Implant Partners™ Primary Hip: Z

SURGICAL TECHNIQUE

implantpartners™

Enabling Clinical Success Without the Excess™

Contents

Implant Partners™ recognizes that proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training, experience, and patient condition. Prior to use of the system, the surgeon should refer to the product Instructions For Use package insert for additional warnings, precautions, indications, contraindications and adverse effects. Instructions For Use package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique and the Instructions For Use package inserts are available on www.implantpartners.com/partner-resources under the link for Prescribing Information.

Please contact Implant Partners™ Customer Service for product availability.

Product Information

chapter 1

Indications

Intended Use

Implant Partners™ acetabular systems are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

Modular shells with porous metal bead coating may be used in either cemented or uncemented arthroplasty.

Indications for Use

1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;

2) inflammatory degenerative joint disease such as rheumatoid arthritis;

3) correction of functional deformity; and,

4) revision procedures where other treatments or devices have failed

Contraindications

Patients should be warned of these contraindications.

Contraindications include:

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 absorption apparent on roentgenogram;

4) skeletally immature patients (patient is less than 21 years of age at the time of surgery);

5) cases where there is inadequate neuromuscular status (e.g., prior paralysis, fusion and/or inadequate abductor strength), poor bone stock, poor skin coverage around the joint which would make the procedure unjustifiable;

6) neuropathic joints;

7) hepatitis or HIV infection;

8) neurological or musculoskeletal disease that may adversely affect gait or weight-bearing.

Patient selection should consider the following factors which could lead to increased risk of failure and can be critical to the eventual success of the procedure: the patient's weight, activity level, and occupation. The patient should not have unrealistic functional expectations for occupations or activities that include substantial walking, running, lifting, or muscle strain.

Device-Specific Warnings and Precautions

Acetabular Fixation Screws

Perforation of the pelvis with dome fixation screws or rim screws is to be completely avoided. Care is to be used when determining and selecting the proper length of screws to be used to prevent perforation of the pelvis.

Modular Acetabular Shell/Liner

Fixation screws, when used, should be fully seated to ensure stable fixation of the shell, and avoid interference with the liner component. Before implanting, be certain the selected shell and liner are compatible. Prior to seating the liner component into the shell component, surgical debris must be cleaned from the interior of the shell and the shell must be thoroughly dried. Debris and fluid may inhibit the liner from locking into the shell component. Failure to properly seat the liner into the shell can lead to disassociation of the liner from the shell.

Note: There is currently no clinical evidence supporting the long term use of large diameter femoral heads with cross-linked polyethylene liners.

The cross-linked Poly Liners are to be used only with the superfinished Implant Partners™ metal heads.

In order to prevent mismatch of tapers:

Modular liners from Implant Partners™ must be used only with shell components of the same system from Implant Partners™ or MicroPort Orthopedics.

The potential long-term biological effects of metal wear debris and metal ion production are not known. Questions regarding carcinogenicity have been raised in literature; no studies have conclusive evidence that metal wear debris or metal ions are carcinogenic.

Modular Acetabular Shell/Liner

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Preoperative Planning

chapter 2

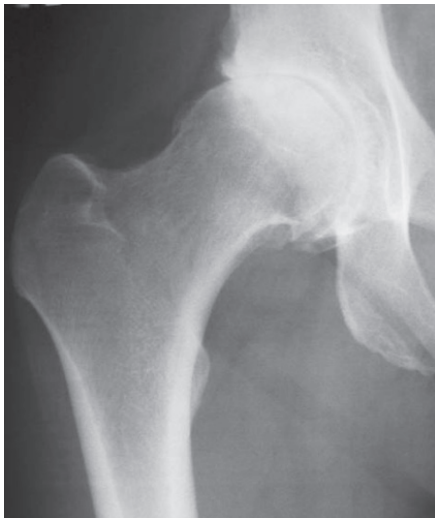


Figure 1 |

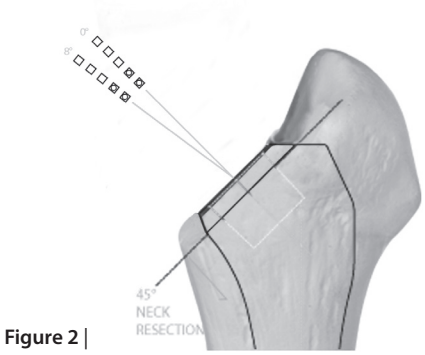


Figure 2 |

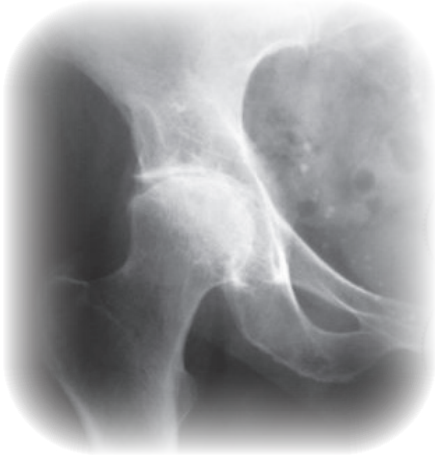


Figure 3 |

Determine limb length discrepancy. Draw a line across the bottom of the ischium on the A/P view. The distance from this horizontal reference line to each lesser trochanter should then be measured. The difference between each measured side is the limb length discrepancy. If there is any asymmetry of the pelvis, or if landmarks are not clear, other means to determine discrepancy should be used.

Determine the femoral head center. Once the center of rotation for the acetabular component has been determined, the center of rotation for the femoral head should be determined. Superimpose the femoral stem templates sequentially on the A/P x-ray with the templates positioned neutrally along the longitudinal axis of the femur. Estimate the metaphyseal and diaphyseal fit and anticipated level of implant insertion using the templates. The approximate femoral size and length of the femoral neck cut can be estimated from the templates. Neck angle and head length, which most closely correspond to the patients femoral head center, can be estimated as well. The squares found along the femoral neck axis represent the expected centers – of rotation for the femoral head. For the ideal head, the square will align atop the previously determined center of rotation for the femoral head. In patients with significant deformity of the femoral head, templating can be performed on the opposite hip if necessary.

Each square represents the center of rotation for a long neck with the corresponding head option (short to long). The squares on the AP template of the stem illustrate the impact of choosing an 8° varus neck relative to the neutral neck position. | **Figures 1** and **2**

The lateral x-ray illustrates the front to back fill of the implant and the position of the implant relative to the femoral anterior bow. If the anterior bow is high, the implant size may be reduced to minimize the risk of fracture. | **Figure 1**

Preoperative Planning for Acetabulum

Preoperative assessment of the appropriate size and position of the acetabular component will provide intraoperative guidance for acetabular reaming.

An A/P x-ray of the pelvis will aid in leg length and offset assessment. Leg length discrepancies should be determined preoperatively and addressed intraoperatively.

Radiographic overlays for the Implant Partners™ Acetabular Cup System are available in 15 percent magnification. | **Figure 3**

CAUTION: ***Accurate preoperative templating requires good quality standardized radiographs of the pelvis and operative hip. Preoperative templating is intended for estimation purposes only. Final component size and position should be determined intraoperatively.***

Surgical Technique

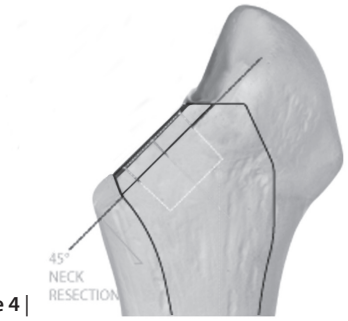


Figure 4 |

Femoral Head Resection

Approximately 10-20mm below the greater trochanter, resect the neck at a 45° angle to the longitudinal axis of the femur. | **Figure 4**

Although a specific instrument (PTGR0410) for the femoral neck resection step is included in Implant Partners™ instrumention, some surgeons prefer using the smallest broach size to mark the level of the initial osteotomy.

Preparing the Acetabulum

Ream the acetabulum sequentially, starting with the smallest reamer (48000040 through 48000066) that conforms to the acetabular cavity. Gradually enlarge the acetabulum by reaming articular cartilage until a continuous surface of cancellous bone is exposed. | **Figure 5**

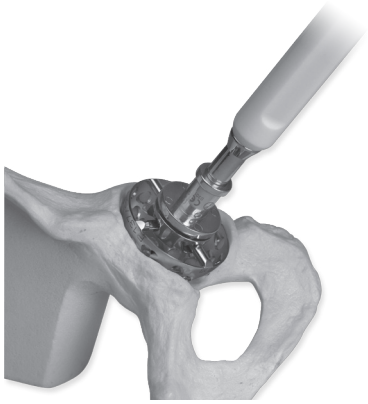


Figure 5 |

IMPLANT PARTNERS™ CUP REAMING GUIDE

Cup Diameter	1mm Press-Fit Ream To:	2mm Press-Fit Ream To:	Group
46mm	46mm	45mm	Group B
48mm	48mm	47mm	Group B
50mm	50mm	49mm	Group C
52mm	52mm	51mm	Group D
54mm	54mm	53mm	Group E
56mm	56mm	55mm	Group F
58mm	58mm	57mm	Group G
60mm	60mm	59mm	Group G
62mm	62mm	61mm	Group G
64mm	64mm	63mm	Group H
66mm	66mm	65mm	Group H

Sizing the Acetabulum

Thread the trial shell (3300GB46 through 3300GH66) onto the impactor handle (8400CP01) to check the size of the acetabulum. The trial shells are a complete hemisphere and are undersized by 1mm compared to the actual implant. The trials also have three large open windows for visualization. The screw holes on the trial shells mimic the location of the screw holes on the implant. | **Figure 6**

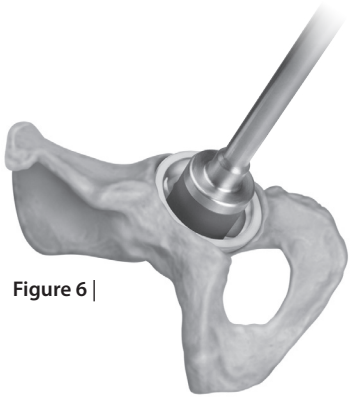


Figure 6 |

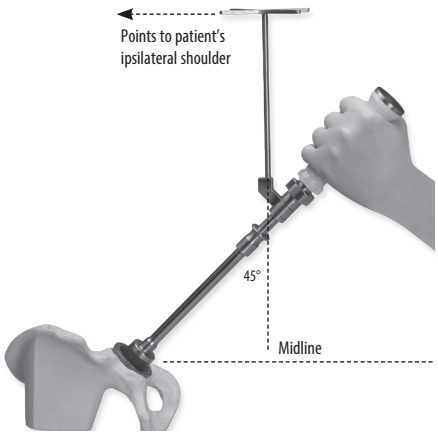


Figure 7 |

Inserting the Shell

Thread the appropriate size shell onto the impactor. When threading the implant shell or trial sizer onto the impactor, care should be taken to avoid damaging the threads of the implant or impactor. While holding the impactor vertical, rotate the shell counterclockwise until a slight drop is felt, then rotate the shell clockwise until tight. Do not over tighten.

An alignment guide (8400CP01) can be mounted to the impactor to aid in positioning the implant at 45° of abduction and 15° of anteversion. The position of the guide can be adjusted by loosening the lock nut and rotating the guide. Once in position, tighten the guide. Place the guide 90° to the midline of the patient to position the shell at 45° abduction. Rotate the guide until the appropriate marked cross bar points to the patient's ipsilateral shoulder. This will place the implant at 15° of anteversion. | **Figure 7**

Laser markings on the rim of the shell corresponding to the location of the screw holes should be positioned between the plane of the anterior superior iliac spine and the anterior inferior iliac spine. Impact the cup into the acetabulum, making sure the screw holes are in the appropriate location. Complete seating of the implant can be confirmed through the apical hole and screw holes. | **Figure 8**

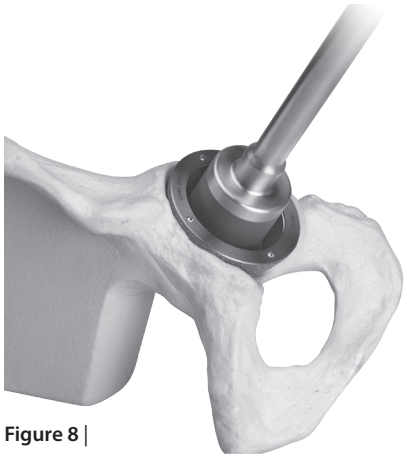


Figure 8 |

CAUTION: ***For surgeon preference of 1mm of press-fit at the dome and rim, please ream line to line or to the exact size of the corresponding reamer and the desired shell implant. For 2mm of press-fit at the dome and rim, please ream under the desired shell implant size by 1mm.***

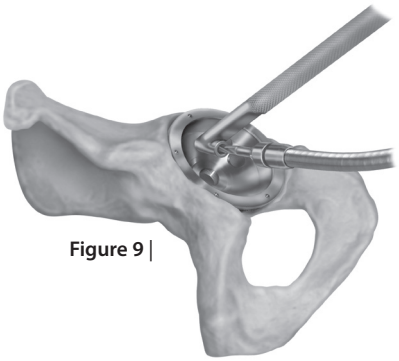


Figure 9 |

Screw Placement

Determine the screw location and select a suitable length drill bit. Drill bits are provided in 3.2 and 4.5mm diameters, in modular (8400FD05, 8400FD08) and non-modular (8400FD03) options. The drill guide (8400DG01) is also available in 3.2 and 4.5mm diameters with fixed angle and adjustable options.

Position the drill guide into the shell, ensuring that it is placed into one of the screw holes. Insert the drill into the guide and carefully drill through the acetabular cortex. | **Figure 9**

Use the screw depth gauge (8400SG01) to determine the appropriate length screw. | **Figure 10**

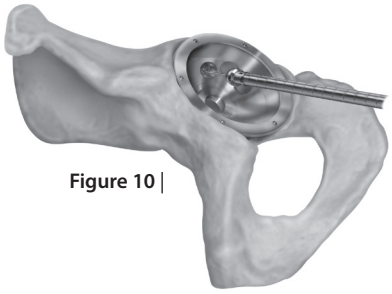


Figure 10 |

If extremely hard bone is encountered, a series of bone taps are provided to aid in screw insertion. Grasp the screw head with the screw-holding forceps (4820SH0000) and utilize the hex screwdriver (8400SD06, 8400SD04) to orient and fixate the screw. Release the screw-holding forceps to allow for the countersinking of the screw head.

Ensure the screw head is completely seated and does not protrude into the shell space, as this may prevent the liner from seating. | **Figure 11**

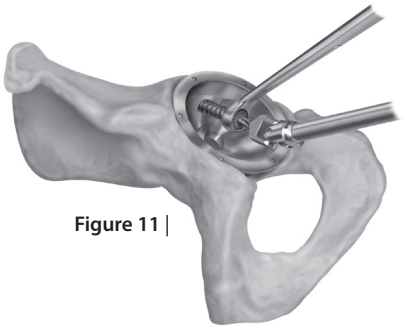


Figure 11 |

Trial Liner Placement

Trial liners are available to evaluate the position of the final implant. The trial liners can be used with the final shell implant and trial liners (standard (3304GB28 through 3304GH36) and lipped (3304LB28 through 3304LH36) can be positioned in any location within the implant to evaluate and determine where the final implant will be seated. | **Figure 12**

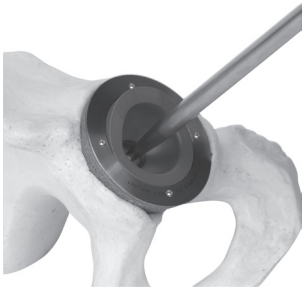


Figure 12 |

IMPLANT PARTNERS™ STANDARD POLY TRIAL LINER

Item Number	Trial Diameter	Group
3304GB28	28mm ID	Group B
3304GC32	32mm ID	Group C
3304GD36	36mm ID	Group D
3304GE36	36mm ID	Group E
3304GF36	36mm ID	Group F
3304GG36	36mm ID	Group G
3304GH36	36mm ID	Group H

IMPLANT PARTNERS™ 15° POLY TRIAL LINERS

Item Number	Trial Diameter	Group
3304LB28	28mm ID	Group B
3304LC32	32mm ID	Group C
3304LD36	36mm ID	Group D
3304LE36	36mm ID	Group E
3304LF36	36mm ID	Group F
3304LG36	36mm ID	Group G
3304LH36	36mm ID	Group H

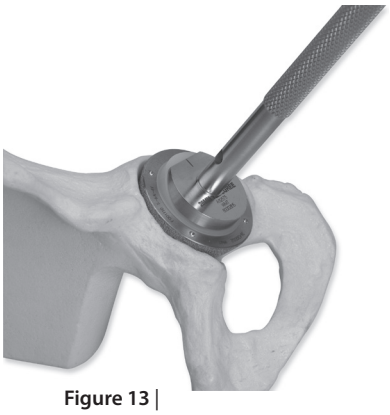


Figure 13 |

Apical Hole Plug Insertion

Do not insert the apical hole plug until after final trial reduction with the trial liners. After the trial reduction, seal the apical hole with the apical hole plug. The poly rod will break off at the plug once it is tightened into the apical hole. A final tightening of the hole plug should be performed using a 3.5mm hex screwdriver.

CAUTION: ***Apical hole plug is sold separately. Part number 3818000200.***

Liner Placement

Clean out any soft tissue from the inner taper area before impacting and engaging the implant and the liner. Insert the liner by hand, ensuring that the face of the liner is parallel with the face of the shell.

To engage the implant liner, assemble the modular trial head impactor (33000015) to the impactor handle (80000010). Tighten the trial head impactor in a clockwise direction until it can no longer be turned. Attach the appropriate femoral head trial (41102800 through 41004800) that corresponds to the liner I.D. Place head trial into the liner and apply a series of firm mallet blows to fully seat and engage the liner. | **Figure 13**

Femoral Preparation

Open the femoral canal with a box osteotome (PRFS0450). The osteotome should be lateralized to ensure a neutral orientation of the implant. | **Figure 14**

Enter the femoral canal with an initial canal finding reamer (4700R09000) attached to the t-handle (K0001016). The proper depth is equal to the length of the templated stem. | **Figure 15**

Figure 14 |

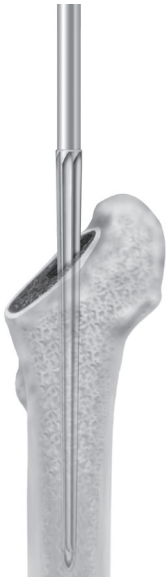


Figure 15 |

DEPTH - INITIAL STARTER REAMER

Implant Size	Implant Length
1	126 mm
2	131 mm
3	136 mm
4	141 mm
5	146 mm
6	151 mm
7	156 mm
8	161 mm
9	166 mm

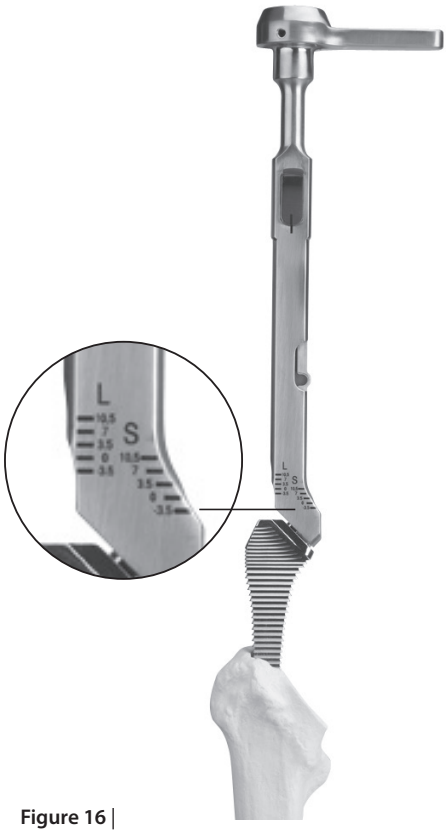


Figure 16 |

Option 1

Attach the broach handle (BROHANTL) to the smallest broach (APA08001). Using a mallet with short, controlled strokes, begin broaching. The L-Scale marks on the broach handle correspond to the center of rotation for neck and the respective femoral head. Sequentially increase broach size. | **Figure 16**

During a posterior approach, a guide rod can be used with the broach handle to provide 20° of implant anteversion. Screw the rod into the superior hole at the proximal end of the broach handle. When inserting the broach, rotate the handle until the guide rod is perpendicular to the floor.

Option 2

Attach the smallest broach to the broach handle. Begin broaching and sequentially increase the broach size.

The correct broach depth is achieved when the base of the polished oval collar rests along the resection. Recognize that the polished collar increases in height as stem size increases. Throughout broaching, continue to apply lateral pressure to ensure neutral alignment of the implant.

Continue broaching until an optimal fit is found. This will be denoted by a change in tone or resistance as the corners of the broach contact the cortical bone of the femur. To verify a secure fit, attempt to rotate the broach relative to the femur. With proper cortical contact, the broach should not twist or move relative to the femur. At this point, leave the broach fully seated in the canal and detach the broach handle to allow for trial reduction.

POTENTIAL DIFFERENCES BETWEEN BROACHED AND TEMPLATED SIZES:

1. The quality of bone plays an integral role in sizing. For soft bone, the broach may seat further than the template indicates and an implant larger than the templated size may be required. For strong, healthy bone, an implant smaller than the templated size may be required.

2. If a broach smaller than the size templated becomes tight, hard bone at the lateral femoral neck may be pushing the broach into varus. Use the lateral edge of the broach to restore a neutral position. Additional broaching may be necessary.

3. If a broach is going in straight and still becomes tight with sizes smaller than templated, a repetitive in/out broach motion may clear excess medial and lateral bone. If still tight, the stem should be appropriately downsized until metaphyseal

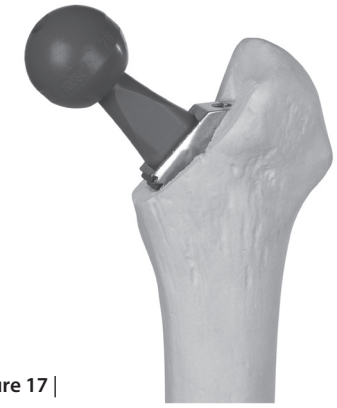


Figure 17 |

bone is engaged.

Perform a reduction with the trial head and femoral neck trial (Standard APA11104 or Increased Offset APA11154). Once a well-balanced hip has been created with a trial head, remove the broach. | **Figure 17**

BRIEF SUMMARY OF IMPLANT PARTNERS™ NECK OPTIONS

- **Straight necks create a neutral neck axis.**
- **Varus 8° necks (Varus or "VV") decrease the inclination angle to 127° (neutral position is 135°); the femoral head shifts medially and inferiorly; leg length is shortened; offset is increased.**

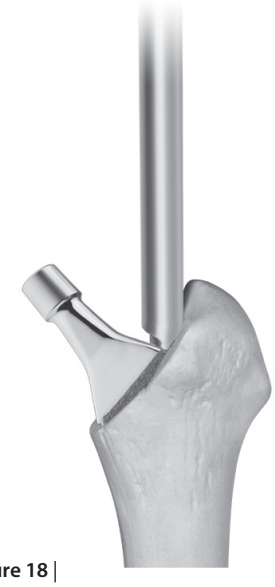


Figure 18 |

Insert the implant into the canal by hand and align proper version before placing the threaded slot impactor (PRFS0460) or bullet tipped impactor (PPF60200) near the proximal lateral shoulder of the implant. | **Figure 18**

Use a mallet with short, controlled strokes to seat the implant. Typically, the final implant is seated with the base of the polished collar along the neck cut.

CAUTION: ***The implant may sit 1-2mm more proud than templated due to the additional 0.5mm thickness per side of the plasma spray. The difference can be addressed during the final trial reduction by selecting the proper head.***

Perform a final trial reduction using the trial heads to reconfirm stability, range of motion and leg length. Affix the femoral head by striking the head impactor with several firm mallet blows. | **Figure 19**

Figure 19 |

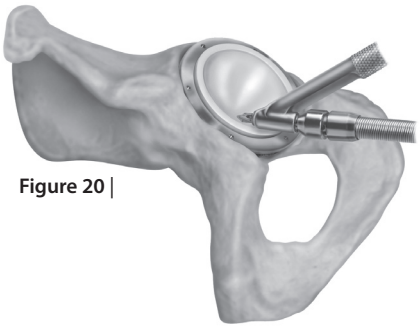


Figure 20 |

Explant Information

FEMUR AND ACETABULUM COMPONENTS

To remove the components, small osteotomes, power saws, or other surgical instruments may be used to disrupt the bone-implant interface. Care must be exhibited to save remaining bone stock as well as to prevent fracture. Once the components have been removed, rongeurs or small osteotomes, as well as other surgical instruments, may be used to remove the remaining implants.

Liner Extraction

To remove a poly liner, utilize the flexible drill bit with an acetabular drill guide and drill a hole slightly off-center from the liner apex. | **Figure 20**

Using a 3.5mm hex screwdriver, thread a 20mm cancellous screw into the drilled hole.

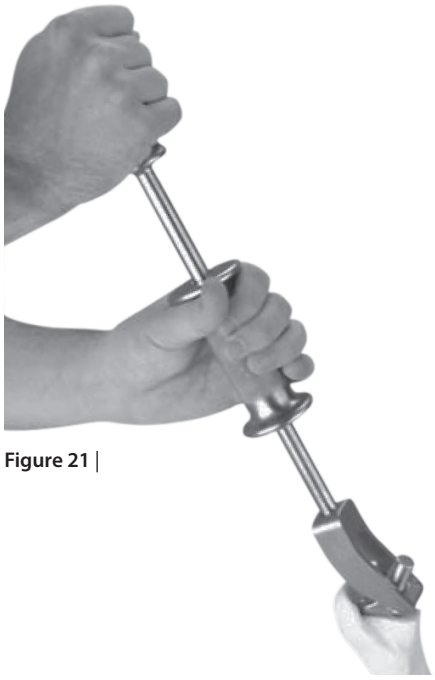


Figure 21 |

Stem Extraction

If necessary, Implant Partners™ instrumentation includes a slaphammer (47000SH0000) with extraction loop for removal of the femoral stem implant. | **Figure 21**

Postoperative Management

Postoperative care is the responsibility of the medical professional.

Ordering Information

IMPLANT PARTNERS™ STEMS - STRAIGHT

Part Number	Description
PHAPS232WD	PLASMA Z FEM SZ 1 STEM STRAIGHT
PHAPS234WD	PLASMA Z FEM SZ 2 STEM STRAIGHT
PHAPS236WD	PLASMA Z FEM SZ 3 STEM STRAIGHT
PHAPS238WD	PLASMA Z FEM SZ 4 STEM STRAIGHT
PHAPS240WD	PLASMA Z FEM SZ 5 STEM STRAIGHT
PHAPS242WD	PLASMA Z FEM SZ 6 STEM STRAIGHT
PHAPS244WD	PLASMA Z FEM SZ 7 STEM STRAIGHT
PHAPS246WD	PLASMA Z FEM SZ 8 STEM STRAIGHT
PHAPS248WD	PLASMA Z FEM SZ 9 STEM STRAIGHT

IMPLANT PARTNERS™ STEMS - VARUS 8°

Part Number	Description
PHAPE232WD	PLASMA Z FEM SZ 1 STEM VARUS 8°
PHAPE234WD	PLASMA Z FEM SZ 2 STEM VARUS 8°
PHAPE236WD	PLASMA Z FEM SZ 3 STEM VARUS 8°
PHAPE238WD	PLASMA Z FEM SZ 4 STEM VARUS 8°
PHAPE240WD	PLASMA Z FEM SZ 5 STEM VARUS 8°
PHAPE242WD	PLASMA Z FEM SZ 6 STEM VARUS 8°
PHAPE244WD	PLASMA Z FEM SZ 7 STEM VARUS 8°
PHAPE246WD	PLASMA Z FEM SZ 8 STEM VARUS 8°
PHAPE248WD	PLASMA Z FEM SZ 9 STEM VARUS 8°

IMPLANT PARTNERS™ POROUS SHELLS

Part Number	Description
DSPCGB46WD	PC SHELL 46MM GROUP B
DSPCGB48WD	PC SHELL 48MM GROUP B
DSPCGC50WD	PC SHELL 50MM GROUP C
DSPCGD52WD	PC SHELL 52MM GROUP D
DSPCGE54WD	PC SHELL 54MM GROUP E
DSPCGF56WD	PC SHELL 56MM GROUP F
DSPCGG58WD	PC SHELL 58MM GROUP G
DSPCGG60WD	PC SHELL 60MM GROUP G
DSPCGG62WD	PC SHELL 62MM GROUP G
DSPCGH64WD	PC SHELL 64MM GROUP H
DSPCGH66WD	PC SHELL 66MM GROUP H

IMPLANT PARTNERS™ NEUTRAL LINERS – CROSS LINKED

Part Number	Description
DLXPGB28WD	28MM STD GROUP B CROSSLINKED POLY LINER
DLXPGC32WD	32MM STD GROUP C CROSSLINKED POLY LINER
DLXPGD36WD	36MM STD GROUP D CROSSLINKED POLY LINER
DLXPGE36WD	36MM STD GROUP E CROSSLINKED POLY LINER
DLXPGF36WD	36MM STD GROUP F CROSSLINKED POLY LINER
DLXPGG36WD	36MM STD GROUP G CROSSLINKED POLY LINER
DLXPGH36WD	36MM STD GROUP H CROSSLINKED POLY LINER

IMPLANT PARTNERS™ LIPPED LINERS – CROSS LINKED

Part Number	Description
DLXPLB28WD	28MM 15DG GROUP B CROSSLINKED POLY LINER
DLXPLC32WD	32MM 15DG GROUP C CROSSLINKED POLY LINER
DLXPLD36WD	36MM 15DG GROUP D CROSSLINKED POLY LINER
DLXPLE36WD	36MM 15DG GROUP E CROSSLINKED POLY LINER
DLXPLF36WD	36MM 15DG GROUP F CROSSLINKED POLY LINER
DLXPLG36WD	36MM 15DG GROUP G CROSSLINKED POLY LINER
DLXPLH36WD	36MM 15DG GROUP H CROSSLINKED POLY LINER

IMPLANT PARTNERS™ 28M AND 32MM HEAD

Part Number	Description
26012801WD	COCR FEMORAL HEAD 28MM SLT TAPER -3.5MM NECK
26012802WD	COCR FEMORAL HEAD 28MM SLT TAPER +0MM NECK
26012803WD	COCR FEMORAL HEAD 28MM SLT TAPER +3.5MM NECK
26012804WD	COCR FEMORAL HEAD 28MM SLT TAPER +7MM NECK
26010007WD	COCR FEMORAL HEAD 32MM SLT TAPER SHORT NECK
26010008WD	COCR FEMORAL HEAD 32MM SLT TAPER MEDIUM NECK
26010009WD	COCR FEMORAL HEAD 32MM SLT TAPER LONG NECK
26010010WD	COCR FEMORAL HEAD 32MM SLT TAPER X-LONG NECK

IMPLANT PARTNERS™ 36MM HEADS

Part Number	Description
26000025WD	COCR FEMORAL HEAD 36MM SLT TAPER SHORT NECK
26000026WD	COCR FEMORAL HEAD 36MM SLT TAPER MEDIUM NECK
26000027WD	COCR FEMORAL HEAD 36MM SLT TAPER LONG NECK
26000028WD	COCR FEMORAL HEAD 36MM SLT TAPER X-LONG NECK

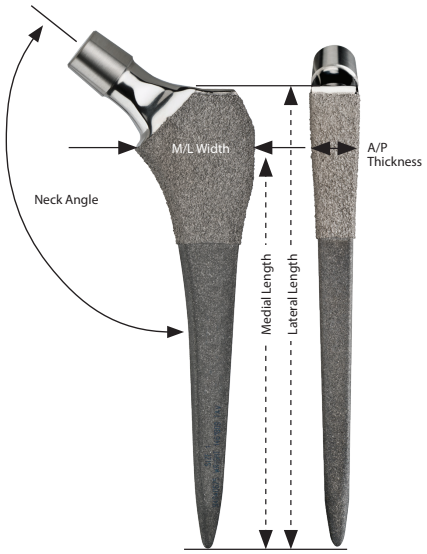
IMPLANT PARTNERS™ SCREWS

Part Number	Description
18080300WD	CANCELLOUS 6.5MM SELF-TAPPING BONE SCREW 1.5cm LENGTH
18080301WD	CANCELLOUS 6.5MM SELF-TAPPING BONE SCREW 2.0cm LENGTH
18080302WD	CANCELLOUS SELF-TAPPING 6.5MM BONE SCREW 2.5cm LENGTH
18080303WD	CANCELLOUS SELF-TAPPING 6.5MM BONE SCREW 3.0cm LENGTH
18080304WD	CANCELLOUS SELF-TAPPING 6.5MM BONE SCREW 3.5cm LENGTH
18080305WD	CANCELLOUS SELF-TAPPING 6.5MM BONE SCREW 4.0cm LENGTH

Implant Dimensions
(mm)

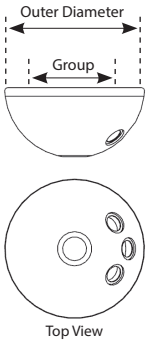
Dimensional Chart (mm)

Size	Medial Length	Lateral Length	Neck Angle (Classic)	M/L Width	A/P Thickness
1	110	126	135°/127°	31	12
2	114	131	135°/127°	32	12
3	118	136	135°/127°	33	12
4	121	141	135°/127°	34	13
5	125	146	135°/127°	35	13
6	128	151	135°/127°	36	13
7	132	156	135°/127°	37	14
8	136	161	135°/127°	39	14
9	139	166	135°/127°	40	14



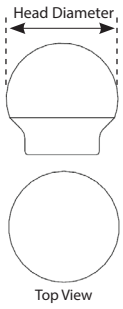
Primary Shell (mm)

Size	Group	Outer Diameter (mm)
46	Group B	46
48	Group B	48
50	Group C	50
52	Group D	52
54	Group E	54
56	Group F	56
58	Group G	58
60	Group G	60
62	Group G	62
64	Group H	64
66	Group H	66



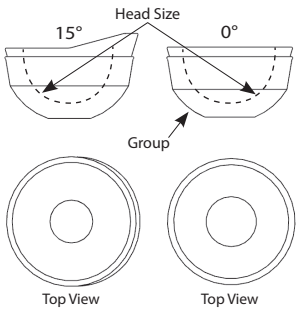
Femoral Head (No Sleeve) (mm)

Size	Head Diameter (mm)	Neck Length (mm)
28 Short	28	-3.5
28 Medium	28	0.0
28 Long	28	+3.5
28 X-Long	28	+7.0
32 Short	32	-3.5
32 Medium	32	0.0
32 Long	32	+3.5
32 X-Long	32	+7.0
36 Short	36	-3.5
36 Medium	36	0.0
36 Long	36	+3.5
36 X-Long	36	+7.0



Cross-Linked Poly Liner (mm)

Size	Group	Head Size (mm)
28	Group B	28
32	Group C	32
36	Group D	36
36	Group E	36
36	Group F	36
36	Group G	36
36	Group H	36



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IMPLANTS MADE IN USA

Implants manufactured by MicroPort Orthopedics

009610B_15-April-2014