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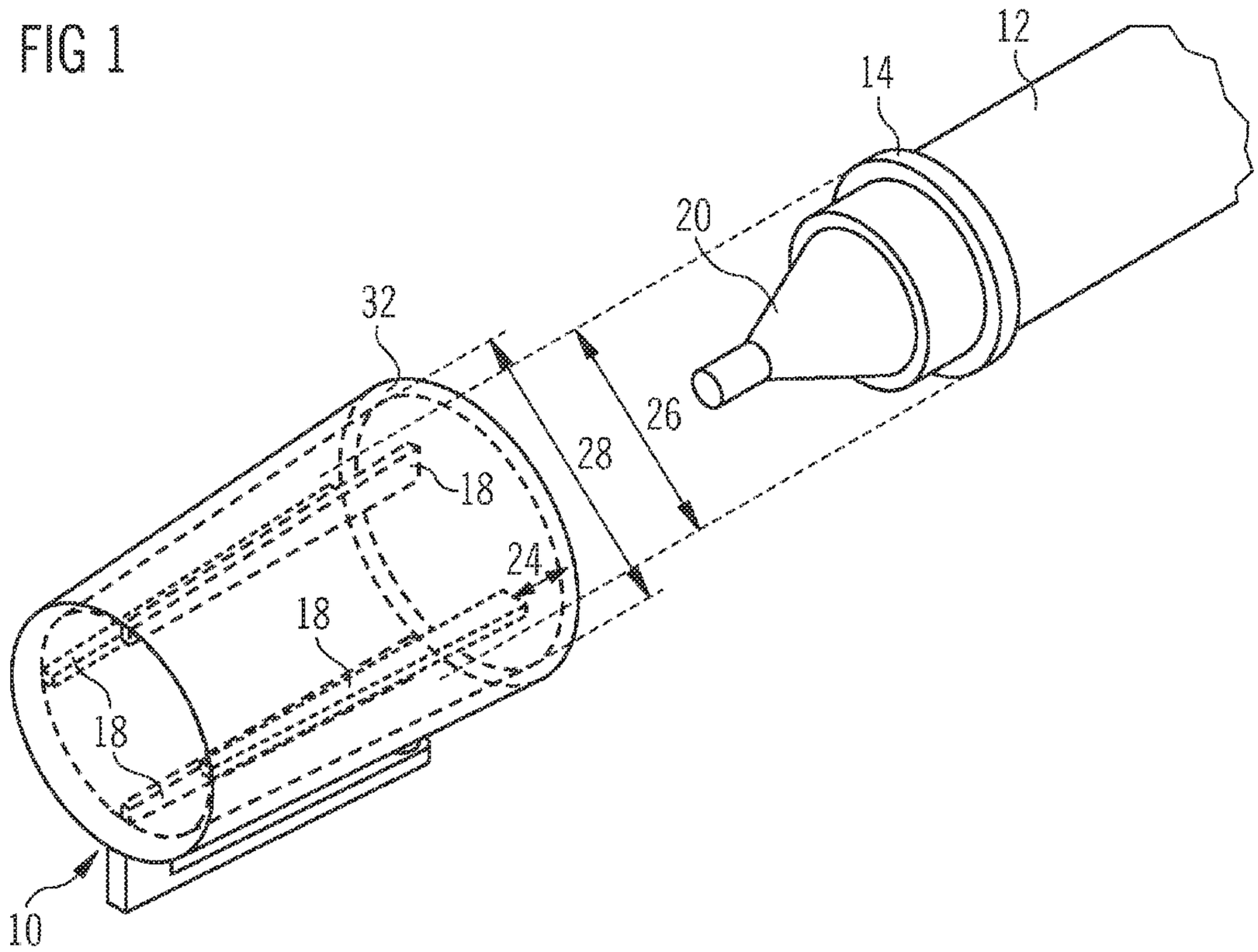
(54) Title: PEN CAP

FIG 1



(57) Abrégé/Abstract:
The present invention refers to a pen cap (10), being capable of covering a distal end of a drug delivery device comprising at least one protruding element (16, 18, 36) located inside the pen cap (10) which prevents that the rim of an outer needle cap (14), while being a protective casing for the needle at the distal end of the drug delivery device, can get stuck within a part of the pen cap (10) if the user puts the pen cap (10) on the drug delivery device. The inner diameter of the pen cap (10) is reduced by means of the at least one protruding element (16, 18, 36), such that the inner diameter of the pen cap (10) is smaller than the largest outer diameter (26) of the outer needle cap (20). Furthermore, the invention relates to a drug delivery device comprising a pen cap (10) with the described protruding elements (16, 18, 36).

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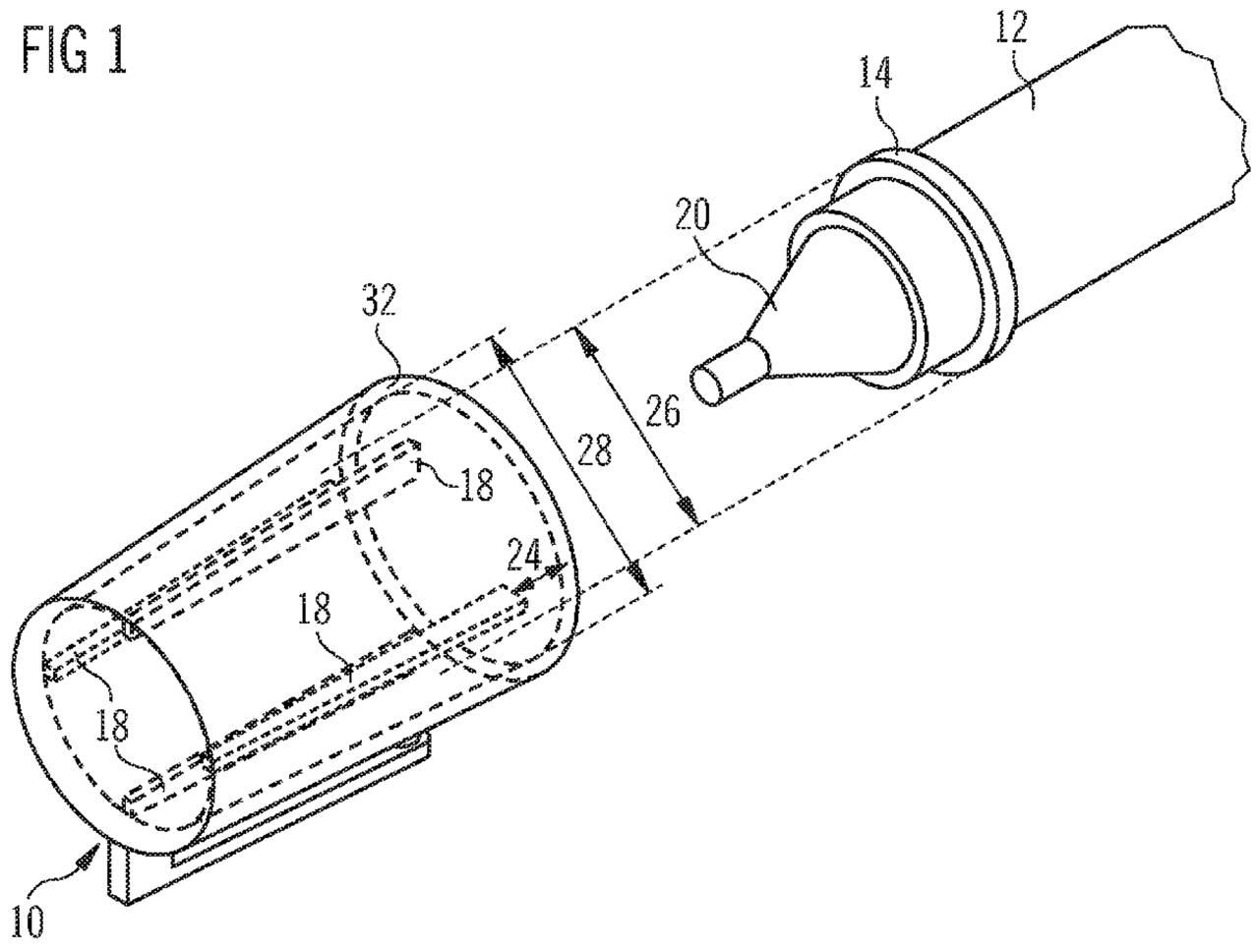
(54) **Title**: PEN CAP

FIG 1



(57) **Abstract**: The present invention refers to a pen cap (10), being capable of covering a distal end of a drug delivery device comprising at least one protruding element (16, 18, 36) located inside the pen cap (10) which prevents that the rim of an outer needle cap (14), while being a protective casing for the needle at the distal end of the drug delivery device, can get stuck within a part of the pen cap (10) if the user puts the pen cap (10) on the drug delivery device. The inner diameter of the pen cap (10) is reduced by means of the at least one protruding element (16, 18, 36), such that the inner diameter of the pen cap (10) is smaller than the largest outer diameter (26) of the outer needle cap (20). Furthermore, the invention relates to a drug delivery device comprising a pen cap (10) with the described protruding elements (16, 18, 36).

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Description

Pen cap

The present invention relates to a pen cap which is used for covering the distal end of a drug delivery device. Furthermore, the present invention relates to a drug delivery device comprising a pen cap.

Drug delivery devices which comprise a removable pen cap are known for example from EP 1 007 115 B1.

Drug delivery devices are to be used in case of a disease where a permanent medication is needed, like for example diabetes. These devices are very comfortable in usage for self-administration of insulin or other medicinal products by a patient. Some reusable pen-type injectors are described in EP 1 923 085 A1 or in EP 0 554 995 A1.

It is an aim of the present invention to provide an improved pen cap for a drug delivery device and therefore an improved drug delivery device.

According to a first aspect of the present invention, a pen cap is provided that is capable of covering a distal end of a drug delivery device, the drug delivery device being adapted to carry a needle at its distal end, the needle being covered by an outer needle cap as a protective casing in a non-use condition. The pen cap may comprise at least one protruding element. The at least one protruding element located inside the pen cap may be adapted and arranged to prevent that the outer needle cap gets stuck within a part of the pen cap when a user mounts the pen cap on the drug delivery device.

In a preferred embodiment, the pen cap has a closed end as well as an open end facing in the opposite direction. At least one protruding element is located inside the pen cap.

The distal end of the drug delivery device is provided with a needle which is covered by an outer needle cap forming a protective casing for the needle. While being a protective casing for the needle at the distal end of the drug delivery device the at least one protruding element inside the pen cap prevents the outer needle cap from getting stuck within the pen cap when the user puts the pen cap on the drug delivery device.

The proximal end of the outer needle cap provides a rim. The inventors have identified that in many cases the rim of the outer needle cap has a diameter that mostly fits into the opening at the open end of the pen cap. When the user puts the pen cap on the drug delivery device it may occur that the rim of the outer needle cap gets jammed within the pen cap. In case the pen cap has at least partly a conic shape with the opening of the cone being directed towards the open end of the cap, the jamming risk is particularly high.

The protruding elements are shaped and sized in such a way that the inner diameter of the pen cap is smaller than the diameter of the rim of the outer needle cap. In a preferred embodiment this is true for all available needle units that fit to the drug delivery device.

In a preferred embodiment, at least one protruding element extends along the longitudinal axis of the pen cap.

The protruding element can extend from the closed end to the open end of the pen cap. As an alternative, the protruding element may be shorter than the pen cap and a leading edge of the protruding element is retracted with regard to the open end of the pen cap.

In any case the rim of the outer needle cap abuts the leading edge of the protruding element while the outer needle cap is inserted in the pen cap.

In a preferred embodiment one end of the at least one protruding element is arranged at the open end of the pen cap.

In a particularly preferred embodiment as seen along the at least one protruding element from its proximal end to its distal end at least one inwardly directed step is provided in the pen cap.

The stepped shape can be provided by arranging at least one stepped protruding element inside the pen cap. The step is radially inwardly directed. The step may divide the region of the pen cap, where the at least one protruding element is arranged, into two parts with different inner diameters. The part with the smaller inner diameter is located in the distal region of the pen cap.

Possibilities to achieve a configuration with smaller diameter in the distal region of the pen cap are given by two stepped protruding elements arranged at opposite sides of the pen cap or by two ring-shaped protruding elements with different inner diameters.

By having different inner diameters with the smallest inner diameter at the distal end of the pen cap, it can be avoided that most commercially available needle units which may comprise different diameters of the outer needle cap can get stuck during insertion in the pen cap.

According to a preferred embodiment of the present invention the at least one protruding element arranged inside the pen cap is a bar.

According to further preferred embodiments, the number and the shape of the protruding elements may vary. In case that a number of two protruding elements is provided, the elements can be arranged for example at opposite sides of the pen cap. In the case of three elements the elements can be arranged in equiangular positions such that they form the corners of an equilateral triangle. In case even more protruding elements are provided, they can form the shape of a ring-like protrusion.

In another preferred embodiment at least one protruding element is a ring.

It is possible to arrange the ring near the open end of the pen cap. Another possibility is to arrange the ring in a small distance to the open end of the pen cap.

According to another preferred embodiment the ring is located directly at the open end of the cap.

In one embodiment the at least one protruding element is made of plastic.

In another embodiment the at least one protruding element is made of metal.

According to another preferred embodiment the at least one protruding element is molded into the cap.

One possible method of manufacturing a pen cap according to the present invention is injection molding. This is particularly preferred in case that the pen cap is made of plastic. In this case, injection molding provides an easy method to manufacture the pen cap and the protruding element in one single process.

In one embodiment the inner diameter of the pen cap is reduced by means of at least one protruding element, such that the inner diameter of the pen cap is smaller than the largest outer diameter of the outer needle cap.

By providing at least one protruding element inside the pen cap, the inner diameter of the pen cap is reduced. The dimension, in particular the radial dimension of the at least one protruding element depends on the reduction of the inner diameter of the pen cap which is required in order to prevent sticking of the outer needle cap in the pen cap.

According to another embodiment a drug delivery device is provided wherein the inner diameter of the pen cap near the open end of the pen cap is reduced by means of at least one protruding element, such that the inner diameter of the pen cap is smaller

than the largest outer diameter of the outer needle cap. The outer needle cap may have its largest outer diameter at the position where the rim is located.

According to a preferred embodiment, a pen cap is provided being capable of covering a distal end of a drug delivery device, the drug delivery device being adapted to carry a needle at its distal end, the needle being covered by an outer needle cap as a protective casing in a non-use condition. The pen cap comprises at least one protruding element located inside the pen cap which prevents that the outer needle cap gets stuck within a part of the pen cap when a user mounts the pen cap on the drug delivery device.

In the following the invention is described in further details with references to the drawings, wherein

Figure 1 shows the distal end of a drug delivery device comprising the housing with an outer needle cap on top of a needle unit and the pen cap with the protruding elements,

Figure 2a shows a top view of the open end of the pen cap comprising a ring-shaped protruding element,

Figure 2b shows a top view of the open end of the pen cap comprising three bar-shaped protruding elements,

Figure 3 shows a cross sectional view of the pen cap, the pen cap comprising two stepped protruding elements.

Identical reference signs denote identical or comparable components.

In the embodiment shown in Figure 1 the housing of a drug delivery device comprises a cartridge holder wherein a cartridge 12 containing a medicinal product is located.

The term „medicinal product“, as used herein, preferably means a pharmaceutical formulation containing at least one pharmaceutically active compound,

wherein in one embodiment the pharmaceutically active compound has a molecular weight up to 1500 Da and/or is a peptide, a proteine, a polysaccharide, a vaccine, a DNA, a RNA, a antibody, an enzyme, an antibody, a hormone or an oligonucleotide, or a mixture of the above-mentioned pharmaceutically active compound,

wherein in a further embodiment the pharmaceutically active compound is useful for the treatment and/or prophylaxis of diabetes mellitus or complications associated with diabetes mellitus such as diabetic retinopathy, thromboembolism disorders such as deep vein or pulmonary thromboembolism, acute coronary syndrome (ACS), angina, myocardial infarction, cancer, macular degeneration, inflammation, hay fever, atherosclerosis and/or rheumatoid arthritis,

wherein in a further embodiment the pharmaceutically active compound comprises at least one peptide for the treatment and/or prophylaxis of diabetes mellitus or complications associated with diabetes mellitus such as diabetic retinopathy,

wherein in a further embodiment the pharmaceutically active compound comprises at least one human insulin or a human insulin analogue or derivative, glucagon-like peptide (GLP-1) or an analogue or derivative thereof, or exedin-3 or exedin-4 or an analogue or derivative of exedin-3 or exedin-4.

Insulin analogues are for example Gly(A21), Arg(B31), Arg(B32) human insulin; Lys(B3), Glu(B29) human insulin; Lys(B28), Pro(B29) human insulin; Asp(B28) human insulin; human insulin, wherein proline in position B28 is replaced by Asp, Lys, Leu, Val or Ala and wherein in position B29 Lys may be replaced by Pro; Ala(B26) human insulin; Des(B28-B30) human insulin; Des(B27) human insulin and Des(B30) human insulin.

Insulin derivates are for example B29-N-myristoyl-des(B30) human insulin; B29-N-palmitoyl-des(B30) human insulin; B29-N-myristoyl human insulin; B29-N-palmitoyl human insulin; B28-N-myristoyl LysB28ProB29 human insulin; B28-N-palmitoyl-LysB28ProB29 human insulin; B30-N-myristoyl-ThrB29LysB30 human insulin; B30-N-palmitoyl- ThrB29LysB30 human insulin; B29-N-(N-palmitoyl-Y-glutamyl)-des(B30) human insulin; B29-N-(N-lithocholyl-Y-glutamyl)-des(B30) human insulin; B29-N-(ω-carboxyheptadecanoyl)-des(B30) human insulin and B29-N-(ω-carboxyheptadecanoyl) human insulin.

Exendin-4 for example means Exendin-4(1-39), a peptide of the sequence H-His-Gly-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Leu-Ser-Lys-Gln-Met-Glu-Glu-Glu-Ala-Val-Arg-Leu-Phe-Ile-Glu-Trp-Leu-Lys-Asn-Gly-Gly-Pro-Ser-Ser-Gly-Ala-Pro-Pro-Pro-Ser-NH2.

Exendin-4 derivatives are for example selected from the following list of compounds:

H-(Lys)4-des Pro36, des Pro37 Exendin-4(1-39)-NH2,
H-(Lys)5-des Pro36, des Pro37 Exendin-4(1-39)-NH2,
des Pro36 [Asp28] Exendin-4(1-39),
des Pro36 [IsoAsp28] Exendin-4(1-39),
des Pro36 [Met(O)14, Asp28] Exendin-4(1-39),
des Pro36 [Met(O)14, IsoAsp28] Exendin-4(1-39),
des Pro36 [Trp(O2)25, Asp28] Exendin-4(1-39),
des Pro36 [Trp(O2)25, IsoAsp28] Exendin-4(1-39),
des Pro36 [Met(O)14 Trp(O2)25, Asp28] Exendin-4(1-39),
des Pro36 [Met(O)14 Trp(O2)25, IsoAsp28] Exendin-4(1-39); or

des Pro36 [Asp28] Exendin-4(1-39),
des Pro36 [IsoAsp28] Exendin-4(1-39),
des Pro36 [Met(O)14, Asp28] Exendin-4(1-39),
des Pro36 [Met(O)14, IsoAsp28] Exendin-4(1-39),
des Pro36 [Trp(O2)25, Asp28] Exendin-4(1-39),
des Pro36 [Trp(O2)25, IsoAsp28] Exendin-4(1-39),

des Pro36 [Met(O)14 Trp(O2)25, Asp28] Exendin-4(1-39),
des Pro36 [Met(O)14 Trp(O2)25, IsoAsp28] Exendin-4(1-39),
wherein the group -Lys6-NH2 may be bound to the C-terminus of the Exendin-4 derivative;

or an Exendin-4 derivative of the sequence
H-(Lys)6-des Pro36 [Asp28] Exendin-4(1-39)-Lys6-NH2,
des Asp28 Pro36, Pro37, Pro38Exendin-4(1-39)-NH2,
H-(Lys)6-des Pro36, Pro38 [Asp28] Exendin-4(1-39)-NH2,
H-Asn-(Glu)5des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-NH2,
des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36 [Trp(O2)25, Asp28] Exendin-4(1-39)-Lys6-NH2,
H-des Asp28 Pro36, Pro37, Pro38 [Trp(O2)25] Exendin-4(1-39)-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Trp(O2)25, Asp28] Exendin-4(1-39)-NH2,
H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Trp(O2)25, Asp28] Exendin-4(1-39)-NH2,
des Pro36, Pro37, Pro38 [Trp(O2)25, Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Trp(O2)25, Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Trp(O2)25, Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36 [Met(O)14, Asp28] Exendin-4(1-39)-Lys6-NH2,
des Met(O)14 Asp28 Pro36, Pro37, Pro38 Exendin-4(1-39)-NH2,
H-(Lys)6-desPro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-NH2,
H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-NH2,
des Pro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-Asn-(Glu)5 des Pro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-Lys6-des Pro36 [Met(O)14, Trp(O2)25, Asp28] Exendin-4(1-39)-Lys6-NH2,
H-des Asp28 Pro36, Pro37, Pro38 [Met(O)14, Trp(O2)25] Exendin-4(1-39)-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-NH2,

H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Met(O)14, Trp(O2)25, Asp28] Exendin-4(1-39)-NH2,

des Pro36, Pro37, Pro38 [Met(O)14, Trp(O2)25, Asp28] Exendin-4(1-39)-(Lys)6-NH2,

H-(Lys)6-des Pro36, Pro37, Pro38 [Met(O)14, Trp(O2)25, Asp28] Exendin-4(S1-39)-(Lys)6-NH2,

H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Met(O)14, Trp(O2)25, Asp28] Exendin-4(1-39)-(Lys)6-NH2;

or a pharmaceutically acceptable salt or solvate of any one of the afore-mentioned Exedin-4 derivative.

Hormones are for example hypophysis hormones or hypothalamus hormones or regulatory active peptides and their antagonists as listed in Rote Liste, ed. 2008, Chapter 50, such as Gonadotropine (Follitropin, Lutropin, Choriongonadotropin, Menotropin), Somatropine (Somatropin), Desmopressin, Terlipressin, Gonadorelin, Triptorelin, Leuprorelin, Buserelin, Nafarelin, Goserelin.

A polysaccharide is for example a glucosaminoglycane, a hyaluronic acid, a heparin, a low molecular weight heparin or an ultra low molecular weight heparin or a derivative thereof, or a sulphated, e.g. a poly-sulphated form of the above-mentioned polysaccharides, and/or a pharmaceutically acceptable salt thereof. An example of a pharmaceutically acceptable salt of a poly-sulphated low molecular weight heparin is enoxaparin sodium.

Pharmaceutically acceptable salts are for example acid addition salts and basic salts. Acid addition salts are e.g. HCl or HBr salts. Basic salts are e.g. salts having a cation selected from alkali or alkaline, e.g. Na+, or K+, or Ca2+, or an ammonium ion N+(R1)(R2)(R3)(R4), wherein R1 to R4 independently of each other mean: hydrogen, an optionally substituted C1-C6-alkyl group, an optionally substituted C2-C6-alkenyl group, an optionally substituted C6-C10-aryl group, or an optionally substituted C6-C10-heteroaryl group. Further examples of pharmaceutically acceptable salts are described in "Remington's Pharmaceutical Sciences" 17. ed. Alfonso R. Gennaro

(Ed.), Mark Publishing Company, Easton, Pa., U.S.A., 1985 and in Encyclopedia of Pharmaceutical Technology.

Pharmaceutically acceptable solvates are for example hydrates.

An outer needle cap 20 is located at the distal end of the drug delivery device. This outer needle cap 20 covers a sterile needle unit which in turn is covered by an inner needle cap not explicitly shown in Figure 1. The outer needle cap 20 comprises a distal and a proximal end which are both formed cylindrically. The diameter of the distal cylindrical part is smaller than the diameter of the proximal cylindrical part. The proximal cylindrical part of the outer needle cap 20 is limited by a rim 14. This rim 14 forms the part of the outer needle cap 20 with the largest diameter. A connecting part is arranged between the distal end of the cylindrical part with the larger diameter and the proximal end of the cylindrical part with the smaller diameter.

Inside the conic shaped pen cap 10, protruding elements 18 are arranged to prevent that the rim 14 of the outer needle cap 20 gets stuck within the pen cap 10 when the outer needle cap 20 is inserted in the pen cap 10. Each protruding element 18 is bar-shaped and arranged along the longitudinal axis of the pen cap 10 and extends between the proximal and the distal end of the pen cap 10. The leading edges of the protruding elements are located at a distance 24 from the open end of the pen cap 10.

The size and shape of the protruding elements 18 were chosen in such a way that the inner diameter 30 of the pen cap is smaller than the outer diameter 28 of the rim of the outer needle cap 20. Here the inner diameter 30 of the pen cap 10 is limited by the inner ends of the protruding elements.

By trying to insert the outer needle cap 20 into the pen cap 10 the surface of the rim 14 of the outer needle cap 20 will mechanically cooperate with, in particular abut, the leading edges of each of the four protruding elements 18 shown in Figure 1. As such, it is prevented that the distal end of the drug delivery device with an outer needle cap 20 on top of the needle is fully inserted into the pen cap 10 and gets stuck within the pen

cap 10. This is possible, because of the fact that the outer diameter of the rim 14 at the proximal end of the outer needle 20 cap is smaller than the inner diameter 28 at the open end of the pen cap.

Figure 2a shows a top view of the open end of a pen cap 32 with a ring-shaped protruding element 16 inside the pen cap 10. This ring-shaped element 16 is located near the open end of the pen cap 32. This ring-shaped protruding element narrows the inner diameter 30.

Figure 2b shows a top view of the open end of the pen cap 32 with three bar-shaped protruding elements 18 arranged along the longitudinal axis between the proximal and the distal end of the pen cap 10. These three bar-shaped protruding elements 18 narrow the inner diameter 30.

Figure 3 shows a cross sectional view of a pen cap 10 with two stepped protruding elements 36 arranged at opposite sides of the pen cap 10. The two stepped protruding elements 36 are arranged in a distance 24 to the open end of the pen cap 32. The inner diameter of the pen cap 28 is reduced by the two protruding elements. The inner diameter in the distal region of the pen cap 34 is smaller than the inner diameter 30 in the proximal region of the protruding elements 36. The inner diameter in the distal region of the pen cap 34 should be greater than the outer diameter of a tapered cartridge or cartridge holder, which is not shown in the figure. The cartridge or cartridge holder may thus be still inserted into the pen cap 10 while most commercially available outer needle caps 20 are reliably prevented from getting stuck in the pen cap 10.

The present examples and embodiments are to be considered as illustrative and not restrictive, and the invention is not to be limited to the details given herein, but may be modified within the scope and equivalence of the appended claims.

Reference numerals

10 pen cap
12 cartridge
14 rim of the outer needle cap
16 ring-shaped protruding element
18 bar-shaped protruding element
20 outer needle cap
24 distance to the open end of the pen cap
26 outer diameter of the outer needle cap
28 inner diameter at the open end of the pen cap
30 inner diameter of the pen cap
32 open end of the pen cap
34 inner diameter in the distal region of the pen cap
36 stepped protruding element

Claims

1. A pen cap (10), being capable of covering a distal end of a drug delivery device, the drug delivery device being adapted to carry a needle at its distal end, the needle being covered by an outer needle cap (20) as a protective casing in a non-use condition, wherein the pen cap (10) comprises at least one protruding element (16, 18, 36) located inside the pen cap (10) which prevents that the outer needle cap (20) gets stuck within a part of the pen cap (10) when a user mounts the pen cap (10) on the drug delivery device, wherein the inner diameter of the pen cap (10) is reduced by means of the at least one protruding element (16, 18, 36), such that the inner diameter of the pen cap (10) is smaller than the largest outer diameter (26) of the outer needle cap (20).

2. A pen cap (10) according to claim 1,
wherein the at least one protruding element (16, 18, 36) extends along the longitudinal axis of the pen cap (10).

3. A pen cap (10) according to claim 1 or 2,
wherein one end of the at least one protruding element (16, 18, 36) is arranged at the open end (32) of the pen cap (10).

4. A pen cap (10) according to one of the previous claims,
wherein a leading edge of the at least one protruding element (16, 18, 36) is retracted with regard to the open end (32) of the pen cap (10).

5. A pen cap (10) according to one of the previous claims,
wherein as seen along the at least one protruding element (16, 18, 36) from its proximal end to its distal end at least one inwardly directed step is provided in the pen cap (10).

6. A pen cap (10) according to one of the previous claims,
wherein the at least one protruding element is a bar (18).

7. A pen cap (10) according to one of the previous claims, wherein the at least one protruding element is a ring (16).

8. A pen cap (10) according to one of the previous claims, wherein two protruding elements (16, 18, 36) are located at opposite sides of the pen cap (10).

9. A pen cap (10) according to one of the previous claims, wherein the at least one protruding element (16, 18, 36) is made of plastic.

10. A pen cap (10) according to one of the previous claims, wherein the at least one protruding element (16, 18, 36) is made of metal.

11. A pen cap (10) according to one of the previous claims, wherein the protruding element (16, 18, 36) is molded into the cap.

12. A drug delivery device comprising a pen cap (10) according to any one of the previous claims, a needle unit at the distal end of the housing and the outer needle cap (20).

13. A drug delivery device according to claim 12, wherein the inner diameter (28) at the open end of the pen cap (10) is reduced by means of at least one protruding element (16, 18, 36), such that the inner diameter (30) of the pen cap (10) is smaller than the outer diameter (26) of the outer needle cap (20).

FIG 1

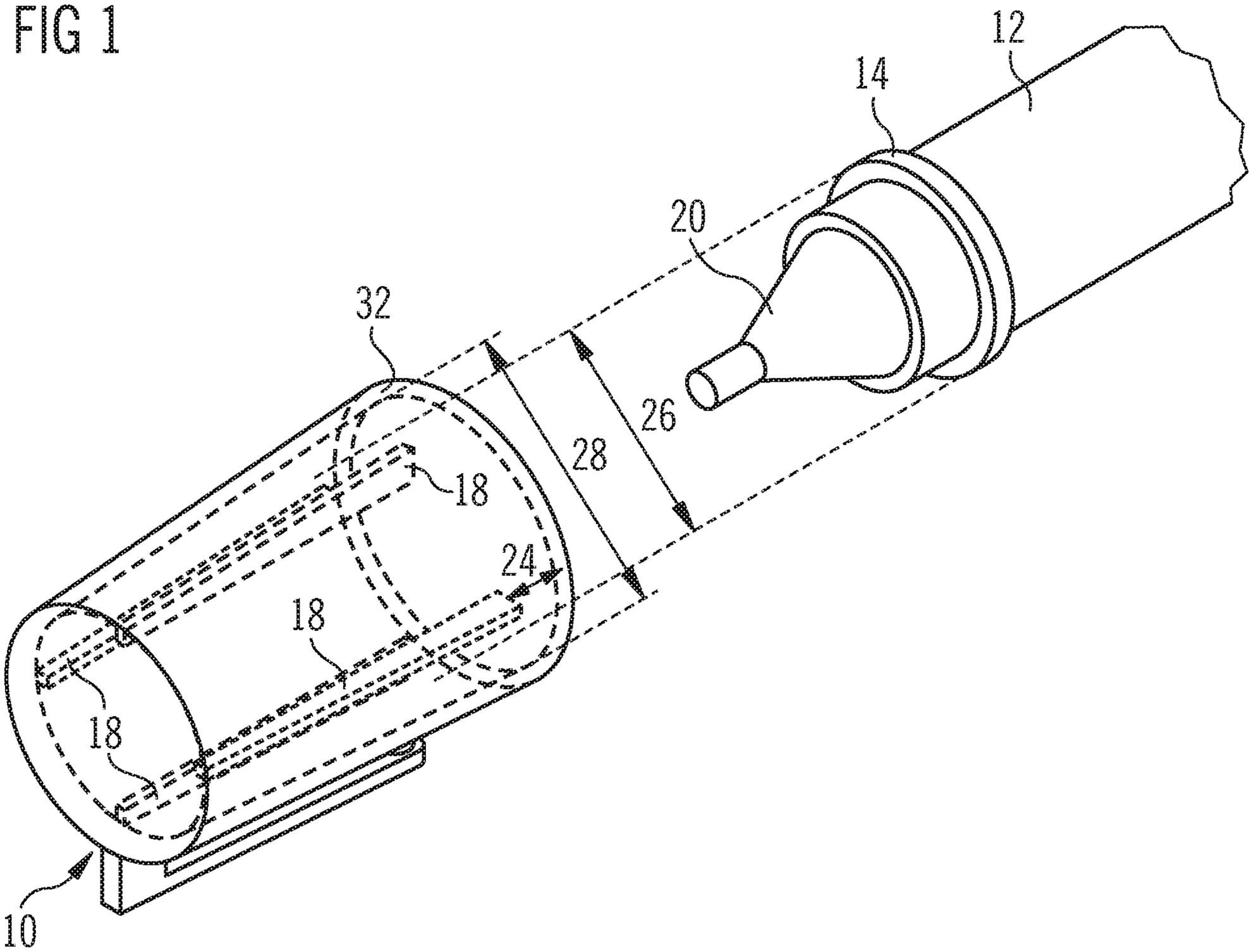

FIG 2

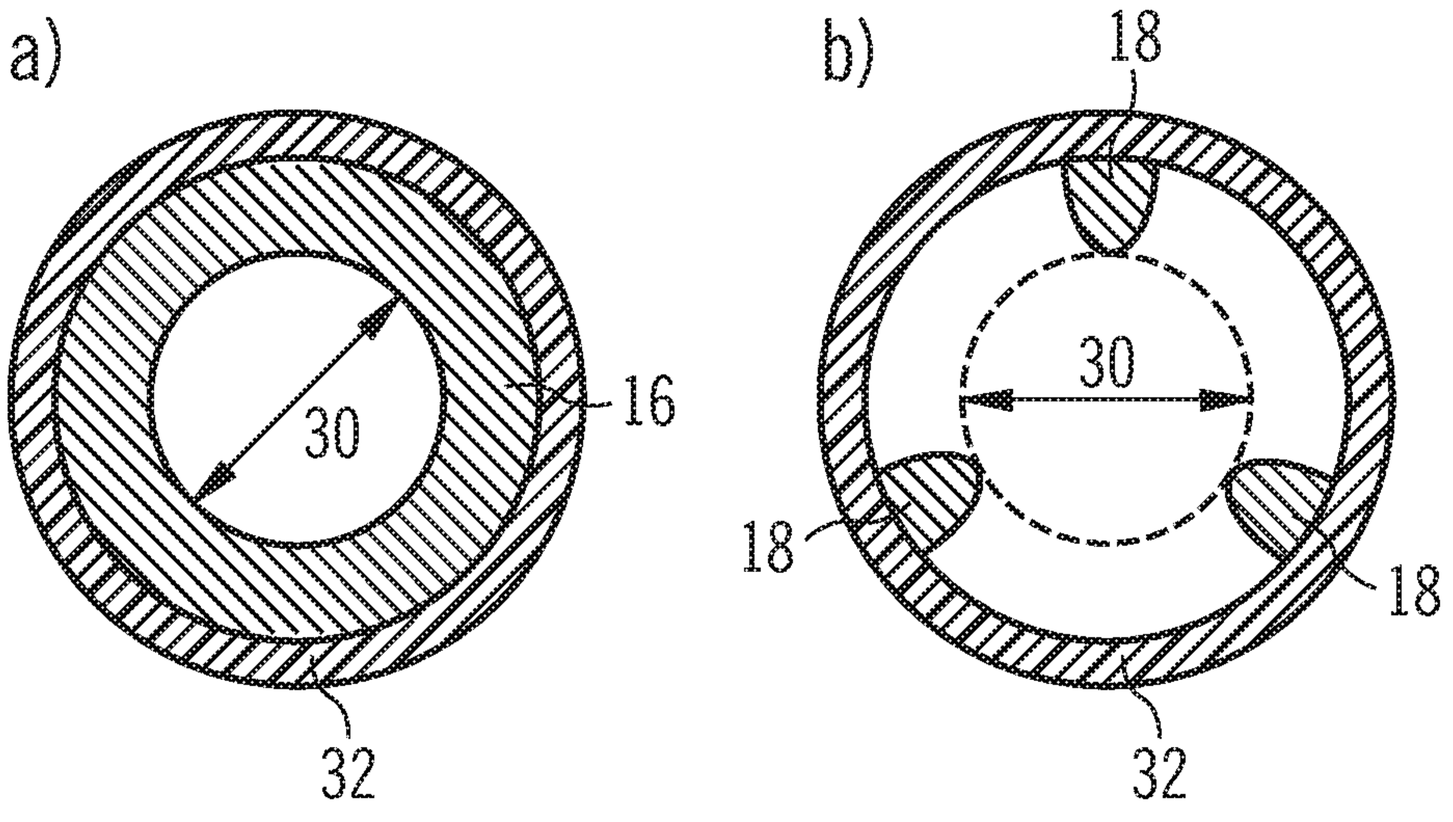

FIG 3

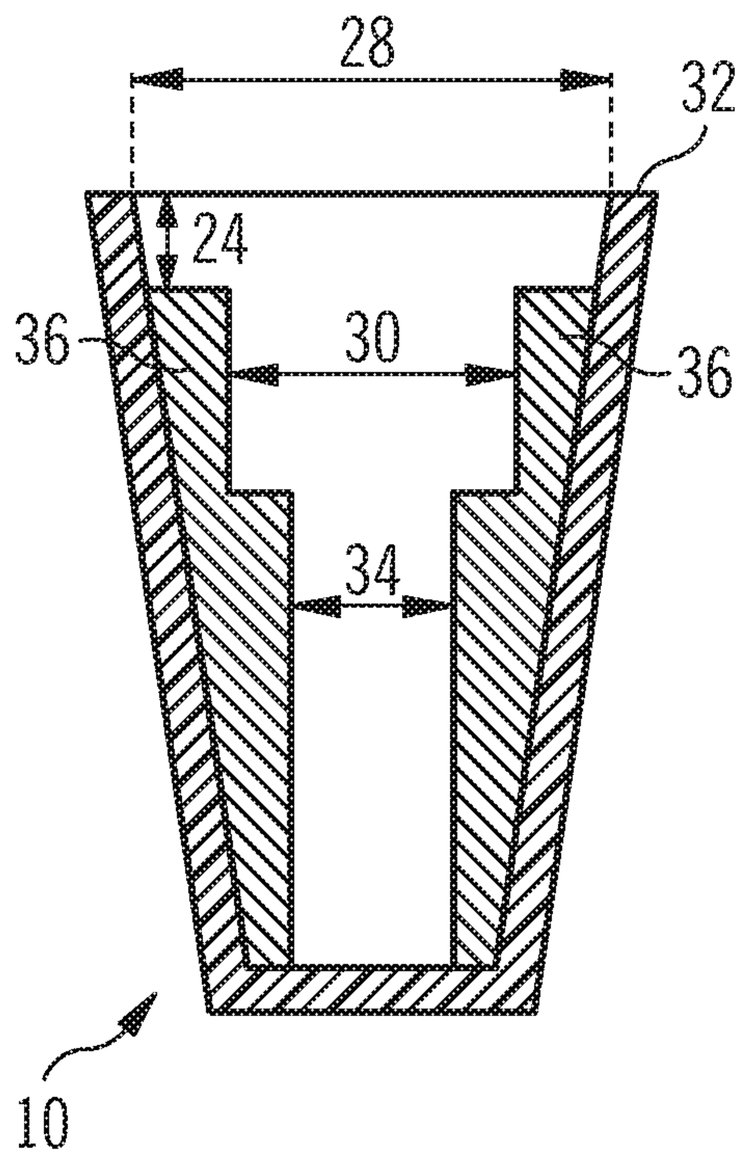

FIG 1