



UNITED
ORTHOPEDIC®

DESIGN RATIONALE

Conformity™ Stem Femoral Hip System

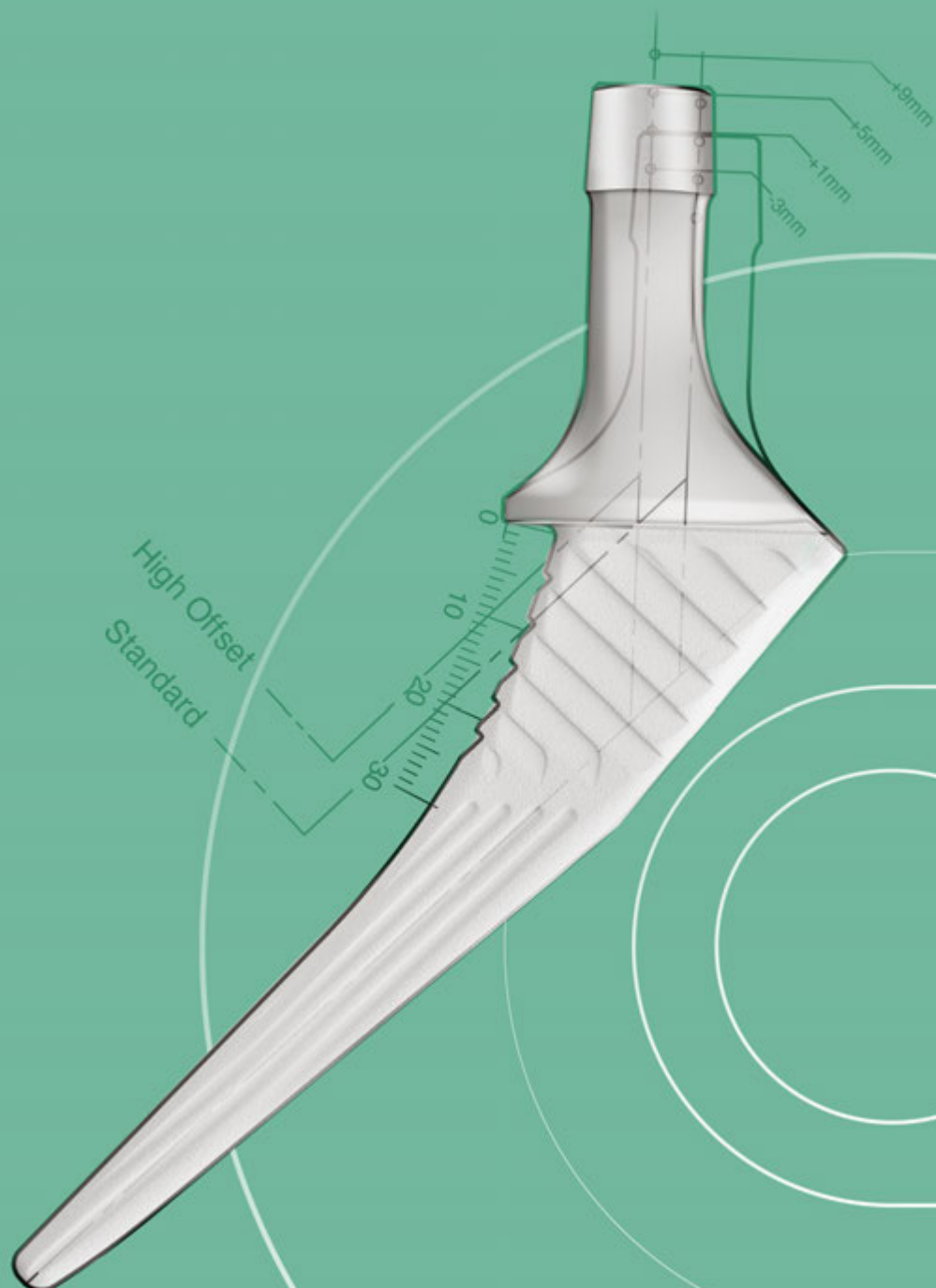


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ABOUT CONFORMITY

Established in 1993, United places great importance on 'Integrity,' 'Innovation,' and 'Quality.'

Driven by an 'Each Step We Care' philosophy, we focus on continual and genuine collaborative efforts in Research and Development to design and develop innovative and adaptive products and services to satisfy and meet evolving needs within the orthopedic community.

Conformity follows the classic concept of a fully-hydroxyapatite (HA) coating on the stem. It is designed based upon the well-documented Corail Stem, to facilitate stem fixation, an important and noteworthy feature for implant stability and longevity.

- Collared -

Standard
11 sizes



High Offset
11 sizes



Coxa Vara
10 sizes



Short Neck
3 sizes



The collared hip stem structure provides support at the medial metaphysis to help avoid stem subsidence after insertion.

Offering solutions for lower neck-shaft angles or smaller sized patients with a shorter femoral neck from an anatomical perspective.

Conformity is a comprehensive hip arthroplasty solution platform, consisting of 77 stems with multiple neck options; collared and collarless features which provide additional structural support for stem fixation; and cementless and cemented options to offer surgeons with various solutions for clinical situations and to provide the implant that best meets the patient's needs. Optimized dimensional parameters are applied to the stem design to maximize biomechanical advantages and to facilitate long-term implant fixation.

- Collarless -

Standard
11 sizes



High Offset
11 sizes



Basic stem design with Standard and High Offset options enable the surgeon to finely adjust the soft tissue tension to achieve joint stability.

- Cemented -

Standard
10 sizes



High Offset
10 sizes



An alternate solution when encountering poor bone quality, insufficient stability due to bone loss, or ambiguous canal geometry.

STEM STABILITY

Fully Coated HA Stem Options

Global registries have reported increasing trends towards younger, more active population groups who benefit from better 10-year stem survivorship with cementless stems^[1-3]. The Conformity cementless stem offers 155 µm of fully coated HA (Figure 1) to advance osseointegration for prolonged implant longevity.

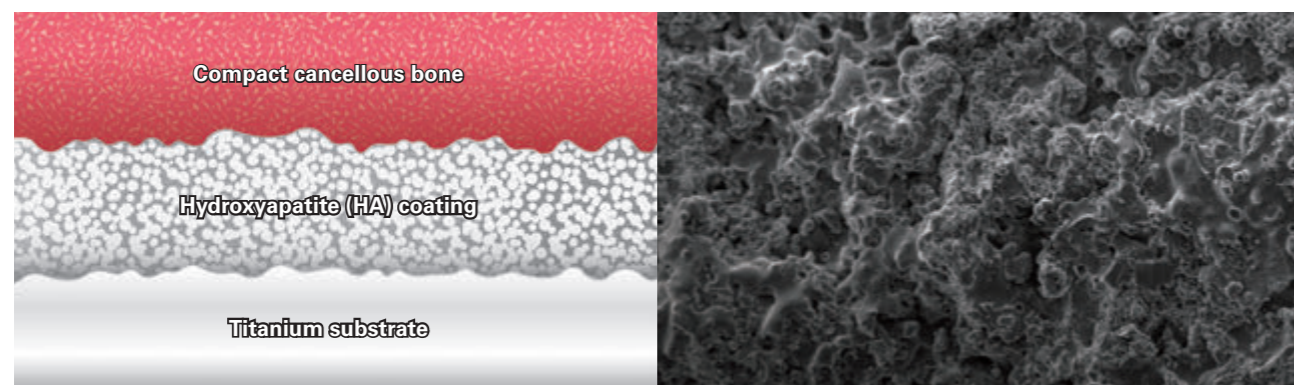


Figure 1: (Left) HA coating layers produce roughened surfaces that interact and tightly compact cancellous bone beds to establish a stable primary fixation^[4,5]. (Right) The microscopic view of Conformity HA coating layer^[5].

The titanium stem is coated with a denser HA coating layer to facilitate adhesion onto the stem surface without adversely affecting coating performance^[6]. Overtime, the gradual dissolution of the thick HA coating layer will release HA composites with osteoconductive properties to promote bone osseointegration onto the stem surface^[6-8]. The release of sufficient HA composites will be necessary to achieve successful secondary fixation, reducing early aseptic loosening, and prolonging implant longevity^[7,9].

Shifting Cross-Sectioned Geometry

Conformity is designed with quadrangular cross-sections and a thin conical tip (Figure 2) to provide initial fixation and stability. Uniquely shifting cross-sectioned geometries towards the distal region facilitates the gradual reduction of stiffness gradients, lowering distal mechanical stresses to minimize stress shielding complications, such as cortex thinning^[3,8].

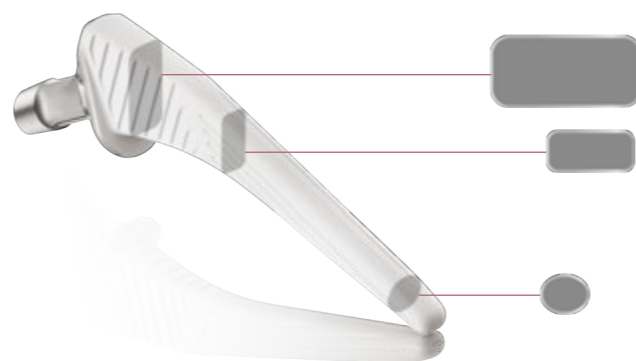


Figure 2: Conformity stem is characterized by its uniquely shifting stem geometries^[5].

The proximally flared and tapered region facilitates cancellous bone compaction to establish a dense cancellous bone bed for 4-point fixation (Figure 3), enhancing axial and rotational stability through mechanical stem anchorage^[8,10].

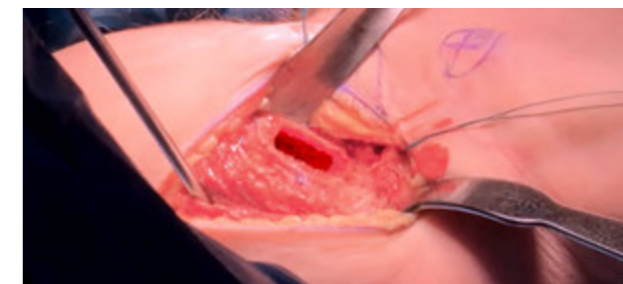


Figure 3: Tapered stem geometry forms tightly compacted cancellous bone beds, providing rigid mechanical stem anchorage for stable primary stability^[10].

Proximal Medial Stepped Structure

Conformity is designed with medial stepped structures at the proximal region to reduce the risk of intraoperative hoop-stress fractures and improve stem loading profiles.

During implantation, the differing mechanical properties between bone and stem significantly alter internal loading mechanisms, causing unnatural formations of hoop stresses at the proximal region. Thus, increasing the risk of intraoperative hoop-stress fractures^[8,11-14].

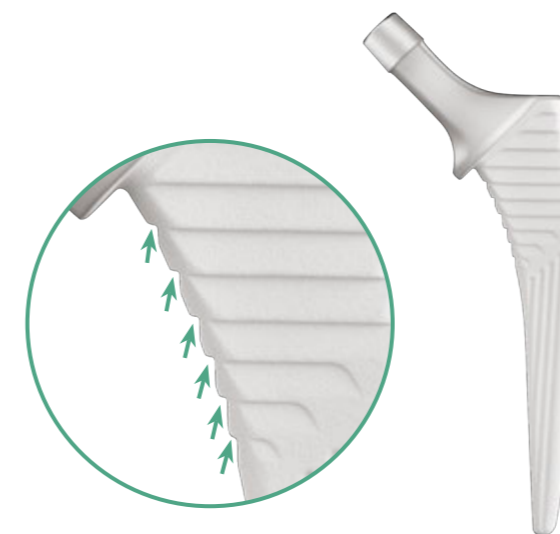


Figure 4: The Conformity's medial stepped structures reduce medial loading stresses by transferring medial load patterns into compressive load patterns. Thus, minimizing stress shielding complications, facilitating axial stability and minimizing stem subsidence^[5].

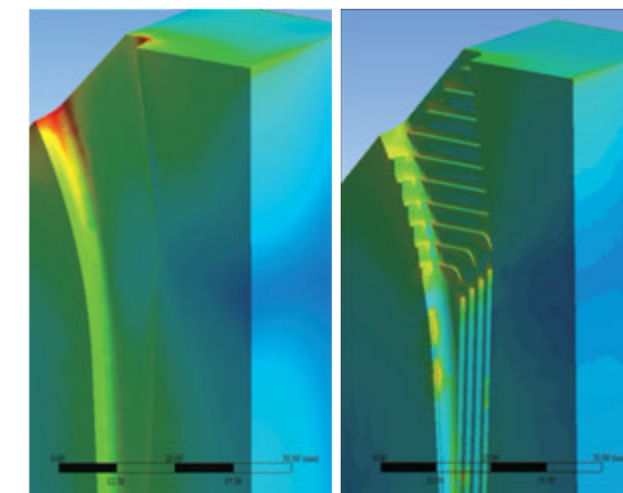


Figure 5: The simulation model of (Right) Conformity demonstrates a lower medial stress loading profile compared to (Left) the one without stepped structure^[5].

Medial stepped structures (Figure 4) promote more efficient transfer of hoop stress at the medial proximal region to compressive stresses, aiding in the formation of tightly compacted cancellous cell beds for better stem stability during impaction. The transfer of compression load patterns at the proximal region reduces overloading at the distal region (Figure 5), minimizing stress shielding complications^[13].

Stepped & Grooved Structures

Conformity is designed with horizontal steps at the proximal region and vertical grooves at the distal region to increase bone-implant contact interfaces, enhancing initial stem fixation and improving joint stability by minimizing the risks of stem subsidence and aseptic loosening^[13].



Horizontal steps in the anterior, posterior and medial surfaces resist compressive loading, enhancing axial stability to minimize stem subsidence and enhance stem fixation^[13,15].

Vertical grooves in all distal surfaces resist torque and shear stresses, enhancing rotational stability to minimize aseptic loosening^[16-18]. In addition, grooved structures at the distal region facilitate reduced mechanical stresses by lowering stiffness gradients to closely resemble surrounding bone environment^[11,13].



Collared & Collarless Cementless Stems

Collared Option

Conformity requires good primary stability to encourage good long-term osseointegration. A collared structure achieves immediate primary implant stability by providing these patients with an additional structural support to minimize stem subsidence and 'windshield wiping' effects^[13,19]. Thus, ensuring proper primary implant positioning to advance long-term bone osseointegration. In addition, the collared structure may accelerate patient recovery with immediate weight-bearing activities^[3,8].



Collarless Option

A collarless cementless Conformity option relies on the rigid primary fixation of the stem and the gradual dissolution of the HA coating to release composites with osteoconductive properties to promote bone osseointegration onto the stem surface for long-term fixation.

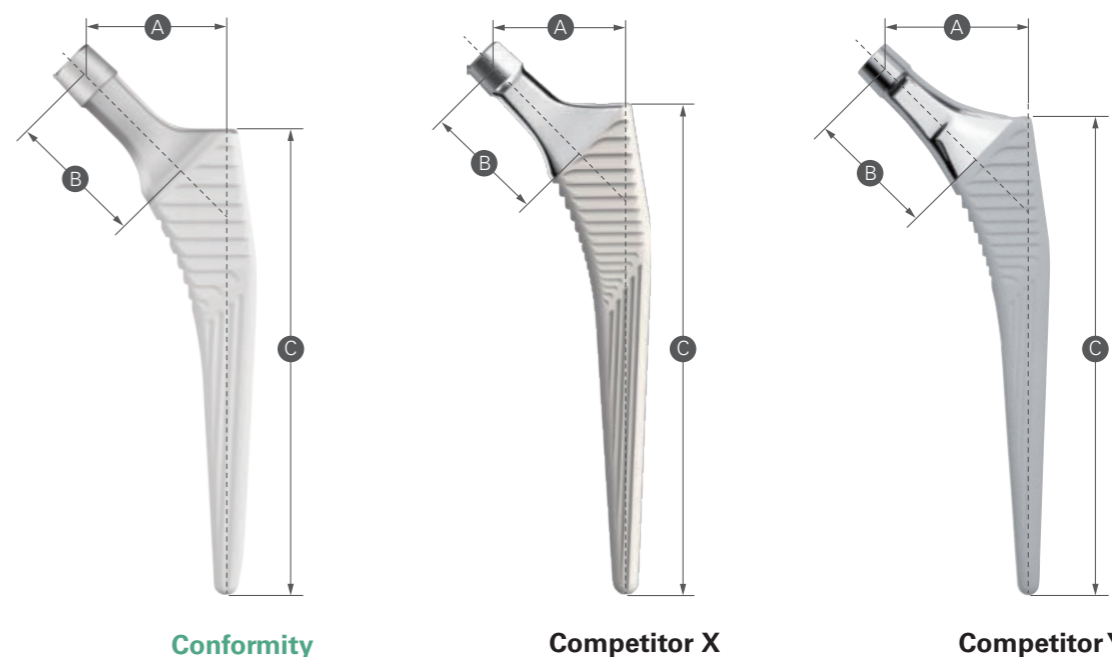


Collarless stems display similar mid-term survivorship to collared stems when stabilized. Hence, the choice between a collared and collarless femoral stem will be largely based on surgeon preference^[20].

BONE PRESERVATION

Small Stem Profile

Conformity has a smaller stem profile with a shorter stem length compared to Competitor X and a shorter neck offset compared to Competitor X and Y. Thus, achieving improved bone preservation by facilitating more bone retention, especially important with the growing trend of younger and more active patients who may require potential revision surgeries^[1-3,14].



A Offset			B Neck Length		C Stem Length		
Conformity	Competitor X	Competitor Y	Conformity	Competitor X	Conformity	Competitor X	Competitor Y
36	38.3	39	35.5	39	115	115	94
36.5	38.8	40			119.5	130	109
37.5	39.5	40			124	140	119
38	40.3	41			128.5	145	124
39	41	42			133	150	129
39.2	41.7	43			137.5	155	134
40	42.3	43			142	160	139
41	43	44			146.5	165	144
41.5	43.8	45			151	170	149
42.5	44.8	46			155.5	180	159
43.5	45.8	47			160	190	169

*These competitor stems are currently commercially marketed devices.

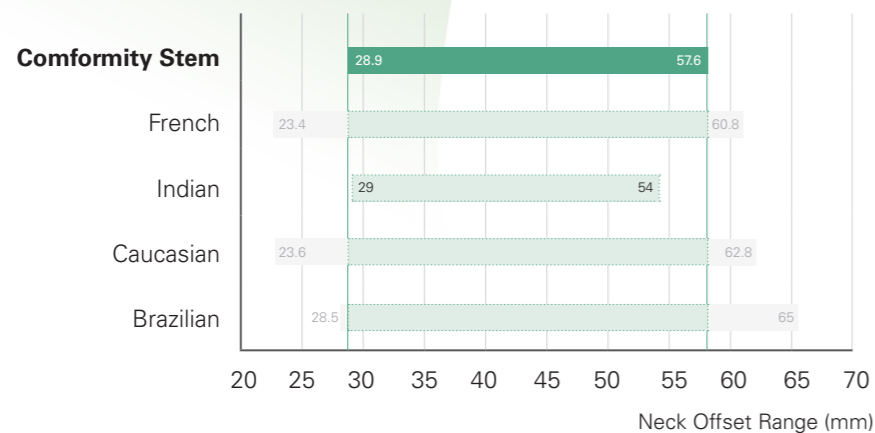
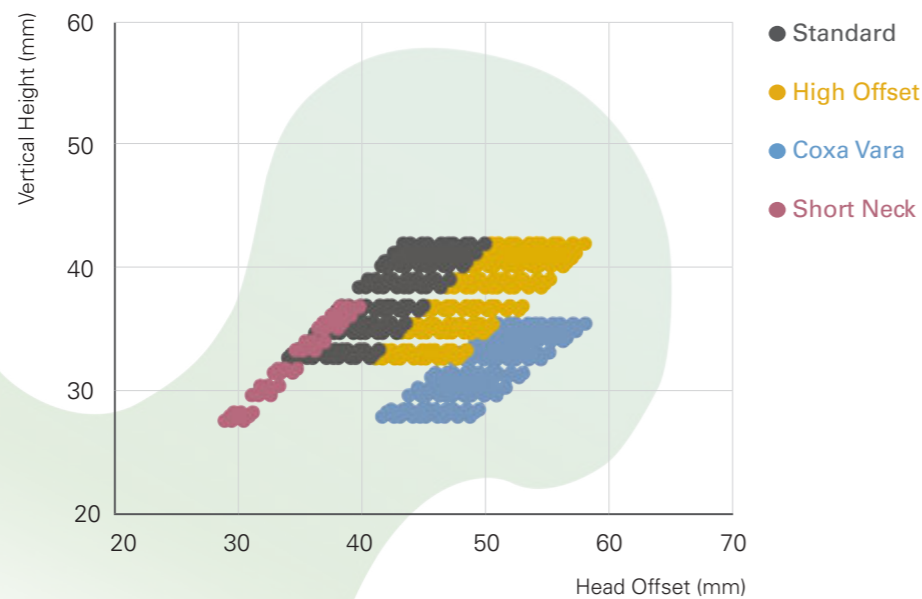
Unit : mm

JOINT RESTORATION

Neck Offset Option

The neck offset configurations (Standard, High Offset, Short Neck, Coxa Vara) and head offset adjustments of Conformity are able to achieve a femoral head offset range within 28.9 mm and 57.6 mm. Based on several anthropometric studies on different patient population, these configurations are sufficient to cover a large majority of anthropometric measurements from varying patient population^[21-26].

Type	Neck Angle (°)	Offset Range (mm)
Standard	135	36.0-43.5
High Offset		43.0-50.5
Short Neck		31.0-32.5
Coxa Vara	125	43.0-50.5



ROM Performance

Reduced Neck Thickness

Conformity is designed with a larger head-neck ratio (**Figure 6**) to increase ROM functionality and improve the patients' quality of life^[13, 27]. The reduction of material in the neck area of the stem increases head-neck ratio without significantly compromising on the mechanical strength, enhancing ROM to more efficiently assist the performance of most required daily activities, such as squatting and stair climbing^[28].

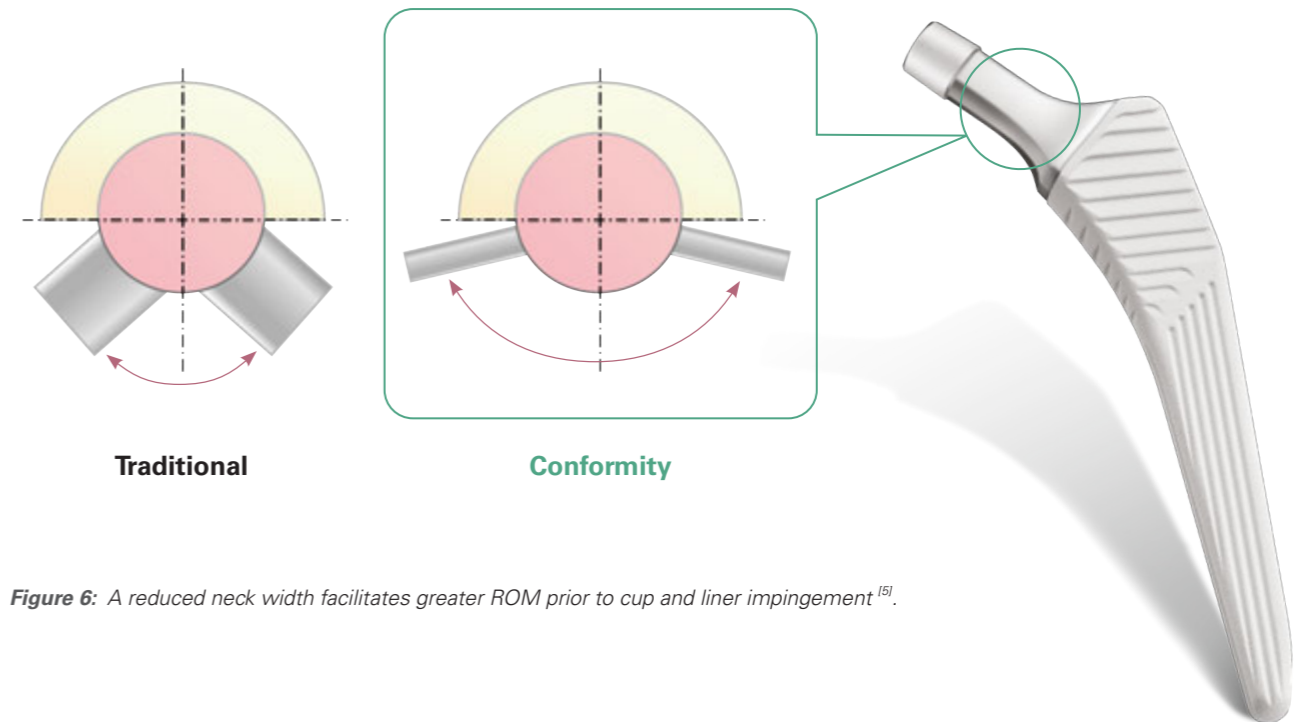


Figure 6: A reduced neck width facilitates greater ROM prior to cup and liner impingement^[6].

Cup / Head	Neutral Liner	Head	FLEX-EXT (°)	ABD-ADD (°)
46 / 32	1406-7247	Φ 32 mm, +0 mm	192.5	133.5
50 / 32	1406-7250	Φ 32 mm, +0 mm	192.5	133.6
50 / 36	1406-7251	Φ 36 mm, +0 mm	197.5	137.2
54 / 36	1406-7254	Φ 36 mm, +0 mm	197.5	137.1

* This is the results of a test report^[6] on the ROM performance of Conformity and U-Motion II cup.

SURGICAL PRACTICALITY

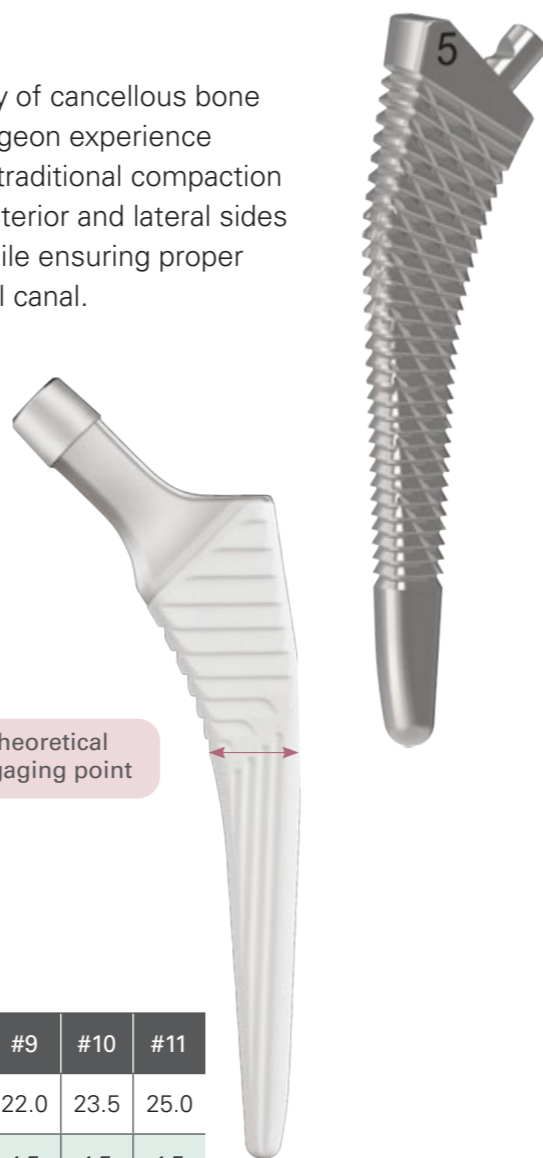
Easier Stem Implantation

Recently, minimally invasive surgery has become increasingly popular in the surgical community because of minimized wound complications, improved patient pain and recovery by performing smaller surgical incision sites compared to standard incisions^[29, 30].

Conformity has the added benefit over longer stems during minimally invasive surgery because of its smaller stem profile and thin, slightly slanted distal tip which facilitate surgeons with increased range of stem maneuverability and flexibility for easier implantation into smaller and more limited operative surgical site exposures. Hence, reducing the risk of cortical wall impingement and minimizing intraoperative complications^[29, 30].

Femoral Broaches

Sharp broaches are designed to maintain the philosophy of cancellous bone compaction and bone preservation while enhancing surgeon experience during femoral canal preparation. The sharp broach has traditional compaction teeth combined with serrated teeth on the anterior, posterior and lateral sides of the broach designed to preserve patient anatomy while ensuring proper lateralization and adequate fit of the stem in the femoral canal.



Refined Proximal Width

Distally engaged stems may suffer from up to 90% of proximal bone loss^[31]. Conformity has refined sizing options, with a 0.75 mm size increment between stem size 1 and 2, and a consistent 1.5 mm size increment for stem sizes 3 to 11, to facilitate surgeons with easier intraoperative implant size selections to achieve a more effective implant-bone interface fit in patients with different femoral profiles. Hence, providing stable mechanical fixation at the proximal region for long-term osseointegration^[30, 32, 33].

Theoretical engaging point

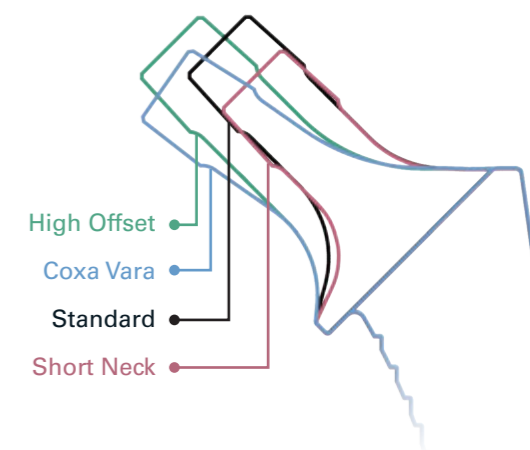
United Conformity

Size	#1	#2	#3	#4	#5	#6	#7	#8	#9	#10	#11
M/L Width	10.75	11.5	13.0	14.5	16.0	17.5	19.0	20.5	22.0	23.5	25.0
Increment	-	0.75	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5

Unit : mm

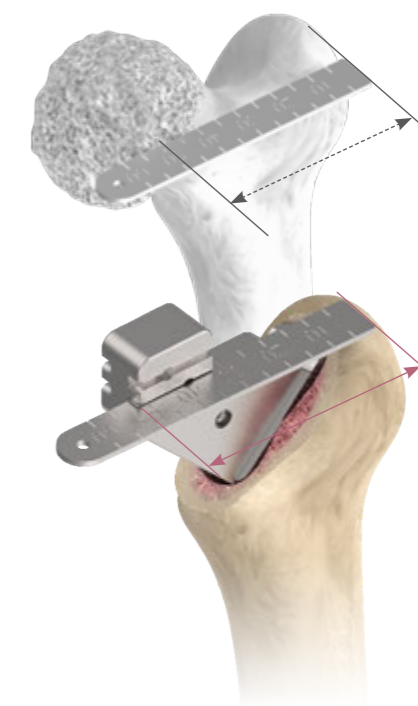
Various Neck Offset Configurations

Conformity has four neck offset (Standard, High Offset, Coxa Vara, Short Neck) options and several head offset selections. Surgeons can determine the most optimal neck offset configurations between the range of 28.9 mm and 57.6 mm with the neck template ruler and neck template instrumentation to achieve proper restoration of abductor muscle tension to prolong implant survivorship in patient with varying conditions^[21, 34-36].



Patients with increased Coxa Vara hips have a smaller neck-shaft angle and larger neck offset, especially in female patients and some ethnic groups^[24, 37, 38]. In this scenario, standard offsets result in loose abductor muscle tensioning, increasing rotational freedom and reducing joint stability, leading to dislocation risks^[13]. High Offset options assist surgeons with achieving greater offset lengthening and adjustments to adapt to these clinical cases.

Patients with smaller body constitutions require shorter neck offsets^[39, 40]. In this scenario, standard offsets result in an increased horizontal and vertical neck positioning, which may result in leg length discrepancy and increased implant failure^[40, 41]. Hence, the Short Neck offset options assist surgeons with shortening neck offsets to adapt to these clinical cases.



Head Size	CoCr 22* / 26 mm					CoCr 28/32/36 mm					Ceramic 28 mm			Ceramic 32 mm			Ceramic 36 / 40 mm						
	Head Offset	-2	+0	+3	+6	+9	-3	+0	+2.5	+5	+7.5	+10	-2.5	+1	+4	-3	+1	+5	+8	-3	+1	+5	+9
Standard (#1-#11)	#1	35	36	38	40	42	34	36	38	40	41	43	34	37	39	34	37	40	42	34	37	40	42
	#2	35	37	39	41	43	34	37	38	40	42	44	35	37	39	34	37	40	42	34	37	40	43
	#3	36	38	40	42	44	35	38	39	41	43	45	36	38	40	35	38	41	43	35	38	41	44
	#4	37	38	40	42	44	36	38	40	42	43	45	36	39	41	36	39	42	44	36	39	42	44
	#5	38	39	41	43	45	37	39	41	43	44	46	37	40	42	37	40	43	45	37	40	43	45
	#6	38	40	42	44	46	37	40	41	43	45	47	38	40	42	37	40	43	45	37	40	43	46
	#7	39	40	42	44	46	38	40	42	44	45	47	38	41	43	38	41	44	46	38	41	44	46
	#8	40	41	43	45	47	39	41	43	45	46	48	39	42	44	39	42	45	47	39	42	45	47
	#9	40	42	44	46	48	39	42	43	45	47	49	40	42	44	39	42	45	47	39	42	45	48
	#10	41	43	45	47	49	40	43	44	46	48	50	41	43	45	40	43	46	48	40	43	46	49
	#11	42	44	46	48	50	41	44	45	47	49	51	42	44	46	41	44	47	49	41	44	47	50

High Offset (#1-#11) Coxa Vara (#2-#11)	#1	42	43	45	47	49	41	43	45	47	48	50	41	44	46	41	44	47	49	41	44	47	49
	#2	42	44	46	48	50	41	44	45	47	49	51	42	44	46	41	44	47	49	41	44	47	50
	#3	43	45	47	49	51	42	45	46	48	50	52	43	45	47	42	45	48	50	42	45	48	51
	#4	44	45	47	49	51	43	45	47	49	50	52	43	46	48	43	46	49	51	43	46	49	51
	#5	45	46	48	50	52	44	46	48	50	51	53	44	47	49	44	47	50	52	44	47	50	52
	#6	45	47	49	51	53	44	47	48	50	52	54	45	47	49	44	47	50	52	44	47	50	53
	#7	46	47	49	51	53	45	47	49	51	52	54	45	48	50	45	48	51	53	45	48	51	53
	#8	47	48	50	52	54	46	48	50	52	53	55	46	49	51	46	49	52	54	46	49	52	54
	#9	47	49	51	53	55	46	49	50	52	54	56	47	49	51	46	49	52	54	46	49	52	55
	#10	48	50	52	54	56	47	50	51	53	55	57	48	50	52	47	50	53	55	47	50	53	56
	#11	49	51	53	55	57	48	51	52	54	56	58	49	51	53	48	51	54	56	48	51	54	57

Short Neck (#1-#3)	#1	30	31	33	35	37	29	31	33	35	36	38	29	32	34	29	32	35	37	29	32	35	37
	#2	30	32	34	36	38	29	32	33	35	37	39	30	32	34	29	32	35	37	29	32	35	38
	#3	31	33	35	37	39	30	33	34	36	38	40	31	33	35	30	33	36	38	30	33	36	39

* The actual spherical diameter of a 22 mm metal head is 22.2 mm.

Unit : mm

Adaptive Cemented Stem Technique

Cemented stem options are suitable when proper stem fixation cannot be achieved in patients with the cementless stem options. Two cementation techniques may be selected for the cementation process^[42, 43].

Technique 1: A standard cement mantle thickness around the implant (*Figure 7*).

Technique 2: A non-uniform, thin cement mantle thickness (<2 mm) may occur as a result of patient morphologic variations, such as inconsistent canal geometries. However, following the ‘French Paradox’ principle, this technique will still provide adequate fixation for favorable outcomes because the stem has a 4-point engagement with the dense cancellous bone bed (*Figure 7*). Hence preventing detrimental stem subsidence.

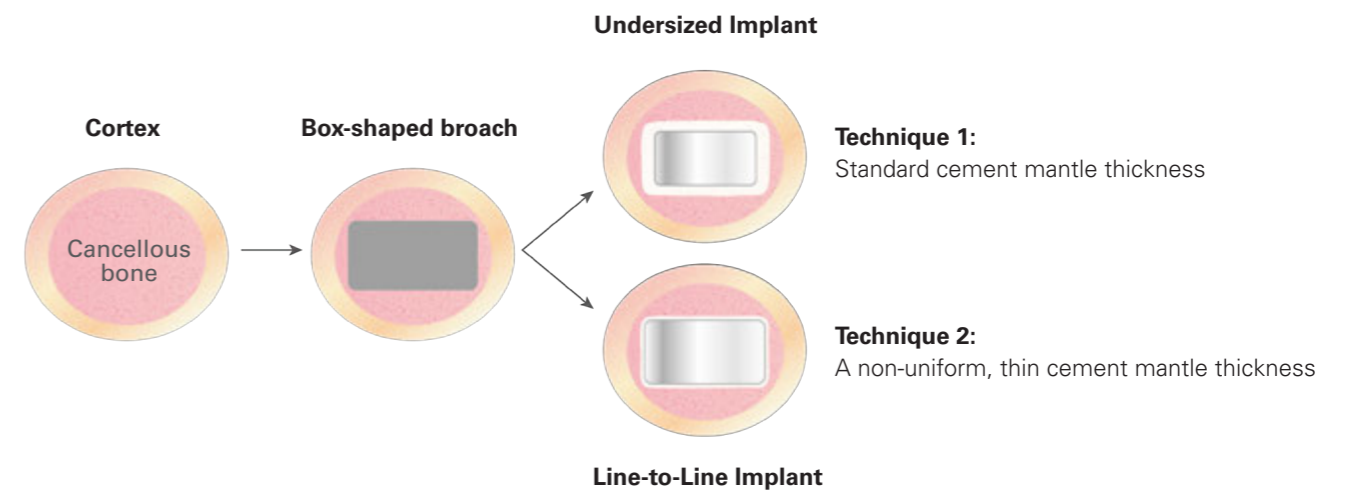


Figure 7:

Despite the varying cementation techniques, the cement mantle thickness will still result in adequate stem fixation for favorable outcomes^[42].

Broach #	1	2	3	4	5	6	7	8	9	10	11
Stem #	Cement Mantle (mm)										
1	*	0.385	1.135								
2		*	0.75	1.5							
3			*	0.75	1.5						
4				*	0.75	1.5					
5					*	0.75	1.5				
6						*	0.75	1.5			
7							*	0.75	1.5		
8								*	0.75	1.5	
9									*	0.75	1.5
10										*	0.75

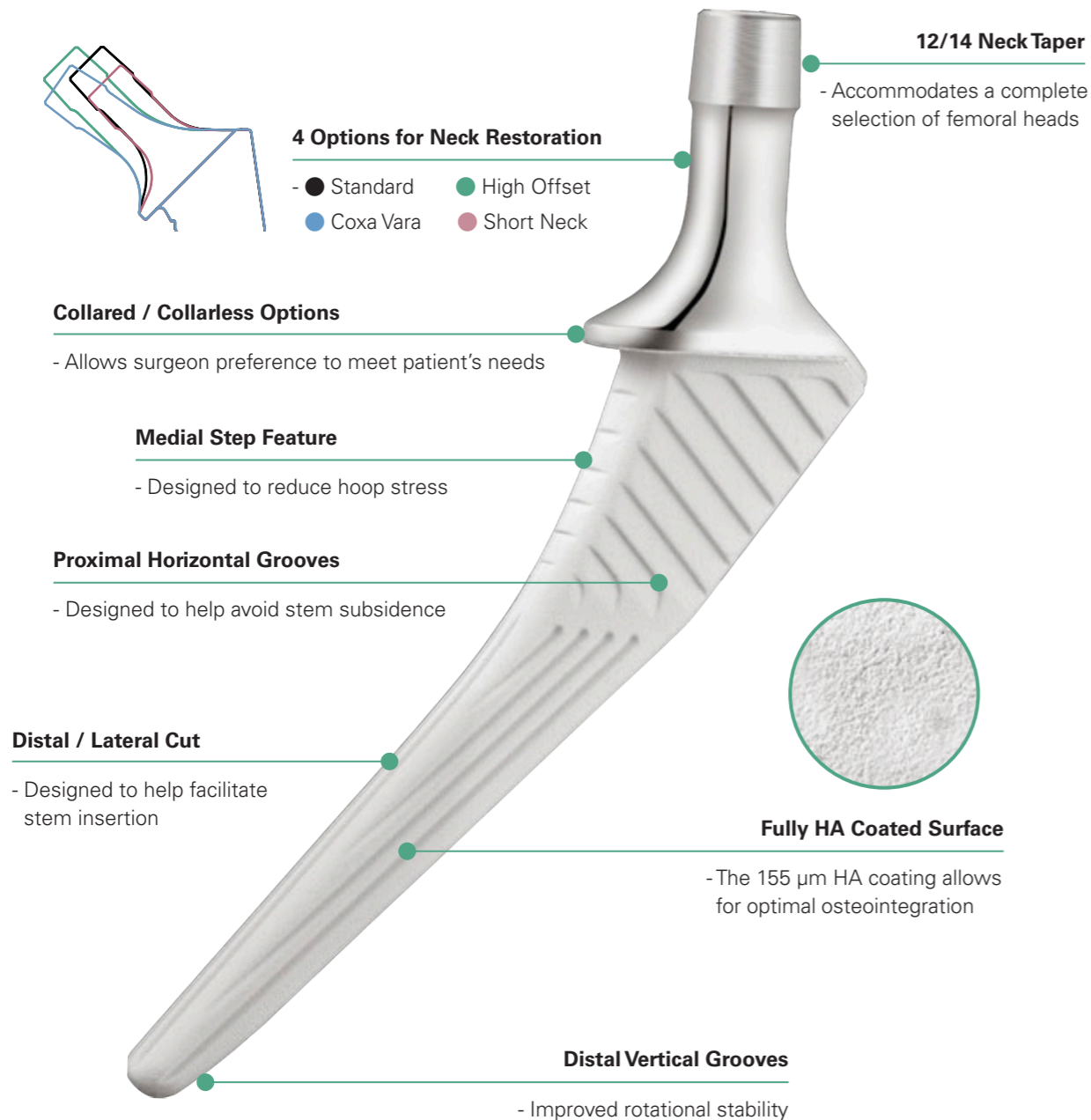
* Line-to-line stem insertion

SUMMARY

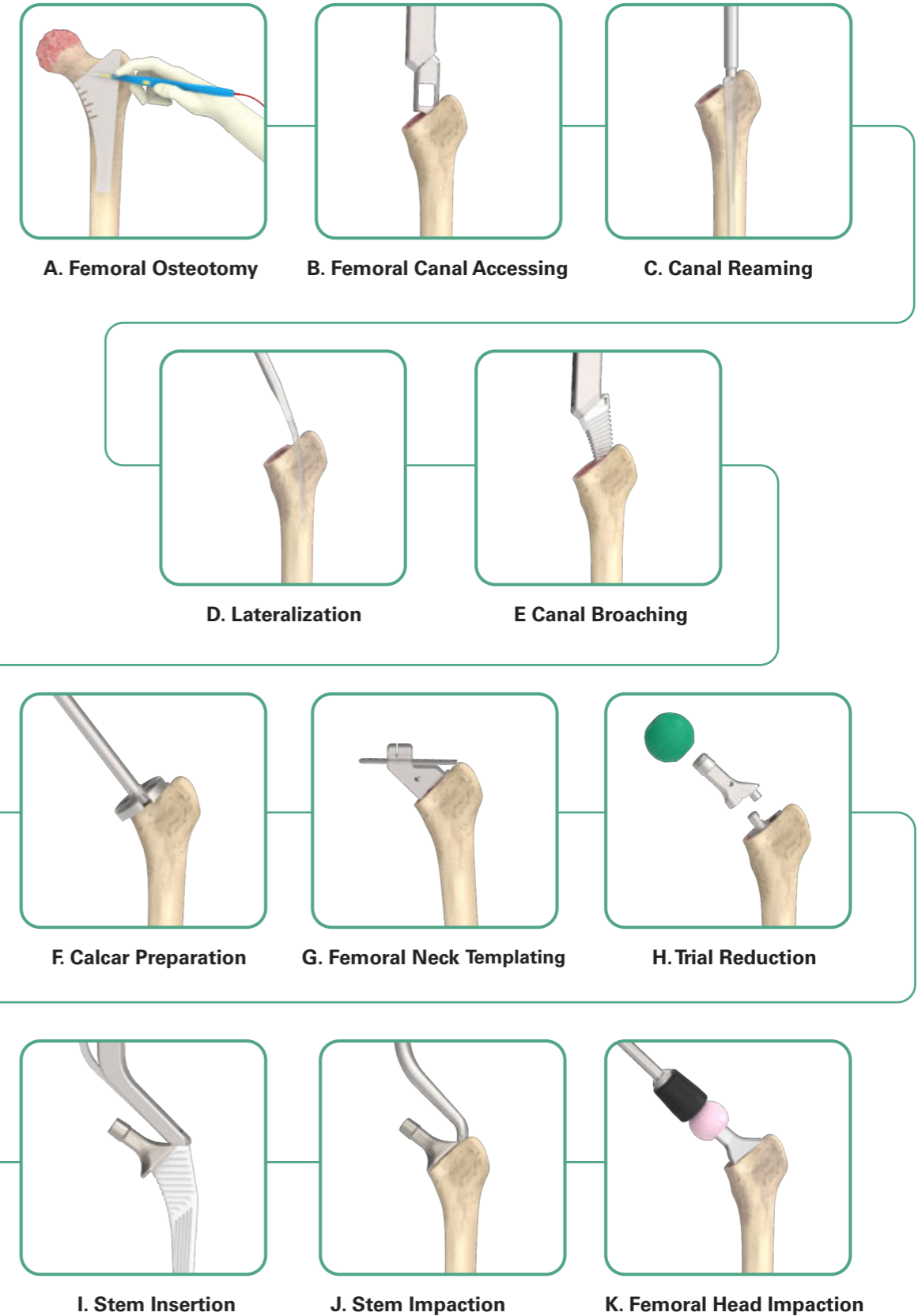
The Conformity stem is a classic, fully Hydroxyapatite (HA) coated with 155 µm thickness to promote ideal osteointegration. A compaction broaching technique is utilized to help provide initial stability and preserve bone stock and blood supply.

The Conformity stem is designed with a unique profile for ideal biomechanical performance. Various neck offset options enable the surgeon to finely adjust the tension for soft tissues around the hip joint to help achieve better joint stability.

PRODUCT FEATURES



SURGICAL OVERVIEW



PRODUCT CHART

Catalog Number	Description
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Conformity, Collared

Standard



High Offset



Standard

1110 - 1001	1110 - 1201	# 1
1110 - 1002	1110 - 1202	# 2
1110 - 1003	1110 - 1203	# 3
1110 - 1004	1110 - 1204	# 4
1110 - 1005	1110 - 1205	# 5
1110 - 1006	1110 - 1206	# 6
1110 - 1007	1110 - 1207	# 7
1110 - 1008	1110 - 1208	# 8
1110 - 1009	1110 - 1209	# 9
1110 - 1010	1110 - 1210	# 10
1110 - 1011	1110 - 1211	# 11

High Offset

Conformity, Collarless

Standard



High Offset



Standard

1110 - 3001	1110 - 3201	# 1
1110 - 3002	1110 - 3202	# 2
1110 - 3003	1110 - 3203	# 3
1110 - 3004	1110 - 3204	# 4
1110 - 3005	1110 - 3205	# 5
1110 - 3006	1110 - 3206	# 6
1110 - 3007	1110 - 3207	# 7
1110 - 3008	1110 - 3208	# 8
1110 - 3009	1110 - 3209	# 9
1110 - 3010	1110 - 3210	# 10
1110 - 3011	1110 - 3211	# 11

High Offset

Conformity, Coxa Vara



Coxa Vara

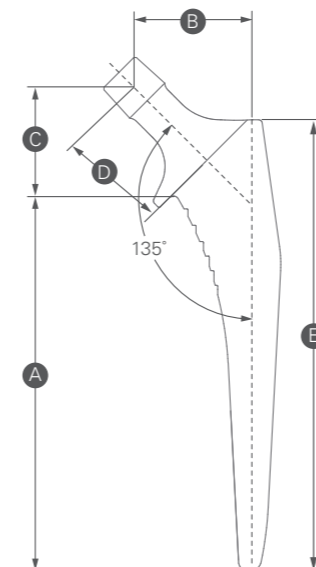
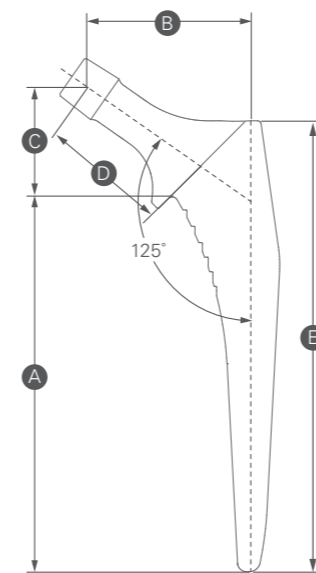
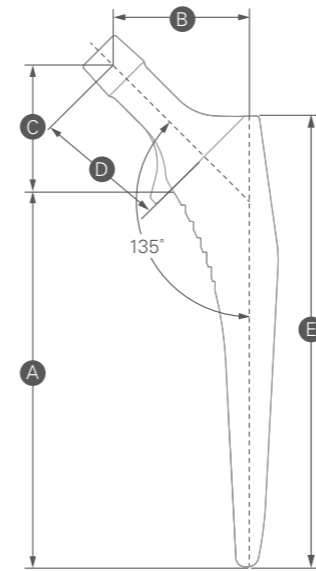
1110 - 5202	# 2
1110 - 5203	# 3
1110 - 5204	# 4
1110 - 5205	# 5
1110 - 5206	# 6
1110 - 5207	# 7
1110 - 5208	# 8
1110 - 5209	# 9
1110 - 5210	# 10
1110 - 5211	# 11

Conformity, Short Neck



Short Neck

1110 - 1401	# 1
1110 - 1402	# 2
1110 - 1403	# 3



Collared & Collarless

Size	A Medial Length	B Offset		C Vertical Height	D Neck Length		E Lateral Length
		Standard	High Offset		Standard	High Offset	
#1	95	36	43	34	35.5	40.5	115
#2	99.5	36.5	43.5	34	35.5	40.5	119.5
#3	104	37.5	44.5	34	35.5	40.5	124
#4	108.5	38	45	34	35.5	40.5	128.5
#5	113	39	46	34	35.5	40.5	133
#6	117.5	39.2	46.5	34	35.5	40.5	137.5
#7	122	40	47	34	35.5	40.5	142
#8	126.5	41	48	34	35.5	40.5	146.5
#9	131	41.5	48.5	34	35.5	40.5	151
#10	135.5	42.5	49.5	34	35.5	40.5	155.5
#11	140	43.5	50.5	34	35.5	40.5	160

Unit : mm

Coxa Vara

Size	A Medial Length	B Offset	C Vertical Height	D Neck Length	E Lateral Length
#2	99.5	43.5	29	37.5	119.5
#3	104	44.5	29	37.5	124
#4	108.5	45	29	37.5	128.5
#5	113	46	29	37.5	133
#6	117.5	46.5	29	37.5	137.5
#7	122	47	29	37.5	142
#8	126.5	48	29	37.5	146.5
#9	131	48.5	29	37.5	151
#10	135.5	49.5	29	37.5	155.5
#11	140	50.5	29	37.5	160

Unit : mm

Short Neck

Size	A Medial Length	B Offset	C Vertical Height	D Neck Length	E Lateral Length
#1	95	31	29	28.5	115
#2	99.5	31.5	29	28.5	119.5
#3	104	32.5	29	28.5	124

Unit : mm

PRODUCT CHART

Catalog Number Description

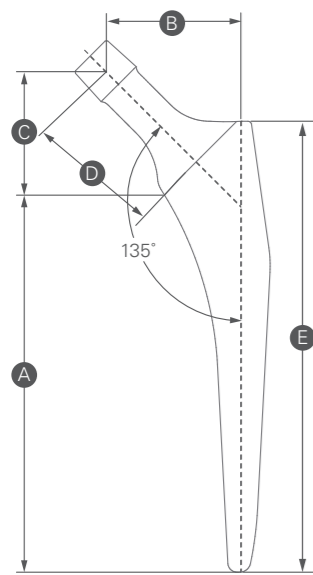
Conformity, Cemented

Standard

High Offset



Standard	High Offset	Description
1110 - 7001	1110 - 7201	# 1
1110 - 7002	1110 - 7202	# 2
1110 - 7003	1110 - 7203	# 3
1110 - 7004	1110 - 7204	# 4
1110 - 7005	1110 - 7205	# 5
1110 - 7006	1110 - 7206	# 6
1110 - 7007	1110 - 7207	# 7
1110 - 7008	1110 - 7208	# 8
1110 - 7009	1110 - 7209	# 9
1110 - 7010	1110 - 7210	# 10



Size	A Medial Length	B Offset		C Vertical Height	D Neck Length		E Lateral Length
		Standard	High Offset		Standard	High Offset	
#1	95	36	43	34	35.5	40.5	115
#2	99.5	36.5	43.5	34	35.5	40.5	119.5
#3	104	37.5	44.5	34	35.5	40.5	124
#4	108.5	38	45	34	35.5	40.5	128.5
#5	113	39	46	34	35.5	40.5	133
#6	117.5	39.2	46.5	34	35.5	40.5	137.5
#7	122	40	47	34	35.5	40.5	142
#8	126.5	41	48	34	35.5	40.5	146.5
#9	131	41.5	48.5	34	35.5	40.5	151
#10	135.5	42.5	49.5	34	35.5	40.5	155.5

Unit : mm

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