6.2 Glove Change (Negative & Positive Pressure) under sterile conditions

The gloves are the weakest part of an isolator and damage can happen easily. The check of the gloves should be a routine procedure performed every time the operator is working on the isolator. Once a whole or suspected damage is detected, immediate action should be taken to secure the isolator and replace the glove as soon as possible.

First action
Secure the Isolator by clamping the sleeve where the damage has been detected using one of the NKP sleeve clamps.

Component Parts

2 Sleeve Clamps (NKP)
Glove change bag (NKP)
Replacement Glove
Replacement Glove Cuff (or existing)
Replacement 3" (75mm) 'O' Ring (or existing)
1" (25mm) White Stretch Tape (NKP)
Sterilisation solution
Atomiser gun / compressor
Waste Bag and Paper Towels
Personal protective clothing

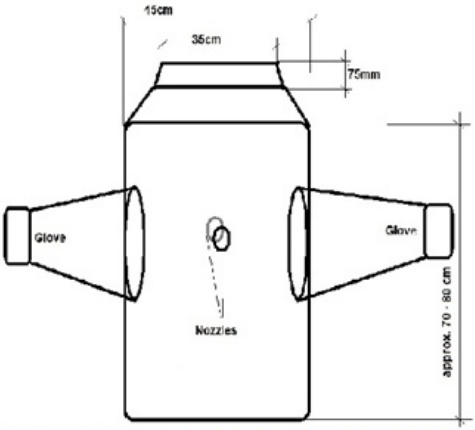
Tools
Scissors

Procedure

After clamping the sleeve, the Isolator contents are now safe and the damaged glove can be removed, by taking off the tape and simply pulling the glove with its fittings out of the sleeve. The area below the clamp on the sleeve is now "compromised" and not clean! This clamp has to stay in place until the glove change is complete!!!

A simple way to replace the glove is to now assemble a new glove with the cuff and O-Ring as described in Appendix B. To sterilise the area inside the sleeve and glove spray or pour some of your sterilant inside the sleeve before fitting the new glove (point 5- appendix B). With this version you need to be aware that there is a risk of incomplete decontamination if not performed properly.

The safest way to achieve a glove change in sterile conditions is the use of the "NKP Glove changing Bag":



There are spray nozzles at the front and the back of the glove-change-bag to enable easy spraying of sleeve and clamps

1. Attach sleeve clamp to affected sleeve
2. Remove the tape around the glove cuff to remove the damaged glove
3. Assemble glove with the cuff as described in appendix B up to step 4 only!
4. Clean the sleeve on the Isolator if any apparent dirt is visible and dry off as much as possible.
5. Using the glove change bag and second clamp place the assembled glove inside the bag and attach to the sleeve. Do not forget the second O-Ring.
6. Clamping it securely ABOVE the current clamp.

7. Using the help of a second person if possible spray all Items inside the bag carefully with your sterilisation solution. Take special care to cover the area around the clamp – inside the sleeve covering all areas well
8. Incubate according to your sterilisation procedures (at least 30mins)
9. Attach the glove to the sleeve following steps 5 to 9 / glove assembly appendix B - inside the glove change bag.
10. Making sure the glove has the correct orientation and is securely attached you can carefully remove the second clamp and glove change bag wearing suitable personal protection
11. Dry the area on the glove assembly carefully without removing the glove again from the sleeve until as dry as possible
12. Follow step 10 and secure the glove with the tape.

Dispose of any waste as per your Health and Safety instructions for chemical hazardous waste.