G7[®]Acetabular System BiSpherical Shell

Surgical Technique

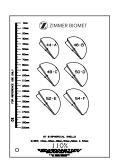


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Quick Reference Surgical Technique



Step 1: Preoperative Planning



Step 2: Reaming



Step 3: Instrument Selection



Step 4: Shell Trialing (optional)



Step 5: Shell Insertion



Step 6: Supplemental Screw Insertion (optional)



Step 7: Liner Trialing



Step 8: Liner Insertion



Step 9: Final Reduction

ONDE: There may be slight variations in colors between components.

Quick Reference Polyethylene Guide

Polyethylene Articulation Sizing (Neutral, High Wall, 10 Degree Face Changing & +5 mm Liners)

Shell	Shell Size		Head Size (mm)				
(m	m)	28	32	36	40	44	
42 44	А	28					
46	В	28	32				
48	С	28	32				
50	D	28	32	36			
52	Е	28	32	36			
54 56	F	28	32	36	40		
58	G	20	22	26	40		
60	G	28	32	36	40		
62 64	Н		32	36	40	44	
66	I			36	40	44	

10 Degree Face Changing Leg Length Chart

Shell Size (mm)		Offset (mm)	Leg Length (mm)	Lateralization (mm)
42 44	А	3.2	2.4	2.1
46	В	3.6	2.7	2.3
48	С	3.7	2.8	2.4
50	D	3.9	3	2.6
52	Е	4.1	3.1	2.7
54 56	F	4.3	3.2	2.8
58 60	G	4.4	3.4	2.9
62 64	Н	4.8	3.6	3.1
66	I	5.1	3.9	3.3

Quick Reference Polyethylene Thickness Guide

≈ Minimum Poly Liner Thickness at 45° (mm) (Neutral, High Wall, 10 Degree Face Changing & Freedom[®] Constrained Liners)

Shell	Shell Size		Head Size (mm)				
(m	m)	28	32	36	40	44	
42	А	4.3					
44	A	4.5					
46	В	6.3	4.3				
48	С	7.3	5.3				
50	D	8.3	6.3	4.3			
52	Е	9.3	7.3	5.3			
54	F	10.3	8.3	6.3	4.3		
56	Г	10.5	0.3	0.5	4.5		
58	G	11.3	9.3	7.3	5.3		
60	G	11.5	9.5	7.5	5.5		
62	Н		11.3	9.3	7.3	5.3	
64	11		11.5	9.5	7.5	5.5	
66	I			11.3	9.3	7.3	

≈ Minimum Poly Liner Thickness at Apex (mm) (Neutral, High Wall, 10 Degree Face Changing & Freedom Constrained Liners)

Sh	ell Size		Head Size (mm)				
	(mm)	28	32	36	40	44	
42	A	4.7					
44		4.7					
46	б В	6.7	4.7				
48	B C	7.7	5.7				
50) D	8.7	6.7	4.7			
52	E E	9.7	7.7	5.7			
54	F	10.7	0.7	67	47		
56		10.7	8.7	6.7	4.7		
58	G G	11.7	9.7	7.7	5.7		
60		11.7	9.7	1.1	5.7		
62	: H		11.7	9.7	7.7	5.7	
64	Ļ		11./	9.7	1.1	5.7	
66	5 I			11.7	9.7	7.7	



Quick Reference Polyethylene Thickness Guide

≈ +5 Poly Liner Thickness at 45° (mm)

S	Shell Size			Head Size (mm)				
	(mm)	28	32	36	40	44	
	12 14	А	7.4					
4	16	В	9.4	7.4				
4	18	С	10.4	8.4				
5	50	D	11.4	9.4	7.4			
5	52	Е	12.4	10.4	8.4			
	54 56	F	13.4	11.4	9.4	7.4		
	58 50	G	14.4	12.4	10.4	8.4		
	52 54	Н		14.4	12.4	10.4	8.4	
e	66	I			14.4	12.4	10.4	

 \approx +5 Poly Liner Thickness at Apex (mm)

Shell Size			Head Size (mm)					
(m	m)	28	32	36	40	44		
42 44	А	9.7						
46	В	11.7	9.7					
48	С	12.7	10.7					
50	D	13.7	11.7	9.7				
52	Е	14.7	12.7	10.7				
54 56	F	15.7	13.7	11.7	9.7			
58 60	G	16.7	14.7	12.7	10.7			
62 64	Н		16.7	14.7	12.7	10.7		
66	I			16.7	14.7	12.7		



Quick Reference Polyethylene Thickness Guide

Freedom Constrained Sizing Chart

Shell Size		Hea	d Size (r	mm)
(m	m)	28	32	36
42	А			
44	A			
46	В		32	
48	С		32	
50	D			36
52	Е			36
54	F			36
56	Г			50
58	G			36
60	G			30
62	Ц			26
64	Н			36
66	I			36

G7 Ceramic Articulation

:	Shell Size			Head Siz	e (mm)	
	(mm)	28 32		36	40
	42	А				
	44	~				
	46	В	B 28			
	48	С		C 32		
	50	D		D 32		
	52	Е		E 32	E 36	
	54	F		F 32	F 36	
	56	1		1 52	1 30	
11	58	G		G 32	G 36	G 40
	60	u		U 52	u 50	u 40
	62	Н		Н 32	H 36	H 40
	64	11		11 32	11-50	11 40
	66	I		I 32	I 36	I 40

Dual Mobility

Letter Designation	Shell Size	Liner Size (I.D. in mm)	Bearing Size (O.D. in mm)	Bearing Thickness (mm)	Femoral Head Size (mm)	CoCr Head	Ceramic Head
А	42 - A 44 - A	32	32	4.6	22.2	\checkmark	~
В	46 - B	36	36	6.6	22.2	\checkmark	\checkmark
С	48 - C	38	38	4.8	28	\checkmark	\checkmark
D	50 - D	40	40	5.8	28	\checkmark	\checkmark
E	52 - E	42	42	6.8	28	\checkmark	\checkmark
F	54 - F 56 - F	44	44	7.8	28	\checkmark	¥
6	58 - G	10	4.0	0.0	20		
G	60 - G	46	46	8.8	28	~	~
	62 - H	50	50	10.0	20		
Н	64 - H	50	50	10.8	28	~	\checkmark
I.	66 - I	54	54	12.8	28	\checkmark	\checkmark

Surgical Technique



G7 Acetabular System Color & Letter Coding Key

Color and Liner Size	Shell Size(s)
А	42,44 mm
В	46 mm
С	48 mm
D	50 mm
E	52 mm
F	54,56 mm
G	58,60 mm
Н	62,64 mm
1	66 mm

Figure 1

Figure 2

Device Description

The BiSpherical design of the G7 acetabular shell is intended to provide fixation and stability with its unique macrostructure. Multiple bearing options are available, including Vitamin E Stabilized and highly crosslinked polyethylene Liners, Ceramic Liners and Dual Mobility Cobalt Chrome Liners.

The G7 Acetabular System utilizes a unique color coding system designed to offer an efficient operating experience. The provisional shells, provisional liners, labels and face plate impactors match the color anodized on the rim and letter designation of the acetabular shell implant (Figure 1). The G7 Acetabular System color and letter coding key is listed in Figure 2.

Note: Implant identification should be made using letter and size information. Color coding should be used only as a secondary reference. There may be slight variations in colors between components.

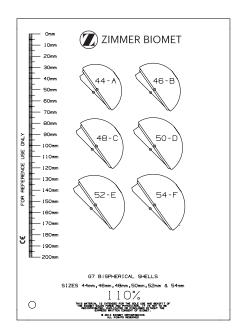
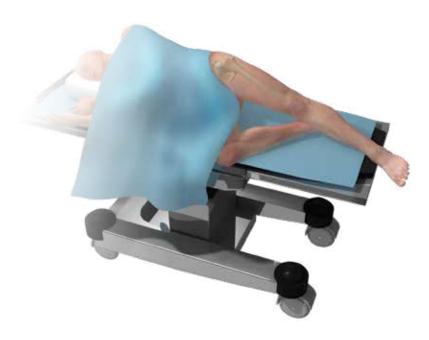


Figure 3

Preoperative Templating

Accurate preoperative planning and acetabular templating help determine the size, desired location and position of the acetabular shell and are essential parts of the surgical process. Templating is best performed with an A/P pelvis radiograph with the limb internally rotated approximately 15 degrees. This allows more accurate determination of femoral offset, radiographic leg length inequality, and referencing of contralateral hip, if required.

When examining the A/P radiograph, the shell should be positioned against, but not medial to, the radiographic teardrop at 40 degrees of inclination. Acetabular shell size is best determined on a crosstable lateral radiograph. If the patient's anatomy is obscured, it may be helpful to check the acetabular component size on the contralateral hip radiograph, as well. Make note of the shell size that fills the acetabular space appropriately and fits the anterior to posterior diameter of the native acetabulum, keeping in mind that final decision on shell size should be made during surgery when adequate visualization of the acetabulum is achieved.



Patient Positioning

The G7 Acetabular System is designed to be used with all surgical approaches (Figure 4).

Acetabular Exposure

Prior to reaming, acetabular exposure should be adequate and the anterior, posterior and superior walls should be directly visible. The medial acetabular wall, which dictates the depth of the reaming, should be uncovered offloor osteophytes or pulvinar pad. Specialized acetabular retractors are available to help facilitate exposure for whichever approach is chosen.



Example Shell Implant Size and Reaming Options

Shell Implant
Size on Box Label: 48 mm
Measures: 50 mm (at the shell rim)
Reaming Options
48 mm (2 mm press-fit)

50 mm (line-to-line)

49 mm (1 mm press-fit)

Table 1



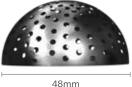
Figure 5

Figure 6

Acetabular Reaming

Determine a starting reamer size from the preoperative template and from the measured diameter of the resected Femoral Head. This is typically 6–8 mm smaller than the Femoral Head diameter. Reamer handles are provided as straight or curved (offset). Use is dictated by surgeon preference, surgical exposure, and patient body composition. During the reaming process, frequently determine the amount of anterior and posterior acetabular bone remaining to avoid reaming away the wall and compromising fixation.

Beginning with a small reamer, apply constant pressure first toward the medial wall, appropriately medializing the acetabulum for optimal hip biomechanics and the normal center of hip rotation. Gradually progress to larger reamers, while maintaining concentricity within the acetabular cavity until bleeding subchondral bone is exposed (Figure 5). The preferred acetabular orientation is 40 degrees inclination and 20 degrees of anteversion, but final acetabular position depends on patient anatomy and may vary slightly with approach. Final orientation of the acetabular implant is also dictated by the amount of version of the femoral implant (i.e., greater anteversion of the acetabular component may be required in the case of a retroverted stem).





49mm



50mm

Acetabular Reamer Labeled 48 mm Measures 48 mm

Provisional Shell Labeled 48 mm Measures 49 mm (at the rim)

Implant Shell Shell Size on Box Label 48 mm Implant Labeled 48 mm Measures 50 mm (at the rim)

Figure 7a

Figure 7b

Acetabular Reaming (cont.)

Once reaming is complete, use the provisional shells to confirm the position and accuracy of the reaming. Final shaping must be achieved using the hemispherical grater reamer to ensure a congruent fit between the shell and the acetabulum.

Optional Shell Trialing and Alignment with Shell Gauge Handle

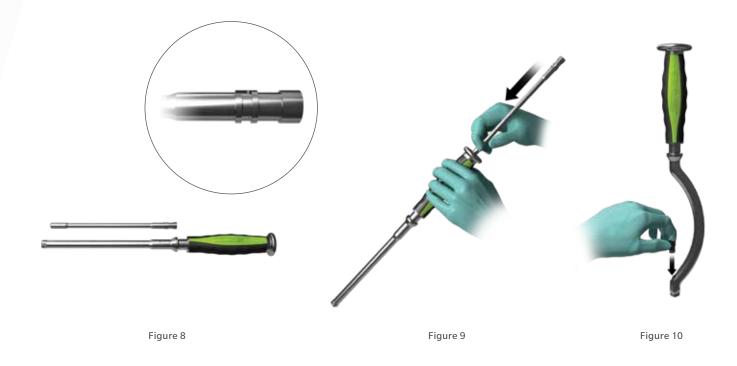
Once the desired ream has been achieved, select the appropriate provisional shell. Depending on the reamer size, the provisional shell is oversized by 1 mm (at the rim) to evaluate press-fit (Figure 7a).

The shell gauge handle may be threaded to the acetabular shell provisional and used to gauge the size of the reamed acetabulum (Figure 7b).

Place the provisional shell into the acetabulum at approximately 40 degrees of inclination and 20 degrees of anteversion.

Approximate version can be obtained by using the transverse acetabular ligament or by referencing the opening of the acetabular component 90 degrees off of the sciatic notch.

ONOTE: Do not impact on the shell gauge handle.



Optional Shell Trialing and Alignment with Inserter Handle

The straight monoblock, curved or straight modular inserter handle can also be used to insert the provisional shell.

Modular Handle Assembly

When using the curved or straight modular handle, place the appropriate threaded shaft into the handle through the hole in the strike plate of the straight modular handle (Figures 8 and 9), or the hole at the distal tip of the curved inserter handle (Figure 10).

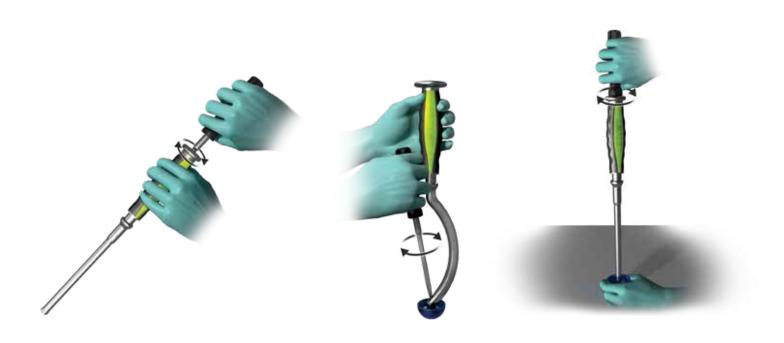


Figure 12

Figure 13

Optional Shell Trialing and Alignment with Inserter Handle (cont.)

Modular Handle Assembly (cont.)

Insert the ball hex driver into the hole in the strike plate of the straight handle or the hole at the distal tip of the curved handle and turn to advance the threaded shaft until the threads are exposed (Figures 11 and 12).

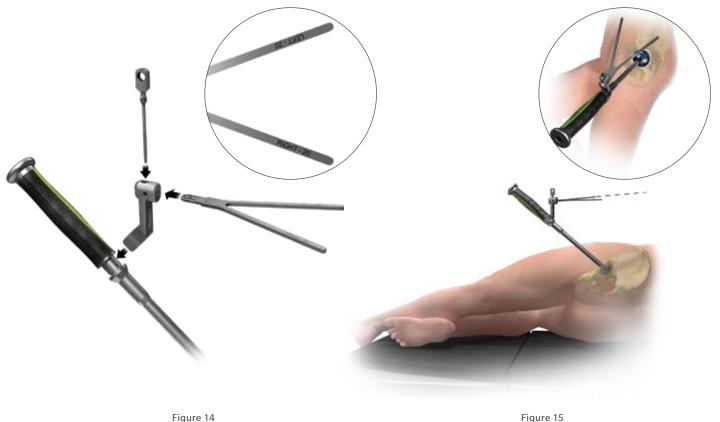
Line up the square tip of the insertion handle with the square at the apex of the provisional shell. Turn the ball hex driver in a clockwise direction to advance the thread into the provisional shell (Figure 13). Remove the ball hex driver from the handle. Ensure that the provisional shell is securely fastened to the handle by lightly pulling on the provisional shell prior to impaction.

The provisional shell is disassembled from the handle by re-inserting the ball hex driver and turning counter-clockwise.

Monoblock Handle Assembly

If using the G7 Straight Monoblock Inserter Handle, line up the thread of the insertion handle with the thread of the provisional shell and rotate the handle clockwise. Ensure that the shell is securely fastened to the handle by lightly pulling on the provisional shell prior to impaction.

The provisional shell is disassembled by rotating the handle counter-clockwise



Optional Shell Trialing and Alignment with Inserter Handle (cont.)

Positioning Guides

Approximate version can be obtained by using the transverse acetabular ligament or by referencing the opening of the acetabular component 90 degrees off of the sciatic notch. Alternatively, a positioning guide may be used.

The Lateral and Anterior Supine G7 positioning guides are designed to aid in proper insertion of the acetabular component.

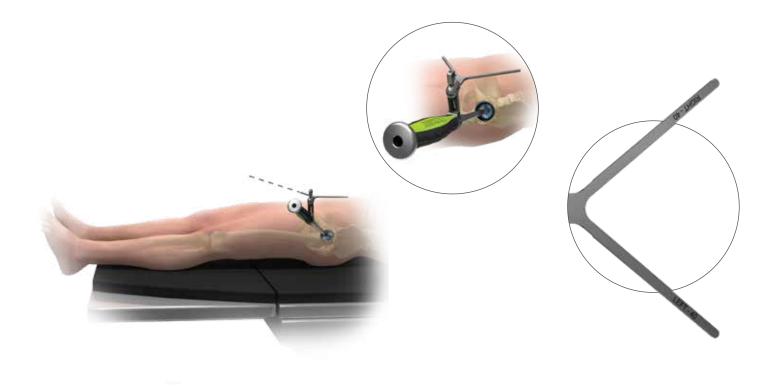
Assemble the positioning guide construct on the back table before securing to the insertion handle. To assemble the positioning guide construct, connect the positioning guide post to the insertion handle by sliding the guide post into the opening between the handle grip and the shaft. Slide the lateral or anterior supine positioning guide into the flat opening on the guide post. When the positioning guide construct is in place, tighten the positioning guide rod to secure the construct to the handle (Figure 14).

 Note: Only hand tighten the positioning guide rod to avoid damaging the rod.

Lateral Guide

When positioning the acetabular shell, the lateral guide arms should be parallel to the table, aimed toward the patient's ipsilateral shoulder (Figure 15).

For the **right hip**, use the reference arm of the "V" shaped guide labeled "RIGHT." For the left hip, use the reference arm of the "V" shaped guide labeled "LEFT" (Figure 14).



Optional Shell Trialing and Alignment with Inserter Handle (cont.)

Anterior Supine Guide

When positioning the acetabular shell, the **anterior supine** positioning guide arms should be parallel to the table, aligned with the patient's spinal column (Figure 16).

For the **right hip**, use the reference arm of the "V" shaped guide labeled "**RIGHT**." For the **left hip**, use the reference arm of the "V" shaped guide labeled "**LEFT**" (Figure 16).

● Note: The primary reference for acetabular shell position should be based on the patient's anatomy. These instruments rely significantly on patient position and are designed to be used only as a secondary verification. If at any time there is concern about acetabular position, the orientation may be verified with intraoperative fluoroscopy or with intraoperative radiographs. A true A/P pelvis without rotation is best indicated when the tip of the coccyx lines up with the pubic symphysis and is within 1–2 cm of the symphysis.

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Figure 18b

Figure 17

Optional Shell Trialing and Alignment with Inserter Handle (cont.)

Provisional Shell Impaction

Lightly impact the provisional shell and confirm complete seating through the cutouts on the provisional shell (Figure 17). Remove any soft tissue or osteophytes from the acetabular rim that overhang the edge of the provisional component to obtain proper seating. If the provisional shell is unstable, or if there are gaps between the provisional shell and the acetabulum, it may be necessary to increase the diameter of the final reamer. However, in some instances it may not be possible to increase the reamed diameter. If this is the case, then supplementary screw fixation may be necessary. Once satisfied with the seating of the provisional shell it can be removed from the acetabulum or disassembled from the inserter to perform optional liner trialing.

● Note: Levering on the inserter handle or impacting the handle on a location other than the strike plate to reposition the shell may damage the threads.

Optional Liner Trialing with Provisional Shell

Following seating of the provisional shell, select the appropriate provisional liner size, as indicated alphabetically and by color, in the desired liner configuration.

Insert the provisional liner into the provisional shell by hand. Utilize a 3.5 mm hex screwdriver to tighten the screw in the dome of the provisional liner into the apical hole of the provisional shell (Figures 18a and 18b).

ONOTE: Do not overtighten the provisional liner.

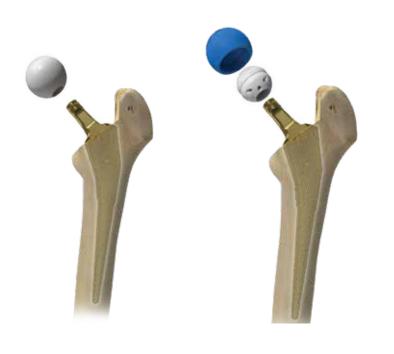




Figure 19a

Figure 19b

Figure 20

Optional Trial Reduction and Range of Motion

Select the appropriate provisional head, head diameter and neck length to achieve desired leg length and needed lateralization as determined by the surgeon. These determinations can be made during preoperative templating, but final adjustments are made intraoperatively.

Polyethylene and Ceramic Liners

Insert the provisional head onto the implanted stem or broach and reduce the hip (Figures 19a and 20).

Dual Mobility

Assemble the provisional head onto the trunnion. Select the appropriate dual mobility bearing provisional as indicated alphabetically and by color and assemble to the provisional head and reduce the hip (figures 19b and 20). Ensure the provisional head is seated fully on the trunnion. Check for joint stability and range of motion, making any necessary adjustments to restore joint mechanics. Make certain that prominent impinging bone and/or osteophytes are removed from the periphery of the acetabulum to maximize range of motion and stability. Make note of all provisional components used and then remove all provisionals.

Note: If using the G7 self-retaining provisional head in combination with a Type 1 reduced taper, a click is felt and/or heard when the provisional head is fully seated.



Acetabular Shell Insertion

The straight monoblock, curved or straight modular inserter handles are used for the final implant shell insertion.

● Note: Limited hole shells are packaged with the screw holes pre-plugged. Should screw fixation be necessary, the screw hole covers should be removed using a 3.5 mm hex driver prior to shell insertion.

Modular Handle Assembly

When using the curved or straight modular handle, place the appropriate threaded shaft into the handle through the hole in the strike plate of the straight modular handle (Figures 21 and 22), or the hole at the distal tip of the curved inserter handle (Figure 23).

Insert the ball hex driver into the hole in the strike plate of the straight handle or the hole at the distal tip of the curved handle and turn to advance the threaded shaft until the threads are exposed.

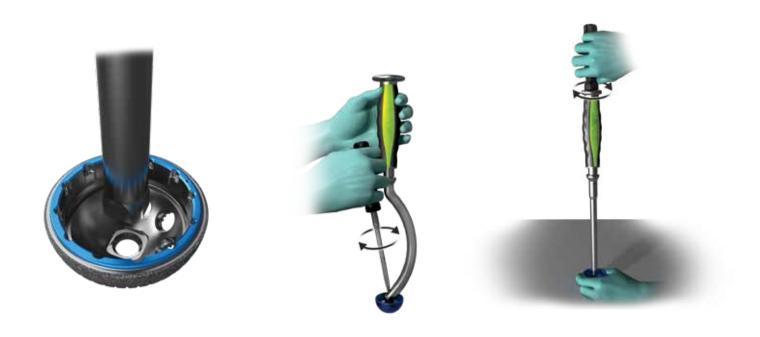


Figure 25

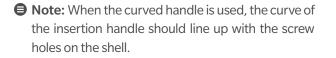
Figure 26

Acetabular Shell Insertion (cont.)

Modular Handle Assembly (cont.)

Line up the square tip of the insertion handle with the square at the apex of the shell (Figure 24). Turn the ball hex driver in a clockwise direction to advance the thread into the shell (Figure 25). Remove the ball hex driver from the handle. Ensure that the shell is securely fastened to the handle by lightly pulling on the shell.

The shell is disassembled by re-inserting the ball hex driver and turning counter-clockwise.



Monoblock Handle Assembly

If using the G7 Straight Monoblock Inserter Handle, line up the thread of the insertion handle with the thread of the shell (Figure 24) and rotate the handle clockwise. Ensure that the shell is securely fastened to the handle by lightly pulling on the shell prior to impaction (Figure 26).

The shell is disassembled by rotating the handle counter-clockwise.



Figure 28

Acetabular Shell Insertion (cont.)

Optional Face Plate Impaction

Alternatively, each inserter handle may also be utilized to insert the shell with a face plate impactor. Select the appropriately-sized impactor plate that matches alphabetically and by color to the implant. Thread the impactor plate onto the insertion handle with the word "insert" facing the user (Figure 27). The face plate impactor will align with any of the anti-rotation tabs on the face of the shell for impaction. These plates may be used with or without the optional quick connect bolt, which threads onto the face plate impactor (Figure 28). This bolt then snaps into the apical hole of the implant to retain the shell on the face impactor. Once inserted, the face plate is disengaged from the shell by lightly pulling backwards.



Acetabular Shell Insertion (cont.)

Optional Use of Positioning Guide

The Lateral and Anterior Supine G7 positioning guides are designed to aid in proper insertion of the acetabular component. Utilizing the positioning guide as a reference, determine the correct position and alignment of the acetabular shell. For proper use instructions, see positioning guide section (Pages 12-13). In addition, approximate version can be obtained by using the transverse ligament or by referencing the opening of the acetabular component 90 degrees off of the sciatic notch. Position of the acetabular shell is crucial for optimizing wear, reducing impingement, reducing dislocation and reducing potential adverse outcomes.

Note: Consideration should be given to the location of screw holes prior to impaction if screws will be used.

Shell Impaction

Use a mallet to impact the handle on the strike plate, driving the shell into the acetabulum. If using the G7 Straight Monoblock Inserter Handle, ensure it is fully threaded to the mating component prior to impaction. While impacting, note the position of the screw holes to obtain the optimal position for screw placement, typically in the posterior/superior quadrant of the acetabulum (Figure 29). There are 2 indents on the shell rim to provide a secondary reference in identifying screw hole locations after the implant is inserted.

Gently toggle the insertion handle to make certain the shell is stable. Once the implant is fully seated, the shell can be disassembled from the handle.



Acetabular Shell Insertion (cont.)

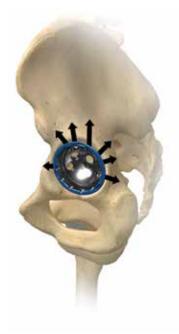
Check through the apical hole to determine whether the shell is in full contact with the floor of the acetabulum. If not, the impactor handle may be reattached to the shell for further impaction until the shell is fully seated. Failure to fully seat the shell into the acetabulum may compromise the quality of fixation. The force required to fully seat the implant depends on multiple factors including quality of bone, diameter of acetabulum and amount of under ream.

- Note: Levering on the inserter handle or impacting the handle on a location other than the strike plate to reposition the shell may damage the threads.
- Note: In the unlikely event that the inserter handle threads may fracture during impaction and be left in the apical hole of the acetabular shell, utilize the Thread Extractor instrument for removal. The tapered tip of the Thread Extractor may be engaged in the small through hole of the fractured threads, allowing the fractured threads to be removed from the apical hole of the acetabular shell (Figure 30).



Limited hole configuration

Figure 31



Multi hole configuration

Figure 32

Supplemental Screw Fixation

For primary cases where good bone stock is present and the shell is firmly seated within the acetabulum, the use of fixation screws is generally unnecessary. However, in cases where press-fit stability is in question, or where the bone quality is not optimal, supplementary screw fixation is advised.

Screw placement must be chosen carefully to avoid injury to neurovascular structures. Optimal position for screw placement is typically in the posterior/ superior quadrant of the acetabulum (Figure 31 and 32). Care should also be exercised when supplementary screw fixation is required to avoid damaging or scratching the internal surfaces of the acetabular components. Use of the dual angle drill guide is required for accurate screw placement. Consideration should be given to placement of a screw near the dome of the implant first to prevent possible shifting of the implant caused when placing peripheral screws. Note: Placement of screws outside of the "safe zone" may inadvertently injure neurovascular structures and should be utilized at the discretion of the operating surgeon. When using G7 Limited Hole shells, screws should never be placed in the anterior/medial area of the acetabulum.

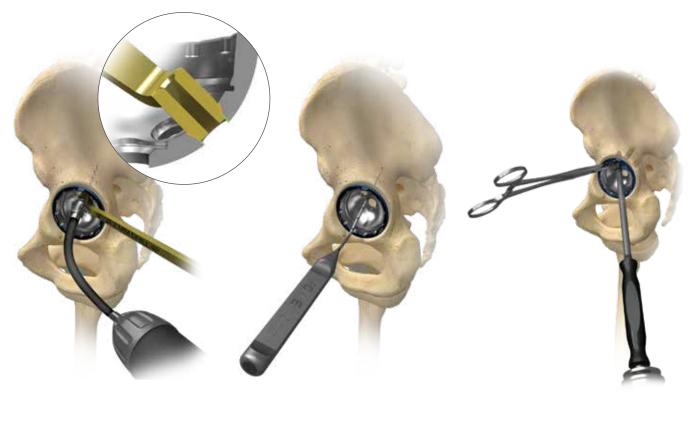


Figure 34

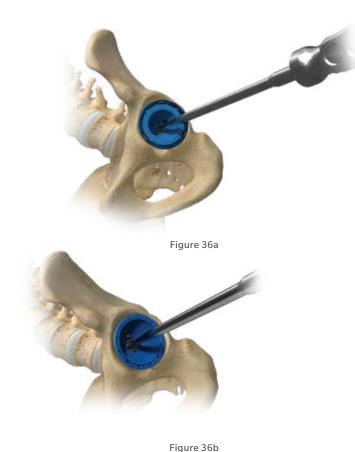
Figure 35

Supplemental Screw Fixation (cont.)

Use the dual angle drill guide to drill a pilot hole in the desired screw hole. Make certain the drill guide is fully seated and locked into position within the screw hole BEFORE the drill bit begins to engage bone (Figure 33). This will ensure the appropriate screw direction can be achieved. The G7 screw holes allow approximately 15 degrees of variability. Screws oriented outside this range may result in incomplete seating of the screws and prominent screw heads within the shell, which could impede insertion of the liner. When drilling into the posterior/superior quadrant, place a finger posteriorly into the sciatic notch to ensure the screw cannot penetrate too deeply.

The drill bits are available in variable lengths. However, 30 or 40 mm drill bits are most commonly utilized. The drill bit chosen should be dictated by surgeon choice and the projected length of the screws. To ensure proper seating of the G7 acetabular screw after drilling pilot holes, it is important to remove all bone debris from the screw hole prior to placing the screw. After measuring the depth of the hole with the depth gauge (Figure 34), select the 6.5 mm screw with the corresponding length and insert it into the hole with the 3.5 mm hex screwdriver and screw forceps (Figure 35). Place additional screws, as needed. Screws should not be placed in the apical hole of the shell.

- Note: Levering on the drill bit during drilling may cause damage to the drill bit.
- Note: Use only the gold colored drill guide with G7 implants. G7 gold colored screws and Zimmer self-tapping bone screws may both be used with G7 implants.
- Note: Check that all screw heads are seated below the inner surface of the shell to allow proper liner seating.



Optional Liner Trialing with Final Implant

Clean and dry the shell and clear all soft tissue from around its perimeter. If another trial reduction is desired, utilize the provisional liner selected during the earlier trial reduction that matches the letter designation and rim color of the shell. Insert the provisional liner into the shell by hand, then utilizing a 3.5 mm hex screwdriver, tighten the screw in the dome of the provisional liner into the apical hole of the final implant (Figures 36a and 36b).

- **ONDER** Note: Do not overtighten the provisional liner.
- **ONDE:** For ease of insertion, ensure the screw in the dome of the liner provisional is aligned with the apical hole of the final implant.

Polyethylene and Ceramic Liner Trialing

Assemble the provisional head onto the trunnion of the broach or implanted femoral stem and ensure it is fully seated. Perform a trial reduction (Figure 37).

 Note: G7 provisional heads are designed with a retaining feature. A click is felt and/or heard when the provisional head is fully seated.

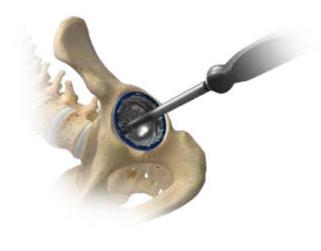
Dual Mobility Liner Trialing

Assemble the provisional head onto the trunnion of the broach or implanted femoral stem and ensure it is fully seated. Select the appropriate dual mobility bearing provisional as indicated alphabetically and by color and assemble to the provisional head (Figure 37). Perform a trial reduction.

Freedom Constrained Liner Trialing

Determine the desired neck length and head size and select the appropriate Freedom provisional head. Assemble the Freedom provisional head onto trunnion of the broach of implanted femoral stem and ensure it is fully seated. Perform a trial reduction.

 Note: Only Freedom provisional heads are compatible for trialing with Freedom implant liners.



Optional Liner Trialing with Final Implant (cont.)

Trial Reduction

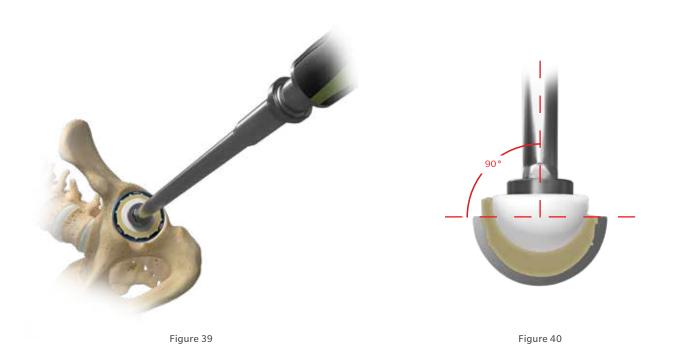
When performing the trial reduction check for joint stability and range of motion, making any necessary adjustments to restore joint mechanics. Make certain that prominent impinging bone and/or osteophytes are removed from the periphery of the acetabulum to maximize range of motion and stability. Make note of all provisional components used and then remove all provisionals.

Note: When using a High Wall or 10 Degree Face Changing liner, note the position of the liner to maintain orientation during final seating or adjust rotation as necessary in order to minimize impingement and optimize stability.

Optional Apical Plug

If desired, the apical hole in the acetabular shell can be covered with the plug packaged with the implant. Place the apical hole plug on the 3.5 mm hex screwdriver. Align the plug with the apical hole and twist the screwdriver clockwise to tighten the plug (Figure 38). Placing a drop of blood on the end of the screwdriver prior to attaching it to the apical hole plug may aid in retention of the plug on the screwdriver tip.

- Note: Only G7 Limited Hole Shells are packaged with an apical plug.
- Note: The apical plug cannot be used when using the ceramic liner or CoCr Dual Mobility Liner.



Polyethylene Liner Insertion

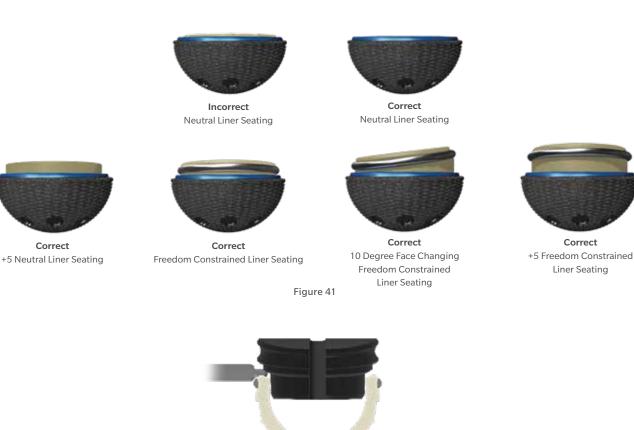
The definitive polyethylene liner may now be introduced. The color on the liner label should match the color anodized on the rim of the acetabular shell. Ensure the interior of the shell is dry and free of debris and overhanging soft tissue is removed.

Manually place the liner into the shell, ensuring the scallops are correctly aligned with the recessed areas on the shell. Apply manual pressure to the dome region to provisionally secure the liner in place by lightly engaging the scallops. Utilizing the appropriately-sized G7 ball impactor, place the tip of the impactor on the dome of the liner with the handle perpendicular to the face of the shell (Figure 39).

Note: When inserting a 10 degree liner, the higher side of the liner should be placed superiorly and the insertion handle must be perpendicular with the face of the shell (Figure 40). Do not angle the handle to match the angled face of the liner. Note: The etched line on the face of the 10 Degree Face Changing and High Wall liners is located in the middle of the elevated portion of the liner. This feature visually confirms the location of the elevated portion and aids in proper orientation during liner insertion.

Strike the impactor with the mallet to begin impaction. Continue to impact with the handle perpendicular to the face of the shell until the liner is fully seated.

● Note: If the liner becomes tilted during initial impaction, it is recommended that you do not impact the sides of the liner and instead manually remove and reseat the liner prior to additional impaction. Once in place, begin impaction again by delivering several firm mallet strikes with the tip of the impactor in the dome of the liner.



Freedom Plug Removal Cross Section

Figure 42

Polyethylene Liner Insertion (cont.)

Check to ensure the liner is fully seated by running your finger around the face of the shell. When properly seated, the polyethylene scallops will sit flush with, or slightly below, the face of the shell (Figure 41).

- Note: The impaction force needed to fully seat the liner into the acetabular shell may be dependent on liner size, liner style and polyethylene thickness. To ensure complete seating of the liner, it may be necessary to utilize an impaction force similar to that which is needed to insert the acetabular shell.
- Note: The ball impactor is slightly undersized to prevent excessive forces at the rim that may cause polyethylene deformation and prevent full seating.

Freedom Constrained Liner Insertion

Remove the black plug covering the mouth of the liner with the Freedom plug removal tool (Figure 42). Discard this plug. Place the liner into the acetabular shell. When satisfied with placement, place the tip of the appropriately sized G7 Freedom ball impactor on the dome of the liner and strike the impactor with the mallet to ensure proper seating of the liner. When properly seated, there will be a visible gap between the constraining ring and the face of the shell. Pull on the liner by hand after insertion to ensure proper seating has been achieved.

● Note: The diameter of the G7 36 mm size D Freedom liner ring is slightly larger than the G7 50 mm D shell. Care should be taken when using this construct to ensure overhanging bone and tissue do not interfere with the liner seating within the shell.

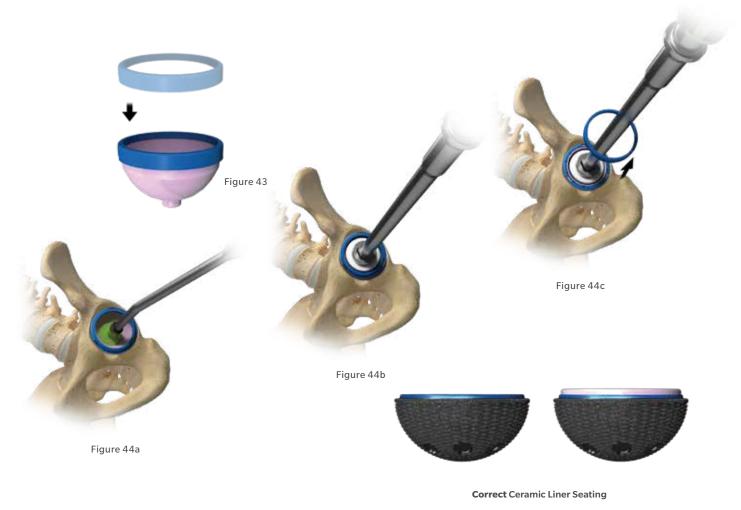


Figure 44d

Ceramic Liner Insertion

Option 1: Hard Bearing Inserter Ring

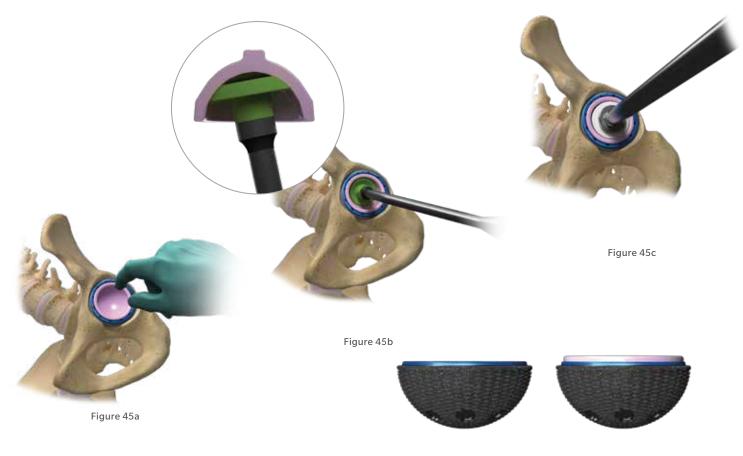
The definitive ceramic liner may now be introduced. Ensure the apical plug is not present at the dome of the shell and that the interior of the shell and all tapers are dry and free of debris.

Select the appropriate hard bearing inserter ring, as indicated alphabetically and by color. The inserter ring is designed to properly align the taper interface for accurate seating of the ceramic liner and Its color will match the rim of the acetabular shell. Press the hard bearing inserter ring onto the face of the definitive liner implant (Figure 43). Visually verify the ring is fully seated against the face of the liner.

Utilizing the straight insertion handle with a suction cup attached or the bent suction cup handle, gently seat the liner into the taper (Figure 44a). Ensure the hard bearing inserter ring evenly contacts the face of the shell prior to impaction. Utilizing the appropriately-sized liner impactor, impact the definitive liner with several moderate mallet strikes (Figure 44b). During impaction, the hard bearing inserter ring will disengage from the definitive liner and should be removed (Figure 44c). When properly seated, the liner will sit flush with, or slightly above, the face of the shell (Figure 44d).

- Note: The definitive liner must be seated with impaction force. Pushing the liner into the shell by hand may result in malalignment. Failure to follow these instructions may result in damaged liners.
- Note: The hard bearing inserter ring is only intended to ensure proper alignment of the liner and should not be used as an indicator that the liner is fully engaged or seated. The liner may need to be impacted several times to ensure the taper is fully seated.

Important: Care should be taken not to scratch the taper surface of either the bearing or the shell. If the liner must be removed for any reason, a new shell must be inserted before inserting another ceramic liner.



Correct Ceramic Liner Seating Figure 46

Ceramic Liner Insertion (cont.)

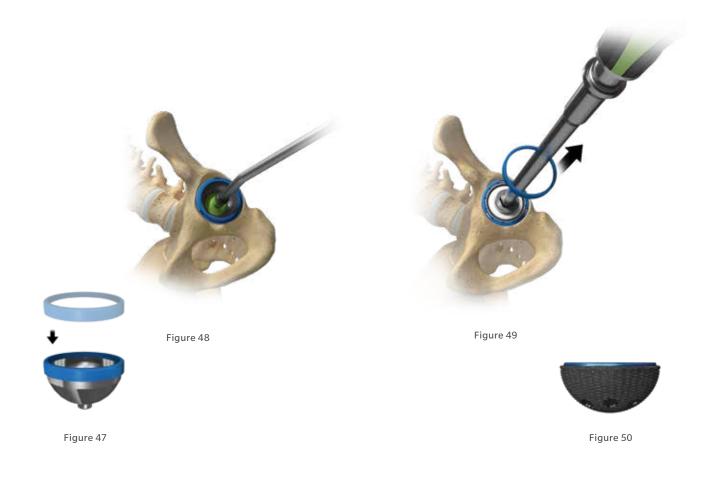
Option 2: Suction Cup Alignment Only

Utilizing the straight insertion handle with a suction cup attached, first position the suction cup on the liner at the 11 o'clock position (Figure 44). This angular placement helps to ensure straight seating of the liner.

Once attached to the suction cup, align the ceramic liner with the most anterior point of the acetabular shell, leading with the attachment point of the suction cup (Figure 45b). Gently seat the liner into the taper. The button on the back of the liner will help aid alignment. Once inserted, push on the liner to seat fully. Rotate the suction cup clockwise to disengage from the liner. Prior to impaction, ensure the edge of the liner is properly aligned in relation to the face of the rim. Utilizing the appropriately-sized liner impactor, place the tip of the impactor on the dome of the liner and strike the impactor with the mallet to ensure proper seating of the liner (Figure 45c). Check to ensure the liner is fully seated by running your finger around the face of the shell. When properly seated, the liner will sit flush with, or slightly above, the face of the shell (Figure 46).

IMPORTANT: Care should be taken not to scratch the taper surface of either the bearing or the shell. If the liner must be removed for any reason, a new shell must be inserted before inserting another ceramic liner.

● Note: To release a ceramic liner which is malpositioned, the G7 Tamp instrument is available. Align the tabs of the face plate to the recessed outer lip on the face of the shell. Hit the impactor area with the mallet several times to cause vibration and loosen the liner. Use the suction cup to grasp the liner and remove from the shell.



Dual Mobility CoCr Liner Insertion

The definitive dual mobility CoCr liner implant may now be introduced. Ensure the apical plug is not present at the dome of the shell and that the interior of the shell and all tapers are dry and free of debris.

Select the appropriate hard bearing inserter ring, as indicated alphabetically and by color. The inserter ring is designed to properly align the taper interface for seating of the metal liner, and its color will match the rim of the acetabular shell. Press the hard bearing inserter ring onto the face of the definitive liner implant (Figure 47). Visually verify the ring is fully seated against the face of the liner.

Utilizing the straight insertion handle with a suction cup attached or the bent suction cup handle, gently seat the liner into the shell (Figure 48). Select the appropriate ball impactor and secure it onto the inserter handle. It is recommended to use the 32 mm ball impactor for liner sizes 42 mm and smaller and the 44 mm ball impactor for liner sizes 44 mm and larger. Ensure the hard bearing inserter ring evenly contacts the face of the shell, prior to impaction. Impact the definitive liner with several moderate mallet strikes. During impaction, the hard bearing inserter ring will disengage from the definitive liner and should be removed (Figure 49). When properly seated, the liner will sit flush with the face of the shell (Figure 50).

- Note: The definitive liner must be seated with impaction force. Pushing the liner into the shell by hand may result in malalignment. Failure to follow these instructions may result in damaged liners.
- Note: The hard bearing inserter ring is for aligning the dual mobility CoCr liner to the acetabular shell only. The inserter ring does not confirm that the CoCr liner is fully seated and is not intended to protect the taper from damage.
- Important: Care should be taken not to scratch the taper surface of the dual mobility CoCr liner or the shell, as damage may compromise locking mechanism performance.





Figure 52

Assembly of Dual Mobility Bearing and Femoral Head

Select the appropriate Dual Mobility Bearing corresponding to the definitive CoCr Dual Mobility Liner implanted.

Next, select the appropriately sized modular head corresponding to the Dual Mobility Bearing selected and the preferred head offset determined during trial reduction.

Note: It is not recommended to utilize skirted heads.

Option 1: Back Table assembly of the Dual Mobility Bearing Construct

The Dual Mobility Head Press can be used to assemble the Dual Mobility Bearing Construct on the back table. Completely unscrew (open) the Head Press. Slide the baseplate onto the forked end of the press (Figure 51). Tighten the baseplate to the press with the knob (Figure 52).



Figure 54

Assembly of Dual Mobility Bearing and Femoral Head (cont.)

Place the femoral head on the black lug of the baseplate (Figure 53). Position and hold the polyethylene bearing above the femoral head. Rotate the press handle clockwise until the head is forced into the polyethylene bearing (Figure 54) and a distinctive "pop" is heard.

- Note: If using a ceramic head with a taper adaptor, insert the appropriate taper sleeve prior to placing the head on the black lug.
- Note: Due to large diameter size, bearings 50mm or larger may need to be rotated around the femoral head to reach vertical alignment inside the head press.

Open the press by rotating the handle counterclockwise. Check that the femoral head rotates freely within the polyethylene bearing. If it does not rotate freely, the femoral head is not properly engaged. In this case, place the construct back on the bearing press and repeat the compression steps.

Option 2: In-Situ preparation of the Dual Mobility Bearing Construct

Alternatively, the Dual Mobility Head Press may be used to assemble the Dual Mobility Bearing Construct with the Modular Head already assembled to the Stem Trunnion.

Position the forked end of the press around the neck of the femoral stem and hold the polyethylene bearing above the femoral head. Rotate the press handle clockwise until the head is assembled into the polyethylene bearing and a distinctive "pop" is heard.

Open the press by rotating the handle counterclockwise and check that the dual mobility bearing rotates freely on the modular head. If it does not rotate freely, the femoral head is not properly engaged. In this case, place the head press back on the bearing press and repeat the compression steps.





Modular Head or Dual Mobility Construct Impaction

With the definitive acetabular liner in place, and upon completion of femoral implantation and trial reduction, the corresponding modular head or dual mobility bearing construct can now be implanted. After fully seating the femoral component, position the modular head or dual mobility bearing construct onto a dry and clean trunnion. Fully seat the modular head or dual mobility bearing construct by means of firm axial impaction utilizing the Femoral Head impactor and mallet (Figure 55).

- Note: Using a non-compatible bearing impactor could damage the Dual Mobility Bearing.
- Note: Do not insert a damaged Dual Mobility Bearing. Do not insert a Dual Mobility Bearing into a damaged or improperly oriented/positioned shell.

Note: If using a modular ceramic head with a taper sleeve insert, it is important that the taper sleeve is new as a used taper can reduce fatigue strength of ceramic components.

Figure 56

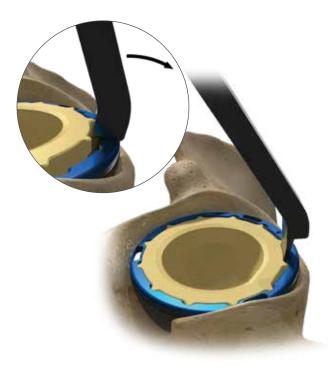
Note: When utilizing the Freedom Constrained liner, position the Freedom head on the stem so that the marking on the head is located in the most superior position prior to impaction (Figure 56).



Final Reduction

Once all final implants have been placed, perform the final reduction of the hip. Check for joint stability and range of motion, making any necessary adjustments to restore joint mechanics (Figure 57).

Note: When reducing the hip using the Freedom Constrained liner and head, ensure that the marking on the head is still in the superior position on the stem. Reduce the joint by aligning the flat aspect of the head with the liner's mouth. Full reduction may produce an audible "snap". Cycle the joint through a full range of motion to ensure stability, checking that there is no early impingement.



Polyethylene Liner Removal

Liner Removal Using Polyethylene Liner Removal Tool

Should it be necessary to remove the liner from the shell, the polyethylene liner removal tool can be used to disassociate the liner. To remove the liner, insert the pointed tip of the liner removal tool between the liner and the shell with the tip positioned between the liner scallops. Start insertion with the grip angled toward the inner diameter of the shell. As the wedge is driven between the shell and the liner, gradually rotate the grip until vertical. Impact the polyethylene liner removal tool until the shoulder fully rests on the face of the shell (Figure 58).

Apply a lever force to the liner by pressing against the shaft of the liner removal tool.

It may be necessary to do this in several locations around the face of the shell to disengage the locking mechanism. The polyethylene liner will lever out of the shell once the locking mechanism has been disrupted.

- Note: Avoid driving the metal tip along the tapered region of the shell to prevent damage to the taper during liner extraction.
- Note: The polyethylene liner removal tool should only be used on a well-fixed shell or a shell with acetabular screws.

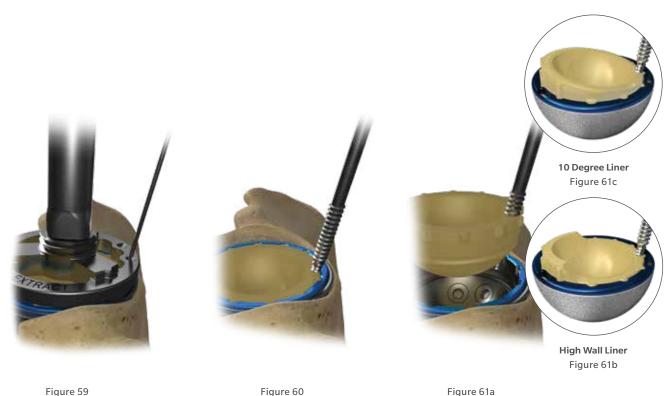


Figure 60

Polyethylene Liner Removal (cont.)

Neutral Liner Removal Using G7 Polyethylene **Liner Removal Drill Bit and Screw**

If using the G7 polyethylene Liner Removal Drill Bit and Screw, first select the face plate corresponding to the letter and color of the shell size implanted. Turn the face plate upside down so that the word "extract" is facing you and attach it to an insertion handle. Align the tabs of the face plate to the recessed areas on the face of the shell.

Insert the G7 polyethylene Liner Removal Drill Bit into either drill hole of the face plate (Figure 59). Drill a pilot hole for the polyethylene removal screw and advance until the shoulder of the drill bit touches the face plate.

Remove the face plate and handle. Using the ratcheting screwdriver handle, insert the polyethylene Liner Removal Screw into the pilot hole, advancing it all the way to the shell dome to remove the liner (Figures 60 and 61a).

10 Degree Face Changing and High Wall Liner Removal with G7 Polyethylene Liner Removal **Drill Bit and Screw**

Position the G7 polyethylene Liner Removal Drill Bit at the face of the polyethylene liner. Angle the drill bit at approximately 15 degrees from the axis of the shell and drill a pilot hole for the polyethylene removal screw (Figures 61b and 61c).

Should the drill cut through into the inner diameter of the polyethylene, drill a new hole in an alternate location around the rim, slightly decreasing the entrance angle relative to the axis of the shell.

Drill the pilot hole until the shoulder of the drill bit touches the face of the liner or the drill tip touches the dome of the shell. Using the ratcheting screwdriver handle, insert the polyethylene Liner Removal Screw into the polyethylene and advance it all the way to the shell dome to remove the liner.



Figure 63

Figure 64

Polyethylene Liner Removal (cont.)

Freedom Constrained Liner Removal using G7 Polyethylene Liner Removal Drill Bit and Screw

Place the G7 Polyethylene Liner Removal Drill Bit at the interface of the liner and the constraining ring. Angle the drill bit at approximately 15° from the axis of the shell and drill a pilot hole for the polyethylene removal screw (Figure 62).

The drill should only enter the polyethylene, but remain close to the constraining ring.

Should the drill cut through into the inner diameter of the polyethylene, drill a new hole in an alternate location around the rim, slightly decreasing the entrance angle relative to the axis of the shell.

Drill the pilot hole until the shoulder of the drill bit touches the face of the liner. Insert the Polyethylene Liner Removal Screw into the polyethylene and advance it all the way to the shell dome to remove the liner (Figure 63 and 64).

- Note: The polyethylene Liner Removal Drill Bit and polyethylene Liner Removal Screw are delivered sterile for single use.
- Note: If the screw enters one of the shell screw holes, remove the screw and repeat in an alternate location with a new drill bit and screw.
- Note: For Freedom Constrained Liner sizes I & J, the polyethylene removal drill bit may be inserted through the exposed polyethylene scallops or the polyethylene liner removal tool may be used in the same manner as with non-constraining liners.
- Note: When removing a Freedom 10 Degree Face Changing liner, align the drill bit with the black line located on the raised portion of the liner and ensure the angle of the removal screw is nearly perpendicular to the face of the shell before drilling the pilot hole.



Figure 66

Figure 67

Ceramic Liner Removal

Should it be necessary to remove the ceramic liner, the face plate impactors can be used. Select the appropriate face plate that matches the letter and color of the implant. Turn the face plate impactor upside down so that the word "extract" is facing you and attach it to the straight inserter handle. Align the tabs of the face plate to the recessed outer lip on the face of the shell (Figure 65). Hit the inserter handle with the mallet several times to cause vibration that will loosen the liner. Use the suction cup to grasp the liner and remove from the shell (Figure 66). To release a ceramic liner which is malpositioned, the G7 Tamp instrument is available. Align the tamp with to the recessed outer lip on the face of the shell (Figure 67). Hit the impactor area with the mallet several times to cause vibration and loosen the liner. Use the suction cup to grasp the liner and remove from the shell.

Note: The G7 Tamp should only be used on a well-fixed shell or a shell with acetabular screws.



Figure 68a

Dual Mobility CoCr Liner Removal

Should it be necessary to remove the dual mobility CoCr liner, the insertion/extractor faceplates can be used. Select the appropriate faceplate that matches the letter and color of the implant. Turn the insertion faceplate upside down so that the word "extract" is facing you and attach it to the impactor handle. Line the tabs up to the recessed outer lip on the face of the shell (Figure 68a). Hit the impactor handle with the mallet several times to cause vibration and loosen the liner. Use the suction cup to grasp the liner and remove from the shell.

The G7 Tamp instrument is also available for liner removal. Line the tamp up to the recessed outer lip on the face of the shell (Figure 68b). Hit the impactor area with the mallet several times to cause vibration and loosen the liner. It may be necessary to do this in multiple locations on the face of the shell. Use the suction cup to grasp the liner and remove it from the shell.

- Note: The G7 Tamp should only be used on a well fixed shell or a shell with acetabular screws.
- Note: Visual inspection of the shell taper surface should be done prior to placing another CoCr liner into the shell. Surface damage may compromise locking mechanism performance.



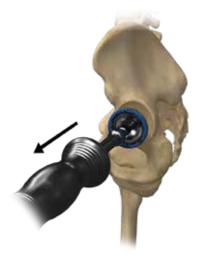


Figure 70

Dual Mobility Bearing Construct Removal

In the event the head and bearing need to be removed from the femoral stem, align the tip of the offset punch on the back side of the femoral head and drive the head off the stem with a mallet (Figure 69).

It is recommended that new heads be used anytime parts are replaced, as unseen damage to the taper junction or head tolerances can negatively affect the performance of the implant. Always inspect the stem trunnion prior to continued use.

Shell Removal

Before removing the acetabular shell, ensure all bone screws have been removed. Thread the extractor tool to a standard slap hammer and thread into the apical hole of the shell. Utilize the slap hammer to pull the shell directly out of the acetabulum, conserving as much bone as possible (Figure 70). Once the component is removed, careful evaluation of the acetabulum is suggested, with close attention to the integrity of the anterior/posterior columns and the medial wall. Any osteolytic cysts should be curetted and irrigated.

Inserter Handle Disassembly





Figure 72

Straight Inserter Handle Disassembly

To disassemble for cleaning, place a 3.5 mm hex screwdriver in the tip of the threaded shaft. Turn the screwdriver clockwise while pushing lightly to disengage the threaded shaft from the handle (Figure 71).

Curved Inserter Handle Disassembly

To disassemble for cleaning, place a 3.5 mm hex screwdriver in the tip of the threaded insert. Turn the screwdriver clockwise while pushing lightly to disengage the insert (Figure 72).

Notes	

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