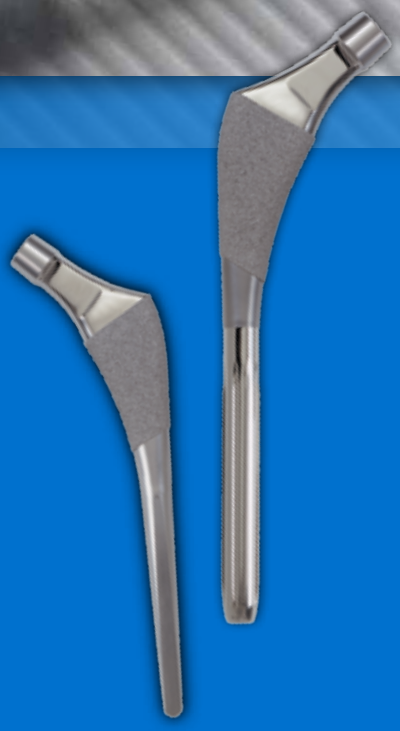
EXACTECH | HIP



NOVATION®
Comprehensive Hip System

Femoral Stems

Exactech®

NOVATION®

Comprehensive Hip System

In Latin, it's the root of innovation. In orthopaedic surgery, it's the ultimate goal. At Exactech, it's a multi-faceted system of the most outstanding innovations in hip replacement. For the surgeon, Novation means stable reconstruction, with the best and brightest in bearing alternatives, for the widest range of anatomies.

To the patient, it means a renewed outlook on life.

A Masterfully Crafted Plan

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 a variety of situations 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.

The Novation femoral system includes:

Femoral Stems — The Novation system femoral stem offering is designed to meet a wide range of fixation philosophies such as proximally loaded fit-and-fill press-fit stems, stems with adjunctive distal rotational control and a tapered-wedge option that facilitates insertion in smaller incisions and accommodates various surgical approaches. A cemented version also is available for those situations where a press-fit stem may not be the best option for the patient. This family of femoral stems features design elements required for today's active patients such as a neck geometry that allows for greater range of motion as well as a variety of offsets to accommodate varying anatomies. A low-demand version is available to provide for the specialized needs of patients with fractures or minimal physical activity.

Instrumentation — A core set of instruments supports the fit-and-fill press-fit options while allowing the surgeon to easily switch to a cemented stem intra-operatively should the need arise. This same set of core instruments also will allow the low-demand version to be implanted without any change in surgical technique. The tapered-wedge stem utilizes a similar set of instrumentation and can be used in a variety of surgical approaches including the direct anterior approach.

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Novation Tapered, Splined & Cemented Plus

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

Tapered stems rely on proximal fixation and three-point contact for initial stability. The dual-taper design, with a gradual taper in the M/L plane and a more rapid transition in the A/P plane, accommodates the anterior bow of the femur while providing the wedge effect needed for stability.

Cemented Plus stems are designed to utilize the same instruments used with the Tapered and Splined preparation. This allows for simple preparation and ease of intra-operative transition to a cemented stem should the need arise.

Splined stems also rely on proximal fixation for initial stability and are enhanced by the distal splines for added rotational stability. In cases of proximal/distal mismatch, the Splined stem is also available in a Reduced Distal Diameter (RDD) option. A coronal slot reduces stiffness of the stem by up to 20 percent in the larger sizes.[1]

Novation primary femoral press-fit stem sizes range from 9mm to 18mm (in 1mm increments) near the midpoint of the stem.

A A 12/14 neck taper allows coupling with numerous bearing surfaces.

B Highly polished neck cross-section is minimized on the medial aspect to increase range of motion, decreasing the chance of post-operative dislocation, while material on the lateral side is maintained for strength.[2]

C Independent insertion/extraction features on the press-fit stem allow the stems to be inserted in a controlled manner or removed without damaging the neck of the implant.

D Circumferential titanium plasma coating provides the scratch fit necessary for initial mechanical fixation.[3,4] Hydroxyapatite (HA) coating is an option on both the tapered and splined stems. The 45 micron HA coating is in an optimal thickness range.[5]

E Patented distal tip design reduces stress concentration at the distal stem and bone interface, which has been shown to reduce the incidence of thigh pain.[6,7]

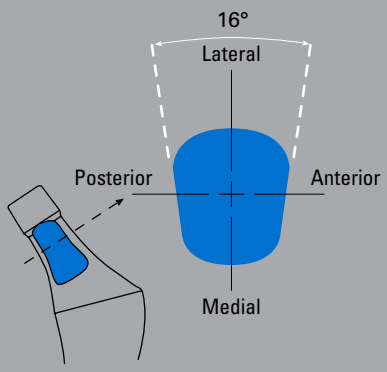
F Splines on the highly polished distal portion of the stem add 1mm press fit to provide rotational resistance and allow proximal load sharing. A RDD option in the Splined femoral stem allows for a distal geometry that is 2mm smaller in diameter than the standard Splined stem.

Stable Reconstruction

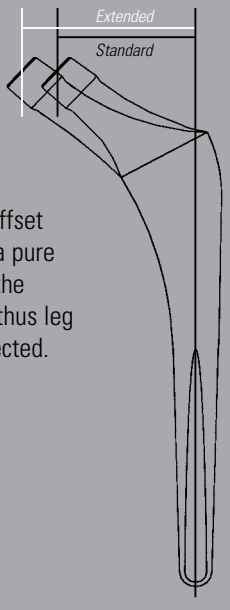
Novation femoral stems have been designed to enhance both initial and long-term stability of the implant within the femoral canal as well as provide options to ensure a stable construct within the joint capsule.

Stability...in Motion

As the major complication in total hip arthroplasty, many efforts are designed to reduce the incidence of dislocation. The Exactech signature neck cross-section is minimized on the medial aspect to increase range of motion, decreasing the chance of post-operative dislocation, while material on the lateral side is maintained for strength.



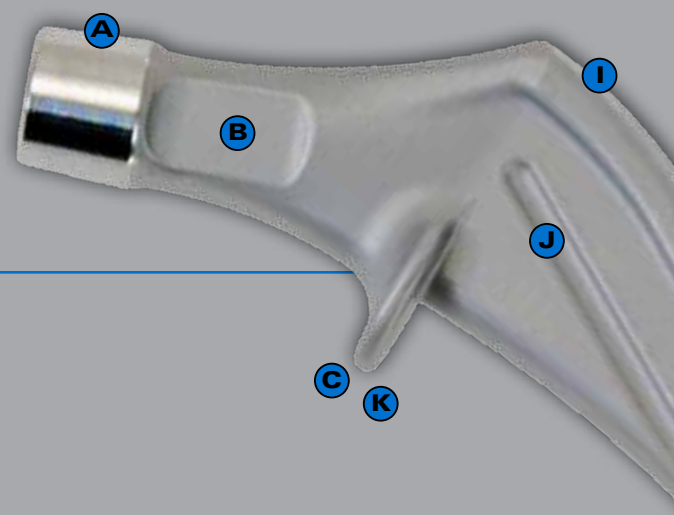
A 131-degree neck angle has been shown to effectively reproduce femoral anatomy in most patients.[9,10] The Novation stems feature two offset options while maintaining the same neck angle. This allows tensioning of the joint capsule without affecting leg length.



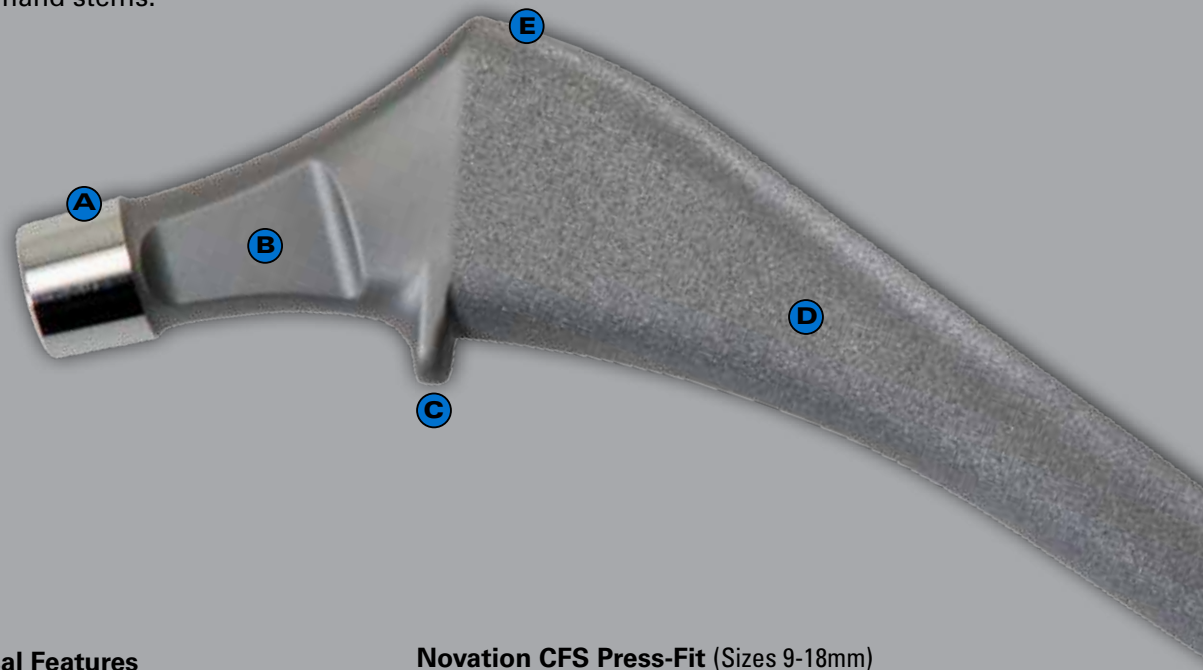
The extended offset is achieved by a pure lateral shift of the proximal neck; thus leg length is unaffected.

- **G** Parabolic tip design provides gradual stress transfer at the distal bone interface[8]
- **H** Cobra flange enhances stem stability
- **I** Collar enhances cement pressurization and stress transmission to medial femoral neck
- **J** Forged cobalt chrome maximizes fatigue strength
- **K** Distal PMMA centralizer ensures consistent cement mantle.

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 and Splined preparation. This allows for simple preparation and utilization of the same instrumentation for both low- and high-demand stems.

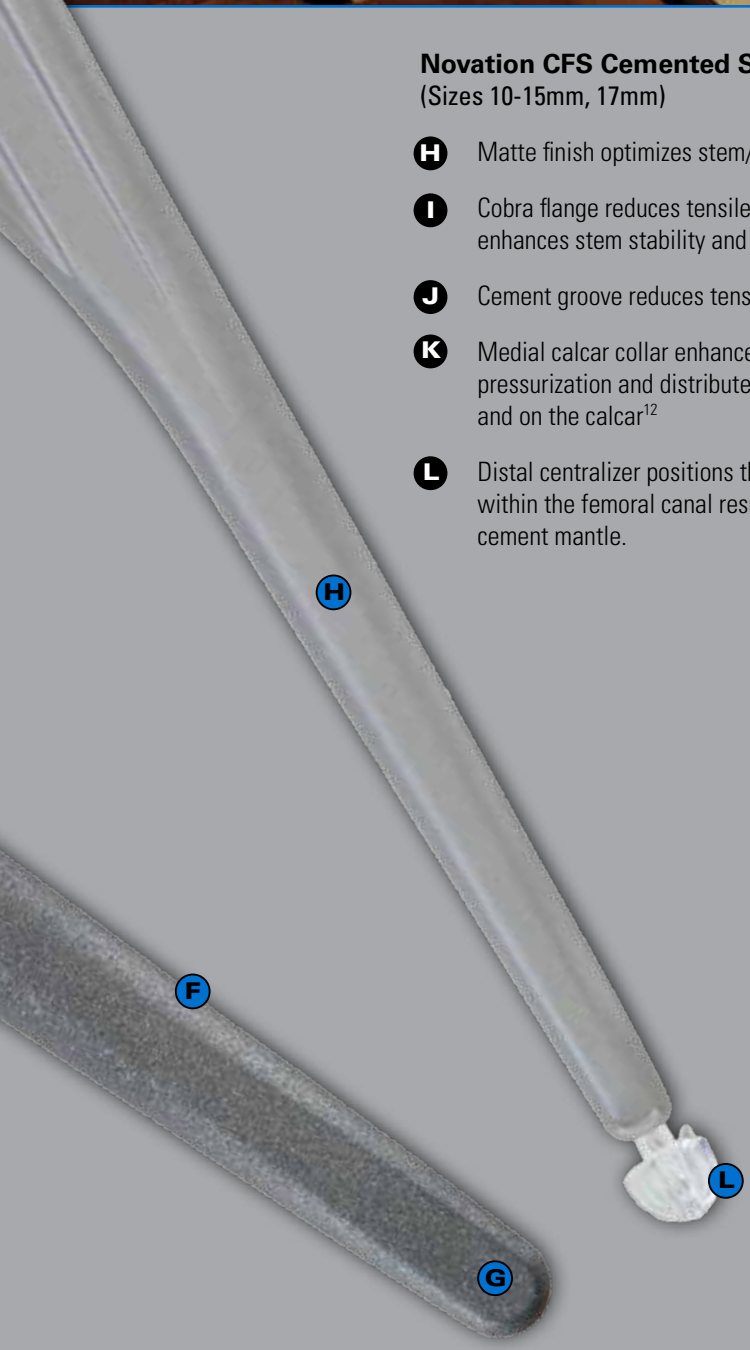


Novation CFS Universal Features

- **A** 12/14 taper is compatible with Cobalt Chrome and Ziramic™ Zirconia femoral heads in varying sizes, which provides optimal range of motion and enhanced intra-operative flexibility
- **B** Neck cross-section is minimized on the medial aspect to increase range of motion, decreasing the chance of post-operative dislocation, while material on the lateral side is maintained for strength.[2]
- **C** Available in Collared (Standard Offset) only.

Novation CFS Press-Fit (Sizes 9-18mm)

- **D** Grit blast titanium surface designed to provide initial and long-term stability[11]
- **E** Trapezoidal cross-section to provide rotational stability, proximal fit and A/P fill[12]
- **F** Shortened overall length, with 3-degree taper in the M/L and a 5-degree taper in the A/P plane, allowing for three-point fixation
- **G** Patented distal tip design reduces stress concentration at the distal stem and bone interface, which has been shown to reduce the incidence of thigh pain.[6,7]



Novation CFS Cemented Sizes
(Sizes 10-15mm, 17mm)

- **H** Matte finish optimizes stem/cement interface[12]
- **I** Cobra flange reduces tensile cement stresses and enhances stem stability and cement performance[12]
- **J** Cement groove reduces tensile stresses in cement[12]
- **K** Medial calcar collar enhances cement pressurization and distributes stress in the bone and on the calcar[12]
- **L** Distal centralizer positions the stem centrally within the femoral canal resulting in an even cement mantle.

Unipolar Design Advantages

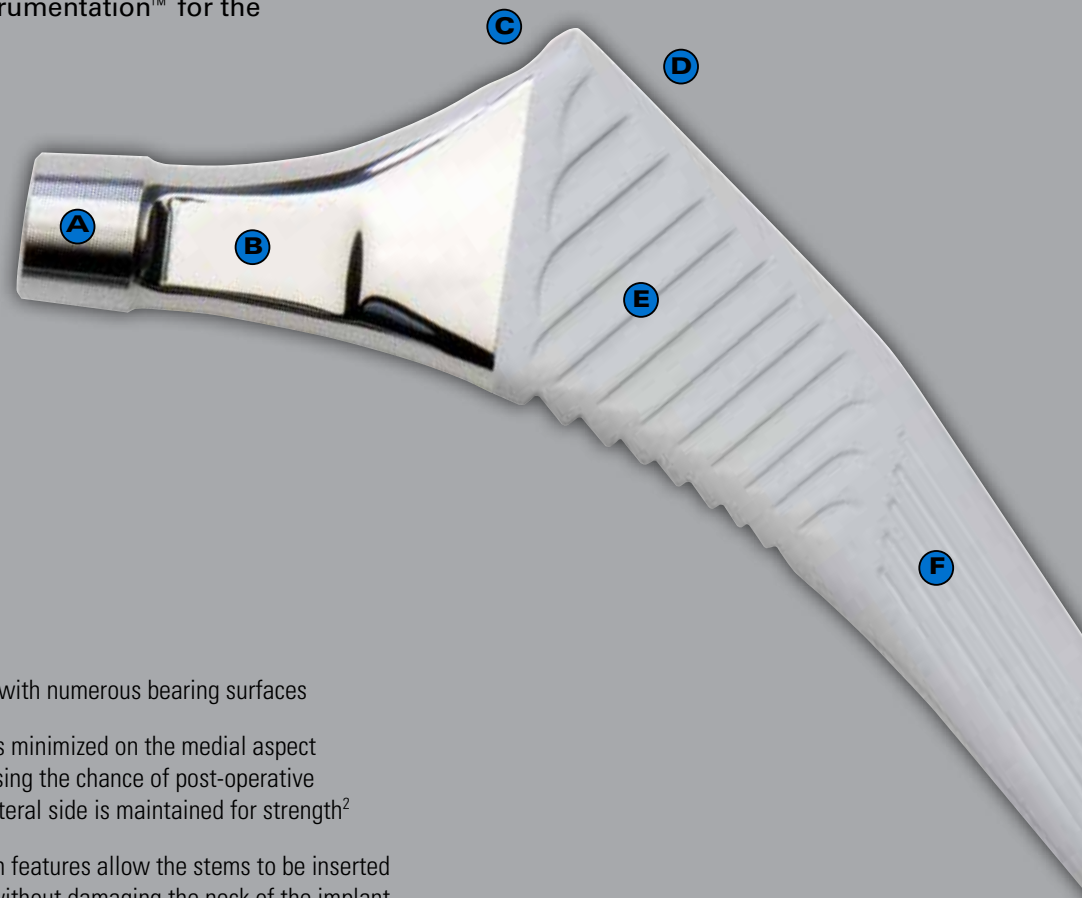
- Modular design
- Five neck-length options: -3.5mm, +0mm, +3.5mm, +7mm, +10mm
- Fully machined wrought cobalt chrome shell designed for accurate fit and minimized wear
- Precision-machined tapers designed for optimum locking capabilities

Bipolar Design Advantages

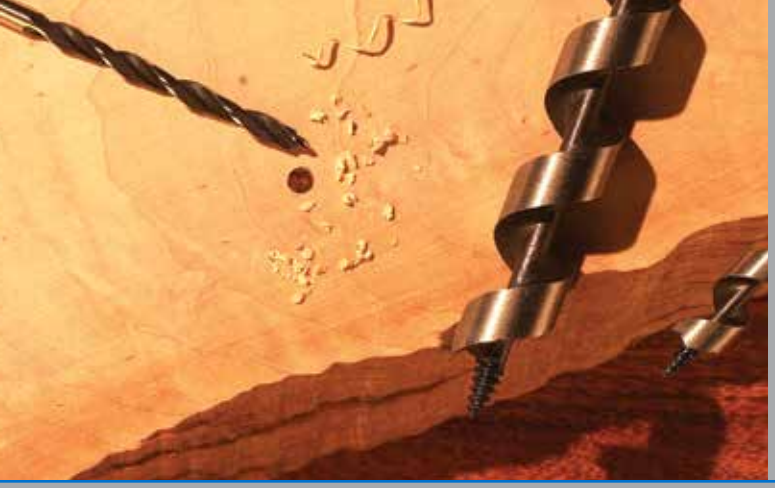
- Easy assembly with hand pressure
- Excellent locking integrity
- Disassembles with one simple instrument
- Designed to maximize polyethylene durability
- Optimal positive eccentricity throughout range of sizes
- Precision-machined forged cobalt chrome shell designed for accurate fit and minimized wear

Novation® Element®

The Novation® Element's® tapered-wedge stem philosophy, combined with Exactech's signature neck geometry, is designed to provide surgeons with excellent initial fixation and long-term stability paired with the Novation Element standard instrumentation or the Novation Element A+ Instrumentation™ for the direct anterior approach.



- **A** A 12/14 neck taper allows coupling with numerous bearing surfaces
- **B** Highly polished neck cross-section is minimized on the medial aspect to increase range of motion, decreasing the chance of post-operative dislocation, while material on the lateral side is maintained for strength[2]
- **C** Independent insertion and extraction features allow the stems to be inserted in a controlled manner or removed without damaging the neck of the implant
- **D** The tapered-wedge geometry with a low-profile lateral shoulder facilitates insertion in smaller incisions and various surgical approaches
- **E** Horizontal proximal grooves convert hoop stress to compressive loads
- **F** Extensively HA coated. HA coating has been shown to provide the potential for initial fixation.[5]



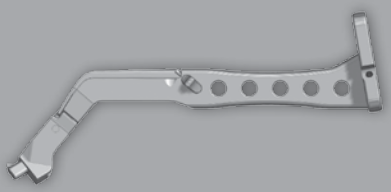
Low-Profile Instrumentation

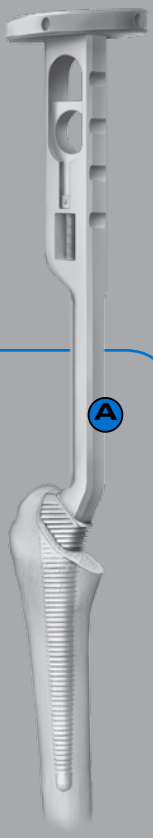
The Novation "Low Profile" family of instruments provides implant-specific tools to support the surgeon's effort to minimize incision size, reduce soft tissue trauma and optimize patient outcomes. Unique instruments like the calcar planer with a replaceable blade ensure that the instrument is always sharp, providing easier preparation of the medial calcar.

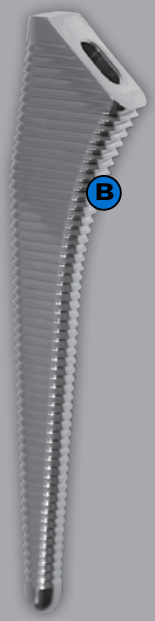
Novation A+ Instrumentation

With intuitive instrumentation, the Novation A+ Instruments are designed to facilitate the muscle-sparing anterior approach in a wide range of patients. The Novation A+ Instruments include a complete set of retractors designed specifically to facilitate the direct anterior approach as well as an anterior-specific canal finder, Novation A+ Box Osteotome and Novation A+ Lateralizing Broach.

Novation A+ Broach Handle – The key to clearing soft tissue while preparing the femur is not only mobilization of the femur through proper soft tissue management, but also having instruments that are offset. The side-specific broach handle has offsets in the anterior and lateral plane as well as an external twist at the connection to the broach. These features, combined with alignment markings on the strike plate, allow for broach impaction and removal clearance even in overweight patients.







A Broach Handle
The Novation Broach Handle allows visualization of the proximal femur as it is being prepared due to its low-profile geometry. In addition, the broach handle can be easily assembled and disassembled from the broach so the flow of the surgical procedure is not interrupted.

B Compaction Broaches
The Novation system broaches are designed to be bone conserving while still enabling accurate preparation of the femoral cavity. Utilizing these broaches, the surgeon prepares the femur by compacting and reshaping, not removing, the intramedullary canal for optimal implant stability.

C Offset Stem Inserter
This low-profile instrument allows control for the placement of the final femoral stem in a single, controlled manner while preventing impingement of the greater trochanter during impaction.

A Great Day in the O.R.℠

Founded by an orthopaedic surgeon and bio-medical engineer, Exactech is committed to making every day a great day in the O.R.—for the surgeon, the O.R. staff and above all, for the patient.

Along with innovative implants and instrumentation for total joint replacement, Exactech provides pre-primary, bone cement and biological solutions to meet your needs throughout the entire case.

Experience Exactech. *A Great Day in the O.R.℠*

Novation Crown Cup®

With a goal of creating a more stable hip replacement, the Novation Crown Cup uses a sizing scheme that allows the largest head possible while maximizing polyethylene thickness. Crown Cup acetabular shell configurations include no-hole, cluster-hole and multi-hole shells with titanium plasma spray coating. Research has shown that titanium plasma spray is designed to provide excellent 'scratch fit' for initial stability and is proven as a bone friendly ongrowth surface.[13]

Novation Ceramic AHS®

The Novation Ceramic AHS is designed to minimize osteolysis by utilizing an alumina ceramic bearing that provides significantly lower wear debris generation over traditional bearing surfaces.[14,15] Offered in a cluster-hole configuration, the Ceramic AHS shells are designed with an 18-degree internal taper to provide a secure locking mechanism to minimize micromotion and backside wear.

Femoral Heads

Exactech offers three different modular femoral head options – Cobalt Chrome, Ziramic™ Zirconia and BIOLOX®*forte* Alumina – with multiple offsets to accommodate all types of patients' anatomies and surgeon philosophies.

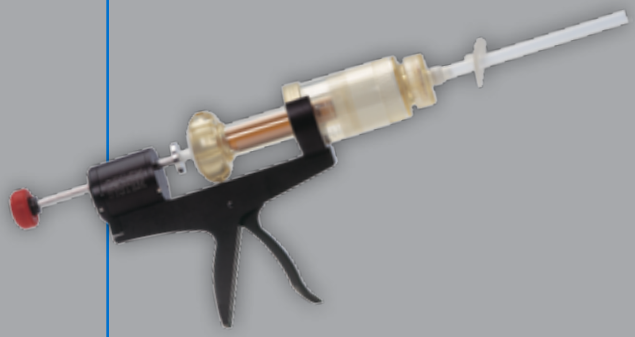
The commitment that defines the Exactech brand.

Biologic Solutions

Exactech is shaping the future of bone repair. Its full scope of biologic materials features demineralized bone matrix in a thermoplastic carrier, with or without cortical cancellous bone chips. For a bone graft that doesn't wash away, is 100 percent tested and terminally sterilized, Exactech Biologics are the natural choice.[16]

Accelerate® Concentrating System

Platelet rich plasma (PRP) gel has global applications in a variety of surgical procedures including total joint replacement, bone repair and facial cosmetic and reconstructive surgery. Its ability to speed healing and improve patient outcomes has been well documented.[17] The easy-to-use Accelerate Concentrating System provides a fast and convenient method for processing PRP in the operating room from a small amount of patient's blood.



Bone Cement

Cemex® bone cement features a unique low monomer formula that has been clinically proven in Europe for more than two decades.[18] Available in a self-contained delivery system or hand mix options, the Cemex family of products are designed to offer surgeons and operating room personnel simplicity, safety and reliability in bone cement.

InterSpace® Hip Spacer

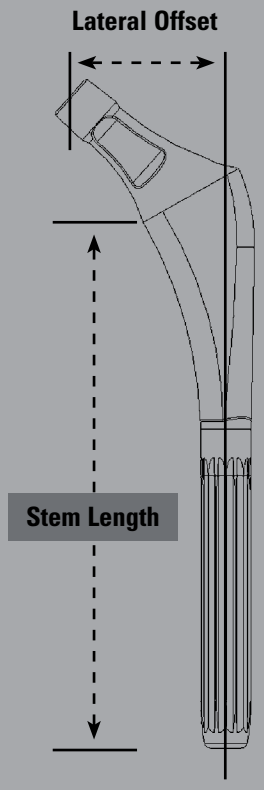
InterSpace® Hip is a pre-formed, partial load-bearing device consisting of Gentamicin-impregnated PMMA bone cement molded onto a stainless steel reinforcing core. It maintains joint space, allows limited mobility and provides for predictable, consistent antibiotic release locally.[19]

SYSTEM SPECIFICATIONS AND IMPLANT ORDERING INFORMATION

Tapered, Splined and Cemented Plus

Size (mm)	Stem Length (mm)**			Standard Lateral Offset with following head lengths (mm)					Extended Lateral Offset with following head lengths (mm)				
	Tapered*	Splined*	Cemented Plus	-3.5	+0	+3.5	+7	+10	-3.5	+0	+3.5	+7	+10
9	120	130	N/A	30	33	36	38	41	36	39	41	44	46
10	125	135	115	31	34	37	39	42	37	40	42	45	47
11	125	135	121	32	35	38	40	43	40	43	46	48	51
12	130	140	126	34	37	40	42	45	44	47	50	52	55
13	130	140	126	34	37	40	42	45	44	47	50	52	55
14	135	145	126	34	37	40	42	45	44	47	50	52	55
15	135	145	126	34	37	40	42	45	44	47	50	52	55
16	140	150	N/A	36	39	42	44	47	46	49	52	54	57
17	140	150	136	37	40	43	45	48	47	50	53	55	58
18	145	155	N/A	38	41	44	46	49	48	51	54	56	59

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



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

Element

Size (mm)	Stem Length (mm)**	Standard Lateral Offset with following head lengths (mm)					Extended Lateral Offset with following head lengths (mm)				
	Element	-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.*

CFS

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	N/A	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	N/A	36	39	42	44	47
17	140	136	37	40	43	45	48
18	145	N/A	38	41	44	46	49

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

FEMORAL STEM ORDERING INFORMATION

Tapered and Cemented Plus

Size (mm)	Tapered*				Cemented Plus	
	Standard Offset w/o HA	Standard Offset w/HA	Extended Offset w/o HA	Extended Offset w/HA	Standard Offset	Extended Offset
9	160-00-09	160-10-09	160-01-09	160-11-09	N/A	N/A
10	160-00-10	160-10-10	160-01-10	160-11-10	160-70-10	N/A
11	160-00-11	160-10-11	160-01-11	160-11-11	160-70-11	160-71-11
12	160-00-12	160-10-12	160-01-12	160-11-12	160-70-12	160-71-12
13	160-00-13	160-10-13	160-01-13	160-11-13	160-70-13	160-71-13
14	160-00-14	160-10-14	160-01-14	160-11-14	160-70-14	160-71-14
15	160-00-15	160-10-15	160-01-15	160-11-15	160-70-15	160-71-15
16	160-00-16	160-10-16	160-01-16	160-11-16	N/A	N/A
17	160-00-17	160-10-17	160-01-17	160-11-17	160-70-17	160-71-17
18	160-00-18	160-10-18	160-01-18	160-11-18	N/A	N/A

Splined and Splined RDD

Size (mm)	Splined*				Splined RDD*			
	Standard Offset w/o HA	Standard Offset w/HA	Extended Offset w/o HA	Extended Offset w/HA	Standard Offset w/o HA	Standard Offset w/HA	Extended Offset w/o HA	Extended Offset w/HA
9	160-20-09	160-30-09	160-21-09	160-31-09	N/A	N/A	N/A	N/A
10	160-20-10	160-30-10	160-21-10	160-31-10	N/A	N/A	N/A	N/A
11	160-20-11	160-30-11	160-21-11	160-31-11	160-22-11	160-32-11	160-23-11	160-33-11
12	160-20-12	160-30-12	160-21-12	160-31-12	160-22-12	160-32-12	160-23-12	160-33-12
13	160-20-13	160-30-13	160-21-13	160-31-13	160-22-13	160-32-13	160-23-13	160-33-13
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16	160-20-16	160-30-16	160-21-16	160-31-16	160-22-16	160-32-16	160-23-16	160-33-16
17	160-20-17	160-30-17	160-21-17	160-31-17	160-22-17	160-32-17	160-23-17	160-33-17
18	160-20-18	160-30-18	160-21-18	160-31-18	160-22-18	160-32-18	160-23-18	160-33-18

CFS

Size (mm)	CFS Press-Fit* Standard Offset	CFS Cemented Standard Offset
9	168-00-09	N/A
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	N/A
17	168-00-17	168-50-17
18	168-00-18	N/A

Element

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

**Stem diameter is measured midshaft*

References

1. Data on file at Exactech.
2. **Sychterz CJ, Claus AM, Engh CA.** What we have learned about long-term cementless fixation from autopsy retrievals. *Clin Orthop Relat Res.* 2002 Dec;(405):79-91.
3. **Hoaglund FT, Low WD.** Anatomy of the femoral neck and head, with comparative data from Caucasians and Hong Kong Chinese. *Clin Orthop Relat Res.* 1980 Oct;(152):10-6.
4. **Emerson RH Jr, Sanders SB, Head WC, Higgins L.** Effect of circumferential plasma-spray porous coating on the rate of femoral osteolysis after total hip arthroplasty. *J Bone Joint Surg Am.* 1999 Sep;81(9):1291-8.
5. **Geesink R, de Groot K, Klein CP.** Chemical implant fixation using hydroxylapatite coatings. The development of a human total hip prosthesis for chemical fixation to bone using hydroxylapatite coatings on titanium substrates. *Clin Orthop Relat Res.* 1987 Dec;(225):147-70.
6. U.S. Patent #5,152,799.
7. **Englehardt JA, Tomaszwski PR.** Hip stem and tip geometry: a theoretical model for thigh pain. Proceedings of the 37th Annual Meeting of the Orthopaedic Research Society. 1991, p. 270.
8. **Petty W.** Thigh pain following cementless total hip implantation addressed by new femoral design. *Orthopedic Special Edition,* Vol. 2 No. 2.
9. **Robinson RP, Simonian PT, Gradisar IM, Ching RP.** Joint motion and surface contact area related to component position in total hip arthroplasty. *J Bone Joint Surg Br.* 1997 Jan; 79(1):140-6.
10. **Noble PC, Alexander JW, Lindahl LJ, Yew DT, Granberry WM, Tullos HS.** The anatomic basis of femoral component Design. *Clin Orthop Relat Res.*1988 Oct;(235):148-65.
11. Data on file at Exactech. TR-2009-023. Clinical evaluation of the Exactech hip systems femoral stems.
12. **Petty W**. Results of primary total hip arthroplasty. In: *Total Joint Replacement.* Ed. by W. Petty. Philadelphia, W.B. Saunders Co., 1991,p. 315-48.
13. Data on file at Exactech. 711-12-80. Titanium plasma spray technical profile.
14. **Taylor SK, Serekian P, Manley M.** Wear performance of a contemporary alumina: Alumina bearing couple under hip joint simulation. Trans. 44th Annual Meeting, ORS, 51, 1998.
15. **Greenwald AS, et al.** Alternative Bearing Services. *J Bone Joint Surg Am.* 2001; 83:68-S72.
16. Data on file at Exactech. 713-00-90. Opteform/Optefil Testing Summary.
17. **Pietrzak WS, Eppley BL.** Platelet rich plasma: biology and new technology. *J Craniofac Surg.* 2005 Nov;16(6):1043-54.
18. **Nivbrant B, Kärrholm J, Röhrl S, Hassander H, Wesslén B.** Bone cement with reduced proportion of monomer in total hip arthroplasty: preclinical evaluation and randomized study of 47 cases with 5 years' follow-up. *Acta Orthop Scand.* 2001 Dec; 72(6):572-84.
19. **Bertazzoni Minelli E, Benini A, Magnan B, Bartolozzi P.** Release of gentamicin and vancomycin from temporary human hip spacers in two-stage revision of infected arthroplasty. *J Antimicrob Chemother.* 2004 Feb;53(2):329-34. Epub 2003 Dec 19.

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