Needle Remover Device Design Transfer Package

The purpose of this Design Transfer Package is to provide a complete technical background of the needle remover device in order to facilitate a smooth design transfer to new manufacturers.

The Design Transfer Package consists of the following:

- Introduction: Technology Need
- Description: Key Components
- Design Considerations
- Draft Instructions for Use
- Open Issues: Looking Ahead

Introduction: Technology Need

Each year, more than 16 billion injections are administered worldwide. Concerns about injection safety, primarily through reuse of syringes, have become a major public health priority. Estimates indicate that more than 50% of injections in developing countries are unsafe.[1] Unsafe injections account for 33% of new hepatitis B infections, 42% of new hepatitis C infections, and 2% of new HIV infections.[2] Approximately 90% of injections in most developing countries are curative and are given with standard disposable syringes—syringes that are frequently reused.

The main tool to prevent reuse of non-sterile syringes and needles is use of auto-disable (AD) injection devices. Ironically, as awareness of the dangers of needle reuse leads to the increased use of AD syringes, the volume of contaminated sharps waste will grow exponentially, with estimates of 700 million AD syringes being procured by 2005 for global immunization programs alone. However, the number of non-AD syringes remains at over 90% of the total number of syringes used for all injections.

Safely removing the needle from the used syringe immediately after the injection can play a key role in safe injection. Appropriate needle removal devices address the key transmission risks related to bloodborne pathogens: reuse, improper disposal, and accidental needle stick. Needle removers disable the needle and syringe preventing reuse, the primary transmission risk of bloodborne infection. They prevent patient to community risk by ensuring that, should syringes escape the waste management process, the needle hazard is removed and contained. Needle removers also address accidental needle-stick by facilitating immediate removal and containment of the needle. Removing and containing the needle can also facilitate waste disposal by reducing volumes of infectious waste requiring special handling and by requiring fewer safety boxes (since syringes without needles can be packed 20%-60% more densely in safety boxes).

Needle-removal devices separate the needle from a syringe or the plastic hub of a needle by means of a simple mechanical action and collect the needles in a secure container within the device. After point-of-use needle removal, two forms of waste are created: “defanged”

[1] WHO Injection Safety, Quality of Immunization Services [QIS], August 28, 1998.

[2] WHO, SIGN. Injection Safety. WHO/BCT/DCT/01.3. 2001.

syringes and contained needles (see figure 1). The filled needle container can be emptied into a protected pit or other final containment system, and the defanged syringes can be placed in a safety box for final disposal. The user then replaces the disposed-of needle container by screwing on a new, clean container.

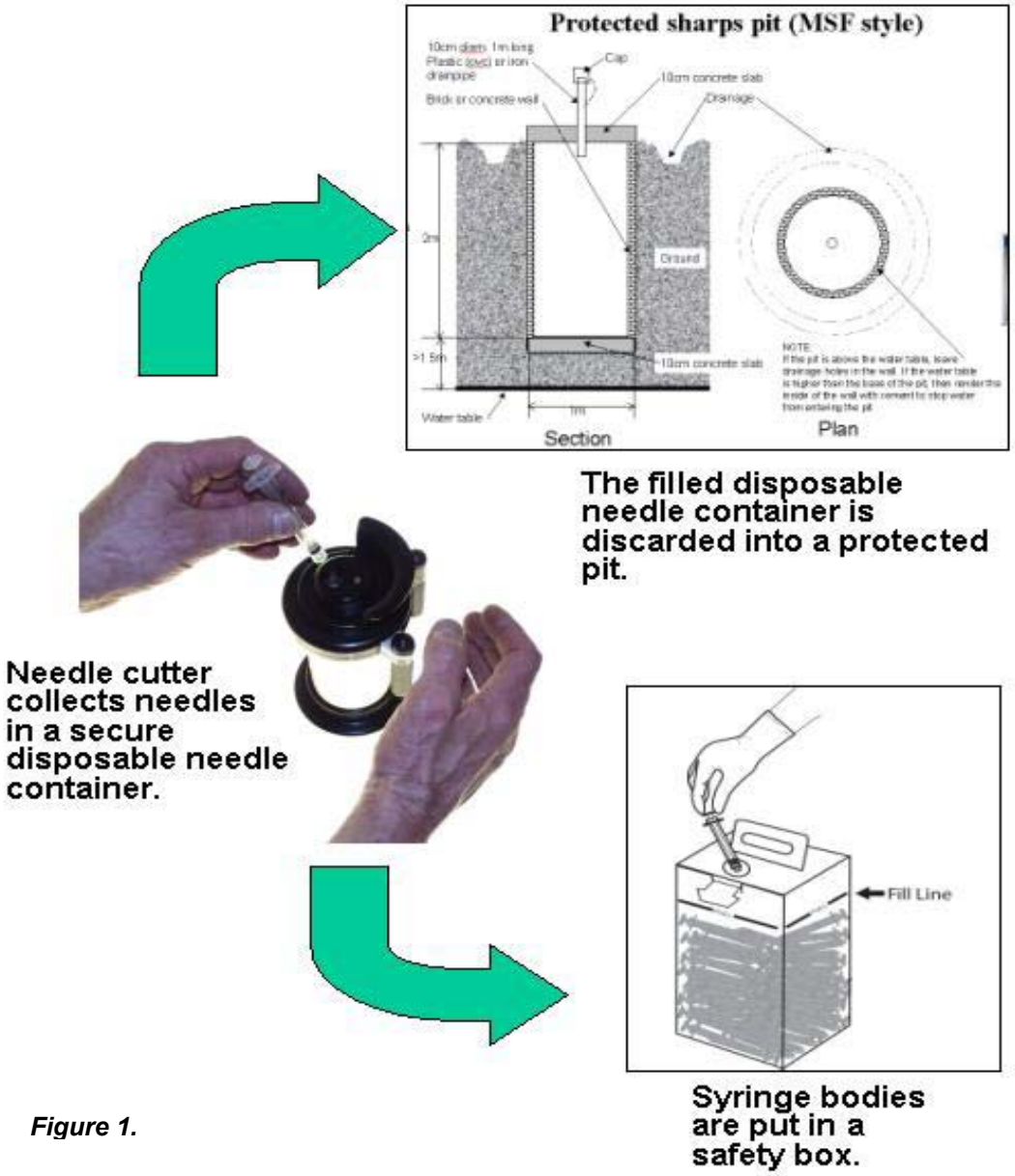


Figure 1.

Several trials with needle remover prototypes in Senegal, East Africa, India, and Indonesia have been very informative, and feedback from these studies has been integrated into the design process. The result is a refined prototype that better suits the needs of the users.

Description: Key Components

The mechanical concept behind the Needle remover device is simple. The needle and the lower section of the plastic hub are sheared off from the syringe when two identical, concentric blades, whose inner circumference is tapered to a sharp cutting edge, slide over one another (see figure 2). The needle then drops into a needle collection container where it is stored until the container is full.

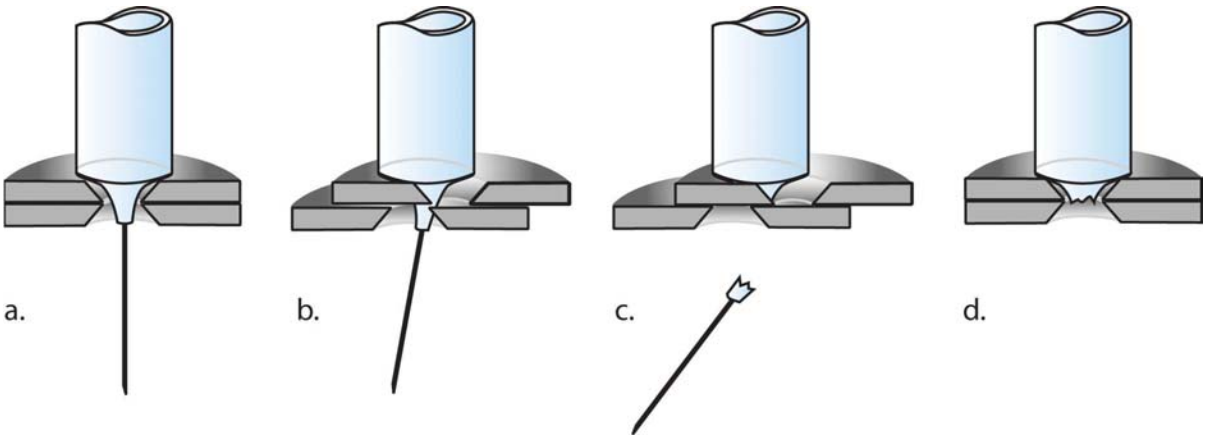


Figure 2.

The key components of the needle remover device are as follows:

- Needle entry target area: A funnel-like counter-bore leading into the cutting blades acts as a needle entry target area. The large, tapered geometry easily directs needles, from approach angles up to 45° into the blade pair hole.

- Handles: Easy to grip handles provide the mechanical advantage necessary for a smooth, easy cut that does not result in user fatigue or repetitive-motion injuries.

- Cutting blades: A pair of hardened, stainless steel blades provides an estimated 18,000 cuts before replacement is required. Additional cutting blade sets are stored in a holder in the cutter assembly and can be accessed and changed using a screwdriver only. The blades rotate randomly, varying the cutting edge and prolonging blade life. Blades are safe to handle because the cutting edge is on the inner circumference.

- Needle collection container: The needle collection container, made from clear or translucent plastic, holds between 150 and 300 needles. A fill line indicates when the container should be replaced. The container is disposable and is not intended for reuse.

- Base: A base provides a sturdy foundation to the cutter assembly to prevent tipping. The base and container may be an integrated unit.

- Lid: Screw-on lids, provided with the needle collection containers, are used to seal the full containers to prevent leakage and subsequent contamination during transport. The container is screwed on to the cutter using the same lid threads. When the container and cutter are assembled, the lid can be used to seal off the cutter funnel area and provide further leakage protection when the cutter is not in use.

- Spring return: The spring return resets the blades and handles automatically after the user releases the handles. The reset device is automatically ready to cut the next needle.

- Handle locking mechanism: A locking mechanism holds the handles and blades in the cutting position (blades overlapping) to prevent needles from moving into the needle entry target area during transport. This position provides an additional barrier to contamination or needle spillage.

- Hand shield: The hand shield protects the user from splatter, needle stick, and contamination.

The current prototype incorporates many elements from the World Health Organization specification (draft) for needle removers. A more detailed set of specifications has been organized into the Product Requirement Specification (PRS). The PRS is a “wish list” for the final, market-ready embodiment of the device. While the current prototype has been designed to incorporate many of these requirements, compliance with the PRS has not been fully verified.

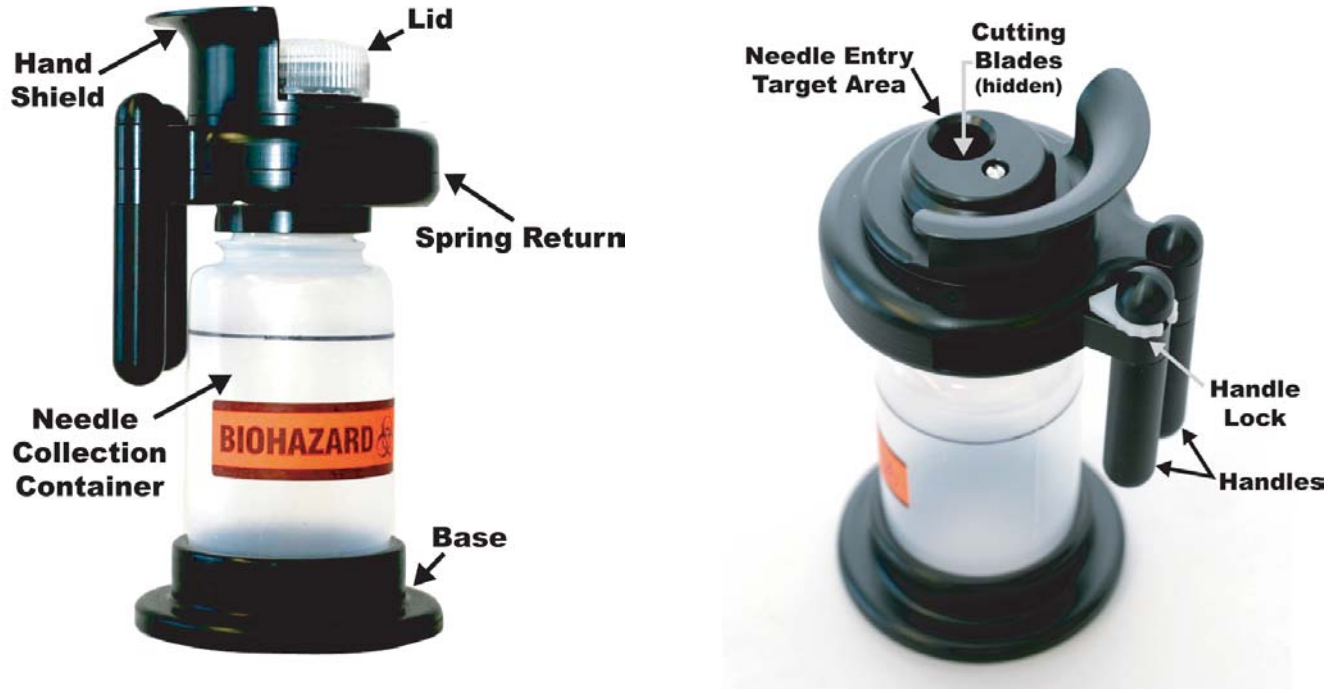


Figure 3.

Design Considerations

1. Introduction

1.1 Purpose/Scope

The purpose of this specification is to establish a structured set of technical guidelines to serve as the basis for refinement and commercialization of the needle remover device. These requirements address theory of operation and the intended use of the device, including the needs of the user and requirements of governing organizations.

1.2 Intended Use

The needle remover device is intended for use by health care workers in developing nations who administer curative or vaccination injections. Device design and instructions for use should encourage users to cut or destroy the needle from a syringe immediately after administering an injection. Once a day, or when full, the needle collection container is removed, capped, and disposed of in a safe manner, preferably buried in a sharps pit such as specified by Medicins sans Frontieres (MSF). The user then attaches a new, clean container.

1.3 Specification Overview

This specification is organized into three major sections. The first two sections introduce the device and list the standards applicable to the device. The third section contains the design requirements for the device. Each requirement is marked with a unique number: R-XX.

2. Standards, Guidance and Regulations

S-1 Supplemental Guidance on Pre-market Notifications for Medical Devices with Sharps Injury Prevention Features; Guidance for Industry and FDA (December 31, 2002)

S-2 World Health Organization (WHO) specification E12/NR.1 procedure E10/PROC/2 [draft]

S-3 Australian Standard AS 4031-1992. *Non-reusable Containers of Sharp Medical Items Used in Health Care Areas*, Standards Australia, Homebush NSW.

S-4 E10 Standard test procedures for injection accessories (Safety box and incineration container E/10/Proc/1 1998

3. Requirements

(S-X refers to the appropriate reference)

3.1 Cutter Assembly Physical Requirements (cutter with needle container attached)

R-01 Size: The assembly should be portable such that, with minimal adjustment, may be contained by a 5-inch (125 mm) diameter by 8-inch (200 mm) length

cylinder. “Fit in a backpack concept.”

R-02 Weight: The assembly should weigh less than 1.5 lbs., empty.

R-03 Weather resistance: The assembly should be resistant to degradation, corrosion or breakage due to sun exposure, rain, temperature extremes, or other elements normally found in its intended use environment.

R-04 Chemical resistance: The assembly should be resistant to chemicals commonly used for disinfecting the device, such as 10% bleach solution. The device should show no degradation after testing to simulate 365 cleaning cycles.

R-05 Tip angle: The assembly, empty or full, should not tip over when placed on a 23-degree non-slip plane.

R-06 Autoclavable: The assembly must meet all other physical requirements after 12 sterilizing autoclave cycles.

R-07 Drop test: The performance and safety of the device should not be compromised by dropping from a height of 39” (1 meter) onto a concrete surface. (S-2)

R-08 Portability: For safety reasons, the device should always be used at the time and exact place of the administration of injections. The device should therefore be readily portable by the lowest quartile of female operators. (S-2)

3.2 Needle Collection Container Physical Requirements

R-09 Size: The needle collection container should be able to slip into a standard, MSF sharps burial pit with a 4” (100 mm) diameter access pipe.

R-010 Tumble test: The container should be filled with needles then subjected to 100 drops from 315” (800 mm). No needles should fall out of the container. Not more than one needle should pierce through any of the sides. The container should not be seriously deteriorated in
any way. (S-4)

R-011 Capacity: The container should accommodate 150 to 300 needles without affecting operation of the cutter.

R-012 Transparency: The container wall should be clear enough to allow the user to visually detect the level of needles in the container. (S-2)

R-013 Perceived value: The container should be of a material and geometry such that it is not considered useful, valuable, or otherwise pilferable for any use other than its intended use.

R-014 Large mouth: Container mouth should be no less than a 2” (50 mm) diameter to reduce the hazards of container pouring and reuse.

3.3 Assembly Performance Requirements

R-015 Needle insertion: All needles should insert easily, with little or no force, into cutting device.

R-016 Needle size: The standard configuration device should disable wet or dry needles, 0.4” - 3.0” (10-76 mm) in length, and 18-28 gauge diameter. (S-2)

R-017 Needle type: The device should disable both the needle and syringe barrel of needles most common to the region of use including fixed luer, luer lock, luer slip, or snap on. (S-2)

R-018 Cycle time: Cycle time to remove, cut, or destroy a needle should not exceed 10 seconds. (S-2) Should not exceed 5 seconds.

R-019 Ease of use: It should be possible to cut or destroy 100 needles from their

syringe consecutively, without fatigue, for the lowest quartile of female operators in the region of use. (S-2)

R-020 Needle entry geometry: Insertion of the needle into the device should be allowed for all non-critical angles relative to the entry point. A needle entry target area should be recessed, concave, smooth, and at least 0.75” (20 mm) in diameter. (S-2)

R-021 Complete cutting: The blade configuration should ensure complete cutting of the needle. Incomplete shearing or other modes of disabling the needle, such as crimping or bending, are not allowed.

R-022 Automatic reset: The handles should spring back to the initial position when released so that they are ready for the next cut.

R-023 Anti-fouling mechanism: The cutting mechanism should be designed so that epoxy or other needle remnants do not jam the device.

R-024 Container attachment: Separation and attachment of the cutting device to the needle container should be safe, clean, and easy. The container must attach securely to the device so that tipping or dropping does not separate the container from the assembly.

R-025 Operating environment: The performance of the device should not be compromised by exposure to ambient conditions of 110°F (43°C), 90% relative humidity for one week. (S-2)

R-026 Skill level: The device should be operated with minimal training by persons with a primary-level education or greater. (S-2)

R-027 Bent needles: The device should cut needles bent up to 30 degrees.

3.4 Life Cycle

R-028 Life cycle (device): Based on an assumption of average daily use of 300 needles, the life of the cutting device should be 365 days (approximately 110,000 uses). The only maintenance required during the life cycle should be blade replacement.

R-029 Life cycle (blade): The life cycle of the cutting blade should be 60 days (18,000 cuts). Three additional blade pairs should be provided with the device. Used blades should not be re-sharpened but should be disposed of in the needle container as sharps waste.

R-030 Reliability: Over the defined device life cycle, the device should meet all cutter assembly physical and performance requirements defined in sections 3.1 and 3.3.

3.5 Cost and Manufacturability

R-031 Target manufacturing cost: $15.

R-032 Injection molded parts: Prototype machined plastic parts should be designed for compatibility with injection mold manufacturing.

R-033 Simplicity: Minimize total number of parts in the assembly.

R-034 All devices should be manufactured in accordance with the appropriate standards for function and safety, including ISO 9002 and MDD 93/42/ECC.

3.6 Safety

R-035 Hand location: Hand to needle distance, while operating the device, should be

greater than 1.5” (38 mm).

R-036 Splatter and contamination shield: The device should have a contamination shield barrier between the funnel and the handles.

R-037 Blade edge protection: The device’s cutting blades should not create a cut hazard for the user either with or without the container connected.

R-038 Leak-proof: The device should not leak any liquid contents when in the upright position.

R-039 Spill proof: With cap properly fastened, the device should not spill in any orientation.

R-040 Needle escapement prevention: The construction should minimize the occurrence of needles migrating from the container into the funnel.

R-041 Lid (cutter): The cutter should connect to a removable lid that prevents needles from falling out of the container in any orientation of the assembly.

R-042 Lid (container): The container should connect to a removable lid that prevents needles from falling out in any orientation of the container. Container lid and cutter lid should be interchangeable.

R-043 During or after normal use of the device, there should be no detectable contamination of:

- The hands, other exposed skin, or clothing of the operator.
- The surfaces or working areas adjacent to and surrounding the device.
- The outer surfaces of the device accessible to the user, except the needle entry target area. (S-2)

R-044 After cleaning the device according to manufacturer’s instructions, there should be no detectable contamination of:

- All external parts and surfaces of the device.
- All reusable, internal parts accessible to the user during cleaning.
- The needle entry target area. (S-2)

3.7 Device Labeling

R-045 Fill line: The container should have a durable, well indicated “fill line” around its entire circumference. Container: International biohazard marking. (S-3)

R-046 Language: The labeling will be printed in language appropriate for the region(s) in which the product is intended for use.

R-047 Use only with collection container properly installed: the device should have a clear, non-verbal label to warn the user that the device must not be operated without the needle collection container in place. (S-2)

3.8 Instructions

R-048 Fill line warning: Instructions should include the following: “Operation above this line may cause improper operation and damage to the cutting device. When needle level reaches the fill line, separate cutter from needle container, cap the container, and dispose of properly.”

R-049 Language: Instructions should be printed in language appropriate for the region(s) in which the product is intended for use.

R-050 Operation: Complete instructions should include directions for operation, cleaning, maintenance, and disposal of the device and accessories. (S-1)

3.9 Ergonomics

R-051 User position: The device should be comfortably operated by 5-95th percentile adults in standing and seated positions with the device resting on a tabletop. One hand holds the syringe while the other hand squeezes device handles.

R-052 Dexterity: The device should be operated easily by left- or right-handed operators.

R-053 Squeeze force: The maximum force required to cut a standard (21 g) needle should be less than 15 lbf. (67 N).

R-054 Pinch points: Normal operation should not result in pinching of the user's hands.

R-055 Single, smooth cut: A successful cutting operation should be a smooth, single squeeze and release.

R-056 Repetitive use injury: The device handles should be designed to minimize repetitive use injuries such as carpal tunnel syndrome.

Open Issues: Looking Ahead

Lessons learned from the needle cutter prototypes have led to a number of open issues which consist of trade-offs, issues unique to the prototype embodiment, refinements and device characteristics that are not finalized because more testing data is required before decisions can be made. This section captures these issues. R-XXX refers to the requirement outlined in the PRS.

1. **Collection container:** The needle collection container is an off-the-shelf, 250-ml polypropylene bottle. There are several issues with this design:

    - Under noncompliant use, the bottle is shaken to remove the needles. The needles do not pour out because they become jammed in the small, funnel-like opening. A wider mouth container, either off-the-shelf or custom, should be evaluated to determine if needles could be poured out.
    - The container capacity should accommodate a full day's use of needles at a standard primary health care center (R-011). This number is estimated to be 300 needles a day. Offering the product with a standard size container and an optional range of container sizes should be evaluated for cost-effectiveness and need.
    - The puncture resistance of the container has yet to be evaluated in a drop test. (R-010)
    - A self-stable container, which does not require a separate base to meet the tip angle requirement (R-05), should be evaluated for cost-effectiveness as compared with the off-the-shelf container option.
    - Hand clearance between the container and handles could be improved in a redesign that incorporated a recess in the container.
    - A new design should incorporate features that discourage the collection containers from being used for non-cutter uses.
    - The needle remover device should be compatible with off-the-shelf containers that are available in the countries where it is distributed.

2. **Compatibility and complete disabling:**

- "Compatibility" refers to a needle and syringe assembly, which, when inserted into the device, allows for separation of the needle from the syringe.
- "Sharps containment" refers to a cut, which completely removes all metal sharps from the syringe and contains them in the needle collection container.
- "Complete disabling" refers to separation of needle and syringe, which prevents syringe and needle reuse.
- "Incomplete disabling" refers to any cut that allows for reuse of the syringe or needle.
- "Incomplete cutting" refers to cuts that require additional maneuvering of the syringe, such as twisting, to separate the needle from the syringe.

Because of the wide variety of needles available worldwide, it is very difficult to envision a device that is compatible with and will completely disable all needles and all syringes and provide sharps containment. No such device currently exists. All needle removers compromise certain syringe types. The challenge is to determine what trade-offs are acceptable. Furthermore, a thorough knowledge and wide sampling of needles from the candidate use regions are necessary to establish acceptable trade-offs. Here is a closer look at the trade-offs of the current prototype with a blade inner diameter hole of .24" (6.1 mm):

- The device does not completely disable luer slip syringes. Although the tip of the luer fitting is cut off, enough fitting remains (approximately 0.22" [5.5mm]) such that luer slip syringes can be reused by reattaching a needle/hub. The minimum tip length after cutting, for complete disabling is 0.12" (3 mm).
- The device does not completely disable the needle hub of luer slip syringes since the needle can be reattached to an intact male luer fitting.
- The device does not completely disable luer lock syringes. The needle hub remnant can be removed with pliers and a new hub reattached.
- The device does not ensure sharps containment with all needle/syringe types. Small needle remnants (sharps) sometimes remain with the syringe after disabling some fixed-needle syringes.
- Ring-like hub remnants occasionally clog the funnel. The remnants must be removed prior to the next cutting. Removal methods risk contamination.

Several solutions have been suggested to the above issues but each has its own limitations. No single solution addresses each problem completely. In order to accommodate a broader range of needles and syringes, the device was recently modified for trials in India. The modification increased the blade inner diameter to 0.30" (7.7 mm). Trade-offs from this modification are as follows:

- The device can now be used to cut luer slip syringes a second time to ensure complete disabling (tip length < 0.12" [3 mm]). However, cut remnants collecting in the device funnel jam the device and must be removed.
- Incomplete cutting occurs more frequently due to the reduced overlap of the blades. Rotation of the syringe or bending may be required to separate the needle from the syringe.
- Cutting depth control has been lost for small syringes, such as the BCG, that now slide through the hole. Complete disabling can still be achieved by careful positioning

(a graphic guide would be beneficial) but reliability has been compromised and more responsibility has been placed on the user.
- This redesign does not address several issues such as incomplete disabling of luer lock syringes, Uniject syringes, glass syringes, > 5-ml syringes, and metal needle hubs.

3. **Ergonomic soundness:** The ergonomic soundness of the current prototype should be evaluated in a fatigue study. Preliminary user forums suggest that a more user-friendly handle design would reduce fatigue and repetitive motion injuries. An over-hand, horizontal grip that allows for standing use should also be evaluated.

4. **Plastics material study:** The current prototype plastic parts do not meet the minimum drop test requirement (R-07). Chemical resistance (R-04), autoclavability (R-06), and weather resistance (R-03) have not been verified. A study of appropriate materials should be conducted. Plastic parts should be redesigned for moldability.

5. **Blade pair:** The durability of the blade (R-029) as well as its chemical (R-04) and weather resistance (R-03) are unverified. A full material study as well as bench testing is required. Furthermore, a cost evaluation of the blade manufacturing methods is necessary.

6. **Carrying strap versus carrying case:** Both of these options have their benefits and should be evaluated side by side in field trials. Recent feedback from India indicated that a shoulder strap was desired for outreach settings. An alternative to the strap is a high quality, protective carrying case with shoulder strap, which might increase the perceived value and hence improve the handling of the device as well as provide added protection. Neither of these options has been developed yet.

7. **Cost and manufacturability:** A bill of materials, listing assemblies, subassemblies, and individual parts should be constructed. Cost of individual custom manufactured parts, bought parts, and labor should be evaluated at quantities of 10,000, 100,000, and 1,000,000 units.

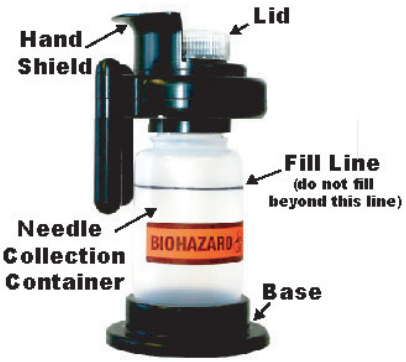
8. **Cutter disable interlock:** A Mechanical interlock to prevent needle cutting when the needle collection container is not attached would be a good addition to the design.

Draft Instructions for Use

The draft instructions on the following pages were developed for this needle remover device.

Needle Remover Device
User Instructions

Parts



Operation

1

Remove lid. Release handle lock to open handles.

2

With handles open, insert syringe into funnel.

3

Hold syringe firmly in funnel while squeezing handles. Remove syringe while handles still closed.

4

Release handles allowing needle to fall into the container. Discard syringe appropriately.

Removing Container

1

To remove the container, lock handles in place. Hold the container firmly while unscrewing the needle remover counterclockwise.

2

Screw lid onto container and remove base from container.

Properly dispose of full containers.

Needle Remover Device User Instructions

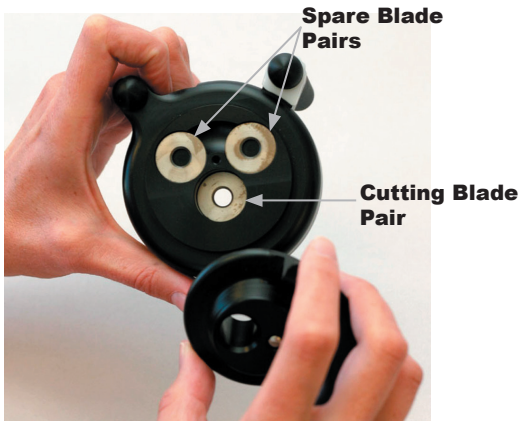
Replacing Container

To replace container, hold new containerfirmly while screwing device clockwise until secure. Replace base.

Cleaning

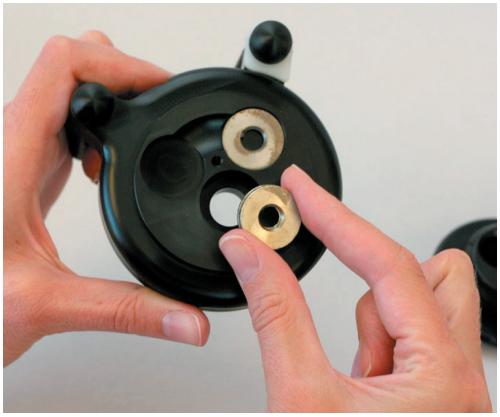
- Remove container from needle remover device and wipe with a wet cloth. A mild detergent may be used if desired, or device may be wiped with alcohol.
- Do NOT use bleach (sodium hypochlorite), Cidex, or other chemical disinfectants to clean the needle remover device.
- Once container is full, remove container, cover with lid, and dispose of properly.

Blade Replacement



1

Loosen blade holder release screw and remove blade holder. While holding spare blades in, turn needle remover upside down to remove used blades. Dispose of used blades properly.



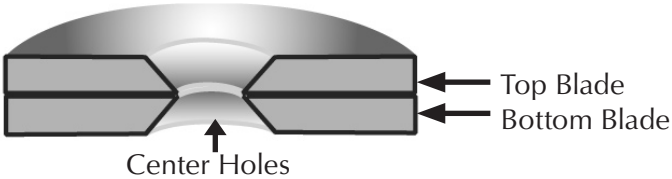
2

Insert new pair of blades into funnel as depicted below (Blade Orientation). Reattach blade holder to needle remover and tighten release screw.

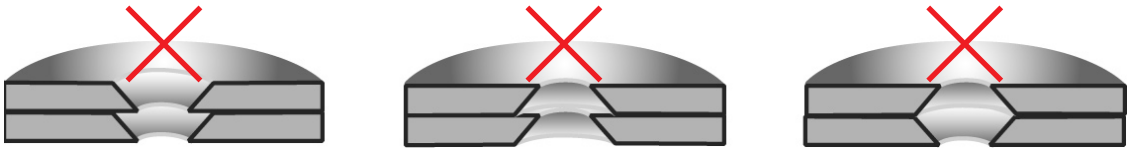
Blade Orientation

The diagrams below represent cross-section views of the two blades on top of one another. Proper orientation is critical to both functionality and durability of the needle remover device. When replacing the blade sets, make sure they are oriented with non-beveled sides placed together as shown below.

Proper Blade Orientation



Incorrect Blade Orientation



Contact

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