Surgical Technique

This device is not available for commercial distribution in the United States.
General Description of the Implant

The Maxera Cup (Fig. 1) is a monoblock BIOLOX™ delta acetabular solution that is intended to be used in conjunction with BIOLOX OPTION* and BIOLOX delta* heads with an appropriate, corresponding diameter.

Primary fixation is achieved by underreaming the acetabulum to achieve a press-fit. The external surfaces of the cup include paired fins which provide supplemental fixation and a titanium vacuum plasma spray coating (Ti-VPS) to create a scratch fit.

Patient Selection

Indications/Intended Use**

• For non-cemented use in skeletally mature individuals undergoing primary surgery for rehabilitating hips damaged as a result of noninflammatory degenerative joint disease (NIDJD) including but not limited to osteoarthritis, avascular necrosis, post-traumatic arthritis and congenital hip dysplasia and inflammatory joint disease (IJD), e.g., rheumatoid arthritis, if bone quality is adequate.

† Trademark of CeramTec GmbH

* For additional information on BIOLOX OPTION and BIOLOX delta heads, please refer to the latest version of Design Rationale Ref. 06.01454.012

**Please refer to the Package Insert for the list of contraindications
Overview of Implant Sizing

The true external diameter (Fig. 2) of the Maxera Cup component corresponds directly to the labeled size. Adequate bone stock is necessary for a press-fit application. Surgical judgment is required to assess appropriate reaming, in order to achieve an optimal press-fit. Optimal press-fit will be achieved by careful acetabular bone preparation and accurate implant placement.

Note: The Maxera Cup in sizes 50mm to 66mm is a full hemisphere while sizes 42mm, 44mm, 46mm and 48mm have an extended cylinder making them taller than a full hemisphere. (Fig. 3)

Note: The cups are labeled with their actual diameter, i.e., a cup size 44mm/56mm has an inside diameter of 44mm and an outside diameter of 56mm. An implant sized 2mm over the reamed preparation (size of last reamer used) will provide 2mm press-fit. A 1mm press-fit may be desired with hard bone.

Note: The 40mm through 47mm Shell Provisionals have an extended cylinder and duplicate the height of the implant.

WARNING: Do not attempt to remove the preassembled ceramic liner which is locked into the shell’s cavity.

The height of the Shell Provisional corresponds to the appropriate implant, i.e., the 44mm and 45mm Shell Provisional is the same height as the 46mm Maxera Cup. This allows the surgeon to accurately assess the depth and orientation of the final implant based on the trial position. We recommend careful Shell Provisional placement to assess for adequate bone preparation. When inserting the actual implant, the previous position of the Shell Provisional provides important visual cues to the surgeon that the final implant is fully seated in the desired position.

Cup component corresponds to the appropriate BIOLOX OPTION or BIOLOX delta femoral head component. (Fig. 4)

For further combination options please refer to www.productcompatibility.zimmer.com.

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**Table: Sizing Guide Matrix.**

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Fig. 2

A Maxera Cup size 36/46 has a nominal outside diameter of 46mm and an inside diameter of 36mm.

Fig. 3

Note: Extended 180° Hemisphere (40mm-47mm) and 180° Hemisphere (48mm-65mm).

Cylinder Height Comparison.
Preoperative Planning
Accurate preoperative planning and acetabular templating are essential.

Important Parameters for Planning the Procedure
- planned optimal position of the acetabular component
- center of rotation
- size of the implant
- depth
- final component position
- achieving the recommended abduction angle

Templates of the Maxera Cup component are available for preoperative planning (Fig. 5). They are available in 115% magnification for conventional radiographs and 100% magnification for digital X-rays. It is necessary to combine these templates with that of the chosen stem by making the centers of rotation correspond. The final size of the prosthesis is determined during the surgical procedure. When templating, it is important to establish the planned optimal position of the acetabular component, center of rotation, size of the implant, depth, and final component position. Achieving an abduction angle to a maximum of 45 degrees and 10 to a maximum of 20 degrees of anteversion is appropriate in most cases. Variation in placement of the cup will depend on the patient’s anatomy and intraoperative surgical judgement.

Fig. 5
AP Templating View.
Surgical Approach

The Maxera Cup may be implanted using a variety of surgical approaches. The specific approach depends on the surgeon’s preference and therefore may differ from the procedure shown.

**Note:** Each surgeon’s approach may vary. The surgical approach must provide adequate exposure to visualize the entire acetabular rim.

The Maxera Cup should not be used in cases where there is inadequate or poor bone quality to support the implant.

Acetabular Preparation

The acetabular labrum is completely excised, and any large peripheral osteophytes are removed. The ligamentum teres is excised, and the true floor of the acetabulum (i.e., true acetabular region) is identified. (Fig. 6)

**Technique Tip:** It is important to visualize the entire bony rim of the acetabulum (Fig. 7). This will help when using Shell Provisionals to assess the depth reamed. It will also reduce the likelihood of soft tissue entrapment which may prevent the cup from fully seating.
Reaming

The Maxera Cup is a full 180° hemisphere for sizes 50mm to 66mm.

Note: As previously mentioned (Page 3), the four smallest sizes (42mm, 44mm, 46mm, and 48mm) have an extended cylinder. The extended cylinder may be exposed or proud of the reamed acetabular cavity per surgeon assessment of the patient.

This technique demonstrates the use of 180° hemispherical reamers to prepare the acetabulum (Fig. 8). If another type of reamer is used, reaming should be adjusted per the surgeon’s discretion.

• Hold the reamer steady and apply pressure in the same direction that the prosthesis will be implanted. Start with a reamer at least 2–4mm smaller than the templated implant size. Care should be taken not to over-medialize.

• Acetabular reaming must progress in 1–2mm increments with frequent assessment of the depth and orientation of the prepared acetabular bone, coverage, and rim integrity (Fig. 9). To achieve the appropriate abduction angle, some of the posterior-superior portion of the implant may be uncovered, as long as adequate initial press-fit is achieved.

• Sequential reaming should be carried out until adequate acetabular preparation has been achieved, as assessed by careful use of the Shell Provisionals.

• Regular use of Shell Provisionals as reaming progresses is highly recommended to determine the depth of reaming.

• **Technique Tip:** In hard bone, it is advisable to use reamers in 1mm increments when approaching the definitive acetabular size.
Use of the Acetabular Shell Provisionals

- Place the selected size Shell Provisional inverted (i.e., cup and pins facing up) so the Inserter Handle can mate with the two pins at the pole of the Shell Provisional. Ensure that the mating shape features of the Inserter Handle are aligned for insertion. (Fig. 10)
- Snap the Inserter Handle into the Shell Provisional for a temporary hold prior to locking the assembly with the Locking Screw.
- Insert Ball Head Hex Screwdriver through the window and into the Locking Screw at the tip of the Inserter Handle. (Fig. 11)
- While holding the Shell Provisional in place, securely thread the Locking Screw into the Polar Hole of the Shell Provisional.

Note: This acetabular implant does not allow the option of cup repositioning after final implantation. The success of acetabular implantation and subsequent fixation is dependent on achieving adequate primary stability. For this reason, acetabular Shell Provisionals of 1mm increments are provided to allow optimal assessment of the acetabulum as preparation progresses. (Fig. 12)

Note: It is highly recommended that the surgeon uses 1mm increments in Shell Provisional sizing to ensure optimal press-fit (either 1 or 2mm, based on surgeon preference and discretion) for the conditions present at the time of implantation. The accuracy of reaming and the optimal position of the implant are assessed using an acetabular Shell Provisional the same size as the last reamer used. (Fig. 13)
• Attach the Alignment Frame (or Alignment Guide) to the Inserter Handle and tighten the Thumb Screw (Fig. 14a).

Refer to the diagrams for use instructions on the lateral and supine approaches. (Pages 14, 15, 16, 17)

Note: The Shell Provisional is often used in assessing press-fit, acetabular depth, coverage, orientation, and sphericity. (Fig. 14b).

Note: For Shell Provisional sizes 40mm-47mm, utilize the GOLD-coated Maxera Shell Provisionals that are marked “Maxera”. For Shell Provisional sizes 48mm-65mm, only use Shell Provisionals compatible with the Maxera Cup (refer to the list of compatible components on Pages 18 through 22).

WARNING: Do not use any other Shell Provisionals for sizes 40mm-47mm due to the required extended cylinder on the Maxera Shell Provisionals for the noted size range.

• Resistance to fully seating and removing the Shell Provisional, which is the same size as the reamer, indicates that the rim is too tight and that it will be difficult to insert the corresponding acetabular component. In this case, the surgeon may decide to remain with the existing press-fit, or to use a reamer 1mm larger to achieve a lower press-fit.

• Once the initial assessment with the line-to-line Shell Provisional suggests that the acetabular preparation is correct and complete, a Shell Provisional that is 1mm oversized may be used to assess bone quality, interference fit, and projected implant stability. (Fig. 15)

• Press-fit check with the Shell Provisional should not exceed 1mm larger than the reamer used prior to assessment. A desired press-fit of 2mm should only be used during final implant placement.

Note: For final implant placement, either a 1mm or 2mm press-fit is needed to ensure optimal fixation (based on surgeon preference and discretion for the conditions present at the time of implantation).

Note: Instruments are available to support cup alignment. For further information, please refer to the alignment device explanation at the end of the surgical technique.
Note: It is important to remove any rim osteophytes that may block the full insertion or alter the optimal position of the final implant.

Note: The Shell Provisionals duplicate the height of the implant and indicate the position of the rim of the acetabular component once it is fully seated.

Note: If adequate implant stability is not achieved with a press-fit using the Maxera Cup design, a switch to a modular press-fit cup offering supplementary fixation options is suggested.

**Technique Tip:** When final press-fit and cup position are determined with the Shell Provisional, it is important to note landmarks of cup depth, abduction angle, and anteversion. (Fig. 16)

- Carefully inspect the acetabulum to ensure that all surgical debris has been removed. After the final Shell Provisional is removed, irrigate with USP (United States Pharmacopeia) purified water or sterile saline solution before placement of the acetabular cup.

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Determine landmarks with Shell Provisional in place.
Acetabular Implant Insertion

The Maxera Cup is packaged with a Plastic Barrier over the ceramic cup surface. The Plastic Barrier must be used with the appropriately sized Maxera Cup Inserter for the placement of the acetabular component into the acetabulum.

- The Plastic Barrier is a single-use component that is utilized to protect and insert the Maxera Cup into its place. Take extra caution to not dispose of or drop the Plastic Barrier prior to implant placement. If sterility of the Plastic Barrier is compromised, it can be autoclaved once for reuse (refer to the Package Insert for the recommended sterilization specifications).

**WARNING:** The Maxera Cup Inserter MUST be used with the Plastic Barrier.

**WARNING:** The Maxera Cup must be implanted with a fully-seated Plastic Barrier and a Maxera Cup Inserter construct. Only use components compatible with the Maxera Cup (refer to the list of compatible components on Pages 18 through 22).

1. Mounting of the Acetabular Component

- The acetabular component is removed from the packaging and placed on the blister pack prior to mounting to the inserter assembly. For ease in assembly, insert and seat the Plastic Barrier onto the Maxera Cup Inserter prior to mounting the Maxera Cup onto the assembly. The appropriately sized Maxera Cup Inserter is then mounted on to the acetabular component (e.g., 56mm Maxera Cup with a 56mm Maxera Cup Inserter). (Fig. 17)
- Assemble the Maxera Cup Inserter to the Inserter Handle in the same manner as the Shell Provisional (i.e., mate two pins to shape feature on Inserter Handle).
- The Maxera Cup Inserter has three claws that are 120° apart and line up with the attachment points on the acetabular component. To ensure optimal fixation, one of the claws of the Maxera Cup Inserter should engage the Maxera Cup in alignment to the superior position (i.e., 12 o’clock) of placement with respect to the Inserter Handle. (Fig. 18)
- Prior to tightening assembly, place the Maxera Cup on a flat, sterile surface. Alternatively, the Maxera Cup can be mounted to the Maxera Cup Inserter and Insert Handle assembly by inverting the handle and placing the Maxera Cup onto the Plastic Barrier for ease in claw alignment.
- The Locking Screw is tightened securely with the Ball Head Hex Screwdriver (Fig.19). This will secure the Maxera Cup to the Maxera Cup Inserter.
- Care should be taken to avoid contamination from blood, fluids, gauze, etc., before inserting the cup.
2. Insertion of the Acetabular Component

- Any remaining soft tissue which may prevent the acetabular component from seating during insertion should be excised.
- The insertion step is followed by a separate step of final impaction.

**Note:** The *Maxera* Cup is impacted into the prepared acetabulum. The *Maxera* Cup must be in contact with reamed acetabulum prior to applying impact force.

- It is important to note that the ceramic-on-ceramic *Maxera* Cup may be stiffer than a modular titanium construct, and more force may be required to fully seat the acetabular component during final cup impaction.
- Multiple moderate magnitude impacts (similar in magnitude to a final stem seating impact strike) may be required to ensure complete seating of the cup.
- Check to ensure that the Locking Screw is not loose due to the seating impact. Retightening of the Locking Screw is required if it loosens during impaction.
- A Heavy Mallet may be used to ensure complete seating of the *Maxera* Cup (Fig. 20). Surgical judgement is required to achieve full seating and avoid complication.
- The optimal position of the component is dictated by the orientation and preparation of the true bony acetabulum. Achieving an abduction angle of a maximum of 45 degrees and 10 to a maximum of 20 degrees of anteversion is appropriate in most cases. Variation in placement of the cup will depend on the patient’s anatomy and intraoperative surgical judgement. The alignment instruments support 45 degree placement.
- The surgeon may choose to evaluate the femoral anteversion and make adjustments as necessary, to achieve the optimal net anteversion of the acetabular and femoral components.
- To remove the *Maxera* Cup Inserter assembly from the *Maxera* Cup, turn the fixation screw on the Inserter Handle one complete turn (counter-clockwise) with the Ball Head Hex Screwdriver. Additional turns could result in the premature disassembly of the *Maxera* Cup Inserter from the Inserter Handle.
- The Plastic Barrier is single-use and must be discarded following the placement of the *Maxera* Cup into the acetabulum, and its removal from the *Maxera* Cup Inserter.
- After the cup insertion, irrigate with USP purified water or sterile saline solution. Wipe the cup articulating surface with a sterile gauze.
3. Final Impaction

- The *Maxera* Cup Inserter must not be reattached to the *Maxera* Cup following site placement and removal.

- The BONE-colored *Maxera* Cup Impactors (Fig. 21) are size specific to the inner diameter of each cup (i.e., 32mm, 36mm, 40mm, 44mm, 48mm).

- The *Maxera* Cup Impactor is utilized by the surgeon for final impaction of the *Maxera* Cup. *Maxera* Cup Impactors are used to ensure adequate press-fit is achieved. (Fig. 22)

- Assemble the *Maxera* Cup Impactor to the Inserter Handle in the same manner as the Shell Provisional (i.e., mate two pins to shape feature on Inserter Handle).

**WARNING:** Implants must only be combined with components intended for use with the *Maxera* acetabular system (refer to the list of compatible components on Pages 18 through 22).

**WARNING:** Do not attempt to remove the preassembled ceramic liner which is locked into the shell’s cavity.

**Note:** Ideally, the *Maxera* Cup will fully engage into the anterior and posterior walls, not only to maximize primary stability, but also to reduce the risk of soft tissue irritation. In many cases, in order to obtain optimal acetabular abduction, there will be a small area of cup left exposed superolaterally.

**Note:** Off-axis impaction should be avoided when possible. Ensure the rim of the *Maxera* Cup Impactor is flat against the face of the *Maxera* Cup (Fig. 23). Off-axis impaction may result in a change in cup orientation and loss of initial stability.

**Note:** The 42mm, 44mm, 46mm and 48mm *Maxera* Cup implants will seat based on Shell Provisional trialing and have an extended cylinder that protrudes out of the acetabulum. This is acceptable assuming adequate press-fit is achieved. The edge of the cup has been rounded to minimize soft tissue abrasion.

**WARNING:** The *Maxera* Cup must not be adjusted in the acetabulum after final impaction. Any attempt to move the implant will reduce the primary stability and may lead to early loosening.

**Note:** Upon final seating of the *Maxera* Cup, inspect the cup and ceramic insert to confirm the stability of the construct.

- Carefully inspect the surgical field to ensure that all surgical debris has been removed. Additionally inspect the ceramic insert articulating surfaces for scratches and metal transfer.

- After the cup is fully seated, irrigate with USP purified water or sterile saline solution. Wipe the cup articulating surface with a sterile gauze before reduction of the femoral component, to avoid third body wear.
4. Reduction

- It is important to avoid contact of the ceramic acetabular liner with the metal instrumentation or the metal femoral neck, as this could result in scratching or metal transfer to the liner.

- It is important to avoid contact of the ceramic femoral head with the metal rim of the acetabular component, as this could result in scratching or metal transfer to the head.

- Following reduction, the circumference of the acetabular component should be checked to make sure that there is no entrapment of soft tissue. The hip is then checked for range of movement, impingement, stability and leg length.

**Technique Tip:** Ceramic bearing surfaces (i.e., acetabular cups and femoral heads) should be protected from contact with other materials during hip replacement surgery to avoid minor scraping or damage.³

**Note:** Femoral Head Slides can be utilized to assist with reduction of the head into the cup. The Femoral Head Slides protect the ceramic surfaces during reduction of the ceramic head into the ceramic insert.
Alignment Device Explanation

Example: Lateral Patient Positioning “A-Frame”

The “A-Frame” Alignment extension needs to be parallel with the longitudinal body axis to achieve a 45° inclination (abduction) and 20° anteversion.
Alignment Device Explanation

Example: Lateral Patient Positioning “Gunsight”

The “Gunsight” Alignment alignment extension needs to be parallel with the longitudinal body axis to achieve a 45° inclination (abduction) and a 10° or 20° anteversion depending on the type of alignment guide used.
Alignment Device Explanation
Example: Supine Patient Positioning “A-Frame”

The “A-Frame” Alignment extension needs to be parallel with the longitudinal body axis to achieve a 45° inclination (abduction) and 20° anteversion.
Alignment Device Explanation

Example: Supine Patient Positioning “Gunsight”

The “Gunsight” Alignment alignment extension needs to be parallel with the longitudinal body axis to achieve a 45° inclination (abduction) and a 10° or 20° anteversion depending on the type of alignment guide used.
## Implants

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Maxera Standard Instruments

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Maxera Extended Instruments

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Zimmer MMC® Shell Provisionals

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Femoral Head Provisionals & Adapter Extractor

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Description</th>
<th>Size(s)</th>
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<tbody>
<tr>
<td>00-7895-032-01</td>
<td>Femoral Head Provisional, 32mm</td>
<td>S</td>
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<tr>
<td>00-7895-032-02</td>
<td>Femoral Head Provisional, 32mm</td>
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</tr>
<tr>
<td>00-7895-032-03</td>
<td>Femoral Head Provisional, 32mm</td>
<td>L</td>
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<tr>
<td>00-7895-032-14</td>
<td>Femoral Head Provisional, 32mm</td>
<td>XL</td>
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<tr>
<td>00-7895-036-01</td>
<td>Femoral Head Provisional, 36mm</td>
<td>S</td>
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<tr>
<td>00-7895-036-02</td>
<td>Femoral Head Provisional, 36mm</td>
<td>M</td>
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<td>00-7895-036-03</td>
<td>Femoral Head Provisional, 36mm</td>
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</tr>
<tr>
<td>00-7895-036-04</td>
<td>Femoral Head Provisional, 36mm</td>
<td>XL</td>
</tr>
<tr>
<td>00-7895-040-01</td>
<td>Femoral Head Provisional, 40mm</td>
<td>S</td>
</tr>
<tr>
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<td>Femoral Head Provisional, 40mm</td>
<td>M</td>
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<td>Femoral Head Provisional, 40mm</td>
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<td>00-7895-040-04</td>
<td>Femoral Head Provisional, 40mm</td>
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<td>01.00189.441</td>
<td>Femoral Head Provisional, 44mm</td>
<td>S, M, L, XL with Trial Adapters</td>
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<tr>
<td>01.00189.481</td>
<td>Femoral Head Provisional, 48mm</td>
<td>S, M, L, XL with Trial Adapters</td>
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<td>Head Provisional Trial Adapter</td>
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<td>01.00189.146</td>
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<td>01.00189.148</td>
<td>Head Provisional Trial Adapter</td>
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<td>01.00009.101</td>
<td>Adapter Extractor</td>
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# General Instrument Sets

<table>
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<tr>
<th>Item No.</th>
<th>Description</th>
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<tr>
<td>ZS01.00639.150</td>
<td>General Instrument Set - Straight</td>
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<tr>
<td>00-7804-000-30</td>
<td>Tray</td>
</tr>
<tr>
<td>00-5900-099-00</td>
<td>Tray Cover</td>
</tr>
<tr>
<td>00-7804-015-20</td>
<td>Straight Inserter Handle (2 included in set)</td>
</tr>
<tr>
<td>9375-00-032</td>
<td>Ball Head Hex Screwdriver</td>
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<tr>
<td>00-2237-005-00</td>
<td>Mallet, 3-lb</td>
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<tr>
<td>01.00639.725</td>
<td>Lateral Positioning Guide 20°</td>
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<tr>
<td>01.00639.705</td>
<td>Positioning Guide Spoke (Lateral)</td>
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<th>Item No.</th>
<th>Description</th>
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<td>ZS01.00639.175</td>
<td>General Instrument Set - Offset</td>
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<tr>
<td>00-7804-000-30</td>
<td>Tray</td>
</tr>
<tr>
<td>00-5900-099-00</td>
<td>Tray Cover</td>
</tr>
<tr>
<td>00-7804-025-20</td>
<td>Offset Inserter Handle (2 included in set)</td>
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<tr>
<td>9375-00-032</td>
<td>Ball Head Hex Screwdriver</td>
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<td>00-2237-005-00</td>
<td>Mallet, 3-lb</td>
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<tr>
<td>01.00639.725</td>
<td>Lateral Positioning Guide 20°</td>
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<tr>
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## On Request Alignment Guides

<table>
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<th>Item No.</th>
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<tbody>
<tr>
<td>00-7807-015-01</td>
<td>Supine Alignment Frame</td>
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<td>00-7807-015-02</td>
<td>Lateral Alignment Frame</td>
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<td>Lateral Positioning Guide 10°</td>
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<tr>
<td>01.00639.705</td>
<td>Positioning Guide Spoke (Lateral)</td>
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<tr>
<td>01.00639.735</td>
<td>Supine Positioning Guide 10°</td>
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<tr>
<td>01.00639.755</td>
<td>Positioning Guide Spoke (Supine)</td>
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<tr>
<td>01.00639.745</td>
<td>Supine Positioning Guide 20°</td>
</tr>
<tr>
<td>01.00639.755</td>
<td>Positioning Guide Spoke (Supine)</td>
</tr>
</tbody>
</table>
References


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