Monster® Screw 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 Monster® Screw 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 Monster® Screw System is comprised of screws and washers used for bone fixation. The Monster® Screw is a threaded bone screw which is offered in diameters ranging from 2.0mm to 7.2mm with lengths of 8mm (for smaller diameters) thru 200mm (for larger diameters). Screw washers are also available in four different configurations; flat, dome, split-flat and bowl. Available screws, washers and instrumentation are packaged as a single system. The system instruments include guide wires, guide wire guide, drill bits, drill guides, tissue protectors, depth gauges, countersinks, bone taps, screwdriver shafts, driver handles, small bone distractor & cleaning stylet. These instruments are used to facilitate the placement of the screws.

Not all products are available for sale in all markets. To determine availability in your marketplace, please contact your local Paragon 28 representative.

Implant Materials
All Monster® screws and washers are made from Titanium Alloy (ASTM F136). The instrumentation is made from medical grades of stainless steel, silicone, anodized aluminum and nitinol.

Indications
The Monster® Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation of the foot and ankle, including the tibia, fibula, tarsus, metatarsals, and phalanges and the joints and ligaments coupling said bones, appropriate for the size of the device.

Contraindications
Use of the Monster® Screw System is contraindicated in cases of inflammation, cases of active or suspected sepsis / infection and osteomyelitis; or in patients with certain metabolic diseases.

All applications that are not defined by the indications are contraindicated. 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
- 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
- Known or suspected sensitivity to metal
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur
- Whenever the use of the implant comes into conflict with the anatomical structures of physiological status

Other medical or surgical pre-conditions that could compromise the potentially beneficial procedure, such as:
- The presence of tumors
- Congenital abnormalities
- Immunosuppressive pathologies
- Increased sedimentation rates that cannot be explained by other pathologies
- Increased leukocyte (WBC) count
- Pronounced left shift in the differential leukocyte count

Potential Complications and Adverse Reactions
In any surgical procedure, the potential for complications and adverse reactions exist. The risks and complications with these implants include:
- Loosening, deformation or fracture of the implant
- Acute post-operative wound infections and late infections with possible sepsis
- Migration, subluxation of the implant with resulting reduction in range of movement
- Fractures resulting from unilateral joint loading
- 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
- Corrosion with localized tissue reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone loss due to stress shielding

All possible complications listed here are not typical of Paragon 28®, Inc. products but are in principle observed with any implant. Promptly inform Paragon 28® as soon as complications occur in connection with the implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide Paragon 28® with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28® cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of the osseous implant bed in the case of implants, incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behavior.

Warnings and Precautions
- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Use of an undersized screw in areas of high functional stresses may lead to implant fracture and failure.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants and guide wires are intended for single use only. Re-use may cause product failure and could lead to disease transmission.
- Instruments, guide wires and screws are to be treated as sharps.
- **Do not use other manufacturer's instruments or implants in conjunction with the Monster® Screw System.**

MR Safety Information

MRI Safety Information

A patient with the Paragon 28 Monster Screw System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/Identification of device	**Paragon 28 Monster Screw System**	
Nominal value(s) of Static Magnetic Field [T]	**1.5 T or 3 T**	
Maximum Spatial Field Gradient [T/m and gauss/cm]	**30 T/m (3000 gauss/cm)**	
RF Excitation	**Circularly Polarized (CP)**	
RF Transmit Coil Type	**Body Coil: See scan limitations below. Local Coils: No restrictions on local transmit-receive coils that the device is not within.**	
Operating Mode	**Normal Operating Mode**	
Maximum Head SAR [W/kg]	**3.2 W/kg (Normal Operating Mode)**	
Maximum Whole Body SAR [W/kg]	**See details below**	
Anatomy at Isocenter	**Any anatomical scanning region**	**Anatomy superior to the hips**
Limits on Scan Duration	**1.5 T MRI Systems B_1+RMS ≤ 4.00 µT for 60 minutes of continuous RF* or Whole body average SAR ≤ 0.5 W/kg for 60 minutes of continuous RF***	**1.5 T MRI Systems B_1+RMS ≤ 4.50 µT for 60 minutes of continuous RF* or Whole body average SAR ≤ 2.0 W/kg for 60 minutes of continuous RF***
	3 T MRI Systems B_1+RMS ≤ 1.50 µT for 60 minutes of continuous RF* or Whole body average SAR ≤ 0.3 W/kg for 60 minutes of continuous RF*	**3 T MRI Systems B_1+RMS ≤ 2.00 µT for 60 minutes of continuous RF* or Whole body average SAR ≤ 2.0 W/kg for 60 minutes of continuous RF**
MR Image Artifact	**The presence of this implant may produce an image artifact of 20 mm.**	

If information about a specific parameter is not included, there are no conditions associated with that parameter.

Maintaining Device Effectiveness
- The surgeon should have specific training, experience, and thorough familiarity with the use of screws.
- The surgeon must exercise reasonable judgment when deciding which screw type to use for specific indications.
- The Monster® Screws are not intended to endure excessive abnormal functional stresses.
- The Monster® Screws are intended for temporary fixation only until osteogenesis occurs.
- Failure to use dedicated, unique Monster® Screw System instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
- Carefully inspect the screws prior to use, inspect the instruments before and after each procedure 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.

Cleaning and Decontamination
All implants and instruments must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Compliance is required with the manufacturer's user instructions and recommendations for chemical detergents. Refer to the Paragon 28® Monster® Screw System - Instrument Reprocessing Instructions for Reusable Instruments document P20-CLN-0001. This is also available by calling (+1) (855) 786-2828.

Sterilization

Unless specifically labeled sterile, the implants and instruments are supplied NONSTERILE and MUST be sterilized prior to use. Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. Prior to sterilization, verify that all instruments are in their open and unlocked position within the instrument tray(s). The use of an FDA cleared sterilization wrap, such as the KimGuard® Sterilization Wrap, is recommended. The following validated steam autoclave cycle is recommended:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-Vacuum	270°F (132°C)	4 Min.	45 Min.

Instructions For Use

Only surgeons who are fully experienced in the use of such implants and the required specialized surgical techniques should implant the Monster® Screw System. Refer to the Monster® Screw System Surgical Techniques P20-STG-2001 for complete instructions for use. For product information or to obtain a copy of the surgical technique manual, please contact Paragon 28® by phone, (+1) (855) 786-2828.

Screw Removal (If Necessary)

- Locate implant with intra-operative imaging.
- Palpate head of screw and remove surrounding soft tissue to gain maximum exposure.
- Engage screw head with appropriate driver and rotate counterclockwise until screw is removed.
- OPTION: If screw head is stripped, engage proximal shaft of screw under screw head with a medium sized Kern forcep and continue turning driver shaft and Kern forcep counterclockwise while exerting light pressure upwards with the Kern forcep.
- If screw is integrated into bone, core out with appropriately sized trephine drill.

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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