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Quick Reference Surgical Technique



Step 1: Preoperative Templating



Step 2: Reaming



Step 3:Shell Trialing and Alignment



Step 4:Liner Trialing with Provisional Shell



Step 5: Shell Insertion



Step 6:Supplemental Screw Fixation



Step 7: Liner Insertion



Step 8: Final Reduction

Device Description

The hemispherical design of the Continuum Shell features a Trabecular Metal™ Material surface bonded to a Tivanium® Alloy Substrate. Multiple bearing options are available, including Vivacit-E® Vitamin E Highly Crosslinked Polyethylene, Longevity® Highly Crosslinked Polyethylene, and BIOLOX®* delta Hard Bearing Liners.*

The Continuum Acetabular System is available in uni-hole, cluster hole and multi-hole shell options that, range in size from 40-80 mm (uni- and multi-hole), and 44-80 mm (cluster-hole) in 2 mm increments.



Figure 1

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. 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.

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.

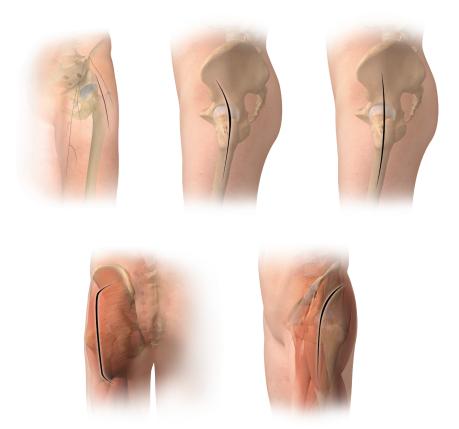


Figure 2

Patient Positioning

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

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



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

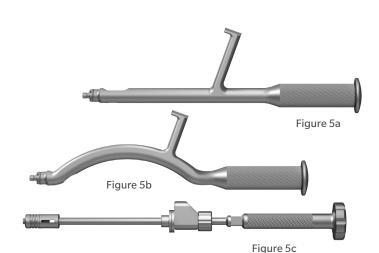
Figure 3



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



Figure 4



Acetabular Reaming

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

The labeled outside diameter 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. The amount of press fit used should be determined at the time of surgery and be based on bone quality.

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.

Optional Shell Trialing and Alignment

Proper care must be taken to assess bone quality and to determine the appropriate implant size and type. Shell implants and provisionals are labeled with the exterior size and a corresponding two letter code (e.g. 56 KK). The matching liner implants and provisionals are identified with the matching letter code and head diameter (e.g. 28 KK, 32 KK or 36 KK).

You may use the straight shell inserter (Figure 5a), hybrid offset shell inserter (Figure 5b) or the Trilogy Cup Positioner (Figure 5c) with the appropriate adapter cap to insert the provisional shell.

■ Note: The 38 mm IT provisional sizer is used to assess the size of the reamed cavity. There is no corresponding size 38 mm implant.





Figure 7



Figure 8

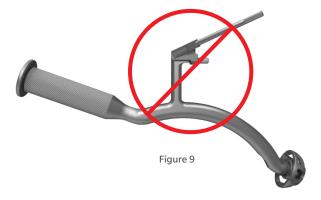
Optional Shell Trialing and Alignment (cont.)

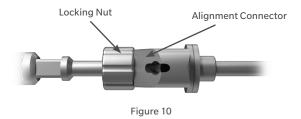
If using the straight shell inserter or hybrid offset shell inserter, place the shell inserter adapter, with or without rotational control, onto the tip of either inserter (Figure 6). Insert the ball head hex driver through the window and into the locking screw at the tip of the inserter (Figure 7). While holding the shell provisional in place, securely thread the locking screw into the polar hole of the shell provisional.

If using the Trilogy Cup Positioner, select the appropriate adapter cap based on shell size (Figure 8).

- Use the micro cap for shell sizes 40-46 mm
- Use the existing Trilogy Cap for shell sizes 48-80 mm

Thread the shell provisional onto the positioner until secure.





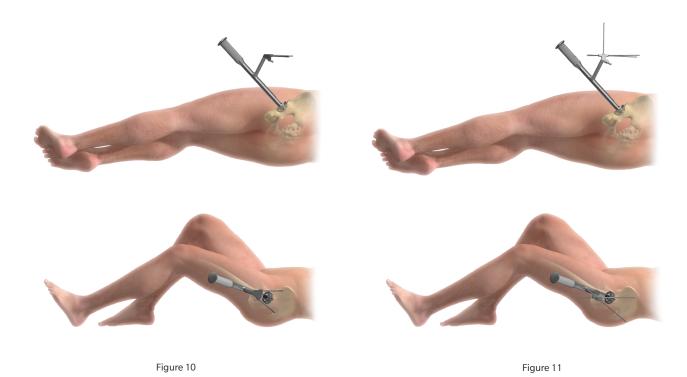
Optional Shell Trialing and Alignment (cont.)

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

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.

Note: The alignment support frame on the shell inserter will not be vertical to the floor and should not be used as a positioning guide (Figure 9). The arms on the guide are used to correctly position the provisional shell and/or implant.

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 (Figure 10). If using either the lateral or supine gunsight guide, insert the alignment rod into the appropriate left or right hole.



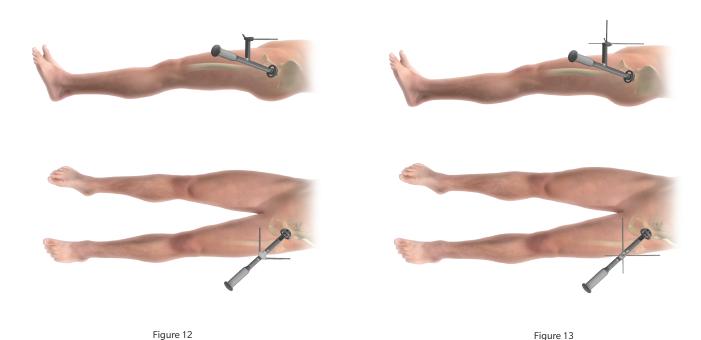
Optional Shell Trialing and Alignment (cont.)

Lateral Patient Positioning: A-frame

Insert the shell provisional into the prepared acetabulum. To achieve 45 degrees of abduction and 20 degrees of forward flexion, ensure that the arms of the alignment guide are 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 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).



Optional Shell Trialing and Alignment (cont.)

Supine Patient Positioning: A-frame

Insert the shell provisional 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 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 13

With the shell provisional in the appropriate alignment, use a mallet to impact the handle of the inserter. To prevent thread damage, verify that the locking screw is fully tightened to the shell provisional as repetitive impacts could cause the screw to loosen.

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.



Figure 14a



Figure 14b

Liner Trialing with Provisional Shell

There are two different provisional liners – one with a locking screw permanently affixed to the provisional liner (Figure 14a), and one with a locking screw that is independent of the provisional liner (Figure 14b).

■ Note: Do not remove the permanently affixed locking screw.

Select the provisional liner size that matches the selected provisional shell, identified by the size and a two letter code (e.g. 50 HH). There are different inner diameter implant sizes available for each shell size. The provisional liner will be identified by the letter code matching the shell diameter and desired inner diameter.

Both types of provisional liners are inserted the same way; however, the provisional liner with independent locking screw must first be assembled by using a hex head driver to insert the provisional locking screw through the polar hole of the provisional liner. The provisional locking screw has a silver ring.

Insert the provisional liner by hand into the provisional shell. If applicable, ensure that the anti-rotation tabs of the provisional liner are engaged in the shell scallops. Thread the locking screw into the polar hole of the shell provisional.

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



Figure 15



Figure 16

Trial Reduction and Range of Motion

Insert a head/neck provisional onto the implanted stem or rasp cone provisional and perform a trial reduction. Check for joint stability and range of motion, making necessary adjustments to restore joint mechanics. 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.

Acetabular Shell Insertion

Similar to provisional shell insertion, the straight shell inserter, hybrid offset inserter, or the Trilogy Cup Positioner may be used to implant the definitive shell.

For use with a Straight Shell Inserter or Hybrid Offset Inserter

There are two adapters for the inserter handles - one allows rotational control and one does not.

The adapter with rotational control has two pins that will fit into slots at the tip of the inserter. If this adapter is used with a cluster-hole shell, the dark etch on the adapter should be in line with the alignment frame on the inserter so that the screw holes can be positioned appropriately. (Figure 15)

Note: The adapter without rotational control will allow the implant to rotate on the inserter, and should be used when it is necessary to position the screw holes in a specific location within the acetabulum.

To insert the implant, follow the same technique for inserting provisional shells using the straight shell inserter or hybrid offset shell inserter (Figure 16).

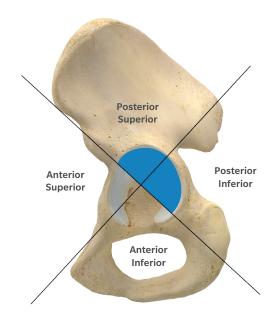


Figure 17

Acetabular Shell Insertion (cont.)

For use with a Trilogy Cup Positioner

When used with a Continuum Shell, the Trilogy Cup Positioner does not have rotational control. Therefore. control of implant orientation is at the discretion of the surgeon and can be adjusted by rotating the position of the alignment connector relative to the shaft of the Trilogy Cup Positioner.

To insert the implant, follow the same technique for inserting provisional shells using the Trilogy Cup Positioner. The impact required to seat the implant is dictated by the bone quality.

When the implant is fully seated, unscrew the positioner from the shell, and then remove the inserter.

- Note: 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. To reposition the implant, remove the shell and reinsert it to achieve desired orientation.
- **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 17).

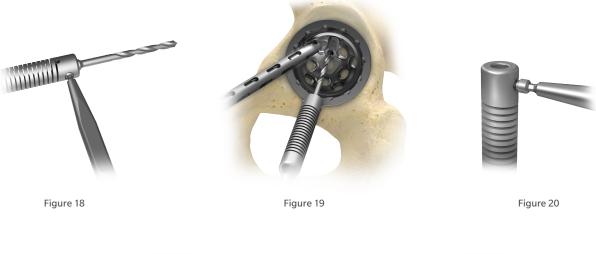








Figure 22

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 18). Position the adjustable drill guide and flex drill into the selected screw hole (Figure 19). 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 counterclockwise 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 20). 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.

After drilling the pilot or tapping the screw hole, use the depth gauge to measure the depth of the screw hole (Figure 21). Select the appropriate length Trilogy Screw. Use a screwdriver to insert it into the selected screw hole (Figure 22). 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.

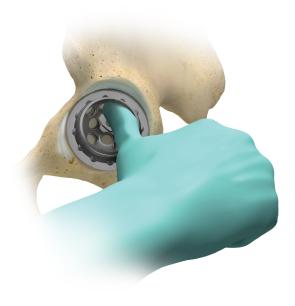






Figure 24

Supplemental Screw Fixation (cont.)

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 23). Screw heads that protrude in to the inner shell can prevent adequate seating of the liner. Use a 3.2 mm diameter drill prior to inserting the 4.5 or 6.5 mm diameter screws. Avoid penetration beyond the inner cortex of the pelvis when drilling holes and inserting screws.

Optional Screw Hole Plugs

Place a screw hole plug on the appropriate hex head driver to ensure it is perpendicular to the screw hole plug. Align the plug and screw hole until the plug clearly drops into the hole.

To lock the plug, turn it in either direction. The plug will lock in place with a partial turn. To remove the hole plug, turn in the opposite direction to release the interference fit (Figure 24). The screw hole plugs are slightly oval in shape and engage by providing an interference fit.

■ Note: The screw hole plugs cannot be used with size 40 mm and size 42 mm shells as the screw holes in these shells were not designed to accept a screw hole plug.

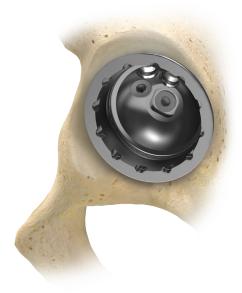


Figure 25

Optional Liner Trialing with Final Implant

Ensure the interior of the shell is dry and free of debris and overhanging soft tissue is removed. Refer to instructions for provisional liner trialing in the "Liner Trialing with Provisional Shell" section.

Optional Dome Hole Plugs

Insert a plug into the polar hole and thread it into place. When correctly inserted, the plug will be slightly inset relative to the interior surface of the shell, but it will be slightly proud within the recessed square at the pole (Figure 25).

■ Note: Do not overtighten the dome hole plug.

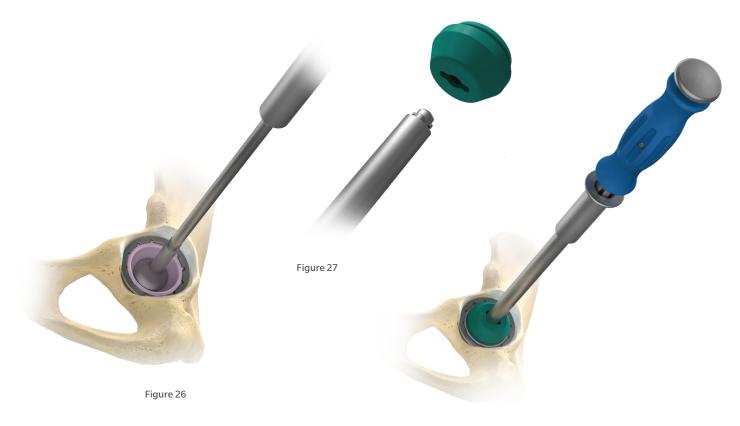


Figure 28

Liner Insertion

Ceramic Liners

Prior to inserting the hard bearing liner, ensure the interior of the shell, the liner, and liner insertion instrument are clean and dry. Inspect the shell to ensure that no damage occurred to the taper, dome hole plugs or screw hole plugs.

Ceramic liners can be inserted by hand or using the liner insertion instrument. If using the liner insertion instrument, insert the suction tip onto the shaft of the instrument up to the etch line. Ensure that the shaft is bottomed out in the suction cup. Saline or water can be used to lubricate the suction cup for easier assembly. Engage the liner and liner insertion instrument by depressing the suction cup in the liner. Insert the liner into the shell and remove the liner insertion instrument by lifting up on the interior rod to release the vacuum (Figure 26).

Note: Do not impact the liner insertion instrument. This is indicated on the instrument using the following symbol.

Select the correct size hard bearing rim impactor or dome impactor, which will match the implant head size (28 mm, 32 mm, 36 mm, or 40 mm). Align the pins on either the straight or curved universal handle with the keyhole slot on the underside of the impactor (Figure 27). Push the impactor onto the handle and twist it in either direction to lock it in place. Center the ceramic liner by rocking the impactor handle with the attached hard bearing rim impactor prior to impaction (Figure 28). This will decrease the likelihood of incorrect liner seating. Palpate the liner to ensure it is uniformly seated prior to impaction.

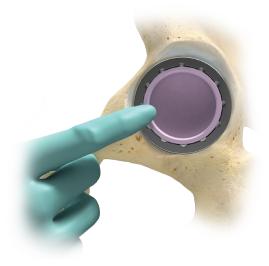


Figure 29

Liner Insertion (cont.)

Ceramic Liners (cont.)

Place the hard bearing rim impactor or dome impactor on the liner. Firmly strike the universal handle once with a mallet to fully seat the liner. Verify that the liner is properly inserted. When fully inserted, it should be flush and level to the face of the shell (Figure 29).

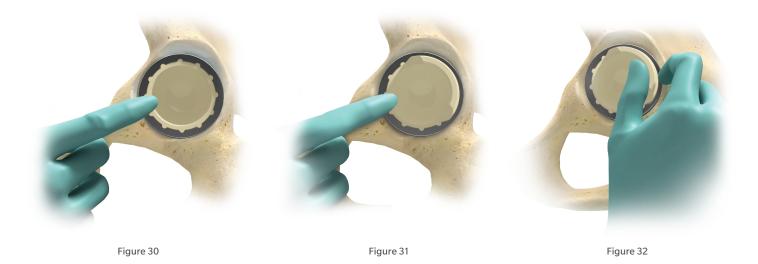
■ Note: The size 40 shells are not designed to accept the hard bearing liners and therefore do not have the integrated taper locking mechanism.

Vivacit-E and Longevity Polyethylene Liners

Vivacit-E Vitamin E Liners and the Longevity Liners have identical geometries.

Prior to inserting the Vivacit-E Liner or Longevity Liner, ensure that the shell interior is clean and dry. Place the final polyethylene liner into the implanted shell by hand, or use the liner insertion instrument. If inserting by hand, spin the liner until scallops engage.

- Note: Before impaction, the polyethylene liner will not be flush with the rim of the shell.
- Note: Smaller inner diameter Longevity Liners (i.e. 22 mm) may not freely disengage from the liner insertion instrument.



Liner Insertion (cont.)

Vivacit-E and Longevity Polyethylene Liners (cont.)

Select the proper size dome impactor and attach it to the universal handle. Align the pins on the universal handle with the keyhole slot on the underside of the impactor. Push the impactor onto the handle and twist in either direction to lock it in place. Verify that the liner is in the desired position prior to impacting it. Place the impactor on the liner and strike the impaction plate until the liner is fully seated..

Note: Once the liner is seated within the shell, it cannot be removed without causing damage to the liner, necessitating removal and disposal.

Neutral Liner

Verify that the neutral polyethylene liner is properly seated by running a finger around the face of the shell to ensure the liner is flush (Figure 30).

Elevated Liner

Verify the elevated polyethylene liner is properly seated by running a finger around the exposed portion of the shell face to ensure the liner is flush relative to the face of the shell (Figure 31). If additional liner seating verification is desired, gently move the elevated portion of the liner to ensure that it is locked into place (Figure 32).

Final Reduction

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

Liner Removal

Upon removal of any liner, inspect the taper and polyethylene locking mechanisms for damage. Take special care not to lever against the shell during liner removal. Once the acetabular shell taper has been deformed through assembly of a hard bearing insert, the shell should not be used with another hard bearing insert.

In the case of revisions involving possible breakage of ceramic components, use either a ceramic on polyethylene or a ceramic on ceramic articulation. If revising to a ceramic liner, the surgeon should also revise the shell. It is not recommended to use a metal on polyethylene pairing in these cases because leftover ceramic third-body particles may cause greater wear of the bearing surface.

After removing a liner, assess the stability and positioning of the newly implanted liner through trial reduction.



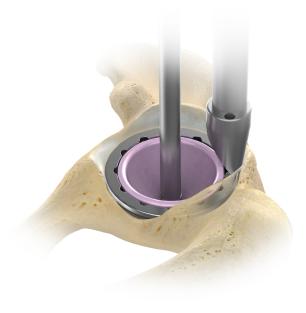


Figure 33 Figure 34

Liner Removal (cont.)

Hard Bearing Liner Removal

Attach the liner insertion instrument to the hard bearing liner by pressing the suction cup in the liner. Ensure that the liner and liner insertion tool are clean and dry prior to attachment. Attach the single point hard bearing remover to the universal handle by aligning the pins on the universal handle with the keyhole slot on the underside of the adapter. Place the tip of the single point hard bearing remover on the face of the implant shell with the alignment tab between the outside edge of the shell and the bone

between scallops on the thickest portion of the shell (Figure 33). Place the tip of the single point hard bearing remover entirely flush onto the edge of the metal shell (Figure 34). Firmly strike the universal handle once with a mallet to dislodge the liner from the shell while pulling on the liner insertion instrument.

■ Note: The single point hard bearing remover should not contact the liner during impaction.





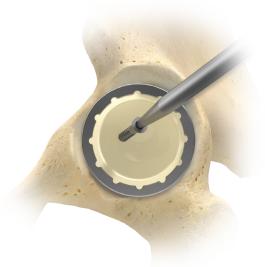


Figure 35 Figure 36 Figure 37

Liner Removal (cont.)

Polyethylene Liner Removal (Bone Screw Method)

Locate a 3.2 mm or 3.5 mm drill bit (included in the screw kit). Drill a pilot hole into the dome of the liner between the pole and the taper region of the shell. Locate a nonself-tapping screw (Figure 35). Do not use a self-tapping screw (Figure 36). Drive the screw into the pilot hole by hand until the liner is lifted out of the shell (Figure 37). Take special care not to damage the shell taper or locking mechanism during removal of the liner.

Intraoperative Shell Removal

Should it be necessary to remove the shell intraoperatively, all supplementary screws and the polar dome hole plug will need to be removed prior to shell extraction. To remove, the appropriate hex head driver is engaged with the screw or dome plug and turned counter clockwise.

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 by impacting the underside of the impaction plate.

If you are using the Trilogy Cup Positioner, place the cap on the end of the inserter. Thread the inserter into the shell polar hole until it is fully engaged. Remove the Trilogy Cup Positioner and shell.

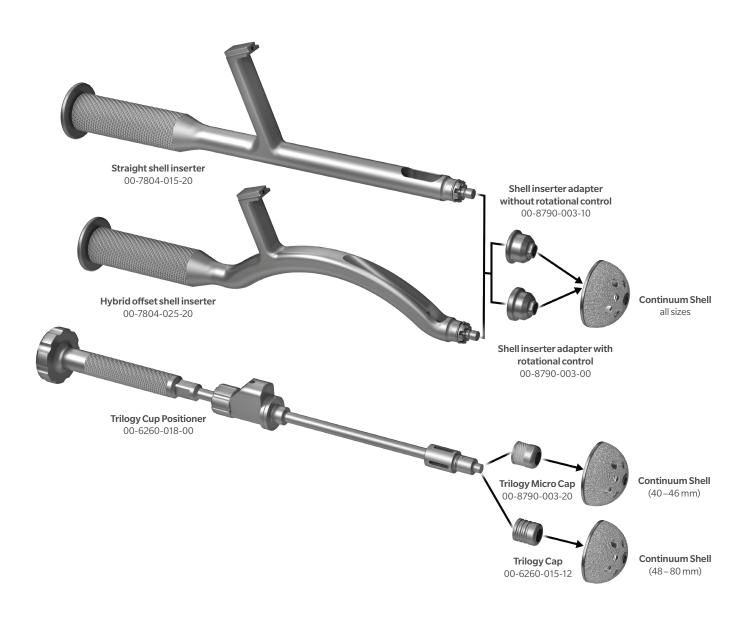
Continuum®/Trilogy® IT/Allofit® IT Acetabular **System Family Tree**



^{*}Not for sale in the US.

^{**}BIOLOX delta hard bearing liners are not available for commercial distribution in the U.S.

Shell Inserter Assembly Guide



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