**DESCRIPTION:**
Integra™ Endoscopic Gastroc Release System (EGR) includes a range of instruments for endoscopic approach to the Gastrocnemius Aponeurosis Recession. The cutting instrument consists of a single-use endoscope attachment for a 4mm 30-degree rigid endoscope with a working length of 157mm or longer for “EGR 157” and a 4mm 30-degree rigid endoscope with a working length of 138mm or longer for “EGR 138.” The cutting instrument features a retracting blade for cutting the gastrocnemius aponeurosis. Associated instruments include an elevator, a cannula, and a cannula obturator, which are all consumable instruments provided sterile.

**INDICATIONS:**
Integra™ Endoscopic Gastroc Release System is indicated in the treatment of posterior heel cord contracture (equinus) in those patients who fail to respond to conservative management.

**CONTRAINDICATIONS:**
- Distortion of anatomy
- Previous soft tissue injury at the surgical site
- Active infection at surgical site
- Bone block equinus, tendoachilles equinus.
- Spastic neuromuscular equinus.

**WARNING:**
- 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.
- 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.

**INSTRUCTIONS FOR USE:**
As the manufacturer of this device, Integra LifeSciences Corporation does not practice medicine and does not recommend this or any other technique for use with a specific patient. The physician or surgeon performing the procedure is responsible for determining and using the appropriate technique with each patient.

Use of the device:
Initial Incision: Palpate the Achilles tendon. Identify a region 10 cm–15 cm proximal to the medial malleolus where the gastrocnemius aponeurosis is located, at its widest point. This is usually 1.5 to 2 cm distal to the distal most portion of the gastrocnemius muscle belly. Make a 1 cm–2 cm 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. This will expose the gastro aponeurosis and obvious synovial fluid.

Creating the Pathway: 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. 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 4 mm, 30° endoscope. The neurovascular structures should be completely protected in the correct placement of the cannula.

Identification of the Gastrocnemius Aponeurosis: Insert the endoscope into the cannula to visualize the gastrocnemius fascia. The aponeurosis is easily visualized, crossing transverse fibers will be noted. Note: if not in the correct layer of tissue, visualization will be difficult. Also of note, in a patient with excessive adipose tissue visualization can be blurred. Using a syringe with saline on the irrigation port, or cotton tip applicators will aid visualization.

This equipment was primarily designed to be used in a uniportal manner, but some surgeons prefer a second portal; see below.

Division of Gastrocnemius Fascia: 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 protected 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. The knee should be 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. 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.
Confirming Adequate Release: First retract the blade by reversing the procedure to deploy the blade. This will allow the surgeon to visualize the posterior leg. After full release of the aponeurosis the gastrocnemius muscle tissue will be easily visualized. The surgeon can redeploy the blade to release any additional fibers initially not cut. In most cases, one pass of the blade will be sufficient to release the aponeurosis. Remove the cutting instrument/endo scope assembly from the cannula and reintroduce just the endoscope to visualize the divided aponeurosis. A complete division is accomplished when the underlying muscle is seen without any intervening fibers of the gastrocnemius aponeurosis. The surgeon will be able to feel an obvious release and immediate improvement in dorsiflexion at the ankle level. In many cases, due to the convex nature of the gastroc aponeurosis, the medial most fibers of the aponeurosis and the plantaris fibers will need to be released under direct visualization with a #15 blade, through the medial incision. Additionally, the surgeon may elect to rotate the camera to view the posterior structures to confirm that the neurovascular structures were not injured. Due to the deep fascia the neurovascular structures in most cases will not be able to be seen through the camera.

**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 Integra Sales Representative/Product Specialist, or visit the Integra website.

**PACKAGING AND STERILIZATION:**
Each blade assembly is provided in a sterile package. Prior to use, inspect the integrity of the package for damage that may compromise sterility of the device. Resterilization and subsequent reuse will dull the blades and may result in cross contamination or impaired function of the product. Sharpness of the blades is not guaranteed with repeated use. If damaged, sterility may be compromised and the product should not be used.

**DISPOSAL INSTRUCTIONS:**
Blade assemblies are designed as single-use, disposable products and should not be re-sterilized or re-used. Once used, the entire system should be discarded according to hospital policy.

**PRODUCT INFORMATION DISCLOSURE:**
INTEGRA LIFESCIENCES CORPORATION HAS EXERCISED REASONABLE CARE IN THE SELECTION OF MATERIALS AND THE MANUFACTURE OF THESE PRODUCTS. INTEGRA EXCLUDES ALL WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. INTEGRA SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THE PRODUCT. INTEGRA NEITHER ASSUMES NOR AUTHORIZES ANY PERSON TO ASSUME FOR IT ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS.

**PRODUCT HANDLING:**
Store the packaged sterile blade unopened until use. When removing the blade from its packaging, observe all relevant aseptic instructions.

**MANUFACTURER:**
Integra LifeSciences Corporation
4900 Charlemar Drive, Building A
Cincinnati, OH 45227

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

**SYMBOLS USED ON LABELING:**

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