plunger of Figure 1.

Figure 3B illustrates a bottom perspective view of the plunger of Figure 1.

Figure 4 illustrates a cross-sectional view of another embodiment of a plunger of the present invention.

Figure 5A illustrates an enlarged cross-sectional view of a portion of the plunger of Figure 4.

Figure 5B illustrates a top perspective view of the plunger of Figure 4.

Figure 6A illustrates a cross-sectional view of another embodiment of a plunger of the present invention.

Figure 6B illustrates an expanded cross-sectional view of the encircled portion of Figure 6A.

Figure 6C illustrates an enlarged cross-sectional view of a portion of the plunger of Figure 6A wherein the syringe has radially expanded and the flanges of the plunger move radially outward to maintain a sealed engagement with the inner wall of the syringe.

Figure 7 illustrates a cross-sectional view of another embodiment of a plunger of the present invention comprising two circumferential sealing members.

Figure 8A illustrates a bottom perspective view of the plunger of Figure 7.

Figure 8B illustrates a top perspective view of the plunger of Figure 7.

Figure 9A illustrates a cross-sectional view of another embodiment of a plunger of the present invention.

Figure 9B illustrates an enlarged cross-sectional view of the encircled portion of Figure 9A.

Figure 9C illustrates an enlarged cross-sectional view of the encircled portion of Figure 9A wherein the syringe has radially expanded and the O-ring has moved

rearward along the ramp portion to maintain a sealed engagement with the inner wall of the syringe.

Detailed Description of the Invention

Figure 1 illustrates a syringe 10 in which a plunger 100 is slidably disposed. In the embodiment of Figure 1, syringe 10 preferably comprises an elongated, generally cylindrical body or barrel section 20. A generally conical or frusto-conical region 30 is preferably positioned at the forward end of cylindrical body 20. A tapered discharge or injection region 40 is preferably positioned at the forward end of transition region 30. Pressurized injection fluid is discharged from syringe tip 45. As clear to one skilled in the art, however, plunger 100 is suitable for use in generally any type of syringe. Examples of syringes suitable for use in the present invention are disclosed in U.S. Patent Nos. 4,006,736, 4,677,980, 5,300,031 and 5,383,858, and in U.S. Patent Application Serial Nos. 08/517,645, filed on August 22, 1995, and entitled "Manufacture of Prefilled Syringes" and 08/748,230, filed on November 12, 1996, and entitled "Prefillable Syringes and Injectors for Use Therewith," the contents of which are incorporated herein by reference.

As used herein to describe syringe 10 and plunger 100, the terms "axial" or "axially" refer generally to an axis A around which syringe 10 and plunger 100 are preferably formed (although not necessarily symmetrically therearound). The terms "proximal" or "rearward" refer generally to an axial direction toward the end of syringe 10 opposite syringe tip 45. The terms "distal" or "forward" refer generally to an axial direction toward the syringe tip 45 of syringe 20. The term "radial" refers generally to a direction normal to axis A.

Plunger 100, as best illustrated in Figures 1 through 3B, preferably comprises a generally cylindrical body portion 110. To most efficiently expel fluid from syringe 10, the forward portion of plunger 100 is preferably shaped to mate with the forward portion of syringe 10. In that regard, plunger 100 preferably comprises a conical

or frusto-conical portion 112 positioned at the forward end of body portion 110. Plunger 100 may also include attachment members 118 adapted to attach to a drive member of a powered injector (not shown).

At least one flexible flange 120 preferably extends around the body portion 110 of plunger 100. Flange 120 is preferably attached to body portion 110 at a rearward end of flange 120. Flange 120 preferably extends radially outwardly (away from body portion 110 and forming an acute angle with the generally cylindrical wall thereof) as it extends forward, thereby forming an annular channel 130 between flange 120 and body portion 110.

During use of syringe 10, fluid within syringe 10 enters annular channel 130. Forward motion of plunger 100 to pressurize and inject fluid contained within syringe 10 results in pressurization of the fluid within annular channel 130. The hydraulic force of the fluid within annular channel 130 forces flange 130 away from body portion 110 and against an inner wall 60 of elongated cylindrical portion 20. As plunger 100 is moved forward, flange 130 is forced against inner wall 60 and prevents any fluid from passing rearward between flange 130 and inner wall 60.

Because plunger 100, unlike currently available syringe plungers, does not rely on elastomeric compression to form a seal with inner wall 60, the force required to advance plunger 100 forward is significantly less than required for currently available plungers. Moreover, the materials for plunger 100 and inner wall 60 can be chosen to have a coefficient of friction less than coefficients of friction common in currently available syringe/plunger combinations. For example, each of plunger 100 and inner wall 60 of syringe 10 can be fabricated from polypropylene to result in a relatively low coefficient of friction. The relatively small force required to advance plunger 100 forward frees plunger 100 and syringe inner wall 60 from the requirement of silicone lubrication required with currently available syringe/plunger combinations. Furthermore, flange 130 maintains a substantially sealing contact with inner wall 60 even as syringe 10 radially expands with increasing pressure during, for example, an injection procedure.

Plunger 100 can be fabricated, for example, via injection molding of a single polymeric material, such as polypropylene. Plunger 100 can also be fabricated, for example, via a coinjection molding process in which a injection moldable elastomer (for example, Santoprene) is injection molded over a harder material (for example, polypropylene or polycarbonate).

As clear to one skilled in the art, the greater the pressure of the fluid within the syringe, the greater the sealing force exerted upon flange 120. At low pressures, however, the radially outward force upon flange 120 may not be sufficient to create a seal adequate to prevent leakage. Moreover, flange 120 may not create a seal adequate to enable drawing of injection fluid into syringe 10 upon rearward movement of plunger 100.

Plunger 100, therefore, preferably further comprises at least one radially outward extending member, such as a rib or ridge 140, positioned rearward of flange 120. More than one ridge 140 (see Figures 3A and 3B) may be provided. Ridge(s) 140 preferably extend radially outward a sufficient length to contact inner wall 60 to create a substantially sealing engagement with inner wall 60. Ridge(s) 140 thereby act as a low-pressure seal to prevent injection fluid from leaking rearward when plunger 100 is advanced at low pressure.

A low-pressure seal can also be effected by other radially extending members, such as a radially outward flared portion 250 of a plunger 200 illustrated in Figures 4 through 5B. Like plunger 100, plunger 200 comprises a flange 220 which extends forward and radially outward from a generally cylindrical portion 210 to create a channel 230. Ridge(s) 140 and flared portion 250 also act to create a seal with inner wall 60 when plunger 100 is moved rearward to draw injection fluid into syringe 10.

Radially outward extending members such as ridge(s) 140 (in connection with flange 120) further act to stabilize plunger 100 to prevent movement of plunger 100 during, for example, an autoclaving or other operation. For this purpose, there may be a plurality of radially extending members positioned at different axial locations on plunger body 110. An axial distance L between the forwardmost sealing edge of the forward radially

extending member (or the point at which flange 120 contacts the syringe wall in the case of a single radially extending member) and the rearwardmost sealing edge of the rearward radially extending member is preferably at least 30% of the syringe internal diameter. Such an approximately 3:1 ratio limits rotational movement of the plunger assembly relative to the syringe axis during the autoclave cycle and any other handling.

In the case of a plurality of radially outward extending members, the plurality of radially outward extending members can comprise different types of radially extending member. For example, a rib or ridge member can be used in combination with a flared portion. In another embodiment illustrated in Figures 6A and 6B, a plunger 300 comprising a flange 320 which extends forward and radially outward from a generally cylindrical portion 310 to create a channel 330. A radially outward extending ridge 340 is preferably positioned at the rearwardmost portion of flange 320 where flange 320 is attached to generally cylindrical portion 310. Ridge 340 acts as a low pressure seal as discussed above. Plunger 300 also comprises a second flange 360 which extends rearward and radially outwardly. Flange 360 is positioned to the rear of ridge 340. Flange 360 is preferably cantilevered rearward and radially outwardly to contact and exert a radially outward force upon the inner wall of the syringe (see Figure 6C). Flange 360 thereby acts as a wiper seal and provides a contamination barrier. Flange 360 and ridge 340 also act to stabilize plunger 300 in the syringe barrel As described above, an axial distance L' between the contact edge of ridge 340 and the contact edge of the rearward flange 360 is preferable at least 30% of the syringe internal diameter.

As illustrated in Figure 6C, flange 320, including ridge 340, move radially outward to maintain a substantially sealing contact with inner wall 60 even as syringe 10 radially expands with increasing pressure during, for example, an injection procedure. Likewise, flange 360 preferably also moves radially outward to maintain a substantially sealing contact with inner wall 60 as syringe 10 radially expands.

As illustrated in Figures 7 through 8B, a plunger 400 may comprise multiple flanges such as flanges 420 and 420' which extend forward and radially outward from a generally cylindrical portion 410 to create multiple channels 430 and 430', respectively.

Typically, only forwardmost flange 420, is pressurized by the fluid within the syringe and thereby forced against the syringe wall to create a high-pressure seal. Flange 420' may act as a backup to flange 420 in this regard, however. Plunger 400 also preferably comprised a rearward, radially outward extending member 440 which functions as a low-pressure seal and (in connection with flanges 420 and 420') as a stabilizing member as described above.

Figures 9A through 9C illustrate another embodiment of the present invention in which a plunger 500 comprises a resilient O-ring 520 in sealing contact with a generally cylindrical body 510 of plunger 500. O-ring 520 is also in sealing engagement with the inner wall of the syringe (not shown). O-ring 520 is seated in a radially inward depression or seating 530 formed around the circumference of body 510. Seating 530 comprises a ramp portion 534 having a forward radius that is smaller than a rearward radius thereof. Ramp portion 534 thus extends or slopes radially outward toward the rear thereof.

As plunger 500 is moved forward, frictional contact with the inner wall of the syringe and increasing fluid pressure force O-ring 520 to move rearward along ramp portion 534 as illustrated in Figure 9C. The increasing radius of ramp portion 535 causes O-ring 520 to exert greater force upon the inner wall of the syringe, thereby ensuring a substantially sealing engagement between O-ring 520 and the inner wall. Thus, the greater the pressure of the fluid within the syringe, the greater the force exerted by O-ring 520 on the inner wall of the syringe. Furthermore, O-ring 520 maintains a substantially sealing contact with inner wall 60 of syringe 10 even as syringe 10 radially expands under increasing pressure.

Seating 530 preferably further comprises a forward abutment portion 538. Abutment portion 538 retains O-ring 520 with seating 530 during rearward motion of plunger 500.

Plunger 500 also preferably comprises a radially extending member to stabilize plunger 500 as discussed above. For example, plunger 500 may comprise a flange 560, which is preferably positioned at the rearward end of plunger 500. Flange 560 is preferably cantilevered rearward and radially outward to contact and exert a radially

outward force upon the inner wall of the syringe. As discussed above, flange 560 thereby forms a substantially sealing engagement with the inner wall of the syringe and acts as a wiper seal to provide a contamination barrier. Flange 560 also acts to stabilize plunger 500 in the syringe barrel. In that regard, the distance between the contact edge of O-ring 520 and the contact edge of flange 560 is preferably at least 30% of the diameter of the inner wall of the syringe.

Although the present invention has been described in detail in connection with the above examples, it is to be understood that such detail is solely for that purpose and that variations can be made by those skilled in the art without departing from the spirit of the invention. The scope of the invention is indicated by the following claims rather than by the foregoing description. All changes to the present invention that fall within the meaning and range of equivalency of the claims are to be embraced within their scope.

WHAT IS CLAIMED IS:

1. A plunger for use in a syringe for the pressurized injection of a fluid contained within the syringe, the plunger comprising: a pressure member extending around the circumference of a body of the plunger in substantially sealing contact therewith, the pressure member being sufficiently flexible to be forced radially outwardly to exert force upon an inner wall of the syringe in response to increasing fluid pressure within the syringe during forward movement of the plunger, the pressure member thereby forming a substantially sealing engagement with the inner wall of the syringe.

2. The plunger of Claim 1 wherein the pressure member comprises a flange attached at a rearward portion thereof to the body of the plunger, the flange extending forward and radially outward to form a channel between the flange and the body of the plunger, the flange being sufficiently flexible to flex radially outwardly to exert force upon the inner wall of the syringe in response to increasing fluid pressure within the channel upon forward motion of the plunger, the flange thereby forming a substantially sealing engagement with the inner wall of the syringe.

3. The plunger of Claim 2, further comprising at least a first circumferential seal member extending radially outward from the body of the plunger to contact and form a seal with the inner wall of the syringe.

4. The plunger of Claim 3 wherein the first circumferential seal member is positioned at or rearward from a position at which the flange is attached to the body of the plunger.

5. The plunger of Claim 3, further comprising at least a second circumferential seal member extending radially outward from the body of the plunger to contact and form a seal with the inner wall of the syringe, the second circumferential seal member being positioned rearward from the position of the first circumferential seal member.

6. The plunger of Claim 5 wherein the axial distance between the first circumferential seal member and the second circumferential seal member is at least 30% of the diameter of the inner wall of the syringe.

7. The plunger of Claim 5 wherein the second circumferential seal member is a flange attached to the plunger member, the flange being cantilevered rearward and radially outward to form a sealing engagement with the inner wall of the syringe.

8. The plunger of Claim 1 wherein the pressure member comprises a resilient O-ring in sealing contact with the body of the plunger and with the inner wall of the syringe, the O-ring being seated in a seating formed around the circumference of the body of the plunger, the seating comprising a ramp portion having a forward radius that is smaller than a rearward radius thereof, the O-ring being sufficiently resilient to move rearward along the ramp portion of the seating as the plunger is moved forward.

9. The plunger of Claim 8, further comprising at least a first circumferential sealing member extending radially outward from the body of the plunger to contact and form a seal with the inner wall of the syringe

10. The plunger of Claim 9 wherein the circumferential seal member is positioned rearward from a position of the O-ring.

11. The plunger of Claim 9 wherein the first circumferential seal member comprises a flange attached to the plunger member, the flange being cantilevered rearward and radially outward to form a sealing engagement with the inner wall of the syringe.

12. The plunger of Claim 9 wherein the axial distance between the flange and the O-ring is at least 30% of the diameter of the inner wall of the syringe.

13. A syringe for injection of a fluid contained within the syringe, the syringe comprising:

an elongated syringe body; and

a plunger slidably disposed within the syringe body, the plunger comprising a pressure member extending around the circumference of a body of the plunger in substantially sealing contact therewith, the pressure member being sufficiently flexible to be forced radially outwardly to exert force upon an inner wall of the syringe body in response to increasing fluid pressure within the syringe during forward movement of the plunger, the pressure member thereby forming a substantially sealing engagement with the inner wall of the syringe.

14. The syringe of Claim 13 wherein the pressure member comprises a flange attached at a rearward portion thereof to the body of the plunger, the flange extending forward and radially outward to form a channel between the flange and the body of the plunger, the flange being sufficiently flexible to flex radially outwardly to exert force upon the inner wall of the syringe body as a result of fluid pressure within the channel upon forward motion of the plunger, the flange thereby forming a substantially sealing engagement with the inner wall of the syringe.

15. The syringe of Claim 13, further comprising at least a first circumferential seal member extending radially outward from the body of the plunger to contact and form a seal with the inner wall of the syringe body.

16. The syringe of Claim 15, wherein the first circumferential seal member is positioned at or rearward from a position at which the flange is attached to the body of the plunger.

17. The syringe of Claim 15, further comprising at least a second circumferential seal member extending radially outward from the body of the plunger to contact and form a seal with the inner wall of the syringe body, the second circumferential seal member being positioned rearward from the position of the first circumferential seal member.

18. The syringe of Claim 17 wherein the axial distance between the first circumferential seal member and the second circumferential seal member is at least 30% of the diameter of the inner wall of the syringe body.

19. The syringe of Claim 17 wherein the second circumferential seal member is a rearward flange attached to the plunger member, the rearward flange being cantilevered rearward and radially outward to form a sealing engagement with the inner wall of the syringe body.

20. The syringe of Claim 13 wherein the pressure member comprises a resilient O-ring in sealing contact with the body of the plunger and with the inner wall of the syringe body, the O-ring being seated in a seating formed around the circumference of the body of the plunger, the seating comprising a ramp portion having a forward radius that is smaller than a rearward radius thereof, the O-ring being sufficiently resilient to move rearward along the ramp portion of the seating as the plunger is moved forward.

21. The syringe of Claim 20 wherein the plunger further comprises at least a first circumferential sealing member extending radially outward from the body of the plunger to contact and form a seal with the inner wall of the syringe body.

22. The syringe of Claim 21 wherein the first circumferential seal member is positioned rearward from a position of the O-ring.

23. The syringe of Claim 21 wherein the first circumferential seal member comprises a flange attached to the plunger member, the flange being cantilevered rearward and radially outward to form a sealing engagement with the inner wall of the syringe body.

24. The syringe of Claim 19 wherein the axial distance between the flange and the O-ring is at least 30% of the diameter of the inner wall of the syringe body.

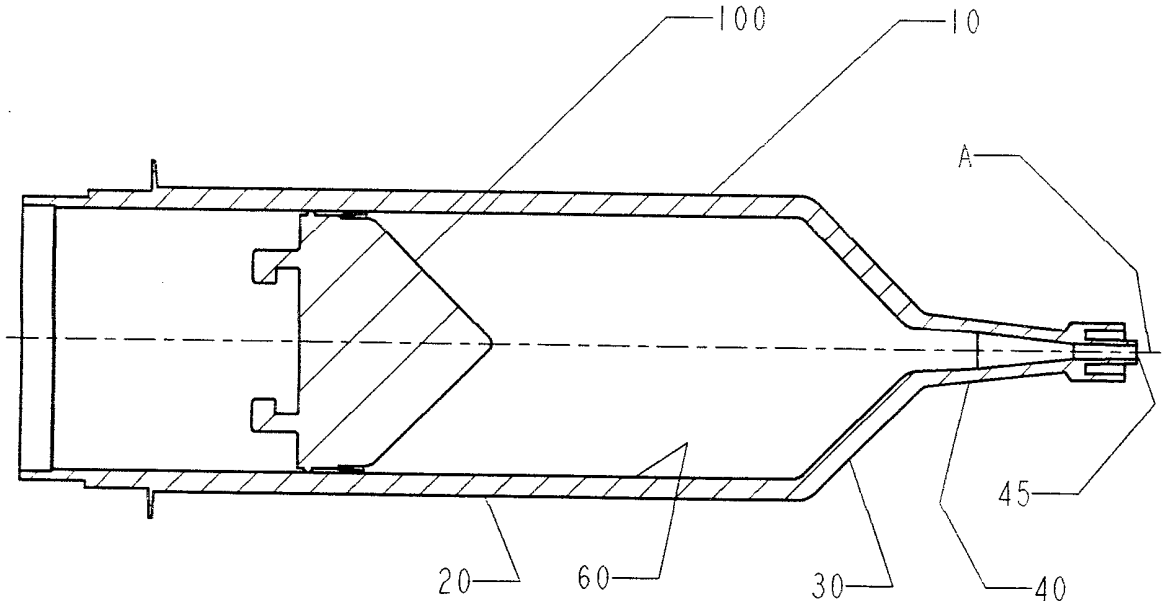


FIGURE 1

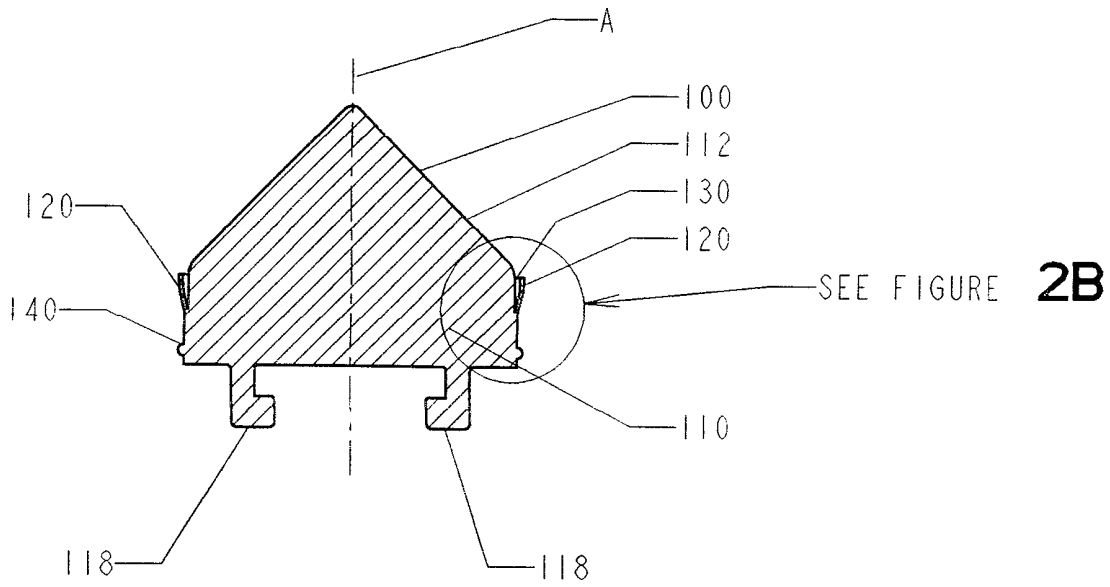


FIGURE 2A

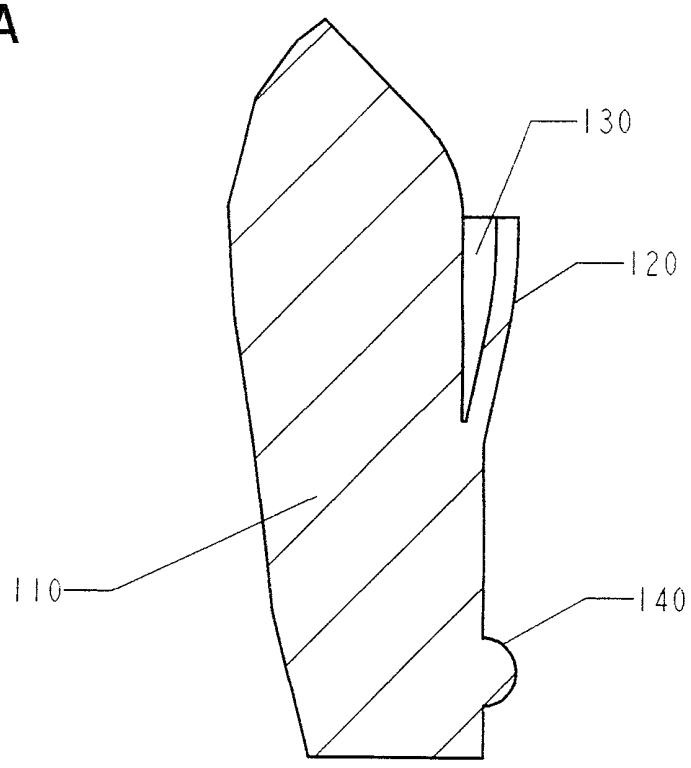


FIGURE 2B

FIGURE 3A

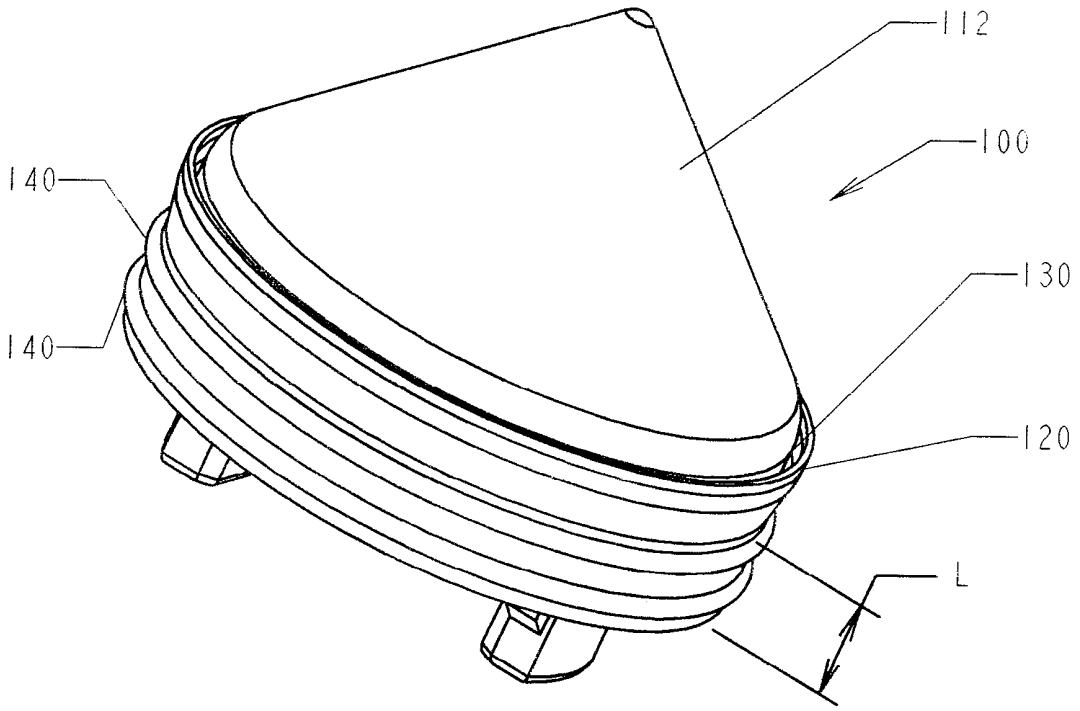
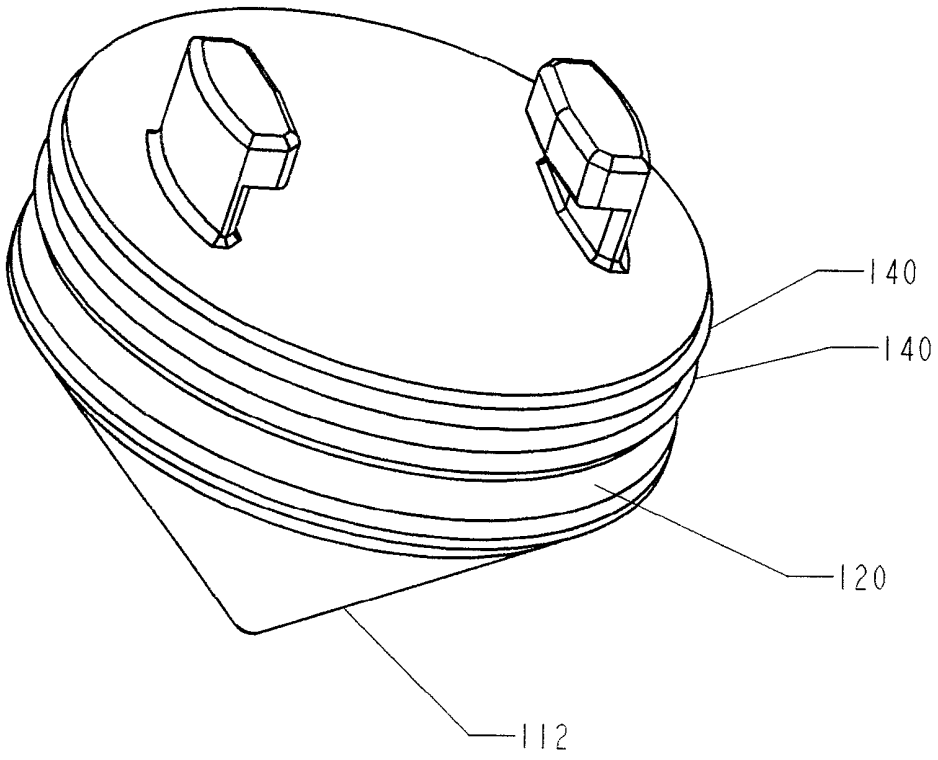


FIGURE 3B



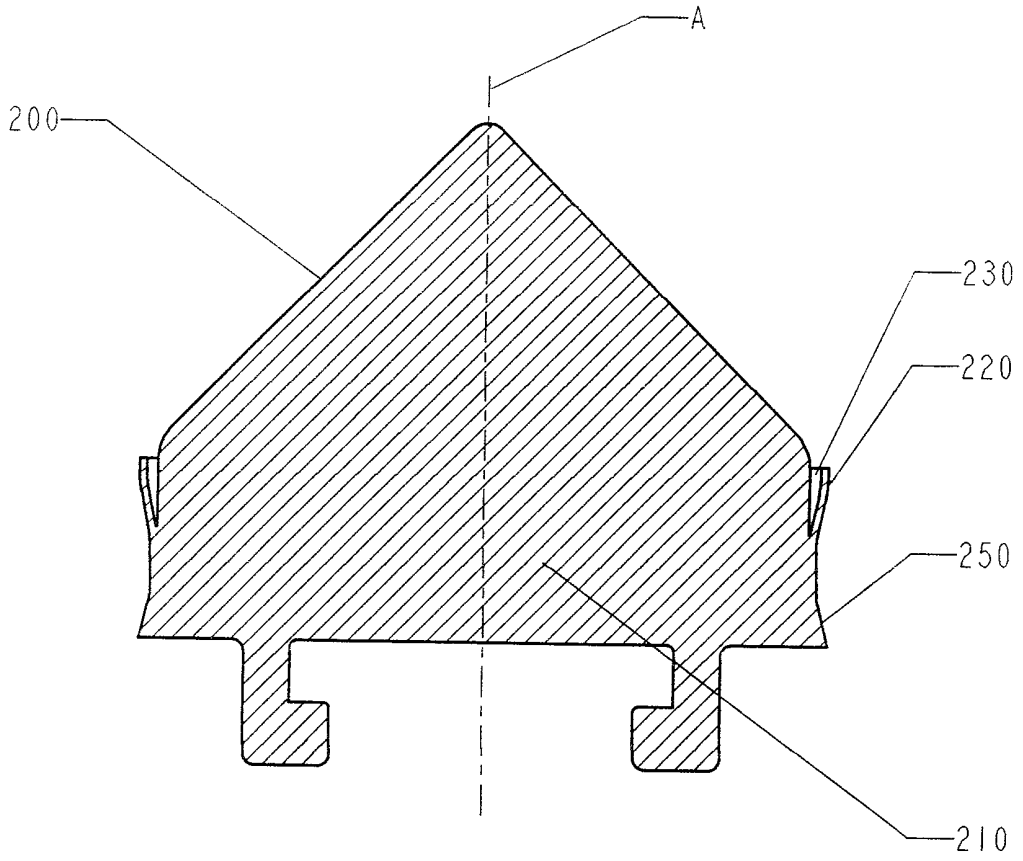


FIGURE 4

FIGURE 5A

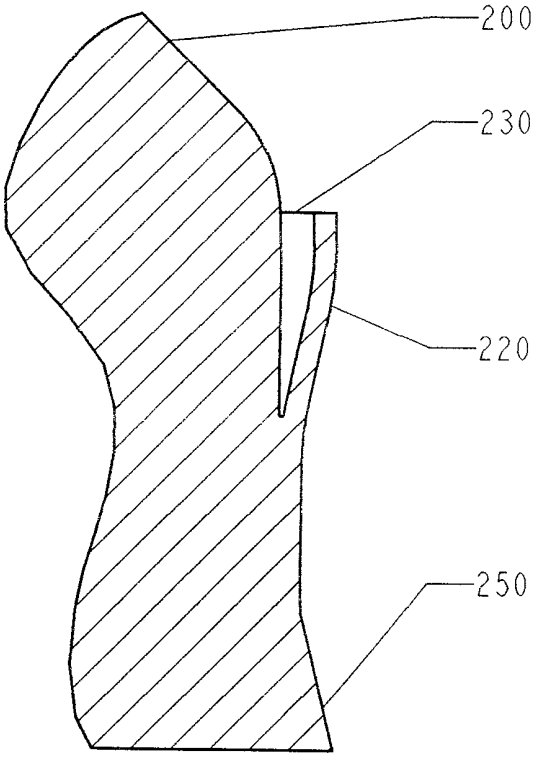
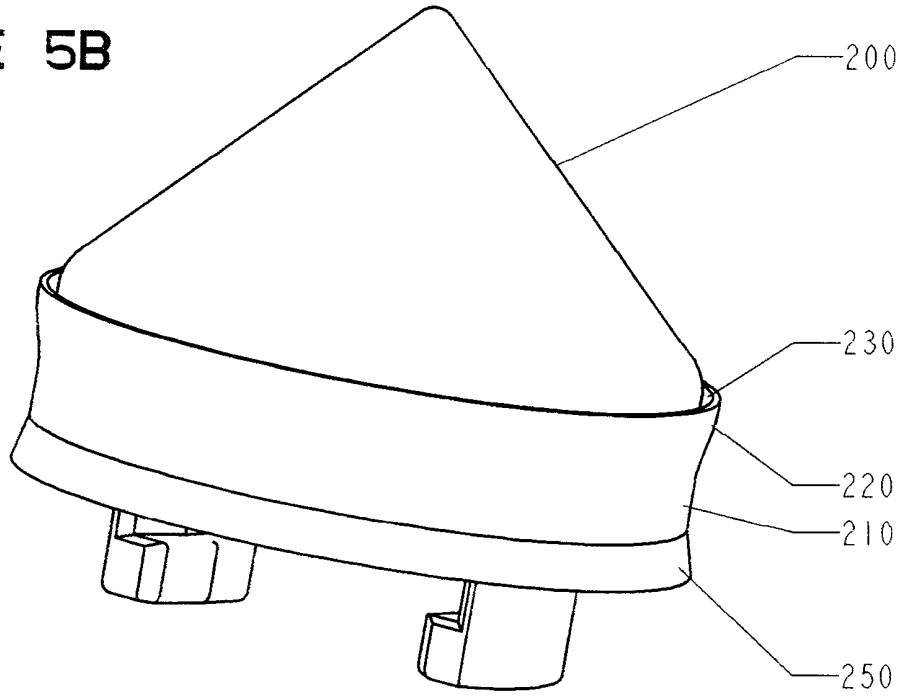


FIGURE 5B



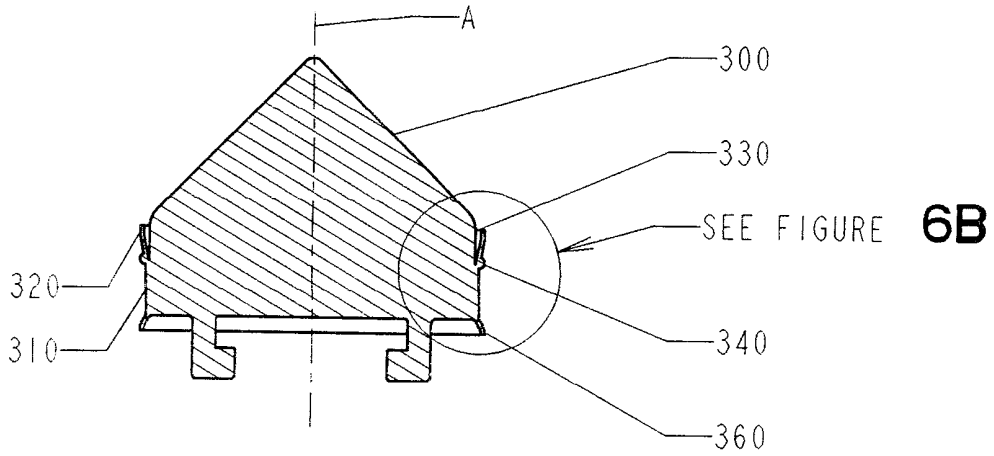


FIGURE 6A

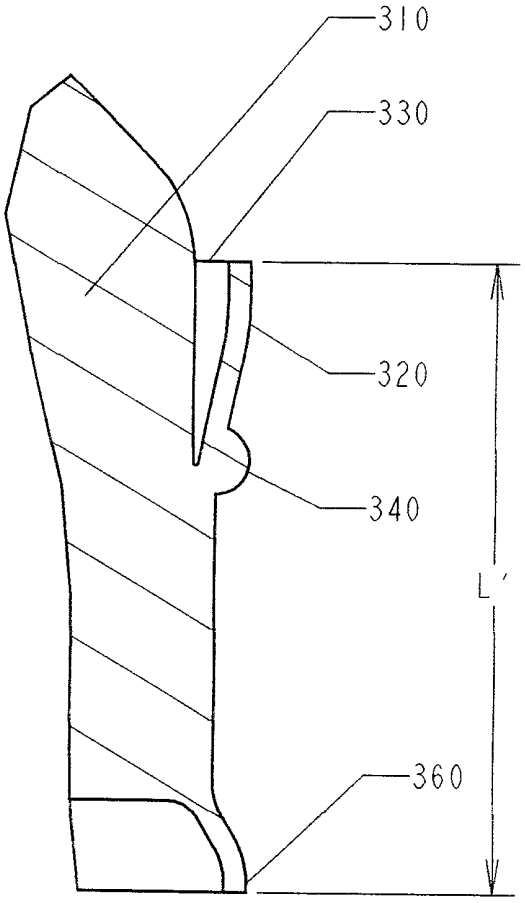


FIGURE 6B

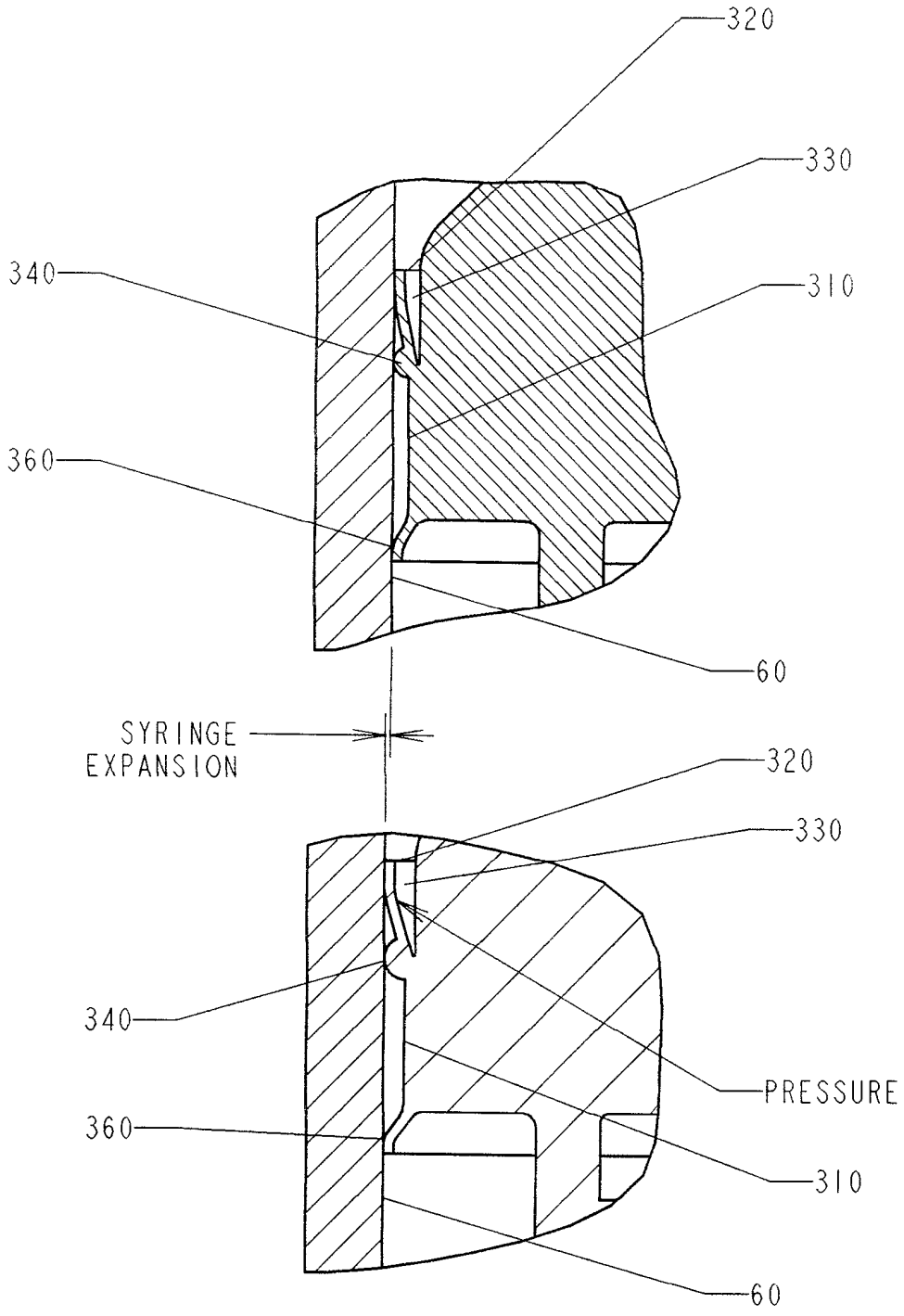

320
330
340
310
360
60
SYRINGE EXPANSION
320
330
340
PRESSURE
360
310
60

FIGURE 6C

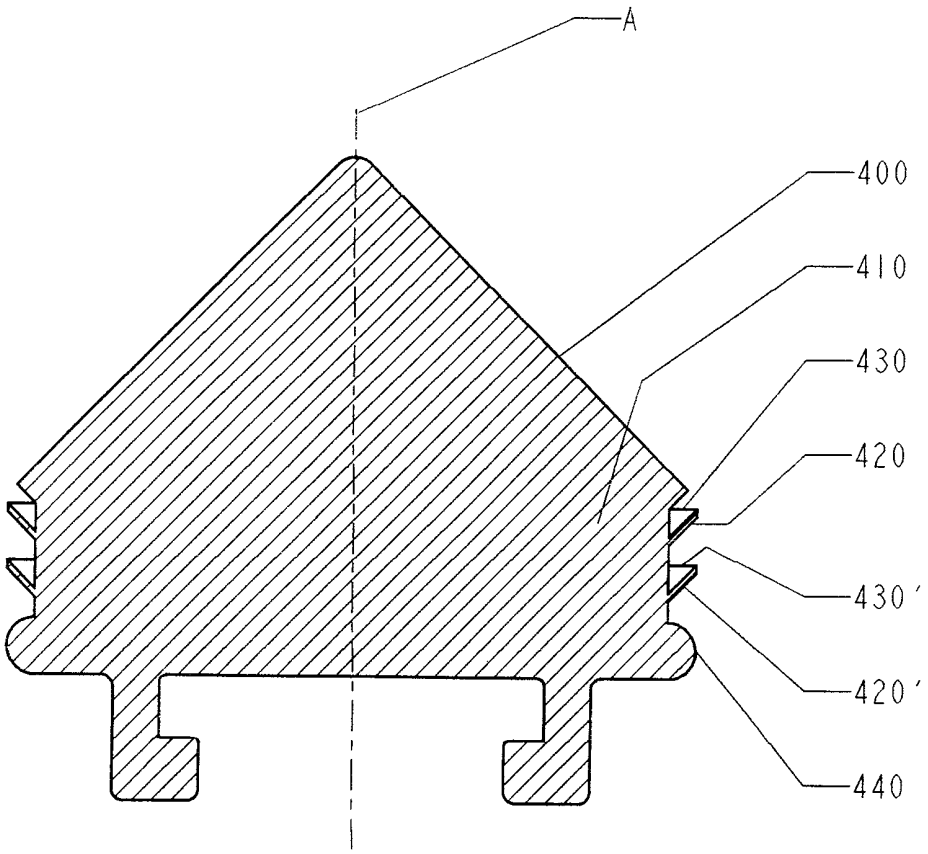


FIGURE 7

FIGURE 8A

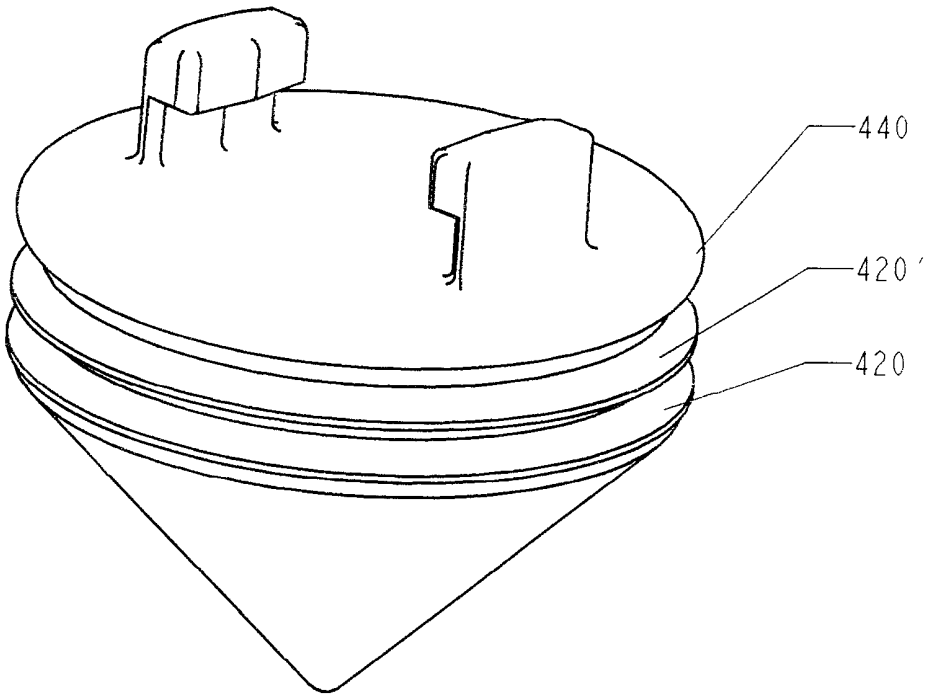
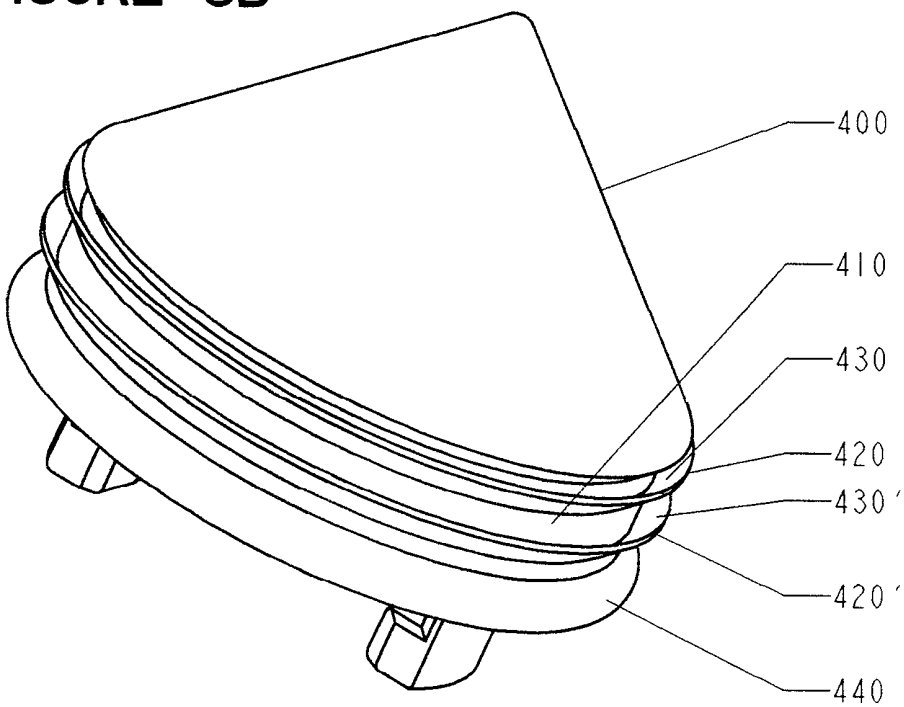


FIGURE 8B



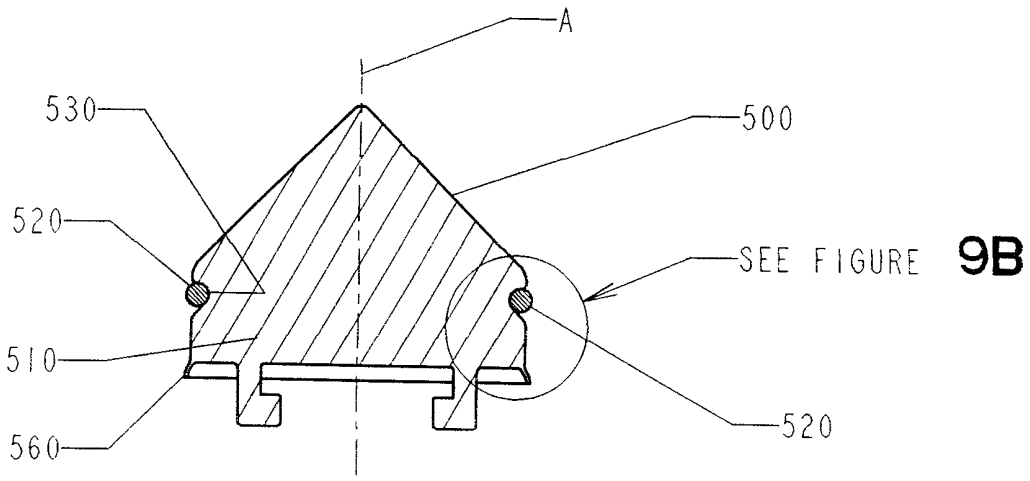


FIGURE 9A

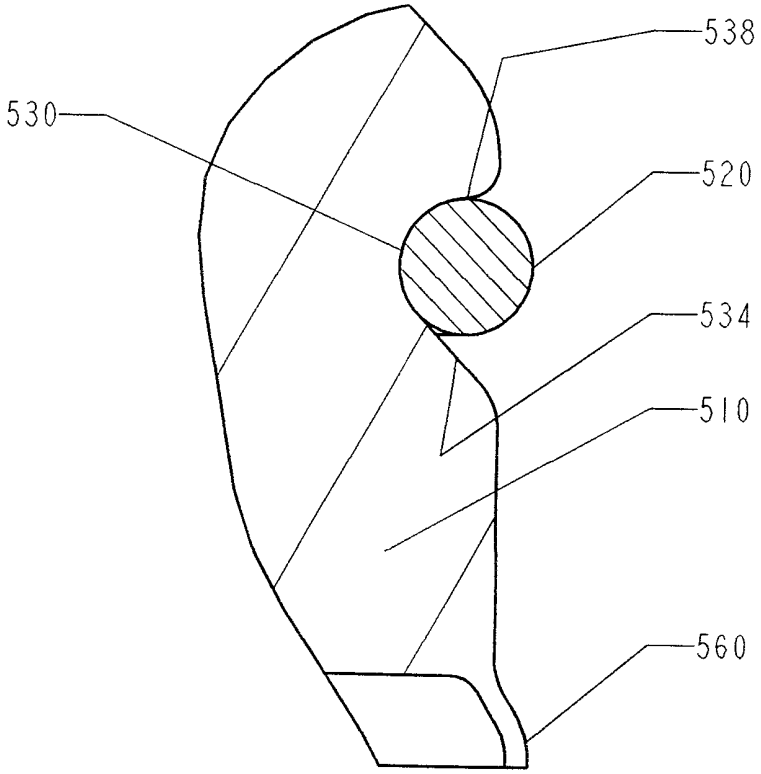


FIGURE 9B

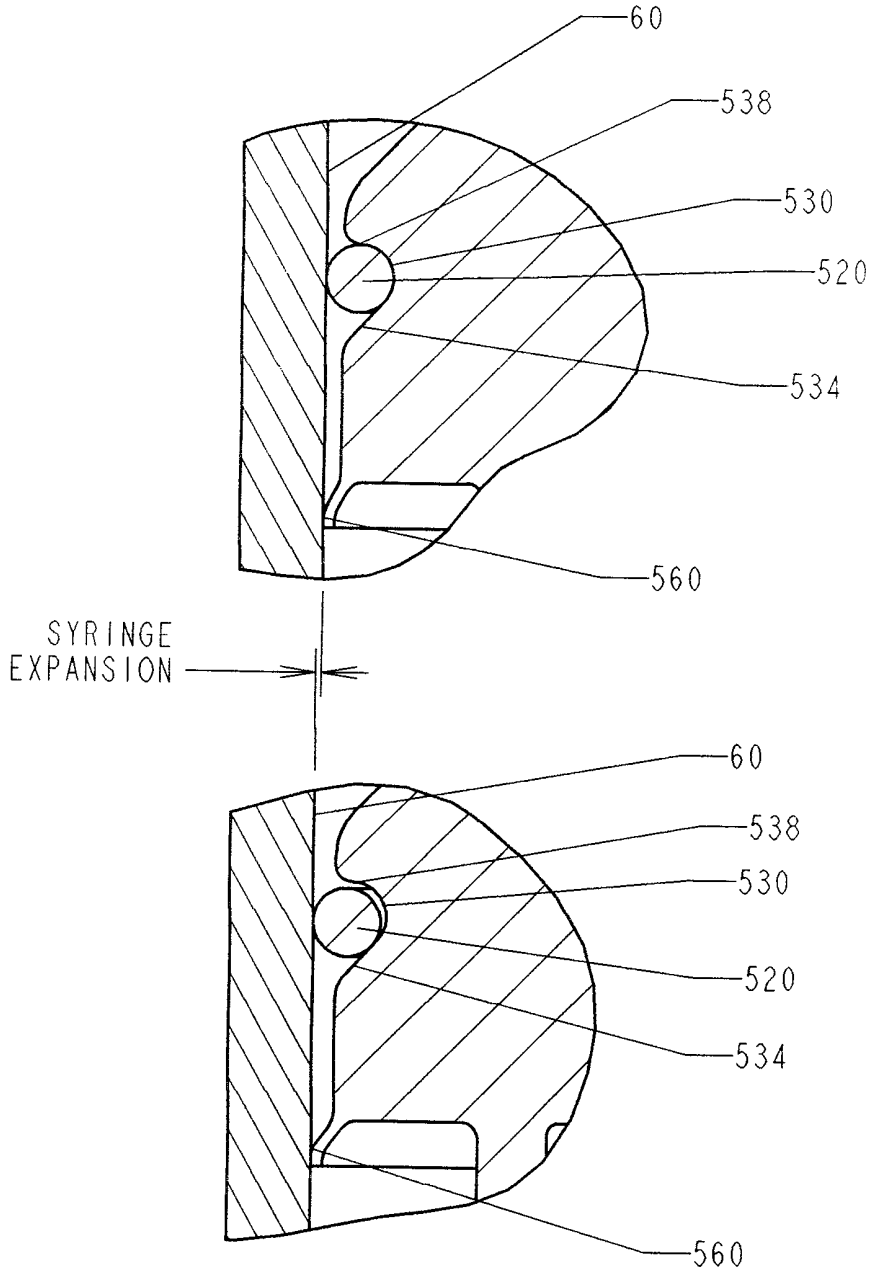

60
538
530
520
534
560
SYRINGE
EXPANSION
60
538
530
520
534
560

FIGURE 9C

INTERNATIONAL SEARCH REPORT

Ir ational Application No
PCT/US 99/03837

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M5/315 F16J15/32

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)
IPC 6 A61M F16J

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 25 14 412 A (PHARMA-GUMMI WIMMER WEST GMBH) 14 October 1976 see page 3, line 15 - page 5, line 11 see figure 2	1-6, 13-18
X	GB 2 012 590 A (THE KENDALL COMPANY) 1 August 1979 see page 1, line 117 - page 2, line 38 see figure 3	1-3, 13-15
A		7,19
X	WO 84 02278 A (KÖZPONTI) 21 June 1984 see page 15, line 4 - page 16, line 11 see figures 1,5	1-4, 13-16
A		7,9-12, 19,21-24

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 May 1999	31/05/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31.651 epo nl, Fax: (+31-70) 340-3016	Schönleben, J

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/03837

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 151 617 A (BAUM) 6 October 1964 see column 2, line 43 - line 69 see figures 3,4	1,8,13, 20
A	EP 0 027 032 A (BENDIX LIMITED) 15 April 1981 see figure 2	8,20

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

In tional Application No
PCT/US 99/03837

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 2514412 A	14-10-1976	NONE	
GB 2012590 A	01-08-1979	CA 1123696 A	18-05-1982
		US 4266557 A	12-05-1981
WO 8402278 A	21-06-1984	AT 45096 T	15-08-1989
		AU 574656 B	14-07-1988
		AU 2270783 A	27-06-1985
		CA 1226496 A	08-09-1987
		CZ 278545 B	16-03-1994
		DD 219675 A	13-03-1985
		DK 325684 A,B,	03-07-1984
		EP 0129576 A	02-01-1985
		FI 842993 A,B	26-07-1984
		IE 55057 B	09-05-1990
		IN 159520 A	23-05-1987
		LT 2173 R	15-10-1993
		LV 5189 A	10-10-1993
		SK 927483 A	07-02-1996
		SU 1625319 A	30-01-1991
		US 4704105 A	03-11-1987
US 3151617 A	06-10-1964	NONE	
EP 27032 A	15-04-1981	AU 532233 B	22-09-1983
		AU 6297180 A	16-04-1981