Max-Ti® Modular Protrusio Cage

A Versatile Solution to Complex Acetabular Reconstruction

The Max-Ti® Modular Protrusio Cage is the only press-fit cage on the market offering the trialing capabilities of a standard modular shell and the versatility of flange augments. Unlike most other protrusio cages, which are typically 2mm thick, the Max-Ti® Cage features a robust 4mm thick cage to maximize strength while still maintaining flexibility.

PPS® Porous Plasma Spray Coated Titanium Construct

- Manufactured from forged, commercially pure titanium for strength, flexibility, and biocompatibility
- Shell and augments are PPS® Porous Plasma Spray coated for initial stability and long-term fixation

Superior Stability

- Screw holes are positioned anatomically and evenly spaced for intraoperative flexibility
- Antero-inferior screw holes allow for fixation into the pubic bone
- Augmentable iliac flanges secure the cage to the ilium
- An ischial flange aids in stability and allows for internal or external placement

Iliac Flange Augments

- Flat and wedge augment configurations provide intraoperative flexibility to attain a secure fit to the best available bone
- Flat flange augments add 6mm of thickness
- Wedge augments can be rotated to adjust to the patient's available bone
- Intelligently designed to allow for two 6.5mm screws
- PPS® Porous Plasma Spray coated

Patent Pending Trialing System

- Trialing system allows for optimal poly positioning before cement is applied
- No cage system on the market offers this technology
Augmentable Iliac Flange

Fully Coated with PPS® Porous Plasma Spray

Antero-Inferior Screw Holes

PPS® Porous Plasma Spray Coated Iliac Flange Augments
**Step 1**

Remove existing acetabular component(s) using contemporary techniques, conserving as much bone as possible. Once the component is removed, careful evaluation of the acetabulum is suggested, with close attention to the integrity of the anterior/posterior columns and the medial wall. Any osteolytic cysts should be curetted and irrigated.

**Step 2**

Inspect the remaining host bone to ascertain columnar defects, rim defects, and defects of the acetabular wall and available host bone. This will assist in determining augment styles that may be required to firmly seat the implant on the host bone.

**Step 3**

The acetabulum should be prepared with acetabular reamers, while maintaining as anatomic a position as possible. Ream only the amount of bone necessary to create an adequate hemispherical cavity for support of an acetabular shell, while maintaining the integrity of both columns and the medial wall.

*Note: Under-ream by 1 mm.*

<table>
<thead>
<tr>
<th>Cage Size</th>
<th>Captured Liner Trial Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>52mm</td>
<td>44mm</td>
</tr>
<tr>
<td>56mm</td>
<td>48mm</td>
</tr>
<tr>
<td>60mm</td>
<td>52mm</td>
</tr>
<tr>
<td>64mm</td>
<td>56mm</td>
</tr>
<tr>
<td>68mm</td>
<td>60mm</td>
</tr>
<tr>
<td>72mm</td>
<td>64mm</td>
</tr>
</tbody>
</table>

**Step 7**

When satisfied with the attainment of proper cage fit and fill, use the hex driver to attach the appropriate captured liner trial to the cage (Figure 7A). Perform a temporary joint reduction in order to verify that the cage construct is appropriately placed. Mark the face of the cage to note position of the final cemented all-poly cup. Remove the captured trial construct from the cage.

**Step 8**

Before implantation of the components, morselized bone graft or DBM may be placed into acetabular defects. If needed, insert the appropriately sized reamer and perform reverse reaming to seat the graft material; repeat until a neoacetabulum is formed.
Use of Flange Augments

Step 6
Flange augment implants are also available to help bridge flat or angled gaps and provide structural support between the posterior iliac flange and ilium. Augment trials are available to assess need and determine choice and rotational position of the optimal augment implant. Bending of the posterior iliac flange may be performed with or without the augment trial in place as described on the following page. If utilized, the augment is attached by securely installing the two screws provided in diagonally opposed holes, thus leaving two additional screw holes available for fixation to bone with 6.5mm bone screws.

Step 4
Check the ischial flange to determine whether it should lay on top of the ischium or be driven into the bone. **If it is determined to lay the flange over top of the ischial bone, go on to Step 5.**

If it is determined that placing the ischial flange inside the bone is optimal, then place a mark on the entry point into the ischium. This is where the ischial blade punch is placed and carefully impacted to create an opening for the flange.

Step 5
If needed, some bending of the flanges can be performed to optimize fit and fixation. While attempting to achieve best fit, bending should be kept to a minimum in order to prevent structural damage to or fracture of the flanges. Refer to the instructions on how to use bending tools on the following page. **If a flange augment is required go to step 6, if not proceed to step 7.**

Step 9
Now, the Max-Ti® cage and augment may be placed into the acetabulum. If required, the ischial flange is driven into the ischium first, followed by the cage. Care should be taken to ensure that the cage and all augment are seated securely against available host bone. Check for proper lateral opening (abduction) and anteversion at this time. The cage construct should be fully stable.

Step 10
If desired, 6.5mm acetabular screws may be placed into any available hole in the dome and/or ischial and iliac flanges. **Note: Care should be taken to avoid nerves and blood vessels running behind the acetabulum.**

Step 11
Note the previous mark made on the cage to assist in placement of the polyethylene cup. Now, cement a polyethylene cup into the Max-Ti® cage, taking care to ensure proper lateral opening (abduction) and anteversion.
The Max-Ti™ bending system provides an easy and precise method for matching this implant to the patient’s anatomy. First, snap the appropriately sized bending hub onto the hub handle. Then, screw the base cage trial/implant onto the hub handle assembly. Now adjust the lever position by turning the handle counterclockwise (to loosen) and then clockwise to tighten into place. Finally, use the appropriate bending tool to grasp the cage, and use the hub handle for additional leverage in bending the cage flanges.

Ischial Flange Bender
(#124091)
The ischial flange bender has a jaw ideally suited for bending this flange. Position the jaws so that the nose grips the flange approximately 1–2mm below the screw hole in the base of the flange. This permits stable bending and allows for proper placement of screws.

Iliac Flange Bender
(#124094)
The iliac flange bender is intended for bending the un-augmented iliac flanges. Position the jaws so that each peg seats into the cage screw holes. Tighten and carefully bend to the desired position.
Flat Augment Iliac Flange Bender (#124095)
The flat augment iliac flange bender is intended for bending iliac flanges augmented with the flat augment. Position the jaws so that the screw heads seat into the holes of the jaw. Tighten and carefully bend to the desired position.

Wedge Augment Iliac Flange Bender (#124096)
The wedge augment iliac flange bender is intended for bending iliac flanges augmented with the wedge augment. Position the jaws so that the rotating head mirrors the augment orientation and the screw heads seat into the holes of the jaw. Tighten and carefully bend to the desired position.
## Ordering Information

### Instruments

<table>
<thead>
<tr>
<th>Max-Ti&lt;sup&gt;®&lt;/sup&gt; Captured Liner Trials</th>
<th>Ball and Spike</th>
<th>Wedge Augment Bending Tool</th>
</tr>
</thead>
<tbody>
<tr>
<td>31-104391 28x44</td>
<td>124090</td>
<td>124096</td>
</tr>
<tr>
<td>31-105849 28x48</td>
<td></td>
<td></td>
</tr>
<tr>
<td>31-105852 28x52</td>
<td></td>
<td>124190</td>
</tr>
<tr>
<td>31-105856 28x56</td>
<td></td>
<td>52mm</td>
</tr>
<tr>
<td>31-105859 28x60</td>
<td></td>
<td>124191</td>
</tr>
<tr>
<td>31-104397 28x64</td>
<td></td>
<td>56mm</td>
</tr>
<tr>
<td>31-104392 32x48</td>
<td>124091</td>
<td>124192</td>
</tr>
<tr>
<td>31-104393 32x52</td>
<td></td>
<td>60mm</td>
</tr>
<tr>
<td>31-104394 32x56</td>
<td>124093</td>
<td>124193</td>
</tr>
<tr>
<td>31-104395 32x60</td>
<td></td>
<td>64mm</td>
</tr>
<tr>
<td>31-104396 32x64</td>
<td>124094</td>
<td>124194</td>
</tr>
<tr>
<td>Freedom&lt;sup&gt;®&lt;/sup&gt; All-Poly Cup Trials</td>
<td></td>
<td>68mm</td>
</tr>
<tr>
<td>31-107123 52mm</td>
<td>124095</td>
<td>124195</td>
</tr>
<tr>
<td>31-107125 56mm</td>
<td></td>
<td>72mm</td>
</tr>
<tr>
<td>31-107127 60mm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Implants

<table>
<thead>
<tr>
<th>Max-Ti&lt;sup&gt;®&lt;/sup&gt; Modular Protrusio Cage</th>
<th>Max-Ti&lt;sup&gt;®&lt;/sup&gt; Iliac Flange Augment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Part No.</td>
<td>Description</td>
</tr>
<tr>
<td>-----------</td>
<td>---------------------</td>
</tr>
<tr>
<td>12420</td>
<td>52mm/Left</td>
</tr>
<tr>
<td>12421</td>
<td>56mm/Left</td>
</tr>
<tr>
<td>12422</td>
<td>60mm/Left</td>
</tr>
<tr>
<td>12423</td>
<td>64mm/Left</td>
</tr>
<tr>
<td>12424</td>
<td>68mm/Left</td>
</tr>
<tr>
<td>12425</td>
<td>72mm/Left</td>
</tr>
<tr>
<td>124320</td>
<td>52mm/Right</td>
</tr>
<tr>
<td>124321</td>
<td>56mm/Right</td>
</tr>
<tr>
<td>124322</td>
<td>60mm/Right</td>
</tr>
<tr>
<td>124323</td>
<td>64mm/Right</td>
</tr>
<tr>
<td>124324</td>
<td>68mm/Right</td>
</tr>
<tr>
<td>124325</td>
<td>72mm/Right</td>
</tr>
</tbody>
</table>
Biomet manufactures acetabular products used in primary and secondary revision applications. These products include malleable acetabular cages, titanium alloy cups, and modular products that utilize various elements for fixation such as flanges, hooks, blades, and augments. These devices are intended to provide support for bone grafts and polyethylene acetabular components. Protrusio cage implants are intended for cemented use only. Protrusio shell acetabular components are intended for use in cemented or non-cemented applications.

Components are available in a variety of designs and size ranges intended for revision applications to address bone defects.

MATERIALS
- **Acetabular Cages**: Commercially Pure Titanium
- **Acetabular Shells**: Titanium Alloy
- **Acetabular Liners**: Ultra-High Molecular Weight Polyethylene (UHMWPE)
- **Screws**: Titanium Alloy
- **Blades**: Titanium Alloy
- **Flanges and Hooks**: Commercially Pure Titanium
- **Augments**: Titanium Alloy

INDICATIONS
Protrusio Cage and acetabular shell implants are intended for use in reconstruction of the hip joint due to disease, deformity or trauma. The devices are intended for general use in skeletally mature individuals undergoing primary and/or secondary revision surgery. The device is a single use implant. The Protrusio Cage is to be used in conjunction with any commercially available polyethylene acetabular cup. Shell components are to be used with Biomet Ringloc Acetabular Liners.

Patient selection factors to be considered include: 1) need to obtain pain relief and improve function, 2) ability and willingness of the patient to follow instructions, including control of weight and activity level, 3) a good nutritional state of the patient, and 4) the patient must have reached full skeletal maturity.

CONTRAINDICATIONS
Absolute contraindications include: infection, sepsis, and osteomyelitis.
Relative contraindications include: 1) uncooperative patient or patient with neurologic disorders who are incapable of following directions, 2) osteoporosis, 3) metabolic disorders which may impair bone formation, 4) osteomalacia, 5) distant foci of infections which may spread to the implant site, 6) rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram, 7) vascular insufficiency, muscular atrophy, or neuromuscular disease.

**WARNINGS**
Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components. 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. Use clean gloves when handling implants. Laboratory testing indicates that implants subjected to body fluids, surgical debris or fatty tissue have lower adhesion strength to cement than implants handled with clean gloves. Do not modify implants. The surgeon is to be thoroughly familiar with the implants and instruments, prior to performing surgery.

1. The Protrusio Cage should not be bent in the same location more than once. Bending of the flange or the cage body can weaken the metal.
2. The Protrusio Cage is a load sharing device and must be fully supported on host bone, allograft or cement. This is not a load-bearing device.
3. In the presence of pelvic discontinuity, insufficient support for the cage will lead to premature failure of the implant or the procedure.
4. Screws are to be fully seated to assure stable fixation. Blade and hook components must be fully seated and secure to prevent premature failure.
5. 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.
6. Perforation entirely through the pelvic bone with flange 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 cause damage to body structures (blood vessels, etc.) located on the interior side of the pelvis.
7. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent 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 at the implant site is critical to minimize wear of the implant articular surfaces. Implant fracture due to cement failure has been reported.

Biomet® joint replacement prostheses provide the surgeon with a means of reducing pain and restoring function for many patients. While these devices are generally successful in attaining these goals they cannot be expected to withstand the activity levels and loads of normal healthy bone and joint tissue.
Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure. The patient is to be advised of the limitation of the reconstruction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive activity, trauma and excessive weight have been implicated with premature failure of the implant by loosening, fracture, and/or wear. 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.

PRECAUTIONS
Specialized instruments are designed for Biomet® joint replacement systems 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, 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, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Biomet recommends that all instruments be regularly inspected for wear and disfigurement.

Do not reuse implants. While an implant may appear undamaged, previous stress may have created 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.

POSSIBLE ADVERSE EFFECTS
1. 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.
2. Early or late postoperative infection and allergic reaction.
3. 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.
4. Loosening or migration of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption, excessive activity.
5. Periarticular calcification or ossification, with or without impediment of joint mobility.
6. Inadequate range of motion due to improper selection or positioning of components.

7. Undesirable shortening of limb.
8. Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity can also contribute to these conditions.
9. Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union or excessive weight.
10. Fretting and crevice corrosion can occur at interfaces between components.
11. Wear and/or deformation of articulating surfaces.
12. Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing, or inadequate reattachment.
13. Problems of the knee or ankle of the affected limb or contralateral limb aggravated by leg length discrepancy, too much femoral medialization or muscle deficiencies.
14. Intraoperative or postoperative bone fracture and/or postoperative pain.
15. Failure of the device or procedure in the presence of pelvic discontinuity.

STERILITY
Prosthetic components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. Do not resterilize. Do not use any component from an opened or damaged package. Do not use implants after expiration date.

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

Authorized Representative: Biomet U.K., Ltd.
Waterton Industrial Estates,
Bridgend, South Wales
CF31 3XA, U.K.

The information contained in this package insert was current on the date this brochure was printed. However, the package insert may have been revised after that date. To obtain a current package insert, please contact Biomet at the contact information provided herein.
This material is intended for the sole use and benefit of the Biomet sales force and physicians. It is not to be redistributed, duplicated or disclosed without the express written consent of Biomet.

The Max-Ti® Modular Protrusion Cage was designed in conjunction with Allen Boyd, M.D., John Cuckler, M.D., and Adolph Lombardi, M.D., F.A.C.S.

Max-Ti® Freedom® and PPS® are trademarks of Biomet Manufacturing Corp.

The Max-Ti® surgical technique is utilized by A. Boyd, M.D., J. Cuckler, M.D., and A. Lombardi, M.D. Biomet, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the prosthesis in each individual patient. Biomet is not responsible for selection of the appropriate surgical technique or device to be used for an individual patient.