Adarsh Vijay | MSc Product Design Engineering

Sharp

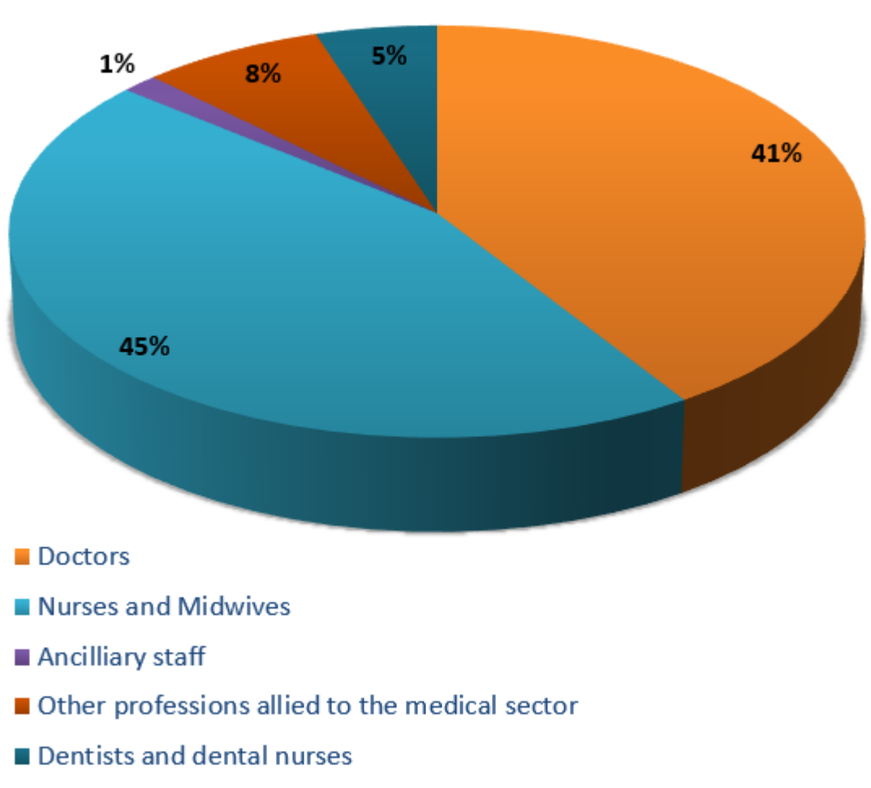
Problem

Sharps is anything that is used to puncture or lacerate the skin. It includes hypodermic needles, scalpels, contaminated glass. guidewires and other medical devices. Out of all infectious wastes produced by the medical industry, sharps waste constitute for 1%

The major problem of sharps waste is sharps injuries which causes transmission of Blood Borne viruses such as HIV, Hepatitis, Epstein Barr virus among others.

Injury from a sharp that was used on a infected person has a infection probability of

30% HBV infection - 1 in 3 people
1.8% HCV infection - 1 in 50 people
0.3% HIV infection - 1 in 300 people



Opportunity

From 2012- 2017, NHS had 1,833 claims for injury which cost them £4,077,441.

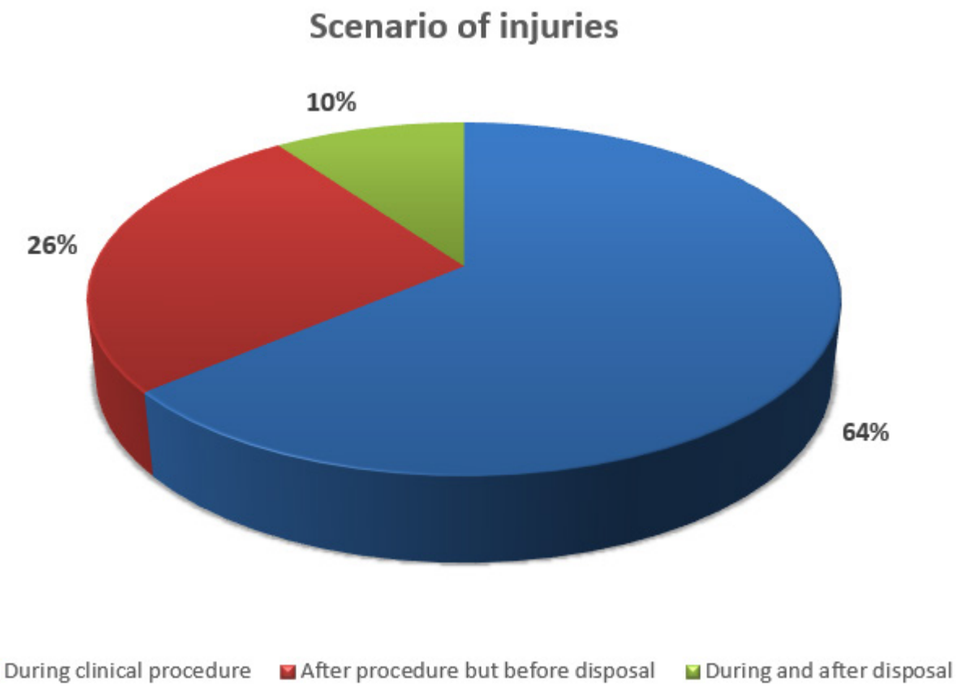
NHS estimate 40,000 needle stick injuries occur within the workplace per year and recognizes that the true figure may be twice this due to under reporting of injuries.

The main causes for injuries as listed by NHS are:

- Non-compliance with standard infection control precautions
- Inadequate disposal of clinical waste
- Overfull sharps bins
- Not using safer sharps and
- Not using Personal Protective equipment

Opportunity Statement:

The aim of this project is to identify individual scenarios of injury and design a solution that helps reduce or eliminate injuries as well as improve waste handling.



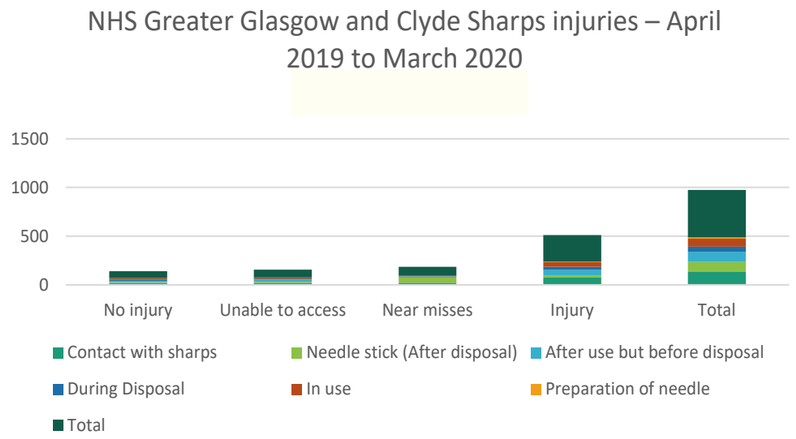
Ethnographic research

Interviews were conducted with doctors, nurses and waste management officers to further understand the depth and scenario of the problem. Nurses and waste management officers were consulted throughout the design processes.

Doctors:
Mostly nurses and clinical staff handle the waste and injections

Nurses:
Normally tend to carry around sharps box if one isn't available in the patient room

Experienced injury when checking if the bins were full or not.



Waste management officer:
The sharps waste is incinerated and a very small amount is recycled by Zero Waste Scotland but none of the recycled products have proven attractive to the commercial world. (Also provided stats on sharps injuries in NHS GG&C 2020)

Product Research

Research began with finding the products used by NHS currently. This helped to understand the performance of the products and to find areas of opportunity for design.

Once NHS Scotland was identified as the WHERE of the opportunity, research was done on the sharps and the waste sharps bins used. In 2013, Glasgow's Victoria infirmary was slammed by health instructors for dirty needle disposal techniques.

Solutions used by other countries was also included in the research which led to the discovery of Needle removers, Needle destroyers, and needle free injection technology.

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Concept Generation

Afew concepts were generated at first to help communicate with nurses and doctors about the intervention of a design to solve the problem of sharps injuries. Following feedback, Sharps bin was finalized as the concept.

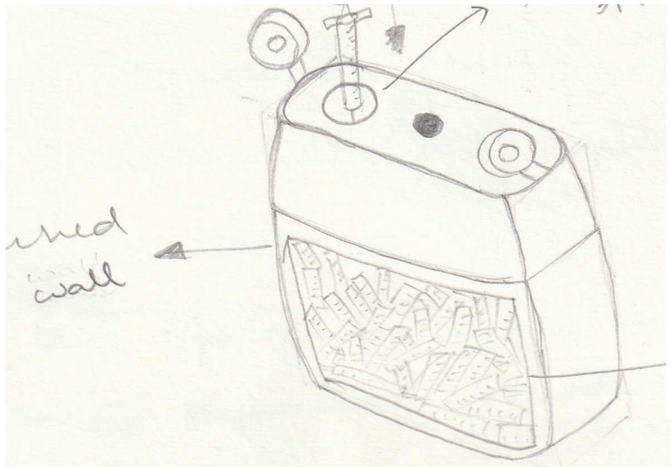
The user requirements developed based on feedback were:

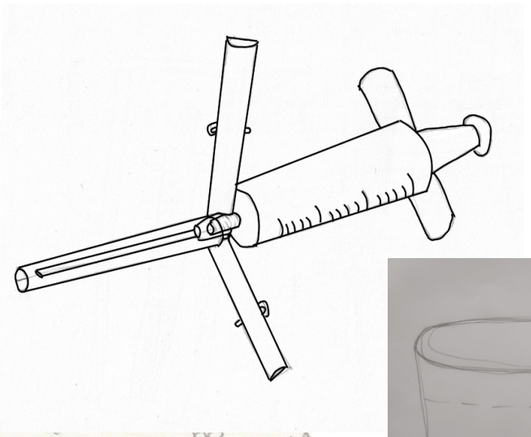
1) Portability
2) Easy to see fill level
3) Low complexity working principle
4) Leak Proof
5) Spill Proof

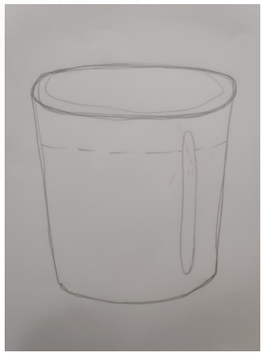
The product requirements based on existing products and the regulations from World Health Organization were found to be:

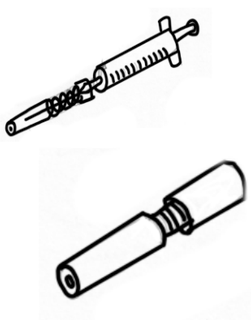
Sharps Bins:
1) Penetration Proof
2) Color coded
3) Sealing when it is 3/4th full
4) Covered input ports to prevent hand entry
5) Economic material and manufacture
6) Dimensions- Based on capacity required
7) Reusable and should withstand steam sterilization
8) Recyclable
9)Regulations: ISO 23907: 2012

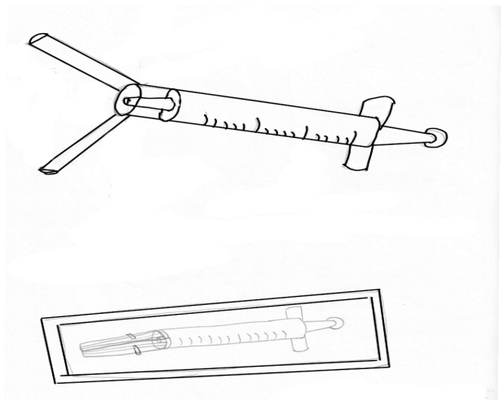
Needle Remover:
1) Needle should enter at any angle from 60-90
2) Self clearing Mechanism
3) Leak proof
4) Visual indication of level
5) Regulations: ISO 20282-1: 2006

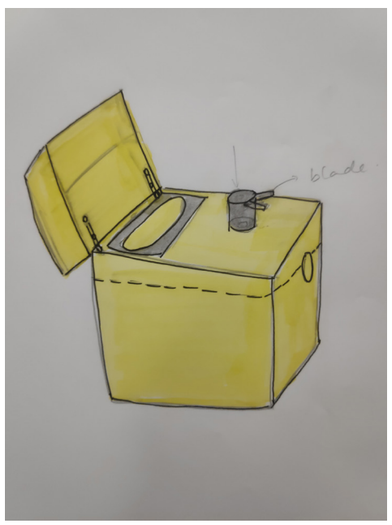


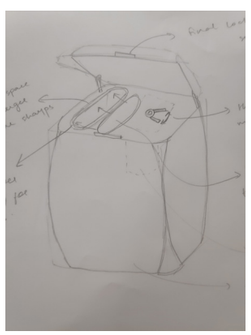


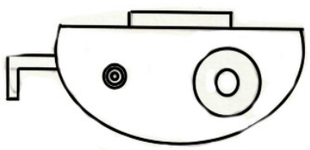


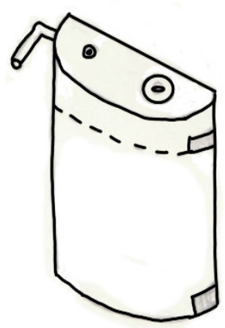




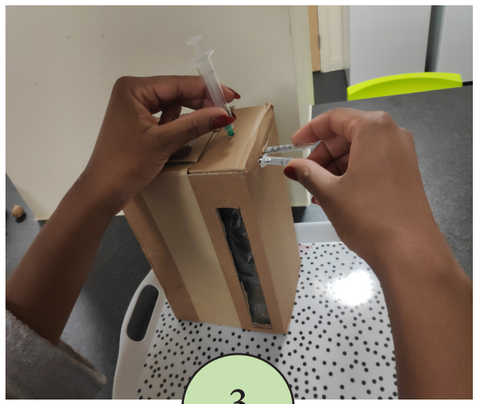








User Experience



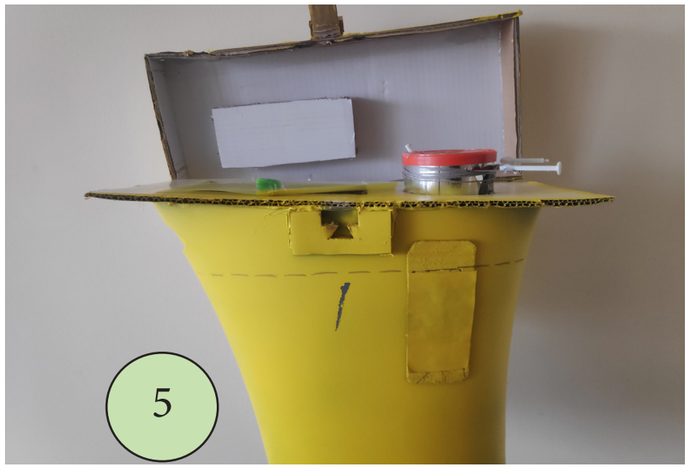
Features:

Prototypes 1 through 3 were developed first with different features.

- Prototype 1 included wall mounting, sensor for fill level and an incorporated needle destroyer.
- Prototype 2 included a complete transparent front section to see levels and an incorporated needle destroyer and was affixable to a medication cart.
- Prototype 3 included a small transparent window to see the fill level and an needle remover and was affixable to a medication tray

Based on the feedback received from nurses, a few of the features were selected for further iteration.

Prototypes 4 and 5 included hub cutters(needle removers), wall mounting and mounting on medication carts, and transparent windows



Insights and operational decisions:

- The sliding input port on prototype 1 redesigned as a flap for ease of access and to accommodate larger sharps
- The needle destroyers were not incorporated as they would require electricity to run which would make steam sterilization difficult and also make the product more expensive.
- The entire front section of transparent window was remodelled as a small window near the fill line as it would show medicines and blood if any.
- A separate two layer system of a base and cap were added to ensure that it is leakprook and provide a base to attach the needle remover to.
- Sensors for detecting fill levels were redesigned as a transparent window as sensors that can withstand steam sterilization would make the product more expensive.
- RFIDs for tracking the bins through use and disinfection was redesigned as an bar code which would be a more cost effective solution.
- Using Needle removers, although not promoted by WHO, it is recognized as a valid procedure followed by various countries.
- All materials and user journey was modelled with steam sterilization in mind because it is currently used by the NHS and other disposal companies to disinfect sharps waste. Hence this product could be disinfected along with the waste and then sent for reuse.
- The input port was designed with a slide to reduce the number of touch points and the touch points were color coded as well.

Material and Manufacture:

Based on the factors of cost, economic batch size and manufacturing processes, various online sources including CES was used to find the perfect material.

Other constrains were cost of material, high fracture toughness, low thermal conductivity to withstand sterilization and also the weight of the waste it would have to store.

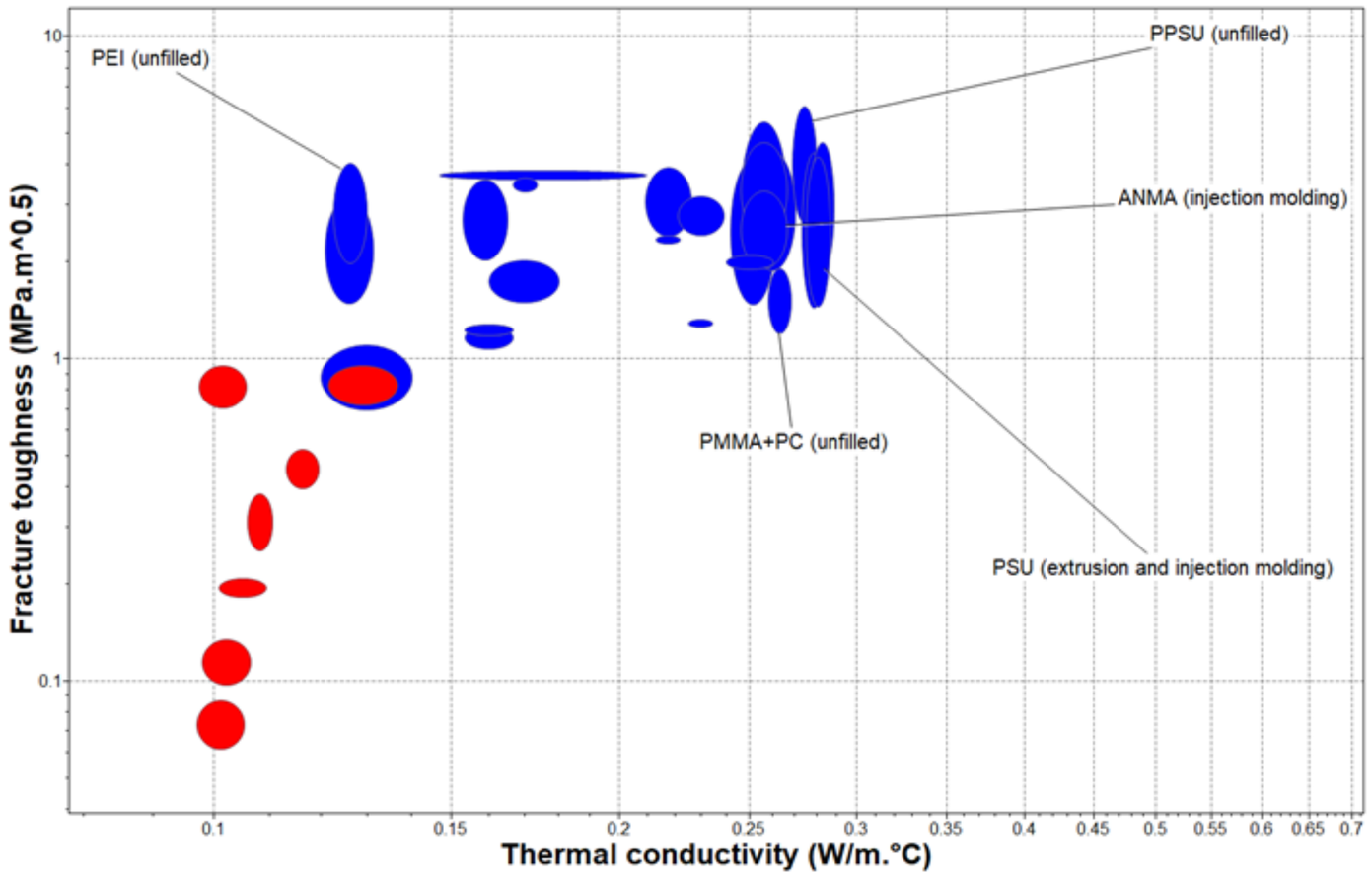
The finalized materials included Polyphenylene Sulfone (PPSU) and stainless steel.

PPSU- The entire body of the product was designed to be manufactured from a single material so as to keep the costs low and also so that they can be disinfected if required. PPSU is a high performance thermoplastic which is rigid, high-strength and transparent. They have high dimensional stability so it has no physical changes when it is exposed to steam.

Stainless steel (just for the blade)- Stainless steel 304 is regarded world over as one of the most suitable materials for manufacture of medical equipment. Stainless steel can withstand steam sterilization and does not rust in the presence of steam. Based on the factors of strength, sterility and its validity in medical applications, this material was selected for the blade in the needle remover.

For ease of manufacture, the section thickness is 4mm which would reduce the cooling
time thereby reducing costs. A draft angle of 2 degrees would be applied to each component for easier mould removal. The curved corners and stepped thickness transitions would make it much easier for injection moulding.

Component	Material	Manufacturing Process
Sharps bin container	Dyed PPSU	Injection moulding
Sharps bin base	Dyed PPSU	Injection moulding
Sharps bin lid	Dyed PPSU	Injection moulding
Needle remover container	PPSU	Injection moulding
Transparent window	PPSU	Injection moulding
Transparent slide	PPSU	Injection moulding
Needle remover blade	Stainless steel	Stamping
Needle remover cap and handle	Dyed PPSU	Injection moulding
Lock	Dyed PPSU	Injection moulding
Handle	Dyed PPSU	Injection moulding



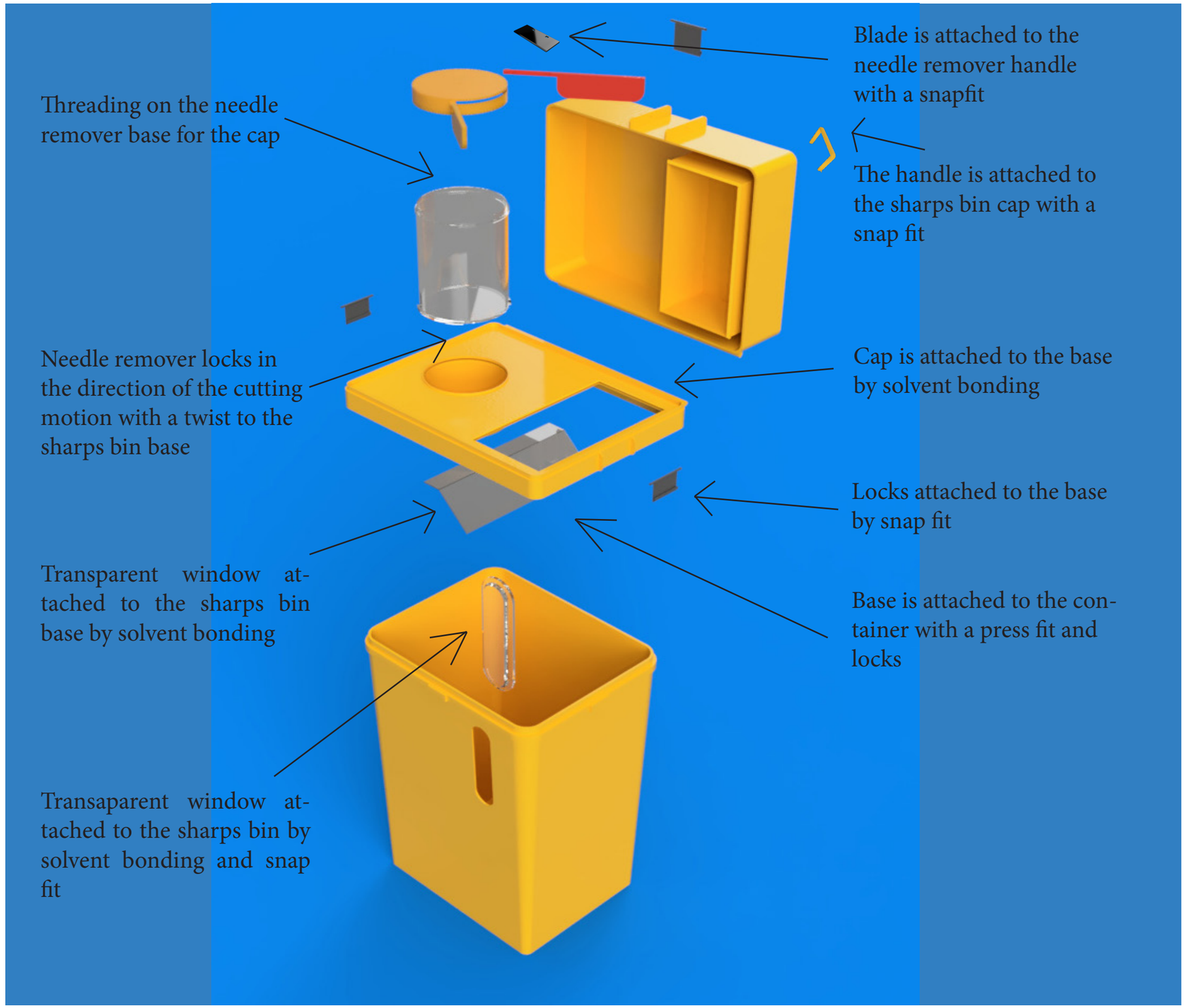
Assembly and Installation:

The assembly of the process was designed to be completed by a single person. The number of components was minimised without compromising the functionality of the product.

With the exception of the sharps bin container, the weight of each component is less than 1 kg. The entire product would be assembled at the place of manufacture in order to save time and money in assembling them in the hospital.

Most of the components would be fixed with a press fit with the exception of the transparent window and slide which would have to be attached using solvent bonding. The sharps bin cap is attached to the base with a straight flat hinge using solvent bonding. The solvent used for adhesive bonding of PPSU is Methylene chloride. The strength of the solvent bonding can be tested by a tensile shear test.

The sharps bin is designed in such a way that the needle remover is removable so if the sharps bin is not immediately accessible in the place where the sharps are used, the needle remover can be detached and carried to the patient.



Cost and Anthropometrics

Product Title:		Sharps container				Max RPN	150
Function:		Hold syringe waste				Date	
Failure Mode:		Unable to deposit more syringes				Staff	
Effect of Failure	Severity	Potential Cause of Failure	Occurrence	Detection Method	Effectiveness	RPN	Recommended Actions
Breakage of sharps bin	9	Overfilling causing breakage	2	Confirm fill level through transparent window	1	18	Regularly check fill levels
		Locking system breaks	4	Durability test	2	72	No action
Product Title:		Needle remover				Max RPN	150
Function:		Cuts and contains needles				Date	
Failure Mode:		Unable to shear needle hub				Staff	
Effect of Failure	Severity	Potential Cause of Failure	Occurrence	Detection Method	Effectiveness	RPN	Recommended Actions
Unable to remove the needle	8	Dulled blade	6	Durability test	3	144	No Action
		Snapped handle	7	Field trials and maximum user loads	2	112	No Action

Anthropometrics and Cutting forces:

The points of stress were found to be in the locks, the wall mount and the handle. The wall mount selected would handle the weight of the product and the weight of the waste stored inside. In the event that the wall mount fails during field testing, it can be replaced with a flat shaped wall mount and an anchor which can hand a load upto 50 lbs which equates to approximately 22.38 kg. The overall weight of the product including the waste was calculated to be 18 kg in an extreme scenario. It can hold 214 70ml syringes or 15000 1ml syringes if the alignment of waste is perfect. It can be assumed that it can hold atmost half the number of syringes that was calculated.

The cutting force required to cut through the needle was calculated to be around 10.4 N. The anthropometric data for grip strength (ages 20-65) are as follows:

- Right hand dominant males: 72 pounds
- Left hand dominant males: 70 pounds
- Right hand dominant males: 68 pounds
- Left hand dominant females: 66 pounds

This would equate to an average of 69 pounds of force which is equal to approximately 307 N. Hence all would be easily able to cut the needle hub.
For the size of the needle remover handle and the handle of the sharps bin anthropometric data of hand widths were used. The 10 cm handle in both cases would fit 99th percentile of all men and women

Cost Analysis:

The material and the manufacturing costs were calculated using the following cost equation:

$$C_{pp} = \frac{mC_m}{(1-f)} + \frac{C_t}{n}\left\{lnt\left(\frac{n}{n_t} + 0.51\right)\right\} + \frac{1}{n}\left[\frac{C_c}{Lt_{wo}} + C_{oh}\right]$$

The assembly costs were calculated using the manual handling data provided by the university. The total cost of manufacturing and assembling the product is £83.30

There would be additional cost that was not factored into this calculation namely,

- The solvent Methylene chloride for adhesive bonding
- Laser etching of biohazard, recycling and barcode symbols
- Extra cost of Danger sticker and name tag for the hospital to fill out
- The transportation costs to and from the hospital
- The wall mount ClipSafe for each product

The extra cost of disinfection of the product is eliminated as it can be steam sterilized along with the waste and then transported back to the hospital.

Product Scenario

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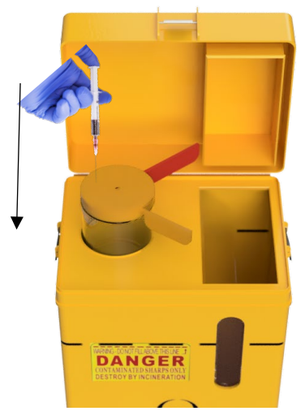
User Journey

1

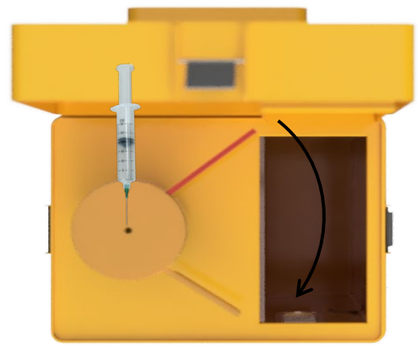
The sharps boxes are wall mounted and will be placed in patient rooms and operation theatres.

2



The used sharp is put inside the port of the needle remover

3



Fingertips or base of the fingers (Make a fist) are used to push the levers together and cut the plastic hub above the needle

4

Deposit the cut sharp (needle removed) into the sharps bin. The transparent slide allows for easy deposit of waste and prevents hand entry

5

Check the transparent window to see if its 3/4th full. (if it is close to the fill line)

6

Remove the needle remover (Can still be used if it is not full) and then sent for further disinfection and waste removal.

Product Features

Immediate isolation of the needle preventing further in-jury to health care workers and sanitation workers

Waste segregation: The nee-dle is collected in the needle remover while the sharps bin contains the syringe waste.
This provides more opportu-nities for waste recycling

The material selected allows for reuse of the product upto 500 cycles. This can combat the single-use products al-ready in the market

Helps prevent reuse of syringes

No extra cost for disinfection as it can be steam sterilized along with the waste.
The material also allows for chemical disinfection

At the end of life of the prod-uct, it is recyclable.

Helps to reduce the waste vol-ume of infectious sharps by isolating the needle.

- 28% of injuries sustained by sanitation workers occurred during Disposal is reduced
- 45% of injuries sus tained by Nurses and midwives through overfull sharps bin is reduced

Conclusion

The final design provides a cost effective solution of a reusable and recyclable sharps bin which im-mediately isolates the needle and also helps to segregate wastes providing more options for re-cycling of wastes. This product will help reduce the amount of sharps injuries experienced by healthcare workers and sanitation workers. This product fulfills all the regulations labelled by the World Health Organization and the Nation-al Health Services. The cost of the product was found to be £83.30

Further Work

The product would have to be tested in the med-ical environment before the design can be final-ized. Issues faced during the field testing would be solved by reiterating the design. As this is a design that could potentially save lives, this de-sign once proven, would be available to the en-tire world for no patent cost. Development of cheap electronic components such as sensors and RFIDs to with-stand steam sterilization would allow for more iterations of the design. Further testing and ad-vancement would make this product obsolete but this product can help solve the current problem of sharps injuries. Maybe it can start up another D-Sharp project.

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