EXACTECH | **HIP**

Operative Technique

ALTEON®

Neck Preserving Femoral Stem

Primary Femoral Solutions

Exactech®

Surgeon focused. Patient driven.™

TABLE OF CONTENTS

The Operative Technique was developed in consultation with:

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INTRODUCTION

The Alteon® Neck Preserving Femoral Stem is a titanium press-fit femoral stem prosthesis designed to preserve proximal femoral bone while providing initial stability and uncemented, biological fixation. The geometry of the Alteon Neck Preserving Femoral Stem allows insertion with traditional surgical approaches and smaller incisions.

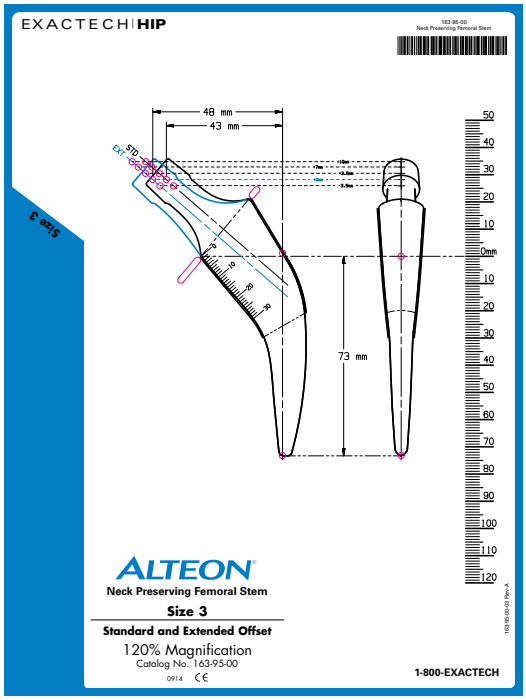


Figure 1
Neck Preserving Femoral Stem Template

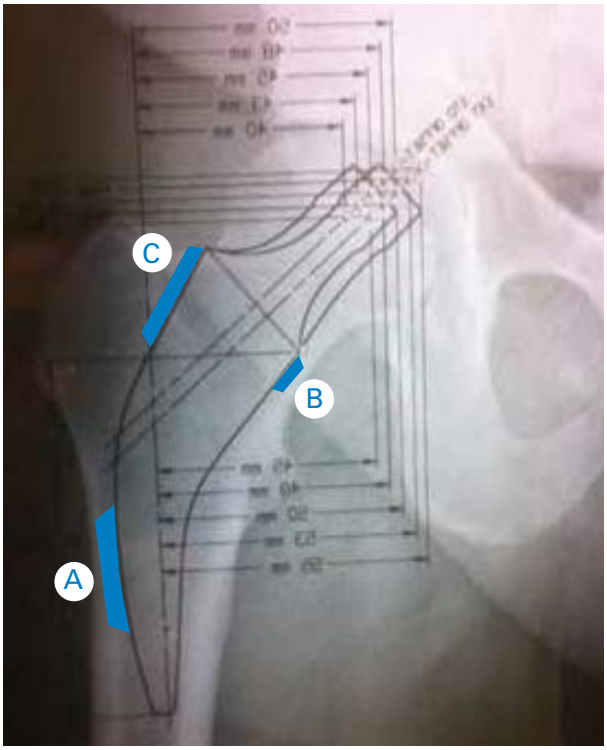


Figure 2
Neck Preserving Femoral Stem Template
(Over X-ray)

PRE-OPERATIVE PLANNING

TOOLS

- A/P radiograph of pelvis centered on the pubic symphysis
- Pencil that will not damage X-ray
- Straight edge
- Neck Preserving Femoral Stem 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 to final implant choice.

Note: *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

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 normal femoral anatomy. On the radiograph, a straight line is drawn across the pelvis touching the inferior edge of both ischial tuberosities and extended in both directions to reach both lesser trochanters. 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."

DETERMINATION OF LIMB LENGTH/ STEM SIZING

The **Neck Preserving Femoral Stem Template** is positioned over the radiograph such that the lateral curve of the femoral stem contacts the lateral endosteal cortex of the femur *(Figure 2, Region A)*. For the selected stem size, the center of rotation of the Neck Preserving Femoral Stem should be aligned with the natural femoral head. The medial edge of the stem should contact the medial calcar *(Figure 2, Region B)* and the stem should also fill the femoral neck of the natural femur medial to lateral such that the stem contacts the lateral calcar *(Figure 2, region C)*. The stem size that meets these criteria should be recorded.

The Neck Preserving Femoral Stem neck resection is intended to be made at approximately the midpoint of the arch created between the proximal border of the lesser trochanter and the intersection of the femoral head and medial femoral neck. After properly

positioning the template of the appropriately sized stem, the templated level of the femoral neck cut is marked through the punch-outs provided on the template. The distance along the medial edge of the femur between this mark and the proximal border of the lesser trochanter should be measured and recorded.

Note: *Most of the time, the chosen prosthetic head (neck length) does not line up with the center of rotation of the acetabulum or even with a mark in the center of the femoral head as a result of the deterioration of the head and acetabulum. In order to restore the desired center of rotation, the head is usually positioned proximal and medial to the center of rotation of the acetabulum. In effect, at the end of the operation the surgeon will be pulling on the limb and lifting the prosthetic femoral head into the acetabulum, thereby recreating the desired femoral offset and length.*

Note: *Templating should be used as a guideline, and not an absolute determination of the appropriate implant sizes and offsets. The final selection of the appropriate implants should be made intra-operatively.*

OPERATIVE TECHNIQUE

The surgical approach of choice is based upon the degree of surgical experience and preference. This technique provides key surgical steps used to implant the Neck Preserving Femoral Stem. For key surgical steps specific to the cup refer to the appropriate acetabular cup preparation technique.

OSTEOTOMY OF THE FEMUR

The level of the femoral neck resection that was determined in pre-operative planning is marked, utilizing the **Osteotomy Guide**, if desired *(Figure 3)*. This mark is most often intended to be made at approximately the midpoint of the arch created between the proximal border of the lesser trochanter and the intersection of the femoral head and medial femoral neck. Fluoroscopy may be used at this time to verify the femoral neck resection level.

In order to help reestablish the patient's leg length, lateral offset, and center of rotation of the femoral head, the femoral neck resection should be based on pre-operative templating.

SURGICAL TIPS

Resect the anterior osteophytes from the acetabulum before using the osteotomy guide. At this point the center of the femoral head can be viewed.

Improved visualization of the acetabulum may be achieved using the ***Inferior Acetabular Retractor*** *to retract inferiorly and depress the femur (Figure 4).*

Figure 3
Femoral Neck Resection (without guide)

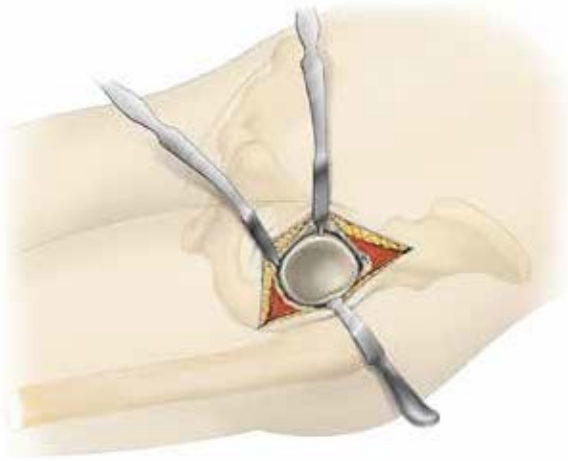


Figure 4
Use of Inferior Acetabular Retractor

Figure 5
Lateral Cortex identification

Figure 6
Neck Preserving Sizing Guide

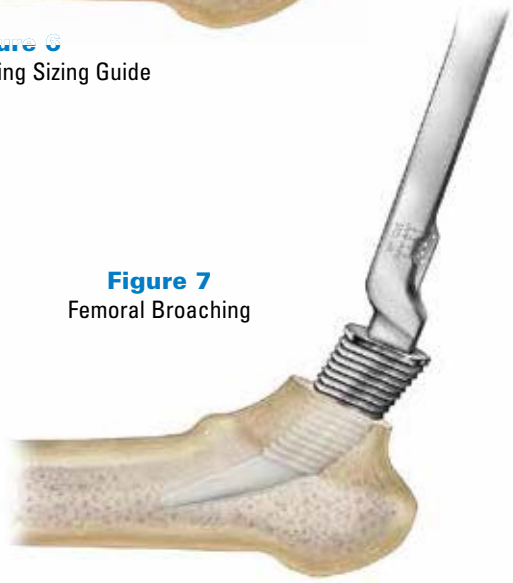


Figure 7
Femoral Broaching

Figure 8
Final Broach

OPENING OF THE FEMORAL CANAL

Universal canal entry instruments are used to gain entry through the femoral neck canal into cancellous bone, creating a portal for entry into the femoral canal. The canal entry instruments also aid in locating the distal lateral cortex *(Figure 5)*.

The Neck Preserving Sizing Guide may be used to approximate the implant size required to ensure the stem contacts the lateral cortex. To use the guide, align the shaft against against the medial aspect of the neck resection, keeping the shaft approximately perpendicular to the resection plane. Ensure sufficient cancellous bone is removed by use of canal entry tools or broaching to allow the Sizing Guide to contact the lateral cortex. The size marking that aligns with the resection plane corresponds to the approximate required implant size *(Figure 6)*.

SURGICAL TIPS

*The **Modular Straight Canal Finder, Neck Preserving Sizing Guide** and **Modular Femoral Head Impactor** should be assembled with the **Modular Handle** prior to use. Ensure these instruments lock properly into the Modular Handle.*

FEMORAL BROACHING

Once the lateral cortex and femoral canal are identified, the **Starter Broach** may be used to further facilitate entry of the broach. Broach up progressively, beginning with the Starter Broach, followed with the **Broach Sizes 2-7** *(Figure 7)*. The Broach is inserted into the femoral canal with the appropriate amount of anteversion. Care should be taken when placing the Broaches as to not perforate the lateral cortex.

Fluoroscopy can be used to verify the position of the Broaches in order to ensure the Broach is sized appropriately, touching the medial calcar and distal lateral cortex. If the Broach is not contacting the distal lateral cortex or the proximal fit of the Broach is not stable, it is recommended that the Broach be advanced further into the femoral canal prior to Broaching with the next larger size.

Note: *As shown in the specification section, the neck length and neck height proportions increase by 3mm for each progressively larger Neck Preserving Femoral Stems for sizes 2 through 5. As the Broach sizes increase, the surgeon should take care to adjust the neck resection so that the desired leg length and offset are achieved with the available femoral head offsets.*

The Broach should be torque tested for rotational stability. If no axial or rotational motion is perceived between the Broach and the femur, the **Broach Handle**

SURGICAL TIPS

If resistance is encountered while preparing the desired stem size, drop down a broach size and re-broach.

The Starter Broach or other canal entry instruments may be used throughout the broaching process to aid in positioning of subsequent broaches or the final implant.

is released from the Broach for trialing *(Figure 8)*.
Note: *The Broach Handle is marked with four holes that indicate the location of the center of rotation of the +0 mm femoral head for each standard offset femoral stem. The size 5 center of rotation hole also applies to the size 6 and 7 centers of rotation. Referencing the pre-operative radiograph and the top of the greater trochanter, fluoroscopy can be used in conjunction with the holes in the Broach Handle to verify the neck resection level so that the center of rotation of the prosthesis will correspond to patients' natural center of rotation.*

CALCAR PREPARATION (OPTIONAL)

Calcar planing can be performed, if desired, in order to remove any bone that protrudes proximal to the level of the impacted broach. The **Calcar Planer Assembly** 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** *(Figure 9)*. After assembly, Calcar Planer Assembly is guided into the hole on the interior surface of the broach coupling feature.

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.*

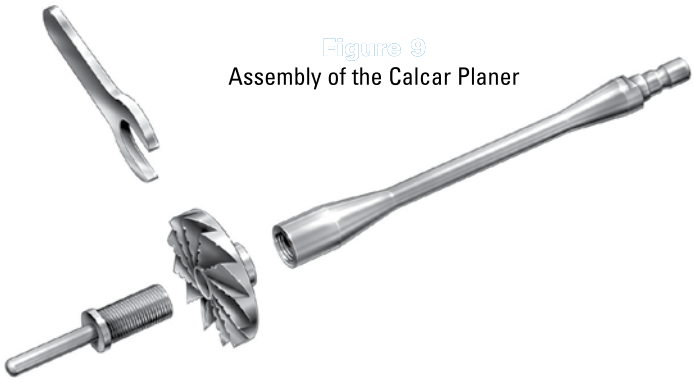


Figure 9
Assembly of the Calcar Planer

TRIAL REDUCTION

Select the appropriate **Neck Trial (Standard or Extended)**. This should be placed in the hole on the superior aspect of the broach *(Figure 10)*. Ensure the correct size and offset Neck Trial is chosen.

Femoral Head Trials have a diameter of 28, 32, 36 and 40mm.

With the Broach in place, it is advisable to use fluoroscopy to assess whether the implant will be adequately seated *(Figure 11)*. The final broach should be touching the three previously indicated regions of cortical contact *(Figure 2, regions A, B and C)*.

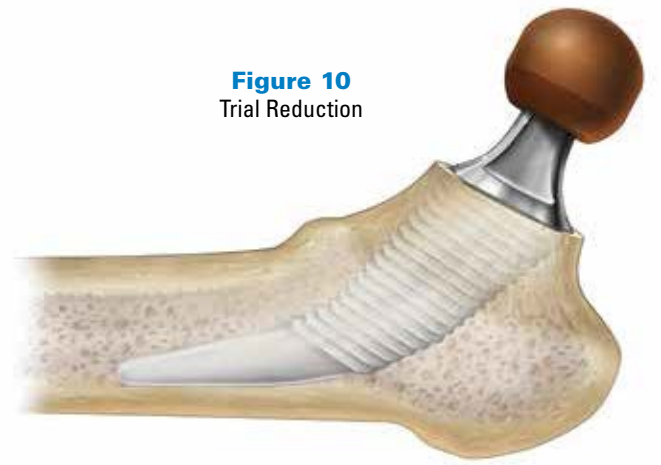


Figure 10
Trial Reduction

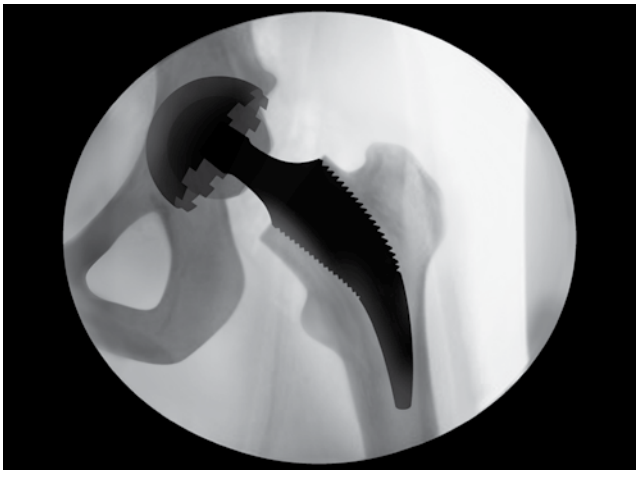


Figure 11
Interoperative Fluoroscopy Broach

SURGICAL TIPS

The level of the femoral neck cut and the anatomic shape of the bone dictate implant positioning of the Broach and Stem. Occasionally the Broach may not appear to contact all three intended regions of fixation in the A/P view, but the broach is determined to be fully stable with respect to the femur. In such cases, fluoroscopy of the lateral view or of additional planes of the femur should be taken to confirm that the Broach has achieved three points of cortical contact.

After components are selected, the hip is dislocated and the trial components are removed. The Broach Handle is reassembled to the Broach and the Broach is removed.

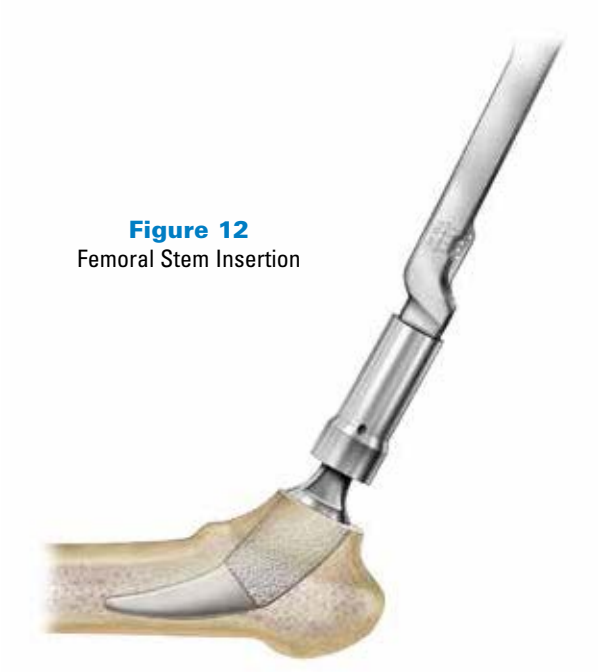


Figure 12
Femoral Stem Insertion

FINAL COMPONENT PLACEMENT

Femoral Stem Insertion

Start with the appropriate Femoral Stem and impact the implant using the **Stem Inserter** attached to the Broach Handle, ensuring correct rotational alignment, version and depth *(Figure 12)*. Verify the stem contacts the cortical bone in the three key regions *(Figure 13)*.

If necessary, allow the bone to adapt to the implant as it is being impacted. Another trial reduction can be performed with the final Femoral Stem and **Femoral Head Trial**.

SURGICAL TIPS

The Femoral Stem is intended to have 0.5mm of circumferential press-fit into the broach cavity; therefore, care should be taken not to over impact the stem.

Depending on the hardness of the bone, the proximal plasma border of the Neck Preserving Femoral Stem may reach a stable position of 2 to 3mm proximal to the proximal surface of the broach.

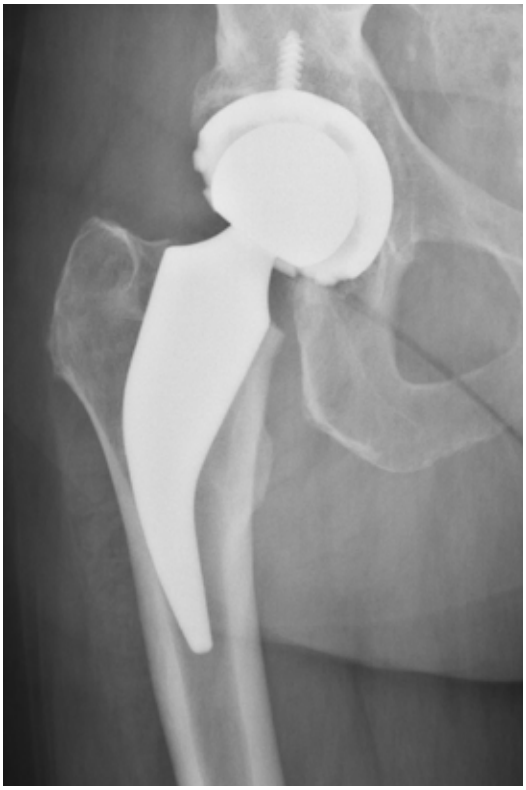


Figure 13
Example Femoral Stem
Cortical Contact

Femoral Head Impaction

Appropriately sized Ceramic or Metallic Femoral Heads may be used with the Neck Preserving Femoral Stem. The trunnion of the Femoral Stem should be clean and dry. If using a ceramic head, place it by hand onto the trunnion with a downward, twisting force and should not be impacted with a mallet. If using a metallic head, place it onto the trunnion of the Femoral Stem and secure it using the **Femoral Head Impactor** *(Figure 14)*.

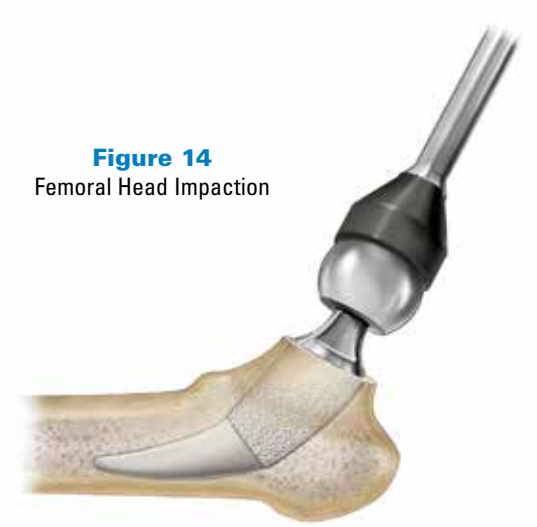


Figure 14
Femoral Head Impaction

Final Reduction

The hip should be reduced and a final check of the limb length, motion and stability should be made.

IMPLANT REMOVAL

If it is necessary to intra-operatively remove a prosthesis, the **Stem Extractor** may be assembled to the Broach Handle to facilitate removal *(Figure 15)*.

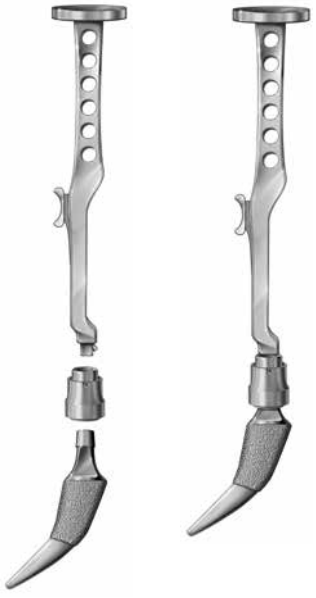
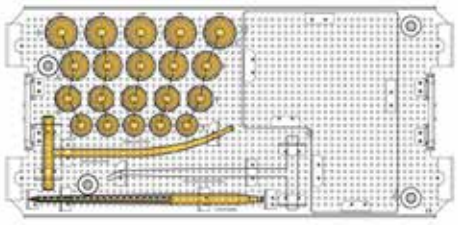


Figure 15
Implant Removal

CLOSURE

The wound should be closed according to the method preferred by the surgeon.

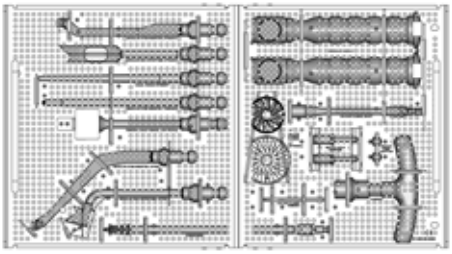
INSTRUMENT LISTING

Catalog Number	Part Description	
01-001-00-0001	Modular Handle	
01-001-00-0010	Neck Preserving Osteotomy Guide Handle	
01-001-01-0001	Modular Stem Inserter, Straight	
01-001-01-0002	Modular Stem Inserter, Offset	
01-001-01-0003	Modular Stem Inserter, Threaded	
01-001-03-0001	Modular Femoral Head Impactor	
01-001-05-0001	Modular Box Osteotome, Straight†	
01-001-05-0003	Modular Box Osteotome, Reduced Offset	
01-001-06-0001	Modular Straight Canal Finder, Blunt	
01-001-06-0002*	Modular Straight Canal Finder, Sharp†	
01-003-00-0001	Core Femoral Lower Tray	

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

INSTRUMENT LISTING

Catalog Number	Part Description
01-003-00-0002	Core Femoral Upper Tray
01-003-04-0001	Calcar Planer Shaft
01-003-04-0002	Calcar Planer Blade, 1.5"†
01-003-04-0004	Calcar Planer Bushing, Broach Hole Adaptor
01-003-04-0005	Calcar Planer Wrench
01-003-06-0003	Curved Canal Finder, Blunt
01-003-06-0004*	Curved Canal Finder, Sharp†
01-003-06-0005*	Kinked Canal Finder
01-003-07-0001	Starter Reamer
10-111-00-0001	Single Level Full Size
10-301-00-0001	Full Size Generic
143-28/32/36/40-93	Femoral Head Trial, 12/14, -3.5
143-28/32/36/40-00	Femoral Head Trial, 12/14, +0
143-28/32/36/40-03	Femoral Head Trial, 12/14, +3.5
143-28/32/36/40-07	Femoral Head Trial, 12/14, +7
143-28/32/36/40-10	Femoral Head Trial, 12/14, +10



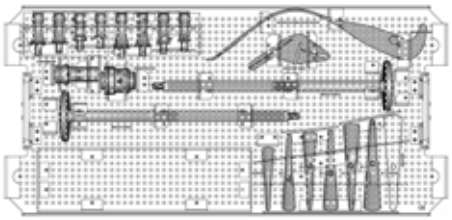
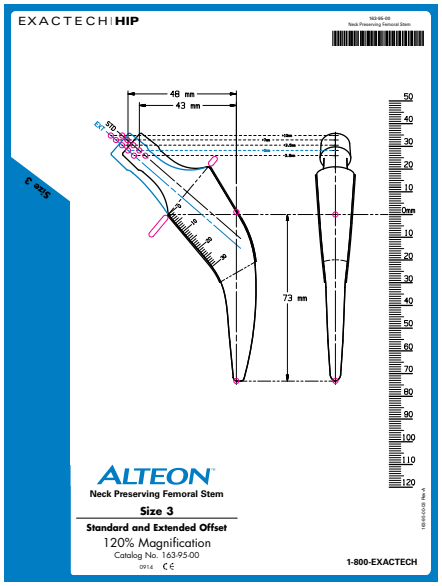
** Items are special order; please contact your Exactech representative to order.*

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

INSTRUMENT LISTING

Catalog Number	Part Description	
163-00-01	Neck Preserving Osteotomy Guide	
163-00-02	Neck Preserving Inferior Acetabular Retractor	
163-00-03	Neck Preserving Stem Inserter	
163-00-08	Neck Preserving Sizing Guide	
163-01-01	Neck Preserving Anterior Osteotomy Guide	
163-02-00	Neck Preserving Broach Handle	
163-02-01	Neck Preserving Broach, Starter	
163-02-02	Neck Preserving Broach, Size 02	
163-02-03	Neck Preserving Broach, Size 03	
163-02-04	Neck Preserving Broach, Size 04	
163-02-05	Neck Preserving Broach, Size 05	
163-02-06	Neck Preserving Broach, Size 06	
163-02-07	Neck Preserving Broach, Size 07	
163-10-01	Neck Preserving Stem Extractor	

INSTRUMENT LISTING

Catalog Number	Part Description	
163-22-02	Neck Preserving Neck Trial, Standard, Size 02	
163-22-03	Neck Preserving Neck Trial, Standard, Size 03	
163-22-04	Neck Preserving Neck Trial, Standard, Size 04	
163-22-05**	Neck Preserving Neck Trial, Standard, Size 05-07**	
163-23-02	Neck Preserving Neck Trial, Extended, Size 02	
163-23-03	Neck Preserving Neck Trial, Extended, Size 03	
163-23-04	Neck Preserving Neck Trial, Extended, Size 04	
163-23-05**	Neck Preserving Neck Trial, Extended, Size 05-07**	
163-63-01	Neck Preserving Instrument Tray Inner	
163-95-00	Neck Preserving X-Ray Template Set	
167-00-01	Hudson Femoral Corkscrew	
301-07-70	Hudson Quick Release T-handle	

***The size 5 neck trials are also used for trialing the size 6 and 7 stems with their respective broaches.*

SYSTEM SPECIFICATIONS

STANDARD OFFSET

Size	A M to L tip 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
2	4.3	74	36	39	41	44	46	22	25	29	32	35	23	25	27	30	32
3	4.8	73	40	43	45	48	50	24	28	31	35	38	26	28	30	33	35
4	5.2	73	44	47	49	52	54	27	31	34	38	41	29	31	33	36	38
5	5.7	78	48	50	53	56	58	30	34	37	41	44	32	34	36	39	41
6	7.5	80	50	53	55	58	60	30	34	37	41	44	32	34	36	39	41
7*	8.6	83	53	55	58	61	63	30	34	37	41	44	32	34	36	39	41

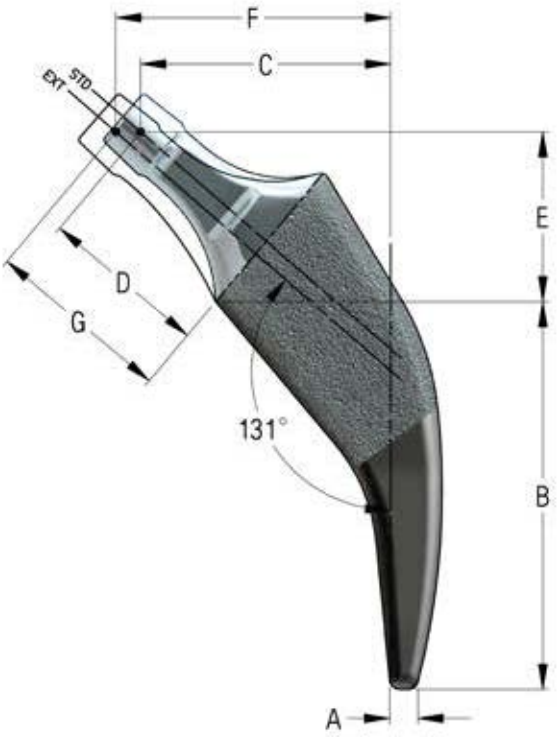
EXTENDED OFFSET

Size	A M to L tip 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
2	4.3	74	41	44	46	49	51	25	29	32	36	39	23	25	27	30	32
3	4.8	73	45	48	50	53	55	28	32	35	39	42	26	28	30	33	35
4	5.2	73	49	52	54	57	59	31	34	38	41	44	29	31	33	36	38
5	5.7	78	53	55	58	61	63	34	37	41	44	47	32	34	36	39	41
6	7.5	80	55	58	60	63	65	34	37	41	44	47	32	34	36	39	41
7*	8.6	83	58	60	63	66	68	34	37	41	44	47	32	34	36	39	41

ORDERING INFORMATION

Stem Size	Standard Offset	Extended Offset
2	162-00-02	162-01-02
3	162-00-03	162-01-03
4	162-00-04	162-01-04
5	162-00-05	162-01-05
6	162-00-06	162-01-06
7*	162-00-07	162-01-07

**Special Order*



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.

NOTES:

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.

 711-68-31 Rev. D 0517

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