

MISTER TENDON™ HARVESTER

SURGICAL TECHNIQUE GUIDE

Mister Tendon™ Harvester System



Exclusively foot & ankle **20**
Paragon®

Mister Tendon™ Harvester System Overview

Acknowledgment:

Paragon 28® would like to thank Thomas San Giovanni, MD for his contribution to the development of the surgical technique guide.

PRODUCT DESCRIPTION

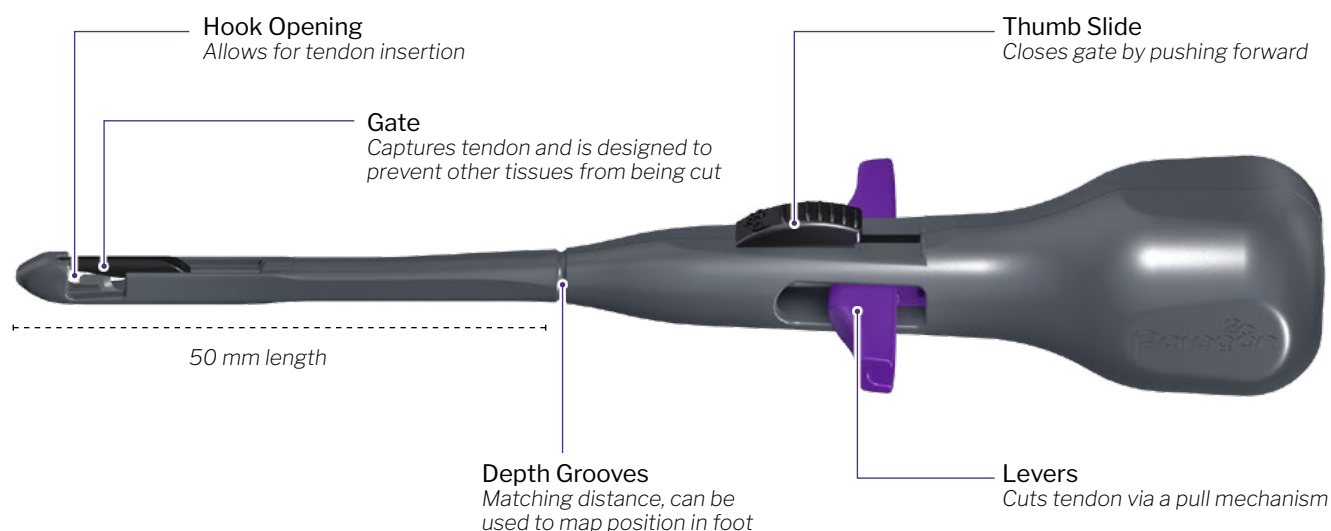
The Paragon 28® Mister Tendon™ Harvester System allows surgeons to perform a distal transection of a tendon via a more proximal incision. As shown within this surgical technique guide, the Flexor Hallucis Longus (FHL) or Flexor Digitorum Longus (FDL) tendon are cut through a minimally invasive incision, harvesting a working length of tendon suitable for tendon transfer procedures. An accessory dilator instrument is provided to help bluntly dissect soft tissue, and is designed to improve harvester access without causing additional damage. The Mister Tendon™ Harvester System is provided sterile-packed and ready for use in tendon transfer procedures.

CONTENTS

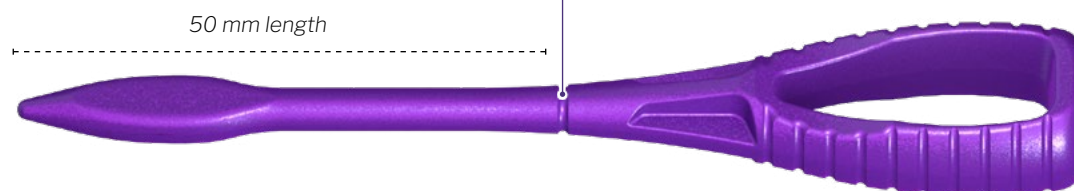
Section 1	MISTER TENDON™ HARVESTER SYSTEM KIT CONTENTS..... 2
Section 2	FDL TENDON HARVEST TECHNIQUE FLEXOR DIGITORUM LONGUS HARVEST TECHNIQUE..... 3-5
Section 3	FHL TENDON HARVEST TECHNIQUE FLEXOR HALLUCIS LONGUS HARVEST TECHNIQUE 6-8
Section 4	CADDY, INDICATIONS, CONTRAINDICATIONS, WARNINGS 9

KIT CONTENTS

Tendon Harvester



Dilator



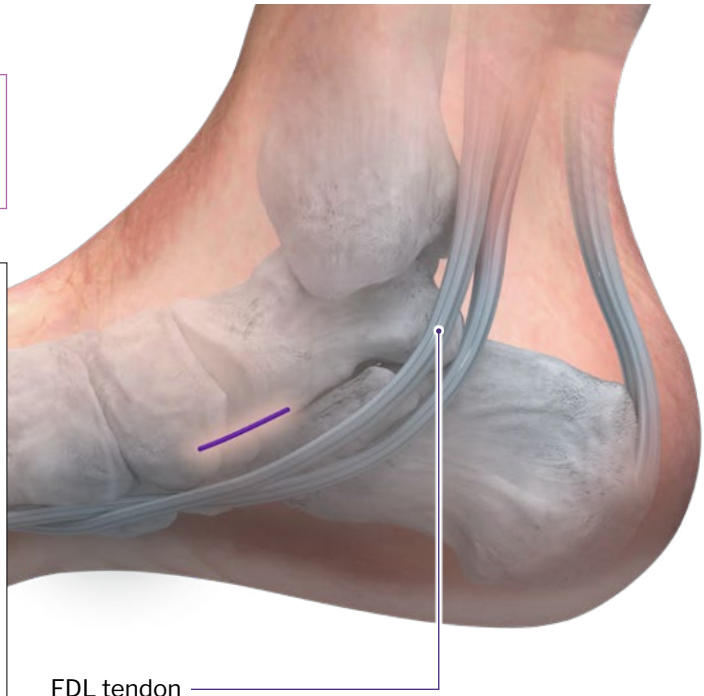
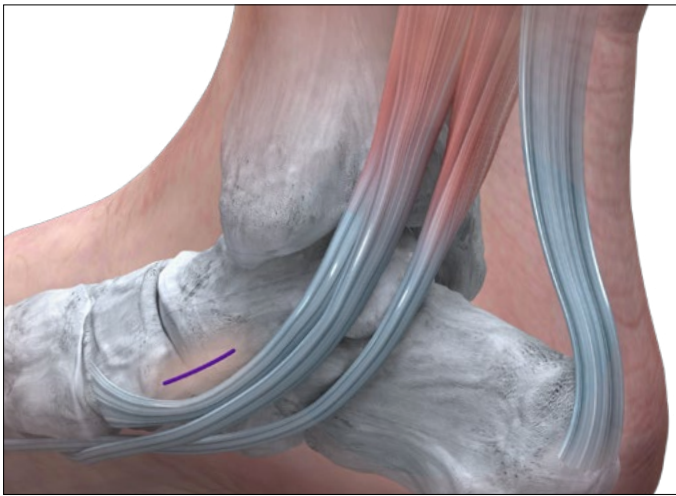
FDL HARVEST

Perform a small (5 mm) incision on the medial aspect of the foot centered over the talonavicular joint.

Perform blunt dissection until the FDL tendon is exposed. Confirm that the exposed tendon is the FDL by gently pulling on it to ensure plantarflexion of the lesser digits.



NOTE: Alternative incisions can be performed per surgeon preference, so long as sufficient access to the tendon is achieved



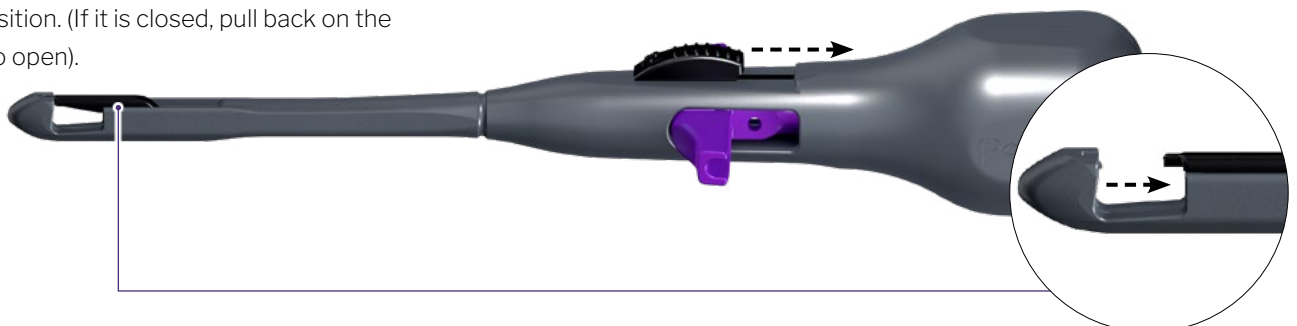
FDL tendon

Insert the Dilator into the incision and push the tip distally through the anatomy, following the path of the FDL tendon until the Knot of Henry is reached. Rotate the Dilator to help open up the space for easier Harvester travel.



Knot of Henry

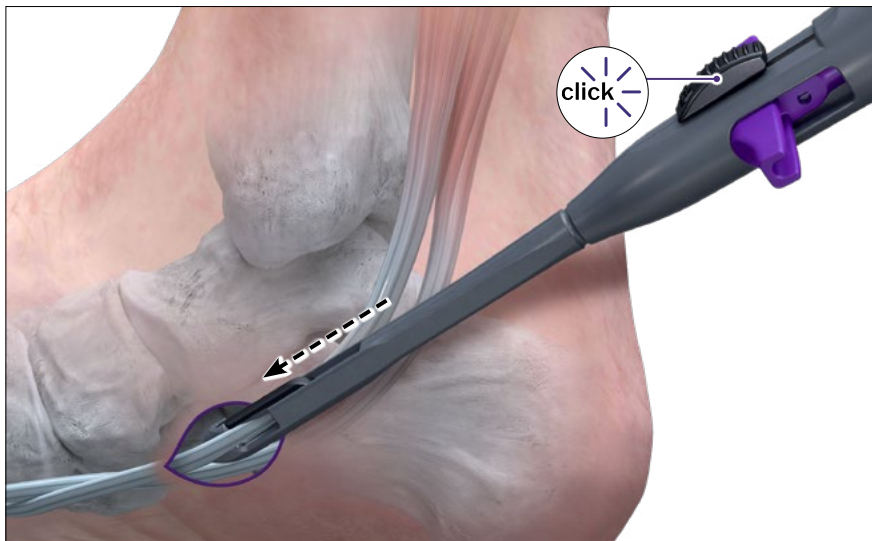
Retrieve the Harvester and ensure that the Gate is in the open position. (If it is closed, pull back on the Thumb Slide to open).



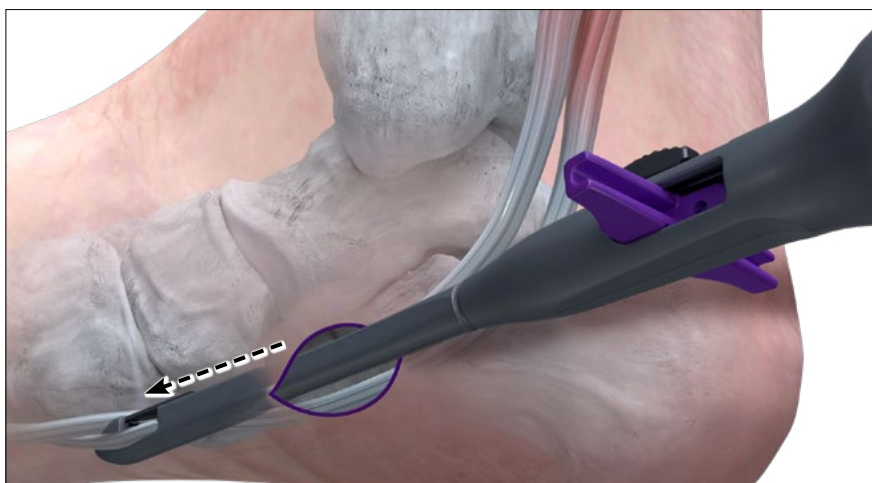
FDL Tendon Harvest Technique

FDL HARVEST

Use the Hook of the Harvester to grab the FDL tendon, then push the Thumb Slide forward until it clicks to close the Gate and capture the tendon.



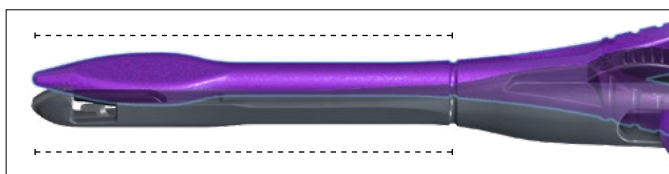
Insert the tip of the Harvester, with the FDL tendon still captured, into the foot through the incision. Push the Harvester tip distally along the anatomy following the path of the captured FDL tendon until the Knot of Henry is reached.



NOTE: If soft tissue resistance is preventing adequate insertion, pull the Harvester back out and use the Dilator to further free up the space as directed previously.



NOTE: The grooves on the Dilator match the grooves on the Harvester with respect to distance from the tip, meaning that the Dilator can be used to map the position of the Harvester within the anatomy.



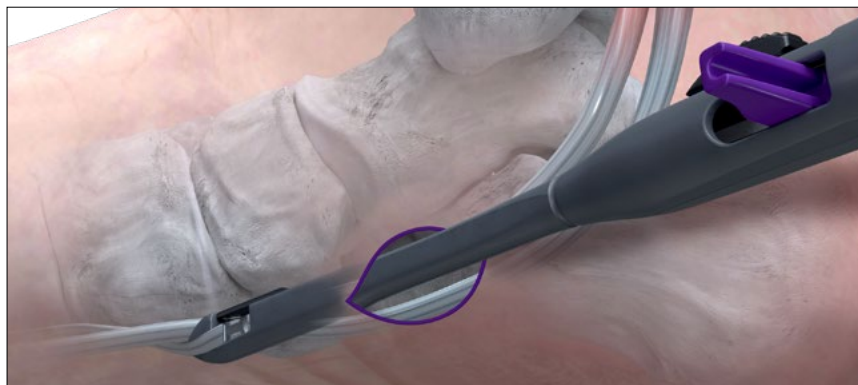
FDL HARVEST

When the Harvester has been inserted to a depth to allow for an appropriate length of tendon harvest, pull back on the Levers using index and middle fingers until the tendon has been severed.



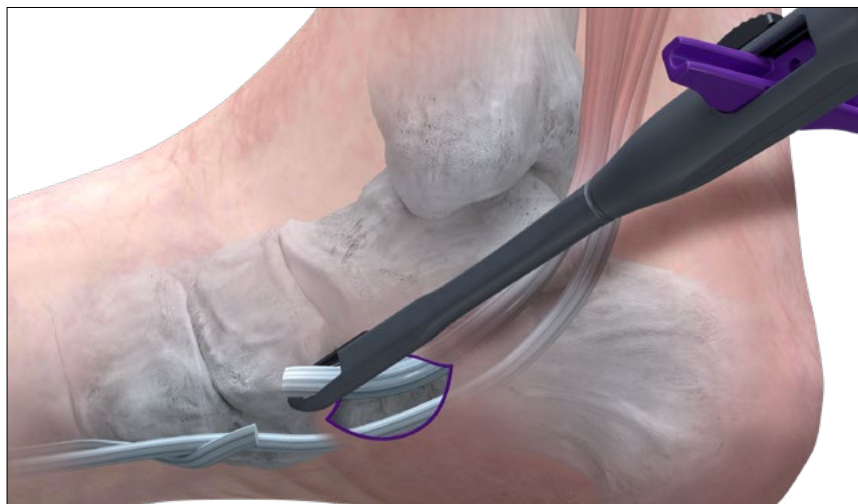
NOTE: The blade comes secured into place to prevent cutting before desired. You will feel an initial release when freeing the blade which also helps gather speed for a clean cut.

TIP: Rotating the harvester handle 90° prior to cutting adds tension for clean cut.



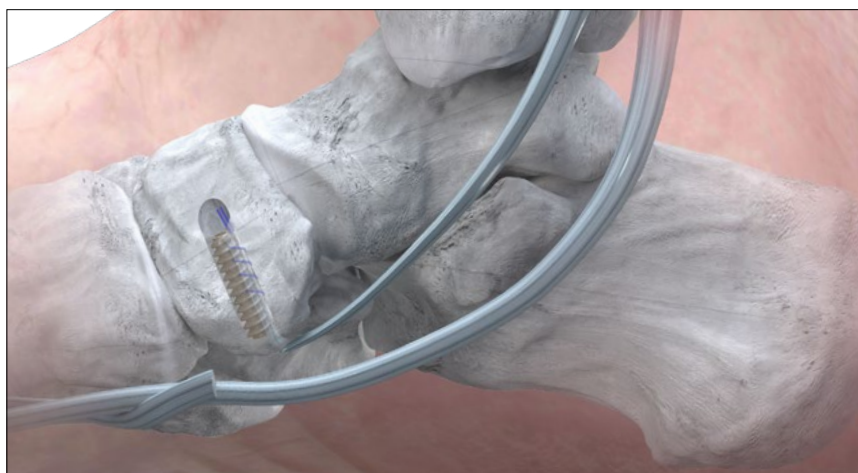
Upon achieving a successful cut, the Harvester will be able to be removed from the anatomy freely. If the tendon is still uncut and captured, ensure that the tendon is not twisted and that there is no impeding soft tissue caught within the Hook before reinserting and attempting the cut again.

If the tendon does not come free automatically when removing the Harvester from the foot, use forceps to pull the tendon from the incision until the cut end is exposed. Proceed to the FDL transfer procedure of choice.



Shown: Complete FDL transfer using the Paragon 28 Grappler® Interference Screw System

NOTE: For final placement of the Grappler Interference Screw please refer to the Grappler® Interference Screw System Surgical Technique Guide - P41-STG-0001

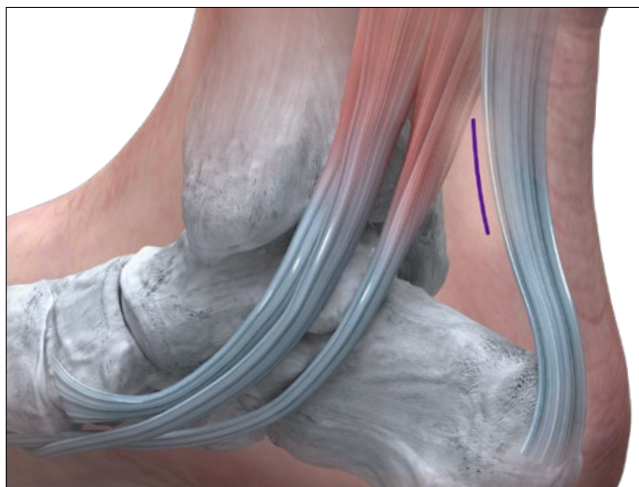


FHL Tendon harvest Technique

FHL HARVEST

Perform a small 5 mm incision on the posterior aspect of the foot, just medial to the Achilles tendon.

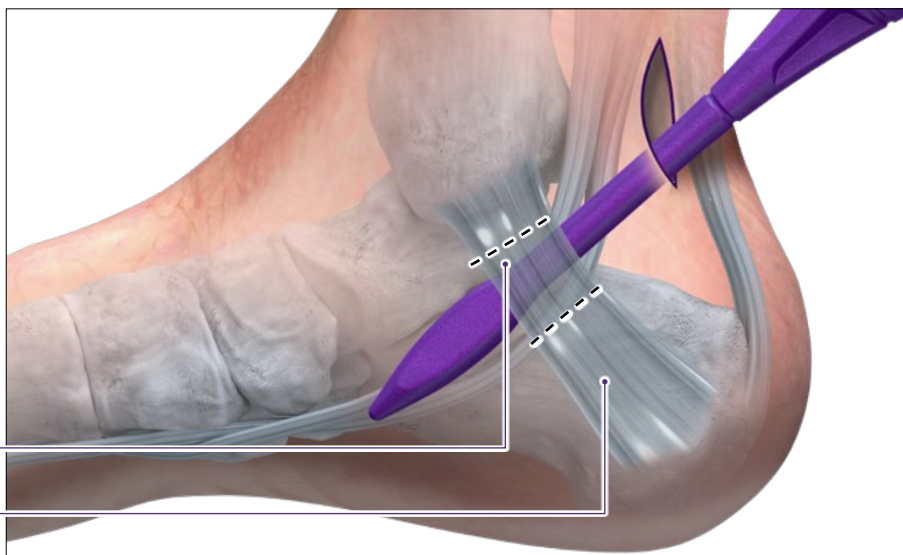
Carefully release the soft tissue until the FHL tendon is exposed. Confirm that the exposed tendon is the FHL by gently pulling on it, which should cause the tip of the hallux to plantarflex.



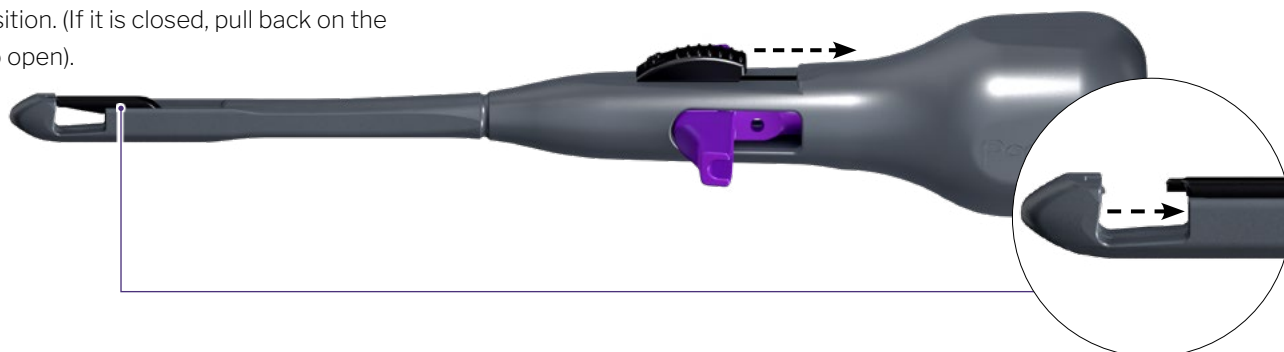
Insert the Dilator into the incision and push the tip distally through the anatomy, following the path of the FHL tendon until the desired depth is reached. Rotate the Dilator to help open up the space for easier Harvester travel.



NOTE: Additional force may be required when passing the Dilator through the tarsal tunnel.

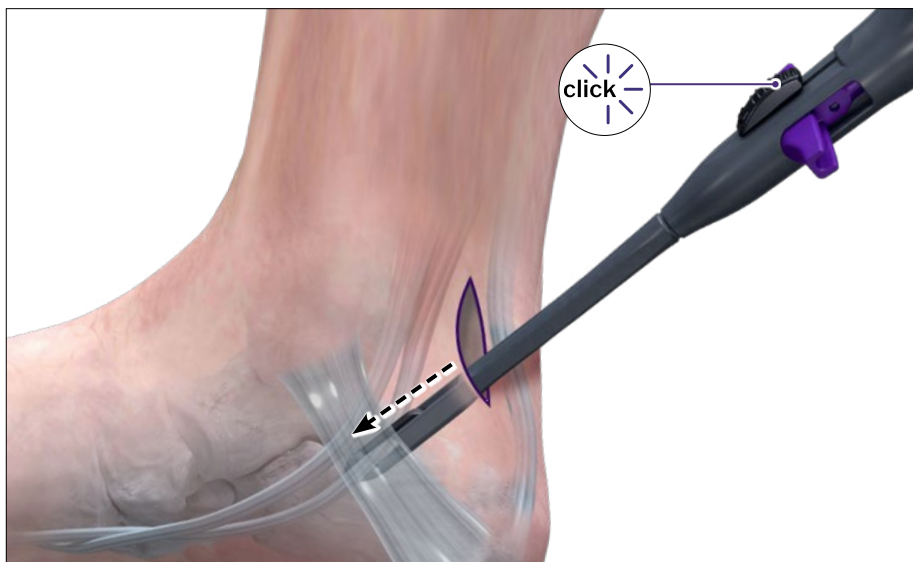


Retrieve the Harvester and ensure that the Gate is in the open position. (If it is closed, pull back on the Thumb Slide to open).



FHL HARVEST

Use the Hook of the Harvester to grab the FHL tendon, then push the Thumb Slide forward until it clicks to capture the tendon.



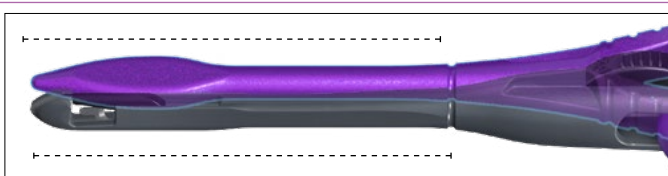
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FHL Tendon harvest Technique

FHL HARVEST

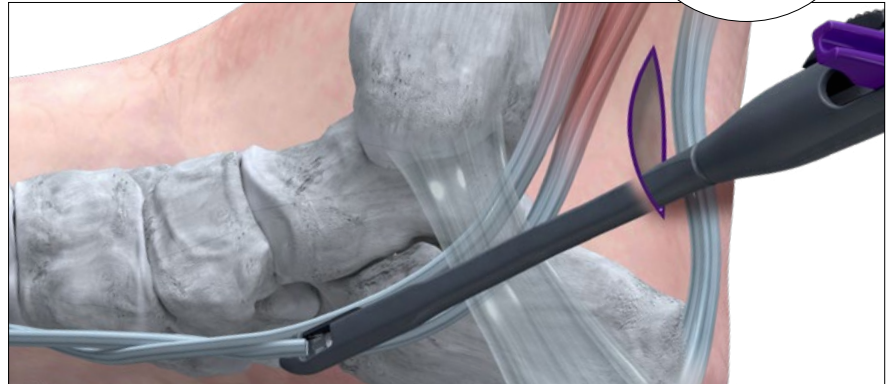
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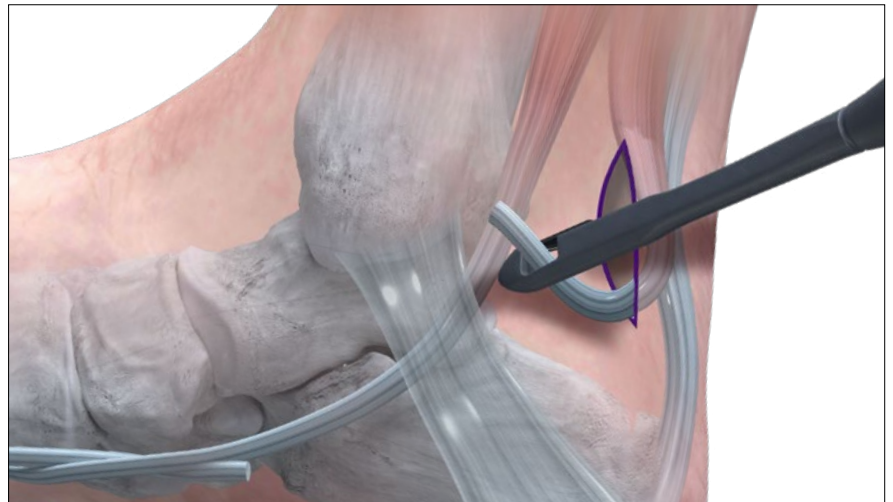
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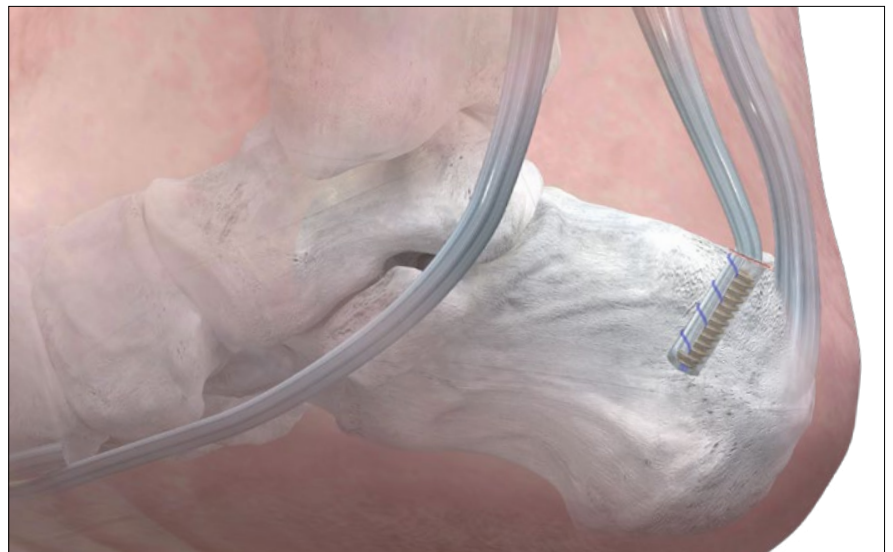
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NOTE: For final placement of the Grappler Interference Screw please refer to the Grappler® Interference Screw System Surgical Technique Guide - P41-STG-0001

STERILE PACKED CADDY LAYOUT

All Mister Tendon Harvester System components are sterile-packed and single-use only.



INDICATIONS, CONTRAINDICATIONS, AND WARNINGS

Refer to www.paragon28.com/ifus for the complete and most current instructions for use document.

INDICATIONS FOR USE

The Paragon 28® Mister Tendon Harvester is intended for general orthopedic surgery.

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications and adverse reactions exist. The risks and complications with general orthopedic surgical procedures include:

- Acute post-operative infections and late infections with possible sepsis
- Thrombosis and embolism
- Wound hematoma and delayed wound healing
- Temporary and protracted functional neurological perturbation
- Increased chance of risk for patients with:
 - Active, suspected or latent infection in the affected area
 - Patients who are physiologically or psychologically inadequate
 - Patients where there is a possibility for conservative treatment

All possible complications listed here are not typical of Paragon 28®, Inc. products but are in principle observed with any surgical procedure. Promptly inform Paragon 28®, Inc. as soon as complications occur in connection with the surgical instruments used. The surgeon is held liable for complications associated with inadequate asepsis, incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behavior.

WARNINGS AND PRECAUTIONS

- The instruments are intended for single use only.
- Instruments are to be treated as sharps.
- **Do not use other manufacturer's implants in conjunction with the Mister Tendon Harvester.**
- **Do not resterilize the Mister Tendon Harvester Instruments.**

NOTES:

MISTER TENDON™ HARVESTER

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Exclusively foot & ankle ²⁸
Paragon®

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DISCLAIMER

The purpose of the Mister Tendon™ Harvester System Surgical Technique Guide is to demonstrate the optionality and functionality of the Mister Tendon™ Harvester implants and instrumentation. Although variations in placement and use of the Mister Tendon™ Harvester System implants can be performed, the fixation options demonstrated in this technique were chosen to demonstrate the functionality of the system and for simplicity of explanation. Other uses for the Mister Tendon™ Harvester System can be employed, appropriate for the size of the device.

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