TeDan Surgical Innovations

STERILIZATION AND CLEANING INSTRUCTIONS

REF LS-1900

DESCRIPTION: HANG 10 MIDLINE RETRACTOR SET

QUANTITY: 1

PRODUCT COMPLAINTS: ANY HEALTH CARE PROFESSIONAL (E.G., CUSTOMER OR USER OF THIS SYSTEM OF PRODUCTS), WHO HAS ANY COMPLAINTS OR WHO HAS EXPERIENCED ANY DISSATISFACTION IN THE PRODUCT QUALITY, IDENTITY, DURABILITY, RELIABILITY, SAFETY, EFFECTIVENESS AND/OR PERFORMANCE, SHOULD NOTIFY TEDAN SURGICAL INNOVATIONS, LLC.

TEDAN SURGICAL INNOVATIONS, LLC
12615 WEST AIRPORT BLVD, SUITE #200
SUGAR LAND, TX 77478 USA
P: 713-726-0886
F: 713-726-0846
SALES@TEDANSURGICAL.COM
WWW.TEDANSURGICAL.COM

Orthofix.com/IFU

CE 0459

EC REP

QNET, BV
KANTSTRAAT 19
NL-5076 NP HAAREN
THE NETHERLANDS

DISTRIBUTED BY:
ORTHOFIX INC.,
3451 PLANO PARKWAY
LEWISVILLE, TX 75056 U.S.A.
TEL: 1-888-298-5700
WWW.ORTHOFIX.COM

Rx ONLY	Federal (U.S.A.) law restricts this device to sale by or on the order of a physcian		
	See Instructions for Use		Manufacturer
REF	Catalogue Number	EC REP	Authorized Representative
NON STERILE	Provided Non-Sterile	LOT	Lot Number

Quality Statement
TeDan Surgical Innovations', LLC (TSI) dedication to delivering state of the art surgical retractor systems has allowed TSI to become the leader in an ever advancing medical industry. TSI strives to meet our customer needs and market demands in a timely manner through our experienced and innovative management team.

Warranty
All reusable products offered by TeDan Surgical Innovations, LLC, are guaranteed by a Lifetime Warranty against defects in materials and workmanship from the date of purchase. TSI's Lifetime Warranty does not cover damages caused by normal wear, failure to follow instructions, misuse and products that have been repaired or modified in ways not approved by TSI. Prepackaged sterile products are warranted to be free from defect until expiration date. Any product that proves to be defective during this period will be repaired or replaced at no charge. TeDan Surgical Innovations, LLC shall not be held responsible for consequential or indirect damage arising from the sale or use of any product.

Please note:
- The color of TSI's Titanium and Aluminum instruments may vary due to the anodizing process or alloy used. Shading or loss of color may also occur after sterilization. This is not a defect in the instrument or material and will not affect the performance of your high quality TSI instrument.
- When loosening, do not force the knob of the articulating arm past the stop. Doing so could damage the ball joint and affect the rigidity of the articulating arm (Figure 1).
- Do not over turn the pivoting mechanism located on the retractor frames. Forcing the pivoting mechanism past stop may cause damage to the device (Figure 2).


Figure 1

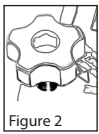
Figure 2

The procedure tested by TSI should be used for sterilization and cleaning. A hospital may choose to follow another procedure in the event that the procedure is validated. In either case, the effectiveness of the procedure should be established. TSI utilized biological indicators to establish the effectiveness of the procedure. Other methods can be found in ISO 17665-1:2006 Standard.

Cleaning Instructions:
Please note in preparation of cleaning:
1. Automated cleaning is not suitable for instruments with long lumens, ball joints, or stainless steel cables (e.g. suction tubes, surgical arms and flexible surgical arms). Such instruments should undergo a manual cleaning prior to sterilization.
2. When applicable, instruments should be cleaned in the open or unlocked position.
3. Flexible Arms: Turn tightening knob counter-clockwise to loosen the internal cable to enable movement of the surgical arm beads to allow fluid to flow between each link prior to placing arm in sonicator. Articulating Arms: Turn tightening knob clockwise to tighten ball joint prior to placing arm in sonicator.
4. Black coated and color anodized components may be negatively affected if aggressive cleaning mediums or appliances (e.g. extreme acidic/alkaline, abrasives) are used. A pH neutral cleaner, which may or may not contain enzymes, (such as Prolystica manufactured by STERIS Corp.) is recommended. Exposure to chlorides or hydrogen peroxide may negatively affect the coating or colorization of the components.

Manual cleaning instructions:
1. Rinse each instrument individually with a steady stream of tap water until gross contaminants are removed. Depending on the complexity of the device, this process should take approximately 1-2 minutes.
2. Place each instrument into a sonicator containing an enzymatic, pH neutral detergent solution prepared according to the manufacturer's instructions and sonicate for 10 minutes.
3. Prepare a wash solution using an enzymatic, pH neutral detergent, in a wash container with tap water using the concentration recommended by the detergent manufacturer.
4. Transfer each instrument to a manual wash container and fully immerse in the cleaning solution prepared in Step 3.

5. While still submerged, any visible contamination and debris should be removed by scrubbing each instrument with an appropriately-sized soft nylon bristle brush until visibly clean, paying particular attention to hard-to-clean areas such as crevices and joints. Depending on the complexity of the device, this process should take approximately 1-2 minutes.
   Using an appropriately sized syringe, flush cannulations at least three times with 50mL of cleaning solution each time. See below for additional instrument specific instructions.
   a. For shafted instruments with cannulae, flush with cleaning solution by inserting the flushing cannula and attaching an appropriately sized syringe filled with cleaning solution.
   b. For applicable instruments, such as Suction Tubes, insert the supplied mandrel into the suction tube lumen to dislodge potentially trapped debris.
   c. For flex arms, turn the tightening knob counter-clockwise to loosen the internal cable to enable movement of the surgical arm beads to allow fluid to flow between each link.
6. Rinse each instrument with deionized water for 30-60 seconds.
7. Dry each instrument using clean, absorbent, low lint wipes to remove excess rinse water.

Automated cleaning instructions:
Use only washer/disinfector machines that have been validated in accordance with ISO 15883.

1. Perform pre-cleaning to remove gross contaminants as follows:
   a. Prepare a wash solution using a pH neutral detergent, in a wash container with tap water using the minimum concentration recommended by the detergent manufacturer.
   b. Submerge and soak in wash solution for a minimum of 1 minute.
   c. Flush any cannulations that may be present two times with 50 ml of cleaning solution each time.
2. While still submerged, remove visible soil by scrubbing with an appropriately sized soft nylon bristle brush for a minimum of 4 minutes until no visible soil is observed.
3. Rinse with flowing deionized water for a minimum of 30 seconds for each instrument.
4. Load instruments into washer/disinfector in accordance with the manufacturer's instructions.
5. Arrange instruments with curved surfaces and cannulations facing downward to prevent pooling of water.
6. Operate the washer/disinfector cycle according to the manufacturer's instructions.

Recommended minimal washer/disinfector parameters:
- Heated wash at 140°F (60°C) for 2 minutes
- Heated tap water rinse at 140°F (60°C) for 20 seconds
- Heated deionized water rinse at 180°F (82°C) for 1 minute
- Forced air drying at 240°F (116°C) for 9 minutes

Surgical arm inspection before use:
Articulating Arms
1. Inspect entire assembly for damage.
2. Hold arm assembly at column and turn central tightening knob clockwise.
3. Check to make sure that arm is rigid at all three joints.
4. Insert arm column into table clamp, turn column tightening lever clockwise and ensure that it holds securely.

Flexible Arms
1. Inspect entire assembly for damage.
2. Turn the flex arm tightening knob clockwise and ensure the arm is sufficiently rigid for intended use.
3. When loosened, check cable between links for fraying. Normal use will eventually cause wear to the steel tensioning cable. If cable shows any frayed or broken wires, the flex arm needs to be replaced immediately.

Note: Fukushima flex arms contain a loosening mechanism located above the flex arm tightening knob. If the flex arm becomes difficult to tighten or too rigid once tightened,

loosen the flex arm tightening knob and adjust the loosening mechanism to desired rigidity (Figure 3)

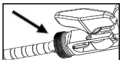
Figure 3

Sterilization Instructions:
Lubricate:
For instruments with moving parts, lubricate joints with a steam-permeable, water soluble instrument lubricant prior to sterilization.
Sterilize:
1. Instruments should be sterilized in the open or unlocked position. Central knob of articulating arms must be opened for sterilization.
2. Instruments should be sterilized by standard cycles using steam with established procedures.
3. We recommend the following sterilization temperature and time.

Gravity
The gravity displacement autoclave process is to sterilize the instruments at 250°F (121°C) for 30 minutes with a 150 minute dry time.

Prevacuum United States Standards
The prevacuum autoclave process is to sterilize the instruments at 270°F (132°C) for 4 minutes with a 30 minute dry time.

Prevacuum EU Standards
The prevacuum autoclave process used to sterilize instruments according to EU standards is at 273°F (134°C) for 18 minutes with a 20 minute dry time.

Autoclave temperatures should not surpass 280°F (137°C), as the handle, insulation or other non-metallic parts may be affected. (Note: The steam autoclave manufacturer may be contacted to confirm appropriate temperatures and sterilization times.)

Store:
Instruments should be stored in a clean dry area with tip protectors.
Please examine instrument prior to use for functionality and damage. When necessary, dispose of products in accordance with national regulations and approved hospital practices for surgical instrumentation disposal.

⚠ **Warning/Precautions:**
1. CAUTION: US Federal law restricts this device to sale by or on the order of a physician.
2. Product is intended to be used by trained surgeons.
3. TSI products are to be used only with the TSI retractor systems and may not be used with other manufacturer's products.
4. End of life is normally determined by wear and damage due to use.
5. Use of this instrument for any purpose, or in any manner other than those described here may cause instrument damage or failure which could result in serious patient injury or death. If needed, all TSI metal products or fragments thereof may be located by means of an X-Ray.
6. To prevent corrosion, instruments made of different alloys should be physically separated during cleaning and sterilization.
7. To maintain intended clamping capacity of the table clamp, do not tighten the rail clamping knob when the articulating arm column is not fully installed.
8. TSI light cables should only be used with the TSI light source (ML-0051).
9. The light source must remain off until the reusable light cable is inserted into the retractor blade(s).
10. Place the light source away from items that are flammable.
11. Once the reusable light cable is connected to the light source, do not place the reusable light cable on drapes, sponges, or any flammable object.
12. Once the reusable light cable is connected to the light source, do not allow the reusable light cable to hang over the side of the sterile field.
13. To verify that the proper amount of light output is achieved, hold single fiber optic end up to room light and look in bifurcated end (ML-0045 and ML-0048) or single end (ML-0047) to check for the percentage black dots seen (the black dots represent broken fibers in the bundle). If greater than fifty percent (50%) of the fibers are broken, the light cable may need to be replaced.