GRIPLASTY™

PATIENT INFORMATION LEAFLET

Griplasty™ System - Base of Thumb

Griplasty™ System - Micro, Mini and Small Suture Anchor

mythumbpain.us

GRIPLASTY™

This Patient Information Leaflet provides information about an implant that your surgeon has recommended for you and will assist you with discussing it with your surgeon.

GRIPLASTY™

Contents

About Griplasty™

Griplasty™ is a treatment option that may be discussed with patients who are living with thumb pain. It is designed to support the base of the thumb after trapeziectomy and help restore grip and function.

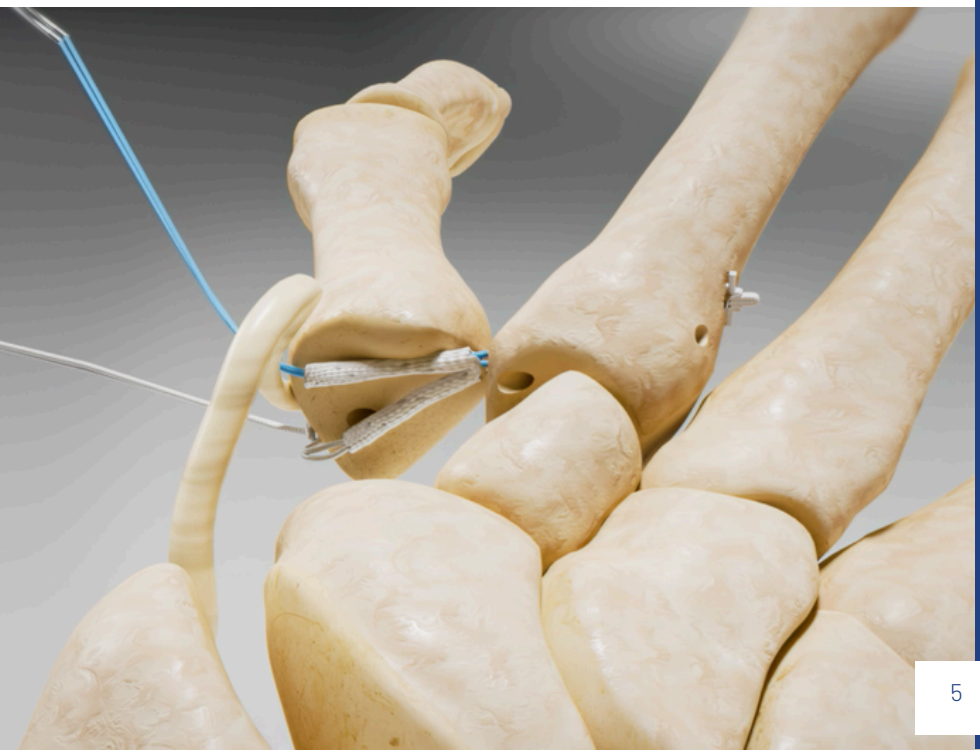
Only a surgeon can determine whether Griplasty™ may be appropriate for you after reviewing your symptoms, medical history, and examination findings.

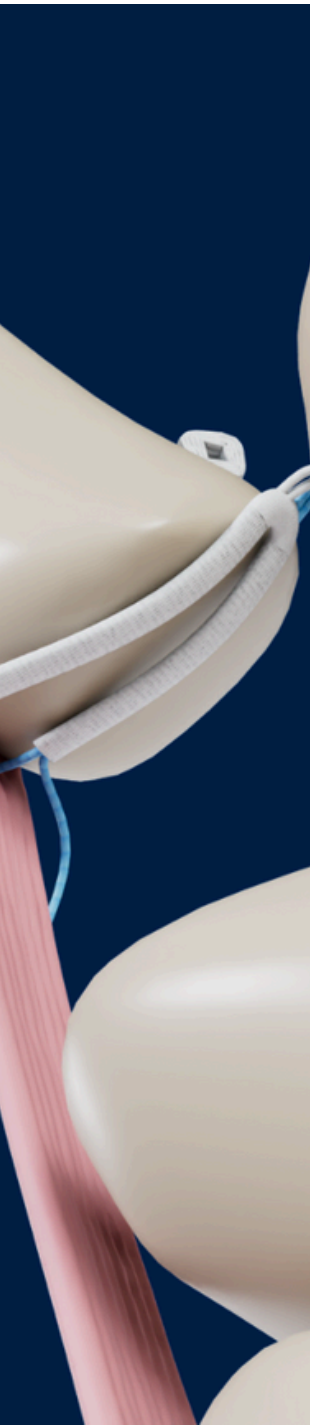
About the device

Griplasty™ suture anchors are intended to be used for suture or tissue fixation in the foot, ankle, knee, hand, wrist, elbow and shoulder. Specific indications are listed below:

Elbow: Biceps tendon reattachment, ulnar or radial collateral ligament reconstruction

Shoulder: Rotator cuff repair, Bankart repair, SLAP lesion repair, Biceps tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.





Hand/Wrist: Scapholunate Ligament Reconstruction, Repair/reconstruction of collateral ligaments, Repair of flexor and extensor tendons at the PIP, DIP and MCP joint for all digits, digital tendon transfers, Carpal ligament reconstruction and carpometacarpal joint arthroplasty (Basal thumb joint arthroplasty)

Foot/Ankle: Lateral stabilization, medial stabilization, achilles tendon repair, metatarsal ligament repair, hallux valgus reconstruction, digital tendon transfers, mid-foot reconstruction

Knee: Medial collateral ligament repair, lateral collateral ligament repair, patellar tendon repair, posterior oblique ligament repair, iliotibial band tenodesis

The device is a permanent implant made from non-absorbable Ultra High Molecular Weight Polyethylene (UHMWPE). The suture dyes may include FD&C Blue 2 (CAS Number: 860-22-0)

The manufacturing process has been validated and is not expected to leave any residuals that could pose a risk to the patient.

When the device should not be used (Contraindications)

Use of the Griplasty™ Suture Anchor implants are contraindicated in the following:

- Cases of inflammation
- Cases of active or suspected sepsis / infection and osteomyelitis
- Patients with certain metabolic diseases

In addition, surgical success can be adversely affected by:

- Acute or chronic infections, local or systemic.
- Vascular, muscular or neurological pathologies that compromise the concerned extremity.

- All concomitant pathologies that could affect the function of the implant.
- Patients with insufficient bone/inadequate bone quantity.
- Osteopathies with reduced bone substance that could affect the function of the implant.
- Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment.
- Patients with foreign body sensitivity or having known allergies that may cause adverse events both peri- and post-operatively.
- Patients with limited blood supply.
- Whenever the instrument or implantation compromises the important anatomical structures.
- The use of this medical device and the placement of hardware or implants must not bridge, disturb or disrupt unfused growth plate.
- Patients with unstable physical and/or mental health conditions.
- Combination of this implant with implants of another origin is contraindicated.

Other medical or surgical pre-conditions that could compromise the potentially beneficial procedure, such as:

1. The presence of tumors.
2. Congenital abnormalities.
3. Immunosuppressive pathologies.
4. Increased sedimentation rates that cannot be explained by other pathologies.
5. Increased leukocyte (WBC) count.
6. Pronounced left shift in the differential leukocyte count.

Warnings, precautions, and risks

In any surgical procedure, the potential for complications and adverse reactions exists. Risks and complications with these implants include:

- Loosening, deformation or failure of the implant.
- Acute post-operative wound infections and late infections with possible sepsis.
- Thrombosis and embolism.
- Wound hematoma and delayed wound healing.
- Temporary and protracted functional neurological perturbation.
- Tissue reactions as the result of allergy or foreign body reaction to dislodged particles.
- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure.
- The device is not intended to endure excessive abnormal functional stresses.
- Surgical procedure and post-operative management may be tailored for a specific patient.

Please discuss any questions you have regarding your surgical procedure or post-operative management with your surgeon.

Postoperative care

The postoperative regimen prescribed by your surgeon should be strictly followed to avoid adverse stresses on the device.

Postoperatively and until healing is complete, fixation provided by this device should be considered as temporary and may not withstand weight bearing or other unsupported stress. The fixation provided by this device should be protected.

Follow-up with your treating physician if you have any unexpected discomfort or concerns.

Magnetic Resonance Imaging (MRI) Safety Information

These devices have not been evaluated for safety and compatibility in the MR environment.

Any concerns should be referred to your treating physician.

About thumb pain

Thumb pain can affect many parts of everyday life. Simple activities such as opening jars, turning keys, gripping objects, preparing meals, using a phone, working with your hands, or enjoying hobbies may start to feel more difficult or uncomfortable.

If thumb pain is beginning to affect your daily routine, learning more about the cause of that pain can be a helpful first step.

Understanding thumb arthritis

Thumb arthritis affects the joint at the base of the thumb. This joint is involved in many everyday hand movements, including pinching, twisting, and gripping.

Over time, wear in this joint can lead to pain, weakness, and difficulty with daily hand use. Thumb arthritis becomes more common with age, and symptoms can vary from person to person.

If you think thumb arthritis may be affecting you, a surgeon can assess your symptoms, examine your thumb, and discuss possible treatment options with you.

Learn more

If you would like to understand more about thumb arthritis and the treatment journey, more information is available on griplasty.com or thumbpain.com.

You can learn more about:

- thumb arthritis and how it may affect daily life.
- possible causes of thumb arthritis pain.
- how thumb arthritis may be assessed.
- patient stories and shared experiences.
- how to find a surgeon near you.

PATIENT STORIES

For some people, it can be helpful to hear from others who have experienced thumb pain themselves.

Griplasty.com includes patient stories from real people sharing how thumb pain affected their everyday lives and why they chose to speak with a surgeon.

These stories are personal experiences. Every patient is different, and each treatment journey is individual.

Griplasty™ may not be suitable for all patients and there are potential risks associated with the procedure. Individual circumstances should be considered and a medical specialist consulted to determine the best treatment options.

FINDING A SURGEON

If you would like to discuss thumb pain and possible treatment options, you can search for a surgeon through the online surgeon finder available on griplasty.com.

A surgeon can help you better understand your symptoms, answer your questions, and explain whether Griplasty™ may be an option for you.

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For more information

Visit: mythumbpain.us

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FIELDORTHOPAEDICS

In Australia, any serious incident related to the device should be reported to the manufacturer (Field Orthopaedics Pty Ltd) and to the Australian Therapeutic Goods Administration (TGA) (tga.gov.au). Any issues related to your Griplasty™ should be reported to your surgeon or your healthcare provider.

For access to this leaflet please visit:

www.mythumbpain.us

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This information contained in this patient information leaflet is not medical advice and is not meant to be a substitute for the advice provided by a surgeon or other qualified medical professional on the use of these products. You should talk with your physician or health care provider for more information about your health condition, and whether Field Orthopaedics products might be appropriate for you. The surgeon who performs any surgical procedure is responsible for determining and using the appropriate techniques for surgical procedures on each individual patient. Field Orthopaedics recommends that surgeons be trained on the use of any particular product before using it in surgery. A surgeon must always rely on their professional medical judgment when deciding whether to use a particular product when treating a particular patient. A surgeon must always refer to the package insert, product label, and/or directions for use before using any Field Orthopaedics product. Products may not be available in all markets because product availability is subject to the regulatory approvals and medical practices in individual markets. Please contact Field Orthopaedics if you have questions about the availability of products in your area.

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