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DESCRIPTION

TECHNICAL FIELD

[0001] This disclosure relates to a removable vacuum pump for creating a vacuum within a prosthetic socket.

BACKGROUND OF THE INVENTION

Field of the Invention

[0002] This invention relates to a removable vacuum pump for creating a vacuum within a prosthetic socket. There is disclosed a system in which a prosthetist may interchange a dummy with either a vacuum pump or a mechanical locking mechanism, thus providing an amputee multiple options when using a prosthetic socket.

Description of the Background Art

[0003] Within the field of prosthetics, a variety of locking mechanisms and vacuum pumps exist to secure the amputees' residual limb within a socket. Traditionally, the socket is made from either a thermoplastic or composite material. The process for constructing a socket is labor intensive and complicated and requires extensive training. Prior to socket construction the prosthetist takes into account the device that will be utilized for securing the amputee's residual limb within the socket, whether a vacuum pump or mechanical lock hereinafter "securing device." In some applications, the securing device is molded into the socket. Still in others, a construction dummy, or component without functionality, but having the geometric properties of the securing device, is obtained and used during construction. After construction has been completed the construction dummy is removed and the securing device is installed into the volume created by the dummy.

[0004] The majority of prosthetic sockets are constructed to accommodate a mechanical lock. This requires the prosthetist to take into account that the liner required will be a locking liner. Said locking liner having a distal attachment suitable for receiving a threaded pin. The threaded pin has serrations that interfere with the mechanical lock when inserted therein. Said prosthetic assembly, that utilizes a mechanical locking device, is generally more cost effective and easier to use than a prosthetic assembly that utilizes a vacuum pump.

[0005] Prosthetic sockets that accommodate a vacuum pump also require the prosthetist to

take into account the specific make and model of the vacuum pump that will be utilized for the socket build. Additionally, the prosthetist must take into account the prosthetic liner that will be used. In the case of a socket utilizing a vacuum pump, the liner would not have a mechanical locking device at the distal end.

[0006] U.S. Patent No. 8,197,555 ("'555 Patent") (Publication Number US 2010/262261 A1) issued to Laghi et al. discloses a vacuum pump of the type listed above. However, the '555 Patent does not address the fundamental difficulty of allowing a prosthetist to manufacture a prosthetic that can use either a mechanical locking mechanism or a vacuum pump. Furthermore, the '555 Patent only discloses using an elastomer material for the spring mechanism within the vacuum pump, thus an elastomeric material only allows for a certain volume of air to be present within the vacuum pump versus having a more dense and compressible material, such as a metal, or a more porous material, such as foam.

[0007] The fundamental problem is that if a prosthetist builds a socket utilizing a vacuum pump and afterwards determines it is incompatible with the amputee (for any number of reasons), the socket must be rebuilt. Not only is cost a consideration, but patient health becomes a factor as the build time is significant and the patient is generally immobile during that time period. The dilemma can equally be viewed from the other perspective in which a prosthetist builds a socket utilizing a mechanical lock and afterwards determines is incompatible with the amputee for any number of reasons. Again, the socket must be rebuilt.

[0008] The present invention overcomes the aforementioned inadequacies by providing the prosthetist with a universally shaped securing device. In other words, the securing device is a vacuum pump and mechanical lock that are geometrically similar so as to be able to interchangeable with another. This allows for a single socket construction to accommodate either securing device.

[0009] The foregoing has outlined some of the pertinent objects of the invention. These objects should be construed to be merely illustrative of some of the more prominent features and applications of the intended invention. Many other beneficial results can be attained by applying the disclosed invention in a different manner or modifying the invention within the scope of the disclosure. Accordingly, other objects and a fuller understanding of the invention may be had by referring to the summary of the invention and the detailed description of the preferred embodiment in addition to the scope of the invention defined by the claims taken in conjunction with the accompanying drawings.

SUMMARY OF THE INVENTION

[0010] The invention is set out in the appended set of claims.

[0011] Embodiments herein are described by way of example and directed to an interchangeable pump-lock prosthetic securing device. The aforementioned state of the art of

prosthetic securing shows the need for improvements, specifically in the ability of the user to switch between a mechanical locking mechanism to a vacuum pump mechanism, depending on the user's needs and applications.

[0012] The pump-lock embodiments described herein satisfies the aforementioned deficiencies because of its unique, interchangeable design and ability to properly distribute externally applied forces.

[0013] Therefore, it is an object to provide a prosthetic socket that is easily manufactured to use either a mechanical lock or a vacuum pump as the securing means to a prosthetic socket.

[0014] Another object is to provide a construction dummy as a placeholder for the mechanical lock or vacuum pump, with the dummy, lock and pump having similar outer dimensions.

[0015] Another object is to provide a foam/metal spring or cushion for the purposes of having a larger reservoir of air to be used during the pumping action of the user.

[0016] Additional features will be described hereinafter which form the subject of the claims of the invention. It should be appreciated by those skilled in the art that the conception and the specific embodiment disclosed may be readily utilized as a basis for modifying or designing other structures for carrying out the same purposes. It should also be realized by those skilled in the art that such equivalent constructions do not depart from the scope of the invention as set forth in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] For a more complete understanding of the present disclosure and its advantages, reference is now made to the following descriptions, taken in conjunction with the accompanying drawings, in which:

Fig. 1 is a perspective view of the dummy (left), vacuum pump (middle) and mechanical locking device (right);

Fig. 2 is a perspective view of the dummy;

Fig. 3 is a perspective view of the vacuum pump;

Fig. 4 an exploded view of the vacuum pump;

Fig. 5 is a top cross-sectional view of the vacuum pump;

Fig. 6 is a side cross-sectional view of the vacuum pump;

Fig. 7 is a front plan view of the convex vacuum pump;

Fig. 8 is a front plan view of the bottom portion of the convex pump in conjunction with a front cross-sectional view of the convex portion of the vacuum pump;

Fig. 9 is a front cross-sectional view of the convex vacuum pump;

Fig. 10 is a top cross-sectional view of the convex vacuum pump;

Fig. 11 is a front cross sectional view of the vacuum pump;

Fig. 12 is a perspective view of the mechanical lock;

Fig. 13 is an exploded view of the mechanical lock;

Fig. 14 is a front cross-sectional view of the dummy positioned within the liner/socket system, showing the residual air between the liner and socket;

Fig. 15 is a front plan view of the dummy positioned relative to the liner with minimal residual air remaining between the two;

Fig. 16 is a front cross-sectional view of the concave vacuum pump positioned within the liner/socket system, showing the residual air between the liner and socket;

Fig. 17 is a front plan view of the concave vacuum pump positioned relative to the liner with minimal residual air remaining between the two;

Fig. 18 is a front cross-sectional view of the mechanical lock positioned relative to the liner with minimal residual air remaining between the two;

Fig. 19 is a front cross-sectional view of the tapered dummy positioned within the liner/socket system, showing the residual air between the liner and socket;

Fig. 20 is a front cross-sectional view of the tapered vacuum pump positioned within the liner/socket system, showing the residual air between the liner and socket;

Fig. 21 is a front cross-sectional view of the tapered mechanical lock positioned within the liner/socket system, showing the residual air between the liner and socket; and

Fig. 22 is a front cross-sectional view of the vacuum pump positioned within the liner/socket system having a one-way valve and also showing the residual air between the liner and socket.

[0018] Similar reference characters refer to similar parts throughout the several views of the drawings.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0019] The following description is of the best mode presently contemplated for carrying out

the invention. This description is not to be taken in a limiting sense, but is made merely for the purpose of describing one or more preferred embodiments of the invention. The scope of the invention should be determined with reference to the claims. The various components of the present invention, and the manner in which they interrelate, are described in greater detail hereinafter.

[0020] Figs. 2 to 17 herein describe embodiments which are within the scope of the claims herein, whereas Figs. 12, 13, 18 and 21 describe embodiments outside the scope of the claims herein.

[0021] As shown in Fig. 1, a dummy **10,** vacuum pump **12,** and mechanical lock **14** each have similar geometries, providing the basis for the invention that each are interchangeable depending on the needs of a user of the prosthetic limb.

[0022] As shown in Fig. 2, the dummy **10** has an upper flat surface **18** and a lower flat surface **22** that are in contact with an annularly extending side wall **20.** The dummy **10** may be tapered or straight based on vacuum strength desired. During the manufacturing of the socket **70,** a prosthetist may firmly position the dummy **10** into the distal end of a socket **71** (Fig. 14) whereupon a pin or other grasping means is inserted into a pin hole **16.** The purpose of the pin hole **16** is to provide a channel for an eventual mechanical locking pin **64** (Fig. 13). Thus, once the socket **70** has been molded to the shape of the user's residual limb, the prosthetist may then remove the dummy **10,** leaving a void within the distal end **71** of the socket **70** having dimensions similar to either the vacuum pump **12** or the mechanical lock **14.**

[0023] As shown in Fig. 3, the vacuum pump **12** has similar dimensions to that of the dummy **10;** however, the vacuum pump **12** can include a concave upper exterior surface **26** that extends conically around the upper portion **28** and down towards the lower portion **30.** In another embodiment, the vacuum pump **12** may have a convex upper exterior surface **48** (Fig. 9) in place of the concave upper exterior surface **26.** The vacuum pump **12** includes a fluid inlet **24** that receives air from a residual space or vacuum **68** (Fig. 16) between the vacuum pump **12** and socket **70** (Fig. 16). The fluid inlet **24** may have any geometry sufficient to receive fluids such as, circular, square, oval, or any irregular shape with respect to standard geometric shapes. The fluid inlet **24** may also have an attached cover, grate, or filter to provide a means to prevent dust, dirt, or any other foreign substance from entering into the interior of the vacuum pump **12.** The fluid inlet **24** may also be located at any point along the concave upper exterior surface **26,** depending on the shape of the user's residual limb for the purpose of providing a perfected location at which the user's residual limb seals the fluid inlet **24** during the user's ambulation.

[0024] The vacuum pump **12** has a housing that is made of an elastomeric material to provide the stretch needed when a user applies pressure during ambulation. Any elastomeric material known or yet to be discovered may be used in the manufacture of the elastomeric housing **72** provided that the proper stretch characteristics are present. This elastomeric housing **72** is the same shape as the dummy **10** to allow for proper fitting by a prosthetist.

[0025] As shown in Fig. 4, the upper portion **28** is connected via a male end connector **32** to the lower portion **30** via the outer fluid channel **44.** The upper portion **28** may be connected to the lower portion **30** by simply applying any adhesive used in the industry in order to properly seal the interior portion of the vacuum pump **12** from any external factors such as air, dirt, dust, etc. A spring member **34** is disposed within the volume of the lower portion **30** and may be composed of a porous material such as foam, or a material such as a metal or elastomer which does not encompass the entire volume of the lower portion **30,** thus allowing fluid to readily circulate throughout the lower portion **30.** The spring member **34** may further be either a helical spring or a device that provides an opposing force proportional to the reduction of the overall height of the spring device. Suitable materials for such a device are elastomers, plastics, foam, bladders, and the like. Furthermore, the vacuum pump **12** may be made of any flexible material to allow for deflection while still being rigid enough to remain secure within the socket.

[0026] As shown in Figs. 5 and 6, the vacuum pump **12** includes an upper one-way check valve **38** near the upper portion **28** and a lower one-way check valve **39** near the lower portion **30.** The vacuum pump **12** may include more than two valves, depending on the needs of the user such as needing a more flexible vacuum pump **12** to account for varying weights of the user. Sealing element **42** extends annularly relative to the vacuum pump **12** to provide a sealing means between the vacuum pump **12** and the socket **70** (shown in Fig. 16). The sealing element **42** may have widely varying geometries such as, finger-like projections, upwardly or downwardly-extending projections, or any other geometry used to create a seal between the vacuum pump **12** and the socket **70.** Moreover, more than one sealing element may be placed as ribs around the vacuum pump **12.**

[0027] Additionally, the lower portion **30** includes a side wall **41,** annularly extending upwards to receive the upper portion **28** via the male end connector **32.** The side wall **41** is spaced from the spring member **34** via the outer fluid channel **44,** which provides a volume sufficient to receive the male end connector **32.** As such, channel **44** acts as a female connector to receive the male end connector **32** of the upper portion **28.** The outer fluid channel **44** may have varying dimensions according the manufacturing techniques such that its volume may vary from small to large and may have a conical formation. Although outer fluid channel **44** has a function of allowing male end connector **32** to attach to the lower portion **30,** it may also allow fluid flow because its volume is primarily composed of air, as opposed to a porous material such as foam or a dense material such as a metal.

[0028] The fluid inlet **24** allows a fluid to enter the interior of the vacuum pump **12** and specifically, the inner fluid channel **40** which is the main conduit to which the fluid is further dispersed either into outer fluid channel **44** or throughout the spring member **34.** Once enough pressure has accumulated within the vacuum pump **12,** the fluid then exits the vacuum pump **12** via the lower one-way valve **39** and out through the fluid outlet **36.** In general, the fluid moving through the fluid inlet is air. Fig. 6 further shows a triangular void **43** that functions to further improve air flow as its volume is primarily composed of air, as opposed to a porous

material such as foam or a dense material such as a metal.

[0029] As shown in Figs. 7-10, the system may also incorporate a convex vacuum pump **46** having a convex upper exterior surface **48.** The overall design of the convex vacuum pump **46** is identical or substantially similar to that of the vacuum pump **12,** except for the dimensions of the convex spring member **50.** The convex spring member **50** of the convex vacuum pump **46** has a convex geometry. Thus, the convex spring member **50** extends throughout the interior of the convex vacuum pump **46,** excluding the volume encompassed by the fluid channels **40** fluidly connected to the fluid inlet **24.**

[0030] As shown in Fig. 11, the spring member **34** is generally positioned within the interior of the vacuum pump **12.** Furthermore, this figure is used in Figs. 16 and 17 to show the placement of the vacuum pump **12** when used in conjunction with the socket 70 (Fig. 16) and liner **66** (Fig. 17).

[0031] As shown in Fig. 12, the system incorporates a mechanical lock **14** which includes an upper portion **56** that has a concave upper surface **53** extending conically down towards a lower portion **58.** The upper portion **56** includes an inlet **52** that is configured to receive a male end **76** (Fig. 18) of a liner **72** (Fig. 18) configured to be fitted with the mechanical lock **14.** The upper portion **56** additionally includes multiple access points **54** to receive a screw or any other grasping means, to firmly secure the mechanical lock **14** to the socket **70.**

[0032] As shown in Fig. 13, the lower portion **58** of the mechanical lock **14** further includes a mechanical locking pin **64** that extends laterally within the lower portion **58** to coincide with the distal end **62** of the inlet **52.** The mechanical locking pin **64** is configured to extend to the exterior of the socket **70** such that the user may push or press the mechanical locking pin **64** to release the male end **76** of the liner **72** configured to be fitted with the mechanical lock **14.** Thus, the mechanical locking pin **64** is configured to be engaged when the male end **76** is fitted within the mechanical lock **14** and disengaged when the male end **76** is absent within the mechanical lock **14.** Specifically, a clasping mechanism **61** is removably housed within the distal end **62** of the inlet **52** and functions by grasping the male end **76** when engaged. When the user desires to remove the liner **72** from the mechanical lock **14,** the mechanical locking pin **64** is pressed, which disengages the clasping mechanism **61** by sliding the clasping mechanism **61** into the bottom portion **58,** thus temporarily removing the clasping mechanism **61** from the distal end **62** of the inlet **52.** The lower portion **58** also includes connections **60** for the purpose of using a set screw, rivets, adhesives, or any other grasping means to connect the lower portion **58** to the upper portion **56.**

[0033] Now that the method of action of the mechanical locking pin **64** has been described, the dummy's **10** pin hole **16** (Fig. 2) can more easily be understood. The purpose of the pin hole **16** is to provide a channel or placeholder for the mechanical locking pm **64.** During manufacturing, the manufacturer places a pin or other place-holding means, partially into the dummy **10** and extending to the exterior of the socket **70.** Thus, once the manufacturing process of the socket **70** is complete, a channel exists for the mechanical locking pin **64** to

extend from the mechanical lock **14** to the exterior of the socket **70,** allowing the user to repeatedly push or press the mechanical locking pin **64.**

[0034] As shown in Figs. 14 and 15, the dummy **10** is firmly positioned relative to the distal end **71** of the socket **70.** Notably, the residual space or vacuum **68** is shown to represent the amount of air between the socket **70** and the liner **66,** that exists before the introduction of the vacuum pump **12.** In Fig. 15, the dummy **10** is designed to fit in a snug manner to the liner **66.**

[0035] As shown in Fig. 16, the vacuum pump **12** is incorporated into the distal end **71** of the socket **70** system. The sealing element **42** is shown to represent a seal between the vacuum pump **12** and the socket **70.** An outlet **73** coincides with the fluid outlet **36** to provide a means of escape for the discharged fluid from within the vacuum pump **12.** As shown in Fig. 17, the vacuum pump **12** is designed to fit in a snug manner to the liner **66.**

[0036] As shown in Fig. 18, the socket **70** is not shown; however, the mechanical lock **14** is shown for the purposes of showing that the male connector **76** connects relative to the mechanical lock **14** via the inlet **52.** As such, once the user dons the liner **66** having mechanical connector **72,** the system can then connected to the mechanical lock **14.**

[0037] Figs. 19-22 each show a separate embodiment from the previous figures. Each of the three main components, the dummy **10,** vacuum pump **12,** and mechanical lock **14** are manufactured such that they have tapered exteriors. Fig. 19 shows a tapered dummy **79** fitted within the distal end **71** of the socket **70.** Fig. 20 shows a tapered vacuum pump **80** fitted within the distal end **71** of the socket **70** and furthermore, the distal end **71** of the socket **70** includes a third one-way check valve **78** for purposes of having an increased outlet for any fluid between the socket **70** and liner **66.** Fig. 21 shows a tapered mechanical lock **82** that receives the liner **66** having mechanical connector **72.** Fig. 22 shows the vacuum pump **12** in a cylindrical configuration fitted within the distal end **71** of the socket **70** and furthermore, the distal end **71** of the socket **70** includes a socket one-way check valve **78** for purposes of having an increased outlet for any fluid between the socket **70** and liner **66.** The circumferential shape of vacuum pump **12** may be any geometry that allows for the creation of a level of vacuum **68** and allows the liner **66** to rest. Such geometries include, but are not limited to, circular, hexagonal, and octagonal.

[0038] As represented in the above figures, the invention provides a secure connection between the user's residual limb **74** and the socket **70** during the user's ambulation. As such, the cross section and modulus of elasticity of the chosen material used for the vacuum pump **12** determines the spring rate of the vacuum pump **12,** which then determines the level of vacuum **68** that will be present between the socket **70** and the liner **66** generated during the user's ambulation. The level of vacuum **68** is important because the secure connection between the socket **70** and the liner **66** is dependent on the level of vacuum **68** present.

[0039] Furthermore, the functioning principle of the vacuum pump **12** involve multiple steps, of which include (1) the material within the pump is compressed during the heel strike and the

stance phases of the user's gait and (2) then the material returns to a full length during the toe-off and the swing phases of the user's gait. These steps are repeated each full cycle of the user's ambulation and thus, the spring member **34** within the vacuum pump **12** must be rigid yet durable enough to last for many cycles. The level of vacuum **68** achieved during the swing phase of the user's gait is equal to the spring rate multiplied by the length of the achieved compression and collectively divided by the cross sectional area of the vacuum pump **12.**

[0040] More specifically, after the socket is fully donned by the user and as the user begins to ambulate, with the initial downward step, the downward force of the residual limb within the socket will force any remnant air within the lower section of the socket out through fluid inlet **24** (Fig. 6), through the upper one-way valve **38,** into the fluid channel **40** and out through the lower one-way valve **39** while simultaneously compressing the spring member **34** downwardly. As the user lifts his limb off the ground for the next step, the spring member **34** expands causing lower one-way valve **39** to close and upper one-way valve **38** to open and draw more air from within the socket 70 in the fluid channel **40.** As the user takes the next step, causing spring member **34** to compress again, the air pressure in fluid channel **40** causes lower one-way valve **39** to open while maintaining upper one-way valve **38** closed thereby relieving air from within fluid channel **45** to be vented through fluid outlet **36.** The cycle is repeated as the user ambulates creating a continuous evacuation of air from within the socket.

[0041] Moreover, many pumps in the industry have been manufactured to include elastomeric springs or cushions; however, metal springs are either equivalent or more efficient due to their density. That is, since the metal springs are denser (requiring less volume) than elastomeric springs or cushions, air may travel more readily throughout the pump, thus providing a more fluid pumping action within the pump and therefore, a more comfortable experience for the user. The metal springs have a spring rate, or pumping action, determined by the shape of the coils, the Young's modulus of the metal used, and the thickness of the wire that is used to make the coils. Thus, the character of the metal spring is determined from its material and construction.

[0042] The spring rate for either elastomeric springs, metal springs, or foam cushion is determined by the cross sectional area of the material multiplied by the modulus of elasticity of the material. The number of steps required to reach steady state of the vacuum pump **12** (or the state at which the user's limb is securely attached within the socket **70**) is a function of (1) the free volume of the socket, (2) the required vacuum level (varying from 16932 to 67728 Pascals (5 to 20 inches Hg,) preferably 16932 to 33864 Pascals (5 to 10 inches Hg)), and (3) the volume of air that is displaced inside the pump during the stance aspect of the user's gait (the volume displaced for a given pump geometry is directly proportional to the compression allowed during the stance phase, the length of compression is fixed by the height ratio of the pump at rest versus the length of the dummy **10** and has values ranging from 3 to 20 mm and preferably 7 to 8 mm).

[0043] The present invention may be embodied in other specific forms without departing from the essential attributes thereof, and it is therefore desired that the present embodiment be

considered in all respects as illustrative and not restrictive, reference being made to the appended claims rather than to the foregoing description to indicate the scope of the invention.

REFERENCES CITED IN THE DESCRIPTION

Cited references

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

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- US2010262261A1 [0006]

PATENTKRAV

1. Aftagelig vakuumpumpe (12) til frembringelse af et vakuum inde i en protesefatning omfattende:

et elastomerhus med en indvendig fluidkanal (40), en øvre, udvendig flade (26) og et udvendigt tætningselement;

et fjederelement (34), en første envejsventil (38), der forhindrer tilbagestrømning af luft, og en anden envejsventil (39), der forhindrer tilbagestrømning af luft, hvor fjederelementet, første envejsventil og anden envejsventil er placeret inde i den indvendige fluidkanal (40);

kendetegnet ved, at elastomerhuset endvidere omfatter et trekantet hulrum (43).

2. Vakuumpumpe (12) ifølge krav 1, hvor den øvre, udvendige flade (26) er konkav.

3. Vakuumpumpe (12) ifølge krav 1, hvor den øvre, udvendige flade (26) er konveks.

4. Vakuumpumpe (12) ifølge krav 1, hvor fjederelementet (34) omfatter et metal.

5. Vakuumpumpe (12) ifølge krav 1, hvor fjederelementet (34) omfatter et skum.

6. Vakuumpumpe (12) ifølge krav 1, hvor fjederelementet (34) omfatter en elastomer.

7. Vakuumpumpe (12) ifølge krav 1, hvor den anden envejsventil (39) tvinger luft til at strømme gennem en tredje envejsventil (78), der er placeret i en protesefatning.

8. Vakuumpumpe (12) ifølge krav 1, hvor elastomerhuset (72) er konisk.

DRAWINGS

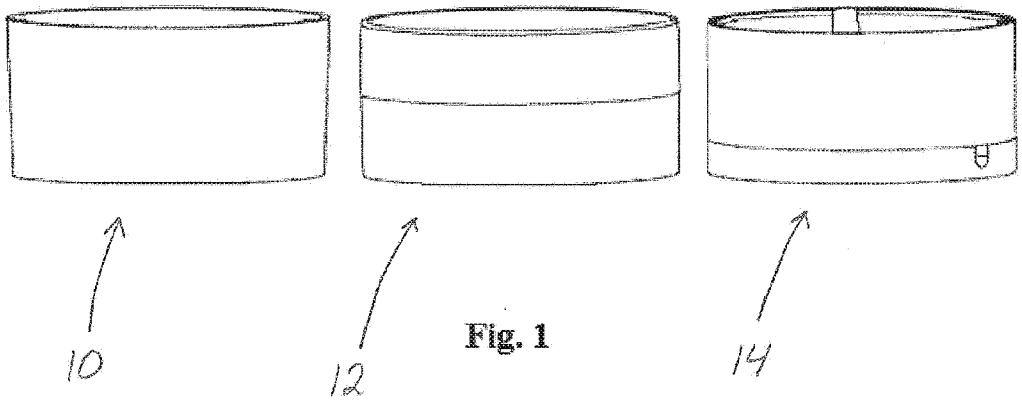


Fig. 1

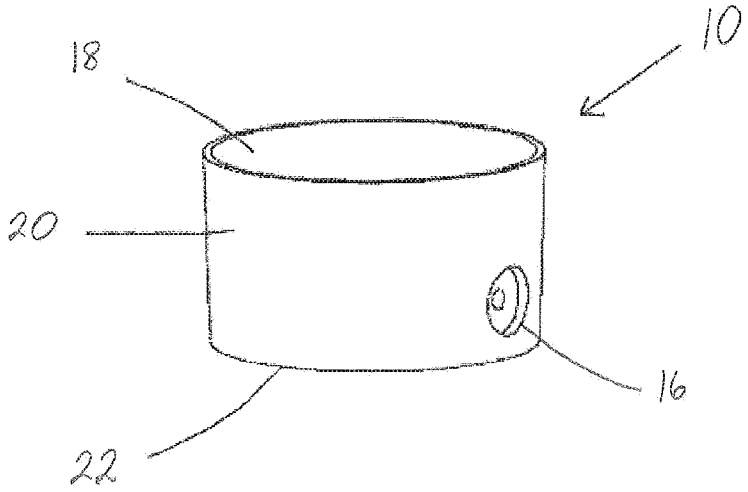


Fig. 2

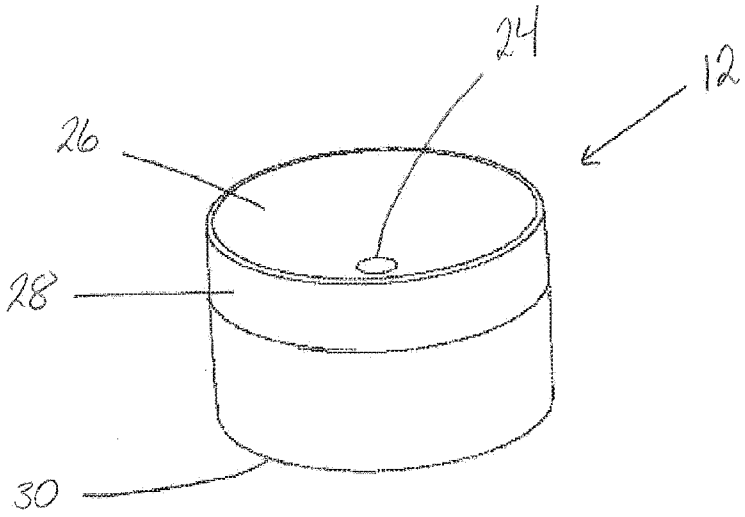


Fig. 3

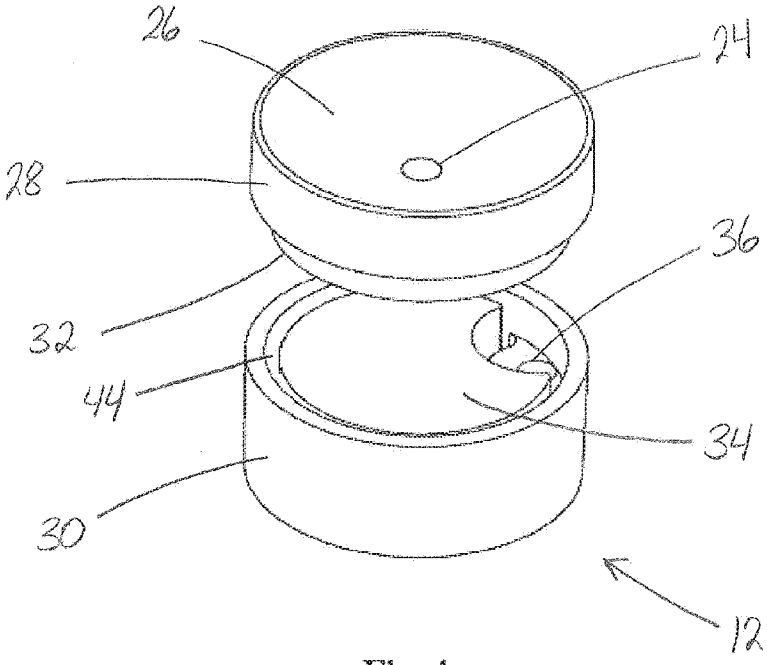


Fig. 4

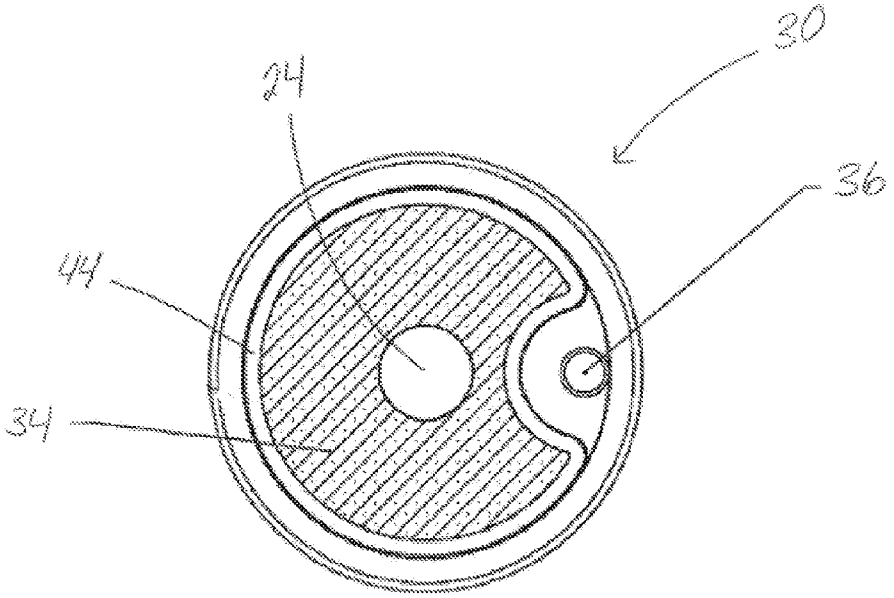


Fig. 5

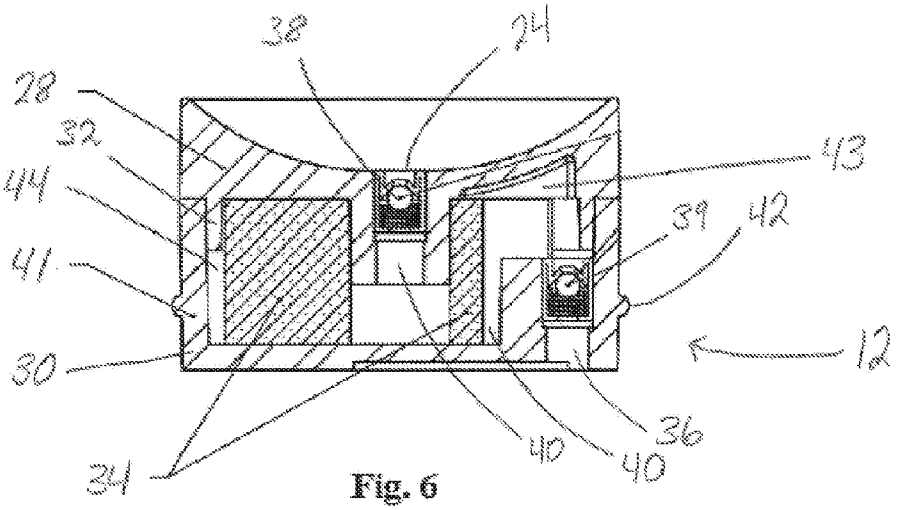


Fig. 6

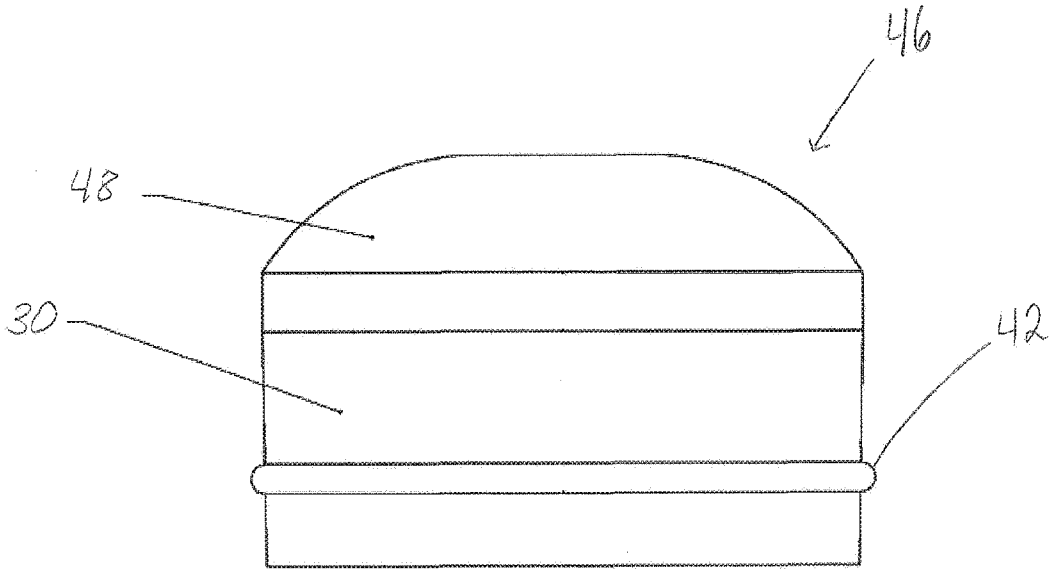


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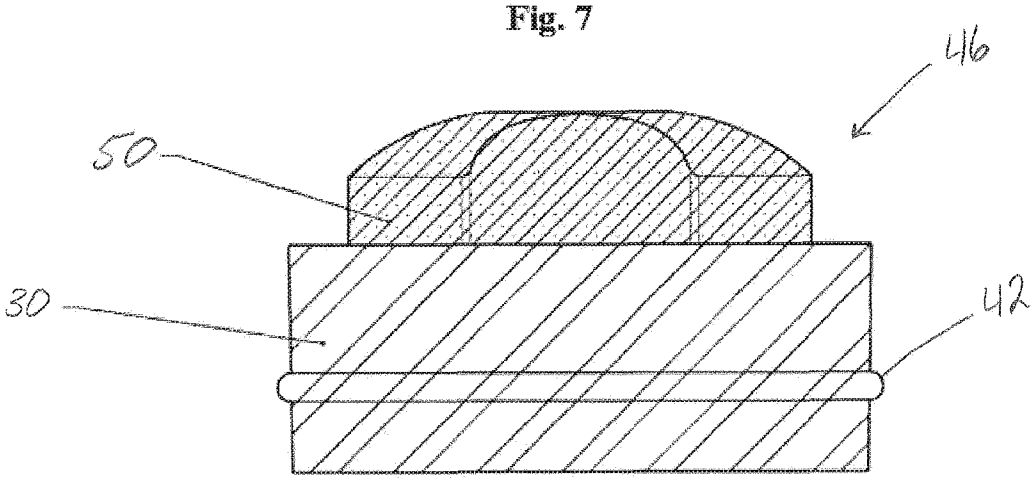


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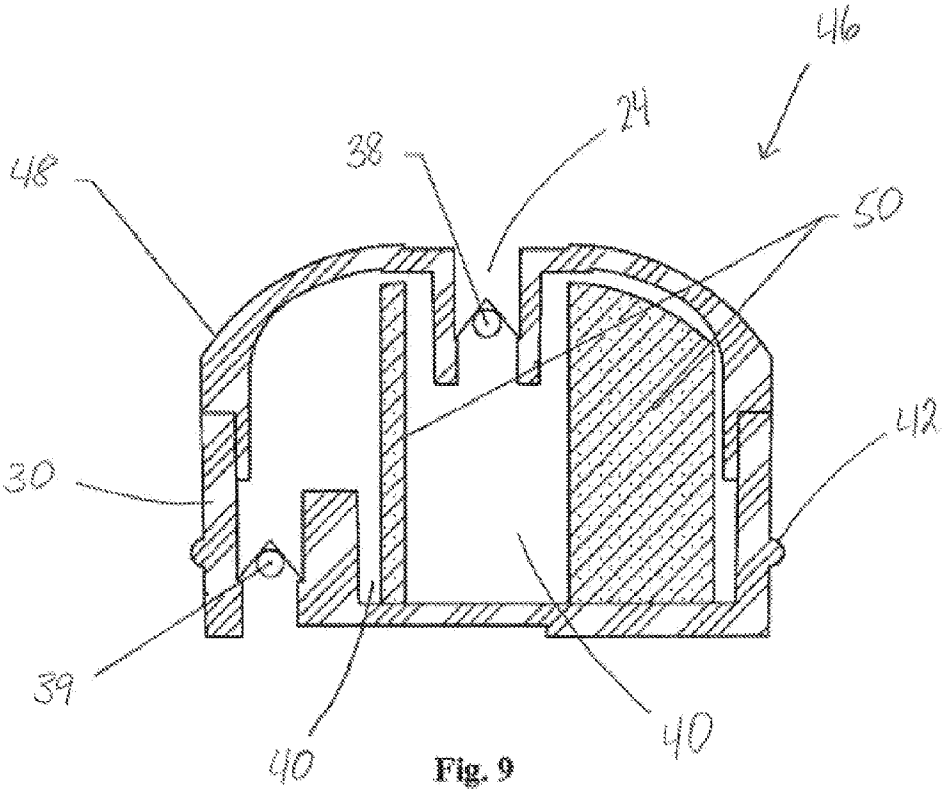


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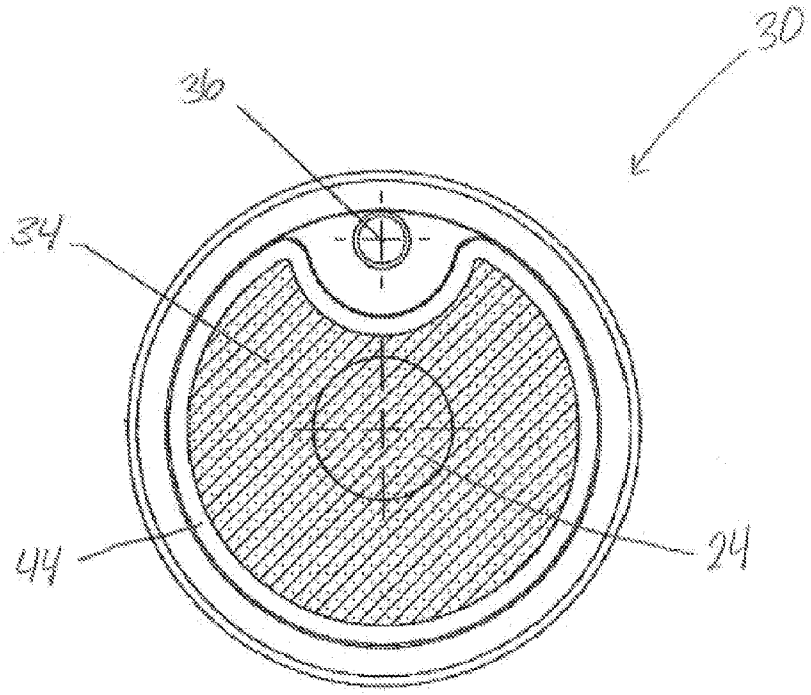


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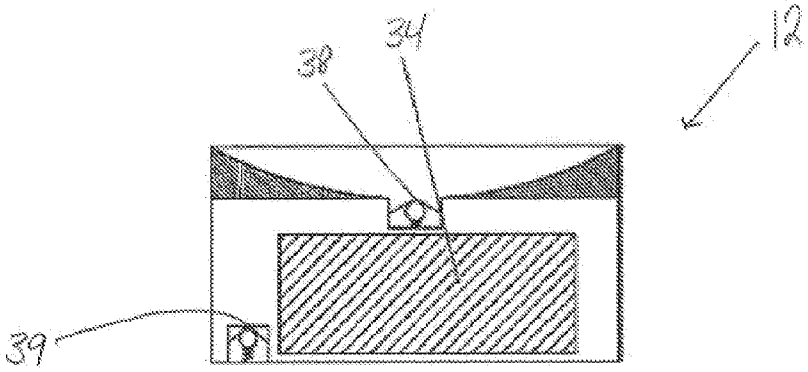


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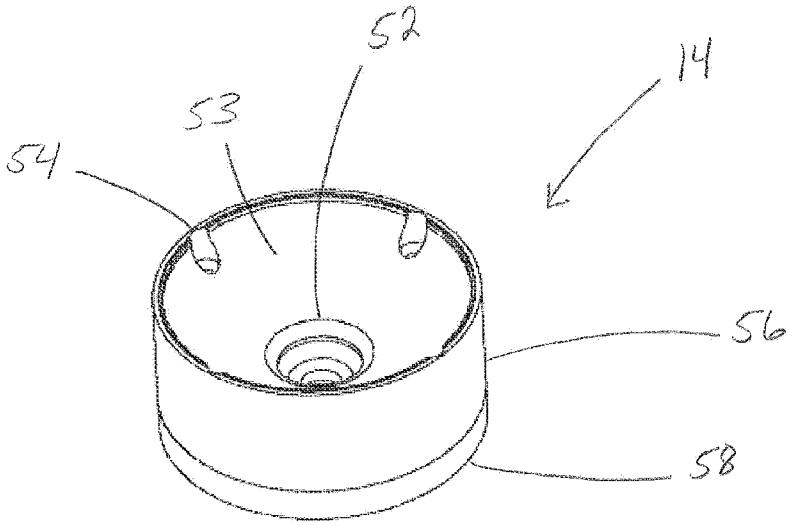


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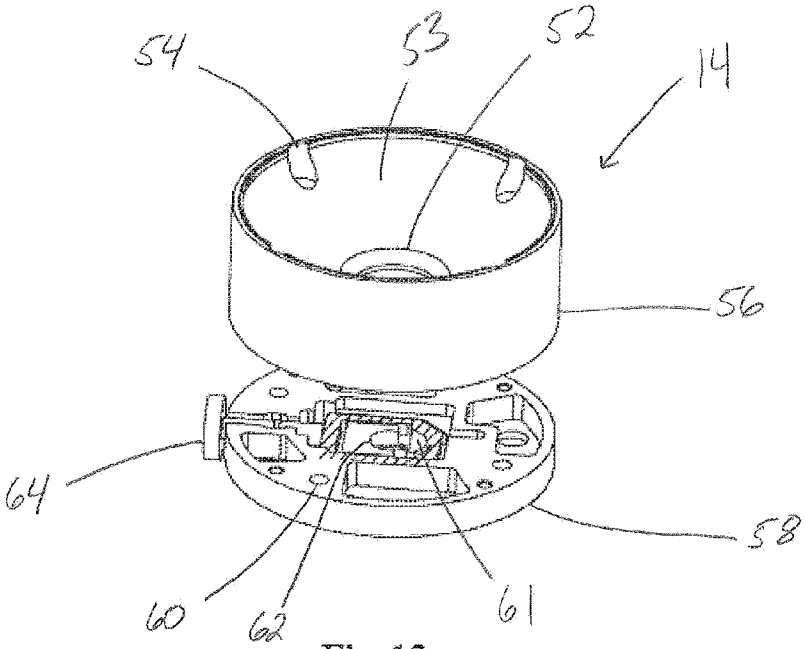


Fig. 13

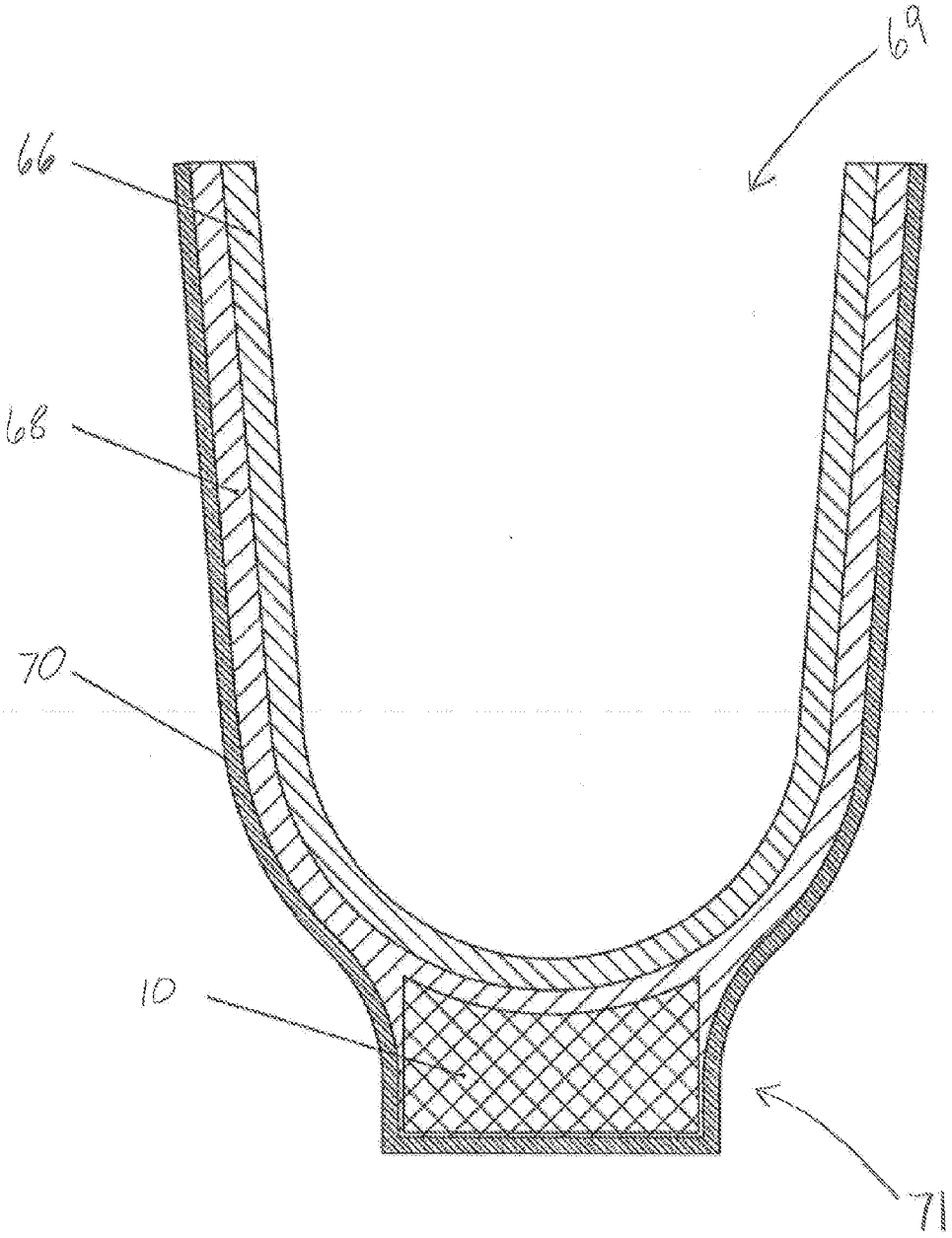


Fig. 14

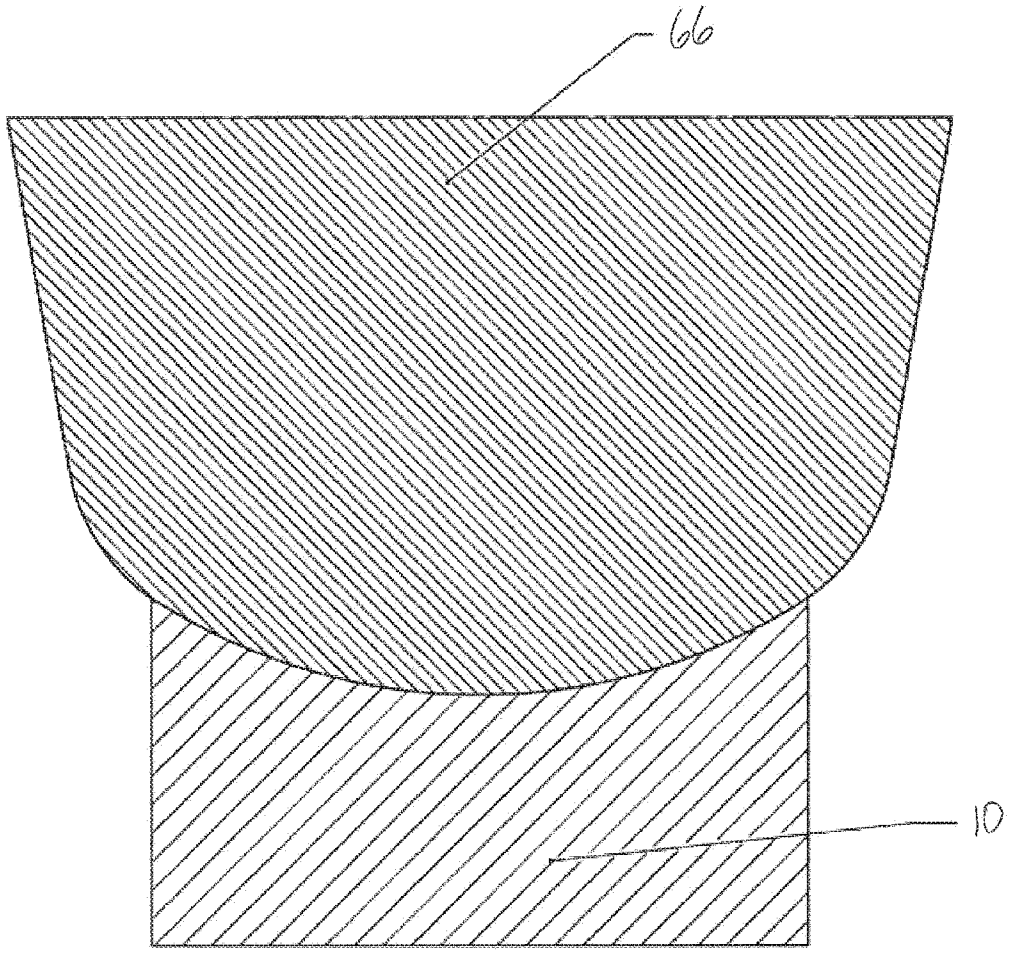


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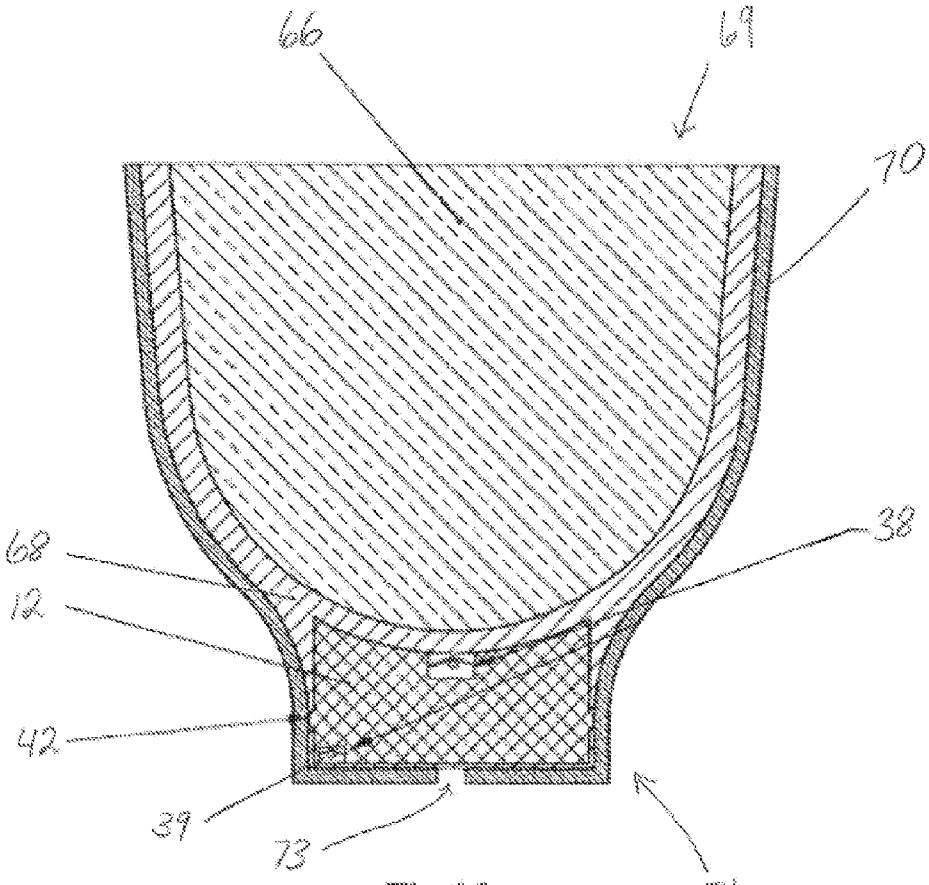


Fig. 16

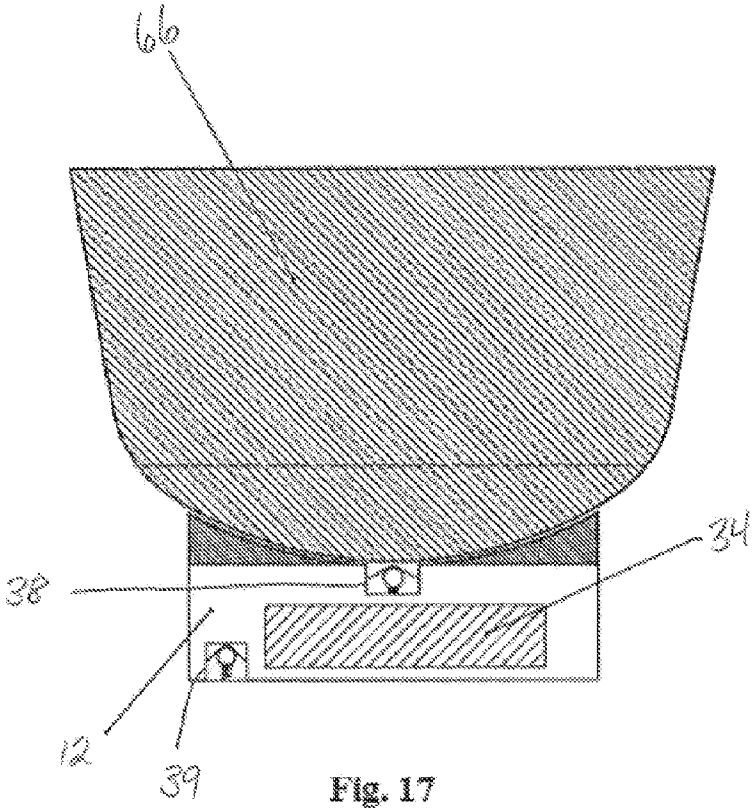


Fig. 17

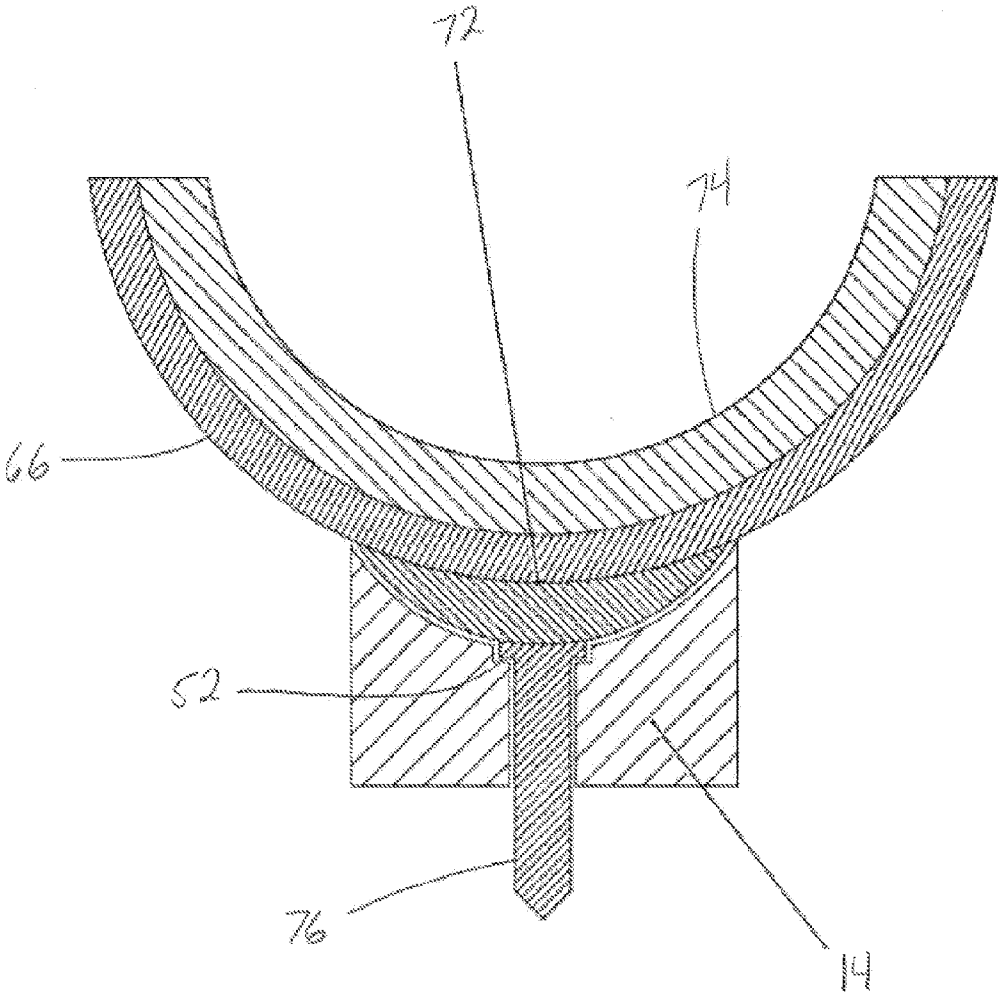


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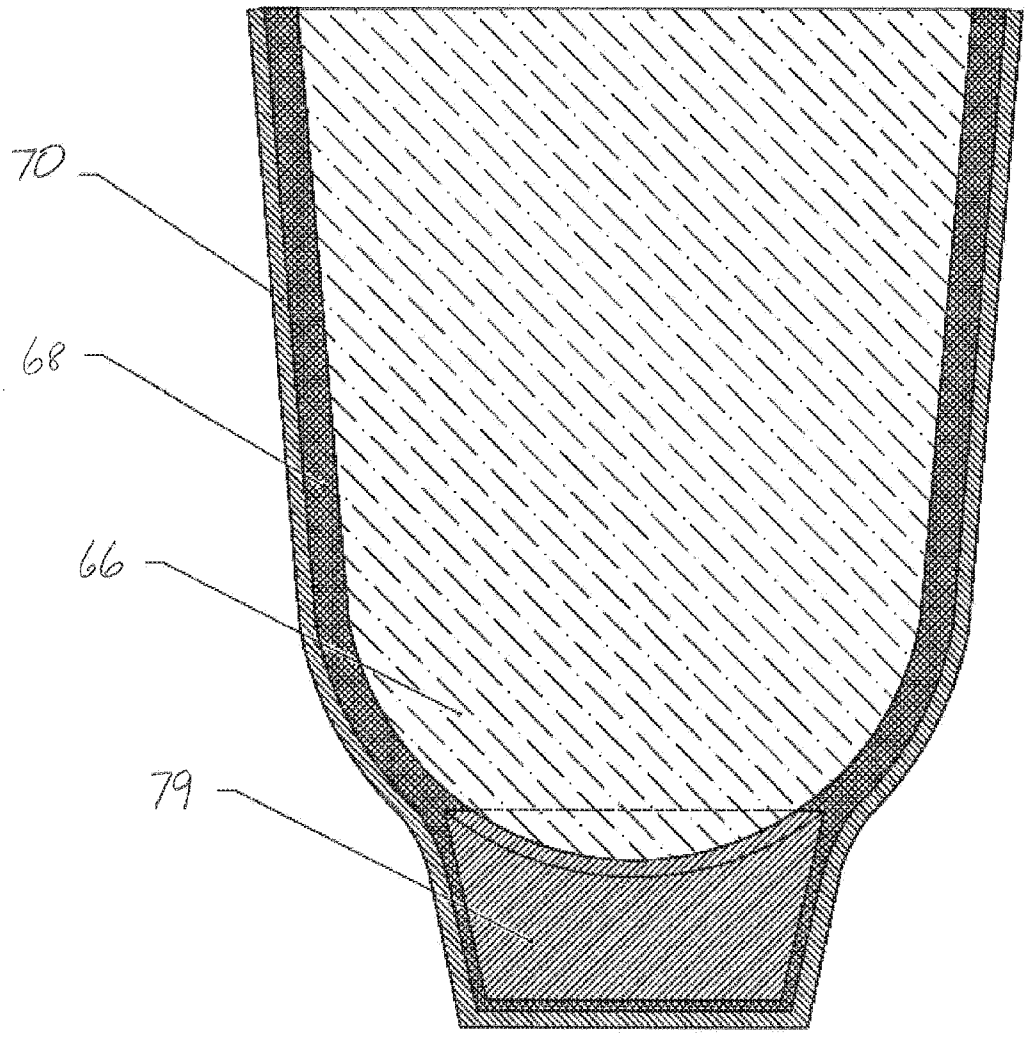


Fig. 19

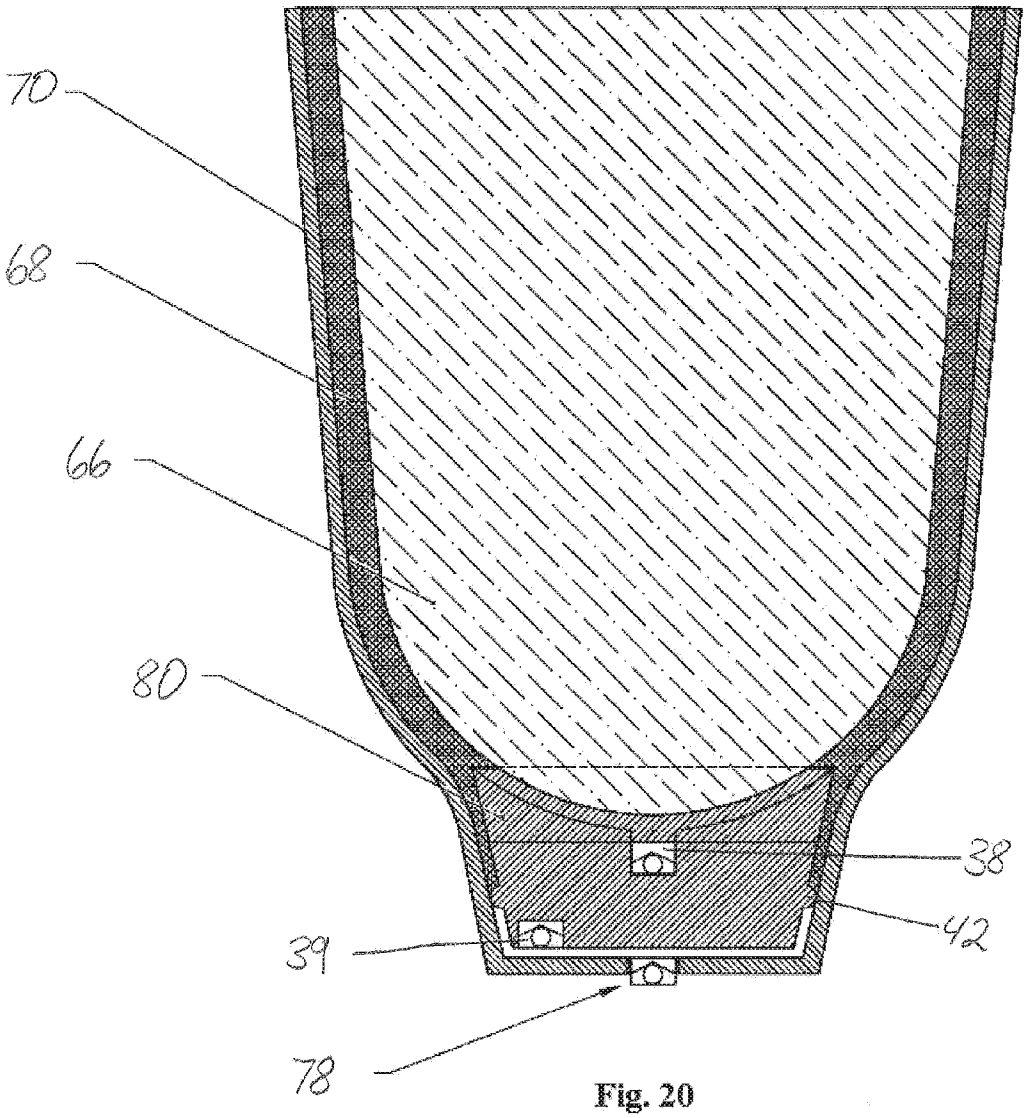


Fig. 20

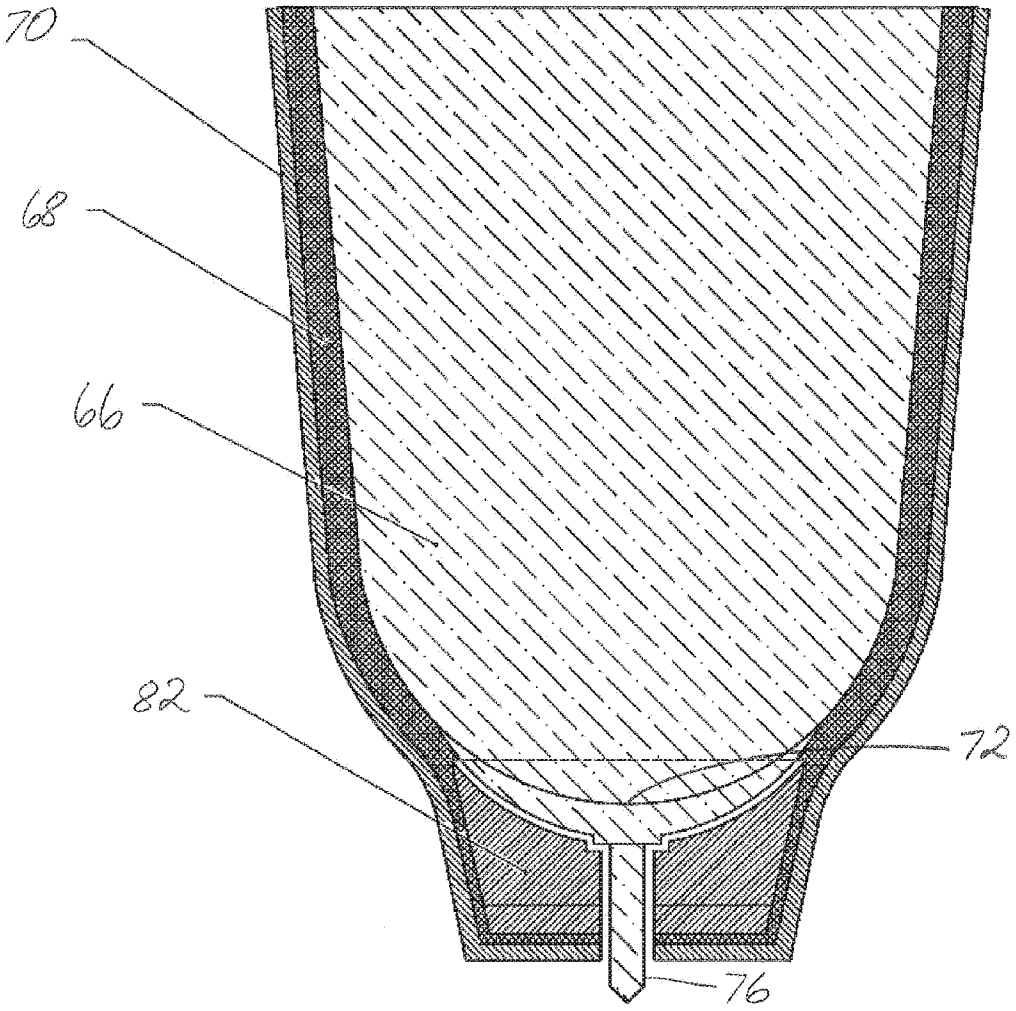


Fig. 21

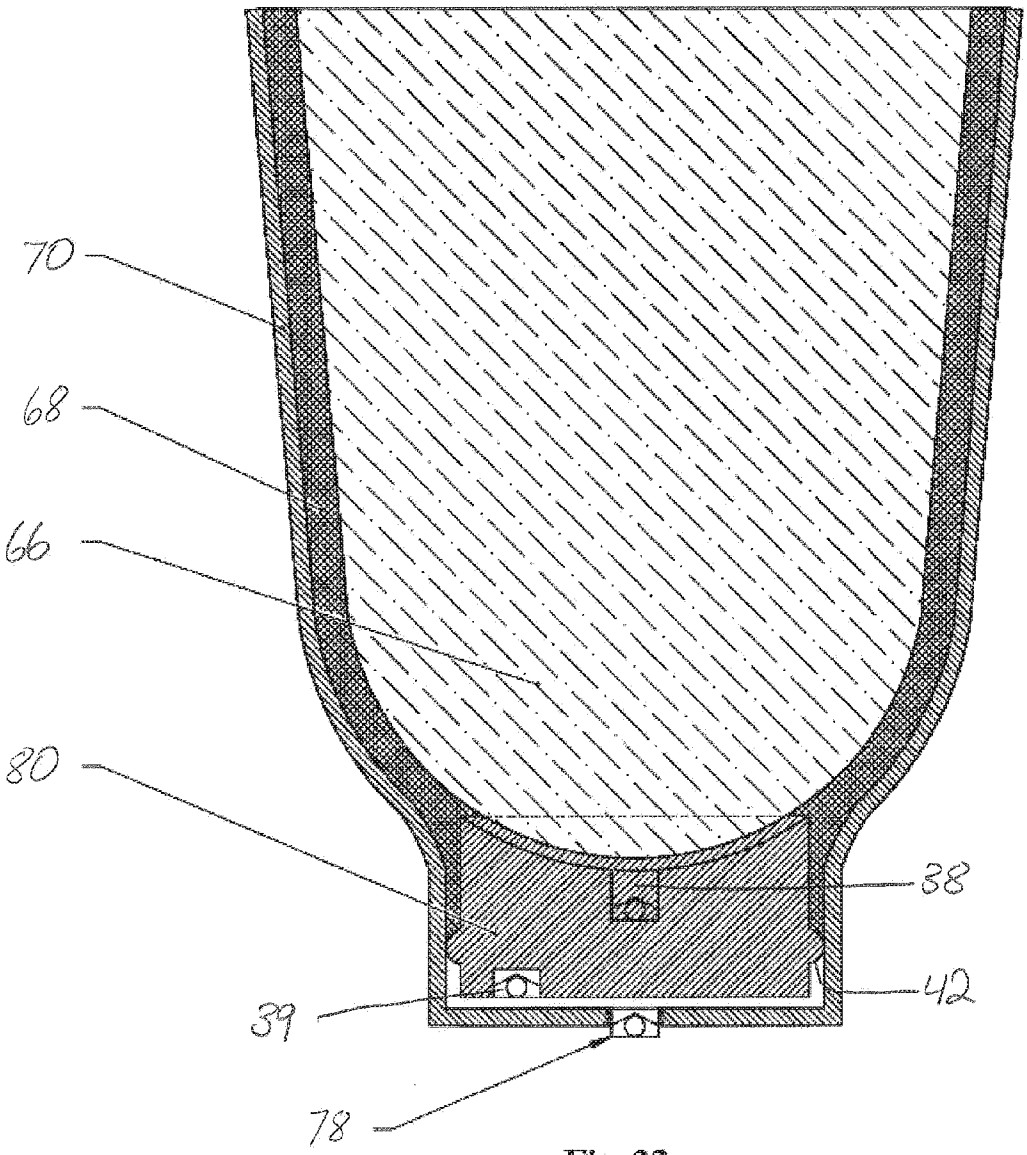


Fig. 22