Instructions for Use - Reusable Surgical Instruments

This instruction for use (IFU) is valid for all reusable surgical instruments supplied by Boss Instruments Ltd. unless otherwise stated with the packaging of the product.

Important Information

Read this instruction carefully before every application and keep it easily accessible for all users.

Carefully read the warnings marked with this symbol. Improper use of the products may result in serious injuries to the patient, the users or third parties.

1 Intended Use

Surgical Instruments are intended for use in the surgical setting for clamping, cutting, dissecting, grasping, probing, retracting and/or suturing. The instruments must be used according to their intended use in the medical fields and by adequately trained and qualified staff only.

The treating physician and/or user is responsible for choosing the correct surgical instrument(s) for specific applications and/or operative use, for having the adequate training and knowledge, and for having sufficient experience regarding the handling of surgical instruments.

The instruments are intended for transient use and should be replaced after such time period has passed.

2 Description of Symbols Used

⚠	Caution
	Consult instructions for use
Rx ONLY	Prescriptive device
REF	Catalogue number
LOT	Batch code
NON STERILE	Non-sterile product
	Manufacturer
MD	Medical device

3 Contraindication

The improper use of a surgical instrument during handling, surgical use or reprocessing, for which they are indicated, may result in damaged or broken instruments. Furthermore, the instruments must be used according to their intended use in the medical fields and by respectively trained and qualified medical personal only. The instruments should not be used in direct contact with the central circulatory system and/or direct contact with central nervous system.

4 Warnings

⚠ Creutzfeldt Jakob Disease/TSE

If this instrument is/was used in a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD), 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 WHO and local regulations for further information. Dry heat, ethanol, formaldehyde and glutaraldehyde have a fixing but no inactivating effect on TSE pathogens (prions). Of the sterilization methods available, only steam sterilization (especially 134°C, 18 minutes) has been shown to have a limited effect.

⚠ Non-Sterile!

Surgical instruments are delivered in a non- sterile condition and must be inspected, cleaned, and sterilized before each use.

5 Cautions

⚠ Caution:

Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

All surgical instruments covered by this IFU are considered to be medical devices for use in human medicine with regards to national and international laws.

⚠ Attention!

Surgical instruments are only designed for surgical use and must not be used for any other purpose. Improper handling and maintenance as well as misuse may result in the premature wear and tear of the instruments.

⚠ Material intolerance

Under no circumstances should the instruments be used if the user becomes aware of the patient being intolerant to their composition. Surgical instruments are made of stainless steel, titanium, titanium alloy, aluminum alloy and other biocompatible, autoclavable, non-metallic materials on an individual basis.

⚠ Functional Impairment

Surgical instruments corrode and their functionality can become impaired if they come into contact with corrosive substances. Therefore, it is essential to follow all applicable cleaning and sterilization guidelines as stated in this IFU.

⚠ Operating Conditions

Surgical instruments require correct maintenance and care in order to guarantee that the devices operate safely. Due to this, functionality testing and a visual inspection should be performed prior to each use.

6 Reprocessing

⚠ Precautions

When reprocessing surgical instruments, always handle with care, wearing protective clothing, gloves and eyewear in accordance with local health & safety requirements.

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.

Delicate surgical instruments require special handling to prevent damage.

Do not use excessive force or place strain on joints; mishandling can result in misalignment or cracks to box locks or jaws.

Aluminum and titanium instruments that are color anodized may lose their color over time through normal use and reprocessing.

Keep ebonized instruments separate from other stainless steel instruments to avoid scratches or damage to the coating.

⚠ Limitations on Reprocessing

Repeated reprocessing has minimal effect on the instruments. Boss Instruments does not define the maximum number of usage or preparation cycles for reusable surgical instruments. The life cycle of an instrument can be dependent upon many factors including the type and length of usage, handling, storage and transport of the

instruments. The end of useful life for metal surgical instruments is normally determined by wear during their use or damage to the instrument. Thorough examination and functional testing before the next use is the best possible way to detect non-functioning instruments.

Reprocessing Instructions

⚠ From Point of Use

Wherever possible, do not allow blood, debris or body fluids to dry on instruments. For best results and to prolong the life of the surgical instruments reprocess immediately after use. If they cannot be reprocessed immediately, use an enzymatic foam spray cleaner to help prevent soil from drying.

All instruments opened in the operating or procedure room should be considered contaminated whether or not they have been used.

⚠ Transport

Soiled instruments should be clearly identified and transported in rigid, puncture-resistant, closed containers or other methods that prevent unnecessary contamination risk.

Preparation for Decontamination

Reprocess all instruments as soon as it is reasonably practical following use.

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.

Do not use high acid (pH 4.0 or lower) or high alkaline (pH 10.8 or higher) products for disinfection. Neutral pH detergents 7.0 – 9.0 are preferred.

If appropriate, disassemble instruments prior to cleaning and sterilization, without the use of tools unless specifically provided by the manufacturer to do so.

Open jaws of hinged instruments for cleaning. Give special attention to joints and serrations when cleaning.

Remove gross contaminants with a steady stream of lukewarm/cool water, not to exceed 35° C (95° F). Rinse each instrument thoroughly. Movable parts must be moved.

Where available, use appropriate cleaning accessories to flush instruments with channels or lumens.

Do not use saline or chlorinated solutions.

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 steel wool, wire brushes, pipe cleaners or abrasive detergents.

Cleaning/Disinfection: Automated

Use only validated washer-disinfector machines with proven effectiveness (e.g. U.S. FDA approval or CE mark according to EN ISO 15883) and low-foaming, non-ionizing cleaning agents and detergents.

Load instruments carefully, leaving box locks and hinges open so that any openings in instruments can drain.

Place instruments with curved surfaces facing down to prevent pooling of water.

Place heavy instruments on the bottom of containers, taking care not to place on delicate instruments or overload wash baskets.

Ensure that soft, highly purified water that is controlled for bacterial endotoxins is used in the final rinse stage.

⚠ Note: Automated cleaning may not be suitable for all lumens and channels, in which case clean manually with a water jet, if available, and an appropriate brush (and stylet if provided) that reaches the depth of the feature. After manually cleaning, pass all instruments through an automatic cleaning cycle to achieve disinfection.

Cleaning/Disinfection: Manual

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 temperature does not exceed 35º C (95º F).

In the first sink, keeping the instrument totally immersed, with an appropriately-sized autoclavable soft nylon brush, apply validated cleaning solution to all surfaces until all soil has been removed. Pay particular attention to serrations, teeth, ratchets, box locks and hinges, always brushing away from the body and avoiding splashing.

Follow all manufacturer's instructions for required concentration, temperature and contact time of the validated cleaning solution.

Ensure rongeurs and hinged instruments are thoroughly cleaned in both open and closed positions.

Use a large syringe or water jet to thoroughly flush all channels and lumens with cleaning solution to remove debris.

In the second sink, rinse instruments thoroughly with soft, highly purified 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

⚠ 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.

Drying

Instruments must be thoroughly dried and all residual moisture must be removed before they are sterilized. Use a soft absorbent towel or cloth to dry external surfaces.

Lubrication

Apply surgical grade (non-silicone, water soluble) lubricants to hinges, box locks and moving parts as per the lubricant manufacturer's instructions.

Inspection and Function Testing

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 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.

Consider removing for repair or replacement any blunt, worn out, flaking, fractured, corroded, stained, discolored or damaged instruments.

Packaging

All instruments should be wrapped or packaged following local procedures; specific requirements can be found in ANSI/AAMI ST79 and/or ISO 11607-1 and EN 868.

Ratcheted instruments should be unlatched. Racks, pins, stringers, or other

specifically designed devices can be used to hold the instruments in the unlatched position.

Rigid container systems may be used for the sterilization of surgical instruments. When such a system is used, all items should be contained within a basket or tray with the container system. Instruments should also be positioned in such a way as to allow sterilant to come into contact with all surfaces. Always follow all container manufacturer's instruction for use. Stacking of containers is allowed if so indicated in the container manufacturer's instruction for use.

Sterilization

Sterilization of products with a fractionated pre-vacuum method has been validated (according to ISO 17665).

Do not exceed 140° C (284° F) during sterilization cycle.

Use only a validated, properly maintained steam sterilizer to conduct all sterilization processes and always follow the sterilizer manufacturer's instructions for use.

Validated exposer time and temperature to achieve 10^{-6} sterility assurance are as follows:

Cycle Type	Minimum Temperature	Minimum Exposure Time / Dry Time *
Pre-vacuum Method	132°C (270° F)	4 minutes / 20 minutes dry time for metal or metal/plastic trays and 45 minutes for all plastic trays

* AAMI/AORN steam sterilization cycles with longer times than those listed are also acceptable

⚠ **Attention!** It is the responsibility of the reprocessor to ensure that the reprocessing, as actually performed using equipment, materials and personnel in the reprocessing facility. Achieve the desired result. 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.

Service and Repair

Do not carry out any repairs or changes to the products yourself. Boss Instruments Ltd. can supply authorized repair services.

⚠ Note: If an instrument is returned to the manufacturer / supplier, the instrument must be decontaminated and sterilized and be accompanied with the relevant documented evidence, otherwise a cleaning charge may apply and delay processing of the repair.

Please contact Boss Instruments Ltd. for additional information.

Boss Instruments Ltd.
104 Sommerfield Drive
Gordonsville, VA 22942 USA
Toll Free (USA): 800-210-2677
Phone: 540-832-5000
Fax: 540-832-5515
www.bossinstruments.com