



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 Primal OCD System devices. It is not a reference for surgical techniques.

GENERAL DESCRIPTION

Primal OCD System devices are sterile single use. The instruments within the sterile kits are devices that are used to assist in the preparation and implantation of the Primal OCD System implants. The instruments will be delivered to the field within packaged sterile kits that correspond to the implant sizes. The stainless-steel K-Wire device within the 4.0mm sterile kit may be used as an implant for stability of the HCT/P plug.

MATERIALS

The Primal OCD System kits contain instruments that are manufactured from stainless steel and ABS polymer as well as a stainless-steel K-Wire that is to be used as an implant.

INTENDED USE/INDICATIONS FOR USE

The Paragon 28® Primal OCD System device kits are intended for 1st MTP OCD surgeries.

The implantable K-wires are indicated for use in the stabilization and fixation of small bones for use in bone reconstruction, osteotomy, arthrodesis, fracture repair and fixation.

CONTRAINDICATIONS

The Primal OCD Device System is contraindicated for use in patients with an active or suspected infection; in patients who are physiologically or psychologically inadequate; in patients previously sensitized to stainless-steel; in patients with insufficient quantity or quality of bone to permit stabilization of the bony segments; in patients with high level of activity; or where there is a possibility for conservative treatment.

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, migration, subluxation, fracture of the device, or premature loss of fixation with the bone which may result in nerve and soft tissue damage
- Acute post-operative wound infections and late infections with possible sepsis and osteomyelitis.
- Thrombosis or embolism
- Tissue necrosis, 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® 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

- **Do not reuse single use devices.** The instruments and K-Wire implant are intended for single use only. Reuse of single-use devices may lead to reduced biomechanical properties and/or fatigue breakage of the devices.
- Do not modify implants or instruments unless specified within the surgical technique manual.
- Do not implant instruments.
- 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.
- K-Wires are to be treated as sharps.
- **Do not use other manufacturer's instruments or implants in conjunction with the Primal OCD System.**

MR SAFETY INFORMATION

The Primal OCD 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 Primal OCD 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.

Instructions for Use

Primal OCD System Devices

MAINTANING DEVICE EFFECTIVENESS

- The product is intended for use by Healthcare Professionals only. The surgeon should have specific training, experience, and thorough familiarity with the device.
- The surgeon must exercise reasonable judgment when deciding to use the device.
- Avoid surface damage if implanting the stainless-steel K-Wire device.
- Surgeons must instruct the patients to report any unusual changes of the operated site to their physician. Surgeon should immediately evaluate the patient if a change at the surgical site has been detected. The surgeon should evaluate the possibility of subsequent clinical failure and discuss with the patient the need for reduced activity levels, and / or possible revision surgery in order to aid bone healing.
- The surgeon should discuss all physical and psychological limitations inherent in the use of external fracture fixation appliances with the patient. Particular attention should be given to premature weight bearing, activity levels and the necessity for periodic medical follow-up.
- If the patient's activity comprises significant impact loads (lifting or heavy muscular activity) the resulting forces could lead to failure of the fixation, the system or both. The system will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.
- The Primal OCD System K-Wire implant is intended for temporary fixation only until osteogenesis occurs.
- Paragon 28® Inc. recommends the use of Paragon 28® Inc. products in a sterile environment.

HANDLING AND STERILIZATION

Sterile Product:

- Paragon 28® Primal OCD System devices 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

- For the implantable stainless-steel K-Wire device removal, instrumentation within the operating room may be used. To free up the implant, a rongeur may be used to expose the end of the implant and a

needle driver may be used to remove it from the bone.

INSTRUCTIONS FOR USE

Only surgeons who are fully experienced in the use of such implants and the required specialized surgical techniques should implant the Primal OCD System. Refer to the system surgical technique 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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