

DESIGN RATIONALE

REFERENCE TOE SYSTEM™

1ST MTP Implant



A GLOBAL EXTREMITY COMPANY

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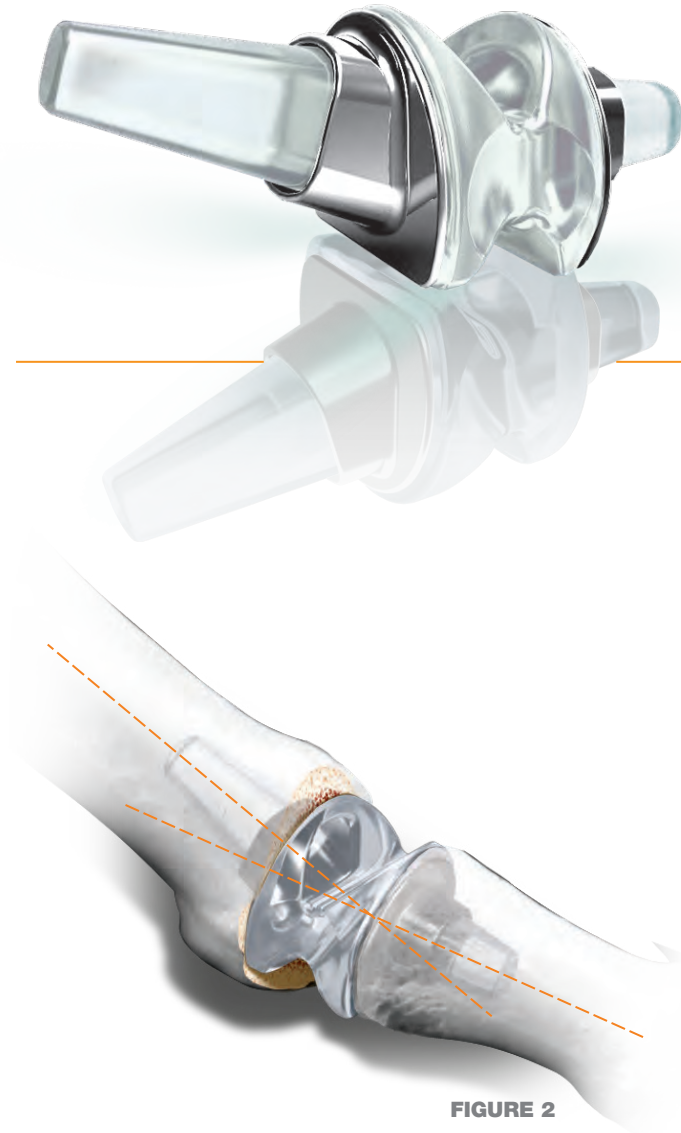


FIGURE 2

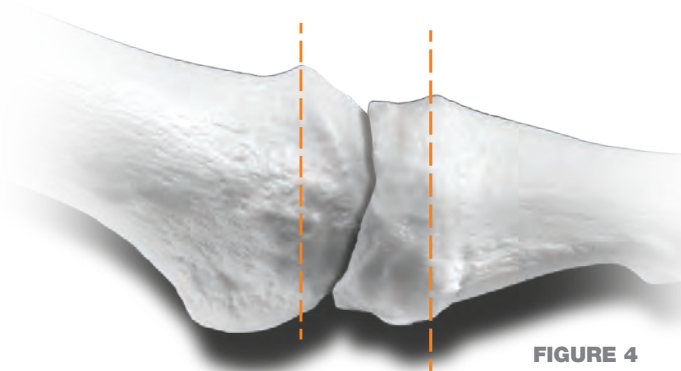


FIGURE 4

OVERVIEW

Silicone toe implant technology has not advanced for over a decade. The core technology from Wright Medical dates back to the 1960's. With the revolution of sterile packaged, single-use disposable product solutions, comes the In2Bones Reference Toe System™ (RTS™). The RTS™ advances the science by incorporating modern joint replacement with state-of-the-art instrumentation. This is the first MPJ replacement system with single-use instruments. The RTS™ implant design marries the complexity of computer modeling and finite element optimization with a reimagined instrument set that produces repeatable results in the simplest way. The RTS™ Silicone Toe offers the next generation flexible joint replacement solution for today's demands.

STRENGTH ANALYSIS

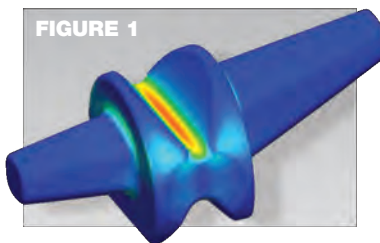


FIGURE 1

The RTS™ implant is equivalent in strength to leading implants currently on the market. Finite element computer models were created of the RTS™ and two competitive implants. A FEA analysis comparing its resulting stress from a given

displacement of two different competitive designs was performed. The stress output results showed equivalent strength to the competitive implants when subjected to an equal displacement load. Figure 1 below is a stress color plot of the RTS™ three-dimensional finite element model where red is designated as the highest stress locations and dark blue is designated as the lowest stress areas. (Figure 1).

IMPLANT DESIGN

- Implant available in 4 sizes to cover the anatomic range of the patient population.
- Anatomically angled proximal stem at 16° to match natural declination angle of the 1st metatarsal. (Figure 2)
- Hourglass body shape to facilitate medial/lateral flexion for fit

into shoes while maintaining a high strength hinge in the sagittal plane for GAIT.

- Hinge design provides excellent strength while still allowing for good range of motion.
- Implants are composed of medical grade ultra high performance, high consistency silicone elastomer designed, manufactured and purified to meet the strictest needs of the healthcare industry.
- Titanium grommets are 100% precision machined to tight tolerances and high polished which results in a consistent, repeatable fit with both the implant and bone interfaces reduces the risk of silicone wear.
- Grommet shape and fit with implant helps resist implant rotation. Press-fit and shape provides a secure fit with the bone.

(Figure 3).

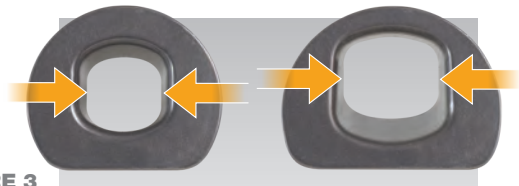


FIGURE 3

INSTRUMENT SET DESIGN

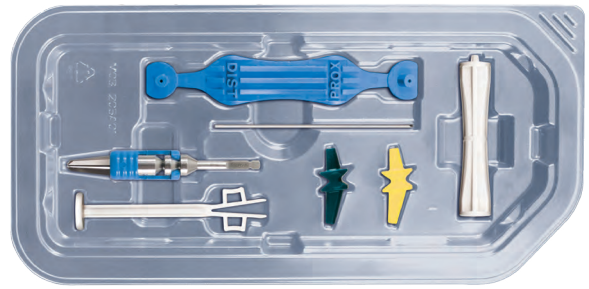
Fully disposable single-use instrumentation for ease of use and reduction of patient risk from re-cleaning, re-sterilization procedures [Patent Pending]. Patient labels and lot coding enables full traceability to each implantation. See *Instrument Set at left*.

- A** Colored silicone trials provided for final size selection and ROM confirmation
- B** Disposable sizing instrument provides an easy size and resection width determination. Patent pending
- C** Ergonomic wireguide with placement assistance features for easy wire insertion
- D** Fully cannulated power reamers with standard small AO quick connection for quick bone preparation
- E** Depth-limiting sleeve for accurate repeatable reaming depth and grommet fit (patent pending)
- F** Purposefully designed Grommet Placer for controlled and confident grommet placement and a self-retaining feature for ease of insertion.
- G** A dedicated grommet impactor to fully seat the grommets in the case of hard bone

No need for broaching or hand-preparing bones to accept the grommets.

TECHNIQUE INNOVATIONS

- Bone joint resections are straight, parallel and aligned with weight bearing so no need for cutting guides. **(Figure 4).**
- The wireguide creates a single point of reference from which the subsequent instruments locate.
- Fast-cutting cannulated reamers with depth stops replace broaching to provide precise grommet fit and reproducible results.
- Trials are provided for final ROM assessment prior to final implant placement.

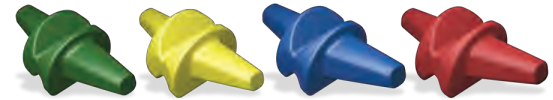


SINGLE USE DISPOSABLE INSTRUMENT KIT

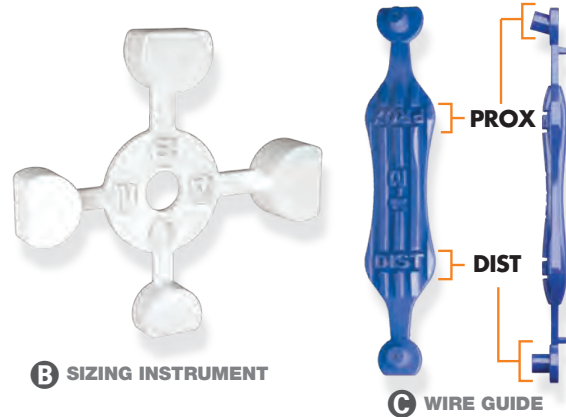
4 SIZES OF IMPLANTS



A



4 CORRESPONDING TRIALS

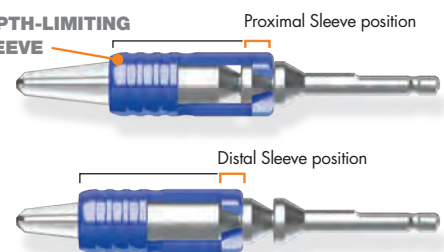


B SIZING INSTRUMENT

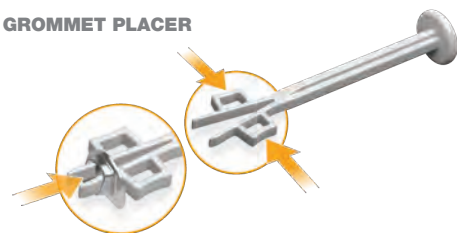
C WIRE GUIDE

D CANNULATED POWER REAMER

E DEPTH-LIMITING SLEEVE



F GROMMET PLACER



G GROMMET IMPACTOR





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