Instructions for Use, Handling, and Processing

Our instruments are designed and manufactured to meet the highest quality standards. We do not accept liability for products that have been modified, subjected to unintended use, or used improperly. Single-use products may not be reused.

Our instruments are not intended to be used with instruments or implants made by manufacturers other than LinkBio Corp. or Waldemar Link GmbH & Co KG, unless otherwise noted.

This IFU is available online; either scan the QR Code or go to: https://coreifu.com/shld

Only available in English.

WARNINGS:	
	• It is presumed that reprocessing personnel of LinkBio Instruments have technical knowledge and expertise. • Medical devices that are sent in for servicing must be processed beforehand in such a way that they cannot constitute a biohazard to third parties. • **Do not expose the Sensor Unit to sonication / ultrasonic cleaning.**

Precautions

Some instruments have cutting edges and sharp surfaces. Users should handle with care to avoid injury. In particular, pay caution to the Standard Probes (87-9133/all variants) which have sharp spikes on the end which make direct patient contact.

Indications for Use

Refer to the CORE Shoulder Surgical Technique for indications for use and contraindications for use.

1. Parts Outside Sterile Field

Components located outside the sterile field do not have patient contact and thus do not require full disinfection.
These components include:

87-9140	CORE Carrying Case
87-9136	CORE Workstation Tablet
87-9137	AC Adapter for Workstation

87-9138-T08	Workstation Stand Base
87-9138-T07	Workstation Stand Pole

Disconnect the AC Adapter and power off the Workstation Tablet before performing any cleaning steps. Perform cleaning by using PDI Healthcare Super Sani-Cloth Wipes with a contact time of at least 2 minutes. Perform multiple wipes to cover the entire surface area. Remove scuffs and stains. Exercise caution when wiping around the openings, vents, and ports; avoid excess liquid pooling in these areas. Do not use any solvents that may damage or discolor paint finishes or plastic components.

2. Parts Inside Sterile Field: First Use

Non-sterile instruments that will be used inside the sterile field must be cleaned and sterilized according to these instructions before first use. These instruments include:

87-9131	COREmote Sensor Unit
87-9133/16L	16mm Left Probe
87-9133/20L	20mm Left Probe
87-9133/24L	24mm Left Probe
87-9133/28L	28mm Left Probe
87-9134	Drill Guide Probe

87-9139	Instrument Tray
87-9133/16R	16mm Right Probe
87-9133/20R	20mm Right Probe
87-9133/24R	24mm Right Probe
87-9133/28R	28mm Right Probe

Before reprocessing an instrument, the persons in charge of the reprocessing unit for medical devices must compare the compatibility of their established reprocessing procedures with those described in this reprocessing instruction. All users in the OR must familiarize themselves with the function of an instrument prior to use.

3. Preparation at the site of use and transport to reprocessing area

The instruments must be cleaned, inspected, and sterilized before each use. For this purpose, they are to be disassembled into their individual parts as far as is intended. Coarse contamination of the instruments must be removed with a lint-free cloth immediately after use to prevent body fluids, tissue residues and other residues from drying on the instruments.

Suitable transport containers must be used for the safe transport of the instruments to the reprocessing area to protect the medical device, the environment and the medical staff.

Careful and proper handling of the instruments must be ensured during transport. Particular care must be taken with sensitive instruments and instruments with cutting edges to prevent damage to the product.

IMPORTANT: Pay caution to the Sensor Unit (87-9131) which is sensitive to drops and sensitive to impact to its edge connector.

- Post-use, when placing the Sensor Unit in the area of instruments to be cleaned, do not allow other heavy instruments to fall onto or crash against its edge connector.
- When placing the Sensor Unit down, at any point, do not drop it, and do not place down on its edge connector.

The instruments must be disposed of dry, and care must be taken not to exceed a period of six hours between use and reprocessing.

4. Cleaning

4.1 Automated Cleaning Procedure

Step	Outlined Procedure in IFU
1	First, rinse the device under cold utility (tap) water for 5 minutes for a pre-cleaning to avoid any protein fixation to the medical device and to remove gross soil. ○ Actuate the button on the Engagement Adapter while rinsing. ○ Use a syringe to flush lumens with a minimum of 20 mL of utility water (If necessary). ○ A soft bristle, M16 style brush can be used in the aid for cleaning.
	Second rinse under warm running (38° to 49°C/100° to 120° F) for a minimum of two (2) minutes to remove visible soil and debris.
2	Prepare a detergent bath using Prolystica 2x Concentrate Enzymatic Pre-Soak and Cleaner, or equivalent neutral-pH enzymatic detergent, at the manufacturer's recommendation using utility (tap) water.
3	Completely immerse the devices in solution and allow the devices to dwell per the detergent's instructions.
	○ While the devices are immersed clean the devices carefully using a soft bristled M16 style brush (taking special care with cavities and other poorly accessible areas) until all visible soiling (if any) has been removed. ○ Use an appropriately-sized, soft-bristled lumen brush to brush any existing lumens. ○ Flush any existing lumens with 25 mL of prepared detergent.
	Note: The enzymatic solution should be changed if it has become visibly contaminated (e.g., with blood) or has become turbid. Do not use any metal brushes or steel wool for cleaning.
4	Take the devices out of the enzymatic solution and rinse for at least 3 minutes in warm (38° to 49°C/100° to 120° F) tap water. Rinse out lumens, openings, and other poorly accessible areas thoroughly.
5	Transfer the devices to an appropriately sized washer basket and place the basket in the washer for processing. Orient the devices to facilitate draining of the lumen in the washer basket. (For example: use an angled brace). Place the empty instrument tray and lid in different locations in the washer. Do not place the lid on the tray in the washer.
	Select the appropriate Automated Washer cycle as listed below.
	Note: Sterile reprocessing departments need to qualify to their own satisfaction any disposable materials, such as pipe cleaners, brushes, and non-linting cloth.

4.2 Automated Washer Parameters

Phase	Recirculation Time (minutes)	Temperature	Detergent Type and Concentration
Pre-Wash	02:00	Cold Tap Water	N/A
Wash	02:00	60°C Tap water (Set Point)	Prolystica 2x Concentrate Enzymatic Pre-Soak and Cleaner 1/8 oz/gal - 1/2 oz/gal
Rinse	01:00	60°C Tap water (Set Point)	N/A
Pure Water Rinse	02:00	82 °C RO/DI water	N/A
Dry Time	09:00	115ºC	N/A

5. Inspection, maintenance and care

After each reprocessing procedure, the instruments must be checked for their operational and instrument-specific functionality.

- In particular, they must be free of visible residues and/or contamination (the use of an illuminated magnifying glass is recommended). Especially lumens and difficult to access areas must be checked.
- Check the functions of the spring-loaded "Engagement Adapter" mechanism at the end of the Sensor Unit, where the Probe plugs into for surgical use.
- Plastic components must be checked for wear and tear due to aging as well as for cracks, embrittlement or chipping. Damaged instruments must be replaced with new or functional instruments.
- Check for legibility of all labeling, including labels of parts outside sterile field and direct marks of parts inside sterile field.
- The Expected Service Life of the Sensor Unit is 50 reprocessing cycles.
    - The Workstation will notify the user when the Sensor Unit reaches its maximum procedure count, at which time it must be returned to LinkBio for evaluation. Contact a LinkBio Representative to exchange the Sensor Unit for a new one.

The service life of instruments depends on the material, design, application and reprocessing. Therefore, do not use damaged instruments, instruments with visible surface changes or instruments whose labeling is no longer clearly recognizable. **Note: Do not carry out any repairs yourself. Service and repairs may only be carried out by suitably qualified personnel of the manufacturer.**

6. Packaging

Cleaned instruments, in assembled condition, should be packaged in the CORE Instrument Tray (87-9139), surrounded by an FDA-cleared sterilization wrap.

7. Sterilization

Sterilization should be done using the CORE Instrument Tray (87-9139) using the following cycle parameters:

Sterilizer Type:	Pre-Vacuum
Temperature:	132°C
Cycle Exposure Time:	4 minutes
Dry Time:	60 minutes
Wire-Rack Cooldown	45 minutes
Test Article Configuration:	Double-Wrapped Tray with Halyard H300 Wrap or equivalent FDA-cleared polypropylene wrap.

With regard to handling and loading, please follow the instructions provided by the manufacturer of your sterilizer.

Do not stack instrument trays during sterilization!

8. Storage

Surgical instruments must always be handled with care, this applies particularly during transport, cleaning, care, sterilization, and storage. Following sterilization, the instruments must be stored in a dust-free and dry place. The storage period must be determined in detail with the person responsible for hygiene at the operator's hygiene officer on a case-by-case basis. Avoid direct sunlight. Improper handling or care as well as misuse can lead to premature wear or damage.

9. Complaints about our products

Complaints must be filed with LinkBio at: complaints@linkbio.com. When filing a complaint, always quote the name or REF number of the relevant component along with the Serial/Lot number, your name, and your contact address. Describe the reason for the complaint in brief.

10. Materials

LinkBio surgical instruments are manufactured from stainless steels for surgical instruments which may contain Nickel, Chromium and other trace elements. Further information on material composition is available upon request. Plastics are also used.

11. Servicing

Medical devices and instruments that are sent in for servicing must be processed beforehand in such a way that they cannot constitute a biohazard to third parties. We will be pleased to provide you with further information about special instrument sets, their applications, disassembly, cleaning, and care.