Device Description

- The Continuum Shell is hemispherical in shape with an exterior of Trabecular Metal™ Material that is bonded to a Tivanium® alloy substrate. The Shell has a snap fit locking groove for acceptance of the Vivacit-E® Vitamin E Highly Crosslinked Polyethylene Neutral or Elevated Liners and the Longevity® Highly Crosslinked Polyethylene Neutral or Elevated Liners. Twelve scallops, equally spaced in 30° increments, included on the Shell face mate with twelve anti-rotation tabs on the Vivacit-E Vitamin E and Longevity Liners. The Shell also has an integrated locking taper mechanism designed to accept Metasul® Hard Bearing Liners.

Indications/Intended Use

Vivacit-E Vitamin E Highly Crosslinked Polyethylene Longevity Highly Crosslinked Polyethylene Liners

- The system is indicated for primary or revision surgery in skeletally mature individuals for rehabilitating hips damaged as a result of noninflammatory degenerative joint disease (NIDJD) or its composite diagnoses of osteoarthritis, avascular necrosis, protrusio acetabuli, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

- The system is intended for use either with or without bone cement in total hip arthroplasty.

Metasul Metal-on-Metal Technology

- Noninflammatory degenerative joint disease (NIDJD) including avascular necrosis, osteoarthritis, post-traumatic arthritis and congenital hip dysplasia and inflammatory joint disease (IJD), e.g. rheumatoid arthritis if bone quality is adequate.

- Failed previous surgery where pain, deformity, or dysfunction persists.

- Revision of previously failed hip arthroplasty.

- Total hip replacements may be considered for younger patients if any unequivocal indication outweighs the risks associated with the age of the patient and modified demands regarding activity and hip joint loading are assured. This includes severely handicapped patients with multiple joint involvement, for whom an immediate need of hip mobility leads to an expectation of significant improvement in the quality of their lives.

- The system is intended for use either with or without bone cement in total hip arthroplasty.
Introduction

- The labeled outside diameter (O.D.) of the acetabular cup represents the true hemispherical diameter of the Implant. 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.
- Shell Implants are labeled with the exterior size and a corresponding two letter code (e.g. 56 KK). The matching Liner Implants are identified with the matching letter code and head diameter (e.g. 28 KK, 32 KK, 36 KK, 40 KK).

Templating

- The primary goal of templating is to estimate the size and position of the acetabular implant.
- 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 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. Templating should start with the A/P radiograph. (Fig. 1)
- The component should NOT be more medial than the cortyloid notch and should NOT be against the radiographic tear drop.
- To avoid vertical cup placement a line drawn along the cup 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.
- The largest component that meets these requirements should be selected. However, the final decision on component size should be made during surgery, when all aspects of the acetabulum can be fully visualized.
Surgical Approach

The Continuum Cup may be implanted using a variety of standard surgical approaches.

Note: While the surgeon’s approach may vary, the approach must provide adequate exposure to visualize the entire acetabular rim.

Acetabular Preparation

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

Note: It is important to visualize the entire bony rim of the acetabulum to reduce the likelihood of soft tissue entrapment which may prevent the cup from seating during insertion.

Note: The 38mm IT Provisional Sizer is used to assess the size of the reamed cavity. There is no corresponding 38mm Implant.

Acetabular Reaming

• From templating and preoperative planning, determine the desired head position.

• Start with a smaller reamer and proceed to the next largest reamer in 1-2mm increments. Reaming depth is based on bone quality but usually is completed after bleeding cancellous bone is exposed.

Note: Take extra care to avoid eccentric reaming by holding the reamer steady. Apply constant pressure in the recommended final Implant orientation of 45 degrees of abduction and 20 degrees of forward flexion.

Caution: Throughout the entire procedure, take care in handling sharp Implants or Instruments.

Shell Provisional Insertion and Alignment

• Proper care must be taken to assess bone quality and to determine the appropriate Implant size and type.

• You may use either the Straight Shell Inserter (Fig. 2a), Hybrid Offset Shell Inserter (Fig 2b) or the Trilogy® Cup Positioner (Fig. 2c) with the appropriate metal cap to Insert the Provisional Shell.

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 the Straight Shell Inserter or Hybrid Offset Shell Inserter. (Fig. 3)

• Insert a Ball Head Hex Driver through the window and into the locking Screw at the tip of the Inserter. (Fig. 4)

• While holding the Shell Provisional in place, securely thread the Locking Screw into the Polar Hole of the Shell Provisional.

• Attach the Alignment Frame or Gunsight Alignment Guide to the Inserter and tighten 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. (Fig. 5) The arms on the Guide are used to correctly position the Provisional Shell and/or Implant. See the diagrams for use instructions on the lateral and supine approaches (Pages 16-19).

- 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 as repetitive impacts could cause the screw to loosen.
- The Shell Provisional has fenestrations to assess proper cup seating inside the acetabulum.
- When the Shell Provisional is fully seated, turn the Driver counterclockwise to loosen the attachment Screw on the Inserter.
- Remove the Inserter.

If using the Trilogy Cup Positioner (Fig. 6):

- Select the appropriate Positioner cap based on shell size.
  - Shells 40-46mm use the Micro Cap (Fig. 7)
  - Shells 48-80mm use the existing Trilogy Cap (Fig. 8)
- Thread the Shell Provisional onto the Positioner until secure.
- Rotate the Alignment Connector to achieve desired shell screw hole orientation.
- Fix the Alignment Connector into place by tightening the Locking Nut.
- Using the small slaphammer on their shafts, impact one of the following Alignment guides in the alignment connector to engage onto the taper:
  - Lateral A-Frame Alignment Guide
  - Supine A-Frame Alignment Guide
  - Lateral Gunsight Alignment Guide
  - Supine Gunsight Alignment Guide

If using Lateral or Supine Gunsight Alignment Guide, insert Alignment Rod into appropriate hole (Left or Right).

See the diagrams for use instructions on the lateral and supine approaches (Pages 16-19).

- With the Shell Provisional in the appropriate alignment, use a mallet to impact the handle of the Positioner.
- When the Shell Provisional is fully seated unscrew the Positioner from the Shell Provisional.
- Thread the Locking Screw into the Polar Hole of the Shell Provisional.
**Provisional Liner Insertion**

**Inserting the Provisional Liner**

- There are two different Provisional Liners. One with a Locking Screw that is independent of the Provisional Liner (Fig. 9) and one with a Locking Screw permanently affixed within the Provisional Liner. (Fig. 10)

**Note:** The Permanently Affixed Locking Screw should not be removed.

- Select the Provisional Liner size that matches the selected Provisional Shell.

- The selected Shell Provisional will be identified through a 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 letter code matching the Shell diameter and desired inner diameter (e.g. 32 HH).

- 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 will have a silver ring.

- For both types of Provisional Liners, the smallest Neutral Provisional Liners in head sizes 32mm, 36mm and 40mm (32 FF, 36 HH and 40 JJ) do not have a Locking Screw and seat with a peg feature.

- 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 Provisional scallops.

**Note:** Do not impact the Provisional Liner as damage may occur.

- Thread the Locking Screw into the Polar Hole of the Shell Provisional.

**Trial Range of Motion**

- Insert a head/neck Provisional onto the Implanted Stem or Rasp Cone Provisional and perform a trial reduction.

- Check for stability and range of motion.

- Remove the Provisional components.

**Note:** Refer to Zimmer’s product compatibility website, www.productcompatibility.zimmer.com, to determine compatibility among all selected components.

**Implant Insertion**

If using the Straight Shell Inserter or Hybrid Offset Inserter:

- There are two Adapters for the Inserter Handles. The Adapter with Rotational Control locks to prevent the Implant from rotating freely on the Inserter handle. 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 to allow for Cluster Hole placement in the posterior superior and posterior inferior quadrants.

**Note:** The Shell Inserter Adapter without Rotational Control will allow the Implant to rotate freely on the Inserter. Use this Adapter when it is necessary to position the Screw Holes in a specific location within the acetabulum.

- The Shell Inserter Adapter with Rotational Control has two pins that will fit into slots at the tip of the Inserter. These pins are not found on the Shell Inserter Adapter without Rotational Control.

- To insert the Implant, follow the same procedure described previously for inserting provisional shells using the Straight Shell Inserter or Hybrid Offset Shell Inserter.

If using the Trilogy Cup Positioner:

- The Trilogy Cup Positioner does not have rotational control. 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 procedure described previously for inserting provisional shells using the Trilogy Cup Positioner.

**Fig. 9**

Provisional Liner with Independent Locking Screw

**Fig. 10**

Provisional Liner with Permanently Affixed Locking Screw
With the Implant in the appropriate position and alignment, use a mallet to impact the handle of the Inserter.

When the Implant is fully seated, turn the Driver counterclockwise to loosen the Attachment Screw on the Inserter.

Remove the Inserter.

Note: The impact required to seat the Implant is dictated by the bone quality.

Note: Do not lever on the Shell or the Shell Inserter to reposition the Implant, as damage may occur to the threads or 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. (Fig. 11) The Continuum Screw Holes are located closer to the Polar region as compared to the Trabecular Metal Shell.

Screw Insertion

If Screw placement is desired:

- Carefully following these steps for Screw insertion can help to minimize Screw push-through or torque-out after initial implantation.
- Drill a pilot hole, using either a Modular or One-Piece Flex Drill.
- If using the Modular Flex Drill attach the selected bit using the Hex Wrench. (Fig. 12) Check the bit to ensure that it is not dull.
- Position the Adjustable Drill Guide and Flex Drill into the selected Screw Hole. (Fig. 13)
- The screw angle may vary by as much as 33 degrees (inclusive). The effective lengths of the three drill bits available are 15mm, 30mm and 45mm.
- Upon seating of the drill bit completely into the drill guide, the drilled holes will correspond to the effective length of the drill bit.
- For sclerotic bone, an option may be to tap the Screw hole.
  - 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.
  - Bicortical tapping the entire depth should be done with care by turning the Tap Handle clockwise.

Set Screw Removal

- 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. (Fig. 14)
- Alternatively, the set screw can be removed by turning it clockwise to fully disengage the set screw and placing it 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. (Fig. 15)
- Select the appropriate length Trilogy Screw.
- Use a Screwdriver to insert it into the selected Screw hole. Screws cannot be inserted into the Polar Hole at the dome of the Shell. (Fig. 16)

**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. Screw heads that protrude into the inner shell can prevent adequate seating of the liner. Use a 3.2mm diameter drill prior to insertion of the 4.5 or 6.5mm diameter screws. Avoid penetration beyond the inner cortex of the pelvis when drilling holes and inserting screws. (Fig. 17)

- 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**.

**Warning:** Avoid Screw placement through the Shell into the anterior inferior and anterior superior quadrants of the acetabulum to prevent injury to the neurovascular structures.
Optional Screw Hole Plugs

Screw Hole Plug

- 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.

Note: The Screw Hole Plugs are slightly oval in shape and engage by providing an interference fit.

- 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. (Fig. 18)

Note: The Screw Hole Plugs cannot be used with 40mm and 42mm shells as the screw holes in these shells were not designed to accept a Screw Hole Plug.

Provisional Liner Positioning

- Clean and dry the cup with a sterile cloth, wipe or sponge to remove third-body debris.
- Clear all soft tissue from around the perimeter of the Shell and assess visualization.
- The smallest Neutral Provisional Liners in head sizes 32 mm, 36 mm and 40 mm (32 FF, 36 HH and 40 JJ) do not have a Locking Screw and seat with a peg feature.
- Insert the Provisional Liner by hand into the Shell.
- If applicable, ensure that the anti-rotation tabs of the Provisional Liner are engaged in the Shell scallops.

Note: Do not impact the Provisional Liner as damage may occur.

- Thread the Locking Screw into the Polar Hole of the Shell.

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. (Fig. 19)
- Take care not to overtighten the Dome Hole Plug.
Liner Insertion Instrument

Metasul Liners

- Prior to inserting the Metasul Liner, ensure the interior of the Shell, the Liner and Liner Insertion Instrument are clean and dry. Also inspect the Shell to ensure that no damage occurred to the taper, Dome Hole Plugs or Screw Hole Plugs.

- Metasul Liners can be inserted by hand or using the Liner Insertion Instrument.

- If using the Liner Insertion Instrument, follow these assembly instructions:
  - 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 tip.
  - Saline or water can be used to lubricate the suction cup for easier assembly.
  - Engage Liner and Liner Insertion Instrument by depressing the suction cup in the Liner.
  - Insert the Liner into the Shell.
  - Remove the Liner Insertion Instrument by lifting up on the interior rod to release the vacuum. (Fig. 20)

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 (28mm, 32mm, 36mm or 40mm).

- Attach the Hard Bearing Rim Impactor or Dome Impactor to either the straight or curved Universal Handle by aligning the pins on the Universal Handle with the keyhole slot on the underside of the Impactor. (Fig. 21)

- Push the Impactor onto the handle and twist it in either direction to lock it in place.
• Center the Metasul Liner by rocking the Universal Handle with the attached Hard Bearing Rim Impactor prior to impaction. *(Fig. 22)* This will decrease the likelihood of incorrect Liner seating.

• Palpate the Liner to ensure it is uniformly seated prior to impaction.

• 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. *(Fig. 23)*

**Note:** Larger sized Metasul Liners may be difficult to handle and assemble given their greater weight.
Vivacit-E Vitamin E Polyethylene Liner

Longevity Polyethylene Liner

- The Vivacit-E Vitamin E Liners and the Longevity Liners have identical geometries.
- Prior to inserting the Vivacit-E Liner or the 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 polyethylene liners (i.e. 22mm) may not freely disengage from the Liner Insertion Instrument.

- 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 the Liner.
- Place the Impactor on the Liner and strike the Liner until it is fully seated.

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

Verifying Liner Seating

**Neutral Liner** Verify that the neutral polyethylene Liner is properly seated by running finger around the face of the Shell to ensure the Liner is flush. *(Fig. 24)*

**Elevated Liner** Verify the elevated polyethylene Liner is 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. *(Fig. 25)* If additional Liner seating verification is desired gently move the elevated portion of the Liner to ensure that it is locked into place. *(Fig. 26)*

Final Reduction

Perform a final reduction and assess range of motion, hip stability, and limb length.

**Fig. 24**
Verify that the Neutral Poly Liner is properly seated into the Shell.

**Fig. 25**
Verify that the Elevated Poly Liner is seated flush into the Shell.

**Fig. 26**
Verify that the elevated portion of the Poly Liner is properly seated into the Shell.
Liner Removal

- Upon removal of any Liner, inspect the taper and polyethylene locking mechanisms for damage.
- Special care should be taken not to lever against the Shell during Liner removal.

**Metasul Liners**

- Attach the Liner Insertion Instrument to the *Metasul* Liner by pressing the Suction Cup in the Liner. Ensure 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 Single Point Hard Bearing Remover.
- 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. *(Fig. 27)*
- Place the tip of the Single Point Hard Bearing Remover entirely flush onto the edge of the metal Shell. *(Fig. 28)*
- Firmly strike the Universal Handle once with a mallet to dislodge the Liner from the Shell while pulling on the Liner Insertion Instrument.
- Once the acetabular Shell taper has been deformed through assembly of a hard bearing insert (*Metasul* insert), the Shell should not be used with another hard bearing insert.

**Note:** The Single Point Hard Bearing Remover should not contact the Liner during impaction.
Polyethylene Liner Removal (Bone Screw Method)

- Locate a 3.2mm or 3.5mm 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 non-self tapping screw. (Fig. 29)
- A self tapping screw should NOT be used. (Fig. 30)
- Drive the screw into the pilot hole by hand until the Liner is lifted out of the Shell. (Fig. 31)
- Special care should be taken not to damage the Shell taper or locking mechanism during removal of the Liner.

Intraoperative Shell Removal

If you are using the Straight Hybrid Inserter or Offset Hybrid 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 secure the locking Screw.
- Remove the inserter and Shell.

If you are using the Trilogy Cup Positioner:
- Place the cap on the end of the Trilogy Cup Positioner.
- Thread the inserter into the Shell Polar Hole until it is fully engaged.
- Remove the Trilogy Cup Positioner and Shell.
**Lateral Patient Positioning “A-Frame”**

- Insert the Shell Provisional or Implant into the prepared acetabulum.
- To achieve 45° of abduction and 20° 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. *(Fig. 32)*
- Patient positioning is the same for the Straight Inserter, Hybrid Offset Inserter and *Trilogy* Cup Positioner.
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° inclination (abduction) and 20° of forward flexion. (Fig. 33)
- Patient positioning is the same for the Straight Inserter, Hybrid Offset Inserter and Trilogy Cup Positioner.
Supine Patient Positioning “A-Frame”

- Insert the Shell Provisional or Implant into the prepared acetabulum.
- To achieve 45° of abduction and 20° of forward flexion, ensure that the Alignment Frame is parallel to the floor and the lateral arm is parallel with the longitudinal body axis. (Fig. 34)
- Patient positioning is the same for the Straight Inserter, Hybrid Offset Inserter and Trilogy Cup Positioner.
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° inclination (abduction) and 20° of forward flexion. (Fig. 35)
- Patient positioning is the same for the Straight Inserter, Hybrid Offset Inserter and Trilogy Cup Positioner.
Shell and Articulation Liner Sizing Chart

The articulation diameter along with its corresponding head diameter is represented by the number in the shaded area of the chart below (e.g. 28mm is a 28mm head and liner combination).

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* 78mm and 80mm Continuum Shells have the same inner diameter and share the same liners.
This documentation is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part. Please refer to the package inserts for important product information, including, but not limited to, contraindications, warnings, precautions, and adverse effects.

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