Smith+Nephew

EGR

Endoscopic Gastrocnemius Release System

Surgical Technique

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Note Bena

The following technique is for informational and educational purposes only. It is not intended to serve as medical advice. It is the responsibility of treating physicians to determine and utilize the appropriate products and techniques according to their own clinical judgment for each of their patients. For more information on the EGR System, including its indications for use, contraindications, and product safety information, please refer to the product's label and the Instructions for Use packaged with the product.

System Description

The ENDOSCOPIC GASTROCNEMIUS RELEASE (ECR) System includes a range of instruments for an endoscopic approach to the gastrocnemius aponeurosis recession. The cutting instrument consists of a single-use endoscope attachment for a 4mm 30° rigid endoscope with a working length of either:

- 157mm or longer “EGR 157” or

- 138mm or longer “EGR 138”

The cutting instrument features a retractable blade for cutting the gastrocnemius aponeurosis. Associated instruments include an fascial elevator, a cannula, and a cannula obturator, which are all provided sterile and are disposable.

Features and Benefits

- The unique features of this product include trigger-activated blade articulation and a method for endoscope locking. This product will only require one portal.
- An articulating blade at the distal end of the instrument capable of selective cutting of the muscle fascia.
- A central lumen through which a 4mm endoscope can be passed.
- A stop feature within the central lumen which provides a reference for the proper positioning of the endoscope.
- A window adjacent to the cutting blade that allows the blade and the surrounding tissue to be clearly visualized through the endoscope.
- A locking mechanism which securely grasps the endoscope’s rigid sheath in order to maintain its proper position for optimal viewing.
- A fluid pathway from the proximal end of the endoscope attachment to a location adjacent to the endoscope’s distal tip.

***See package insert for full prescribing information**

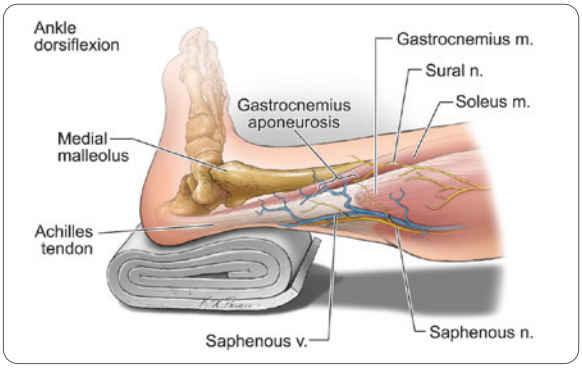


Figure 1-1

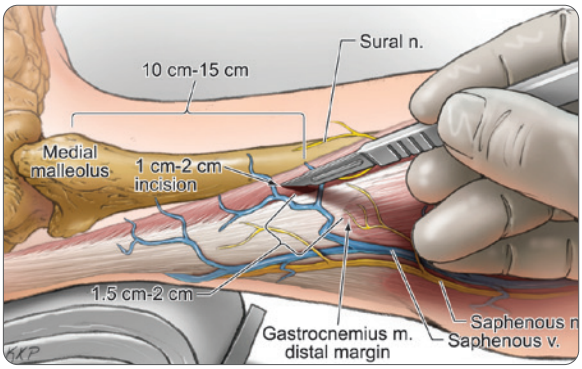


Figure 2-1

Surgical Technique

Step 1 ▪ Positioning the Patient

1-1 The heel may be placed on a sterile bulky towel roll if the patient is supine. This allows the instruments to pass freely. The surgeon must take care, however, to not allow the knee to be in recurvatum when assessing ankle dorsiflexion. Alternatively, as an isolated procedure, the EGR may be performed with the patient in the prone position. General anesthesia is preferred.

Step 2 ▪ Incision

2-1 Palpate the Achilles tendon. Identify a region 10cm–15cm proximal to the medial malleolus where the gastrocnemius aponeurosis is located, at its widest point. This is usually 1.5cm to 2cm distal to the distal most portion of the gastrocnemius muscle belly. Make a 1cm–2cm vertical incision medially, slightly posterior to the medial most portion of the inner ankle/leg.

Use blunt dissection through the subcutaneous tissue, down to the level of the deep fascia.

Make a vertical sharp incision into the deep fascia using a #15 blade (or equivalent). This will expose the gastrocnemius aponeurosis and obvious synovial fluid.

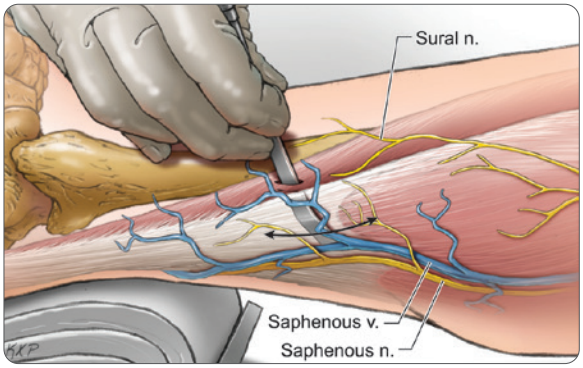


Figure 3-1

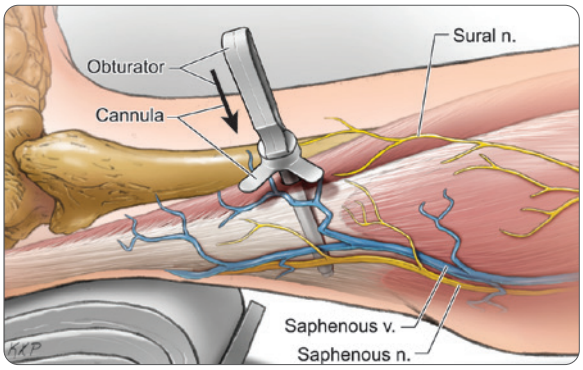


Figure 3-2

Step 3 ▪ Creating the Pathway

3-1 Using the fascial elevator, bluntly separate the deep fascia from the aponeurosis. This will create a layer which protects the neurovascular structures- posterior to the deep fascia, including the saphenous vein, sural nerve and saphenous nerves.

3-2 At this point, with the fascial elevator fully inserted, gently move the elevator proximal and distal to free the aponeurosis from the deep fascia. Insert the obturator into the cannula. Remove the fascial elevator and introduce the cannula/obturator assembly into the same pathway. Remove the obturator from within the cannula and insert a 4mm, 30° endoscope. The neurovascular structures should be completely protected in the correct placement of the cannula.

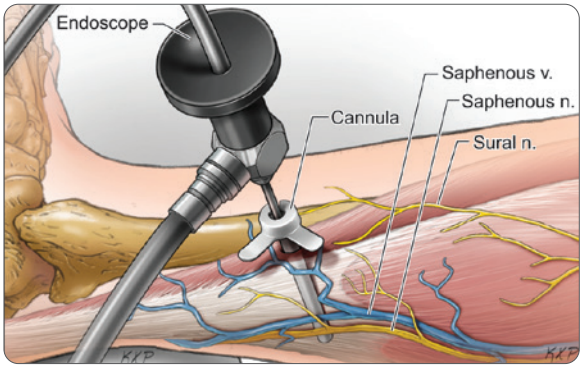


Figure 4-1

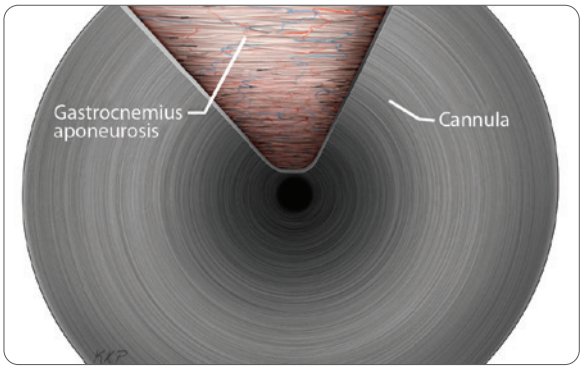


Figure 4-2

Step 4 ▪ Identification of the Gastrocnemius Aponeurosis

4-1 Insert the endoscope into the cannula to visualize the gastrocnemius fascia.

4-2 The aponeurosis is easily visualized: crossing transverse fibers will be noted.

Note: If the device is not in the correct layer of tissue, visualization will be difficult. Also of note, in a patient with lots of adipose tissue visualization can be blurred. Using a syringe with saline on the irrigation port, or cotton tip applicators will aid visualization.

Note: In order to prevent soft tissue obstruction in the blade retraction mechanism, which may result in non-retraction of the device during surgery, it is suggested that a saline connection be introduced into the irrigation port located on the EGR cutting instrument.

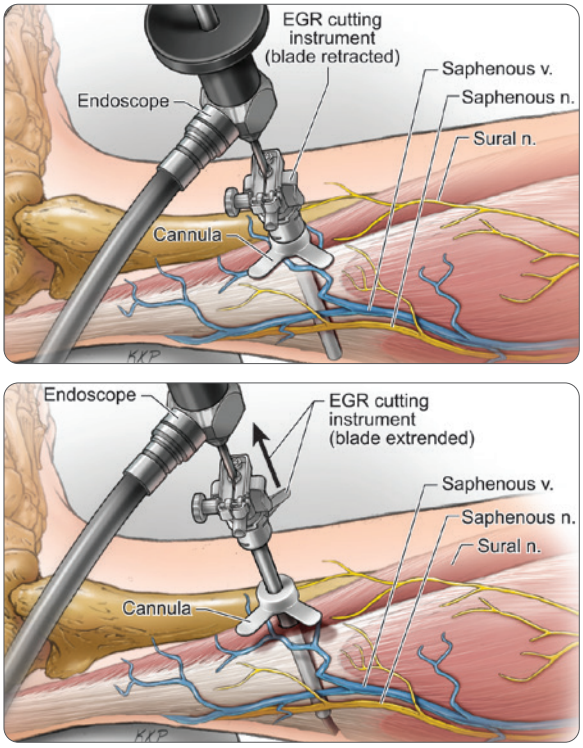


Figure 5-2

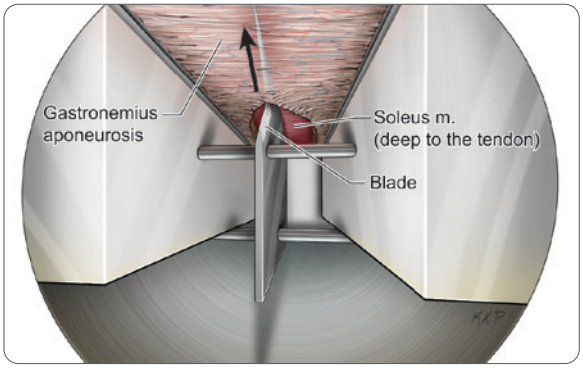


Figure 5-2

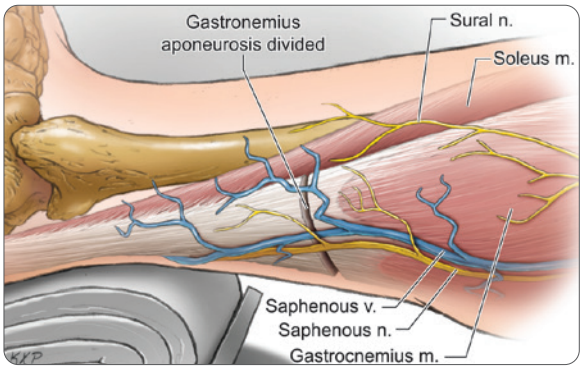


Figure 5-3

Step 5 ▪ Division of Gastrocnemius Aponeurosis

5-1 Temporarily remove the endoscope and insert it through the EGR cutting instrument, locking the two together with the scope clamp. With the blade in the retracted position, introduce the cutting instrument/endoscope assembly into the cannula through the medial port, moving the distal tip of the assembly to the far lateral side of the Gastrocnemius Fascia.

5-2 With the knee fully extended and ankle maximally dorsiflexed creating tension, deploy the blade by rotating the collar and as you observe the monitor, divide the gastrocnemius fascia in a lateral-to-medial direction by withdrawing the instruments through the cannula. Follow the curvature of the gastrocnemius fascia while making your release.

Note: Prior to introducing the EGR cutting instrument/endoscope assembly into the cannula, it is suggested that the retraction handle of the device be manually tested to ensure that deployment/retraction of the blade may be achieved.

Note: The use of excessive intraoperative force on the deployment/retraction handle of the device may result in non-retraction of the blade.

5-3 Keeping dorsiflexion tension while cutting, as well as pushing against the cannula from below, are two technical maneuvers that will increase the depth of the gastrocnemius release, if necessary.

Blade Retracted "0"

Blade Deployed "1"

Warning: Blade assembly is sharp; verify that blade has been retracted before removing.

Essential Product Information

Warnings

- While performing this endoscopic procedure if any problem should arise (such as anatomical anomalies, inadequate visualizations, inability to identify anatomy, or questions concerning technique or instrumentation) the surgeon should abandon the endoscopic gastrocnemius recession and convert to an open procedure.
- Confirm proper cannula placement adjacent to the gastrocnemius fascia prior to employing the EGR instrument. Improper location of recession/incision can lead to tendon damage, possible tendon transection, or neurovascular injury.
- This device was designed to surgically release the gastrocnemius aponeurosis; accordingly, care should be used to avoid cutting muscle ortendon with this instrument.
- Do not use excessive force to place the cannula into the operative pathway.
- Failure to properly release gastrocnemius fascia can lead to under-correction of equinus.

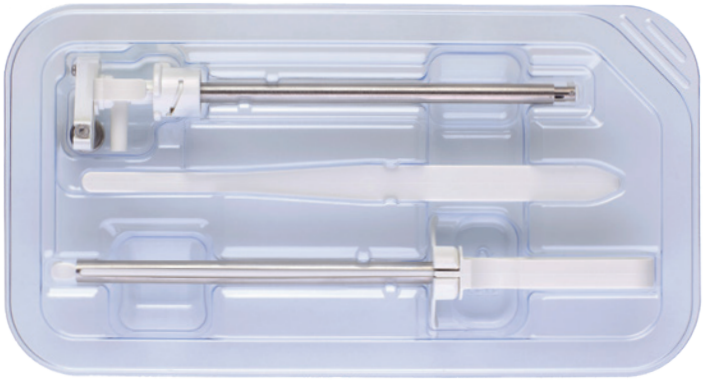
Precautions

For safe and effective use of this system, the surgeon should be familiar with the recommended surgical procedure and the principles of minimally invasive and endoscopic procedures. For a copy of the surgical technique, please contact your local Smith+Nephew Sales Representative/Product Specialist, or visit the S+N website.

ENDOSCOPIC GASTROCNEMIUS RELEASE (EGR) System

Catalog Number	Description
310040	EGR157 Sterile Package Complete*
310138	EGR138 Sterile Package Complete*

* EGR 157 to be used with scopes 157mm or longer
* EGR 138 to be used with scopes 138mm or longer



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