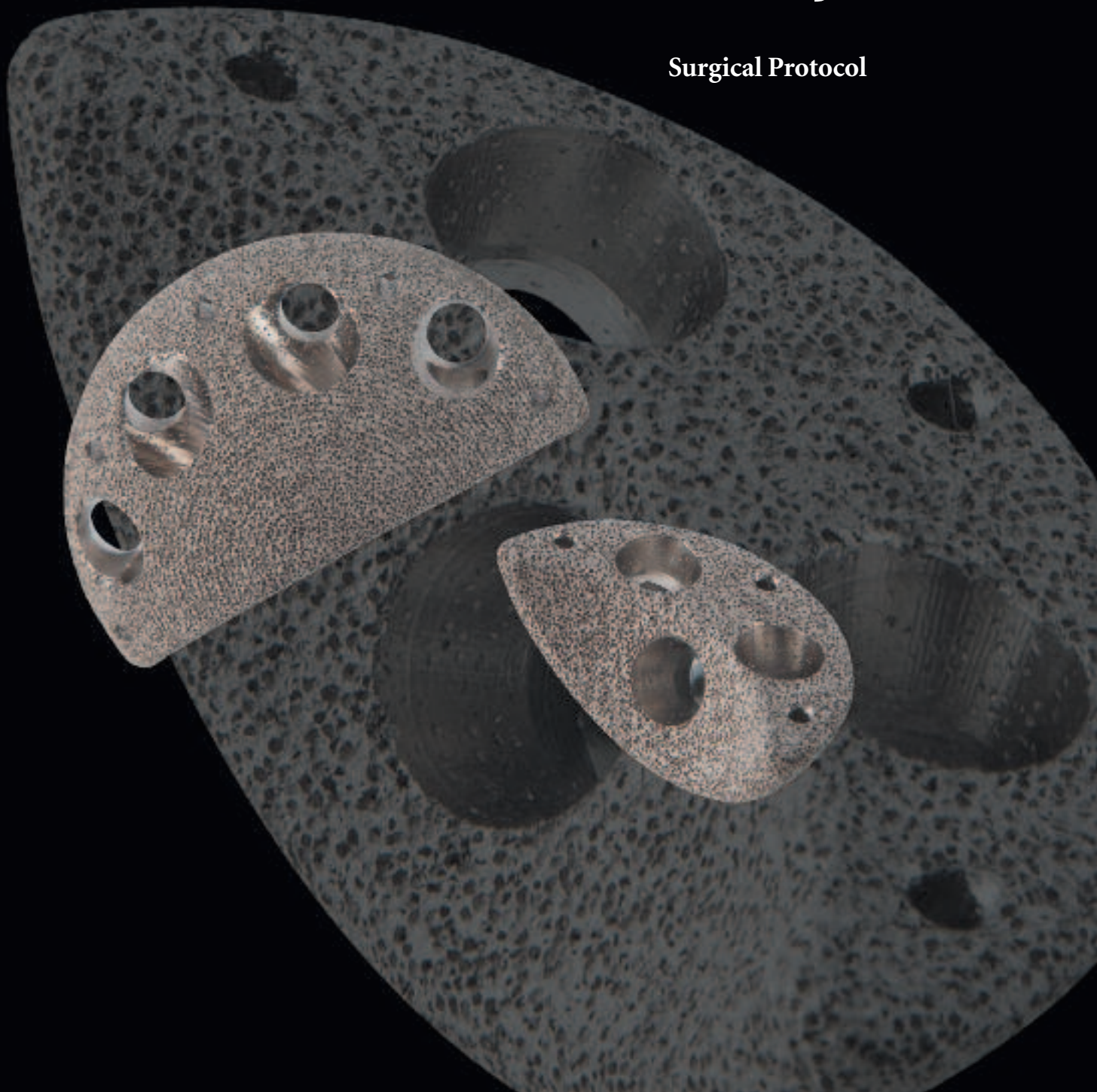
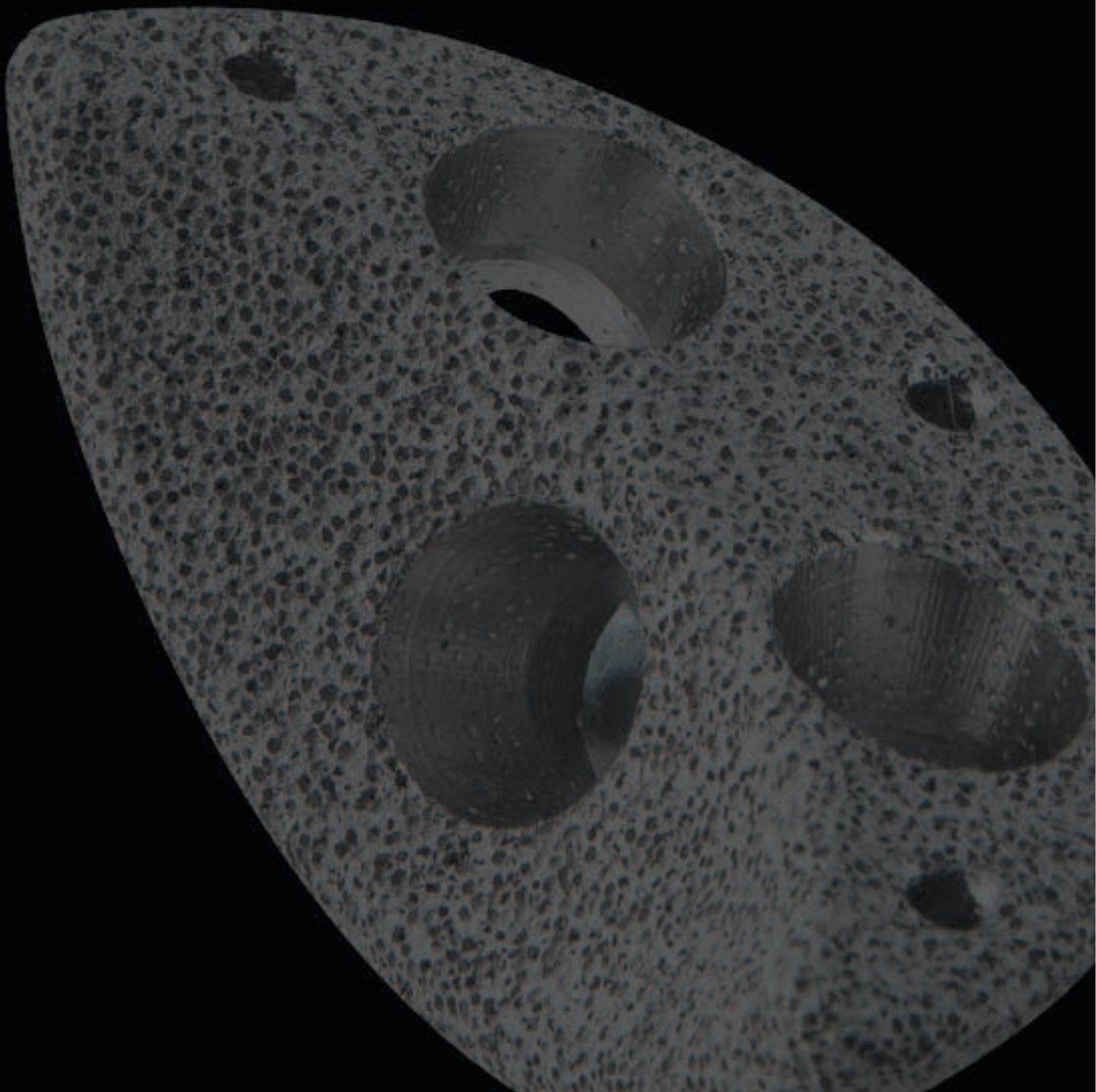
stryker®

Orthopaedics

Restoration®
Acetabular Wedge Augment System

Surgical Protocol





Restoration Acetabular Wedge Augment System

Introduction

The Restoration Acetabular Wedge Augment System is designed for hip surgeries requiring additional Acetabular component support in cases where host bone is insufficient. The Wedge Augments provide surgeons with the intraoperative flexibility to optimize screw placement and the opportunity to attain initial stability during shell implantation.

The Wedge Augments are designed to address a variety of acetabular deficiencies, while conserving host acetabular bone. The size range and orientation of the Wedge Augments help the surgeon to personalize the Augment to the patient's needs, address the defect and restore the patient's joint mechanics.

Indications

General Indications for Total Hip Replacement Components:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Indications Specific to the Acetabular Wedges:

- As an alternative to structural allograft in cases of superior and superior/posterior segmental acetabular deficiencies.

  1) Acetabular Augments are intended for cementless use only to the bone interface; and

  2) are affixed to the mating cup using bone cement.

Contraindications

- Active infection or suspected latent infection in or about the hip joint.
- Bone stock that is inadequate for support or fixation of the prosthesis.
- Skeletal immaturity.
- Any mental or neuromuscular disorder that would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in post-operative care.

Warnings & Precautions

See package insert for warnings, precautions, adverse effects and other essential product information.

This publication sets forth recommended procedures for using Stryker Orthopaedics devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

Pre-operative Planning and X-ray Evaluation

Pre-operative planning is strongly recommended to aid in proper restoration of anatomic head center. This can be achieved by measuring the size of the existing prosthesis being removed and determining the most appropriate Acetabular Shell and Wedge Augment size to be implanted.

Anterior-Posterior (A/P) and Medial-Lateral (M/L) radiographs are necessary for X-ray templating and surgical planning. In cases where the acetabulum is compromised, a full pelvic X-ray of the operative side is helpful to assess the biomechanical requirements of the reconstruction.

Position the acetabular template over the A/P radiograph, aligning the acetabular shell surface with the subchondral bone and attempting to position the head center in the appropriate location.

Depending on patient need and surgeon preference, supplemental fixation and/or plating may be required.

Based on the pre-operative radiographs and possible CT scans, the surgeon must assess the acetabular region and decide if there is a need for supplemental fixation. The need for additional fixation must also be evaluated intraoperatively.

It is ideal to achieve stability by supporting the acetabular component on host bone alone. However, if adequate support and fixation between the Acetabular Shell and the host bone cannot be achieved, then a Wedge Augment should be secured to the available host bone to provide additional contact points for the Acetabular Shell to achieve immediate mechanical stability. The orientation of the Wedge Augment can be determined through evaluation of the bone defect and fit with acetabular bone (**Figures A, B**).

Fig. A

Wedge Augment positioned to address cavitary defect.

Fig. B

Wedge Augment inverted to address cavitary / segmental defect.

Surgical Protocol

Step 1: Preparation of Defect Area

If it is determined that augmentation of the Acetabular Shell is required, it will be necessary to prepare the defect area for augment placement. The bone defect region should be cleared of any soft tissue so that direct bone contact can be obtained by the Wedge Augment. Bone removal should be minimized to take advantage of as much available host bone as possible.

A burr or hemispherical reamer can be used to prepare the surface for the Wedge Augment (**Figure 1**). The Wedge Augment should be secured to the host bone at a location where maximum contact can be achieved between the Wedge Augment and the Acetabular Shell.

The Wedge Augment may be used to help provide additional support in areas of the acetabular wall, dome, rim or columns where defects are present.

Fig. 1

Step 2: Wedge Augment Trial Evaluation

With the appropriate Window Trial positioned in the acetabulum (**Figure 2**), select the Wedge Augment Trial that provides the maximum contact with the Window Trial and best matches the defect. In most cases the outer diameter of the Wedge Augment will be equivalent to the diameter of the last reamer used to prepare the defect. The Wedge Augment Trial can be held in place with forceps (**Figure 3A**) or with the Modular Picador (**Figure 3B** on following page) while performing the assessment.

Fig. 2

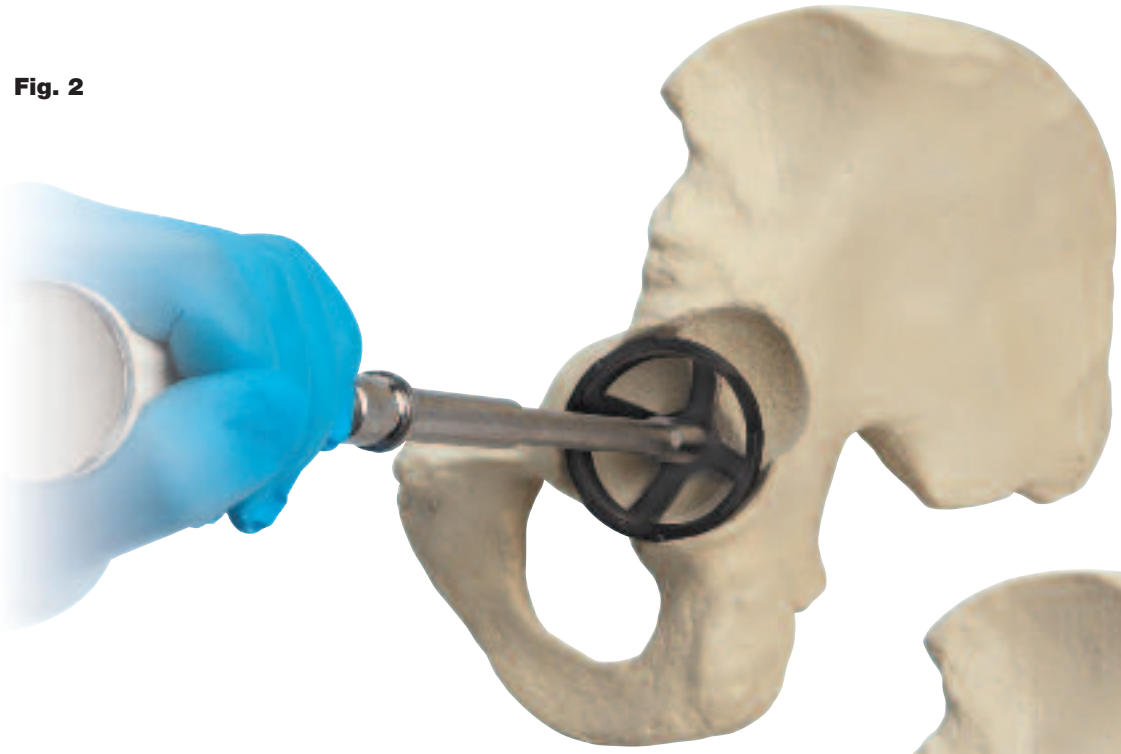
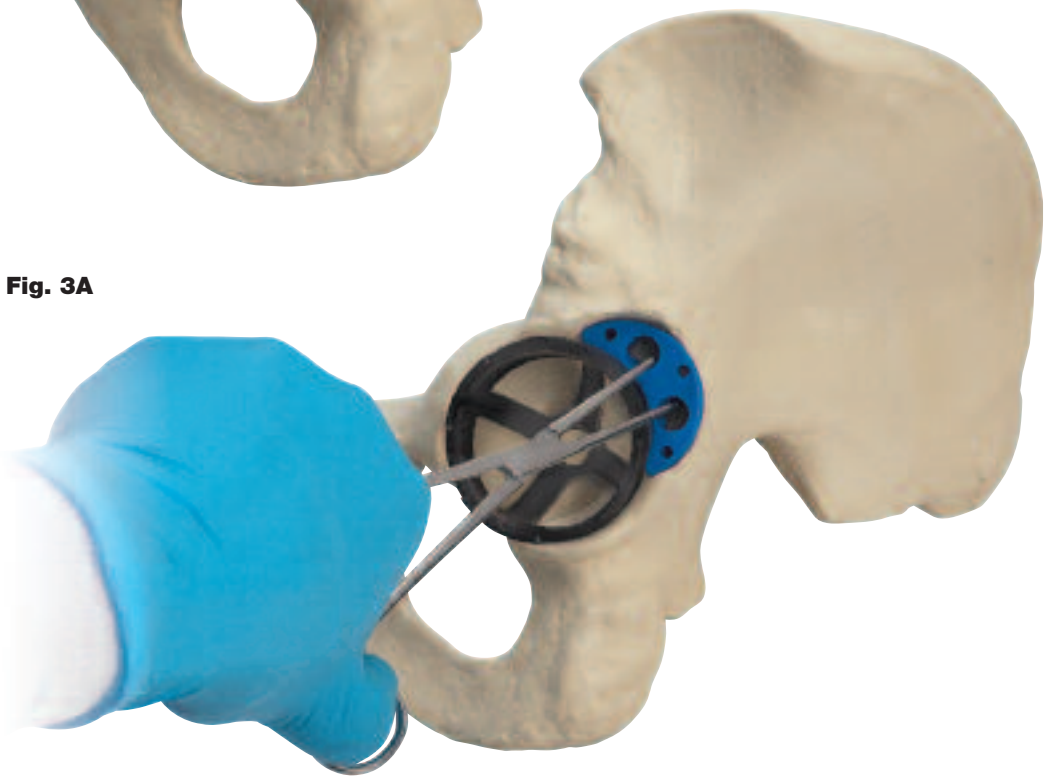


Fig. 3A



Step 2: Wedge Augment Trial Evaluation *(continued)*

To assemble the Modular Picador Shaft to the Modular AO Handle, pull the AO quick connect sleeve away from the Handle, insert the Picador Shaft into the AO coupling and release the sleeve (**Figure 4**). Tug lightly on the end of the Picador Shaft to ensure engagement. If the Picador Shaft pulls out of the Handle repeat this insertion procedure.

Warning

The Modular Picador Shaft is intended to aid in holding the Wedge Trial and Implant in position. Do not use the Modular Picador Shaft as an impaction or prying device. Excessive force on the Modular Picador Shaft can result in damage to the Picador, Wedge Trial or Wedge Augment.

Fig. 3B

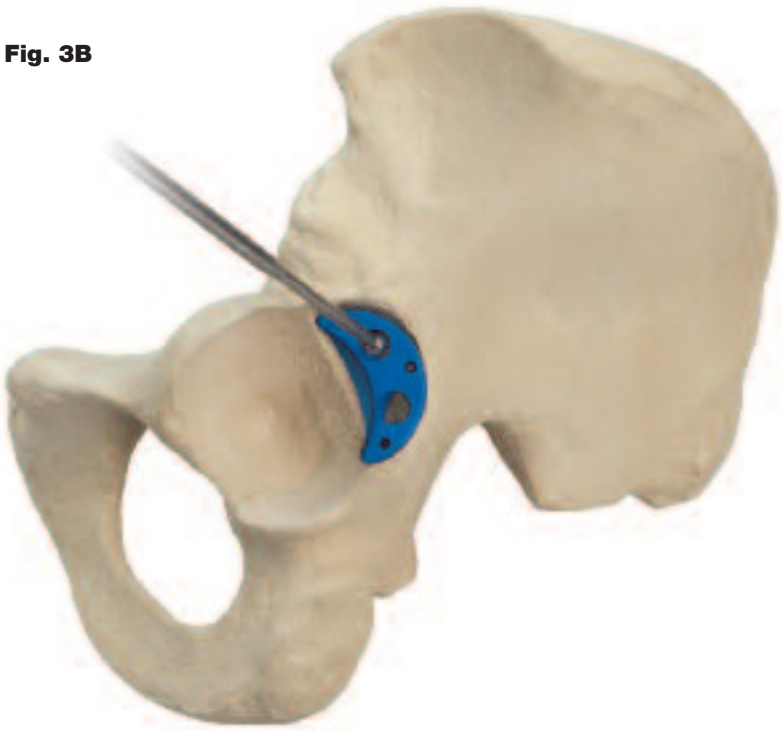


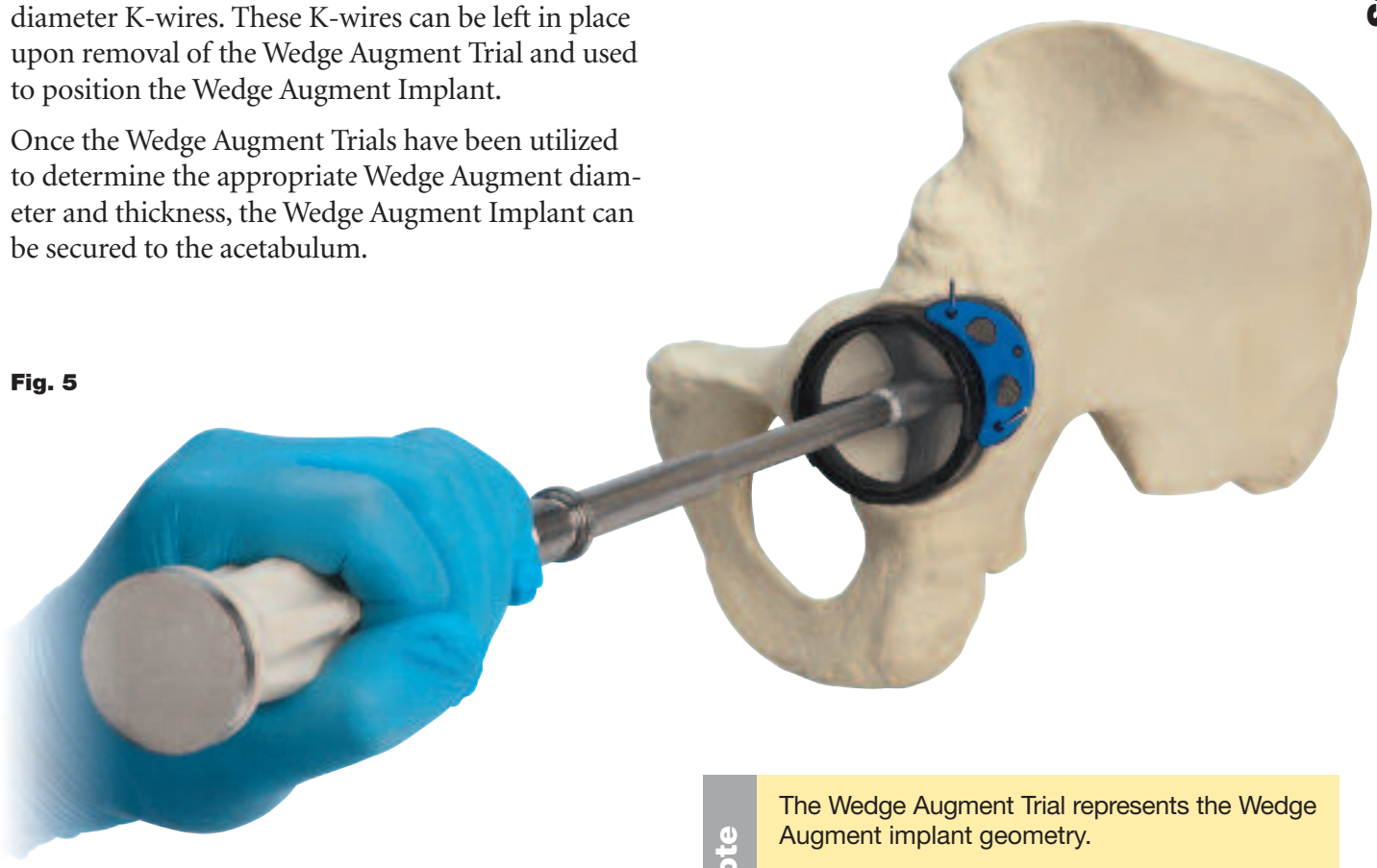
Fig. 4

Modular Picador Shaft and Handle Assembled

K-wires are recommended for this step to help maintain the placement of the Wedge Augment Trial (**Figure 5**). The smaller holes in the Wedge Augment Trial are designed to accommodate 1.6mm – 2.0mm diameter K-wires. These K-wires can be left in place upon removal of the Wedge Augment Trial and used to position the Wedge Augment Implant.

Once the Wedge Augment Trials have been utilized to determine the appropriate Wedge Augment diameter and thickness, the Wedge Augment Implant can be secured to the acetabulum.

Fig. 5



Note

The Wedge Augment Trial represents the Wedge Augment implant geometry.

The Wedge Augments have an ID that is 2mm larger than the OD.

Warning

Caution should be taken when trialing against an Acetabular Shell implant due to possible debris generation.

Holes in Wedge Augment Trial are for visual indications of implant screw hole options. Do not drill through the Wedge Augment Trial.

Intended use for Wedge Augment Trial is to aid in the appropriate selection of Wedge Augment Implant size and placement intraoperatively. Do not impact or implant Wedge Augment Trial.

Caution

Do not pass K-wire beyond the inner table of the pelvis as it may result in injury to the neurovascular structures in the vicinity.

Step 3: Wedge Augment Implantation

Drilling Holes for Wedge Augment

Place the appropriate size Wedge Augment implant into the acetabulum. If K-wires were used with the Wedge Augment Trial and are still in place, the Wedge Augment implant can be inserted in the same orientation, using the K-wires for alignment (**Figure 6**). If K-wires were not used with the Wedge Augment Trial, the Wedge Augment Implant can be held in position with the Modular Picador (**Figure 7**) and K-wires, which may be inserted through the smaller holes in the Wedge Augment implant and into the host bone. This will help provide some initial stability and facilitate the use of GAP (2080-00XX) or Osteolock (5260-5-0XX) 6.5mm screws to obtain rigid fixation of the Wedge Augment against host bone.

Note

In hard bone, the use of 6.5mm dome screws prepared with a 3.2mm drill may be difficult. The use of a 4.0mm drill bit can make the insertion of bone screws easier, without substantial compromise of screw purchase.

Warning

Do not create additional holes in Wedge Augment or remove any Wedge Augment material.

Some holes in the Wedge Augment intersect and cannot be used simultaneously.

The Modular Picador Shaft is intended to aid in holding the Wedge Trial and Implant in position. Do not use the Modular Picador Shaft as an impaction or prying device. Excessive force on the Modular Picador Shaft can result in damage to the Picador, Wedge Trial or Wedge Augment.

Fig. 6

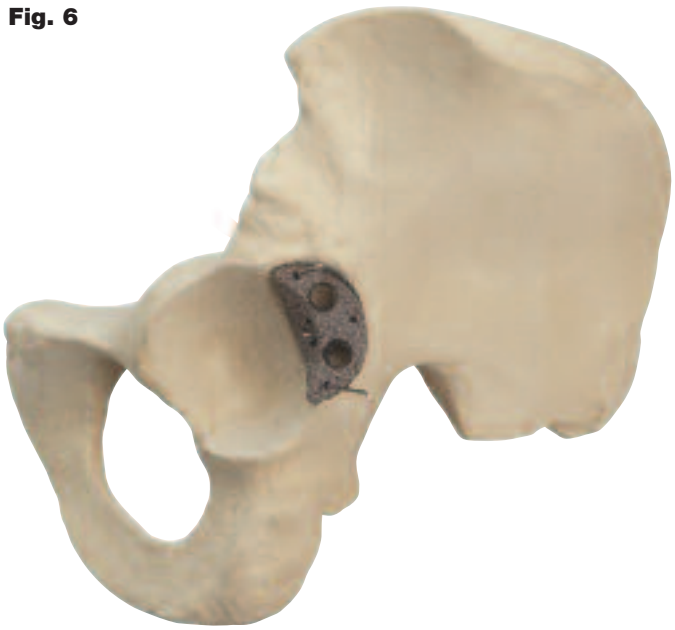
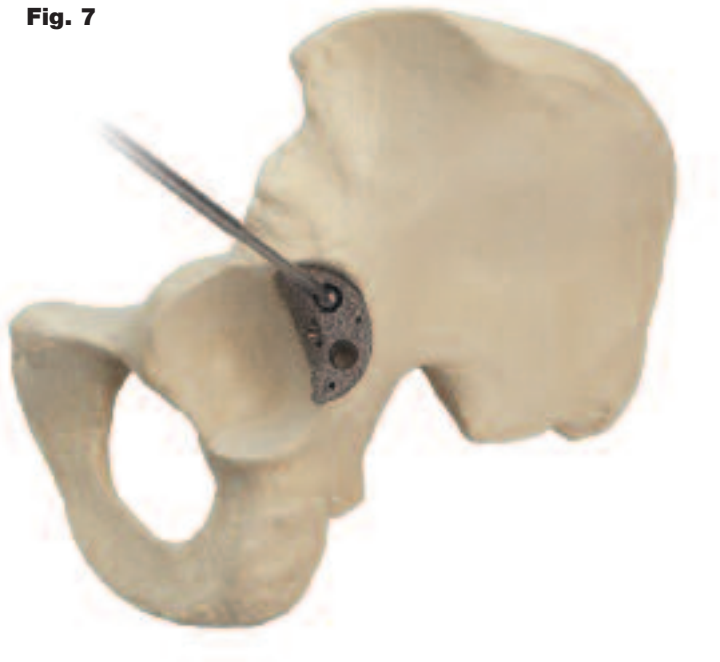


Fig. 7

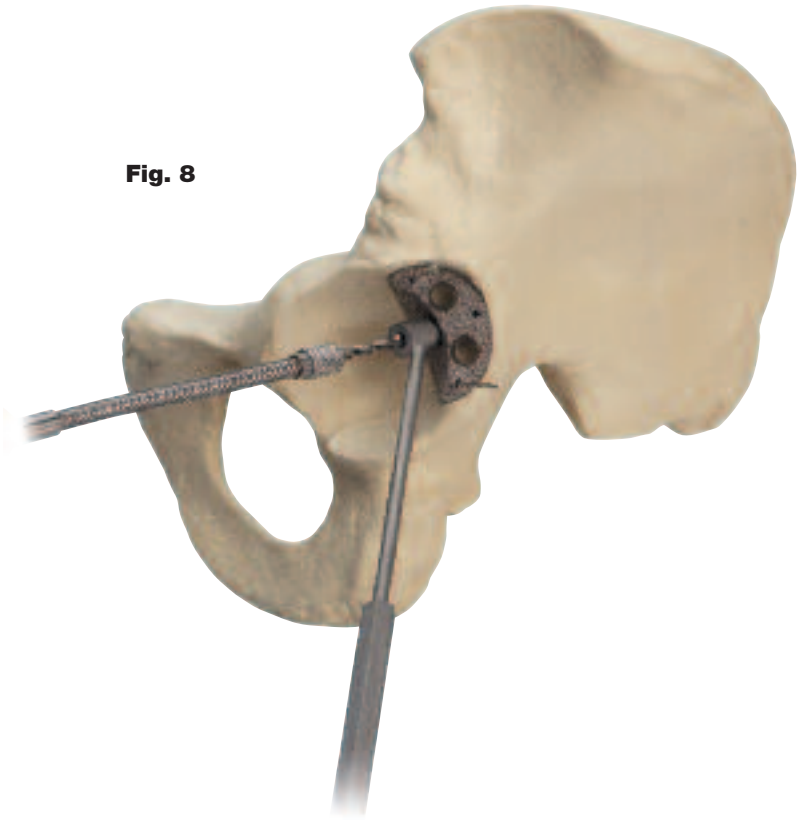


After determination of the proper site for screw placement and rigid fixation of the Wedge Augment to host bone, a Drill Guide (6060-5-310 or 6060-5-300) must be used when drilling the screw hole. A 3.2mm drill is passed through the Drill Guide to the desired depth (**Figure 8**). After drilling, the surface of the Wedge Augment must be clean of any debris prior to screw implantation.

Caution

Do not pass a drill, screw or any other instrumentation beyond the inner table of the pelvis. Malposition of either the shell screw hole orientation, screw hole preparation or improper use of the screws themselves may result in injury to the neurovascular structures in the vicinity.

Fig. 8



Step 3: Wedge Augment Implantation *(continued)*

Inserting Screws to Secure Wedge Augment

The screw hole is sounded to determine the depth of the hole (**Figure 9**). The properly sized 6.5mm screw is then selected and implanted into the bone using the Stryker Orthopedics Screw Driver with a high torque configuration driver head (**Figure 10**).

A sufficient number of screws should be used to attain the desired fixation of the Wedge Augment.

Be aware of the placement of screws in the Wedge Augment as they may affect screw placement in the Acetabular Shell.

Thorough knowledge of the acetabular anatomy is required in order to avoid injury to the neurovascular structures in the vicinity.

Absolute rigid stability of the Wedge Augment against host bone must be achieved for the Wedge Augment to provide sufficient mechanical support for the Acetabular Shell.

After the Wedge Augment is adequately secured, the K-wires must be removed.

Warning After screw implantation, assess that the screw head is flush against the Wedge Augment to help ensure proper seating of the Wedge Augment and Shell.

Fig. 9

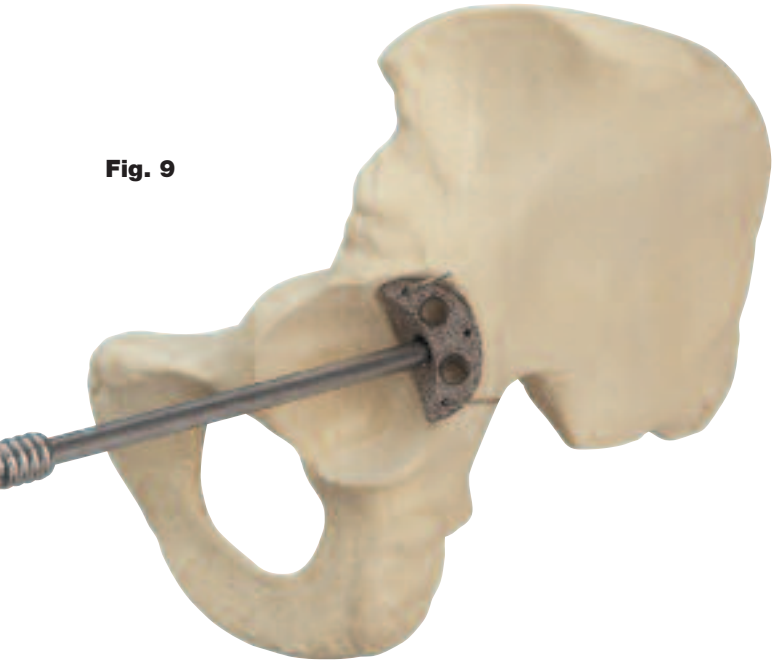
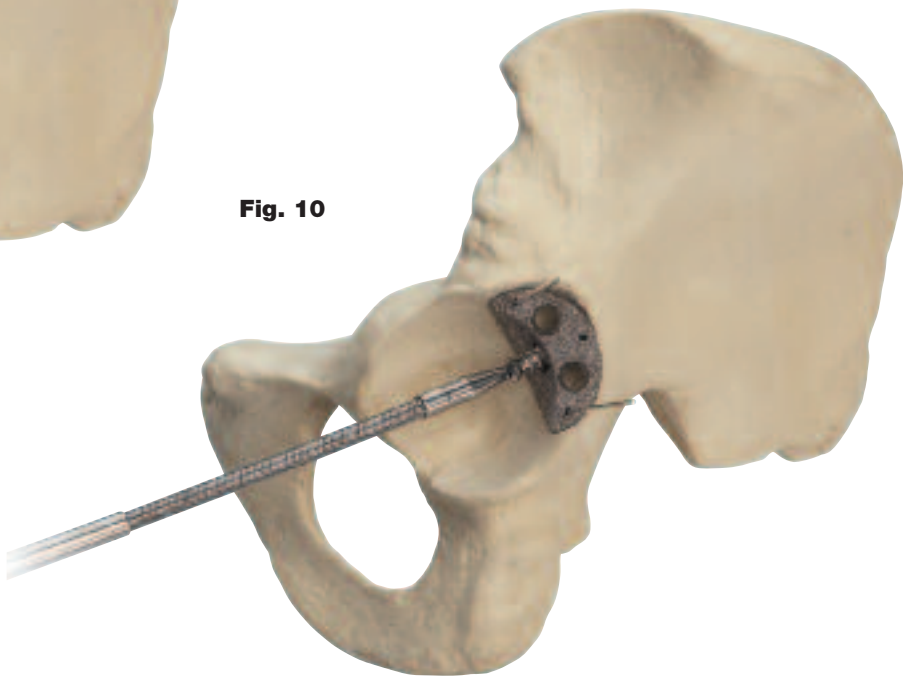


Fig. 10



Step 4: Acetabular Shell Implantation

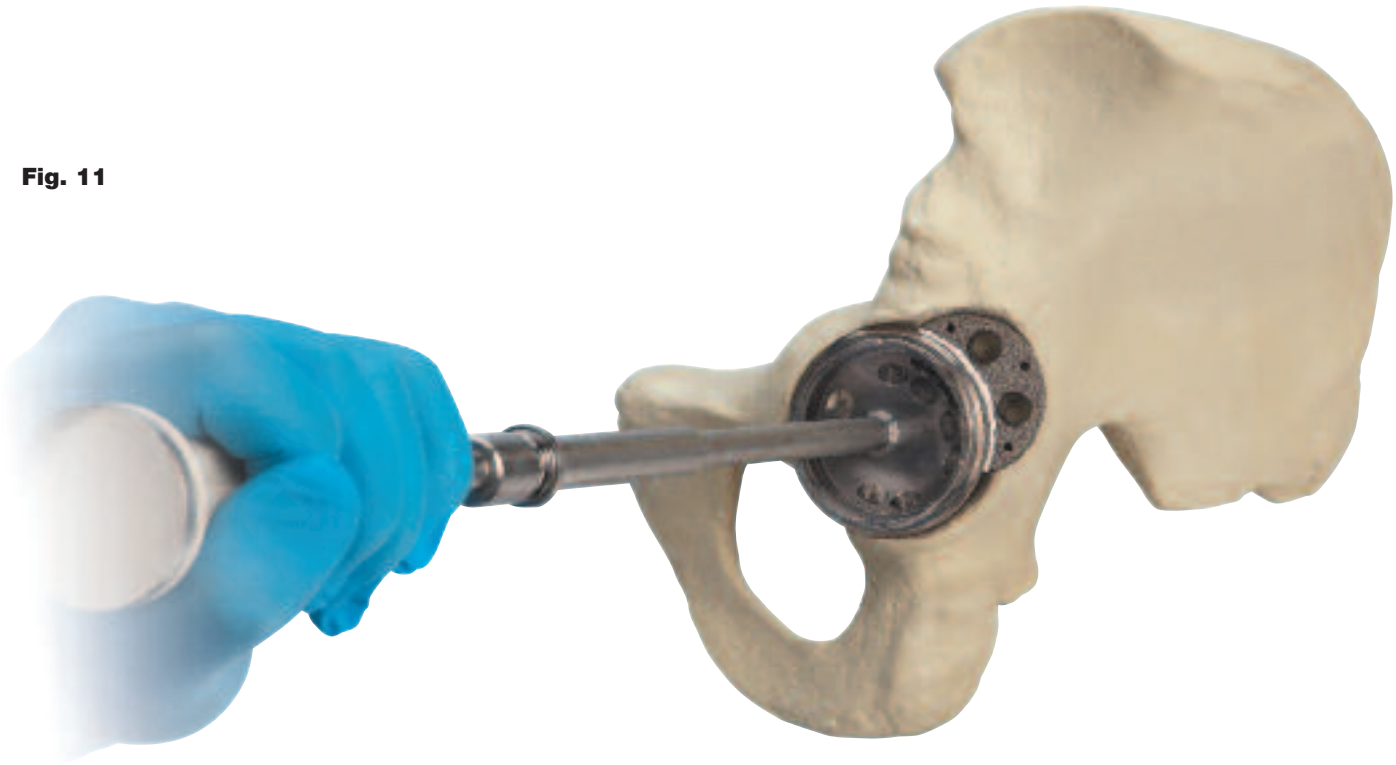
The Wedge Augment is affixed to the mating Acetabular Shell using bone cement. It is recommended to use Simplex bone cement between the Acetabular Shell and Wedge Augment. Prepare the bone cement as per the product's directions. Apply a minimum 2mm cement mantle to the Wedge Augment surface interfacing with the Shell, ensuring there is complete cement coverage between the interfacing surfaces.

Insert the Acetabular Shell into the desired position and hold in place (**Figure 11**). Remove excess cement. After determination of the proper site for screw placement and rigid fixation of the Acetabular Shell to host bone, pass a 3.2mm drill through a drill guide to the desired depth.

Note

Care should be taken to avoid interference with any pre-existing screws.

Fig. 11



Step 4: Acetabular Shell Implantation *(continued)*

The screw hole is then sounded to determine the depth of the hole. The properly sized 6.5mm screw is then selected and implanted into the bone using a Stryker Orthopedics Screw Driver with a high torque configuration driver head. Screw preparation and insertion through the Acetabular Shell must be performed while cement is in a doughy state.

After screw implantation, assess that the screw head is flush against the Acetabular Shell to help ensure proper seating of the Acetabular Insert and Acetabular Shell.

A sufficient number of screws should be used to attain rigid fixation of the Acetabular Shell.

Thorough knowledge of the acetabular anatomy is required in order to avoid injury to the neurovascular structures in the vicinity.

Note

In hard bone, the use of 6.5mm dome screws prepared with a 3.2mm drill may be difficult. The use of a 4.0mm drill bit can make the insertion of bone screws easier, without substantial compromise of screw purchase.

Caution

Do not pass a drill, screw or any other instrumentation beyond the inner table of the pelvis. Malposition of either the shell screw hole orientation, screw hole preparation or improper use of the screws themselves may result in injury to the neurovascular structures in the vicinity.

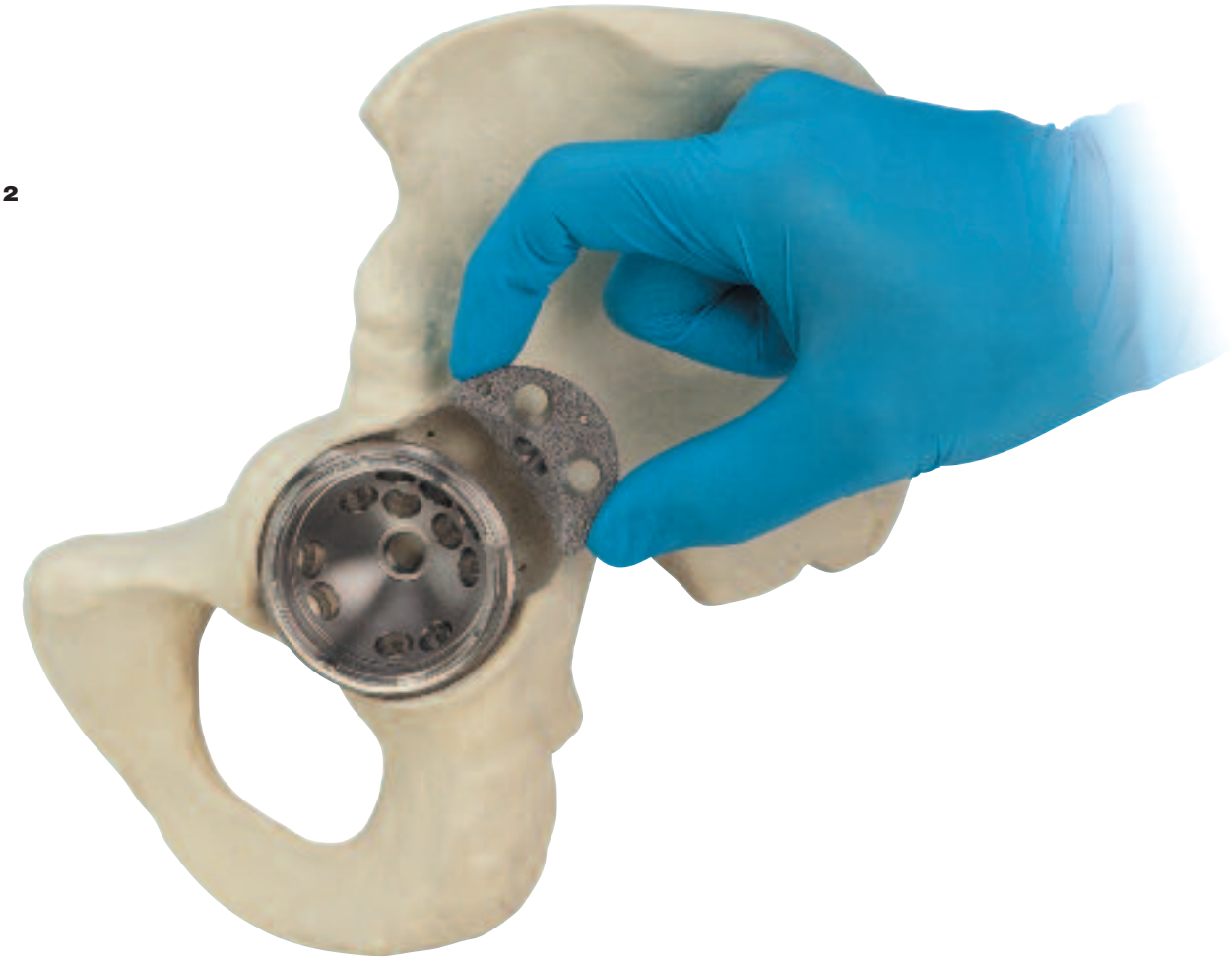
Optional:
Inserting the Acetabular Shell Before the Wedge Augment

There are some clinical situations where the Acetabular Shell is implanted and insufficient stability is attained. This situation may require the insertion of a Wedge Augment after the Shell is implanted.

The Shell should be in the desired final position in the acetabulum. Screws may be inserted at this time if desired, keeping in mind their placement so as to not inhibit the placement of the Acetabular Wedge Augment.

In this scenario, with the acetabular shell in place, reamers cannot be safely used to mill a space for the wedge augment. As such, a burr may be utilized, but care should be taken to avoid the generation of debris by avoidance of contact of the burr with the acetabular shell and screws. Trialing and implantation of the Wedge Augment is performed as described previously (**Figure 12**).

Fig. 12



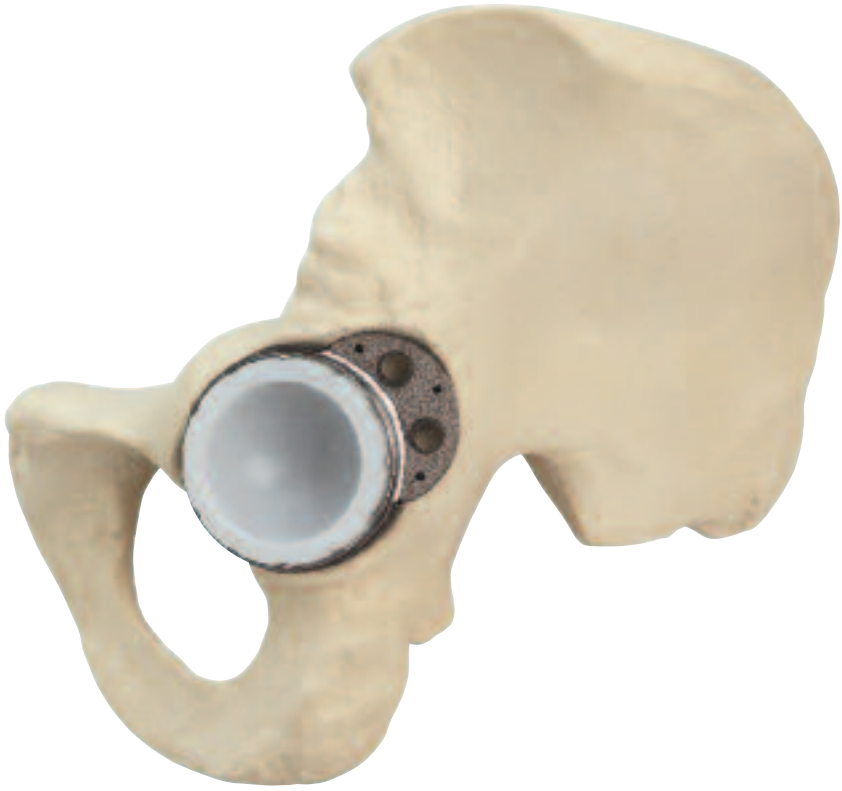
Step 5: Trial Insert Reduction

After the Acetabular Shell and Wedge Augment have been implanted, place the Trial Insert into the Acetabular Shell. At this point, the patient should be taken through a complete range of motion using the final selected implant sizes. Careful assessment of impingement at extreme range of motion should be performed. A final check of hip mechanics should be completed to include range of motion consistent with the patient's normal daily activities. At this point, joint laxity should also be assessed, understanding the type of anesthetic used and its effects of soft tissue.

Step 6: Acetabular Insert Implantation

Refer to Stryker Acetabular Shell surgical protocol for instructions on acetabular insert implantation.

Note For complete instructions on shell, insert and head implantation, refer to the corresponding Stryker Acetabular System surgical protocol.



Restoration Wedge Augment, Tritanium Shell and X3 Liner

Implant Ordering Information

Restoration Acetabular Wedge Augment Implants

Catalog No.	Description
5096-4615	46mm OD x 15mm Thickness
5096-4620	46mm OD x 20mm Thickness
5096-4625	46mm OD x 25mm Thickness
5096-5015	50mm OD x 15mm Thickness
5096-5020	50mm OD x 20mm Thickness
5096-5025	50mm OD x 25mm Thickness
5096-5415	54mm OD x 15mm Thickness
5096-5420	54mm OD x 20mm Thickness
5096-5425	54mm OD x 25mm Thickness
5096-5815	58mm OD x 15mm Thickness
5096-5820	58mm OD x 20mm Thickness
5096-5825	58mm OD x 25mm Thickness
5096-6215	62mm OD x 15mm Thickness
5096-6220	62mm OD x 20mm Thickness
5096-6225	62mm OD x 25mm Thickness
5096-6615	66mm OD x 15mm Thickness
5096-6620	66mm OD x 20mm Thickness
5096-6625	66mm OD x 25mm Thickness

Stryker Orthopaedics Cancellous 6.5mm Bone Hex Screws*

Catalog No.	Screw Length (mm)
5260-5-012*	12
5260-5-014*	14
5260-5-016*	16
5260-5-018*	18
5260-5-020*	20
5260-5-022*	22
5260-5-024*	24
5260-5-026*	26
5260-5-028*	28
5260-5-030*	30
5260-5-035*	35
5260-5-040*	40
5260-5-045*	45
5260-5-050*	50

Stryker Orthopaedics Cancellous 6.5mm Bone Torx Screws

Catalog No.	Screw Length (mm)
2080-0015	15
2080-0020	20
2080-0025	25
2080-0030	30
2080-0035	35
2080-0040	40
2080-0045	45
2080-0050	50
2080-0055	55
2080-0060	60

Instrumentation Ordering Information

Restoration Acetabular Wedge Augment Trials

Catalog No.	Description
5097-4615	46mm OD x 15mm Thickness
5097-4620	46mm OD x 20mm Thickness
5097-4625	46mm OD x 25mm Thickness
5097-5015	50mm OD x 15mm Thickness
5097-5020	50mm OD x 20mm Thickness
5097-5025	50mm OD x 25mm Thickness
5097-5415	54mm OD x 15mm Thickness
5097-5420	54mm OD x 20mm Thickness
5097-5425	54mm OD x 25mm Thickness
5097-5815	58mm OD x 15mm Thickness
5097-5820	58mm OD x 20mm Thickness
5097-5825	58mm OD x 25mm Thickness
5097-6215	62mm OD x 15mm Thickness
5097-6220	62mm OD x 20mm Thickness
5097-6225	62mm OD x 25mm Thickness
5097-6615	66mm OD x 15mm Thickness
5097-6620	66mm OD x 20mm Thickness
5097-6625	66mm OD x 25mm Thickness

Ancillary Instruments†

Catalog No.	Description
702877†	Depth Gauge For Screws ø4.5/6.5mm (0-150mm)
390164†	K-Wire ø1.6x150mm (10-Pack)
5097-0800†	Modular Picador Shaft
702429†	Modular AO Handle

Cases

Catalog No.	Description
5097-1000	Upper Tray – Wedge Augment Instruments
5900-8114	Outer Case

*These products are NOT CE marked per the Medical Device Directive 93/42/EEC and cannot be marketed, put into service, or implanted in the European Union.

†All Ancillary Instruments can be visualized under X-ray.

Restoration Acetabular Wedge Augment-to-Shell Compatibility

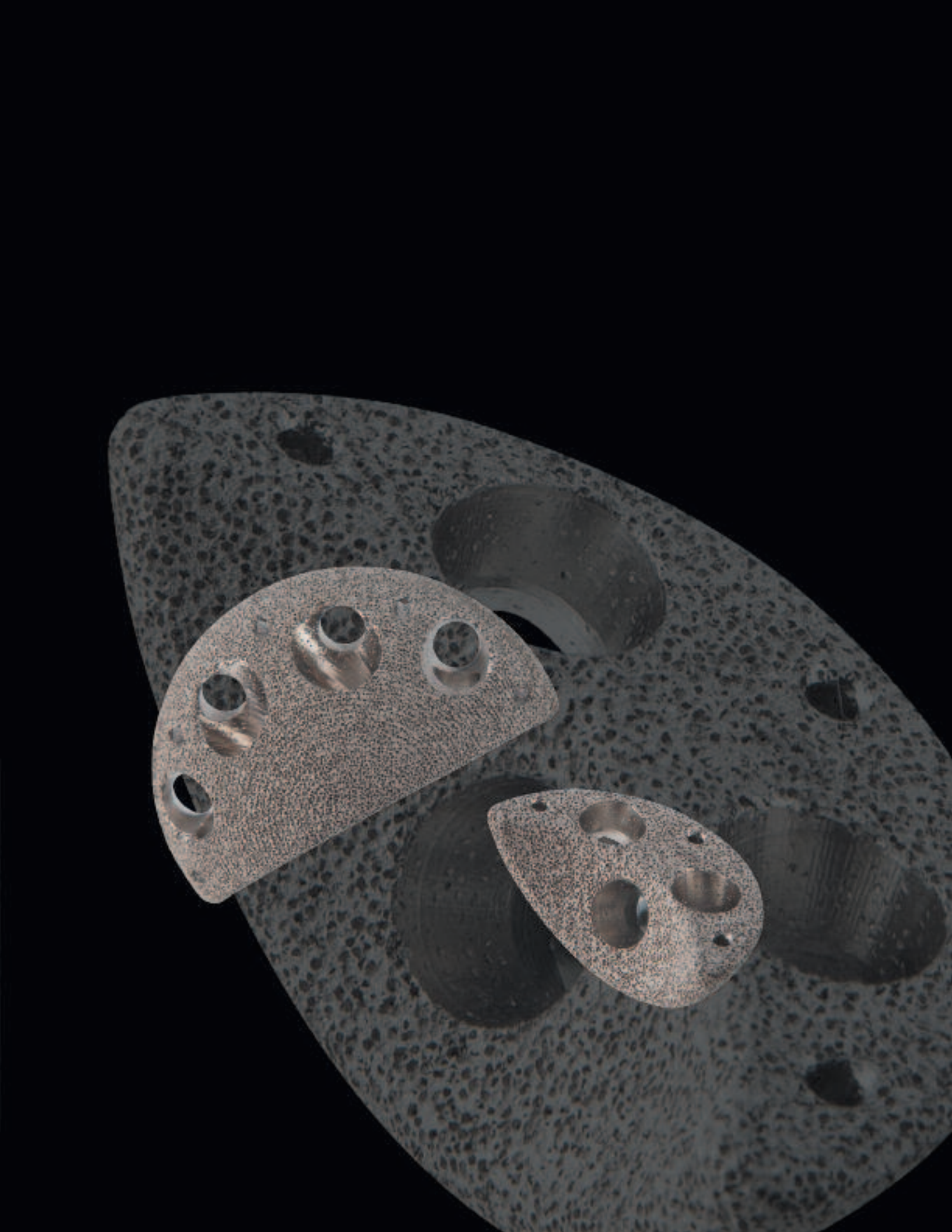
Restoration Acetabular Wedge Augments can be used with Restoration ADM, Secur-Fit, Trident and Tritanium uncemented shells

Restoration Acetabular Wedge Augments can be used with Trident all-polyethylene cemented cups

Catalog No.	Description	Size Range
509-02-XXX	Trident Tritanium Multi-Hole	54-80
500-03-XXX	Tritanium Hemispherical Solid Back	44-72
502-03-XXX	Tritanium Hemispherical Cluster Hole	44-72
502-01-XXX	Trident Hemispherical Cluster	42-74
502-11-XXX	Trident Hemispherical HA Cluster	42-74
500-01-XXX	Trident Hemispherical Solid Back	42-74
500-11-XXX	Trident Hemispherical HA Solid Back	42-74
508-11-XXX	Trident Hemispherical HA Multi-Hole	42-74
542-11-XXX	Trident PSL HA Cluster	40-72
540-11-XXX	Trident PSL HA Solid Back	40-72
65C-XXXX	Trident All Poly Cup - Crossfire	40-66
2051-20XX	Secur-Fit HA PSL	40-72
2051-30XX	Secur-Fit HA PSL - Screwless	40-72
2053-20XX	Secur-Fit HA PSL X'tra	48-80
2053-30XX	Secur-Fit HA PSL X'tra - Screwless	48-80
1235-2-XXX	Restoration ADM	46-64

Outside the U.S., Restoration Acetabular Wedge Augments can be used with either Exeter X3 RimFit or Contemporary all-polyethylene cemented cups

Catalog No.	Description	Size Range
6309-2XXX	Exeter X3 RimFit All Poly	40-60
6309-3XXX	Exeter X3 RimFit All Poly	48-60
6309-4XXX	Exeter X3 RimFit All Poly	56-60
6309-4XXX	Exeter Contemporary All Poly	44-60



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