Stainless Steel Instrument Care & Re-processing

Briggate Medical Company offers a range of high quality surgical instruments crafted from the finest German stainless steel, resistant to corrosion. However, if not treated correctly, even the best stainless steel can lose its colour and be caused to prematurely corrode. Your surgical instrument has been designed for a very specific purpose and should be used accordingly; for example, nail clippers should ONLY be used for cutting nails, nothing else.

**Do not use your clippers to remove scalpel blades from scalpel handles as this WILL damage the clipper beyond repair.**

**Upon Receipt of Instruments**
Surgical instruments are supplied non sterile and must be cleaned and sterilised prior to use according to the procedures outlined in this document, unless stated otherwise on the packaging of the product. Visually inspect and check the surgical instrument for damage and wear.

**Precautions**
Use caution during cleaning and sterilisation to prevent damage, including avoiding a tumbling action. Instruments manufactured from different metals (i.e. Stainless Steel and Nickel) should be processed separately to avoid electrolytic action between the different metals. Keep blackened instruments and instruments made from different steels separate to avoid scratches and removal of the black coating.

**Care & Handling**
The procedures outlined below are recommended to ensure safe handling of biologically contaminated surgical instruments. All instruments must be sterilised before use. **NOTE:** When reprocessing medical devices always follow local Health & Safety procedures.

**Warnings**
Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used. Wherever possible, avoid use of mineral acids and harsh, abrasive agents. No part of the process shall exceed 140° Celcius. Some sensitive materials can be damaged by higher alkaline solutions, (pH > 10). **Note:** Single use devices must not be reprocessed and reused.

**Limitations on Reprocessing**
Repeated processing has minimal effect on the surgical instruments life span. The instruments “end of life” is normally determined by wear and damage in use.

**Reprocessing Procedure**

**1. Pre - Cleaning**
Wherever possible, do not allow blood, debris or bodily fluids to dry on surgical instruments. For best results and to prolong the life of the instrument, reprocess as soon as it is reasonably practical after use. If they cannot be reprocessed immediately, use an enzymatic cleaner to help prevent soil from drying, giving special attention to the blade fitting slots.

**2. Cleaning (Cleaning Precautions)**
Use an appropriate brush ensuring that it reaches the depth of the slots and threaded holes of particular instruments. Do not use abrasive detergents or cleaning materials. Normal tap water contains various minerals which may cause discoloring and corrosion. Distilled water is recommended to be used when cleaning, rinsing, and sterilising your instruments. Ultrasonic cleaning is the most effective and efficient method of instrument cleaning, but does not in any way replace sterilisation.
Ultrasonic cleaning is also the most effective method of cleaning burrs, blacks files and diamond-dust files.

Briggate Medical Company recommends Clinidet or Sonidet detergents for manual and ultrasonic cleaning and Aquasorb towels for drying.

Automated or Manual Cleaning

Automated Cleaning

Use only either TGA approved or validated washer/disinfector machines and low-foaming, non-ionising cleaning agents and detergents following the manufacturer’s instructions for use, warnings, concentrations and recommended cycles. Load instruments carefully so that slots, holes and grooves in the handle can drain. Take care not to overload wash baskets. Ensure that soft, high purity water, which is controlled for bacterial endotoxins, is used in the final rinse stage.

Note: These instructions have been validated using a washer-disinfectant cycle validated to include:
• one pre-wash stage at a minimum of 32°C
• one wash stage at > 60°C
• two rinse stages at > 60°C
• and a final disinfectant rinse stage at >90°C for a minimum holding time of one minute and a minimum drying stage of thirty minutes.

All instruments such as clippers, scissors and forceps should be opened and it is important to avoid excessive stacking and overloading. The detergent used should be an aqueous alkaline wash detergent cleaner with a maximum of pH12 and reverse osmosis water used for the rinse.

Manual Cleaning

Manual cleaning is not advised if an automatic washer/disinfector is available. If this equipment is not available use the following process:

i. Use a double sink system (wash / rinse) dedicated for instrument cleaning, (not used for hand washing). Ensure that the water temperature does not exceed 35°C Celcius.

ii. In the first sink, keeping the instrument submerged, use an autoclavable brush, apply a TGA approved cleaning solution to all surfaces and scrub until all soil has been removed. Pay particular attention to slots, holes and grooves, always brushing away from the body and avoiding splashing.

iii. In the second sink, rinse instruments thoroughly with soft, high purity water, which is controlled for bacterial endotoxins so that the water reaches all parts of the instrument. Then carefully hand dry or use a drying cabinet.

iv. After cleaning, visually inspect all slots and grooves for complete removal of soil and fluids. If ANY soil or fluid is still visible, return the instrument for repeat decontamination.

Note: Manual cleaning is NOT a disinfection process: when manual cleaning is used it may not be possible to disinfect the device prior to further handling. It is also important to take extreme care with any sharp points and use a nylon bristled brush (not stainless steel).

3. Final Inspection

Visually inspect and check the instruments one last time prior to lubrication and/or sterilisation.
4. Lubrication

If lubricants are required they need to be suitable to the sterilising agent and water miscible. They must be used in accordance to the manufactures instructions. Lubrication should not be used to overcome inadequate cleaning practices. Routine lubrication can lead to extremely heavy contamination. There are a number of reasons that stiffness can occur in instruments. This maybe due to:

- flash sterilising
- exposure to saline solutions
- inadequate cleaning,

and in these cases, stiffness will not be corrected by lubrication.

After cleaning and prior to packing for sterilisation, all moving parts to an instrument should be lubricated to the products guidelines. When using steam sterilisation it is vital to use a silicone and oil free lubricant. Never use oil-based lubricants, if you do, ensure that ALL remnants of the oil are completely flushed from the instrument using methylated spirits, prior to sterilisation.

IMPORTANT: After sterilisation, allow your clippers to cool to room temperature before using them. Using warm to hot clippers can cause the hinges or box joints to seize due to the expansion of steel with temperature.

Water-soluble lubricants should be applied to instruments that require lubrication. Instruments should be cleaned before the lubricant is applied. Cleaning, particularly ultrasonic cleaning, removes lubricants from instruments. Lubricants decrease friction between working surfaces. Unless otherwise specified, lubricants should be water soluble to allow steam penetration during sterilization; oil-based products cannot be penetrated. Briggate Medical Company recommends Miltex Spray Lube non-silicone and anti-corrosive for the lubrication of clippers.

5. Sterilisation

Note: All instruments to be packed following local protocol in accordance with AS/NZS 4187 sterilising standard. Use a TGA approved and validated porous steriliser with an air removal stage of 3 negative steam pulses (pressure 1.039 - 0.096 bar a) and five positive steam pulses (0.840 - 2.560 bar a) and a sterilisation temperature of at least 134°C, for a hold time of a minimum of 3 minutes.

Always follow the instructions of the machine manufacturer.

When sterilising multiple instruments in one autoclave cycle, ensure that the manufacturer’s stated maximum load is not exceeded. Ensure instruments are dry prior to sterilisation.

6. Storage

Ensure instruments are dry before storage, and stored in dry, clean conditions at an ambient room temperature.

NOTE: IT IS THE RESPONSIBILITY OF THE REPROCESSOR TO ENSURE THAT THE REPROCESSING IS ACTUALLY PERFORMED USING EQUIPMENT, MATERIALS AND PERSONNEL TO ACHIEVE THE RESULT AS OUTLINED IN THIS DOCUMENT AND TO CURRENT STERILISATION STANDARDS. THIS requires VALIDATION AND ROUTINE MONITORING OF THE PROCESS. LIKEWISE ANY DEVIATION BY THE REPROCESSOR FROM THE INSTRUCTIONS PROVIDED MUST BE PROPERLY EVALUATED FOR EFFECTIVENESS AND POTENTIAL ADVERSE CONSEQUENCES.