SPECIALTY / CUSTOM DEVICES

ATTENTION OPERATING SURGEON

DESCRIPTION
SPECIALTY / CUSTOM DEVICES are intended for patients with conditions that, in the surgeon’s opinion, cannot be satisfactorily treated using standard line implants. These patient-matched design characteristics can place limitations on the size and/or strength of the implant and as such may possess unknown or unforeseeable risks.

WARNING: The patient is to be advised of these limitations and warned that use of the device may involve unknown or unforeseeable risks. The surgeon must be familiar with the implant, its design features, method of application, instruments, and surgical procedure prior to performing surgery. In all cases sound orthopedic practices are to be followed, and the surgeon’s selection of the type of device and its design features must be appropriate for treatment.

MATERIALS
SPECIALTY / CUSTOM DEVICES are made from a variety of materials, depending upon patient need and/or implant design specifications. Possible materials used may include:
- Titanium Alloy
- Cobalt Chromium Alloy
- Stainless Steel
- Ultra-high Molecular Weight Polyethylene (UHMWPE)
- ArCoM XL (highly cross-linked UHMWPE)
- E-Poly (highly cross-linked UHMWPE and \( \alpha \)-tocopherol)
- Polyetheretherketone (PEEK)
- Tantalum
- CP Titanium
- Hydroxyapatite
- Polymeric material

INDICATIONS
SPECIALTY/CUSTOM 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.

1. The devices are designed to treat a unique pathology or physiological condition that other commercially available devices cannot meet, or
2. Is not generally available in finished form through regulatory registration, labeling, or marketing for commercial distribution, or
3. Is assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs of an individual patient.

CONTRAINDICATIONS
SPECIALTY/CUSTOM DEVICES should not be used in patients other than those listed in the physician prescription.

WARNINGS
Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions and a subsequent reduction in the service life of the prosthetic implant. 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. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear. Do not modify implants. The surgeon is to be thoroughly familiar with the implant, instruments, and surgical procedure prior to performing surgery. For further information, contact Biomet.

Use clean gloves when handling implants. The Hydroxyapatite coating on the prosthetic device should only be handled while wearing surgical gloves. Laboratory testing indicates that implants subjected to body fluids, surgical debris, or fatty tissue has lower adhesion strength to cement than implants handled with clean gloves.

1. Use Biomet femoral and modular head component with appropriate matching “Type I Taper”, “Type II Taper”, and “12/14 Taper”.
2. Firmly seat modular head components to minimize dissociation. Thoroughly clean and dry taper prior to attachment of the component to minimize crevice corrosion and improper seating.
3. Acetabular screws are to be fully seated to assure stable fixation and to avoid interference with the acetabular liner component.
4. Prior to seating the liner into the shell component, all surgical debris (tissue fragments, etc.) must be removed from the interior of the shell component, as debris may inhibit the locking mechanism from engaging and securing the liner into the shell component.
5. Perforation entirely through the pelvic bone with dome fixation screws or rim screws is to be completely avoided. Caution is to be used when determining and selecting the length of screws to be used, as perforation through the pelvic bone with screws that are too long can damage body structures (blood vessels, etc.) on the interior side of the pelvis.
6. Tight fixation of all non-cemented components at the time of surgery is critical to the success of the procedure. Each component must properly press fit into the host bone which necessitates precise operative technique and the use of specialized instruments. Bone stock of adequate quality must be present and appraised at the time of surgery.
7. Care is to be taken to ensure complete support of all parts of the device embedded in bone cement to minimize stress concentrations, which may lead to failure of the procedure. Complete preclosure cleaning and removal of bone cement debris, metallic debris, and other surgical debris from the implant site is critical to minimize wear of the implant articular surfaces. Implant fracture due to cement failure has been reported.
8. Correct selection of the implant is extremely important. The potential for success in fracture fixation is increased by the selection of the proper type of implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size and strength of implants. Internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal healthy bone. These devices are not designed to withstand the unsupported stress of full weight bearing, or load bearing.
9. The devices can break when subjected to increased loading associated with nonunion or delayed union. Internal fixation devices are load-sharing devices that hold a fracture in alignment until healing occurs. If healing is delayed, or does not occur, the implant can be expected to break, bend or fail. Loads produced by weight bearing, and activity levels may dictate the longevity of the implant.
10. Implant materials are subject to corrosion. Implanting metals and alloys subjects them to constant changing environments of salts, acids, bases and alkalis that can cause corrosion. 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.
11. Correct handling of implants is extremely important. Do not modify implants. Do not notch or bend implants. Notches or scratches put in the implant during the course of surgery may contribute to breakage. Intraoperative fracture of screws can occur if excessive force (torque) is applied while seating bone screws.
12. Implants can loosen, fracture, corrode, migrate, or cause pain. 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 versus benefits when deciding whether to remove the implant after healing is complete. Adequate postoperative management to reduce the risk of refracture should follow implant removal.
13. Adequately instruct the patient. Postoperative care is important. The patient’s ability and willingness to follow instruction is one of the most important aspects of successful fracture management. Patients with senility, mental illness, alcoholism, and drug abuse may be at higher risk. These patients may ignore instructions and activity restrictions. 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 made
aware and warned of general surgical risks, possible adverse effects, in advance and to follow the instructions of the treating physician. The patient is to be advised of the need for regular postoperative follow-up examination as long as the device remains implanted.

14. Uncemented glenoid components should be used only when there is good quality bone and no significant shoulder instability.

15. Disassociation of the humeral head component from the humeral stem component has been reported. Failure to properly align and completely seat the components together can lead to disassociation. Thoroughly clean and dry tapers prior to attachment of modular head component to minimize the risk of crevice corrosion and improper seating.

16. Dislocation of the bipolar shoulder component has been reported. Closed reduction should be attempted with caution to minimize the risk of disassociation of the bipolar component. Do not use excessive force during closed reduction. The bipolar component may impinge against the glenoid component.

Accepted practices should be followed meticulously in postoperative care. The patient must be advised of the limitations of the reconstruction and the need for protection of the implant from full weight bearing until adequate fixation and healing have occurred. Excessive, unusual and/or awkward movement and/or activity, trauma, excessive weight and obesity have been implicated in premature failure of certain implants by contributing to loosening, fracture, dislocation, subluxation and/or wear. The patient is to be cautioned to govern activities accordingly, protecting the replaced joint from unreasonable stresses.

Loosening of the implants can result in increased production of wear particles, as well as accelerate damage to bone, making successful revision surgery more difficult. The patient is to be made aware and warned of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician, including follow-up visits. The patient is to be warned that the device does not replace normal healthy bone, and that the implant cannot be expected to withstand the activity levels of normal healthy bone, and that the implant can break or be damaged as a result of strenuous activity or trauma.

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.

Do not reuse implants. While an implant may appear undamaged, previous stress may create imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been, even momentarily, placed in a different patient. SPECIALTY / CUSTOM DEVICES are designed specifically for a named patient and must not be used to treat any other patient.

Device is single use only. After use, the device may be a potential biohazard. Reuse of devices labeled for single-use may result in product contamination, patient infection and/or failure of the device to perform as intended.

Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.

PRECAUTIONS
SPECIALTY / CUSTOM 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 utilizing a SPECIALTY / CUSTOM DEVICES, the implant may not fit the patient’s anatomy correctly.

Specialized instruments are designed for SPECIALTY / CUSTOM DEVICES to aid in the accurate implantation of the prosthetic components. The use of instruments or implant components from other systems can result in inaccurate fit, incorrect sizing, excessive wear and device failure. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments that have experienced extensive use or excessive force are susceptible to fracture. Surgical instruments should be used only for their intended purpose. Biomet recommends that all instruments be regularly inspected for wear and disfigurement, prior to surgery.

All trial, packaging, and instrument components must be removed prior to closing the surgical site. Do not implant.

POSSIBLE ADVERSE EFFECTS
1. Peripheral neuropathies have been reported following total joint surgery. Subclinical nerve damage occurs more frequently, possibly as the result of surgical trauma.
2. Nonunion or delayed union, which may lead to breakage of the implant.
3. Limb shortening due to compression of the fracture or bone resorption.
4. Decrease in bone density due to stress shielding.
5. Pain, discomfort, or abnormal sensation due to the presence of the device.
6. Nerve damage due to surgical or preexisting trauma.
7. Necrosis of bone.
9. Inadequate healing.
10. Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
11. Loosening or migration of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption or excessive activity.
12. Periarticular calcification or ossification, with or without impediment of joint mobility.
13. Inadequate range of motion due to improper selection or positioning of components.
15. Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity can also contribute to these conditions.
16. Fatigue fracture of component can occur as a result of loss of fixation strenuous activity, malalignment, trauma, non-union, or excessive weight.
17. Wear and/or deformation of articulating surfaces.
18. Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing, or inadequate reattachment.
19. Problems of the knee or ankle of the affected limb or contralateral limb aggravated by leg length discrepancy, too much femoral medialization or muscled deficiencies.
20. 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 and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear 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. This report, however, did not assess either the clinical relevance of the data or make any definite conclusions as to which metal ions or interactions between metal ions or particulate metals might be responsible for the observed data. The report further cautioned that an association does not necessarily mean a causal relationship, and that any potentially increased risk associated with metal ions needs to be balanced against the benefits resulting from hip replacement.

21. Early or late postoperative infection and/or allergic reaction.
22. 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.
23. Implants can loosen or migrate due to trauma or loss of fixation.
24. Infection can lead to failure of the joint replacement.
25. While rare, fatigue fracture of the implant can occur as a result of strenuous activity, malalignment, or trauma.
26. Fracture of bone at the implantation site can occur while press-fitting (seating) the implant component into the prepared site.

Intraoperative and early postoperative complications can include: 1) bone perforation or fracture, 2) bone fracture can occur while seating the device, 3) damage to blood vessels, 4) temporary or permanent nerve damage resulting in pain or numbness of the affected limb, 5) undesirable shortening of the limb, 6) traumatic arthroplasty of other limb joints from intraoperative positioning of the extremity, 7) cardiovascular disorders including thrombosis, pulmonary embolism or heart attack, 8) hematoma, 9) delayed wound healing, and/or 10) infection.
Late postoperative complications can include: 1) bone fracture due to trauma or excessive loading, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, or bone resorption, 2) periarticular calcification or ossification, with or without impediment to joint mobility, 3) loosening or migration due to malalignment of the components or loss of fixation, and/or 4) bone resorption which may contribute to deteriorating fixation and loosening.

MRI INFORMATION
Biomet Specialty / Custom Devices have not been evaluated for safety and compatibility in the MR environment. The devices have not been tested for heating or migration in the MR environment. The risks associated with a passive implant in an MR environment have been evaluated and are known to include heating, migration, and image artifacts at or near the implant site.

STERILITY
Single Use Only. Do not Reuse. Do not resterilize. Do not use any component from an opened or damaged package. Do not use implants after expiration date.

Gamma Radiation
Prosthetic components are sterilized by exposure to a minimum of 25 kGy of gamma radiation. Metallic components may be resterilized using appropriate procedures for autoclaving. Do not resterilize UHMW polyethylene components.

Gas Plasma
ArComXL components are sterilized by exposure to gas plasma.

Ethylene Oxide Gas (ETO)
Prosthetic components are sterilized by Ethylene Oxide Gas (ETO).

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

Comments regarding this device can be directed to Attn: Regulatory Dept., Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax 574-372-3968.

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CE Mark on the package insert (IFU) is not valid unless there is a CE Mark on the product (description) label.