Table of Content

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:

Orthobion GmbH
Gottlieb-Daimler-Strasse 5
D – 78467 Konstanz
Germany
spine@orthobion.com
www.orthobion.com

CE 0044

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. Any deviation by the processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

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 re-processing cycles
Re-usable 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. Materials

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

5. Warnings and Precautions

It is the responsibility of the medical facility to ensure that reprocessing is performed using the appropriate personnel, equipment and materials in order to achieve the desired result. Operators must ensure that staff involved in reprocessing have received adequate education on reprocessing (e.g., completion of a course) and training on the specific operation of any reprocessing equipment used in the business. No specific training is required for the reprocessing of Orthobion instruments. Equipment and processes should be validated and routinely monitored. Any deviation by the processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

- Disassemble the instruments prior cleaning when needed (See Table Chapter 2). Instructions are described in chapter 9.
- 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.

6. Equipment

EXPECTED EQUIPMENT FOR (RE)PROCESSING)	
Precleaning	• Waterjet pistol, Nonmetallic brushes and tissues • Ultrasonic bath (Reprocessing has been validated using the Sonorex Digitex DT 156 BH (Bandelin GmbH & Co.KG)
Cleaning – automated	• Washer-Disinfector conform to ISO15883 series (Automatic reprocessing has been validated using the Miele Washer-Disinfector PG8535)
Sterilization	• Autoclave conform to EN285 or EN13060 (Sterilization process has been validated using the autoclave Tuttnauer EHS 3870)

7. (Re)Processing

Automated thermal disinfection is the preferred method. Use manual disinfection in the absence of a validated washer-disinfector and follow in order of the following table.

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 instrument in accordance with Table 1 following disassemble instructions (Chapter 8)
Cleaning / Disinfection – automated	The following minimum cycle has been validated to effectively clean the instruments. Tests have been performed on a washer-disinfector Type Miele PG8535 using 0.5% neodisher® Mediclean forte and 0.1% Neodisher®-Z (Dr. Weigert). A- 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 B- Washer-disinfector • Load devices such that cannulations and holes are rinsed and can drain. • Pre-cleaning with cold tap 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 A0-Concept with a A0 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 / Disinfection – manual	A- 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!) B- 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 C- 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)
Preparation for sterilization	• Re-assemble instrument when needed following instructions provided in Chapter 8
Inspection and maintenance	Inspect all instruments after cleaning/disinfection for corrosion, surface damage, flaking, contamination or discoloration, and set aside damaged instruments. • Do not use damaged or worn instruments.

	• Instruments that remain dirty must be cleaned and disinfected again. Failure to properly clean the instruments could lead to inadequate sterilization. For specific critical control points see Table in Chapter 2.
Packaging	The cleaned and disinfected instruments should be packaged in medical grade, steam sterilization packaging (pouch or wrap) compliant to ISO11607-1 and EN 868-2. Singly: • Single devices should be packaged in a medical grade steam sterilization pouch. • The sterilization pouch should be sealed using a validated thermo-sealing process. • Ensure that the pouch is large enough to contain the device without stressing the seals or tearing the pouch. In sets: • Devices may be loaded into dedicated trays or general-purpose sterilization trays. • Ensure that cutting edges are protected. • All devices must be arranged to ensure steam penetration to all instrument surfaces. Instruments should not be stacked or placed in close contact. • Ensure that the load is compatible with the steam sterilizer. • The user must ensure that the instrument case is not tipped or the contents shifted once the devices are arranged in the case. Silicone mats may be used to keep devices in place. • The maximum weight per tray as per local applicable regulations must not be exceeded. • Trays and cases with lids may be wrapped in standard medical grade, steam sterilization wrap using the AAMI double wrap method (ANSI/AAMI ST79) or equivalent in accordance with local packaging procedures.
Sterilization (Preferred method)	No preconditioning step is required for the sterilization of the instruments. Relative humidity range for the work environment shall be of 30-60% as per ANSI/AAMI ST79 guidance. • Use a validated autoclave conforming to EN285 or EN13060 • Sterilizing agent: moist heat by saturated steam.

<table>
<tr>
<td></td>
<td>

Active-air-removal steam sterilization method (pre-vacuum), at least 3 steps.
Exposure time: ≥ 4 minutes
Temperature: 132-135 °C (269.6-275 °F)
Drying time: ≥ 20 minutes

Maximum values of contaminants in condensate from steam supply to the sterilization chamber
<table>
<tr><th>Determinant</th><th>Condensate Large sterilizers (EN 285)</th><th>Condensate Small sterilizers (EN 13060)</th></tr>
<tr><td>Evaporate residues</td><td>-</td><td>≤ 0.1 mg/l</td></tr>
<tr><td>Silicate</td><td colspan="2">≤ 0.1 mg/l</td></tr>
<tr><td>Iron</td><td colspan="2">≤ 0.1 mg/l</td></tr>
<tr><td>Cadmium</td><td colspan="2">≤ 0.005 mg/l</td></tr>
<tr><td>Lead</td><td colspan="2">≤ 0.05 mg/l</td></tr>
<tr><td>Rest of heavy metals (except iron, cadmium and lead)</td><td colspan="2">≤ 0.1 mg/l</td></tr>
<tr><td>Chloride</td><td colspan="2">≤ 0.1 mg/l</td></tr>
<tr><td>Phosphate</td><td colspan="2">≤ 0.1 mg/l</td></tr>
<tr><td>Conductivity (at 20°C)</td><td>≤ 4.3 µS/cm</td><td>≤ 3 µS/cm</td></tr>
<tr><td>pH (20°C)</td><td colspan="2">5 to 7</td></tr>
<tr><td>Appearance</td><td colspan="2">Colourless clean without sediment</td></tr>
<tr><td>Hardness</td><td colspan="2">≤ 0.02 mmol/l</td></tr>
</table>
</td>
</tr>
<tr>
<td>Post-sterilization techniques / activities</td>
<td>

Remove devices from the sterilizer and store them in a suitable environment to sustain the sterile property
Monitor storage environment. Relative humidity range for the storage environment shall be of 30-70% as per ANSI/AAMI ST79 guidance.
Control storage time

</td>
</tr>
</table>

8. ASSEMBLY/DISASSEMBLY OF INSTRUMENTS

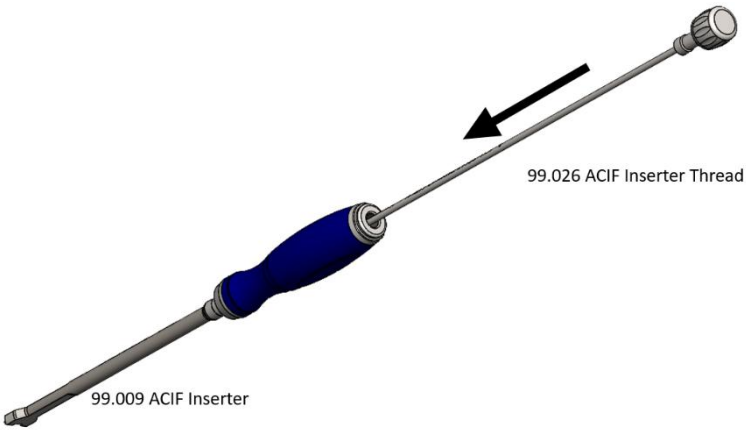
In the following chapter are instruments described, which can be connected or assembled after reprocessing. To disassemble the instruments, follow the instructions in the reverse order. Other instruments do not require disassembly prior reprocessing, see table below.

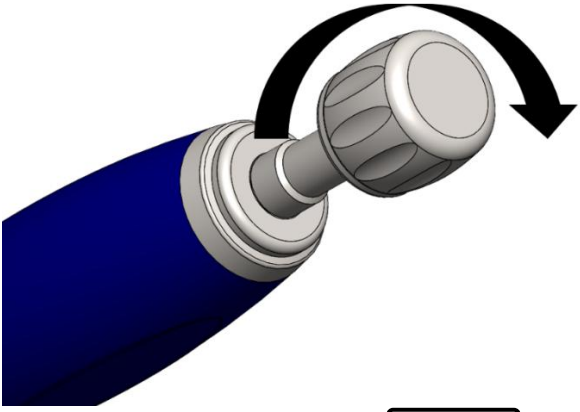
Instruments	Disassembly required?	Performances	Inspection	Reject instrument	Maintenance
All REF starting with 90. or 99.)	(See below)	(See below)	Visual inspection	Presence of rust; Damages; Broken parts;	(See below)
Elevator-type (Hohmann, Retractor, Distractor) REF starting with 90.	No	Push bones/tissues	Visual inspection	Distortion	No
Locking and ratchet mechanisms (Distractors) REF 99.012 – 99.018, -089, 099	No	Hold bones/tissues in place	Function	Loose locking; Excessive play	When necessary, apply a small quantity of surgical grade lubrication oil to the square shaped sections
Impactors/Hammers REF 99.003 and 99.019	No	Impact on devices	Visual inspection	Presence of rust; Damages; Broken parts;	No
Cage inserters/pushers REF 99.002,-004, -006,-009, -025,-026,-121	Yes, see Chapter 8.1 – 8.3	Placement of the cages	Slide instrument in its sheath according to Chapter 8.1 – 8.3	Instrument movement is not smooth and requires effort to move	When necessary, apply a small quantity of surgical grade lubrication oil to threaded sections
Trial cages REF 99.151 – 99.278	No	Standardized sizes	Visual inspection	Excessive play -	No

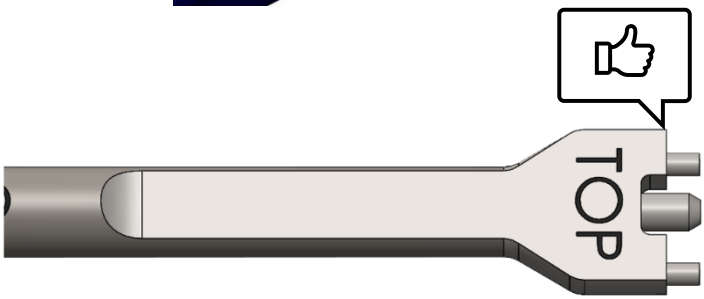
Instruments	Disassembly required?	Performances	Inspection	Reject instrument	Maintenance
Instrument Tray REF JF…. or JG (Manufacturer Aesculap)	No	Transport and instruments organization	Visual inspection	Presence of rust; Damages; Broken parts;	No
Retractor REF 99.501, 99.502, 90.008,-009,-0021-0023, --040	No	Clean endplate	Visual inspection	Nicks; Not continuous edge at the cutting edges	No
Handle 99.005, -035, -036	No	Connection with other Instruments	Function of clutch, see Chapter 8.4	Loose locking; Excessive play	When necessary, apply a small quantity of surgical grade lubrication oil to the clutch

.

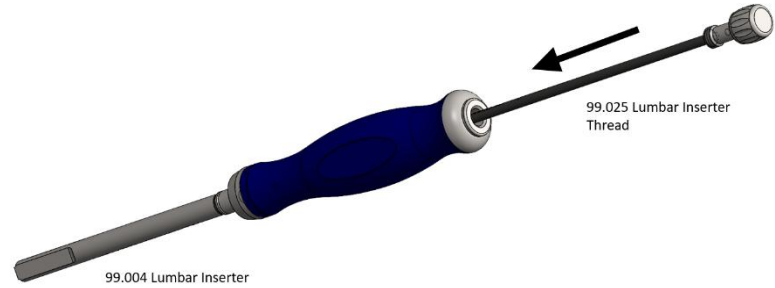
8.1. Cervical Inserter

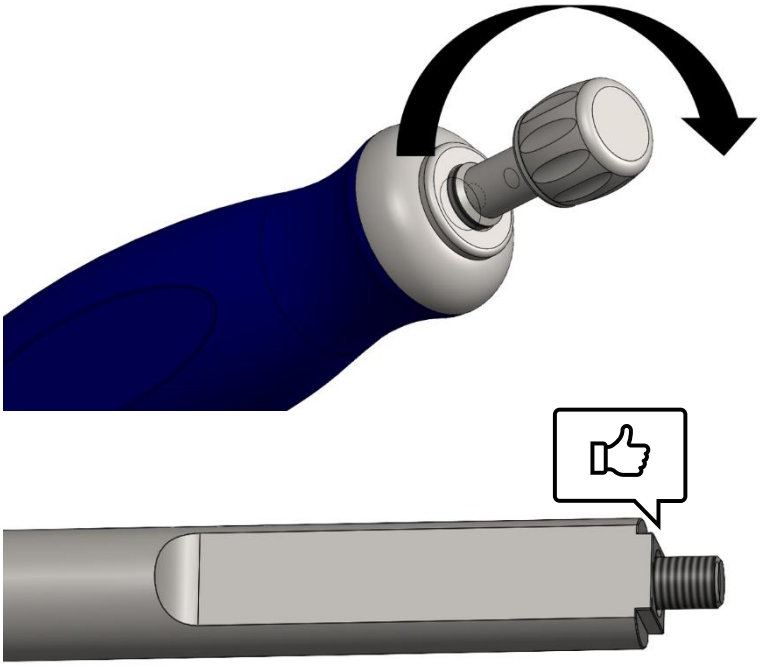




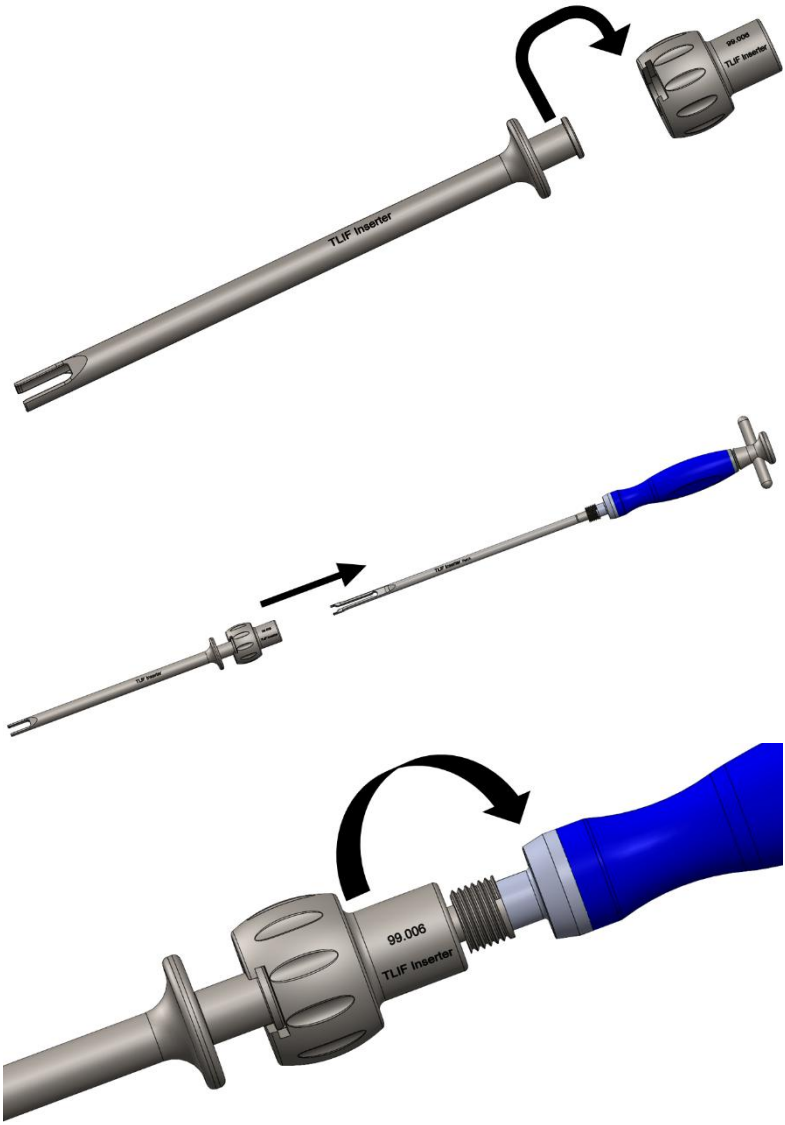


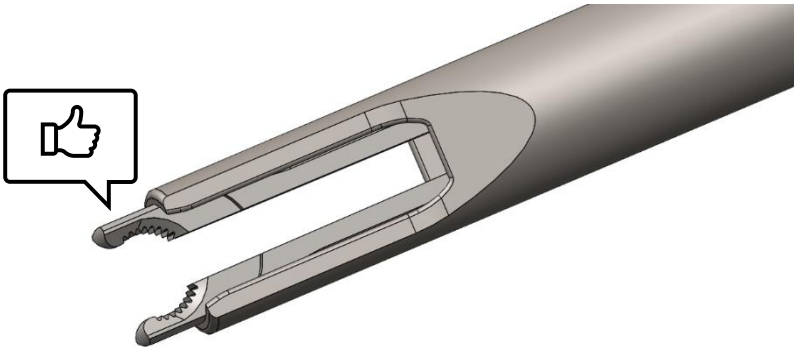
8.2. Inserter PLIF; PTLIF; TLIF





8.3. Inserter TLIF Banana 99.006

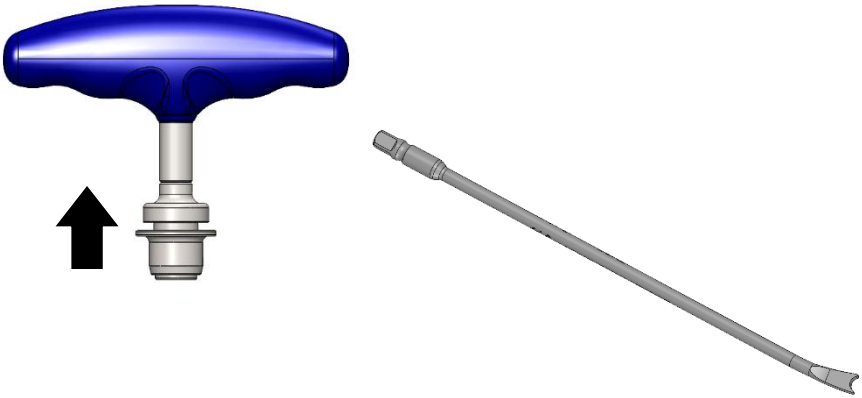




Check for all Instruments in this Chapter, the inserted Instrument shall be good visible on the other end.

8.4. Handle 99.005, -035, -036

Check if the ring of the clutch can be pulled back and snaps back in position.



A Handle can be connected with f.e. 99.002 TLIF Banana Pusher

9. SYMBOLS

In this chapter are the symbols on the label or instrument explained:

	Batch code		Item number
	Medical device		Unique product identifier (Unique Device Identifier)
	Not for pediatric use		Device is supplied non sterile
	Country of manufacture (GER / Germany)		Manufacturer
	Danger! Read accompanying information documents		Follow the instructions
			CE approval and number of the notified body

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 TIR12	Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers
ANSI/AAMI ST79	Comprehensive guide to steam sterilization and sterility assurance in health care facilities
EN285	Sterilization - Steam sterilizers - Large sterilizers
EN 868-2	Packaging for terminally sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods
EN13060	Small steam sterilizers
ISO 15883	Washer-Disinfectors
ISO 11607	Packaging for terminally sterilized medical devices

10. INSTRUMENT SET

The picture below shows an example set for instruments and its fixation. Instrument sets are filled with instruments according to customer requirements. Content may vary and Instruments can be sold separately without tray and fixation.

Yellow: Silicone bar to fix the instruments
Black: Tray for Trial Cages
Instruments can be easily removed from the fixation or tray without tools.