MAVEN™ Patient Specific Instrumentation System

BEFORE USING PRODUCT, READ THE FOLLOWING IMPORTANT INFORMATION

A FULL SYMBOLS GLOSSARY CAN BE FOUND AT: www.paragon28.com/resources

Please check the website, www.paragon28.com/ifus, for the most current instructions for use document.

This booklet is designed to assist in using the MAVEN™ Patient Specific Instrumentation (PSI) System. 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 Paragon 28® MAVEN™ Patient Specific Instrumentation (PSI) system is intended to assist a surgeon with pre-operative planning and transfer of the pre-operative plan to the surgery in total ankle replacement procedures. The system contains several physical and digital outputs including patient-specific anatomical models and guides (physical outputs); and a patient-specific case report (digital or documentation output).

The MAVEN™ PSI System is for use with the APEX 3D™ Total Ankle Replacement System. The contraindications, complications, adverse reactions, warnings and precautions of the APEX 3D™ Total Ankle Replacement System should be considered when using the MAVEN™ PSI System. The APEX 3D™ Total Ankle Replacement System Instructions for Use P10-IFU-0001 can be found at www.paragon28.com/ifus.

MATERIALS

The MAVEN™ PSI guides are manufactured with Nylon.

INDICATIONS FOR USE

The MAVEN™ Patient-Specific Instrumentation System is intended to be used as patient specific surgical instrumentation to assist in the positioning of total ankle replacement components intraoperatively and in guiding the marking of bone before cutting. The MAVEN™ Patient- Specific Instrumentation System is intended for use with the Paragon 28® APEX 3D™ Total Ankle Replacement System and its cleared indications for use, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging CT scans. The MAVEN™ Patient-Specific Instrumentation System is intended for single use only. The Paragon 28® TAR Patient- Specific Case Reports are intended for use with the Paragon 28® APEX 3D™ Total Ankle Replacement System and its cleared indications for use, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging CT scans.

CONTRAINDICATIONS

All applications of the MAVEN™ PSI System that are not defined by the indications are contraindicated. In addition, surgical success can be adversely affected by:

- Patients with significant changes to anatomy occurring after the medical scan used for product definition was obtained. Surgery should occur no later than one year after the patient scans.

WARNINGS AND PRECAUTIONS

- To avoid potentially serious allergic reactions, ensure that the patient is not allergic to the materials used in the guides prior to use.
- To avoid serious injury, patient identification on guides and reports must be verified and confirmed against patient identification prior to use.
- Device(s) are single use only and designed for use with a specific patient only. All unused devices must be destroyed upon the conclusion of the case for which the devices were designed.
- Guides are designed for a specific patient. To avoid the potential for serious injury, guides should not be modified in any way.
- Do not attempt a surgical procedure with faulty, damaged or suspect instruments or case reports. Inspect all components preoperatively to assure utility. Inspect holes to ensure no debris is present.
- MAVEN™ PSI guides are shipped in a non-sterilized state. To avoid possibility of infection, open, clean and sterilize per provided instructions before use.
- These instruments are created based on patient-specific data which may be subject to change at varying rates depending on the patient condition. It is up to the medical provider to determine if the patient's condition or anatomy may have changed sufficiently to require redesign of the device.
- The surgeon is held liable for complications associated with incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behavior.
- Do not to drop or contaminate the device during surgery.
- Improper placement, positioning, and fixation of the instruments may result in unusual stress conditions and a subsequent reduction in service life of the total ankle replacement components.
- **Do not use other manufacturer's instruments or implants in conjunction with the MAVEN™ PSI System.**

HANDLING AND STERILIZATION

Paragon 28®, Inc. packaging is intended to protect instrumentation during shipping. Health care personnel bear the ultimate responsibility for ensuring that any packaging method or material, including a reusable rigid container system, is validated for use in sterilization processing and sterility maintenance in a particular health care facility. Testing should be conducted in the health care facility to assure that conditions essential to sterilization can be achieved. Paragon 28®, Inc. does not accept responsibility or liability arising from a lack of sterility of any medical devices supplied by Paragon 28®, Inc. that should have been sterilized by the end user.

The MAVEN™ PSI guides are supplied non-sterile and should be cleaned using the following validated cleaning method:

1. Prepare neutral pH enzymatic detergent solution following the manufacturer's recommendation.
2. Fully immerse the device in to the prepared detergent and allow the device to soak for 5 minutes.
3. While immersed, use a soft bristle brush to brush this device, paying particular attention to crevices and other hard to reach areas.
4. Use a syringe to flush the holes or lumens and any difficult to reach areas.
5. Rinse the device under running reverse osmosis – deionized water (RO/DI) at ambient temperature.
6. While rinsing, use a syringe to flush the holes and difficult to reach areas.
7. Wipe dry with sterilized lint free cloth or wipes.

Following cleaning, the instruments MUST be sterilized prior to use. Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. The use of an FDA cleared sterilization wrap is recommended. Adhering to the validated steam autoclave cycle is recommended:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-vacuum	270°F (132°C)	4 Minutes	30 Minutes

A 30-minute cool down for DuraForm ProX PA guides is recommended.

Product is intended for use immediately after sterilization only. Do Not Unwrap until ready for use. The presence of any moisture on the wrap should be visually monitored. If any moisture is observed after 60 minutes, then the cycle is not considered sterile. The surgical instruments must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.

INSTRUCTIONS FOR USE

Only surgeons who are fully experienced in the use of such devices and the required specialized surgical techniques should utilize the Paragon 28® MAVEN™ PSI System. Refer to the MAVEN™ PSI Surgical Technique P10-STG-0002 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. In the event of premature failure of an instrument in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide Paragon 28®, Inc. with the instruments in a cleaned, disinfected and sterile condition.

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

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