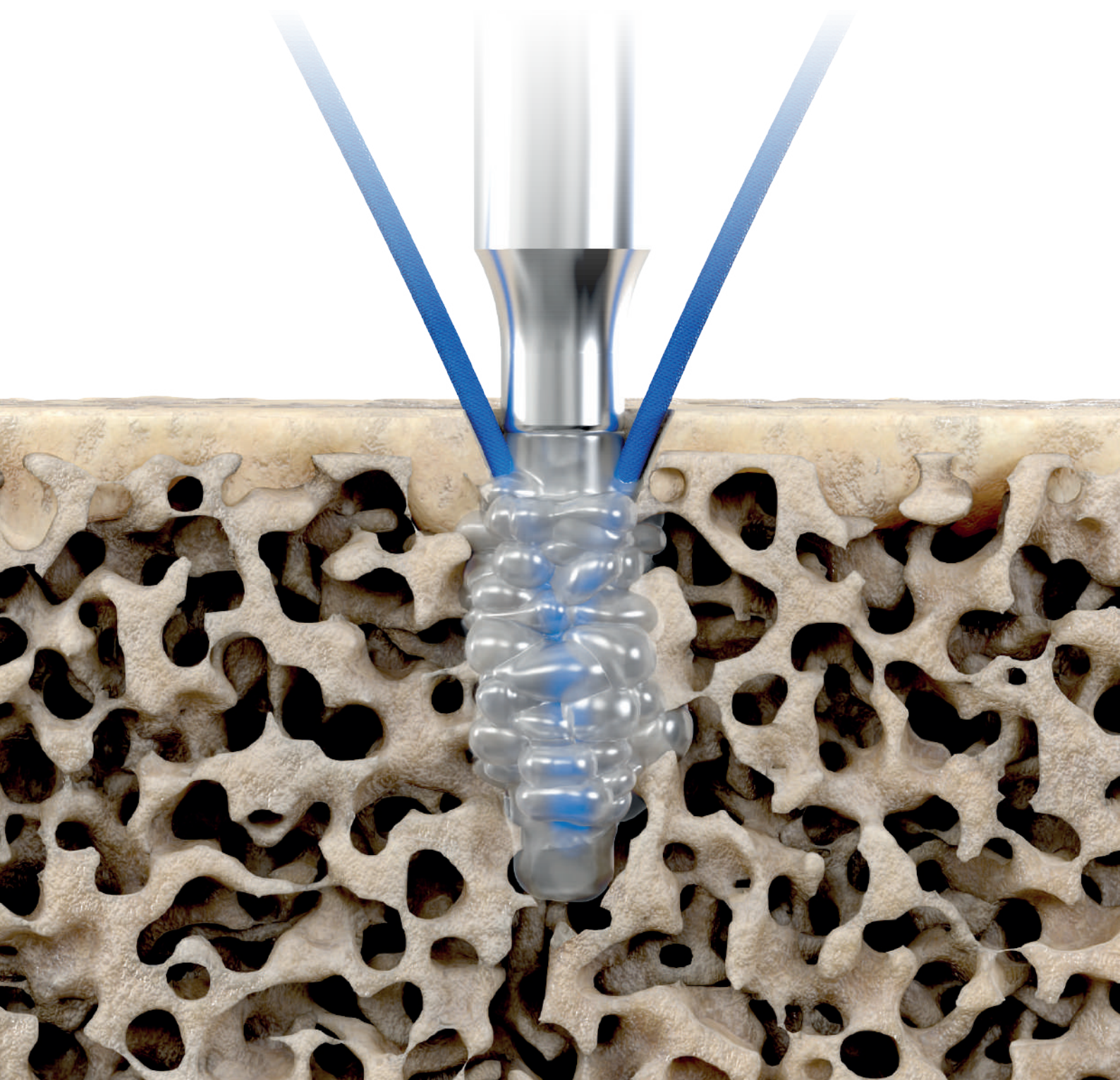


# SUPRA<sup>△</sup>FUSION

## SF Push-in Anchor 2.3

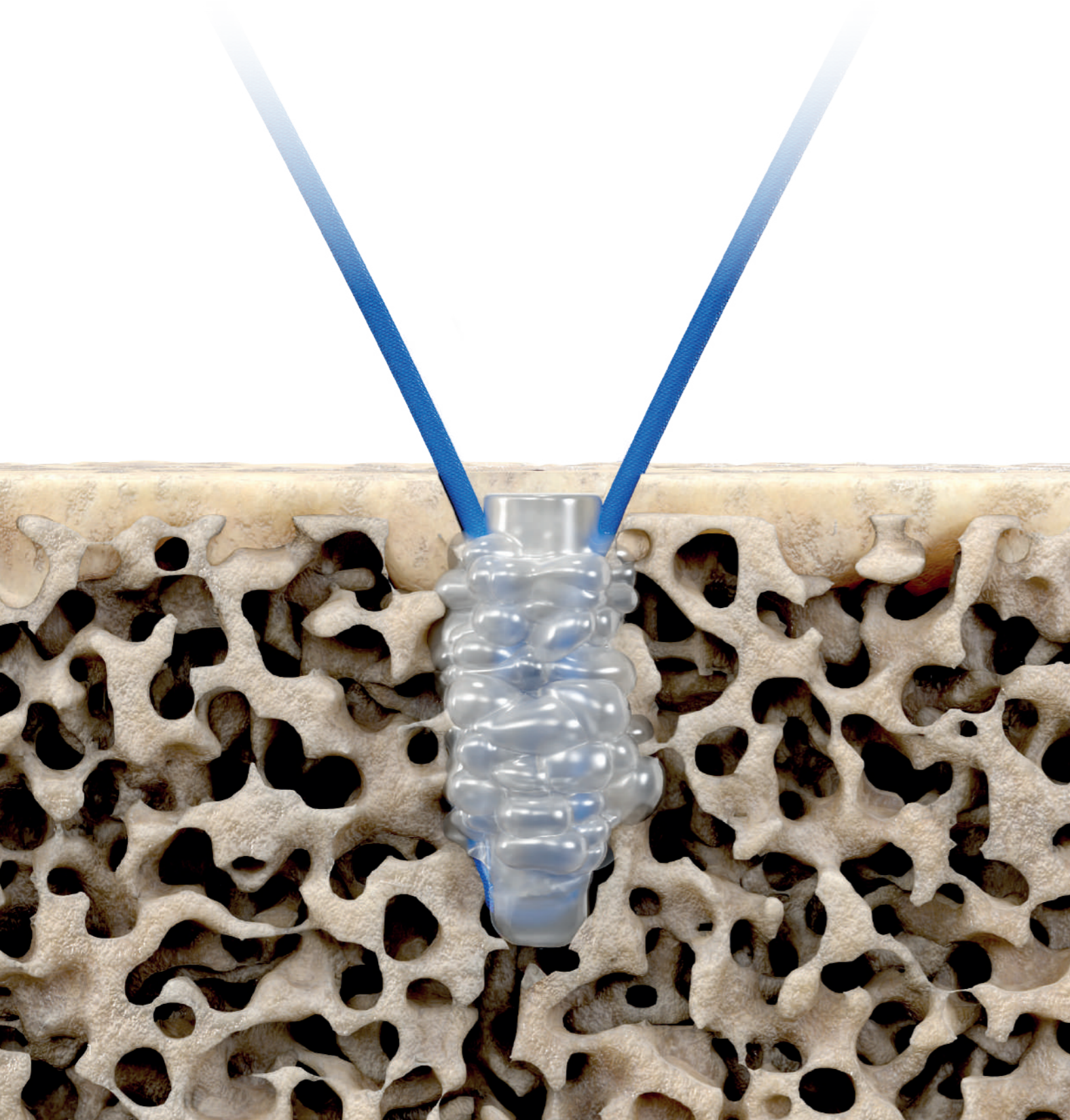
Precise Soft Tissue Fixation





## Intended Use

The SF Push-in Anchor is a resorbable suture anchor for suture or soft tissue fixation to bone in the foot, ankle, hand, wrist, elbow, and shoulder. The SF Push-in Anchor is designed to be inserted with Ultrasonic Energy using the SupraFuser® B Ultrasonic System.



## Indications

### Shoulder

- Bankart Repair
- Capsular Shift
- Capsulo-labral Reconstruction

### Elbow

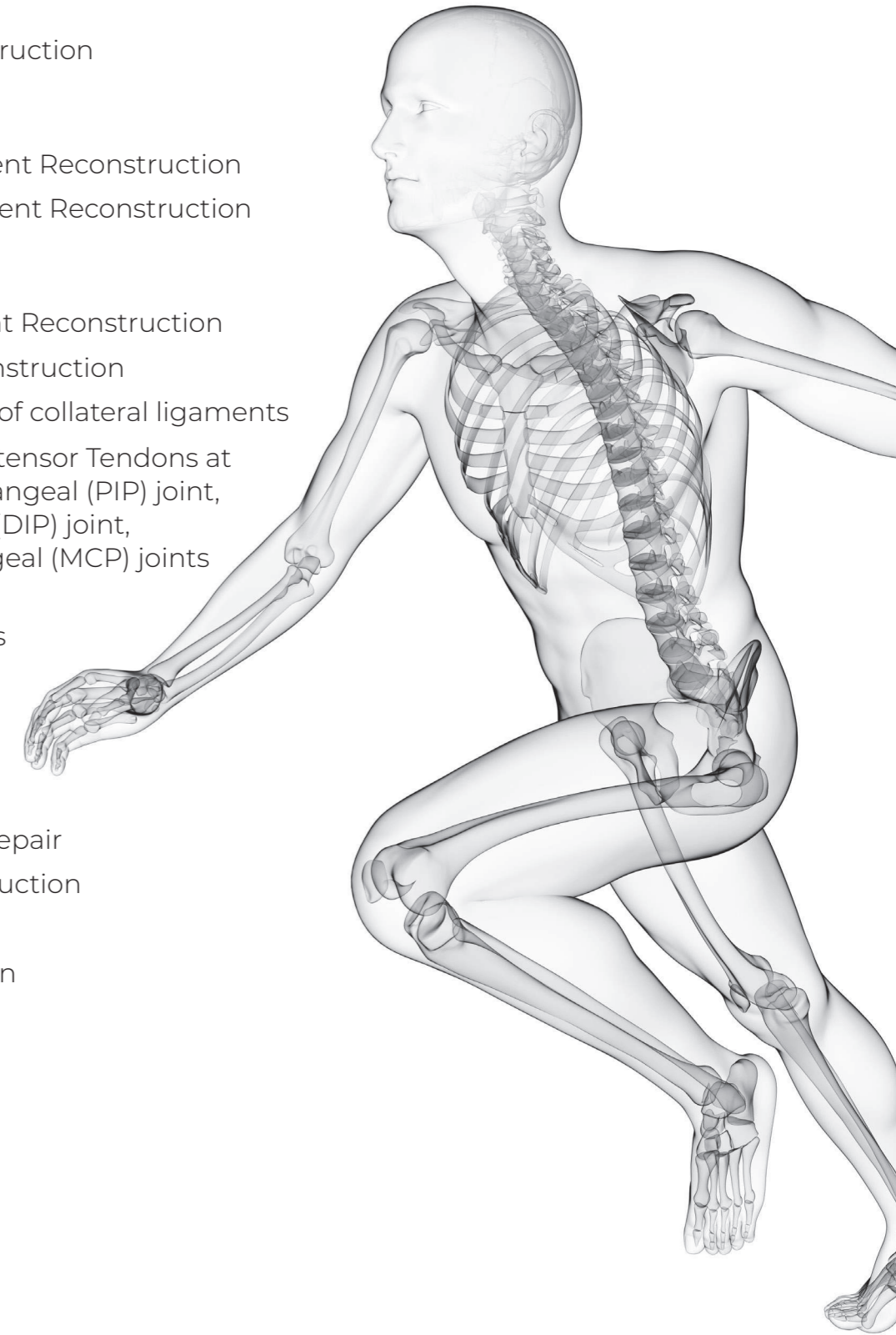
- Ulnar Collateral Ligament Reconstruction
- Radial Collateral Ligament Reconstruction

### Hand & Wrist

- Scapholunate Ligament Reconstruction
- Carpal Ligament Reconstruction
- Repair/Reconstruction of collateral ligaments
- Repair of Flexor and Extensor Tendons at the Proximal Interphalangeal (PIP) joint, Distal Interphalangeal (DIP) joint, and Metacarpophalangeal (MCP) joints for all digits
- Digital tendon transfers

### Foot & Ankle

- Lateral Stabilization
- Medial Stabilization
- Metatarsal Ligament Repair
- Hallux Valgus Reconstruction
- Digital Tendon Transfer
- Mid-foot Reconstruction





## Design Features

### Ultrasonic Design for Seamless Soft-Tissue to-Bone Fixation

#### Enhanced biomechanical strength and no micromotion:

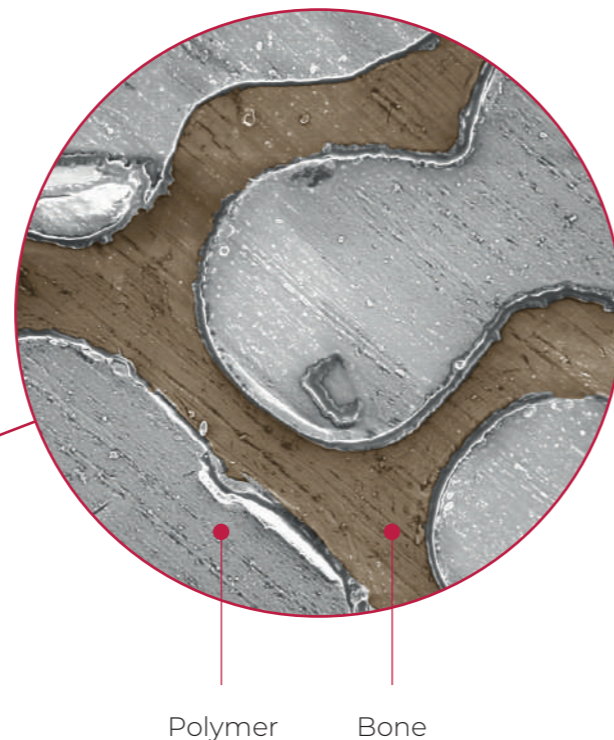
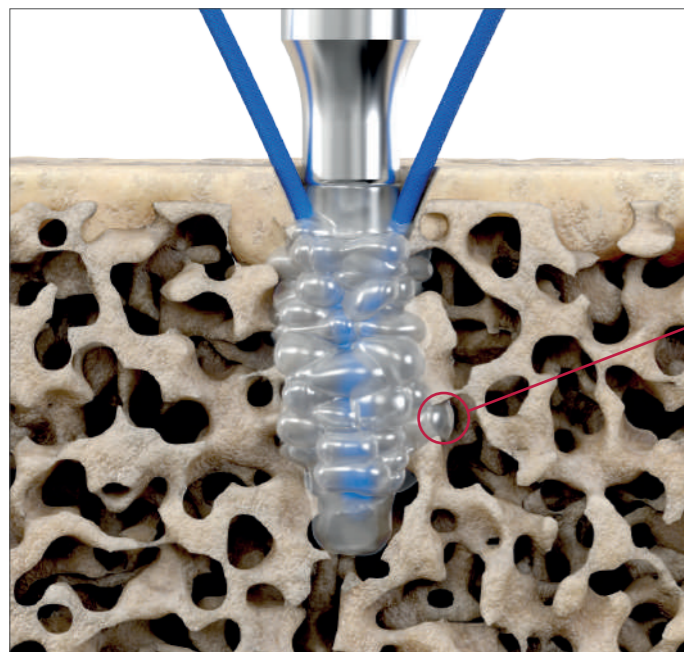
The sophisticated design of the implant surface ensures that the SF Push-in Anchor 2.3 liquefies reliably in contact with bone and bonds homogeneously to the cancellous bone.

By interdigitating with the bone structure, the polymer augments the cancellous bone at the interface to the implant instead of violating it as a thread or barb of an anchor would do.

This augmentation prevents micromotion during cyclic loading and the anchor does not require cortical bone to provide full stability.

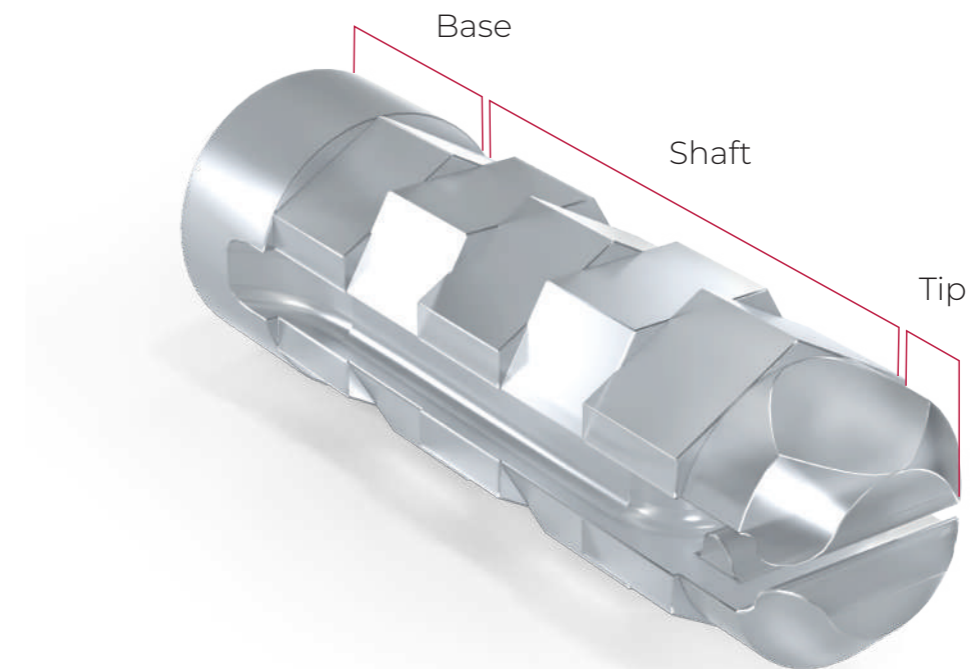
Consequently, the small footprint of the anchor provides unparalleled freedom of implant placement without compromising on fixation strength.

Implantation of the SF Push-in Anchor requires minimal force and is completed within seconds.



## Design Features

### SF Push-in Anchor



#### Implant Base

The head is designed to transfer the ultrasonic vibration generated in the Handpiece of the SupraFuser® B Ultrasonic System.

#### Augmenting Shaft

The shaft has two functions: grooves guide and protect the sutures during the implantation process.

The ridges concentrate the ultrasonic energy and ensure that the surface of the shaft melts consistently, and with the minimum amount of energy.

#### Functional Tip

The SF Push-in Anchor features two transverse apical "click-in" grooves to position the suture before implantation.

*The advantage of this anchor is its stable fixation in cancellous bone in the absence of an intact cortex.*

Kastenberger T. et al. 2020: Archives of Orthopaedic and Trauma Surgery

## Design Features

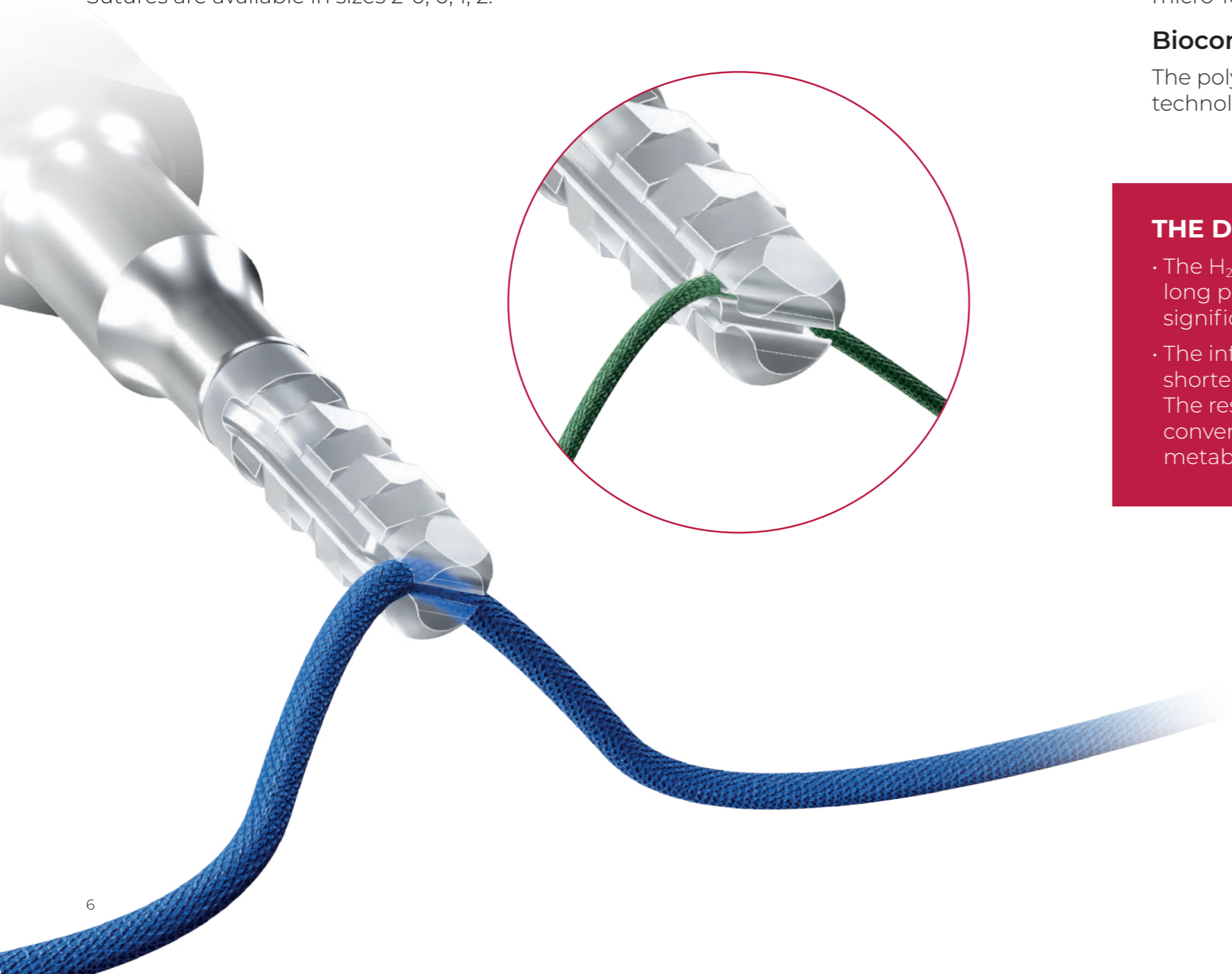
### Suture Compatibility

The specially designed SF Push-in Anchor tip allows maximum flexibility for a choice of sutures according to indication. Various suture-types and -thicknesses can be easily loaded.

The first, distal and larger apical groove fits the heavier sutures, whereas the second, proximal and smaller groove fits the lighter ones.

The SF Push-in Anchor must be used with UHMWPE sutures, a combination of UHMWPE and polyester sutures (USP #2, #0, #2-0, #3-0, or #4-0) or non-resorbable polyethylene terephthalate sutures (USP #2, #0, #2-0, or #3-0).

Sutures are available in sizes 2-0, 0, 1, 2.



## Material

### High strength

The molecular combination of L and DL lactides (70/30) creates a unique strength and complete restorability. The SF Push-in Anchor retains its full strength beyond the healing period.

### Resorbable

The SF Push-in Anchor is degraded by hydrolysis. The degradation products are entirely metabolized and excreted.

### Integrated

The SF Push-in Anchor forms a compelling, connective tissue-free micro-form-fit with the bone.

### Biocompatible

The poly-L(DL) lactide used in combination with SupraFusion technology is also tissue-compatible and clinically established.

### THE DEGRADATION MECHANISM

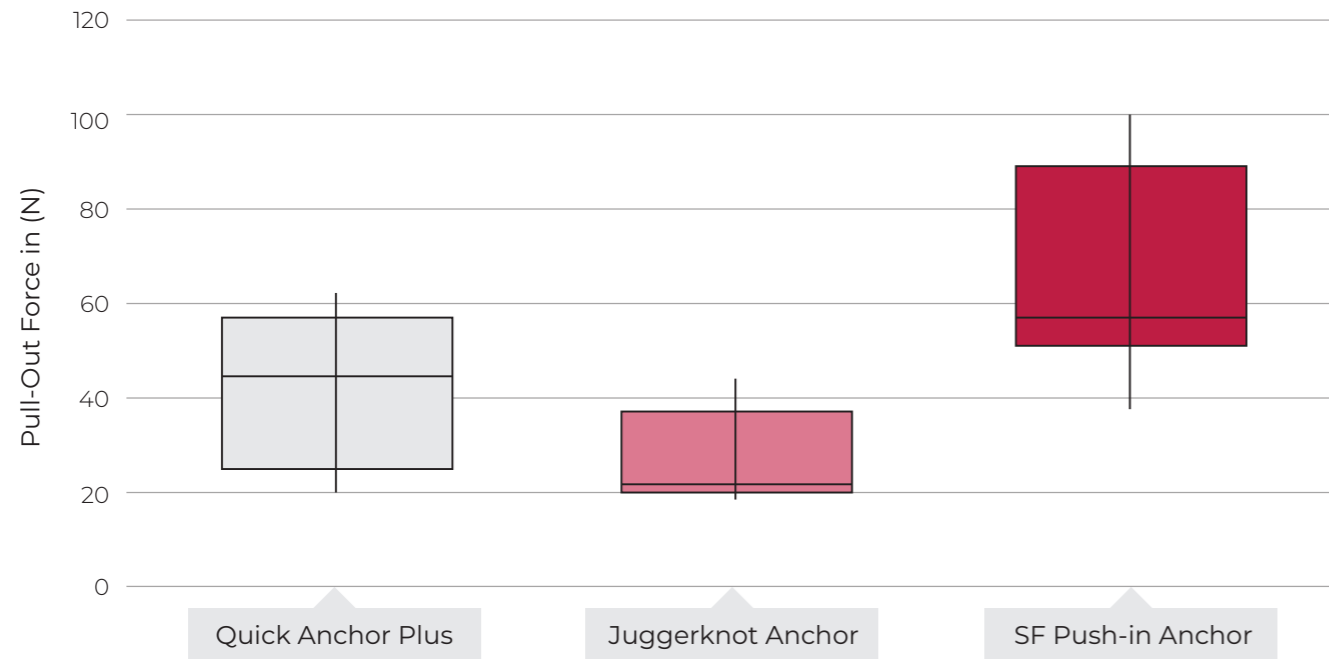
- The H<sub>2</sub>O from the body fluid is infiltrated between the long polymer chains of the poly-L-(DL) lactide without significantly changing the properties of the material.
- The infiltrated H<sub>2</sub>O leads to a continuous shortening of the polymer chains (hydrolysis). The resulting L- and D-lactide molecules are converted into H<sub>2</sub>O and CO<sub>2</sub> via physiological metabolic processes.





# USP

## Higher Pull-Out Strength in Cancellous Bone (Ulnar Collateral Ligament Avulsion Fracture)



Wagner et al., Biomechanical in vitro comparison of suture anchors for thumb UCL repair, 2018.

### Stronger

Higher biomechanical strength compared to competitor's suture anchors, especially if it comes to creep or cyclic loading.

### Smaller

The SF Push-in Anchor is remarkably compact and optimized in its design, reducing trauma without compromising on suture fixation.

### No cortical bone is required

The anchor securely bonds with cancellous bone all around.

### Resorbable

Being entirely made of bioresorbable polymer eliminates the need for a second surgery to remove the implant.

### Unique

The stronger biomechanical strength combined with a smaller footprint and resorbable material provides unique surgical options in terms of anchor placement and functionality.

# Surgical Steps



# Instrumentation

## SupraFuser® B Ultrasonic System

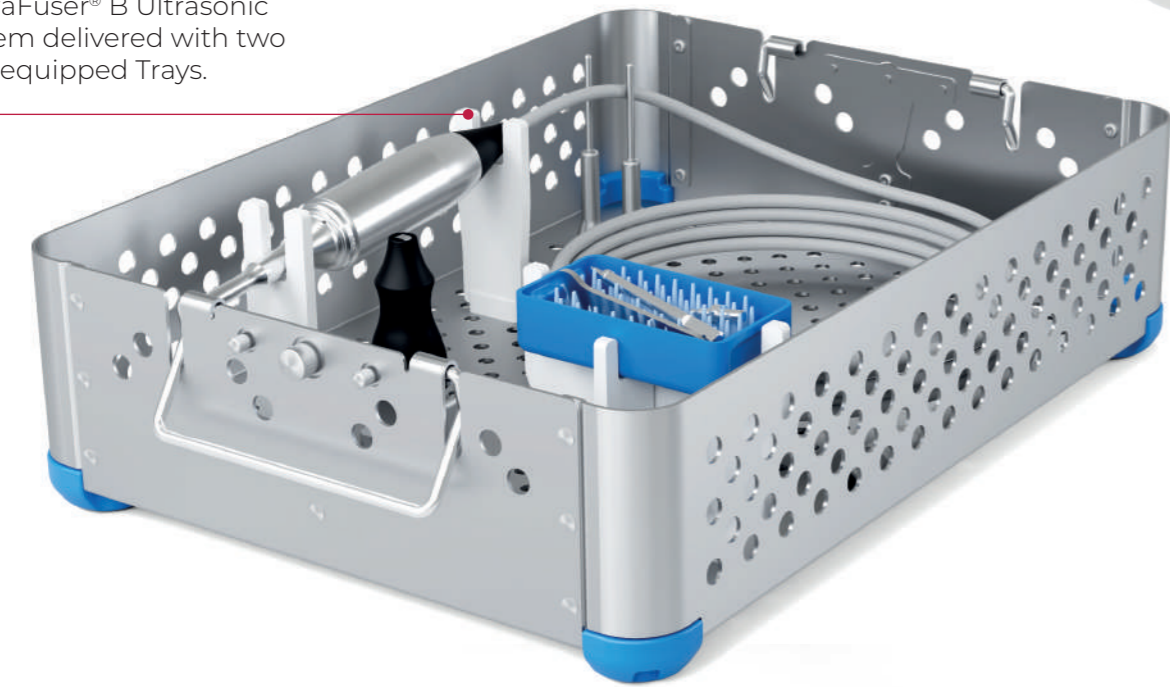
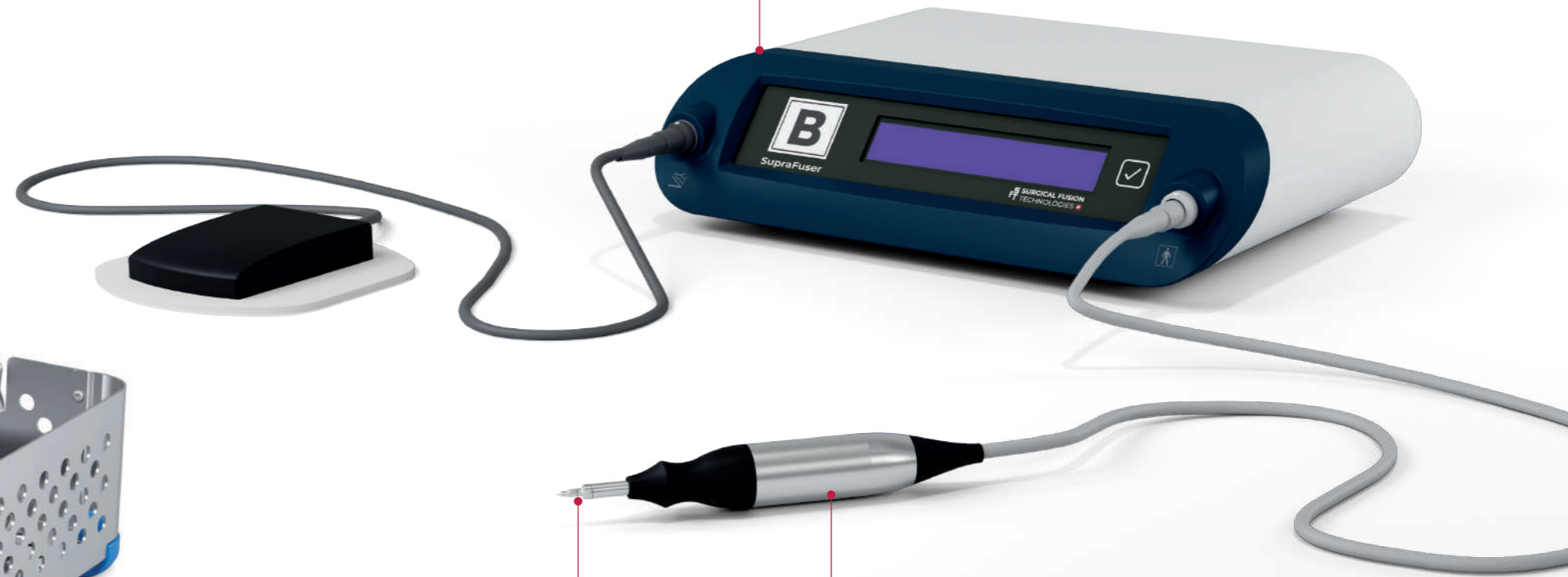
The heart of the SupraFusion technology is the SupraFuser® B Ultrasonic System. Design and performance are optimized for the easy and safe application of our implants.

The SupraFuser® B Ultrasonic System comprises a Handpiece that transmits the ultrasonic vibrations to the implants and is activated by a Footswitch.

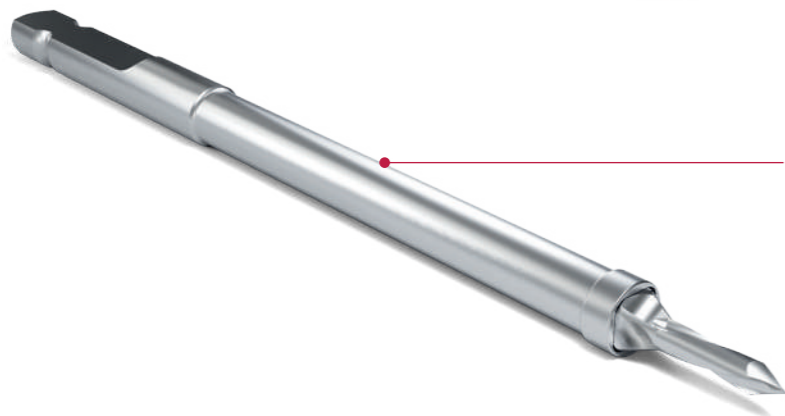
The Handpiece comes within a tray together with dedicated instruments, like the Sonotrode, and the Drill. The system includes sutures that are provided separately.

SupraFuser® B Ultrasonic System delivered with two fully equipped Trays.

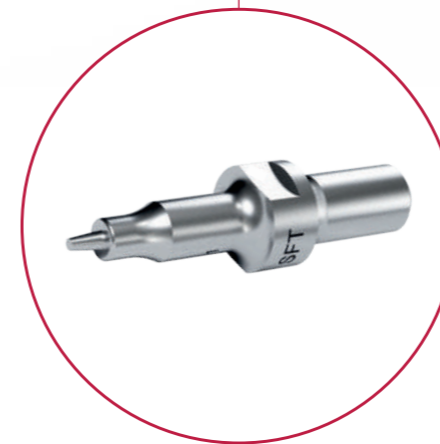
SupraFuser® B Ultrasonic Generator: one-step setup process.



Handpiece with an ergonomic and user-friendly handle.



The Drill with specific drill geometry and integrated drill stop for the SF Push-in Anchor to ensure controlled liquefaction during ultrasonic implantation.



The Sonotrode is designed to hold the implant firmly and to provide optimal visibility of the insertion process.

# SUPRA<sup>△</sup>FUSION

*Precise Soft Tissue Fixation*

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

This document is intended solely for the use of healthcare professionals.

This technique was developed in conjunction with healthcare professionals. A surgeon must always rely on his or her professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Innov8ortho, LLC does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery. The information presented is intended to demonstrate a Innov8ortho, LLC product. A surgeon must always refer to the package insert, product label and/or instructions for use, including the instructions for Cleaning and Sterilization (if applicable), before using any Innov8ortho, LLC product.

The SF Push-in Anchor is protected by US Patent: 9,615,820 B2.

SupraFusion contains licensed technology from WoodWelding AG, Switzerland.

For the Surgical Technique and Instruction for Use, visit [ifu.surgical-fusion.com](http://ifu.surgical-fusion.com)

Innov8ortho, LLC is the exclusive distributor of the SF Push-in Anchor 2.3 and SupraFuser® B Ultrasonic System.



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