NOVATION®
Comprehensive Hip System

CFS Press-Fit and Cemented

RENEWING INNOVATIONS.
ENDURING SOLUTIONS.

Exactech®

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THE NOVATION® CFS™ OPERATIVE TECHNIQUE WAS DEVELOPED IN CONSULTATION WITH:

Quanjun Cui, MD
University of Virginia School of Medicine
Charlottesville, VA

NOVATION® CFS™ FEMORAL STEMS

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 PHILOSOPHIES - SCIENCE FIRST

The Novation Comprehensive Hip System features both splined and tapered press-fit femoral stems as well as collared, matte finish cemented stems. The Novation primary hip platform offers high-demand stems in standard and extended offset and low-demand stems in standard offset.

UNIVERSAL FEATURES

All Novation femoral stems share many mutual design features. The neck flats increase the range of motion of the stem before the potential for impingement and dislocation can occur. A 12/14 taper allows coupling with a wide range of bearing surfaces.

PRESS-FIT STEMS

Novation high-demand press-fit stem designs are manufactured from a proprietary forged titanium alloy and are proximally coated with titanium plasma spray, which uses advanced manufacturing technologies. Novation low-demand stems, like Novation® CFS™ Press-Fit, have a grit-blast titanium surface.

The Novation CFS Press-Fit stems share many attributes of other clinically successful tapered stems — supporting a broach-only operative technique and preserving diaphyseal cortical bone. The bi-planar design, with a 3-degree taper in the M/L plane and a 5-degree taper in the A/P plane, provides rotational stability.

CEMENTED STEMS

The Novation high-demand cemented designs feature a highly polished neck in both standard and extended offsets. The highly polished neck is intended to reduce the generation of polyethylene wear particles during incidental impingement.

The Novation CFS Cemented femoral stems are designed to utilize the same instruments used with the Novation CFS Press-Fit femoral stem preparation. This allows intra-operative transition to a cemented stem should the need arise. Features such as the cobra flange, longitudinal grooves, medial collar and distal centralizer help to optimize cement pressurization and stem placement. In addition, the offset and leg length of the corresponding Novation CFS Press-Fit stems are identical, allowing for accurate replication of leg length and offset following trial reduction.

NOVATION CFS

The Novation CFS Femoral Stems are designed to provide surgeons with excellent initial fixation and long-term stability when paired with the core instruments that support Novation Tapered, Splined and Cemented Plus preparation. This allows for simple preparation and ease of intra-operative transition to a low-demand stem should the need arise.

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 templates with 120 percent magnification rule
- Goniometer/protractor

For traditional templating, the Novation CFS 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. 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

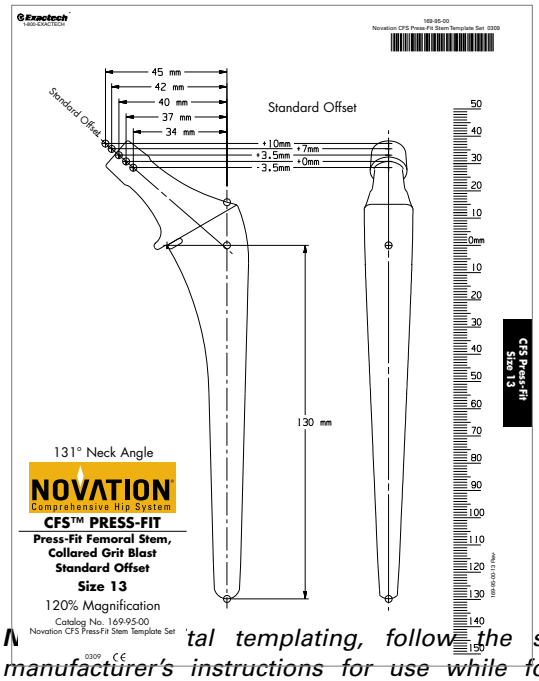
On the X-ray, a straight line is drawn across the bottom of the pelvis touching both ischial tuberosities equally. The line is extended far enough to reach each lesser trochanter. Such a line should be perpendicular to the vertically oriented pubic symphysis. If the line is not vertically oriented, it 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 most 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 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 can be recorded at this time (standard offset option only for Novation CFS Press-Fit and CFS Cemented.) 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.



N tal 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 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. In addition, notice that the broach cavity/cement mantle is indicated on the Cemented templates. **Note:** Due to the 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 and Femoral Head Resection

2

Opening of the Proximal Femur with Round Osteotome

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Determining Canal Diameter with Centralizer Sizer (when using Novation CFS Cemented)

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Femoral Stem Insertion (Press-Fit shown)

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Femoral Head Impaction

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Bipolar Assembly

DETAILED OPERATIVE TECHNIQUE

APPROACH AND EXPOSURE

The Novation femoral stems are compatible with any standard surgical exposure. In this operative technique, the posterolateral 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 Head Resection

The **12/14 Osteotomy Guide** is aligned with the femur by either palpating the femur through the muscles or directing the 12/14 Osteotomy Guide toward the center of the popliteal fossa. The level of the femoral osteotomy site that was determined in pre-operative templating is marked *(Figure 1)*. This mark is most often 5-20mm above the proximal border of the lesser trochanter. Natural varus hips tend to have low-neck cuts. The neck cut may be as low as the level of the lesser trochanter. Conversely, valgus hips tend to have higher neck cuts. If additional mobilization of the femur is needed, an anterior capsulotomy may be performed at this point.

FEMORAL PREPARATION

A. Opening of the Femoral Canal

When using the posterolateral approach, the femur should be placed in 90 degrees of internal rotation and mild flexion. Retractors should be positioned to expose the proximal femur. The **Round Osteotome** is then used to create a portal into the femoral canal *(Figure 2)*.

Figure 1
Osteotomy Guide Placement and Femoral Head Resection

Figure 2
Opening of the Proximal Femur with Round Osteotome

Figure 3
Entry into Femoral Canal

Initial entry into the femoral canal is made with the **T-Handle Starter Reamer** *(Figure 3)*, which is inserted into the canal until the cutting edges begin to engage in the medial aspect of the greater trochanter. The T-Handle Starter Reamer aids in establishing neutral axial position for insertion of the **Novation Tapered Broaches** and the **Novation Lateralizing Reamer.**

B. Lateralizing Reaming

The Novation Lateralizing Reamer should be inserted into the canal until the appropriate markings are taken to the medial aspect of the osteotomy line to ensure that proper axial canal access is achieved during subsequent reaming and broaching *(Figure 4)*. This lateralizing action assists in assuring neutral position in the femur. Note the stem size markings on the Novation Lateralizing Reamer correspond to the specific diameters of odd-sized Novation stems. If an even-sized Novation stem is templated, ream to the medial aspect of the osteotomy line stopping halfway between the two closest odd-sized markings. The blunt, non-cutting pilot of the instrument is designed to contact the inside of the femur without damaging or removing bone.

Figure 4
Lateralizing the Femoral Canal

C. Broach Technique

Broach and Broach Handle Assembly *(Figure 5)* - The **Novation Broach Handle** is assembled to the Novation Tapered Broach by pulling back on the finger trigger, inserting the rectangular body of the Broach Handle into the superior aspect of the Novation Tapered Broach and releasing the lever. (Two Broach Handles only available in full instrumentation set; only one Broach Handle available in Novation CFS Quick Kit.) Care should be taken to ensure that the assembly of the instruments is correct.

Broaching is performed with progressive broach sizes, beginning with a smaller broach than the templated prosthesis; typically two sizes below the templated prosthesis. The Novation Tapered Broach is inserted into the femoral canal in a few degrees of anteversion *(Figure 6)*. Note that indicator markings have been placed on the strike platform of the Novation Broach Handle to aid in broach version. The surgeon should alternate impaction and withdrawal of the Novation Tapered Broach as the final size is approached. When the maximum-sized Novation Tapered Broach is in place, the final Novation Tapered Broach will feel rotationally stable and have no perceived micro-motion; at this time, the Novation Broach Handle is then released from the Novation Tapered Broach for trialing. *If the proximal fit of the Novation Tapered Broach is not adequate, the next larger size Novation Tapered Broach is recommended.*

Stem sizes and lengths can be found in the System Specifications section.

D. Calcar Planing

Calcar planing can be performed, if desired, in order to remove any bone that protrudes above the level of the impacted Novation Tapered Broach by guiding the **Calcar Planar Assembly** into the hole on the superior surface of the Novation Tapered Broach *(Figure 7)*.

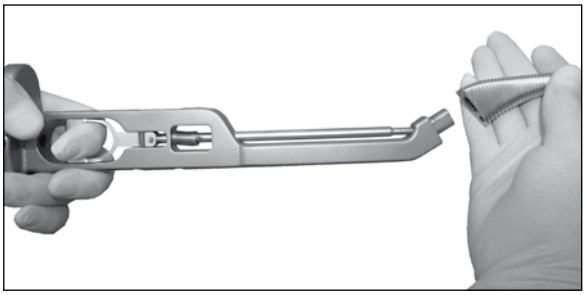


Figure 5
Broach and Broach Handle Assembly

Figure 6
Broach Insertion

Figure 7
Calcar Planing

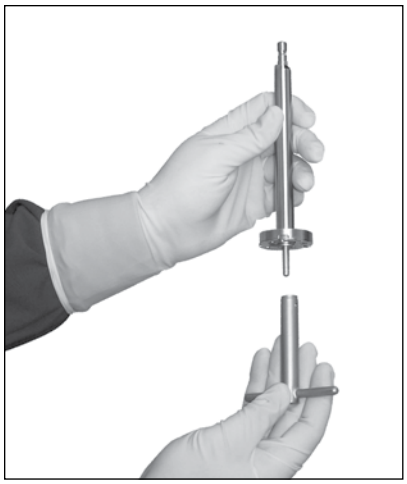


Figure 8
Calcar Planar Blade Replacement

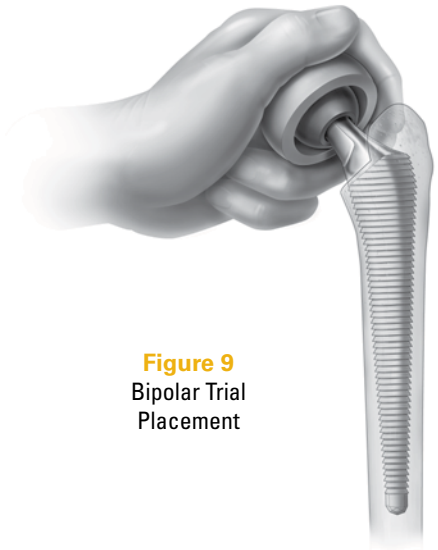


Figure 9
Bipolar Trial Placement

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 blade, replace it with a new blade and tighten with the Calcar Planar Blade Removal Tool *(Figure 8)*.

TRIAL REDUCTION

A. Trial Component Insertion

The appropriate **Novation Neck Trial** should be placed in the hole on the superior aspect of the Novation Tapered Broach. Be sure the correct size and offset Neck Trial is chosen.

Note: *There is no extended offset option for Novation CFS Press-Fit or CFS Cemented.*

Measure the resected native femoral head with the **Bipolar Femoral Head Template** to appropriately size the outer diameter **Bipolar Trial**. Assemble the **Bipolar Trial Handle** to the **Bipolar Trial Handle Adapter**. Then, select the appropriately sized Bipolar Trial to assess the replaced femoral head's fit with the acetabulum.

Place the **Femoral Head Trial** or the **12/14 Unipolar Trial Adapter** on the trunnion of the Novation Neck Trial *(Figure 9)*. Next, place the Bipolar Trial over the assembled Femoral Head Trial for trial reduction.

B. Joint Stability Determination

Limb length can be assessed by evaluating the relationship of the level of the greater trochanter tip to the femoral head center of rotation. Limb length is also compared to the opposite limb by palpating the knees through the drapes. Other methods may also be used. The hip should be taken through a range of motion to assure stability. If required, the chosen neck length and/or offset can be modified to alter the tension of the joint as well as leg length.

C. Trial Component Removal

After components are selected, the hip is dislocated and the head trials and Novation Neck Trial are removed. The Novation Broach Handle is reassembled to the Novation Tapered Broach and the Broach is removed.

CEMENTED FEMORAL STEM PREPARATION

A. Broach and Trial Reduction Technique

The trial reduction described in the previous steps also will be used for the cemented stem. Note that since there are fewer choices in the cemented version, it is necessary to broach to a minimum of the Novation Tapered Broach, size 10. The corresponding implant is slightly down-sized to accommodate a cement mantle of the appropriate thickness. In addition, the corresponding Novation Neck Trial also will replicate the leg length and offset of the cemented femoral stem.

As with the Press-Fit, the final Cemented stem size should be based on the final Novation Tapered Broach used.

B. Determining Canal Diameter with Centralizer Sizer

When it is desired to use the Novation CFS Cemented Femoral Stem, it is recommended to use the **Centralizer Sizer** as a guide for the pre-formed PMMA Distal Centralizer selection. Refer to Stem Specifications on page 13 for stem lengths of the CFS Cemented femoral stems. Corresponding measurements are located on the Centralizer Sizer in order to help determine the appropriate depth to measure canal diameter *(Figure 10)*. Insert the Centralizer Sizer to the appropriate depth and squeeze the actuator. The inner diameter of the femoral canal can be read on the proximal portion of the instrument. Remove the Centralizer Sizer, reset the ring and reinsert it into the femoral canal rotated 90 degrees in order to gain more information on the canal size. Read the measurement again and choose the smaller size to guide the selection of the Distal Centralizer.

FINAL REDUCTION

A. Final Stem Insertion — Press-Fit Femoral Stems

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 and depth *(Figure 11)*. 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 Trials.

B. Final Stem Insertion — Cemented Femoral Stems

The Distal Centralizer chosen in the previous steps is placed on the distal end of the appropriately sized femoral stem. Cement is inserted into the proximal femur by whichever cementing technique is desired. By hand or using the Offset Stem Inserter, place the femoral stem into the femur taking notice of femoral stem version *(Figure 12)*. It is important

Figure 10
Determining Canal Diameter with Centralizer Sizer

Figure 11
Press-Fit Femoral Stem Insertion

Figure 12
Cemented Femoral Stem Insertion

Figure 13
Femoral Head Impaction

Figure 14
Bipolar Head Placement

Figure 15
"Wish Bone" Removal

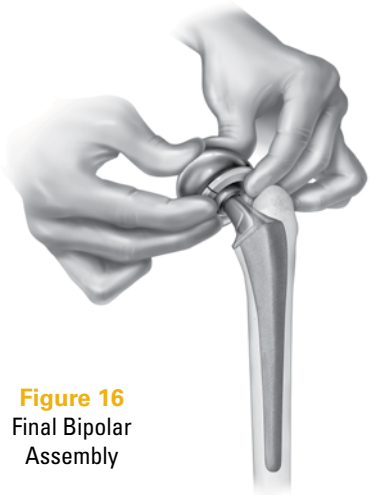


Figure 16
Final Bipolar Assembly

not to move the stem in a retrograde fashion once insertion has begun as the Distal Centralizer can become disassociated from the femoral stem. Once the stem is in the desired position, remove the Offset Stem Inserter and allow the cement to cure.

C. Femoral Head Impaction/Endoprostheses

Note: *Please follow chosen endoprostheses method found on pages 11 and 12.*

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 13)*. Zirconia Ziramic™ heads are placed by hand with a downward, twisting force and should not be impacted with a mallet.

D. 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.

FINAL BIPOLAR HEAD IMPACTION

A. Method 1: Bipolar Assembly

After cleaning and drying the femoral neck trunnion, impact the appropriate Femoral Head onto the femoral stem with the 12/14 Femoral Head Impactor.

Place Femoral Head in the bipolar component *(Figure 14)*. Remove the "wish bone" and discard *(Figure 15)*. Press the locking ring until an audible snap occurs. Component is now fully assembled *(Figure 16)*.

Figure 17
"Wish Bone" Removal

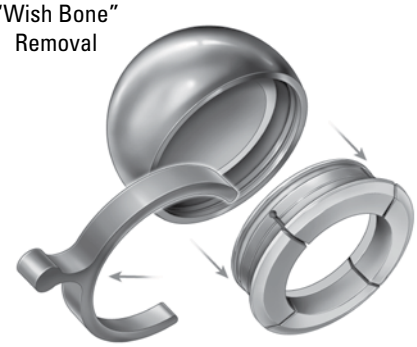


Figure 18
Final Head Placement

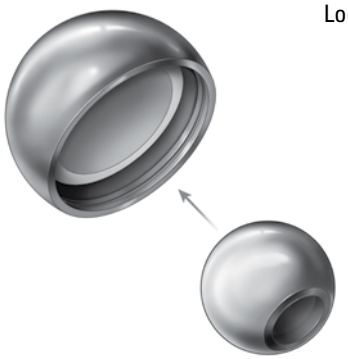


Figure 19
Replace Locking Ring

B. Method 2: Bipolar Assembly (Alternative Method)

Note: *If Method 2 Bipolar Assembly is chosen, the steps must occur before Femoral Head Impaction.*

Remove the "wish bone" and discard. Remove the locking ring *(Figure 17)*. Place the Femoral Head into the Bipolar Shell *(Figure 18)*. Replace the locking ring *(Figure 19)*.

Note: *Back-table assembly is required for first three steps of this Bipolar Assembly method.*

Assemble with finger pressure until an audible snap occurs *(Figure 20)*. The selected femoral head component is placed onto the taper of the femoral stem and secured using the 12/14 Femoral Head Impactor *(Figure 21)*. Zirconia Ziramic™ heads are placed by hand with a downward, twisting force and should not be impacted with a mallet.

FINAL UNIPOLAR HEAD IMPACTION

Unipolar Assembly

After cleaning and drying the femoral neck trunnion, place the appropriate 12/14 Unipolar Sleeve onto the femoral stem using firm manual pressure. Clean and dry the outer portion of the 12/14 Unipolar Sleeve and place the Unipolar Head onto the 12/14 Unipolar Sleeve. Impact the Unipolar Head onto the 12/14 Unipolar Sleeve using the 12/14 Femoral Head Impactor.

Figure 20
Bipolar Assembly

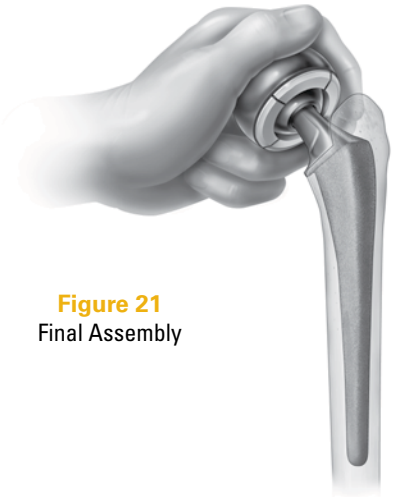


Figure 21
Final Assembly

SYSTEM SPECIFICATIONS

Size (mm)*	Stem Length (mm)**		Standard Lateral Offset with following head lengths (mm)				
	CFS Press-Fit	CFS Cemented	-3.5	+0	+3.5	+7	+10***
9	120		30	33	36	38	41
10	125	115	31	34	37	39	42
11	125	121	32	35	38	40	43
12	130	126	34	37	40	42	45
13	130	126	34	37	40	42	45
14	135	126	34	37	40	42	45
15	135	126	34	37	40	42	45
16	140		36	39	42	44	47
17	140	136	37	40	43	45	48
18	145		38	41	44	46	49

Note: For each change in head length, vertical leg length changes approximately 2.3mm.

FEMORAL ORDERING INFORMATION

DISTAL CENTRALIZER ORDERING INFORMATION

Sizes (mm)	Part Numbers
10	PC-10
11	PC-11
12	PC-12
13	PC-13
14	PC-14
15	PC-15
16	PC-16
17	PC-17

UNIPOLAR SLEEVES

Neck Lengths (mm)	Part Numbers
-3.5	102-60-97
+0	102-60-00
+3.5	102-60-03
+7	102-60-07
+10	102-60-10

Sizes (mm)	UNIPOLAR HEADS Part Numbers	BIPOLAR HEADS Part Numbers
40	n/a	BP-2840
41	n/a	BP-2841
42	102-20-42	BP-2842
43	102-20-43	BP-2843
44	102-20-44	BP-2844
45	102-20-45	BP-2845
46	102-20-46	BP-2846
47	102-20-47	BP-2847
48	102-20-48	BP-2848
49	102-20-49	BP-2849
50	102-20-50	BP-2850
51	102-20-51	BP-2851
52	102-20-52	BP-2852
53	102-20-53	BP-2853
54	102-20-54	BP-2854
55	102-20-55	BP-2855
57	n/a	BP-2857
59	n/a	BP-2859
61	n/a	BP-2861

** Stem diameter is measured midshaft ** Stem length is measured from medial resection level *** Skirted heads*

FEMORAL ORDERING INFORMATION

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†	142-28-93	142-28-00	142-28-03	142-28-07	142-28-10***
	148-28-93	148-28-00	148-28-03	148-28-07***	148-28-10***
32	142-32-93	142-32-00	142-32-03	142-32-07	142-32-10***
	148-32-93	148-32-00	148-32-03	148-32-07***	148-32-10***
36	142-36-93	142-36-00	142-36-03	142-36-07	142-36-10
	148-36-93	148-36-00	148-36-03	148-36-07***	148-36-10***

CoCr Zirconia

Note: *The Novation CFS femoral stems are not approved for use with BIOLOXforte® Alumina femoral heads.*

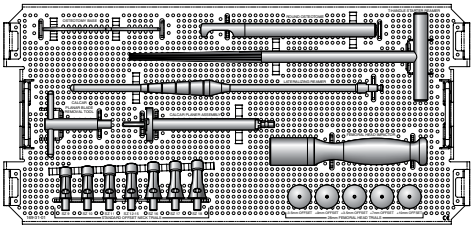
FEMORAL STEM ORDERING INFORMATION

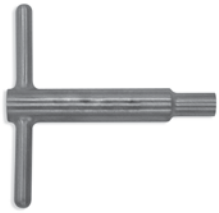
Size (mm)*	Tapered	Cemented
	Standard Offset	Standard Offset
9	168-00-09	
10	168-00-10	168-50-10
11	168-00-11	168-50-11
12	168-00-12	168-50-12
13	168-00-13	168-50-13
14	168-00-14	168-50-14
15	168-00-15	168-50-15
16	168-00-16	
17	168-00-17	168-50-17
18	168-00-18	

** Stem diameter is measured midshaft ** Stem length is measured from medial resection level *** Skirted heads † Special order*

INSTRUMENT LISTING

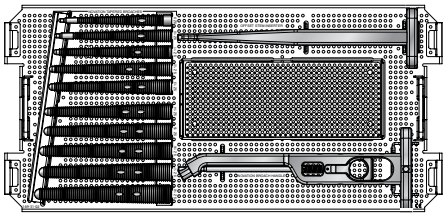
Catalog Number	Part Description
169-31-01	**Novation CFS Core Tray**
113-03-04	T-Handle Starter Reamer
143-28-93	28mm Femoral Head Trial, 12/14, O-Ring, -3.5mm
143-28-00	28mm Femoral Head Trial, 12/14, O-Ring, +0mm
143-28-03	28mm Femoral Head Trial, 12/14, O-Ring, +3.5mm
143-28-07	28mm Femoral Head Trial, 12/14, O-Ring, +7mm
143-28-10	28mm Femoral Head Trial, 12/14, O-Ring, +10mm
151-00-01	Round Osteotome
153-00-02	12/14 Femoral Head Impactor
161-00-03	12/14 Osteotomy Guide
161-00-07	Replacement Calcar Planar Blade
161-00-24	Calcar Planar Assembly
161-00-25	Calcar Planar Blade Removal Tool
161-06-00	Novation Lateralizing Reamer
161-22-09	Novation Standard Offset Neck Trial, Size 9
161-22-10	Novation Standard Offset Neck Trial, Size 10
161-22-11	Novation Standard Offset Neck Trial, Size 11
161-22-12	Novation Standard Offset Neck Trial, Size 12-15
161-22-16	Novation Standard Offset Neck Trial, Size 16
161-22-17	Novation Standard Offset Neck Trial, Size 17
161-22-18	Novation Standard Offset Neck Trial, Size 18





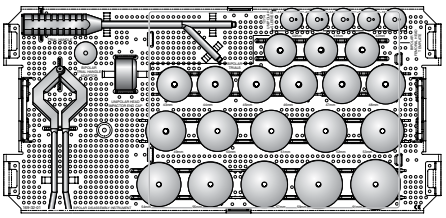
INSTRUMENT LISTING

Catalog Number	Part Description
169-31-02	**Novation CFS Broach Tray**
101-09-00*	Centralizer Sizer
161-01-01	Offset Stem Inserter
161-02-00	Novation Broach Handle
161-02-09	Novation Tapered Broach, Size 9
161-02-10	Novation Tapered Broach, Size 10
161-02-11	Novation Tapered Broach, Size 11
161-02-12	Novation Tapered Broach, Size 12
161-02-13	Novation Tapered Broach, Size 13
161-02-14	Novation Tapered Broach, Size 14
161-02-15	Novation Tapered Broach, Size 15
161-02-16	Novation Tapered Broach, Size 16
161-02-17	Novation Tapered Broach, Size 17
161-02-18	Novation Tapered Broach, Size 18
167-00-01*	Novation A+ Hudson Femoral Corkscrew
301-07-70*	Hudson T-Handle



*Special order

Catalog Number	Part Description
169-32-01	Novation Bipolar Tray

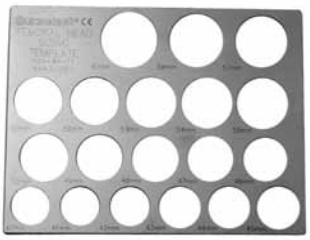


103-44-01	Bipolar Disassembly

103-44-02	Bipolar Trial Handle, Angled

103-44-03	Bipolar Trial Handle Adapter

103-44-11	Bipolar Femoral Head Template



103-44-40	Bipolar Trial, 40mm
103-44-41	Bipolar Trial, 41mm
103-44-42	Bipolar Trial, 42mm
103-44-43	Bipolar Trial, 43mm
103-44-44	Bipolar Trial, 44mm
103-44-45	Bipolar Trial, 45mm
103-44-46	Bipolar Trial, 46mm
103-44-47	Bipolar Trial, 47mm
103-44-48	Bipolar Trial, 48mm
103-44-49	Bipolar Trial, 49mm
103-44-50	Bipolar Trial, 50mm
103-44-51	Bipolar Trial, 51mm
103-44-52	Bipolar Trial, 52mm
103-44-53	Bipolar Trial, 53mm
103-44-54	Bipolar Trial, 54mm
103-44-55	Bipolar Trial, 55mm
103-44-57	Bipolar Trial, 57mm
103-44-59	Bipolar Trial, 59mm
103-44-61	Bipolar Trial, 61mm

103-61-97*	Unipolar Trial Adapter, 12/14, O-Ring, -3.5mm
103-61-00*	Unipolar Trial Adapter, 12/14, O-Ring, +0mm
103-61-03*	Unipolar Trial Adapter, 12/14, O-Ring, +3.5mm
103-61-07*	Unipolar Trial Adapter, 12/14, O-Ring, +7mm
103-61-10*	Unipolar Trial Adapter, 12/14, O-Ring, +10mm

*Special order

For additional device information, refer to the Exactech Novation Hip System – Instructions for Use.

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.

Authorized European Representative
MediMark® Europe
11, rue Emile Zola B.P. 2332
38033 Grenoble Cedex 2
France

Worldwide Offices

Exactech Corporate Headquarters

2320 NW 66th Court
Gainesville, FL 32653 USA
Tel: +1 800-EXACTECH
+1 352-377-1140
Fax: +1 352-378-2617
+1 800-329-3922

Exactech Asia

Room 825 CIMIC Tower
1090 Century Boulevard
Pu Dong, Shanghai 200120
P.R. China
Tel: +86 21-5835-3677
Fax: +86 21-5054-1683

Exactech Canada

2-3055 Homestead Drive
Mount Hope, ON
LOR 1W0
Canada
Tel: +1 866-549-7600
+1 905-679-1100
Fax: +1 905-679-1200

Exactech Japan

1-23-1, Ooi, Shinagawa-ku
Tokyo 140-0014
Japan
Tel: +81 3-37-781200
Fax: +81 3-37-781300

Exactech United Kingdom

Grosvenor House
Prospect Hill, Redditch
B97 4DL United Kingdom
Tel: +44 1527-591-555
Fax: +44 1527-591-044

France Medica
A subsidiary of Exactech

Parc D'Innovation
Le Pythagore BP 40154
Rue Jean Sapidus
67404 Illkirch Cedex, France
Tel: +33 388-673-712
Fax: +33 388-664-420

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352-377-1140
1-800-EXACTECH
www.exac.com

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