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(54) **MULTI-COMPONENT HANDLING AND DELIVERY SYSTEM**

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(57) **ABSTRACT**

A multi-component handling and delivering system, and its methods of use, comprising a fully integrated structure for combining chemical and other components. The system eliminates the requirement for independent component transfer and atmospheric escape of any chemical vapors during handling and combining. The invention is useful to combine bone cement components (i.e., bone cement power and liquid monomer) to form bone cement.

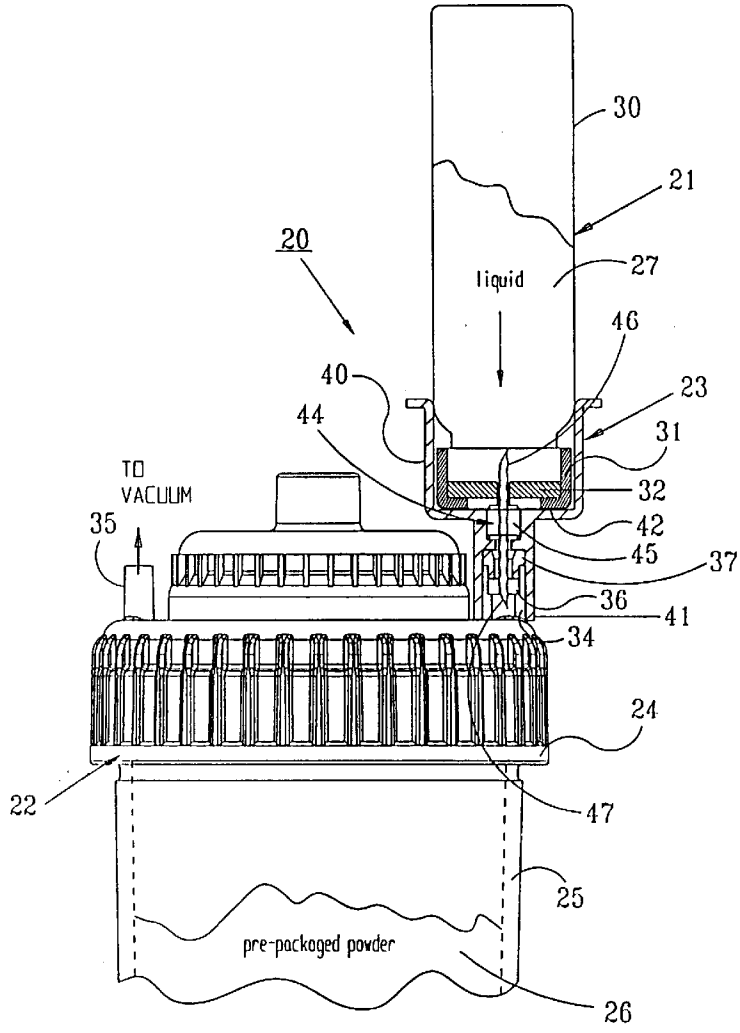


FIG. 1

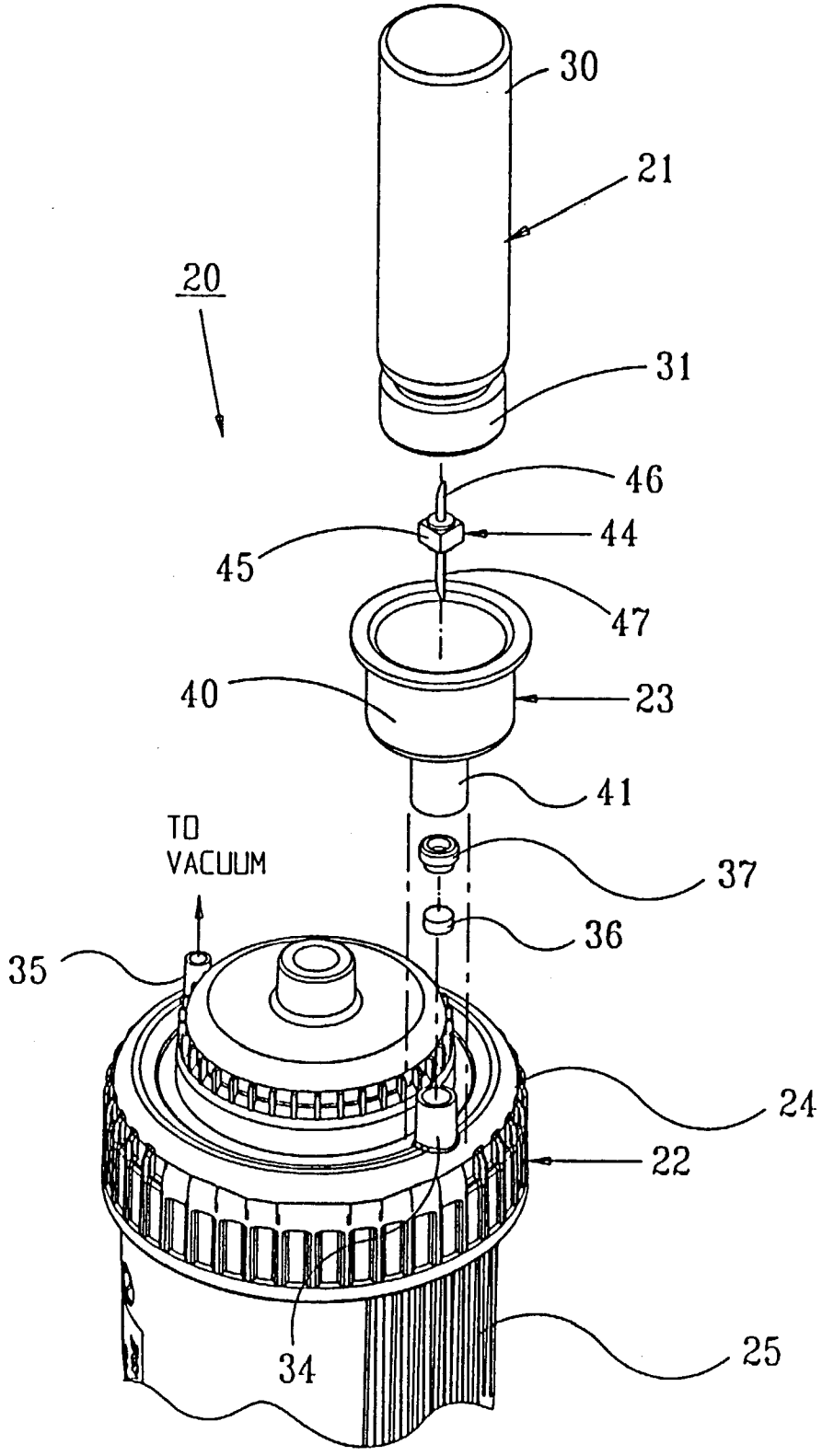


FIG. 2

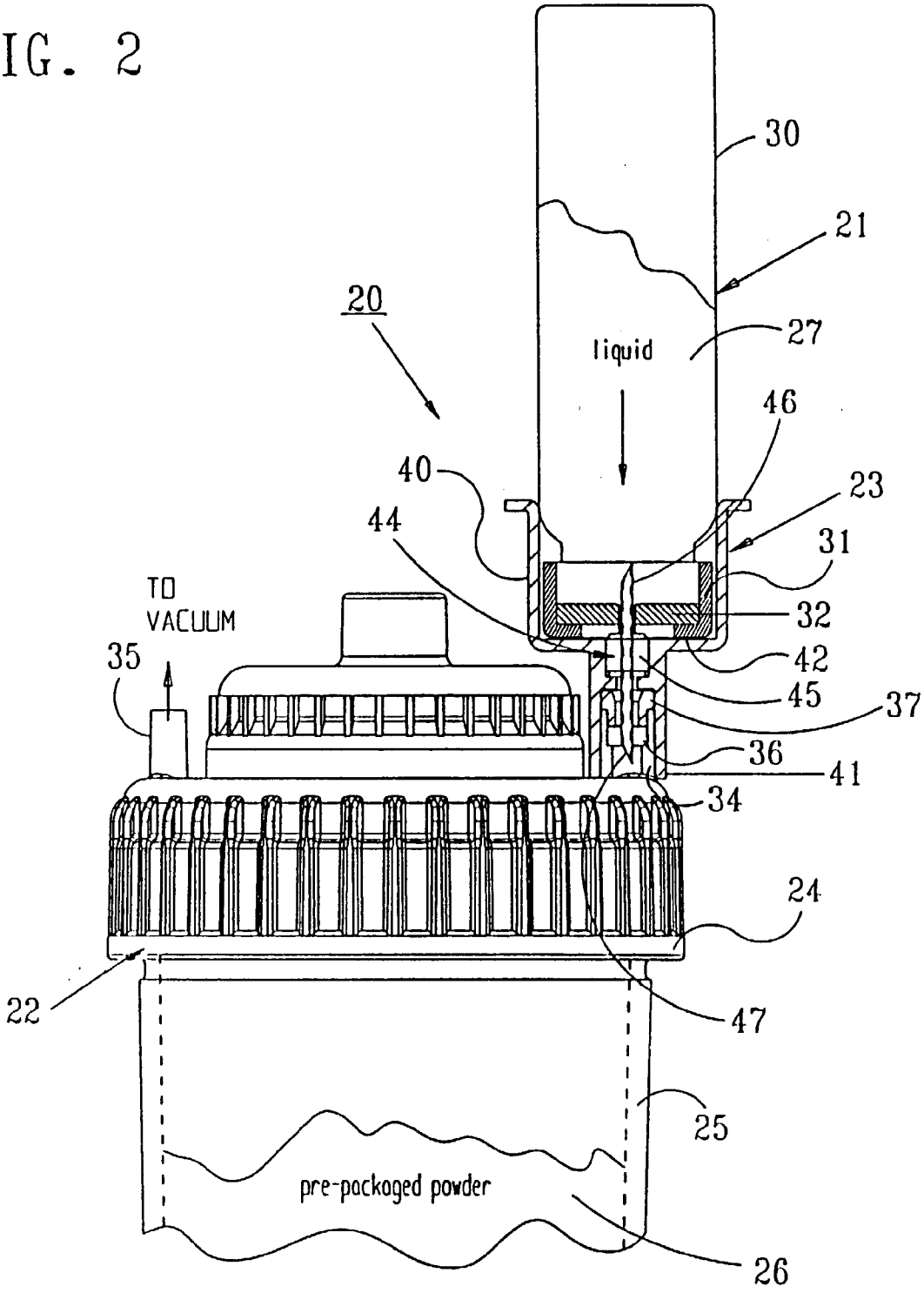

30
21
20
liquid
27
46
40
23
44
31
TO
VACUUM
32
35
42
45
37
36
41
34
24
22
47
25
pre-packaged powder
26

FIG. 3

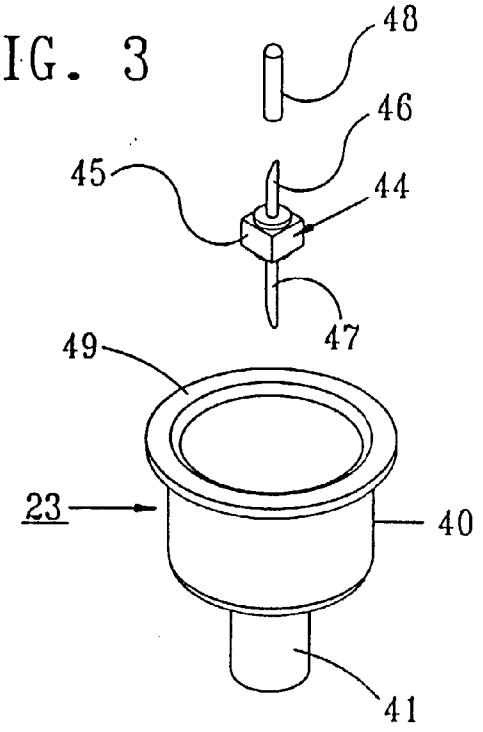


FIG. 4

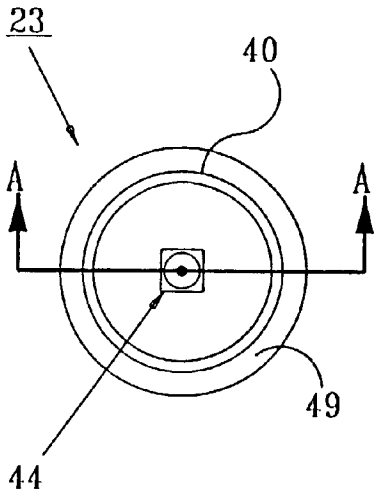


FIG. 5

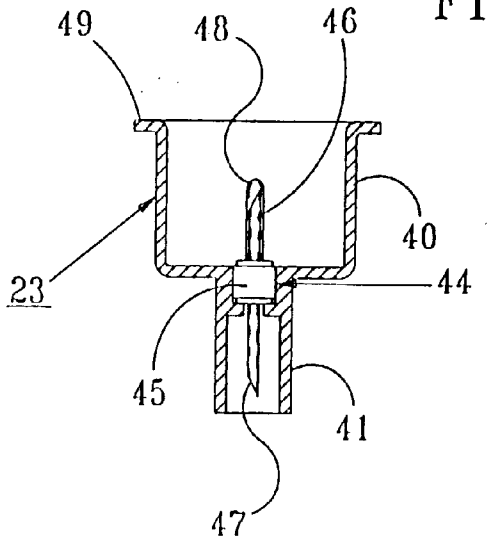


FIG. 6

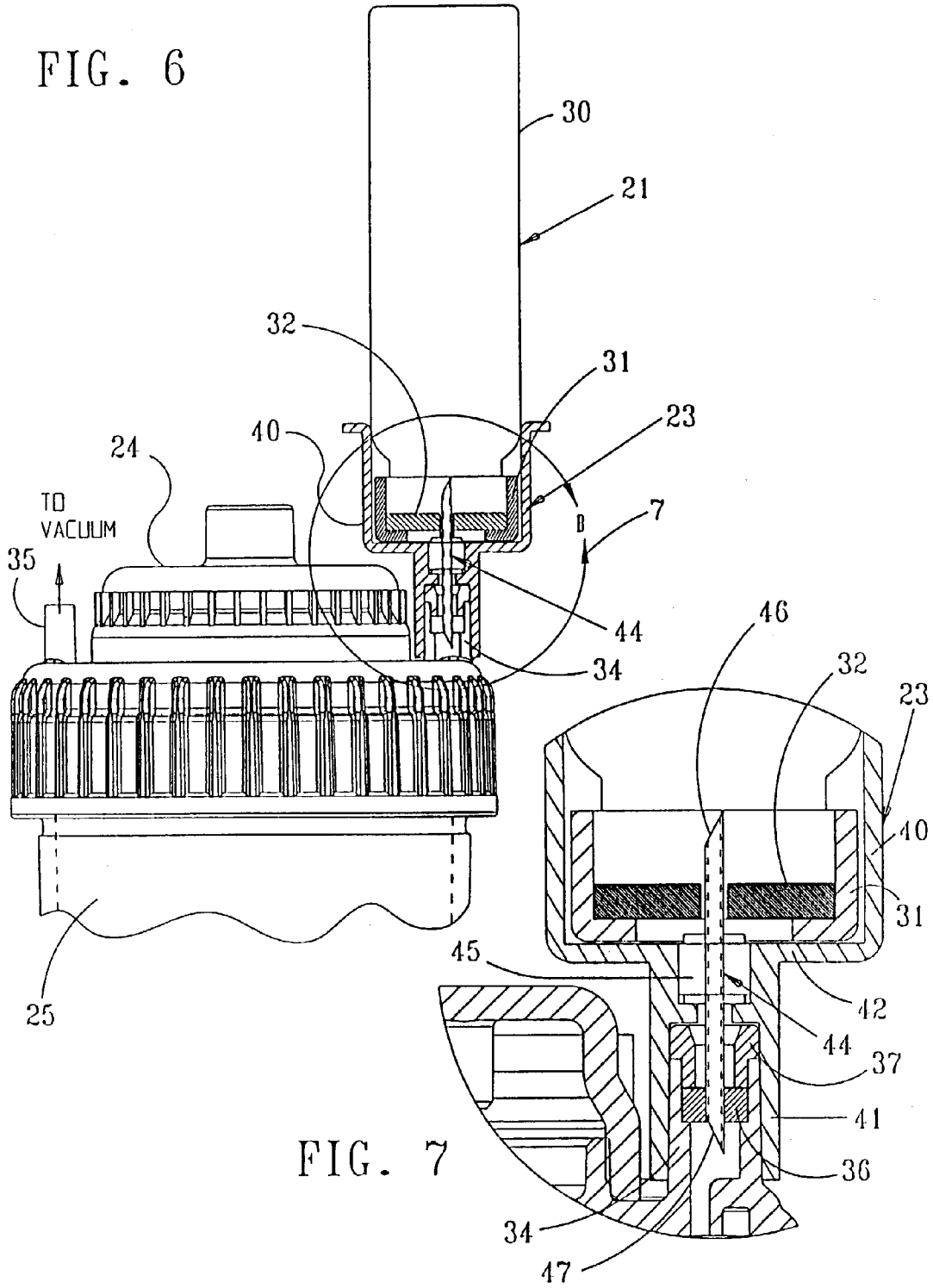

30
21
32
31
23
40
24
TO
VACUUM
35
7
44
34
25
46
32
23
40
31
45
42
44
37
41
36
34
47

FIG. 7

FIG. 8

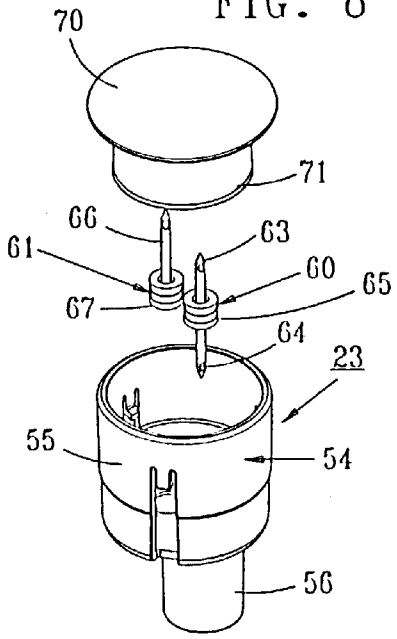


FIG. 9

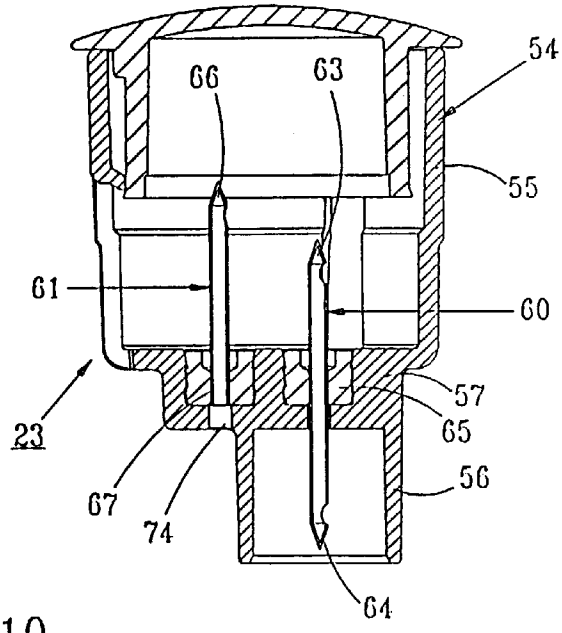


FIG. 10

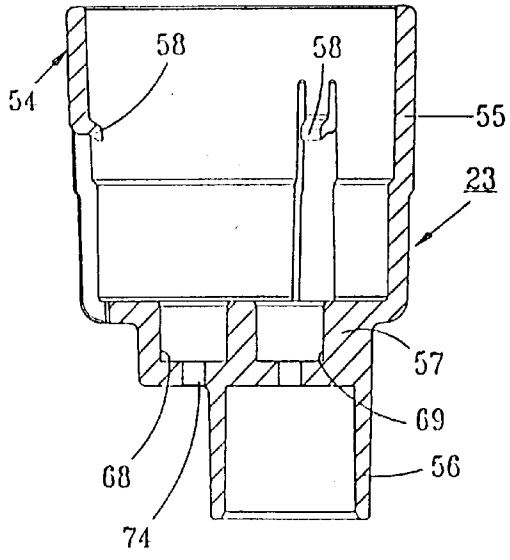
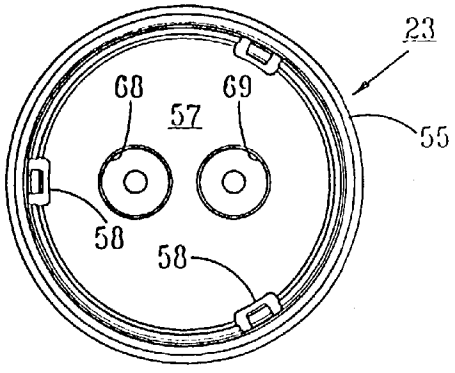


FIG. 11



MULTI-COMPONENT HANDLING AND DELIVERY SYSTEM

[0001] This application is a continuation-in-part of application Ser. No. 10/266,053, filed on Oct. 7, 2002, entitled Multi-Component, Product Handling And Delivery System, which application is hereby incorporated herein by reference.

TECHNICAL FIELD

[0002] This invention relates to a multi-component system for enabling at least two components to be positioned in a vessel for subsequent processing. This system is particularly useful in the handling, combining, and delivery of bone cements.

BACKGROUND

[0003] In many surgical procedures, particularly orthopedic procedures, it has now become common to affix a prosthesis to a bone or joint structure for improving the strength, rigidity, and movement of the bone/joint structure. Although such prosthetic devices have been widely used, hip joints and knee joints are the most common examples of areas where prosthetic devices are used to reduce or eliminate pain and suffering that exists from typical leg movements.

[0004] As part of these operations, it has become common practice to secure the prosthesis to the bone or joint using bone cement, formed by combining or mixing a powdered polymer and a liquid monomer. Once intermixed, the two components must be thoroughly blended together to achieve the required consistency for the fully mixed bone cement, with the fully mixed bone cement then being loaded into a dispensing apparatus for placement in the desired area for affixing the prosthesis to the desired site.

[0005] In most applications, the two components forming the bone cement are mixed in a vessel and, once fully mixed, are manually transferred from the vessel to a dispensing member. Typically, devices such as caulking guns are employed, for dispensing the fully mixed bone cement to the precisely desired location of the patient. This process is extremely unpleasant for individuals mixing the bone cement, since the mixed bone cement contains an offensive, noxious odor. Furthermore, removal of the mixed bone cement from the vessel into the caulking gun is cumbersome, time consuming, and has the potential for being mishandled and/or dropped.

[0006] Another problem typically encountered with prior art systems is the difficulty encountered with air being entrapped in the mixed bone cement. The presence of air pockets or air bubbles in the mixed bone cement is undesirable. Since it is important that the bone cement added to the bone area for affixing the prosthetic be virtually free of any entrapped air bubbles or air pockets, most prior art systems demand mixing of the powder and liquid under vacuum conditions. As a result, added limitations are incurred on the flexibility of the vessel and the ability to mix the two-part bone cement mixture in any desired location.

[0007] Some prior art systems have enabled the mixing to be performed in one vessel that then is directly connected to a feeding system for enabling the mixed bone cement to be added to a holding tube for use with the dispensing caulking gun. However, a separate dispensing system is required and extra handling and exposure of the mixed bone cement to the surrounding personnel is required. Furthermore, care must be exercised during the transfer of the mixed bone cement to the dispenser, since air is frequently introduced into the bone cement during this transfer operation as well as the risk of dropping or spilling the material.

[0008] More recently, a unitary, fully integrated, bone cement handling system has been attained. This unique achievement is realized by creating a single housing or member that comprises a vessel for combining component integrally operating with a delivery chamber or tube. The delivery chamber terminates with a portal through which the mixed bone cement is directly dispensed to any desired location.

[0009] In order to provide a vessel for combining that can be operated independently of the delivery chamber, the combining vessel and the delivery chamber of the integrated system are movable between two alternate positions. In the first position, each of the combining vessel and the delivery chamber are sealed from the other, while in the second position, the two are in direct communication with each other.

[0010] By employing this new development, the two components forming the bone cement are placed in the combining vessel and combined, preferably, with complete assurance that no unmixed bone cement will enter the delivery chamber. In a preferred embodiment, complete mixing of the bone cement is assured by providing, in some embodiments, an integrated counter and display that informs the operator the exact time at which the bone cement components have been thoroughly intermixed.

[0011] Once the two components forming the bone cement are fully intermixed with each other, to provide the desired bone cement product, the integrated system of the present invention is moved from its first sealed position to its second open position, enabling the fully mixed bone cement to be transferred from the combining vessel directly into the delivery chamber. When desired and under the complete control of the operator, the mixed bone cement is advanced through the delivery chamber to a delivery portal, formed at the terminating end thereof. Then, the fully intermixed bone cement is dispensed through the portal directly to the desired location where the product is to be used.

[0012] Although this prior art integrated bone cement handling and delivery system has been successful in overcoming many prior art problems, one problem that has continued to plague this industry is the difficulty encountered in the delivery, shipment, and transfer of the two components that form the bone cement. As is well-known, bone cement comprises a first component that consists of a liquid monomer and a second component that consists of a dry powder.

[0013] These components must be kept separate from each other until the user is ready to intermix the components to form the desired bone cement. Typically, the dry powder is stored in a flexible bag, pouch, or similar container, while the liquid monomer is stored for shipment and handling in a vial or tube, usually formed from glass.

[0014] In use, the container holding the dry powder that forms a second component is opened and the powder is

placed in the vessel. Then, when creation of the bone cement is desired, the glass vial or tube holding the liquid monomer is opened and the monomer is added to the powder. Thereafter, the two components are thoroughly intermixed with each other.

[0015] In attempting to expedite the opening of the vial or tube holding the liquid monomer, as well as reduce any exposure to the foul odor possessed by the liquid monomer, various prior art systems have been developed for enabling the user to insert the sealed vial or tube into an area of the vessel and then break the vial or tube for releasing the liquid monomer directly into the dry powder.

[0016] These prior art systems all require that the broken glass pieces or shards of the vial/tube must be separately retained and prevented from reaching the bone cement product. In attempting to satisfy this requirement, substantial construction and operational difficulties have occurred with these prior art systems. Furthermore, in other prior art systems, manual addition of the monomer is required, exposing the user to the foul odor of the monomer and the substantial difficulties typically encountered in handling such products.

SUMMARY

[0017] In one embodiment, the invention is directed to a multi-component handling and delivering system, and its methods of use, comprising a fully integrated structure that eliminates the requirement for independent transfer of the components that form a mixed bone cement, eliminates atmospheric escape of chemical vapors, and eliminates the dangers associated with breakage of glass vials or tubes.

[0018] In another embodiment, the invention is directed to a multi-component handling and delivering system wherein the components that are combined to form bone cement (i.e., bone cement power and liquid monomer) are maintained separately from each other in a combining vessel and a seal container respectively until actual combining is initiated. The liquid monomer is dispensed from the sealed container directly into the combining vessel, preferably, in a closed loop manner, without exposure of the components to the user and without breakage of the sealed container holding the liquid monomer.

[0019] Throughout the following disclosure, the multi-component handling and delivery system is detailed as a component of an integrated bone cement handling and delivery system. Due to the unique attributes and substantial advances that have been achieved by the integrated handling and delivery system of the invention, it is equally applicable to all cases where two or more components are combined or mixed.

[0020] In another embodiment of the invention, the multi-component handling and delivering system comprises a combining vessel within which the dry bone cement powder is stored during shipment and distribution. Alternatively, if desired, the powder material may be contained in a sealed bag, pouch, container, or the like that is opened to dispense the powder directly into the vessel.

[0021] In addition, the multi-component handling and delivering system comprises a sealed container, for containing the first component. For example, for containing the first component of bone cement, such as liquid monomer. The sealed container can be any suitable container adaptable to create a flow path to the vessel. For example, the sealed container can be flexible or non-flexible plastic or other polymer, preferably, a chemically resistant plastic or polymer. In another embodiment, the sealed container comprises a glass vial or tube.

[0022] In certain embodiments, vacuum is used as the means to cause the sealed-container contents to transfer into the vessel. In these embodiments, the vessel will comprise a vacuum portal for attachment to a vacuum supply. In other embodiments, the sealed container can be constructed such that the system of the invention can operate without vacuum. The sealed container will comprise the means to transfer the container contents into the vessel. In these embodiments, the vacuum portal is not required. In one such embodiment, the sealed container is a chemically resistant squeeze bottle or flexible bag so that the container's contents can be squeezed into the vessel. In another such embodiment, the sealed container is preloaded with a pressurized gas along with the monomer or other contents. The pressurized gas functions to push the monomer out of the container upon creating a flow path by connection to the transfer assembly.

[0023] Preferably, the sealed container comprises a cap or closure. In the preferred construction, the cap or closure incorporates a zone or integrally formed area that comprises a sealing membrane, such as an elastomeric material, for example, plastics, rubbers, silicones, and the like. Thus, the sealing-membrane-bearing container allows a transfer conduit, such as a syringe needle or similar hollow piercing element to enter the sealing membrane to gain access to the liquid monomer, without any loss of liquid monomer through the puncture that has been formed or escape of chemical vapors.

[0024] Caps or closures of this nature are well known in the medical field, with the sealing membrane commonly referred to as a "septa". Typically, such caps or closures are found on vials or containers incorporating liquid medicines that are dispensed through transfer conduits, such as hypodermic needles or syringes. By piercing the sealing membrane or septa with a syringe needle, entry into the vial is attained, without loss of any contents through the cap or closure. This is due to the ability of the sealing membrane to seal about the syringe needle when inserted. In addition, once the syringe has been filled and the syringe needle withdrawn, the sealing membrane closes the puncture formed by the syringe needle, preventing any leakage of medicine therethrough.

[0025] In order to attain the desired transfer of the liquid monomer from the sealed vial or tube directly into the dry powder, without exposing the user to the liquid monomer, the multi-component product handling and delivering system of the present invention comprises a transfer assembly, preferably, a fluid transfer assembly. The transfer assembly of the invention is constructed for cooperating with the sealed container containing the liquid monomer and the vessel for extracting all of the liquid monomer from the container in a closed loop operation and directly delivering the liquid monomer into the vessel containing the dry powder. This transfer operation is achieved upon demand by the user, while preventing the liquid monomer from being exposed to the user or to the surrounding area.

[0026] In its preferred construction, the present invention, the transfer assembly comprises a housing incorporating two

portal bearing mounting collars formed thereon and two cooperating, hollow, piercing elements integrally affixed therewith. In the preferred construction, the two cooperating hollow piercing elements comprise hypodermic needle-like constructions that are coaxially associated with each other to provide a substantially continuous elongated flow path therethrough.

[0027] In addition, each piercing element comprises a sharp tip portion constructed for piercing through septa-like materials (used for construction of the sealing membranes) associated with the vessel and the monomer-bearing sealed container. Furthermore, one piercing element is associated with one mounting collar of the transfer assembly.

[0028] In addition, the vessel of the present invention incorporates an access portal for cooperating with one of the mounting collars of the transfer assembly and a vacuum portal constructed for being connected to a vacuum source. By employing these elements, a closed loop, substantially sealed, delivery of the liquid monomer directly into the dry powder for forming the bone cement in the vessel is attained.

[0029] In the preferred construction, the access portal of the vessel, that is constructed for being inter-engaged with a mounting collar of the transfer assembly, incorporates a small sealing membrane formed of elastomeric material mounted therein. By employing elastomeric material such as elastomeric plastics, rubbers, silicones, and the like, the interior of the vessel is maintained sealed, accessible only by the insertion of a transfer conduit, such as a syringe needle through the sealing membrane.

[0030] In operation, whenever a user is ready to form the bone cement for use in a particular application, the dry powder is placed in the vessel, unless the dry powder has previously been stored and sealed therein. Then, the liquid-monomer-containing sealed container is selected and the first collar of the housing of the transfer assembly is telescopically mounted directly onto the sealing-membrane-bearing cap or closure of the sealed container. This telescopic mounting procedure causes the syringe-like piercing element associated therewith to be inserted through the sealing membrane, thereby gaining access to the interior of the sealed container.

[0031] Thereafter, the second collar of the housing of the transfer assembly is mounted directly on the collar-receiving access portal of the vessel. This mounting procedure causes the second piercing element of the transfer assembly to be inserted through the sealing membrane mounted in the access portal of the vessel. In this way, direct communication between the interior of the sealed container and the vessel is established, in a closed-loop, sealed construction.

[0032] Once all of the components are mounted in place, the vacuum connected to the vacuum portal of the vessel is activated causing the liquid monomer to be drawn through the piercing elements of the transfer assembly, causing the liquid monomer to be fed directly onto the dry powder contained in the vessel. Once all of the liquid monomer has been transferred into the combining vessel, the empty sealed container is removed, along with the transfer assembly, and combining or mixing of the two components is initiated.

[0033] As is evident from the foregoing discussion, the removal of the transfer assembly from the access portal of the vessel causes of the sealing membrane mounted therein to be immediately closed, as soon as the piercing element is removed therefrom. As a result, the interior of the combining vessel is continuously sealed from the surrounding environment, preventing any unwanted foul odors to emanate from the vessel.

[0034] The invention accordingly comprises the features of construction, combination of elements and arrangement of parts that will be exemplified in the construction hereinafter set forth, and the scope of the invention will be indicated in the claims.

THE DRAWINGS

[0035] For a fuller understanding of the nature of the invention, reference should be had to the following detailed description taken in connection with the accompanying drawings, in which:

[0036] **FIG. 1** is an exploded perspective view, partially broken away, depicting the multi-component product handling and delivering system of the present invention;

[0037] **FIG. 2** is a side elevation view, partially broken away and partially in cross-section depicting the multi-component product handling and delivering system of **FIG. 1** fully assembled;

[0038] **FIG. 3** is an exploded perspective view of the transfer assembly member of the multi-component product handling and delivering system of present invention;

[0039] **FIG. 4** is a top plan view of the transfer assembly of **FIG. 3**;

[0040] **FIG. 5** is a cross-sectional side elevation view of the transfer assembly taken along the line **5-5** of **FIG. 4**;

[0041] **FIG. 6** is a side elevation view of the fully assembled multi-component system of the present invention, partially broken away and partially in cross-section;

[0042] **FIG. 7** is an enlarged cross-sectional side elevation view detailing area **7** of **FIG. 6**;

[0043] **FIG. 8** is an exploded perspective view of an alternate embodiment of the transfer assembly of the present invention;

[0044] **FIG. 9** is a cross-sectional side elevation view of the transfer assembly of **FIG. 8**;

[0045] **FIG. 10** is a cross-sectional side elevation view of the housing forming the transfer assembly of **FIG. 8**; and

[0046] **FIG. 11** is a top plan view of the housing of **FIG. 10**.

DETAILED DISCLOSURE

[0047] By referring to FIGS. **1-11**, along with the following detailed discussion, the construction and operation of the preferred multi-component product handling and delivering systems of the present invention can best be understood. However, as will become evident from this disclosure, further alternate embodiments of the present invention can be implemented without departing from the scope of the present invention. Consequently, the embodiments detailed in FIGS. **1-11**, and in the following detailed disclosure, are intended for exemplary purposes, and not as a limitation of the present invention.

[0048] The present invention can be employed with any type of vessel used to intermix the two or more components. Thus, the present invention is not limited to combing or mixing bone cements.

[0049] The components of the multi-component product handling and delivering systems of the present invention can be packaged and sold together as a kit.

[0050] In **FIGS. 1, 2, 6,** and **7**, multi-component product handling and delivering system **20** of the present invention is fully depicted as comprising container **21**, integrated bone cement handling and delivery system **22**, and transfer assembly **23**, preferably, a fluid transfer assembly. Container **21** is preferably a sealed container, more preferably, a sealed container designed for containing corrosive chemicals, such as liquid monomer. As used herein, "sealed" means that the container's contents are prevented from leaking during handling and transport and protected from air. As shown, integrated bone cement handling and delivery system **22** comprises cover **24** that is threadedly mounting to vessel **25**.

[0051] In the preferred construction and implementation of the present invention, the second component of the bone cement, which comprises dry powder **26**, is stored in vessel **25** of bone cement handling and delivery system **22**, as clearly shown in **FIG. 2**. However, if desired, dry powder **26** may be stored in any suitable container, bag, or pouch that is opened just prior to use with the powder being added to vessel **25**.

[0052] In addition to preferably shipping dry powder **26** in vessel **25** of bone cement handling and delivery system **22**, the first component, which comprises liquid monomer **27**, is contained in sealed container **21**. Sealed container **21** can be any suitable container adaptable to create a flow path to the vessel by way of transfer assembly **23**. For example, sealed container **21** can be flexible or non-flexible plastic or other polymer, preferably, a chemically resistant plastic or polymer. In one preferred embodiment, sealed container **21** comprises glass vial or tube **30** having a single opening or portal on which cap or closure **31** is mounted.

[0053] As detailed above, cap or closure **31** of sealed container **21** comprises an integrally formed sealing membrane, preferably, a septa to provide access to the interior of glass vial/tube **30**. Sealing membrane **32** comprises a generally conventional construction, formed of elastomeric material, which typically comprises elastomeric plastics, rubbers, silicones, and the like. In this way, liquid monomer **27** is sealed within glass tube/vial **30**, while providing access to the interior of tube/vial **30** only upon creating a flow path, for example, by using a transfer conduit, such as a suitable syringe needle.

[0054] In certain embodiments, vacuum is used to cause the sealed-container contents to transfer into the vessel. In these embodiments, the vessel will comprise vacuum portal **35** for attachment to a vacuum supply. In other embodiments, sealed container **21** can be constructed such that the system of the invention can operate without vacuum. Sealed container **21** will comprise the means to transfer the container contents into vessel **25**. In these embodiments, vacuum portal **35** is not required. In one such embodiment, sealed container **21** is a chemically resistant squeeze bottle or flexible bag so that container **21**'s contents can be squeezed into the vessel **25**. In another such embodiment, sealed container **21** is preloaded with a pressurized gas that functions to push the monomer out of container **21** upon creating a flow path by connection to transfer assembly **23**. Preferably, container **21**'s contents (e.g., monomer) is preloaded along with the pressurized gas.

[0055] In addition, cover **24** of bone cement handling and delivery system **22** comprises a access portal **34** and vacuum portal **35** that are mounted thereto and provide access to the interior of vessel **24**. Vacuum portal **35** comprises a generally conventional construction that enables a vacuum source to be connected thereto, using any suitable vacuum connection. In addition, access portal **34** comprises a sealing membrane **36**, preferably, a septa-like disk mounted in access portal **34** for sealing the interior of vessel **25** from the ambient air, while also enabling access to the interior of vessel **25** to be achieved by creating a flow path, for example by employing a transfer conduit, such as a suitable needle or syringe.

[0056] Finally, holder **37** is employed for maintaining sealing membrane **36** in the precisely desired position within access portal **34**. By forming holder **37** with two separate and distinct diameters, one portion of holder **37** is inserted into access portal **34**, while the second, larger diameter portion thereof engages the outer terminating edge of access portal **34**. In this way, sealing membrane **36** is securely maintained in the desired position within access portal **34**.

[0057] The construction of transfer assembly **23** of the present invention is completed by providing for mating engagement thereof with cap **31** of sealed container **21** and access portal **34** of cover **24** of handling and delivery system **22**. As fully depicted in FIGS. **1-7**, in its preferred embodiment, transfer assembly **23** comprises collar portions **40** and **41**, interconnected with each other along support plate **42**. In addition, collar portions **40** and **41** preferably comprise generally cylindrical shapes and are coaxially aligned with each other.

[0058] In addition, collar portion **40** is constructed with an inside diameter dimensioned for co-operative, frictional engagement with cap **31** of sealed container **21**. In this way, when transfer assembly **23** is mounted to sealed container **21**, transfer assembly **23** is frictionally engaged securely with sealed container **21**, preventing any unwanted, easy dislodgment of sealed container **21** from assembly **23**.

[0059] Similarly, collar **41** comprises an inside dimension constructed for mating, cooperative, sliding engagement with access portal **34** of cover **24**. In addition, by designing collar **41** with an inside dimension that is slightly greater than the outside dimension of access portal **34**, secure holding engagement of transfer assembly **23** with access portal **34** is achieved whenever assembly **23** is telescopically mounted into overlying engagement with access portal **34**.

[0060] In order to complete the construction of transfer assembly **23**, a mechanism for providing a flow path between the vessel and the sealed container, is provided. The preferred flow path is created by a transfer conduit, such as dual ended piercing conduit **44** (double-tipped syringe needle). As depicted, transfer conduit **44** comprises a support base **45**, a syringe needle forming member **46** mounted to one surface of support base **45** and a syringe needle forming member **47** mounted to the opposed surface of support base **45**.

[0061] In the preferred construction, syringe needle forming members **46** and **47** comprise elongated, hollow tubes mounted to support base **45** in coaxial alignment with each other, forming a continuous, elongated flow path therebetween. In addition, each syringe needle forming member **46** and **47** comprises sharp, pointed, distal ends constructed for piercing the sealing membrane **36** (any septa-like material) for gaining access to the interior associated with the sealing membrane.

[0062] In addition, base **45** of piercing element **44** is securely mounted in transfer assembly **23**, preferably affixed in support plate **42**. When mounted in its secure position, syringe needle forming member **46** extends into collar portion **40**, substantially centrally disposed therein. In this position, syringe needle forming member **46** is peripherally surrounded by the wall forming collar portion **40** with its sharp, distal end extending toward the opening of collar **40**.

[0063] Similarly, syringe needle forming member **47** is securely positioned to be centrally disposed within collar portion **40**, peripherally surrounded by the wall forming collar **41**. In addition, the sharp distal end of syringe needle forming portion **47** extends towards the open end of collar **41**.

[0064] By employing this construction, the telescopic axial advance of transfer assembly **23** into engagement with sealed container **21** and access portal **34** of cover **24**, causes syringe needle forming portions **46** and **47** to pierce the sealing membranes **32** and **36** and establish a direct fluid transfer flow path between sealed container **21** and vessel **25**. In the preferred construction, in order to eliminate any unwanted injuries, tip cover **48** is preferably mounted to syringe needle forming member **46**. Since the diameter of collar portion **40** is large enough to enable a finger tip to enter its open end, the use of cover **48** prior to engagement of cover **40** onto cap **31** provides the desired protection.

[0065] In addition, in the preferred construction, collar **40** comprises radially extending flange **49** formed on its terminating end. By employing flange **49**, ease of use and control of collar **40** is provided.

[0066] By referring to FIGS. **8-11**, along with the following detailed discussion, the construction of an alternate, preferred embodiment of transfer assembly **23** of the present invention is provided. In this embodiment, transfer assembly **23** comprises a housing **54** that incorporates collar portions **55** and **56**, interconnected to each other by support wall **57**. In the preferred embodiment, collar portions **55** and **56** preferably comprise generally cylindrical shapes and are vertically aligned with each other. In addition, the central axis of each collar portion is parallel to each other and offset from each other.

[0067] As with the embodiment detailed above, collar portion **56** comprises an inside diameter constructed for mating, co-operative, sliding engagement with access portal **34** of cover **24**. In addition, by designing collar portion **56** with an inside diameter that is slightly greater than the outside diameter of access portal **34**, secure holding engagement of transfer assembly **23** with access portal **34** is achieved whenever assembly **23** is telescopically mounted into overlying engagement with access portal **34**.

[0068] In addition, collar portion **55** comprises an inside diameter dimensioned for cooperative, frictional engagement with cap **31** of sealed container **21**. In addition, in this embodiment, collar portion **55** comprises a plurality of tabs **58** mounted to the inside wall of collar portion **55** that extend radially inwardly therefrom. In addition, tabs **58** are formed on the inside wall of collar portion **55** in a vertical position that is slightly greater than the vertical height of cap **31** of sealed container **21**. Finally, in the preferred construction, tabs **58** are formed about the inside wall of collar portion **55** substantially equidistant from each other, thereby being spaced apart a distance of about 120°.

[0069] By employing this construction, whenever sealed container **21** is telescopically inserted into collar portion **55** of transfer assembly **23**, cap **31** of sealed container **21** is frictionally engaged with collar portion **55**, securely locked in position by tabs **58** engaging the edge of cap **31** and preventing telescopic removal of sealed container **21** from collar portion **55**. In this way, once sealed container **21** has been mounted in secure, locked engagement with transfer assembly **23**, dislodgment or removal of sealed container **21** from collar **55** is prevented.

[0070] Furthermore, in this embodiment of the invention, transfer assembly **23** comprises gas-flow aperture **74** comprising gas-flow conduit **61** mounted in support wall **57** and transfer conduit **60** also mounted in support wall **57**. Preferably, transfer conduit **60** and gas-flow conduit **61** are independent syringe needles. As shown in **FIGS. 8 and 9**, transfer conduit **60** comprises an elongated, continuous, tubular member that defines an elongated flow path and incorporates two separate and independent piercing ends **63** and **64** mounted to support base **65**. In another embodiment, conduit **60** is molded directly into housing **54** and, thus, collar **65** is not required.

[0071] With support base **65** of transfer conduit **60** mounted in receiving hole **69** of support wall **57** of transfer assembly **23**, piercing end **63** extends from support wall **57** into the interior of collar portion **55**, while piercing end **64** extends from support wall **57** into collar portion **56**. In this way, as detailed above, whenever transfer assembly **23** is mounted to access portal **34** of vessel **25**, and sealed container **21** is mounted to transfer assembly **23**, the monomer contained in sealed container **21** is able to be transferred through transfer conduit **60** into vessel **25**.

[0072] In this embodiment of the present invention, transfer assembly **23** also comprises a gas-flow conduit **61** that incorporates an elongated, cylindrically shaped, hollow piercing element **66** mounted to support base **67**. In the preferred construction, support base **67** is mounted in receiving hole **68** formed in support wall **57** of transfer assembly **23**, with hollow piercing element **66** extending therefrom into the interior of collar portion **55**. In addition, base **67** of gas-flow conduit **61** cooperates with gas-flow aperture **74** formed in support wall **57**, thereby providing an air flow path from the ambient surroundings through hollow gas-flow conduit **61** into the interior of sealed container **21** whenever sealed container **21** is mounted in collar **55**.

[0073] By employing this embodiment of the present invention, transfer assembly **23** provides assurance that the monomer stored in sealed container **21** is capable of flowing freely through transfer conduit **60** into vessel **25** whenever the monomer is desired for being added into vessel **25**. By providing a separate gas flow pathway (preferably ambient air) through gas-flow aperture **74** and gas-flow conduit **61**,

gas, such as nitrogen, argon, or other inert gas or air is constantly replaced in sealed container **21** as the monomer is withdrawn therefrom. In this way, the creation of a partial vacuum is avoided and free flow of the monomer is provided.

[**0074**] In the preferred construction, this embodiment of the present invention is completed by incorporating cover **70** that is constructed for being mounted in collar portion **55** for preventing and blocking any unwanted entry into collar portion **55**, prior to the insertion of sealed container **21**. In this way, contact with the terminating ends of piercing elements **63** and **66** is prevented and any unwanted or accidental injury is avoided.

[**0075**] In the preferred construction, cover **70** comprises an outwardly extending rim **71** formed on the base thereof, which cooperates with inwardly extending tabs **58**, in order to secure cover **70** in the desired position. In addition, whenever monomer bearing sealed container **21** is ready for insertion in collar portion **55**, cover **70** is easily removed from its secured position, thereby enabling sealed container **21** to be telescopically inserted and locked in position in collar portion **55**.

[**0076**] In view of the above disclosure and Figs., it is clear that in one embodiment, the invention comprises a kit for combining a first component and a second component comprising:

[**0077**] a. a sealed container for containing the first component;

[**0078**] b. a vessel comprising an access portal, for containing the second component;

[**0079**] c. means for causing the first component to transfer into the vessel; and

[**0080**] d. a transfer assembly for providing a flow path between the sealed container and the vessel,

[**0081**] wherein, in operation, when the sealed container comprises the first component, the means for causing the first component to transfer into the vessel causes the first component to transfer into the vessel by way of the flow path.

[**0082**] In another embodiment, the invention is directed to a method for combining a first component and a second component comprising:

[**0083**] (a) connecting a sealed container containing the first component to a vessel comprising an access portal, the connection being made by way of a transfer assembly for providing a flow path between the sealed container and the vessel; and

[**0084**] (b) activating a means for causing the first component to transfer into the vessel to cause the first component to transfer into the vessel by way of the flow path.

[**0085**] Although the present invention has been described in considerable detail with reference to certain preferred embodiments and versions, other versions and embodiments are possible. Therefore, the scope of the appended claims should not be limited to the description of the versions and embodiments expressly disclosed herein.

What is claimed is:

1. A kit for combining a first component and a second component comprising:

a. a sealed container for containing the first component;

b. a vessel comprising an access portal, for containing the second component;

c. means for causing the first component to transfer into the vessel; and

d. a transfer assembly for providing a flow path between the sealed container and the vessel,

wherein, in operation, when the sealed container comprises the first component, the means for causing the first component to transfer into the vessel causes the first component to transfer into the vessel by way of the flow path.

2. The kit of claim 1, wherein the vessel comprises a vacuum portal as the means for causing the first component to transfer into the vessel.

3. The kit of claim 1, wherein the sealed container comprises a pressurized gas as the means for causing the first component to transfer into the vessel.

4. The kit of claim 1, wherein the sealed container is flexible to provide the means for causing the first component to transfer into the vessel.

5. The kit of claim 1, wherein the flow path comprises a transfer conduit.

6. The kit of claim 1, wherein the sealed container comprises a first sealing membrane and wherein the flow path is between the first sealing membrane and the access portal.

7. The kit of claim 1, wherein the access portal comprises a second sealing membrane.

8. The kit of claim 6, wherein the sealed container comprises a cap and the cap comprises the first sealing membrane.

9. The kit of claim 1, wherein the sealed container actually contains the first component and the first component comprises a liquid.

10. The kit of claim 9, wherein the liquid is a monomer.

11. The kit of claim 1, wherein the vessel actually contains the second component and the second component comprises a solid.

12. The kit of claim 11, wherein the solid is bone cement powder.

13. The kit of claim 1, wherein the sealed container actually comprises a liquid monomer as the first component and the vessel actually comprises bone cement powder as the second component for combining with the monomer to form bone cement.

14. The kit of claim 2, wherein the transfer assembly comprises a housing which housing comprises:

(a) a first mounting collar constructed for mating engagement with the sealed container for receiving and securely holding the sealed container; and

(b) a second mounting collar constructed for mounting engagement with the access portal of the vessel,

wherein the transfer conduit is mounted in the housing and extends between the first collar and the second collar for providing the flow path therebetween.

15. The kit of claim 14, wherein the housing further comprises a support plate between the first mounting collar and the second mounting collar and the transfer conduit is mounted to the support plate.

16. The kit of claim 2, wherein the transfer conduit comprises two opposed terminating ends, each comprising a sharp, piercing edge.

17. The kit of claim 14, wherein the transfer assembly further comprises a gas-flow aperture formed in the housing for providing gas flow into the sealed container to lessen or avoid vacuum formation in the container during operation.

18. The kit of claim 14, wherein the first mounting collar comprises a plurality of tabs on an inside wall, wherein the tabs radially extend inwardly from the wall and positioned for mating, locking engagement of the sealed container.

19. The kit of claim 18, wherein the housing further comprises a cover for engaging the radially extending tabs and for covering the first mounting collar.

20. A method for combining a first component and a second component comprising:

(a) connecting a sealed container containing the first component to a vessel comprising an access portal, the connection being made by way of a transfer assembly for providing a flow path between the sealed container and the vessel; and

(b) activating a means for causing the first component to transfer into the vessel to cause the first component to transfer into the vessel by way of the flow path.

21. The method of claim 20, wherein the vessel comprises a vacuum portal as the means for causing the first component to transfer into the vessel.

22. The method of claim 20, wherein the sealed container comprises a pressurized gas as the means for causing the first component to transfer into the vessel.

23. The method of claim 20, wherein the sealed container is flexible to provide the means for causing the first component to transfer into the vessel.

24. The method of claim 20, wherein the flow path comprises a transfer conduit.

25. The method of claim 20, wherein the sealed container comprises a first sealing membrane and wherein the flow path is between the first sealing membrane and the access portal.

26. The method of claim 20, wherein the access portal comprises a second sealing membrane.

27. The method of claim 26, wherein the sealed container comprises a cap and the cap comprises the first sealing membrane.

28. The method of claim 20, wherein the first component comprises a liquid.

29. The method of claim 28, wherein the liquid is a monomer.

30. The method of claim 29, wherein the vessel actually contains the second component and the second component comprises a solid.

31. The method of claim 30, wherein the solid is bone cement powder for combining with the monomer to form bone cement..

32. The method of claim 24, wherein the transfer assembly comprises a housing which housing comprises:

(a) a first mounting collar constructed for mating engagement with the sealed container for receiving and securely holding the sealed container; and

(b) a second mounting collar constructed for mounting engagement with the access portal of the vessel,

wherein the transfer conduit is mounted in the housing and extends between the first collar and the second collar for providing the flow path therebetween.

33. The method of claim 32, wherein the housing further comprises a support plate between the first mounting collar and the second mounting collar and the transfer conduit is mounted to the support plate.

34. The method of claim 24, wherein the transfer conduit comprises two opposed terminating ends, each comprising a sharp, piercing edge.

35. The method of claim 32, wherein the transfer assembly further comprises a gas-flow aperture formed in the housing for providing gas flow into the sealed container to lessen or avoid vacuum formation in the container during operation.

36. The method of claim 32, wherein the first mounting collar comprises a plurality of tabs on an inside wall, wherein the tabs radially extend inwardly from the wall and positioned for mating, locking engagement of the sealed container.

37. The method of claim 36, wherein the housing further comprises a cover for engaging the radially extending tabs and for covering the first mounting collar.

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