EXACTECH | **HIP**

Operative Technique

ALTEON

Highly Polished Femoral Stem

Primary Femoral Solutions

exactech

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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® HPS Femoral Stem. For key surgical steps specific to the cup, refer to the appropriate acetabular technique.

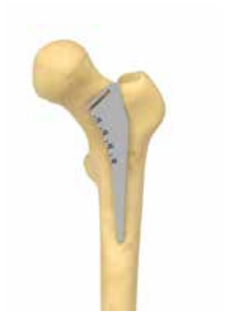
DESIGN TEAM

Daniel Godoy, MD, is an orthopaedic surgeon, specializing in hip replacements at the Italian Hospital in Buenos Aires, Argentina. He completed his residency at the Italian Hospital in 1996 and fellowships at Joint Replacements, Joint Replacements Sir John Charnely in 1997; AO/ASF in Kantonspital Liestal in 1998, Switzerland; and at the Mayo Clinic in Rochester, Minnesota in 1999.

Saul Martinez, MD, is the department chief of the orthopaedic and traumatology department and instructor at the Hospital Santa Clara in Bogota, Columbia. Dr. Martinez serves as the fellows instructor at the Military University at Granada, chapter member of the Colombian Hip and Knee Society and international member of AAHKS.

Flávio Turibio, MD, is an orthopaedic surgeon, specializing in Hip Surgery as the Clinical Director of Hospital Santa Marcelina Itaquera in São Paulo, Brazil. He holds a master's degree in Orthopedic Surgery from the Federal University of São Paulo (1991) and a PhD in Orthopedics and Traumatology from the Federal University of São Paulo (1996).

OPERATIVE TECHNIQUE OVERVIEW



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Align Osteotomy Guide

Figure B
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Figure C
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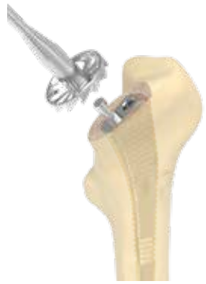

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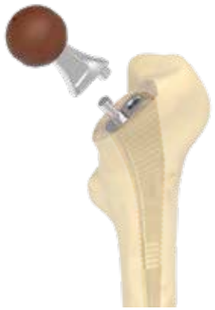
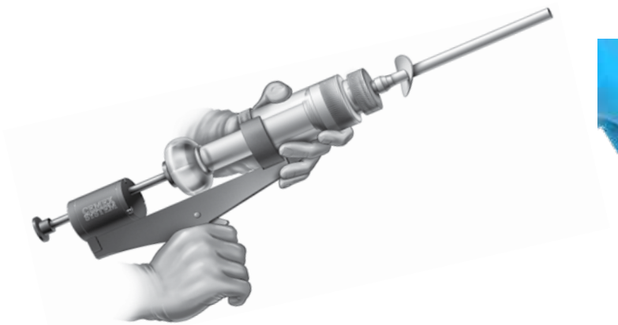


Figure E
Trial Components



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Femoral Stem Insertion

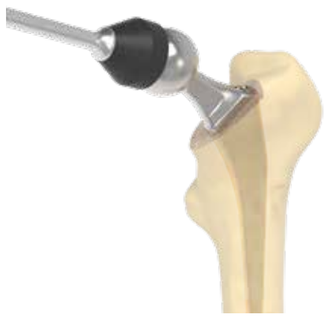


Figure I
Femoral Head Impaction

PRE-OPERATIVE PLANNING

TOOLS

- Digital A/P radiograph of pelvis centered on the pubic symphysis
- **Alteon® HPS Femoral Stem Digital Template Set** with 120 percent magnification rule

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

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® HPS Femoral Stem Template Set 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. When the template is in the desired position, the level of the femoral neck cut and femoral head center of rotation is marked. Record the appropriate size, lateral offset (Standard or Extended), femoral head offset and level of the femoral neck resection.

SURGICAL TIPS

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 soft-tissue tensioning occurs in the operating room using available options of stem offset, head offset and liner configuration.

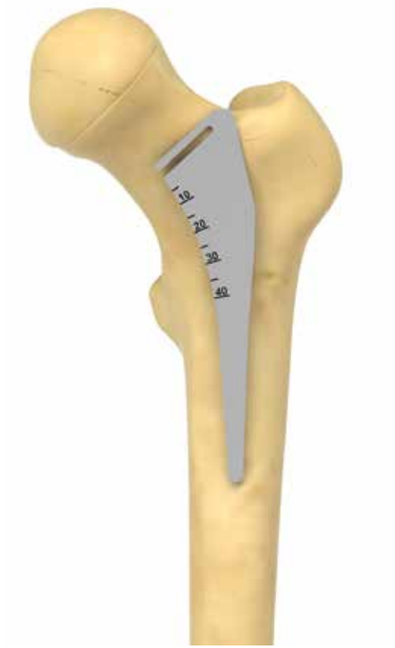


Figure 1
Osteotomy of the Femur

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 1)*. 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.

Figure 2
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 2)*. 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.

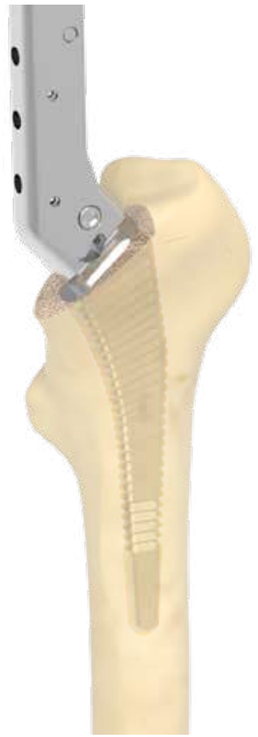


Figure 3
Femoral Broaching

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. 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 *(Figure 3)*. 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.

Figure 4
Calcar Planer Assembly

Figure 5
Proper Calcar Planer Assembly

Figure 6
Improper Calcar Planer Assembly

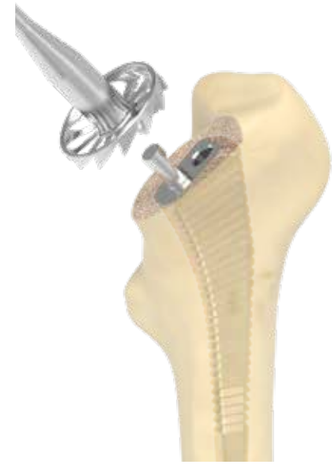


Figure 7
Calcar Planing

ASSEMBLY TIPS

The assembled **Calcar Planer** *(Figure 5)* 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 4-6*).

Calcar Preparation
(Optional step)

Perform calcar planing, in order to remove any bone that protrudes above the level of the impacted Broach by guiding the Calcar Planer onto the guidance surface feature of the Broach *(Figure 7)*.

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.*

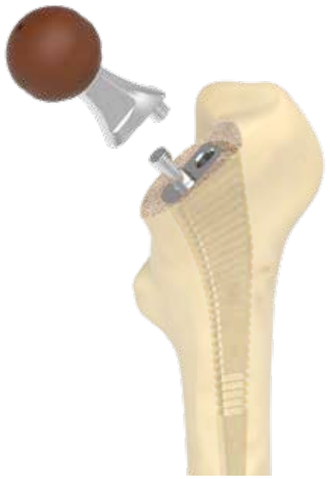
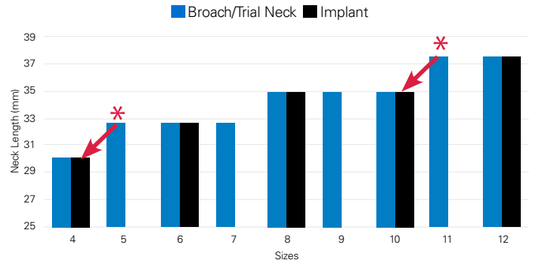
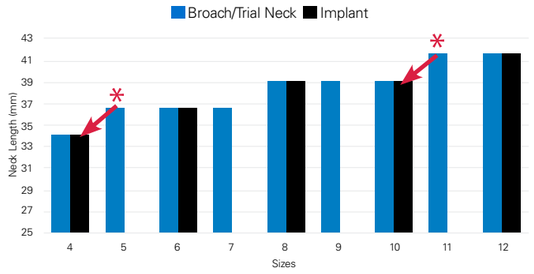


Figure 8
Trial Reduction

STANDARD OFFSET NECK LENGTH



EXTENDED OFFSET NECK LENGTH



**When the final selected broach is an odd number, the surgeon must downsize the implant. When stopping at sizes 5 and 11 broaches, the broach and trial neck produce a longer neck length than the corresponding implant. To recreate a similar leg length and offset, a longer head length may be required. It is recommended to perform a trial reduction on the final Femoral Stem using Femoral Trial Heads to confirm the proper Head Implant size selection.*

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 8)*.

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.

NOTE: *The HPS femoral stems are only available in even sizes, however the broaches are available in both even and odd sizing. Due to this offering, the implant to be cemented should be equal or smaller in size than the last broach. Cement Mantle thickness can be found on page 10. The implant size specifications are on page 12.*

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.

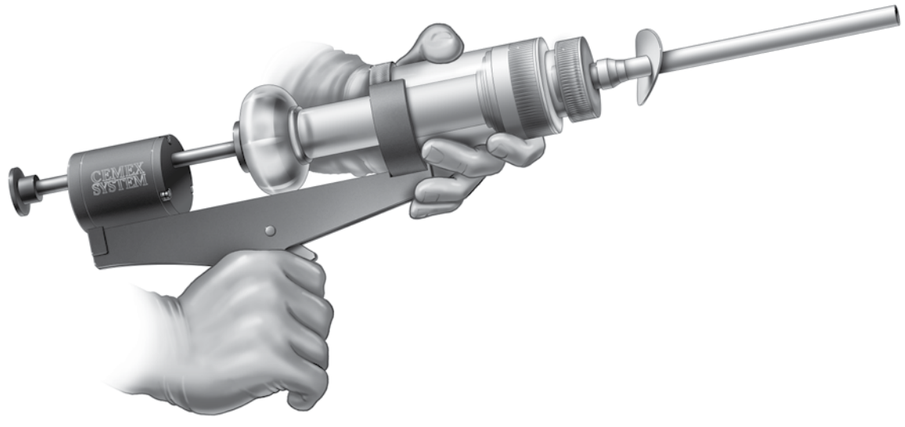


Figure 9
Cementation

Cementation Technique

Use pulsatile lavage to clear the femoral canal of debris and open the interstices of the bone. Insert the selected cement restrictor implant. Implant dimensions are on page 12. After cement restrictor insertion, press a swab down the femoral canal to help dry and remove any remaining debris.

Mix the bone cement per Cemex Mixing Technique (715-01-01) *(Figure 9)*. Using the Cemex System Gun, start at the distal part of the canal and inject the cement while retrograding proximally, allowing the cement to gently press the nozzle back, until the canal is filled.

Cut the nozzle and place the Cement Pressurizer over the end. Insert the pressurizer into the canal with a downward pressure and continually inject cement during the pressurization period to allow good interdigitation of the cement into the cancellous bone.

Figure 10
Femoral Stem Insertion for Final Component Placement

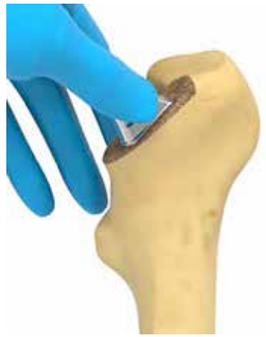


Figure 11
Femoral Stem Insertion

CEMENT MANTLE CHART

Broach Size	-M-L Cement Mantle Thickness (mm) Stem Size 4	6	8	10	12	Distal A-P Cement Mantle Thickness (mm) Stem Size 4	6	8	10	12
4	0.7	-	-	-	-	0.7	-	-	-	-
5	1.1	-	-	-	-	0.8	-	-	-	-
6	-	0.7	-	-	-	-	0.7	-	-	-
7	-	1.3	-	-	-	-	0.9	-	-	-
8	-	-	0.7	-	-	-	-	0.7	-	-
9	-	-	1.3	-	-	-	-	0.9	-	-
10	-	-	-	0.7	-	-	-	-	0.7	-
11	-	-	-	1.3	-	-	-	-	0.9	-
12	-	-	-	-	0.7	-	-	-	-	0.7
13	-	-	-	-	1.4	-	-	-	-	0.9
14	-	-	-	-	-	-	-	-	-	-
15	-	-	-	-	-	-	-	-	-	-

FINAL COMPONENT PLACEMENT

Final Stem Insertion

Select the appropriate Femoral stem and insert the implant into the cement filled femoral canal using the desired Stem Inserter or by hand, ensuring correct rotational alignment, version and depth.

Proceed to insert until the desired level is met on the medial calcar of the stem *(Figure 10)*. Continue to hold the implant in place keeping appropriate pressure on the cement mantle to maintain correct orientation of the implant until the cement has cured *(Figure 11)*. Another trial reduction can be performed with the final Femoral Stem and Femoral Head Trial.

SURGICAL TIPS

- The Stem Inserters and Femoral Head Impactor are assembled with the **Modular Handle** prior to use. Ensure tools properly lock into the Modular Handle.
- Remove excess cement with a curette prior to the cement curing.

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.

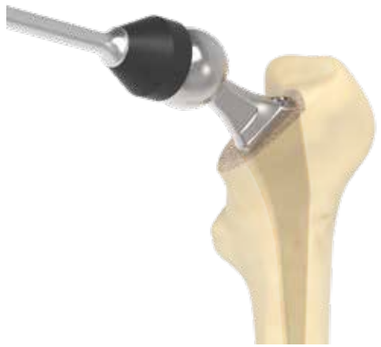


Figure 12
Femoral Head Impaction

Figure 13
Threaded Stem Extraction

Figure 14
Trunion Stem Extraction

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

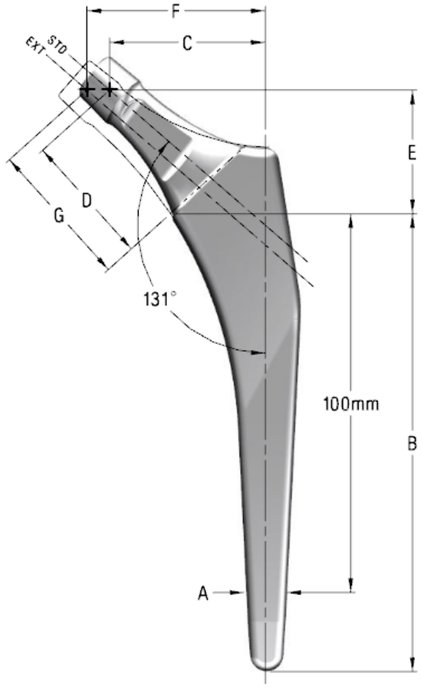
Reduce the hip and perform a final check of length, range of motion and stability.

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 13 and 14)*.

CLOSURE

Close the wound according to the preferred method.



STANDARD OFFSET

Size	A M to L Width (mm)	B Stem Length (mm)	C Lateral offset with the following head lengths (mm)					D Neck length with the following head lengths (mm)					E Vertical offset with the following head lengths (mm)				
			-3.5	0	3.5	7	10	-3.5	0	3.5	7	10	-3.5	0	3.5	7	10
4	4.9	100	32.9	35.5	38.2	40.8	43.1	26.5	30.0	33.5	36.9	39.9	26.1	28.5	30.6	32.9	34.9
6	7.1	105	35.5	38.1	40.8	43.4	45.7	29	32.5	35.9	39.4	42.4	27.9	30.4	32.6	34.9	36.8
8	9.6	110	38.4	41	43.7	46.3	48.6	31.5	35.0	38.5	41.9	44.9	29.8	32.1	34.3	36.6	38.6
10	11.9	116	39.5	42.2	44.8	47.5	49.7										
12	14.5	121	42.6	45.2	47.8	50.5	52.7	34	37.5	40	44.5	47.4	31.6	33.9	36.2	38.5	40.4

EXTENDED OFFSET

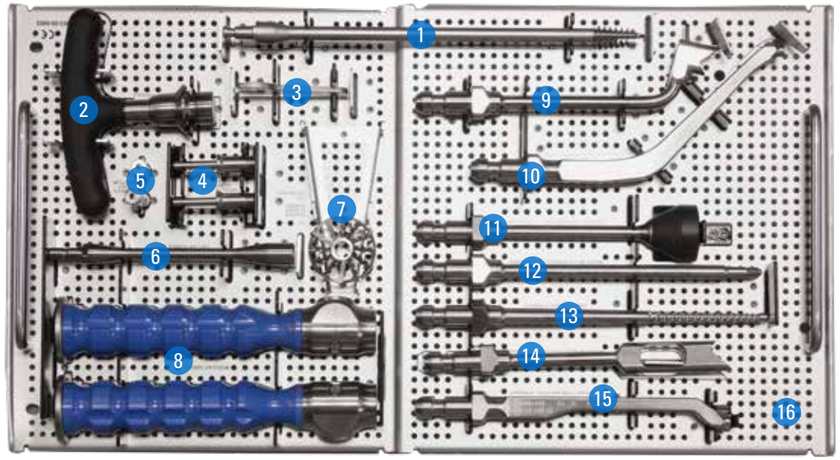
Size	A M to L Width (mm)	B Stem Length (mm)	F Lateral offset with the following head lengths (mm)					G Neck length with the following head lengths (mm)					E Vertical offset with the following head lengths (mm)				
			-3.5	0	3.5	7	10	-3.5	0	3.5	7	10	-3.5	0	3.5	7	10
4	4.9	100	38.9	41.5	44.2	46.8	49.1	30.5	34.0	37.5	40.9	43.9	26.1	28.5	30.6	32.9	34.9
6	7.1	105	41.5	44.1	46.8	49.4	51.7	33	36.5	39.9	43.4	46.4	27.9	30.4	32.6	34.9	36.8
8	9.6	110	44.4	47.0	49.7	52.3	54.6	35.5	39.0	42.5	45.9	48.9	29.8	32.1	34.3	36.6	38.6
10	11.9	116	45.5	48.2	50.8	53.5	55.7										
12	14.5	121	48.6	51.2	53.8	56.5	58.7	38	41.5	44	48.5	51.4	31.6	33.9	36.2	38.5	40.4

IMPLANT ORDERING INFORMATION

Stem Size	Standard Offset	Extended Offset
4	190-60-04	190-61-04
6	190-60-06	190-61-06
8	190-60-08	190-61-08
10	190-60-10	190-61-10
12	190-60-12	190-61-12

CEMENT ORDERING INFORMATION

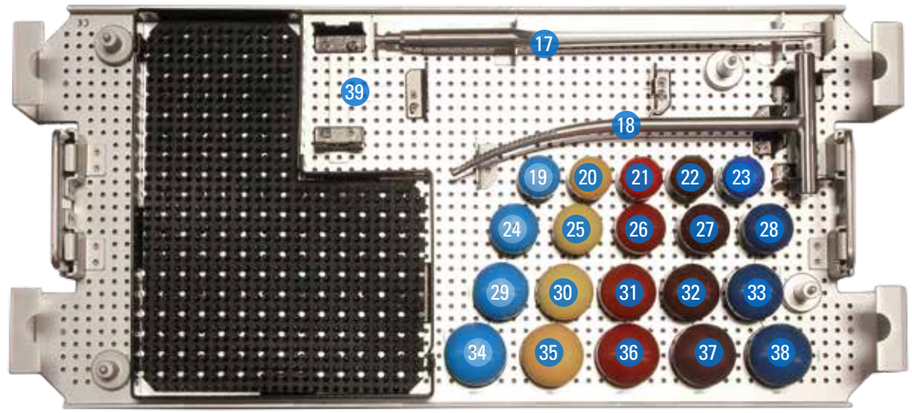
Please see Cemex Mixing Technique (715-01-01) for ordering information.



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

Site	Item	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

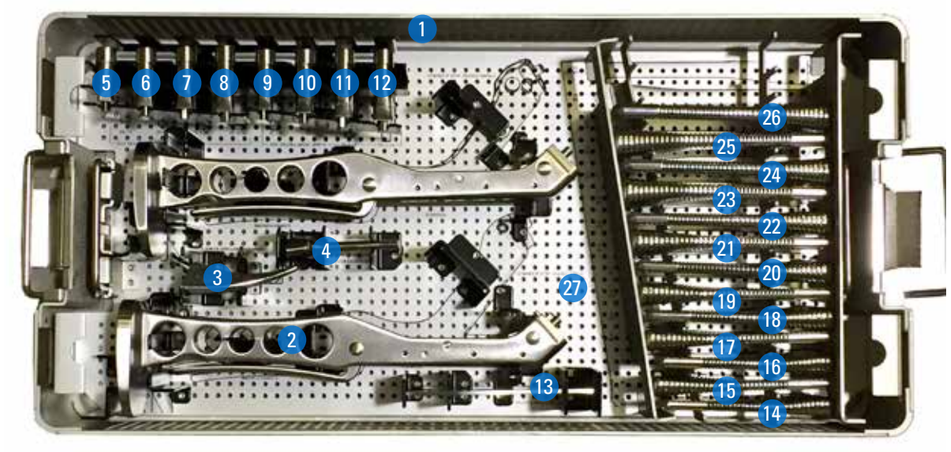
† Instruments have sharp features; use caution when handling these instruments to avoid injury to user or patient.



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

Site	Item	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.



KIT-1491P Alteon HA/HPS Femoral Stem Instruments

Site	Qty	Item	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	Item	Item Description	Image
2	01-003-02-0001	Broach Handle, Curved, Single Offset	
1	01-003-02-0004	Broach Handle, Dual Offset, Left	
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

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 Highly Polished Femoral Stems are intended for cemented 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 thesurgeon 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.

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

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