



## Mister Tendon™ Harvester

**BEFORE USING PRODUCT, READ THE FOLLOWING IMPORTANT INFORMATION A FULL SYMBOLS GLOSSARY CAN BE FOUND AT: [www.paragon28.com/resources](http://www.paragon28.com/resources)**

**Please check the website, [www.paragon28.com/ifus](http://www.paragon28.com/ifus), for the most current instructions for use document.**

This booklet is designed to assist in using the Mister Tendon Harvester. It is not a reference for surgical techniques.

### CAUTION

Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician.

### GENERAL DESCRIPTION

The Mister Tendon Harvester is a sterile, single use instrument. It is a handheld device with a shaft that enters an incision to harvest a tendon such as the flexor hallucis longus (FHL) or flexor digitorum longus (FDL). The Mister Tendon Harvester is provided in a sterile kit alongside a dilator to bluntly dissect soft tissue attachments prior to inserting the Tendon Harvester.

### INSTRUMENT MATERIALS

The instrumentation of the Mister Tendon Harvester is manufactured from medical grades of stainless steel and ABS.

### INTENDED 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.**

### MAINTAINING DEVICE EFFECTIVENESS

- The surgeon should have specific training, experience, and thorough familiarity with the use of Mister Tendon Harvester
- Carefully inspect the instruments prior to use to assure they are in proper operational condition. Instruments which are faulty, damaged or suspect should not be used.
- Paragon 28®, Inc. recommends the use of Paragon 28®, Inc.

products in a sterile environment.

### HANDLING AND STERILIZATION

#### ***Sterile Product:***

Paragon 28® Mister Tendon Harvester instruments are provided sterile using Ethylene Oxide. Do not re-sterilize. SINGLE USE ONLY. The risk of re-use of device includes potential for patient to develop infection. Do not use instruments after expiration date. Packages for instruments should be intact upon receipt.

Instruments in sterile packaging should be inspected to ensure that the package has not been damaged or previously opened. If the inner package integrity has been compromised, DO NOT USE THE INSTRUMENT. Contact the manufacturer for further instructions. The instruments should be opened using aseptic technique. The instrument should only be opened after the correct size has been determined. Once the seal of the product is broken, the product should not be re-sterilized.

All instruments should be stored in a clean, dry environment.

### INSTRUCTIONS FOR USE

Only surgeons who are fully experienced in the use of such instruments and the required specialized surgical techniques should use the Paragon 28® Mister Tendon Harvester. Refer to the Mister Tendon Harvester Surgical Technique P68-STG-0001 for complete instructions for use. For product information or to obtain a copy of the surgical technique manual, please contact Paragon 28®, Inc. by phone, (855) 786-2828.

### PRODUCT COMPLAINTS

The customer or health care provider should report any dissatisfaction with the product quality, labeling, or performance to Paragon 28®, Inc. immediately. Paragon 28®, Inc. should be notified immediately of any product malfunction by telephone or written correspondence. When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint.

**Please contact company for product inquiries, cleaning instructions and surgical techniques, or to report any adverse event.**



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