



Megalodon Dynamic Compression 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 Megalodon Dynamic Compression System. It is not a reference for surgical techniques.

GENERAL DESCRIPTION

The Megalodon Dynamic Compression System consists of nickel titanium alloy implants and the instruments necessary for the treatment of pathologies of the foot and ankle. Implant sizes range from 25mm to 30mm.

MATERIALS

The Megalodon implants are manufactured from Nickel Titanium Alloy (Nitinol). The instrumentation is manufactured from implant grade titanium alloy, medical grade polymer and stainless steel.

INTENDED USE/INDICATIONS FOR USE

The Megalodon Dynamic Compression System implants are indicated for use in osteotomy, arthrodesis and fragment fixation of bones and joint of the foot including fixation of small bone fragments (i.e., small fragments of bone which are not comminuted to the extent to preclude staple placement) located in the long bones of the lower extremities such as the fibula and tibia.

CONTRAINDICATIONS

Use of the Megalodon Dynamic Compression System is contraindicated in the following instances:

- Active or suspected infection or osteomyelitis
- Vascular, muscular or neurological pathologies that compromise the concerned extremity
- Poor bone quality, i.e. osteoporotic bone that is susceptible to fracture
- Known or suspected sensitivity to metal or foreign bodies
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur
- Physical conditions that may hinder the healing process
- Conditions that limit the patient's ability or willingness to follow postoperative instructions

- Whenever the use of the implant comes into conflict with the anatomical structures of physiological status

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications and adverse reactions exist. These do not include all adverse effects which can occur with surgery, but are important considerations particular to metallic internal stabilization devices.

- Infection
- Loosening, deformation, migration or fracture of the implant
- Fractures resulting from unilateral joint loading
- 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® products but are in principle observed with any implant and/or surgical instrument. Promptly inform Paragon 28® in the event that 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 product(s) in a clean, disinfected and sterile condition. Paragon 28® cannot accept used implants that that do not meet these criteria. 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 non-compliant patient behavior.

WARNINGS AND PRECAUTIONS

- For safe and effective use of the Megalodon Dynamic Compression System, the surgeon should be familiar with the procedure and devices and must exercise reasonable judgment in use of the device. Improper selection, placement or positioning may result in reduced lifetime of the implant(s).
- 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.
- Do not resterilize the Megalodon Dynamic Compression System implants or instruments. The implants and instruments are intended for single use only.
- Instruments are to be treated as sharps.
- Do not use other manufacturer's instruments or implants in conjunction with the Megalodon Dynamic Compression System. Failure to use the provided, unique Megalodon Dynamic Compression 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 implants, instruments and packaging prior to use

to assure they are in proper operational condition. Instruments which are faulty, damaged or suspect should not be used.

MR SAFETY INFORMATION

The Megalodon Dynamic Compression System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Megalodon Dynamic Compression System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

HANDLING AND STERILIZATION

Sterile Product:

- Paragon 28® Megalodon Dynamic Compression System product provided sterile are sterilized using gamma irradiation.
- Do not re-sterilize. SINGLE USE ONLY.
- The risk of re-use of the device includes potential for patient to develop infection. Do not use devices after expiration date. Packages for product must be intact upon receipt.
- Product 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 DEVICE. Contact the manufacturer for further instructions. The product should be opened using aseptic technique. Once the seal of the product is broken, the product should not be re-sterilized.
- All sterile product should be stored in a clean, dry environment.

DEVICE REMOVAL

- Instrumentation can be provided for device removal.
- Removal instructions are provided in the Megalodon Dynamic Compression System Surgical Technique (P72-STG- 0002).

INSTRUCTIONS FOR USE

Only surgeons who are fully experienced in the use of such implants and the required specialized surgical techniques should implant the Megalodon Dynamic Compression System. Refer to the Megalodon Dynamic Compression System Surgical Technique P72-STG- 0002 for complete instructions for use. For product information or to obtain a copy of the surgical technique manual, please contact Paragon 28® by phone at (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® immediately. Paragon 28® 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 Paragon 28® for product inquiries, cleaning instructions and surgical techniques, or to report any adverse event.

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



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