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Trilogy®
Acetabular System

Surgical Technique

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Quick Reference Surgical Technique

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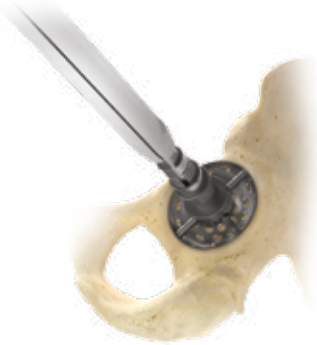

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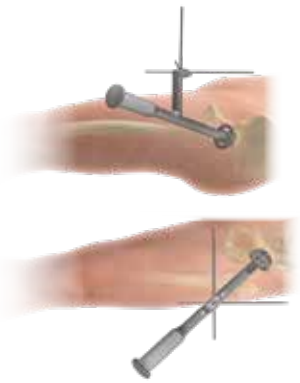

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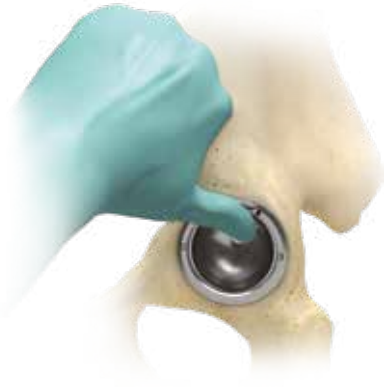

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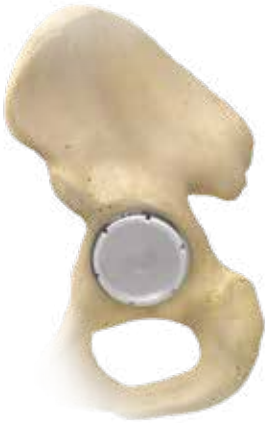


Step 7:
Final Reduction

Figure 1

Device Description

The Trilogy Acetabular System is designed to help restore kinematic function by addressing the challenges associated with primary and revision acetabular reconstruction. The full-hemisphere, modular system builds on the clinical heritage of the Harris/Galante and HGP II Porous Acetabular Components. The complete range of sizes and options, combined with proven design features, makes it possible to select an acetabular component that meets both patient need and surgeon preference.

Preoperative Templating

Accurate preoperative planning and acetabular templating help determine the size, desired location and position of the acetabular shell, and are an essential part of the surgical process. The primary goal of templating is to estimate the size and position of the acetabular implant. Templating should start with the A/P radiograph (Figure 1).

When examining the A/P radiograph, the shell should be positioned against, but not medial to, the radiographic teardrop. 45 degrees of abduction and 20 degrees of forward flexion is recommended in most cases. Use of the alignment guides with various patient positions is outlined in later sections of the technique. To avoid vertical shell placement, a line drawn along the shell template opening should intersect the obturator foramen. It may be helpful to cross-check the acetabular component size on the lateral radiograph, which can provide a view of the hemispherical subchondral bone.

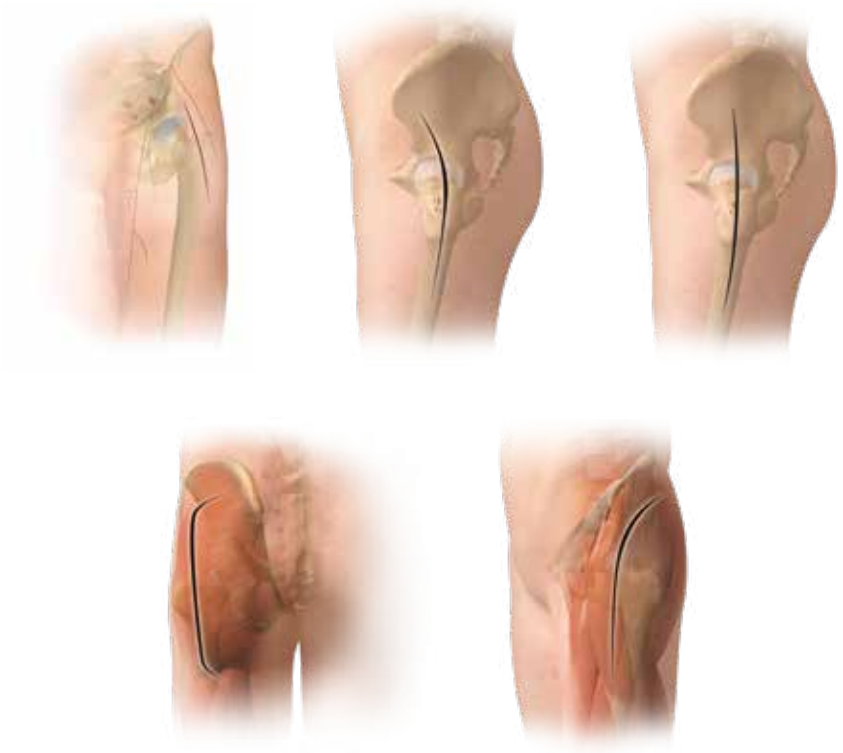


Figure 2

Preoperative Templating (cont.)

Make note of the shell size that fills the acetabular space appropriately and fits the anterior to posterior diameter of the native acetabulum, keeping in mind that final decision on shell size should be made during surgery when adequate visualization of the acetabulum is achieved.

Note: To increase the accuracy of templating, digital imaging or X-rays with magnification markers should be used. The magnification of the X-rays and the templates should be compared when sizing the Implant.

Patient Positioning

Patient position should be determined by surgeon's preferred approach (Figure 2).

Acetabular Reamer
(54 mm Reamer has a 54 mm outer diameter)

Shell Provisional
(54 mm Provisional has a 54 mm outer diameter)

Acetabular Shell
(54 mm Trilogy Cup has a 54 mm outer diameter)

Figure 3

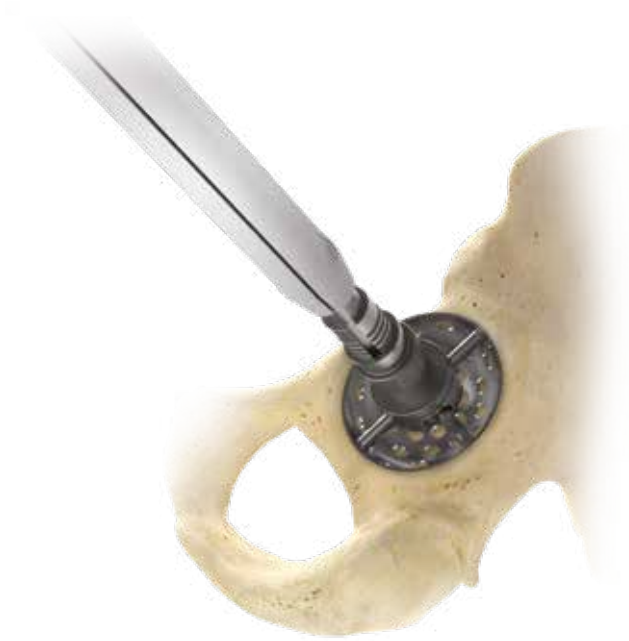


Figure 4

Acetabular Exposure

Excise the acetabular labrum and remove any large peripheral osteophytes. Excise the ligamentum teres to expose the true floor of the acetabulum.

Ensure visualization of the entire bony rim of the acetabulum to reduce the likelihood of soft tissue entrapment which may prevent the shell from seating during insertion.

Acetabular Reaming

Determine the desired head position based on templating and preoperative planning.

The labeled outside diameter (OD) of the acetabular shell represents the true hemispherical diameter of the implant (Figure 3). An appropriate undersized reamer must be used to prepare the acetabulum if a press-fit condition is desired.

Warning: The Trilogy Acetabular Shell is a full hemisphere, and adequate bone stock is necessary for a press-fit application.

Note: A shell sized 2 mm over the reamed preparation (size of last reamer shell used) will provide a 2 mm press-fit.

Start with a smaller reamer and proceed to the next largest reamer in 1-2 mm increments. Hold the reamer assembly steady to avoid eccentric reaming (Figure 4). Reaming depth is based on bone quality, but usually is completed after bleeding cancellous bone is exposed.

Figure 5a

Figure 5b

Figure 5c

Optional Shell Trialing and Alignment

Ensure the patient is in the correct position. Select the provisional shell that is the same size as the last even-numbered reamer used. Thread the provisional shell onto the positioner securely.

You may use the Trilogy Cup Positioner (Figure 5a), or either the straight shell inserter (Figure 5b) or the hybrid offset shell inserter (Figure 5c) with the appropriate hybrid shell adaptor to insert the provisional shell. Refer to the Shell Inserter Diagram in the Appendix for additional information.

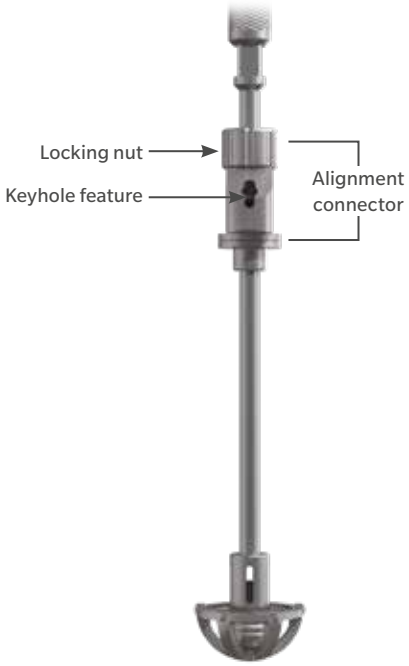


Figure 6

Figure 7a

Figure 7b

Optional Shell Trialing and Alignment (cont.)

If using the Trilogy Cup Positioner, thread the shell provisional onto the positioner until secure. Rotate the alignment connector so that the keyhole feature faces out of the wound. Fix the alignment connector in place by tightening the locking nut (Figure 6).

If using the straight shell inserter or hybrid offset shell inserter, place the appropriate hybrid rim adaptor onto the tip of the inserter. Insert the ball head hex driver through the window and into the locking screw at the tip of the inserter. While holding the shell provisional in place, thread the locking screw into the polar hole of the shell provisional until secure (Figure 7a-b).

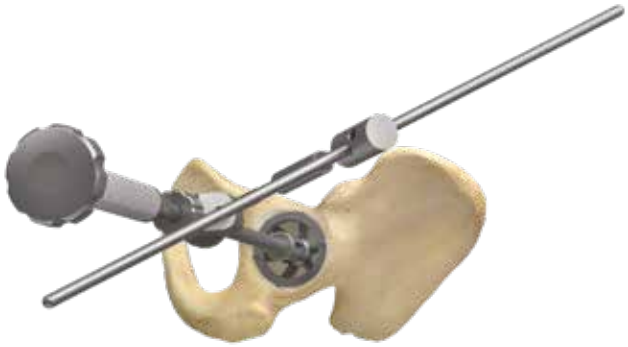


Figure 8a

Figure 9a

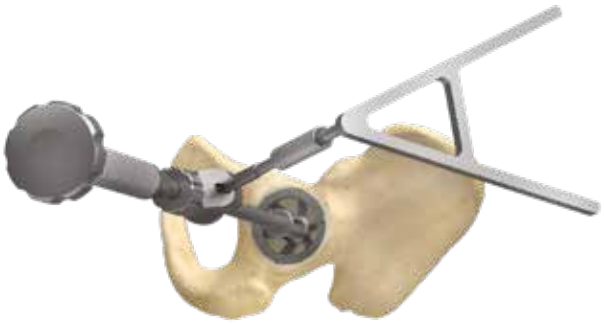


Figure 8b

Figure 9b

Optional Shell Trialing and Alignment (cont.)

Optional lateral and supine alignment guides are designed to aid in proper insertion of the acetabular component. "A-frame" alignment guides and "gun-sight" alignment guides are available for each of the handles designed to insert Trilogy Shells.

Attach the alignment frame or gunsight alignment guide to the Trilogy Cup Positioner by using the small slap hammer on their shafts to impact the guide into the keyhole of the alignment connector. Rotate the alignment connector so that the alignment guide is in the appropriate position relative to the desired screw hole orientation. Fix the alignment connector into place by tightening the locking nut (Figures 8a-b). If using either the lateral or supine gunsight guide, insert the alignment rod into the appropriate left or right hole.

Attach the alignment frame or gunsight alignment guide to the straight shell inserter or hybrid offset shell inserter and secure by tightening the thumb screw (Figure 9a-b).

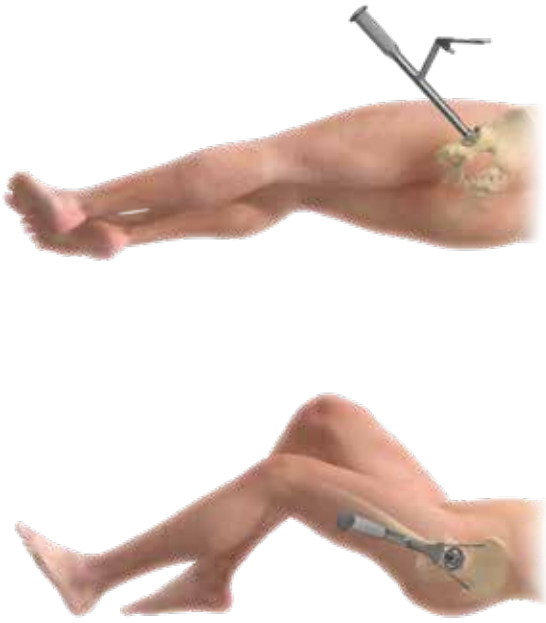


Figure 10

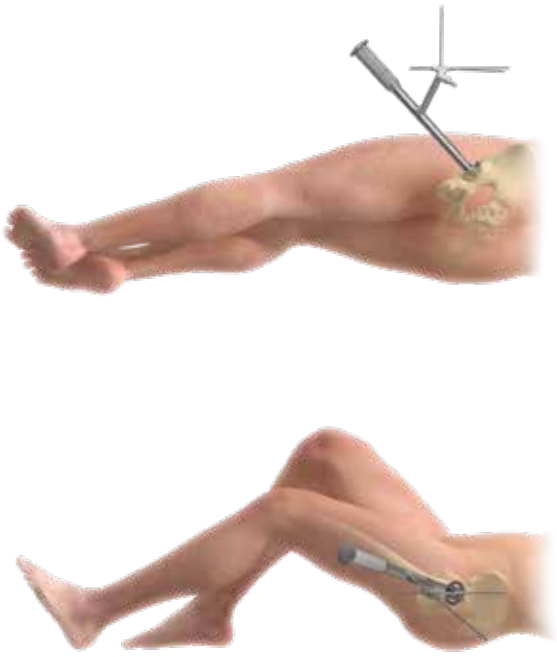


Figure 11

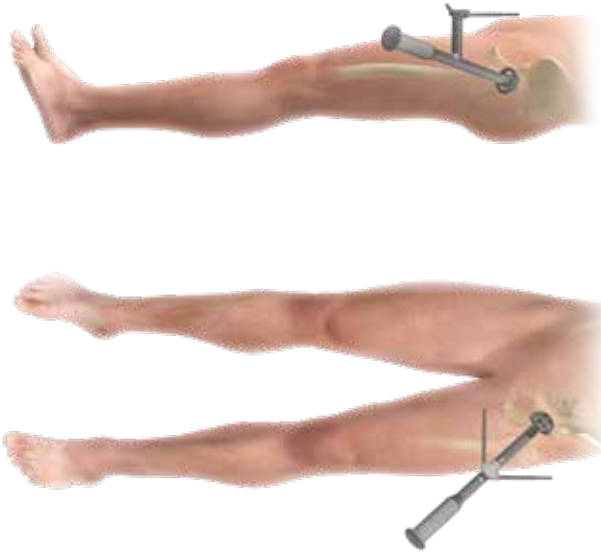
Optional Shell Trialing and Alignment (cont.)

Lateral Patient Positioning: A-frame

Insert the shell provisional or implant into the prepared acetabulum. To achieve 45 degrees of abduction and 20 degrees of forward flexion, ensure that the alignment frame is parallel to the floor and the anterior rod of the alignment frame is in line with the longitudinal body axis (Figure 10).

Lateral Patient Positioning: Gunsight

Insert the shell provisional or implant into the prepared acetabulum. The gunsight alignment extension needs to be parallel with the longitudinal body axis to achieve a 45 degree inclination (abduction) and 20 degrees of forward flexion (Figure 11).



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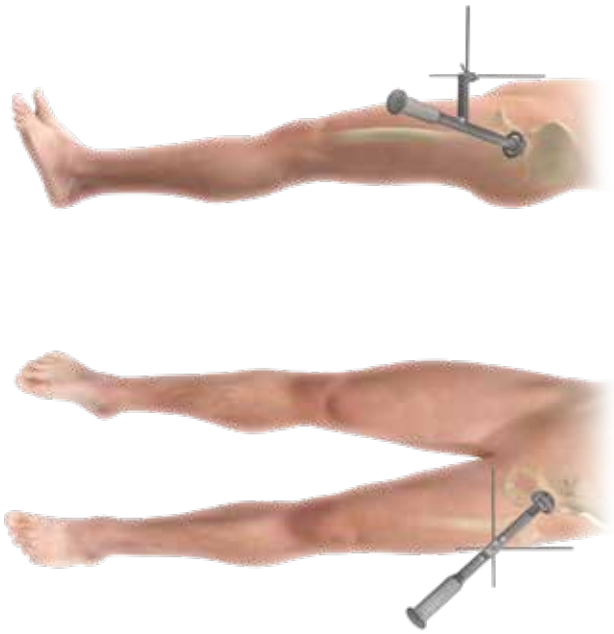


Figure 13

Optional Shell Trialing & Alignment (cont.)

Supine Patient Positioning: A-frame

Insert the shell provisional or implant into the prepared acetabulum. To achieve 45 degrees of abduction and 20 degrees of forward flexion, ensure that the alignment frame is parallel to the floor and the lateral arm is parallel with the longitudinal body axis (Figure 12).

Supine Patient Positioning: Gunsight

Insert the shell provisional or implant into the prepared acetabulum. The gunsight alignment extension needs to be parallel with the longitudinal body axis to achieve a 45 degree inclination (abduction) and 20 degrees of forward flexion (Figure 13).

Note: Patient positioning is the same for the straight inserter, hybrid offset inserter and Trilogy Cup Positioner.

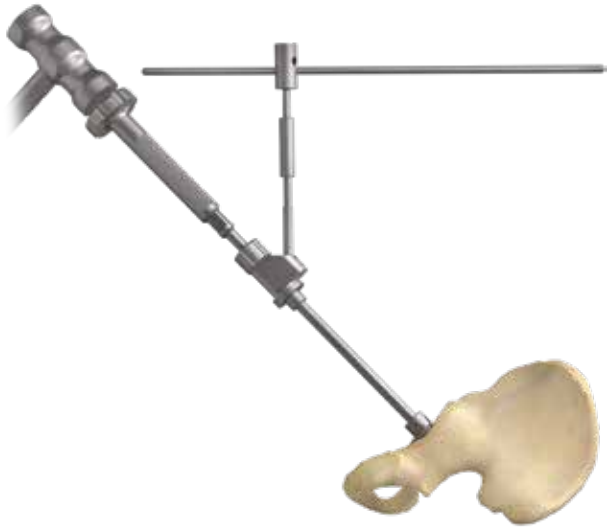


Figure 14

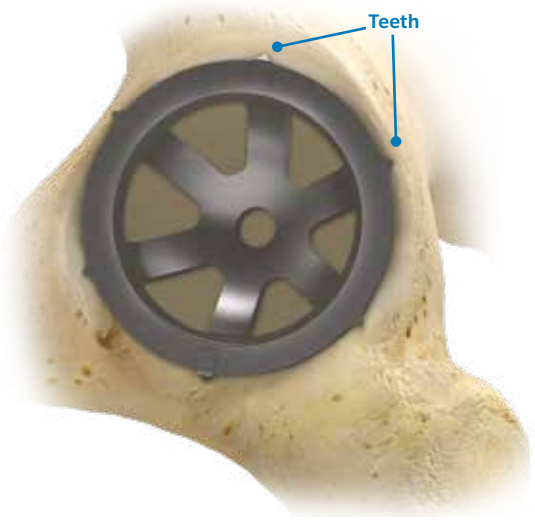


Figure 15

Optional Shell Trialing & Alignment (cont.)

With the shell provisional in the appropriate alignment, use a mallet to impact the handle of the inserter (Figure 14).

The shell provisional has windows to assess proper shell seating inside the acetabulum. When the shell provisional is fully seated, unscrew the positioner from the shell provisional if using the Trilogy Cup Positioner. If using the straight or hybrid offset inserter, reinsert the ball hex driver into the locking screw and turn it counterclockwise. Remove the inserter.

Note: The provisional shell has protruding, 1 mm teeth around the rim for stability during trial reduction. (Figure 15).

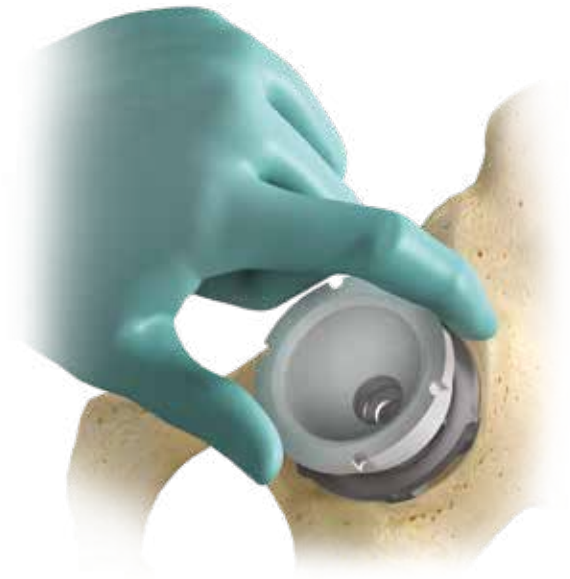


Figure 16

Figure 17

Liner Trialing with Provisional Shell

Select the provisional liner size that matches the previously selected provisional shell. Insert the provisional liner by hand into the provisional shell (Figure 16).

Trial Reduction and Range of Motion

Perform trial reduction. After determining the appropriate style, face angle, and position, mark the bone opposite the positioning mark on the liner. This mark serves as a reference later when positioning the definitive implant.

Note: The provisional liner polar screw can be used to lock the provisional liner and provisional shell together during trial reduction (Figure 17).

Warning: Do not impact the provisional liner as damage may occur.

Make certain that prominent impinging bone and/or osteophytes are removed from the periphery of the acetabulum to maximize range of motion and stability. Make note of all provisional components used before removing all provisionals.

Note: Refer to Zimmer Biomet's product compatibility website, www.zimmerbiomet.com, to determine compatibility among all selected components.

Figure 18a

Figure 18b

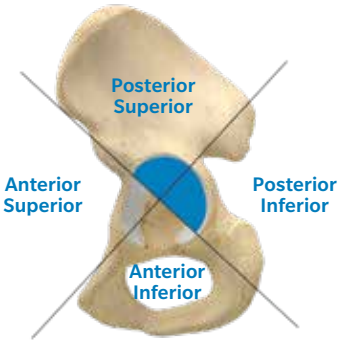


Figure 19a

Figure 19b

Acetabular Shell Insertion

Similar to provisional shell insertion, the Trilogy Cup Positioner, or the straight shell inserter or hybrid offset inserter with the appropriate adaptor may be used for final shell insertion.

To insert the implant, follow the same procedure described previously for inserting provisional shells using the corresponding inserter.

With the implant in the appropriate position and alignment, use a mallet to impact the handle of the inserter. The impact required to seat the implant is dictated by the bone quality. Due to impaction, it may be necessary to periodically re-tighten the collet, locking nut, or locking screw depending on the inserter used.

Note: If using the Trilogy Cup Inserter, a rim impactor can also be to impact the shell. Remove the cap from the cup positioner and replace the rim impactor (Figure 18a-b). The rim impactor size should correspond with the implant size selected. The implant should be threaded onto the positioner securely. The force of impaction will be applied primarily to the rim of the implant.

When the implant is fully seated, unscrew the positioner from the shell, and then remove the inserter. Do not lever on the shell or the shell inserter to reposition the implant, as damage may occur to the threads of inner diameter of the shell.

Note: The potential for neurologic and vascular injury can be minimized if the posterior quadrants are used for transacetabular screw placement. The shell should be positioned to allow screw placement in the posterior superior and/or posterior inferior quadrants of the acetabulum (Figure 19a-b)

Figure 20

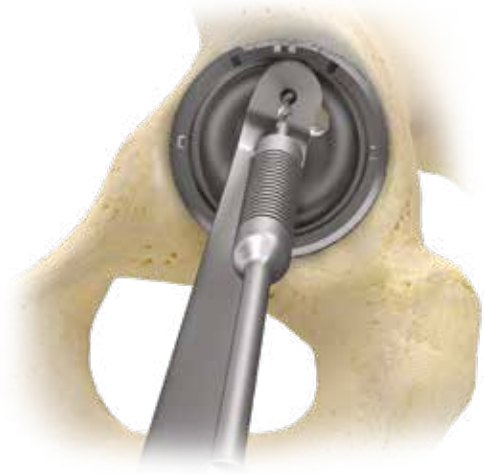


Figure 21

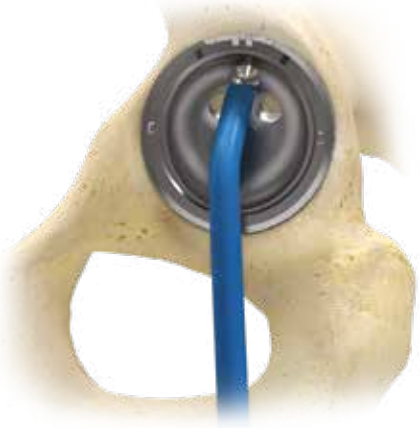
Figure 22

Supplemental Screw Fixation

Choose screw placement carefully to avoid injury to neurovascular structures. Begin by drilling a pilot hole. To do so, attach the appropriate length bit to the modular flex shaft using the hex wrench (Figure 20) Position the adjustable drill guide and flex drill into the selected screw hole (Figure 21). The screw angle may be adjusted by as much as 18 degrees in any direction. The effective lengths of the three drill bits available are 15 mm, 30 mm and 45 mm.

Once the drill bit is completely seated into the drill guide, the drilled holes will correspond to the effective length of the drill bit. For sclerotic bone, tapping the screw hole may be an option. Attach the modular tap shaft into the modular handle by pulling back on the snap-lock collet and aligning the hole in the shaft with the etched line on the collet. Attach the appropriate tap to the modular tap shaft. Bi-cortical tapping the entire depth should be done with care by turning the tap handle clockwise.

Note: To loosen the set screw, turn it counter-clockwise until the thread fully disengages from the flexible shaft. The set screw will be captured in the flexible drill shaft between the threads and the screw stop (Figure 22). Alternatively, the set screw can be removed by turning it clockwise to fully disengage the set screw and placed into the set screw holder in the instrument tray. After either loosening or removing the set screw, remove the drill bit.



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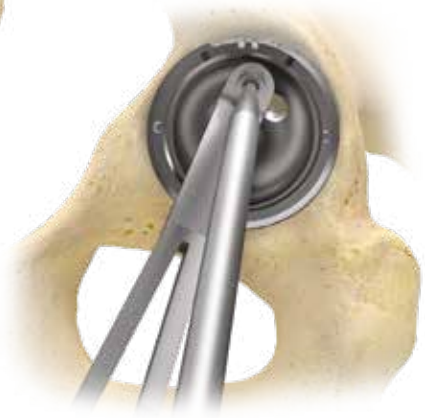


Figure 24

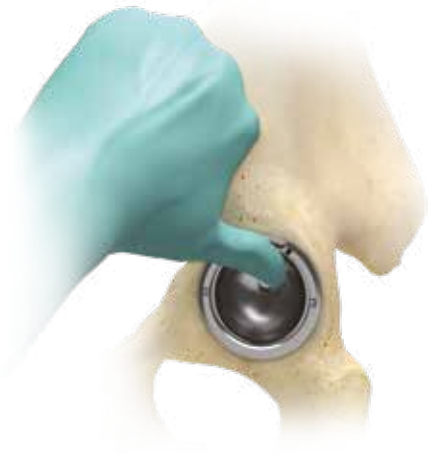


Figure 25

Supplemental Screw Fixation (cont.)

After drilling the pilot or tapping the screw hole, use the depth gauge to measure the depth of the screw hole (Figure 23). Select the appropriate length Trilogy Screw. Use a screwdriver to insert it into the selected screw hole (Figure 24).

Screws cannot be inserted into the polar hole at the dome of the shell. Place additional screws as necessary. Carefully evaluate the bone quality, and avoid over tightening the screws.

To remove a screw, engage the screw with a hex head driver and turn it counterclockwise.

Note: Countersink screw heads below the interior surface of the shell to prevent the liner from contacting the screw head. Ensure that the screw heads are properly seated (Figure 25). Screw heads that protrude in to the inner shell can prevent adequate seating of the liner. Use a 3.2mm diameter drill prior to inserting of the 4.5mm or 6.5mm diameter screws. Avoid penetration beyond the inner cortex of pelvis when drilling holes and inserting screws.

Figure 26

Figure 27

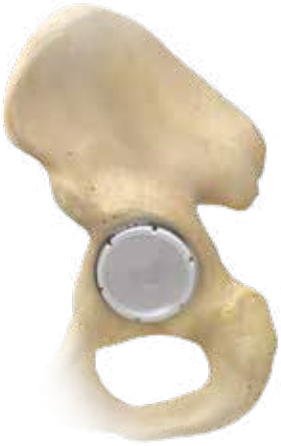


Figure 28

Optional Liner Trialing with Final Implant

Ensure the interior of the shell is dry and free of debris and overhanging soft tissue is removed. Insert the provisional liner into the prosthesis to check for appropriate style, face angle, and position. The anti-rotational slots on the provisional liner should line up with the two anti-rotational tabs and black etch marks located on the rim of the shell (Figure 26).

Polyethylene Liner Insertion

Push the liner into the shell (Figure 27). Impaction may be necessary to fully engage the liner into shell. Watch for the locking tabs to open and then close together. There will be a 2 mm to 3 mm gap between the locking ring tabs. The prosthetic liner is fully seated when the locking ring tabs can be moved from side-to-side with a probe. The ring serves to lock the liner in place. It must float freely inside the shell to function properly.

Final Reduction

Once final implants have been placed, perform a final reduction and assess range of motion, hip stability, and limb length (Figure 28).

Figure 30b

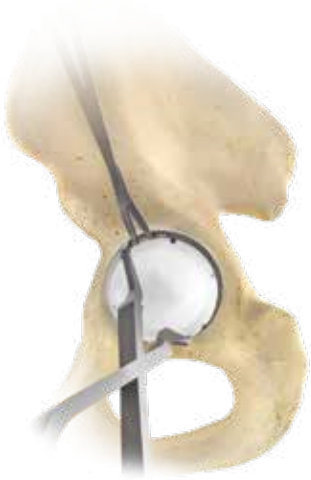


Figure 29

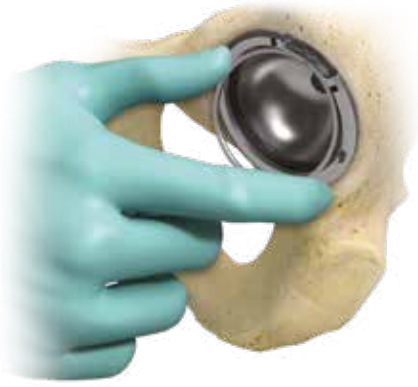


Figure 30a

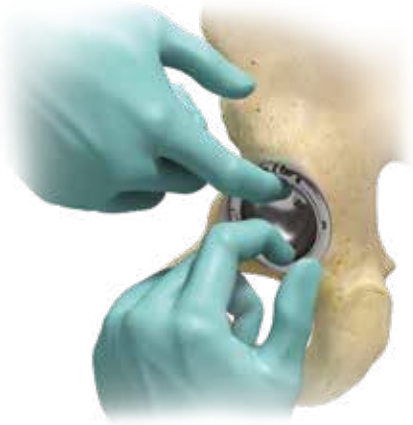


Figure 31

Implant Removal

Intraoperative Shell Removal

If you are using the Trilogy Cup Positioner, thread the inserter into the shell polar hole until it is fully engaged. Remove the positioner and shell.

If you are using the straight shell inserter or hybrid offset shell inserter, place an adapter on the end of the inserter handle. Place the inserter with attached adapter into the shell polar hole. Turn the locking screw clockwise to engage the shell with the locking screw. Remove the inserter and shell

Locking Ring Replacement and Liner Removal

If upon inspection, it is determined that the locking ring is not functioning properly or has become damaged, it must be replaced. If seated, the liner is removed using the disassembly device to open the ring, while at the same time using the liner extractor to clamp and lift the liner out of the shell (Figure 29).

To remove the old ring, push the ring to the side of the shell and grab the exposed portion on the opposite side of the shell. A firm and steady grip is required (Figure 30a-b). To insert a new ring, first insert the tabs of the ring with the text facing up into the locking ring window. Then, press the ring into place (Figure 31). When properly seated, the ring will first pop into place and then float freely in the shell. Liner assembly can now take place.

Appendix

Trabecular Metal Modular/Trilogy Acetabular System Family Tree

Acetabular Shells

Trilogy HATCP Solid, Cluster and Multi-Hole

TM Modular Solid, Cluster and Multi-Hole

Trilogy Solid, Cluster and Multi-Hole

Liners

Longevity® and Conventional Poly

Neutral

10 degree Elevated

20 degree Elevated

7 mm Offset (Longevity only)

Constrained with cutouts (Longevity only)

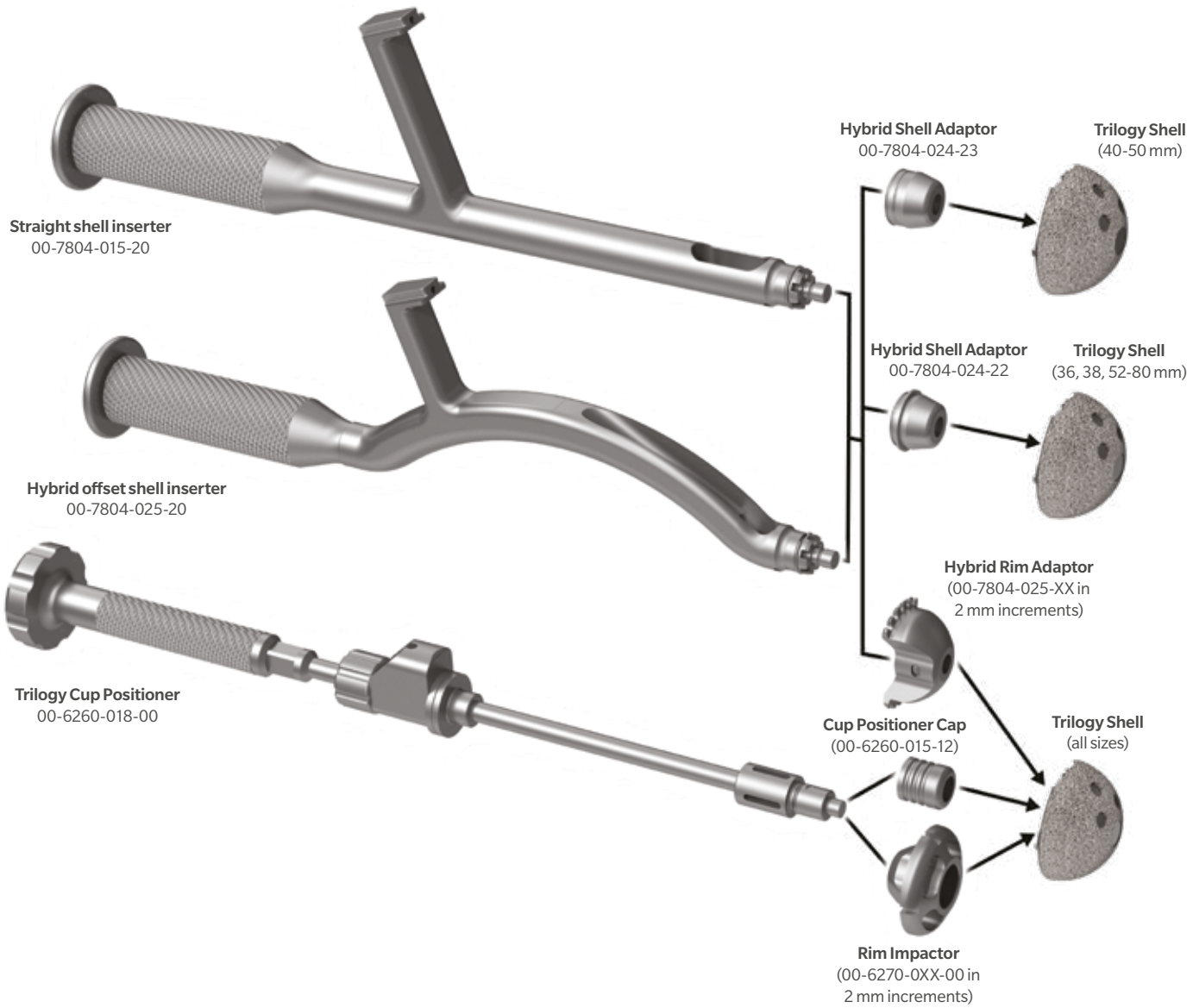
Femoral Heads

CoCr Modular

BIOLOX® *delta*

BIOLOX® *delta* Option

Shell Inserter Assembly Guide



Notes

Trilogy Acetabular System In The Magnetic Resonance (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.

Non-clinical testing has demonstrated that the TRILOGY ACETABULAR SYSTEM is MR Conditional as indicated by the symbol. A patient with this device can be safely scanned in a MR system meeting the following conditions:

MR INFORMATION

Safety information for the use of MRI procedures (i.e. imaging, angiography, functional imaging, spectroscopy, etc.) pertains to shielded MRI systems under the following specifications:

Static magnetic field of 1.5-Tesla (1.5 T) and 3.0-Tesla (3.0 T)

Maximum spatial gradient field of 1300 Gauss/cm when used with a stainless steel hip component and 2500Gauss/cm when used with a cobalt-chromium alloy or titanium alloy hip component.

Maximum MR System reported, whole-body-averaged specific absorption rate (SAR) of:

2 W/kg for 15 minutes of scanning for patient landmarks above the umbilicus and

1 W/kg for 15 minutes of scanning for patient landmarks below the umbilicus

Quadrature Transmit Mode only.

Padding for protection against Radio Frequency (RF) burns should be placed between the wall of the bore and extremities.

Insulating padding between the knees to prevent legs from touching.

Arms and hands of the patient should not touch each other implants may require a lowering of MR limits.

MR Heating

Under the scan conditions defined above, the implants are expected to produce a maximum temperature rise of less than 3ºC after 15 minutes of continuous scanning.

IMAGE ARTIFACTS

In non-clinical testing, the image artifact caused by the device extends up to 100mm from stainless steel implants and 80 mm from titanium and cobalt chromium implants when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

OTHER

In non-clinical 3.0 T testing, the materials used in Zimmer systems did not produce any magnetically induced displacement force or torque that would result in migration of the devices in the spatial gradient and static fields identified above.

This material is intended for health care professionals. Distribution to any other recipient is prohibited.

For indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert or contact your local representative; visit www.zimmerbiomet.com for additional product information.

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Check for country product clearances and reference product specific instructions for use.

Not for distribution in France.

This surgical technique is applicable to part numbers included within ordering information `1681.X-GLBL-Trilogy Acetabular System Ordering Information'

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