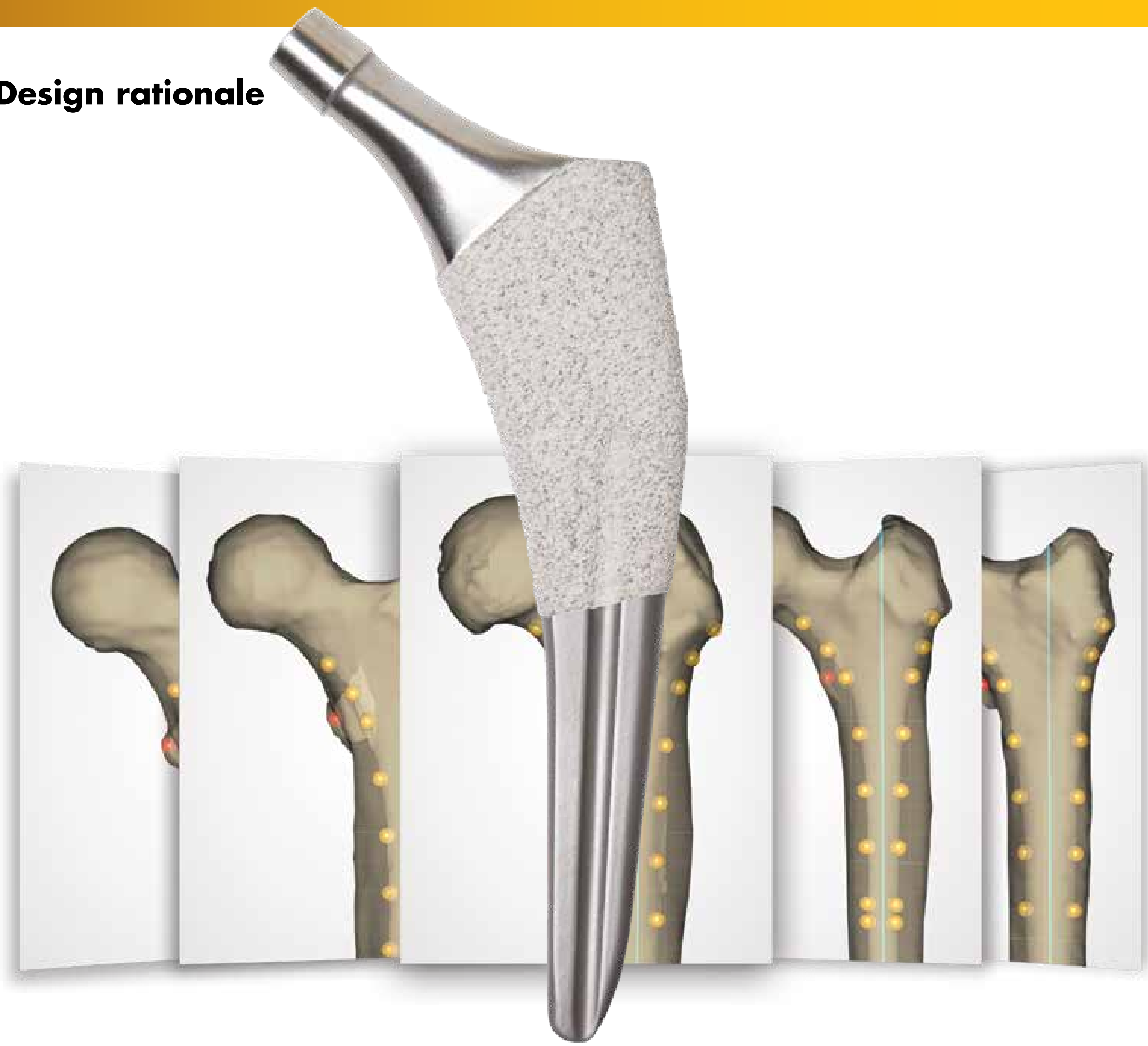
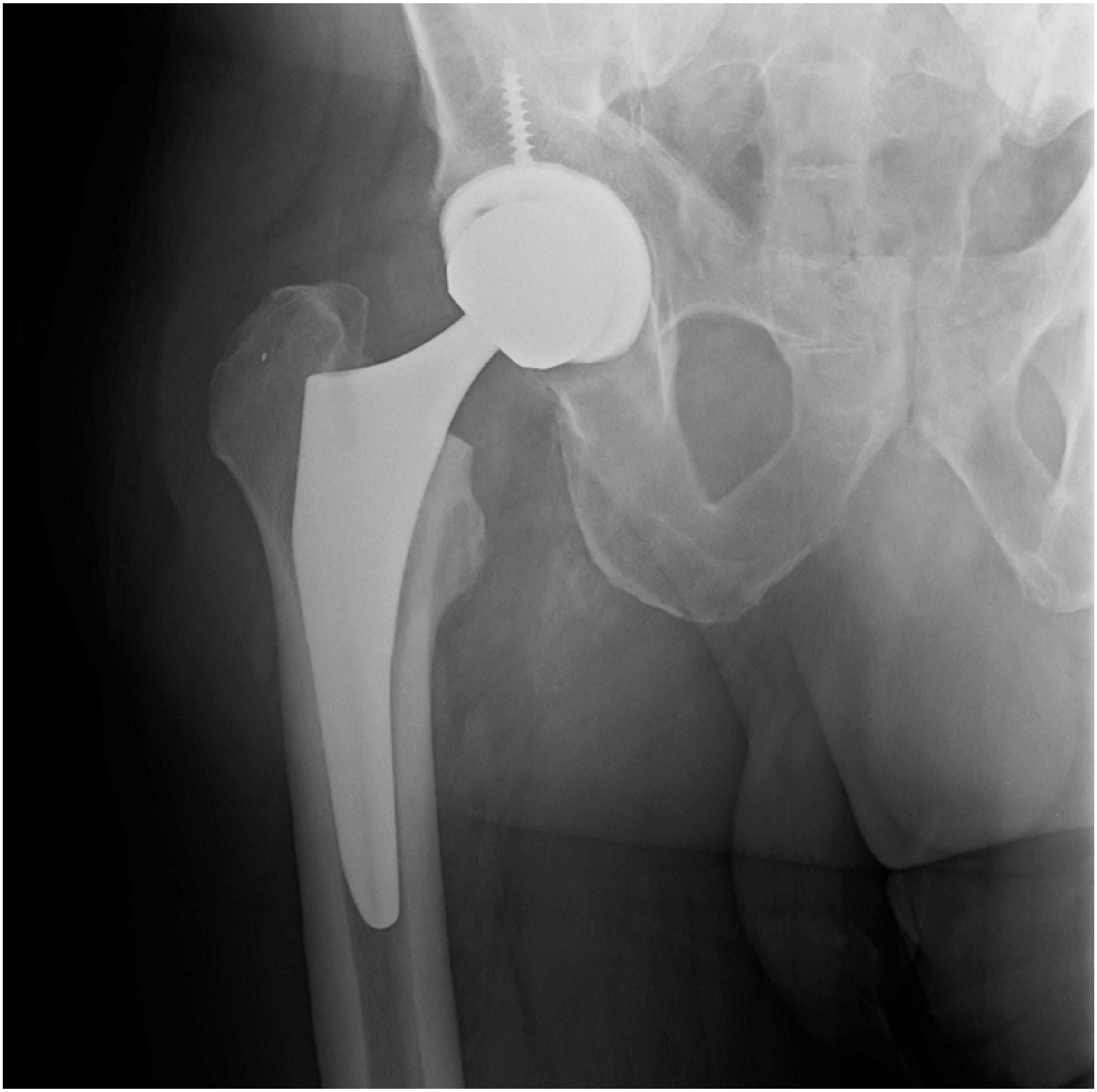
Accolade® II
Femoral Hip Stem

Design rationale



Designed to fit more patients, designed to fit your approach.



Addressing modern demands with novel technology.

The global THA population is evolving to include a younger[1], more active[2], and more demanding[3] patient. Many femoral stem designs on the market today predate the emergence of this novel demand. Subsequently, an opportunity to enhance the conventional femoral stem design exists.

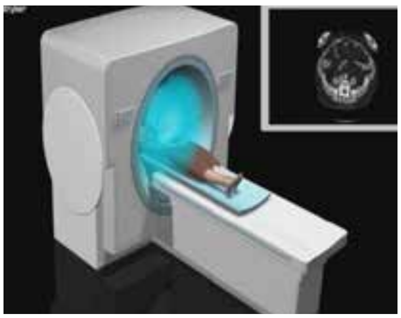
Conventional tapered wedge femoral stems have achieved popularity due to their simplicity and excellent clinical results[4,5]. Despite these results, literature indicates that there are still unmet clinical needs[6,7,8]. Incidence of subsidence[6], distal-only implant engagement[7], and peri-prosthetic fracture[8] suggest a clinical need for an improved implant fit for this novel patient population.

Stryker, along with key industry leaders, embarked to develop a novel femoral stem. This design would build from the sound principles of tapered wedge philosophy to meet the unique needs of the current patient population. At the heart of this development was a unique technology called Stryker Orthopaedic Modeling and Analytics, or SOMA. As a system that enables population-based design, SOMA has powerful functionality with which to design, model, and analyze novel orthopaedic devices.

Stryker utilized SOMA technology to design a novel stem building upon the conventional tapered wedge femoral design, incorporating unique features to allow for an enhanced implant fit in today's patient population[9]. By establishing an increased canal fit and fill[9], Accolade II has been shown to allow for improved stability[10], decreased intraoperative femoral fractures[11], as well as excellent survivorship and functional outcomes[12,13], ultimately leading to satisfied patients[13,14].

SOMA technology

Utilizing the proprietary SOMA technology, Stryker was able to complete one of the largest proximal femoral bone morphology studies ever undertaken[13]. An illustrated look at the process by which SOMA technology is employed in implant design is described below.



CT acquisition

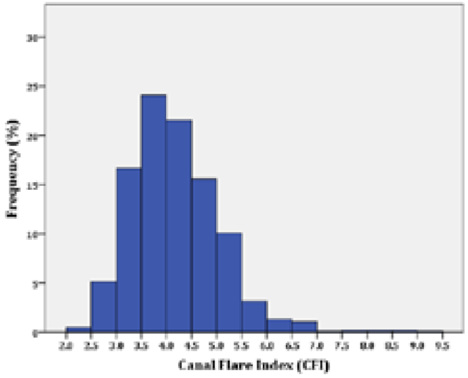
The SOMA database continues to aquire new CT scans, and currently contains over 16,500 bones[14]

Segmentation

Once acquired, all bones are segmented into inner and outer cortices

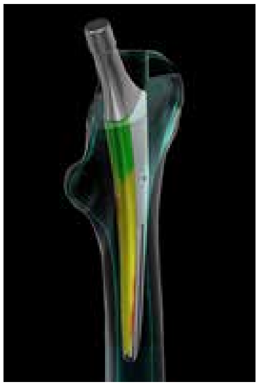
Analysis

Using SOMA tools, bone morphology can be studied in a highly accurate and reproducible manner.



Design input

The results of these studies, such as the population Canal Flare Index, can be utilized in implant design



Validation

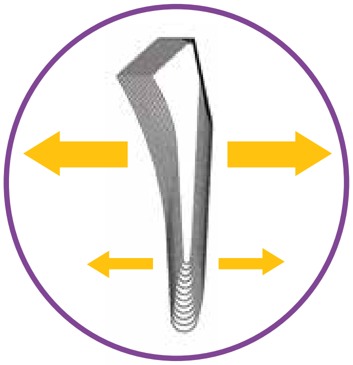
The resulting implant design can then be validated using SOMA fitting tools.

Three key SOMA-designed features

Bone morphology data allowed Stryker an unprecedented look at femoral anatomy, and assisted in the design of a novel femoral stem. The SOMA input* was instrumental in the establishment of three key design features of Accolade II:

Unique size-specific medial curvature

increasing proximal conformity to improve primary stability[14,15]



Enhanced proximal-distal proportions[16]

shown to mimic canal anatomy to avoid distal only engagement and achieve cortical fit[8,16]

Optimized stem length

enables muscle-sparing approaches without sacrificing stability[15,17]

*SOMA-design of Accolade II based on 556 CT scans.

Unique size-specific medial curvature

Initial stability is critical to long-term implant performance[6]. Early subsidence and micromotion has been established as a strong indicator for implant failure[6]. Initial stability may be increased by creating a higher conformity between the implant and the femoral cortices, leading to a larger area of contact[19].

Analyzing the SOMA morphology study data*, it was observed that a constant medial curvature may not allow for a conforming canal fit throughout varying femoral sizes.

This population-based input influenced Stryker to incorporate the market's first size-specific medial curvature into Accolade II. This feature was designed to enable a more conforming proximal cortical fit[15], which has been shown to allow for improved implant stability[19].

Using femurs from the SOMA database*, fit patterns of Accolade II can be compared to conventional tapered wedge designs. The three examples below illustrate how Accolade II achieves a more conforming canal fit throughout varying bone sizes.

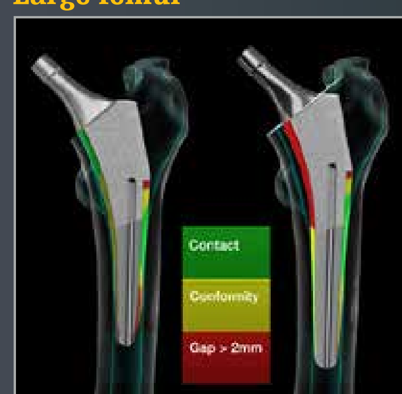
Small femur

Accolade II | Conventional tapered wedge

Medium femur

Accolade II | Conventional tapered wedge

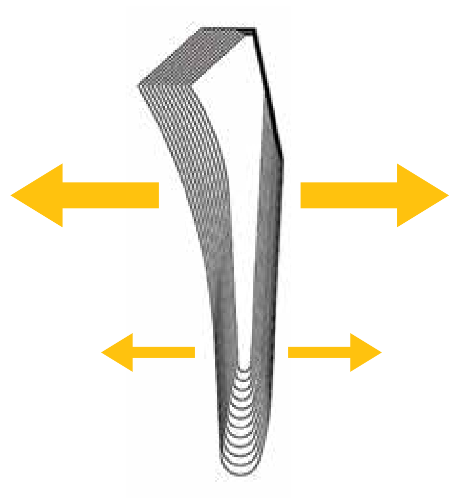
Large femur



Accolade II | Conventional tapered wedge

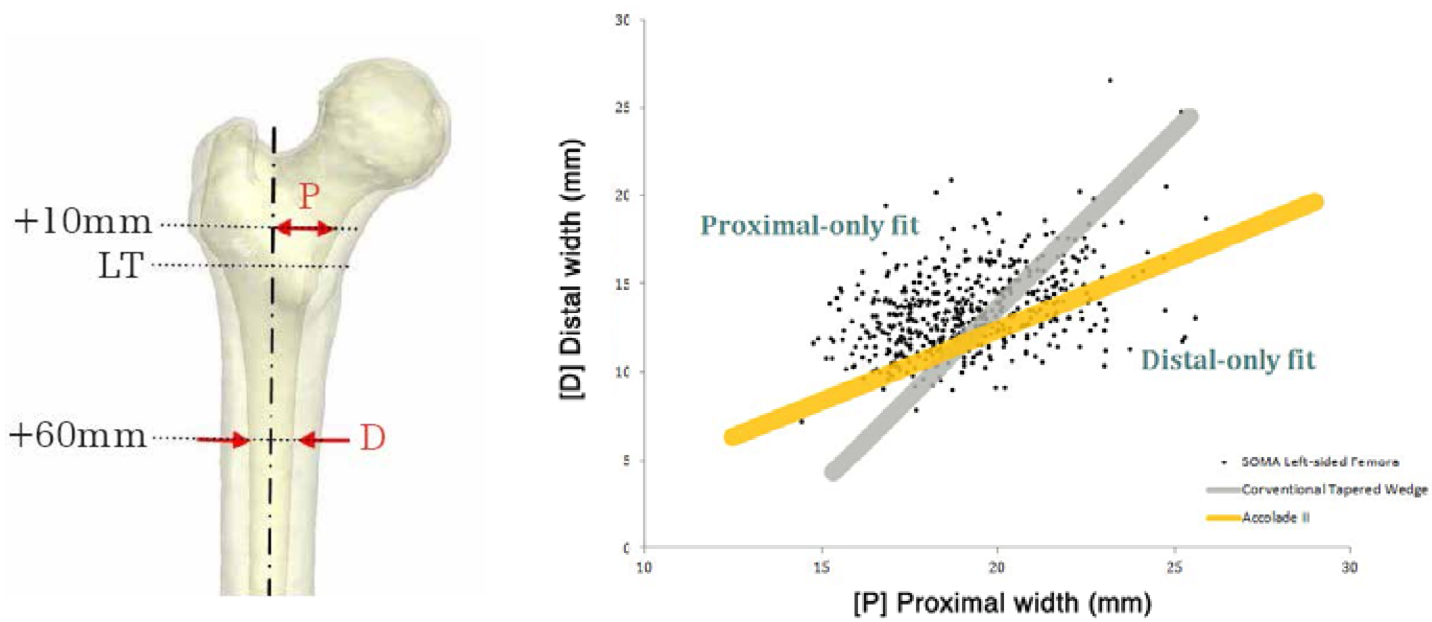
Enhanced proximal-distal proportions

Distal-only engaged femoral stems can experience stress shielding[19] and consequently may lead to elevated failure rates due to loosening and migration[9]. In order to better mimic the femoral anatomy and avoid distal-only engagement, a more anatomic implant growth rate is needed.



Utilizing the SOMA femoral morphology study*, a more anthropomorphic proximal-distal stem growth rate was identified. This rate led to enhanced implant proportions[13], as the distal geometry of Accolade II increases in size less than the proximal geometry. These proportions enable Accolade II to achieve a significantly better canal fit and fill,[9] and Accolade II has shown a decreased incidence of distal-only engagement[9].

Comparing implant fit



In the graph above, the proximal (P) and distal (D) measurements of a population of 556 femurs were plotted (black dots) against the corresponding stem diameters of Accolade II (gold) and a conventional tapered wedge design (grey). Accolade II achieved more fully-conforming and proximal-only fit types compared to the conventional design, while subsequently **reducing distal-only fit by 14%**.[16]

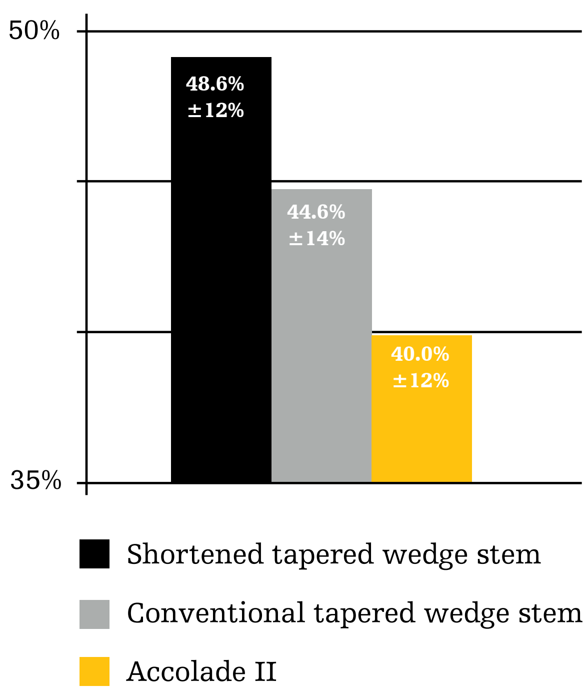
Optimized stem length

Popularity of muscle-sparing approaches and bone conserving fundamentals have led to a trend in shortening of stem length[20]. However, there exists a complex relationship between stem length and implant stability[20]. Shortening stem length without geometry optimization has been shown to increase the potential for micromotion[20], which is a strong indicator for implant failure[6].

Accolade II utilized the SOMA database* and stability analyses to establish an optimized length for each stem size which not only accommodates muscle-sparing approaches[20], but demonstrated improved initial stability[10].

"simply shortening a standard tapered wedge design may reduce the primary stability"[17]

Mean % of HA coated stem surface that experienced micromotion >50μm[17]



Designed to fit your approach

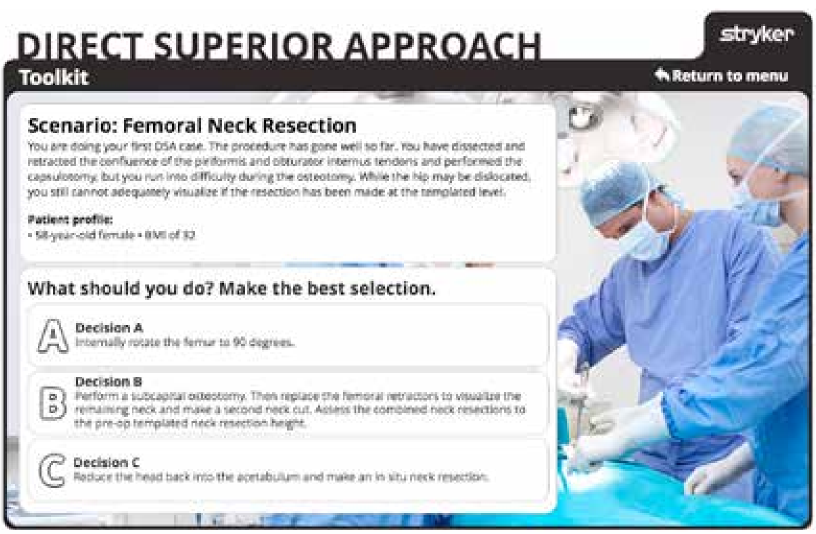
Muscle-sparing surgical approaches continue to gain popularity, due to the potential patient benefits of faster recovery[21,22], less pain[21,22] and greater satisfaction[23].

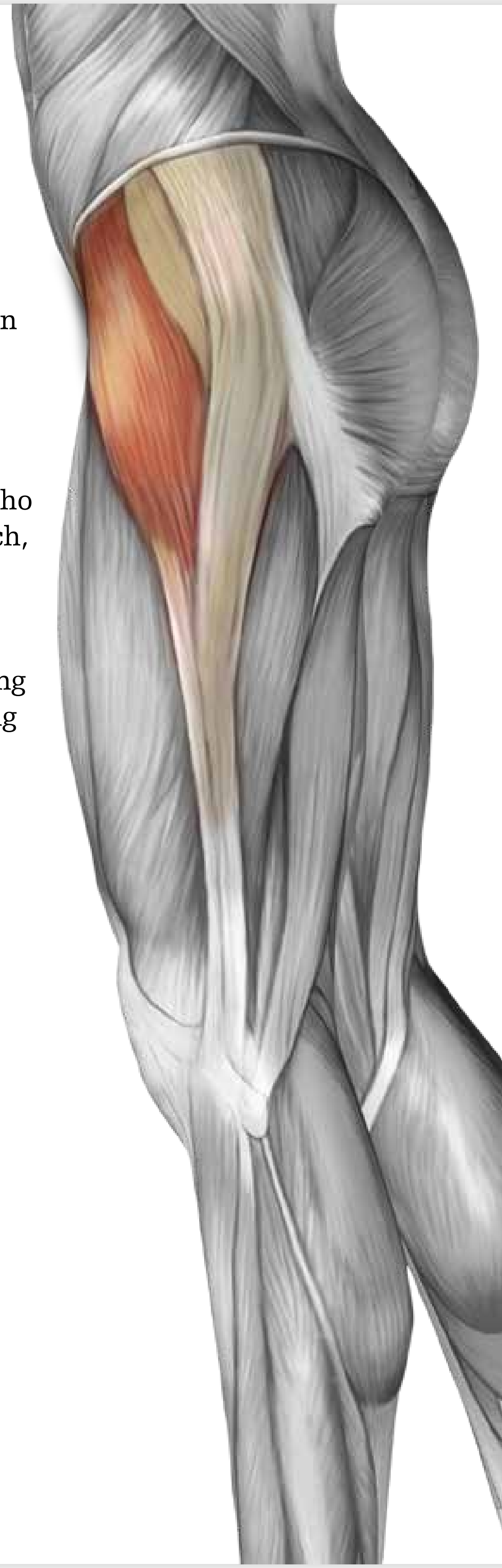
Stryker's portfolio of muscle-sparing techniques features modern instrumentation and dynamic Medical Education programs to support the **Direct Anterior Approach** and the **Direct Superior Approach**.

The new Direct Superior Approach was designed for surgeons who prefer the fundamentals and familiarity of the posterior approach, but seek to provide the next evolution in muscle-sparing THA surgical techniques for their patients.

Stryker has developed a training platform to help surgeons during the learning curve of a new surgical approach, Stryker's Training Academy.

For access to Stryker's Training Academy, contact your local Stryker sales representative.





Clinical performance

"Significantly better overall canal **fit**"[9] than conventional tapered wedge design

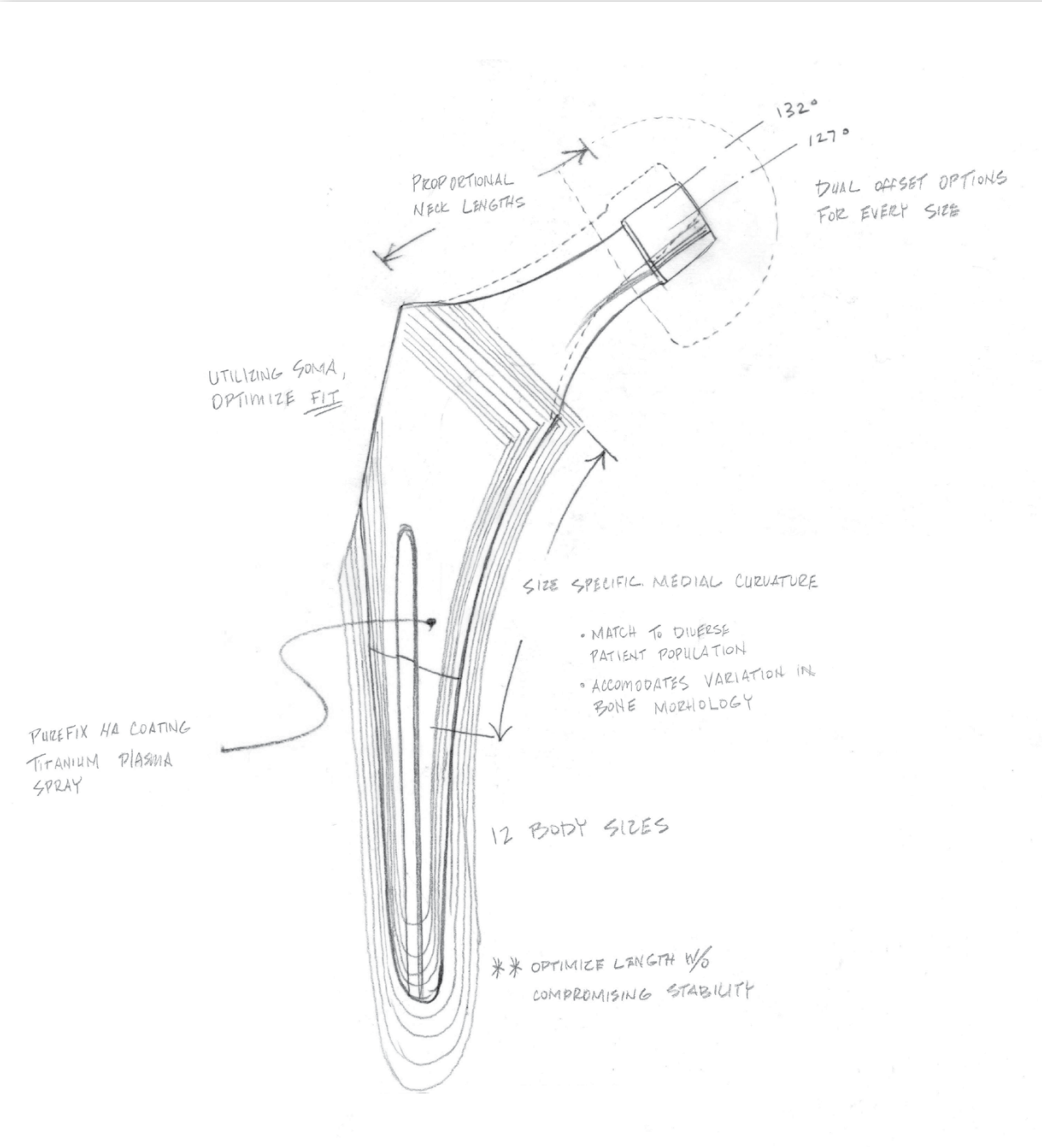
over
400,000
implanted worldwide[24]

over
16,500
bones*
in SOMA database[14]

99.2%
survivorship
for Accolade II pursuant to a 3.5-year mean study[12]

less than
0.1mm
subsidence pursuant to
2-year RSA study[10]

5x
less intraoperative fractures
observed compared to conventional tapered wedge[11]


132°
127°
PROPORTIONAL NECK LENGTHS
DUAL OFFSET OPTIONS FOR EVERY SIZE
UTILIZING SOMA, OPTIMIZE FIT
SIZE SPECIFIC MEDIAL CURVATURE
• MATCH TO DIVERSE PATIENT POPULATION
• ACCOMODATES VARIATION IN BONE MORPHOLOGY
PUREFIX HA COATING TITANIUM PLASMA SPRAY
12 BODY SIZES
** OPTIMIZE LENGTH W/O COMPROMISING STABILITY

Accolade II Implant catalog numbers

Part number	Size	Neck angle
6720-0027	0	132°
6720-0127	1	
6720-0230	2	
6720-0330	3	
6720-0435	4	
6720-0535	5	
6720-0635	6	
6720-0737	7	
6720-0837	8	
6720-0937	9	
6720-1040	10	
6720-1140	11	

6721-0027	0	127°
6721-0127	1	
6721-0230	2	
6721-0330	3	
6721-0435	4	
6721-0535	5	
6721-0635	6	
6721-0737	7	
6721-0837	8	
6721-0937	9	
6721-1040	10	
6721-1140	11	

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*SOMA-design of Accolade II based on 556 CT scans.

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