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1. Purpose

These instructions are recommended for the care, cleaning, maintenance and sterilization of reusable Orthobion orthopedic manual surgical instruments. This document is intended to assist health care personnel in safe handling practices, effective reprocessing and maintenance of Orthobion reusable instruments. It provides information complementary to the instructions for use in fulfillment of the European Council Directive 93/42/EEC, Annex 1, section 13.6 (h).
The instructions are intended to assist the hospital and central supply management in developing procedures for safe and effective reprocessing of Orthobion instrument sets.
Please consult the applicable surgical technique for selection and use of a device and check the full labeling for other necessary information. Surgical technique brochures may be by requested from a distributor or from Orthobion GmbH. directly. Those using brochures published more than two years before the surgical intervention are advised to obtain an updated version.

Hospital personnel may be directly involved in handling instruments from Orthobion. Hospital directors and other management in each of these departments should be informed of these instructions and recommendations to ensure safe and effective reprocessing and to prevent damage or misuse of reusable devices.
Orthobion GmbH. devices can only be used by surgeons who are fully familiar with the surgical technique required and who have been trained to this end. The operating surgeon must take care not to use the instruments to exert inappropriate stress on the patient or the implants and must scrupulously comply with any operating procedure described in the surgical technique provided. For example, the forces exerted when repositioning an instrument in-situ must not be excessive as this is likely to cause injury to the patient.

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

CONTACT:
See brochure for telephone and address of local representative/distributor, or contact:

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D – 78467 Konstanz
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2. Scope

This instruction manual provides information on the care, cleaning, disinfection, maintenance and sterilization of manual surgical instruments and is applicable to all reusable medical devices manufactured and/or distributed by Orthobion.

Basis UDI: 4050762OrthInstrumentsY8

Orthobion Instruments are a Class I product, designed with respect to body orifices and not for connection with active medical devices.
Orthobion Cervical and Lumbar Instruments are intended for a transient use during a spinal surgery with Orthobion spinal cages.
Orthobion Hohmann Instruments are intended for a transient use during a hip or knee surgery
Orthobion Instruments are not indicated for pediatric surgeries.
Orthobion Instruments can be used without any accessory.

Other reprocessing procedures, as described in this instruction for use, are not allowed.

Devices not labeled as sterile are non-sterile. The packaging of all sterile devices should be inspected for flaws in the sterile barrier or expiration of shelf life before opening. In the presence of such a flaw or expiration of shelf life, the product must be assumed non-sterile.

In the event of contamination of reusable devices, or expiration of shelf life or in the case of devices supplied non-sterile, the device must be subjected to an appropriate and validated cleaning process and sterilization procedure.
Orthobion Instruments are validated for 100 reprocessing cycles. Use the instructions chart below for (re)processing medical devices.

	Supplied non-sterile	Expiration shelf life	Contaminated with body fluids	Contaminated other	Over 100 reprocessing cycles
Reusable device	(Re)process	(Re)process	(Re)process	(Re)process	Discard

CAUTIONS	• Long, narrow cannulations and blind holes require particular attention during cleaning. • Always clean cannulated devices intra-operatively to prevent accumulation of bone debris in the cannulation. • Microsurgical instruments should be cleaned separately from other instruments. • For good maintenance, reusable instruments must be pre-cleaned, cleaned and sterilized immediately after surgery.
Limitations on reprocessing	• Repeated processing has minimal effect on these products. Orthobion Instruments are validated for 100 (re)processing cycles..

3. Important Notes

Any Orthobion Instruments are not designed and indicated to be in contact with the central nervous system. The instrument 99.122 Retractor is only to protect the central nervous system from damage. To move the central nervous system please use Instruments, which are indicated for this use.

4. Symbols

LOT
Batch code

Non sterile

REF
Catalogue number


Manufacturer

QTY
Quantity


Manufacturing date


Caution, consult documents


CE Approval

℞ONLY
Only trained surgeons

5. Materials

Ti = Titanium and its alloys
S = Stainless steel
P = Polymer
C = Carbon Composite

6. Warnings and Precautions

- The Orthobion Instruments are not designated to clean or sterilize in a tray. The tray is only for organization and transportation.
- Before using / sterilization check instruments optically and functionally. If there are f.e. rust, damages, broken parts reject the instrument immediately.
- All threads are easy to handle, a dismantle of single Instruments in components (f.e. 99.019 Hamer into Handle, Shaft etc.) is not necessary.
- Universal Precautions should be observed by all hospital personnel that work with contaminated or potentially contaminated medical devices. Caution should be exercised when handling devices with sharp points or cutting edges.
- Personal Protective Equipment should be worn when handling or working with contaminated or potentially contaminated materials, devices and equipment. The Protective Equipment includes gown, mask, goggles or face shield, gloves and shoe covers.
- Cleaning agents with low foaming surfactants should be used during manual cleaning procedures to ensure that instruments are visible in the cleaning solution. Manual scrubbing with brushes should always be performed with the instrument below the surface of the cleaning solution to prevent generation of aerosols and splashing. Cleaning agents must be completely rinsed from device surfaces to prevent accumulation of detergent residue.
- Mineral oil or silicone lubricants should not be used in the cleaning process of Orthobion Instruments
- Do not stack instruments or place heavy devices on top of delicate instruments
- Descaling agents that includes morpholine should not be used in steam sterilizers. Steam sterilizers should be descaled in accordance with the instruction of the manufacturer.

7. (Re)Processing

INSTRUCTIONS CHART FOR (RE)PROCESSING MEDICAL DEVICES	
Preparation at the point of use	• Remove gross soil
Containment and transportation	• It is recommended that the devices are reprocessed as soon as is reasonably practical following use
Preparation for cleaning	• Disassemble where possible following assemble/disassemble instructions
Cleaning – automated	Pre-cleaning • Rinse excess soil from device with cold (<40°C) tap water and nonmetallic brush for at least 1 min • Flush inner lumen with water jet pistol or 50 ml cold (<40°C) tap water using a syringe (without needle!) • Soak in ultrasonic bath for 15 minutes in mild detergent (e.g. 0.5% Neodisher® Mediclean forte) • Rinse with demineralized water (<40°C) for at least 1 min • Repeat cycle until no visible residuals are left Washer-disinfector • Load devices such that hinges are open and cannulations and holes are rinsed and can drain. • Pre-cleaning with cold tab water (<40°C) for 4 min. • Cleaning with alkaline detergent for 5 min at 55°C (e.g. 0.5% Neodisher® Mediclean forte) • Neutralization with e.g. 0.1% Neodisher®-Z for 1 min at 40°C • Rinse with deionized cold water<40°C [Critical Water according to AAMI TIR 34]) for 2 min • Thermal disinfection with demineralized water at minimum 90 °C for 5 minutes (Following the A_0-Concept with a A_0 value >3000)

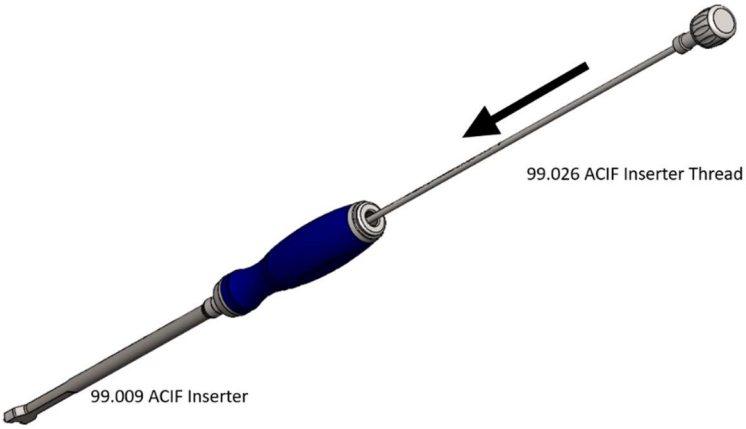
	• 40 min hot air drying at 110°C (program parameter) • When unloading, check cannulations, holes, etc. for complete removal of visible soil. • If necessary, repeat cycle or use manual cleaning.
Cleaning – manual	Pre-cleaning • Rinse excess soil from device with tap water and nonmetallic brush • Flush inner lumen with water jet pistol or 50 ml water using a syringe (without needle!) Manual cleaning • Soak device in ultrasonic bath for 15 minutes in mild detergent • Using nonmetallic brush, apply detergent solution to all surfaces ensuring that hinged instruments are cleaned in both open and closed positions • Pay close attention to threads and hard to reach areas. • Clean cannulations and holes using an appropriate brush ensuring that full depth of the feature is reached • Flush inner lumen with water jet pistol or 50 ml water using a syringe (without needle!) • Rinse with demineralized water. • Ensure that running water passes through cannulations, and that blind holes are repeatedly filled and emptied • Repeat cycle until no visible residuals are left
Manual Disinfection:	• Plunge Instruments in a RKI (Robert Koch Institut), VAH (Verbund für Angewandte Hygiene e.V.) or FDA listed disinfectant. Obey the Instruction for use from the disinfectant manufacturer. • All surfaces of the device must be in contact with the disinfectant; moving parts are to be actuated.

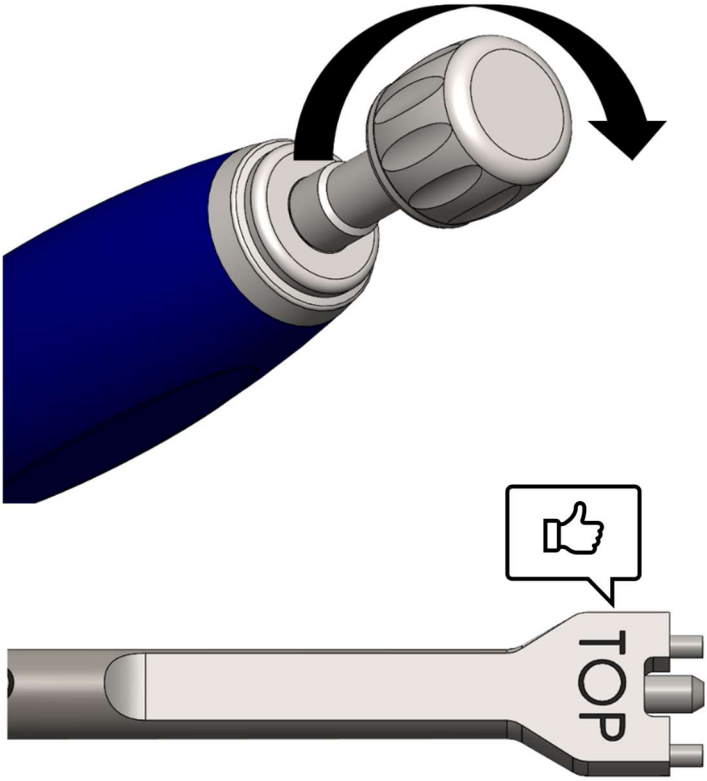
	• Rinse with demineralized water.
Drying	• Dry devices after cleaning with lint-free cloth, or • When drying is achieved as part of a washer-disinfector cycle, do not exceed 120 °C (248 °F)
Maintenance	• Apply a small quantity of surgical grade lubrication oil to hinges and threaded sections. • Discard blunt, bent, worn or damaged devices.
Inspection and testing	• Hinged instruments: Check for smooth movement of hinge without excessive “play.” • Locking and ratchet mechanisms should be checked for action. • Threaded devices must run smoothly. • All devices: Visually inspect for damage and wear. Cutting edges should be free of nicks and present a continuous edge. • Check devices with long, slender features (particularly rotating instruments) for distortion. Where devices form part of a larger assembly, check assembly with mating components. • Assemble where possible following assemble/disassemble instructions
Packaging	• Singly: A standard packaging material may be used. Ensure that the pack is large enough to contain the device(s) without stressing the seals. • In sets: Devices may be loaded into dedicated trays or general-purpose sterilization trays. Ensure that cutting edges are protected. Double wrap the trays using appropriate method.
Sterilization (Preferred method)	• Dynamic-air-removal steam sterilization method (pre-vacuum), at least 3x • Exposure time: 4 minutes • Temperature: 132 °C (269.6 °F) • Pressure: 3.0 bar (45 PSI) • Drying time: >20 minutes
Storage	• Control environment • Control storage time

8. ASSEMBLY OF INSTRUMENTS

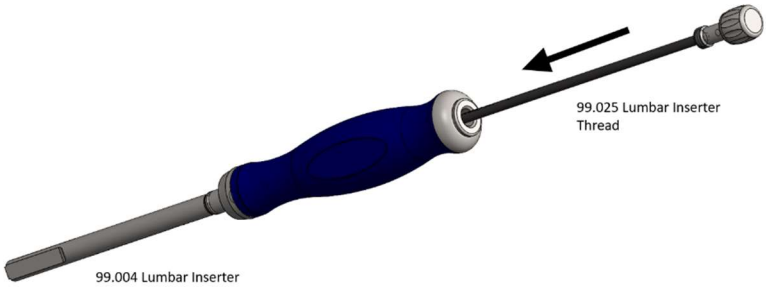
In the following chapter are all instruments described, which can be connected or assembled after reprocessing

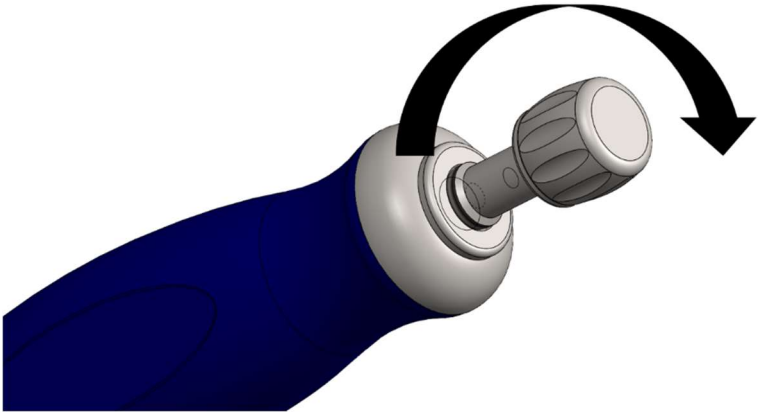
8.1. Cervical Inserter

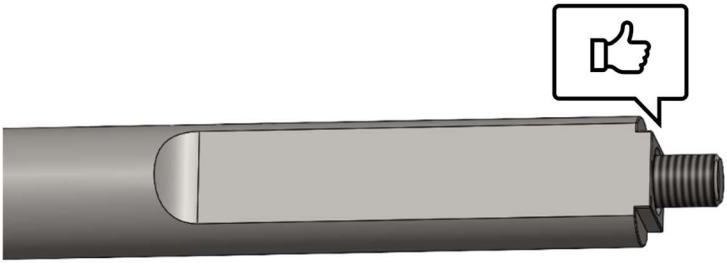



TOP

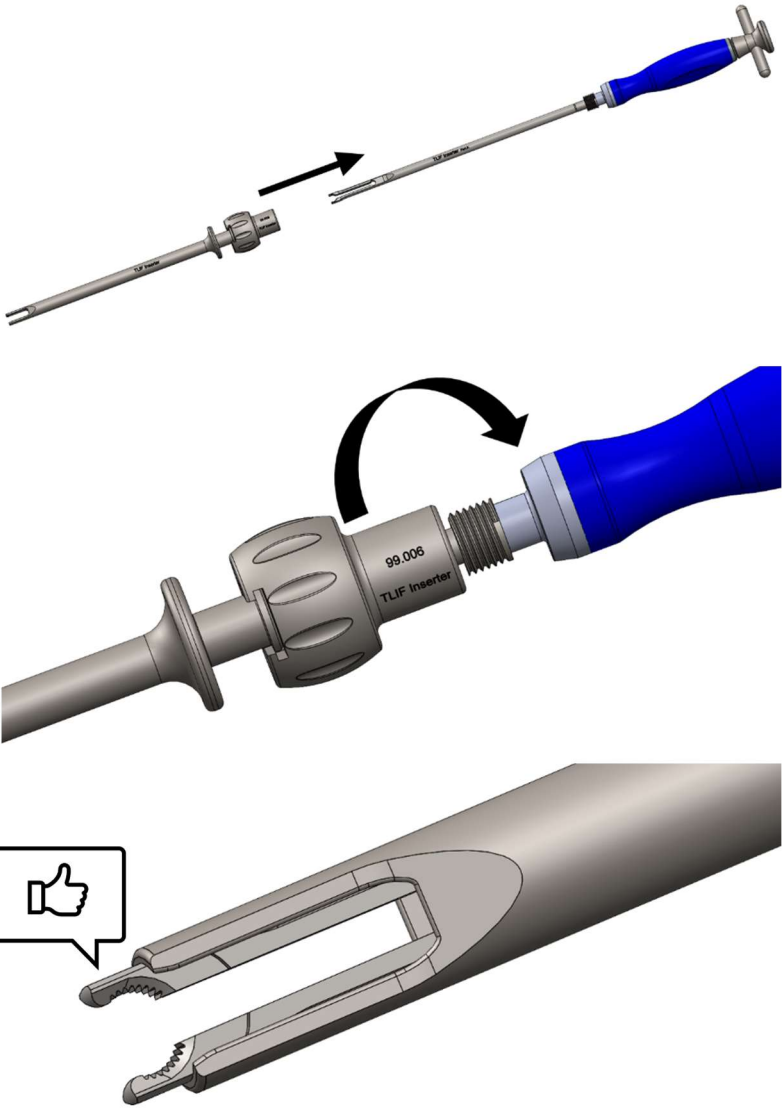
8.2. Inserter PLIF; PTLIF; TLIF







8.3. Inserter TLIF Banana 99.006


99.006
TLIF Inserter

ADDITIONAL STERILIZATION INFORMATION

When sterilizing multiple devices in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded. The cleaning, sterilization and storage processes is validated by the manufacturer as listed above but must be also validated by the hospital. The autoclave must be regularly checked to guarantee that the recommended sterilization temperature is reached for the entire exposure time. If sterilization containers with paper filters are used, it is advisable to use a new filter for each sterilization. If after having followed this sterilization method there is still water in the sterilization containers or on/inside the device, the device must be dried and sterilization repeated.

For further information concerning cleaning and sterilization, please consult:

AAMI Technical Information Report (TIR) 12	
EN285:2006 + A2	Sterilization - Steam sterilizers - Large sterilizers
ISO15883	Washer-Disinfectors
EN 868	Packaging materials and systems for medical devices which are to be sterilized
ISO11607	Packaging for terminally sterilized medical devices