TeDan Surgical Innovations

TeDan Surgical Innovations
Surgical Access Systems

INSTRUCTIONS FOR USE

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TEDAN SURGICAL INNOVATIONS SURGICAL ACCESS SYSTEMS INSTRUCTIONS FOR USE

1. Introduction:
This Instruction for Use (IFU) is supplied for TeDan Surgical Innovations Inc. (TSI) non-sterile, reusable and single-use surgical access instruments only.

1.1 Indications for Use and Intended Purpose:
Surgical access and exposure instrumentation for use in a sterile setting for Neurological, Orthopedic, Spine, General and Heart Surgery.

1.2 Intended Patient Groups:
Patients for which access and exposure during surgery is required.

1.3 Intended User Groups:
Licensed practicing physicians who have been informed of the use of TSI Surgical Access Systems. It is also expected that clinical assistants are knowledgeable in setting up these devices.

1.4 Contraindication:
No known contraindications exist.

1.5 Intended Clinical Benefits:
TSI Surgical Access Systems enable access and exposure of the surgical site.

1.6 Potential Adverse Effects:
Injury, trauma, infection and delayed procedure.

1.7 Prior to Use:
Clean and sterilize all components according to the Cleaning and Sterilization Instructions provided below.

2. Cleaning and Sterilization Warnings:
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 any knob past the stop. Doing so could damage the device (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).

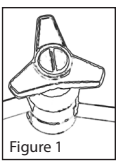
Figure 1

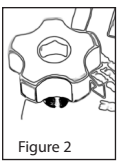
Figure 2

2.1 Reprocessing Instructions:
The following validated reprocessing steps should be used for reprocessing of TSI products. Other methods used for reprocessing of TSI devices shall be validated by the user prior to implementation.

3. Cleaning Instructions:
3.1 Point of Use:
1. Directly after use, remove coarse contamination from the instrument and keep the instrument moist for transit to the processing site. Prior to cleaning and sterilization do not use any fixing agents or hot water >104°F (>40°C) since this may lead to the fixation of residue and can interfere with the cleaning process.
2. Where applicable, multi-component instruments should be disassembled for appropriate cleaning. Care should be exercised to avoid losing small components.
3. For suction tubes, draw sufficient volume of water through the suction tube using an available vacuum source, to provide adequate removal of all gross contaminants.
4. Perform cleaning as soon as is reasonably practical following use. Allowing instrumentation to dry with fluids and debris may result in staining, corrosion, and increased difficulty in the removal of contaminants.
5. During the transport of the instruments to the processing site, store contaminated instrument(s) securely in a closed container to avoid damage to the instrument and/or contamination of the environment.

3.2 Supplies and Equipment Needed for Cleaning:
- Ultrasonic Cleaner
- Pre-cleaning and Manual Cleaning enzymatic, pH Neutral Cleaner: such as Prolystica 2x Concentrate Enzymatic Pre-Soak and Cleaner
  - Soft Nylon Bristle Brush such as 3-1000 Integra Miltex Premium Grade Nylon Bristle Brush should be used for exterior surface cleaning. For internal cleaning, a brush size appropriate to the lumen inner diameter (ID) should be used.

    *For suctions a micro brush appropriate to lumen size, shall be used.
- Automated Cleaning enzymatic, pH Neutral Cleaner: such as Prolystica 2x Concentrate Enzymatic Pre-Soak and Cleaner
- 60 ml Syringe with Needle
- Soft Bristled Brush (ex. M16)
- Tap, Deionized (DI), Reverse Osmosis (RO), or filtered water for processing

4. Cleaning:
*Automated cleaning is not suitable for instruments with long lumens, shafted lumen, ball joints, or braided cables (e.g. suction tubes, shim inserter tools, chordometers, articulating surgical arms, and flexible surgical arms), or scalp hook bands. Such instruments should only undergo manual cleaning.

1. For both Manual and Automated Cleaning, all instruments, apart from the Articulating Arm, should be cleaned in the open or unlocked position.

- Flexible Arms: Turn tightening knob counterclockwise to loosen the internal cable to enable movement of the surgical arm beads to allow water or detergent to flow between each link prior to placing arm in sonicator.
- Suctions: Remove wire mandrel from suction tube lumen and process alongside suction tube.
- Shim Inserter Tools: Disassemble. To disassemble hold the distal end of the device while turning the adjustment knob clockwise to remove the shaft and knob. Do not force the knob-the shaft should disengage freely.
- Chordometer: Turn the knob counterclockwise to loosen the measurement shaft.
- Articulating Arms: Turn tightening knob clockwise to tighten ball joint prior to placing arm in sonicator. The knob should be tightened enough to prevent manipulation of the arm.

2. An enzymatic, pH neutral cleaner is recommended.
   - Black coated and color anodized components may be negatively affected if aggressive cleaning mediums or appliances (e.g. extreme acidic/alkaline, abrasives) are used.
   - Exposure to chlorides or hydrogen peroxide may negatively affect the coating or colorization of the components.

For the purposes of this IFU, the table below defines cold, lukewarm, and hot water temperatures (per AAMI TIR12:2010).

Temperature Description	°Celsius	°Fahrenheit
Cold	<22°C	<72°F
Lukewarm	22°- 43°C	72°-110°F
Hot	>43°C	>110°F

4.1 Manual Cleaning Instructions:

1. Rinse each instrument individually with a steady stream of lukewarm tap water for a minimum of 2 minutes or until gross contaminants are removed.
   - For Suction Tubes, insert the supplied mandrel into the suction tube lumen to dislodge potentially trapped debris. Remove mandrel for further processing.
   - For Flex Arms, slide the surgical arm beads to allow water to flow between each link.
2. Place each instrument into a sonicator containing a solution of enzymatic, pH neutral detergent prepared according to the manufacturer's instructions, using lukewarm tap water. Sonicate for 10 minutes.
   - Ensure lumens are flushed to remove air bubbles prior to sonication.
3. In a manual wash container, prepare an enzymatic, pH neutral detergent wash solution, per detergent manufacturer's instructions, using lukewarm tap water.
4. Transfer each instrument from the sonicator to the manual wash container, and fully immerse in the cleaning solution prepared in Step 3.
5. While still submerged, using a soft nylon bristled brush, such as M16, brush each instrument for a minimum of 1 minute, to remove any visible contamination and debris, paying particular attention to hard-

to-clean areas such as crevices and joints. Repeat the process until all visible contamination is removed.

- For blades with lumens and shafted instruments with lumens (that are not suction tubes), use appropriately sized lumen brush to scrub the interior of lumen and soft bristled brush, such as M16, to brush the exterior of the lumen. Using a 60ml syringe, flush lumens with 25mL of cleaning solution, a minimum of 3 times, or until no soil is visible.
- For Suction Tubes, insert the supplied mandrel into the suction tube lumen, or use appropriately sized lumen brush, to dislodge any trapped soil. Remove mandrel for further processing. Use appropriately sized lumen brush to scrub the interior of lumen and soft bristled brush, such as M16, to brush the exterior of the lumen. Using a 60ml syringe with needle, flush the lumen with 25ml of cleaning solution 3 times, or until the solution shows no evidence of contamination.
- For Flex Arms, turn the tightening knob counterclockwise to loosen the internal cable to enable movement of the surgical arm beads to allow cleaning solution fluid to flow between each link.
- For Shim Inserter Tools, use appropriately sized lumen brush to scrub the interior of lumen and soft bristled brush, such as M16, to brush the exterior of the lumen. Use a 60ml syringe with needle to flush the lumen with a minimum of 25ml of cleaning solution 3 times or until the solution runs clean and there is no evidence of contamination.
- For Chordometers, use a 60ml syringe with needle to flush the lumen with a minimum of 25ml of cleaning solution 3 times or until the solution runs clean and there is no evidence of contamination.

6. Rinse each instrument with lukewarm tap water for a minimum of 2 minutes, or until no visible soil remains.
   - For items with lumens, using a 60ml syringe with needle, flush the lumen with 25ml of lukewarm water 3 times.
   - For Flex Arms, slide the surgical arm beads to allow water to flow between each link.
7. Dry each instrument using clean, absorbent, lint-free wipes, or pressurized air, to remove excess rinse water.

4.2 Automated Cleaning Instructions:

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

Suction Tubes, Shim Inserter Tools, Chordometers, Articulating Surgical Arms, Flexible Surgical Arms, and Scalp Hook Bands should not be cleaned using the Automated Method. These devices should be cleaned using the Manual Cleaning Process (detailed above).

1. Perform pre-cleaning to remove gross contaminants as follows:
   - Rinse with running, lukewarm, DI, RO, or filtered water for a minimum of 1 minute for each instrument to remove gross contaminants.
   - In a manual wash container, prepare an enzymatic, pH neutral detergent wash solution, per detergent manufacturer's instructions, using lukewarm tap water. Submerge and soak instruments in wash solution for a minimum of 1 minute.

- While still submerged, remove visible soil by scrubbing with a soft, nylon bristle brush for a minimum of 4 minutes or until no visible soil is observed.
- Use appropriately sized lumen brush to scrub the interior of lumen and soft bristled, nylon brush to brush the exterior of the lumen. Brush for a minimum of 1 minute, or until no soil is visible.

2. Rinse with running, lukewarm, DI, RO, or filtered water for a minimum of 1 minute for each instrument.
3. Load instruments into washer/disinfector in accordance with the manufacturer's instructions.
   - Arrange instruments with curved surfaces and lumens facing downward to prevent pooling of water on the instrument.
4. Operate the washer/disinfector cycle according to the manufacturer's instructions.

Recommended minimal Automated washer/disinfector cycle parameters:

- Pre-wash rinse with cold tap water for 2 minutes.
- Heated wash at 140°F (60°C) for 2 minutes using an enzymatic, pH neutral cleaner such as Prolystica Ultra Concentrate Enzymatic Cleaner.
- Heated tap water rinse at 140°F (60°C) for 20 seconds
- Heated deionized water rinse at 180°F (82°C) for 2 minutes
- Forced air drying at 240°F (116°C) for 9 minutes
- If any residual moisture is observed, wipe dry with absorbent, lint free cloth, or pressurized air for lumens.

5. Post Cleaning Inspection:
After cleaning, visually inspect each test article with the naked eye under normal lighting conditions to determine if all visible soil (e.g. blood protein substances and other debris) has been removed. If any soil is still visible, repeat cleaning steps.

5.1 Surgical Arm Inspection

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)

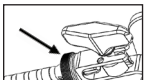
Figure 3

Note: Loosen articulating arms prior to sterilization.

6. Sterilization Instructions:
6.1 Lubricate:
For instruments with moving parts, lubricate joints with a steam-permeable, water soluble instrument lubricant prior to sterilization.

6.2 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.)

7. 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.

8. Reporting Serious Incidents:
Any serious incidents that have occurred in relation to the device should be reported to TSI and the Competent Authority of the Member State in which the user and/or patient is established. Adverse events and incidents can be reported to TSI per contact information on the device packaging.

9. Product Lifetime:
End of life is normally determined by wear and damage due to use. Refer to the Post Cleaning Instructions above to ensure that the products function as outlined.

10. Warnings/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. 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.
5. To prevent corrosion, instruments made of different alloys should be physically separated during cleaning and sterilization.
6. 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.
7. TSI light cables should only be used with the TSI light source (ML-0051).
8. The light source must remain off until the light cable is inserted into the retractor blade(s).
9. Place the light source away from items that are flammable.
10. Once the light cable is connected to the light source, do not place the light cable on drapes, sponges, or any flammable object.
11. Once the light cable is connected to the light source, do not allow the light cable to hang over the side of the sterile field.
12. Reusable Light Cables Only: To verify that the proper amount of light output is achieved, hold single fiber optic end of light cable up to room light and look in bifurcated end 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 should be replaced.
13. Single use devices may not be reused. Reuse may compromise structural integrity.
14. CJD (Creutzfeldt-Jakob Disease): Discard or destroy any product that comes in contact with or is exposed to patients with CJD, or anyone suspected of CJD. TSI does not provide any validated instructions to eliminate risk of cross-contamination.
15. To prevent damage to the screws and forks on the connection points of the Retractor Ring, assemble and disassemble ring on a flat surface.
16. Adjusting any Flex Arm's position without loosening tension knob will cause cable wear.
17. Acute bending of any Flex Arms will cause cable damage/ wear.
18. DO NOT FORCE ANY KNOBS PAST STOP.
19. TSI products have not been tested for use in Magnetic Resonance (MR) environments. Do not use in MR environments or with MR equipment.

See **www.tedansurgical.com/symbolsglossary** for the Symbols & Device Markings Glossary.

To view information on our Warranty please refer to:
www.tedansurgical.com/general-terms-conditions