
Agent: SEAGER, Glenn, M.; Crompton Seager & Tufte LLC, 1221 Nicollet Avenue, Suite 800, Minneapolis, Minnesota 55403 (US).


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**Title:** SHARPS CONTAINER FOR "NO-TOUCH," SEQUENTIAL SAFE STORAGE OF USED PEN NEEDLES

**Abstract:** A sharps container for safe reception and storage of used pen needles and used medical syringes may comprise a housing which supports a rotatable member. A used pen needle receiving and ejecting apparatus may be connected to the rotatable member. Used pen needles may be inserted into the receiving apparatus. As the receiving and ejecting apparatus is rotated, a cam follower connected to the ejecting apparatus may engage a cam within the housing to cause the ejection of the used pen needle from the receiving apparatus into the housing. The rotatable member may also have an elongated recess sized to receive a medical syringe. Manual rotation of the rotatable member may rotate the elongated recess to drop the medical syringe into the housing.
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SHARPS CONTAINER FOR "NO-TOUCH," SEQUENTIAL SAFE STORAGE OF USED PEN NEEDLES

BACKGROUND AND FIELD OF THE INVENTION

[0001] This invention relates generally to a "sharps" container for both used pen needles (sometimes hereafter referred to as "PNs") and used medical syringes (sometimes hereafter referred to as "MSs") and specifically to a sharps container for used PNs which provides the safe (no-touch) sequential feeding or insertion of used PNs into the container for safe storage therein. Pen needles are initially received by the user in the form of a pen needle assembly ("PNA"). The invention, importantly, also provides for safe, convenient transportation of a plurality of unused pen needle assemblies (PNAs) within the same sharps container (but hygienically isolated from the used PNs) and for dispensing said unused PNAs from the sharps container.

[0002] Because of well known health issues, the safe disposal of "sharps" such as used pen needles, pen needle assemblies, and syringes has long been a high priority for medical related professional facilities and industries. Prior art sharps containers are found in public venues such as hospitals, medical clinics, and retail establishments. These containers are usually securely attached to some base means and have a lock means to permit controlled and safe removal of used "sharps."

[0003] There are also prior art "portable" sharps containers for syringes, examples being U.S. Patents 5,494,158 and 6,685,017 showing sharps containers which necessarily are large because of the size of the elongated syringes.

[0004] Medical delivery pens (hereinafter sometimes "MDPs") have, more recently, become widely used instead of or in addition to syringes, e.g., by diabetics, who frequently inject themselves several times a day with accurately measured, adjustable, pre-selected amounts of insulin or other medication. Medical delivery pens include a reservoir of medication and a distal end adapted to be attached (usually by thread means) to a pen needle assembly (PNA). As is well known (see, for example Figure 1 of U.S. Patent 5,545,145), the pen needle assembly has (within an outer, generally cylindrical shield 28) a generally cylindrical housing 26 within which is mounted an axially extending hollow needle 21, (i) the proximal end 24 of which punctures a seal in the distal end 16 of the medical delivery pen 10 (to allow
the flow there-through of medication) when the delivery pen is screwed into the proximal end of the pen needle cylindrical housing 26, and (ii) the distal end 22 of which is for insertion into tissue of the person requiring the medication. The pen needle assemblies typically include a removable thin sterile seal covering the proximal (large diameter) end of the said outer shield and a removable tube-like shield covering the distal portion of the hollow needle. The assembled pen needle assembly is then factory sterilized. The user of a pen needle assembly removes the seal from the outer shield, screws the pen into the proximal end of the pen needle housing, removes the outer and tube-like shields, sets the medical delivery pen for the desired dose of medication, and then inserts the distal end of the pen needle into the target tissue following which the medical delivery pen is actuated to deliver the desired dose of medication through the hollow needle into said tissue.

[0005] Many diabetics routinely administer medication to themselves several times a day by injection of a pre-selected quantity of insulin (or substitute medication) in liquid form; the correct amount of medication can be determined from prior professional medical instruction or by use of convenient portable blood analysis kits which are small, compact and provide rapid indicators of the user’s blood sugar level. The several daily injections are often done away from the diabetic’s home or residence which has made the use of the portable, convenient medical delivery pens widespread. The aforesaid testing kits and the medical delivery pens are relatively small in size and can easily fit within a woman’s purse or equivalent. A typical scenario for a diabetic at a restaurant for a meal is to first use the blood sugar testing kit to obtain an indicator of his or her blood sugar level. This information then facilitates programming or adjusting the medical delivery pen to deliver the desired quantity of medication. Then the pen with an attached PN (a PNA sans the outer protective shield) is used to inject the medication. These steps require a relatively short length of time and can be done with minimum loss of privacy.

[0006] Some people requiring multiple daily medicine injections use both medical syringes and medical delivery pens (MDPs) with PNs. For example, a diabetic may use a medical syringe (with a pre-selected amount of medication) at the beginning of the day and then shift to MDPs for subsequent injections that day because of convenience for use outside of their residence and also some users
feel less discomfort from a PN injection as compared to that from a syringe needle-type injection.

[0007] MDPs are also widely used by doctors, nurses and other professionals in their duties. Many individuals will request (sometimes insist) that an injection be done with a pen needle rather than a syringe. The aforementioned professionals are especially mindful of possible dangers from a needle stick and the possible unwanted "sticks" that occur in the professional world.

[0008] In a perfect world, the user (both individual and professional) of a pen needle assembly would, after the first use of a pen needle, carefully detach the used PN from the medical delivery pen and safely dispose said PN. The approved disposal procedure is (i) insertion of the distal end of the needle into the tube-like shield (sometimes omitted) and thence the shielded needle and PN cylindrical housing into the outer shield, (ii) unscrewing of the medical delivery pen from the proximal end of the pen needle cylindrical housing, and (iii) careful placement of the used pen needle assembly into a safe sharps container. Further, in the "perfect" world, the user of a medical syringe would safely dispose the used syringe into a safe sharps container. Alas, the recommended procedure is not always followed. Used (and potentially dangerous) PNs or PNAs are routinely left in unsafe places where third parties may unwittingly be "stuck." Examples of such unsafe places are purses, the pockets on the back of aircraft seats, private and public wastebaskets, garbage cans, dumpsters and empty milk or other unsafe containers.

[0009] Further, the above described disposal procedure requires that the user (or associate) handle or hold the PN while the pen is unscrewed therefrom; this creates the possibility of a potentially dangerous "stick". Also, if the user (or associate) tries to insert the PN into the outer shield to form a PNA, then additional handling is again required with the possibility of a "stick".

[0010] One prior art example of a container for unused and used pen needle assemblies is U.S. 5,545,145 which shows a tube containing a small number of unused pen needle assemblies arranged in axial alignment. This patent also teaches that, as unused assemblies are removed from one end of the tube, then a used assembly may be inserted into the tube from the other end. The tube is adapted to be attached to the side of a medical delivery pen. This arrangement has significant shortcomings. The capacity is quite limited and, potentially
dangerous "sticks" could occur when a user (or associate) tries to insert a used PN (with or without the protective outer shield) into the used end of the tube.

[0011] The present invention provides a unique sharps container having (i) a totally "no-touch" means for a user of a PNA to transfer a used PN from a pen into the container for safe storage therein without, as indicated, any touching of the used PN by the user, and (ii) a companion means for the safe storage of used medical syringes in the container.

SUMMARY OF THE INVENTION

[0012] This invention may provide a unique sharps container for (i) safe manual, sequential disposing of used PNs into the container for safe storage therein, (ii) safe storage of used medical syringes in the same container using the same rotatable means which is used for the PN disposal, (iii) hygienically separate safe transportation and storage of unused PNAAs within the same unique container and (iv) means for controlled dispensing of said unused PNAAs via an exit opening in said container. Additionally certain embodiments of our invention may provide for sharps containers which, in addition to the function of safe storage of used PNs, may have means for safe dispensing of bulk quantities of unused PNAAs; this is a function which has special applicability in clinics and the like where large numbers of unused PNAAs are required for daily requirements.

[0013] The illustrative container may have a housing means with an internal storage space sized to hold a plurality of used PNs and used medical syringes. A used PN receiving and ejecting means may be provided within the housing and may include (i) rotatable means connected to the housing for rotation about an axis, (ii) an ejector assembly connected to the rotatable means (to rotate therewith about the axis) and including a cam follower means, and (iii) cam means on the housing positioned to contact and actuate the cam follower means upon rotation of the rotatable means, the "actuation" of the cam follower means may cause the "ejection" of the PN into the container. Used medical syringes may be stored in the same container, being disposed therein by means including the same rotatable means used for used PN disposal.

[0014] The invention may also provide a sharps container which may be especially useful for an individual such as a diabetic who may require several daily doses of medication, which doses are required throughout the day (frequently at
meal time) and thus may occur at the user's residence but may often be at other locations such as the user's place of work, at a restaurant, in an automobile or aircraft, etc. Thus, the container may have a convenient supply of unused PNA to be used as required as well as the aforementioned means for the safe disposal of used PNs. Several different arrangements are shown for the storage and dispensing of unused PNA. The container may conveniently be relatively compact and sized to fit within a woman's purse or equivalent. Alternately, the container may be sized larger to facilitate the storage therein of a large number of unused PNA and, further, may be structured to dispense unused PNA either sequentially or in bulk. The container provided by this invention may facilitate disposal of both used PNs and used medical syringes, regard being given to some diabetics daily use of both types of apparatus.

**BRIEF DESCRIPTION OF THE DRAWINGS**

[0015] Figure 1 is a top, side isometric view of the preferred embodiment of a PN sharps container provided by the invention.

[0016] Figure 2 is a side view, partly in section, of the container of Figure 1.

[0017] Figure 3 is an enlarged view of that part of the top 12A of the housing that includes a port or opening 13 as shown in Figure 2 and as viewed along section lines 3-3 thereof.

[0018] Figure 4 is an enlarged view of the ejector means 30 shown in Figure 2 as viewed along section lines 4-4 thereof and including a pen needle 50 positioned in the ejector means 30.

[0019] Figure 5A is a cross-section view of the ejector means 30 as viewed along section lines 5A-5A of Figure 4, this view showing the pen needle 50.

[0020] Figure 5B is a cross-section view of the ejector means 30 as viewed along section lines 5B-5B of Figure 4 but with the pen needle 50 removed to enable the showing of ribs 35 of the ejector means 30.

[0021] Figures 6 and 7 are somewhat schematic views of the housing and the ejector means showing the ejector means in two orientations when rotated about the axis by the manually rotatable means.

[0022] Figure 8 is a cross-section view of the rotatable means as viewed along section lines 8-8 of Figure 2.
Figure 9 is a top, side isometric view of the preferred embodiment of the sharps container provided by our invention; this view shows the rotatable means 220 oriented to receive a used PN 250.

Figure 10 is an isometric view of the same container shown in Figure 9 with the rotatable means 220 oriented to receive a used medical syringe 260.

Figure 11 is a cross-sectional view of the rotatable means.

Figure 12 is a cross-sectional view of the rotatable means as viewed along section lines 4-4 of Figure 11; this view shows a used pen needle 250 positioned in the pen needle ejector assembly.

Figure 12A is a view very similar to Figure 12 except showing the rotatable means rotated clockwise so that cam means within the housing has actuated cam follower means of the ejector member to eject a PN into the container.

Figure 13 is an isometric view of the rotatable means.

Figure 14 is a cross-sectional view of the pen needle ejector assembly (with the elongated ejector member axially displaced to the left of the elongated means) as viewed along section lines 6-6 of Figure 12.

Figure 15 is a top, side isometric view of a preferred embodiment of a PN sharps container provided by the invention.

Figure 16A is a view of a plurality of PNAs connected to a flexible tape and coiled in an unused PNA storage compartment in the container of Figure 15 as viewed along section lines 2-2 thereof.

Figure 16B is a view similar to that of Figure 16A (but for an alternate preferred embodiment of the invention) with a plurality of unused PNAs attached to a tape means but oriented 90 degrees from the orientation of the PNAs in Figure 16A.

Figure 16C is a cross-sectional view of Figure 16B as viewed along section lines 2C-2C thereof.

Figure 17 is a plan view of the tape means 359 used with the PNAs depicted in Figure 16A.

Figure 18 is a plan view of the tape means 369 used with the PNAs depicted in Figure 16B.

Figures 19, 20, and 21 show, respectively, our invention with alternate means in the bottom portion of the housing means for the storage and dispensing of unused PNAs.
Figure 19A is a cross-sectional view of a bin means for dispensing unused PNAs as viewed along section lines 5A-5A of Figure 19.

Figure 20A is a cross-sectional view of a drawer means 380 for dispensing unused PNAs as viewed along section lines 6A-6A of Figure 20.

Figure 21A is a cross-sectional view of the unused PNA storage and dispensing means of the sharps container AA-3.

**DETAILED DESCRIPTION OF THE INVENTION**

In Figure 1 an illustrative sharps container AA may provide a means for the safe, i.e., "no direct human touching" storage of used pen needles. The container AA may comprise a housing 10 which may have a bottom or storage section 11 and an upper or cover section 12 which may fit together as is shown clearly in Figures 2, 6 and 7 to define an internal storage space sized to facilitate the safe storage of a plurality of used pen needles. Thus section 11 may have sides and a bottom surface 11A for receiving the used pen needles and a top edge 11B with a rim 11'. Cover section 12, as viewed in Figures 6 and 7 may have a curved shape about an axis. The top 12A of the cover section 12 may have an opening 13 sized to permit the axial insertion therethrough of a used pen needle PN also identified in the drawings by reference numeral 50. The bottom edge 12B of the cover section 12 may have an inwardly extending latch portion which co-acts with rim 11' to provide a locking means for sections 11 and 12. Section 12 may have two planar ends 12' and 12'' shown best in Figure 2.

Figure 1 shows, in phantom, a medical delivery pen (MDP) of the well known types currently used having at the distal end thereof male thread means for attachment to female threads in the proximal end of a pen needle 50. It should be understood that pen needle 50 shown in Figure 1 may have already been used and the user may desire to safely remove the used pen needle from the pen and thence place the used pen needle into safe storage means. The pen needle 50 may have a cylindrical surface 51 with a pre-selected outer diameter. The cylindrical surface 51 may also have a plurality of longitudinally extending shallow grooves 54 (see Figures 1, 2 and 4) which co-act with ribs 35 of the pen needle receiving and ejecting assembly 30, described below, to hold the pen needle against rotation about its longitudinal axis when the user unscrews the pen therefrom.
[0042] A rotatable means, which may be manually rotatable, may comprise an external knob 14 with connected shafts 15’ and 15” and a central collar 16 rotably supported by bearing means 12C and 12D in ends 12’ and 12” respectively of the housing for rotation, relative to the housing, about a rotational axis RA. The collar 16 may have a central bore sized to receive and firmly hold the ejector assembly 30 and additionally may have means 16A and 16B for attachment thereto of the inboard ends of shafts 15’ and 15”. Shaft 15’ may have a bore 15A with a square cross-section for receiving a square cross-section shaft 14 A connected to external knob 14. Thus rotation of the knob 14 may rotate the ejector assembly 30 about the rotational axis RA.

[0043] The ejector assembly 30, for this embodiment, is shown to comprise an elongated tubular member 31 having two ends, an upper end 31’ and a lower end 31”’. The upper end 31’ per se is best shown in Figure 5B and may comprise a bore 33 sized to receive the aforesaid pre-selected outer cylindrical surface 51 of used pen needle 50. Bore 33 may axially extend from end 31’ a pre-selected distance terminating with an inwardly extending shoulder means 34’. A plurality of axially extending ribs 35 may be integral with tubular member 31 and may extend radially inward from the sides of the bore 33 a sufficient amount so as to engage the shallow grooves 54 of the pen needle 50 to provide the above described holding function.

[0044] The remaining bore of tubular member 31 may be identified by reference numeral 32; thus bores 32 and 33 together may have a pre-selected axial length, the two ends of which are defined by the ends 31’ and 31”’ of the tubular member 31. Importantly, the ends 31’ and 31”’ may be approximately equidistant from the rotational axis RA. Further, the total axial length of the tubular member 31 may be pre-selected, regard being given to the size of the housing 10, so that it may be rotated about the rotational axis RA without contacting the inside surface 12AA of the housing but yet have the end 31’ (for the used pen needle receiving function) adjacent to opening 13 of the housing.

[0045] An elongated ejector means 40 may have a pre-selected axial length and a cylindrical shape 40’ sized to snugly, but slidably fit within bores 32 and 33 (for relative axial movement therewith) is shown in Figures 2, 5A, 5B, 6 and 7. At the top of a first end 40A (as shown in Figure 5A) of the ejector means
40, a longitudinally extending bore 40'' may be provided which extends to an end surface 40''' which is adjacent to the bottom or second end 40B. End 40B may be curved to provide a cam follower surface. It is important to note that end 40B normally extends a pre-selected distance beyond the end 31'' of tubular member 31; this is shown in Figure 5A.

The ejector means 40 may include an integral pair of latch arms 41 and 42 having, respectively, latch means 41' and 42' for engagement with shoulder means 34'; this may provide a holding function to prevent the ejector means 40 from being moved axially out of the tubular member 31 (downward as shown in Figure 5A). However, as described below, the entire ejector means 40 may be, during the used pen needle ejection phase, moved upwardly (as shown in Figure 5A) by the camming action of cam follower 40B contacting the cam surface 12AA on the inside of housing 10. Figure 7 shows the ejector means 40 at its maximum axial displacement relative to the tubular member 31. Such upward, axial motion of the ejector means relative to the member 31, while sufficient to eject the used pen needle, may be limited by a stop means 40AA (on ejector means 40) abutting against an internal shoulder 31AA of member 31.

Figure 5A shows the used pen needle 50 positioned in the recessed bore 33 with the cylindrical surface 51 and associated grooves 54 in firm engagement with bore 33 and its associated ribs 35. Referring to Figure 5B, it may be seen that the ribs 35 may be slightly tapered from top 35' to bottom 35''; this taper function of ribs 35 in combination with reverse tapers of the grooves 54 on the cylindrical surface 51 of the used pen needle may facilitate the aforesaid firm holding of the pen needle. To explain further, when the pen user inserts the pen needle 50 through the opening 13 of the housing and thence into the recessed bore 33, there may be enough axially force applied by the user via the pen to the pen needle to firmly engage the pen needle to the member 31 following which the user may unscrew the pen from the pen needle. Figure 5A also shows the radial wall 52 of the pen needle, and the centrally positioned, axially extending hollow needle 53 having a proximal end 53' and a distal end 53''. The bore 40'' may be axially sized to accommodate all expected lengths of needles.
Referring to Figure 6, it is seen that the used pen needle receiving and ejecting means 30 may be oriented about the rotational axis RA so that the end 31 may be adjacent to and aligned with the opening 13 of the housing 12. It should be understood, for this explanation, that a used pen needle may already be positioned within bore 33 as aforesaid. In this view, the cam follower 40B is shown extending out end 31' of tubular member 31. To eject the pen needle, the knob 14 may be rotated clockwise as shown in Figure 6; this rotation continues to the orientation shown in Figure 7. Beginning prior to this point the cam follower 40B may have had initial contact with the inside curved surface 12AA of the housing. As the clockwise rotation continues the cam follower (and the entire ejector means 40) may be subjected to an axial force tending to move the ejector means 40 in the axial direction toward end 31'. The end result may be that the used pen needle 50 may be ejected out of the bore 33 into the bottom of the housing as is shown in Figure 7. Note in Figure 7 that the end 40A of the ejector 40 may be co-planar with end 31' of tubular member 31. The magnitude of the axial force applied to the used pen needle 50 during the ejection may be a function of the level of co-action between the ribs 35 and grooves 54; the force may vary to impart a range of velocities to the ejected pen needle. In all cases, the invention may provide for the safe storage of the used pen needles; the ejection velocity of the used pen needle may be irrelevant because they are confined within the housing.

The apparatus may then be available to safely dispose of additional used pen needle assemblies. The user may rotate the knob 14 to an angular position as shown in Figures 1 and 6 whereat the next used pen needle (on the end of a pen) may be inserted, via opening 13, into the bore 33.

It will be understood that the pen user does not have to touch the used pen needle either to (i) remove the used pen needle from the pen, or (ii) dispose the used pen needle into a safe storage means.

In Figure 9 an illustrative multi-function sharps container 200AA may provide a single apparatus for both the safe, i.e., "no direct human touching" storage of used pen needles and for the safe storage of medical syringes. The container 200AA may comprise a housing 210 which may include a first portion and a second portion, which may be a bottom or storage section 211 and an upper or cover section 212 which may fit, and lock, together as is shown clearly in
Figures 9, 10 and 12A to define an internal storage space sized to facilitate the safe storage of a plurality of used pen needles and medical syringes. Thus section 211 may have sides and a bottom surface 211’ defining a cup-like means for receiving used pen needles and medical syringes and a top edge with a rim 211A having an outward extending shoulder. Cover section 212 may have a longitudinally extending curved cross sectional shape shown in Figures 9, 10, 12 and 12A. The top of cover section 212 may have a longitudinally extending opening defined by laterally spaced-apart sides 212B’ and 212C’, the spacing being pre-selected to admit an axially oriented medical syringe 260 as is depicted in Figure 10.

Importantly, Cover 212 may include an internal partition 212AA having a cam surface means 212AA’ (see Figures 12 and 12A); the cam surface means 212AA’ may be positioned for an initial contact with cam follower means 240C (described below) as the rotatable means 220 is rotated and, after additional rotation thereof, cause the ejection of a PN into the container. Cover 212 may have a lower, inward extending rim 212A adapted to coact with said shoulder on rim 211A of section 211 to lock the sections 211 and 212 together as shown in Figure 12A.

Cover 212 also has opposed end portions 212D/212F and 212E/212E’ for rotatably supporting a rotatable means 220 for rotation about a rotational axis RA. The rotatable means 220 may comprise an elongated cylindrically shaped member (see, in particular, Figure 13) having a central hollow core 221 connected at the ends thereof to bearing elements 220A and 225. Bearing element 220A may be supported by cover end portions 212E/212E’ and bearing element 225 may be supported by cover end portions 212D/212F. Bearing element 225 may further serve as a means for rotating the rotatable means; it has a circular, longitudinally extending outer rim 225’ and a cross rib 226 adapted for engagement by the fingers of a human user for manual rotation of the rotatable means 220.

Integrally connected to the hollow core 221 may be three axially aligned sets of fan shaped segments 222/222’, 223/223’ and 224/224’ (see Figures 11, 12 and 13). The segments may be axially aligned as best shown in Figure 13. Each segment in said set of segments may have exterior curved surfaces concentric with core 221 and extending circumferentially approximately 90
degrees; Figure 12 shows the opposed curved surfaces 223 and 223'. The rotatable means 220 may further include a pair or opposed, longitudinally extending used syringe receiving means SRM-1 and SRM-2 (see Figures 12 and 12A) defined by inwardly extending curved surfaces of segments 222/222', 223/223' and 224/224'; for example Figure 12 identifies curved surfaces (i) 223A and 223A' and (ii) 223B and 223B' for defining the center (of three) portions of SRM-2 and SRM-1 respectively.

The curved exterior surface of segment 223 may have an opening 233 (Figures 9 and 14) for admitting the axial insertion of a PN 250 into a pen needle receiving and holding recess 231A described in more detail below. The curved exterior surface of segment 223' may have an opening 235 sized to admit the relative axial movement of the cam follower end of an ejector member 240. Openings 233 and 235 may define an ejector axis EA (see Figures 9 and 14). The ejector assembly may further comprise, in part, a pair of axially aligned tubular elements 231 and 232 positioned along the ejector axis EA and connected to and radially extending from core 221 on opposite sides thereof as shown in Figures 12 and 14. Core 221 may have a pair of aligned, opposed longitudinally elongated slots 221" and 221"" through which spaced-apart legs 241 and 242 on one end of the ejector member 240 may be inserted to form the assembly shown in Figures 12 and 12A. The ejector member 240 may further have a rounded cam follower surface 240C at the other end thereof. The total axial length of ejector member 240 may be pre-selected so that the axial ends 241' and 242' of legs 241 and 242 may be initially in abutting contact with the radially extending portion of a pen needle positioned in pen needle receiving means 231A in the outboard end of tubular element 231 as is shown in Figure 12; concurrently the cam follower surface 240C may initially extend beyond the surface 223' a pre-selected amount as also is shown in Figure 12. The legs 241 and 242 may have latch means 241" and 242" respectively which, after insertion of the legs through slots 221" and 221"", coact with shoulder means 231' at the inner end of tubular element 231 to hold member 240 in assembled relation with member 220.

Pen needle receiving means 231A may include a plurality of inwardly extending ribs 234 for gripping an inserted PN and preventing rotation of the PN about the ejector axis EA.
Figure 9 shows, in phantom, a medical delivery pen (MDP) of the well known types currently used having at the distal end thereof male thread means for attachment to female threads in the proximal end of a pen needle 250. It should be understood that pen needle 250 shown in Figure 9 may have already been used and the user desires to safely remove the used pen needle from the pen and thence place the used pen needle into safe storage means. The pen needle 250 may have a cylindrical surface 251 with a pre-selected outer diameter. The cylindrical surface 251 may also have a plurality of longitudinally extending shallow grooves 254 which co-act with ribs 234 of the pen needle receiving recess 231A to hold the pen needle against rotation about its longitudinal axis when the user unscrews the MDP therefrom.

To safely dispose and store a used PN, the user may hold the MDP to axially guide the attached PN 250 through opening 233 of the rotatable means 220 into recess 231A of the pen needle receiving and ejecting means, the coacting ribs 234 and shallow slots 254 preventing rotation of the PN about the ejector axis EA to thus facilitate the manual unscrewing of the MDP from the PN. Figure 12 shows a PN in recess 231A, the rotatable means 220 may have been rotated 90 degrees clockwise following the insertion of the PN into the recess. At this orientation the rounded cam follower end 240C may be approaching the housing cam means 212 AA'; continued clockwise rotation of the rotatable means 220 brings end 240C into contact with cam means 212 AA' to initiate axial movement of the ejector member 240 along the ejector axis EA to the right as shown in Figure 12, said axial movement being transferred by the end surfaces 241' and 242' of member 240 to the PN. As the clockwise rotation continues to the position shown in Figure 12A the ejector member 240 may have moved axially sufficiently to eject the PN into the container as is also depicted in Figure 12A.

Additional used pen needles may be sequentially safely disposed and stored by following the same procedure. The rotatable means 220 may be oriented with the opening 233 in the position shown in Figure 9.

To safely dispose and store a medical syringe, the rotatable means 220 may be oriented with one of the syringe receiving means SRM-1 or SRM-2 in the position shown in Figure 12, i.e. with a SRM in register with the cover opening defined by cover edges 212B' and 212C'. Then, as depicted in Figure
10, the used syringe 260 may be placed into the SRM. Next the rotatable means 220 may be rotated manually either direction sufficiently for the used syringe to fall away and down into the storage area of the section 211 of the container. Figure 12A depicts the clockwise rotation of the rotatable means 220 carrying a used syringe 260A positioned in SRM-1; continued clockwise rotation may discharge the syringe into section 211 of the container.

[0061] Thus the user of medical syringes and pen needles may have a single container for the safe disposal and storage of both sharps after the use thereof. It will be understood that the pen user does not have to touch the used pen needle either to (i) remove the used pen needle from the pen, or (ii) dispose the used pen needle into a safe storage means. The medical syringe receiving and disposal means provided by our invention may increase the safety for the user.

[0062] The syringe receiving means SRM-1 and SRM-2 may, besides the specifically described function of receiving medical syringes (MSs), may also be used to receive used pen needle assemblies (PNAs) for disposal into the container.

[0063] Figure 15 shows an illustrative sharps container 300AA having a means for the safe, i.e., "no direct human touching" storage of used pen needles. The container may comprise a housing 310 having a first or bottom storage and dispensing portion 311 and a second or upper cover portion 312 which fit together as shown. The first portion 311 is, in turn, divided into two parallel oriented portions 311A and 311B by a partition 311AA integral with portion 311 and positioned to facilitate (i) the safe storage of a plurality of used PNs and (ii) the safe storage and dispensing of unused PNAs as is shown in Figure 15.

[0064] Cover portion 312 of the housing means 310 may have a curved shape about a rotational axis RA. The top of the cover 312 may have an opening 313 sized to permit the axial insertion therethrough of a used pen needle PN identified in the drawings by reference numeral 350.

[0065] Figure 15 also shows, in phantom, a medical delivery pen (MDP) which is representative of the well known types currently used and having at the distal end thereof male thread means for attachment to female threads in the proximal end of a pen needle 350. It should be assumed that pen needle 350 shown in Figure 15 may have already been used and the user desires to safely remove the used pen needle from the pen and thence place the used pen needle
into safe storage means. The pen needle 350 may have a cylindrical surface 351 with a pre-selected outer diameter. The cylindrical surface may also have a plurality of longitudinally extending shallow grooves 354 which co-act with radially extending ribs of a used pen needle receiving and ejecting assembly 330 to hold the pen needle against rotation about its longitudinal axis when the user unscrews the MDP therefrom. Set forth below is a summary of the details and functions of the used pen needle receiving and ejecting assembly.

[0066] A rotatable means may comprise an external knob 314 with connected shafts 315' and 315'' and a central collar 316 rotatably supported by bearing means in end walls of the housing cover 312 section for rotation, relative to the housing, about a rotational axis RA. The collar 316 may have a central bore sized to receive and firmly hold the used pen needle receiving and ejector assembly 330 and additionally may have means for attachment thereto of the inboard ends of shafts 315' and 315''. Thus rotation of the knob 314 will rotate the ejector assembly 330 about the rotational axis RA.

[0067] The ejector assembly 330, for this illustrative embodiment, is shown to comprise a first member or elongated tubular member having first and second ends. The total axial length of the elongated tubular member may be pre-selected, regard being given to the dimensions of the cover section 312, so that the tubular member may be rotated about the rotational axis without contacting the inside surface 312 of the housing but yet have the used pen needle receiving end thereof sufficiently adjacent to the opening 313 to provide the used pen needle receiving function.

[0068] An elongated ejector means may have a pre-selected axial length and a cylindrical shape sized to slidably fit within the elongated tubular member for relative axial movement therewith; a rounded cam follower end 340C of the ejector means being shown in Figure 15. It is important to note that end 340C of the ejector means may normally, i.e. initially, extends a pre-selected distance beyond one end of the tubular member as is shown in Figure 19A. The terms "normally" and "initially" may cover the case when the cam follower end 340C is not in contact with its co-acting cam means. The co-acting cam means may be positioned within and fixed to the cover section 312 and may, in fact, be the inside curved surface of cover section 312.
Thus, rotation of the knob 314 (and thus the entire used pen needle receiving and ejecting means 330) may cause contact by the cam follower 340C with the aforesaid cam means to force the ejector means axially within the elongated tubular means to push, i.e. eject a used pen needle out from its received position into the used pen needle storage portion 311A.

It will be understood that the pen user may not have to touch the used pen needle either to (i) remove the used pen needle from the pen, or (ii) dispose the used pen needle into a safe storage means.

The illustrative unused PNA storage and dispensing portion 311B of the housing is shown in several, alternate configurations. The first is shown in Figure 16A. One of the side walls 311' of storage section 311B may include an exit opening 311'B' and an internal side wall 311BB to permit withdrawal of unused PNAs 360, 361, 362......360N attached to a flexible tape means 359 by being positioned in serial, spaced apart holes 359' in the tape as is shown in Figure 17. Figure 16A shows clearly the PNAs within the storage space, coiled around side wall 311BB, and exiting at opening 311B'. Figure 15 also shows the tape 359 with connected PNAs 360 et seq. available, upon demand, to the MDP user at exit opening 311B'; the user of the unused PNAs may pull on the end of the tape 359 to receive the desired number of unused PNAs.

An alternate unused PNA storage and dispensing configuration 311B is shown in Figures 16B and 16C. Again, a side wall 311' may have an exit opening 311'B'. Within the storage and dispensing portion 311B may be (i) a pair of angled interior walls CC' positioned in the corners as shown and (ii) a spiraled guide means DD having a first end DD' attached to a side 311 of the portion and a second end DD'' generally centrally positioned in the portion. A plurality of unused PNAs (370, 371, 372, 373......370N) may be depicted connected in a serial, spaced-apart configuration to a tape 369. The tape 369 with attached PNAs may be configured in a coil and is shown following the spiral guide means DD. The PNAs may be attached to the tape 369 by suitable means such as an adhesive, the cylindrical sides of the PNAs may be the zone of attachment to the tape. The spiral guide means DD thus facilitates the loading and dispensing of unused PNAs into and out of the storage space.

Other configurations for the storage and dispensing the unused PNAs also may be used. The configuration depicted in Figures 16B and 16C may have an
advantage of an increased number of PNAs being storable in a given container footprint as compared to that of Figure 16A.

[0074] It will be noted that the configurations depicted in Figures 15-16C may be especially useful in the sequential dispensing of unused PNAs, the user may pull out only the next available PNA. However, the user may pull out several PNAs if that were desired.

[0075] The following embodiments of our invention facilitate the simultaneous safe dispensing of a plurality of unused PNAs from the sharps container; for some applications such as use in a clinic, this function may be very desirable.

[0076] Figure 19 shows a sharps container 300AA-1 which may be very similar to container 300AA shown in Figure 15; it may have the same used PN receiving, ejecting and storage means as container 300AA. However, the unused PNA storage and dispensing means may be different; it may be configured to facilitate the dispensing of more than one unused PNA at the same time, i.e., a means to provide unused PNAs in bulk quantities.

[0077] Thus container 300AA-1 may have a housing means with partition 311AA separating used PN storage portion 311A from unused PNA storage and dispensing portion 311B. An exit opening 311S at the left side of portion 311B (as viewed in Figure 19) may be provided, within which may be a bin-like member 370 that may be rotatably positioned. Bin member 370 may have (i) two angularly-displaced-apart longitudinally extending surfaces 370a and 370b, joined at 370AA to form a V-shaped cross section as is shown in Figure 19A and (ii) end surfaces means 370c and 370d to form a unitary pocket means sized to hold a plurality of unused PNAs. Bin member 370 may be supported by bearing means 311P so that it may be rotated (by use of a tab 370') between an open or dispensing position as shown in Figure 19 and a closed position where surface 370a may be coplanar with the side 311 of the housing. When bin member 370 may be in the closed position, additional unused PNAs may be transferred into said pocket as can be seen in Figure 19A. End surface means 370c and 370d have stop means 370c' and 370d' to limit the outward rotation of the bin member 370.

[0078] Figure 20 depicts another sharps container 300AA-2 which may have the same used PN receiving, ejecting and storage means as container 300AA of Figure 15 but may provide an alternate, multiple unused PNA dispensing apparatus.
Thus container 300AA-2 may have partition 311AA for defining used PN storage portion 311A and unused PNA storage and dispensing portion 311B. An exit opening 311S' at the left side of portion 311B (as viewed in Figure 20) may be provided and may be sized to admit the transverse motion of a drawer 380 in and out of the housing to an unused PNA dispensing position shown in Figure 20. The drawer has a bottom 380a, two sides 380b and 380c, a front 380d (with transversely extending pull tab 380'), and back ramp-like means 380e. Stop means 380c' and 380d' on the sides of the drawer limit the outward travel thereof. In operation, the drawer, holding unused PNAs 381, 382, 383 and 384, may be manually pulled out (by the user using tab 380') from portion 311B to the position shown in Figure 20 to allow the user to remove said unused PNAs. Manual closing of the drawer 380 may result in the front 380d being coplanar with the side 311 of the housing and, importantly, the ramp means 380e, as the drawer is closing, coacts with unused PNAs in portion 311b to transfer some into the drawer for additional dispensing to a user as is clearly shown in Figure 20A.

Another embodiment of our invention may be the sharps container 300AA-3 depicted in Figures 21 and 307A which may also uses the same used PN receiving, ejecting and storage means as container 300AA. Partition 311AA may again define the used PN storage portion 311A; however the unused PNA portion may be divided into two sub-portions 311B-1 and 311B-2 defined by a partition 311FF integral with side 311 of the housing and extending parallel to the bottom 311EE of the housing (best shown in Figure 21A). The vertical height of the sub-portions may be pre-selected to allow for the storage of unused PNAs arranged with the proximal ends thereof abutting the bottom members 391 and 401 of a pair of tray means 390 and 400 respectively. Tray 390 may also have a front 392 sized to match the exit opening 4415'' between members 311EE and 311FF. Tray 400 may also have a front 402 sized to match the exit opening 415''' between members 311A and 311FF. Fronts 392 and 402 may have engagement means 392' and 402' respectively for facilitating the manual withdrawal of the trays from the housing means.

A large number of unused PNAs may be positioned on each of trays 390 and 400. Tray 390 has PNAs 395, 396 ......390N and tray 400 has PNAs 405, 406......400N; the PNAs, as indicated, may be oriented with the proximal
ends abutting their respective trays. The PNAs may be secured by a suitable adhesive means to the trays. This orientation of the PNAs may permit an increase in the number of unused PNAs for a given size container.

While we have shown our preferred embodiments of the invention, it will be understood that variations may be made without departing from the inventive concept. Accordingly, the invention is to be limited only by the scope of the following claims.
In the Claims:

1. A sharps container for storage of pen needles comprising:
   a housing means with a space sized to facilitate the storage of a plurality of pen needles; and
   used pen needle receiving and ejecting means within said housing means.

2. The sharps container of claim 1 wherein the used pen needle receiving and ejecting means comprises:
   a rotatable means connected to said housing means for rotation relative to said housing means about an axis;
   an ejector assembly connected to said rotatable means to be rotated about said axis; and
   cam means within said housing.

3. The sharps container of claim 2 wherein the ejector assembly comprises:
   an elongated means having recessed means at a first end thereof sized to receive a used pen needle;
   an ejector member connected to said elongated member for relative axial movement therewith and having (a) cam follower means at one end thereof initially positioned a pre-selected axial distance along said ejector axis beyond a second end of said elongated means, and (b) a second end initially positioned adjacent said used pen receiving means; and
   wherein said cam means is positioned for an initial contacting of said cam follower means when said rotatable member and said ejector assembly is rotated about said rotational axis.

4. The sharps container of claim 3 wherein said cam means moves said ejector member axially with respect to said elongated means toward said first end so that a second end of said ejector member provides a pen needle ejecting motion.

5. The sharps container of claim 4 whereby, when a pen needle is positioned in said recessed means and said rotatable means is rotated about said axis sufficiently so that said cam follower means contacts said cam means, said ejector
member will force said pen needle axially out of said recessed means into said container storage space.

6. The sharps container of claim 5 wherein the housing means stores used pen needles.

7. The sharps container of claim 6 wherein said elongated means comprises a tube means of pre-selected axial length having first and second ends and an internal bore within which is positioned said ejector member.

8. The sharps container of claim 6 further including an opening in said housing sized to admit the axial insertion of a used pen needle therethrough.

9. The sharps container of claim 8 wherein said ejector assembly is selectively oriented about said axis by rotation of said rotatable means between (i) an initial position with said recessed means being adjacent to and in alignment with said opening to facilitate the axial insertion of an used pen needle into said recessed means, and (ii) a second position whereat said cam follower means engages said cam means, following which additional rotation of said ejector assembly about said axis causes the ejection of a used pen needle from said recessed means into said housing for safe storage therein.

10. The sharps container of claim 2 wherein said ejector assembly comprising a member having (i) elongated bore means of pre-selected axial length and first and second ends, said first end of said bore means being sized to receive said pre-selected outer diameter of a pen needle, (ii) said bore means having shoulder means adjacent to said first end, and (iii) elongated ejector means positioned within said bore means with latch means at one end thereof for engagement with said shoulder means and with cam follower means at a second end thereof, said ejector means being axially sized so that said cam follower means extends beyond said second end of said bore means when said latch means is in engagement with said shoulder means,
wherein said cam means moves said latch means of said ejector means axially away from said shoulder means toward said first end of said bore means to provide an ejecting motion; and

whereby, when a pen needle is positioned in said first end of said bore and said manually rotatable means and connected ejector means is rotated about said axis sufficiently so that said cam follower means contacts said cam means, said ejector means will force said pen needle axially out of said bore means into said container storage space.

11. The sharps container of claim 10 wherein said ejector assembly comprises a tube means of pre-selected axial length having first and second ends and an internal bore within which is movably positioned said ejector means.

12. The sharps container of claim 11 wherein said internal bore includes a shoulder adjacent to said first end of said tube means and the portion of said internal bore between said first end of said tube means and said shoulder means is sized to closely receive said pre-selected outer diameter of a pen needle.

13. The sharps container of claim 12 wherein said portion of said internal bore includes radially extending means for gripping said pre-selected outer diameter of a pen needle.

14. The sharps container of claim 12 including an opening in said housing sized to allow the axial insertion of a pen needle therethrough, and said used pen needle receiving and ejecting means being oriented with respect to said opening so that said first end of said bore means may be rotated into close proximity to said opening to facilitate the insertion of an used pen needle therein.

15. The sharps container of claim 12 wherein said cam means is integral with said housing.

16. The sharps container of claim 5 wherein said recessed means of said elongated member includes radially extending means.
17. The sharps container of claim 16 wherein said radially extending means comprises a plurality of longitudinally extending ribs.

18. The sharps container of claim 17 wherein said longitudinally extending ribs are longitudinally tapered to facilitate engagement with a used pen needle positioned in said recessed means.

19. The sharps container of claim 3 further comprising:

used medical syringe receiving and disposal means comprising means included in said rotatable means (i) for receiving a used medical syringe, and (ii) following a pre-selected rotation of said rotatable means about said rotational axis, for disposing said used medical syringe into said container storage space,

whereby, (a) when a used pen needle is positioned in said pen needle receiving means and said manually rotatable means is rotated a pre-selected amount about said rotational axis from said position of said initial contacting so that said cam follower means progressively contacts said cam means to move said ejector means along said ejector axis to force said used pen needle axially out of said pen needle receiving means into said container storage space, and (b) when a used medical syringe is received by said means included in said rotatable means for receiving a used medical syringe and said rotatable means is rotated said pre-selected rotation about said rotational axis, said used medical syringe will be disposed into said container storage space.

20. The sharps container of claim 19 wherein the container also facilitates the insertion, for safe disposal, and the safe storage of used medical syringes into said container.

21. The sharps container of claim 20 further characterized by rotatable means comprising (i) an elongated cylindrically shaped member supported on opposite ends thereof on said housing means and disposed in an elongated opening in said housing sized to receive said elongated cylindrically shaped member, and (ii) at least one elongated recess in said elongated cylindrically shaped member sized to receive at least one used medical syringe.
22. The sharps container of claim 21 including said used pen needle ejector assembly being mounted on said elongated cylindrically shaped member with said ejector axis being oriented at an angle to said rotational axis.

23. The sharps container of claim 22 wherein (i) said elongated cylindrically shaped member has two of said elongated recesses disposed longitudinally on opposite sides of said rotational axis, and (ii) said used pen needle ejector assembly is mounted, as aforesaid, so that said ejector axis is normal to said rotational axis.

24. The sharps container of claim 23 further characterized by said elongated means of said ejector assembly including two, axially aligned and axially spaced apart tubular means connected to said elongated cylindrically shaped member and having bore means for receiving said ejector member.

25. The sharps container of claim 24 wherein a first of said tubular means has recessed means at an end thereof sized to receive a used pen needle.

26. The sharps container of claim 23 wherein said cylindrically shaped member has a longitudinally extending central core portion including a central means for supporting said elongated ejector member for movement, relative to said cylindrically shaped member, along said ejector axis.

27. The sharps container of claim 26 wherein said cylindrically shaped member includes first and second axially aligned and axially spaced apart tubular means axially aligned with and on opposite sides of said central means, said tubular means having bore means for receiving said elongated ejector member, and said first of said tubular means having means for receiving a used pen needle.

28. The sharps container of claim 27 wherein said elongated ejector member is initially positioned, for relative axial motion along said ejector axis relative to said aligned central means and said first and second tubular means, so that (i) said cam follower means is positioned a pre-selected distance beyond said second of said
tubular means, and (ii) said second end of said ejector member is positioned adjacent to said means for receiving a used pen needle.

29. The sharps container of claim 28 wherein said second end of said elongated ejector member includes means for accommodating an axially extending used needle attached to a pen needle positioned in said used needle receiving means.

30. The sharps container of claim 21 wherein said rotatable cylindrically shaped member is characterized so that said at least one elongated recess is parallel to said rotational axis and is adapted, when in a first angular orientation relative to said housing means, to receive a used medical syringe and is adapted, when in a second angular position relative to said housing means, to dispose of said used medical syringe into said container.

31. The sharps container of claim 23 wherein said ejector axis is positioned intermediate said two longitudinally disposed recesses.

32. The sharps container of claim 28 wherein said second end of said elongated ejector member comprises two axially extending legs laterally spaced-apart a pre-selected distance for permitting the unobstructed positioning therebetween of a used needle of a pen needle received by said used pen needle receiving means.

33. The sharps container of claim 28 including means on said elongated ejector member for limiting the axial displacement of said cam follower means beyond said pre-selected axial distance along said ejector axis.

34. The sharps container of claim 33 wherein said means for limiting axial displacement of said cam follower means includes (i) a pair of spaced apart legs integral with said elongated ejector member, and (ii) shoulder means on said housing means.

35. The sharps container of claim 5 wherein the container further facilitates (i) the safe transportation of a large number of unused pen needle assemblies, (ii) the safe dispensing of said unused pen needle assemblies from said
container, wherein said housing means is sized to hold, in at least a portion thereof, a plurality of unused pen needle assemblies, said housing having an opening for facilitating the withdrawal of unused pen needle assemblies.

36. The sharps container of claim 35 further including an insertion opening in said housing sized to admit the axial insertion of a used pen needle therethrough.

37. The sharps container of claim 36 including a plurality of unused pen needle assemblies attached, in spaced-apart, series relationship, to a coiled, flexible tape means and positioned in said bottom portion of said housing means so that said unused pen needle assemblies may be dispensed through said exit opening.

38. The sharps container of claim 37 including a plurality of unused pen needle assemblies positioned in said portion of said housing means and means for dispensing said unused pen needle assemblies through said opening.

39. The sharps container of claim 38 wherein said pen needle assemblies each comprise an outer cylindrical shield, a cylindrical surface, and a proximal end.

40. The sharps container of claim 39 wherein said tape means has a plurality of serial, spaced-apart openings sized to receive said outer cylindrical shields of said pen needle assemblies.

41. The sharps container of claim 39 wherein said cylindrical surfaces of said pen needle assemblies are attached to said flexible tape means.

42. The sharps container of claim 39 wherein said pen needle assemblies are attached to said flexible tape means with said proximal ends thereof being adjacent to said flexible tape means.

43. The sharps container of claim 38 wherein said means for dispensing said unused pen needle assemblies dispenses said unused pen needle assemblies sequentially.
44. The sharps container of claim 37 wherein said housing means includes a second portion sized to receive for storage used pen needles, said housing having partition means separating said first and second portions; wherein said used pen needle receiving and ejecting means includes means for rotating said ejector assembly about said axis relative to said housing means.

45. The sharps container of claim 44 including (i) a plurality of unused pen needle assemblies positioned in said first portion of said housing means and (ii) means for dispensing a plurality of unused pen needle assemblies from said first portion of said housing mean through said first portion exit opening.

46. The sharps container of claim 45 wherein said means for dispensing a plurality of unused pen needle assemblies includes a bin member rotatably connected to said first portion of said housing means, sized to hold a plurality of unused pen needle assemblies, and movable between a closed position and an open position.

47. The sharps container of claim 45 wherein said means for dispensing a plurality of unused pen needle assemblies includes tray means having a first position within said first portion of said housing means, adapted to hold thereon a plurality of unused pen needle assemblies, and supported by said first portion of said housing means for relative transverse/lateral movement therewith to a second position whereat at least a portion of said tray means is outside of said first portion of said housing means whereat unused pen needle assemblies are positioned for dispensing and use.

48. The sharps container of claim 47 including a plurality of said tray means each adapted to hold a plurality of unused pen needle assemblies.

49. The sharps container of claim 45 wherein said means for dispensing a plurality of unused pen needle assemblies from said first portion of said housing means comprises an unused pen needle receiving member, movably connected to said housing means, proximate to said first portion exit opening, and movable between a first position for receiving said unused pen needle assemblies, thence through said first portion exit opening to a second position for dispensing of said unused pen needle assemblies.
50. The sharps container of claim 49 wherein said unused pen needle receiving member comprises tray means.

51. The sharps container of claim 49 wherein said unused pen needle receiving member comprises a plurality of tray means.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M5/32

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M B65F A61B

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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X Further documents are listed in the continuation of box C.

X Patent family members are listed in annex.

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Date of the actual completion of the international search

21 October 2005

Date of mailing of the international search report

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Name and mailing address of the ISA

European Patent Office, P.B. 5816 Patentlaan 2 NL - 2280 HV Rijswijk Tel: (+31-70) 340-2040, TX: 31 651 epo nl, Fax: (+31-70) 340-3016

Authorized officer

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