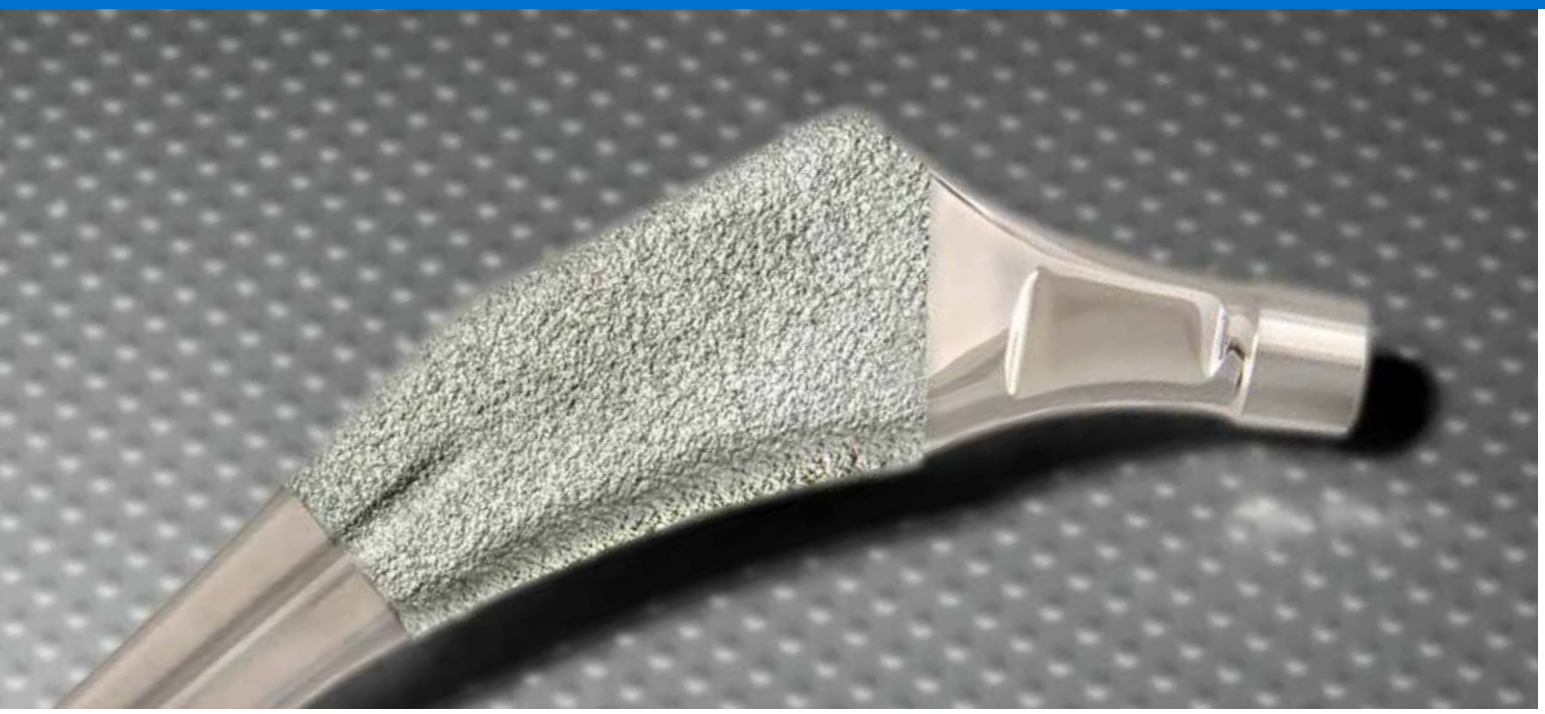
EXACTECH | **HIP**

Operative Technique



ALTEON®

Tapered Wedge Femoral Stem

Primary Femoral Solutions

Exactech®

Surgeon focused. Patient driven.™

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INTRODUCTION

The goal of the surgical approach is to establish adequate visualization in order to evaluate stability and leg length and restore kinematic function of the joint. 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® Tapered Wedge Femoral Stem. For key surgical steps specific to the cup, refer to the appropriate acetabular technique.

OPERATIVE TECHNIQUE OVERVIEW

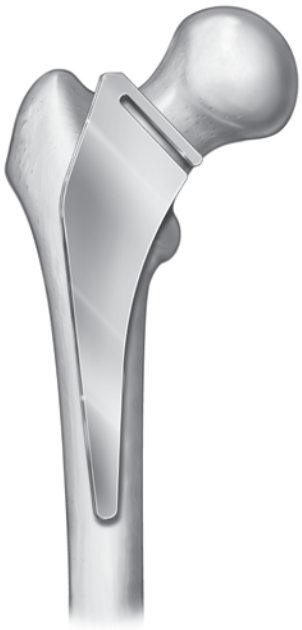


Figure A
Osteotomy of the Femur

Figure B
Opening of the Femoral Canal

Figure C
Femoral Preparation

Figure D
Calcar Preparation (Optional)

Figure E
Trial Reduction

Figure F
Final Component Placement

PRE-OPERATIVE PLANNING

TOOLS

- A/P radiograph of pelvis centered on the pubic symphysis
- Pencil that will not damage X-ray
- Straight edge
- Alteon® Tapered Wedge Template Set with 120 percent magnification rule *(Figure 1)*
- Goniometer/protractor

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

DETERMINATION OF LEG LENGTH

Select and position the appropriate **Alteon Tapered Wedge Template** 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 Tapered Wedge Femoral Stem is designed for mediolateral cortical engagement within the tapered portion of the proximal femoral canal.

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.

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

Note: *Templating is an important part of pre-operative preparation, and should only serve as a guide. 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.*

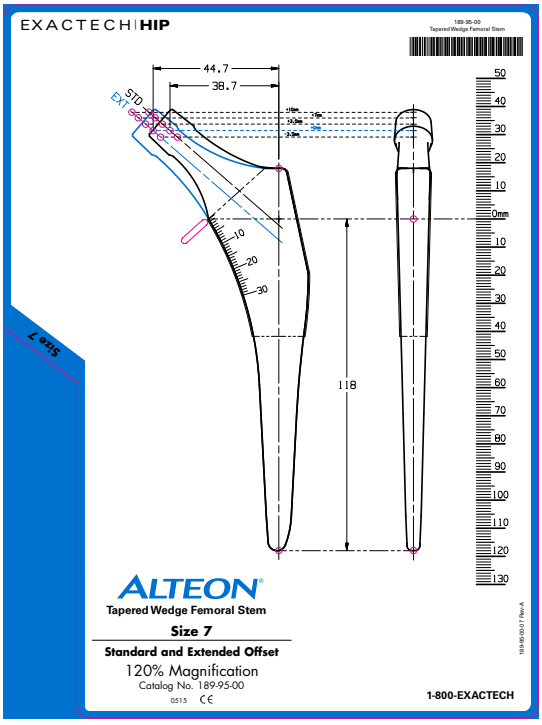


Figure 1
Alteon Tapered Wedge Stem Template

DETAILED OPERATIVE TECHNIQUE

APPROACH AND OSTEOTOMY

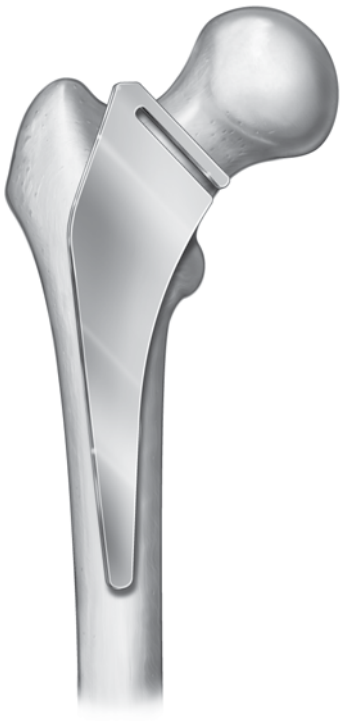


Figure 2
Osteotomy of the Femur

Figure 3
Opening of the Femoral Canal

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 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 TIP
Resect the anterior osteophytes from the acetabulum before using the Osteotomy Guide. At this point the center of the femoral head can be viewed.

OPENING OF THE FEMORAL CANAL

Use a **Box Osteotome** to remove a wedge of cancellous 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 TIP
The Modular Box Osteotome and Canal Entry Tools are assembled with the Modular Handle prior to use. Ensure these tools properly lock into the Modular Handle.

Figure 4
Femoral Preparation

FEMORAL PREPARATION

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.

***Note:** The Canal Entry Tools are very sharp and should be handled with caution.*

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. While referencing the femoral neck resection which was determined by pre-operative templating, impact the Broach Handle until the Broach reaches an axially-stable position.

SURGICAL TIP
Tapered Wedge users have found that sinking the Broach 3 to 4mm below the neck resection provides an indication the next size Broach will be appropriate for the femur.

Should the Broach reach an axially-stable position (no longer advances) less than 3mm below the femoral neck resection, the current size Broach has been shown to be the appropriate size for the femur release the Broach Handle from the Broach for trialing *(Figure 4).*

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

CALCAR PREPARATION (OPTIONAL)

Figure 5
Calcar Preparation

Figure 6
Trial Reduction

CALCAR PREPARATION (OPTIONAL)

Calcar Planing can be performed, if desired, 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 5)*.

SURGICAL TIP

The assembled Calcar Planer *(Figure 5)* is created by threading the Calcar Planer Shaft into the Calcar Planer Adaptor which captures the Calcar Planer Blade. The assembly is tightened, or loosened, using the supplied Calcar Planer Wrench.

Note: *While calcar planing, ensure that the calcar planer blade remains parallel to the face of the broach. Excessive bending forces applied to the calcar planer tip may cause it to fracture or wear.*

TRIAL REDUCTION

Trial Component Insertion

Place the appropriate **Femoral 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 6)*.

Figure 7
Final Component Placement

Trial Component Removal

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

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

FINAL COMPONENT PLACEMENT

Final Stem Insertion

Select the appropriate femoral stem and impact using the desired Stem Inserter ensuring correct rotational alignment, version and depth. If necessary, allow the bone to adapt to the implant as it is being impacted *(Figure 7)*. Another trial reduction can be performed with the final femoral stem and Femoral Head Trial.

Femoral Head Impaction

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. Place ceramic heads by hand with a downward, twisting force and do not impact with a mallet.

SURGICAL TIP
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.

Final Reduction

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

IMPLANT REMOVAL

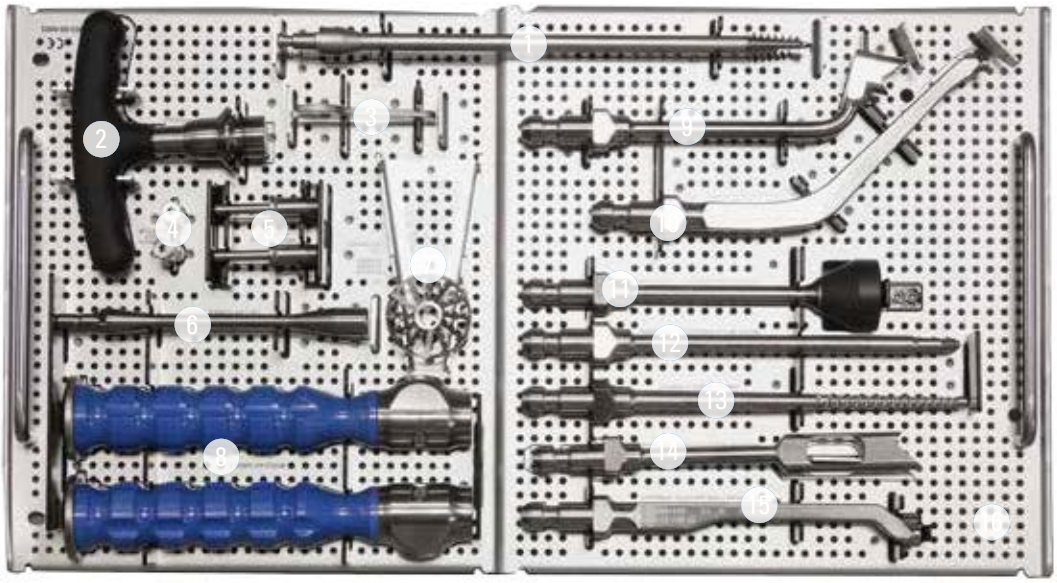
If it is necessary to intraoperatively remove a prosthesis, the **Stem Extractor** may be assembled to the Broach Handle to facilitate removal.

SURGICAL TIP
The **Anterior Extractor** must remain aligned with the mid-plane of the Femoral Stem so that it locks onto the neck flats. Should the Anterior Extractor disassociate from the neck of the Femoral Stem, confirm the Anterior Extractor is aligned with the mid-plane of the Femoral Stem.

CLOSURE

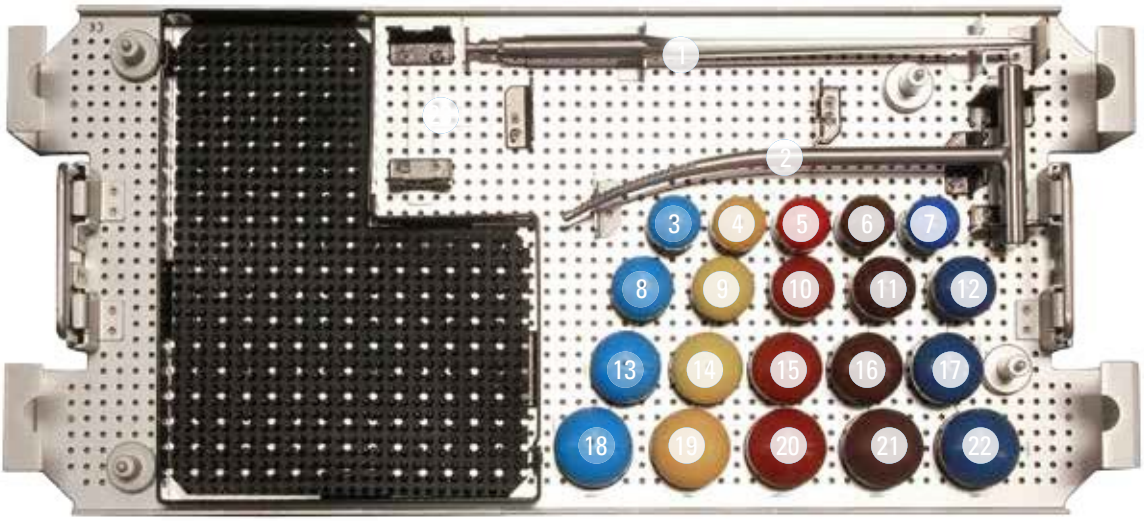
Close the wound according to the preferred method.

TRAY LAYOUT



ALTEON COMMON FEMORAL INSTRUMENTS (UPPER LEVEL TRAY)

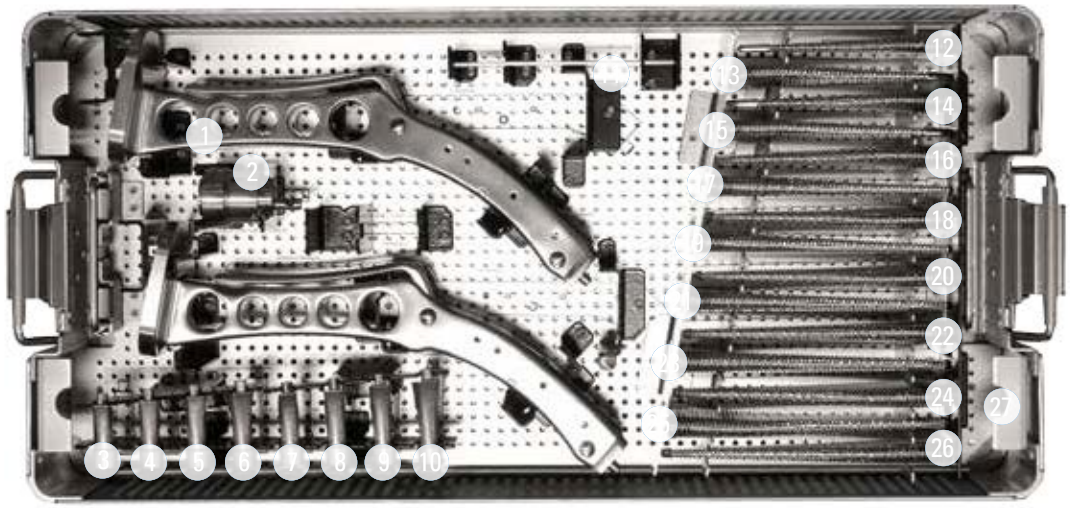
Site	Qty	Item	Item Description
Not Pictured	1	10-111-00-0001	Instrument Outer Case, Single-Level
Not Pictured	1	10-301-01-0001	Instrument Outer Case, Lid
1	1	167-00-01	Corkscrew, Sharp
2	1	301-07-70	Small T-Handle
3	1	01-003-04-0005	Calcar Planer Wrench
4	2	01-003-04-0004	Calcar Planer Bushing, Broach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



ALTEON COMMON FEMORAL INSTRUMENTS (LOWER LEVEL TRAY)

Site	Qty	Item	Item Description
1	1	01-003-07-0001	Starter Reamer
2	1	01-003-06-0003	Curved Canal Finder, Blunt
3	1	143-28-10	Femoral Head Trial, 28, +10mm, O-Ring, 12/14
4	1	143-28-07	Femoral Head Trial, 28, +7mm, O-Ring, 12/14
5	1	143-28-03	Femoral Head Trial, 28, +3.5mm, O-Ring, 12/14
6	1	143-28-00	Femoral Head Trial, 28, +0mm, O-Ring, 12/14
7	1	143-28-93	Femoral Head Trial, 28, -3.5mm, O-Ring, 12/14
8	1	143-32-10	Femoral Head Trial, 32, +10mm, O-Ring, 12/14
9	1	143-32-07	Femoral Head Trial, 32, +7mm, O-Ring, 12/14
10	1	143-32-03	Femoral Head Trial, 32, +3.5mm, O-Ring, 12/14
11	1	143-32-00	Femoral Head Trial, 32, +0mm, O-Ring, 12/14
12	1	143-32-93	Femoral Head Trial, 32, -3.5mm, O-Ring, 12/14
13	1	143-36-10	Femoral Head Trial, 36, +10mm, O-Ring, 12/14
14	1	143-36-07	Femoral Head Trial, 36, +7mm, O-Ring, 12/14
15	1	143-36-03	Femoral Head Trial, 36, +3.5mm, O-Ring, 12/14
16	1	143-36-00	Femoral Head Trial, 36, +0mm, O-Ring, 12/14
17	1	143-36-93	Femoral Head Trial, 36, -3.5mm, O-Ring, 12/14
18	1	143-40-10	Femoral Head Trial, 36, +10mm, O-Ring, 12/14
19	1	143-40-07	Femoral Head Trial, 40, +7mm, O-Ring, 12/14
20	1	143-40-03	Femoral Head Trial, 40, +3.5mm, O-Ring, 12/14
21	1	143-40-00	Femoral Head Trial, 40, +0mm, O-Ring, 12/14
22	1	143-40-93	Femoral Head Trial, 40, -3.5mm, O-Ring, 12/14
23	1	01-003-00-0001	Common Femoral Tray, Lower Inner Tray

TRAY LAYOUT



ALTEON TAPERED WEDGE – ANTERIOR APPROACH (PICTURED)
ALTEON TAPERED WEDGE – ALL OTHER APPROACHES*

Site	Qty	Item	Item Description
Not Pictured	1	10-301-00-0001	Instrument Outer Case, Single-Level
Not Pictured	1	10-111-00-0001	Instrument Outer Case, Lid
1	2	01-003-02-0001	Broach Handle, Curved, Single Offset
2	1	01-003-10-0001	Stem Extractor, Trunion Adaptor
3	1	189-22-01	Tapered Wedge Neck Trial, STD, Size 1-4
4	1	189-22-05	Tapered Wedge Neck Trial, STD, Size 5-7
5	1	189-22-08	Tapered Wedge Neck Trial, STD, Size 8-10
6	1	189-22-11	Tapered Wedge Neck Trial, STD, Size 11-17
7	1	189-22-01	Tapered Wedge Neck Trial, EXT, Size 1-4
8	1	189-22-05	Tapered Wedge Neck Trial, EXT, Size 5-7
9	1	189-22-08	Tapered Wedge Neck Trial, EXT, Size 8-10
10	1	189-22-11	Tapered Wedge Neck Trial, EXT, Size 11-17
11	1	189-00-00	Tapered Wedge Osteotomy Guide
12	1	189-02-01	Tapered Wedge Broach, Size 1
13	1	189-02-02	Tapered Wedge Broach, Size 2
14	1	189-02-03	Tapered Wedge Broach, Size 3
15	1	189-02-04	Tapered Wedge Broach, Size 4
16	1	189-02-05	Tapered Wedge Broach, Size 5
17	1	189-02-06	Tapered Wedge Broach, Size 6
18	1	189-02-07	Tapered Wedge Broach, Size 7
19	1	189-02-08	Tapered Wedge Broach, Size 8
20	1	189-02-09	Tapered Wedge Broach, Size 9
21	1	189-02-10	Tapered Wedge Broach, Size 10
22	1	189-02-11	Tapered Wedge Broach, Size 11
23	1	189-02-12	Tapered Wedge Broach, Size 12
24	1	189-02-13	Tapered Wedge Broach, Size 13
25	1	189-02-14	Tapered Wedge Broach, Size 14
26	1	189-02-15	Tapered Wedge Broach, Size 15
27	1	189-89-01	Alteon Tapered Wedge, Inner Tray

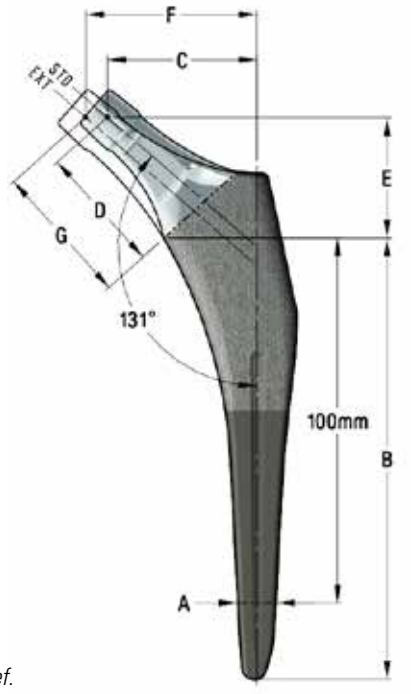
***ADDITIONAL INSTRUMENTS:**

Qty	Item	Item Description	Image
2	01-003-02-0003	Broach Handle, Straight	
1	01-003-10-0002	Stem Extractor, Threaded	
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	01-003-06-0006	Canal Finder, Starter Broach	
1	01-003-06-0007	Canal Finder, Lateralizing Broach	
1	189-02-16	Tapered Wedge Broach, Size 16	
1	189-02-17	Tapered Wedge Broach, Size 17	
1	189-12-01	Tapered Wedge Diamond Tooth Broach, Size 1	
1	189-12-02	Tapered Wedge Diamond Tooth Broach, Size 2	
1	189-12-03	Tapered Wedge Diamond Tooth Broach, Size 3	
1	189-12-04	Tapered Wedge Diamond Tooth Broach, Size 4	
1	189-12-05	Tapered Wedge Diamond Tooth Broach, Size 5	
1	189-12-06	Tapered Wedge Diamond Tooth Broach, Size 6	
1	189-12-07	Tapered Wedge Diamond Tooth Broach, Size 7	
1	189-12-08	Tapered Wedge Diamond Tooth Broach, Size 8	
1	189-12-09	Tapered Wedge Diamond Tooth Broach, Size 9	
1	189-12-10	Tapered Wedge Diamond Tooth Broach, Size 10	
1	189-12-11	Tapered Wedge Diamond Tooth Broach, Size 11	
1	189-12-12	Tapered Wedge Diamond Tooth Broach, Size 12	
1	189-12-13	Tapered Wedge Diamond Tooth Broach, Size 13	
1	189-12-14	Tapered Wedge Diamond Tooth Broach, Size 14	
1	189-12-15	Tapered Wedge Diamond Tooth Broach, Size 15	
1	189-12-16	Tapered Wedge Diamond Tooth Broach, Size 16	
1	189-12-17	Tapered Wedge Diamond Tooth Broach, Size 17	

SYSTEM SPECIFICATIONS

STANDARD OFFSET

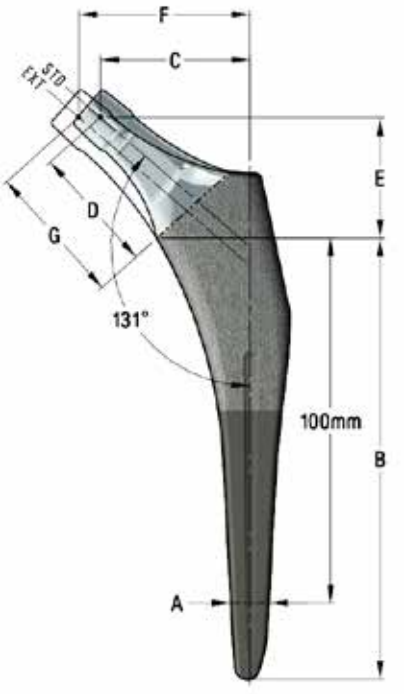
Size	A	B	C					D					E				
	M to L width	Stem Length (mm)	Lateral Offset with the following head lengths (mm)					Neck Length with the following head lengths (mm)					Vertical Offset with the following head lengths (mm)				
			-3.5	0	3.5	7	10	-3.5	0	3.5	7	10	-3.5	0	3.5	7	10
1	4.5*	100	31.4	34.1	36.7	39.4	41.6	26.5	30.0	33.5	36.9	39.9	27.2	29.5	31.8	34.1	36.1
2	5.25*	103	31.9	34.6	37.2	39.9	42.1										
3	6.0*	106	32.4	35.1	37.7	40.4	42.6										
4	6.75*	109	32.9	35.6	38.2	40.9	43.1										
5	7.5	112	35.1	37.7	40.3	43.0	45.2	29.0	32.5	36.0	39.4	42.4	29.1	31.4	33.7	36.0	38.0
6	8.5	115	35.6	38.2	40.8	43.5	45.7										
7	9.5	118	36.1	38.7	41.3	44.0	46.2										
8	10.5	121	38.3	40.9	43.6	46.2	48.5	31.5	35.0	38.5	41.9	44.9	30.9	33.2	35.5	37.8	39.8
9	11.5	124	38.8	41.4	44.1	46.7	49.0										
10	12.5	127	39.4	42.0	44.7	47.3	49.6										
11	13.5	130	41.9	44.6	47.2	49.9	52.1	34.0	37.5	41.0	44.4	47.4	32.7	35.0	37.3	39.6	41.6
12	14.75	133	42.7	45.4	48.0	50.7	52.9										
13	16.0	136	43.7	46.4	49.0	51.7	53.9										
14	17.25	139	44.7	47.4	50.0	52.7	54.9										
15	18.5	142	45.7	48.4	51.0	53.7	55.9										
16**	19.75	145	46.7	49.4	52.0	54.7	56.9										
17**	21.0	148	47.7	50.4	53.0	55.7	57.9										



** Measured diameter vs. m/l width due to lateral relief.*

EXTENDED OFFSET

Size	A	B	F					G					E				
	M to L width	Stem Length (mm)	Lateral Offset with the following head lengths (mm)					Neck Length with the following head lengths (mm)					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
1	4.5*	100	37.5	40.1	42.7	45.4	47.6	30.6	34.0	37.5	41.0	44.0	27.2	29.5	31.8	34.1	36.1
2	5.25*	103	38.0	40.6	43.2	45.9	48.1										
3	6.0*	106	38.5	41.1	43.7	46.4	48.6										
4	6.75*	109	39.0	41.6	44.2	46.9	49.1										
5	7.5	112	41.1	43.7	46.3	49.0	51.2	33.0	36.5	40.0	43.5	46.4	29.1	31.4	33.7	36.0	38.0
6	8.5	115	41.6	44.2	46.8	49.5	51.7										
7	9.5	118	42.1	44.7	47.3	50.0	52.2										
8	10.5	121	44.3	46.9	49.5	52.2	54.4	35.5	39.0	42.5	45.9	48.9	30.9	33.2	35.5	37.8	39.8
9	11.5	124	44.8	47.4	50.0	52.7	54.9										
10	12.5	127	45.4	48.0	50.6	53.3	55.5										
11	13.5	130	48.0	50.6	53.2	55.9	58.1	38.1	41.5	45.0	48.5	51.5	32.7	35.0	37.3	39.6	41.6
12	14.75	133	48.8	51.4	54.0	56.7	58.9										
13	16.0	136	49.8	52.4	55.0	57.7	59.9										
14	17.25	139	50.8	53.4	56.0	58.7	60.9										
15	18.5	142	51.8	54.4	57.0	59.7	61.9										
16**	19.75	145	52.8	55.4	58.0	60.7	62.9										
17**	21.0	148	53.8	56.4	59.0	61.7	63.9										



IMPLANT ORDERING INFORMATION

Stem Size	Thermal Plasma Spray (TPS)	
	Standard Offset	Extended Offset
1	188-00-01	188-01-01
2	188-00-02	188-01-02
3	188-00-03	188-01-03
4	188-00-04	188-01-04
5	188-00-05	188-01-05
6	188-00-06	188-01-06
7	188-00-07	188-01-07
8	188-00-08	188-01-08
9	188-00-09	188-01-09
10	188-00-10	188-01-10
11	188-00-11	188-01-11
12	188-00-12	188-01-12
13	188-00-13	188-01-13
14	188-00-14	188-01-14
15	188-00-15	188-01-15
16**	188-00-16	188-01-16
17**	188-00-17	188-01-17

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.

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Exactech, Inc. 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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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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