



Trabecular Metal™ Acetabular Restrictor and Augment

Surgical Technique



The Best Thing Next To Bone™

Acetabular Assessment and Preparation

Intra-operatively, carefully assess any acetabular bone defects present. Note the location, extent, and type of bone defect. It is equally important to assess the quality and location of the host bone that remains for support of the acetabular reconstruction.

Use progressively larger reamers to prepare the acetabulum for the Revision Shell or other *Trabecular Metal* Cups. Hold the reamer steady in the intended position and orientation in which the cup will be implanted.

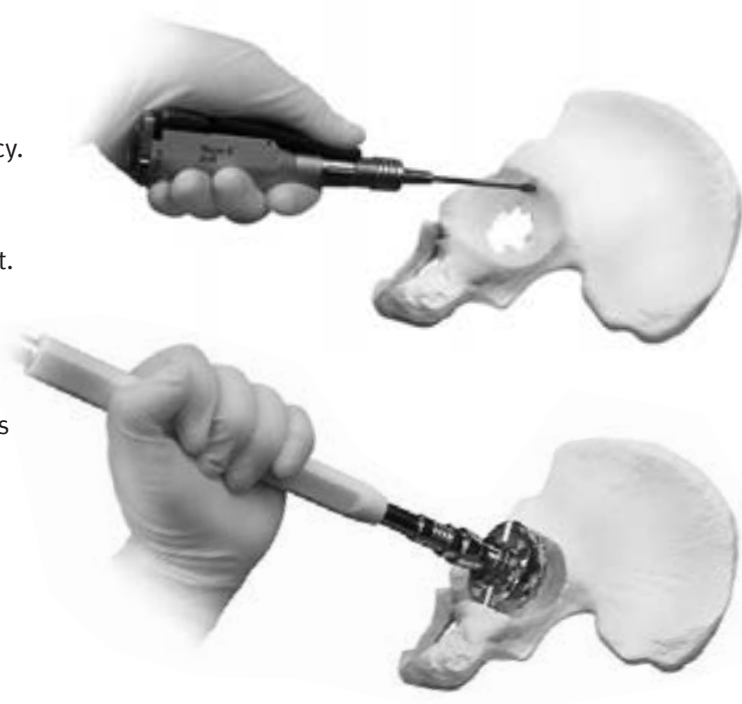
Following acetabular preparation, reassess the acetabulum to evaluate the quality of bone and defect type. Determine if an Acetabular Restrictor and/or Augment is necessary. If both are deemed necessary, the Restrictor is placed first, then the Augment.



1 Acetabular Augment Bone Preparation

If augmentation is elected, minimize the removal of any additional bone in the areas of bone deficiency. If needed, use a hemispherical reamer or burr to smooth the surface of the defect to facilitate stable placement and impaction of the Acetabular Augment.

Note: The Augment is a partial hemisphere. The smallest size reamer corresponding to an Augment outer diameter size is 50mm while the largest is 70mm. Consider the size array of Augments if choosing a reamer for defect preparation.



2 Augment Sizing

Effort should be made to provide for anatomical positioning of the cup. Use Acetabular Cup Provisionals (*Trabecular Metal* Revision Shell Provisional shown here) along with Acetabular Augment Provisionals to facilitate decision making on the proper combination and position. Choose the Cup Provisional that is the same size as the last reamer used. Select the Augment Provisional size to match the defect or the last reamer used to prepare the defect. The Augment Provisional can be held in place with the Augment Provisional Forceps or a Pin. Ensure maximum host bone contact against the surface of the Augment Provisional in order to gain maximum support for the implant.

Note: Different thicknesses are available for each size Augment Provisional.



3 Augment Insertion

Assemble the Torque Limiter onto the screwdriver (A).

Note: This will help prevent advancement of screw heads through the Augment screw holes and stripping of the threads formed in the bone.

Insert the Acetabular Augment implant using the Augment Implant Forceps. Pre-drill bone holes as needed (B).

A depth gauge can be used to aid in determining screw lengths. Hold the implant in place and fix as appropriate with 6.5mm screws through the three screw holes provided (C). Ensure careful screw placement to avoid vascular and neurological injury.

Note: The center rib screw hole on the 20mm and 30mm thick augments cannot be used simultaneously with the center hole on the top face (D).

Once the Augment is secure and stable, evaluate its fit against the host bone and the fit of the cup provisional by reintroducing the cup provisional in order to ensure proper support for the cup. The Augment should be secure and stable against the host bone, independent of any subsequent cup implant.

Note: The Augment can be placed in a variety of positions to fit into the defect. One option is shown here.



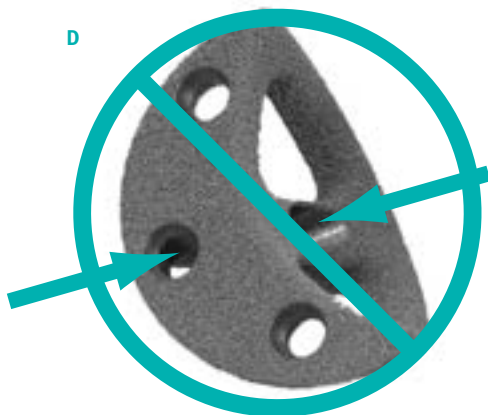
A



B



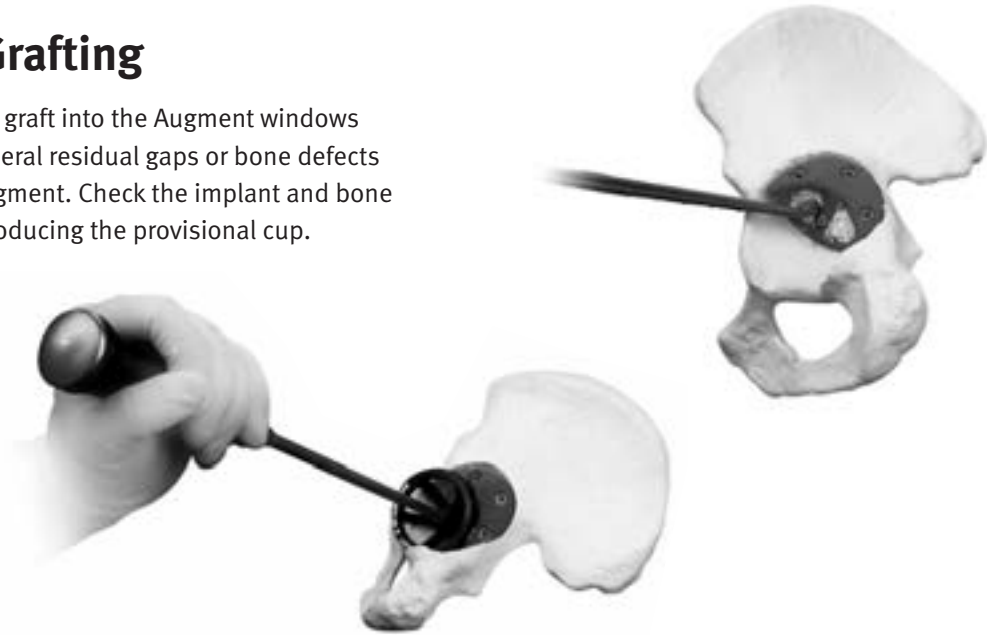
C



D

4 Bone Grafting

Pack morsellized bone graft into the Augment windows and around any peripheral residual gaps or bone defects in the region of the Augment. Check the implant and bone graft position by reintroducing the provisional cup.



5 Revision Shell Insertion

Place PALACOS® bone cement* in a doughy state across the concave surface of the Acetabular Augment that will contact the cup. Take care to limit the cement to this location and prevent cement from extruding into the depths of the acetabulum where it might impede bone ingrowth into the *Trabecular Metal* augment. Fixation to all areas in contact with the host bone should remain uncemented. The Augment is now prepared to accept a cup.

Note: Insert the cup in its proper orientation prior to cement curing.

Note: Cup screw holes may be aligned with the augment windows as desired. This accommodates securing the cup with bone screw placement through the Acetabular Augment. Contact should be avoided between the bone screws and the Augment. Bone wax may be used to fill the center rib screw hole if unused. Bone wax may also be placed over the center rib screw head when present.



* PALACOS® is a trademark of Heraeus Kulzer GmbH
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1 Acetabular Restrictor Restrictor Sizing

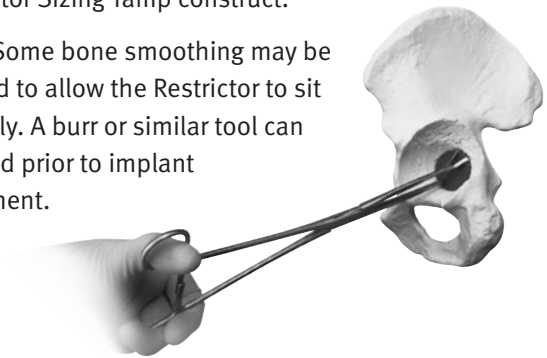
Thread the Sizing Tamp onto the provisional shell handle and introduce into the acetabulum. Use the Sizing Tamp to select an implant size appropriate for adequate defect coverage.



2 Restrictor Insertion

Select the Acetabular Restrictor implant that matches the size selected when using the Sizing Tamp. The Acetabular Restrictor Inserter/Positioner can be used to facilitate placement of the Restrictor into the acetabulum. Place the implant to allow a gap between the Restrictor and the cup that can be filled with bone graft or cement. Impact the Restrictor into final position using the Restrictor Sizing Tamp construct.

Note: Some bone smoothing may be needed to allow the Restrictor to sit properly. A burr or similar tool can be used prior to implant placement.



3 Bone Grafting

Place morsellized bone graft over the top of the Restrictor and then compact with the Restrictor Sizing Tamp construct.

Note: This is necessary to avoid contact between the Acetabular Restrictor and the cup.

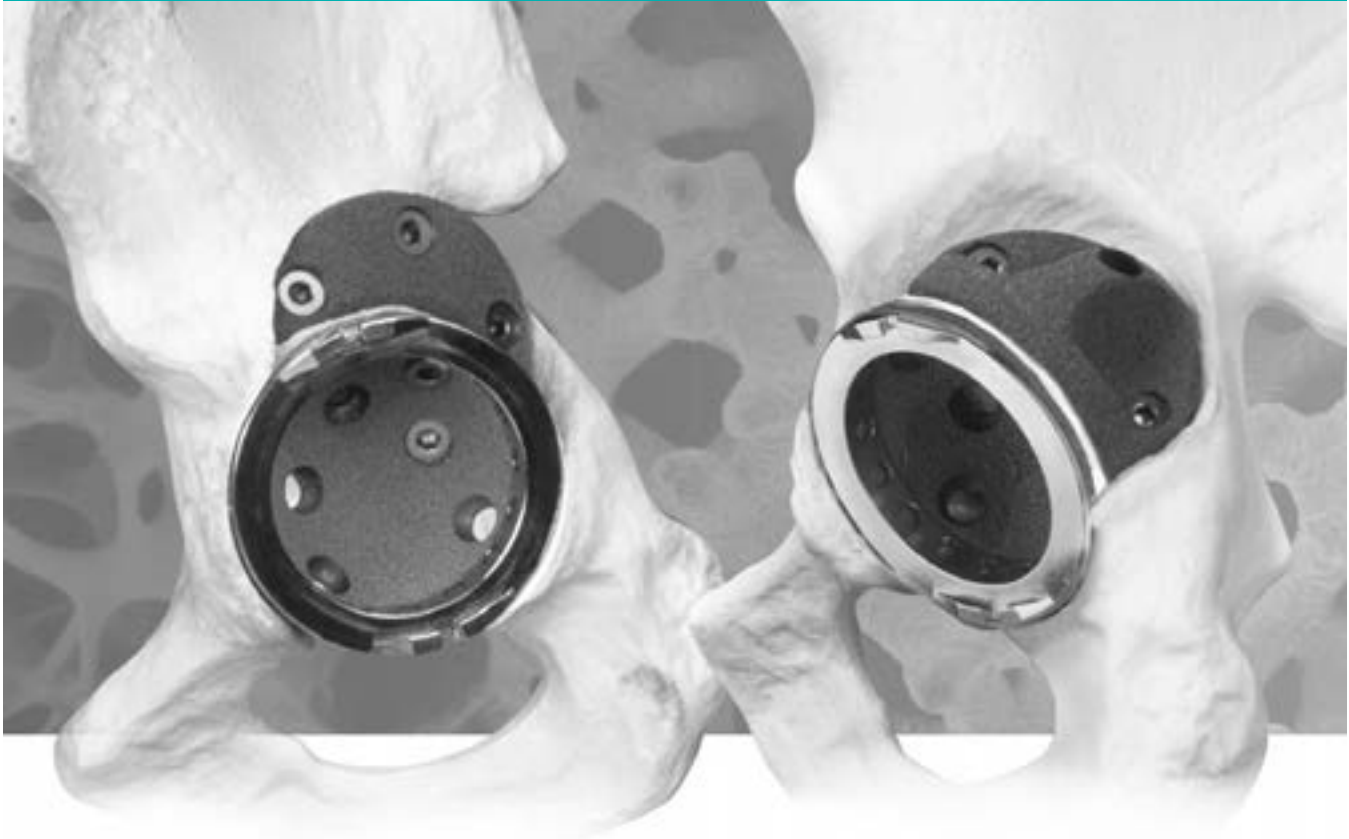


4 Final Preparation

The acetabulum is now ready to accept an Acetabular Augment, if necessary, or a cup.

Note: If screws will be used in the cup or Augment, it is important to note the location of the Restrictor so that screws do not come in contact with the Restrictor.





Bone Void Filler

- The Augment and Restrictor fill bone deficiencies as an alternative to preparing and using structural allografts.¹
- Host bone is conserved while the implant size, position, and orientation are determined by the defect.
- Acetabular Cup position and patient kinematics remain uncompromised, as when using structural grafts.
- The Augment, shaped similar to a partial hemisphere, comes in four thicknesses and six sizes, allowing for fit in various defects.



The Restrictor is concave and comes in three diameters, allowing for coverage of medial wall defects and containment of morsellized bone graft.



Biological Fixation with Structural Support

- Fully interconnected trabecular structure with two to three times the porosity of other implant materials enables extensive tissue ingrowth and strong attachment.²
- *Trabecular Metal* material acts as a scaffolding for bone ingrowth and remodeling while providing load bearing structural support.¹
- High coefficient of friction against bone provides enhanced initial stability.²
- Low stiffness of *Trabecular Metal* material can produce more normal physiological loading and reduce stress shielding.³
- Augment windows provide significant volume for morsellized bone graft, which may aid in bone growth and remodeling.⁴

1 Nehme, Lewallen, Hanssen. Modular Porous Metal Augments for Treatment of Severe Acetabular Bone Loss During Revision Hip Arthroplasty. *Clinical Orthopaedics and Related Research*, No. 429, December 2004. pp201-208.
 2 Bobyn JD, Hacking SA, Chan SP, et al. Characterization of a new porous tantalum biomaterial for reconstructive orthopaedics. *Scientific Exhibit, Proc of AAOS*, Anaheim, CA. 1999.
 3 Pedersen DR, Brown TD, Poggie RA. Finite element analysis of periacetabular stress of cemented, metal-backed, and porous tantalum-backed acetabular components. *45th Annual Orthopaedic Research Society Meeting*, Anaheim, CA. 1999.
 4 Steinberg ME, Garino JP, editors. *Revision total hip arthroplasty*. Lippincott Williams and Wilkins; 1999; Philadelphia, PA.

Acetabular Augment

Cat. No.	Description
00-4894-050-10	Acetabular Augment, Size 50, 10mm Thick
00-4894-054-10	Acetabular Augment, Size 54, 10mm Thick
00-4894-058-10	Acetabular Augment, Size 58, 10mm Thick
00-4894-062-10	Acetabular Augment, Size 62, 10mm Thick
00-4894-066-10	Acetabular Augment, Size 66, 10mm Thick
00-4894-070-10	Acetabular Augment, Size 70, 10mm Thick
00-4894-050-15	Acetabular Augment, Size 50, 15mm Thick
00-4894-054-15	Acetabular Augment, Size 54, 15mm Thick
00-4894-058-15	Acetabular Augment, Size 58, 15mm Thick
00-4894-062-15	Acetabular Augment, Size 62, 15mm Thick
00-4894-066-15	Acetabular Augment, Size 66, 15mm Thick
00-4894-070-15	Acetabular Augment, Size 70, 15mm Thick
00-4894-050-20	Acetabular Augment, Size 50, 20mm Thick
00-4894-054-20	Acetabular Augment, Size 54, 20mm Thick
00-4894-058-20	Acetabular Augment, Size 58, 20mm Thick
00-4894-062-20	Acetabular Augment, Size 62, 20mm Thick
00-4894-066-20	Acetabular Augment, Size 66, 20mm Thick
00-4894-050-30	Acetabular Augment, Size 50, 30mm Thick
00-4894-054-30	Acetabular Augment, Size 54, 30mm Thick
00-4894-058-30	Acetabular Augment, Size 58, 30mm Thick
00-4894-062-30	Acetabular Augment, Size 62, 30mm Thick
00-4894-066-30	Acetabular Augment, Size 66, 30mm Thick



Acetabular Restrictor

Cat. No.	Description
00-4199-001-26	Restrictor, 26mm diameter
00-4199-001-32	Restrictor, 32mm diameter
00-4199-001-38	Restrictor, 38mm diameter



HGP II Bone Screws

Cat. No.	Description
00-6624-065-20	6.5mm x 20mm
00-6624-065-25	6.5mm x 25mm
00-6624-065-30	6.5mm x 30mm
00-6624-065-35	6.5mm x 35mm
00-6624-065-40	6.5mm x 40mm
00-6624-065-50	6.5mm x 50mm
00-6624-065-60	6.5mm x 60mm

Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.



Screw instruments

Cat. No.	Description
00-6260-099-02	<i>Trilogy</i> ® Holed Instrument Set (Includes one each of the following:)
00-6260-002-00	Flex Shaft w/ Modular Connector
00-6260-003-01	Drill Bit, 15mm length
00-6260-003-02	Drill Bit, 30mm length
00-6260-003-03	Drill Bit, 45mm length
00-6260-006-00	Drill Guide
00-6260-007-01	Tap, 4.5mm dia.
00-6260-007-02	Tap, 6.5mm dia.
00-6260-008-01	Tap Guide, 4.5mm dia.
00-6260-008-02	Tap Guide, 6.5mm dia.
00-6260-010-00	Tap Handle
00-6260-024-00	Straight Screwdriver
00-6260-025-00	Universal Screwdriver
00-6260-026-00	Modular Universal Handle
00-6260-013-00	Screw Holding Forceps, 15°
00-6260-014-00	Screw Holding Forceps, 45°
00-6611-098-00	Depth Gauge
00-6260-085-01	Case (Including base and lid)
00-4215-200-00	Screwdriver Torque Limiter (ordered separately, not in kit)

Instruments

Cat. No.	Description
00-7105-004-00	TM Acetabular Augment Instrument Set (includes one each of the following:)
00-7106-020-00	TM Acetabular Augment Instrument Case
00-4216-050-10	Acetabular Augment, Provisional, Size 50, 10mm Thick
00-4216-054-10	Acetabular Augment, Provisional, Size 54, 10mm Thick
00-4216-058-10	Acetabular Augment, Provisional, Size 58, 10mm Thick
00-4216-062-10	Acetabular Augment, Provisional, Size 62, 10mm Thick
00-4216-066-10	Acetabular Augment, Provisional, Size 66, 10 mm Thick
00-4216-070-10	Acetabular Augment, Provisional, Size 70, 10 mm Thick
00-4216-050-15	Acetabular Augment, Provisional, Size 50, 15mm Thick
00-4216-054-15	Acetabular Augment, Provisional, Size 54, 15mm Thick
00-4216-058-15	Acetabular Augment, Provisional, Size 58, 15mm Thick
00-4216-062-15	Acetabular Augment, Provisional, Size 62, 15mm Thick
00-4216-066-15	Acetabular Augment, Provisional, Size 66, 15mm Thick
00-4216-070-15	Acetabular Augment, Provisional, Size 70, 15 mm Thick
00-4216-050-20	Acetabular Augment, Provisional, Size 50, 20mm Thick
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00-4216-050-30	Acetabular Augment, Provisional, Size 50, 30mm Thick
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00-4216-058-30	Acetabular Augment, Provisional, Size 58, 30mm Thick
00-4216-062-30	Acetabular Augment, Provisional, Size 62, 30mm Thick
00-4216-066-30	Acetabular Augment, Provisional, Size 66, 30mm Thick
00-4200-164-00	Restrictor Sizing Tamp, 26mm dia.
00-4200-165-00	Restrictor Sizing Tamp, 32mm dia.
00-4200-166-00	Restrictor Sizing Tamp, 38 mm dia.
00-4200-167-00	*Restrictor Inserter/Positioner
00-4215-200-00	*Screwdriver Torque Limiter
00-4215-100-00	*Augment Implant Forceps
00-4215-110-00	*Augment Provisional Forceps



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Please refer to package insert for complete product information, including contraindications, warnings, precautions and adverse effects.

