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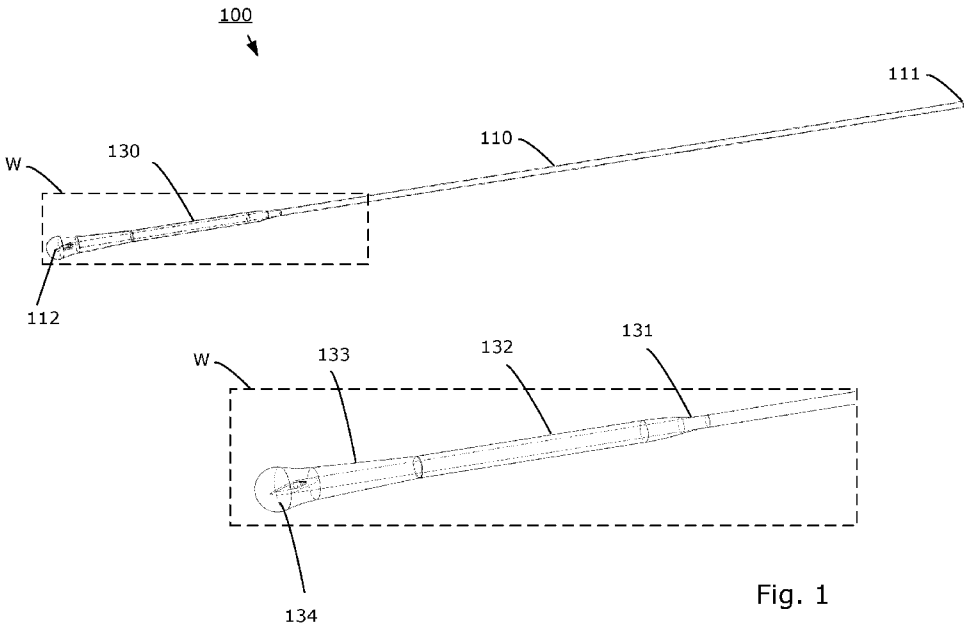

Fig. 1

(57) Abstract: 1. A coated needle cannula (100, 300) comprising an elongate coating (130, 330) of a flexible material providing a sterile barrier. The coating extends along the needle cannula between a first end, at a hollow tubular body, to a second end, at a distal end of the needle cannula. Hereby the coating covers a portion of the needle cannula (110, 310) and the needle tip. The coating (130, 330) directly contacts the needle cannula (110, 310) and provides an initial adhesion between the coating (130, 330) and the cannula (110, 310). The initial adhesion between the cannula and the coating (130, 330) can be irreversibly broken, wherein the coating (130, 330) is longitudinally compressible, and wherein the needle tip can pierce the second end of the coating (130, 330), in response to the application of a longitudinal compression force to the second end of the coating at the second end of the coating.

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COATED NEEDLE CANNULA

The present invention relates to a coated needle cannula, wherein the coating is longitudinally compressible. In another aspect the invention relates to a method of manufacturing said coated needle cannula. In an further aspect, the invention relates to a needle assembly comprising a plurality of said coated needle cannulas.

BACKGROUND OF THE INVENTION

Cannulas for injection of medical drugs needs to be kept sterile prior to use. For that reason, needle units for injection devices and cannulas on syringes has for many years been delivered with the cannula or the entire unit inside a hard casing and wrapped in an airtight wrapping, inside which sterile conditions are maintained.

Unwrapping and removing protective casings from needle units and syringes requires some efforts from the user and introduces several steps in preparing a device for injection. This increases the complexity of the task of administering an injection and to people with reduced eyesight and reduced motorial skills, e.g., elderly people, the unwrapping, fitting and preparation is difficult. The sterile wrapping is also responsible for a significant use of resources and materials that needs to be disposed of after use.

These problems can to some extend be mitigated by the introduction of a needle magazine solution. Such magazines can be mounted on the drug delivery device and comprises a plurality of needles adapted to be brought into fluid connection with a drug reservoir. However, cannulas inside needle magazines also needs to be kept sterile prior to use, which complicates the design and wrapping of a needle magazine. If the entire magazine is wrapped to maintain sterility, the sterile barrier is broken when the magazine is unwrapped and although a first cannula may be used immediately after, the remaining cannulas in the magazine still needs to be kept sterile. Magazines in which each cannula must be unwrapped by the user prior to use is a very impractical solution.

Thus, magazines are usually designed as sealed units, where the cannulas are housed inside a sealed volume. This makes magazine design and production complicated, as cannulas needs to exit the sealed, sterile volume during use without introducing an opening in the sterile barrier of the remaining cannulas. Furthermore, the used cannula usually returns to the magazine storage after use, whereby it is now non-sterile and inside the sealed volume, which necessitates the remaining cannulas not yet used to be sealed from the used cannulas.

WO2017/189162 to Becton, Dickinson and Company discloses a needle magazine or needle unit with a plurality of needles, wherein each of the plurality of needles includes a first sterility barrier at a proximal end of the needle and a second barrier at a sharpened distal end of the needle. The sterility barriers are composed of, for example,, a soft non-coring elastomer such as silicone, isoprene or butyl. By moving the needle in the proximal direction the proximal barrier is pierced, and by moving it in the distal direction the distal barrier is pierced.

Other protective sleeves have been developed for cannulas serving different purposes.

US 2004/0034318 A1 (fig. 9) discloses a device for withdrawal of blood comprising a cannula with a protective material, wherein the material to prevent contamination is fitted to the distal end of the needle. The material is illustrated as a plug sliding down the needle, as the needle pierces the material.

WO2009/031144 to Sindolor Medical discloses a syringe device, a needle, a sterile needle envelope (SNE), and a needle urging means (NUM) causing a relative longitudinal displacement of a distal needle edge against a distal end of the SNE, when operation of the syringe device is initiated by, e.g., a user of syringe device. As a result, of said longitudinal displacement, the distal needle edge may perforate or fracture the distal SNE end. The SNE may be connected to reciprocating needle injecting means. In some embodiments of the invention, the needle may be operatively coupled to a plunger of the syringe device, in a manner such that longitudinal displacement of plunger results in a longitudinal displacement of the distal needle edge towards the distal SNE end. Longitudinal displacement of distal needle edge towards distal SNE end may be accomplished, for example, by telescopically lengthening the needle, by longitudinally displacing the needle towards distal SNE end or by other suitable NUM. The longitudinal displacement causes the engagement of distal needle edge with distal SNE end, whereby distal needle edge and/or distal SNE end may be configured such that said engagement results in a perforation of distal SNE end.

US5290254 (V. L. Vallencourt) discloses a shielded cannula assembly including a housing, a hollow hypodermic needle mounted in and extending from the housing and a tubular shield extending from the housing concentrically about the needle. The tubular shield is exposed to the environment and is formed with a resilient longitudinally collapsible portion and a cap at the distal end of the tubular portion. As indicated, the tubular portion is of constant outside diameter and is disposed concentrically about the hollow nee-

dle and is of relatively thin thickness to permit longitudinal collapsing while being relatively thicker than the outside diameter of the needle to be protective. The cap is relatively rigid relative to the collapsible tubular portion and has an outside diameter greater than the outside diameter of the tubular portion. The cap has a T-shaped cross-section. In addition, the cap defines a transverse wall at the distal end of the shield in order to form a sealed chamber with the tubular portion in order to contain the needle therein in a sterile condition. The transverse wall is made of a thickness and of a material to permit penetration of the sharp end of the needle therethrough in response to longitudinal collapsing of the tubular portion. The transverse wall is also of a nature to reseal in response to withdrawal of the needle therefrom, for example, upon expansion of the tubular portion 15.

US9682197B2 to Itech JV Development Company disclose a similar solution using protective flexible sleeve with a rigid cap, and an optimized distance between the outer diameter (OD) of the cannula and the inner diameter (ID) of the sleeve. While it is possible to reduce the distance between the ID of the silicone sleeve and the OD of the metal of the needle by a small, finite amount, if it is reduced to be much less than 0.00375 inches on each side, the resistance increases, and the amount of force for insertion also increases. With such small differences between the needle's outer diameter and the sleeve's inner diameter, there is also a tendency for the sleeve to roll in on itself, as opposed to collapsing, unless a second piece is secured to the tip to prevent this from happening, as in the dumbbell shaped version. Smaller distances between the sleeve and needle also become problematic because the production tolerances of the sleeve materials ID and the needle OD can vary and can lead to contact, friction, and the need for more force for injection, particularly with the smaller needles and sleeve sizes.

Similar solutions where a sleeve covers the needle are disclosed in GB2321014 (N. J. Middleton), US20140261861 (Becton Dickinson), WO2012022810 (Novo Nordisk), WO2016042162 (Medterial).

Further solutions for providing a sterile sealing for each cannula and not requiring removal of sealing prior to use is needed in needle units with a plurality needles, and would also be desirable in other injection devices to reduce the number of necessary steps of preparing the device for injection.

Therefore, it is an object of the present invention to provide further developments of a hollow needle cannula with a protective covering, wherein the covering is adapted to pro-

vide sterility until the needle cannula is to be used. It is a further object of the invention to provide a needle unit with plurality of needles for a drug delivery device, wherein the needle unit with a plurality of needles comprises a plurality of said hollow needle cannula with a protective covering to provide a more compact and safe device, and which device is safe to use during the application of all the needles within an extended period of time. In particular it is an object to keep the individual needles sterile until the individual needle is applied for an injection. It is further an object of the present invention to provide a method of using and producing said needle cannula with a protective covering. It is further an object of the present invention to provide a method of using a drug delivery device together with the needle unit comprising the plurality of needle cannulas with a protective covering.

DISCLOSURE OF THE INVENTION

In the disclosure of the present invention, embodiments and aspects will be described which will address one or more of the above objects or which will address objects apparent from the below disclosure as well as from the description of exemplary embodiments.

In a first aspect of the present disclosure is provided a coated needle cannula, wherein the coated needle cannula comprises:

- an elongate needle cannula comprising a hollow tubular body extending in a longitudinal direction between a first end and a second end, wherein the second end comprises a sharp needle tip,
- an elongate coating of a flexible material providing a sterile barrier, wherein the coating extends along the needle cannula between a first end, positioned at the hollow tubular body, to a second end, positioned at the second end of the needle cannula, and whereby the coating covers a portion of the needle cannula 110 and the needle tip;

wherein the coating directly contacts the needle cannula and provides an initial adhesion between the coating and the cannula;

wherein the initial adhesion between the cannula and the coating can be irreversibly broken, wherein the coating is longitudinally compressible, and wherein the needle tip can pierce the second end of the coating, in response to the application of a longitudinal compression force to the second end of the coating at the second end of the coating.

Hereby, is provided a coated needle cannula wherein the coating directly contacts the needle cannula. A coating is a covering that is applied to the surface of a substrate. As the coating is customized to the substrate it is applied to, the requirements to production

tolerances are eliminated. That is in contrast to fitting a protective sleeve unto a needle cannula. Furthermore, as the applied coating material solidifies it creates an initial adhesion between the solidified coating and the needle cannula, which can be used to design the threshold for the compression required to remove the coating. Hereby is furthermore provided a hollow needle cannula with a protective covering, wherein the covering is adapted to provide sterility until the needle cannula is to be used.

In a further aspect, the elongate coating can be folded to form a longitudinally compressible structure.

A foldable coating allows a lower compression force to be used in order to remove the coating from the second end of the cannula. Folding and collapsing a foldable structure can be designed to compress in response to a different compression force, e.g. a smaller and more constant force, than the compression force required for compression of an unbendable rigid structure or sliding a rigid structure.

In a further aspect, the longitudinally compressible structure has a tubular bellows like shape, whereby a more constant compression force will be required for the removal of coating.

In a further aspect, the coating comprises an initial uncompressed state wherein the initial adhesion is provided, and a compressed state, wherein the coating is folded and forms a tubular bellows like shape, and wherein the initial adhesion is broken.

In a further aspect, the elongate coating comprises a tubular portion with a constant thickness along the longitudinal direction, whereby the tubular portion can be folded and longitudinally compressed with a constant compression force. Hereby, is provided a coating structure with homogeneous mechanical properties, which can be used to obtain a more constant required compression force, for removing the coating.

In a further aspect, the coating comprises a head portion, wherein the head portion is deformable from a drop like shape with a first longitudinal extension to a collar like shape with a second longitudinal extension, in response to longitudinal compression, wherein the second longitudinal extension is shorter than the first longitudinal extension, and wherein the formable collar is adapted for sliding along the cannula and for transferring a compression force to a portion of the elongate coating next to the head portion.

Hereby, is provided a head structure design, which makes the process of removing the coating more robust to obtain less variation in the quality. Furthermore, the head portion is not foldable, and a different compression force may therefore be required for compressing the head, than for folding the tubular portion.

In a further aspect, the needle cannula comprises a middle portion between the first and the second end, for fixed attachment to a needle hub, wherein the first end of the elongate coating is positioned between the middle portion and the second end of the needle cannula, wherein the elongate coating is adapted to fold and form a tubular bellows like structure in a compressed state, in response to a first compression of the coating, and wherein the tubular bellows like structure is adapted to slide towards the middle section, in response to a further application of a compression force to the second end of the coating. Hereby is provided a needle cannula that can be rigidly attached to a needle hub.

In a further aspect, the second end of the needle cannula is the distal end, and wherein the sharp tip is a distal tip adapted for piercing the skin of a patient. Hereby, is provided a cannula for piercing the skin.

In a further aspect, the first end of the needle cannula is the proximal end, wherein the second end further comprises a proximal sharp tip adapted for piercing a septum, wherein the proximal end comprises a proximal elongate coating of a flexible material providing a sterile barrier, wherein the proximal coating extends along the needle cannula between a first end, at the hollow tubular body, to a second end, at the proximal end of the needle cannula, and whereby the proximal coating covers a portion of the needle cannula (110) and the proximal needle tip;

wherein the proximal coating directly contacts the needle cannula and provides an initial adhesion between the proximal coating and the cannula;

wherein the initial adhesion between the cannula and the proximal coating can be irreversibly broken, wherein the proximal coating is longitudinally compressible, and wherein the proximal needle tip can pierce the second end of the proximal coating, in response to the application of a longitudinal compression force to the second end of the coating at the second end of the coating. Hereby, is provided a needle cannula with a coating on each end.

In a further aspect, the second end is the proximal end, and wherein the sharp tip is adapted for piercing a septum. Hereby is provided a needle cannula coated at the proximal end and adapted for piercing a septum.

In a further aspect, the thickness of the coating increases towards the second end of the coating to form a head, wherein the sharp tip is further protected against unintentional piercing, and whereby the contact surface for the longitudinal force is increased, and whereby the head can be used to compress the coating. Hereby is provided a coated needle cannula wherein the risk of unintentional piercing is reduced.

In a further aspect, the coating comprises an inner layer providing adhesion to the needle cannula and an outer layer providing a sterile barrier. Hereby, is provided an increased design variability in order to obtain a sterile needle tip.

In another aspect is provided a method of manufacturing a coated needle cannula as disclosed above, wherein the method comprises applying the coating material onto the needle cannula, whereby the formed elongate coating adheres directly to the needle cannula.

In a further aspect of the method, the coating is applied by dipping the cannula in a high-viscosity coating material or wherein the coating is applied by spraying the coating material onto the cannula.

In a further aspect the method further comprises curing the applied coating material.

In a further aspect, the method further comprises integrally forming the tubular portion and the head portion on the needle cannula.

In another aspect is provided a coated needle cannula as disclosed above and obtainable by a method as disclosed above.

In another aspect is provided a method of manufacturing a coated needle cannula as described above, wherein the method comprises applying the coating by folding a thin foil of the coating material around the sharp tip and the second end of the needle cannula. The method further comprises welding the foil along the needle cannula, and thereby forming an envelope around the cannula, and heating the formed envelope until the coating material adheres to the cannula.

In another aspect is provided a coated needle cannula as disclosed above and obtainable by a method as disclosed above.

In another aspect is provided a needle assembly with a plurality of needles, wherein the needle assembly comprises a plurality of coated needle cannulas, as disclosed above. As the coating is applied directly to the cannula, a small diameter of the coated needle can be obtained. This effect utilized a compact design, wherein the coated cannulas can be positioned in relatively close proximity.

Hereby is provided a needle assembly with plurality of needles, wherein the needle assembly can be used with a drug delivery device. The needle assembly with the plurality of needles comprises a plurality of said hollow needle cannula with a protective covering to provide a more compact and safe device, and which device is safe to use during the application of all the needles within an extended period of time. The individual needles can be kept sterile until the individual needle is applied for an injection.

In a further aspect, the needle assembly is adapted to uncover the plurality of coated needle cannulas sequentially for a single time use during a period of use, whereby the unused needle cannulas can be preserved in a sterile condition until the single time use.

In a further aspect, the needle assembly is adapted to pierce a septum with two or more of the coated needle cannulas according to any of the previous aspects, and thereby contemporaneously uncovering the two or more coated needle cannulas. Hereby, is utilized a design wherein more cannulas can be uncovered at the same time.

In another aspect is provided a drug delivery device comprising:
-a drug filled cartridge with a septum,
-a drug expelling mechanism for expelling a drug from the cartridge and through an outlet,
-a needle unit comprising a needle hub and a coated needle cannula 300 fixed to the hub, the coated needle cannula comprises a coating covering a proximal tip of the cannula,

wherein the proximal end of the cannula is adapted for piercing the septum and establishing fluid communication with the cartridge, and a distal end is adapted for insertion into the skin of a user,

the drug delivery device further comprises a collapsible portion arranged between the needle hub, and the a cartridge,

wherein the coating directly contacts the needle cannula and provides an initial adhesion between the coating and the cannula,

wherein the initial adhesion between the cannula and the coating can be irreversibly broken, wherein the coating is longitudinally compressible, and wherein the proximal needle tip can pierce the coating, in response to the application of a longitudinal compression force to the coating,

wherein the drug delivery comprises: (i) an initial state, wherein the collapsible portion separates the cannula and the cartridge, and (ii) a collapsed state wherein the collapsible portion has been compressed, wherein the cannula pierces the septum, the coating is compressed, and wherein fluid communication has been established.

Hereby is provided a needle assembly with plurality of needles, wherein the needle assembly can be used with a drug delivery device. The needle assembly with the plurality of needles comprises a plurality of said hollow needle cannula with a protective covering to provide a more compact and safe device, and which device is safe to use during the application of all the needles within an extended period of time. The individual needles can be kept sterile until the individual needle is applied for an injection.

BRIEF DESCRIPTION OF THE DRAWINGS

In the following embodiments of the invention will be described with reference to the drawings:

Figure 1 illustrates a coated needle cannula according to the present disclosure, comprising a hollow tubular needle cannula with a distal end having a sharp tip, and a proximal end.

Figure 2A to 2G, collectively referred to as figure 2, illustrate the different states of the coated needle cannula of figure 1 during operation.

Figure 3A to 3C, collectively referred to as figure 3, illustrate a needle unit with four coated needle cannulas as shown in figure 1.

Figure 4 illustrates a drug delivery device according implementing a coated needle cannula according to the present disclosure.

Figure 5A and 5B illustrate a close up of a portion of the drug delivery device 400 of figure 4.

Figure 6A to 6F illustrates the working principle of the drug delivery device of figure 4.

In the figures like structures are mainly identified by like reference numerals. Reference numbers comprising a first number followed by a "." and a second number is used to denote a functional or structural detail of a structure. In this way the first number indicates a primary (relatively large) structure and the second number indicates a secondary (relatively small) structure or a specific function.

DESCRIPTION OF EXEMPLARY EMBODIMENTS

When in the following terms such as "upper" and "lower", "right" and "left", "horizontal" and "vertical" or similar relative expressions are used, these only refer to the appended figures and not necessarily to an actual situation of use. The shown figures are schematic representations for which reason the configuration of the different structures as well as their relative dimensions are intended to serve illustrative purposes only. When the term member is used for a given component it can be used to define a unitary component or a portion of a component, having one or more functions.

In the following detailed description, numerous specific details are set forth in order to provide a thorough understanding of the present disclosure. However, it will be apparent to one of ordinary skill in the art that the present disclosure may be practiced without these specific details.

It will also be understood that, although the terms first, second, etc. may be used herein to describe various elements or positions, these elements or positions should not be limited by these terms. These terms are only used to distinguish one element or position from another. For example, a first subject could be termed a second subject, and, similarly, a second subject could be termed a first subject, without departing from the scope of the present disclosure. The first subject and the second subject are both subjects, but they are not the same subject. Furthermore, the terms "subject," "user," and "patient" are used interchangeably herein.

As used herein, the term distal and proximal end is in analogy with the terminology from anatomy used to describe the end situated away from or nearest the point of attachment to the body. Therefore, the distal end of an injection device is defined in a context, where a user holds the device in a ready to inject position, whereby the end with the injection needle will be the distal end and the opposite end will be the proximal end. Furthermore, distal and proximal ends of individual components of the device is also defined in that context.

As used herein, a positive axial or longitudinal direction is defined from the proximal end towards the distal end. A positive axial direction and a distal direction are used interchangeably with the same meaning. Similar, the definitions of a negative axial direction and a proximal direction are used interchangeably with the same meaning. A central axis of the device is defined through the centre of the device in the positive axial direction, which is also referred to as a longitudinal axis, with the same meaning.

As used herein, a positive radial direction is defined along a radial axis originating at the central axis and with a direction perpendicular to the central axis.

A positive circumferential or positive angular direction is defined for a point positioned at a radial distance from the central axis, wherein the positive circumferential direction is the counterclockwise direction when observed in the negative axial direction. The circumferential direction is perpendicular to the axial and radial direction.

Both the radial and the circumferential direction are herein referred to as transverse directions, as they are transverse or normal to the axial direction. The transverse plane is herein defined as a plane spanned by two vectors in the radial and circumferential direction, and with the central axis as the normal vector.

The present disclosure describes a solution to the problem of providing individually sealed sterile needle cannulas, wherein it is not required to remove the sealing in an additional manual step prior to injection or first use. In an embodiment of the present disclosure is provided a needle cannula with a flexible coating at the tip, such that when pressure is applied on the coating, the cannula will pierce the coating and the coating will collapse or fold up along the stem of the cannula, as the cannula is inserted.

Figure 1 illustrates a coated needle cannula 100 according to the present disclosure, comprising a hollow tubular needle cannula 110 with a distal end 112 having a sharp tip, and a proximal end 111. As illustrated the distal end 112 and the sharp tip is sealed by a coating 130, coated directly on the needle cannula 110. As seen in the zoom window w, the illustrated coating comprises a tubular body portion 132 with a constant outer diameter, and a head portion 134 with a variable outer diameter. A least a portion of the head portion 134 has an outer diameter larger than the outer diameter of the tubular portion, and a least a portion of the head portion 134 extends from the distal end 112 and to a position distal to the distal end 112 of the cannula 110. The tubular portion extends from

an intermediate position of the cannula 110, which is between the distal 112 and the proximal end 111, and towards the head portion 134. The coating 130 may further comprise a proximal cone portion 131 extending in a proximal direction from the tubular portion 132, starting with an outer diameter equal to the outer diameter of the tubular body portion 132, and decreasing in the proximal direction to form a truncated cone shape (cone wherein the tip has been cut-away). The coating may further comprise an intermediate cone portion 133, extending between the tubular portion 132 and the head portion 134, the intermediate cone portion 133 may form a truncated cone shape, and the outer diameter increases in the distal direction from an outer diameter equal to the tubular portion 132. The thickness of the material layer for the head portion is larger than the thickness of the material layer of the body portion 132. The increased material thickness in the area around the tip of the needle reduces the risk of premature tearing of the coating, and reduces the risk of unintentional piercing during storage.

The coating 130 is attached directly to a portion of the needle cannula 110, whereby the remaining portion of the needle cannula 110 can be attached to a needle hub, as described later and illustrated in figure 3 (needle hub 230). Thereby, the needle cannula 130 can be attached to the needle hub without interfering with the coating 130.

In some embodiments, the coated needle cannula 100 comprises a sharp tip at the proximal end 111 adapted for piercing a septum. The coating is applied to a portion of the cannula that covers the proximal end 111 and the sharp tip. A portion of the cannula is not coated and can be attached, e.g., glued, to a needle hub without interfering with the coating 130.

In some embodiments, the coated needle cannula 100 comprises a sharp tip at both the proximal end 111 and the distal end 112. The coating 130 is applied to a distal portion of the cannula, and thereby covering the distal end 112 and the sharp tip. Furthermore, the coating 130 is applied to a proximal portion of the needle cannula 110, and thereby covering the proximal end 111 and the sharp tip. An intermediate portion of the cannula is not coated and can be attached, e.g., glued, to a needle hub without interfering with the coating 130.

In an alternative embodiment the largest diameter of the head portion equal the outer diameter of the tubular portion. In an alternative embodiment, the coating 130 does not comprise a proximal cone portion 131, and in a further alternative the coating 130 does not comprise an intermediate cone portion 133.

In an alternative embodiment, the coating is silicone based, and in a further alternative the coating comprises an anti-bacterial agent.

In an alternative embodiment, the coating 130 comprises a tubular portion and a head portion, which are integrally formed on the needle cannula 110.

In a method according to the present disclosure, the coating 130 is silicone based and is applied by coating the silicone based coating material onto the needle cannula 110. The coating may be applied by dipping the cannula in a high-viscosity fluid that cures by reaction with air humidity, by UV-light, or by heat. In an alternative method is used a 2 two-component mixture consisting of filler and hardener, which hardens over time after mixing. As the material has been cured or hardened an initial amount of adhesion energy is established between the coating and the cannula, which together with the bending and friction energy determines the compression force required to remove the coating, during compression.

In a further embodiment of the method, the coating comprises an anti-bacterial agent, and the anti-bacterial agent may be added to the coating material to improve the performance of the sterility barrier and reduce sensitivity so small imperfections or damages to the coating sealing off the needle.

The material must be sufficiently adhesive to remain attached to the cannula 110 even if subjected to moderate force. However, is should also adhere sufficiently little to the cannula to allow the material to slip, roll or peel of the cannula, as the cannula is inserted into the skin, without requiring a significant increase of force necessary for the sealed needle to be inserted into the skin.

Figure 2 illustrates the different states of the coated needle 100 during operation. As the sharp needle tip penetrates the coating 130 and enters the skin 150, the skin pushes the coating in the proximal direction, and the coating is compressed and folds along the body of the cannula 110.

Figure 2A illustrates the state of the coated needle 100 prior to insertion, figure 2B illustrates the coating 130 touching the skin 150, and figure 2C illustrates the head portion 132 of the coating 130 in a compressed and deformed state due to a compressional force from the skin 150, the sharp tip of the cannula 110 has pierced the coating 130.

Figure 2D illustrates the coating in a state of further compression, wherein the sharp tip can enter the skin. The sharp tip extends through the coating 130 and into the skin 150, the distal most portion of the tubular portion 132 (or intermediate cone portion 133) of the coating is folded and compressed in the axial direction. Initially the head portion 134 is rounded and formed like a drop. In response to compression, the head portion 132 is deformed and forms a collar. In response to further compression the collar will start to slide along the cannula. The sliding movement of the compressed collar, will compress the distal most portion of the tubular portion 132, and at a certain threshold, the energy required to bend the distal most portion, release the distal most portion from the cannula and slide the head portion 134 along the needle cannula 110 is exceeded by the compression energy delivered by the skin, whereby the distal most portion will be detached, bend and allow further axial compression. When the distal most portion of the tubular portion 132 is fully compressed, due to further compression, the compression force on next potion, which is the portion proximal and next to the distal most portion of the tubular portion 132, will increase. The next portion will then bend and allow the transferring of compression force to the next to the next portion, which is the portion proximal and next to the next portion. The energy required to bend the tubular portion of the coating, is determined by the mechanical properties and the thickness of the coating material, and the energy required to detach the coating from the cannula 110 is determined by the adhesion between the coating material and the cannula 110, and the sliding energy is determined by friction and normal forces. In that aspect, variations between static friction and dynamic friction will create some fluctuation in the applied compression energy. Such a variation is known as stick-slilp friction. In addition, energy required for dynamic friction may increase slightly, as the coating is folding and creates a larger sliding contact area with the cannula.

Figure 2E illustrates the coating in a state of further compression, wherein the cannula 110 extends further from the coating and into the skin 150. On the figure, the head has been deformed into a collar like shape, the distal most portion of the tubular portion 132, the next portion, and the next to the next portion has been folded and compressed, and looks like beads on a line. Due to the homogeneous mechanical properties, physical properties (e.g., adhesion) and constant thickness, along the axis of the tubular portion 132, the folded portions will be of equal size.

Figure 2F, illustrates the coating in a state of further compression, wherein the needle cannula extends from the coating 130 and into the skin at the desired injection depth.

Figure 2G, the coated needle 100 is withdrawn from the skin after the medicament has been delivered, the coating material remains folded up along the cannula 110 after the needle has been withdrawn. As the coating material is folded, some conservative energy will be stored in the coating, however the conservative energy does not exceed the energy required to exceed adhesion and friction between the coating material and the cannula, thereby the coating 130 will stay compressed after compression.

As the initial adhesion between the coating and the cannula, was created during the coating process, this initial condition cannot be recreated even if the coating was pulled back in place after removal by compression. Therefore, as the initial adhesion is broken, the removal of the coating is said to be irreversible. The entire interface between the cannula and the coaring forms an initial portion of adhesion, wherein a portion of the initial contact points can be irreversibly broken, whereby the coating can be longitudinally compressed, and whereby the needle tip can pierce the coating, in response to the application of a longitudinal compression force to the coating at the second end 112.

The sealing may be applied as a coating on the needle by dipping or spraying the material onto the cannula. However, it is very important that sealing material does not enter the lumen of the cannula, since this would introduce a significant risk of leaving a plug in the cannula, when the cannula penetrates the sealing and enters the skin. Such a plug may prevent flow through the cannula and thus prevent the injection from being performed. A plug in the cannula may also be flushed out by the hydraulic pressure of the drug to be injected, whereby the small piece of sealing will be deposited in the user's skin.

The risk of plugging of the cannula is also present, even if flow of sealing material into the lumen of the cannula is prevented, when the needle cuts through and exits the sealing coating. This may be avoided by designing the cannula tip accordingly. It may also be beneficial to ensure a small clearance between the cannula tip and the sealing material inside the seal. Therefore, in some embodiments the coated needle cannula 100 comprises an axial gap between a sharp tip of the cannula 110 and the coating 130.

In an embodiment according to the present disclosure, the coating may also be applied by folding a thin foil in a short distance in front of the cannula tip and weld the foil along the cannula on both sides, such that a small "bag" is made containing the cannula tip. Such a bag would obviously be able to slide easily of the cannula and it is therefore fixed

by heating the foil to almost melting to enable the foil to adhere to the cannula. In some embodiments, at least the layer of the foil in contact with the cannula is melted. The foil may be selected such that is shows similar characteristics as shrinking plastics for cable production, which would allow the "bag" to shrink and adhere to the cannula.

In an alternative, embodiment the coated needle 101 is mounted in a drug delivery device, and hidden behind a shield with a distal plate with an aperture allowing the needle to pass, and at the same time compress and remove the coating. In an alternative embodiment the distal plate is substituted with a septum, with the same functionality.

EP20157959.6 and PCT/EP2021/053752 filed by Novo Nordisk describe an injection device having a plurality of integrated needle assemblies wherein each of the needle cannula assemblies can be brought to an injection position for ejecting one of the fixed doses. The distal end of the plurality of needles are positioned in the same plug until their first use. The application is hereby integrated by reference. The distal end of such a device, holding the plurality of needles, can be considered an integrated needle unit with a plurality of needle cannulas, which can be considered a needle magazine integrated with the injection device. Therefore, in an embodiment of the present disclosure a needle unit with a plurality of needle cannulas may comprise a shield guide, which may be a part of the housing structure, a telescopically movable shield, a plurality of coated needle cannulas and a needle operating mechanism.

EP21162044.8 filed by Novo Nordisk describes an alternative injection device having a plurality of integrated needle assemblies, wherein each needle can be inserted sequentially. Each of the needles cannulas is having a sharp proximal and distal tip, and the tips could advantageously be provided with a coating according to the present application. For such an embodiment, the sterility barrier of the proximal tip is broken, as the proximal tip pierces a septum to establish fluid communication with a reservoir of the drug delivery device. Similarly, the sterility barrier of the distal tip would be broken afterwards, as the distal tip pierces the skin of a subject, a distal septum or an aperture in a distal plate of a shield slightly smaller than the head portion of the coating.

Figure 3A to 3C illustrates a needle unit 200 with four coated needle cannulas according to the present disclosure. The device is shown in three different states during operation. Although not illustrated the needle unit 200 may also comprise a shield and a shield guide. Alternatively, the shield and the shield guide are regarded as parts of the injection device. In some alternatives the needle unit or the injection device may also comprise a

distal plate with apertures or a distal septum allowing the needle to pass and to compress the coating. Thereby only the cannula is allowed to pass the apertures and enter the skin. Alternatively, the distal end of the injection device is open or opened and the coating is adapted to be compressed by the skin.

Figure 3A illustrates the needle unit 200 with a plurality of coated needle cannulas 100 in a first state. The figure illustrates only components necessary for explaining the integration of the coated needle cannulas into the needle unit, and for integrating or connecting the needle unit to an injection device. Figure 3A illustrates a cartridge 210, a tower 220 with a proximal end 221 and a distal end 222. The tower 220 comprises a plurality of channels corresponding to the plurality of coated needle cannulas 100. The coated needle cannulas 100 are positioned in the channels, and the channels are adapted to guide the coated needle cannulas 100 during proximal and distal movements. Each of the needle cannulas 110 are fixed in a needle hub 230, which is slidably arranged in the tower 220. At the proximal end 221, the tower 220 comprises a portion adapted to receive the cartridge. As illustrated. The proximal end 111 of each of the needle cannulas 110, has pierced a septum at the distal end of the cartridge. The needle cannulas 110 have therefore established fluid communication with the drug in the cartridge 210. The distal end 112 and the sharp tip of the needle cannulas 110 is covered by the coating 130. One of the cannulas 110 is illustrated with a transparent coating 130, whereby the distal end 112 and the sharp tip is visible. The coating may be compressed by the skin of the subject or by a not shown plate with apertures.

Figure 3B illustrates the needle assembly 200 in a second state, wherein one of the 4 coated needle cannulas 100 has been moved in a distal direction, by a needle operating mechanism. As also seen, the coating 130 has been compressed, and the distal end 112 of the needle cannula 110 extends from the compressed coating 130.

Figure 3C illustrates the needle assembly 200 in a third state, wherein each of the cannulas 110 are position in a retracted position with a compressed coating 130. Each of the coatings 130 have been compressed by sequentially moving a coated needle cannula 100 distally to the injection position, compressing the coating 130, injecting the drug, and retracting the coating needle cannula 100 to the proximal position. This procedure is repeated until all of the 4 coated needle cannulas have been used.

Figure 4-6 illustrates an alternative embodiment of a drug delivery device 400 comprising a coated needle cannula 300 according to the present disclosure, wherein a coating 330

covers the proximal tip 311 in an initial state, and wherein the distal tip 312 is uncoated. The coated needle cannula 300 comprises a cannula 310 with a coating 330. Figure 4 illustrates the entire device 400 in perspective, wherein an angular portion of the housing is broken away to show internal details. Figure 5A and 5B is a zoom in on the device of figure 4 and illustrates the device 400 in an initial and a collapsed state during operation. Figure 6A to figure 6F show a cross section of more states of the device 400 during operation. As the coated needle cannula 100 the coated needle cannula 300 is designed to peel of and fold up.

The device 400 comprises a syringe housing 410, a piston 412, and a piston rod 414 which can be operated directly by the user. The drug delivery device 400 further comprises a hub 420 comprising a central plate with an aperture for receiving the cannula 310. The hub is positioned proximal to a closed front plate of the syringe housing 410. The front plate also comprises an aperture for receiving the cannula and allowing a distal end of the cannula to extend from the housing 410. The hub 420 further comprises a collapsible skirt portion 421 extending in the proximal direction and extends to a front surface of a cartridge 440. The piston 412 is received in the cartridge at the proximal end, and the distal end is closed by a pierceable septum 430. The cartridge is slidably arranged between a proximal position seen in Fig. 4 and 5A, and a distal position shown in fig. 5B. In fig. 5B the collapsible skirt portion has collapsed due to the compression between the cartridge and the closed front plate of the syringe housing 410.

The illustrated drug delivery device 400 allows a simple production and handling of the drug-filled glass, as the device is designed for using a simple standard prefilled cartridge, which has been produced in large quantities in decades. Compared to syringes with a staked needle, the cartridge and the needle are handled separate, and the needle is therefore not damaged during filling of the glass. This also allows for a sub-assembly of the housing 410 with needle hub 410, cannula 310, collapsible skirt portion 421 and a needle cap, to have a device 400 with a prefilled cartridge and directly operable piston rod fitted.

In an alternative embodiment, the same type of coating is used in both ends of the cannula. The specifications to coating material, properties of the coating material and the required behaviour of a coating folding, is similar when the needle is designed for penetrating the users skin compared to penetrating a rubber septum 430 in a prefilled drug-cartridge 440. The illustrated rubber septum consists of two layers. The inner layer pro-

vides a drug barrier and the outer layer seals against the cap and protects the inner layer.

The working principle of folding the coating on the backneedle during and injection is similar when comparing piercing the skin, as in figure 2, and a septum 430, as for an embodiment wherein the coating 330 is arranged to cover the proximal tip of the cannula 311, as shown in figure 4A.

The drug delivery device 400 can activated in a priming operation by a user. The drug delivery device 400 can be activated by pushing the piston rod, the piston and the cartridge with one finger, while holding the syringe housing 410 with the other fingers. Thereby, the collapsible skirt portion 421 providing a distancer between the central plate of the hub 420 and the cartridge collapses and the cartridge 440 moves forward inside the syringe housing 410, whereby the cannula 310 will penetrate the septum 430. This will prime the device and allow air in the cannula and a small amount of drug to be expelled prior to inserting the cannula in the skin.

Although the device may be primed prior to insertion in the skin, a use sequence shown in fig. 6A to 6F illustrates a use-sequence in which needle is inserted in the skin prior to activation and thereby prior to priming the device 400.

In an alternative embodiment, the neck of cartridge is extended and a second collapsible portion is placed between the needle hub 420 and the front plate at the distal end of the housing 410. Hereby, the coated needle cannula 300 can remain protected inside the housing during storage and handling. If the second collapsible portion is less stiff than the first collapsible portion, the needle will protrude before it is primed, in a priming operation.

Therefore in such an embodiment, the first collapsible portion between the central plate of the hub and the cartridge can be made weaker than second collapsible distancer between the central plate of the hub and the housing. When the plunger actuator is activated, the cartridge, the first collapsible distancer and the needle cannula moves forward, to expose the cannula front end, and stops when second collapsible potion is fully compressed or collapsed.

This would prevent the cannula from moving further forward, due to the hub and the first collapsible portion would start to buckle and collapse, allowing the cartridge to move fur-

ther forward, whereby the coating would be peeled or folded back onto the cannula, as the cannula penetrated the septum and entered the drug-filled volume of the cartridge.

Figure 6A illustrated the drug delivery device 400 in an initial state wherein the collapsible portion 421 separates the cannula 310 and the cartridge 440. The cannula 310 is also not inserted into the skin. Figure 6B illustrates the drug delivery device in the initial state, wherein the cannula is inserted into the skin 150. Figure 6C illustrates a state between the initial state and a collapsed state. The collapsible portion 421 has started to collapse and the cannula 310 is starting to pierce the septum 430. Figure 6D illustrates the drug delivery device in the collapsed state, wherein the cannula has pierced the septum and established fluid communication. The collapsible portion 421 is fully collapsed. The initial adhesion between the coating 330 and the cannula 310 has been broken. The coating is compressed and folded back onto the needle cannula 310. Figure 6E illustrates the drug delivery device in the collapsed state, and wherein a drug is delivered through the cannula 310. Figure 6E illustrates the drug delivery device in the collapsed state, wherein the piston has been moved to a distal position to deliver the entire content of drug. The needle 310 is removed from the skin 150.

FURTHER EMBODIMENTS

1. A coated needle cannula (100, 300), wherein the coated needle cannula (100, 300) comprises:

- an elongate needle cannula (110, 310) comprising a hollow tubular body extending in a longitudinal direction between a first end (111, 312) and a second end (112, 311), wherein the second end comprises a sharp needle tip,
- an elongate coating (130, 330) of a flexible material providing a sterile barrier, wherein the coating extends along the needle cannula between a first end, at the hollow tubular body, to a second end, at the second end of the needle cannula, and whereby the coating covers a portion of the needle cannula (110, 310) and the needle tip;

wherein the coating (130, 330) directly contacts the needle cannula (110, 310) and provides an initial adhesion between the coating (130, 330) and the cannula (110, 310);

wherein the initial adhesion between the cannula (110, 310) and the coating (130, 330) can be irreversibly broken, wherein the coating (130, 330) is longitudinally compressible, and wherein the needle tip can pierce the second end of the coating (130, 330), in response to the application of a longitudinal compression force to the second end of the coating at the second end of the coating.

2. A coated needle cannula (100, 300) according to embodiment 1, wherein the coating (130, 330) can be folded to form a longitudinally compressible structure.

3. A coated needle cannula (100, 300) according to any of the previous embodiments, wherein the coating comprises an initial uncompressed state wherein the initial adhesion is provided, and a compressed state, wherein the coating is folded and forms a tubular bellows like shape, and wherein the initial adhesion is broken.

4. A coated needle cannula (100, 300) according to any of the previous embodiments, wherein the elongate coating (130, 330) comprises a tubular portion (132) with a constant thickness along the longitudinal direction, whereby the tubular portion can be folded and longitudinally compressed with a constant compression force.

5. A coated needle cannula (100, 300) according to any of the previous embodiments, wherein the coating comprises a head portion (134), wherein the head portion is deformable from a drop like shape with a first longitudinal extension to a collar like shape with a second longitudinal extension, in response to longitudinal compression, wherein the second longitudinal extension is shorter than the first longitudinal extension, and wherein the formable collar is adapted for sliding along the cannula and for transferring a compression force to a portion of the elongate coating (130, 330) next to the head portion.

6. A coated needle cannula (100, 300) according to any of the previous embodiments, wherein the needle cannula (110, 310) comprises a middle portion between the first and the second end, for fixed attachment to a needle hub, wherein the first end of the elongate coating is positioned between the middle portion and the second end of the needle cannula (110, 310), wherein the elongate coating (130, 330) is adapted to fold and form a tubular bellows like structure in a compressed state, in response to a first compression of the coating, and wherein the tubular bellows like structure is adapted to slide towards the middle section, in response to a further application of a compression force to the second end of the coating.

7. A coated needle cannula (100) according to any of the previous embodiments, wherein the second end of the needle cannula (110) is the distal end (112), and wherein the sharp tip is a distal tip adapted for piercing the skin of a patient.

8. A coated needle cannula (100) according to any of the previous embodiments, wherein the first end of the needle cannula (110) is the proximal end (111), wherein the second

end further comprises a proximal sharp tip adapted for piercing a septum, wherein the proximal end (111) comprises a proximal elongate coating of a flexible material providing a sterile barrier, wherein the proximal coating extends along the needle cannula between a first end, at the hollow tubular body, to a second end, at the proximal end (111) of the needle cannula (110), and whereby the proximal coating covers a portion of the needle cannula (110) and the proximal needle tip;

wherein the proximal coating directly contacts the needle cannula (110) and provides an initial adhesion between the proximal coating and the cannula (110);

wherein the initial adhesion between the cannula (110) and the proximal coating can be irreversibly broken, wherein the proximal coating is longitudinally compressible, and wherein the proximal needle tip can pierce the second end of the proximal coating, in response to the application of a longitudinal compression force to the second end of the coating at the second end of the coating.

9. A coated needle cannula (300) according to any of the embodiments 1-6, wherein the second end is the proximal end (311), and wherein the sharp tip is adapted for piercing a septum.

10. A coated needle cannula (100, 300) according to any of the previous embodiments, wherein the thickness of the coating (130, 330) increases towards the second end of the coating to form a head, wherein the sharp tip is further protected against unintentional piercing, and whereby the contact surface for the longitudinal force is increased, and whereby the head can be used to compress the coating.

11. A coated needle cannula (100, 300) according to any of the previous embodiments, wherein the coating (130, 330) comprises an inner layer providing adhesion to the needle cannula and an outer layer providing a sterile barrier.

12. A method of manufacturing a coated needle cannula (130, 330) according to any of the previous embodiments, wherein the method comprises applying the coating material onto the needle cannula, whereby the formed elongate coating (130, 330) adheres directly to the needle cannula.

13. A method of manufacturing a coated needle cannula (130, 330) according to embodiment 12, wherein the coating (130, 330) is applied by dipping the cannula (110, 310) in

a high-viscosity coating material or wherein the coating is applied by spraying the coating material onto the cannula (110, 310).

14. A method of manufacturing a coated needle cannula (130, 330) according to any of the embodiments 12-13, wherein the method further comprises curing the applied coating material.

15. A method of manufacturing a coated needle cannula (130, 330) according to any of embodiments 12-14, wherein the method further comprises integrally forming the tubular portion and the head portion on the needle cannula.

16. A coated needle cannula (130, 330) according to any of the embodiments 1-11 obtainable by a method according to any of the embodiments 12-15.

17. A method of manufacturing a coated needle cannula (130, 330) according to any of the embodiments 1-4, 6-9 and 11, wherein the method comprises applying the coating by folding a thin foil of the coating material around the sharp tip and second end of the needle cannula (110, 310), welding the foil along the needle cannula (110, 310) and thereby forming an envelope around the cannula, and heating the formed envelope until the coating material adheres to the cannula.

18. A coated needle cannula (130, 330) according to any of the embodiments 1-4, 6-9 and 11 obtainable by a method according to embodiment 14.

19. A needle assembly with a plurality of needles, wherein the needle assembly comprises a plurality of coated needle cannulas (130, 330) according to any of the embodiments 1-11, 16 and 18.

20. A needle assembly with a plurality of needles according to embodiment 19, wherein the needle assembly is adapted to uncover the plurality of coated needle cannulas (130, 330) sequentially for a single time use during a period of use, whereby the unused needle cannulas (110, 310) can be preserved in a sterile condition until the single time use.

21. A needle assembly according to any of embodiments 19 and 20, wherein the needle assembly is adapted to pierce a septum with two or more of the coated needle cannulas (100, 300) according to any of the embodiments 1-11, and thereby contemporaneously uncovering the two or more coated needle cannulas (100, 300).

22. A drug delivery device comprising:
-a drug filled cartridge 440 with a septum 430,
-a drug expelling mechanism for expelling a drug from the cartridge and through an outlet,
-a needle unit comprising a needle hub 420 and a coated needle cannula 300 fixed to the hub 420, the coated needle cannula 300 comprises a coating 330 covering a proximal tip 311 of the cannula 310,

wherein the proximal end 311 of the cannula is adapted for piercing the septum and establishing fluid communication with the cartridge 440, and a distal end 312 is adapted for insertion into the skin of a user,

the drug delivery device further comprises a collapsible portion 421 arranged between the needle hub 420, and the a cartridge 440,

wherein the coating (330) directly contacts the needle cannula (310) and provides an initial adhesion between the coating (330) and the cannula (310),

wherein the initial adhesion between the cannula (310) and the coating (330) can be irreversibly broken, wherein the coating (330) is longitudinally compressible, and wherein the proximal needle tip 311 can pierce the coating (330), in response to the application of a longitudinal compression force to the coating,

wherein the drug delivery comprises: (i) an initial state, wherein the collapsible portion 321 separates the cannula 310 and the cartridge 440, and (ii) a collapsed state wherein the collapsible portion 321 has been compressed, wherein the cannula 310 pierces the septum 430, the coating 330 is compressed, and wherein fluid communication has been established.

23. A drug delivery device according to embodiment 22, wherein the collapsible portion 421 is a skirt portion extending proximally from a central plate of the hub 420.

In the above description of exemplary embodiments, the different structures and means providing the described functionality for the different components have been described to a degree to which the concept of the present invention will be apparent to the skilled reader. The detailed construction and specification for the different components are con-

sidered the object of a normal design procedure performed by the skilled person along the lines set out in the present specification.

CLAIMS

1. A coated needle cannula (100, 300), wherein the coated needle cannula (100) comprises:

- an elongate needle cannula (110) comprising a hollow tubular body extending in a longitudinal direction between a first end (111, 312) and a second end (112, 311), wherein the second end comprises a sharp needle tip,

- an elongate coating (130, 330) of a flexible material providing a sterile barrier, wherein the coating extends along the needle cannula between a first end, at the hollow tubular body, to a second end, at the second end of the needle cannula, and whereby the coating covers a portion of the needle cannula (110, 310) and the needle tip;

wherein the coating (130, 330) directly contacts the needle cannula (110, 310) and provides an initial adhesion between the coating (130, 330) and the cannula (110, 310);

wherein the initial adhesion between the cannula (110) and the coating (130) can be irreversibly broken, wherein the coating (130) is longitudinally compressible, and wherein the needle tip can pierce the second end of the coating (130), in response to the application of a longitudinal compression force to the second end of the coating at the second end of the coating.

2. A coated needle cannula (100, 300) according to claim 1, wherein the coating (130) can be folded to form a longitudinally compressible structure.

3. A coated needle cannula (100, 300) according to any of the previous claims, wherein the coating comprises an initial uncompressed state wherein the initial adhesion is provided, and a compressed state, wherein the coating is folded and forms a tubular bellows like shape, and wherein the initial adhesion is broken.

4. A coated needle cannula (100, 300) according to any of the previous claims, wherein the elongate coating (130) comprises a tubular portion (132) with a constant thickness along the longitudinal direction, whereby the tubular portion can be folded and longitudinally compressed with a constant compression force.

5. A coated needle cannula (100, 300) according to any of the previous claims, wherein the coating comprises a head portion (134), wherein the head portion is deformable from a drop like shape with a first longitudinal extension to a collar like shape with a second longitudinal extension, in response to longitudinal compression, wherein the second lon-

gitudinal extension is shorter than the first longitudinal extension, and wherein the formable collar is adapted for sliding along the cannula and for transferring a compression force to a portion of the elongate coating (130) next to the head portion.

6. A coated needle cannula (100, 300) according to any of the previous claims, wherein the needle cannula (110) comprises a middle portion between the first and the second end, for fixed attachment to a needle hub, wherein the first end of the elongate coating is positioned between the middle portion and the second end of the needle cannula (110), wherein the elongate coating (130) is adapted to fold and form a tubular bellows like structure in a compressed state, in response to a first compression of the coating, and wherein the tubular bellows like structure is adapted to slide towards the middle section, in response to a further application of a compression force to the second end of the coating.

7. A coated needle cannula (100) according to any of the previous claims, wherein the second end of the needle cannula (110) is the distal end (112), and wherein the sharp tip is a distal tip adapted for piercing the skin of a patient.

8. A coated needle cannula (100) according to any of the previous claims, wherein the first end of the needle cannula (110) is the proximal end (111), wherein the second end further comprises a proximal sharp tip adapted for piercing a septum, wherein the proximal end (111) comprises a proximal elongate coating (130) of a flexible material providing a sterile barrier, wherein the proximal coating (130) extends along the needle cannula between a first end, at the hollow tubular body, to a second end, at the proximal end (111) of the needle cannula (110), and whereby the proximal coating covers a portion of the needle cannula (110) and the proximal needle tip;

wherein the proximal coating (130) directly contacts the needle cannula (110) and provides an initial adhesion between the proximal coating (130) and the cannula (110);

wherein the initial adhesion between the cannula (110) and the proximal coating (130) can be irreversibly broken, wherein the proximal coating (130) is longitudinally compressible, and wherein the proximal needle tip can pierce the second end of the proximal coating (130), in response to the application of a longitudinal compression force to the second end of the coating at the second end of the coating.

9. A coated needle cannula (300) according to any of the claims 1-6, wherein the second end is the proximal end (311), and wherein the sharp tip is adapted for piercing a septum (330).

10. A coated needle cannula (100, 300) according to any of the previous claims, wherein the thickness of the coating (130, 330) increases towards the second end of the coating to form a head, wherein the sharp tip is further protected against unintentional piercing, and whereby the contact surface for the longitudinal force is increased, and whereby the head can be used to compress the coating.

11. A coated needle cannula (100, 300) according to any of the previous claims, wherein the coating (130, 330) comprises an inner layer providing adhesion to the needle cannula and an outer layer providing a sterile barrier.

12. A method of manufacturing a coated needle cannula (130, 330) according to any of the previous claims, wherein the method comprises applying the coating material onto the needle cannula, whereby the formed elongate coating (130, 330) adheres directly to the needle cannula.

13. A coated needle cannula (130, 330) according to any of the claims 1-11 obtainable by a method according to claim 12.

14. A needle assembly with a plurality of needles, wherein the needle assembly comprises a plurality of coated needle cannulas (130, 330) according to any of the claims 1-11 and 13.

15. A needle assembly with a plurality of needles according to claim 14, wherein the needle assembly is adapted to uncover the plurality of coated needle cannulas (130, 330) sequentially for a single time use during a period of use, whereby the unused needle cannulas (110, 310) can be preserved in a sterile condition until the single time use.

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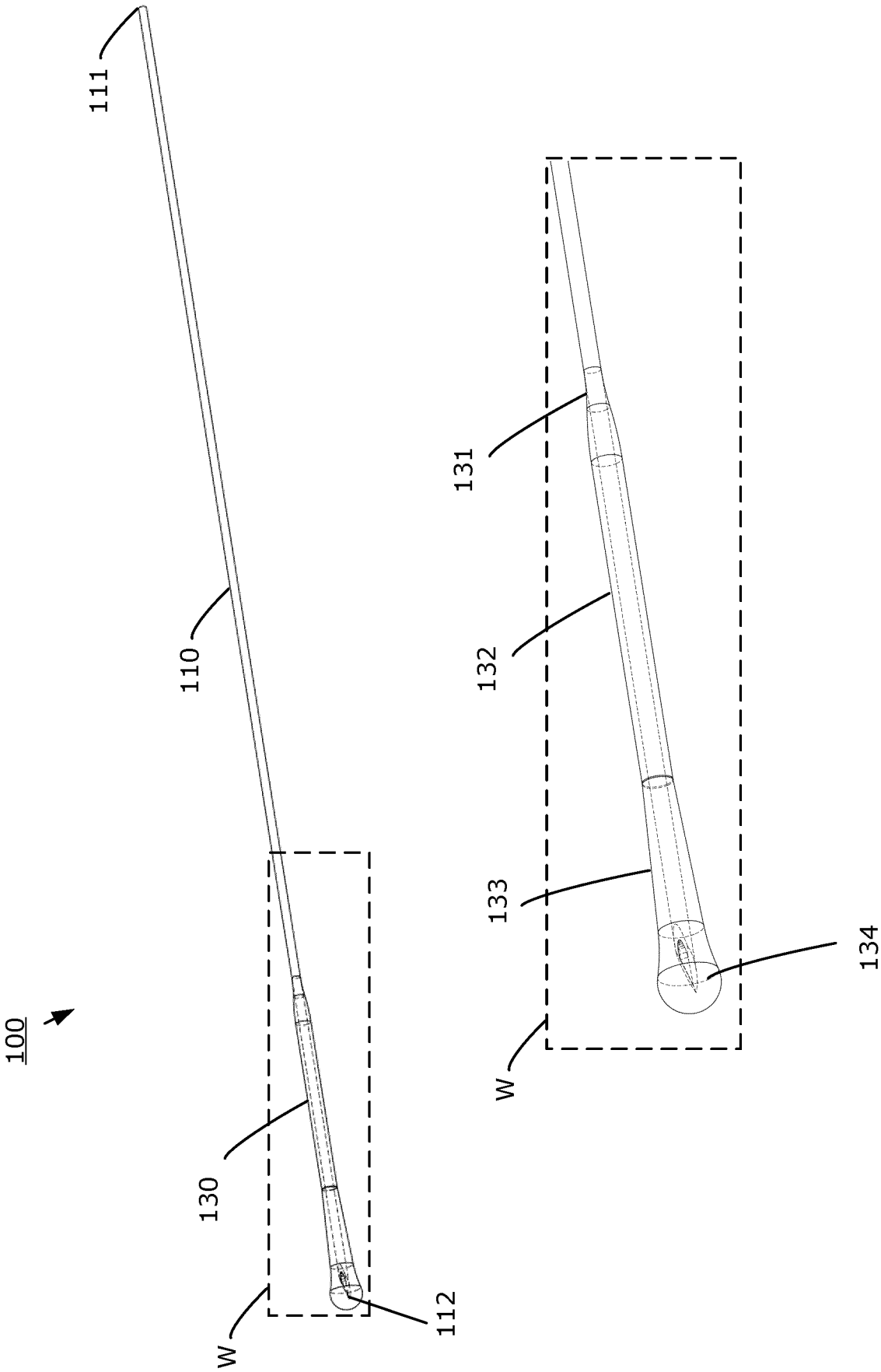

Fig. 1

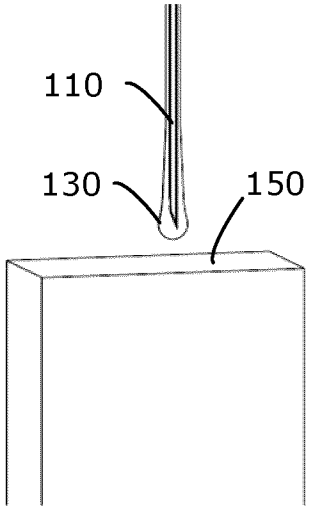

Fig. 2A

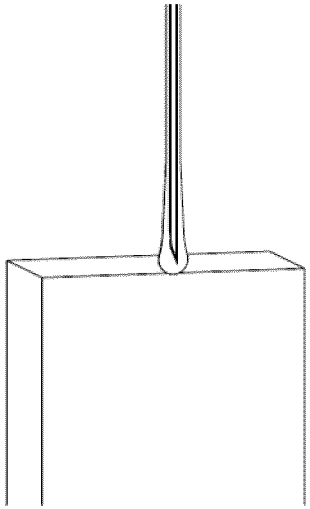

Fig. 2B

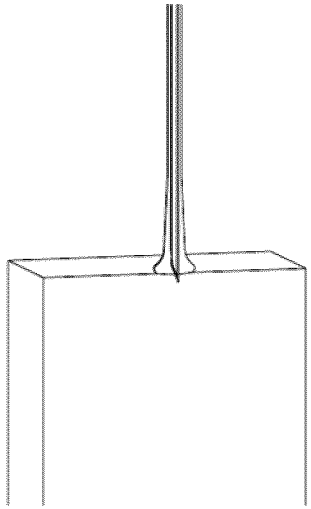

Fig. 2C

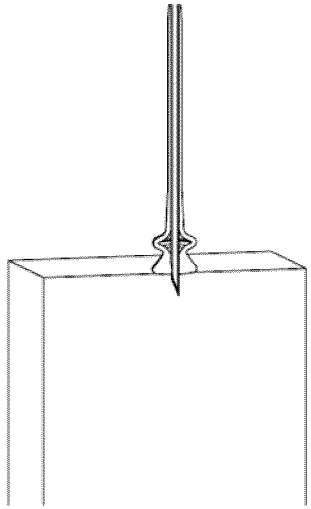

Fig. 2D

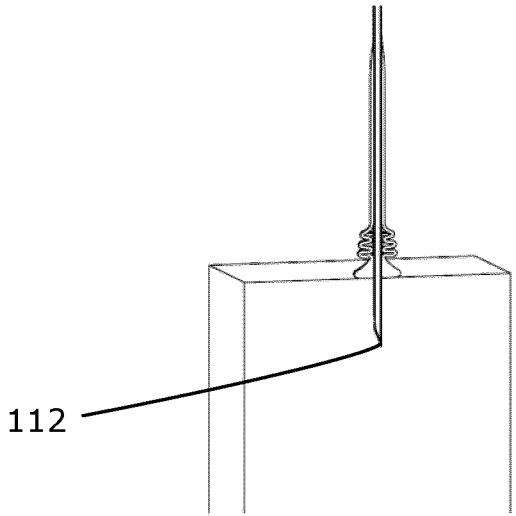

Fig. 2E

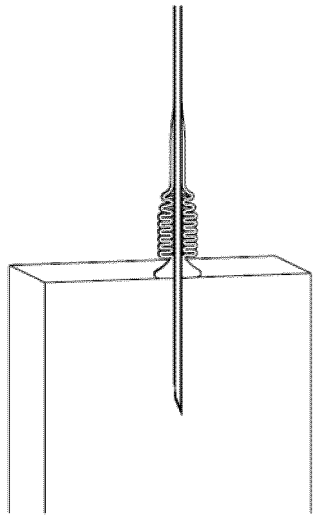

Fig. 2F

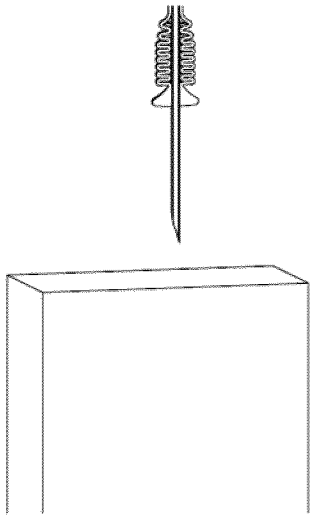

Fig. 2G

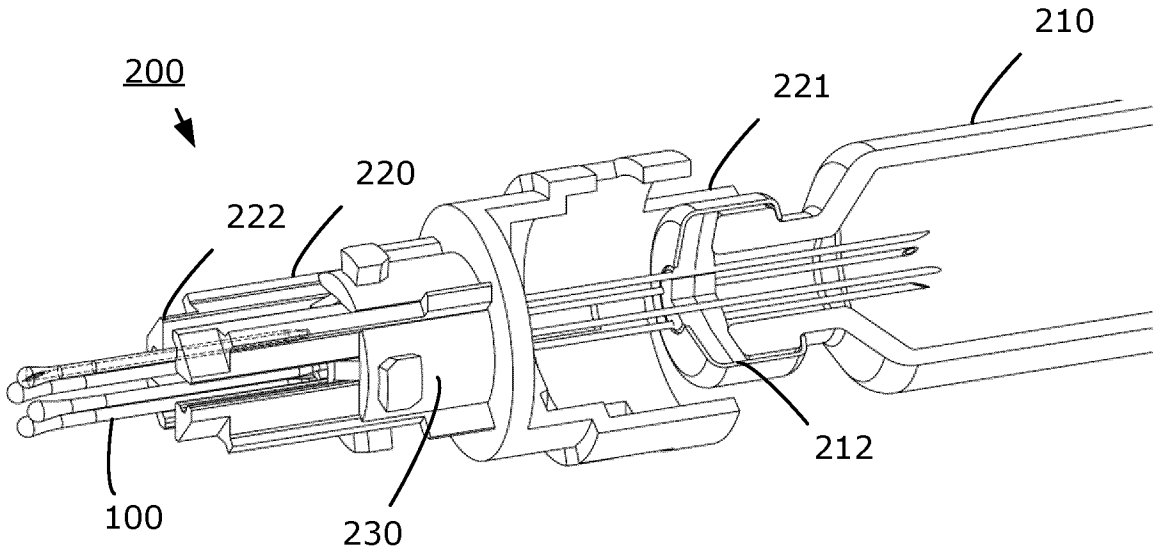

Fig. 3A

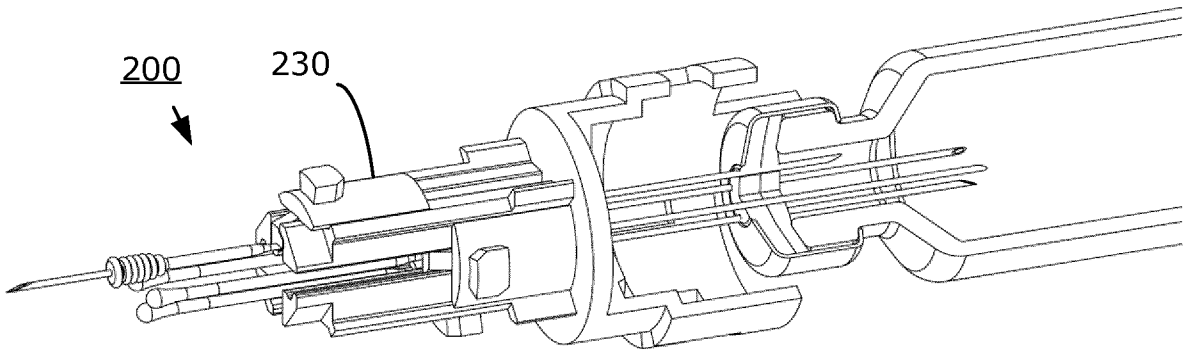

Fig. 3B

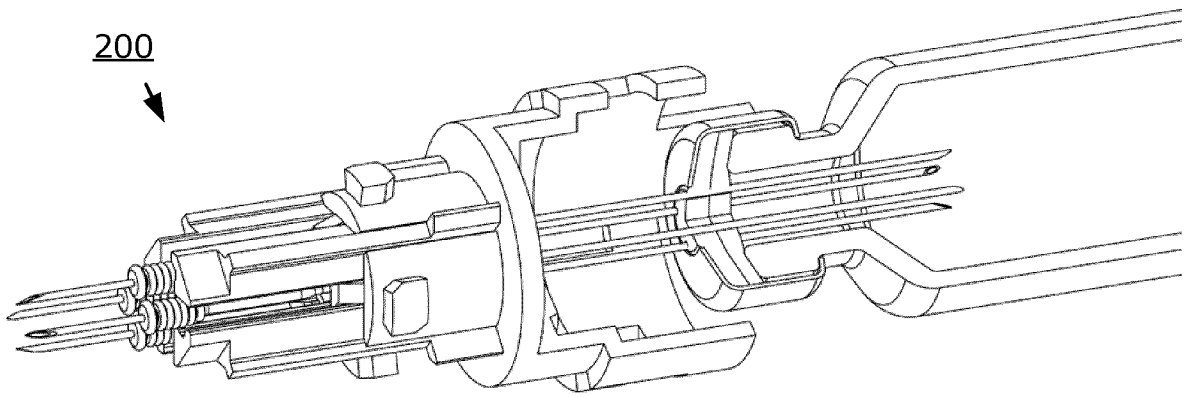

Fig. 3C

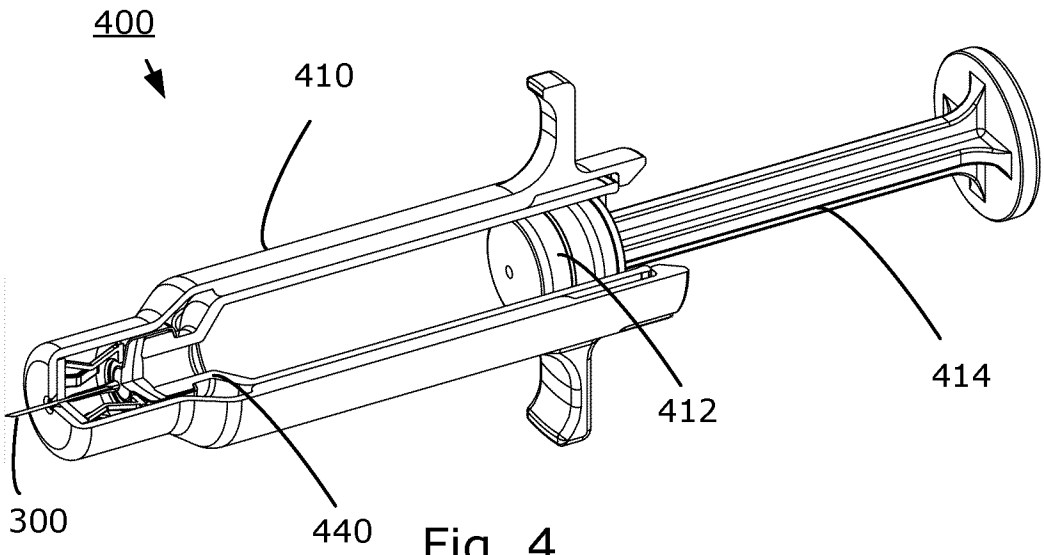

Fig. 4

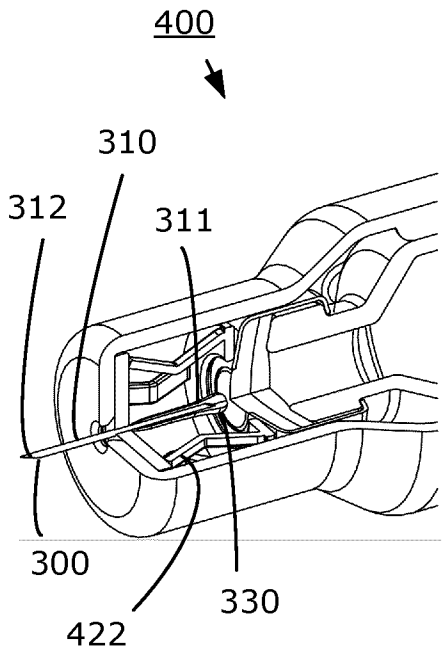

Fig. 5A

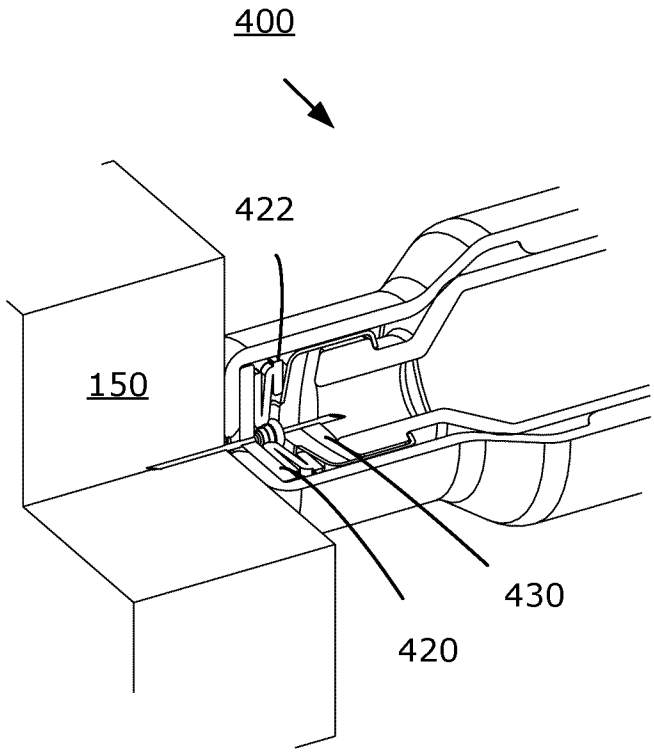

Fig. 5B

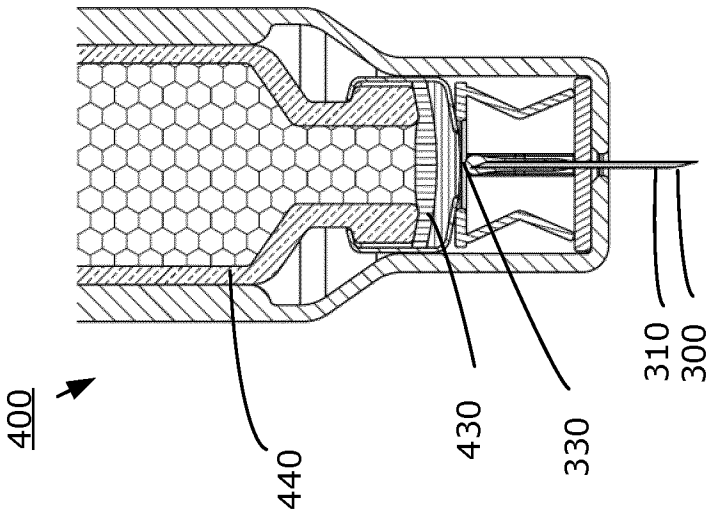

Fig. 6A

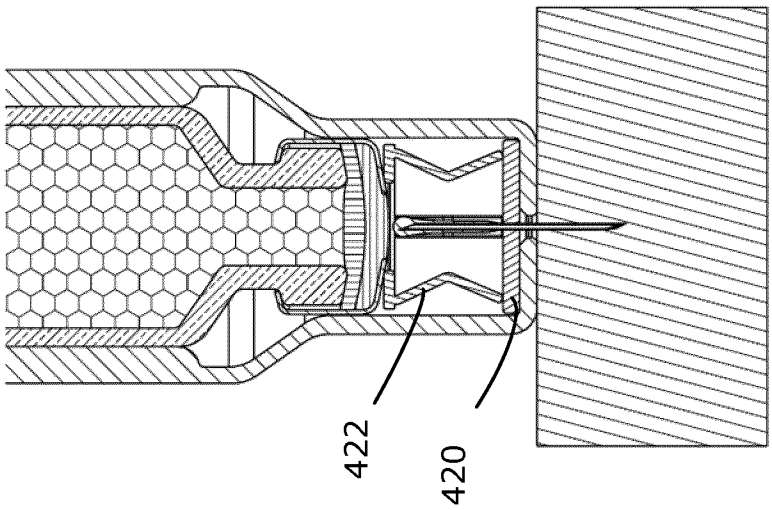

Fig. 6B

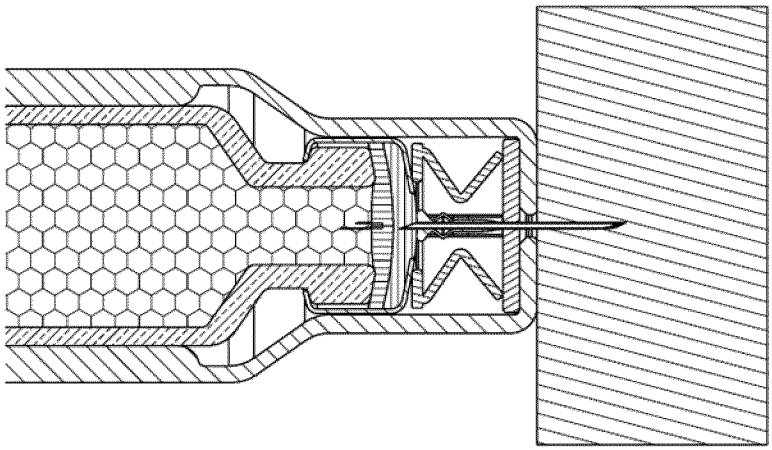

Fig. 6C

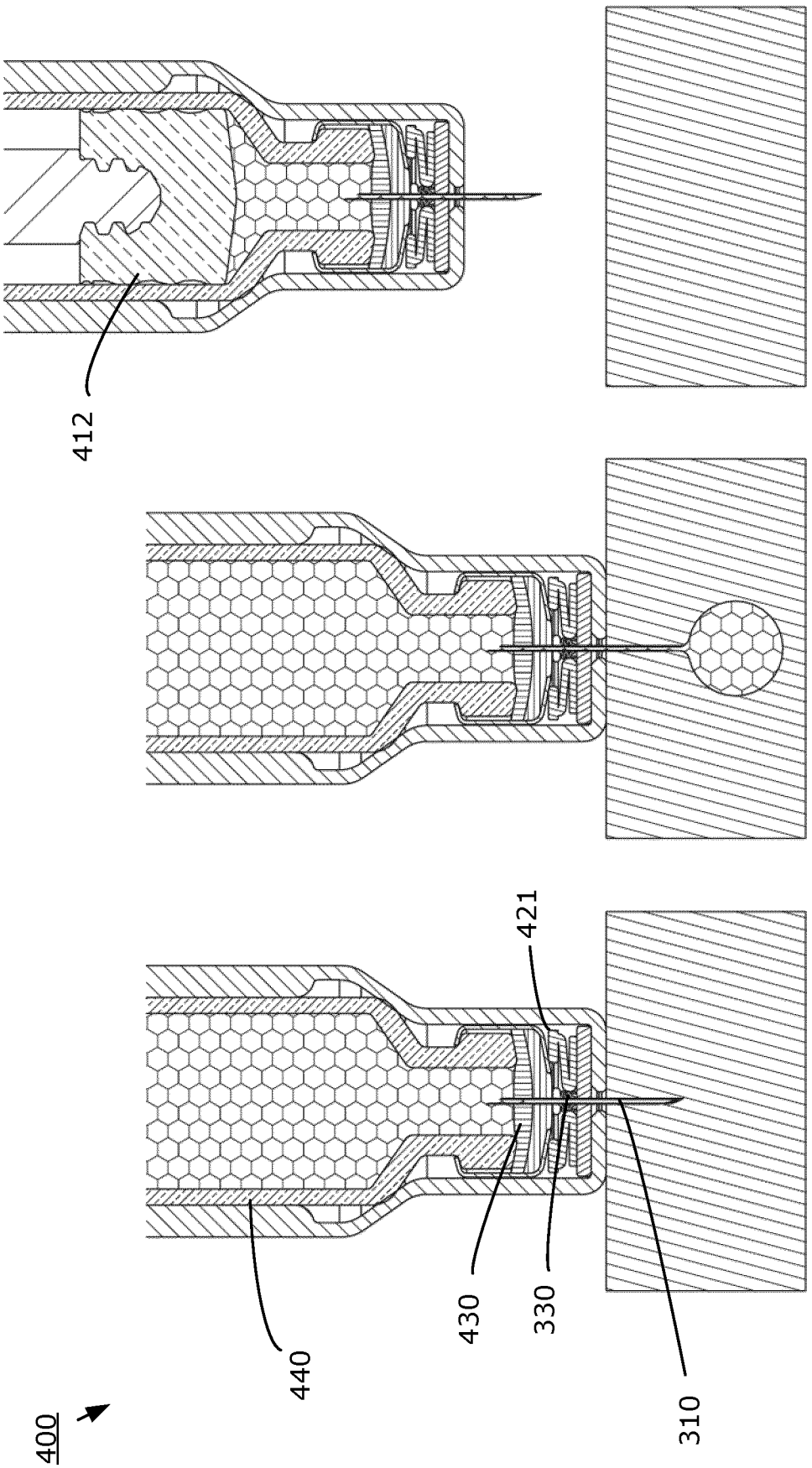

Fig. 6D

Fig. 6E

Fig. 6F

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2021/069144

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/32
ADD.

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)
A61M

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 practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2009/031144 A1 (SINDOLOR MEDICAL LTD [IL]; BRONFELD ZEEV [IL]) 12 March 2009 (2009-03-12) cited in the application	1,7,9, 12-15
A	paragraphs [0018] - [0026]; figures 2a-b	2-6,8,10
A	US 5 290 254 A (VAILLANCOURT VINCENT L [US]) 1 March 1994 (1994-03-01) cited in the application figures 1-4	1-15
A	US 2009/062737 A1 (SUN WILLIAM Y [US]) 5 March 2009 (2009-03-05) paragraph [0006]; figure 1	1-15
A	US 2010/042137 A1 (ORONSKY BRYAN T [US] ET AL) 18 February 2010 (2010-02-18) paragraphs [0040] - [0042]; figure 1	1-15

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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

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

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 September 2021	24/09/2021

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Herz, Markus

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2021/069144

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2009031144 A1	12-03-2009	NONE	
US 5290254 A	01-03-1994	US 5290254 A	01-03-1994
		US 5312366 A	17-05-1994
US 2009062737 A1	05-03-2009	NONE	
US 2010042137 A1	18-02-2010	US 2010042137 A1	18-02-2010
		WO 2009105564 A2	27-08-2009