Instructions for Use for Custom-Made Devices

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.

DESCRIPTION

Custom-made devices are those that are manufacturing in accordance with the prescription of a health care professional to be used solely by the prescribed user to treat the prescribed patient. These devices are intended for patients with conditions that, in the professional's opinion, cannot be satisfactorily treated using commercially available devices. The custom-made device is intended to provide the most effective treatment for the patient by meeting their unique needs.

Paragon 28 custom-made devices are composed of various materials including cobalt-chrome, titanium, titanium with titanium nitride coating and Nylon. Custom-made devices are provided clean, but NON-STERILE. Non-sterile products MUST undergo a sterilization process by the health care provider in order to render the device STERILE prior to implantation.

INDICATIONS FOR USE

Custom-made devices are created or modified in order to comply with the order of an individual physician. It is intended for use by an individual patient named in such order of a physician. The indications are determined by the Surgeon.

CONTRAINDICATIONS

Custom-made devices should not be used in patients other than those listed in the product labeling and/or the physician prescription. The contraindications are determined by the Surgeon.

WARNINGS

- Improper selection, placement, positioning, alignment and fixation of custom-made devices may result in unusual stress conditions and a subsequent reduction in the service life of the device.
- Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear. Inspect the devices prior to use. Do not use damaged or deformed devices.
- Putting dissimilar metals and alloys in contact with each other can accelerate the corrosion process that may enhance fracture of implants. Every effort should be made to use compatible metals and alloys when marrying them to a common goal, i.e., screws and plates.
- Internal fixation devices aid the surgeon in the alignment and stabilization of skeletal fractures and provide a means of fracture management in reconstructive surgical applications. While these devices are generally successful in attaining these goals, they cannot be expected to replace normal healthy bone or withstand the stress placed upon the device by full or partial weight bearing or load bearing, particularly in the presence of nonunion, delayed union, or incomplete healing. Metallic bone fixation devices are internal splints that align the fracture until normal healing occurs.
- The size and shape of bones and soft tissue place limitations on the size and strength of implants. If there is delayed union or nonunion of bone in the presence of weight bearing, or load bearing, the implant could eventually break. Therefore, it is important that immobilization (use of external support, walking aids, braces, etc.) of the fracture site be maintained until firm bony union (confirmed by clinical and radiographic examination) is established.
- If an implant remains implanted after complete healing, the implant may cause stress shielding, which may increase the risk of, refracture in an active patient. The surgeon should weigh the risks verses benefits when deciding whether to remove the implant after healing is complete.
- Accepted practices should be followed meticulously in postoperative care. Excessive, unusual and/or awkward movement and/or activity, trauma, excessive weight, obesity and noncompliance due to psychological conditions have been implicated in premature failure of certain implants.
- The patient must be cautioned to govern activities, accordingly, protecting the implant from unreasonable stresses. Noncompliance with postoperative instructions could lead to adverse effects.
- The patient must be advised of the limitations and warned that use of the device may involve unknown or unforeseeable risks. Avoid full weight bearing until adequate fixation and healing have occurred.
- Do not modify custom-made devices.
- Do not reuse custom-made devices. Custom-made
- Do not implant the instruments.

Paragon 28, Inc. does not make any claims related to the performance or intended use of the custom-made device. The physician requesting the device is responsible for identifying proper use of the device and for any consequences resulting from its use. It is the physician's responsibility to ensure that the hospital and patient are properly informed of the intent to use a custom-made device to treat the patient's disorder. The physician is required to inform the patient of the risks associated with its use. In particular, the risks associated with the absence of biomechanical and clinical performance data.

PRECAUTIONS

- Custom-made devices are designed from patient data such as radiograph (X-ray), computed tomography (CT), or magnetic resonance imaging (MRI). Over time, a patient's anatomy can change. If a significant amount of time has elapsed from the time of collection of the patient data (date of scan) to the time of surgery, the custom-made device may not fit the patient's anatomy correctly.
- Surgical instruments and implants may only be used for surgeries, for which the designated application of the instrument and implant is explicitly necessary and defined.
- Only and exclusively Paragon 28 specially manufactured instruments and implants (contained in the respective set) are to be used. If using other instruments and implants, function, warranty and liability are omitted.

POSSIBLE ADVERSE EFFECTS

- Peripheral neuropathies have been reported following surgery. Subclinical nerve damage occurs more frequently, possibly as the result of surgical trauma.
- Nonunion or delayed union, which may lead to breakage of the implant.
- Limb shortening due to compression of the fracture or bone resorption.
- Decrease in bone density due to stress shielding.
- Pain, discomfort, or abnormal sensation due to the presence of the device.
- Nerve damage due to surgical or preexisting trauma.
- Necrosis of bone.
- Pain.
- Inadequate healing.
- Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris, manufacturing residuals, and discoloration from metallic and polyethylene components of implants may be present in adjacent tissue or fluid. It has been reported that

debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant. Further, there has been a report regarding an association between articulating surfaces of 1) CoCrMo alloy on CoCrMo alloy, 2) CoCrMo alloy on polyethylene, and 3) Titanium alloy on polyethylene in hip replacements and increased genotoxicity.
- Early or late postoperative infection and/or allergic reaction.
- Dislocation and subluxation of implant components have been reported resulting from improper positioning of implant components. Muscle and fibrous tissue laxity can also contribute to these conditions.
- Implants can loosen or migrate due to trauma or loss of fixation.
- Infection can lead to failure of the implant.
- Bending of implant.
- While rare, fatigue fracture of the implant can occur as a result of strenuous activity, malalignment, or trauma.
- Fracture of bone at the implantation site can occur while press-fitting (seating) the implant component into the prepared site.

MR SAFETY INFORMATION

Custom-made devices have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of this device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

MAINTAINING DEVICE EFFECTIVENESS

- Malalignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure.
- Inadequate preclosure cleaning (removal of surgical debris) can lead to excessive wear.
- It is mandatory that the user, surgeon and surgery personnel are thoroughly acquainted with the implants, instruments, and surgical procedure prior to performing surgery.
- Patient selection factors that should be considered include: 1) need to obtain pain relief and improve function, 2) ability of the patient to follow instructions, and 3) a good nutritional state of the patient.
- Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.
- Adequately instruct the patient. Patients with senility, mental illness, alcoholism, and drug abuse may be at higher risk. The patient is to be instructed in the use of external supports, walking aids, and braces that are intended to immobilize the fracture site and limit weight bearing or load bearing. The patient is to be made fully aware and warned that the device does not replace normal healthy bone, and that the device can break, bend or be damaged as a result of stress, activity, load bearing, or weight bearing.
- The patient is to be advised of the need for regular postoperative follow-up examination as long as the device remains implanted.

HANDLING AND STERILIZATION

Non-sterile Paragon 28® custom-made devices are supplied in a cleaned condition in clean packaging materials. Further cleaning other than sterilization is not required. **Use care in handling a device once the device is removed from the packaging in order to prevent any inadvertent contamination, damage, or otherwise jeopardize the integrity of the device.**

RESPONSIBILITIES OF THE USER

General. Health care personnel bear the ultimate responsibility for ensuring that any packaging method or material is suitable for use in sterilization processing and sterility maintenance. Custom-made devices 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 devices are in their open and disassembled positions within the tray(s). The use of an FDA cleared sterilization wraps or pouches is recommended.

Individual users must validate the steam autoclaving procedures used on-site.

STERILITY

Custom-made devices supplied by Paragon 28 have been cleaned and inspected. Unless otherwise indicated, these devices are NOT STERILE and MUST be sterilized prior to use. Single Use Only. Do Not Reuse. Do not use any component from an opened or damaged package.

Paragon 28 custom-made devices must be steam autoclaved.

Custom-made devices shall be autoclaved using a full cycle. The recommended cycle for steam sterilization that has been validated by Paragon 28 under laboratory conditions is as follow:

- Use a validated, properly maintained and calibrated steam sterilizer following the manufactures recommendations to ensure that the maximum load is not exceeded.
- Effective steam sterilization can be achieved using the following cycles:

Cycle	Temperature	Exposure Time	Dry Time	Cool Time
Pre-vacuum	270°F (132°C)	4 Minutes	45 Minutes	30 Minutes

STORAGE AND SHELF LIFE

Custom-made devices that have been wrapped to maintain sterility should be stored in a constant, well-regulated environment for temperature and humidity. Devices should not be subject to environmental extremes including temperature and moisture. Care must be exercised in the handling of wrapped devices to prevent damage to the sterile barrier. The health care facility should establish a shelf life for wrapped devices based upon the type of sterile wrap used and the recommendations of the sterile wrap manufacturer. The user must be aware that maintenance of sterility is event-related and that the probability of a contaminating event increases over time, with handling, and whether woven or non- woven materials, pouches, or container systems are used as the packaging method.

DISCLAIMER

Paragon 28 has verified through laboratory testing that custom-made devices are suitable for the specific sterilization methods and cycles for which they have been tested.

Health care personnel bear the ultimate responsibility for ensuring that any particular packaging method or material, including a reusable rigid container system, is suitable for use in sterilization processing and sterility maintenance in a particular health care facility. Testing should be conducted in the health care facility to ensure that requirements and conditions essential to sterilization can be achieved.

In the event that health care personnel fail to properly sterilize the device as required, Paragon 28 does not accept responsibility or liability for any damages or otherwise arising from a lack of sterility of an implantable device supplied in a clean but non-sterile condition.

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 the company for product inquiries or to report any adverse event.

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