





HA Femoral Stem Primary Femoral Solutions





TABLE OF CONTENTS

OBJECTIVES1
DESIGN TEAM1
OPERATIVE TECHNIQUE OVERVIEW
PRE-OPERATIVE PLANNING
TOOLS
ESTABLISHMENT OF REFERENCE POINTS
DETERMINE LIMB LENGTH
DETAILED OPERATIVE TECHNIQUE
APPROACH AND OSTEOTOMY4
FEMORAL CANAL ENTRY5
FEMORAL CANAL BROACHING6
Broach Assembly/Disassembly6
Femoral Broaching6
Calcar Preparation7
TRIAL REDUCTION8
Trial Component Insertion8
Trial Component Removal8
FINAL COMPONENT PLACEMENT9
Final Stem Insertion9
Femoral Head Impaction9
FINAL REDUCTION9
IMPLANT REMOVAL10
CLOSURE10
INSTRUMENT LISTING 11
IMPLANT ORDERING INFORMATION12
INDICATIONS FOR USE

OBJECTIVES

The goal of the surgical approach is to establish adequate visualization to evaluate stability and leg length 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® HA Femoral Stem. For key surgical steps specific to the cup, refer to the appropriate acetabular technique.

DESIGNTEAM

COREY BURAK, MD, is a board-certified orthopaedic surgeon. Dr. Burak received his medical degree from SUNY–HSC at Syracuse College of Medicine in New York. Dr. Burak served his general surgery internship at Saint Vincent's Hospital and Medical Center in New York City and his orthopaedic surgery residency at Tulane University Hospital and Medical Center in New Orleans, La. It was at Tulane where he completed a research fellowship in adult reconstruction under the renowned Robert L. Barrack, MD. In addition, Dr. Burak completed a fellowship in hip and knee arthroplasty at Dorr Arthritis Institute in Los Angeles.

PROFESSOR CESARE FALDINI, MD, is a practicing orthopaedic physician and chairman of the Rizolli-Siciliy Department, Head of the Service of Orthopaedic and Trauma Surgery at the Rizzoli Institute in Bagheria, Italy. He received his medical degree from the University of Pisa, Italy in 1996. Professor Faldini completed his residency at the Rizzoli Orthopaedic Institute in Bologna, Italy and has held several academic positions at the Rizzoli Institute.

JOSEPH LOCKER, MD, is an orthopaedic surgeon at The Orthopaedic Institute in Ocala, Fla. He completed his residency at Tulane University Medical Center. Dr. Locker specializes in anterior total hip replacement, sports medicine, arthroscopic surgery, and joint replacement and reconstructive surgery. He has been an instructor for various surgical techniques and product information since 2006.

JEFF PIERSON, MD, practices with Franciscan St. Francis Health in Carmel, Ind. He attended The Johns Hopkins University School of Medicine in Baltimore where he received his medical degree. He completed his general surgery internship at Northwestern University Medical Center, Chicago, and his orthopaedic residency at the Hospital for Special Surgery in New York, N.Y. In addition, Dr. Pierson completed his orthopaedic fellowship in adult hip and knee reconstruction at Harvard University.

SAM SYDNEY, MD, is an orthopaedic surgeon with Orthopaedic Associates of Central Maryland. He completed a residency at Sinai Hospital/Johns Hopkins University; his residency and fellowship at University of Maryland Hospital; and an additional fellowship at Joint Implant Surgeons, Inc. He is a clinical instructor of orthopaedics at the University of Maryland. Dr. Sydney is a lecturer and instructor of minimally invasive total joint techniques for the American Academy of Orthopaedic Surgeons.

OPERATIVE TECHNIQUE OVERVIEW



Figure A Align Osteotomy Guide







Figure C Femoral Broaching



Figure D Calcar Planing

Figure E Trial Components Figure F Femoral Stem Insertion Figure G Femoral Head Impaction

PRE-OPERATIVE PLANNING

TOOLS

- A/P radiograph of pelvis centered on the pubic symphysis
- Pencil that will not damage x-ray
- Straight edge
- Alteon[®] HA Femoral Stem Template Set with 120
 percent magnification rule
- Goniometer/protractor

Traditional templating methods may be used. For an estimated determination of the required offset, vertical limb length and stem size, the following detailed templating method may be used to help guide the surgeon in final implant choice.

ESTABLISHMENT OF REFERENCE POINTS

On the radiograph, a straight line is drawn across the bottom of the pelvis touching both ischial tuberosities equally. The line is extended far enough to reach each lesser trochanter. Such a line should be perpendicular to the vertically oriented pubic symphysis. If the line is not vertically oriented, it should be confirmed that the patient's pelvis was not tilted when the radiograph was taken. If the ischial tuberosities are poorly defined, the line should be drawn through the inferior portion of both obturator foramina or the inferior aspect of both teardrops. Templating is recommended to determine the unique anatomic and mechanical features of the patient, and to establish pre-operative reference points that assist in the reconstruction of the patient's natural femoral anatomy.

DETERMINE LIMB LENGTH

Select and position the appropriate Alteon® HA Femoral Stem Template Set (see *Figure 1*) over the x-ray so the central axis of the stem aligns with the central axis of the femoral canal and one of the available femoral head options creates the desired center of rotation. The Alteon HA Femoral Stem is designed to seat in cancellous bone, therefore cortical contact with the stem outline should be avoided when templating. When the template is in the desired position, the level of the femoral neck cut and femoral head center of rotation is marked through the punch-outs provided on the template. Record the appropriate size, lateral offset (Standard or Extended), femoral head offset and level of the femoral neck resection.

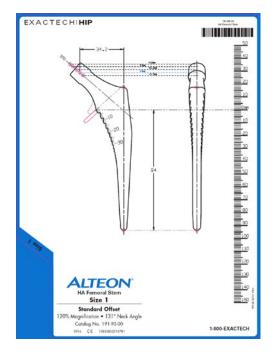


Figure 1 Alteon HA Femoral Stem X-ray Template

SURGICAL TIPS

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

• Templating is an important part of pre-operative preparation, and should only serve as a guide. Templating is generally plus or minus two sizes of the final implant size depending on bone quality. Final decision making concerning fit, size and softtissue tensioning occurs in the operating room using available options of stem offset, head offset and liner configuration.

APPROACH AND OSTEOTOMY



Figure 2 Align Osteotomy Guide

APPROACH AND OSTEOTOMY

The surgical approach of choice is based upon the degree of surgical experience and preference. Align the **Osteotomy Guide** with the long axis of the femur and mark the level of the femoral osteotomy within the slot on the guide as determined in the pre-operative templating exercise (*Figure 2*). Resect the femoral neck at this level in order to help re-establish the patient's limb length, lateral offset, and center of rotation of the femoral head.

SURGICAL TIPS

Prior to using the osteotomy guide, ensure sufficient exposure such that the center of the femoral head is visible. If necessary, resect any anterior osteophytes from the acetabulum.

FEMORAL CANAL ENTRY



Figure 3 Femoral Canal Entry

FEMORAL CANAL ENTRY

Use the **Box Osteotome** to remove a wedge of bone, creating a portal for entry into the femoral canal *(Figure 3)*. This Box Osteotome may aid in establishing an axial position for insertion of broaches. Additional **Canal Entry Tools** can be used to gain access to the femoral canal.

SURGICAL TIPS

- The Box Osteotome and **Modular Canal Entry Tools** are assembled with the **Modular Handle** prior to use. Ensure these tools properly lock into the Modular Handle by aligning the flat surfaces of the tools with the rectangular feature at the end of the handle. An audible click can be heard when the tools are properly connected.
- Utilize the Box Osteotome to remove lateral cortical bone to ensure clearance for the broaches and stem.

FEMORAL CANAL BROACHING



Figure 4 Femoral Broaching

Broach Assembly/Disassembly

Assemble the **Broach Handle** to the **Broach** by releasing the locking mechanism, mating the body of the Broach Handle to the superior aspect of the Broach and then engaging the locking mechanism (*Figure 4*). Check for proper orientation and full engagement. Care should be taken to ensure that the assembly of the instruments is correct.

Femoral Broaching

Broach up progressively, beginning with the smallest size. Insert the Broach into the femoral canal with the desired amount of anteversion. Alternate impaction and withdrawal of the Broach as the final size is approached. Release the Broach Handle from the Broach for trialing once broach is axially and rotationally stable.

SURGICAL TIPS

• If resistance is encountered while preparing the desired stem size, drop down a broach size and re-broach. The **Canal Entry Tools** may also be used throughout the procedure to aid in positioning of the subsequent Broaches or the final implant.

• If rotational stability is to be tested, it should be done on the final broach (after axial stability is achieved), to avoid wallowing out the prepared cancellous bed to ensure proper fit of the final implant.

Note: While broaching, limit the lateral bending forces applied. Excessive bending forces in the lateral direction may cause the broach post to fracture.

CALCAR PREPARATION



ASSEMBLY TIPS

The assembled **Calcar Planer** (*Figure 6*) is created by threading the **Calcar Planer Shaft** over the **Calcar Planer Adaptor** which captures the **Calcar Planer Blade**. The assembly is tightened, or loosened, using the supplied **Calcar Planer Wrench**. Ensure the hexagonal feature of the adaptor sits within the hexagonal feature on the blade (*Figures 5-7*).

Calcar Preparation

(Mandatory for Collared Stem, Optional for Collarless)

Perform calcar planing, in order to remove any bone that protrudes above the level of the impacted Alteon HA Broach by guiding the Calcar Planer onto the guidance surface feature of the Broach (*Figure 8*).

SURGICAL TIPS

Start Calcar Planer blade before resting the planer on the bone to minimize risk of bone fracture.

Note: While calcar planing, ensure the calcar planer remains parallel to the face of the broach. Excessive bending forces to the Calcar Planer may cause it to fracture or wear.

TRIAL REDUCTION



Trial Components

TRIAL REDUCTION

Trial Component Insertion

Place the appropriate **Neck Trial** onto the guidance surface feature of the Broach. Be sure the correct size and offset (Standard or Extended) Neck Trial is chosen. Make sure, when inserting the Neck Trial, the size and offset etch markings are facing laterally. Select an appropriate **Femoral Head Trial** and assemble for trial reduction (*Figure 9*).

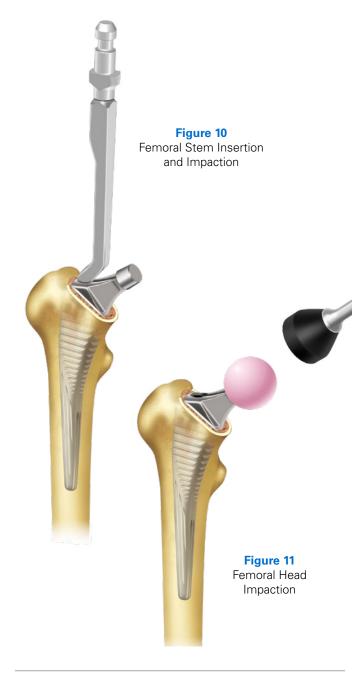
Trial Component Removal

Decide the final components for implantation. Dislocate the hip, and remove the trial components. Reassemble the Broach Handle to the Broach and remove.

SURGICAL TIPS

The Broaches and Neck Trials include design features to ensure that only the designated Neck Trial will mate with the corresponding size Broach.

DETAILED OPERATIVE TECHNIQUE FINAL COMPONENT PLACEMENT



FINAL COMPONENT PLACEMENT

Final Stem Insertion

Select the appropriate Femoral Stem and impact using the desired **Stem Inserter**, ensuring correct version and depth *(Figure 10)*. Another trial reduction can be performed with the final Femoral Stem and Femoral Head Trial.

- The Stem Inserters and Femoral Head Impactor are assembled with the **Modular Handle** prior to use. Ensure these tools properly lock into the Modular Handle.
- The non-threaded **Stem Inserters** provide rotational control while impacting the stem.

Femoral Head Impaction

For CoCr heads: Clean and dry the taper of the femoral stem. Place the selected femoral head component onto the taper of the femoral stem and secure it using the Femoral Head Impactor. Apply one or several moderate strikes of the mallet on the Femoral Head Impactor in alignment with the head axis to affix the femoral head to the stem taper.

For Biolox[®]delta ceramic heads: Clean and dry the taper of the femoral stem. Confirm stem/head compatibility and confirm that the stem and head taper are free of damage. Fit the selected femoral head component onto the stem taper by exerting slight axial pressure on the head component while simultaneously twisting until fully seated. Place the polymer-faced Femoral Head Impactor on the pole of the femoral head and tap gently with a mallet in alignment with the head axis to secure the taper connection. Consult the Instructions for Use accompanying the ceramic femoral head for all installation instructions and warnings.

For Biolox®OPTION heads: After assuring the tapers are clean and dry, assemble the metal adapter and the femoral head per the instructions for use accompanying the Biolox®OPTION components. Clean and dry the taper of the femoral stem. Inspect the stem taper to determine its condition is undamaged or acceptable per the instructions for use accompanying the Biolox®OPTION components. Fit the selected femoral head component onto the stem taper by exerting slight axial pressure on the head component while simultaneously twisting until fully seated. Place the polymer-faced Femoral Head Impactor on the pole of the femoral head and tap gently with a mallet in alignment with the head axis to secure the taper connection. Consult the Instructions for Use accompanying the Biolox®OPTION component for all installation instructions and warnings.

Note: DO NOT use metal-faced mallets and DO NOT impact forcefully during installation of ceramic components. Excessive impaction force may cause fracture or early failure. DO NOT directly impact femoral head with a mallet.

FINAL REDUCTION



Figure 12 Threaded Stem Extraction

Figure 13 Trunion Stem Extraction

FINAL REDUCTION

Reduce the hip and perform a final check of length, range of motion and stability.

IMPLANT REMOVAL

If it is necessary to intraoperatively remove a prosthesis, the **Stem Extractor** may be assembled to the Broach Handle to facilitate removal *(Figures 12 and 13).*

CLOSURE

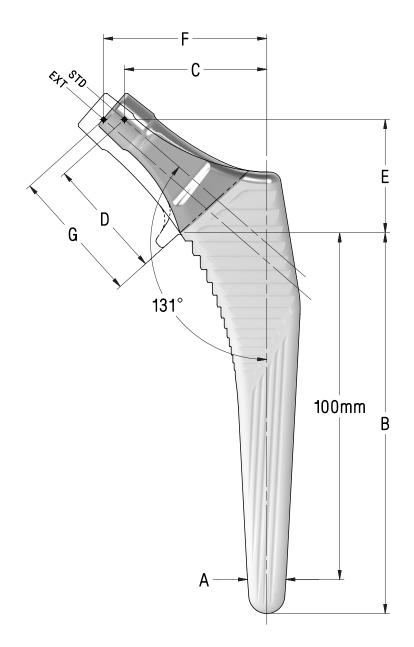
Close the wound according to the preferred method.

IMPLANT ORDERING INFORMATION

	Colla	arless	Collared					
Stem Size	Standard Offset	Extended Offset	Standard Offset	Extended Offset				
1	190-00-01	N/A	190-10-01	N/A				
2	190-00-02	190-01-02	190-10-02	190-11-02				
3	190-20-03	190-21-03	190-30-03	190-31-03				
4	190-20-04	190-21-04	190-30-04	190-31-04				
5	190-20-05	190-21-05	190-30-05	190-31-05				
6	190-20-06	190-21-06	190-30-06	190-31-06				
7	190-20-07	190-21-07	190-30-07	190-31-07				
8	190-20-08	190-21-08	190-30-08	190-31-08				
9	190-20-09	190-21-09	190-30-09	190-31-09				
10	190-20-10	190-21-10	190-30-10	190-31-10				
11	190-20-11	190-21-11	190-30-11	190-31-11				
12	190-20-12	190-21-12	190-30-12	190-31-12				
13	190-20-13	190-21-13	190-30-13	190-31-13				
14*	190-20-14	190-21-14	190-30-14	190-31-14				
15*	190-20-15	190-21-15	190-30-15	190-31-15				

* Items are special order; please contact your Exactech Representative to order.

SYSTEM SPECIFICATIONS



SYSTEM SPECIFICATIONS

	A	В	С				D					E					
Size	M to L Width	Stem Length	Later	al offse head	t with t lengths		owing	Neck length with the following head lengths (mm)			Vertical offset with the following head lengths (mm)						
	(mm)	(mm)	-3.5	0	3.5	7	10	-3.5	0	3.5	7	10	-3.5	0	3.5	7	10
1	4.3*	94	31.6	34.2	36.9	39.5	41.8										
2	5.2*	94	32.0	34.7	37.3	40.0	42.2	26.5	30.0	33.5	20.0	39.9	26.7	29.0	31.3	22.0	25.5
3	6.0*	96	32.5	35.1	37.7	40.4	42.7	20.5	30.0	33.5	36.9	39.9	20.7	29.0	31.3	33.6	35.5
4	6.9	99	32.9	35.5	38.2	40.8	43.1										
5	7.7	102	34.9	37.6	40.2	42.9	45.1										
6	8.9	104	35.5	38.2	40.8	43.4	45.7	29.0	32.5	36.0	39.4	42.4	28.6	30.9	33.2	35.5	37.4
7	10.0	107	36.1	38.7	41.4	44.0	46.3										
8	11.2	110	38.4	41.1	43.7	46.3	48.6										
9	12.3	113	39.0	41.6	44.3	46.9	49.2	31.5	35.0	38.5	41.9	44.9	30.4	32.7	35.0	37.3	39.2
10	13.5	115	39.6	42.2	44.8	47.5	49.7										
11	14.6	118	41.9	44.5	47.1	49.8	52.1										
12	16.0	121	42.6	45.2	47.9	50.5	52.8										
13	17.5	123	43.3	45.9	48.6	51.2	53.5	34.0	37.5	41.0	44.4	47.4	32.2	34.5	36.8	39.1	41.0
14**	18.9	126	44.0	46.6	49.3	51.9	54.2										
15**	20.3	129	44.7	47.4	50.0	52.6	54.9										

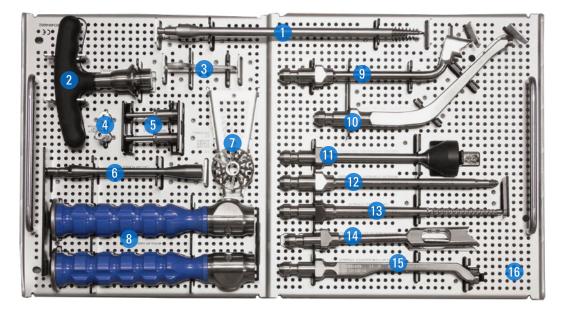
STANDARD OFFSET

EXTENDED OFFSET

	Α	В	F				G				E									
Size				et with the following I lengths (mm)			Neck length with the following head lengths (mm)				Vertical offset with the following head lengths (mm)									
	(mm)	(mm)	-3.5	0	3.5	7	10	-3.5	0	3.5	7	10	-3.5	0	3.5	7	10			
2	5.2*	94	38.0	40.7	43.3	46.0	48.2													
3	6.0*	96	38.5	41.1	43.7	46.4	48.7	30.5	34.0	37.5	40.9	43.9	26.7	29.0	31.3	33.6	35.5			
4	6.9	99	38.9	41.5	44.2	46.8	49.1													
5	7.7	102	40.9	43.6	46.2	48.9	51.1													
6	8.9	104	41.5	44.2	46.8	49.4	51.7	33.0	33.0	33.0	33.0	36.5	40.0	43.4	46.4	28.6	30.9	33.2	35.5	37.4
7	10.0	107	42.1	44.7	47.4	50.0	52.3													
8	11.2	110	44.4	47.1	49.7	52.3	54.6													
9	12.3	113	45.0	47.6	50.3	52.9	55.2	35.5	39.0	42.5	45.9	48.9	30.4	32.7	35.0	37.3	39.2			
10	13.5	115	45.6	48.2	50.8	53.5	55.7													
11	14.6	118	47.9	50.5	53.1	55.8	58.1													
12	16.0	121	48.6	51.2	53.9	56.5	58.8													
13	17.5	123	49.3	51.9	54.6	57.2	59.5	38.0	41.5	45.0	48.4	51.4	32.2	34.5	36.8	39.1	41.0			
14**	18.9	126	50.0	52.6	55.3	57.9	60.2													
15**	20.3	129	50.7	53.4	56.0	58.6	60.9													

* Projected width. For comparison purposes only. **Items are special order; please contact your Exactech Representative to order.

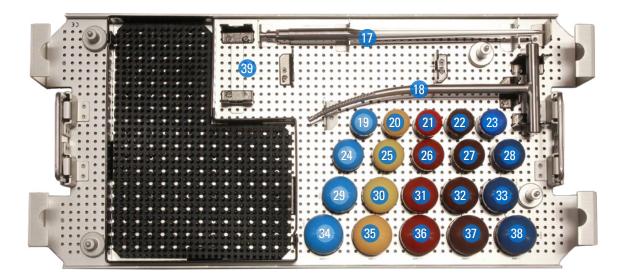
TRAY LAYOUT



KIT-1003 Alteon Common Femoral Instruments (Upper Level Tray)

Site	ltem	Item Description
Not Pictured	10-111-00-0001	Instrument Outer Case, Single-Level
Not Pictured	10-301-01-0001	Instrument Outer Case, Lid
1	167-00-01 ⁺	Corkscrew, Sharp
2	301-07-70	Small T-Handle
3	01-003-04-0005	Calcar Planer Wrench
4	01-003-04-0004	Calcar Planer Bushing, Broach Hole Adaptor
5	01-003-04-0003	Calcar Planer Bushing, Broach Post Adaptor
6	01-003-04-0001	Calcar Planer Assembly, Shaft
7	01-003-04-0002*	Calcar Planer Blade, 1.5"
8	01-001-00-0001	Modular Handle
9	01-001-05-0003 ⁺	Modular Box Osteotome, Reduced Offset
10	01-001-01-0002	Modular Stem Inserter, Offset
11	01-001-03-0001	Modular Femoral Head Impactor
12	01-001-01-0003	Modular Stem Inserter, Threaded
13	01-001-06-0001	Modular Straight Canal Finder, Blunt
14	01-001-05-0001*	Modular Box Osteotome, Straight
15	01-001-01-0001	Modular Stem Inserter, Straight
16	01-003-00-0002	Common Femoral Tray, Upper Inner Tray

t Instruments have sharp features; use caution when handling these instruments to avoid injury to user or patient.

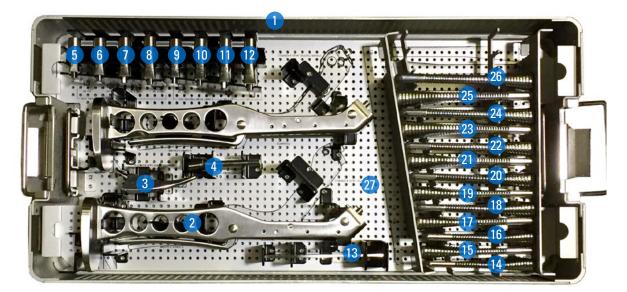


KIT-1003 Alteon Common Femoral Instruments (Lower Level Tray)

Site	ltem	Item Description
17	01-003-07-0001 *	Starter Reamer
18	01-003-06-0003 [†]	Curved Canal Finder, Blunt
19	143-28-10	Femoral Head Trial, 28, +10mm, O-Ring, 12/14
20	143-28-07	Femoral Head Trial, 28, +7mm, O-Ring, 12/14
21	143-28-03	Femoral Head Trial, 28, +3.5mm, O-Ring, 12/14
22	143-28-00	Femoral Head Trial, 28, +0mm, O-Ring, 12/14
23	143-28-93	Femoral Head Trial, 28, -3.5mm, O-Ring, 12/14
24	143-32-10	Femoral Head Trial, 32, +10mm, O-Ring, 12/14
25	143-32-07	Femoral Head Trial, 32, +7mm, O-Ring, 12/14
26	143-32-03	Femoral Head Trial, 32, +3.5mm, O-Ring, 12/14
27	143-32-00	Femoral Head Trial, 32, +0mm, O-Ring, 12/14
28	143-32-93	Femoral Head Trial, 32, -3.5mm, O-Ring, 12/14
29	143-36-10	Femoral Head Trial, 36, +10mm, O-Ring, 12/14
30	143-36-07	Femoral Head Trial, 36, +7mm, O-Ring, 12/14
31	143-36-03	Femoral Head Trial, 36, +3.5mm, O-Ring, 12/14
32	143-36-00	Femoral Head Trial, 36, +0mm, O-Ring, 12/14
33	143-36-93	Femoral Head Trial, 36, -3.5mm, O-Ring, 12/14
34	143-40-10*	Femoral Head Trial, 40, +10mm, O-Ring, 12/14
35	143-40-07*	Femoral Head Trial, 40, +7mm, O-Ring, 12/14
36	143-40-03*	Femoral Head Trial, 40, +3.5mm, O-Ring, 12/14
37	143-40-00*	Femoral Head Trial, 40, +0mm, O-Ring, 12/14
38	143-40-93*	Femoral Head Trial, 40, -3.5mm, O-Ring, 12/14
39	01-003-00-0001	Common Femoral Tray, Lower Inner Tray

*Special Order Only. *†* Instruments have sharp features; use caution when handling these instruments to avoid injury to user or patient.

TRAY LAYOUT



KIT-1491P Alteon HA Femoral Stem Instruments (Posterior Approach)

Site	Qty	ltem	Item Description
Not Pictured	1	10-301-00-0001	Instrument Outer Case, Lid
1	1	10-111-00-0001	Instrument Outer Case, Single Level
2	2	01-003-02-0003	Broach Handle, Straight
3	1	01-003-06-0006	Canal Finder, Starter Broach
4	1	01-003-10-0002	Stem Extractor, Threaded
5	1	01-003-22-0104	Alteon Neck Trial, STD, Size 1-4
6	1	01-003-22-0507	Alteon Neck Trial, STD, Size 5-7
7	1	01-003-22-0810	Alteon Neck Trial, STD, Size 8-10
8	1	01-003-22-1117	Alteon Neck Trial, STD, Size 11-17
9	1	01-003-23-0104	Alteon Neck Trial, EXT, Size 1-4
10	1	01-003-23-0507	Alteon Neck Trial, EXT, Size 5-7
11	1	01-003-23-0810	Alteon Neck Trial, EXT, Size 8-10
12	1	01-003-23-1117	Alteon Neck Trial, EXT, Size 11-17
13	1	189-00-00	Alteon Osteotomy Guide
14	1	191-02-01	HA Compaction Broach, Size 1
15	1	191-02-02	HA Compaction Broach, Size 2
16	1	191-03-03	HA Compaction Broach, Size 3
17	1	191-03-04	HA Compaction Broach, Size 4
18	1	191-03-05	HA Compaction Broach, Size 5
19	1	191-03-06	HA Compaction Broach, Size 6
20	1	191-03-07	HA Compaction Broach, Size 7
21	1	191-03-08	HA Compaction Broach, Size 8
22	1	191-03-09	HA Compaction Broach, Size 9
23	1	191-03-10	HA Compaction Broach, Size 10
24	1	191-03-11	HA Compaction Broach, Size 11
25	1	191-03-12	HA Compaction Broach, Size 12
26	1	191-03-13	HA Compaction Broach, Size 13
27	1	189-89-03	Alteon HA, Inner Tray

***ADDITIONAL INSTRUMENTS:**

Qty	ltem	Item Description	Image
2	01-003-02-0001	Broach Handle, Curved, Single Offset	CCCC
1	01-003-02-0004	Broach Handle, Dual Offset, Left	- Oliver
1	01-003-02-0005	Broach Handle, Dual Offset, Right	
1	01-003-04-0007	Calcar Planer Wrench, Long	
1	01-003-10-0001	Stem Extractor, Trunnion Adaptor	
1	01-003-06-0007 [†]	Canal Finder, Lateralizing Broach	
1	191-03-14* 191-03-15*	HA Compaction Broach, Size 14 HA Compaction Broach, Size 15	
1	4251-4080***	Exactech Straight Anterior Broach Handle	

*Special Order Only.

[†] Instruments have sharp features; use caution when handling these instruments to avoid injury to user or patient. ***This instrument is not included in the Exactech Kits but can be ordered and shipped separately, which includes its IFU and reprocessing instructions.

INDICATIONS FOR USE

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.

Exactech Alteon HA femoral stems are intended for press-fit fixation.

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.

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.

The products discussed herein may be available under different trademarks in different countries. All copyrights, and pending and registered trademarks, are property of Exactech, Inc. This material is intended for the sole use and benefit of the Exactech sales force and physicians. It should not be redistributed, duplicated or disclosed without the express written consent of Exactech, Inc. ©2024 Exactech, Inc. OPTECH-000109 Rev/A US Version 092524

Exactech is proud to have offices and distributors around the globe. For more information about Exactech products available in your country, please visit www.exac.com



EXACTECH, INC. 2320 NW 66TH COURT GAINESVILLE, FL 32653 USA

+1 352.377.1140 +1 800.EXACTECH +1 352.378.2617 (FAX) www.exac.com