EXACTECH | **HIP**

Operative Technique

ALTEON®

Cup and XLE Liner

Exactech®

TABLE OF CONTENTS

OBJECTIVES

The goal of the surgical approach is to establish adequate visualization to evaluate stability of the acetabular component and restore kinematic function. The surgical approach of choice is based upon the degree of surgical experience and preference. This technique provides key surgical steps to implant the Alteon® Cup. For key surgical steps specific to the stem, refer to the appropriate femoral operative technique.

DESIGN TEAM

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WILLIAM HEFLEY, MD, *is a board-certified orthopaedic surgeon in Little Rock, Ark. Dr. Hefley received his medical degree from Vanderbilt University and completed his residency at the University of Arkansas. He specializes in minimally invasive hip, knee and shoulder surgery and total joint replacement and is a frequent lecturer on joint replacement techniques domestically and abroad.*

JOSE RODRIGUEZ, MD, *is an adult reconstruction and joint replacement surgeon at the Hospital for Special Surgery in New York. Dr. Rodriguez completed his medical school education at Columbia University College of Physicians and Surgeons, and his residency training at the Hospital for Special Surgery. He completed two fellowship programs—one at Lenox Hill Hospital for arthritis surgery and joint reconstruction, and the other at the University of Berne, Switzerland, for surgery of the hip, and the surgical treatment of fractures.*

TIM VAN DE LEUR, MD, *specializes in total knee and hip replacement and reconstruction. Dr. van de Leur completed his residency in Canada at the University of Alberta and fellowship at Thomas Jefferson University.*

OPERATIVE TECHNIQUE OVERVIEW

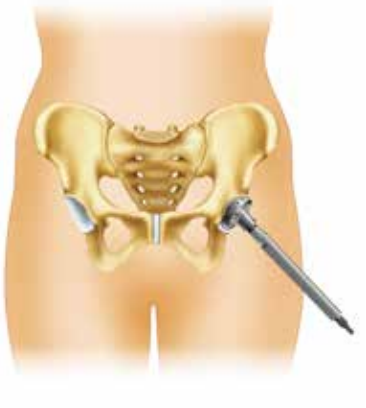


Figure A
Acetabular Reaming

Figure B
Cup Trial Placement

Figure C
Assembly of Acetabular Cup

Figure D
Cup Impaction

Figure E
Adjunctive Fixation
(optional)

Figure F
Insert Polyethylene Liner

PRE-OPERATIVE PLANNING

TEMPLATING

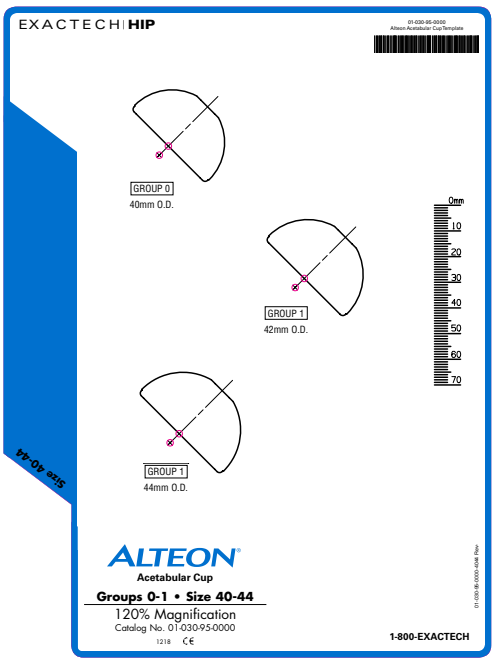
Accurate pre-operative planning and acetabular templating are recommended for obtaining a successful outcome. Estimate the acetabular size utilizing the Alteon Cup hip templates along with the appropriate femoral templates in the A/P view. The desired magnification for all imaging should be 120 percent, which corresponds to the templates provided for the Alteon Cup.

For the A/P view, the patient is placed supine with both extremities placed in 15 degrees of internal rotation to position the head and neck parallel to the coronal plane. The radiograph should be centered on the symphysis pubis and should clearly show the acetabular construct with the endosteal and periosteal contours of the femoral head, neck and proximal femur.

For traditional 'hard-copy' templating, estimate the acetabular component size by placing the overlay templates on the film selecting a size that matches the contour of the patient's acetabulum without the removal of excessive subchondral bone. To ensure a congruent fit, the medial position of the acetabular template should be lateral to the lateral aspect of the teardrop with the inferior part of the cup level with the obturator foramen and the superior position marked by the true superior edge of the acetabulum.

Templating should be done on the affected side, but the contralateral side may also be templated to confirm size. Mark the center of rotation and the expected acetabular component size on the radiograph of the femur.

***Note:** For digital templating, follow the software manufacturer's instructions for use while following the preceding instructions regarding placement and implant fit.*



X-ray template
(Catalog Number 01-030-95-0000)*

DETAILED OPERATIVE TECHNIQUE

APPROACH AND EXPOSURE

Figure 1a
Reamer Handle - Straight

Figure 1b
Reamer Handle - Offset

If pre-operative planning was performed, it is recommended two sizes larger and two sizes smaller than the size estimated by pre-operative planning be available at the time of surgery. If the surgeon chooses to omit pre-operative planning, the entire prosthesis size range should be available at the time of the surgery. Selecting the correct type of prosthesis with the correct size for each specific application is essential to the success of the procedure.

APPROACH AND EXPOSURE

This operative technique assumes that the patient has been positioned in the lateral decubitus position. However, the Alteon Platform Acetabular instrumentation is compatible with any standard approach necessary to gain exposure of the acetabulum.

ACETABULAR REAMING

Step 1: Assemble the acetabular **Reamer Handle** *(Figure 1a and 1b)* into the power source. Assemble an **Acetabular Reamer** 4 to 6mm smaller than the size templated onto the Reamer Handle.

Note: *An* **Offset Reamer Handle** *is available to help facilitate the Direct Anterior Approach.*

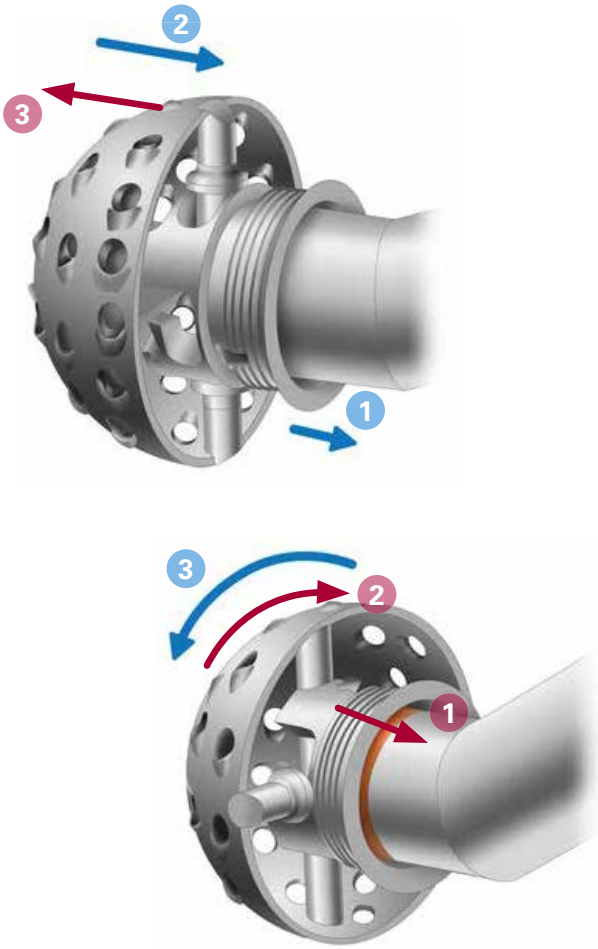


Figure 2
Acetabular Reamer Assembly (Blue Arrows) and Disassembly (Red Arrows)

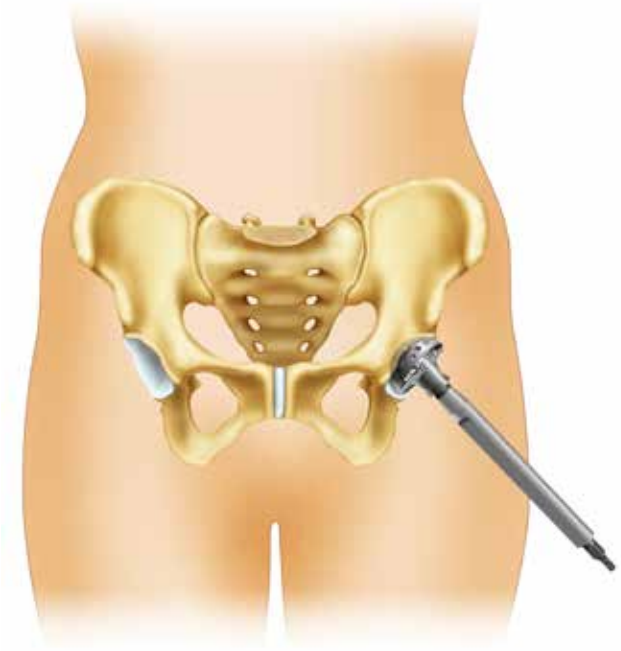


Figure 3
Acetabular Reaming in 45 Degrees of Abduction and 20 Degrees of Anteversion

Acetabular Reamer Assembly/Disassembly* *(Figure 2)*

Step 1a: Engage the opening of the reamer handle with the bar of the reamer. The release sleeve will move backward.

Step 1b: Turn the reamer counterclockwise until hearing an audible "click." The release sleeve will move back to its initial position.

Step 2: Circumferential exposure of the acetabulum is essential prior to beginning reaming.

Osteophytes and peripheral soft tissue should be removed to assess the acetabular rim.

****Note:** While using the reamer handle, all parts should be safely assembled to avoid poor precision reaming and potential injuries to the patient and user. For complete instruction, please refer to the Instructions for Use available at www.incipiodevices.com.*

Step 3: Initial reaming may be directed more medially, though subsequent reaming should be done in 45 degrees of abduction and 20 degrees of anteversion *(Figure 3)*.

Step 4: To disassemble the reamer reverse the steps identified in Steps 1a and 1b. Refer to the Red arrows and steps identified in *Figure 2*.

Step 5: Continue reaming incrementally until the articular cartilage has been removed and bleeding bone has been exposed along the superior dome anterior and posterior walls. Care should be taken to avoid excessive acetabular thinning and to maintain as much subchondral bone as possible. To provide 1mm of press-fit when implanting the Alteon Cup, reaming should stop on an even size reamer **and the labeled implant size should match the final reamer.**

***Note:** Alteon Cups are available in even millimeter increments (see System Specifications on page 15 for complete offerings).*

DETAILED OPERATIVE TECHNIQUE

ACETABULAR TRIALING

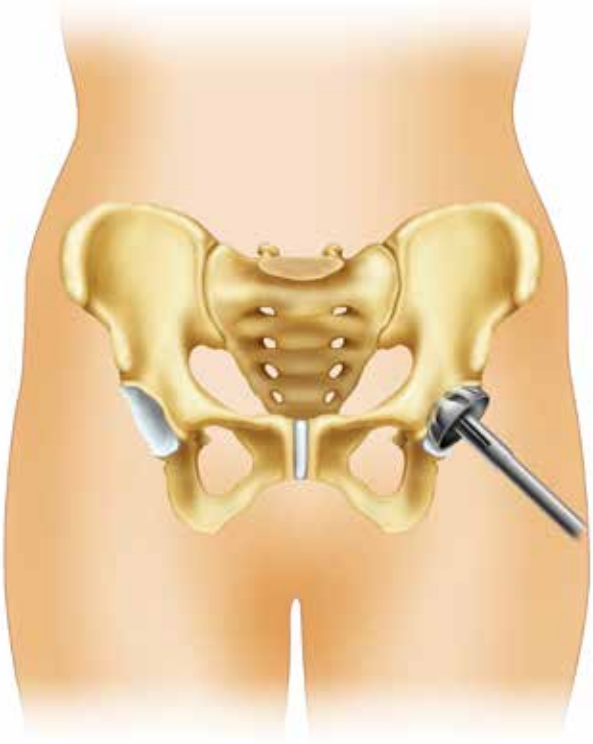


Figure 4
Cup Trial Placement

ACETABULAR CUP TRIALING

Step 1: Use of a cup trial is recommended prior to selection of the definitive Acetabular cup. Assemble the appropriate **Cup Trial** onto the selected **Cup Impactor** and insert into the reamed acetabulum *(Figure 4)*. Trialing of the cup will determine reaming accuracy as well as judge the final placement of the acetabular implant relative to the peripheral rim.

Step 2: Check quality of fit and bone apposition and remove the Cup Trial. Actual implant provides 1mm of press fit over the normally sized cup trial.

Figure 5a
Assembly of Acetabular Cup

Figure 5b
Lever Action Offset Cup Impactor

Note: *See instrument listing for alternative cup impactor options.*

ACETABULAR CUP IMPLANTATION

Step 1: Select the desired Alteon Cup configuration (Cluster-Hole or Multi-Hole). Choose the appropriately sized Acetabular Cup based on reaming and bone quality. The Alteon Cup is oversized a total of 1mm as compared to the Acetabular Reamer and Cup Trial in order to provide an appropriately secure interference fit. Under-reaming is usually not necessary where adequate bone stock is present. For example, if the last Acetabular Reamer used was size 50mm, then a size 50mm Acetabular Cup is typically implanted, providing 1mm of press fit.

Step 2: The Alteon Cup instrumentation offers different options for cup impactor connections based on the surgeons preference. Assemble the appropriate sized cup onto the cup impactor as described:

For the **Lever Action Cup Impactors**, release the handle by pressing the handle button. Insert the tip into the recessed area at the apex of the cup. Squeeze the lever to engage the cup impactor. Press the handle button to release the lever and disengage from the cup.

For the **Novation Threaded Locking Cup Impactors**, insert the tip into the recessed area at the apex of the cup and rotate the strike plate clockwise to tighten the cup to the impactor. Rotate the strike plate counterclockwise to disengage from the cup.

For the **Novation Cup Impactors**, squeeze the handle of the Cup Impactor and inserting the tip into the recessed area at the apex of the cup. Release the handle to engage the Cup Impactor. To release, squeeze the handle of the cup impactor to disengage from the cup.

Note: *When using the Offset version of the Cup Impactors, the plane of the strike plate aligns with the plane created by the face of the cup and can be helpful to visualize alignment in-situ.*

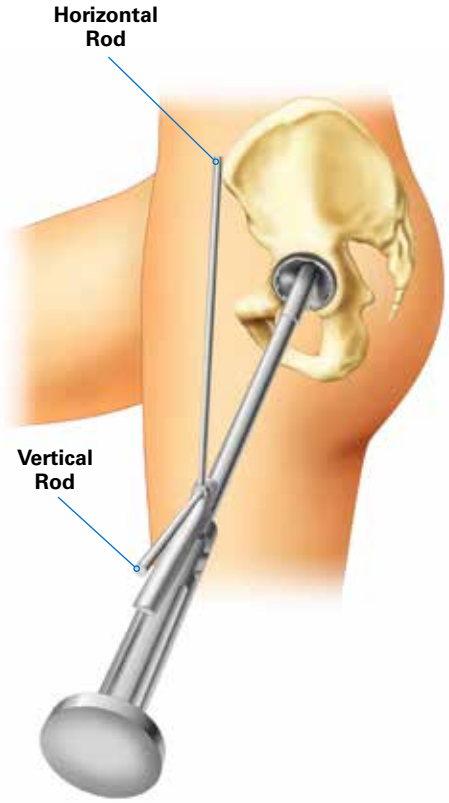


Figure 6a
Cup Impaction – 20 Degrees Anteversion

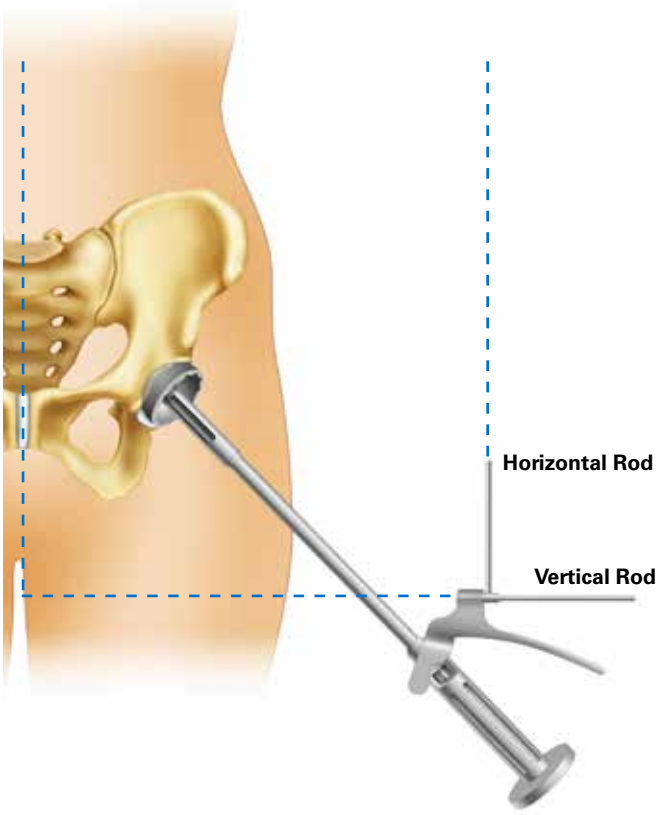


Figure 6b
Cup Impaction – 45 Degrees of Cup Inclination

Optional Step 3: Assemble the **Alignment Guide** to the Cup Impactor. Once assembled, rotate the Alignment Guide to the appropriate L/R marking on the Cup Impactor. Introduce the cup into the reamed acetabulum. Prior to Impaction, the *horizontal rod* of the Alignment Guide should be positioned parallel to the long axis of the body *(Figure 6a)* for a 20-degree anteverted cup position (if patient is in the lateral decubitus position) while the *vertical rod* should be pointed towards the ceiling, perpendicular to the ground for 45 degrees of cup inclination *(Figure 6b)*. Correct alignment for typical anatomy is approximately 45 degrees of inclination and 20 degrees of anteversion as indicated by the Alignment Guide. Seating of the Acetabular Cup at this position is recommended to ensure proper positioning and to decrease the potential for dislocation and impingement.

Note: *For Cup Impactors without an attachment for the Alignment Guide, the* ***Alignment Guide Adaptor*** *is provided as a clip-on adaptor. The Alignment Guide Adaptor provides the same angular inclination and version references as the described in Step 3.*

Note: *For surgical approaches with the patient positioned supine on the operative table, no inclination or version guides are provided. It is recommended the surgeon follow anatomic landmarks or utilize fluoroscopy to confirm cup positioning.*

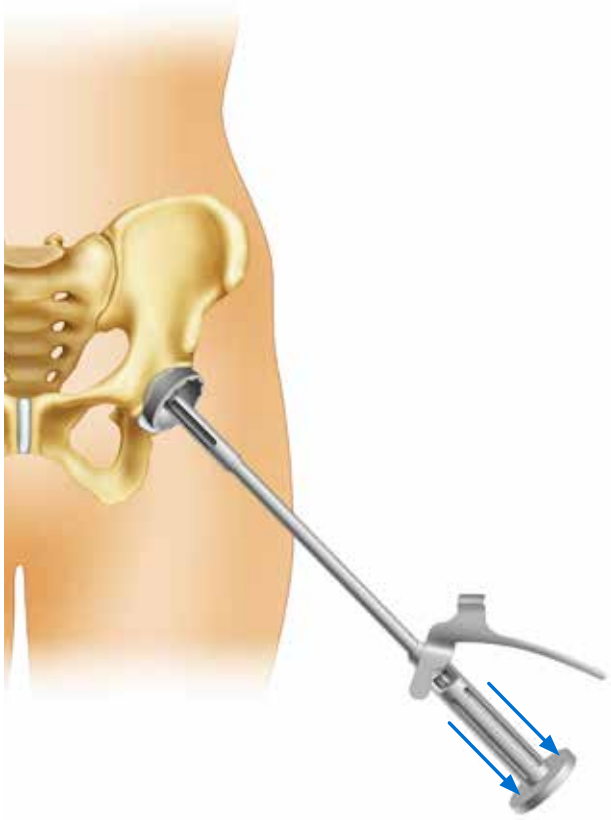


Figure 7
Repositioning the Cup

Step 4: With the cup oriented in the desired inclination and version, impact the cup impactor until the acetabular implant is firmly fixed within the acetabulum, with no gaps between the cup and the acetabulum. Stability of the bone-implant interface should be checked by applying a moment to the cup impactor or by applying moderate force to several areas on the rim of the prosthesis. If the cup rotates within the acetabulum or is not stable following an applied moment, a larger cup must be selected and the bone preparation process should be repeated by reaming to a larger size.

Note: *When applying a moment to the cup impactor to check cup stability or to reposition the cup, the cup impactor may disassociate from the acetabular cup. If this happens, realign the cup impactor into the cup and attach the cup impactor to the cup as described in Step 2.*

Step 5: Following implantation, should the surgeon desire a change in inclination or version of the cup, it is recommended a cup impactor with a retrograde strike plate be assembled to the cup. The surgeon can retrograde impact the cup impactor to break the press-fit of the cup into the reamed acetabulum *(Figure 7)*. Repeat Step 4 to implant the cup.

ADJUNCTIVE FIXATION (OPTIONAL)

Figure 8a
Ensure Drill Guide is fully seated in screw holes

Figure 8b
Drill to appropriate depth

ADJUNCTIVE FIXATION (OPTIONAL)

Step 1: If adjunctive fixation is required, the Cluster Hole and Multi-Hole Cup configurations offer dome holes that accept 6.5mm Bone Screws. If 6.5mm Bone Screws are to be used, select the **3.2mm Articulating Drill Driver** or **Flexible Drill** of desired length. **4.5mm Articulating Drill Drivers** are also available.

Note: *When positioning the Acetabular Cup and screw fixation holes, keep in mind that the best quality bone for fixation screw holes is the superior, medial (weight bearing) region of the acetabulum. Due to intrapelvic vascularity, screw placement in the medial aspect of the acetabulum must be carefully considered.*

Step 2: Drill to the appropriate depth pilot hole using the **3.2mm Drill Guide** for each screw placed. Be certain that the **3.2mm Drill Guide** is fully seated in the screw hole before drilling *(Figure 8a and 8b).* A **4.5mm Drill Guide** is also available.

Note: *Refer to table on page 24 for Drill Bit Functional Lengths.*

Figure 9
Use Depth Gauge to determine length of screw

Figure 10
Seat Screw in Cup

Step 3: Use the **Depth Gauge** to determine the length of the screw. The indicated screw length is measured from the base of the cup screw hole *(Figure 9)*.

Step 4: Assemble the **Ratchet Handle** to the **6.5mm Hex Driver, Articulating** (for 6.5mm Bone Screws). Insert the appropriate bone screw taking care to fully seat the screw *(Figure 10)*. The acetabular cup holes allow +/- 11 degrees of screw angulation for proper seating of the screw. Failure to seat the screw could result in impingement with the locking mechanism of the mating acetabular liner.

DETAILED OPERATIVE TECHNIQUE

LINER TRIALING

Group	Cup Size (mm)	Group Color	Standard Liner LARGEST ID Option (mm)
0	40	Green	22
1	42, 44	Grey	28
2	46	Magenta	32
3	48	Blue	32
4	50	Yellow	36
5	52	Red	36
6	54	Light Green	40
7	56, 58, 60	Orange	40
8	62, 64, 66, 68	White	40

Table 1
Cup & Liner Groupings

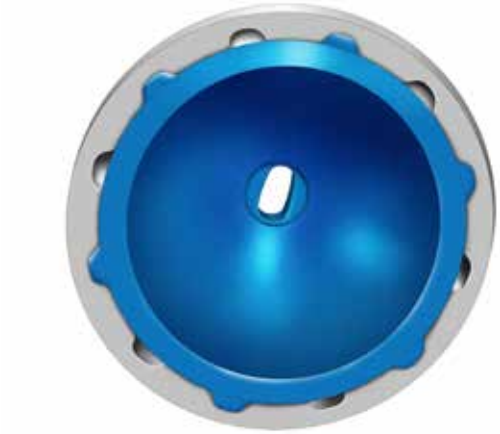


Figure 11
Place the Liner Trial into the Acetabular Cup

LINER TRIALING

Step 1: Use of an acetabular **Liner Trial** is recommended prior to insertion of the definitive liner into the Acetabular Cup. Select the appropriately sized Liner Trial in the desired liner configuration according to the acetabular cup inserted *(Table 1)*.

Note: *Additional liner options that are available include Extended Coverage, 5mm Lateralized and 10-Degree Face Changing. See instrument and implant listing for full details.*

Step 2: Ensure that the inner diameter of the Acetabular Cup and all mating surfaces are clear from soft tissue and debris before placing the Liner Trial.

Step 3: Place the Liner Trial into the Acetabular Cup. The Liner Trial should remain in place until after trial reductions have been performed *(Figure 11)*.

Note: *It is recommended to insert the liner trials by hand and not to impact the liner trials.*

Figure 12
Assemble the Alteon Liner Driver Head to the Liner Driver Handle

Figure 13
Seat the final Liner implant into the Alteon Cup using the Liner Driver

LINER INSERTION

Step 1: Remove the Liner Trial using the **Liner Trial Extractor**. Place the T-Handle into the central slot of the Liner Trial, rotate approximately 90 degrees and then pull on the T-Handle to remove the Liner Trial. Ensure that the internal taper of the Acetabular Cup is clear from soft tissue and debris.

Step 2: Select the appropriately sized Liner in the desired configuration and gently insert by hand, taking care to ensure that the scallops of the liner enter the slots at the superior region of the Acetabular Cup.

Step 3: Assemble the appropriate diameter **Liner Driver Head** on the end of the **Liner Driver** *(Figure 12)*. With a mallet, strike the driving platform of the Liner Driver with one sharp blow. Once seated, the top surface of the liner will be flush with the rim around the circumference of the implant construct *(Figure 13)*.

Note: *Should the Liner need to be removed, assemble the* ***Poly Removal Tool*** *to the Ratchet Handle by pulling the release on the Ratchet Handle and sliding the non-sharp end of the Poly Removal Tool into the Ratchet Handle. Engage the screw tip into the liner by hand until the locking mechanism is disengaged and the liner can be pulled out. The screw tip should be inserted into the liner near the dome, within 10° of the apical lock, to avoid damaging the taper of the cup.*

POST-OPERATIVE CARE

CLOSURE AND POST-OPERATIVE CARE

Close the wound according to the preferred method.

Regular, long-term post-operative follow-up should be undertaken to detect early signs of component wear and loosening, and to consider the course of action to be taken if such events occur. Extreme care in patient handling (e.g., moving patient, placing on bedpans, changing clothes, etc.) immediately after surgery is necessary. A continuing periodic follow-up is recommended. Periodic x-rays should be taken to detect evidence of positional changes, loosening, bone loss and/or device fracture. All patients should be instructed on the limitations of the prosthesis and the possibility of subsequent surgery. The patient should be warned against unassisted activity, particularly use of toilet facilities and other activities requiring excessive motion of the hip. Patients should be informed that their weight and activity level might affect the longevity of the implant. Patients should be advised to report any pain, decrease in range of motion, swelling, fever or unusual sounds (e.g. clicking or squeaking) as this may indicate positional changes in the implant that could lead to premature failure.

The Alteon Cup Acetabular Cups incorporate a 1mm press fit into the sizing of the implants.

ALTEON CUP CONFIGURATIONS

Cluster Hole Cup

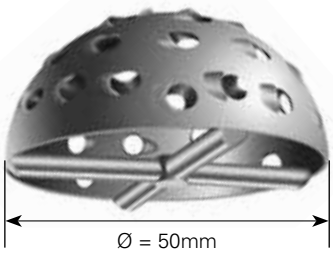
Groups	Total Number of Screw Holes
0 - 1	2
2 - 8	3

Multi Hole Cup

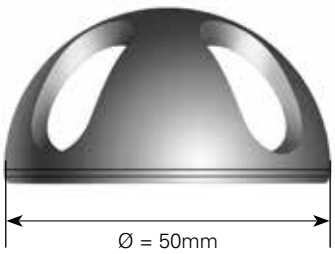
Groups	Total Number of Screw Holes
0 - 1	6
2 - 6	8
7	10
8	12

Length (mm)	Alteon® 6.5mm Bone Screws
15	180-65-15
20	180-65-20
25	180-65-25
30	180-65-30
35	180-65-35
40	180-65-40
45	180-65-45
50	180-65-50*
55	180-65-55*
60	180-65-60*
70	180-65-70*
80	180-65-80*

**Special order only.*



Reamer



Trial

Implant

ALTEON LINER CONFIGURATIONS

Neutral

Extended Coverage*
(Lipped)

+5mm Lateralized

+5mm Lateralized,
10° Face Changing*

**22mm ID Option Not Available*

SYSTEM SPECIFICATIONS

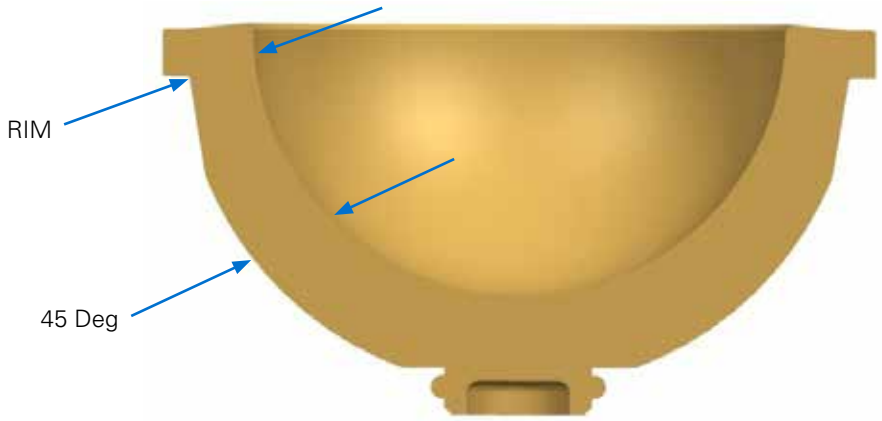
NEUTRAL AND EXTENDED COVERAGE LINER THICKNESSES PER GROUP

Liner Group	Thickness (mm)	22mm Head*		28mm Head		32mm Head		36mm Head		40mm Head	
		45 Deg	RIM	45 Deg	RIM	45 Deg	RIM	45 Deg	RIM	45 Deg	RIM
0*		6.6	4.7	-	-	-	-	-	-	-	-
1		-	-	4.8	3.6	-	-	-	-	-	-
2		-	-	-	-	4.8	3.6	-	-	-	-
3		-	-	-	-	5.8	4.6	-	-	-	-
4		-	-	-	-	6.8	5.5	4.8	3.5	-	-
5		-	-	-	-	7.8	6.5	5.8	4.5	-	-
6		-	-	-	-	8.8	7.5	6.8	5.5	4.8	3.5
7		-	-	-	-	-	-	7.8	6.5	5.8	4.5
8		-	-	-	-	-	-	9.8	8.5	7.8	6.5

LATERALIZED AND 10 DEGREE FACE CHANGING LINER THICKNESSES PER GROUP

Liner Group	Thickness (mm)	22mm Head*		28mm Head		32mm Head		36mm Head		40mm Head	
		45 Deg	RIM	45 Deg	RIM	45 Deg	RIM	45 Deg	RIM	45 Deg	RIM
0*		9.2	6.4	-	-	-	-	-	-	-	-
1		-	-	8.2	5.2	-	-	-	-	-	-
2		-	-	-	-	8.0	5.0	-	-	-	-
3		-	-	-	-	9.0	6.0	-	-	-	-
4		-	-	-	-	10.0	6.9	8.0	4.9	-	-
5		-	-	-	-	10.9	7.8	8.9	5.8	-	-
6		-	-	-	-	12.0	8.8	10.0	6.8	8.0	4.8
7		-	-	-	-	-	-	10.9	7.7	8.9	5.7
8		-	-	-	-	-	-	12.9	9.6	10.9	7.6

**22mm ID Option Not Available in Extended Coverage or 10 Degree Face Changing Configurations*



LINER AND FEMORAL HEAD OPTIONS

Group	Neutral	Extended Coverage	+5mm Lateralized	10° Face Changing, +5mm Lateralized
0 (Dark Green)	22	N/A	22	N/A
1 (Grey)	28	28	28	28
2 (Magenta)	32	32	32	32
3 (Blue)	32	32	32	32
4 (Yellow)	32,36	32,36	32,36	32,36
5 (Red)	32,36	32,36	32,36	32,36
6 (Light Green)	32,36,40	32,36,40	32,36,40	32,36,40
7 (Orange)	36,40	36,40	36,40	36,40
8 (White)	36,40	36,40	36,40	36,40

IMPLANT ORDERING INFORMATION

ALTEON® CUPS

Group	Cluster-Hole		Multi-Hole		Size (mm)	Group Color
0	01-030-01-0040	OPT-1500s	01-030-02-0040	OPT-1502s	40	Green
1	01-030-01-0142	OPT-1500s	01-030-02-0142	OPT-1502s	42	Grey
	01-030-01-0144	OPT-1500s	01-030-02-0144	OPT-1502s	44	Grey
2	01-030-01-0246	KIT-1500	01-030-02-0246	KIT-1502	46	Magenta
3	01-030-01-0348	KIT-1500	01-030-02-0348	KIT-1502	48	Blue
4	01-030-01-0450	KIT-1500	01-030-02-0450	KIT-1502	50	Yellow
5	01-030-01-0552	KIT-1500	01-030-02-0552	KIT-1502	52	Red
6	01-030-01-0654	KIT-1500	01-030-02-0654	KIT-1502	54	Light Green
7	01-030-01-0756	KIT-1500	01-030-02-0756	KIT-1502	56	Orange
	01-030-01-0758	KIT-1500	01-030-02-0758	KIT-1502	58	Orange
	01-030-01-0760	KIT-1500	01-030-02-0760	KIT-1502	60	Orange
8	01-030-01-0862	OPT-1500xl	01-030-02-0862	OPT-1502xl	62	White
	01-030-01-0864	OPT-1500xl	01-030-02-0864	OPT-1502xl	64	White
	01-030-01-0866	OPT-1500xl	01-030-02-0866	OPT-1502xl	66	White
	01-030-01-0868	OPT-1500xl	01-030-02-0868	OPT-1502xl	68	White

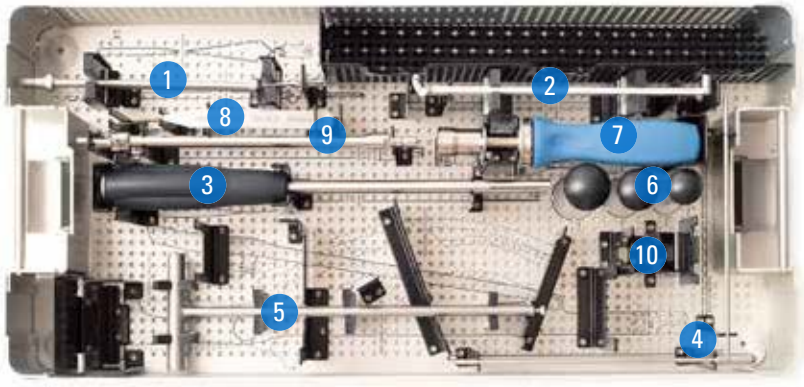
Alteon® XLE Liners

Group	Cup Diameter	Liner ID	XLE Neutral Liner		XLE Extended Coverage Liner	
0	40mm	22mm	01-030-40-0022	OPT-1506s	N/A	N/A
1	42/44mm	28mm	01-030-40-0128	OPT-1506s	01-030-42-0128	OPT-1508s
2	46mm	32mm	01-030-40-0232	*KIT-1506*	01-030-42-0232	*KIT-1508*
3	48mm	32mm	01-030-40-0332	*KIT-1506*	01-030-42-0332	*KIT-1508*
4	50mm	32mm	01-030-40-0432	*KIT-1506*	01-030-42-0432	*KIT-1508*
		36mm	01-030-40-0436	*KIT-1506*	01-030-42-0436	*KIT-1508*
5	52mm	32mm	01-030-40-0532	*KIT-1506*	01-030-42-0532	*KIT-1508*
		36mm	01-030-40-0536	*KIT-1506*	01-030-42-0536	*KIT-1508*
6	54mm	32mm	01-030-40-0632	*KIT-1506*	01-030-42-0632	*KIT-1508*
		36mm	01-030-40-0636	*KIT-1506*	01-030-42-0636	*KIT-1508*
		40mm	01-030-40-0640	**OPT-1506i**	01-030-42-0640	**OPT-1508i**
7	56/58/60mm	36mm	01-030-40-0736	*KIT-1506*	01-030-42-0736	*KIT-1508*
		40mm	01-030-40-0740	**OPT-1506i**	01-030-42-0740	**OPT-1508i**
8	62/64/66/68mm	36mm	01-030-40-0836	***OPT-1506xl***	01-030-42-0836	***OPT-1508xl***
		40mm	01-030-40-0840	**OPT-1506i**	01-030-42-0840	***OPT-1508i***

Alteon® XLE Liners

Group	Cup Diameter	Liner ID	XLE +5 Lateralized Liner		XLE 10° Face Changing Liner	
0	40mm	22mm	01-030-46-0022	OPT-1512s	N/A	N/A
1	42/44mm	28mm	01-030-46-0128	OPT-1512s	01-030-48-0128	OPT-1510s
2	46mm	32mm	01-030-46-0232	*KIT-1512*	01-030-48-0232	*KIT-1510*
3	48mm	32mm	01-030-46-0332	*KIT-1512*	01-030-48-0332	*KIT-1510*
4	50mm	32mm	01-030-46-0432	*KIT-1512*	01-030-48-0432	*KIT-1510*
		36mm	01-030-46-0436	*KIT-1512*	01-030-48-0436	*KIT-1510*
5	52mm	32mm	01-030-46-0532	*KIT-1512*	01-030-48-0532	*KIT-1510*
		36mm	01-030-46-0536	*KIT-1512*	01-030-48-0536	*KIT-1510*
6	54mm	32mm	01-030-46-0632	*KIT-1512*	01-030-48-0632	*KIT-1510*
		36mm	01-030-46-0636	*KIT-1512*	01-030-48-0636	*KIT-1510*
		40mm	01-030-46-0640	**OPT-1512i**	01-030-48-0640	**OPT-1510i**
7	56/58/60mm	36mm	01-030-46-0736	***KIT-1512***	01-030-48-0736	*KIT-1510*
		40mm	01-030-46-0740	**OPT-1512i**	01-030-48-0740	**OPT-1510i**
8	62/64/66/68mm	36mm	01-030-46-0836	***OPT-1512xl***	01-030-48-0836	***OPT-1510xl***
		40mm	01-030-46-0840	**OPT-1512i**	01-030-48-0840	**OPT-1510i**

TRAY LAYOUT



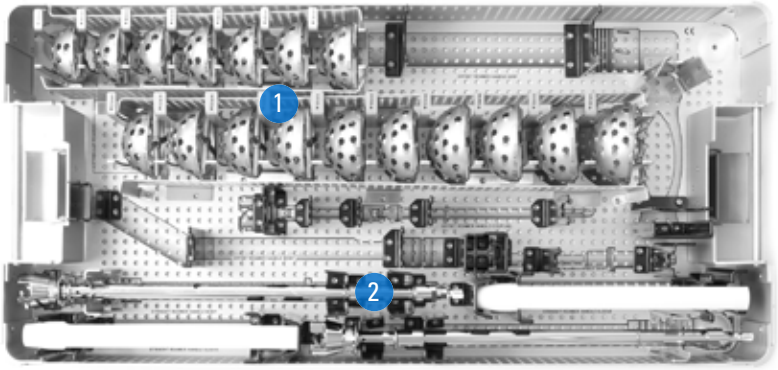
KIT-1503 Alteon Cup Acetabular Instruments

Site	QTY	Item	Item Description
1	1	01-007-04-3230	Articulating Drill Driver, 3.2 x 30mm
	1	01-007-04-4530	Articulating Drill Driver, 4.5 x 30mm
2	1	01-007-05-0032	3.2mm Drill Guide
	1	01-007-05-0045	4.5mm Drill Guide
3	1	01-007-30-0000	Liner Driver
	1	01-101-00-0030	Alteon Cup Acetabular Instrument Tray
	1	10-321-00-0001	Instrument Tray Lid, Full Size
4	1	121-01-01	Alignment Guide
5	1	131-01-02	Liner Trial Extractor
6	1	141-01-28	Liner Driver Head, 28mm
	1	141-01-32	Liner Driver Head, 32mm
	1	141-01-36	Liner Driver Head, 36mm
7	1	181-00-08	Ratchet Handle
8	1	181-00-27	Depth Gauge
9	1	181-65-02	6.5mm Hex Driver, Articulating
10	1	01-007-40-0003	Alignment Guide Adaptor

Cup Impactor

Kit	QTY	Item	Item Description	Image
OPT-1503O	1	181-02-00	Lever Action Offset Cup Impactor	
OPT-1503OT	1	50341402*	Alteon Offset Threaded Cup Impactor	
OPT-1503ST	1	01-007-20-0006	Alteon Straight Threaded Cup Impactor	
OPT-173ST	1	121-02-00	Novation Straight Threaded Locking Cup Impactor	
OPT-173OT	1	181-02-01	Novation Offset Threaded Locking Cup Impactor	
OPT-173S	1	121-01-00	Novation Straight Cup Impactor	
OPT-173O	1	121-01-02	Novation Offset Cup Impactor	

**These are distributed products, please refer to the back page for cleaning and repocessing information.*



KIT-1505 Alteon Cup Acetabular Reamers, Crossbar

Site	QTY	Item	Item Description
	1	50142044*	Crossbar Acetabular Reamer, Size 44
	1	50142045*	Crossbar Acetabular Reamer, Size 45
	1	50142046*	Crossbar Acetabular Reamer, Size 46
	1	50142047*	Crossbar Acetabular Reamer, Size 47
	1	50142048*	Crossbar Acetabular Reamer, Size 48
	1	50142049*	Crossbar Acetabular Reamer, Size 49
	1	50142050*	Crossbar Acetabular Reamer, Size 50
	1	50142051*	Crossbar Acetabular Reamer, Size 51
1	1	50142052*	Crossbar Acetabular Reamer, Size 52
	1	50142053*	Crossbar Acetabular Reamer, Size 53
	1	50142054*	Crossbar Acetabular Reamer, Size 54
	1	50142055*	Crossbar Acetabular Reamer, Size 55
	1	50142056*	Crossbar Acetabular Reamer, Size 56
	1	50142057*	Crossbar Acetabular Reamer, Size 57
	1	50142058*	Crossbar Acetabular Reamer, Size 58
	1	50142059*	Crossbar Acetabular Reamer, Size 59
	1	50142060*	Crossbar Acetabular Reamer, Size 60
	1	01-101-00-0010	Alteon Cup Acetabular Reamer Tray
	1	10-321-00-0001	Instrument Tray Lid, Full Size

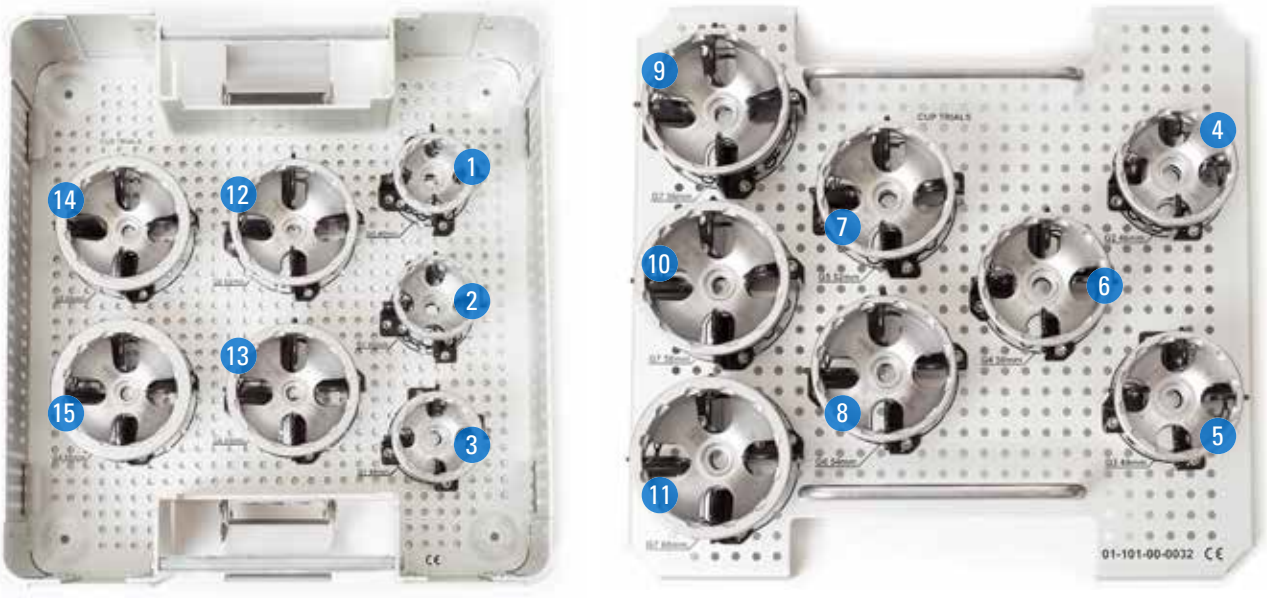
**These are distributed products, please refer to the back page for cleaning and repocessing information.*

Reamer Driver Handles

Kit	Qty	Item	Item Description	Image
OPT-1501ST	2	50245164*	Straight Reamer Handle, Non Locking	
OPT-1501O	1	50245118*	Offset Reamer Driver Handle, Non Locking	
		50245161*	Straight Reamer Handle, Locking	
		50245112*	Straight Reamer Handle, Non Locking	

**These are distributed products, please refer to the back page for cleaning and repocessing information.*

TRAY LAYOUT



KIT-1515 Alteon Cup Trials

Site	QTY	Item	Item Description
1	1	01-031-00-0040	Alteon Cup Trial, G0 Size 40
2	1	01-031-00-0142	Alteon Cup Trial, G1 Size 42
3	1	01-031-00-0144	Alteon Cup Trial, G1 Size 44
4	1	01-031-00-0246	Alteon Cup Trial, G2 Size 46
5	1	01-031-00-0348	Alteon Cup Trial, G3 Size 48
6	1	01-031-00-0450	Alteon Cup Trial, G4 Size 50
7	1	01-031-00-0552	Alteon Cup Trial, G5 Size 52
8	1	01-031-00-0654	Alteon Cup Trial, G6 Size 54
9	1	01-031-00-0756	Alteon Cup Trial, G7 Size 56
10	1	01-031-00-0758	Alteon Cup Trial, G7 Size 58
11	1	01-031-00-0760	Alteon Cup Trial, G7 Size 60
12	1	01-031-00-0862	Alteon Cup Trial, G8 Size 62
13	1	01-031-00-0864	Alteon Cup Trial, G8 Size 64
14	1	01-031-00-0866	Alteon Cup Trial, G8 Size 66
15	1	01-031-00-0868	Alteon Cup Trial, G8 Size 68
	1	01-101-00-0031	Alteon Cup Trials Tray, Lower
	1	01-101-00-0032	Alteon Cup Trials Tray, Upper
	1	10-322-00-0001	Instrument Tray Lid, Half Size

KIT-1507 Alteon Neutral and Extended Coverage Liner Trials

QTY	Item	Item Description
1	01-031-40-0232	Alteon Liner Trial Neutral G2 32
1	01-031-40-0332	Alteon Liner Trial Neutral G3 32
1	01-031-40-0432	Alteon Liner Trial Neutral G4 32
1	01-031-40-0436	Alteon Liner Trial Neutral G4 36
1	01-031-40-0532	Alteon Liner Trial Neutral G5 32
1	01-031-40-0536	Alteon Liner Trial Neutral G5 36
1	01-031-40-0632	Alteon Liner Trial Neutral G6 32
1	01-031-40-0636	Alteon Liner Trial Neutral G6 36
1	01-031-40-0736	Alteon Liner Trial Neutral G7 36
1	01-031-42-0232	Alteon Liner Trial Extended Coverage G2 32
1	01-031-42-0332	Alteon Liner Trial Extended Coverage G3 32
1	01-031-42-0432	Alteon Liner Trial Extended Coverage G4 32
1	01-031-42-0436	Alteon Liner Trial Extended Coverage G4 36
1	01-031-42-0532	Alteon Liner Trial Extended Coverage G5 32
1	01-031-42-0536	Alteon Liner Trial Extended Coverage G5 36
1	01-031-42-0632	Alteon Liner Trial Extended Coverage G6 32
1	01-031-42-0636	Alteon Liner Trial Extended Coverage G6 36
1	01-031-42-0736	Alteon Liner Trial Extended Coverage G7 36
1	01-101-00-0041	Alteon Liner Trial Instrument Tray, Lower
1	01-101-00-0042	Alteon Liner Trial Instrument Tray, Upper
1	10-322-00-0001	Instrument Tray Lid, Half Size

OPT-1507I Alteon 40mm Liner Trials

QTY	Item	Item Description
1	01-031-40-0640	Alteon Liner Trial Neutral G6 40
1	01-031-40-0740	Alteon Liner Trial Neutral G7 40
1	01-031-40-0840	Alteon Liner Trial Neutral G8 40
1	01-031-42-0640	Alteon Liner Trial Extended Coverage G6 40
1	01-031-42-0740	Alteon Liner Trial Extended Coverage G7 40
1	01-031-42-0840	Alteon Liner Trial Extended Coverage G8 40
1	01-031-46-0640	Alteon Liner Trial +5 Lateralized G6 40
1	01-031-46-0740	Alteon Liner Trial +5 Lateralized G7 40
1	01-031-46-0840	Alteon Liner Trial +5 Lateralized G8 40
1	01-031-48-0640	Alteon Liner Trial 10° Face Changing G6 40
1	01-031-48-0740	Alteon Liner Trial 10° Face Changing G7 40
1	01-031-48-0840	Alteon Liner Trial 10° Face Changing G8 40
1	01-101-00-0040	Alteon 40mm Liner Trial Tray
1	10-322-00-0001	Instrument Tray Lid, Half Size

TRAY LAYOUT

KIT-1511 Alteon Lateralized and Face Changing Liner Trials

QTY	Item	Item Description
1	01-031-46-0232	Alteon Liner Trial +5 Lateralized G2 32
1	01-031-46-0332	Alteon Liner Trial +5 Lateralized G3 32
1	01-031-46-0432	Alteon Liner Trial +5 Lateralized G4 32
1	01-031-46-0436	Alteon Liner Trial +5 Lateralized G4 36
1	01-031-46-0532	Alteon Liner Trial +5 Lateralized G5 32
1	01-031-46-0536	Alteon Liner Trial +5 Lateralized G5 36
1	01-031-46-0632	Alteon Liner Trial +5 Lateralized G6 32
1	01-031-46-0636	Alteon Liner Trial +5 Lateralized G6 36
1	01-031-46-0736	Alteon Liner Trial +5 Lateralized G7 36
1	01-031-48-0232	Alteon Liner Trial 10° Face Changing G2 32
1	01-031-48-0332	Alteon Liner Trial 10° Face Changing G3 32
1	01-031-48-0432	Alteon Liner Trial 10° Face Changing G4 32
1	01-031-48-0436	Alteon Liner Trial 10° Face Changing G4 36
1	01-031-48-0532	Alteon Liner Trial 10° Face Changing G5 32
1	01-031-48-0536	Alteon Liner Trial 10° Face Changing G5 36
1	01-031-48-0632	Alteon Liner Trial 10° Face Changing G6 32
1	01-031-48-0636	Alteon Liner Trial 10° Face Changing G6 36
1	01-031-48-0736	Alteon Liner Trial 10° Face Changing G7 36
1	01-101-00-0043	Alteon Lateralized/Face Changing Liner Trial Instrument Tray, Lower
1	01-101-00-0044	Alteon Lateralized/Face Changing Liner Trial Instrument Tray, Upper
1	10-322-00-0001	Instrument Tray Lid, Half Size

OPT-121422

QTY	Item	Item Description
1	141-01-22	Liner Driver Head 22mm
1	143-22-00	O-Ring Head Trial 22mm, +0 12/14
1	143-22-03	O-Ring Head Trial 22mm, +3.5 12/14
1	143-22-07	O-Ring Head Trial 22mm, +7 12/14
1	143-22-10	O-Ring Head Trial 22mm, +10 12/14

OPT-121440

QTY	Item	Item Description
1	141-01-40	Liner Driver Head 40mm
1	143-40-00	Head Trial, 40 OD, +0
1	143-40-03	Head Trial, 40 OD, +3.5
1	143-40-07	Head Trial, 40 OD, +7
1	143-40-10	Head Trial, 40 OD, +10
1	143-40-93	Head Trial, 40 OD, -3.5

Lenkbar Flexible Drill Bits

Straight Drill Bit Part Number	Description	Lenkbar Flexible Drill Bit Part Number	Novation Drill Guides (18mm)	Alteon Drill Guides (13mm)	For use with which screw length
101-05-20	3.2mm Drill Bit 20mm 1Pk	32135-38H-17*	20mm	25mm	Up to 20mm (up to 25 w/ new guides)
101-05-30	3.2mm Drill Bit 30mm 1Pk	32135-52H-17*	34mm	39mm	Up to 35mm
101-05-40	3.2mm Drill Bit 40mm 1Pk	32135-66H-17*	48mm	53mm	Up to 50mm
101-45-20	4.5mm Drill Bit 20mm	45135-38H-17*	20mm	25mm	Up to 20mm (up to 25 w/ new guides)
101-45-30	4.5mm Drill Bit 30mm	45135-52H-17*	34mm	39mm	Up to 35mm
101-45-40	4.5mm Drill Bit 40mm	45135-66H-17*	48mm	53mm	Up to 50mm

**These are distributed products. For full instructions for use, please go to the Lenkbar website at www.lenkbar.com.*

OPT-1505 Alteon Small and XL Crossbar Reamers and Liner Trials

QTY	Item	Item Description
1	01-031-40-0022	Alteon Liner Trial Neutral G0 22
1	01-031-40-0128	Alteon Liner Trial Neutral G1 28
1	01-031-40-0836	Alteon Liner Trial Neutral G8 36
1	01-031-42-0128	Alteon Liner Trial Extended Coverage G1 28
1	01-031-42-0836	Alteon Liner Trial Extended Coverage G8 36
1	01-031-46-0022	Alteon Liner Trial +5 Lateralized G0 22
1	01-031-46-0128	Alteon Liner Trial +5 Lateralized G1 28
1	01-031-46-0836	Alteon Liner Trial +5 Lateralized G8 36
1	01-031-48-0128	Alteon Liner Trial 10° Face Changing G1 28
1	01-031-48-0836	Alteon Liner Trial 10° Face Changing G8 36
1	01-101-00-0020	Alteon Sm/Lg Trial and Reamer Instrument Tray, Lower
1	01-101-00-0021	Alteon Sm/Lg Trial and Reamer Instrument Tray, Upper
1	50142038	Crossbar Acetabular Reamer Size 38
1	50142039	Crossbar Acetabular Reamer Size 39
1	50142040	Crossbar Acetabular Reamer Size 40
1	50142041	Crossbar Acetabular Reamer Size 41
1	50142042	Crossbar Acetabular Reamer Size 42
1	50142043	Crossbar Acetabular Reamer Size 43
1	50142061	Crossbar Acetabular Reamer Size 61
1	50142062	Crossbar Acetabular Reamer Size 62
1	50142063	Crossbar Acetabular Reamer Size 63
1	50142064	Crossbar Acetabular Reamer Size 64
1	50142065	Crossbar Acetabular Reamer Size 65
1	50142066	Crossbar Acetabular Reamer Size 66
1	50142067	Crossbar Acetabular Reamer Size 67
1	50142068	Crossbar Acetabular Reamer Size 68
1	10-322-00-0001	Instrument Tray Lid, Half Size

Additional Instruments

QTY	Item	Item Description
1	183-00-38	Single Bar, Acetabular Reamer, Size 38
1	183-00-39	Single Bar, Acetabular Reamer, Size 39
1	183-00-40	Single Bar, Acetabular Reamer, Size 40
1	183-00-41	Single Bar, Acetabular Reamer, Size 41
1	183-00-42	Single Bar, Acetabular Reamer, Size 42
1	183-00-43	Single Bar, Acetabular Reamer, Size 43
1	183-00-44	Single Bar, Acetabular Reamer, Size 44
1	183-00-45	Single Bar, Acetabular Reamer, Size 45
1	183-00-46	Single Bar, Acetabular Reamer, Size 46
1	183-00-47	Single Bar, Acetabular Reamer, Size 47
1	183-00-48	Single Bar, Acetabular Reamer, Size 48
1	183-00-49	Single Bar, Acetabular Reamer, Size 49
1	183-00-50	Single Bar, Acetabular Reamer, Size 50
1	183-00-51	Single Bar, Acetabular Reamer, Size 51
1	183-00-52	Single Bar, Acetabular Reamer, Size 52
1	183-00-53	Single Bar, Acetabular Reamer, Size 53
1	183-00-54	Single Bar, Acetabular Reamer, Size 54
1	183-00-55	Single Bar, Acetabular Reamer, Size 55
1	183-00-56	Single Bar, Acetabular Reamer, Size 56
1	183-00-57	Single Bar, Acetabular Reamer, Size 57
1	183-00-58	Single Bar, Acetabular Reamer, Size 58
1	183-00-59	Single Bar, Acetabular Reamer, Size 59
1	183-00-60	Single Bar, Acetabular Reamer, Size 60
1	183-00-61	Single Bar, Acetabular Reamer, Size 61
1	183-00-62	Single Bar, Acetabular Reamer, Size 62
1	183-00-63	Single Bar, Acetabular Reamer, Size 63
1	183-00-64	Single Bar, Acetabular Reamer, Size 64
1	183-00-65	Single Bar, Acetabular Reamer, Size 65
1	183-00-66	Single Bar, Acetabular Reamer, Size 66
1	183-00-67	Single Bar, Acetabular Reamer, Size 67
1	183-00-68	Single Bar, Acetabular Reamer, Size 68

Additional Instruments (Cont.)

QTY	Item	Item Description
1	123-00-38	Alternative Crossbar Acetabular Reamer Size 38
1	123-00-39	Alternative Crossbar Acetabular Reamer Size 39
1	123-00-40	Alternative Crossbar Acetabular Reamer Size 40
1	123-00-41	Alternative Crossbar Acetabular Reamer Size 41
1	123-00-42	Alternative Crossbar Acetabular Reamer Size 42
1	123-00-43	Alternative Crossbar Acetabular Reamer Size 43
1	123-00-44	Alternative Crossbar Acetabular Reamer Size 44
1	123-00-45	Alternative Crossbar Acetabular Reamer Size 45
1	123-00-46	Alternative Crossbar Acetabular Reamer Size 46
1	123-00-47	Alternative Crossbar Acetabular Reamer Size 47
1	123-00-48	Alternative Crossbar Acetabular Reamer Size 48
1	123-00-49	Alternative Crossbar Acetabular Reamer Size 49
1	123-00-50	Alternative Crossbar Acetabular Reamer Size 50
1	123-00-51	Alternative Crossbar Acetabular Reamer Size 51
1	123-00-52	Alternative Crossbar Acetabular Reamer Size 52
1	123-00-53	Alternative Crossbar Acetabular Reamer Size 53
1	123-00-54	Alternative Crossbar Acetabular Reamer Size 54
1	123-00-55	Alternative Crossbar Acetabular Reamer Size 55
1	123-00-56	Alternative Crossbar Acetabular Reamer Size 56
1	123-00-57	Alternative Crossbar Acetabular Reamer Size 57
1	123-00-58	Alternative Crossbar Acetabular Reamer Size 58
1	123-00-59	Alternative Crossbar Acetabular Reamer Size 59
1	123-00-60	Alternative Crossbar Acetabular Reamer Size 60
1	123-00-61	Alternative Crossbar Acetabular Reamer Size 61
1	123-00-62	Alternative Crossbar Acetabular Reamer Size 62
1	123-00-63	Alternative Crossbar Acetabular Reamer Size 63
1	123-00-64	Alternative Crossbar Acetabular Reamer Size 64
1	123-00-65	Alternative Crossbar Acetabular Reamer Size 65
1	123-00-66	Alternative Crossbar Acetabular Reamer Size 66
1	123-00-67	Alternative Crossbar Acetabular Reamer Size 67
1	123-00-68	Alternative Crossbar Acetabular Reamer Size 68
1	01-030-95-0000	Alteon Acetabular X-Ray 120% Templates

INDICATIONS FOR USE

All Exactech Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of Exactech Hip Systems are also potentially indicated for ankylosing spondylitis, congenital hip dysplasia, revision of failed previous reconstructions where sufficient bone stock is present and to restore mobility resulting from previous fusion.

- Cemented femoral stems and cemented acetabular cups are intended for cemented fixation only.
- Press-fit femoral stems and acetabular cups are intended for press-fit fixation.
- Femoral heads and endoprostheses are intended for use in cemented and press-fit applications.

CONTRAINDICATIONS FOR USE

Use of the Exactech Hip Systems is contraindicated in the following situations:

- Patients with suspected or confirmed systemic infection or a secondary remote infection.
- Patients with inadequate or malformed bone that precludes adequate insertion or fixation of the prosthesis.
- Patients with neuromuscular disorders that do not allow control of the joint.
- The unipolar and bipolar endoprostheses are also contraindicated for use in patients with evidence of degenerative changes in the acetabulum and/or pelvic fractures.
- Patient's age, weight or activity level would cause the surgeon to expect early failure of the system.

Reusable surgical instruments are supplied nonsterile and must be cleaned and sterilized prior to use. The reprocessing of reusable surgical instruments is not covered in this Instructions for Use. Consult the Exactech Reprocessing Instructions for Reusable Surgical Instruments. Refer to www.incipiodevices.com for reprocessing instructions on distributed products.

For additional device information, refer to the Exactech Hip System–Instructions for Use for a device description, indications, contraindications, precautions and warnings. For further product information, please contact Customer Service, Exactech, Inc., 2320 NW 66th Court, Gainesville, Florida 32653-1630, USA. (352) 377-1140, (800) 392-2832 or FAX (352) 378-2617.

Exactech, as the manufacturer of this device, does not practice medicine, and is not responsible for recommending the appropriate surgical technique for use on a particular patient. These guidelines are intended to be solely informational and each surgeon must evaluate the appropriateness of these guidelines based on his or her personal medical training and experience. Prior to use of this system, the surgeon should refer to the product package insert for comprehensive warnings, precautions, indications for use, contraindications and adverse effects.

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