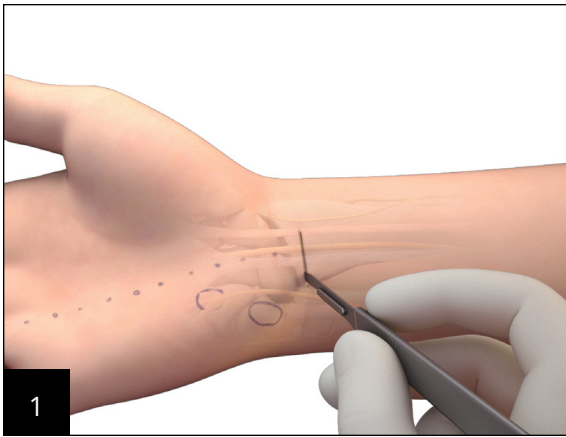


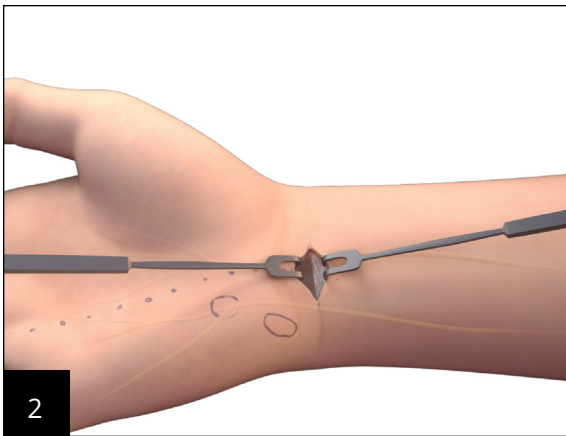
SmartRelease® ECTR

Surgical Technique Guide



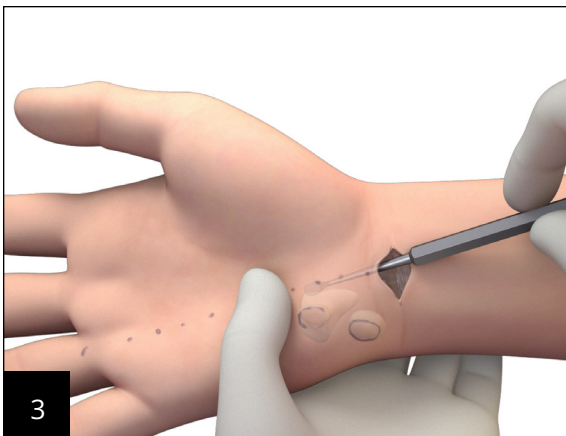


Make a 1–2 cm transverse incision between the tendons of the flexor carpi radialis and the flexor carpi ulnaris in the proximal flexion crease of the wrist. Stop short of the subcutaneous tissues/nerves. Use a spreading longitudinal dissection to protect these nerves and expose the forearm fascia.

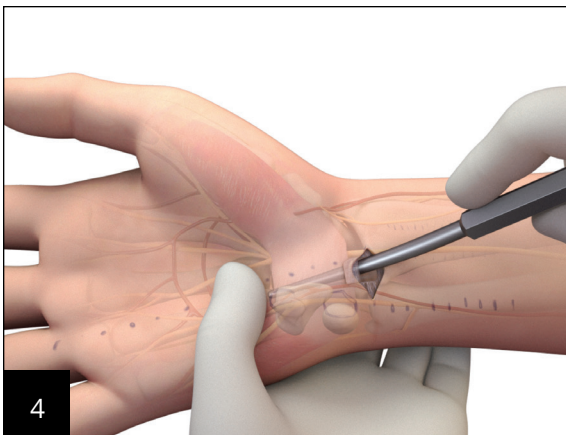


Elevate the distal edge of the fascia from the underlying flexor tenosynovium (ulnar bursa) with skin hooks.

WARNING: The median nerve is immediately beneath the fascia. Use caution when making the incision in the fascia. Use a pair of forceps to pick up the fascia before incising the fascia superficial to the median nerve.

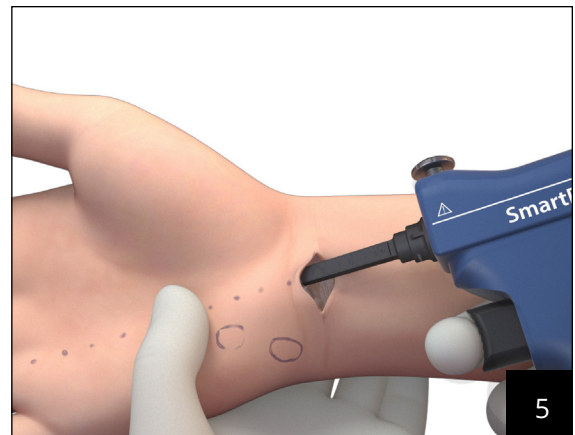


Position the synovium elevator in line with the base of the ring finger, radial to the hook of the hamate. Using the synovium elevator, feel the roughness (“washboard effect”) of the transverse fibers of the transverse carpal ligament. Continue to separate the ulnar bursa (synovium) distally until its tip is palpable at the distal end of the carpal tunnel.



While aiming at the base of the ring finger and holding the wrist in slight extension, gently pass the hamate finder distally down the ulnar side of the tunnel, hugging the hook of the hamate until the finder's curved tip can be palpated subcutaneously as it exits the carpal tunnel.

Holding the patient's wrist in slight extension, insert the blade assembly into the carpal tunnel, pressing the viewing window snugly against the deep side of the ligament. Advance the instrument distally, aiming at the base of the ring finger and hugging the hook of the hamate.

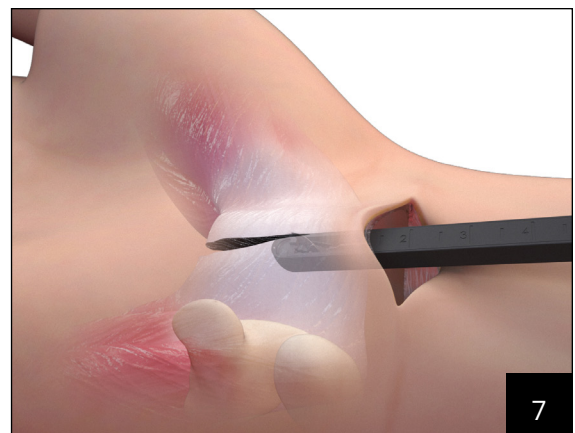


Use proximal-to-distal passes to accurately define an ulnar "strip" of the transverse carpal ligament. Transverse fibers of the ligament should be visible within this strip*. Palpating with the thumb, define the distal margin of the ligament at its junction with a pad of fat and align the point of entry markers at this junction. Elevate the blade so that it engages the distal margin of the ligament.

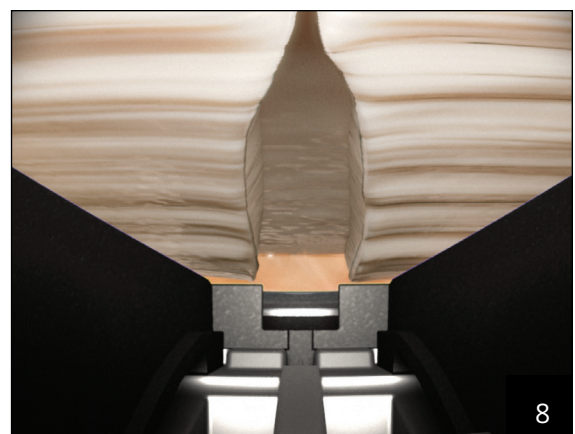
*WARNING: Do not cut tissue without proper and adequate visualization. Exercise caution deploying cutting blade when the median nerve, or other sensitive tissue, is visible.

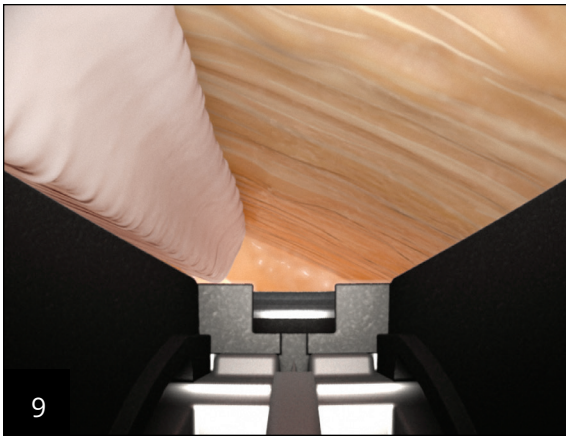


Withdraw the blade assembly to divide the distal one half of the transverse ligament. Release the trigger to retract the blade. Divide the distal remaining fibers that are just proximal to the fat pad which may at times hide or cover these fibers.



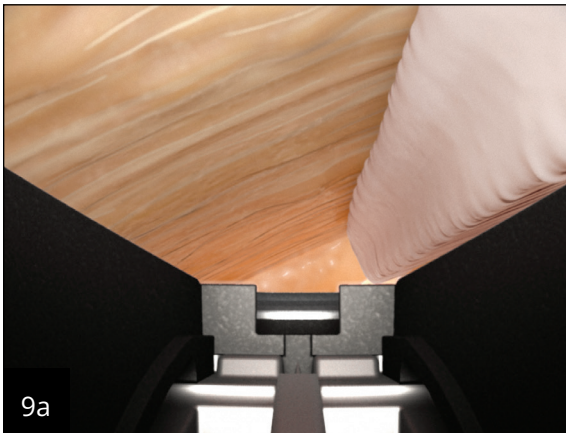
Reposition the blade assembly window to check for a complete release of the distal half of the transverse carpal ligament. Use partial or complete elevation of the blade to selectively divide the proximal half and the remaining collagen fibers with interposed fat and/or muscle.





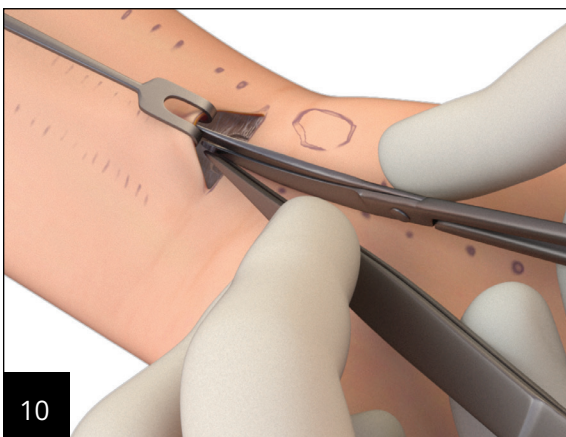
Reinsert the blade assembly (blade retracted) to inspect the completeness of the ligament division and for potentially troublesome arterial bleeders. With the blade retracted, the assembly may be rotated after a complete release to allow the surgeon to inspect the cut edges of ligament.

When additional cuts are necessary, be sure to position the window of the blade assembly in, and/or between, the cut edges of the ligament to avoid injuring the median nerve. Partial blade elevation is frequently useful in completing the ligament division to avoid dividing tissues superficial to the ligament.



In addition to the video monitor image, completeness of ligament division can be assessed by:

- Sensing the reduced “pressure” upon the instrument when it is reinserted in a decompressed carpal tunnel
- Noting the more subcutaneous course of the blade assembly after division
- Palpating the divided ligament with the hamate finders
- Inserting a small right-angle retractor and looking directly inside of the released carpal tunnel at the cut edges of the ligament



Using tenotomy scissors, release the forearm fascia proximal to the skin incision, taking care to protect the median nerve. Release the tourniquet (if used) and slowly withdraw the instrument.

The use of an intracuticular suture to close the skin gives the best cosmetic result. Following wound closure, dress the wrist and hand by a method that allows full thumb use and opposition post-operatively.

Indications for Use

The SmartRelease® by MicroAire Endoscopic Soft Tissue Release System is indicated for carpal tunnel release in the wrist.

Contraindications

The SmartRelease® by MicroAire Endoscopic Carpal Tunnel Release System is not intended for use in patients with severe or significant abnormalities of the wrist (carpal tunnel), including distal radial deformities, rheumatoid and other synovitis

System Warnings

- The surgeon is specifically advised not to use the instrument to explore and/or treat any structure other than the transverse carpal ligament within, or outside of, the carpal tunnel. Failure to heed this warning can lead to damage to the median or ulnar nerve, flexor tendons or superficial palmar arterial arch.
- The surgeon should not cut tissue without proper and adequate visualization and should exercise caution deploying the cutting blade when the median nerve, or other sensitive tissue, is visible.
- If the Disposable Blade Assembly fails to retract while in the carpal tunnel, release the blade lock screw and separate the Disposable Blade Assembly from the SmartRelease handpiece leaving Disposable Blade Assembly in the carpal tunnel. If blade is still extended, do not remove from carpal tunnel; convert to open procedure.

Pre-Operative Technique

The surgical suite should be set up to offer the surgeon the best view of the video monitor. The surgeon should be able to easily shift his/her view upward from the surgical field to the video image.

The patient's hand is positioned supine, with the arm abducted 75-80 degrees. The hand should be positioned palm up on a hand table equidistant between the surgical assistant and the surgeon.

The procedure can be done with the preferred anesthetic (General, MAC, Local or Regional Anesthesia) of the surgeon.

In the surgical suite—before the patient is brought into surgery with the intention of performing the procedure endoscopically—the SmartRelease system should be fully assembled and checked for correct operation, which includes blade elevation and retraction and a clear video image. The equipment, including the instruments and the video monitor, should be positioned relative to the operating table and surgeon's position after the extremity is prepped and draped.

Troubleshooting Guide

1. Assemble and pre-warm the system by turning on the camera, light source and monitor. White-balance and adjust the focus. (See **Note 2**)
2. Observe for any of the listed conditions and follow the recommended resolution and preventative steps below.

Condition	Cause	Solution	Prevention
Fogging (before insertion into carpal tunnel)	Moisture inside camera coupler and endoscope lens interface. A single drop of moisture can cause fogging at this juncture.	Disassemble and thoroughly dry the endoscope lens and camera coupler interface with isopropyl alcohol or an anti-fogging agent and a sterile cotton swab. (See Note 1)	Use an anti-fogging agent to dry the endoscope lens prior to assembly. Dry the endoscope lens and camera coupler interface prior to assembly. Assemble the endoscope, light source and camera before the initial skin incision to pre-warm the system. (See Note 2)
	Moisture trapped between the endoscope lens optics and the eyepiece.	Return to an authorized MicroAire agent for repair.	Protect the endoscope in its autoclave case during processing and between uses. (See Note 3)
Fogging (after insertion into carpal tunnel)	Condensation due to temperature differences between endoscope, handpiece and patient body temperature.	Dip or wipe the endoscope tip in sterile anti-fogging agent and wipe dry. Keep the device inside the carpal tunnel until the endoscope warms to patient body temperature, approximately 45 seconds.	Assemble the endoscope, light source and camera before the initial skin incision to pre-warm the system. (See Note 2). Allow enough time between procedures to allow the endoscope to air-dry in its autoclave case.
	Moisture inside the camera coupler and endoscope lens interface. (A single drop of moisture can cause fogging at this juncture.)	Disassemble and thoroughly dry the endoscope lens and camera coupler interface with isopropyl alcohol or an anti-fogging agent and sterile cotton swab (See Note 1).	For back-to-back cases with insufficient time between processing and surgical procedure, place the handpiece and instruments into pan of sterile room temperature water/ saline immediately following autoclaving. (See Note 4).
	Excess fluid inside the carpal tunnel.	Soak up the fluid with a sterile cotton swab.	Avoid injecting anesthetics into the carpal tunnel. Dry the endoscope completely after processing.
	Moisture trapped between the endoscope lens optics and the eyepiece.	Return to MicroAire Repair Center for repair.	Protect the endoscope in its autoclave case during processing and between uses. (See Note 3)
Fuzzy or no picture	Damaged endoscope.	Return to an authorized MicroAire agent for repair.	Protect the endoscope in its autoclave case during processing and between uses. (See Note 3)
Blade fails to retract	Excessive contact with or friction between the endoscope and the blade assembly.	Disconnect the endoscope from the handpiece. When the blade retracts discard and replace the whole blade assembly to continue the procedure.	Follow surgical protocol by checking the fully assembled device prior to the initial incision including blade elevation and retraction.
	Locking screw is over-tightened.	Release the locking screw and use the endoscopic view to confirm blade retraction. If the blade remains extended, leave the blade assembly inside the carpal tunnel and separate the blade assembly from the handpiece. If the blade continues to remain extended, keep the blade assembly in-situ and convert to an open procedure.	Tighten the locking screw until it is finger-tight but do not over-tighten which can result in blade non-retraction.
Sticky trigger	Debris lodged around the trigger.	Clean the handpiece according to the IFU. If the issue continues contact MicroAire.	Send the handpiece back to MicroAire for maintenance.

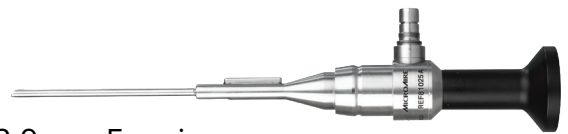
NOTES:

1. Beware of contamination caused by disassembling the camera and the endoscope in the sterile field.
2. Assembly and pre-warming of the system prior to surgery helps prevent fogging caused by temperature differences between the endoscope and patient's tissue. In addition, this step serves to check the equipment's functionality and the clarity of the visualization system before the start the procedure.
3. Proper handling of the endoscope will extend its life expectancy. Always store the endoscope in its autoclave case for processing and between uses.
4. Do not place the endoscope into cool sterile water or saline immediately following autoclave completion. The extreme temperature difference could damage the scope. The scope will quickly cool down on its own following autoclaving.

SmartRelease® Components and Part Numbers



SmartRelease®
Aluminum Handpiece (83014)



2.9mm Eyepiece
Autoclavable Endoscope (81025)

Low Profile Disposable Blade Assembly
Single (83030-1)
6-pack (83030-6)



Dilator - Small (81026)



Dilator - Medium (81027)



Elevator (81029)



Standard Disposable Blade Assembly
Single (81010-1)
6-pack (81010-6)



Coequal to Standard Blade Assembly (81061)



Coequal to Low Profile Blade Assembly (83061)



SmartRelease® by MicroAire
Endoscopic Carpal Tunnel Release Surgical Technique Guide

LIT-ECTR-TECH Rev E

To learn more about SmartRelease® by MicroAire, visit microaire.com/products/smartrelease.

To order online, visit microaire.com/request-a-quote.

For more information or to order directly, contact _____ at _____.

Instructions for Use

MicroAire device and system Instructions for Use (IFU) are maintained by an external electronic directory, enLabel's eIFU. Visit [MICROAIRE.EIFU.COM](https://microaire.com/ifu) to access current, past, and multilingual versions of all SmartRelease® ECTR IFUs.

MICROAIRE®



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