

Design rationale

Insignia[®]

Hip Stem



Data driven design aligned to your approach

Founded on Stryker's signature principles of implant fit, function and flexibility, Insignia is your **collared, metaphyseal-filling** hip stem designed specifically for muscle-sparing approaches. Combined with Trident II and MDM, you're poised to elevate the standard of care for hips.

Stryker Orthopaedics Modeling and Analytics

Insignia continues Stryker's heritage of 3D CT-based implant design through SOMA (Stryker Orthopaedics Modeling and Analytics) technology, the world's largest collection of high-resolution CT-based scans of upper and lower extremities. SOMA's unparalleled bone database is leveraged through an intelligent, 3D modeling software system that allows Stryker to instantaneously test how an implant fits different types of anatomies, from bones with tight distal canals to bones with thin cortices.

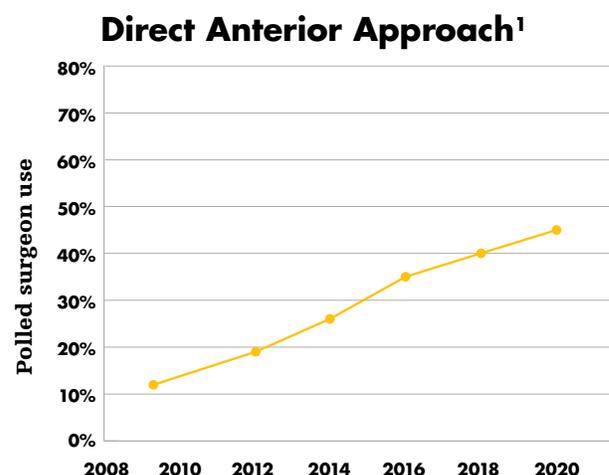
First used in Accolade II with its size-specific medial curvature, SOMA allowed Stryker to design and test unique implant features to allow for an enhanced implant fit across various femoral morphologies.

Insignia is your collared, metaphyseal-filling stem, designed using SOMA* to provide one simple option for all bone types.

Addressing today's needs for tomorrow's patients

Today's THA landscape has shifted dramatically over the past decade with muscle-sparing approaches, like Direct Anterior, now accounting for approximately 45% of performed procedures.¹ Simultaneously, healthcare has shifted to combined payment models and new sites of care, like ambulatory surgical centers, which have experienced an increasing demand for patients to be discharged in less than 24 hours.

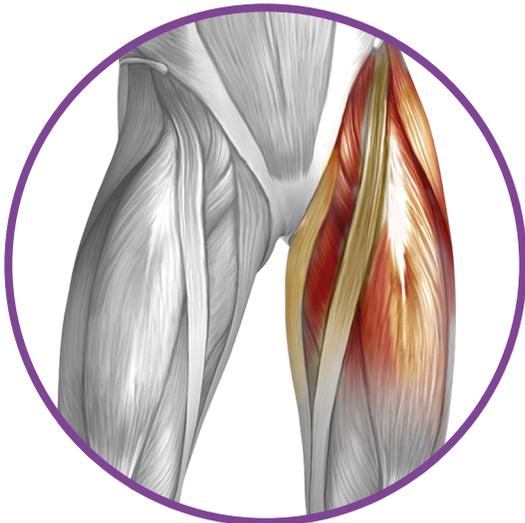
Many current femoral stem designs predate the emergence of this novel demand. Short, fully HA coated stems have achieved popularity due to their simplicity and ease of insertion. Incidences of proximal-distal mismatch, distal potting, collar overhang,



subsidence, and periprosthetic fracture suggest a need for a data-driven implant to enhance implant fit across today's patient population.^{3,4,5}

With this goal in mind, Stryker set out to create an implant which capitalizes on the clinically successful designs of Accolade II and Secur-Fit to meet the unique needs of today's patient population and muscle-sparing approaches.^{2,6,7} **The result: the Insignia Hip Stem.**

Design principles



Fit

- SOMA-designed geometries
- Tri-Stage™ Broach
- Slim-distal profile
- Dorr A bone friendly

Function

- Size-specific collar
- Purefix Hydroxyapatite (HA) coating
- Direct lateral offset
- SOMA-verified femoral offset
- Proportional neck lengths

Flexibility

- Aligned to your approach
- Designed for ease of insertion
- Broaching efficiency
- Mako SmartRobotics™
- Market-leading implant portfolio

Fit

SOMA-designed body geometries

Founded on Stryker's legacy of clinically successful and market leading stem designs, Insignia's body geometry incorporates the SOMA design of Accolade II and the trapezoidal design of Secur-Fit to optimize cortical engagement and proximal fill.^{6,7}



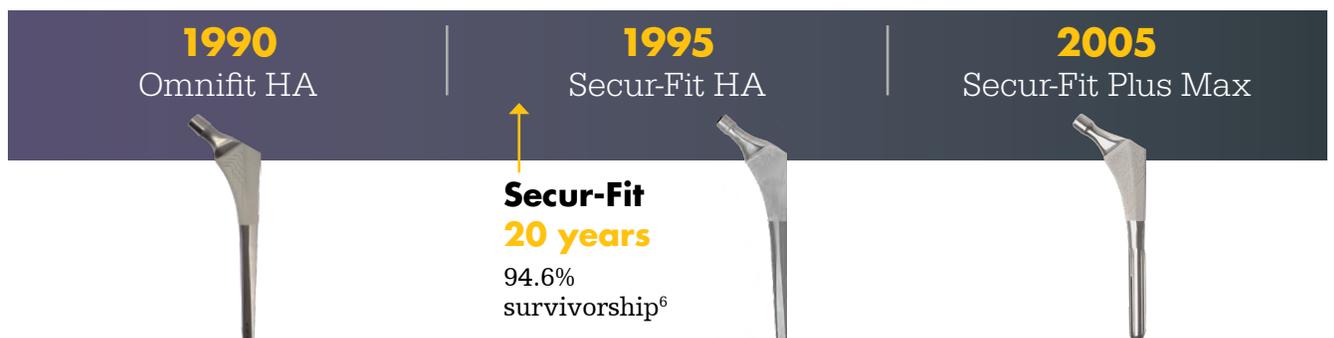
Size-specific medial curvature

Insignia leverages Accolade II's clinically successful Medial / Lateral (M/L) body geometry, including the size-specific medial curvature.^{6,8,9} This SOMA-designed* feature has demonstrated a more conforming proximal cortical fit for improved stability^{10,11} and maintained 100% bone mineral density of the medial calcar at 5 years.¹²

Accolade II's features have driven it to become the market-leading tapered wedge stem¹³ in the U.S. with over 1 million stems implanted worldwide.¹⁴

*SOMA-design based on 556 CT scans.

Leading with Stryker's legacy



Metaphyseal-filling design

Insignia builds upon the heritage of Omnifit and Secur-Fit that has defined Stryker's fit and fill stems for decades. Since its first implantation in 1995, Secur-Fit has the lowest revision rates and the longest follow-up in the Australian Joint Registry at 20 years.⁶

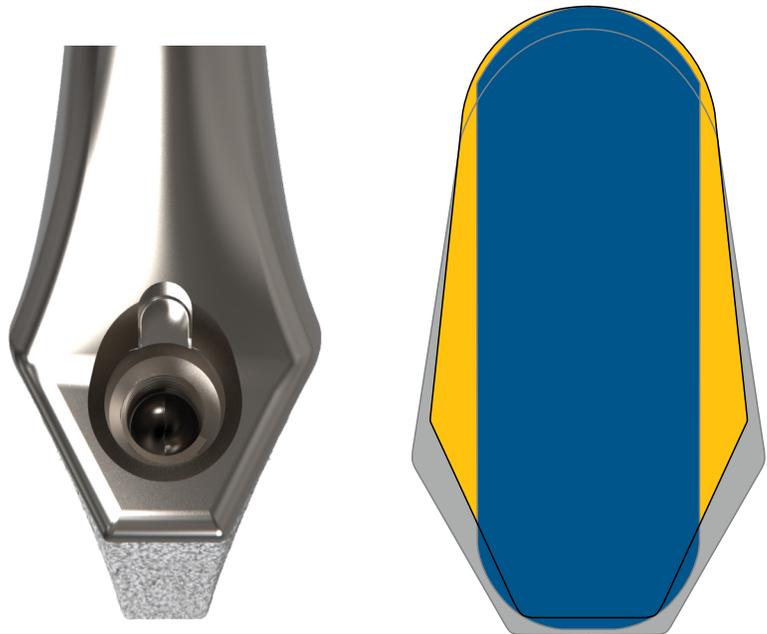
Optimized A/P fill†

The Anterior / Posterior (A/P) body geometry of Insignia capitalizes on the trapezoidal design of Secur-Fit to enhance rotational and axial stability.⁷

The optimized A/P fill of Insignia prioritizes M/L fit prior to A/P filling of the femur. Insignia's geometry is designed to be more bone preserving while enhancing initial stability compared to a clinically successful fit and fill stem.^{6,7,15}

Insignia's metaphyseal-filling geometry significantly reduced broaching effort compared to a traditional fit and fill stem.¹⁶

†Optimization subject to particular design constraints.



■ Secur-Fit ■ Insignia ■ Accolade II

<p>2012 Accolade II</p> 	<p>2013 Secur-Fit Advanced</p> 	<p>2021 Insignia</p> 
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Accolade II
U.S. Market Leading
Tapered wedge stem¹³

Broach with confidence

Tri-Stage™ Broach

The Tri-Stage Broach is Stryker's first instrument designed with SOMA technology.

The unique broach features three tooth geometries to prepare a tapered press fit region to provide an accurate and reproducible stem seating height relative to the final broach.¹⁷

Broach-only design

Coupled with its market differentiating broach design, Insignia accommodates varying sized femoral canals which may reduce the need for femoral clear out reaming, especially in Dorr Type A femurs.



Extraction

M/L: Extraction teeth facilitate cancellous bone removal for enhanced cortical fit⁷



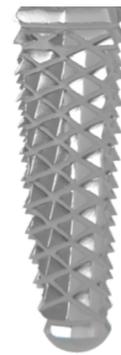
Compaction

A/P: Compaction teeth enable bone preservation and initial stability



Distally Cutting

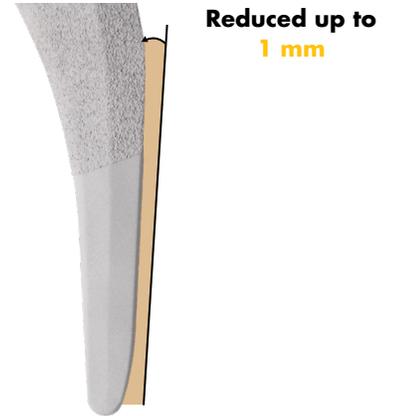
Distal: Distal diamond cutting teeth help remove diaphyseal bone and are oversized by 0.5mm to promote proximal fit



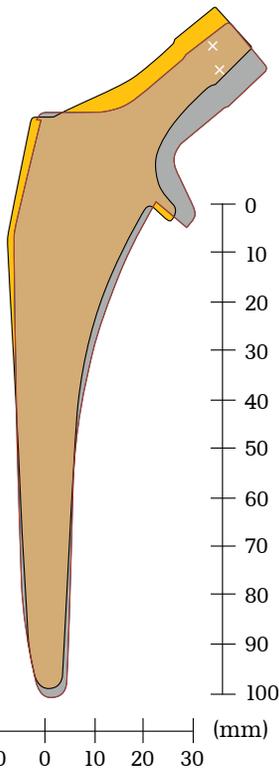
Universal fit

Slim distal profile

Insignia's distal lateral geometry has been reduced up to 1mm throughout the size range compared to Accolade II.



A/P view



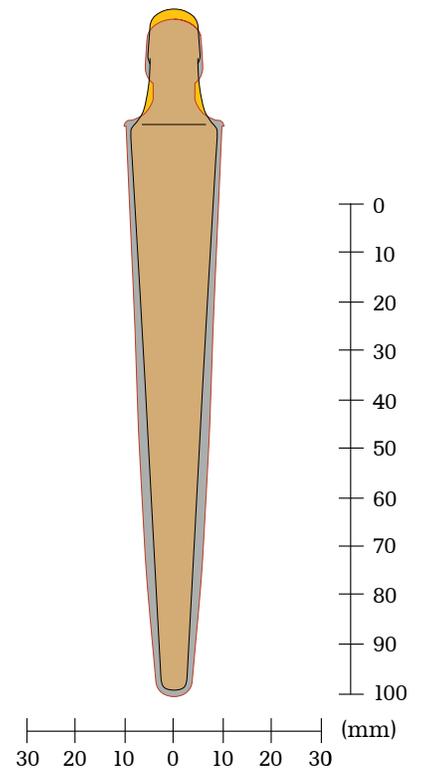
Insignia (gold) Standard Size 2 shown next to comparable triple-taper stem.

Dorr A bone friendly

Differentiating from other triple taper stem designs, Insignia accommodates Dorr A bone in the A/P view through its size-specific medial curvature and collar sizes in the smaller stem sizes.

Additionally, Insignia's large stem sizes are slimmer in the M/L view than currently marketed triple taper stem designs to account for varying femoral morphology and assist in broaching efficiency.

M/L view



Insignia (gold) Standard Size 10 shown next to comparable triple-taper stem.

Function

Adjunct stability

Periprosthetic fractures continue to be a major complication and concern during the early postoperative period due to costly hospital readmission requirements and a high one-year mortality rate.¹⁸⁻²¹

With this in mind, enhancing rotational stability was a crucial objective in Insignia's collared design. Studies have shown that a collar enables initial rotational implant stability and a reduced potential for periprosthetic fracture and subsidence when flush with the calcar.¹⁸⁻²¹

Size-specific collar

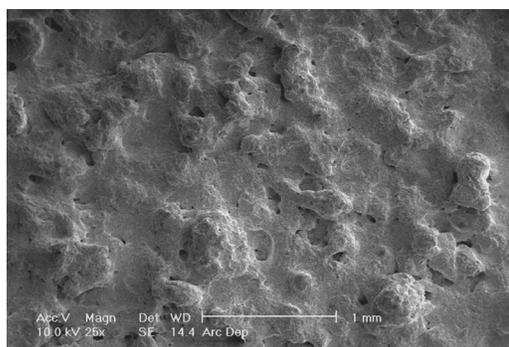
Insignia features a SOMA-designed, size-specific collar (5-7mm) to maximize calcar coverage, while minimizing overhang across various femoral morphologies.⁷

Insignia's collar sizes increase proportionally to the implant body to help minimize the likelihood of psoas impingement from implant overhang.³

The underside of Insignia's collar has 50 microns of HA coating over a grit-blasted surface to ensure flush collar contact to the calcar and a reproducible stem to final broach seating height.¹⁷

Collar sizing (mm) ²²⁻²⁵		
	Size	Coating
Stryker Insignia	5-7	.05 HA
DePuy Synthes Actis	8	.375 Duofix
DePuy Synthes Corail	6 - 8	.115 HA

Purefix Hydroxyapatite (HA) coating



Insignia is fully HA coated with a 50-micron plasma sprayed of PureFix HA over plasma-sprayed commercially pure titanium proximally for fixation. Designed to balance fixation, the underside of the collar and distal stem tip feature an HA coating over a grit-blasted surface.

Purefix HA has over 20 years of clinical experience and has demonstrated 95.3% survivorship in stems with 40-70 microns of coating.⁶

Differentiated by data

Advanced offset functionality is significant for patient-specific and case-specific needs. Insignia is designed to provide the case-to-case confidence you need to restore a patient's hip biomechanics while meeting your operative goals.



Direct lateral offset

Insignia features a direct lateral offset and a 132° neck angle, which provides the ability to lateralize +5mm across the size range and enable independent adjustment of offset while maintaining leg length.

SOMA-verified femoral offset

Insignia utilized SOMA to establish a market-leading femoral offset coverage to effectively recreate patient biomechanics across the widest range of femoral anatomy.²⁴⁻²⁸

Femoral offset range comparison (mm)

- Insignia
- ML Taper
- Taperloc
- Actis
- Corail
- Polarstem
- Avenir

27.5

21

20

17

14.6

12.1

11.8

Flexibility

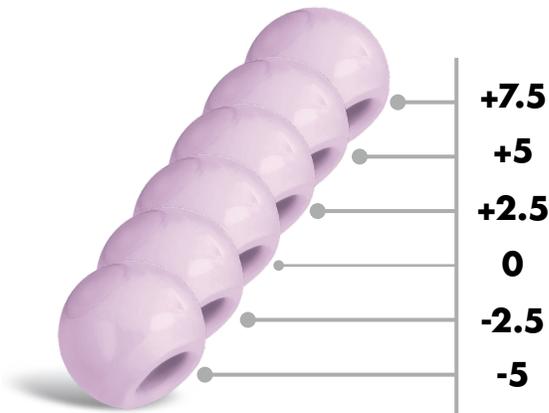
Advanced biomechanics

Balanced lateralization

The +5mm of direct lateral offset was designed to provide freedom of choice to use a standard or high offset stem without being limited on head offset size due to lateralization.

Proportional neck lengths and a robust head offset size range allow diverse options to further achieve your patient's biomechanic goals.

36mm BioloX Delta Ceramic head offering



Direct lateral offset^{†24-27}

Stryker Insignia	+5mm
DePuy Synthes Actis	+6mm, +8mm
DePuy Synthes Corail	+7mm
Zimmer Biomet Avenir Complete	+6mm
Smith and Nephew Polarstem	+3.5mm

Proportional neck lengths

Insignia incorporates neck lengths that grow incrementally relative to body size. A constant neck length relies heavily on a large selection of femoral head lengths to recreate normal joint space, which could possibly lead to smaller stems using minus heads and the opposite on larger stems.

Insignia was designed with incremental neck lengths to achieve proper joint stability most often with a standard +0mm femoral head.

Proportional neck lengths (mm)



Aligned to your approach

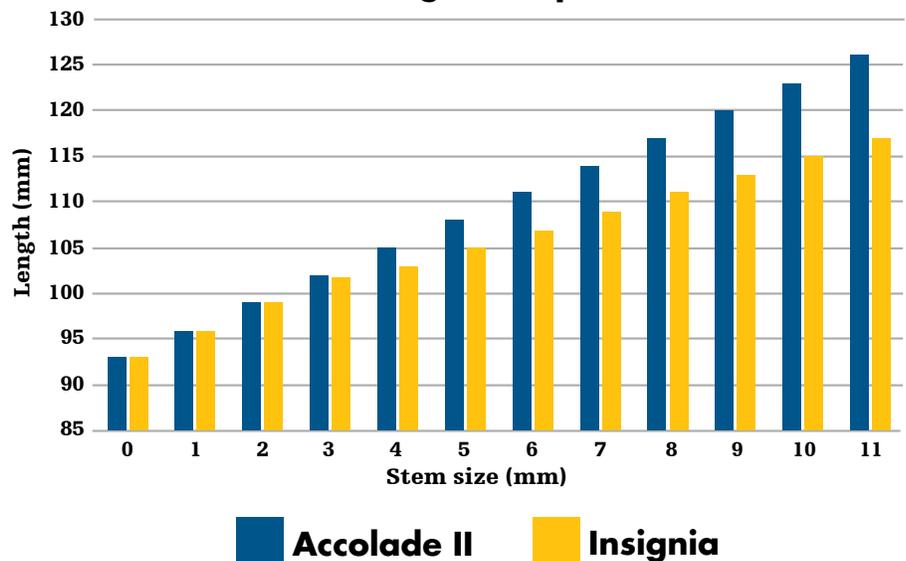
Whether your choice of implant is based upon surgical approach, operative efficiencies, or total hip construct- Insignia is focused on providing flexibility where it matters.

Stryker's comprehensive hip portfolio coupled with Insignia is designed specifically for modern muscle sparing approach like Direct Anterior. No matter your surgical approach, have confidence in Insignia's capability to meet your demand of implant fit and function.

Ease of insertion

Insignia's low-profile shoulder, short stem lengths, and distal relief are designed for ease of lateralization and insertion during muscle-sparing approaches.

Stem length comparison

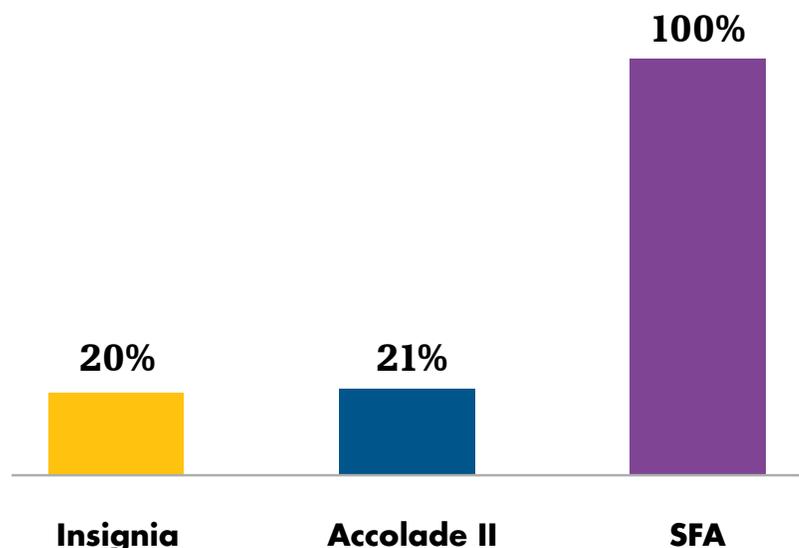


An evolutionary step in operative efficiency starts with data-driven implant and broach design.

Broaching efficiency

Insignia's metaphyseal-filling geometry combined with the Tri-Stage™ Broach significantly reduces broaching effort compared to a clinically successful fit and fill stem design in lab testing.²⁹

Average broaching effort



Flexibility

Know more, because fit matters

Mako SmartRobotics™ enabled

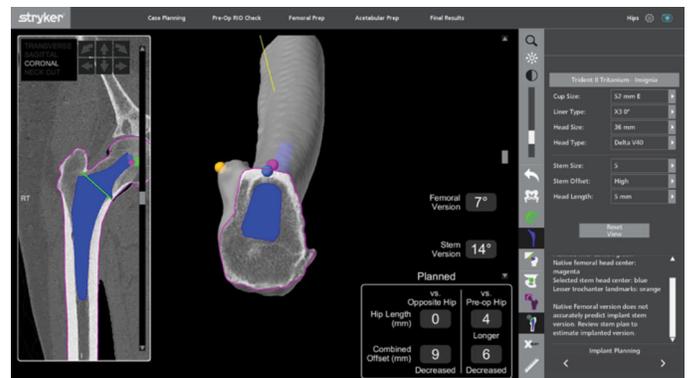
Mako SmartRobotics™ with Insignia[†] empowers you to know more through CT based planning, unlocking patient specific planning and robotic-arm assisted execution allowing you to preserve bone and achieve precise implant placement.

†Mako Total Hip 4.1 software, US only



Plan stem size and position using 3D CT-based planning

- Assess collar positioning and stem seating height
- Plan and measure neck resection using the digital ruler
- Track broach version (enhanced workflow only)



Flexibility

Strength in numbers

Trident II

Address instability through Insignia's metaphyseal filling design combined with Trident II's market leading femoral head-shell size offerings.³⁰

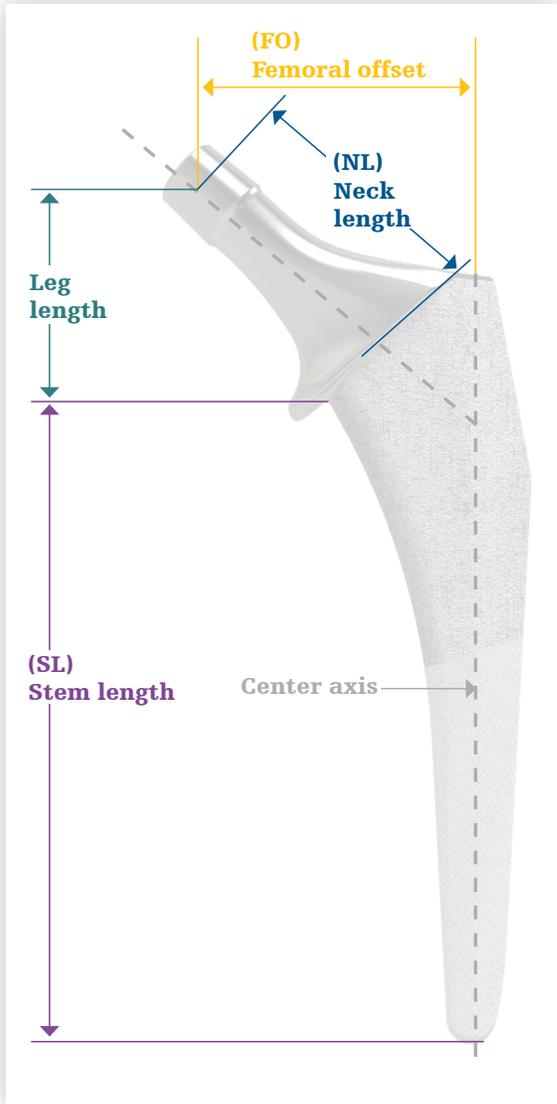
Trident II Tritanium is the latest Stryker implant to incorporate our additive manufactured Tritanium and X3 highly cross-linked polyethylene inserts. Since its launch in 2018, over 350,000 Trident II Tritanium shells have been implanted.³¹

MDM

MDM, the market's first³² modular dual mobility device, is compatible with Insignia. With over 10 years of clinical history, MDM has been implanted in over 250,000 THA cases across 47 countries³² and is the most studied modular dual mobility implant in literature with over 50+ peer-reviewed publications.³³ MDM is designed to help prevent dislocation³⁴⁻³⁸ and assist your operative goals of stability³⁴, longevity³⁹⁻⁴² and advanced fixation.



Ordering information



Part number	Size	Stem length (mm)	Neck length (mm)	Leg length (mm)	Femoral offset (mm)	Distal diameter (mm)
7000-5500	0 Standard	93	30.5	30	30	7
7000-5501	1 Standard	96	30.5	30	31.5	7
7000-5502	2 Standard	99	32.5	32	34	8
7000-5503	3 Standard	101	32.5	32	35.5	9
7000-5504	4 Standard	103	32.5	32	37	10
7000-5505	5 Standard	105	35	34	40	11
7000-5506	6 Standard	107	35	34	41.5	13
7000-5507	7 Standard	109	38	36	45	14
7000-5508	8 Standard	111	38	36	46.5	15
7000-5509	9 Standard	113	38	36	48	16
7000-5510	10 Standard	115	40.5	38	51	17
7000-5511	11 Standard	117	40.5	38	52.5	18
High						
7000-6600	0 High	93	33.5	30	35	7
7000-6601	1 High	96	33.5	30	36.5	7
7000-6602	2 High	99	36	32	39	8
7000-6603	3 High	101	36	32	40.5	9
7000-6604	4 High	103	36	32	42	10
7000-6605	5 High	105	38.5	34	45	11
7000-6606	6 High	107	38.5	34	46.5	13
7000-6607	7 High	109	41	36	50	14
7000-6608	8 High	111	41	36	51.5	15
7000-6609	9 High	113	41	36	53	16
7000-6610	10 High	115	43.5	38	56	17
7000-6611	11 High	117	43.5	38	57.5	18

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