A needle assembly enabling safe disposal of a needle unit, comprising an outer cover adapted to accommodate a needle unit, the outer cover having a first end, and a second closed end. The needle assembly further comprises a removable part adapted to be removed during the process of opening the needle assembly, wherein the removable part comprises a foil, a cap supporting part, a cap adapted to be supported by the cap supporting part. The needle assembly is adapted to be operated between three modes. A first mode where the foil is attached to the outer cover and thereby adapted to cover at least a portion of the first end of the outer cover, and wherein the cap is attached to the cap supporting part. A second mode in which the removable part and the outer cover are separated from each other, whereby at least a portion of the first end of the outer cover is uncovered, whereby the second mode enables a needle unit to exit from or enter into the outer cover. A third mode wherein the cap is attached to the outer cover and thereby adapted to cover the first end of the outer cover, whereby the third mode enables safe disposal of a needle unit.
Needle assembly with cap for safe disposal of a pen needle

THE TECHNICAL FIELD OF THE INVENTION:
The invention relates to a needle assembly for accommodating a needle unit in a sterile condition before use, and in a condition for safe disposal after use. More particularly, the invention relates to a needle assembly with a cap, which enables safe disposal of a needle unit.

DESCRIPTION OF RELATED ART:
Needle units for medical devices are used in large numbers and for various applications, where fluids are injected to or extracted from the body. Needle units can therefore interface with many different medical devices as syringes, pens, infusion sets etc.

Pen needle units are particularly used by people suffering from diabetes, who have to inject themselves with insulin at a daily basis. For this purpose a great number of different pen systems have been developed over the last 30 years. Common for pen injectors is that they contain a container or cartridge containing the liquid drug to be injected. In order to transfer the liquid drug from the injection pen and into the body of the patient a pen needle unit is used. Such double-pointed pen-needle units have a needle cannula with a non-injection end (proximal end) which penetrates into the cartridge when the pen needle unit is attached to the injection pen and a patient end (distal end) that enters into the body of the patient during injection to create a liquid communication between the inner of the cartridge and the patient. A pen needle unit further comprises a hub carrying the cannula and the hub is usually provided with means for attaching the pen needle assembly to the injection pen. However, pen needle units are also used to treat other medical diseases.

Such pen needle assemblies are typically disposable and are discarded after one single use. The problem presented by the disposal of a pen needle assembly, and indeed, by any handling of the pen needle assembly, is the potential risk of being injured by any of the sharp ends of the needle cannula. This is particular dangerous when following after the penetration of a patients skin since the needle cannula then may be contaminated and therefore capable of spreading diseases such as hepatitis and HIV.

US 201 1/0071471 (DIBIASI et al.) allegedly discloses a needle assembly where an outer cover and reversible cap provides a sharps container. The reversible cap connects to the outer cover in a first position before the needle is used, and in a second position after the
needle is used. US 2009/0069752 A1 (ABHIJITSINH et al.) discloses a needle assembly for accommodating a needle unit.

SUMMARY OF THE INVENTION:

It is an object of the present invention to provide a needle assembly, where a needle unit can be contained in a sterile condition before use, and in a condition for safe disposal after use. Another object of the present invention is to provide a needle assembly, where a needle unit can be safely disposed in an outer cover of the assembly, and where the needle unit can be sterilized in a bulk sterilization process. The invention may also solve further problems that will be apparent from the disclosure of the exemplary embodiments.

In one aspect, the present invention relates to a needle assembly enabling safe disposal of a needle unit, comprising:

- an outer cover adapted to accommodate a needle unit, the outer cover is having a first end and a second closed end;
- a removable part adapted to be removed during the process of opening the needle assembly, wherein the removable part comprises:
  - a foil;
  - a cap supporting part;
- a cap adapted to be supported by the cap supporting part;
- wherein the needle assembly is adapted to be operated between:
  - a first mode where the foil is attached to the outer cover and thereby adapted to cover at least a portion of the first end of the outer cover, and wherein the cap is attached to the cap supporting part;
  - a second mode in which the removable part and the outer cover are separated from each other, whereby at least a portion of the first end of the outer cover is uncovered, whereby the second mode enables a needle unit to exit from or enter into the outer cover; and
  - a third mode wherein the cap is attached to the outer cover and thereby adapted to cover the first end of the outer cover, whereby the third mode enables safe disposal of a needle unit.

The present invention provides a needle assembly, with an outer cover adapted to accommodate a needle unit. The needle unit comprises a removable part comprising a cap, which can be used to recap or cover an open end of the outer cover after use.
The components of the removable part can, at least in the first mode, be interconnected and can be removed as a single unit, when it is separated from the outer cover. In the second mode, wherein the removable part and the outer cover are separated from each other, the removable part and the outer cover are apart and not connected. The outer cover without the removable part, and thereby the cap, is smaller than the unit comprising the outer cover and the removable part as a connected unit. Therefore, the separation of the removable part from the outer cover, allows the outer cover to be used in a new way during handling, e.g., the outer cover can fit into a confined space defined by a pen cap, and can be used as a needle cap under a pen cap.

The needle unit can be operated from a first mode, where the foil covers at least a portion of the open end. As the foil covers at least a portion of the first end of the outer cover, this invention allows conventional bulk sterilization, as the sterilizing agent, e.g., gas or steam, may diffuse through the foil and thereby sterilize an accommodated needle unit. In some embodiments the cap supporting part, in the first mode, is adapted to support a cap in such a way that it is ensured that at least a portion of the first end of the outer cover is covered by the foil only, i.e., the cap may cover a portion of the first end of the outer cover, another portion may be covered by both the cap and the foil, another portion may be covered by the cap only, and at least a portion of the outer cover may be covered by the foil only. Thereby, it is ensured that a sterilizing gas can enter the outer cover through the foil and sterilize an accommodated needle unit, and the foil may therefore be a sterile barrier. In some embodiments, in the first mode, the cap supporting part may be connected to the foil.

In the second mode, the removable part comprising the foil has been separated from the outer cover, and in this mode it is possible to get access to an accommodated needle, or to put a needle into the outer cover. In the second mode, an accommodated needle may be mounted on an injection device. In some embodiments the injection device may be an injection pen. The outer cover containing the needle may be mounted on the needle mount of the injection device, and the outer cover may be used to handle the needle unit to minimize the risk of accidental needle injuries. When the needle unit is mounted, the outer cover may be pulled or lifted off the needle unit, and the needle unit may be ready for use. After use the outer cover, may be put back onto the mounted needle unit, and the outer cover is used to demount and handle the needle unit. In some embodiments the outer cover may be accommodated by a cap for an injection device or a pen cap, and in some embodiments the needle cannula may further be covered by an inner needle shield. In some embodiments, in the
second mode, the cap may be attached to the cap supporting part, and the cap supporting part may be connected to the foil.

In the third mode, the removable part is attached to the outer cover, by safely covering the first end of the outer cover with the cap. The cap prevents direct access to an accommodated needle, and thereby allows safe disposal. In some embodiments the cap may be irreversibly connected to the outer cover, and thereby prevent access to an accommodated needle.

In some embodiments, in the third mode, the cap may be attached to the cap supporting part, and the cap supporting part may be connected to the foil. This allows for an easy disposal of all the parts of the assembly.

In some embodiments the needle assembly according to the invention comprises a needle unit having a needle cannula, and a needle hub for receiving the needle cannula, and wherein the needle unit is adapted to be accommodated in the outer cover.

In some embodiments the removable part further comprises a foil supporting part having a foil attachment surface being attached to the foil. The foil attachment surface is adapted to ensure a sufficiently large surface to seal off the first end of the outer cover, and the foil may either be welded or glued to the attachment surface.

In some embodiments the outer cover, in the second mode, is adapted to be receivable by an outer cap for an injection device. In the second mode, the removable part comprising the foil supporting part having the attachment surface has been separated from the outer cover, and leaves the outer cover as a smaller structure or a smaller dimension. Due to the requirements to an attachment surface, in order to be adapted to provide a sufficient surface for attaching the foil, the attachment surface and the foil attachment part may increase the outer diameter of the assembly. Therefore, the assembly may not be receivable by an outer cap of an injection device before the removable part and the foil supporting part has been removed.

In some embodiments the foil supporting part may be connected to the outer cover through a weakened structure, which allows the removable part to be separated from the cover along the weakened structure. And in some embodiments the foil supporting part may be a flange or a substantially ring shaped part.
In some embodiments, the invention relates to a needle assembly wherein the outer cover is connected to the foil supporting part defines a first largest outer dimension or diameter \( D \);
- wherein the outer cover separated from the foil supporting part defines a second largest outer dimension or diameter \( d \); and
- wherein the second largest outer dimension or diameter \( d \) is smaller than the first largest outer dimension or diameter \( D \).

In some embodiments, the first largest outer dimension or diameter \( D \) is larger than an inner diameter of an outer cap for an injection device, and wherein the second largest outer diameter \( d \) is smaller than the inner diameter of the cap for the injection device. In some embodiments, the outer cap for an injection device is a pen cap.

In some embodiments, the foil is a peelable foil, which may be made of paper or aluminum.

In another aspect, the invention relates to an injection system comprising an injection device, a cap for the injection device and a needle assembly according to the present invention. The injection device is having a main part with a needle mount and a mount for the cap for the injection device. In some embodiments, the injection device may be an injection pen, and the cap for the injection device may be a pen cap.

In another aspect, the invention relates to a method of handling a needle assembly according to the present invention, wherein the method comprises the steps of:
- separating the removable part from the outer cover;
- taking the needle unit out of the outer cover;
- returning the needle unit to the outer cover;
- attaching the cap of the removable part on the open end of the outer cover, and thereby preparing the needle assembly for safe disposal.

In some embodiments, a needle unit may be disposed of, when it is accommodated in the outer cover in which the needle unit was provided, and using the cap from the same assembly to close the first end of the outer cover.

In another aspect, the invention relates to a method of handling a needle assembly according to the present invention, wherein the method comprises the steps of:
- providing a first needle assembly having a first needle unit, a first outer cover and a first removable part;
- separating the first removable part from the first outer cover
- taking the first needle unit out of the first outer cover,
- returning the first needle unit into the first outer cover;
- providing a second needle assembly having a second removable part;
- attaching the cap of the second removable part on the open end of the first outer cover, and thereby preparing an assembly comprising the first needle unit, the first outer cover, and the cap of the second removable part for safe disposal.

In some embodiments a needle unit may be disposed of, using the outer cover in which it was provided, and using the cap from another assembly to cover the first end of the outer cover. This may in particular be useful, when the outer cover has been used as a needle shield covering a needle unit mounted on an injection device. In this case, the cover from the assembly, in which the needle unit was provided, may already be disposed or may simply be lost due to the duration between opening of the first assembly, and the need for disposing the accommodated needle unit.

In other words, a user may open the needle assembly and dispose the removable part. The user may mount the needle unit and the outer cover on the injection device, and he may further use the injection device with the mounted needle for one or more injections. The user may further accommodate the needle unit and outer cover in a cap for an injection device, and when he decides to mount a new needle unit he uses the outer cover from the "old" needle assembly and the cap from the "new" needle assembly to dispose the "old" needle unit.

In some embodiments the invention relates to a method for handling a needle assembly according to the present invention further comprising the steps of:
- providing an injection device having a main part with a needle mount and a cap for the injection device for covering the needle mount;
- mounting the first needle unit and the first outer cover on the needle mount;
- mounting the cap for the injection device on the main part of the injection device, whereby the cap for the injection device accommodates the first needle unit and the first outer cover;
- returning the first needle unit into the first outer cover;
- providing a second needle assembly having a second removable part;
attaching the cap of the second removable part on the open end of the first outer cover, and thereby preparing an assembly comprising the first needle unit, the first outer cover, and the cap of the second removable part for safe disposal.

In some embodiments the invention further comprising the step of disposing the first removable part.

The order or sequence of handling or activity steps mentioned above may vary from the listed sequence, when it makes sense, i.e., the step "providing a second needle assembly" may be listed and performed before "providing a first needle assembly", but it may, as an example, not make sense to return the needle unit before it is taken out.

**DEFINITIONS:**

An "injection pen" is typically an injection apparatus having an oblong or elongated shape somewhat like a pen for writing. Although such pens usually have a tubular cross-section, they could easily have a different cross-section such as triangular, rectangular or square or any variation around these geometries.

The term "Needle Cannula" is used to describe the actual conduit performing the penetration of the skin during injection. A needle cannula is usually made from a metallic material and connected to a hub to form a complete injection needle also often referred to as a "needle unit". A needle cannula could however also be made from a polymeric material or a glass material. The needle cannula is mounted in a "hub", which also carries the connecting means for connecting the injection needle to a medical device and is usually moulded from a suitable thermoplastic material. The "connecting means" could as examples be a luer coupling, a bayonet coupling, a threaded connection or any combination thereof e.g. a combination as described in EP 1,536,854.

"Cartridge" is the term used to describe the container containing the drug. Cartridges are usually made from glass but could also be moulded from any suitable polymer. A cartridge or ampoule is preferably sealed at one end by a pierceable membrane which can be pierced e.g. by the non-patient end of a needle cannula. The opposite end is typically closed by a plunger or piston made from rubber or a suitable polymer. The plunger or piston can be slidably moved inside the cartridge. The space between the pierceable membrane and the mov-
able plunger holds the drug which is pressed out as the plunger decreased the volume of the space holding the drug. However, any kind of container - rigid or flexible - can be used to contain the drug.

5 **BRIEF DESCRIPTION OF THE DRAWINGS:**

The invention will be explained more fully below in connection with detailed embodiment and with reference to the drawings in which:

10 Fig. 1 Shows an exploded view of a needle assembly according to a first embodiment of the invention.

Fig. 2 Shows an exploded view of a needle assembly according to a second embodiment of the invention.

Fig. 3 Shows a cap to be supported by a cap supporting part.

15 Fig. 4 Shows a needle assembly according to a third embodiment of the invention, wherein the assembly is in a first mode.

Fig. 5 Shows the needle assembly of figure 4 in a second mode.

Fig. 6 Shows the needle assembly of figure 4 in a third mode.

Fig. 7 Illustrates the definition of some important parameters.

The figures are schematic and simplified for clarity, and they just show details, which are essential to the understanding of the invention, while other details are left out. Throughout, the same reference numerals may be used for identical or corresponding parts.

25 **DETAILED DESCRIPTION OF EMBODIMENT:**

When, in the following, terms as "upper" and "lower", "right" and "left", "horizontal" and "vertical", "clockwise" and "counter clockwise" or similar relative expressions are used, these only refer to the appended figures and not 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.

In that context it may be convenient to define that the term "distal end" in the appended figures is meant to refer to the end of the needle cannula penetrating the patient whereas the
term "proximal end" is meant to refer to the opposite end pointing away from the patient in a situation of use.

Fig. 1 shows an exploded view of an embodiment according to the first invention. The figure shows a needle assembly 1 comprising an outer cover 2 adapted to accommodate a needle unit having a hub 3 with a needle cannula 11, and the outer cover 2 is having a first end 7 and a second closed end 8. The needle cannula is having a front needle 12 to penetrate the skin of a patient, and a back needle 13 to establish a fluid connection between the front needle and a drug containing reservoir of an injection device (not shown). The hub 3 is having an internal surface with means for connecting the hub to a needle mount of the injection device, e.g., a thread or bayonet pins to be received by corresponding structures on the needle mount.

Fig. 1 also shows a removable part adapted to be removed during the process of opening the needle assembly, i.e., opening the needle assembly in order to enable access to an accommodated needle. The removable part comprises a foil 4, a cap supporting part 14, and a cap 81 (fig. 3) adapted to be supported by the cap supporting part 14. On fig. 1 the cap supporting part 14 is an integrated handle of the foil. A cap 81 which can be connected to the cap supporting part 14, is shown on fig. 3. The shown cap has a capping surface 82, surrounded by a rim 83 having a lip 84 adapted to engage a structure (not shown) on the outer cover 2. The cap could be connected to the handle on any of its surfaces. It may, however, be preferred to use the back side, which is opposite to the capping surface 82, or an outer surface of the rim 83, as this will ensure that the cap 81 can capture the outer cover 2, without hindrance from the cap supporting part 14.

The needle assembly 1 is adapted to be operated between a first mode, a second mode and a third mode. In the first mode, the foil 4 is attached to the outer cover 2, and the foil 4 is thereby adapted to cover at least a portion of the first end 7 of the outer cover 2. The outer cover 2 may have a foil attachment part 6 to provide a sufficient structure or surface for attaching the foil by e.g. welding. As the foil 4 can be penetrated by a sterilizing agent, the needle assembly and an accommodated needle unit can be sterilized or made aseptic in the first mode. For the embodiment shown in fig. 1 and 3, the cap 81 may be attached to the cap supporting part 14, and the foil 4, according to the shown embodiment, is adapted to cover substantially the entire first end 7 of the outer cover 2. In the first mode, the needle assembly is ready for use and the accommodated needle unit may be in a sterile or aseptic condition.
In the second mode, the removable part and the outer cover 2 are separated from each other, whereby at least a portion of the first end 7 of the outer cover 2 is uncovered. The second mode enables a needle unit to exit from or enter into the outer cover 2. For the embodiment shown in fig. 1 and 3, the assembly is adapted to uncover substantially the entire open end 7, when the outer cover 2 is separated from the removable part 4. In the second mode, the needle assembly has been opened, and the barrier, i.e., the foil, is broken. In this intermediate mode, the needle unit is available for an injection, and may be returned to the outer cover after use, in order to prepare the needle assembly for disposal.

In the third mode, the cap 81 is attached to the outer cover 2 and thereby adapted to cover the first end 7 of the outer cover 2, whereby the third mode enables safe disposal of a needle unit. The cap may further be irreversibly attached to the outer cover, and thereby prevent access to a disposed needle. This feature may be obtained by an inner surface of the rim 83 being slightly and inwardly sloped, which ensures a smooth and reversible insertion of the outer cover 2 into the cap 81, until a structure (not shown) on the outer surface of the outer cover 2 reaches the lip 84. When the structure is inserted further, the lip 84 snaps on to the structure on the outer cover 2, and may produce a tactile or audible signal. The signal may be perceived by the user, and indicates that the cap has been irreversibly attached.

In the second and the third mode the cap 81 may be separated from the cap supporting part 14, but it is considered to be easier to keep track on all the parts, if the cap 81, the cap supporting part 14, and the foil 4 are connected to each other. This ensures that all the parts are disposed in a safe and easy manner.

Fig. 2 and 3 shows another embodiment of a needle assembly according to the invention. The needle assembly 51 comprises an outer cover 52 adapted to accommodate a needle hub 53 with a needle cannula 61. The outer cover is having a first end 57 and a second closed end 58, and a removable part, adapted to be removed during the process of opening the needle assembly. The removable part comprises a foil 54, a cap supporting part 60 or 64, which may be a handle 60 connected to or integrated with a foil supporting part 56, or a handle 64 connected to or integrated with the foil 54. The removable part further comprises a cap 81 (shown on fig. 3) adapted to be supported by the cap supporting part 60 or 64, i.e., in the embodiment shown on fig. 2 the cap 81 may be connected to the handle 60 of the foil supporting part 56, or the handle 64 of the foil 54.
The needle assembly 51 is adapted to be operated between a first mode, a second mode and a third mode. In the first mode, the foil 54 is attached to the foil supporting part 56 of the outer cover 52, and thereby adapted to cover at least a portion of the first end 57 of the outer cover 52. The cap 81 is attached to the cap supporting part 60 or 64.

In the second mode, in which the removable part and the outer cover 52 are separated from each other, whereby at least a portion of the first end 57 of the outer cover 52 is uncovered. The second mode enables a needle unit to exit from or enter into the outer cover 52.

In the third mode, the cap 81 is attached to the outer cover 52 and thereby adapted to cover the first end 57 of the outer cover 52, whereby the third mode enables safe disposal of a needle unit.

Fig. 4-7 shows a needle assembly 101 enabling safe disposal of a needle unit, comprising an outer cover 102 adapted to accommodate a needle unit (not shown). The outer cover is having a first end 107 and a second closed end 108. The assembly further comprises a removable part adapted to be removed during the process of opening the needle assembly, wherein the removable part comprises a foil 104, a cap supporting part 110, a cap 115 adapted to be supported by the cap supporting part 110. In the shown embodiment the cap 115 is integrat-ed with the supporting part 110.

The needle assembly is adapted to be operated between a first, second and a third mode. In the first mode shown on fig. 4, the foil is attached to the outer cover 102, and thereby adapted to cover at least a portion of the first end 107 of the outer cover 102, and the cap 115 is attached to the cap supporting part 110.

In the second mode shown on fig. 5, the removable part and the outer cover 102 are separated from each other, whereby at least a portion of the first end 107 of the outer cover 102 is uncovered, whereby the second mode enables a needle unit to exit from or enter into the outer cover 102.

In the third mode shown on fig. 6, the cap 115 is attached to the outer cover 102 and thereby adapted to cover the first end 107 of the outer cover 102, whereby the third mode enables safe disposal of a needle unit.
For the embodiments shown on fig 2-7 the removable part comprises a foil supporting part 56, 106 having a foil attachment surface 59, 109 being attached to the foil 54, 104, in the first mode. When the needle assembly enters the second mode, the removable part and the outer cover 52, 102 is separated, and the remaining outer cover can be adapted to fit under a cap or cover of an injection device. In this case, the need of an inner needle cap 5 (shown on fig. 1) is eliminated, as the function, of protecting the needle cannula under a cap for an injection device, could be provided by the outer cover.

The needle assembly could more specific be adapted to have a large dimension or appearance in the first mode, where it is ensured that the outer cover 52, 102 has a foil supporting part 56, 106, which enables sufficient support surface for foil attachment during the first mode, and where the outer cover 52, 102 has a smaller dimension in the second mode, which enables the assembly to be received under a cap of an injection device.

Fig. 7 shows an embodiment wherein the outer cover 102 is connected to the foil supporting part in the first mode, and fig. 7 further illustrates the definition of a first largest outer diameter (D). In the second mode, the outer cover separated from the foil supporting part defines a second largest outer diameter (d), which is smaller than the first largest outer diameter (D). In this case it has to be ensured that (D) is large enough to provide sufficient surface for foil attachment, and that (d) is smaller than the inner diameter of a cap for an injection device. The cap for the injection device could, as an example, be a pen cap.

A method according to the invention of handling a needle assembly as described above, in order to insure safe disposal is to separate the removable part from the outer cover, take the needle unit out of the outer cover, wherein it may be used for the purpose of an insulin injection. After the injection, it may be desired to dispose the needle unit, and the needle unit may therefore be returned to the outer cover. Hereafter, the cap of the removable part, may be attached on the open end of the outer cover, and the assembly is now in a mode where it may be safely disposed.

Another method according to the invention, may be to provide a first needle assembly having a first needle unit, a first outer cover and a first removable part. In the following step, the first removable part is separated from the first outer cover, and the first needle unit may be taken out and used for an injection. If the dimension, of the first outer cover is smaller than the in-
ner diameter of the cap of an injection device, it may be desired to dispose the first removable part and use the first outer cover as a needle shield underneath the cap of the injection device. When it is desired to dispose the first needle unit and use a second needle unit, the first needle unit is returned to the first outer cover. Hereafter is provided a second needle assembly, where the cap of the second removable part is used to cover the open end of the first outer cover. The first needle unit is thereby safely accommodated in the first outer cover, and retained therein by the cap of the second removable part. This combined unit is therefore ready for safe disposal, and the second needle unit may be mounted on an injection device an used for future injections. In this way, a safe disposal is provided by the outer cover from the used needle assembly, and the cap from the new needle assembly. However, it may also be possible to dispose the used needle unit in the outer cover from the new needle assembly, and cap with the cap from the new needle assembly. In this case, the outer cover from the old needle assembly could be used as a needle shield, but it may be preferred always to use the outer cover from the new needle assembly due to hygienic and sanitary issues.

Some preferred embodiments have been shown in the foregoing, but it should be stressed that the invention is not limited to these, but may be embodied in other ways within the subject matter defined in the following claims.

****
Claims:

1. A needle assembly (1, 51, 101) enabling safe disposal of a needle unit, comprising:
   - an outer cover (2, 52, 102) adapted to accommodate a needle unit, the outer cover is
     having a first end (7, 57, 107) and a second closed end (8, 58, 108);
   - a removable part adapted to be removed during the process of opening the needle as-
     sembly, wherein the removable part comprises:
     - a foil (4, 54, 104);
     - a cap supporting part (14, 60, 64, 110);
     - a cap (81, 115) adapted to be supported by the cap supporting part (14, 60, 64, 110);
   - wherein the needle assembly (1, 51, 101) is adapted to be operated between:
     - a first mode, where the foil is attached to the outer cover (2, 52, 102), and thereby
       adapted to cover at least a portion of the first end (7, 57, 107) of the outer cover
       (2, 52, 102), and wherein the cap (81, 115) is attached to the cap supporting part
       (14, 60, 64, 110);
     - a second mode, in which the removable part and the outer cover (2, 52, 102) are
       separated from each other, whereby at least a portion of the first end (7, 57, 107)
       of the outer cover (2, 52, 102) is uncovered, whereby the second mode enables a
       needle unit to exit from or enter into the outer cover (2, 52 102); and
     - a third mode, wherein the cap (81, 115) is attached to the outer cover (2, 52, 102)
       and thereby adapted to cover the first end (7, 57, 107) of the outer cover (2, 52, 102),
       whereby the third mode enables safe disposal of a needle unit.

2. A needle assembly according to claim 1 further comprising a needle unit having a needle
   cannula (11, 61), and a needle hub (3, 53) for receiving the needle cannula (11, 61), and
   wherein the needle unit is adapted to be accommodated in the outer cover (2, 52, 102).

3. A needle assembly according to any of the previous claims, wherein the foil (4, 54, 104),
   the cap supporting part (14, 60, 64, 110), and the cap (81, 115) are connected to each
   other.

4. A needle assembly according to any of the previous claims comprising a foil having a
   sterile or aseptic barrier, where the barrier is adapted to allow diffusion of sterilizing
   agents across the barrier.
5. A needle assembly according to any of the previous claims wherein the needle assembly is adapted to enable access to an accommodated needle, when the needle assembly is in the second mode.

6. A needle assembly according to any of the previous claims wherein the removable part further comprises a foil supporting part (56, 106) having a foil attachment surface (59, 109) being attached to the foil (54, 104);

7. A needle assembly according to claim 6, wherein the outer cover (52, 102), when the needle assembly is in the second mode, is adapted to be receivable by an outer cap for an injection device.

8. A needle assembly according to any of the claims 6-7,

- wherein the outer cover (52, 102) is connected to the foil supporting part defines a first largest outer diameter (D);
- wherein the outer cover separated from the foil supporting part defines a second largest outer diameter (d); and
- wherein the second largest outer diameter (d) is smaller than the first largest outer diameter (D).

9. A needle assembly according to claim 7 wherein the first largest outer diameter (D) is larger than an inner diameter (d) of an outer cap for an injection device, and wherein the second largest outer diameter is smaller than the inner diameter of the cap for the injection device.

10. A needle assembly according to any of claims 7 and 9 wherein the outer cap for an injection device is a pen cap.

11. A needle assembly according to any of the preceding claims where the foil (4, 54, 104) is a peelable foil.

12. A method of handling a needle assembly according to any of the preceding claims, wherein the method comprises the steps of:

- separating the removable part from the outer cover;
- taking the needle unit out of the outer cover;
- returning the needle unit to the outer cover;
- attaching the cap of the removable part on the open end of the outer cover, and thereby preparing the needle assembly for safe disposal.

13. A method of handling a needle assembly according to any of claims 1-11, the method comprises the steps of:
- providing a first needle assembly having a first needle unit, a first outer cover and a first removable part;
- separating the first removable part from the first outer cover
- taking the first needle unit out of the first outer cover,
- returning the first needle unit into the first outer cover;
- providing a second needle assembly having a second removable part;
- attaching the cap of the second removable part on the open end of the first outer cover, and thereby preparing an assembly comprising the first needle unit, the first outer cover, and the cap of the second removable part for safe disposal.

14. A method according to claim 9 for handling a needle assembly according to claims 1-11 and an injection device, the method further comprises the steps of:
- providing an injection device having a main part with a needle mount and a cap for the injection device for covering the needle mount;
- mounting the first needle unit and the first outer cover on the needle mount;
- mounting the cap for the injection device on the main part of the injection device, whereby the cap for the injection device accommodates the needle unit and the outer cover.

15. A method according to claims 12-14 further comprising the step of disposing the first removable part.
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<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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<th>X</th>
<th>Further documents are listed in the continuation of Box C.</th>
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Date of the actual completion of the international search
15 January 2016

Date of mailing of the international search report
25/01/2016

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Nei ller, Frederi c
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