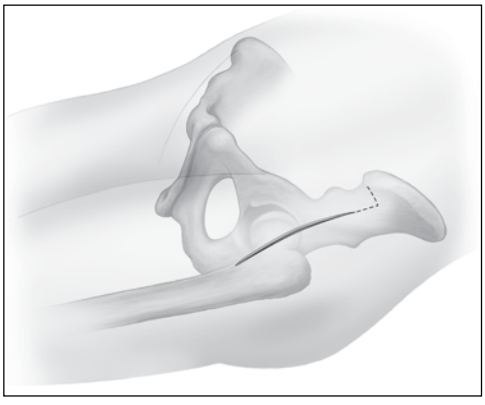
EXACTECH | **HIP**

Operative Technique

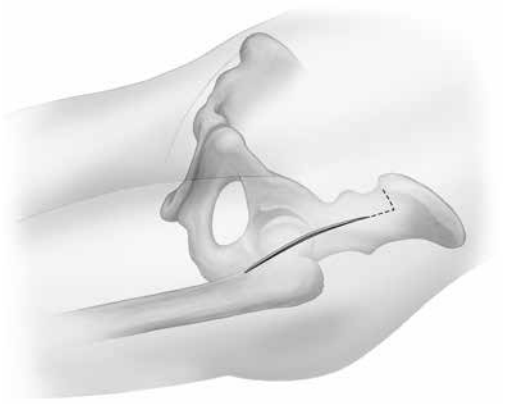


NOVATION®
Comprehensive Hip System

Anterior Approach Utilizing Novation® Element® and A+ Instrumentation

Renewing Innovations.
Enduring Solutions.

Exactech® *Surgeon focused. Patient driven.™*



The Anterior Approach Operative Technique was developed in consultation with:

John Aldridge, MD
Newport News, VA

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INTRODUCTION

Like the art of fine woodworking, the Novation® Comprehensive Hip System design began with the end in mind. Before launching into development, Exactech's engineers and design team surgeons established a comprehensive plan. Their goal: to provide a system of femoral stems, acetabular components and surgical instrumentation that would address any situation encountered during primary total hip replacement.

They let science be their guide and conducted an extensive research review to identify the best of the best in design and materials. These proven features were blended with masterfully crafted innovations. The result: a comprehensive hip system that provides stable reconstruction of the widest range of anatomies, state-of-the-art bearing surfaces and low profile instrumentation and implants that are compatible with a multitude of surgical approaches.

DESIGN PHILOSOPHY

The Novation® Element® is designed as a fully coated Hydroxyapatite (HA) stem with proximal horizontal grooves designed to convert hoop stress to compressive loads and vertical distal grooves designed to achieve rotational. The geometry of this tapered-wedge stem facilitates insertion in low-profile incisions and surgical approaches, including specialized instrumentation designed specifically for the anterior approach.

PRE-OPERATIVE PLANNING

TOOLS

- A/P and lateral radiographs
- Pencil that will not damage radiograph
- Straight edge
- Novation Element templates with 120 percent magnification rule
- 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 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

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 normal femoral anatomy.

DETERMINATION OF LIMB LENGTH

The Novation Element femoral template is positioned over the radiograph so that the central axis of the stem is in line with the central axis of the femoral canal.

The template should then be moved vertically until the desired neck length choice is approximately at the center of rotation of the templated acetabulum.

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. The appropriate lateral offset, either Standard or Extended, can be recorded at this time. The head usually is 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.*

When the template is in proper position, the level of the femoral neck cut is marked through the punch-outs provided on the template. The distance of the neck cut above the lesser trochanter can then be measured and recorded.

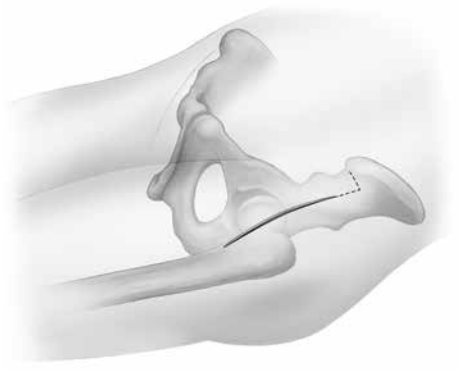
STEM SIZING

After placing the Novation Element templates on the radiograph over the proximal femur at the femoral height determined by the previous steps, the surgeon can choose a size that allows the desired canal fill. The Novation Element is designed to seat in cancellous bone, therefore cortical contact should be avoided when templating.

Note: *Due to the Standard and Extended offset options and numerous neck lengths of the heads, final implant selection will be made intra-operatively.*

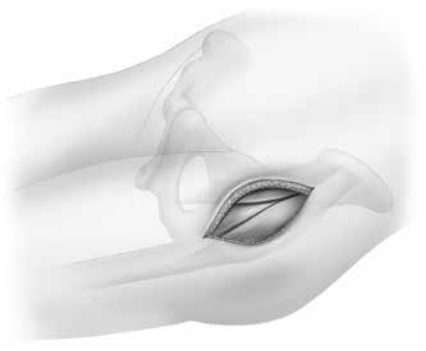
The anticipated stem size can now be recorded.

OPERATIVE TECHNIQUE OVERVIEW



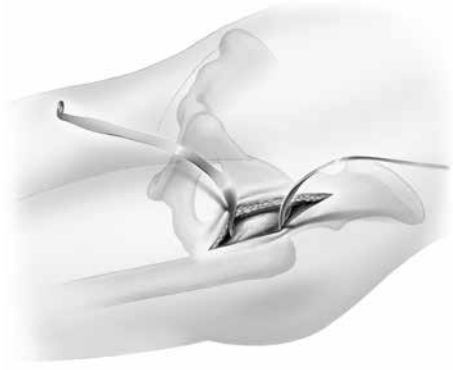
1

Incision for Anterior Approach



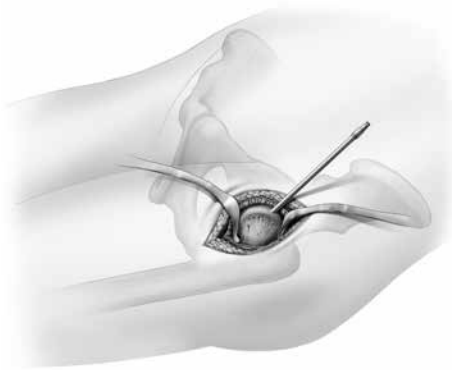
2

Identification of Intermuscular Interval



3

Anterior-Superior Capsulotomy



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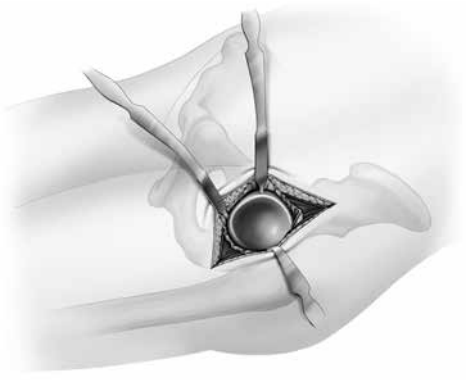
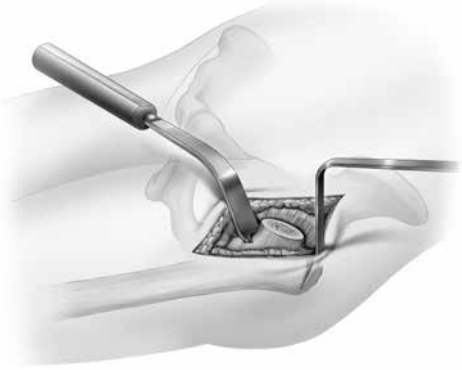
Placement of A+ Hudson Femoral Corkscrew and Osteotomy



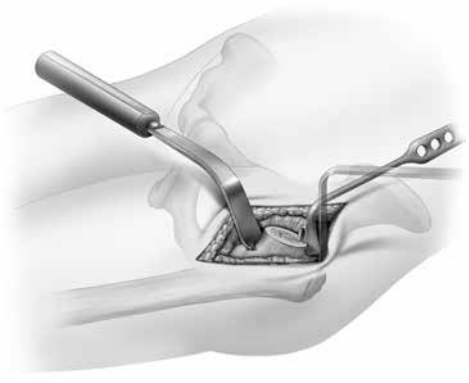
5

Acetabular Exposure



6

Proximal Femoral Exposure

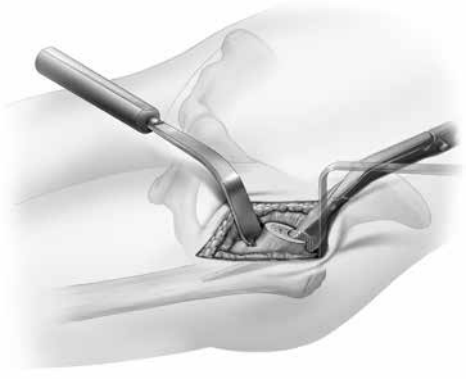


7

Opening of Femoral Canal Utilizing A+ Box Osteotome

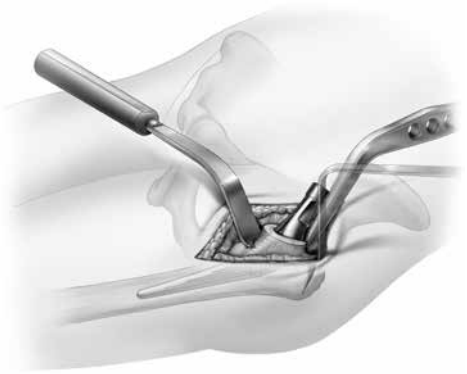
8a

Opening of Femoral Canal Utilizing A+ Starter Broach



8b

Femoral Broaching



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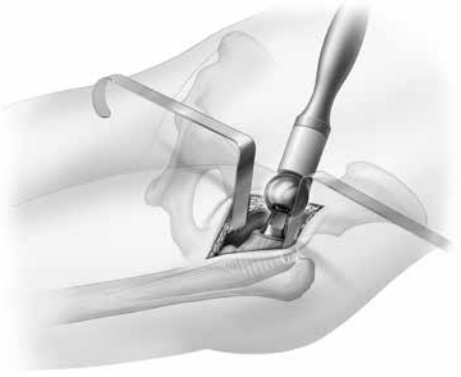
Femoral Stem Insertion



10

Femoral Head Impaction

Note: *The medical illustrations included in this technique depict the basic steps of the anterior approach. Specific steps can be found in the Detailed Operative Technique.*

DETAILED OPERATIVE TECHNIQUE

PATIENT POSITIONING

Position the patient supine on a fluoroscopy-capable table. There are a number of available options to assist in the manipulation of the patient during the anterior approach to hip replacement such as the utilization of a fracture table, a special O.R. table or table-mounted retractors. The surgeon can choose whichever method is preferred to accomplish the manipulation of the operative leg.

The O.R. table must be able to extend at the hip and the hip must be positioned to permit fluoroscopic views of both hips and the obturator foramen.

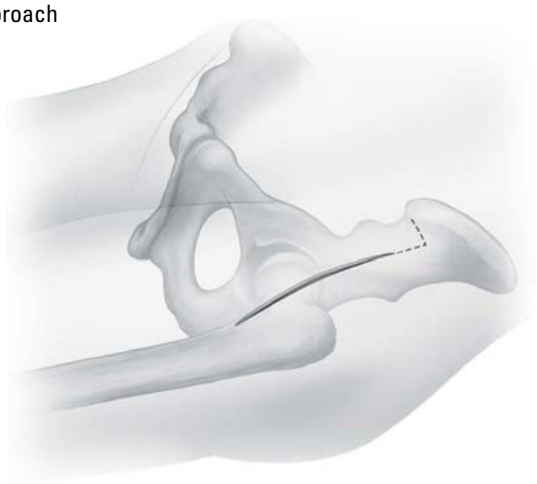
Check leg lengths in supine position and correlate with the hip radiographs for later reference.

The non-operative hip is placed in neutral or mild internal rotation (to maximize offset), neutral extension and slight abduction, and will serve as a radiographic reference for the operated side.

APPROACH AND EXPOSURE

The incision is determined using the Anterior Superior Iliac Spine (ASIS) as a reference. The starting point for the incision is two centimeters distal and four to six centimeters lateral to the ASIS. An oblique incision is made slightly lateral to the intermuscular space between the tensor fascia lata on the lateral side and the sartorius on the medial side. The incision is approximately centered over the greater trochanter and is slightly larger than the templated acetabular shell diameter *(Figure 1)*. At this location, the subcutaneous tissue is usually thin, even in obese patients, thus allowing for easy access to the underlying tissues. The fascia overlying the tensor fascia lata (identified by a pink hue) is then incised in line with the skin incision.

Figure 1
Incision for Anterior Approach



Muscular Dissection

Peel the fascia that is covering the tensor medially, then palpate over the top of the tensor fascia muscle to the femoral neck. The intermuscular interval can be easily developed by finger pressure in a medial direction until the capsule can be palpated *(Figure 2)*. This preparation should be completed without force to prevent damage to the ascending branch of the lateral circumflex femoral artery. Following identification of the artery, tie off or utilize electrocautery to minimize blood loss.

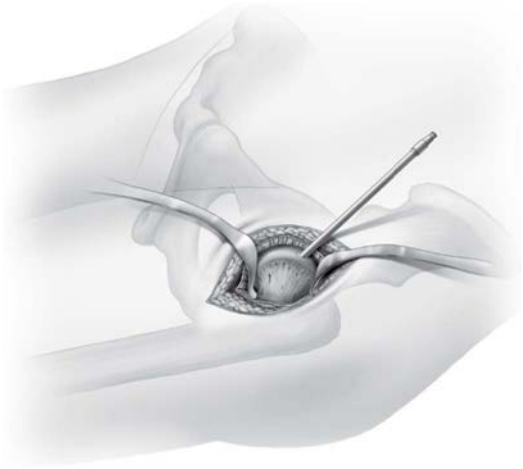
Figure 2
Identification of Intermuscular Interval

A **Novation A+ Cobra Retractor** is placed extracapsular to the lateral capsule to retract the abductors.

A second A+ Cobra Retractor is placed extracapsular on the medial femoral neck *(Figure 3)*.

Figure 3
Anterior-Superior Capsulotomy

Figure 4
Placement of A+ Hudson Femoral Corkscrew and Osteotomy

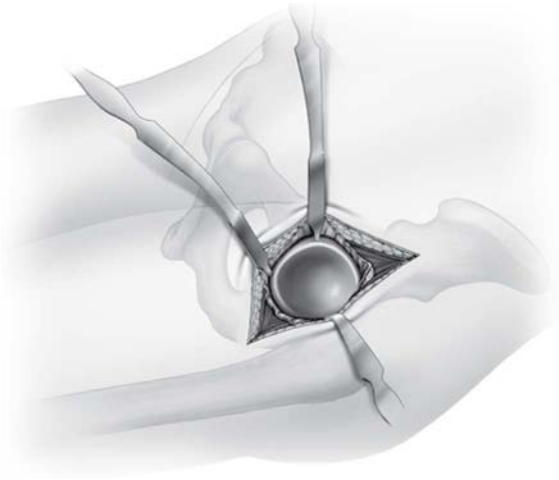


Exposure through Capsule
An anterior-superior capsulotomy is then carried out. The capsulotomy provides excellent visualization and aids in femoral mobilization. Per surgeon preference, the capsule can either be excised or tagged for future repair. The first two A+ Cobra Retractors are now placed inside the capsule for protection when the osteotomy is performed.

OSTEOTOMY OF THE FEMUR

Under power, place the **Novation A+ Hudson Femoral Corkscrew** through the cortical side of the femoral head *(Figure 4)*. It may be necessary to perform two separate parallel cuts to facilitate extraction of the femoral head. If necessary, the initial osteotomy should be at the head/neck junction. The final neck cut should be at the planned osteotomy level based on pre-operative planning utilizing the **Novation Element Osteotomy Guide**, if desired. Traction can be applied to the leg to prevent the saw blade from binding. Attach the **Hudson Quick Release T-Handle** and spin the head to rupture the ligamentum teres. This will aid with dislocation. The A+ Cobra Retractors can be removed and distraction and external rotation of the leg can be applied to aid in the removal of the femoral head. Fluoroscopy may be brought in at this time in order to verify the femoral neck resection level.

Figure 5
Acetabular Exposure



EXPOSURE OF THE ACETABULUM

After exposing the borders of the acetabulum, two or three **Novation A+ Hohmann Retractors** are placed *(Figure 5)*.

The first A+ Hohmann Retractor is placed on the anterior-lateral acetabular rim and retracts tissues medially and inferiorly.

The second A+ Hohmann Retractor is placed on the posterior acetabular rim. This retractor is used to spread tissues laterally and superiorly, and to depress the femur posteriorly.

(Optional) The third A+ Hohmann Retractor is placed on the superior acetabular rim. This retractor is used to spread tissues medially and superiorly.

ACETABULAR PREPARATION AND SHELL IMPLANTATION

Follow standard technique for acetabular preparation and shell implantation (refer to **Novation Crown Cup Operative Technique – Lit# 711-65-30)**. Fluoroscopy can be utilized throughout the reaming process in order to better visualize orientation and size.

EXPOSURE OF THE PROXIMAL FEMUR

The operative leg is positioned in slight adduction (approximately 20 degrees) and 90-120 degrees of external rotation in order to obtain the necessary access to the proximal femur. Hyperextension of the operative leg can be performed to aid in the exposure of the proximal femur.

The **Novation A+ Femoral Elevator** is placed medially to the femur at the level of the lesser trochanter and calcar, and retracted medially. The femur is progressively lifted until the osteotomy plane can be reached through the skin incision *(Figure 6)*.

The **Novation A+ 90-Degree Hohmann Retractor** is placed lateral to the proximal femur and retracted superiorly and laterally *(Figure 6)*.

Exposure and elevation of the proximal femur is aided by removing the capsule starting along the anterior side of the resection line and moving superior to the greater trochanter until the insertion point of piriformis is exposed. Visualization of the greater trochanter will aid in lateralization and reconstructing the patient's natural anatomy. Elevation of the femur can be done in a variety of ways, such as manual lifting with a bone hook or utilizing other commercially available means.

Figure 6
Proximal Femoral Exposure

FEMORAL PREPARATION

Opening of the Femoral Canal

The **Novation A+ Box Osteotome** is used to remove a wedge of cancellous bone, creating a portal for entry into the femoral canal *(Figure 7)*. The A+ Box Osteotome may aid in establishing an axial position for insertion of broaches.

Broach Assembly/Disassembly

The **Novation A+ Broach Handle** (left or right) is assembled to the **Novation A+ Starter Broach** or **Element Broach** by pushing the trigger to allow the latch mechanism to open. Insert the rectangular body of the A+ Broach Handle into the superior aspect of the Broach and close the latch mechanism. Care should be taken to ensure that the assembly of the instruments is correct.

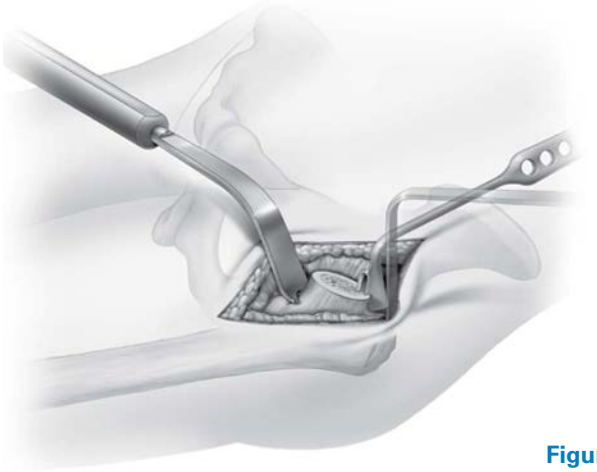


Figure 7
Opening of Femoral Canal Utilizing A+ Box Osteotome

Figure 8a
Opening of Femoral Canal
Utilizing A+ Starter Broach

Figure 8b
Femoral Broaching

Femoral Broaching
Femoral broaching is started by utilizing the A+ Starter Broach to identify the correct orientation of the femoral canal. Care should be taken when placing the A+ Starter Broach as to not perforate the femoral cortex and should be gently placed by hand with limited impaction with a mallet. Fluoroscopy can be used to verify the position of the A+ Starter Broach *(Figure 8a)*.

Broaching is then performed with progressive broach sizes, beginning with a smaller Broach than the templated prosthesis. The Broach is inserted into the femoral canal with the appropriate amount of anteversion. The surgeon should alternate impaction and withdrawal of the Broach as the final size is approached. The **Novation A+ Lateralizing Broach** can be attached to the A+ Broach Handle and used throughout the broaching process to ensure neutral positioning of the subsequent Broaches and final implant. Fluoroscopy can be used to verify the position of the Broaches in order to ensure neutral placement *(Figure 8b)*.

If using the Compaction Broaches:

The compaction-style broaches provide a bed of compacted cancellous bone to interface with the implant. When gaining access to the femur, the surgeon should be sure to lateralize into the greater trochanter and broach neutral, as varus placement of the broach could lead to an undersized stem. While broaching, the surgeon should be looking for the medial corners of the broach to contact the medial calcar and the broach to fill the femoral cavity from medial to lateral. As progressive broach sizes are used, the surgeon can assess the stability of the broach by the resistance following impaction and carefully performing a torque test using the broach handle.

The **Version Assist Bar** may be attached to the A+ Broach Handle to aid in determining Broach stability and orientation. Once the maximum size Broach is in place, the A+ Broach Handle is released from the Broach for trialing.

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 Planar Assembly** into the hole on the interior surface of the Broach attachment opening.

Calcar Blade Replacement - If necessary, a **Replacement Calcar Planar Blade** can be used to ensure proper removal of excess bone. Use the **Calcar Planar Blade Removal Tool** to remove the used Calcar Planar Blade, replace it with a new Calcar Planar Blade and tighten with the Calcar Planar Blade Removal Tool.

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

The appropriate **Element Offset Neck Trial** should be placed in the hole on the superior aspect of the Broach. Be sure the correct size and offset (Standard or Extended) Neck Trial is chosen. Care should be taken to place the Neck Trial onto the Broach with the size markings being placed nearest to the greater trochanter. An appropriate **Femoral Head Trial** is selected and assembled for trial reduction. **The Novation A+ Hibbs Retractor** can be used to aid in visualization during the remaining reductions and dislocations.

Trial Component Removal

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

FINAL COMPONENT PLACEMENT

Femoral Stem Insertion

The appropriate Femoral Stem is chosen and placed into the prepared broach cavity. The Novation A+ Stem Inserter is used to complete impaction of the Femoral Stem. The Femoral Stem is impacted taking care to ensure correct rotational alignment, version and depth *(Figure 9)*. It may be necessary to 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.

Femoral Head Impaction

The taper of the Femoral Stem should be clean and dry. The selected femoral head component is placed onto the taper of the Femoral Stem and secured using the **12/14 Femoral Head Impactor** *(Figure 10)*. Ceramic heads are placed by hand with a downward, twisting force and should not be impacted with a mallet.

Final Reduction

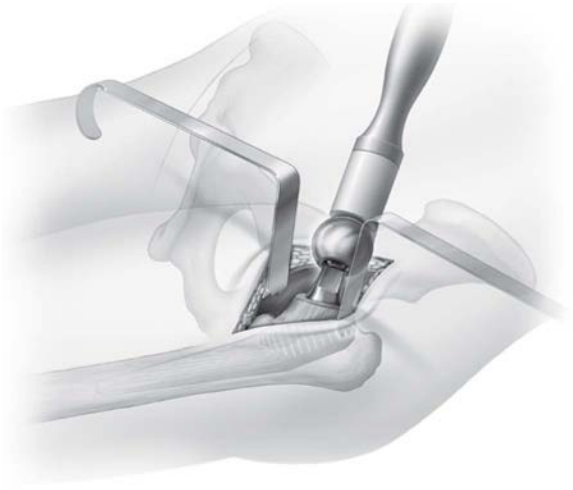
The hip should be reduced and a final check of the length, motion and stability should be made.

CLOSURE

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

Figure 9
Femoral Stem Insertion

Figure 10
Femoral Head Impaction



SYSTEM SPECIFICATIONS AND IMPLANT ORDERING INFORMATION

FEMORAL STEM ORDERING INFORMATION

Size (mm)	Collarless		Collared
	Standard Offset	Extended Offset	Standard Offset
8	164-01-08	164-02-08	164-03-08
9	164-01-09	164-02-09	164-03-09
10	164-01-10	164-02-10	164-03-10
11	164-01-11	164-02-11	164-03-11
12	164-01-12	164-02-12	164-03-12
13	164-01-13	164-02-13	164-03-13
14	164-01-14	164-02-14	164-03-14
15	164-01-15	164-02-15	164-03-15
16	164-01-16	164-02-16	164-03-16
17	164-01-17	164-02-17	164-03-17
18	164-01-18	164-02-18	164-03-18

FEMORAL HEAD ORDERING INFORMATION

Size (mm)	Neck Length				
	-3.5	0	+3.5	+7	+10
22***		142-22-00	142-22-03	142-22-07**	142-22-10**
28	140-28-93	140-28-00	140-28-03		
	142-28-93	142-28-00	142-28-03	142-28-07	142-28-10**
	170-28-93	170-28-00	170-28-03		
32	140-32-93	140-32-00	140-32-03		
	142-32-93	142-32-00	142-32-03	142-32-07	142-32-10**
	170-32-93	170-32-00	170-32-03	170-32-07	
36	140-36-93	140-36-00	140-36-03		
	142-36-93	142-36-00	142-36-03	142-36-07	142-36-10
	170-36-93	170-36-00	170-36-03	170-36-07	
40	142-40-93	142-40-00	142-40-03	142-40-07	142-40-10
	170-40-93	170-40-00	170-40-03	170-40-07	

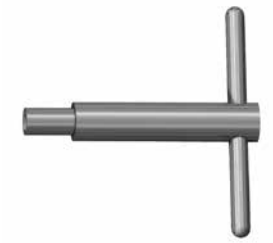
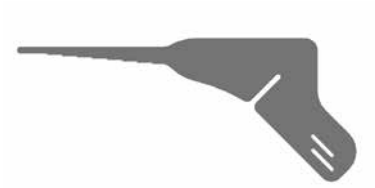
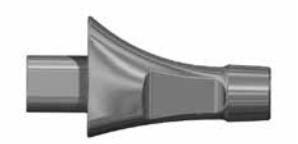
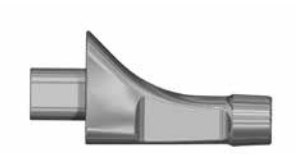
■ Alumina ■ CoCr ■ Delta

** Special order* *** Skirted heads*

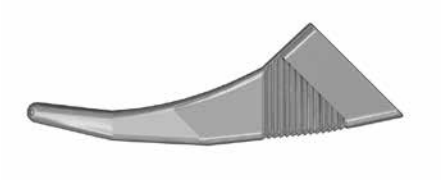
INSTRUMENT LISTING

Catalog Number	Part Description
109-00-00	Universal Femoral Stem Extractor
113-03-03	Slap Hammer
141-22-00*	22mm Femoral Head Trial, 12/14, +0mm
141-22-03*	22mm Femoral Head Trial, 12/14, +3.5mm
141-22-07*	22mm Femoral Head Trial, 12/14, +7mm
141-22-10*	22mm Femoral Head Trial, 12/14, +10mm
143-28-93	28mm Femoral Head Trial, 12/14, O-Ring, -3.5mm
143-28-00	28mm Femoral Head Trial, 12/14, O-Ring, +0mm
143-28-03	28mm Femoral Head Trial, 12/14, O-Ring, +3.5mm
143-28-07	28mm Femoral Head Trial, 12/14, O-Ring, +7mm
143-28-10	28mm Femoral Head Trial, 12/14, O-Ring, +10mm
143-32-93	32mm Femoral Head Trial, 12/14, O-Ring, -3.5mm
143-32-00	32mm Femoral Head Trial, 12/14, O-Ring, +0mm
143-32-03	32mm Femoral Head Trial, 12/14, O-Ring, +3.5mm
143-32-07	32mm Femoral Head Trial, 12/14, O-Ring, +7mm
143-32-10	32mm Femoral Head Trial, 12/14, O-Ring, +10mm
143-36-93	36mm Femoral Head Trial, 12/14, O-Ring, -3.5mm
143-36-00	36mm Femoral Head Trial, 12/14, O-Ring, +0mm
143-36-03	36mm Femoral Head Trial, 12/14, O-Ring, +3.5mm
143-36-07	36mm Femoral Head Trial, 12/14, O-Ring, +7mm
143-36-10	36mm Femoral Head Trial, 12/14, O-Ring, +10mm
153-00-02	12/14 Femoral Head Impactor
161-00-07	Replacement Calcar Planar Blade

*Special order

Catalog Number	Part Description	
161-00-24	Calcar Planar Assembly	
161-00-25	Calcar Planar Blade Removal Tool	
161-02-02	Version Assist Bar	
165-00-05	Novation Element Osteotomy Guide	
165-01-08 165-01-11 165-01-14	Element Standard Offset Neck Trial, Size 8-10 Element Standard Offset Neck Trial, Size 11-13 Element Standard Offset Neck Trial, Size 14-18	
165-02-08 165-02-11 165-02-14	Element Extended Offset Neck Trial, Size 8-10 Element Extended Offset Neck Trial, Size 11-13 Element Extended Offset Neck Trial, Size 14-18	
165-00-08 165-00-09 165-00-10 165-00-11 165-00-12 165-00-13 165-00-14 165-00-15 165-00-16 165-00-17 165-00-18	Element Broach, Size 8 Element Broach, Size 9 Element Broach, Size 10 Element Broach, Size 11 Element Broach, Size 12 Element Broach, Size 13 Element Broach, Size 14 Element Broach, Size 15 Element Broach, Size 16 Element Broach, Size 17 Element Broach, Size 18	
167-00-00	Novation A+ Stem Inserter	

INSTRUMENT LISTING

Catalog Number	Part Description	
167-00-01	Novation A+ Hudson Femoral Corkscrew	
167-00-02	Novation A+ Starter Broach	
167-00-03	Novation A+ Box Osteotome	
167-00-04	Novation A+ Lateralizing Broach	
167-01-00	Novation A+ Broach Handle, Left	
167-02-00	Novation A+ Broach Handle, Right	
167-03-01	Novation A+ Femoral Elevator	
167-03-02	Novation A+ 90-Degree Hohmann Retractor	

Catalog Number	Part Description	
167-03-03	Novation A+ Hohmann Retractor (Qty: 3)	
167-03-04	Novation A+ Hibbs Retractor (Qty: 2)	
167-03-05	Novation A+ Cobra Retractor (Qty: 2)	
301-07-70	Hudson Quick Release T-Handle	

Catalog Number	Additional Instruments	
165-10-08	Element Compaction Broach, Size 8	
165-10-09	Element Compaction Broach, Size 9	
165-10-10	Element Compaction Broach, Size 10	
165-10-11	Element Compaction Broach, Size 11	
165-10-12	Element Compaction Broach, Size 12	
165-10-13	Element Compaction Broach, Size 13	
165-10-14	Element Compaction Broach, Size 14	
165-10-15	Element Compaction Broach, Size 15	
165-10-16	Element Compaction Broach, Size 16	
165-10-17	Element Compaction Broach, Size 17	
165-10-18	Element Compaction Broach, Size 18	

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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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