

MAX-TI[®]
MODULAR PROTRUSIO CAGE



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

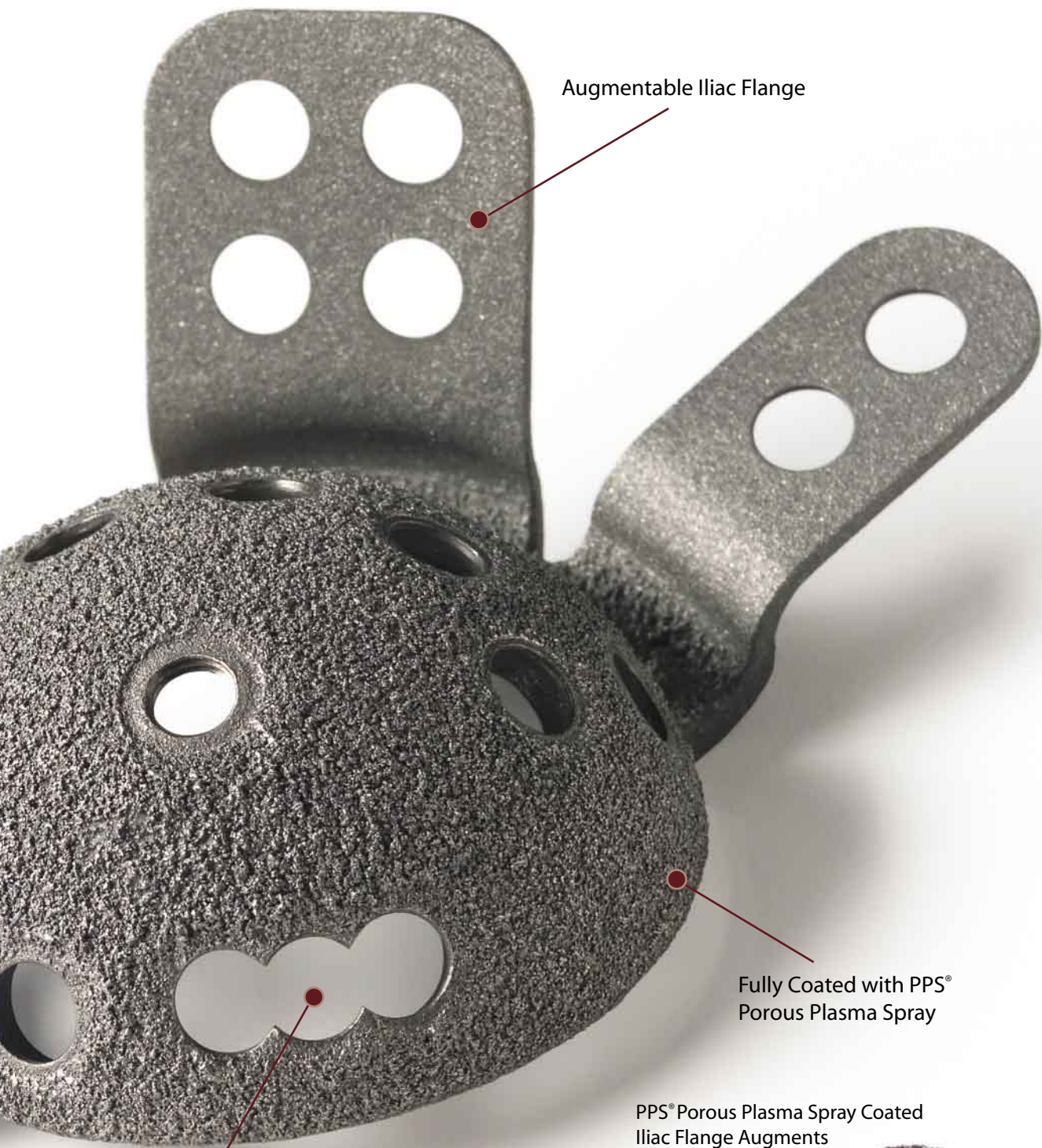
Iliac Flange Augments

- 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



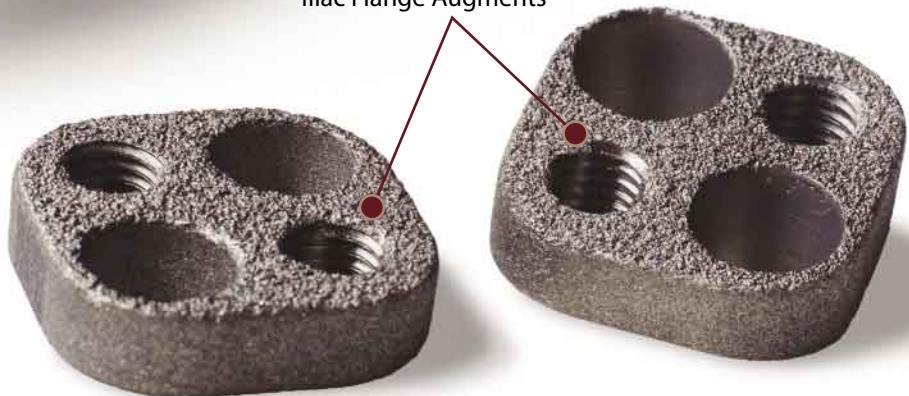


Augmentable Iliac Flange

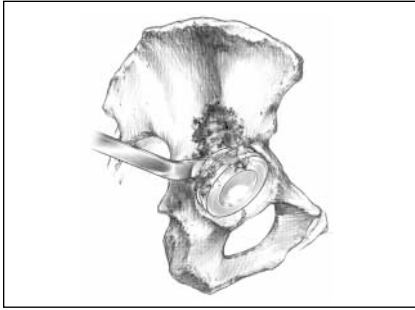
Fully Coated with PPS®
Porous Plasma Spray

Antero-Inferior Screw Holes

PPS® Porous Plasma Spray Coated
Iliac Flange Augments

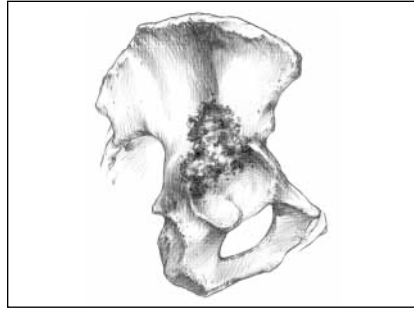


Surgical Technique



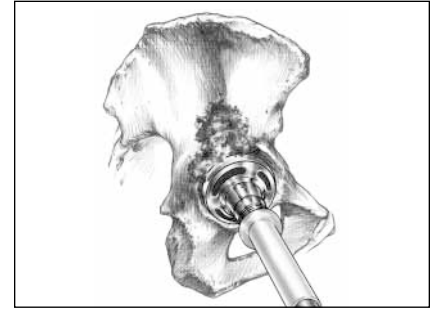
Step 1

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

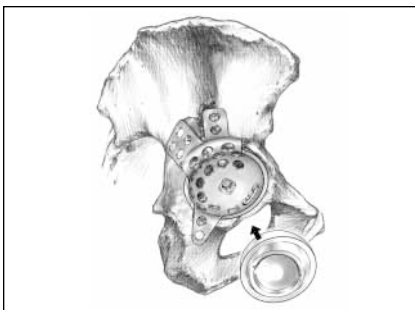
Inspect the remaining host bone to ascertain columnar defects, rim defects, and defects of the acetabular wall and available host bone. This will assist in determining augment styles that may be required to firmly seat the implant on the host bone.



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.

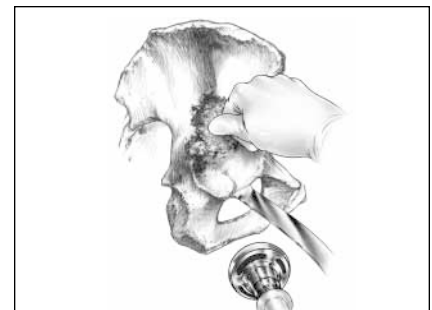


Step 7

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.

Cage Size	Captured Liner Trial Size
52mm	44mm
56mm	48mm
60mm	52mm
64mm	56mm
68mm	60mm
72mm	64mm

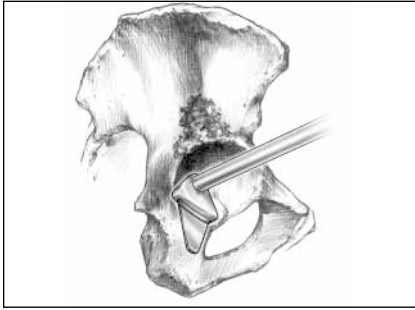
Figure 7A



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.

Surgical Technique

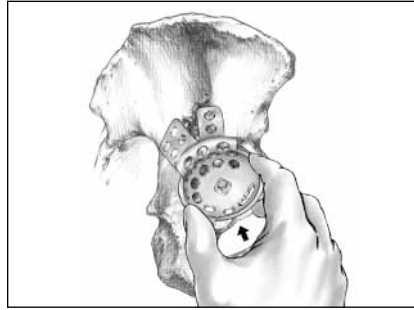


Step 4

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.

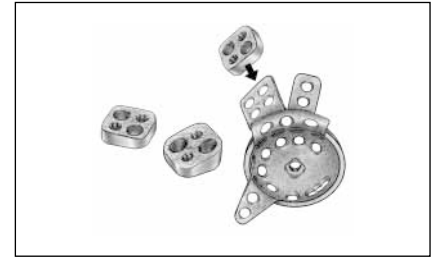
If it is determined that placing the ischial flange inside the bone is optimal, then place a mark on the entry point into the ischium. This is where the ischial blade punch is placed and carefully impacted to create an opening for the flange.



Step 5

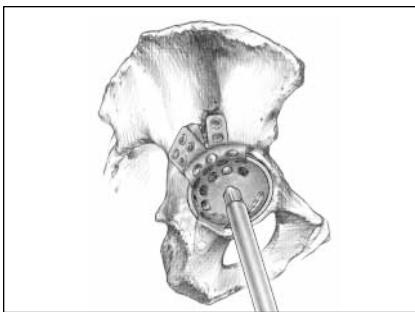
If needed, some bending of the flanges can be performed to optimize fit and fixation. While attempting to achieve best fit, bending should be kept to a minimum in order to prevent structural damage to or fracture of the flanges. Refer to the instructions on how to use bending tools on the following page.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

Use of Flange Augments



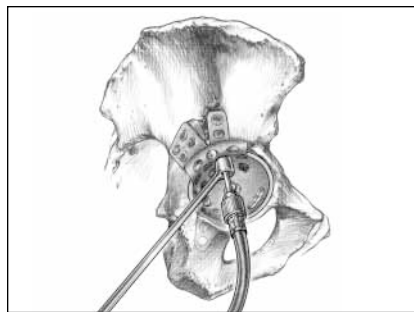
Step 6

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.



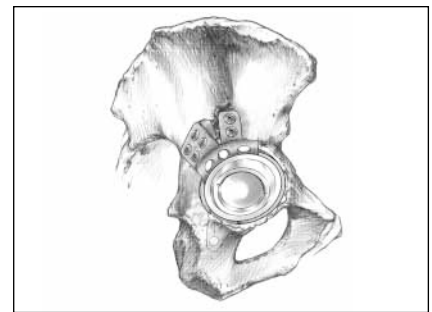
Step 9

Now, the Max-Ti® cage and augments 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 augments 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.**

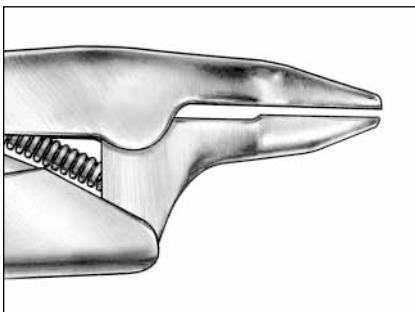
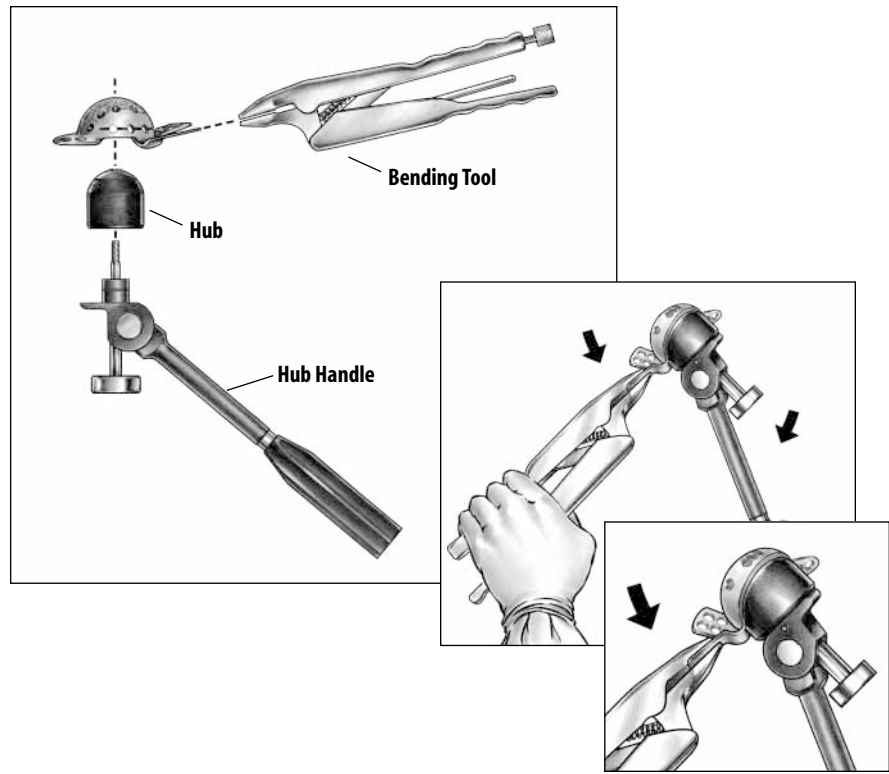


Step 11

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.

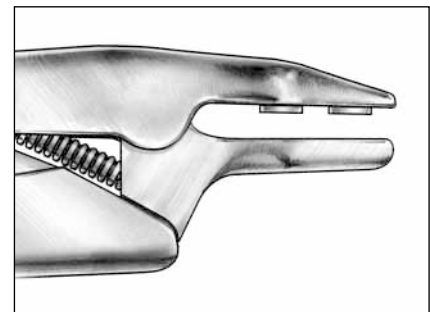
Max-Ti® Bending System

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)

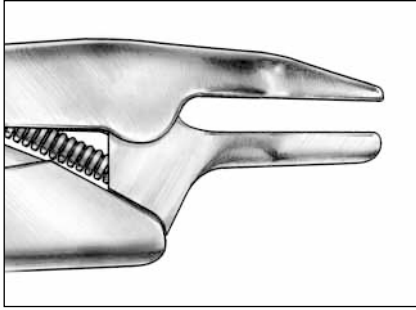
The ischial flange bender has a jaw ideally suited for bending this flange. Position the jaws so that the nose grips the flange approximately 1–2mm below the screw hole in the base of the flange. This permits stable bending and allows for proper placement of screws.



Iliac Flange Bender (#124094)

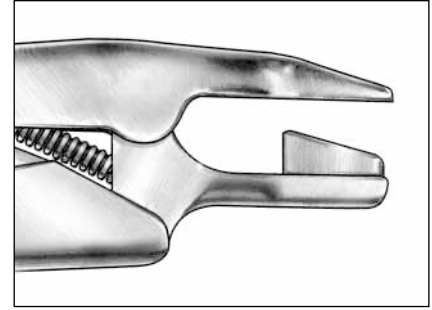
The iliac flange bender is intended for bending the un-augmented iliac flanges. Position the jaws so that each peg seats into the cage screw holes. Tighten and carefully bend to the desired position.

Max-Ti® Bending System



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

Max-Ti® Captured Liner Trials

31-104391	28x44
31-105849	28x48
31-105852	28x52
31-105856	28x56
31-105859	28x60
31-104397	28x64
31-104392	32x48
31-104393	32x52
31-104394	32x56
31-104395	32x60
31-104396	32x64

Freedom® All-Poly Cup Trials

31-107123	52mm
31-107125	56mm
31-107127	60mm

Ball and Spike

124090

Ischial Flange Bending Tool

124091

Large Bio-Bender

124092

Ischial Punch

124093

Iliac Flange Bending Tool

124094

Flat Augment Bending Tool

124095

Wedge Augment Bending Tool

124096

Bender Hub Handle

124190

Bender Hub

124191	52mm
124192	56mm
124193	60mm
124194	64mm
124195	68mm
124196	72mm

Implants

Max-Ti® Modular Protrusio Cage	
Part No.	Description
124220	52mm/Left
124221	56mm/Left
124222	60mm/Left
124223	64mm/Left
124224	68mm/Left
124225	72mm/Left
124320	52mm/Right
124321	56mm/Right
124322	60mm/Right
124323	64mm/Right
124324	68mm/Right
124325	72mm/Right

Max-Ti® Iliac Flange Augment		
Part No.	Provisional	Description
124080	12-121080	6mm, Flat
124082	12-124082	6mm, Wedge

Notes

Biomet Orthopedics, Inc.
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Warsaw, Indiana 46581 USA

01-50-0953
Date: 10/99

Biomet® Protrusio Acetabular Components
Attention Operating Surgeon

DESCRIPTION

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.

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CE0086

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U.S. Patent 6,458,161
Patent Pending on Trialing System

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

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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.

BIOMET®
ORTHOPEDICS, INC.
Driven By Engineering

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