stryker

MDM® X3®
Modular Dual Mobility Acetabular System

Surgical protocol

Catalog

MDM X3 Mobile Bearing Hip System surgical protocol

Table of contents

This publication sets forth detailed recommended procedures for using the MDM X3 Modular Dual Mobility Acetabular System. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

Indications, contraindications and precautions

INDICATIONS for US and Rest of World

The indications for use in total hip arthroplasty include:

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2. Rheumatoid arthritis;
3. Correction of functional deformity;
4. Revision procedures where other treatments or devices have failed; and,
5. Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques
6. Dislocation risks

MDM Liners are intended for cementless use only.

INDICATIONS for EU, EMEA countries requiring CE Mark, and Australia

The indications for use in total hip arthroplasty include:

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2. Correction of functional deformity;
3. Revision procedures where other treatments or devices have failed; and,
4. Dislocation risks

MDM Liners are intended for cementless use only.

Contraindications

1. Overt infection;
2. Distant foci of infections (which may cause hematogenous spread to the implant site);
3. Rapid disease progression as manifested by joint destruction or bone resorption apparent on roentgenogram;
4. Skeletally immature patients; and
5. Cases where there is a loss of abductor musculature, poor bone stock, or poor skin coverage around the hip joint which would make the procedure unjustifiable.

Conditions presenting increased risk of failure include:

1. Uncooperative patient or patient with neurologic disorders, incapable of following instructions;
2. Osteoporosis;
3. Metabolic disorders which may impair bone formation; and
4. Osteomalacia.

Warnings and precautions

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

Additionally, the MDM Liner is not intended for use as a metal-on-metal or ceramic-on-metal articulation. No testing has been conducted to determine that these bearing couples produce favorable mechanical outcomes. Only Stryker 22.2mm or 28mm femoral heads should be inserted into the MDM X3 polyethylene inserts. Further, do not substitute another manufacturer's device for any component of the MDM Acetabular System. Any such use will negate the responsibility of Howmedica Osteonics Corp. for the performance of the resulting mixed component implant.

Before using MDM instrumentation, verify:

- Instruments have been properly disassembled prior to cleaning and sterilization;
- Instruments have been properly assembled post-sterilization;
- Instruments have maintained design integrity; and,
- Proper size configurations are available.

For Instructions for Cleaning, Sterilization, Inspection and Maintenance of Orthopaedic Medical Devices, refer to LSTPI-B, and SLI0001.

Acetabular shell compatibility

The MDM Liner is intended for use with Trident, Trident Tritanium, Restoration Anatomic, and Trident II shells only. The MDM surgical technique should be used in conjunction with the desired Stryker Acetabular Shell System surgical technique for complete guidance on using the shell implant, including technique and instrumentation.

For indications for use of associated products in this protocol, please refer to the following instructions for use (IFU) numbers enclosed within product packaging, or visit ifu.stryker.com:

Trident shells: QIN 4350

Trident Tritanium: QIN 4350 (multihole)

Trident Tritanium: QIN 4397 (solidback & clusterhole)

Restoration Anatomic shells: QIN 4422

Trident II shells: QIN 4430

Introduction

This surgical protocol is a guide to using the MDM Acetabular system with Trident and Trident Tritanium Acetabular systems. For guidance on implanting the acetabular shells, refer to the respective Trident and Trident Tritanium Acetabular system surgical techniques.

For MDM use with Restoration Anatomic and Trident II Acetabular systems, refer to their respective surgical techniques.

Table 1: MDM Liner and Insert compatibility with Trident and Trident Tritanium Shells

	Shell size (mm), liner alpha code							
Trident PSL Shell	44	46, 48	50, 52	54, 56	58, 60	62, 64	66, 68	70, 72
Trident Hemispherical Shell	46	48, 50	52, 54	56, 58	60, 62	64, 66	68, 70	72, 74
Trident Tritanium Hemispherical Shell	48	50, 52	54, 56	58, 60	62, 64	66, 68	70, 72	74-80
Liner Alpha Code	C	D	E	F	G	H	I	J
MDM CoCr Liner	36C	38D	42E	46F	48G	52H	54I	58J
X3 Poly Insert OD (mm)	36	38	42	46	48	52	54	58
X3 Poly Insert ID (mm)	22.2	22.2	28	28	28	28	28	28
Nominal poly thickness (mm)	6.7	7.7	6.8	8.8	9.8	11.8	12.8	14.8

Design rationale

The MDM System is designed to incorporate the following dual points of articulation:

- 22.2mm or 28mm femoral head; and,
- Large polyethylene insert that mimics a femoral head.

Acetabular shell

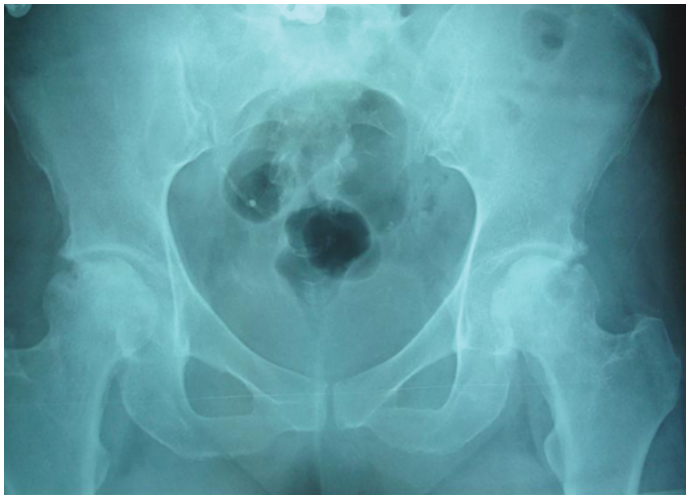
MDM CoCr Liner

Poly insert

Femoral head

Step 1

Preoperative planning and X-ray evaluation



Preoperative planning is an essential part of the procedure, and templating should be performed prior to every case. The preoperative planning process should take qualitative and quantitative factors (including patient bone quality, density and morphology) into consideration in order to evaluate and select the appropriate instrument/ implant system for the patient. X-ray evaluation may also help detect anatomic anomalies that could prevent the intraoperative achievement of the established preoperative goals. Selecting potential implant style and sizes can facilitate operating room preparation and assure availability of an appropriate selection. When it is done using X-rays that have been suitably scaled for magnification, templating allows the surgeon to predict the style, size and position of the implant that may help restore the correct anatomy of the individual patient.

Template planning can be done using acetate templates for printed X-rays or preoperative planning software for digital studies.

Use the appropriate Acetabular Shell System template overlay (listed in section Catalog Information) available through your Stryker representative.

Note

Careful identification and removal of osteophytes can help reduce the possibility of bone-to-bone or component-to-bone impingement.

Additionally, this can aid in the identification of bony landmarks used for cup positioning.

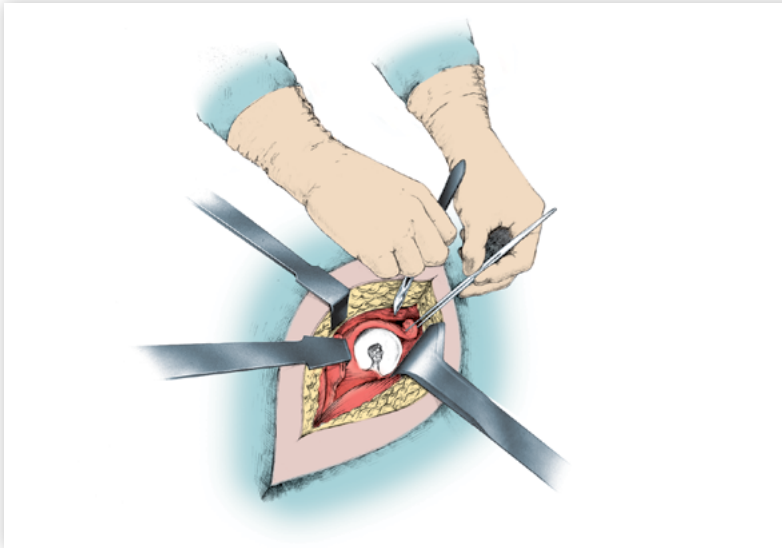


Figure 1

Step 2

Acetabular preparation

The acetabulum is prepared by the release and removal of soft tissue using the surgeon's preferred technique to gain adequate exposure for reaming. Excision of the labrum and osteophytes allows for proper visualization of the bony anatomy and improves ease of reaming.

Stryker Orthopaedics retractors can be utilized to gain acetabular exposure **(Figure 1)**. With the acetabulum exposed, bony defects can be identified.
If necessary, bone grafting options may be considered.

Step 3a

Spherical reaming

Caution

Only the CuttingEdge Spherical Reamers should be used to prepare the acetabulum for the Trident or Trident Tritanium Acetabular Shell components.

To help obtain recommended component positioning in the reaming process, a 45°/20° Abduction/Anteversion Alignment Guide can be attached to the CuttingEdge Reamer Handle **(Figure 2)**.

The Alignment Guide, when perpendicular to the long axis of the patient, is designed to orient the reamer handle at 45° of abduction, thereby placing the axis of the spherical reamer at 45° of inclination **(Figure 3)**. The reamer handle may be positioned at 20° of anteversion by aligning the left/right anteversion rod on the Alignment Guide so that it is parallel to the long axis of the patient.

It is recommended that the initial reaming begin with a CuttingEdge Spherical Reamer that is 4mm smaller than the templated or gauged size. The reamer is attached to the reamer handle by pushing down on the reamer and applying a quarter-turn to lock in place. Reaming progresses in 1mm increments until final sizing is achieved. Surgical judgment is used to assess bone stock, amount of interference, adequacy of medialization and proper amount of reaming as desired.

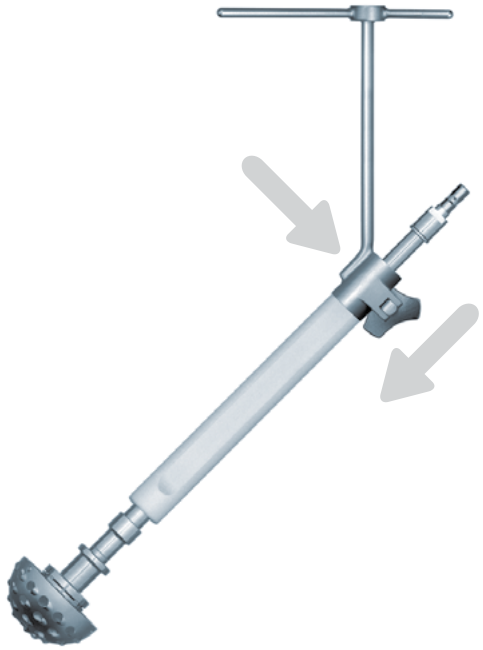


Figure 2

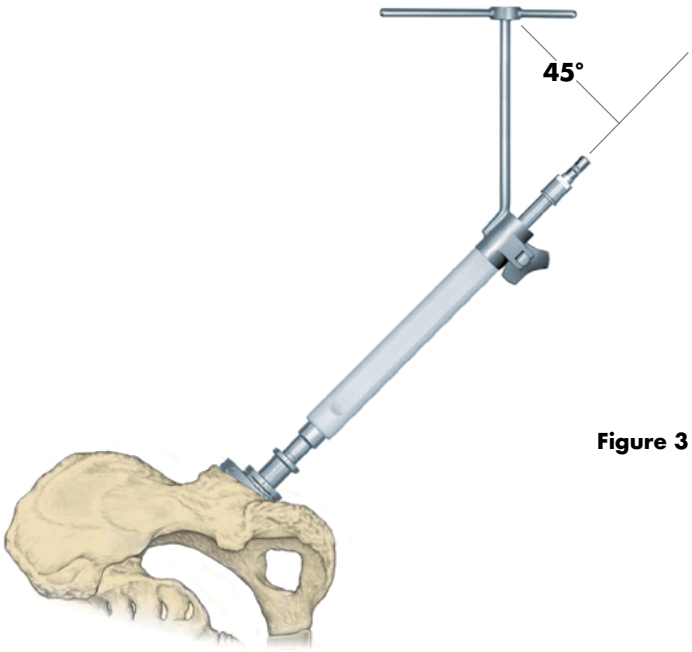


Figure 3

Caution

To help ensure proper functioning of the external Alignment Guides, the patient must be in a lateral decubitus position without pelvic tilt.

Note

Changes in pelvic tilt and pelvic flexion caused by patient positioning on the table, as well as disease in contralateral hip, spine and pelvis may impact a surgeon's ability to achieve component placement of 45°/20° abduction/anteversion.

Tip

Check for and remove internal osteophytes prior to reaming for the implant to prevent lateralizing the shell.

Step 3a

Spherical reaming (continued)

The full profile of the CuttingEdge Spherical Reamer necessitates reaming to the full depth. The reamer head should be driven to the point where the rim/cross bar contacts the acetabular wall at the peripheral lunate region. Removal of the reamer from the handle is performed by pulling back on the locking sleeve and rotating the reamer head a quarter-turn in a clockwise direction **(Figure 4)**.

Care should be taken so as not to enlarge or distort the acetabulum by eccentric reaming. Final acetabular reaming ideally shows the hemispherical acetabulum denuded of cartilage, with the subchondral plate preferably intact, and the acetabular walls preserved.

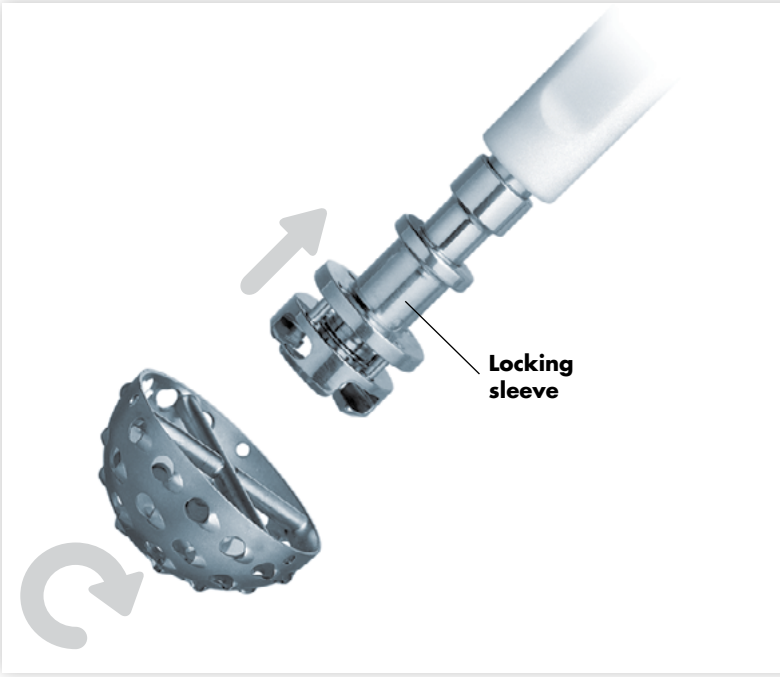


Figure 4

Note

The CuttingEdge Spherical Reamers are very aggressive and perform best when sharp. Care should be taken to protect the reamer from unnecessary handling, as dull or damaged cutting teeth may cause improper reaming. Dull cutting teeth will deflect to cut softer bone and resist hard bone. This situation may result in an irregularly shaped or enlarged acetabulum preparation.

Step 3b

Final reaming

Trident Tritanium Solidback, Clusterhole, and Multihole shell:

Full surgical techniques for the Trident Tritanium Solidback, Clusterhole and Multihole shells can be found in the product-specific surgical protocols.

When implanting the Tritanium Solidback, Clusterhole or Multihole, it is recommended to under-ream by 1mm. As with all manufacturing processes, due to the nature of the coating, the outer diameter may be slightly larger than the size indicated. The surgeon should consider this during acetabular preparation. Depending on acetabular bone quality, the surgeon may choose to ream line-to-line.

When osteoporotic bone is encountered, it is recommended to under-ream by 1mm. When sclerotic bone is encountered, it may be difficult to fully seat the shell with a 1mm interference fit. In this situation, it is recommended to ream line-to-line to reduce the potential for problems that may typically occur in dense bone. Potential challenges implanting acetabular shells may include: acetabular fracture, failure to fully seat the implant or slight deformation of the titanium shell, making seating the insert more difficult.

Note

The amount of interference fit for Trident and Trident Tritanium Acetabular Shells should be determined intraoperatively based upon the patient's bone quality.

Trident Hemispherical:

Full surgical technique details can be found in the Trident Hemispherical surgical protocol.

Under-reaming by 1 to 2mm of the actual Trident Hemispherical shell size is recommended to achieve interference fit.

Trident PSL:

Full surgical technique details can be found in the Trident PSL surgical protocol.

The Trident PSL HA shell periphery is 1.8mm larger than the stated size (e.g., 52mm shell = 53.8mm periphery at the rim of the shell). The size of the Trident PSL HA shell selected should be the same as the largest diameter of the CuttingEdge Spherical Reamer used. Surgical judgment is used to assess bone stock, amount of interference and proper amount of reaming as desired. When implanting the Trident PSL HA shell, the 1.8mm of interference fit is not always necessary when dense, hard, sclerotic bone is encountered.

Step 4

Trial evaluation

Figure 5

Figure 6

Following the reaming procedure, the appropriate Trident or Trident Tritanium Window Trial **(Tables 2-3)**, of the same diameter as the final implant size, is threaded onto the CuttingEdge Shell Positioner/Impactor and placed in the acetabulum to evaluate the size and congruity of the preparation **(Figure 5)**. The trial is "windowed" for visualization and assessment of fit, contact and congruency of the trial within the acetabulum. By inserting the appropriate-sized MDM Liner Trial into the Window Trial **(Figure 6)**, joint mechanics can be evaluated. The MDM Liner Trial is designed with two forceps holes in the dome to assist with insertion and removal. The MDM Liner Trial can be inserted and removed manually or with the use of standard forceps. Trial insert and head reduction can be facilitated at this point – please refer to Step 8 for more detailed information.

Table 2: Trident Window Trial/Trial Liner liner sizing

Window Trial catalog number	Trident Window Trial OD (mm)	Trial Liner alpha code
2208-2044A	44	C
2208-2046A	46	D
2208-2048A	48	D
2208-2050A	50	E
2208-2052A	52	E
2208-2054A	54	F
2208-2056A	56	F
2208-2058A	58	G
2208-2060A	60	G
2208-2062A	62	H
2208-2064A	64	H
2208-2066A	66	I
2208-2068A	68	I
2208-2070A	70	J
2208-2072A	72	J

Table 3: Trident Tritanium Window Trial/Trial Liner sizing

Window Trial catalog number	Tritanium Window Trial OD (mm)	Trial Liner alpha code
2208-4047	47	C
2208-4048S	48	C
2208-4049	49	D
2208-4050	50	D
2208-4051	51	D
2208-4052S	52	D
2208-4053	53	E
2208-4054	54	E
2208-4055	55	E
2208-4056S	56	E
2208-4057	57	F
2208-4058	58	F
2208-4059	59	F
2208-4060S	60	F
2208-4061	61	G
2208-4062	62	G
2208-4063	63	G
2208-4064S	64	G
2208-4065	65	H
2208-4066	66	H
2208-4067	67	H
2208-4068	68	H
2208-4069	69	I
2208-4070	70	I
2208-4071	71	I
2208-4072	72	I
2208-4073	73	J
2208-4074	74	J

Note

Trident Window Trials are black and Trident Tritanium Window Trials are green.

Note

The MDM trials are marked 'trial do not implant'. If there is any reason to believe that the trial has been accidentally implanted, the MDM Liner Trial is radiopaque and would be visible on an X-ray.

Table 4: MDM Liner trials

MDM Liner trial	Alpha code
3200-36C	C
3200-38D	D
3200-42E	E
3200-46F	F
3200-48G	G
3200-52H	H
3200-54I	I
3200-58J	J

Step 5

Shell implantation

After completing the trial reduction, select the appropriately sized Trident or Trident Tritanium Acetabular Shell as clearly identified on the product label. Ensure the patient is in the correct position. At this step it is prudent to reassess patient positioning in the surgical field. If desired, the CuttingEdge Abduction/Anteversion Alignment Guide can be attached to the CuttingEdge Shell Positioner/Impactor to help establish the recommended 45° of abduction/inclination and 20° of anteversion **(Figures 7 and 8).**

Assess the acetabulum and surrounding soft tissue prior to shell introduction to ensure nothing is preventing shell implantation. During shell introduction into the acetabulum, minimize damage to the shell coating by instrumentation such as retractors, and avoid dragging the roughened surface across soft tissue.

Caution

The Alignment Guide may yield inaccurate placement if the pelvis has moved from the original position during intraoperative manipulation. Small changes in pelvic flexion will greatly affect anteversion. The Alignment Guide is only one aid to assist with proper implant positioning. The surgeon must also rely on anatomic landmarks to avoid improper positioning of components.

Note

Proper positioning of the Trident or Trident Tritanium Acetabular Shell will minimize potential impingement and help to provide desired stability and articulation between the insert and head. As with any acetabular system, excessive vertical orientation and/or anteversion of the shell should be avoided as this may lead to premature wear of the insert material.

The Trident or Trident Tritanium Acetabular Shell is threaded onto the impactor at the threaded hole in the dome of the metal shell. It is important to fully engage the threads and seat the impactor against the shell. Failure to fully engage the threads and seat the impactor could result in thread damage and subsequent difficulty removing the impactor from the shell. If the clusterhole screw pattern shell is utilized, the holes are intended to be oriented superiorly **(Figure 9)**.

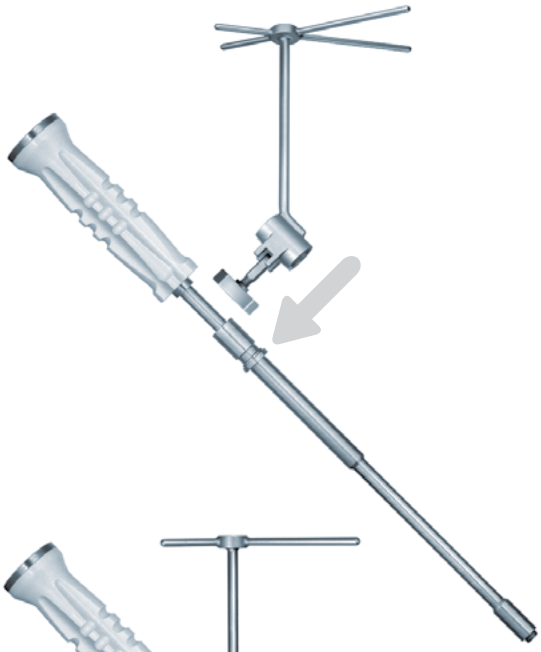


Figure 7

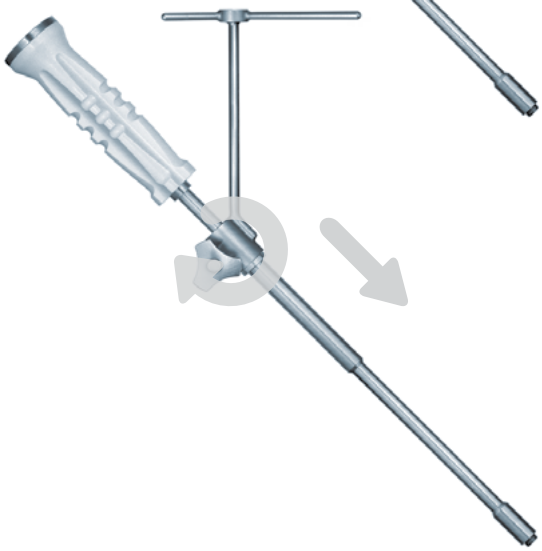


Figure 8

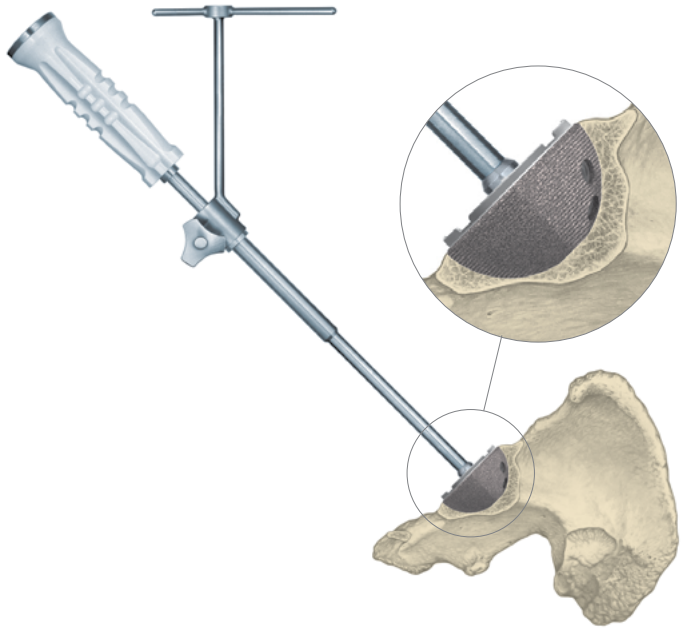


Figure 9

Step 5

Shell implantation (continued)

The recommended metal shell abduction angle of 45° is determined by positioning the Alignment Guide perpendicular to the long axis of the patient **(Figure 10)**. Metal shell anteversion is set at approximately 20° by moving the cup impactor so that the left/right anteversion rod is parallel to the long axis of the patient **(Figure 11)**. The metal shell is impacted into the acetabulum using a mallet until a tight, stable, press-fit is achieved. The thumbscrew on the Alignment Guide is then loosened to remove the guide. After removing the guide, the impactor handle is carefully unthreaded from the shell.

Tip

With any high friction interface, the potential for the cup to change position during insertion is possible due to differential bone densities. Care should be taken to monitor position so that changes can be made as necessary.

While the Alignment Guides are of some assistance, it is important to critically evaluate anatomic landmarks before placement of the acetabular component. These anatomic landmarks include the anterior and posterior walls of the acetabulum, the sciatic notch, the floor and/or acetabular fossa of the acetabulum.

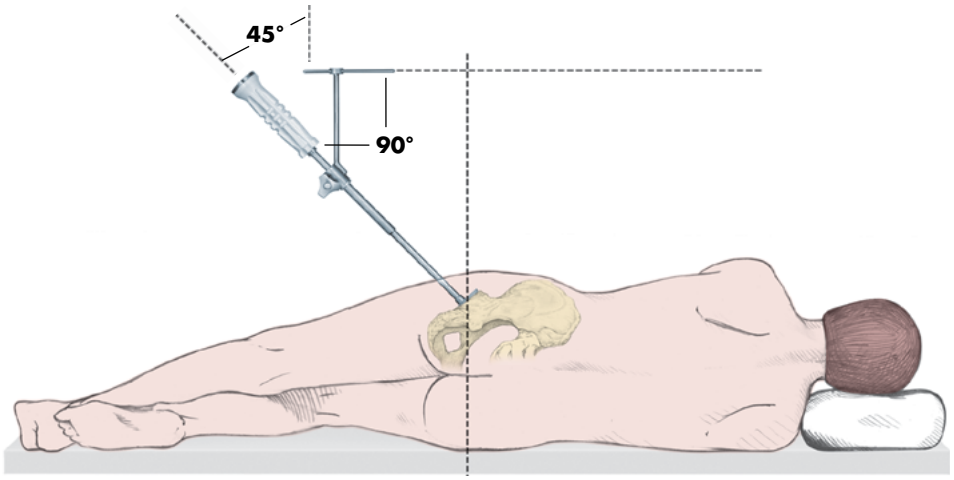


Figure 10
A/P view

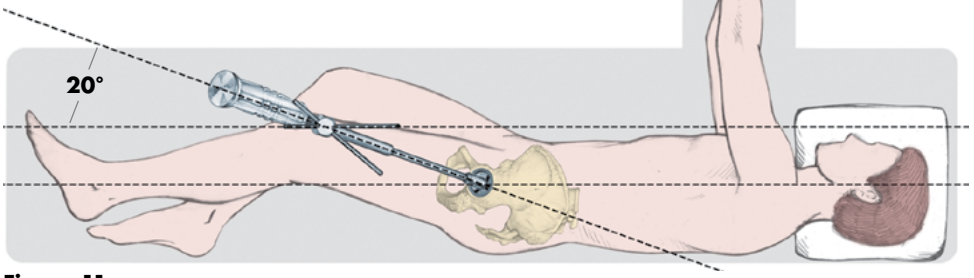


Figure 11
Lateral view

The depth of the shell seating may now be determined by viewing through the threaded hole in the dome. If it is determined that the shell is not fully seated, the CuttingEdge Final Cup Impactor may then be required to assist in impacting the shell until it is completely seated in the prepared acetabulum. If utilizing the optional Acetabular Dome Hole Plug, insert into shell implant threaded dome hole with a Stryker Orthopaedics Torx screwdriver, and assess that the plug is fully threaded into the shell to prevent liner impingement.

Step 5a

Optional screw utilization

If implanting a Clusterhole shell with screws, then only Stryker Orthopaedics Bone Screws can be used. Torx Bone Screws (2030-65XX-1) are designed to be compatible with Trident Hemispherical, Trident PSL and Trident Tritanium Clusterhole shells **(Table 5, Figure 12)**. Gap Torx Bone Screws (2080-00XX) are only compatible with Trident Tritanium Multihole shells **(Table 6, Figure 12)**. Stryker Orthopaedics offers 6.5mm diameter Cancellous Bone Screws which are available in a variety of lengths. Stryker Orthopaedics Cancellous Bone Screws are designed to be inserted or removed only with the assistance of Stryker Orthopaedics screw instruments.

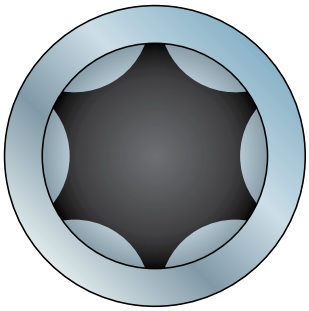


Figure 12
Torx screwhead

Caution

Do not use Stryker Torx Bone Screws (2030-65XX-1) with Trident Tritanium Multihole shells.

Table 5: Stryker Torx 6.5mm Bone Screws for use with Trident Hemispherical, Trident PSL and Trident Tritanium Clusterhole shells

Catalog number	Screw lengths (mm)
2030-6516-1	16
2030-6520-1	20
2030-6525-1	25
2030-6530-1	30
2030-6535-1	35
2030-6540-1	40
2030-6545-1	45
2030-6550-1	50
2030-6555-1	55
2030-6560-1	60

Table 6: Stryker Gap Torx 6.5mm Bone Screws for use with Trident Tritanium Multihole shells

Catalog number	Screw lengths (mm)
2080-0015	15
2080-0020	20
2080-0025	25
2080-0030	30
2080-0035	35
2080-0040	40
2080-0045	45
2080-0050	50
2080-0055	55
2080-0060	60

Step 5a

Optional screw utilization (continued)

After determination of the proper site for screw placement, a 3.3mm diameter drill is passed through a drill guide to the desired depth **(Figure 13)**. It is important to use the appropriate drill guide to keep the pilot hole as straight as possible so that the screw head fully seats. The depth of the hole is then assessed using a depth gauge. The properly sized screw is then selected and implanted into the bone using a Stryker Orthopaedics Screw Driver. After screw implantation, assess that the screw head is seated flush against the shell to help prevent improper seating of the MDM Liner.

Note

Trident Tritanium Acetabular Shells are not intended to be drilled through.

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

Caution

Do not pass a drill, screw or any other instrumentation beyond the inner table of the pelvis. Malposition of either the shell screw hole orientation, screw hole preparation or improper use of the screws themselves may contribute to detrimental clinical consequences.

Do not apply torque in excess of 69 in-lbs. to the screw. This may result in damage to the screw or driver instrument. To reach 69 in-lbs. unnecessary excessive force has to be applied. Power driven screw inserters may exceed this limit.

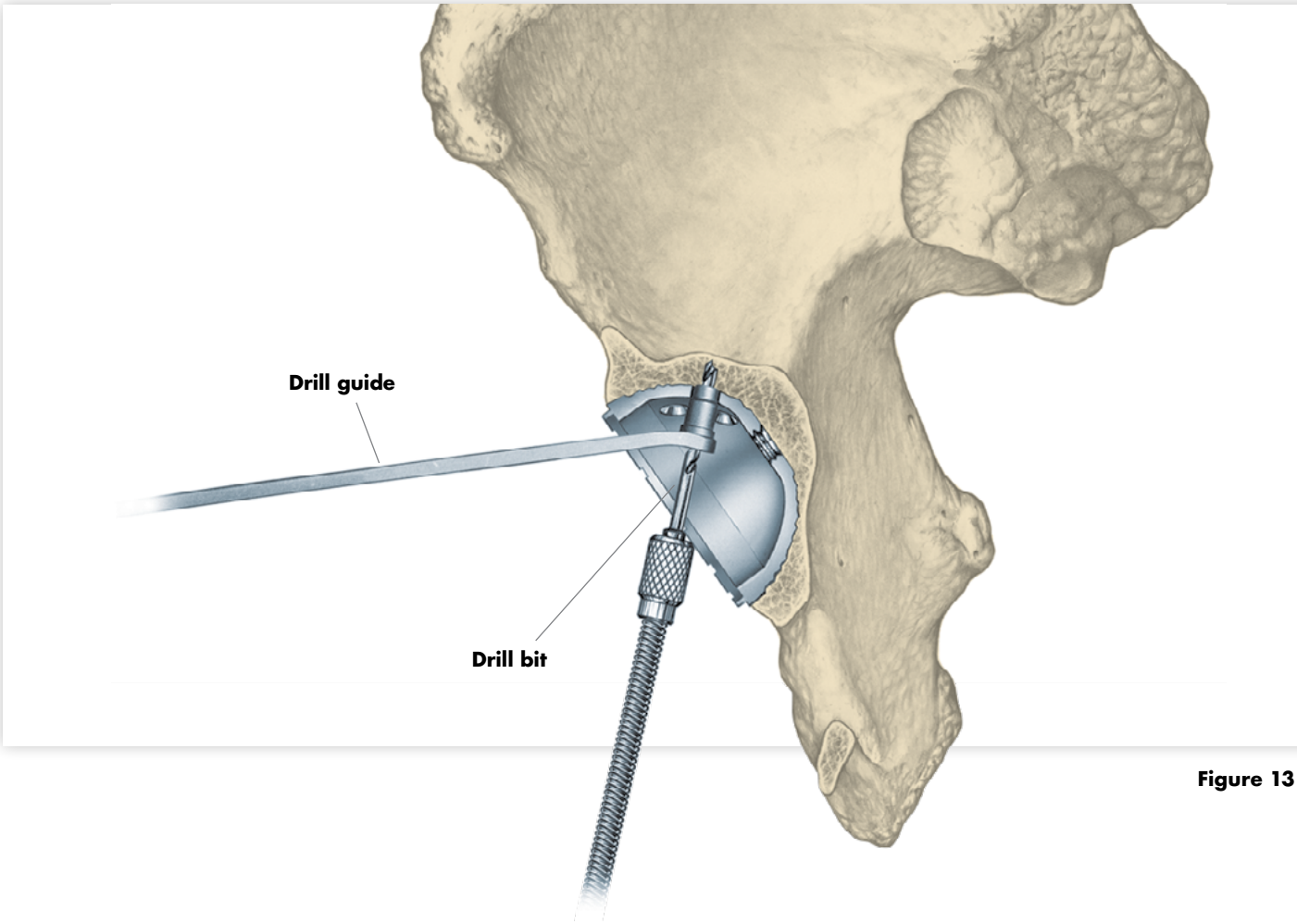


Figure 13

Step 6

Trial insert reduction

After shell implantation, the MDM Trial Liner is designed to provide a final check of hip biomechanics. By inserting the appropriately sized MDM Liner Trial into the shell, joint mechanics can be evaluated. The MDM Liner Trial is designed with two forceps holes in the dome to assist with insertion and removal. The MDM Liner Trial can be inserted and removed manually or with the use of standard forceps. Trial insert and head reduction can be facilitated at this point – please refer to Step 8 for more detailed information.

Step 7

Liner implantation

Figure 14

Figure 15

1. Ensure that the inside of the shell is clean, dry and free of soft tissue or any other debris, which could prevent the liner from properly seating in the shell.
2. Gently introduce the MDM Liner making sure that the liner flange scallops are aligned with the Removal Tool Slots at the rim of the shell **(Figure 14)**. This orientation will allow the liner to rest on the four indexing barbs and will help ensure that the liner is parallel with the shell. Next, slowly turn the liner until it drops into the final pre-locking position. Correct rotational orientation will result in the Liner Tabs aligned with the Removal Tool Slots **(Figure 15)**.

   Apply finger pressure around the rim of the liner first to engage the liner within the shell. It may then be necessary to lightly tap on the rim of the liner with the Final Cup Impactor Handle **(Figure 16)**, working around the rim in all four quadrants, to ensure the liner is properly seated in the shell. The liner is properly seated when there is no further rocking or movement of the liner within the shell. This step should be done prior to final impaction of the liner.

Note

Having a clear view of the rim of the acetabulum will allow easier visualization of the shell's slot and indexing barbs for proper positioning and seating of the liner.

Caution

Care should be taken to avoid damage to the highly polished inner surface of the MDM CoCr Liner.

Care should be taken to ensure that the liner is correctly aligned within the shell. Failure to do so may result in incomplete or incorrect liner engagement.

Step 7

Liner implantation (continued)

Figure 16

3. Select the Impaction Pad (2101-0132) and assemble to the Final Cup Impactor Handle. Ensure the Impaction Pad is threaded tightly onto the Impactor Handle **(Figure 16)**. Strike the handle with approximately four mallet blows to fully seat the liner using a mallet.
4. Verify liner is properly aligned and fully seated into the acetabular shell **(Figure 15)**. Check the taper lock by running a small blunt instrument or the Liner Removal Tool around the periphery of the shell/liner interface. There should not be any space between the rim of the shell and the under side of the liner rim.
5. Visually assess the inner articular surface of the MDM Liner to ensure it is not scratched or damaged prior to the trial insert/head reduction.

Note

As with any modular interface under load, there is a potential for fretting and/or corrosion. Proper alignment and locking of the MDM Liner into the Trident or Trident Tritanium shell may help to minimize this risk.

Note

The Impaction Pad has a limited life expectancy; deformation is expected and should be checked before each use. The instrument must be changed if deformation or cracks are visible. Periodic replacement is required.

Step 8

Trial insert/head reduction

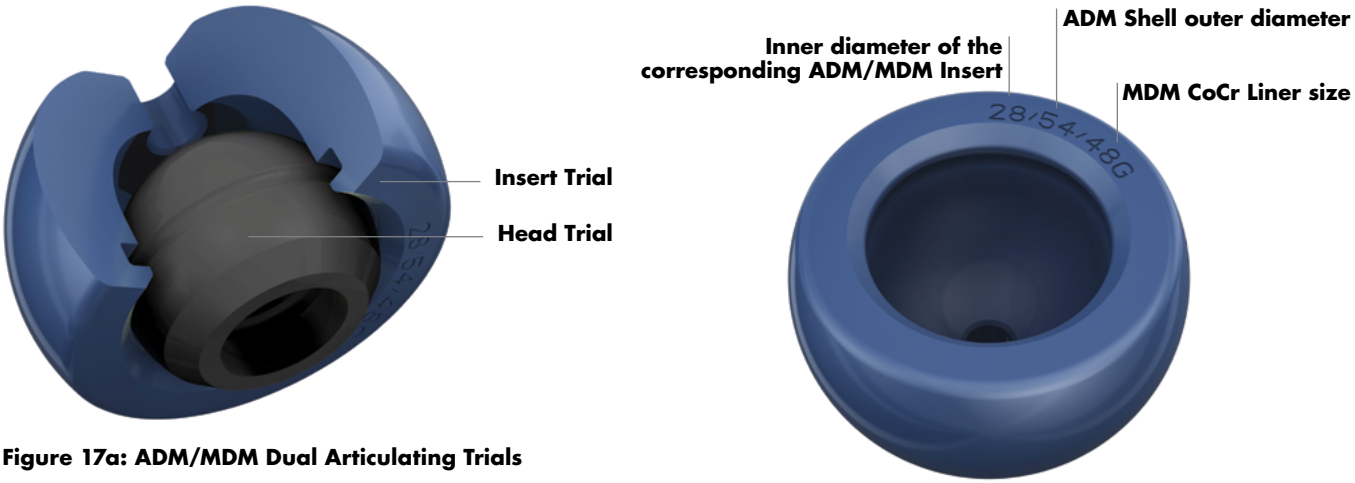


Figure 17a: ADM/MDM Dual Articulating Trials

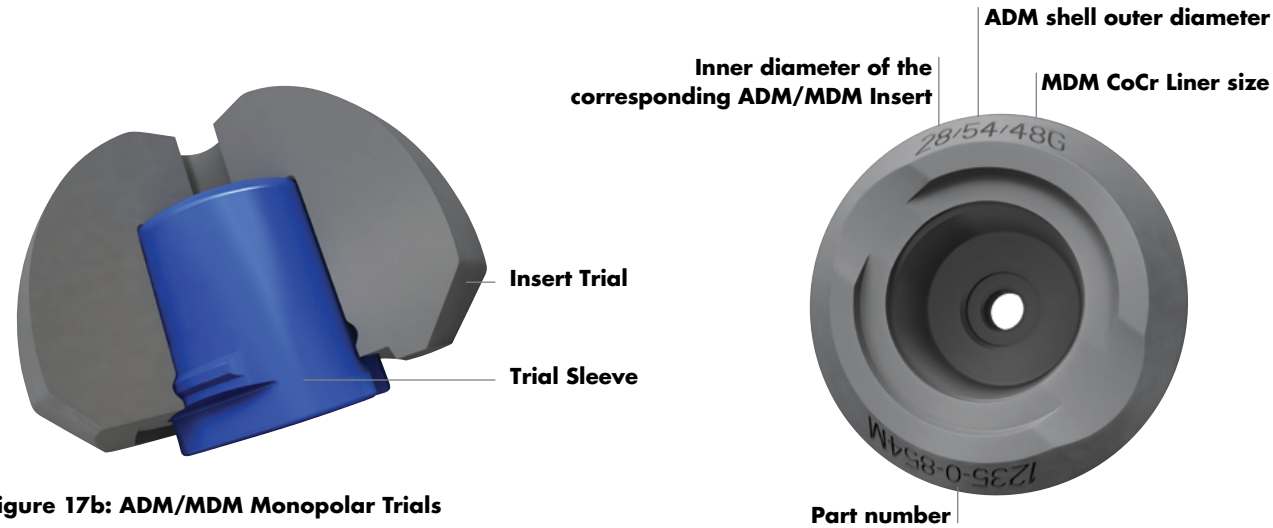


Figure 17b: ADM/MDM Monopolar Trials

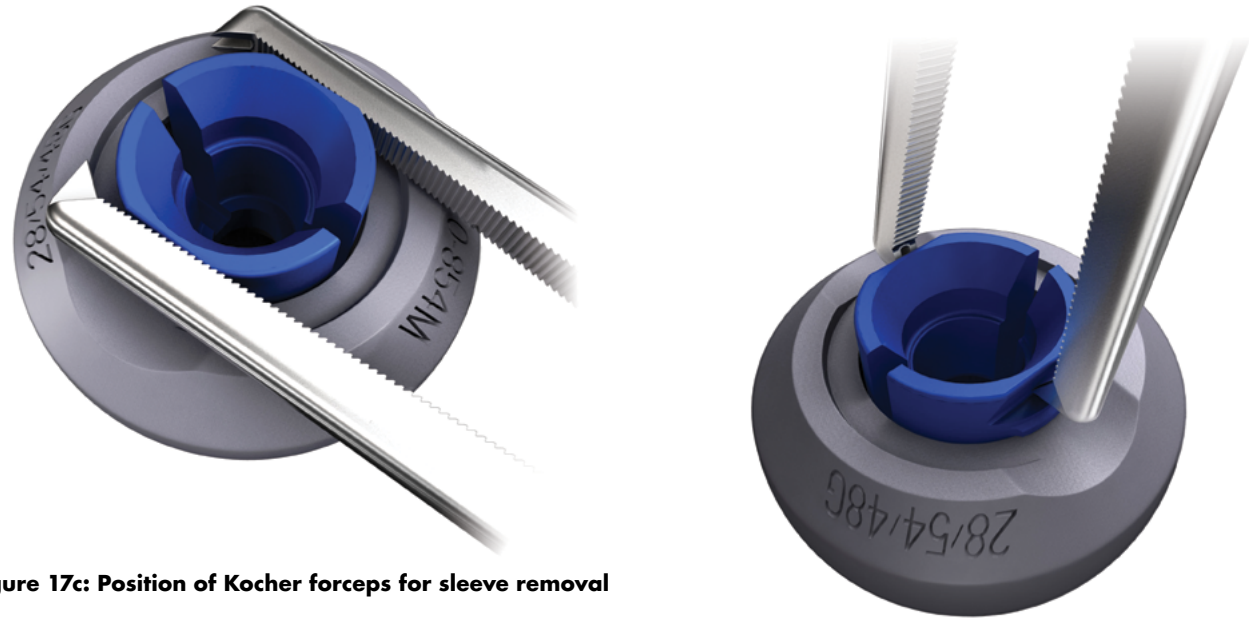


Figure 17c: Position of Kocher forceps for sleeve removal

Step 8

Trial insert/head reduction (continued)

- After shell and MDM Liner implantation, there is an option to use either the ADM/MDM Dual Articulating Trials or the ADM/MDM Monopolar Trials. Both trialing options are designed to facilitate a final check of hip mechanics to include range of motion consistent with the patient's normal daily activities. At this point, joint laxity should also be assessed, taking into consideration the type of anesthetic used and its effects on soft tissue.
- If using the ADM/MDM Dual Articulating Trials, place the 22.2mm or 28mm Head Trial into the appropriate Insert Trial to mimic the final articulation function of the MDM System **(Figure 17a)**. The size of the Insert Trial will correspond with the MDM Liner being implanted **(Table 7)**.
- If using the ADM/MDM Monopolar Trials, place the Trial Sleeve that corresponds to the desired femoral head taper and offset into the appropriate Insert Trial by firmly pushing the Sleeve into the inner geometry of the Insert Trial **(Figure 17b, Tables 7-9)**. Correct assembly of the Trial Sleeve and Insert Trials will produce an audible click. The size of the Insert Trial will correspond with the MDM Liner being implanted **(Tables 7-9)**.
- Place the assembled Dual Articulating or Monopolar Trials onto the neck trial or stem trunnion component. Ensure that the Monopolar Trials are locked by firmly pushing the Insert Trial Sleeve assembly onto the neck trial or stem. Reduce the hip, checking for hip stability and the restoration of leg length. Fine-tuning of hip joint mechanics may be achieved with the use of different +/- offsets.
- Once hip stability and leg length have been checked, the Dual Articulating or Monopolar Trial assembly can be removed from the neck trial or trunnion as one unit. If using the Monopolar Trials, the Trial Sleeve can then be removed from the Insert Trial with the assistance of standard Kocher forceps by squeezing the Trial Sleeve and pulling it out of the Insert Trial **(Figure 17c)**. This can also be accomplished by hand.

Note

The Monopolar Trials are only available for V40 and C-Taper heads. These trials are not compatible with the Definition and Meridian femoral stems from Japan. Additionally, a feature has been included in the Monopolar Trial design to prevent the assembly of Trial Sleeve offsets only available in 28mm heads into 36C and 38D Insert Trials. The Monopolar Trials are marked 'trial do not implant'. If there is any reason to believe that the trial has been accidentally implanted, the Monopolar Insert Trial is radiopaque and would be visible on an X-ray.

Note

When using dual mobility implants, impingement should be carefully assessed and avoided during range of motion. Impingement can result in increased wear in metal-polyethylene systems.

Tip

When using the ADM/MDM Dual Articulating Trials, place the 22.2mm or 28mm trial head onto the neck trial or stem trunnion and place the ADM/MDM Insert Trial into the MDM Liner. The smaller trial head can then be reduced into the Insert Trial for ease of reduction.

Table 7: MDM Liner, X3 insert and femoral head compatibility

MDM Liner	MDM X3 Insert (22.2/28mm ID)	Femoral head size (mm)	MDM Liner Trial	ADM/MDM Dual Articulating Insert Trial	ADM/MDM Monopolar Insert Trial
626-00-36C	1236-2-242 or 7236-2-242	22.2 mm	3200-36C	1235-0-242	1235-0-242M
626-00-38D	1236-2-244 or 7236-2-244	22.2 mm	3200-38D	1235-0-244	1235-0-244M
626-00-42E	1236-2-848 or 7236-2-848	28 mm	3200-42E	1235-0-848	1235-0-848M
626-00-46F	1236-2-852 or 7236-2-852	28 mm	3200-46F	1235-0-852	1235-0-852M
626-00-48G	1236-2-854 or 7236-2-854	28 mm	3200-48G	1235-0-854	1235-0-854M
626-00-52H	1236-2-858 or 7236-2-858	28 mm	3200-52H	1235-0-858	1235-0-858M
626-00-54I	1236-2-860 or 7236-2-860	28 mm	3200-54I	1235-0-860	1235-0-860M
626-00-58J	1236-2-864 or 7236-2-864	28 mm	3200-58J	1235-0-864	1235-0-864M

Step 8

Trial insert/head reduction (continued)

Table 8: Monopolar Trial Sleeve catalog numbers and V40 22.2 and 28mm femoral head options

V40 22.2mm femoral head offsets	Monopolar Trial Sleeve	LFIT CoCr
+0mm	1235-V-1000	✓
+3mm	1235-V-1030	✓
+8mm	1235-V-1080	✓

V40 28mm femoral head offsets	Monopolar Trial Sleeve	LFIT CoCr	BIOLOX *delta*	BIOLOX *delta* Universal	Alumina
-4mm	1235-V-0040	✓	✓		
-2.7mm	1235-V-0027		✓		✓
-2.5mm	1235-V-0025			✓	
+0mm	1235-V-1000	✓	✓	✓	✓
+4mm	1235-V-1040	✓	✓	✓	✓
+6mm	1235-V-1060	✓			
+8mm	1235-V-1080	✓			
+12mm	1235-V-1120	✓			

Table 9: Monopolar Trial Sleeve catalog numbers and C-Taper 22.2 and 28mm femoral head options

C-Taper 22.2mm femoral head offsets	Monopolar Trial Sleeve	LFIT CoCr
+0mm	1235-C-1000	✓
+2.5mm	1235-C-1025	✓
+5mm	1235-C-1050	✓
+10mm	1235-C-1100	✓

C-Taper 28mm femoral head offsets	Monopolar Trial Sleeve	LFIT CoCr	BIOLOX *delta*	BIOLOX *delta* Universal	Alumina
-3mm	1235-C-0030	✓			
-2.5mm	1235-C-0025		✓	✓	✓
+0mm	1235-C-1000	✓	✓	✓	✓
+2.5mm	1235-C-1025	✓	✓	✓	
+5mm	1235-C-1050	✓	✓	✓	✓
+7.5mm	1235-C-1075	✓			
+10mm	1235-C-1100	✓			

Step 9

Insert/head implantation

Back table assembly of the insert and corresponding V40 or C-Taper 22.2mm* or 28mm Head is required **(Figure 18)**. The following instructions must be carefully adhered to:

- Place the Press Stand flat on the table and place the Press onto the Press Stand Pin.
- Put the Femoral Head Supporting Piece into the base of the Press as shown.
- Open the press by turning the T-Handle counterclockwise until the polyethylene insert fits above the femoral head and below the plastic cone portion of the Press.
- Place the femoral head onto the Head Supporting Piece and then place the insert onto the femoral head.
- Once the femoral head and polyethylene insert are in a vertical position, tighten the Press until the head is fully lodged into the insert. After insertion, the air confined between the head and insert is usually released, resulting in a characteristic noise.
- After the head and insert are assembled, verify that the coupling has complete mobility.

Note

Ensure that the inside of the shell is clean and free of soft tissue or other debris, which could prevent the polyethylene insert from properly seating in the shell.

Warning

A metal or ceramic head should not be used in place of the dual mobility insert/head. The MDM Liner is not intended for use as a metal-on-metal or ceramic-on-metal articulation. No testing has been conducted to determine that these bearing couples produce favorable mechanical outcomes. Only Stryker 22.2mm or 28mm femoral heads should be inserted into the MDM X3 polyethylene inserts.

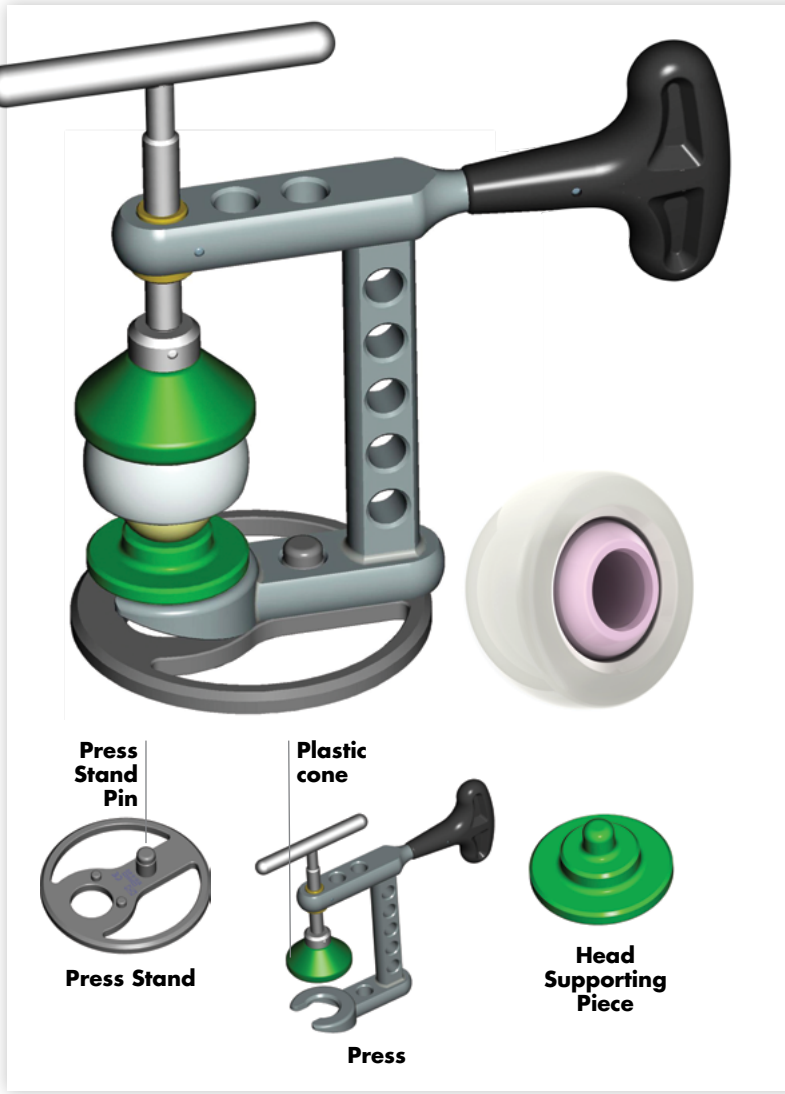


Figure 18

* Stryker Universal, V40 and C-Taper BIOLOX *delta* and Alumina Ceramic heads are not available in 22.2mm. They can only be utilized in inserts compatible with 28mm heads.

Step 10

Reduction and closure

Once the insert and femoral head are assembled, the unit is ready for implantation and reduction. Place the insert/head unit onto the trunnion of the femoral stem and slightly impact with Insert Reduction Tool. Then, by exerting axial traction on the limb and pressure on the insert using the Insert Reduction Tool, reduce the hip and check for laxity, stability, leg length equality and range of motion **(Figure 19)**. The surgical site is then closed according to surgeon preference.

Caution

Care should be taken to avoid damage to the polyethylene insert during reduction as this may lead to premature wear of the insert material.

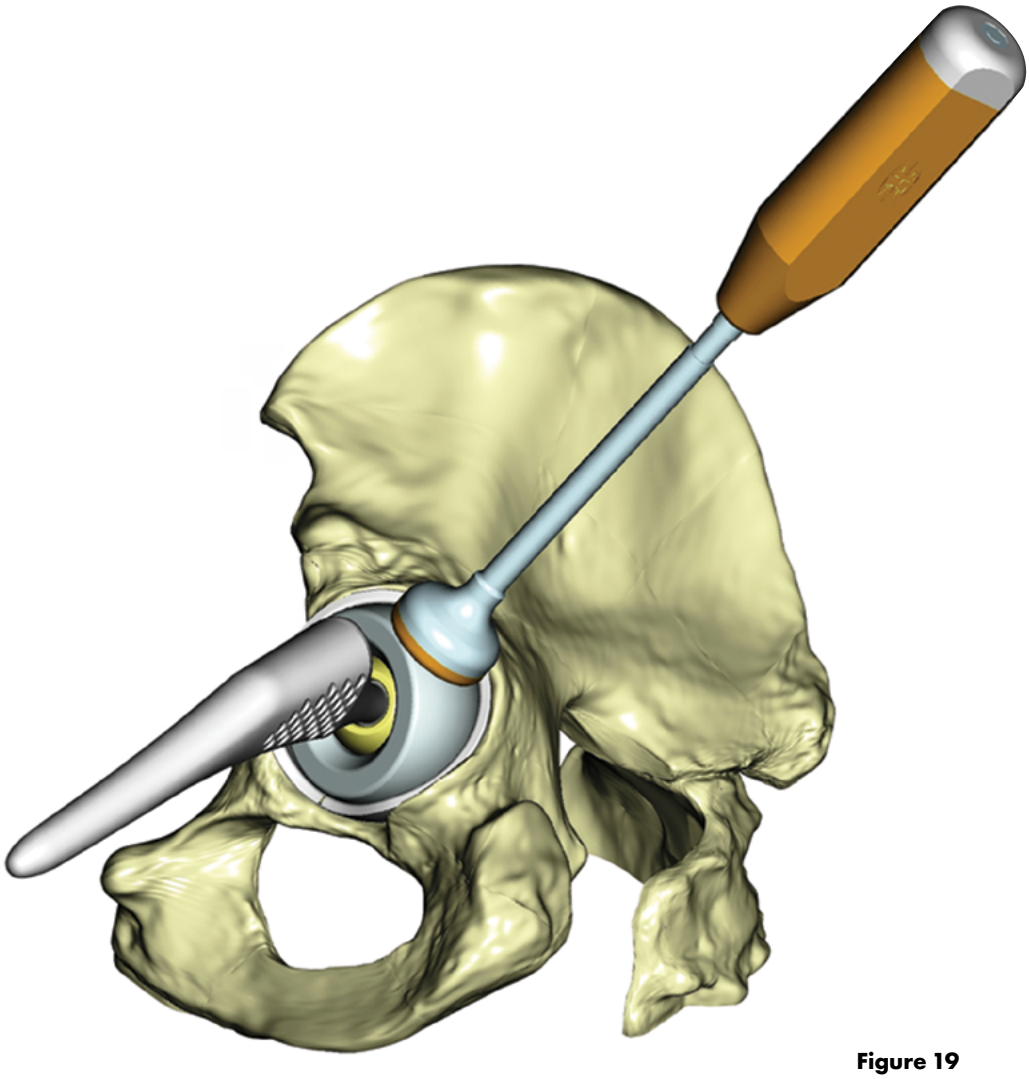


Figure 19

Removal options

Liner shell, insert/head

MDM Liner removal

The Trident Liner Removal Tool (2112-0000) is designed to provide the surgeon with two options for extracting the MDM Liner from the Trident or Trident Tritanium shell.

Figure 20

Figure 21

Option 1: Flat head

Connect the T-Handle (1101-2100) to the L-shaped end of the removal tool. Insert the flat end of the removal tool between the shell and MDM Liner at one of the four notches in the shell rim **(Figure 20**). While applying continuous force toward the center of the shell, twist the T-Handle (like a screwdriver), to dislodge the MDM Liner. Bias the flat head of the tool toward the left when rotating the instrument in a counterclockwise direction to improve its effectiveness. Conversely, biasing the tool toward the right when rotating clockwise may aid in its use. It may be required to repeat this procedure at the other notches in order to successfully disengage the taper.

Note

Prior to performing a liner exchange, visually assess the shell's locking mechanism for damage. If damaged, shell should be replaced.

Option 2: L-shaped

Insert the L-shaped end of the removal tool between the shell and MDM Liner at one of the four notches in the shell rim **(Figure 21)**. Apply continuous force toward the center of the shell, and lever the tool in a plane tangent to the shell's outside edge, to dislodge the MDM Liner. It may be required to repeat this procedure at the other notches in order to successfully disengage the taper. The removal tool may be attached to the Insert Positioner/Impactor Handle to increase leverage and length for larger patients.

Shell removal

Should removal of the shell ever become necessary, an osteotome, compatible shell removal system or small burr can be passed around the cup periphery to loosen the fixation interface. The CuttingEdge Shell Positioner/Impactor Handle can be threaded into the dome hole of the cup. A mallet can be used to assist with the shell removal.

Insert/Head unit removal

Note

Once the polyethylene insert and femoral head are assembled, the two components cannot be disassembled. However, the assembled polyethylene insert and femoral head unit can be removed from the trunnion of the stem. If the insert and head unit needs to be revised for any reason, remove the unit with the Femoral Head Remover Instrument (6059-9-505 – **Figure 22)**.

- Place distal portion of the Femoral Head Removal Instrument over the neck of the stem, while placing the proximal portion of the instrument under the insert and head unit.
- Once the instrument is in position, squeeze the handles together to pry the insert and head unit off of the trunnion of the stem.
- Be sure that the instrument is not pressing against the outer bearing surface of the poly, as this will decrease the effectiveness of the removal tool and will result in a significantly larger force required to separate the head from the stem.

Figure 22

Catalog information

MDM Liner, X3 insert and femoral head compatibility

MDM Liner	MDM X3 Insert (22.2/28mm ID)	Femoral head size (mm)	MDM Liner Trial	ADM/MDM Dual Articulating Insert Trial	ADM/MDM Monopolar Insert trial
626-00-36C	1236-2-242 or 7236-2-242	22.2 mm	3200-36C	1235-0-242	1235-0-242M
626-00-38D	1236-2-244 or 7236-2-244	22.2 mm	3200-38D	1235-0-244	1235-0-244M
626-00-42E	1236-2-848 or 7236-2-848	28 mm	3200-42E	1235-0-848	1235-0-848M
626-00-46F	1236-2-852 or 7236-2-852	28 mm	3200-46F	1235-0-852	1235-0-852M
626-00-48G	1236-2-854 or 7236-2-854	28 mm	3200-48G	1235-0-854	1235-0-854M
626-00-52H	1236-2-858 or 7236-2-858	28 mm	3200-52H	1235-0-858	1235-0-858M
626-00-54I	1236-2-860 or 7236-2-860	28 mm	3200-54I	1235-0-860	1235-0-860M
626-00-58J	1236-2-864 or 7236-2-864	28 mm	3200-58J	1235-0-864	1235-0-864M

Replacement O-ring for Dual Articulating Insert Trials

Catalog number	Description
1235-0-022	For 22.2 mm Trial
1235-0-028	For 28 mm Trial

MDM instruments

Catalog number	Description
5900-8114	MDM Case #
1235-0-306	MDM Tray #
1235-0-020	Insert Reduction Tool
1235-0-008	Press
1235-0-012	Press Stand
1235-0-009	Head Supporting Piece
2112-0000	Liner Removal Tool
6147-3-101	Trident & Tritanium Reamers Tray
2101-0130	Final Cup Impactor
2102-0132	Impaction Pad

Stryker Orthopaedics has only validated these reusable instrument tray/cases for use with CSR wrap. Refer to LSPTI-B (Instructions for Cleaning, Sterilization, Inspection, and Maintenance of Reusable Medical Devices).

Stryker Orthopaedics has validated the following reusable instrument trays with Aesculap's SterilContainer™ System and with CSR wrap. Refer to LSTPI-B (Instructions for Cleaning, Sterilization, Inspection, and Maintenance of Reusable Medical Devices).

Catalog number	Description
6147-0-100	Universal Lid
6147-2-101	MDM Instruments Tray
6147-3-101	Trident & Tritanium Reamers Tray

Catalog information

Trident Tritanium Solidback shells

Catalog number	Shell size (mm)	Rim diameter (mm)
500-03-48C	48	48
500-03-50D	50	50
500-03-52D	52	52
500-03-54E	54	54
500-03-56E	56	56
500-03-58F	58	58
500-03-60F	60	60
500-03-62G	62	62
500-03-64G	64	64
500-03-66H	66	66

Trident Tritanium Clusterhole shells

Catalog number	Shell size (mm)	Rim diameter (mm)
502-03-48C	48	48
502-03-50D	50	50
502-03-52D	52	52
502-03-54E	54	54
502-03-56E	56	56
502-03-58F	58	58
502-03-60F	60	60
502-03-62G	62	62
502-03-64G	64	64
502-03-66H	66	66

Trident Tritanium Multihole shells

Catalog number	Shell size (mm)	Rim diameter (mm)
509-02-54E	54	54
509-02-56E	56	56
509-02-58F	58	58
509-02-60F	60	60
509-02-62G	62	62
509-02-64G	64	64
509-02-66H	66	66
509-02-68H	68	68
509-02-70I	70	70
509-02-72I	72	72
509-02-74J	74	74
509-02-76J	76	76
509-02-78J	78	78
509-02-80J	80	80

Trident Hemispherical HA Solidback shells

Catalog number	Shell size (mm)	Rim diameter (mm)
500-11-46C	46	46
500-11-48D	48	48
500-11-50D	50	50
500-11-52E	52	52
500-11-54E	54	54
500-11-56F	56	56
500-11-58F	58	58
500-11-60G	60	60
500-11-62G	62	62
500-11-64H	64	64
500-11-66H	66	66
500-11-68I	68	68
500-11-70I	70	70
500-11-72J	72	72
500-11-74J	74	74

Trident Hemispherical HA Clusterhole shells

Catalog number	Shell size (mm)	Rim diameter (mm)
502-11-46C	46	46
502-11-48D	48	48
502-11-50D	50	50
502-11-52E	52	52
502-11-54E	54	54
502-11-56F	56	56
502-11-58F	58	58
502-11-60G	60	60
502-11-62G	62	62
502-11-64H	64	64
502-11-66H	66	66
502-11-68I	68	68
502-11-70I	70	70
502-11-72J	72	72
502-11-74J	74	74

Trident Hemispherical HA Multihole shells

Catalog number	Shell size (mm)	Rim diameter (mm)
508-11-46C	46	46
508-11-48D	48	48
508-11-50D	50	50
508-11-52E	52	52
508-11-54E	54	54
508-11-56F	56	56
508-11-58F	58	58
508-11-60G	60	60
508-11-62G	62	62
508-11-64H	64	64
508-11-66H	66	66
508-11-68I	68	68
508-11-70I	70	70
508-11-72J	72	72
508-11-74J	74	74

Catalog information

Trident PSL HA Solidback shells

Catalog number	Shell size (mm)	Rim diameter (mm)
540-11-44C	44	45.8
540-11-46D	46	47.8
540-11-48D	48	49.8
540-11-50E	50	51.8
540-11-52E	52	53.8
540-11-54F	54	55.8
540-11-56F	56	57.8
540-11-58G	58	59.8
540-11-60G	60	61.8
540-11-62H	62	63.8
540-11-64H	64	65.8
540-11-66I	66	67.8
540-11-68I	68	69.8
540-11-70J	70	71.8
540-11-72J	72	73.8

Trident PSL HA Clusterhole shells

Catalog number	Shell size (mm)	Rim diameter (mm)
542-11-44C	44	45.8
542-11-46D	46	47.8
542-11-48D	48	49.8
542-11-50E	50	51.8
542-11-52E	52	53.8
542-11-54F	54	55.8
542-11-56F	56	57.8
542-11-58G	58	59.8
542-11-60G	60	61.8
542-11-62H	62	63.8
542-11-64H	64	65.8
542-11-66I	66	67.8
542-11-68I	68	69.8
542-11-70J	70	71.8
542-11-72J	72	73.8

Shell implant accessories

Catalog number	Description
2060-0000-1	Acetabular Dome Hole Plug

Stryker Torx 6.5mm Bone Screws for use with Trident Hemispherical, Trident PSL and Trident Tritanium Clusterhole shells

Catalog number	Screw lengths (mm)
2030-6516-1	16
2030-6520-1	20
2030-6525-1	25
2030-6530-1	30
2030-6535-1	35
2030-6540-1	40
2030-6545-1	45
2030-6550-1	50
2030-6555-1	55
2030-6560-1	60

Stryker Gap Torx 6.5mm Bone Screws for use with Trident Tritanium Multihole shells

Catalog number	Screw lengths (mm)
2080-0015	15
2080-0020	20
2080-0025	25
2080-0030	30
2080-0035	35
2080-0040	40
2080-0045	45
2080-0050	50
2080-0055	55
2080-0060	60

X-ray templates

Trident Tritanium Solidback and Clusterhole Acetabular System	LTEM102
Trident Tritanium Multihole Acetabular System	LTEM89
Trident PSL Acetabular System	LTEM59 1-6
Trident Hemispherical Acetabular System	LTEM60B 1-2

CE 2797

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