tunnelvision™

Endoscopic Soft Tissue Release System

Instructions for Use

Table of Contents

TUNNELVISION™ INTENDED USE, INDICATIONS, CONTRAINDICATIONS 3
- INDICATIONS FOR USE 3
- CONTRAINDICATIONS 3
- SYSTEM OVERVIEW 3
- ADDITIONAL INFORMATION 3

TUNNELVISION™ INSTRUMENTS AND ACCESSORIES 4

GLOSSARY OF SYMBOLS 5

WARNINGS AND CAUTIONS 5

INSTRUMENTATION ASSEMBLY 6
- 1. ASSEMBLE BLADE ASSEMBLY TO HANDPIECE 6
- 2. ASSEMBLE ENDOSCOPE TO HANDPIECE 7
- 3. ASSEMBLE ENDOSCOPE TO CAMERA 8
- 4. ADJUST CAMERA AND LIGHTING PARAMETERS 8
- 5. ADJUST ENDOSCOPE AND CAMERA 8

INSTRUMENT CLEANING AND STERILIZATION INSTRUCTIONS 9
- 1. INSTRUMENT REUSE LIMITATIONS 9
- 2. DISASSEMBLY 9
- 3. PREPARATION FOR DECONTAMINATION 9
- 4. CLEANING 9
- 5. DISINFECTION 10
- 6. DRYING 10
- 7. MAINTENANCE 10
- 8. STERILIZATION PACKAGING 11
- 9. STERILIZATION 11
- 10. REMOVING DEPOSITS ON THE OPTICAL SURFACES 11

TROUBLESHOOTING GUIDE 12

WARRANTY, SERVICE AND REPAIR 13
- 1. WARRANTY 13
- 2. SERVICE AND REPAIR 13
- 3. ITEM RETURN 13
- 4. DISPOSAL 13

TUNNELVISION™ INTENDED USE, INDICATIONS, CONTRAINDICATIONS

INDICATIONS FOR USE

The TunnelVision Endoscopic Soft Tissue Release System is indicated for use in minimally invasive ligament or fascia release:
• Carpal tunnel release in the wrist
• Cubital tunnel release in the elbow

CONTRAINDICATIONS

The TunnelVision Endoscopic Soft Tissue Release System should not be used on uncooperative or mentally incompetent patients who are unable to follow the postoperative regiment. Anatomical abnormalities affecting safe and effective use of the system, such as those impairing tissue visualization, should be identified and an alternative procedure completed. Specific carpal tunnel and cubital tunnel contraindications and cautions are listed below.

Carpal Tunnel
The TunnelVision System should not be used in patients with severe or significant abnormalities of the surgical site area, including those with an aberrant branch of the median nerve, either ulnarly or transligamentously, that cannot be visualized, missing or floating hook of the hamate, distal radial deformities, unusually tight carpal tunnel, rheumatoid arthritis, or other carpal synovitis.

Cubital Tunnel
The TunnelVision System should not be used in patients with known abnormalities of the elbow, including deformities, severe medial epicondylitis, rheumatoid, bursitis, unusually small elbow, or other synovitis conditions. Congenital anatomical abnormalities, such as abnormalities of the medial elbow and ulnar nerve subluxation, are contraindicated.

SYSTEM OVERVIEW

The TunnelVision Endoscopic Soft Tissue Release System consists of an endoscope paired with a handpiece designed to secure a single-use blade assembly. The carpal tunnel device connects to standard video camera and light sources commonly used for endoscopic or arthroscopic procedures. It is intended for dry use, without the addition of fluids or insufflation gases.

Carpal Tunnel Procedure Overview
The surgeon creates an approximately 1-cm wide transverse incision in the proximal wrist flexion crease and introduces the disposable blade assembly into the carpal tunnel. Viewing the deep side of the transverse carpal ligament through the endoscope camera, the surgeon depresses the trigger on the handpiece to elevate the blade. The ligament is cut as the instrument is withdrawn in a retrograde direction.

Cubital Tunnel Procedure Overview
The surgeon creates an approximately 3-cm longitudinal incision between the medial epicondyle and olecranon and introduces the disposable blade assembly into the cubital tunnel. Viewing the roof of the cubital tunnel fascia through the endoscope camera, the surgeon depresses the trigger on the handpiece to elevate the blade. The fascia is cut as the instrument is withdrawn.

ADDITIONAL INFORMATION

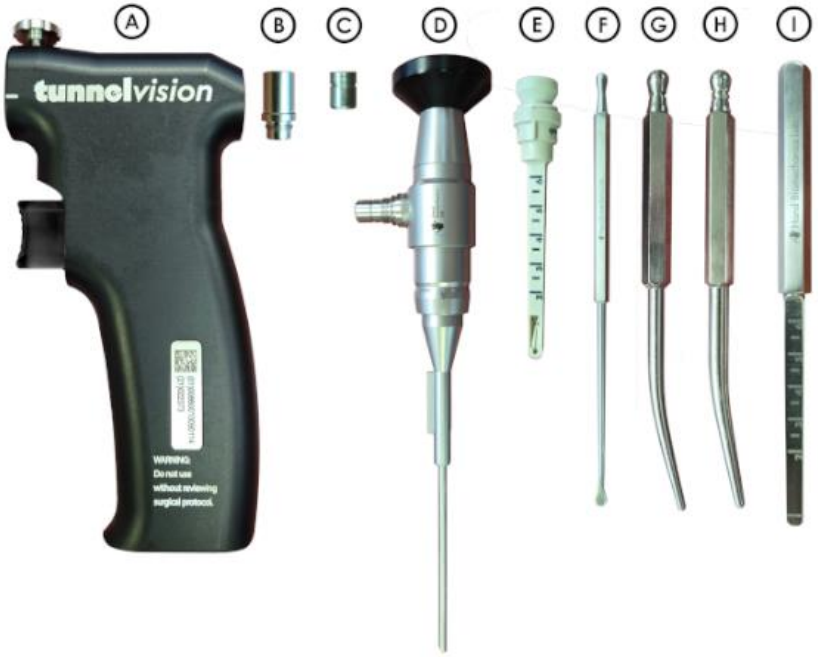
The endoscopic procedures for which TunnelVision is indicated should only be attempted after the surgeon has been trained at a TunnelVision or Hand Biomechanics Lab workshop, a comparable device workshop, or by a qualified training surgeon or trained on a comparable device. Operating room staff should review the TunnelVision Instructions for Use prior to setting up this system.

For detailed surgical steps and additional Warnings and Cautions, consult the TunnelVision Surgical Technique Guide, available at https://tunnelvisionectr.com.

TUNNELVISION™ INSTRUMENTS AND ACCESSORIES

A) TunnelVision Handpiece _____ (REF 146500)
B) Storz/Olympus Light Post Adapter _____ (REF 245700)
C) Wolf/Dyonics Light Post Adapter _____ (REF 245800)
D) TunnelVision Endoscope _____ (REF 145600)
D) TunnelVision Endoscope (Refurbished) _____ (REF 145600-R)
E) HBL Blade Assembly _____ (REF CTR-455)*
F) Synovial Elevator _____ (REF 246100)
G) Small Dilator _____ (REF 245900)
H) Medium Dilator _____ (REF 246000)
I) Coequal Dilator _____ (REF 246300)
J) TunnelVision Sterilization Tray _____ (REF 146400)

* sold separately



NOTE: HBL Blade Assemblies (E) are sold separately and provided sterile via gamma irradiation. These are single-use devices.

WARNING: All other system devices are provided non-sterile and should be reprocessed before first use and every use.

GLOSSARY OF SYMBOLS

Symbol	Reference	Description	Standard
STERILE R	2502	Indicates the product has been gamma irradiated for sterilization.	ISO 15223-1:2021
⚠	0434A / 0434B	Indicates caution is suggested.	
	1051	Indicates the product is single-use.	

WARNINGS AND CAUTIONS

• **WARNING**: Do not use the disposable blade assembly if the sterile packaging is open or damaged.
• **WARNING**: If the blade fails to retract while inside the carpal or cubital tunnel, keep it in-situ and release the locking screw to separate the assembly from the handpiece. If the blade remains elevated, keep it in place and convert to an open procedure.
• **WARNING**: All other system devices are reusable and sent non-sterile and should be sterilized before first use and every use.
• **CAUTION**: Reusable components must be cleaned and sterilized before every use, including first use.
• **CAUTION**: DO NOT exceed a temperature of 280°F (138°C). (Sterilization)
• **CAUTION**: Other sterilization systems/methods have not been tested and are not recommended.
• **CAUTION**: Federal Law (USA) restricts this device to sale by or on the order of a physician or hospital.

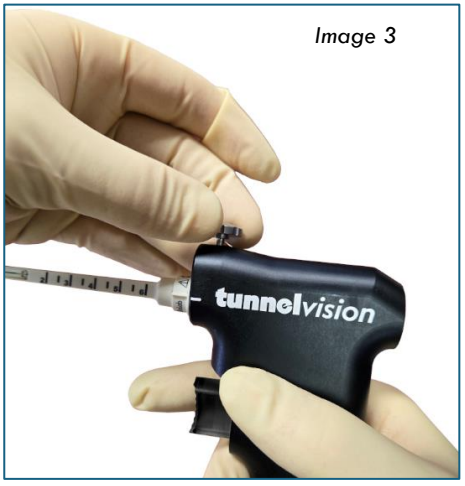
INSTRUMENTATION ASSEMBLY

Always protect the endoscope while it is being transported or in storage. The endoscope may become damaged if dropped or bent. The endoscope and disposable blade assembly are not intended for use as levers or probing instruments.

CAUTION: Endoscopes are fragile.

1. ASSEMBLE BLADE ASSEMBLY TO HANDPIECE

1. Rotate the locking screw located on the top of the handpiece counterclockwise until it reaches its limit. (*Image 1*)
2. Align the blade assembly with the shuttle inside the handpiece blade assembly bore. (*Image 2*)
3. Insert the blade assembly onto the shuttle. A slight twist may be necessary to correctly align the blade assembly key with that of the shuttle.
4. After seating the blade assembly, rotate the locking screw clockwise until it is securely tightened by hand. DO NOT overtighten. (*Image 3*)



2. ASSEMBLE ENDOSCOPE TO HANDPIECE

1. Carefully insert the endoscope into the endoscope bore on the rear of the handpiece. (*Image 4*)

2. Rotate the endoscope until the light post is perpendicular to the flat surface of the blade assembly. (*Image 5*)

Once aligned, push the endoscope into the seated position. The audible click indicates that the endoscope is properly seated. If the endoscope is difficult to insert, gently rotate it until it slides in smoothly without resistance.

NOTE: Avoid hitting the distal end of the endoscope against the handpiece and do not force it into position.

3. To adjust for right- or left-handed operation, loosen the locking screw and turn the connected blade assembly and endoscope to the preferred position.

4. Once the preferred position is set, rotate the locking screw clockwise until it is securely tightened by hand. (*Image 3*).

WARNING: Not securing the blade assembly properly can result in its detachment from the handpiece, potentially causing injury to the patient or damage to the device.

WARNING: Do not tighten the locking screw on the handpiece other than by hand: tightening with a tool may result in damage leading to non-retraction of the blade and may injure the patient.

5. Verify system function by pressing the trigger to confirm smooth blade elevation and retraction. The blade should extend approximately 3.5 mm beyond the flat surface of the blade assembly (*Image 6*), and upon releasing the trigger, it should retract completely beneath the shelf. (*Image 7*).

WARNING: Only proceed with tissue dissection when visualization is clear and unobstructed.

WARNING: The blade is extremely sharp.

Image 4

Image 5

Image 6

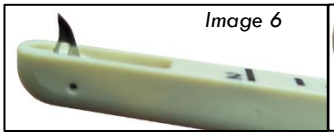
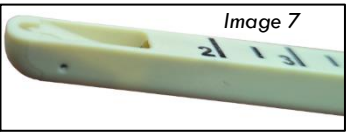


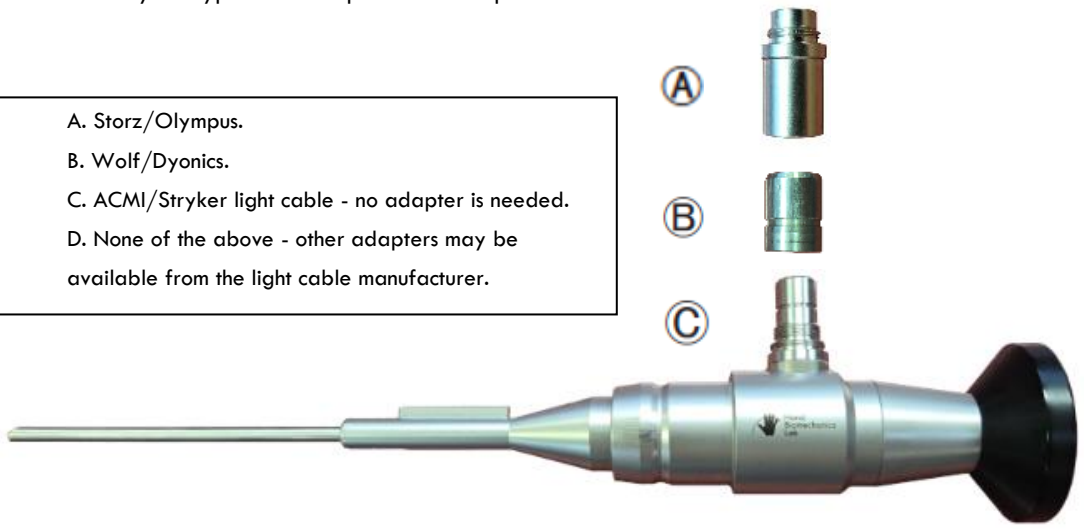
Image 7



3. ASSEMBLE ENDOSCOPE TO CAMERA

1. Connect the endoscope to the camera coupler and light source following the manufacturer's instructions.
2. The list below may be used to identify the type of fiber optic cable adapter needed:

A. Storz/Olympus.
B. Wolf/Dyonics.
C. ACMI/Stryker light cable - no adapter is needed.
D. None of the above - other adapters may be available from the light cable manufacturer.



CAUTION: Make sure the light source mounting is compatible. Use included adapters as required. Do not overtighten.

CAUTION: Handle the endoscope by the main body only. Do not support the endoscope from the distal shaft.

CAUTION: Avoid placing any objects on top of the endoscope.

CAUTION: Do not use tools to attach adapters to the endoscope.

WARNING: Ensure that the light cable is properly attached before using the system.

NOTE: Ensure all cables are secured against tangling before using the system.

4. ADJUST CAMERA AND LIGHTING PARAMETERS

1. Select automatic or manual mode for optimal illumination. White balance the system per the manufacturer's instructions, typically by pressing the white balance button on the camera while focusing on a white surface placed on top of the blade assembly window. This sets the color balance of the camera.
2. To adjust the illumination, place a light-colored cloth towel over the viewing window. In automatic mode, the light source will automatically adjust to meet the camera's requirements. In manual mode, modify the light intensity until the details of the cloth fibers appear clearly defined.
4. If the image lacks clarity, replace the endoscope. If the view is blocked, replace the blade assembly. Should the view remain unclear, discontinue use of the TunnelVision Endoscopic Soft Tissue Release System.

5. ADJUST ENDOSCOPE AND CAMERA

1. Align the view by turning the camera coupler around the endoscope until it is aligned correctly, using the alignment notch as a reference. Once aligned, tighten the locking screw on the coupler*. Focus the camera coupler according to the camera manufacturer's instructions.
2. See Troubleshooting Guide for fogging issues.

*NOTE: For the Stryker® camera, a Stryker Cat. #280-121 spacer may be required at the coupler before tightening the locking mechanism.

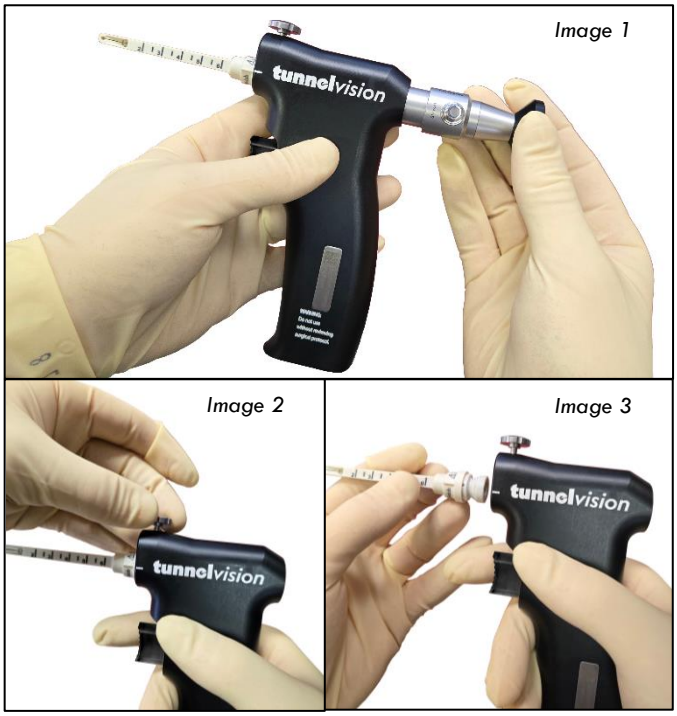
INSTRUMENT CLEANING AND STERILIZATION INSTRUCTIONS

1. INSTRUMENT REUSE LIMITATIONS

Except for the blade assemblies, the instruments and accessories of the TunnelVision System are reusable but have a finite service life. Before and after each use, inspect all components for signs of wear, damage, cleanliness, corrosion, secure connections. Give particular attention to the endoscope, as it is a delicate instrument that requires careful handling. To prevent device contact, use the TunnelVision Sterilization Tray, REF 146400.

2. DISASSEMBLY

1. Detach the light cable and camera from the endoscope.
2. Hold the exposed part of the endoscope and gently press against the handpiece until the endoscope is released. Then pull the endoscope straight out of the handpiece without bending the optical shaft. (*Image 1*)
3. Rotate the locking screw counterclockwise to loosen it. (*Image 2*)
4. Remove the blade assembly by pulling it out. (*Image 3*)
5. Dispose of the blade assembly safely in a designated container.



WARNING: Reuse of the disposable blade assembly may result in patient infection. **DO NOT** re-sterilize and/or reuse the disposable blade assembly. Re-sterilization of the disposable blade assembly has not been assessed or validated, as it is designed and indicated for single-use only.

3. PREPARATION FOR DECONTAMINATION

1. Prevent organic matter from drying on the instruments by wiping them off immediately after use to avoid adhesion.
2. Begin decontaminating reusable components promptly after the surgical procedure is finished.

4. CLEANING

4.1 MANUAL CLEANING

1. Prepare a bath of Prolystica Enzymatic at the manufacturer's recommended concentration (typically 1/2 oz/gal) and warm tap water.
2. Immerse the devices in the detergent solution.
3. Soak the devices for 3 minutes.
4. Following the soak, while the devices are immersed, scrub the handpiece's internal shuttle and endoscope bore, locking screw, trigger surface, and trigger through-hole using an appropriately sized soft-bristle nylon brush for 1 minute.
5. Depress and release the handpiece trigger multiple times. Turn the locking screw multiple times.
6. While immersed in the detergent solution, scrub all external surfaces of all devices using a soft-bristle nylon brush for 1 minute.
7. Immerse the devices in RO/DI water for 2 minutes.
8. Using a lint-free cloth wetted with RO/DI water, while the devices are immersed, wipe the devices for 1 minute.

9. Use a syringe to flush the handpiece shuttle, endoscope bore, locking screw, and trigger with 30 mL of water at each location.
10. Dry the devices with a clean, lint-free cloth. Use compressed air to dry the gaps and blind holes around the handpiece locking screw, trigger, shuttle port, scope port, and trigger through-hole.

CAUTION: Chlorine/Chloride based, or high pH cleaners are not recommended as they can damage the surface finish of the TunnelVision System and/or lead to corrosion of the instruments.

4.2 AUTOMATED CLEANING

Using validated washer-disinfector:

1. Under running cold tap water, wipe the devices with a lint-free cloth to remove gross contamination.
2. While the devices are still under the running cold tap water, use a soft-bristle lumen brush to brush all holes.
3. Transfer the devices to a rack system inside the washer in a way that prevents damage during cleaning.
4. Select an appropriate cycle as listed below using enzymatic detergent and high motor speed.

Stage	Recirculation Time (min:sec)	Temperature	Detergent Type and Concentration (if applicable)
Pre-wash 1	04:00	Cold tap water	N/A
Wash 1	10:00	45°C tap water (set point)	Prolystica Enzymatic (1/2 oz/gal)
Rinse 1	03:00	43° tap water (set point)	N/A
Pure Water Rinse	02:00	43°C RO/DI water	N/A
Dry Time	30:00	100°C	N/A

CAUTION: Do not use abrasive tools to remove contaminants, as this can damage the optical surfaces.

CAUTION: Do not ultrasonic clean the endoscope or use solvents other than isopropyl alcohol.

CAUTION: Failure to follow the disinfectant manufacturer's instructions may lead to device damage.

NOTE: Clean the endoscope lenses at the tip, camera mount, and fiber optic light ends with a cotton swab moistened with isopropyl alcohol to maintain a clear view.

5. DISINFECTION

For reusable surgical instruments, disinfection is acceptable only as a supplement to complete terminal sterilization. See **Sterilization** section.

6. DRYING

Use a soft, lint-free towel or clean and dry compressed air to remove water from the instruments and handpiece.

NOTE: Even surgical instruments made from high-quality stainless steel require thorough drying to prevent corrosion. Before sterilization, inspect all devices for surface, joint, and lumen cleanliness, as well as for proper function and signs of wear.

7. MAINTENANCE

To maintain device safety and performance, follow these steps:

1. Examine each device to confirm that all visible blood and debris have been removed.

2. Look for signs of damage or wear, such as faded or unreadable identification markings, corrosion, or cracking.
3. Test the handpiece moving parts to ensure smooth operation across the full range of motion.
4. For the handpiece, verify that the endoscope connects and separates easily.

NOTE: If there is any concern about an instrument's proper function, contact Hand Biomechanics Lab, Inc.

8. STERILIZATION PACKAGING

1. Load all instruments into the TunnelVision Sterilization Tray (REF 146400).
2. Use an FDA cleared medical grade steam sterilization wrap following the AAMI double wrap method. (ANSI/AAMI ST79:2017)

9. STERILIZATION

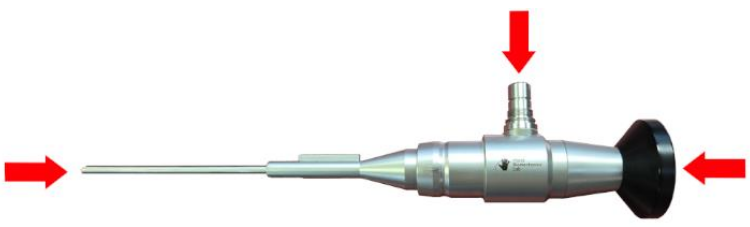
Prevacuum Sterilization	For Instruments In or Outside of Tray Ref# 46400
Temperature	132ºC
Full Cycle Time	4 minutes
Drying Time	60 minutes
Cool-Down Time	30 minutes outside of the chamber on a wire rack
Configuration	Individually wrapped in an FDA- cleared medical grade steam sterilization wrap using envelope folding techniques.

10. REMOVING DEPOSITS ON THE OPTICAL SURFACES

1. During autoclaving, deposits may form on the three endoscope optical surfaces (shown below). These deposits can diminish optical performance, resulting in a cloudy image. They can be removed by using a commercially available biocompatible polishing paste in accordance with the manufacturer's instructions.
2. In general, to remove deposits, apply a small amount of polishing paste to a clean, cotton-tipped swab. Gently press the swab against the optical surface and clean using a circular motion. Rinse the surface with tap water to remove any residue, then follow the cleaning procedure outlined in this IFU.

   NOTE: Polishing paste cleaning is not part of the standard cleaning routine and should only performed as needed.

Endoscope Optical Surfaces



TROUBLESHOOTING GUIDE

1. Power on the camera, light source, and monitor to pre-warm the system. Perform white balancing and adjust the focus.
2. Check for any of the conditions listed below and apply the corresponding solution and preventive measures.

Symptom	Fuzzy, foggy, or no image	Blade remains elevated	Trigger binds or sticks
Solution	1) Disassemble and dry the camera coupler to endoscope interface with isopropyl alcohol or anti-fogging agent and a sterile cotton swab. If the image remains poor, continue. 2) Apply anti-fogging agent to endoscope tip and wipe dry. Allow device temperature to equalize with patient's body (~45 seconds). If the image remains poor, continue. 3) Absorb excess fluid inside the surgical site using a sterile cotton swab. If the image remains poor, return the endoscope to Hand Biomechanics Lab for repair.	1) Leave the blade assembly inside the surgical site. 2) Loosen the locking screw on the handpiece. If the blade remains elevated, continue. 3) Remove the endoscope from the handpiece. If the blade remains elevated, continue. 4) Separate the blade assembly from the handpiece. If the blade remains elevated, leave the blade assembly in place and convert to an open procedure.	1) Clean accumulated debris in the handpiece per the IFU paying particular attention to the area around the trigger and the trigger through hole on the bottom of the handle. If the trigger remains sticky, return the handpiece to Hand Biomechanics Lab for repair.
Prevention	Store the endoscope in the protective Sterile Tray between procedures. Air dry the endoscope, then assemble the system to prewarm it prior to the procedure. Dipping the system components in room temperature sterile water or saline for approximately 1 minute will help equalize temperatures and prevent image problems.	Before surgery, verify proper function and ensure the blade elevates and retracts correctly.	During cleaning, depress and release the trigger multiple times. Before surgery, verify proper function and ensure the blade elevates and retracts correctly.

WARRANTY, SERVICE AND REPAIR

1. WARRANTY

Hand Biomechanics Lab warrants the TunnelVision Endoscopic Soft Tissue Release System will be free from defects in material and workmanship for a period of one (1) year from the date of original purchase by the end customer. The warranty is limited to repair or replacement of the product at no cost.

The warranty shall be void in cases of abuse, misuse, operation outside a normal surgical environment, disassembly, alteration, or repair by any party not authorized by Hand Biomechanics Lab, or if the product has not been used in a reasonable manner consistent with the written instructions herein.

All other warranties, whether expressed or implied, including but not limited to warranties of merchantability and fitness for a particular purpose, are hereby excluded. Hand Biomechanics Lab disclaims any liability for incidental or consequential damage.

2. SERVICE AND REPAIR

Should any equipment issues occur, please contact Customer Service at:
Telephone: 916-923-5073
Email: info@handbiolab.com
Do not disassemble or attempt to repair the equipment. Servicing is strictly limited to authorized Hand Biomechanics Lab representatives. Any unauthorized service will void the warranty.

3. ITEM RETURN

1. **Obtain an RMA Number:** Contact Customer Service to request a Return Material Authorization (RMA) number. Returns without an RMA may face processing delays or tracking issues.
2. **Clean Equipment:** Thoroughly clean and disinfect the equipment before shipment.
3. **Include Problem Description:** Provide a detailed description of the issue, including how and where it was used, along with a contact name and phone number.
4. **Provide Purchase Information:**
   - If under warranty, include the purchase date.
   - If out of warranty, include a purchase order number.
5. **Shipping Instructions:** In the United States, ship the merchandise by Express Mail, Federal Express, or UPS to avoid delays. All shipping charges must be prepaid by the customer.
6. **Repair Estimates:** If you require a cost estimate before repairs begin, include a contact name and phone number.
7. **Return Shipping:** Hand Biomechanics Lab will repair the item and return it via 2nd Day Air within the United States unless otherwise specified.
8. **Return Address:**
   Hand Biomechanics Lab, Inc.
   Attn: (contact Customer Service for specific instructions)
   77 Scripps Drive, Suite 104
   Sacramento CA 95825
   Phone: +1 916-923-5073

4. DISPOSAL

To minimize the risk of contamination by biological waste, all devices should be thoroughly cleaned and sterilized prior to disposal. Disposal must comply with applicable local, state and federal laws and regulations.

Users and/or patients are required to report any serious incidents to Hand Biomechanics Lab as well as the Competent Authority of their Member State or the relevant local regulatory authority where they are located.

These companies are not affiliated with Hand Biomechanics Lab:
- Storz, Registered Trademark of KARL STORZ GmbH & Co.
- Olympus, Registered Trademark of Olympus America Inc.
- Wolf, Rx Only, Registered Trademark of Richard Wolf Medical Instruments Corporation
- Dyonics, Registered Trademark of Smith & Nephew
- ACMI, Registered Trademark of Olympus America Inc.
- Stryker, Registered Trademark of Stryker
- Steris, Registered Trademark of Steris Corporation
- MicroAire, Registered Trademark of MicroAire Surgical Instruments
- HSW, Registered Trademark of Henke-Sass, Wolf

℞ Only

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician or hospital.

Proudly Made in U.S.A.
Endoscopes and Light Post Adapters Made in Germany
Sterilization Tray Made in China

tunnelvision™
https://tunnelvisionectr.com

Hand Biomechanics Lab, Inc.
77 Scripps Drive, Suite 104
Sacramento, CA 95825

Phone: +1 916-923-5073
https://handbiolab.com

348700 125-008