tunnelvision™

Endoscopic Soft Tissue Release System

Endoscopic Cubital Tunnel Release (ECuTR)
Surgical Technique Guide

Table of Contents

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 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 The ligament is cut as the instrument is withdrawn in a retrograde direction.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

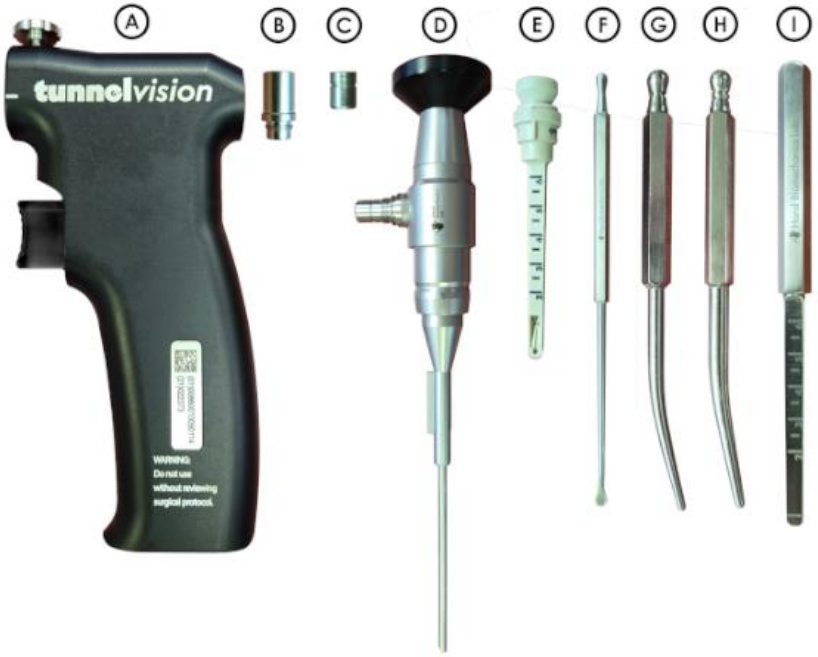
The endoscopic procedures for which TunnelVision is indicated should only be attempted after the surgeon has been trained at a TunnelVision or Hand Biomechanics Lab workshop, a comparable device workshop, or by a qualified training surgeon or trained on a comparable device. Operating room staff should 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.
• **WARNING**: Failure to follow the Surgical Technique may result in permanent injury to the patient. If issues arise while performing this technique, such as unanticipated anatomical anomalies, poor visibility, difficulty identifying anatomy, or questions concerning technique or instrumentation, the surgeon should abandon the endoscopic cubital tunnel release and convert to an open cubital tunnel release.
• **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.

PREPARATION AND PROCEDURE SETUP

The following devices and equipment are needed in the sterile field prior to surgery.

CAUTION: Endoscopes are fragile.

INSTRUMENTATION

Hand Biomechanics Lab TunnelVision System

- TunnelVision Handpiece
- TunnelVision Endoscope with Light Post Adapters
- Synovial Elevator, Small Dilator, Medium Dilator, and Coequal Dilator
- HBL Blade Assembly, sold separately

Recommended Facility Provided Equipment

- Endoscopy tower (camera and light source)
- 2 double-pronged skin hooks
- 2 Senn rake retractors
- 2 Ragnell right angle retractors
- Army-Navy, Aufricht, or equivalent retractor
- Adson forceps
- Hemostat
- Tenotomy scissors
- Scalpel handle with #15 blade
- Sterile skin marking pen
- Antifog solution or wipes

PRIOR TO SURGERY

Before the patient is brought into the surgical suite, the Hand Biomechanics Lab® TunnelVision™ System should be checked for correct operation, which includes blade elevation and retraction and a clear video image. Turn on the camera, light source and monitor. Adjust white balance using a white diffuse cloth or sponge and then lay a blue or green towel on the window, using the fabric of the towel to set the light intensity and focus on the mid and distal portion of the window. Observe for any sign of fogging. Fogging prior to insertion into the patient's body signifies moisture or water in the blade assembly. Fogging after insertion into the cubital tunnel may be condensation caused by the temperature difference between the scope and the patient's body or could signify excess fluid inside of the cubital tunnel. A fuzzy or darkened view could signify a damaged endoscope, which would require the scope to be returned to Hand Biomechanics Lab for service. The positioning of the equipment relative to the operating table and surgeon, including the instruments and monitor, should be assessed and adjusted as necessary after the arm is prepped and draped.

SURGICAL SUITE SETUP

The surgical suite should be arranged such that the surgeon has an optimal view of the video monitor and is properly oriented to the patient's operative arm. The surgeon should be able to shift their gaze easily between the surgical field and the video image.

The surgeon should position themselves so that the TunnelVision™ handpiece, held naturally in the hand, aligns the blade assembly with the optimal path along the course of the ulnar nerve. Surgeons typically adopt an axillary position and rotate the blade assembly and camera 180° between releasing the proximal fascia to the forearm fascia.

The endoscopy light source, camera, and monitor are most commonly placed across the hand table from the surgeon on a wheeled cart, with the endoscope cable secured to a drape proximal to the incision site to avoid tension or drag. The surgeon's assistant should be positioned opposite the surgeon, taking care not to obstruct the surgeon's view of the monitor. A scrub nurse may optionally be present at the end of the table, at the surgeon's discretion.

PATIENT PREPARATION

The arm is prepped and draped in the usual sterile fashion. The patient is positioned supine with the palm up, arm extended on a hand table, and the elbow flexed to approximately 90°. Draping should expose the medial aspect of the elbow from the mid-upper arm through the proximal forearm. Care should be taken to avoid pressure on the ulnar nerve at the elbow.

A tourniquet should be applied. Using an Esmarch bandage, the upper extremity from the hand to the arm proximal to the elbow should be exsanguinated prior to inflation of the tourniquet.

ANESTHESIA

Options include general, MAC or local and regional anesthesia. Some surgeons prefer to perform the technique under general anesthesia to minimize the possibility of patient movement during the procedure.

Regional anesthesia such as a brachial plexus block may provide excellent postoperative analgesia; however, care should be taken to avoid injecting fluid in or around the cubital tunnel, as excess fluid can obscure endoscopic visualization.

Local anesthetic infiltration may supplement other techniques but should not be used to distend the cubital tunnel itself. Regardless of the method chosen, the surgeon should ensure that the patient remains immobile throughout the endoscopic release.

OPERATIVE TECHNIQUE

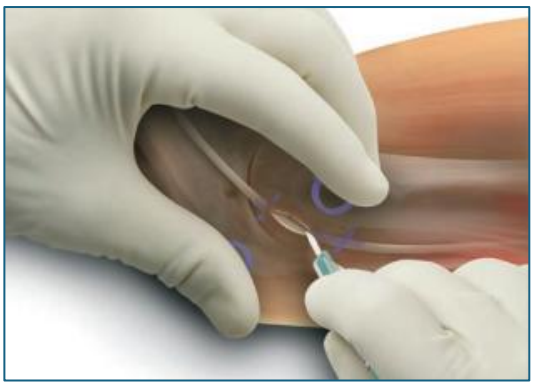
IDENTIFY AND MARK KEY LANDMARKS

Before tourniquet inflation, outline the following structures with a sterile marker:

- Medial epicondyle
- Olecranon process
- Course of the ulnar nerve between the two landmarks
- Planned incision: 2–3cm longitudinal line midway between the epicondyle and olecranon, directly over the ulnar groove.

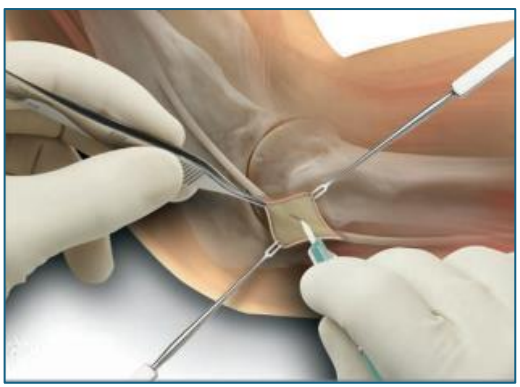
SKIN INCISION

Create a 2–3cm transverse incision in the marked interval. [Figure 2] Carry dissection through subcutaneous tissue with care to avoid branches of the medial antebrachial cutaneous nerve. Expose the roof of the cubital tunnel fascia.



FASCIA EXPOSURE

Identify the thickened fascial bands forming the roof of the cubital tunnel. [Figure 3] Protect the ulnar nerve throughout. Incise the fascia longitudinally to create an entry point for the blade assembly. Confirm visualization of the ulnar nerve proximally and distally before proceeding.



PREPARE THE CANAL

Introduce the TunnelVision™ synovial elevator along the course of the ulnar nerve, separating fascial bands from the nerve surface. [Figure 4] Maintain a path along the nerve without circumferential dissection. Sequentially dilate the tunnel with the small, medium, and coequal dilators until the passage accommodates the blade assembly.

INTRODUCE THE BLADE ASSEMBLY

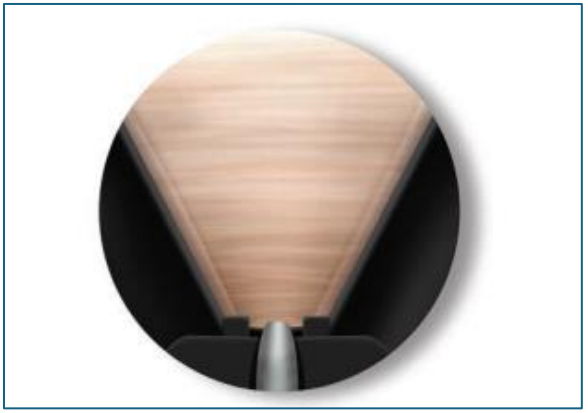
Verify smooth blade extension and retraction. Insert the blade assembly into the cubital tunnel, keeping the window oriented against the fascial roof and away from the nerve. Advance distally until the fascia is visualized in the field of view. Ensure that only the fascial fibers, and not the ulnar nerve, occupy the cutting corridor. [Figure 5]

ORIENT TO THE FASCIAL ROOF

Advance the blade assembly until the endoscopic view demonstrates the fascial roof of the cubital tunnel. [Figure 6] Confirm that the viewing window contains only fascial fibers and that the ulnar nerve lies completely outside the cutting corridor.

Adjust the orientation of the blade assembly to follow the course of the nerve while keeping the window pressed against the fascial roof. If any portion of the nerve or other soft tissue is visible within the cutting path, reposition until the field is clear before proceeding.

If needed, partially elevate the blade as a preview to confirm where the dissection will begin. Proceed only once visualization of the fascia is clear and the nerve is excluded from the viewing path.



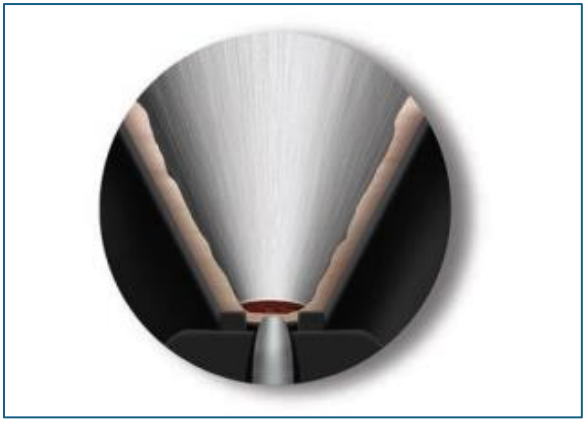
RELEASE THE PROXIMAL FASCIA

Elevate the blade and withdraw the assembly to divide the proximal segment of the fascia. Retract the blade completely and confirm endoscopically that all visible fibers in this segment have been divided. If small bands remain, release them before continuing.

Elevate the blade again and divide the distal segment of the fascia. Retract the blade and inspect for any remaining fibers. [Figure 7] Divide any that remain until the decompressed fascia forms a clear, uninterrupted window along the upper arm. [Figure 8]

RELEASE THE FOREARM FASCIA

After completing dissection of the proximal and distal upper arm fascia, address the forearm segment in a stepwise manner. Elevate the subcutaneous tissue to provide a clear view, then introduce the blade assembly. [Figure 9] Confirm that only fascial fibers occupy the viewing corridor and that no neurovascular structures are present before cutting.



Begin by releasing the distal portion of the fascia near the muscular transition, then progress proximally in controlled steps. Leave a short segment of proximal fascia intact initially to allow reinsertion of the blade for endoscopic inspection of the distal release. Once full visualization confirms that the distal fibers have been divided, return to release the remaining proximal segment.

Withdraw the blade assembly while inspecting the tunnel. Release any small fascial bands still present until the ulnar nerve is fully decompressed throughout the forearm segment.

If applicable, release the tourniquet.

CLOSE THE WOUND

Close the skin with an absorbable or intracuticular suture. Apply a light dressing. Early motion is encouraged. Patients typically resume daily activity within a few days but should avoid heavy lifting or direct elbow pressure for 4–6 weeks.

TROUBLESHOOTING GUIDE

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.

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, 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

348900 125-008