

EXACTECH | HIP

Operative Technique



NOVATION[®]
Comprehensive Hip System

Element[®]

*Renewing Innovations.
Enduring Solutions.*





TABLE OF CONTENTS

PRE-OPERATIVE PLANNING	1
OPERATIVE TECHNIQUE OVERVIEW	2
DETAILED OPERATIVE TECHNIQUE	4
APPROACH AND EXPOSURE	4
DISLOCATION AND OSTEOTOMY	4
FEMORAL PREPARATION	4
TRIAL REDUCTION	6
FINAL REDUCTION	7
CLOSURE	7
SYSTEM SPECIFICATIONS AND	
IMPLANT ORDERING INFORMATION	8
INSTRUMENT LISTING	10

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 and vertical distal grooves designed to convert hoop stress to compressive loads and achieve rotational and axial stability. 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.

The Novation Element stem's neck region was engineered with more material on the lateral aspect to maintain strength and less material on the medial aspect to increase range of motion.

The Novation Element has two offsets, standard and extended. By maintaining a 135-degree neck angle, offset may be adjusted without affecting leg length. The fully coated HA stem, of 80 microns, is designed for osseointegration to provide excellent short- and long-term fixation.

PRE-OPERATIVE PLANNING

TOOLS

- A/P X-ray of pelvis centered on the pubic symphysis
- Pencil that will not damage X-ray
- 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.

ESTABLISHMENT OF REFERENCE POINTS

On the X-ray, 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 X-ray 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

For traditional 'hard-copy' templating, the Novation Element femoral template is positioned over the X-ray 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.

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

STEM SIZING

After placing the Novation Element templates on the X-ray 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

Osteotomy Guide Placement



2

Opening of the Proximal Femur with Box Osteotome



3

Entry into Femoral Canal



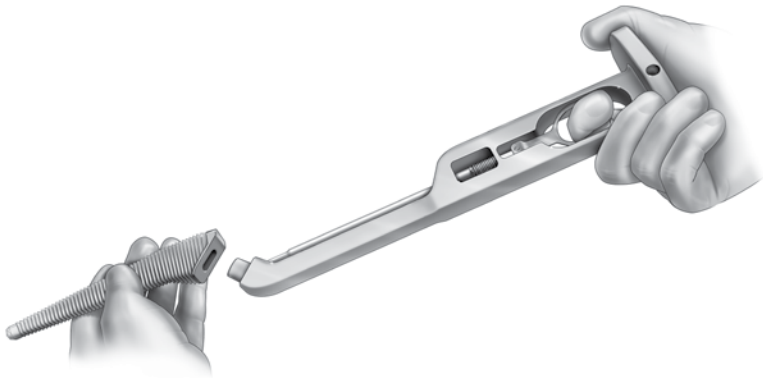
6

Calcar Preparation (Optional)



7

Trial Component Insertion



4

**Broach Assembly/
Disassembly**



5

Broach Insertion



8

Femoral Stem Insertion



9

Femoral Head Impaction

DETAILED OPERATIVE TECHNIQUE

APPROACH AND EXPOSURE

The Novation femoral stems are compatible with any standard surgical exposure. In this operative technique, the posterior lateral approach is described.

DISLOCATION AND OSTEOTOMY

A. Hip Dislocation

The hip should be dislocated by flexion, adduction and internal rotation. Placing a bone hook around the femoral neck may help in difficult cases. Soft tissues along the intertrochanteric line to the proximal border of the lesser trochanter should be cleared. When tight, the gluteus maximus tendon may be released to improve exposure. The limb should be positioned at 90 degrees internal rotation of the hip.

B. Femoral Osteotomy

The **Novation Element Osteotomy Guide** is aligned with the femur by either palpating the femur through the muscles or directing the Osteotomy Guide toward the center of the popliteal fossa (*Figure 1*). The level of the femoral osteotomy site that was determined in pre-operative templating is marked. This mark is most often 1cm above the proximal border of the lesser trochanter.

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

FEMORAL PREPARATION

A. Opening of the Femoral Canal

The **Box Osteotome** is then used to remove a wedge of cancellous 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.

Initial entry into the femoral canal is made with the **T-Handle Starter Reamer** (*Figure 3*).

The T-Handle Starter Reamer is inserted into the canal until the cutting edges begin to engage in the medial aspect of the greater trochanter. Lateralizing the Starter Reamer at this step assists in assuring neutral position in the femur.



Figure 1
Osteotomy Guide Placement

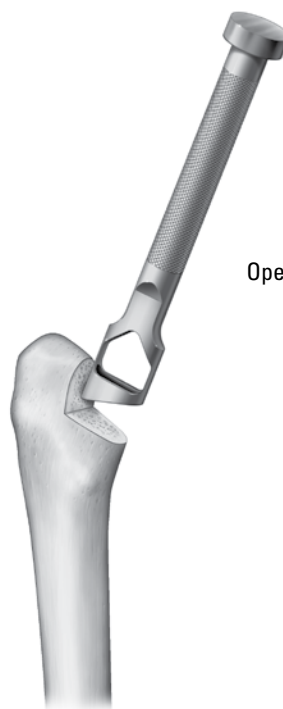


Figure 2
Opening of the Proximal Femur
with Box Osteotome



Figure 3
Entry into Femoral Canal

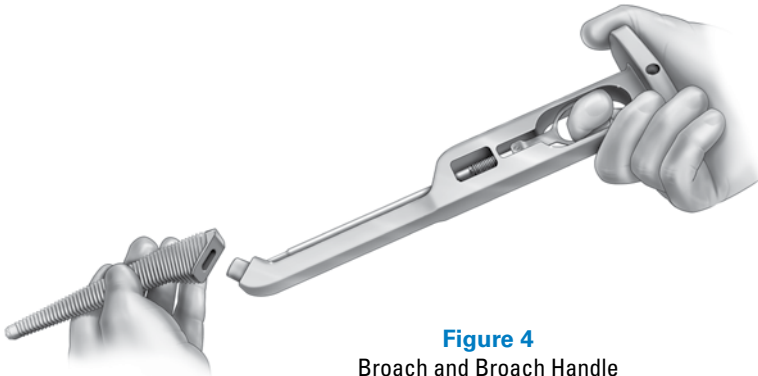


Figure 4
Broach and Broach Handle
Assembly

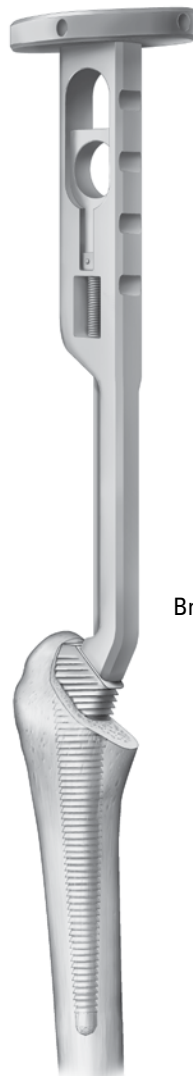


Figure 5
Broach Insertion

B. Broach Assembly/Disassembly

The **Element Broach Handle** is assembled to the **Element Broach** by pulling back the trigger while inserting the rectangular body of the Element Broach Handle into the superior aspect of the Broach and releasing the lever (*Figure 4*). Care should be taken to ensure that the assembly of the instruments is correct.

C. Femoral Broaching

Broaching is performed with progressive broach sizes, beginning with the smallest Broach. The Broach is inserted into the femoral canal in a few degrees of anteversion (*Figure 5*). The surgeon should alternate impaction and withdrawal of the Broach as the final size is approached. A **Slap Hammer** or mallet may be used. The **Version Assist Bar** may be attached to the Broach Handle to aid in determining Broach stability. Once the maximum size Broach is in place, the Broach Handle is released from the Broach for trialing.

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.

D. Calcar Preparation (Optional)

Calcar planing can be performed, if desired, in order to remove any bone that protrudes above the level of the impacted Element Broach by guiding the **Calcar Planar Assembly** into the hole on the interior surface of the broach attachment opening (*Figure 6*).

Calcar Planar 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 blade, replace it with a new blade and tighten with the 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

A. Trial Component Insertion

The appropriate **Element Neck Trial** should be placed in the hole on the superior aspect of the Broach. Be sure the correct size and offset (STD or EXT) Neck Trial is chosen. Make sure, when inserting the Element Neck Trial, that the size and offset etch markings are facing laterally (*Figure 7*). An appropriate **Femoral Head Trial** is selected and assembled for trial reduction.

B. Trial Component Removal

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.

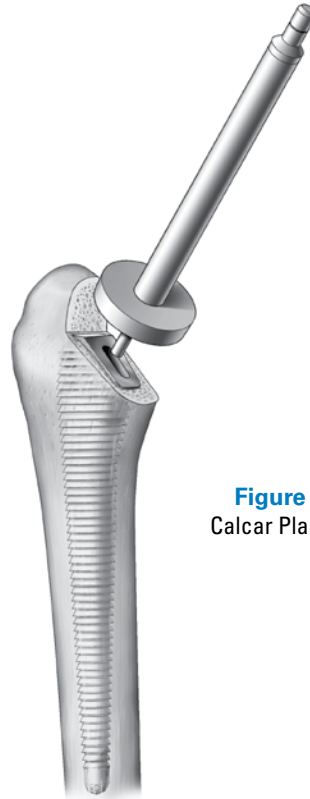


Figure 6
Calcar Planing



Figure 7
Trial Component Insertion



Figure 8
Femoral Stem Insertion

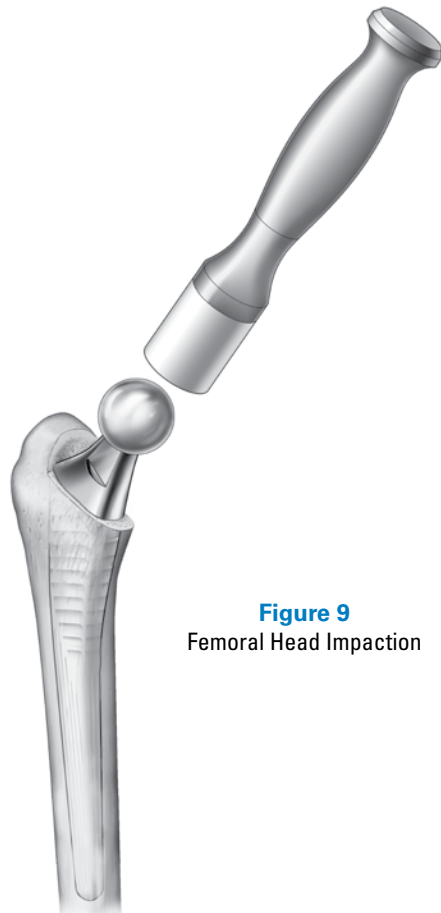


Figure 9
Femoral Head Impaction

FINAL REDUCTION

A. Femoral Stem Insertion

The appropriate femoral stem is chosen and assembled to the **Offset Stem Inserter**. The femoral stem is impacted taking care to ensure correct rotational alignment, version and depth (*Figure 8*). 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.

B. 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 9*). Ceramic heads are placed by hand with a downward, twisting force and should **not** be impacted with a mallet.

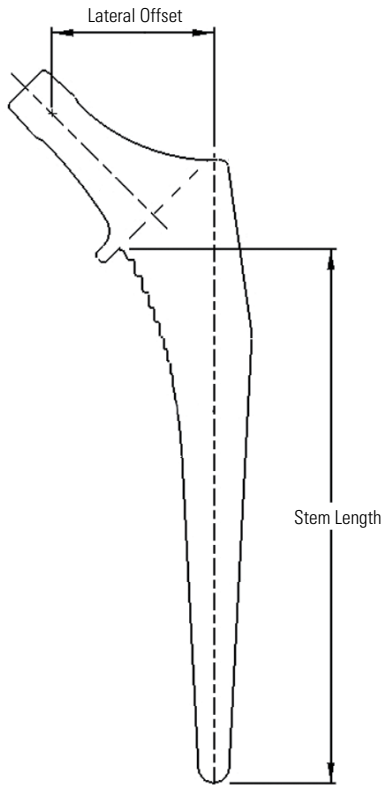
C. Final Range of Motion

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.

SYSTEM SPECIFICATIONS AND IMPLANT ORDERING INFORMATION



ELEMENT STEM DETAILS

Size (mm)	Stem Length (mm)*	Standard Lateral Offset with following head lengths (mm)					Extended Lateral Offset with following head lengths (mm)				
		-3.5	0	+3.5	+7	+10	-3.5	0	+3.5	+7	+10
8	94	37	39	41	44	46	44	46	48	51	53
9	109	37	40	42	45	47	44	47	49	52	54
10	119	38	40	43	45	47	45	47	50	52	54
11	124	39	41	44	46	48	46	48	51	53	55
12	129	39	42	44	47	49	46	49	51	54	56
13	134	40	43	45	47	50	47	50	52	54	57
14	139	41	43	46	48	50	48	50	53	55	57
15	144	42	44	47	49	51	49	51	54	56	58
16	149	42	45	47	50	52	49	52	54	57	59
17	159	43	46	48	51	53	50	53	55	58	60
18	169	44	47	49	51	54	51	54	56	58	61

Note: For each change in head length, vertical leg length changes approximately 2.5mm.

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

* Stem length is measured from medial resection level ** Skirted heads ***Special order
 †Special order ††Size 28 +7mm requires BIOLOX®Option

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



INSTRUMENT LISTING

Catalog Number	Part Description
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165-31-00	Novation Element Core Instrument Case
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109-00-00	Universal Femoral Stem Extractor
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113-03-02	Box Osteotome
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113-03-03	Slap Hammer
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113-03-04	T-Handle Starter Reamer
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153-00-02	12/14 Femoral Head Impactor
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Catalog Number **Part Description**

161-00-06 Slap Hammer Adapter



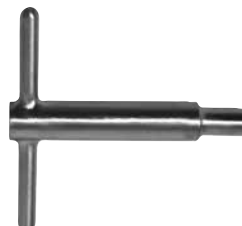
161-00-07 Replacement Calcar Planar Blade



161-00-24 Calcar Planar Assembly



161-00-25 Calcar Planar Blade Removal Tool



165-00-05 Novation Element Osteotomy Guide



Catalog Number	Part Description
165-32-00	Novation Element Femoral Broach/Trial Instrument Case
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
143-40-93	40mm Femoral Head Trial, 12/14, O-Ring, -3.5mm
143-40-00	40mm Femoral Head Trial, 12/14, O-Ring, +0mm
143-40-03	40mm Femoral Head Trial, 12/14, O-Ring, +3.5mm
143-40-07	40mm Femoral Head Trial, 12/14, O-Ring, +7mm
143-40-10	40mm Femoral Head Trial, 12/14, O-Ring, +10mm



161-02-02 Version Assist Bar



161-01-01 Offset Stem Inserter



165-00-00 Element Broach Handle



*Special order

Catalog Number Part Description

165-00-08	Element Broach, Size 8
165-00-09	Element Broach, Size 9
165-00-10	Element Broach, Size 10
165-00-11	Element Broach, Size 11
165-00-12	Element Broach, Size 12
165-00-13	Element Broach, Size 13
165-00-14	Element Broach, Size 14
165-00-15	Element Broach, Size 15
165-00-16	Element Broach, Size 16
165-00-17	Element Broach, Size 17
165-00-18	Element Broach, Size 18



165-01-08	Element Standard Offset Neck Trial, Size 8-10
165-01-11	Element Standard Offset Neck Trial, Size 11-13
165-01-14	Element Standard Offset Neck Trial, Size 14-18



165-02-08	Element Extended Offset Neck Trial, Size 8-10
165-02-11	Element Extended Offset Neck Trial, Size 11-13
165-02-14	Element Extended Offset Neck Trial, Size 14-18



167-00-04	Novation A+ Lateralizing Broach
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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



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

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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