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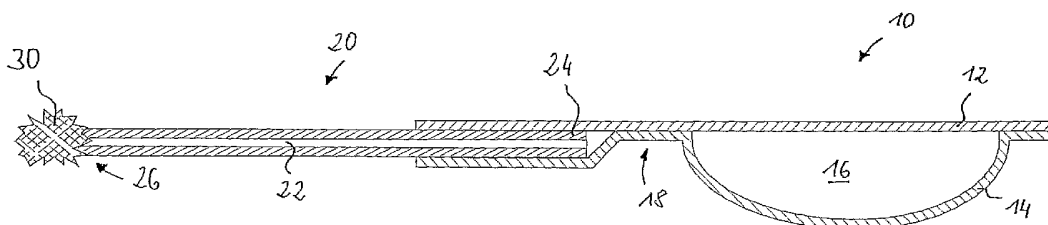
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(54) Title: A SINGLE-USE STORAGE AND APPLICATION DEVICE FOR A DENTAL MATERIAL HAVING FLOWABILITY



(57) Abstract: A single-use storage and application device for a dental material having flowability, said device comprising: (a) a reservoir container having a compressible container wall, said reservoir container being adapted for (a-1) storing said dental material and (a-2) delivering said dental material during use upon compression of said container wall; and (b) a cannula having a passage extending from the proximal end to the distal end of the cannula, said distal end comprising a bibulous material adapted for (b-1) soaking in said dental material delivered during use from said reservoir container via said passage and (b-2) releasing said dental material after being soaked in said bibulous material for applying said dental material to an application site; whereby said device is adapted for (i) preventing a flow of said dental material from said reservoir container through said passage during storage, (ii) providing a fluid-flow communication from said reservoir container through said passage I during use, and (iii) providing a flow resistance for the dental material such that said dental material is prevented from spurting out of said distal end.

**A single-use storage and application device for
a dental material having flowability**

Technical field and background of the invention

The present invention relates to a single-use storage and application device for a dental material having flowability.

In the dental field dental materials having flowability are provided in bottles, sealed storage containers as disclosed in EP 1 153 579 A2, an applicator device as disclosed in WO 03/061508, or cartridges as disclosed in US 6,503,084 B2.

A direct application of dental material to an application site, e.g. a tooth or a restoration, is not possible from bottles or the storage containers disclosed in EP 1 153 579 A2. Hence, an additional application device such as a brush is necessary for applying the dental material to the application site.

By contrast, the applicator device and cartridge disclosed in WO 03/061508 and US 6,503,084 B2, respectively, allow direct application of dental material to an application site. However, the applicator device of WO 03/061508 is a device comprising a valve and a rather complicated control and dispense equipment, whereby a large amount of dental material is stored in a reservoir of the applicator device. The cartridges disclosed in US 6,503,084 B2 are designed for paste-like or honey-like dental materials having high viscosity and only low flowability, such as dental filling materials. Moreover, also a rather complicated application ejector device as disclosed in EP 0 744 161 A1 is necessary for pressing the dental material out of the cartridge to an application site. Further, the use of the applicator device of WO 03/061508 and the cartridges of US 6,503,084 B2 do not allow the application of a thin layer of a dental material having flowability. Further, the known applicator device and system of cartridge and application ejector device do not provide the possibility to disperse a thin layer of applied material evenly on the surface of the application site. Particularly, the known applicator device and system of cartridge and application ejector do not provide the possibility to rub the dental material into the application site. Moreover, the practical use of the known applicator device and the cartridge

has shown that these containers are not leakproof in case that a dental material containing a solvent has to be stored.

Further, a device for storing and dispensing small quantities of liquids, e.g. for single-use, were disclosed in US 6,105 761 for a single-part material and in WO 01/64544 for a multi-part material. In this specification a single-part material means a material consisting of one or more than one component, whereby the material is stored in one compartment. A multi-part material means a material consisting of at least two components stored in at least two compartments. The single-use devices for storing and dispensing small amounts of liquids as disclosed in US 6,105,761 and WO 01/64544 are preferable in view of hygienic aspects when compared to multiple-use storing and application systems. Further, the single-use devices disclosed in US 6,105,761 and WO 01/64544 are leakproof in case that a dental material containing a solvent is stored. Furthermore, WO 01/64544 discloses that the device for storing and dispensing a flowable substance comprises an open ended pocket for dispensing the substance, whereby the pocket may act as an application device in case that the pocket is formed as a cannula. However, the device disclosed by WO 01/64544 is made of two sheets such that the pocket has only low rigidity even when formed as a cannula for direct application of the flowable substance. Thus, the pocket is not stable enough for rubbing the dental material into the application site. Furthermore, WO 01/64544 discloses for repeated application of the flowable substance only the use of an additional application instrument such as a brush. Thus, application of the flowable substance in thin layers requires more steps by immersing the brush into the pocket. Namely, such brush is described only for immersing the brush into the flowable substance provided during use in the pocket. Furthermore, WO 01/64544 teaches to store the application instrument in the pocket during storage and during dispensing the flowable material into the pocket. Thus, WO 01/64544 does not disclose the provision of a storage and application device adapted for providing a flow resistance for the flowable substance such that the flowable substance is prevented from spurting out of the pocket during flow of the flowable material from its reservoir into the pocket. WO 01/64544 is silent to the provision of a suitable flow resistance for the flowable substance during its flow from the reservoir into the pocket. By contrast, it would be advantageously for the device of WO 01/64544 if the flow resistance for the flowable material would be decreased during its flow from the reservoir into the pocket, in order to sufficiently wet the brush stored in the pocket. However, in case that the open ended pocket formed as a cannula of the device disclosed in WO 01/64544 is employed without the

provision of a flow-resistance for the dental material, there arises the severe problem that the flowable substance will spurt out of the distal end of the pocket formed as a cannula. Thus, in the dental field direct application of the flowable substance may lead to unwanted spill of the flowable substance into the throat of a patient or onto sensitive tissue surrounding the application site.

Further application devices are known from US-A 2003/0198918, US-A 2003/0146117 and US-A 6,685,013 (published on February 03, 2004). None of the embodiments disclosed in these references contains a joining piece connected to a reservoir container and comprising a seat for the proximal end of a cannula.

Accordingly, it is the object of the present invention to provide a storage and application device which allows reliable storage of a dental material having flowability, even in case that a solvent is contained therein, and simple, fast, hygienic, and safe application of the dental material to an application site.

Summary of the present invention

Accordingly, the present invention provides a single-use storage and application device for a dental material having flowability, said device comprising:

- (a) a reservoir container having a compressible container wall comprising at least one composite foil comprising a polymeric and a metallic layer; and
- (b) a cannula having a passage extending from the proximal end to the distal end of the cannula, said distal end comprising a bibulous material; and
- (c) a joining piece connected to said reservoir container and comprising a seat for the proximal end of said cannula.

The device is adapted for

- (i) preventing a flow of said dental material from said reservoir container through said passage during storage by a foil, a seal or a sliding gate of the joining piece,
- (ii) providing a fluid-flow communication from said reservoir container through said passage during use due to disruption of the foil, breaking of the seal or sliding the sliding gate, and

- (iii) providing a flow resistance for the dental material such that said dental material is prevented from spurting out of said distal end.

The reservoir container of the device is adapted for

- (a-1) storing said dental material and
- (a-2) delivering said dental material during use upon compression of said container wall.

The cannula of the device is adapted for

- (b-1) soaking in or absorbing said dental material delivered during use from said reservoir container via said passage and
- (b-2) releasing said dental material after being soaked in said bibulous material for applying said dental material to an application site.

The present invention also provides a method for manufacturing a single-use storage and application device for a dental material having flowability according to the invention. The method comprises the steps of:

- (i) deep drawing a reservoir container bottom foil for providing at least one pocket on the bottom foil for receiving dental material,
- (ii) providing a joining piece into a joining piece receiving portion of the bottom foil;
- (iii) sealing the bottom foil with a lid foil to provide a bottom and lid foil assembly having the joining piece sandwiched therebetween;
- (iv) punching the bottom and cover foil assembly so as to provide a reservoir container containing the joining piece as a sealing member.

Preferably, the method further comprises the step of filling a pocket on the bottom foil with dental material prior to sealing the bottom foil with the lid foil. The method may further comprise a step of

- (v) attaching a cannula to the joining piece.

Furthermore, the present invention provides the use of a device according to the present invention for storing dental material.

Particularly, the reservoir container of the device according to the present invention may comprise at least one compartment adapted for storing said dental material. More particularly, the dental material may be a multi-part material comprising at least two components. The reservoir container may comprise at least two compartments whereby each compartment may contain at least one part of a multi-part material.

The compressible container wall comprises at least one composite foil comprising a polymeric and a metallic layer. The polymeric material comprises preferably a polyamide, a polyester, a polycyclic olefine such as Topas[®], and/or a polyolefine. The metallic layer comprises preferably aluminum. Preferably, the composite foil has a deep-drawing property suitable for cold forming. More preferably, the composite foil is a laminate comprising as polymeric material a polycyclic olefine.

According to a particular embodiment of the present invention, the reservoir container comprises at least two composite foils interconnected at least partly to each other for forming said reservoir container. The employment of two composite foils for forming the reservoir container facilitates the manufacture of the device of the present invention when compared to a case wherein the device comprises only one composite foil. When two foils are employed one of the foils may be deep drawn for providing a pocket for receiving the dental material, and after filling the dental material into the pocket, the pocket may be closed by connecting the second composite foil to the first composite foil at a portion surrounding the pocket.

Connection of a composite foil, preferably mutual connection of the same composite foil at a connection portion, or mutual connection of two composite foils at a connection portion may be achieved by hot sealing or glueing. On the other hand, an interconnection of one or two composite foils is preferably disconnected or separated at least at a portion of the interconnection at a disconnection zone or break zone in response to compression applied to the compressible reservoir container wall. Such a disconnection zone may be provided by connecting the composite foil(s) by the same means as at the other connection portions, such as hot sealing or glueing. In case of sealing, the predetermined disconnection zone may be obtained by using a different, specifically a lower, temperature than at the other connection portions which shall not be disconnected upon compression of the compressible container wall. According to a further embodiment, a predetermined disconnection zone may be provided by

incorporating particles or chips of a peel-off film or other foreign particles or chips which reduce the adherence between permanent sealing composite foils. According to a further embodiment of the present invention, the predetermined disconnection zone may consist in a common embossing of the composite foils, a bend, a twist or in a common application of several of these measures. Moreover, it is possible to achieve a connection and disconnection, respectively, at a disconnection zone by providing a clamp externally applied to the composite foil(s).

Preferably, the composite foil(s) provide a diffusion barrier with respect to the dental material to be received in a compartment formed of the composite foil(s). Particularly preferred is an embodiment whereby a composite foil having a deep-drawing property is formed of a polycyclic olefine layer, preferably of Topas[®], an aluminum layer, and a polyolefine layer, preferably of polyethylene. A polyethylene terephthalate layer may be provided between the aluminum layer and the polyethylene layer.

The provision of the above described disconnection zone is an optional additional possibility of preventing a flow of the dental material from the reservoir container through the passage of the cannula during storage, and of providing a fluid-flow communication from the reservoir container through the passage during use upon compression of the compressible container wall. Namely, such disconnection zone may be adapted for disconnection or break upon compression of the container wall. A disconnection of the composite foil(s) at a predetermined disconnection zone is preferably designed with respect to spacing and strength of adherence between the composite foil(s) at the connection portion(s).

The device of the present invention comprises a joining piece for preventing a flow of the dental material from the reservoir container through the passage of the cannula during storage, and of providing a fluid-flow communication from the reservoir container through the passage during use may be achieved by providing a joining piece, preferably consisting of a polymer or a metallic material. Such joining piece is preferably connected to said reservoir container and comprises a seat for the proximal end of the cannula. Particularly, the joining piece may comprise a foil blocking the fluid-flow communication from said reservoir container through said passage. Such foil prevents a flow of dental material from the reservoir container through the passage of the cannula during storage as long as the foil is not disrupted. The foil may be provided at a side of the joining piece facing the proximal end of the cannula or at the opposite

side facing away from the proximal end of the cannula and facing the reservoir container. Moreover, the foil may be provided within the joining piece. For providing a fluid-flow communication from the reservoir container through the passage during use, the foil may be disrupted, preferably, by the cannula. The cannula may be provided as a separate part of the single-use storage and application device of the present invention. Upon use, the cannula may be forced into the foil blocking the fluid-flow communication from the reservoir container through the passage for disrupting the foil. Upon disruption of the foil by the cannula, a fluid-flow communication from the reservoir container through the passage is provided. More preferably, the joining piece comprises a seat for the proximal end of the cannula such that the cannula is already provided in the joining piece during storage. According to this embodiment, the proximal end seated in the joining piece may be forced deeper into the joining piece for disrupting the foil upon use. According to a further preferred embodiment of the present invention, the joining piece may comprise a seal which is breakable and which provides the above described fluid-flow communication when broken apart from the joining piece. Moreover, a further preferred embodiment of the joining piece may comprise a sliding gate having an aperture, which sliding gate is slidable for providing the fluid-flow communication. Furthermore, flow of the dental material from the reservoir container through the passage during storage may be provided by employing a cannula which is closed. Preferably, the cannula may be closed by applying pressure or heat to the distal end for closing, preferably melting, the terminal end of the cannula at the distal end. A fluid-flow communication from the reservoir container through the passage during use may be provided by opening the closed cannula, preferably by cutting off the closed terminal end. According to a further embodiment of the present invention, the distal end of the cannula may be closed by a cap. Preferably, the cap is connected to the distal end by means of a positive lock, preferably a snapping connection, a bayonet locking, or a thread.

The single-use storage and application device of the present invention provides a flow resistance for the dental material such that the dental material is prevented from spurting out of the distal end. This may be achieved e.g. by adapting the dimensions of the cannula, particularly the length of the cannula and/or the inner diameter of the cannula, and/or the amount of dental material contained in the single-use storage and application device. Thus, the velocity of dental material flowing through the passage of the cannula may be adjusted. Particularly, the cannula may have a length of 30 to 80 mm, preferably 30 to 60 mm.

Furthermore, the cannula may have an inner diameter of 0.1 to 1 mm, preferably 0.3 to 0.7 mm. Moreover, the cannula may have an outer diameter of 0.5 to 2.5 mm, preferably 0.5 to 1.5 mm. Furthermore, the amount of dental material for single-use is dependent on the purpose of the dental material. Particularly, the dental material may be an adhesive, a sealer, an etching gel, a varnish, a flowable composite, or a staining solution for tissue having caries. And the amount of the dental material in the single-use storage and application device may range between 50 μ l and 1.0 ml, preferably 100 μ l and 750 μ l, more preferably 200 μ l and 500 μ l.

According to a further embodiment of the present invention the flow resistance for the dental material such that the dental material is prevented from spurting out of the distal end may be provided by adjusting the penetrability and capacity of the bibulous material for soaking in the dental material delivered from the cannula. The bibulous material may comprise a sponge, bristles, a fleece, fibrous material, fibers, and/or filaments. Preferably, the bibulous material may be applied to the cannula according to the following process. A cannula, preferably of polymeric material, may be treated with plasma for activating the outer surface of cannula. Then an adhesive may be applied to the activated surface. The activation may improve the adherence of the adhesive to the cannula. After that, air or an inert gas may be blown through the cannula. Then current may be applied to the cannula. Afterwards, fibers, filaments, and/or chips, preferably of a polymeric material, more preferably of a polymer foam, is applied to the cannula. This embodiment is particularly preferred for providing a cannula comprising a bibulous material, since penetrability and capacity of the bibulous material for soaking in the dental material may be adjusted easily. According to a particularly preferred embodiment of the present invention, the capacity of the bibulous material is large enough for completely soaking in the dental material delivered via the cannula. This embodiment improves the handling of the single-use storage and application device during application of the dental material to an application site. According to a further embodiment of the present invention the cannula may comprise a brush as a bibulous material.

According to a further embodiment of the present invention, the flow resistance for the dental material such that said dental material is prevented from spurting out of said distal end may be provided in the single-use storage and application device of the present invention by providing a joining piece. The joining piece is preferably connected to the reservoir container by mechanical means, gluing or by thermal connection processes, such as hot sealing. Preferably,

the joining piece has a passage with a labyrinth or an adjusted, preferably decreased, diameter. Thus, the velocity of dental material flowing through the passage of the cannula may be lowered. A reduction of the velocity of material flowing through the passage is preferred in case that the reservoir container is provided with a predetermined disconnection zone between one or two or more composite foil(s), since upon compression of the compressible container wall and upon disconnection of the predetermined disconnection zone, the dental material tends to have a remarkable high flow. A flow resistance for the dental material may be provided in a further preferred embodiment of the present application, by a single-use storage and application device comprising an inset having openings and being penetrable to the dental material. The inset may comprise a porous material, woven cloth, interlacing, grid or mesh, glass frit, sponge, or multilayered sieves. The provision of an inset is particularly preferred, since the inset may act as a means for mixing the components of a multi-part material. The inset may be provided within the joining piece. Further it may be provided at a side facing the proximal end of the cannula or at the opposite side of the joining piece facing away from the proximal end of the cannula.

Preferably, the cannula comprises a polymer, preferably selected from a polyamide, a polyolefine, a polycarbonate, and a polyester. Alternatively, the cannula comprises a metallic material, preferably selected from alloy steel or an alloy of nickel and titanium. Particularly preferred is an embodiment, whereby the cannula can be bent such that the distal end of the cannula is offset at an angle of up to 90°, preferably about 45°, with regard to the proximal end. A cannula comprising alloy steel and/or an alloy of nickel and titanium is preferred, since such a cannula maintains reliable its bent shape and function upon being bent. Furthermore, a second cannula, preferably for enclosing the first cannula, may be provided, preferably in case that the first cannula is made of a polymeric material, for stabilizing the first cannula. The second cannula may be shorter than the first cannula. In case that the second cannula is shorter than the first cannula, a predefined flexing and/or bending portion of the first cannula is provided. Alternatively, a stiffening or reinforcing element may be provided at the outer surface of the (first) cannula.

According to a particular preferred embodiment of the present invention, the single-use storage and application device comprises the dental material, preferably in an amount sufficient for single-use or application to one patient.

Brief description of the drawings

Fig. 1 is a sectional side view of a single-use storage and application device for a dental material having flowability according to the present invention.

Fig. 2 is a sectional side view of a further embodiment of a single-use storage and application device according to the present invention.

Fig. 3 is a sectional side view of a further embodiment of a single-use storage and application device according to the present invention.

Fig. 4 is a sectional side view of a further embodiment of a single-use storage and application device according to the present invention.

Fig. 5 is a sectional side view of a further embodiment of a single-use storage and application device according to the present invention.

Fig. 6 is a sectional side view of a further embodiment of a single-use storage and application device according to the present invention.

Fig. 7A is a sectional side view of a joining piece comprised in a preferred embodiment of a single-use storage and application device according to the present invention.

Fig. 7B is a front view of the joining piece of Fig. 7A according to the plane indicated by 7B-7B in Fig. 7A.

Fig. 8A is a sectional side view of a further embodiment of a joining piece and a cannula comprised in a preferred embodiment of a single-use storage and application device according to the present invention.

Fig. 8B is a front view of the joining piece of Fig. 8A according to the plane indicated by 8B-8B in Fig. 8A.

Fig. 9A is a sectional side view of a further embodiment of a joining piece and a cannula comprised in a preferred embodiment of a single-use storage and application device according to the present invention.

Fig. 9B is a front view of the joining piece of Fig. 9A according to the plane indicated by 9B-9B in Fig. 9A.

Fig. 10A is a sectional side view of a further embodiment of a joining piece and a cannula comprised in a preferred embodiment of a single-use storage and application device according to the present invention.

Fig. 10B is a front view of the joining piece of Fig. 10A according to the plane indicated by 10B-

10B in Fig. 10A.

Fig. 11A and 11B are front views of a further embodiment of a joining piece comprised in a preferred embodiment of a single-use storage and application device according to the present invention.

Fig. 12A and 12B are sectional side views of a preferred embodiment of a cannula comprised in a preferred embodiment of a single-use storage and application device according to the present invention.

Fig. 13A and 13B are sectional side views of a further embodiment of a cannula comprised in a preferred embodiment of a single-use storage and application device according to the present invention.

Fig. 14 is a sectional side view of a further preferred embodiment of a single-use storage and application device according to the present invention.

Detailed description of the preferred embodiments

The present invention is now described in further detail with reference to the accompanying drawings. Corresponding or equivalent elements of the present invention illustrated in different drawings are designated with the same numerals.

Fig. 1 shows a single-use storage and application device according to the present invention. It is suitable for storing and applying a dental material having flowability. The single-use storage and application device comprises a reservoir container 10 having a compressible container wall. The compressible container wall is formed of two composite foils 12 and 14. These two composite foils 12 and 14 are interconnected at least partially for forming a compartment 16 for storing the dental material. Thus, the reservoir container 10 is adapted for storing the dental material. Interconnection of the two composite foils 12, 14 may be achieved by hot sealing or gluing. Further, the single-use storage and application device comprises a cannula 20 having a passage 22 extending from the proximal end 24 to the distal end 26 of the cannula. The proximal end 24 of the cannula 20 is connected to the two composite foils 12 and 14. The distal end 26 comprises a bibulous material 30 adapted for soaking in the dental material delivered during use from the reservoir container 10 via the passage 22. Further, the bibulous material 30 is adapted for releasing the dental material after being soaked in the bibulous material for applying the dental material to an application site. The single-use storage and application

device is adapted for preventing a flow of dental material enclosed by the compartment 16 of the reservoir container 10 through the passage 22 during storage. This is accomplished in the single-use storage and application device of Fig. 1 in that the two composite foils 12 and 14 are interconnected at a predefined disconnection zone 18 between the proximal end 24 of the cannula and the compartment 16 such that no fluid-flow communication is possible between the proximal end 24 and the compartment 16 during storage. However, upon compression of the compressible container wall the two composite foils 12 and 14 are disconnected at the disconnection zone 18 and provide a fluid-flow communication from said reservoir container 10 through said passage 22 during use. Thus, the compressible container is adapted for delivering the dental material enclosed by the compartment 16 during use upon compression of the container wall. The length of the cannula 20 and/or its inner diameter are adapted for providing such a high flow resistance for the dental material such that the velocity of the dental material flowing from the reservoir container through the passage to the distal end of the cannula is reduced. Hence, the dental material is prevented from spurting out of the distal end during use upon compression of the container wall. In case that the cannula is not long enough and/or in case that the inner diameter is not small enough, the dental material will spurt out of the distal end upon compression of the container wall. Namely, upon compression of the container wall and disconnection of the disconnection zone 18 dental material may tend to flow from the reservoir container 10 through the passage 22 with a remarkable high velocity such that the dental material will spurt out of the distal end 26 in case that the dimensions of the cannula are not adapted accordingly. According to another embodiment of the present invention, the bibulous material 30 has reduced penetrability such that a high flow resistance is provided to the dental material reaching the distal end for reducing the flow of the dental material and for preventing it from spurting out of the distal end 26.

Fig. 2 shows a further embodiment of a single-use storage and application device according to the present invention. This embodiment comprises essentially the same features as the embodiment of Fig. 1. However, the storage and application device of Fig. 2 comprises further a joining element 40. The joining element 40 is connected to the proximal end 24 of the cannula 20 and to the composite foils 12 and 14. The single-use storage and application device has also a disconnection zone 18 for providing a fluid-flow communication between the reservoir container 10 and the passage 22 of the cannula upon compression of the compressible container wall formed of the composite foils 12 and 14. However, the velocity of the dental

material 4 flowing upon disconnection of the disconnection zone through the passage 22 of the cannula is reduced by the joining element 40 having a passage 42 which is adjacent to the proximal end of the cannula 20. Further the passage 42 runs into a portion 44 having a reduced inner diameter sufficient for increasing the flow resistance of the dental material such that optionally in combination with the dimensions of the length of the cannula and the inner diameter of the cannula a flow resistance is provided that is high enough for preventing the dental material from spurting out of the distal end of the cannula upon use.

Fig. 3 shows a further embodiment of a single-use storage and application device according to the present invention. This embodiment comprises essentially the same features as the embodiment of Fig. 2. However, the storage and application device of Fig. 3 comprises further an inset 50 adapted for reducing the velocity of the dental material flowing into the cannula 20. The inset 50 is seated in a recess or bore 52 of the joining element 40. The inset 50 is provided at a side of the joining element facing the reservoir container 10 and facing away from the proximal end 24 of the cannula 20. Alternatively, the inset 50 may be provided within the joining element 40 or at the side facing the proximal end of the cannula and facing away from the reservoir container 10. Further, the joining element 40 comprises the seat 54 adapted for receiving the proximal end 24 of the cannula 20. The seat 54 improves the reliable connection and adherence of the cannula 20 within the joining element 40. Thus, the provision of the joining piece 40 provides a reliable connection and adherence of the cannula to the joining piece and of the joining piece to the reservoir container 10 and thus a reliable connection and adherence of the cannula to the reservoir container. Furthermore, the distal end 26 of the cannula 20 is tapered. The tapering improves the sight of the user when applying dental material to an application site e.g. a tooth cavity.

Fig. 4 shows a further embodiment of a single-use storage and application device according to the present invention. This embodiment comprises essentially the same features as the embodiment of Fig. 3. However, the storage and application device of Fig. 4 comprises further a second compartment 17. The first compartment 16 is formed of the composite foil 14 connected partially to the composite foil 12, as shown in the sectional side view at the portions 18' and 18". The compartment 17 is formed of the composite foil 14 connected partially to the composite foil 12, as shown in the sectional side view at the portions 18''' and 18"". The portions 18', 18", 18''', and 18"" are formed as predetermined disconnection zones adapted for

being disconnected upon compression of the container wall. Further, the composite foil 14 is connected at the portion 18'''' as a predetermined disconnection zone adapted for being disconnected upon compression.

The disconnection zones 18', 18'', 18''', 18'''' and 18''''' may have the same or different strength of adherence. The compartments 16 and 17 may receive at least one component of a multi-part dental material.

Fig. 5 shows a single-use storage and application device according to the present invention, suitable for a dental material having flowability. It comprises the reservoir container 10 having a compressible container wall formed of the two composite foils 12 and 14. The foils 12 and 14 are connected mutually at the portion 15. The foils are connected at the portion 15 such that the connection is not disconnected upon compression of the container wall. Further, the foils 12 and 14 are connected to the joining piece 40. The foils 12 and 14 form the compartment 16 for receiving a dental material having flowability. Further, the joining piece 40 comprises the seat 54 for receiving the proximal end 24 of the cannula 20. The proximal end 24 of the cannula is firmly connected to the seat 54 and thus to the joining element 40. Further, the joining element 40 comprises the seal 60, preferably of a polymer material. The seal 60 blocks the flow of dental material received in the compartment 16 from the reservoir container 10 through the passage 22 of the cannula 20. However, the seal 60 is breakable and provides a fluid-flow communication when broken apart from the joining piece 40 between the reservoir container 10, notably the compartment 16, and the passage 22 of the cannula 20. Furthermore, the joining piece 40 has a passage having a reduced diameter 44 for providing a flow resistance to dental material in order to prevent the same from spurting out of the distal end 26 of the cannula 20 upon use.

Fig. 6 shows a further embodiment of a single-use storage and application device according to the present invention. This embodiment comprises essentially the same features as the embodiment of Fig. 5. However, the storage and application device of Fig. 6 comprises only one composite foil 12 forming a compartment in which the dental material 4 is received.

Fig. 7A and 7B show a joining element 40 of the single-use storage and application device as shown in Fig. 6 in further detail. The joining element 40 comprises the seal 60 and the passage 42 adapted as seat for receiving the proximal end of a cannula (not shown). The passage 42

runs into a portion 44 having a reduced diameter which provides a flow resistance for dental material such that the dental material is prevented from spurting out of the distal end of a cannula inserted into the joining element 40 upon use of the single-use storage and application device. Fig. 7B shows the side of the joining element 40 facing a reservoir container (not shown), as indicated by the line 7B-7B in Fig. 7A.

Fig. 8A and 8B show a joining element 40 of a further embodiment of a single-use storage and application device of the present invention. The joining element 40 comprises the passage 42 forming a seat for the proximal end of the cannula 20. The cannula 20 is provided as a separate part of the single-use storage and application device. The joining piece 40 comprises the foil 70 provided at the left side of the joining piece and facing the proximal end 24 of the cannula 20. It blocks a flow of dental material received in a reservoir container (not shown) connected to the opposite (right) side of the joining piece 40. Fig. 8B is a front view of the (right) side of the joining element 40, which side faces the reservoir container (not shown) as indicated by the line 8B-8B in Fig. 8A. The proximal end of the cannula 20 is chamfered for facilitating disruption of the foil 70 when the proximal end 24 of the cannula 20 is forced through the foil 70 into the passage or seat 42 of the joining piece for providing a fluid-flow communication from the reservoir container through the passage 22 of the cannula 20 during use.

Fig. 9A and 9B show a further embodiment of a joining piece of a single-use storage and application device according to the present invention. This embodiment comprises essentially the same features as the embodiment of Fig. 8A and 8B. However, the cannula 20 having the passage 22 is not provided as a separate part. By contrast, it is received in the joining element 40, particularly in the passage 42 adapted as a seat for the proximal end 24 of the cannula 20. This embodiment has the advantage that the cannula is connected to the joining piece 40. There may be provided means which allow further insertion of the cannula 20 into the passage or seat 42, but prevent the cannula from becoming loose and lost or disconnected from the joining piece 40. Preferably, the contact surfaces of the cannula 20 and joining piece 40 are designed for forming a snug fit. Further, the foil 70 is provided at the side of the joining piece 40 facing a reservoir container (not shown) connected to the joining piece 40. Fig. 9B is a view of the plane as indicated by the line 9B-9B in Fig. 9A.

Fig. 10A and 10B show a further embodiment of a joining piece of a single-use storage and

application device according to the present invention. This embodiment comprises essentially the same features as the embodiment of Fig. 9A and 9B. The cannula 20 is not provided as a separate part. It is received in the joining element 40, particularly in the passage 42 adapted as a seat for the proximal end 24 of the cannula 20. This embodiment has the advantage that the cannula is connected to the joining piece 40. There may be provided means (not shown) which allow further insertion of the cannula 20 into the passage 42 but prevent the cannula from becoming loose and lost or disconnected from the joining piece 40. Further, the passage 42 in the joining element 40 has a shape which is formed complementary to the chamfered proximal end of the cannula. This embodiment has the advantage that the user cannot insert the cannula through the joining element into the reservoir container. Thus, unwanted disruption of the compressible container wall of the reservoir tank is avoided. Further, reliable and safe use of the single-use storage and application device of the present invention is further improved. Further, the foil 70 is provided within the joining piece 40. Fig. 10B is a view of the plane as indicated by the line 10B-10B in Fig. 10A. The outer shape of the joining piece 40 differs from the outer shape of the joining elements shown in Fig. 7B to 9B. Generally, the joining element of the single-use storage and application device of the present invention may have any outer shape as long as a firm and reliable connection to the reservoir container and to the cannula is possible.

Fig. 11A and 11B show a further embodiment of a joining piece of a single-use storage and application device according to the present invention. The joining piece 40 comprises the sliding gate 80 having an aperture 82. The sliding gate is slidable as indicated by the arrow 84 and provides a fluid-flow communication from a reservoir container connected to the joining element 40 to the passage in a cannula through the passage 42 in the joining element 40. The passage 42 may function as a seat for the proximal end of the cannula. Fig. 11A shows the joining element 40 whereby the passage 42 and thus the passage of a cannula is blocked by the sliding gate 80. Fig. 11B shows the joining element 40 whereby the aperture 82 of the sliding gate is slid downwards as indicated by arrow 84 in Fig. 11A into the seat or passage 42. Thus, a fluid-flow communication from a reservoir container connected to the joining element is provided to the passage of a cannula inserted into the seat or passage 42 of the joining piece 40.

Fig. 12A and 12B show the distal end 26 of a preferred cannula of a single-use storage and

application device according to the present invention. Fig. 12A shows a cannula 20 which is closed at the distal end 26. It is closed after having applied heat to the distal end, such that the terminal end 27 of the cannula is melted. A fluid-flow communication from a reservoir container through the passage 22 of the cannula during use may be provided by cutting off the closed terminal end 27. Fig. 12B shows the cannula 20 of Fig. 12A whereby the terminal end is cut off.

Fig. 13A and 13B show a further embodiment of a preferred cannula of a single-use storage and application device according to the present invention. The distal end 26 of the cannula 20 is adapted for receiving the cap 90. Namely, the distal end 26 comprises an annular ring 29 provided for insertion into an annular groove 92 provided in the cap 92. The ring 29 and groove 92 are adapted to form a snapping connection. Alternatively, the cap 90 may be connected to the distal end 26 of the cannula 20 by means of a bayonet locking or a thread. Fig. 13B shows the cannula of Fig. 13A which is inserted into the cap 90. The embodiment illustrated in Fig. 13A and 13B has the advantage that the bibulous material 30 is protected during storage. According to a preferred embodiment of the present invention the whole single-use storage and application device of the present invention is packed within a packaging during storage.

Fig. 14 shows a further preferred embodiment of a single-use storage and application device according to the present invention. The device is suitable for storing and applying a two component dental material having flowability when both components are mixed. The single-use storage and application device comprises a reservoir container having a compressible container wall. The compressible container walls are formed by two composite foils 12 and 14. Preferably, composite foil 12 imparts stability to the device by having a suitable stiffness. Composite foil 14 is designed to form two adjacent compartments 16, 17 for storing dental components, whereby the compartments are sealed by composite foil 14. Composite foils 12 and 14 are connected in a sealing manner for forming compartments 16 and 17 for storing the dental material. Interconnection of the composite foils 12, 14 may be achieved by hot sealing or gluing. Further, the single-use storage and application device comprises a cannula 20 having a passage 22 extending from the proximal end 24 to the distal end 26 of the cannula. The proximal end 24 of the cannula 20 is connected to the composite foils 12 and 14. Preferably, a connector 40 is used. The distal end 26 comprises a bibulous material 30 adapted for soaking in the dental material delivered during use from the reservoir container 10 via the passage 22. Further, the bibulous material 30 is adapted for releasing the dental material after being soaked

in the bibulous material for applying the dental material to an application site. The single-use storage and application device is adapted for preventing a flow of dental material enclosed by the compartment 16 of the reservoir container 10 through the passage 22 during storage. This is accomplished in the single-use storage and application device of Fig. 14 in that the composite foils 12 and 14 are interconnected at predefined disconnection zones 18' and 18" between the proximal end 24 of the cannula and the compartment 16, and between compartments 16 and 17 such that no fluid-flow communication is possible between the proximal end 24 and the compartment 16, and compartments 16 and 17 during storage. However, upon compression of the compressible container wall the two composite foils 12 and 14 are disconnected at the disconnection zones 18' and 18" and provide a fluid-flow communication from compartment 17 through compartment 16 and through said passage 22 during use. Thus, the compressible container is adapted for delivering the dental material enclosed by the compartments 16 and 17 during use upon compression of the container wall. The length of the cannula 20 and/or its inner diameter are adapted for providing such a high flow resistance for the dental material such that the velocity of the dental material flowing from the reservoir container through the passage to the distal end of the cannula is reduced. Hence, the dental material is prevented from spurting out of the distal end during use upon compression of the container wall. In case that the cannula is not long enough and/or in case that the inner diameter is not small enough, the dental material will spurt out of the distal end upon compression of the container wall. Namely, upon compression of the container wall and disconnection of the disconnection zones 18' and 18" dental material may tend to flow from the reservoir container 10 through the passage 22 with a remarkable high velocity such that the dental material will spurt out of the distal end 26 in case that the dimensions of the cannula are not adapted accordingly. According to a further embodiment of the present invention, the bibulous material 30 may have reduced penetrability such that a high flow resistance is provided to the dental material reaching the distal end for reducing the flow of the dental material and for preventing it from spurting out of the distal end 26. The storage and application device of Fig. 14 further comprises a joining element 40. The joining element 40 is connected to the proximal end 24 of the cannula 20 and to the composite foils 12 and 14.

The single-use storage and application device of the present invention may be used as follows. For providing a fluid-flow communication from the reservoir container 10 through the passage 22 during use, a predetermined disconnection or break zone 18 or several predetermined

disconnection or break zones 18' to 18'''' are opened or disconnected by applying pressure or compression onto the composite foil(s) 12 and/or 14. Such pressure or compression may be simply applied to the composite foil(s) 12 and/or 14 by compressing the composite foil(s) between two fingers, preferably the thumb and the forefinger (Fig. 1 to 4). This embodiment of the present invention has the advantage that the single-use storage and application device of the present invention may be maneuvered e.g. into the oral environment, whereby flow of dental material from a reservoir container through the passage of the application cannula is still prevented. According to another preferred embodiment of the present invention, a fluid-flow communication from the reservoir container 10 through the passage 22 during use may be achieved by breaking a seal 60 apart or away from the joining piece 40 (Fig. 5, 6, 7A, and 7B). Moreover, a fluid-flow communication from the reservoir container 10 through the passage 22 during use may be achieved by sliding the sliding gate 80 having the aperture 82 such that the fluid-flow communication is established (Fig. 11A and 11B). Furthermore, a fluid-flow communication from the reservoir container 10 through the passage 22 during use may be achieved by pressing the cannula 20 provided in a seat of a joining piece 40 deeper into the joining piece such that the proximal end of the cannula disrupts the foil 70 provided in or at the joining piece 40 (Fig. 9A, 9B, 10A, and 10B). These embodiments are particularly preferred since the cannula is connected optionally via the joining piece 40 to the reservoir container 10. Thus, all these embodiments can be operated generally with only one hand of the user. Alternatively, a cannula may be provided as a separate part and may be inserted into a joining piece 40 as illustrated e.g. in Fig. 8A. However, operation of this system requires generally two hands of the user.

After having provided a fluid-flow communication from the reservoir container 10 through the passage 22 of the application cannula 20, dental material enclosed by the reservoir container 10 may be delivered from the reservoir container through the passage 22, optionally through the joining element 40, to the distal end of the cannula. Delivery of the dental material is achieved by compressing the compressible wall of the reservoir container. Such compression may be simply applied to the compressible wall of the reservoir container by compressing the compressible wall between two fingers, preferably the thumb and the forefinger of the user. Thus, the delivery may be controlled very easily. Further, the delivery may be conducted continuously or gradually by simply applying pressure onto the compressible wall. Hence, control of the delivery and application of more than one thin layer of dental material is possible

without spilling. Namely, the single-use storage and application device of the present invention provides a flow resistance for the dental material such that the dental material is prevented from spurting out of said distal end of the cannula. Thus, the danger of spilling dental material onto sensitive tissue surrounding an application site or into the throat of a patient is eliminated. The provision of such flow resistance is achieved

- (1) by adapting the penetrability and capacity of the bibulous material 30 provided at the distal end of the cannula 20, and/or
- (2) by adjusting the amount of the dental material 4 enclosed by the reservoir container 10, and/or
- (3) by accommodating the dimensions of the cannula 20, preferably its length and inner diameter, and/or
- (4) by providing a joining element 40 comprising a passage having a labyrinth and/or a reduced diameter 44, and/or
- (5) by providing a joining element 40 comprising the inset 50.

By applying one or a combination of these measures (1) to (5), safe application of the dental material to an application site is achieved.

Furthermore, after having simply applied the dental material to the application site, e.g. in more than one thin layer, the dental material may be rubbed into the tissue of the application site by the bibulous material 30. For this treatment no additional application instrument is necessary.

Furthermore, there is no problem in view of hygienic aspects when compared to multiple-use dispensing systems, since the storage and application device of the present invention is adapted for single use

Claims

1. A single-use storage and application device for a dental material having flowability, said device comprising:
 - (a) a reservoir container having a compressible container wall comprising at least one composite foil comprising a polymeric and a metallic layer, said reservoir container being adapted for
 - (a-1) storing said dental material and
 - (a-2) delivering said dental material during use upon compression of said container wall; and
 - (b) a cannula having a passage extending from the proximal end to the distal end of the cannula, said distal end comprising a bibulous material adapted for
 - (b-1) soaking in said dental material delivered during use from said reservoir container via said passage and
 - (b-2) releasing said dental material after being soaked in said bibulous material for applying said dental material to an application site; and
 - (c) a joining piece connected to said reservoir container and comprising a seat for the proximal end of said cannula,whereby said device is adapted for
 - (i) preventing a flow of said dental material from said reservoir container through said passage during storage by a foil, a seal or a sliding gate of the joining piece,
 - (ii) providing a fluid-flow communication from said reservoir container through said passage during use due to disruption of the foil, beaking of the seal or sliding the sliding gate, and
 - (iii) providing a flow resistance for the dental material such that said dental material is prevented from spurting out of said distal end.
2. The device according to claim 1, whereby said reservoir container comprises at least one compartment adapted for storing said dental material.
3. The device according to claim 1 or 2, whereby said dental material is a multi-part material comprising at least two components.

4. The device according to claim 3, whereby said reservoir container comprises at least two compartments whereby each compartment contains at least one part of said multi-part material.
5. The device according to one of claims 1 to 4, which comprises an inset having openings and being penetrable to said dental material.
6. The device according to claim 5, whereby said inset comprises a porous material, woven cloth, interlacing, grid or mesh, glass frit, sponge, or multilayered sieves.
7. The device according to claim 5 or 6, whereby said inset is adapted for mixing the components of a multi-part material.
8. The device according to claim 1 to 7, whereby said composite foil has a deep-drawing property suitable for cold forming.
9. The device according to one of claims 8 or 9, whereby said composite foil is a laminate comprising as polymeric material a polycyclic olefine.
10. The device according to one of claims 8 to 10, whereby said reservoir container comprises at least two composite foils interconnected at least partly to each other for forming said reservoir container.
11. The device according to claim 10, whereby said interconnection can be disconnected at least at a portion of the interconnection in response to compression applied to the compressible reservoir container wall.
12. The device according to one of claims 1 to 11, which comprises a joining piece consisting of a polymer or a metallic material.
13. The device according to one of claims 1 to 12, whereby said joining piece comprises a foil blocking the fluid-flow communication from said reservoir container through said passage.

14. The device according to claim 13, whereby said joining piece is connected to the proximal end of said cannula.
15. The device according to one of claims 12 to 14, whereby said joining piece comprises a seal which is breakable and which provides said fluid-flow communication when broken apart from said joining piece.
16. The device according to one of claims 13 to 15, whereby said joining piece comprises a sliding gate having an aperture which is slidable for providing said fluid-flow communication.
17. The device according to one of claims 1 to 16, whereby said cannula comprises a polymer, preferably selected from a polyamide, a polyolefine, a polycarbonate, and a polyester, and/or a metallic material, preferably selected from alloy steel or an alloy of nickel and titanium.
18. The device according to one of claims 1 to 17, whereby said cannula can be bent such that the distal end of the cannula is offset at an angle of up to 90°, preferably 30 to 70° with regard to the proximal end.
19. The device according to one of claims 1 to 18, whereby said cannula has a length of 30 to 80 mm, preferably 30 to 60 mm.
20. The device according to one of claims 1 to 19, whereby said cannula has an inner diameter of 0.1 to 1 mm, preferably 0.3 to 0.7 mm.
21. The device according to one of claims 1 to 20, whereby said cannula has an outer diameter of 0.5 to 2.5 mm, preferably 0.5 to 1.5 mm.
22. The device according to one of claims 1 to 21, whereby said dental material is an adhesive, a sealer, an etching gel, a varnish, a flowable composite, a staining solution for tissue having caries.

23. The device according to one of claims 1 to 22, which comprises said dental material.
24. A single-use storage and application device for a multi-pack dental material having flowability, said device comprising:
- (a) a reservoir container having a compressible container wall which comprises at least two compartments, said reservoir container being adapted for
 - (a-1) storing said packs of the dental material in the compartments adjacent to each other and separated by a releasable sealing connection, and
 - (a-2) delivering said dental material during use upon compression of said container wall whereby a fluid flow connection is established between the compartments and
 - (b) a cannula having a passage extending from the proximal end to the distal end of the cannula, said distal end comprising a bibulous material adapted for
 - (b-1) soaking in said dental material delivered during use from said reservoir container via said passage and
 - (b-2) releasing said dental material after being soaked in said bibulous material for applying said dental material to an application site;
- whereby said device is adapted for
- (i) preventing a flow of said dental material from said reservoir container through said passage during storage,
 - (ii) providing a fluid-flow communication from said reservoir container through said passage during use,
 - (iii) providing a flow resistance for the dental material such that said dental material is prevented from spurting out of said distal end.
 - (iv) mixing of the content of the different compartments within the device for forming the dental material.
25. The single-use storage and application device for a multi-pack dental material according to claim 24, characterized by two compartments provided in the container adjacent to each other along the extension of the longitudinal axis of the cannula.
26. The single-use storage and application device for a multi-pack dental material according to claim 24 or 25 further characterized by the features as specified in any one of claims

5 to 23.

27. A method for manufacturing a single-use storage and application device for a dental material having flowability according to any one of the preceding claims, which comprises the steps of:
- (i) deep drawing a reservoir container bottom foil for providing at least one pocket on the bottom foil for receiving dental material,
 - (ii) providing a joining piece into a joining piece receiving portion of the bottom foil;
 - (iii) sealing the bottom foil with a lid foil to provide a bottom and lid foil assembly having the joining piece sandwiched therebetween;
 - (iv) punching the bottom and cover foil assembly so as to provide a reservoir container containing the joining piece as a sealing member.
28. The method for manufacturing a single-use storage and application device for a dental material having flowability according to claim 27, wherein the method further comprises the step of filling a pocket on the bottom foil with dental material prior to sealing the bottom foil with the lid foil.
29. The method for manufacturing a single-use storage and application device for a dental material having flowability according to claim 27 or 28, which further comprises
- (v) attaching a cannula to the joining piece.
30. Use of a device for a dental material having flowability according to any one of claims 1 to 26 for storing dental material.

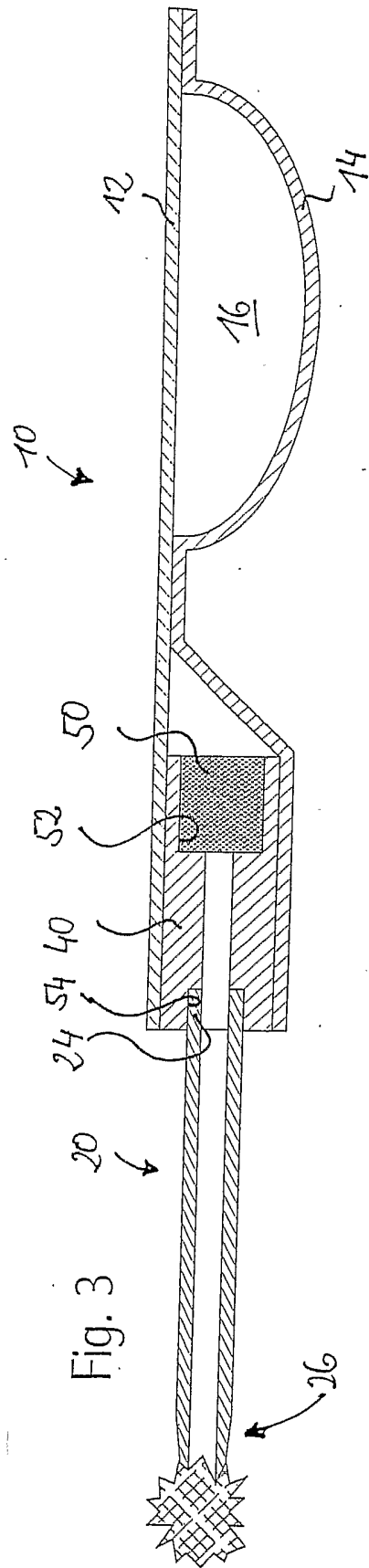
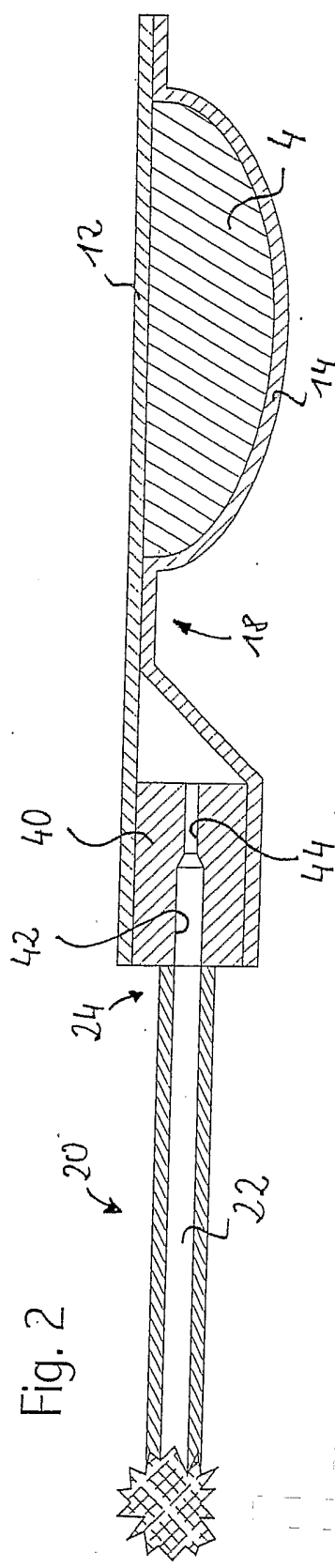
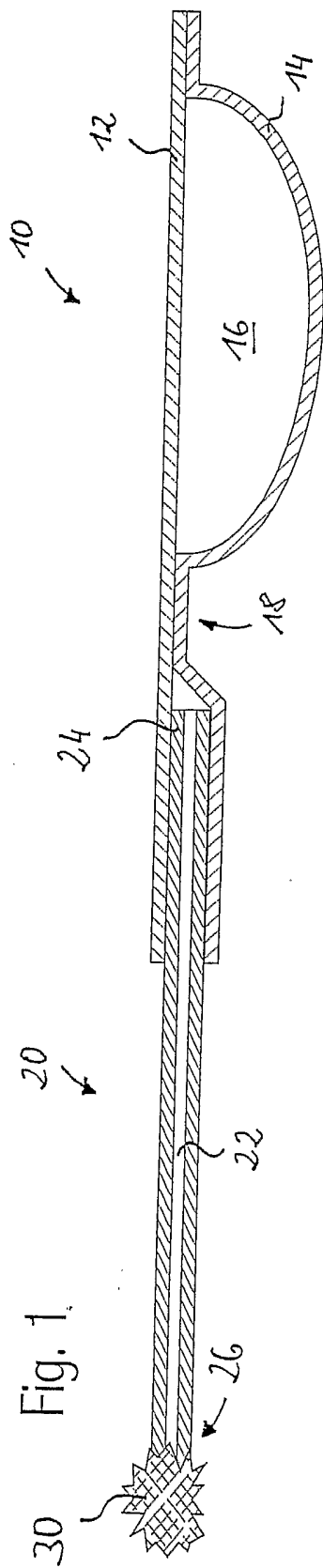


Fig. 4

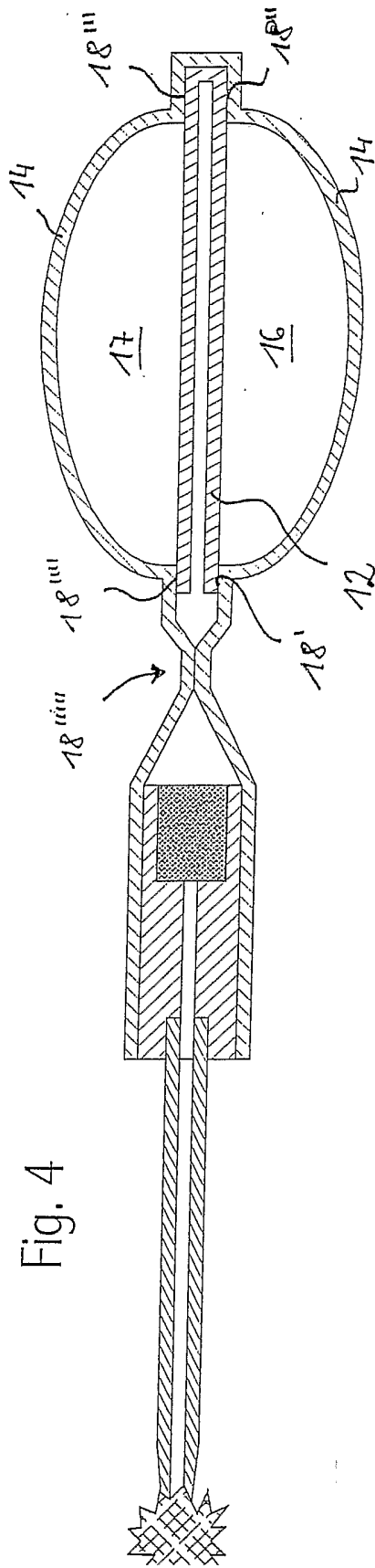


Fig. 5

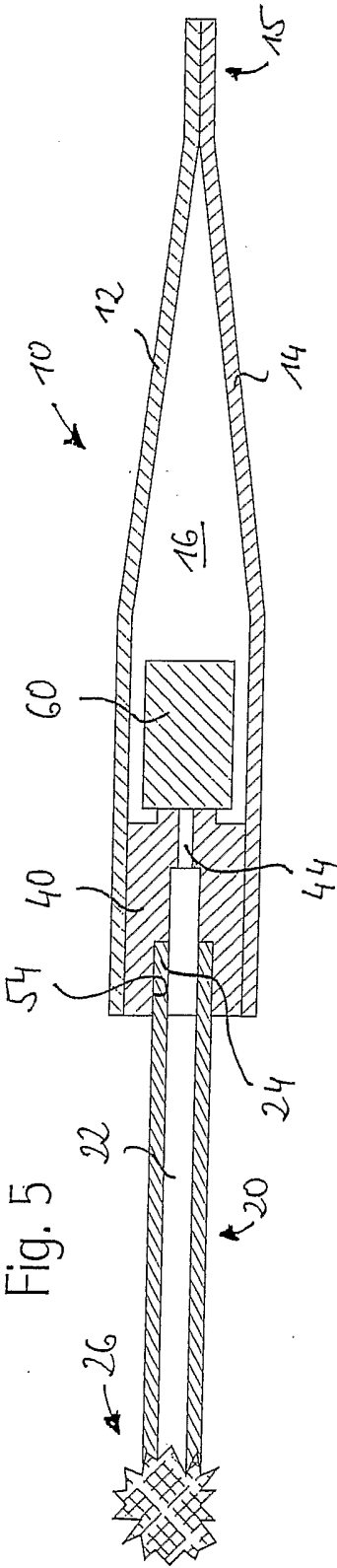
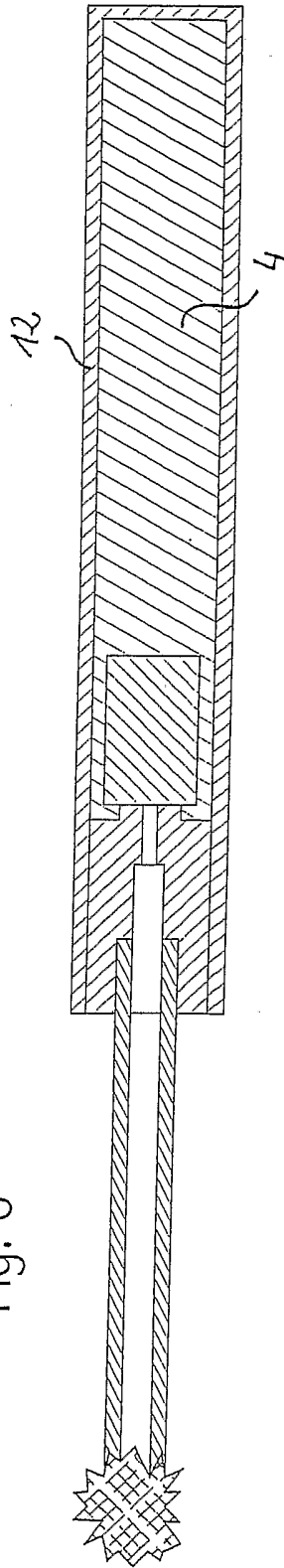
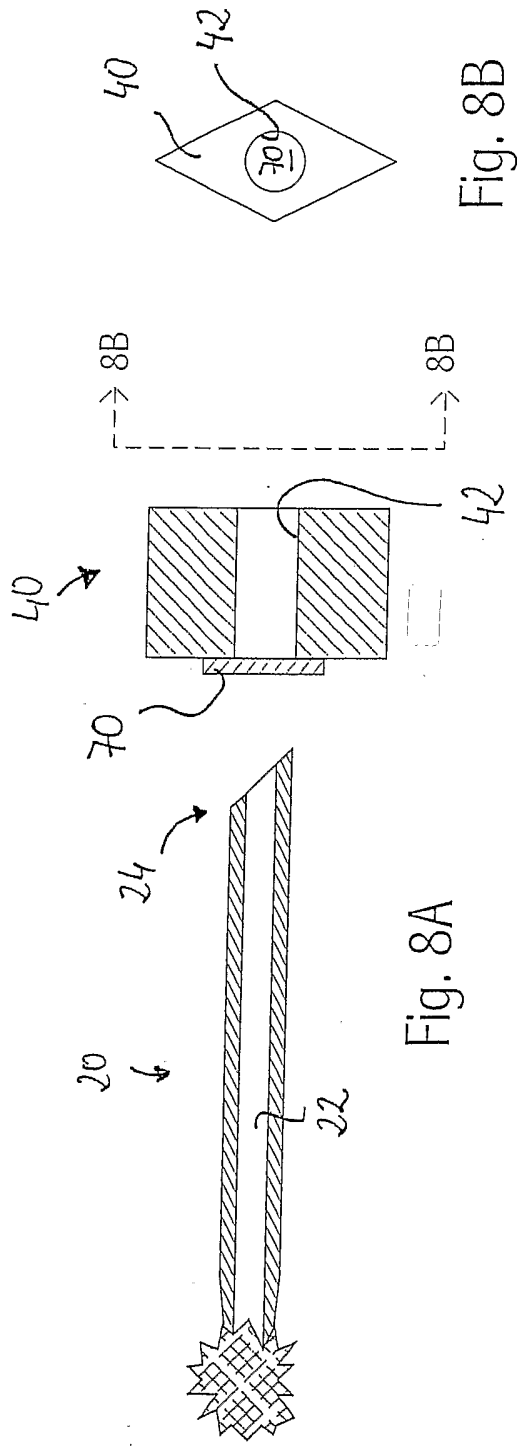
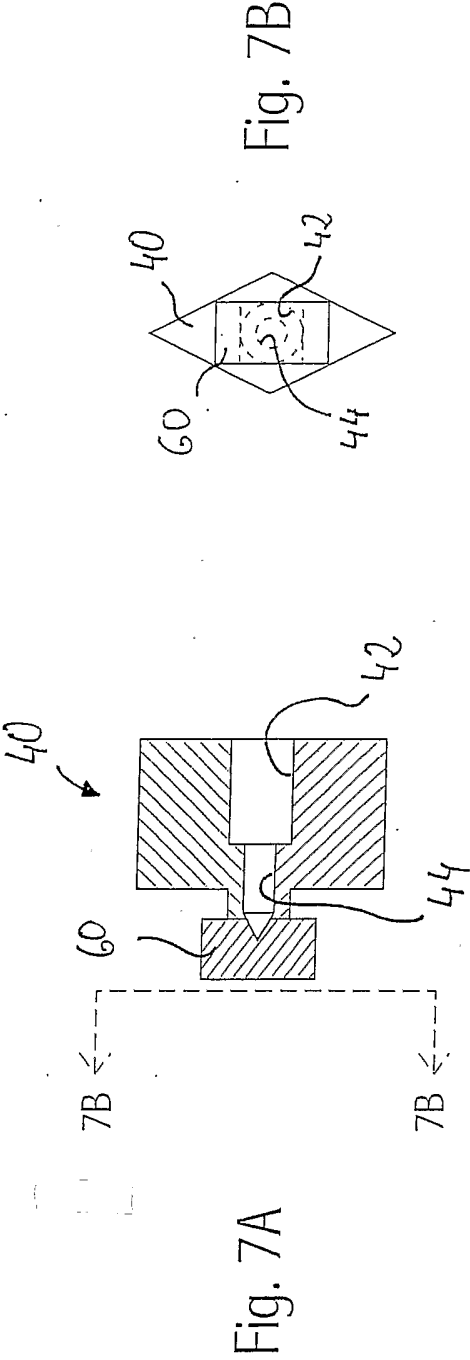


Fig. 6





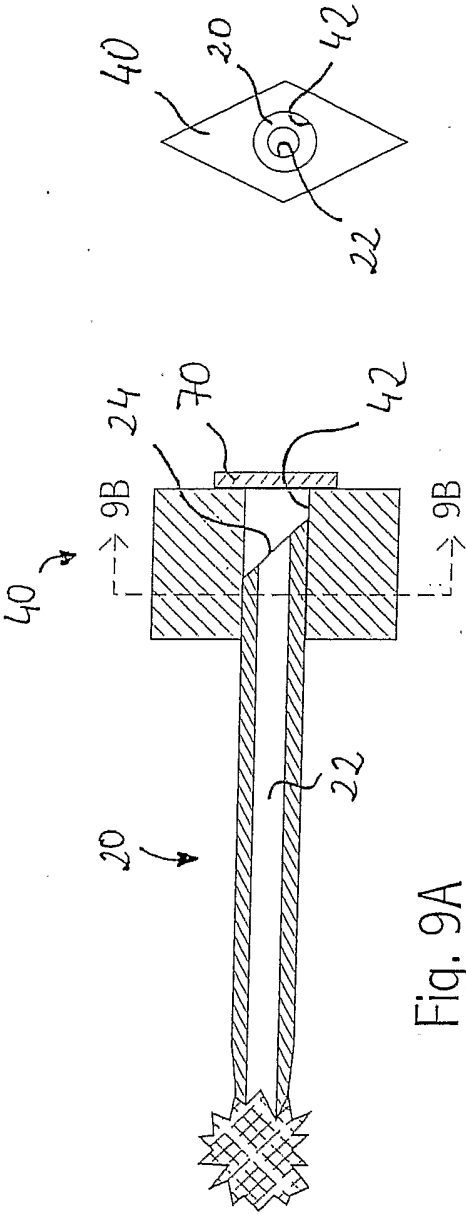


Fig. 9A

Fig. 9B

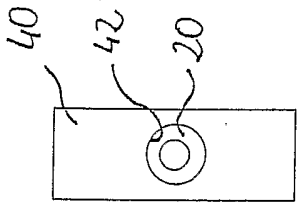


Fig. 10B

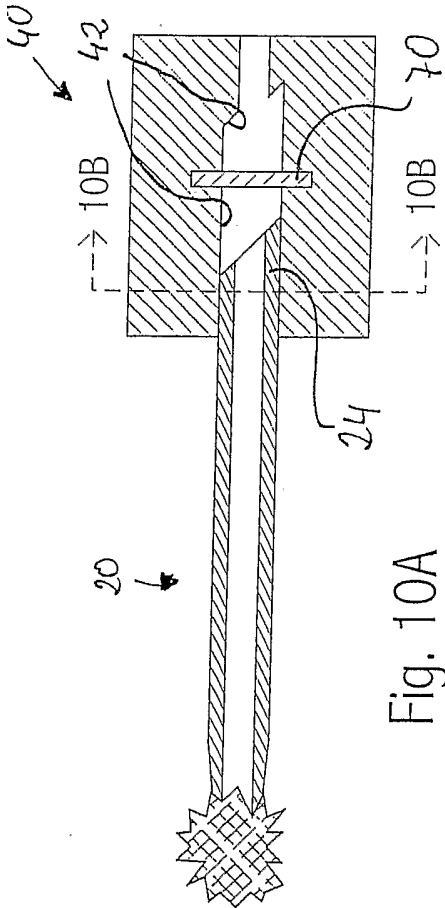
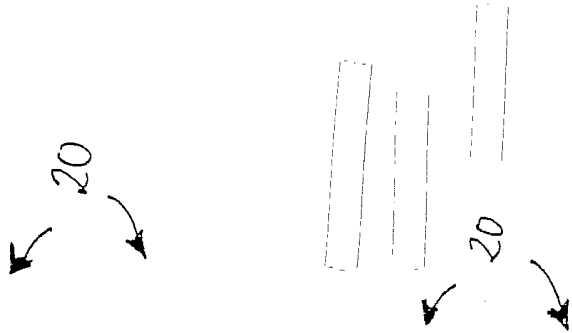
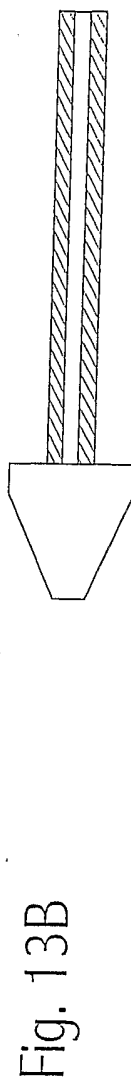
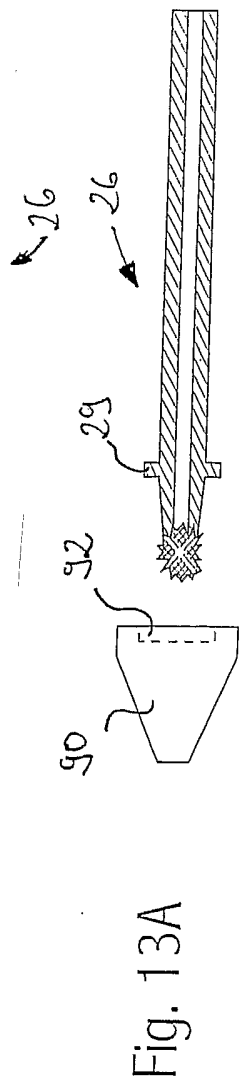
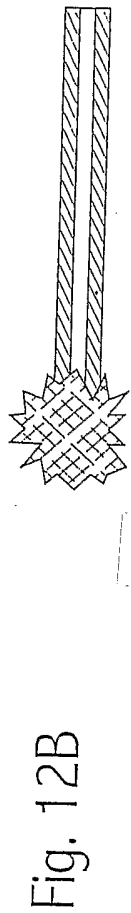
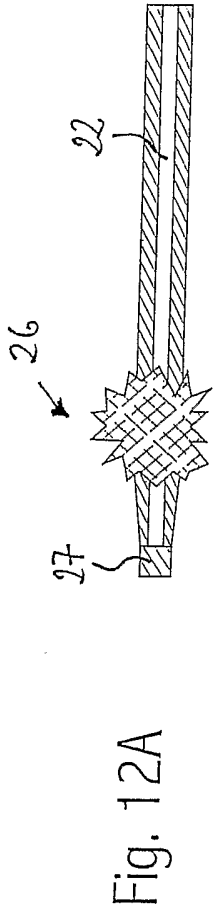
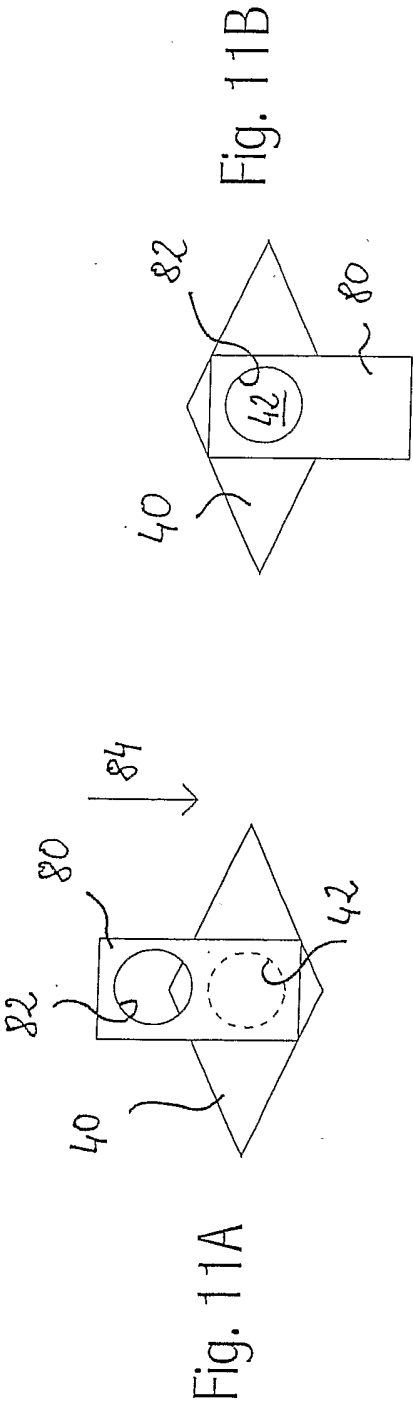


Fig. 10A



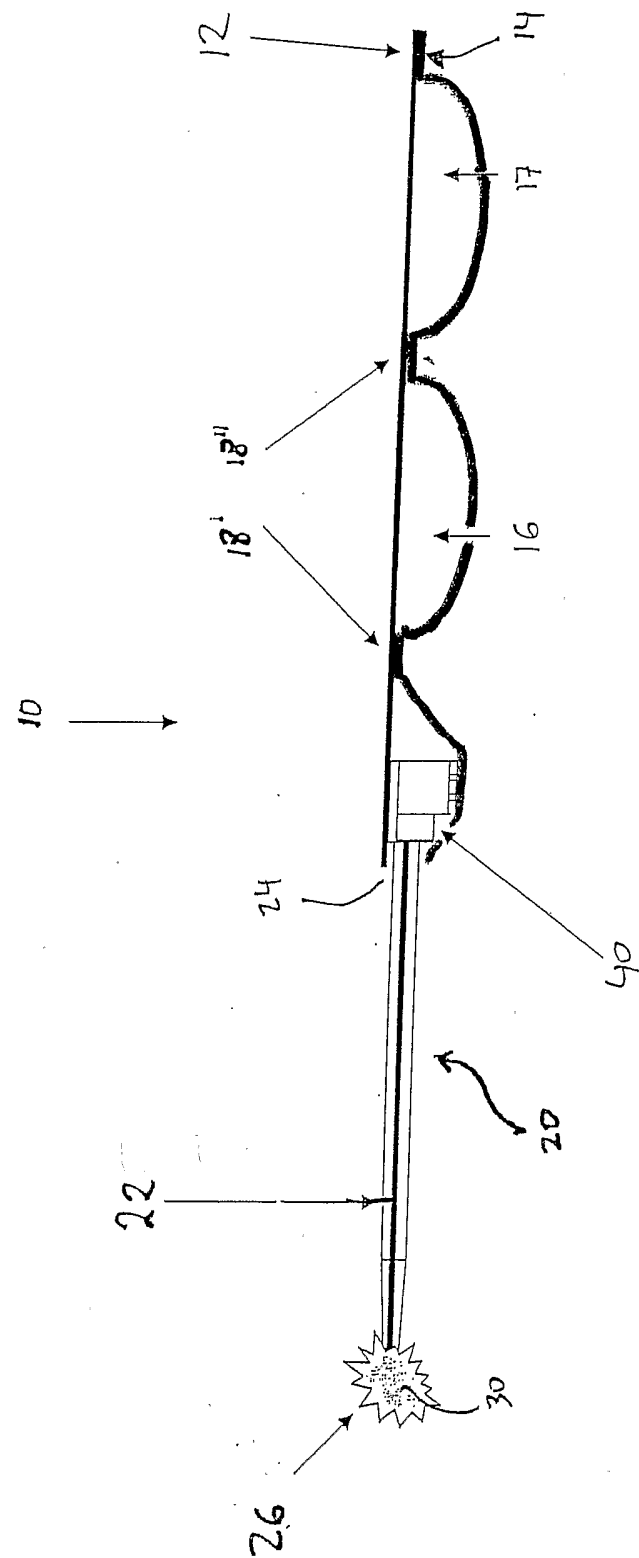


Fig. 14

INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP2004/012673

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61C5/06 A61M35/00 A46B11/00 B65D81/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61C A61M A45D A46B B65D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|--|-----------------------|
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| Y | abstract paragraph '0042!; figure 14 | 24-26 |
| Y | US 2003/146117 A1 (RAIA ET AL.) 7 August 2003 (2003-08-07) the whole document | 24-26 |
| A | US 6 503 084 B2 (EVERS ET AL.) 7 January 2003 (2003-01-07) cited in the application column 5, line 28 - line 37; figure 9 | 1, 24 |



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

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Date of the actual completion of the international search

8 February 2005

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14/02/2005

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP2004/012673

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