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[Continued on next page]

(54) Title: SELF-SEALING SEPTUM DEVICE

(57) Abstract: A septum and a needle system in which the septum after being pierced by the needle and the needle has been withdrawn is capable of self sealing. A sampling system based on a septum and a needle system in which the septum after being pierced by the needle and the needle has been withdrawn is capable of self sealing and a method of using it. The use of a self sealing material such as a low Shore A durometer (<40 Shore), a silicone gel rubber such as nitrile rubber, polyurethanes, elastomeric thermoplastics or rubbery thermoplastics, contained within or adjacent a region of the septum through which the needle passes ensures that the piercing of the septum material by the needle is healed and is liquid tight after the needle has been withdrawn,

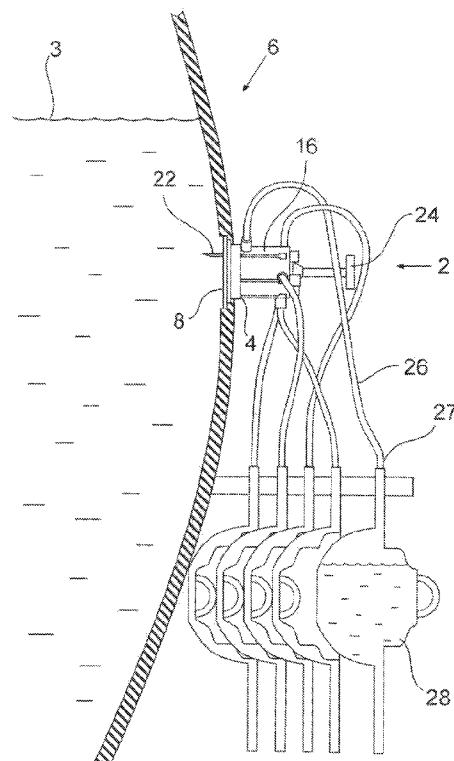


Figure 1
Prior Art

WO 2013/130951 A1



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ML, MR, NE, SN, TD, TG). Published:

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SELF-SEALING SEPTUM DEVICE

This invention relates to a self-sealing septum device. More particularly, it relates to a self-sealing septum device for use with a needle based sampling system.

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Cross-Reference to Related Applications

The present application claims the benefit of priority of European Patent Application No. 12290070.7, filing date March 1, 2012, incorporated by reference herein in its entirety.

10

BACKGROUND OF THE INVENTION

The current state of the art for sampling systems used for biological manufacture such as bioreactors, storage tanks, downstream processing equipment such as filtration equipment is a system based on a sampling needle that pierces a septum.

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These systems are well-known such as the NovaSeptum® sampling device available from Millipore Corporation and are shown in US 6, 032, 543 and US 2011/0155258 A1. Such a system and its components are shown in Figures 1-3.

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The system 2 has a front piece 4 which attaches to the vessel 6 or a fitting on a pipe or piece of equipment that contains a liquid 3 to be sampled. The system 2 is connected to the vessel 6 and the like via a NAConnect® flange available from Millipore Corporation or a Tri-Clover ® clamp or other such well-known means for attaching one component to another. The front piece has a front face 8, with one or more openings 10 extending through it from the front face 8 to a back face 12. The front piece 4 may have depressions 11 formed on the back face 12 to center the septum 20 of the sampling system 2. The front piece 4 also has a central attachment extension 14 extending outwardly from the back face 12 in a direction away from the front face 8. A housing 16, containing one or more shafts 18 for holding a septum 20 and a needle 22 and a central shaft 15 for the central attachment extension 14 and the housing 16 is attached to the back face 12 of the front piece 4 and the shafts 18 are in alignment with the one or more openings 10 on the back face 12 of the front piece 4. The needle 22 has a hollow lumen 21. A septum 20 is held against opening 10 of the back face by the housing 16 and the attachment means 24 and the central shaft 14. The needle 22 is located in the shaft 18 behind the septum 20. The rear portion 23 of the needle 22 has a first end 25 of a conduit 26 attached to it. The other end 27 of the conduit 26 is attached to a sample bag 28 for holding a sample withdrawn from the vessel 6 by the system 2. The needle 22 has a trigger 30 to actuate it and

move it forward and backward in the shaft 18. The shaft 18, housing 16 and /or trigger 30 limits the travel of the needle 22.

In use, the system is assembled by placing a septum 20 against each opening 10 on the back face 12 of the front piece 4. A needle 22 is located behind the septum 20 and the housing 16 is attached to the central attachment extension 14 and attachment means 24 to compress the septum 22 against the back face 12 to form a liquid tight seal with the opening 10. The front piece 4 is attached to the vessel 6 and then the vessel 6 is steamed to sterilize it before use. At the same time the surface of the septum 22 facing the opening 10 is also steam sterilized.

When one wishes to take a sample, the needle 22 is moved forward, piercing the septum 20 and allowing liquid in the vessel 6 to flow through the lumen 21 to the conduit 26 and into the sample bag 28. When the sample has been taken, the needle 22 is moved back through the septum 20. As the septum 20 is under compression, the hole created by the needle 22 is closed by the pressure applied to the septum 20 by the assembled system 2. The conduit 26 is cut so that the sample bag 28 can be further processed as desired. The vessel is eventually drained and the vessel and face of the device including the surface of the septum 22 over the opening 10 are again steam sterilized to kill any remaining biological matter that remains.

Generally, the hole in the septum 22 created by the needle 20 piercing the septum 22 remains sealed both while the septum is compressed by the system 2 and even after the system 2 has been disassembled.

However there is always the concern that the hole does not remain sealed and that some leakage of the fluid in the needle 22 and the remaining portion of the conduit 26 will occur. This would be considered a biohazard and could cause some safety and product contamination issues.

The present invention overcomes these concerns.

SUMMARY OF THE INVENTION

The present invention relates to a self-sealing septum that seals the hole created by the piercing of the septum by the needle.

The self-sealing septum can be a material contained within the septum which seals the hole by itself. It can alternatively be a material which cures upon the exposure of that material to heat or steam. Alternatively, it can be a layer of sealing material located between the septum and the needle rather than being within the septum itself.

A first embodiment of the present invention is a sampling device having a septum in which a layer of self sealing material is encapsulated within the thickness of the septum such that the needle of the device passes through or pierces the layer when it is moved toward and away from the vessel during a sample taking procedure. The self sealing material seals the hole created by the movement of the needle through the septum creating a liquid tight seal in the septum after the needle has been used.

5 A second embodiment is to use a separate layer of self sealing material placed between the first surface of the septum and the needle when the needle is in its retracted position. The self sealing material seals the piercing of the septum created by the movement of
10 the needle through the septum creating a liquid tight seal in the septum after the needle has been used and retracted behind the septum.

A third embodiment is to use either the first or second embodiment in a sampling system such as is taught by US 6, 032, 543 or US 2011/0155258 A1.

15 A further embodiment of the present invention is to provide a self sealing material that doesn't interfere with the movement of the needle through the septum, that is compatible with the material of the septum and which provides a good liquid tight seal of the piercing caused by the travel of the needle through the septum, even when there is no compressive force applied to one or more sides of the septum. Such materials include but are not limited to silicone gels and low Shore durometer silicones such as a silicone with a Shore of less than 40, preferably
20 less than 35, more preferably with a Shore between 10 and 35 and most preferably between 20 and 35; elastomeric thermoplastics, other rubbers such as nitrile rubber, rubbery thermoplastics such as styrene block copolymers and various thermosets such as polyurethane.. The self-sealing septum can be a material contained within the septum which seals the piercing by itself. It can alternatively be a material which cures upon the exposure of that material to heat or
25 steam.

Another embodiment is to use a low Shore A durometer (less than 40, preferably 10-30 and more preferably 10-20 Shore A durometer) as the sealing material.

IN THE DRAWINGS:

30 Figure 1 shows a partial cross section partial planar view of a septum based sampling system.

Figure 2 shows an exploded view of a portion of the sampling system of the prior art.

Figure 3 shows a septum and needle of the sampler system of the prior art in cross-sectional view.

Figure 4 shows a first embodiment of a septum and needle of the sampler system of the present invention in cross-sectional view.

Figure 5 shows a second embodiment of a septum and needle of the sampler system of the present invention in cross-sectional view.

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DETAILED DESCRIPTION OF THE INVENTION

Figure 4 shows a first embodiment of the present invention. To the extent that the elements are the same the same reference numbers will be used to identify them.

In this embodiment the septum 20 has a region containing self sealing material 30. The region 30 is located inwardly of either the first surface 32 or the second surface 34 of the septum 20 so that the needle 22, as it pierces the septum 20, travels through the region 30 both on its way past the second surface 34 and again as it retracts toward the first surface 32. The material contained within this region 30 effectively seals the piercing of the septum material left by the needle 22 in its travels through the septum 20 ensuring a good liquid tight seal.

Figure 5 is a second embodiment of the present invention and similar in most ways to that of Figure 4 except that in this instance the needle 22 is not starting from a position of being within a portion of the septum 20 in its retracted position. Rather it is within a channel 36 and kept above the first surface of the septum until it is moved through the septum and both surfaces of the septum to draw a sample. As with the first embodiment the material contained within this region 30 effectively seals the piercing of the septum material left by the needle 22 in its travels through the septum 20 ensuring a good liquid tight seal.

Figure 6 shows another embodiment of the present invention for use with a system of US 2011/0155268 A1. In this instance the septum can be a separate piece retained on the back face of the front piece. The septum 20 has a channel 36 like that of Figure 5 in which the needle 22 resides in its retracted position above the first surface 32. It works in the same way as that of Figures 4 and 5.

Figure 7 shows another embodiment that may be used with either embodiment of Figures 5 or 6. The self sealing material 30 instead of being formed within the septum material is a separate pad 38 that is inserted into the channel 36 so that it is located adjacent the first surface 32 of the septum 20. The needle 22 is located adjacent the pad of material 38 and travels through the pad 38 and the septum 20 as it moves to its active position beyond the second face 34 of the septum 20. When the needle 22 returns to its retracted position the material of the pad 38 ensures a liquid tight seal is formed.

The self sealing material may be any material that doesn't interfere with the movement of the needle 22 through the septum 20, that is compatible with the material of the septum 20 and which provides a good liquid tight seal of the piercing caused by the travel of the needle 22 through the septum 20, even when there is no compressive force applied to one or more sides 5 of the septum. Such materials include but are not limited to silicone gels and low Shore durometer silicone such as a silicone with a Shore of less than 40, preferably less than 35, more preferably with a Shore between 10 and 35 and most preferably between 20 and 35. One such material is Silpuran® low shore (ex 10 shore A). Another is a silicone gel such as Dow Corning dielectric gels. A further material can be an elastomeric thermoplastics such as Santoprene® elastomer available from Advanced Elastomer Systems LP. Other rubbers such 10 as nitrile rubber, various thermosets such as polyurethane or rubbery thermoplastics such as various styrene block copolymers and the like can be used so long as they have the ability to seal the hole in the material caused by the passage of the needle through the material.

The self-sealing septum can be a material contained within the septum which seals the 15 hole by itself. It can alternatively be a material which cures upon the exposure of that material to heat or steam. Alternatively, it can be a layer of sealing material located between the septum and the needle rather than being within the septum itself.

The needle can be a hollow needle having a lumen running through at least a portion 20 of it to a position at which the conduit is attached. The needle may have a sharp hollow point at its front end as shown in Figure 4. The lumen is exposed from the front of the needle to the point at which it is connected to the conduit in such an embodiment. Alternatively, the needle have a sharp closed point with an opening formed along a portion of its length which extends 25 through the septum in use to allow liquid to flow into the lumen and then on to the conduit attached to a rearward portion of the needle.

In practice, the septum of Figures 4-6 is formed with the sealing material encapsulated 30 within it. This can be accomplished by a variety of methods such as overmolding and injection molding. Alternatively, one can form a septum with a closed second surface and an open first surface and a cavity positioned between the second surface and the open first surface into which is injected the sealing material. The first surface is then closed by molding additional septum material over the cavity.

In practice, the septum of Figure 7 is formed with the sealing material being a separate pad that is inserted into the channel so that it is located adjacent the first surface of the 35 septum. This pad can be formed by a variety of methods. For example, one can simply form a disk of material that has been cured so as it can be handled and simply inserted into the

channel. One can form a sheet of silicone or silicone gel and punch out a piece that fits into the channel and simply insert the pad and retain it by a friction fit. Alternatively, one can add the material to the channel after septum formation and allow the material to cure in place forming the desired layer adjacent the first surface of the septum and the needle in its retracted position when the septum is assembled into a sampling device.

Prophetic Example

A septum device according to US 6, 032, 543 is formed with an encapsulated self sealing layer of low durometer Silpuran® shore A of 10 durometer formed as shown in Figures 10 4-6. The septum has a tube at the rear portion of the needle connected to a sample bag. The septum is loaded into a NovaSeptum® holder of US 6, 032, 543 which is attached to the side of a stainless steel vessel via a NACConnect® flange available from Millipore Corporation of Billerica, Massachusetts.

The face of the holder and the septum are steam sterilized along with the interior of the 15 vessel. Water is added to the vessel to a level higher than that of the septum device.

The needle is moved to pierce the septum and take a sample from the vessel. The sample flows through the needle's lumen into the tube and then the bag. The needle is then withdrawn back through the septum to its closed position. The septum is then checked for leaks and none are found. The bag is then removed as described in US 6, 032, 543 using a 20 NovaSeal™ hand crimper available from Millipore Corporation of Billerica, Massachusetts.

The tank is drained and the septum device removed from the holder. No water is found to leak through the septum even when pressure is applied to the water in the bag.

CLAIMS

WHAT WE CLAIM:

- 1) A self sealing septum and needle system comprising a septum and a needle for piercing the septum, the septum and needle being held in a housing, the septum having a first side adjacent the needle and a second side on a side opposite a thickness of the septum from the first side and a region of sealing material selected from the group consisting of materials that are capable of self sealing after being pierced by the needle.
- 2) A method of sealing a septum comprising providing a septum and a needle for piercing the septum, the septum having a first side adjacent the needle and a second side on a side opposite a thickness of the septum from the first side and a region of sealing material selected from the group consisting of materials that are capable of self sealing after being pierced by the needle, the needle and septum being retained within a housing, the housing being attached to a vessel such that the septum faces the vessel, inserting the needle through the septum and the second side to draw a liquid from the vessel, retracting the needle back though the thickness of the septum to the first side of the septum and allowing the region of sealing material to seal the piercing caused by the needle to the septum.
- 3) A sampler device comprising a septum and a needle for piercing the septum, the needle and septum being contained within a housing, the septum having a first side adjacent the needle and a second side on a side opposite that of the needle, a thickness of the septum from the first side and a region of sealing material selected from the group consisting of materials that are capable of self sealing after being pierced by the needle, the needle having an opening in a surface of the needle adjacent the first surface of the septum and which is exposed to an outside atmosphere when the needle has pierced the septum, a tube attached to a portion of the needle away from the first surface of the septum and a bag attached to the tubing.
- 4) The system of claim 1 wherein the self sealing material region is selected from the group consisting of within the septum and adjacent the first surface of the septum and the needle.

- 5) The method of claim 2 wherein the self sealing material region is selected from the group consisting of within the septum and adjacent the first surface of the septum and the needle.
- 6) The device of claim 3 wherein the self sealing material region is selected from the group consisting of within the septum and adjacent the first surface of the septum and the needle.
- 7) The system of claim 1 wherein the needle has an open point and a lumen running through its interior and the opening is adjacent the first surface of the septum.
- 8) The method of claim 2 wherein the needle has an open point and a lumen running through its interior and the opening is adjacent the first surface of the septum.
- 9) The device of claim 3 wherein needle has an open point and a lumen running through its interior and the opening is adjacent the first surface of the septum.
- 10) The system of claim 1 wherein the sealing material is selected from the group consisting of silicone gels, low durometer silicones, nitrile rubbers, polyurethanes, elastomeric thermoplastics and rubbery thermoplastics.
- 11) The method of claim 2 where in the self sealing material region is selected from the group consisting of silicone gels, low durometer silicones, nitrile rubbers, polyurethanes, elastomeric thermoplastics and rubbery thermoplastics..
- 12) The device of claim 3 where in the self sealing material region is selected from the group consisting of silicone gels, low durometer silicones, nitrile rubbers, polyurethanes, elastomeric thermoplastics and rubbery thermoplastics.

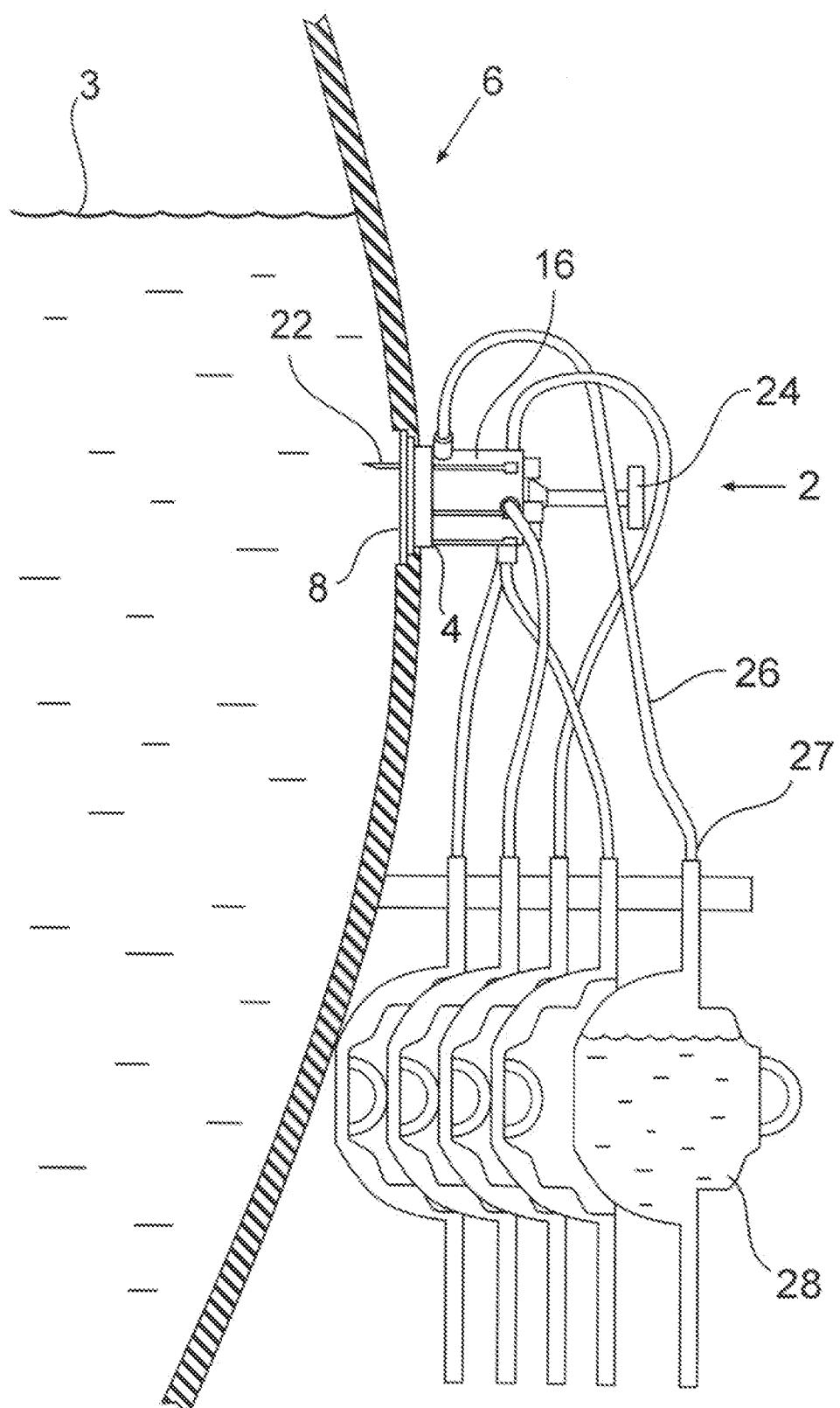


Figure 1
Prior Art

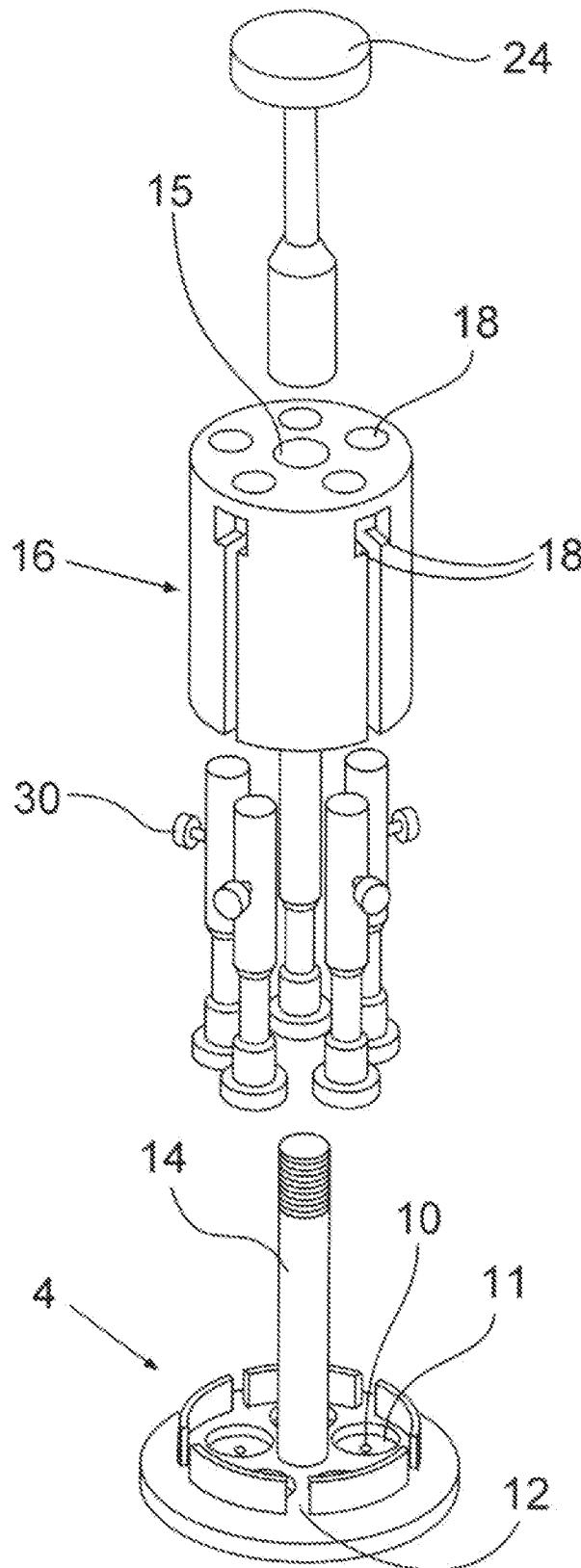


Figure 2
Prior Art

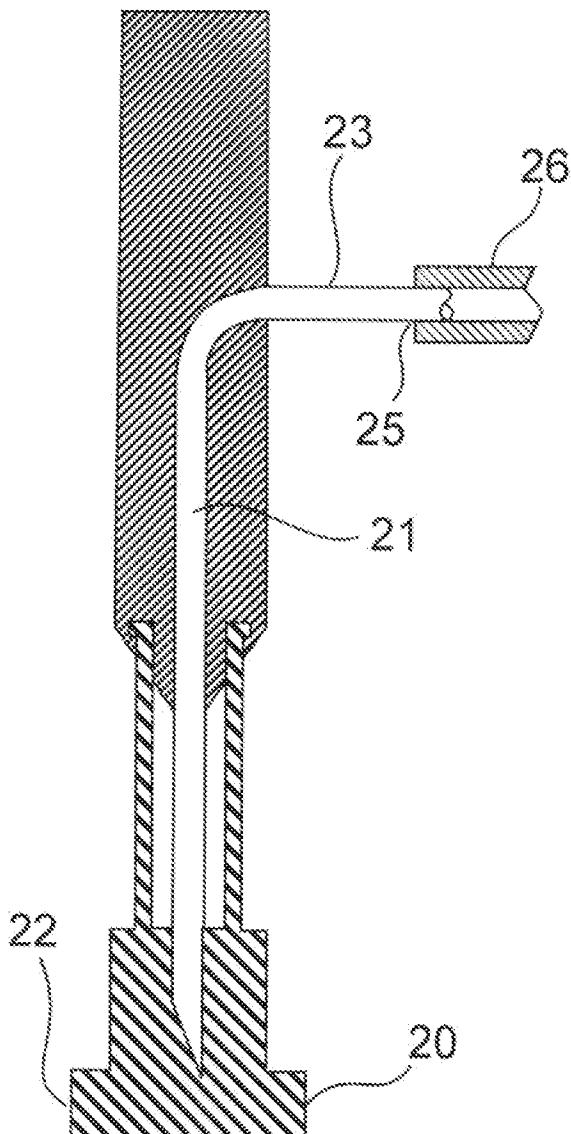


Figure 3

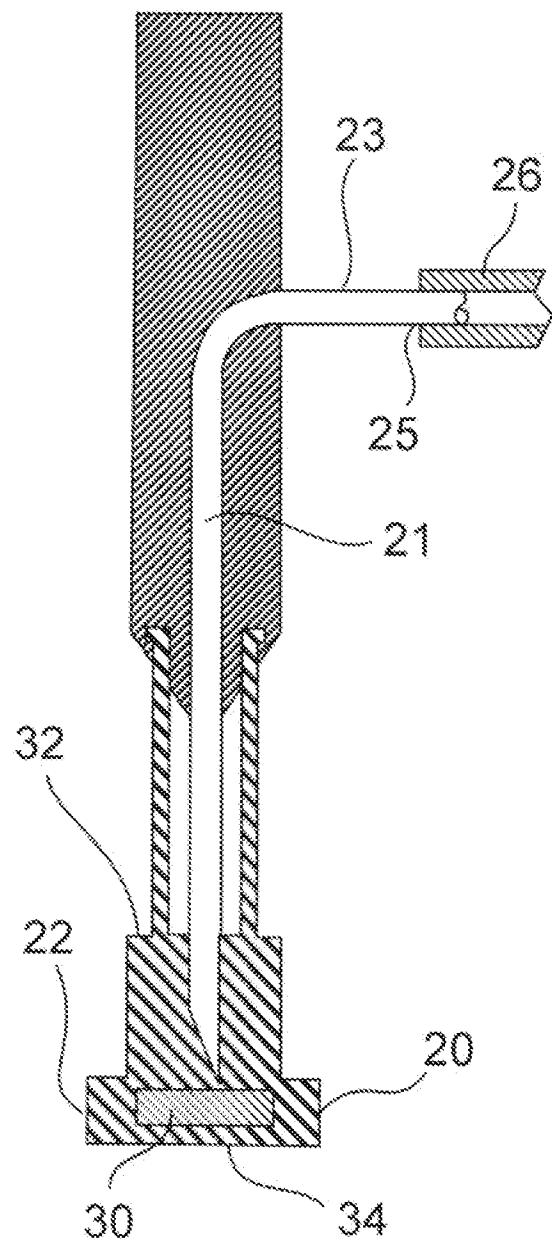


Figure 4

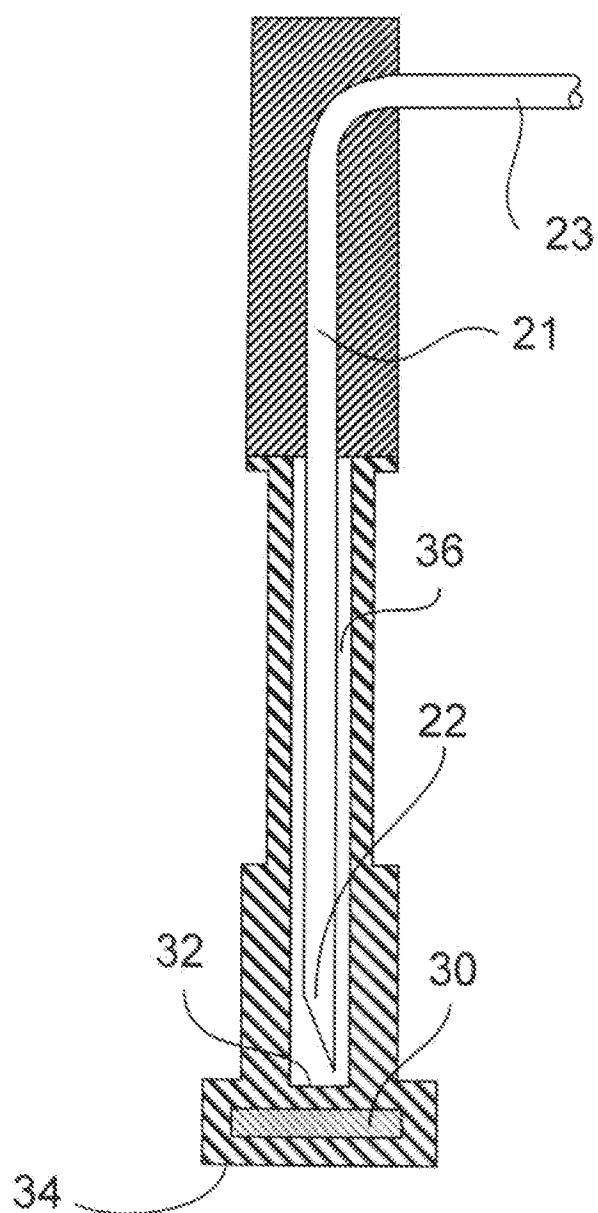


Figure 5

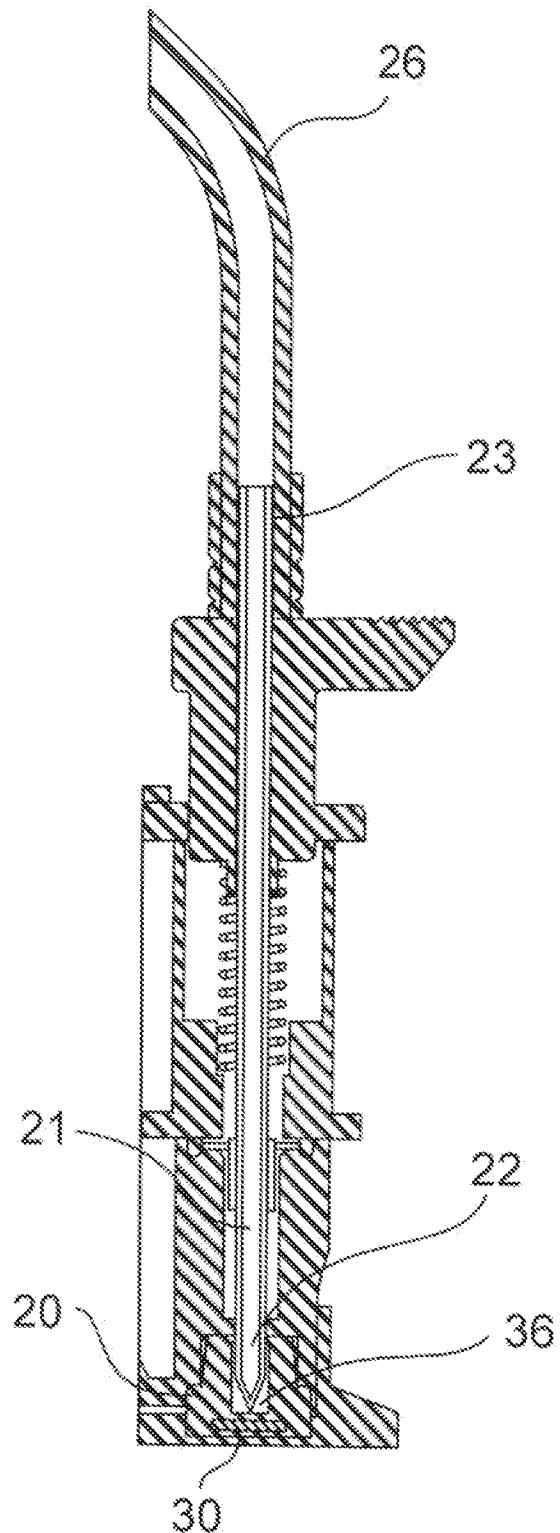


Figure 6

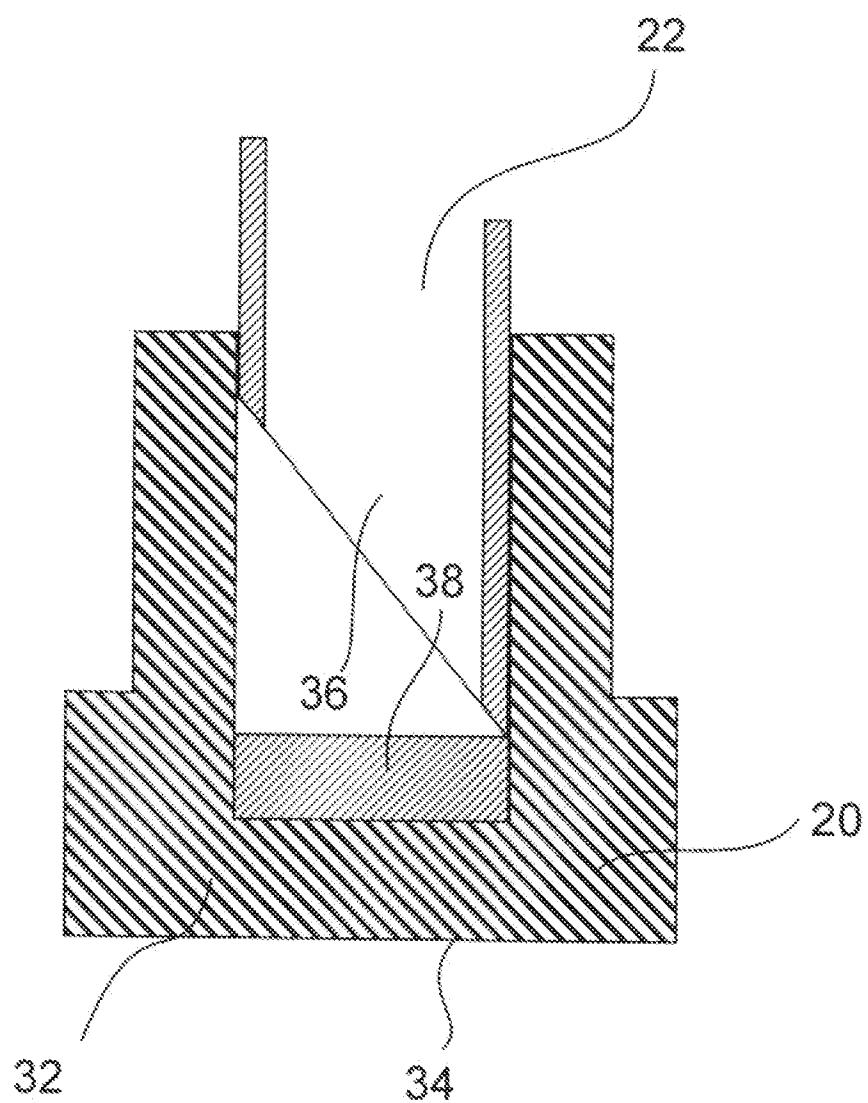


Figure 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/028587

A. CLASSIFICATION OF SUBJECT MATTER**G01N 1/02(2006.01)i, A61M 39/04(2006.01)i**

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)

G01N 1/02; G01N 1/12; A61M 5/00; A61M 39/04

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
 Korean utility models and applications for utility models
 Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
 eKOMPASS(KIPO internal) & Keywords: septum, silicone, seal, needle, pierce, insert, retract, rubber and elastomeric

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6149632 A (LANDUYT, CHRISTOPHE VAN) 21 November 2000 See abstract; column 1, line 26 - column 2, line 65; claims 1-3 and figures 1-3.	1-12
A	US 4755173 A (KONOPKA et al.) 05 July 1988 See abstract; column 8, line 5 - column 10, line 54 and figures 5A-9	1-12
A	US 5713858 A (HERUTH et al.) 03 February 1998 See abstract; column 6, line 57 - column 7, line 11 and figures 5-6.	1-12
A	US 5792104 A (SPECKMAN et al.) 11 August 1998 See abstract; claim 12 and figures 1-4.	1-12
A	US 6032543 A (ARTHUN et al.) 07 March 2000 See abstract; claim 1 and figures 1-7.	1-12

 Further documents are listed in the continuation of Box C. See patent family 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 application or patent 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 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
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Date of the actual completion of the international search 27 May 2013 (27.05.2013)	Date of mailing of the international search report 04 June 2013 (04.06.2013)
Name and mailing address of the ISA/KR  Korean Intellectual Property Office 189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer AHN, Jae Yul Telephone No. 82-42-481-8525

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2013/028587

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