

SINEFIX™

REVOLUTIONIZING ROTATOR CUFF REPAIR

Addressing biomechanical fixation and critical role of blood circulation on tendon to bone healing.

- Simple surgical technique that does not require suture management or knot tying.
- Higher pull-out forces than double row fixation.
- Anticipate improved tendon to bone fixation with less implants.
- Even pressure load over the tendon ensuring good blood circulation.
- Minimize punctual pressure aiming to reduce risk of loosening post-surgery.
- Demonstrates less gap formation than double row fixation to optimize contact pressure.



Philip Kasten, MD, PhD
Leading Specialist in Shoulder Orthopedics & Trauma Surgery;
Lead Investigator of the Pre-market Clinical Study

"I believe that SINEFIX has favorable biomechanics and will result in optimal tendon cell growth back to the bone. We have completed our first clinical cases which will help assess the **usability and efficacy of the implant** while building our clinical experience."



THE SINEFIX SYSTEM

The SINEFIX implant is made of PEEK and can be used to re-attach a ruptured rotator cuff tendon up to 2cm.

Dedicated instrument set includes:

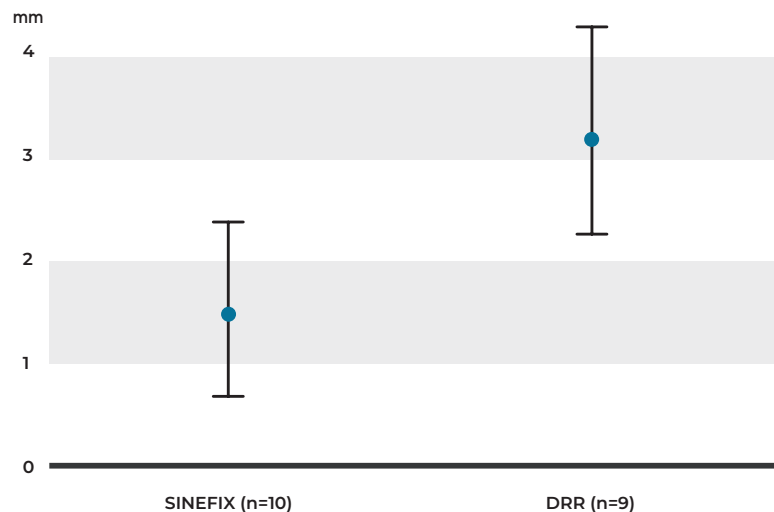
- 12mm Trocar
- Base Plate Inserter
- Lateral Anchor Inserter
- Repusher



Rotator Cuff Refixation: A Biomechanical Evaluation of a New Implant

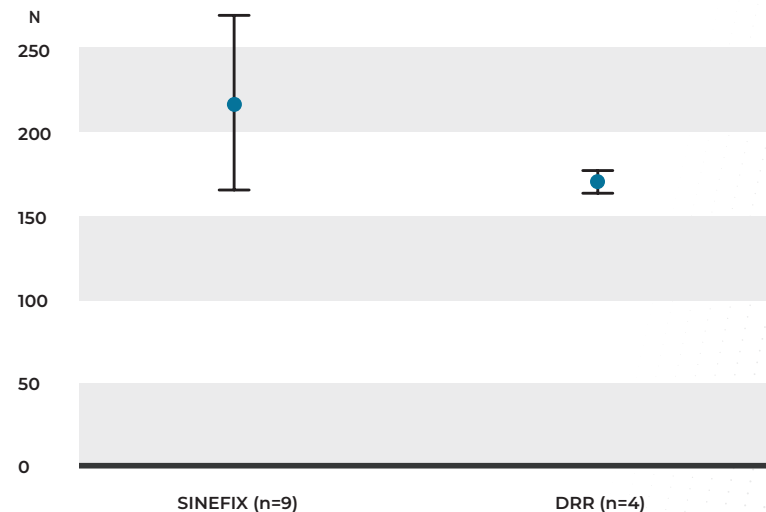
Philip Kasten, Jordi Borst, Daphne Gengler, Huub ter Braak, Friedrich Dehlinger³, Lukas Floess⁴, Stefan Welte³

GAP FORMATION UNDER CYCLIC LOADING UP TO 62 N



All (n=10) tendons refixed with SINEFIX™ survived cyclic loading up to 62N with a gap formation up to 1.49 millimeter (SD 0.84). In contrast, with the DR method, one tendon remained less stable (n=9) with a gap formation of 3.19 millimeters (SD 0.91) ($p=0.001$).

PULLOUT FORCES



The maximum pullout forces with SINEFIX™ (n=6) were 215N (SD 55) versus DRR (n=4) with 166N (SD 15) ($p=0.084$).

The Sinefix implant has at least as high maximum pullout forces and gap formation as a double-row refixation (DRR) with “all-suture” anchors during cyclic loading.



Stefan Welte, MD
Co-Founder of Inovedis;
Trauma & Orthopedic Surgeon

“There have been limited enhancements in rotator cuff repair outcomes due to industry’s emphasis on the biomechanical aspects. We saw a potential oversight on the biological front and focused in on the critical role of circulation. SINEFIX is designed to share the tension and force over the repair site to better maintain blood circulation, thus promoting better results than those of suture anchors.”



Learn more at www.inovedis.com

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CAUTION: SINEFIX is intended for soft tissue to bone reattachment in rotator cuff repairs for tendon ruptures up to 2 cm. U.S. Federal law restricts this device to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device.

Models used for illustrative purposes only. SINEFIX is not approved for sale outside the U.S.

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Manufacturer



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