Instructions for Use: Non-Sterile Reusable Orthopaedic Surgical Instruments

Instructions for Use: DBS-IFU-001_RevA Issue Date: Jun-2023

Caution:
Carefully read all the instructions and be familiar with the surgical technique(s) before use of the system. This product must only be used by trained and qualified persons aware of the directions for use.
U.S. Federal law restricts this device to sale, distribution, and use by or on the order of a physician.

1 GENERAL INSTRUCTIONS

The surgeon must be knowledgeable in the medical and surgical aspects of the parts and their mechanical limitations. ***DBS*** instruments should only be used with approved devices and accessories.

2 DESCRIPTION

a) Surgical instrumentation may include a device, a storage tray, and a lid. Each instrument is identified by a reference or part number and a manufacturing batch (lot) number. This information is on the instrument.
b) Only a qualified surgeon may use the instrumentation by following current data on progress in the science and art of surgery and with the manufacturer's recommendations in the following documents: marketing leaflet, operating techniques, templates, etc.
c) The surgeon must ensure the equipment is in good working order before using it.
d) Some small precision instruments have a limited life, and this can be further decreased by a lack of care in handling the equipment or providing inadequate protection. Any faulty instrument (worn out, incorrect handling, inadequate upkeep) must be discarded.
d) **Precautions before use**: The instruments are clean but NOT STERILE on delivery. Before use, the hospital is responsible for decontaminating, cleaning, and sterilizing the instrumentation using validated methods. The following recommendations do not replace current health regulations (standards, good practices, guides, national recommendations, ministerial documents, etc.).

3 INDICATIONS

a) The DBS-Dynamic Balancer is indicated for use in total knee arthroplasty (TKA) procedures to aid in the intraoperative balancing of soft tissue structures. The device assists in the objective measurement of distraction forces between the tibia and the femur.
b) The device is intended for use in operating room settings, under the guidance of trained medical professionals who are proficient in performing TKA procedures.

4 INTRODUCTION

a) Before any operating room procedures, the packaging should be removed, and a visual inspection conducted to ensure that all the instruments are in good condition.
b) The instruments consisting of removable components should be disassembled before decontamination, cleaning, and sterilization. Articulated instruments should be opened to ensure every notch is cleaned.

5 CLEANING AND DECONTAMINATION

a) Cleaning, decontamination, and sterilization are mandatory before introducing instruments into a sterile surgical field or returning the product to ***DBS***. Cleaning, decontamination, and sterilization are mandatory after the instrument is used in a surgical procedure. Cleaning and decontamination aim to decrease the initial bacteria population, facilitate later cleaning, protect staff handling the instruments, and avoid environmental contamination.
b) Immediately after use, the instruments should be opened and immersed in distilled water or placed on a tray and covered with a damp towel.
c) Saline must not be used because of its corrosive effect on stainless steel. The equipment must be decontaminated as quickly as possible after use. It should also be remembered that certain agents may discolor or corrode the instruments. This includes agents containing bleach, hypochlorite solutions, sodium chloride, formalin, and glutaraldehyde.
d) Rinse water should be highly purified water (treated by reverse osmosis or distillation) or distilled water (if there is not an endotoxin issue).
e) MANUAL CLEANING:

- Prepare a decontaminant solution according to the manufacturer's recommendations using lukewarm water. The solution must be at a temperature of less than 30°C to prevent bacteria from adhering to the instruments. Fully immerse the articles in the prepared solution, actuating them through their full range of motion, flushing all hard-to-reach areas using an appropriately sized syringe with a minimum of 50 mL of the prepared detergent per article, and then allow the article to soak for the minimum amount of time as stated in the precautions for the use of the decontaminant.
- After the minimum soak, brush the articles thoroughly using a soft-bristled brush (M16) beneath the surface of the prepared solution until all visible soil has been removed. Hard-to-reach areas require special attention during cleaning.
- Remove the articles from the solution and thoroughly rinse under running water until all solution residues are removed. Actuate the articles through their full range of motion while rinsing. During rinsing, thoroughly brush the articles using a soft-bristled brush (M16), paying special attention to hard-to-reach areas. Actuate the articles through their full range of motion while brushing. During rinsing, flush the articles thoroughly using an appropriately sized syringe with a minimum of 50 mL of water per article, paying special attention to hard-to-reach areas. Actuate the articles through their full range of motion while flushing.
- Dry the articles using a clean, soft cloth and filtered pressurized air (≤ 40 psi). Visually inspect the articles for cleanliness.
- After drying and the visual check for cleanliness are complete, lubricate all moving parts with a water-soluble instrument lubricant before sterilization. Acceptable water-soluble lubricants may include but are not limited to: Steris Hinge-Free® Instrument Lubricant and Sklar Instru-Guard™ Lube (10-1636 or 10-1635). Apply lubricants per the manufacturer's instructions. Lubrication is key to preserving the proper function of your instruments.

f) AUTOMATED CLEANING

- Automated cleaning should not be used in isolation. It is required that automated cleaning be utilized in conjunction with manual cleaning.
- Thoroughly rinse the articles under running water using a disposable paper towel to remove gross contamination.
- Transfer the articles into the automatic washer/disinfector for processing. Orient the articles at an incline to facilitate drainage.
- Select the cleaning cycle.
- Set the cleaning cycle to high and to the following set of parameters.

Phase	Recirculation Time	Temperature	Detergent, Concentration
Pre-wash 1	2 minutes	Cold water	N/A
Enzyme Wash	2 minutes	Hot water	Enzol®, 1 oz/gal
Wash 1	2 minutes	151° F (66° C)	Valsure® Neutral, ¾ oz/gal
Rinse 1	2 minutes	Hot water	N/A
Drying	7 minutes	187° F (86° C)	N/A

- Remove the articles from the automatic washer/disinfector. If moisture remains on the articles, dry them using a clean, soft cloth and filtered pressurized air.
- After drying, lubricate all moving parts with a water-soluble instrument lubricant. Acceptable water-soluble lubricants may include but are not limited to: Steris Hinge-Free® Instrument Lubricant and Sklar Instru-Guard™ Lube (10-1636 or 10-1635). Apply lubricants per the manufacturer's instructions. Lubrication is key to preserving the proper function of your instruments.

6 STERILIZATION

a) The instruments, containers and tray are suitable for sterilization by steam at a temperature of no more than 140°C. We recommend Standard NF EN 17665. The instruments should be prepared so that all surfaces are in direct contact with the steam. Hinged instruments and sliding devices should be opened, complex instruments should be dismantled, and all parts should be safely secured in the sterilization box. As a guideline, the following sterilization method is recommended:

STEAM AUTOCLAVE PRE-VACUUM
Condition: Use Instrument Trays
Preconditioning: 3 pulses
Temperature: 270° F (132° C)
Time: 4 minutes
Drying Time: 20 minutes

Note: Drying time is subject to variation depending on machine load.

b) The sterilizer's manufacturer's recommendations should be strictly followed. The sterilization process and adjustment of the autoclaves should be checked regularly. If there is residual dampness in the sterilization box after the sterilization cycle, proceed as follows:

- Do not open the box immediately after use.
- Increase the drying time unless tests show that the exposure time has been adequate to obtain the required time for sterilization.
- Make additional perforations in the box to facilitate the run-off of the residual humidity.

c) The recommendations on sterilization are only given as a guideline. Under no circumstances can the manufacturer be held responsible for the sterility of devices sterilized within the hospital.

7 MAINTENANCE, STORAGE, AND HANDLING

a) Instruments are to be stored in dry, clean surroundings at room temperature, in their original packaging or sterilization tray, respectively, and follow AS/NZS4187:2003.
b) Surgical instruments should be handled and stored with care. Instruments should be carefully stored in an appropriate, dry, clean environment. Instruments must not be stored in contact with, or close to, products that may have a corrosive effect.
c) Procedures to be implemented after use: The hospital is responsible for decontaminating, cleaning, and sterilizing the instrumentation (full box or single instrument) following the manufacturer's recommendations. Any missing or damaged instrument should be reported to your representative, distributor, or manufacturer.

8 INSPECTION AND FUNCTION TESTING

DBS reusable instruments are designed for many procedures and endure many sterilization cycles. Before each sterilization cycle, visually inspect for damage and wear. An instrument should be considered at its end of use if it shows signs of deterioration, corrosion, discoloration, pitting, cracking, nicking of edges, or excessive deformation. Confirm the smooth movement of hinged instruments without excessive "play." Locking (ratchet) mechanisms should be checked for action. Check instruments with long slender features (particularly rotating instruments) for distortion. Where part of a larger assembly, check assembly with mating components.

9 LIMITED WARRANTY / LIABILITY

DBS products are sold with a limited warranty to the original purchaser against defects in quality and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

DBS shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly, arising from using this product. ***DBS*** neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this product. ***DBS*** intends that these instruments be used only by physicians having received appropriate training in orthopedic surgical techniques.

10 CONTACT INFORMATION

If more than 2 years have elapsed between the date of issue/revision of this document and the date of patient consultation, contact the appropriate ***DBS*** location for current information. For further information or questions about sales and service please contact your local sales representative or the appropriate ***DBS*** location as listed below:

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11 LABEL SYMBOL LEGEND