LINK®

US-H50_005_2022-09
MAR-01306, Vers. 5

Rx only

Reprocessing Instructions

For U.S. Distribution Only

For further information please refer to the U.S. section of our website:

www.ifu-us.link-ortho.com

A list of instrument article numbers and their associated UDIs can be found on our website.

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Legend of label symbols and descriptions

	Manufacturer
US | DIST	U.S. Distributor
	Observe the enclosed instructions for use
	Consult instructions for use
	Single-use device, not for reuse
Qty.	Number of units in the package
	Store in a place protected from sunlight
REF	Article number
SN	Serial number
LOT	Batch number
ONR	Order number
Rx only	Caution: Federal law restricts this device to sale by or on the order of a physician
	Date of manufacture (YYYY-MM-DD)
	Use by date (YYYY-MM-DD)
	Caution, fragile
	Store in a dry place
	Do not use if packaging is damaged
NON STERILE	Non-sterile
STERILE | EO	Sterilized using Ethylene Oxide
STERILE |	Sterilized using steam or dry heat
STERILE | R	Sterilisation by radiation
MD	Medical Device
MAT	Material Number
UDI	UDI Number
	Brush

 Rinse

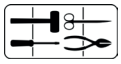
 Oil

 Time period

 Upper tray

 Lower tray

 Cleaning Instruction

 Pack Template

 Warning; Sharp element

 Warning

 Contains hazardous substances

Further information on the symbols glossary can be found on our website.

Warnings:

- The reuse of LINK single-use products is not permissible.
- The package inserts provided with the devices do not contain all of the information necessary for the selection and application of the devices. For proper handling, refer to other product-related instructions, such as those for the surgical technique associated with the relevant system and, if necessary, any special handling recommendations.
- Products made of plastic (e.g. polyamide (PA), polyethylene (PE), polyoxymethylene (POM), ultra high molecular weight polyethylene (UHMWPE)) may not be localizable using external imaging procedures.
- For the processing of LINK instruments, it is presumed that the personnel 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 hazard to third parties.

1. First use

Non-sterile instruments must be cleaned, disinfected and sterilized according to these instructions before first use. Before reprocessing an instrument, the persons in charge of the reprocessing unit for medical devices (AEMP) 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.

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

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

3. Cleaning

3.1 Manual cleaning and manual disinfection

In individual cases, refer to the additional, instrument-specific W. LINK cleaning and maintenance instructions.
For the cleaning steps described below, use a pH-neutral enzyme cleaning solution according to the manufacturer specifications of the cleaning chemicals.

3.1.1 Manual cleaning

Remove the instruments from the trays, disassemble and rinse them under running water for at least 5 minutes (temperature < 86°F, potable water quality).
After rinsing, immerse the instruments completely in a cleaning bath with pH-neutral enzyme cleaning solution; select the exposure time, solution temperature and concentration according to the manufacturer‘s instructions of the cleaning chemicals, at least 5 minutes. Use a soft and suitable plastic brush to clean surfaces, crevices, lumens and other difficult-to-reach areas until the visible residues have been removed.

Note: The enzymatic solution must be changed if it has become visibly contaminated (e.g., with blood) or has become turbid.

Remove the instruments from the cleaning solution and rinse them with cold potable water for at least 3 minutes. Rinse out lumina, openings and other difficult-to-access areas thoroughly.
The use of ultrasound is necessary to remove stubborn contamination in difficult-to-reach areas. The ultrasonic bath must be filled according to the manufacturer‘s instructions and a suitable cleaning agent (ph-neutral enzymatic detergent suitable for ultrasonic cleaning) added to the water. When determining the cleaning concentration and the water temperature, follow the manufacturers instructions of the cleaning chemicals. Place the instruments on trays and immerse them completely in the cleaning solution of the ultrasonic bath.
Recommended cleaning conditions:

- Ultrasonic frequency: 25-40 kHz
- Time: at least 15 minutes

After ultrasonic cleaning, rinse the instruments with critical water in conformance with AAMI TIR34:2008 for 3 minutes to remove any detergent residues.
Inspect instruments visually for cleanliness (an illuminated magnifying glass is recommended) and repeat the above described procedure until no more visible contamination is present. Dry with a clean, absorbent and lint-free disposable cloth.

Note: When cleaning manually, pay particular attention to holes, lumens, grooves and joint surfaces. Reprocessors need to qualify to their own satisfaction any disposable materials, such as pipe-cleaners, brushes, and lint-free cloth.

3.1.2 Manual disinfection

Immerse the rinsed instruments completely in the active cleaning disinfectant bath and allow to act according to the manufacturer of the disinfection chemicals (at least 15 minutes). The manufacturer‘s instructions, in particular concentration and temperature, must be followed.
Remove the instruments from the disinfectant solution and rinse the instruments for at least one minute with sterile-filtered deionized water obtained by ultrafiltration, RO (reverse osmosis), DI (deionization) and/or distillation or a combination of these. Rinse out lumina, openings and other difficult-to-access areas thoroughly.
The instruments must be dried with a clean, absorbent and lint-free disposable cloth.

4. 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. Principally, functions such as measuring functions, compatibilities, cutting edges, tips, connections, locks, notches and moving components are to be checked. Plastic components and instruments must be checked for wear and tear due to ageing as well as for cracks, embrittlement or chipping. Rotary instruments must be checked for deformation. The disassembled instruments must be assembled and checked for functional testing.
Damaged instruments must be replaced with new or functional instruments.
Perform an inspection or functional test of the instruments after each reprocessing procedure. To reduce friction and wear after cleaning and thermal disinfection, hinge joints, screw threads and other moving parts must be lubricated with an oil suitable for the sterilization process used (spray can, oil pen or dropper bottle) (one to two applications). In individual cases, also refer to the additional, instrument-specific LINK cleaning and maintenance instructions.

Note: The care product must be based on paraffin, biocompatible, steam sterilizable and steam-permeable according to the valid European or United States Pharmacopoeias.

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.

5. Packaging

Cleaned and disinfected instruments, in assembled condition, must be packaged with a validated sterile barrier system for sterilization. Ensure that the packaging is compatible with the sterilization process.
Sterilization can be performed using FDA cleared sterilization wraps or in a dedicated tray in a sterilization container.

6. Sterilization

Our instruments are designed for sterilization in Pre-Vacuum using the following cycle parameters:

Procedure	Fractionated pre-vacuum process
Temperature	132°C / 270°F
Hold time	4 min
Drying time	20 min*

***Note: Instrument Trays with "LinkBio Corp." name and logo on the tray lid require longer dry time. For trays with "LinkBio Corp." name and logo on the lid, consult the LinkBio Corp. IFU document 87-1000-IFU-01.**

Care must be taken to ensure that before the instruments are sterilized they have been disassembled and opened. With regard to handling and loading please follow the instructions provided by the manufacturer of your sterilizer.
Do not stack instrument trays during sterilization!
Sterilization can be performed using FDA cleared sterilization wraps or in a dedicated tray in a sterilization container.

7. 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. Avoid direct sunlight. Improper handling or care as well as misuse can lead to premature wear or damage.

8. Complaints about our products

Complaints of whatever kind must be filed with Waldemar Link at:
complaint@link-ortho.com
When filing a complaint, always quote the name or REF number of the relevant component along with the LOT and SN number, your name and your contact address. Describe the reason for the complaint in brief.

9. Servicing

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