TightLine Development

IMPORTANT INFORMATION

Reusable Instruments Instructions for Use

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EC REP

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Description

The Reusable Instruments are used to facilitate implant removal and revision during surgical procedures.

General Safety Notes

1. Product shall only be used and maintained by qualified and trained healthcare practitioners.
2. Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and the limitations of the product.
3. It is the duty of the user to ensure that maintenance procedures are followed, resources and materials are available to capable personnel, and hospital protocols and policies are followed.
4. Users should always wear appropriate personal protective equipment when using and maintaining the product.

Warnings

1. Care should be taken not to cut through surgical gloves when handling and to consider the risk of infection if a cut appears.
2. Product is provided with packing material inside a box. Do not use if the package is damaged.
3. Product must not contact fluoride or chloride-based products nor fat-based detergents.
4. Mixing of components from different suppliers is not recommended for reasons of compatibility, mechanics, and design. TightLine Development disclaims any liability in case of incompatible components from different sources being used.
5. Sterilization trays should only be loaded with TightLine Development instruments and loaded weight must not exceed 25lbs.

Point of Use Care

1. Wipe blood and debris from device throughout surgical procedure to prevent it from drying onto the surface. Flush cannulated instruments once with sterile water to prevent the drying of soil and/or debris to the inside.
2. The instruments require pre-cleaning directly after usage (within 2 hours, to prevent drying).

Basics of Cleaning and Disinfection

1. If possible, the automated cleaning and disinfection procedure should be used for cleaning and disinfection of the instruments. The manual procedure, even in case of application of an ultrasonic bath, should only be used if the automated procedure is not available.
2. The decontamination/pre-cleaning steps are to be performed in both cases.

Preparation for Decontamination/Pre-cleaning

1. All instruments require manual processing directly after usage (within 2 hours to prevent drying), prior to cleaning and disinfection. Pay special attention to lumen/cannulation of instruments.
2. Disassemble any modular instruments or components and/or open instruments completely prior to cleaning, disinfection, and sterilization. Refer to specific disassembly instructions provided with the instruments when needed.

3. Soak and/or rinse the instruments prior to cleaning to loosen any visible soil or debris. Use a freshly prepared enzymatic cleaning detergent (pH ≤8.5) to soak the instruments. Follow detergent manufacturer's instructions for use regarding concentration, temperature, and soaking time. Assist cleaning by brushing with a soft bristle brush. Do not use steel wool or abrasive cleaners.
4. Use cold tap water (<40°C/104°F) for a minimum of 1 minute to rinse the instruments.

Automated Cleaning and Disinfection using a Washer/Disinfector

1. Decontamination/pre-cleaning steps shall be followed prior to the automated method listed below.
2. Place the disassembled instruments in the Washer/Disinfector in such a way they are not in contact with each other.
3. Ensure that all the design features of the devices are accessible to cleaning: all the hinges are open, all the cannulations and holes can drain.
4. Start the standard instrument washer/disinfector cycle with the following minimal parameters:

TABLE 1

Cycle	Exposure Time	Temperature	Detergent
Prewash	2 minutes	Cold tap water (<40°C/104°F)	N/A
Wash	5 minutes	>60°C (140°F)	Neutral pH enzymatic detergent
Neutralization	2 minutes	Cold tap water (<40°C/104°F)	N/A
Rinse	1 minute	Cold tap water (<40°C/104°F)	N/A
Thermal disinfection	5 minutes	>90°C (194°F)	N/A
Drying	7-30 minutes	Hot air 100-120°C (212-248°F)	N/A

5. Check instruments for visible soil. Repeat cleaning if soil is visible.
6. Follow detergent manufacturer's instructions for use regarding concentration, temperature, and soaking time.
7. The washer/disinfector manufacturer's operating instructions and recommended guidelines shall be followed. Use only washer/disinfectors that have been approved according to ISO 15883. The washer/disinfector must be properly installed, maintained, and calibrated.

Manual Cleaning and Disinfection

1. Rinse the pre-cleaned instruments intensively under running cold tap water (<40°C/104°F) for a minimum of 2 minutes by application of jet pistol.
2. Submerge the instruments in a freshly prepared enzymatic cleaning detergent (pH ≤8.5) solution. Follow detergent manufacturer's instructions regarding concentration, temperature, and soaking time as well as post-rinsing. Ensure complete soaking of lumens by dragging through cleaning solution. Use soft bristle brush to assist cleaning (complete brushing of all inner and outer surfaces). To clean the cannulation of cannulated instruments, the nylon brush should be rotated through the length of the cannulation. Do not use steel wool or abrasive cleaners. Activate joints, handles, and other moveable device features to expose all areas to the detergent solution.
3. In case of taps or other instruments with deep grooves or complex geometries, assist cleaning by ultrasonic treatment at a frequency of 35 kHz for the same time used on initial soaking.
4. Remove the instruments from the cleaning solution and rinse the instruments thoroughly with deionized or purified water at least three times for a minimum of 1 minute. Ensure a complete soaking of lumens, cannulas, and other hard-to-reach areas. Activate joints, handles, and other moveable device features to rinse thoroughly.
5. Submerge the instruments in a freshly prepared enzymatic disinfectant solution. Follow disinfectant manufacturer's instructions regarding concentration, temperature, and soaking time as well as post-rinsing. Ensure complete soaking of lumens by dragging through disinfectant solution. Activate joints, handles, and other moveable device features to expose all areas to the disinfectant solution.

6. Remove the instruments of the disinfectant solution and rinse the instruments thoroughly with deionized or purified water at least five times for a minimum of 1 minute. Ensure complete soaking of lumens, cannulations, or other hard to reach areas. Activate joints, handles, and other moveable device features to rinse thoroughly.
7. Visually inspect the instruments and repeat the cleaning process if needed until no visible soil remains on the instruments. Recesses and hidden areas should be carefully inspected to ensure that entrapped or other residual materials are completely removed.
8. Dry the instruments using a fresh, clean, soft, lint-free cloth. To avoid water residue, insufflate cavities of instruments by using clean, oil-, and particle- free compressed air.

Inspection

1. Instruments should be inspected after processing, prior to sterilization.
2. Carefully inspect each instrument to ensure that all visible blood and soil has been removed.
3. Visually inspect instruments for damage, wear, and/or rust. If damage, wear, and/or rust that may compromise the function of the instrument are noted, do not use the instrument and notify the appropriate personnel.
4. Check the action of moving parts to ensure smooth operation throughout the intended range of motion.
5. Check instruments with long slender features (particularly rotating instruments) for distortion.
6. Where instruments form part of a larger assembly, check that the devices assemble readily with mating components.
7. Instrument oils or grease shall not be used.

Packaging

1. The cleaned and disinfected instrument must be packaged in its disassembled state.
2. When packaging individual instruments, use medical grade single-use steam sterilization pouches of appropriate size to double pack single instruments.
3. When packaging the instruments in sterilization trays with lid, use medical grade steam sterilization wrap with the double wrap method. Sterilization trays with lid may also be placed in an approved sterilization container with a gasket lid for sterilization.
4. Packaging and wrap shall conform to EN ISO 11607 and be suitable for steam sterilization (temperature resistance up to at least 138°C (280°F), with sufficient steam permeability).

Sterilization

1. Instruments are intended to be sterilized by the steam autoclaving procedure (pre-vacuum - at least three vacuum cycles/fractionated vacuum procedure) regularly used in the hospital (according to EN 285/EN 13060, validated according to EN ISO 17665-1).

TABLE 2

Cycle	Exposure Time	Temperature
Pre-vacuum	4 to 18 minutes	132/134°C (270/273°F)

2. ETO sterilization and cold sterilization techniques must not be used. TightLine Development disclaims any liability for any problem resulting from the use of these sterilization methods.
3. The recommended dry times for cases can range from 20 minutes to 60 minutes. Dry times may be highly variable due to difference in sterile barrier system and weight of complete load. The user should employ verifiable methods (e.g. visual inspection) to confirm adequate drying.
4. Ensure that the sterilization indicator inside the basket confirms that the content has been sterilized.
5. Do not use the instruments if still hot. Let the instruments cool down to room temperature before starting the surgery.
6. The autoclave manufacturer's operating instructions and recommended guidelines for maximum sterilization load should be followed. The autoclave must be properly installed, maintained, and calibrated. Only approved sterilization equipment and wrap/pouches should be used by the end-user.

7. It is the sole responsibility of the end-user to ensure the clean and sterile conditions of the instruments. The statutory requirements and hygienic provisions of each country must be observed.

Maintenance

1. Repeated reprocessing that include decontamination, cleaning, and sterilization have minimal effects on instruments. Product lifetime is determined by wear and damage due to use. Frequently used instruments must be replaced regularly.
2. Torque limiting devices, torque wrenches, or similar instruments may require specific inspection for accuracy and/or recalibration. Refer to the instructions indicated in the surgical technique or from the distributor.
3. Lubricate hinges, threads, and other moving parts with a commercial water-based surgical grade instrument lubricant to reduce friction and wear. Follow lubricant manufacturer's instructions.

Storage and Handling

1. Storage zones should be away from areas of humidity to avoid excessive corrosion. This recommendation is equally valid for the transport and packaging.
2. Store in a dry, clean, and dust free environment at temperatures between 5°C to 40°C (41°F to 104°F).

Important Statement

It is strictly prohibited to carry out any modification whatsoever. Only TightLine Development has the competence to carry out such work. If this recommendation is not followed, TightLine Development disclaims any liability for any subsequent consequences.

Symbols

REF	Catalogue number *(ISO 15223-1, Clause 5.1.6)*		Date of manufacture *(ISO 15223-1, Clause 5.1.3)*		Caution *(ISO 15223-1, Clause 5.4.4)*
LOT	Lot number *(ISO 15223-1, Clause 5.1.5)*		Non-sterile *(ISO 15223-1, Clause 5.2.7)*		Consult instruction for use *(ISO 15223-1, Clause 5.4.3)*
	Keep dry *(ISO 15223-1, Clause 5.3.4)*	SN	Serial number *(ISO 15223-1, Clause 5.1.7)*		Consult instruction for use *(non-standard)*
	Manufacturer *(ISO 15223-1, Clause 5.1.1)*	STERILE	Sterilize using steam or dry heat *(ISO 15223-1, Clause 5.2.5)*		Recyclable *(non-standard)*
EC REP	Authorized European Representative *(ISO 15223-1, Clause 5.1.2)*	Rx only	Prescription only *(21 CFR 801.15(c)(1)(i)F)*		

Product Family

The TightLine Development IFU is applicable to reusable instrument products.