DESIGN RATIONALE
RADIUS OF CURVATURE
DESIGN RATIONALE

This optimized fit was determined by three anatomical studies which:
1. Characterized the native femoral anatomy
2. Validated the resulting fit of the nails in the distal femur

NAIL FIT VALIDATION:
TFNA SYSTEM AND FEMORAL RECON NAIL

Based on the results of the femoral anatomy characterization, both nails were designed with a 1.0m ROC.

RESULTS
Less Nail Protrusion Through the Inner Cortex
The TFNA Nail had a 38% smaller mean total surface area of nail protrusion from the inner cortex surface than Gamma3.

Improved Distal Fit
• The distal nail tip was positioned in the far anterior cortex in 59% of Gamma3 samples (vs. 31% TFNA and 21% FRN)
• The FRN and TFNA nails both had a considerably higher number of center positions than the Gamma3 nail (35% and 25% vs 14%)

TFNA Nail and FRN: A Similar Fit in the Distal Femur
Despite minor differences in proximal nail shape, there was no statistical difference detected in distal nail tip position between the FRN and TFNA Nail group indicating a similar fit and resulting position in the distal femur.

FEMORAL ANATOMY CHARACTERIZATION
Prior to the development of the TFNA Nail, a comprehensive anatomical study of the femur was warranted to properly characterize the radius of curvature of the native anatomy and serve as the basis for a new nail design.

METHODOLOGY
• 90 3D bone models were constructed from CT Data
• A computer generated software was used to create the reference geometries for the proximal anatomy and the shaft antecurvature

The results of the study indicated an overall ROC of 885mm, suggesting that an ROC of 1m would achieve an improved fit in the investigated population.

COMPLICATIONS FROM NON-ANATOMIC FEMORAL NAIL FIT

Despite decreases in nail radius of curvature (ROC) over the last decades, recent studies still report the existence of misfit between the curve of the natural femoral anatomy of some patients and the curve of the nail. This can lead to distal cortical impingement, which may occur in up to 25% of hip fracture repair cases. This complication may lead to a fracture at the distal nail tip, called anterior perforation, which requires revision surgery.

NAIL SYSTEM

<table>
<thead>
<tr>
<th>NAIL SYSTEM</th>
<th>ROC</th>
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<tbody>
<tr>
<td>Stryker Gamma 3® &amp; T2</td>
<td>1.5m, 2.0m</td>
</tr>
<tr>
<td>S&amp;N Trigen® Interfan</td>
<td>1.5m, 2.0m</td>
</tr>
<tr>
<td>Zimeno® Natural Nail</td>
<td>1.27m-1.53m</td>
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</tbody>
</table>

3D Implantation Comparison

The results of the study indicated an overall ROC of 885mm, suggesting that an ROC of 1m would achieve an improved fit in the investigated population.

* Bench test results may not be indicative of clinical performance

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