Document No. IFU-C12021/ Rev. 4

instruments have a smooth movement without excess play; locking mechanisms (such as ratchets) fasten securely and close easily; long, slender instruments are not distorted; any component parts fit and assemble correctly with mating components.

- Close instruments with a ratchet lock in the first ratchet position before sterilization to avoid temperature-induced stress cracks in the box locks.
- For devices that may be impacted, check that the device is not damaged to the extent that it malfunctions or that burrs have been produced that could damage tissues or surgical gloves.
- Defective or damaged products must be sort out for repair or replacement in case of any blunt, worn out, porous, deformed, corroded, stained, discolored instruments.

If an instrument is returned to the manufacturer / supplier, the instrument must be decontaminated and sterilized and be accompanied with the relevant documented evidence.

11. PACKAGING

All instruments should be packed in single use sterilized packaging and / or sterilization containers in accordance to BS EN ISO 11607, BS EN 868 and (HTM) 01-01.

12. STERILIZATION

- Ensure that the instruments are fully cleaned, dried and lubricated before sterilization.
- Use only CE marked and validated steam sterilizer, always follow instructions of the machine manufacturer.
- Protect sharp tips and place heavy instruments on the bottom, do not exceed manufacturer's stated load (10 kg - recommended load).
- A SAL (Sterility Assurance Level) of 10-6 must be achieved.

Sterilization of instruments by applying a pre-vacuum process (according to BS EN ISO 13060 / BS EN ISO 17665) under consideration of the respective country requirements the parameters for the pre-vacuum cycle are:

Cycle Type / Pressure	Recommended Min. / Max. temperature	Minimum exposure time / dry time*
3 Phases of Pre-Vacuum steam / at least 60 millibar	134°C - 137°C	3 to 5 minutes / 10 to 15 minutes dry time

Other forms of sterilization (i.e. Low temperature steam and Formaldehyde, Ethylene Oxide and Gas Plasma) can also be used. However, always follow the instructions for use as issued by the manufacturer and consult with them in case of any doubt over the suitability of process used. Further cleaning and sterilizing guidelines are available in Health Technical Memorandum (HTM)

13. STORAGE

All sterile wrapped instruments should be stored in dry, clean and dust free environment at modest temperatures of 5°C to 40°C, and at a constant humidity. Instruments should be stored individually in their shipping carton or in a protective tray with partitions. Protect tips, edges etc. with tubing, protecting caps, gauze or fabric. Make sure that no chemicals are close to or in the storage area. The distance between shelf and floor should be at least 30cm. Storage duration time is to be determined by the user.

14. DISPOSAL

End of service life instruments must be decontaminated and sterilized prior to disposal. Disposal should be in accordance with the guidelines of healthcare facility and local waste management protocols.

Do not use any damaged products.

15. GUARANTEE

Our products are made of high grade medical stainless steel and undergo a strict quality checks before being delivered. In case of any error or inconvenience, please feel free to contact our service department. We cannot provide any guarantee weather the instruments are suitable for the respective intervention. This has to be determined by the user.

*we cannot accept liability for random or consequential damage, we accept no liability if it can be proven that these instructions for use were violated.

REPROCESSING VALIDATION STUDY INFORMATION

For Validation study, following test devices, materials & machines have been used:

Detergent: Neodisher FA - Dr. Weigert UK Ltd
Endozime Enzymatic - Ruhof Corporation
Neutralizer: Neodisher Z - Dr. Weigert UK Ltd
Washer / Disinfector: Miele 7735 CD
Instrument Rack: Miele E 327-06
Key Hole Surgery Rack: Miele E 450
Further Decontamination Details: Health Technical Memorandum (HTM) 01-01

ADDITIONAL INSTRUCTIONS

If the described chemistry and machines are not available, it is the duty of the user to validate his process. It is the duty of the user to ensure that the reprocessing processes including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.

APPLICABLE DIRECTIVES, STANDARDS AND REFERENCES FOR IFU

Medical device directive 93/42/EEC Class I
BS EN ISO 7153-1
BS EN ISO 11607
BS EN ISO 15883
BS EN ISO 13060
BS EN ISO 17665
BS EN 868
Health Technical Memorandum (HTM) 01-01

SYMBOLS USED IN LABELING

Manufacturer

EC REP — European authorized representative

Consult instructions for use

Indicate a potential risk

CE marking according to Directive 93/42 EEC

LOT — Lot number

REF — Catalogue number

NON STERILE — Not sterile - sterile prior to use

Store in dry place

Protect from sunlight

Surgimax Instruments Ltd
Unit 108 Ivy Business Centre
Manchester England
M35 9BG

Tel: +44 (0) 161302 2744
Fax: +44 (0) 161302 2734
Email: sales@surgimax.co.uk
Internet: www.surgimax.co.uk

EC REP

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo n18
C.P 29006 Málaga-Spain
Tel: +34 951 214 054
E: info@cmcmedicaldevices.com
Internet: www.cmcmedicaldevices.com

surgimax™
saving lives

surgical instruments
chirurgische instrumente
instrumentos quirúrgicos
instruments chirurgicaux
strumenti chirurgici

Instructions for use
Gebrauchsanweisung
Instrucciones de uso
Mode d'emploi
Istruzioni per l'uso

DEVICE (S)

The following instructions are for all reusable medical devices supplied by Surgimax Instruments unless otherwise stated on packaging of the product. In order to minimize hazards for patients and users these directions must be closely obeyed. These instructions are intended for use only by persons with the required knowledge and training in a health care facility.

FIRST USE (INITIAL USE)

All instruments are supplied as non-sterile unless otherwise stated on the label, remove all packaging including plastic protection sleeves on instruments tips. Each instrument must be cleaned, rinsed and sterilized before it is used.

INTENDED USE

Surgical instruments are intended to perform specific functions such as clamping, cutting, dissecting, grasping, probing, retracting, suturing and other similar procedures. The user decides according to his specialized knowledge whether the instrument may suitable for the intended purpose.

MATERIALS

The instruments have been made from medical grade stainless steel in accordance to BS EN ISO 7153-1.

WARNINGS

- If this instrument is / was used in a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD) disease or an HIV infetion, the instrument cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross-contamination. Consult local regulations for further infomation.
- The surgical instrument must be inspected, cleaned and sterilized before each surgical procedure. No part of the process shall exceed 137°C.
- Avoid high alkaline solutions (pH>10) which can damage some sensitive materials (e.g. Aluminium).
- Follow instructions and warnings as issued by the manufacturer of any decontaminants, disinfectants and cleaning agents.

CAUTIONS

- When reprocessing surgical instruments, always handle with care, protective clothing, gloves and eyewear must be worn. The instruments must not be overstressed by twisting or levering as this may cause misalignment or cracking of the instruments.
- Delicate and sharp surgical instruments require special handling in baskets or containers to prevent damage.
- Instruments manufactured from different metals should be processed separately to avoid electrolytic action between the metals resulting in pitting and rusting of stainless steel instruments.
- Instruments made of stainless steel must not be put in physiological saline or chlorinated solutions (NaCl), as longer contact may lead to corrosion damages.
- Keep ebonized (blackened) instruments separate from other stainless steel instruments. Avoid mechanical cleaning processe and abrasive cleaners as these can scratch the surface and remove the ebonized coating.

LIMITATIONS ON REPROCESSING

- Repeated processing has minimal effect on instruments, due to the design and the used materials it is possible to fit a define limit of min. 100 practicable maintenance cycles. However, the lifetime of surgical instruments is determined by the function / wear and damage due to the intended surgical use.
- Any specific limitations on the number of reprocessing cycles shall be made available with the instrument, in case of damage the device must be reprocessed before sending back to Surgimax for repair.

REPROCESSING INSTRUCTIONS

1. INITIAL TREATMENT AT POINT OF USE

Remove gross debris from instruments with an absorbent wipes and steady stream of cold water (<35°C) immediately after use to prevent drying on of blood and body fluids which are highly corrosive, in additional blood can produce stains that are difficult to remove.

It is important to reprocess instruments that have been exposed to blood, if they cannot be reprocessed immediately, use an enzymatic foam spray cleaner to help prevent soil from drying.

2. TRANSPORTATION

Avoid mechanical damage during transportation to the processing area (e.g. do not mix heavy devices with delicate and sharp items). Pay particular attention to cutting edges to avoid injury and damage to or by the instrument. Ensure safe storage and transportation of instruments in a closed container or wire basket.

3. PREPARATION FOR DECONTAMINATION

- Reprocess all instruments as soon as it is reasonably practical following use.
- If appropriate, disassemble devices prior to reprocessing, open jaws of hinged instruments for cleaning and give special attention to joints and serrations.
- Instruments must be placed on adequate supports or trays. The nature of the supports or trays must not have any negative influence on the result of the following cleaning and disinfetion by rinsing or ultrasonic treatment.
- Do not soak instruments in hot water, alcohol, disinfectants or antiseptics to avoid coagulation of mucus, blood or other body fluids. Do not exceed 2 hours soaking in any solution.
- Do not use high acid (pH 4.0 or lower) or high alkaline (pH 10 or higher) products for disinfection. Neutral pH detergents 7.0 - 9.0 are preferred.
- Wherever possible avoid use of steel wool, wire brushes, harsh mineral acids and abrasive agents.

4. PRE-CLEANING (ULTRASONIC)

- Submerge the instruments into cold tap water for at least 5 minutes. Disassemble the instruments If possible and brush under cold tap water until all visible residues are removed. Inner lumens, threads and holes are flushed each with a water jet pistol for minimum 10 seconds in the pulsed mode.
- All Instruments must be placed in open position to effectively clean hinges, box locks and other moving parts. Keep joints open and ratchets unlocked.
- Then Immerse the instruments into an ultrasonic bath with an alkaline or enzymatic detergent (0.5%) and treat with ultrasound for 15 minutes at 40°C. Avoid over-crowding of instruments and place heavier instruments at the bottom of the basket. For delicate and sharp instruments, give extra care to prevent damage.
- Rinse instruments after ultrasonic cleaning with cold water to remove cleaning solution. Use distilled or demineralized water if possible.
- Do not place dissimilar metals (stainless, copper, chrome-plated etc.) in the same cleaning cycle.
- Change solution frequently and follow ultrasonic cleaner manufacturer's operating instructions.

5. CLEANING

5.1 AUTOMATIC CLEANING

For automatic cleaning, carefully load instruments, leaving box locks and hinges open on an instrument tray. Dismantlable instruments must be taken apart as far as possible. Give extra care for delicate instruments while placing heavy items on bottom and curved surfaces facing down to prevent pooling of water. Put the tray on an instrument rack in the washer disinfector and start the cycle as under:

5.1.1
1 min. pre-cleaning with cold water (<35°C)

5.1.2
draining

5.1.3
3 min. pre-cleaning with cold water (<35°C)

5.1.4
draining

5.1.5
5 min. cleaning at 55°C with 0.5 % alkaline; or at 45°C with an enzymatic detergent.

5.1.6
draining

5.1.7
3 min. neutralization with warm water (>40°C) and neutral izer

5.1.8
draining

5.1.9
2 min. rinsing with warm desalinated water (>40°C)

5.1.10
draining

Automated cleaning may not be suitable for all lumens and cannula, in which case clean manually with a water jet gun or with an appropriate brush that reaches the depth of the feature. After manually cleaning, pass all devices through an automatic cleaning cycle to achieve disinfection.

5.2 MANUAL CLEANING

In case of manual cleaning, the used detergents must be compatible in order to avoid any negative influence on the cleaning / disinfection result. Manual cleaning is not advised if an automatic washer-disinfector is available. If this equipment is not available, use the following process for manual cleaning.

- Use a double sink system (wash / rinse) dedicated for instrument cleaning (not used for hand washing). Ensure that the water tem perature does not exceed 35°C.
- In the first sink (Wash), keeping the instrument submerged, use a soft nylon brush to manually scrub instruments and apply CE marked cleaning solution to all surfaces until all soil has been removed. Always brush away from the body and avoid splashing. Do not use steel wool or steel wire brushes.
- In the second sink (Rinse), rinse instruments thoroughly with soft, high purified water which is controlled for bacterial endotoxins, pay close attention to hinged areas, box locks and moving parts and ensure that no debris remains. If necessary, a high pressure hose must be used, then carefully hand dry.
- The suitable detergent (Neutral pH detergents 7.0 – 9.0) must be used for the treatment of surgical instruments.
- The manufacturer's instructions regarding concentration and reaction time must be strictly obeyed.

Manual cleaning is NOT a disinfection process.

6. DISINFECTION

6.1 AUTOMATIC DISINFECTION

Automated thermal disinfection must be done with desalinated water in washer / disinfector under consideration of national requirements in regards to A0-value (see BS EN ISO 15883).

6.2 CHEMICAL DISINFECTION

For chemical disinfection, a suitable detergent must be used, rinse
instruments thoroughly after disinfection under running water. Do not use bleach (sodium hypochlorite).

Disinfection is not an alternative to Sterilization.

7. CLEANING INSPECTION

After cleaning, visually inspect all surfaces, ratchets, box locks, holes, channels and lumens for complete removal of soil and fluids. If ANY soil or fluid is still visible, return the instrument for repeat decontamination.

8. DRYING

8.1 AUTOMATIC DRYING

Instruments must be thoroughly dried and all residual moisture must be removed before they are sterilized. Automated drying cycle of washer/disinfector is performed to dry outer sides of the instruments.

8.2 MANUAL DRYING

For manual drying of instruments, a lint free towel or soft cloth can be used to dry external surfaces. Insufflate cavities of instruments by using sterile compressed air.

9. LUBRICATION

Apply surgical grade (non-silicone, water soluble) lubricants to hinges, box locks and moving parts as per the lubricant manufacturer's instructions. Do not use industrial oils or lubricants.

10. FUNCTION TESTING AND MAINTENANCE

- Visually inspect and check all instruments for damage and wear; cutting edges are free of nicks and present a continuous edge; jaws and teeth align correctly; all articulated