



PiroVue™
Gastrocnemius Recession System

DESCRIPTION

The Nextremity Solutions, Inc. PiroVue™ Gastroc Recession System is a single-use, sterile-packed instrument set. This instrument set provides the surgeon the needed tools to successfully lengthen and address gastrocnemius equinus through a soft tissue recession, primarily of the gastrocnemius and soleus fascia.

SYSTEM COMPONENTS

PiroVue™ Gastroc Recession System

Recession Blade	Surgical-grade stainless steel and Polyarylamide
Recession Guide	Polyarylamide
Skin Protector	Polycarbonate

CONTRAINDICATIONS

- Blood supply limitations and previous or active infections that may inhibit healing.
- Surgical procedures other than for the described use.
- Patients with conditions that limit their ability or willingness to follow postoperative care instructions.

POTENTIAL ADVERSE EFFECTS

- Infection, deep and superficial.
- Nerve damage due to surgical trauma.
- Inadequate healing.
- Decreased muscle strength or atrophy.
- Pain, soft tissue discomfort or abnormal sensation.

PRECAUTIONS

- It is mandatory that the user, surgeon and surgery personnel are acquainted with the respective surgical technique.
- Surgical instruments may only be used for surgeries for which the designated application of the instrument is explicitly necessary and defined.
- The trained expert staff is obligated to examine the instrument and its sterile packaging for damage prior to use. In case of the instrument or its packaging being damaged or deformed, it is not to be used.

WARNINGS

- Cutting edges, blades, tips, etc. can be very sensitive to mishandling. Thus, these instruments must be handled with care.
- Care should be taken to ensure safe handling of the instrument. The system includes an exposed blade that protrudes from the guide when engaged. Review product function prior to use.

- The PiroVue™ Gastroc Release System has not been evaluated for safety and compatibility in the MRI environment. It has not been tested for heating or migration in the MRI environment.

DIRECTIONS FOR USE

Warning: The PiroVue™ Gastroc Release System should only be used with the supplied, dedicated instruments.

1. Carefully remove the guide from the packaging. **Do not** engage the blade with the guide.
2. Place the guide in the desired intra-muscular location between the gastrocnemius and soleus muscle belly.
3. Rotate the guide 90 degrees to create a gap to visualize the fascia. Visualize that the guide is in the correct location, that the cutting slit is in the correct location, and that the lateral muscle belly is hooked by the guide. Reposition if necessary.
4. Hold guide in place while manipulating knee and foot flexion to desired position.
5. **Ensure fingers are clear of the cutting slit.** Hold the guide in position by the handle to maintain hand position away from blade.
6. Adjust position of skin protector as necessary to protect skin and soft tissues.
7. With foot and knee positioned to tension the tissue, introduce blade assembly into the rear of the guide. Take care to orient the cutting surface of the blade toward the cutting slit in the guide.
8. Advance the blade assembly until the blade assembly handle terminates at the rear of the guide or until the desired recession is achieved.
9. Rotate guide 90 degrees and remove guide and blade assembly simultaneously from the incision.
10. Visualize to ensure recession of fascia is adequate.

See the PiroVue™ Surgical Technique for complete illustrated information.

CAUTION: Do not reuse any portion of the device.

HOW SUPPLIED

PiroVue™ Gastroc Release System is available as a sterile surgical kit(s). The components of the PiroVue™ Gastroc Release System are for single use only. **DO NOT RE-STERILIZE. DO NOT REUSE.** If product is reused it may cause infection and may compromise the mechanical integrity of the product, which may lead to failure.

STORAGE AND HANDLING

Store in a cool, dry place and in a manner that protects the integrity of the packaging of all implants and instruments.

PACKAGING AND LABELING

1. Nextremity Solutions devices should be accepted only if the factory packaging and labeling arrive intact.
2. Contact Customer Service if the package has been opened or altered.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Nextremity Solutions® and PiroVue™ are trademarks of Nextremity Solutions, Inc. These products are covered by one or more U.S. and international patents pending. All rights reserved. Printed in the USA



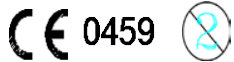
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