

SmartRelease[®]

Endoscopic
Gastrocnemius
Recession



MICROAIRE[®]
For Surgery. For Life.[™]

Endoscopic Gastrocnemius Recession Surgical Technique

NOTE: The SmartRelease® Lower Extremity System is not yet CE approved.

Introduction

This Surgical Technique is provided as an educational tool and clinical aid to assist medical professionals in the proper protocol for the MicroAire® SmartRelease® endoscopic gastrocnemius recession instrumentation. For effective use, surgeons must possess a thorough knowledge and understanding of leg anatomy and the endoscopic technique using the MicroAire® SmartRelease® system. Instructional videos and cadaver workshops are available through MicroAire Surgical Instruments.

Those considering using the MicroAire® SmartRelease® system should only do so after successfully completing MicroAire's required surgical training as well as the relevant training mandated in the professional guidelines of any pertinent hospital, institution or society. For training dates and locations, visit www.microaire.com.

Failure to follow the Surgical Technique may result in permanent injury to the patient. If, while performing this technique, any problems should arise, such as anatomical anomalies, inadequate visualization, inability to identify anatomy or questions concerning technique or instrumentation, the surgeon should abandon the endoscopic gastrocnemius recession and convert to another gastrocnemius recession procedure.

These pages are not intended to provide medical advice or physician instruction on the appropriate use of products produced or supplied by MicroAire Surgical Instruments, its affiliates, related companies, or its licensors or other partners.

NOTE: The MicroAire® SmartRelease® system uses a dry procedure. No fluid or gas should be introduced into the surgical site during this procedure.

System Description and Intended Use

Intended Use

The MicroAire® SmartRelease® Endoscopic Soft Tissue Release System is comprised of an endoscope and a handpiece that holds a disposable blade assembly. The gastrocnemius release device attaches to any standard video camera and light source used in endoscopic/arthroscopic procedures. The surgeon introduces the disposable blade assembly into the medial skin incision portal. Viewing of the gastrocnemius aponeurosis through a window at the tip of the instrument, the surgeon elevates the blade to cut the aponeurosis as the instrument is withdrawn.

Contraindications

The MicroAire® SmartRelease Endoscopic Gastrocnemius Recession System is not intended for use in patients with severe or significant anatomical abnormalities, including patients with congenital anatomical abnormalities, blood supply limitations and previous infections that may retard healing.

Warnings

The surgeon is specifically advised not to use the instrument to explore and/or treat any structure other than the gastrocnemius aponeurosis. Failure to heed this warning can lead to damage of the surrounding tissues and structures.

If the surgeon is unable to clearly visualize the gastrocnemius aponeurosis with definite medial and lateral edges, the blade assembly should be withdrawn and the procedure should be converted to another gastrocnemius recession procedure.

If the surgeon has any questions or concerns regarding patient anatomy, the surgical approach or the instrument function — or if the view is any less than adequate — the instrument should be withdrawn and the procedure converted to another gastrocnemius recession procedure.

Failure to follow the proper training and surgical technique can result in permanent injury to the patient. Endoscopic recession of the gastrocnemius aponeurosis using the MicroAire® SmartRelease® system should not be attempted until the surgeon has been trained at a MicroAire-sponsored workshop. This training requires thorough familiarity with this Surgical Technique, the Instructions for Use and gaining hands-on experience with a trained surgeon who is experienced with the device. The procedure should be performed on cadaveric specimens before initial use. Operating room staff should thoroughly review the MicroAire® SmartRelease® Instructions for Use prior to set up of this system.

Definitions

NOTE: Indicates the easiest means of carrying out techniques.

CAUTION: Indicates special procedures or precautions that must be followed to avoid damaging the system instrumentation.

WARNING: Indicates that the safety of the patient and hospital personnel could be involved.

Review full list of Notes, Cautions, and Warnings in the Instructions for Use (IM-EPFR-EGR).

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Instrumentation

SmartRelease® Instruments and Accessories

A	SmartRelease® Aluminum Handpiece	REF 85014
B	Disposable Standard Blade Assembly	REF 84040-1 or 84040-6
C	Disposable Onyx™ Blade Assembly	REF 85050-1 or 85050-6
D	2.9mm Eyepiece Autoclavable Endoscope	REF 81025
E	Endoscope Light Post Adapter, Storz®/Olympus®	REF 81151
F	Endoscope Light Post Adapter, Wolf®/Dyonics®	REF 81152
G	Elevator	REF 85029
H	Dilator — Small	REF 85026
I	Dilator — Medium	REF 85027
J	Dilator — Coequal to Standard Blade Assembly	REF 84061
K	Dilator — Coequal to Onyx™ Blade Assembly	REF 85061
L	Instrument Sterilization Tray	REF 85040

FIGURE i



For additional information, consult the MicroAir Instructions for Use (REF: IM-EPFR-EGR)

Troubleshooting Guide for Endoscope Fogging

In order to quickly identify the source of the fogging problem and formulate the appropriate solution, you should:

1. Assemble the system before the surgeon makes the skin incision to start the procedure.
2. Turn on the camera, light source and monitor. White balance using a white sponge and then lay a blue or green towel on the window using the fabric of the towel to set the light intensity and to focus on both the mid and distal portion of the window.
3. Observe for any signs of fogging.

NOTE: Beware of contamination caused by disassembling the camera and the endoscope in the sterile field.

Condition	Cause	Solution	Prevention
Fogging—before insertion into surgical site	Moisture inside camera coupler and endoscope lens interface. A single drop of moisture can cause fogging at this juncture.	Disassemble and thoroughly dry endoscope lens and camera coupler interface with alcohol or anti-fog agent and sterile cotton swab.	Pre-warm system by connecting light source and camera before surgeon makes the skin incision. Use anti-fog agent to dry before assembly. Thoroughly dry endoscope lens and camera coupler interface with cotton swab before assembly.
	Moisture trapped within endoscope between endoscope lens optics and endoscope eyepiece.	Return to MicroAire Repair Center for repair.	Protect endoscope in its autoclave case during processing and when not in use.
Fogging—after insertion into surgical site	Condensation due to temperature difference between endoscope, SmartRelease® handpiece and patient's tissue.	Attempt to warm endoscope to patient's tissue temperature: 1. Keep device inside patient until endoscope warms up to body temperature, approximately 45 seconds. 2. Dip or wipe endoscope tip in sterile anti-fog agent and wipe dry.	Pre-warm system by connecting light source and camera before surgeon makes the skin incision. For the Eyepiece Endoscope: If there is sufficient time between processing and skin incision, allow endoscope to air dry in its autoclave case between procedures.
	Moisture inside camera coupler and endoscope lens interface. A single drop of moisture can cause fogging at this juncture.	Disassemble and thoroughly dry endoscope lens and camera coupler interface with alcohol or anti-fog agent and sterile cotton swab.	For back-to-back cases with out sufficient time between processing and the skin incision, place the SmartRelease® handpiece and instruments into pan of sterile room temperature water/saline immediately following autoclaving.
	Excess fluid inside surgical site.	Soak up fluid with sterile cotton swab	Avoid injecting anesthetics into the surgical site. Be sure endoscope is completely dry after processing.
Fuzzy or no picture	Moisture trapped within endoscope between endoscope lens optics and endoscope eyepiece.	Return to MicroAire Repair Center for repair.	Protect endoscope in its autoclavable case during processing or when not in use.
	Damaged endoscope.	Return scope to MicroAire Repair Center for repair.	Protect endoscope in its autoclave case during processing or when not in use.

For additional information, consult the MicroAire Instructions for Use (REF: IM-EPFR-EGR)

Surgical Setup

Two physical considerations dictate the best surgical setup: the surgeon's orientation with respect to the video monitor and the patient's operative leg. 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 gaze upward from the surgical field to the video image.

The patient is positioned supine or prone (surgeons preference) on the operating room table with the leg slightly elevated using a sterile bulky towel. A well-padded thigh tourniquet should be used for this procedure. Standard skin preparation should be performed. Sterile draping should be performed according to standard operative protocol. The foot and leg should be fully exsanguinated.

The surgeon's hand, when holding the instrument, should naturally align the blade assembly so that it points from the medial side of the leg to the lateral side of the leg, perpendicular to the gastrocnemius aponeurosis. Adjusting the blade location so the blade protrudes from the top or bottom of the device may prove useful in conserving the device's natural lateral-grip use. The surgeon should stand on the medial side of the leg as the gastrocnemius aponeurosis is being released.

To conduct a gastrocnemius aponeurosis recession using the MicroAire® SmartRelease® system, the sterile field should include:

- 1 pair of tenotomy scissors
- 1 dilator — small*
- 1 sterile skin marking pen
- 1 dilator — medium*
- 1 scalpel, #15 blade
- 1 dilator — coequal to blade assembly*
- 2 Ragnell right angle retractors
- 1 elevator*
- 2 Senn rake retractors
- *(Included with MicroAire® SmartRelease®)

Before exsanguination and elevation of the thigh tourniquet, it is recommended that the surgeon mark key anatomical landmarks on the patient's leg using a sterile skin marking pen: the gastrocnemius muscle belly, medial aspect of the gastrocnemius aponeurosis (if palpable), and the approximate location of the sural nerve from between the two heads of the gastrocnemius, distally to 1 cm posterior of the lateral malleolus at the ankle.

The surgeon should take this time and also plan the incision mark, as described in Step 1 of the Surgical Technique.

IMPORTANT

In the surgical suite—before the patient is brought into surgery with the intention of performing the procedure endoscopically—the MicroAire® 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.

Operative Technique

ANESTHESIA

A general or regional anesthetic is strongly recommended and is dependent on adjunct procedures being performed. Local anesthetic increases tissue fluid, which can obscure endoscopic viewing and cause lens fogging. **Only when the surgeon has gained experience with the surgical approach and instrumentation should the procedure be performed using local anesthesia.**

When local anesthesia is used, the tourniquet is elevated and a volume of one percent lidocaine with epinephrine is injected subcutaneously near the incision site on the medial side of the leg. Use the least amount of local anesthesia possible. Avoid injecting the local anesthesia superficial to the gastrocnemius aponeurosis as it will compromise the endoscopic view of the aponeurosis.

STEP 1

Making the Incision on the Medial Side of the Leg

After marking of key anatomical structures as detailed on page 5, place the incision mark 12–14 cm proximal to the posterior calcaneal tuberosity or 2 cm distal to the palpated heads of the gastrocnemius muscle and slightly anterior to the medial border of the gastrocnemius aponeurosis. Make a 1–2 cm vertical incision and use a spreading, longitudinal dissection through the subcutaneous fat and deep crural fascia until the gastrocnemius aponeurosis is exposed.

NOTE

In patients with larger legs or excess adipose tissue, applying dorsiflexion force of the ankle can ease locating the medial head of the gastrocnemius¹

IMPORTANT

When beginning the local anesthesia, it is important that the patient receive minimal or no sedation. A sedated patient may move abruptly in response to discomfort when instrumentation is being introduced into the surgical site. Frequently, local anesthesia requires support with other anesthetic agents as prescribed by the anesthetist or surgeon.

To help minimize the opportunity for patient injury under local anesthesia, **it is very important that:**

- (1) The surgeon and assistant be prepared to manually restrain any sudden movements by the patient; and
- (2) The instruments (i.e. elevator, dilators, and blade assembly) should be inserted into the leg in a manner that will help avoid injury to tissues and structures in the leg should the patient move suddenly.

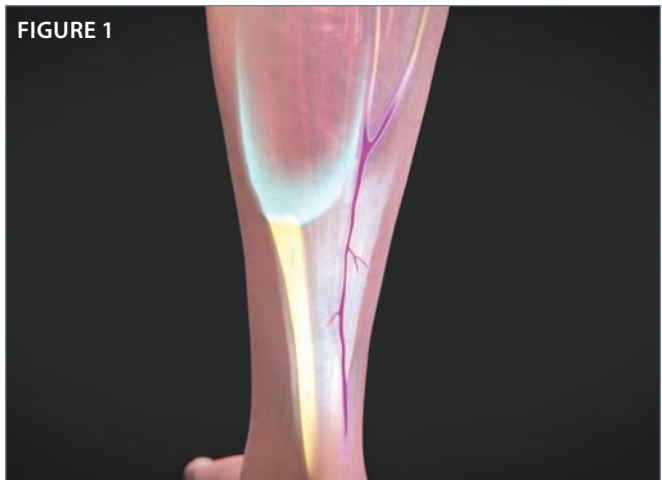


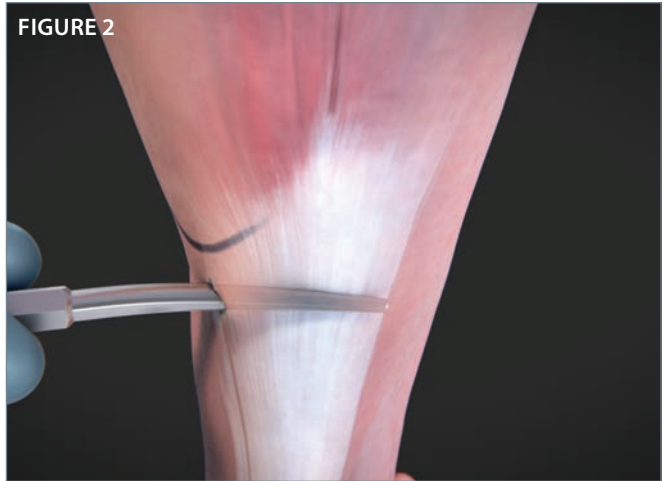
FIGURE 1

STEP 2**Creating the Path for the Instrument**

Insert the dilators to expand the tissue gap between the deep fascia and gastrocnemius aponeurosis, starting with a small dilator and ending with the coequal to the blade assembly. Push along the aponeurosis to (a) create a larger path for the instrument and (b) attempt to displace some of the soft tissue from the surface of the aponeurosis.

WARNING

Care should be taken when creating the pathway deep to the crural fascia. Superficial to the deep fascia are the neurovascular structures, including the saphenous vein, sural nerve, and saphenous nerves.²

FIGURE 2**STEP 3****Introducing the Blade Assembly**

Insert the blade assembly into the incision and path created in the previous steps. Locate the lateral edge of the gastrocnemius aponeurosis, and press the viewing window snugly against the aponeurosis. Ensure no anatomical structures are in-between the blade assembly and the gastrocnemius aponeurosis.*

NOTE

Blade extension and retraction should be checked before insertion into the patient's leg.

To avoid injury to surrounding structures, during the cutting stroke it is imperative that the flat surface of the blade assembly be pressed and held snugly against the gastrocnemius aponeurosis.

FIGURE 3**CAUTION**

Do not attempt to use this device to explore the surrounding anatomy. This device is designed for viewing and releasing the gastrocnemius aponeurosis. Using the blade assembly as a probe or lever may cause severe damage to the patient and can damage the endoscope's optical train or break the blade assembly.

Applying excessive pressure to the endoscope and blade assembly may damage the endoscope's optics. An unclear image may indicate fogging. Please refer to the Troubleshooting section on page 4.

*If blade assembly viewing tip is obstructed due to soft tissue/fluid:

1. Remove the handpiece and blade assembly from the surgical site
2. Suction, forceps or sterile gauze can be used to remove excess soft tissue/fluid

STEP 4

Incising the Gastrocnemius Aponeurosis

After confident in a clear endoscopic view of the aponeurosis and a well-planned location to begin the incision of the lateral portion, press the blade assembly against the gastrocnemius aponeurosis while manually dorsiflexing the patient's ankle. Engage the trigger to raise the blade, cutting the gastrocnemius aponeurosis from lateral to medial. Maintain pressure against the aponeurosis and manual dorsiflexion while proceeding with the cut. Continue until the desired amount of aponeurosis has been fully resected and the fibers of the muscle belly can be visualized endoscopically, or until desired amount of dorsiflexion is obtained.

NOTE

Multiple passes with the blade may be needed to fully resect the gastrocnemius aponeurosis. Holding the ankle dorsiflexed will put tension on the aponeurosis, assisting in an adequate recession.¹

CAUTION

If adipose tissue prolapses into the field of view and completely compromises the view, lower the blade, remove the assembly, and clean the scope. Do not cut the aponeurosis with a compromised field of view.

WARNING

Blade extension and retraction should be checked following assembly of the device and before use on the patient. When fully extended, the blade forms an approximate 80-degree angle to the flat surface of the blade assembly and measures approximately 3.5 mm in height. If the blade does not extend and retract properly during system checkout, the device should not be used.

In rare cases, the sural nerve can be adhered to the gastrocnemius aponeurosis. Ensure that no key anatomical structures are between the blade assembly and the gastrocnemius aponeurosis before incising.¹

If the blade fails to retract after the trigger is released, follow these steps for safe removal:

1. Release the blade lock screw while supporting the handpiece. Use the scope to view the blade to ensure blade retraction.
2. If the blade remains elevated, carefully separate the blade assembly from the handpiece, leaving the blade assembly in the leg of the patient. Use the endoscope to view the blade position as the handpiece is removed from the blade assembly. The blade assembly is left in the leg.
3. If the blade has not returned to a retracted position, do not remove the blade assembly from the leg through the endoscopic portal. Convert to an open procedure to remove the blade assembly. Inspect the blade assembly to make sure no parts are missing. If a part is missing, take an x-ray of the patient's leg.

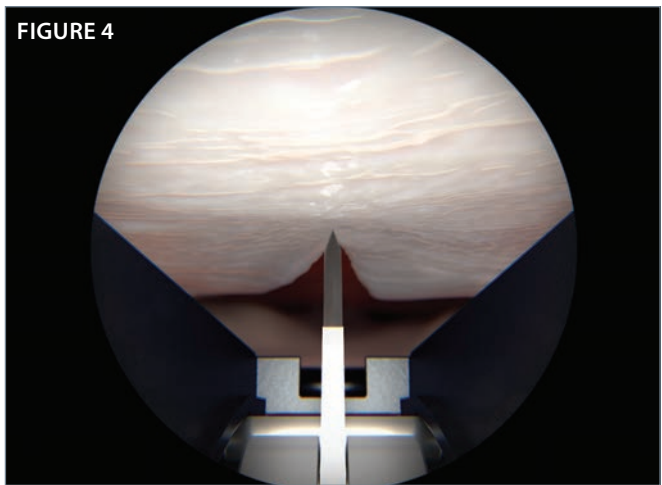


FIGURE 4

STEP 5

Inspecting the Incised Gastrocnemius Aponeurosis

Fully retract the blade by releasing the trigger. Inspect the aponeurosis division by reinserting the blade assembly. The assembly can be rotated with the blade retracted to fully inspect the cut. Assure that there are no remaining fibers within the released portion of the aponeurosis and the underlying muscle belly is visualized.

NOTE

Blade extension and retraction should be checked before insertion into the patient's leg.

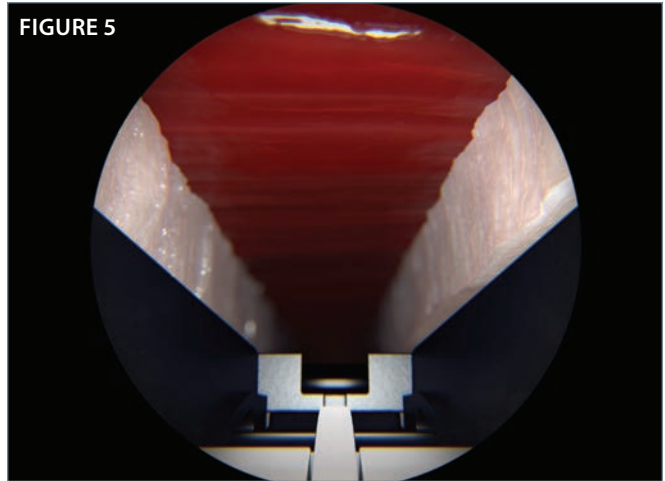
The far medial fibers of the gastrocnemius aponeurosis may be difficult to resect with the device, these remaining fibers can be incised under direct visualization using scissors or a scalpel.

STEP 6

Closing and Dressing the Wound

Use sutures to close the wound completely and dress the closed wound.

FIGURE 5



SmartRelease® Ordering Information

System Components

85014	SmartRelease® Aluminum Handpiece
81025	2.9mm Eyepiece Autoclavable Endoscope
85026	Dilator — Small
85027	Dilator — Medium
85029	Elevator
84061	Dilator— Coequal to Standard Blade Assembly
85061	Dilator— Coequal to Onyx™ Blade Assembly
85040	Instrument Sterilization Tray

Disposable Blades

84040-1	Disposable Standard Blade Assembly (Single Pack)
84040-6	Disposable Standard Blade Assembly (Six Pack)
85050-1	Disposable Onyx™ Blade Assembly (Single Pack)
85050-6	Disposable Onyx™ Blade Assembly (Six Pack)

Parts & Accessories

81151	Endoscope Light Post Adapter, Storz®/Olympus® fitting
81152	Endoscope Light Post Adapter, Wolf®/Dyonics® fitting

Refurbished Endoscopes*

81025A	Refurbished 2.9mm Eyepiece Autoclavable Endoscope
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* Refurbished endoscopes are sold only with a core scope exchange.

1. Schroeder, S. M. Uniportal Endoscopic Gastrocnemius Recession for Treatment of Gastrocnemius Equinus with a Dedicated EGR System with Retractable Blade. *The Journal of Foot and Ankle Surgery*. 2012; 51: 714-719.
2. Pinney, S. J., Sangeorzan, B. J., & Hansen, S. T. Surgical Anatomy of the Gastrocnemius Recession (Strayer Procedure). *Foot & Ankle International*. 2004; 25(4), 247-250.

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