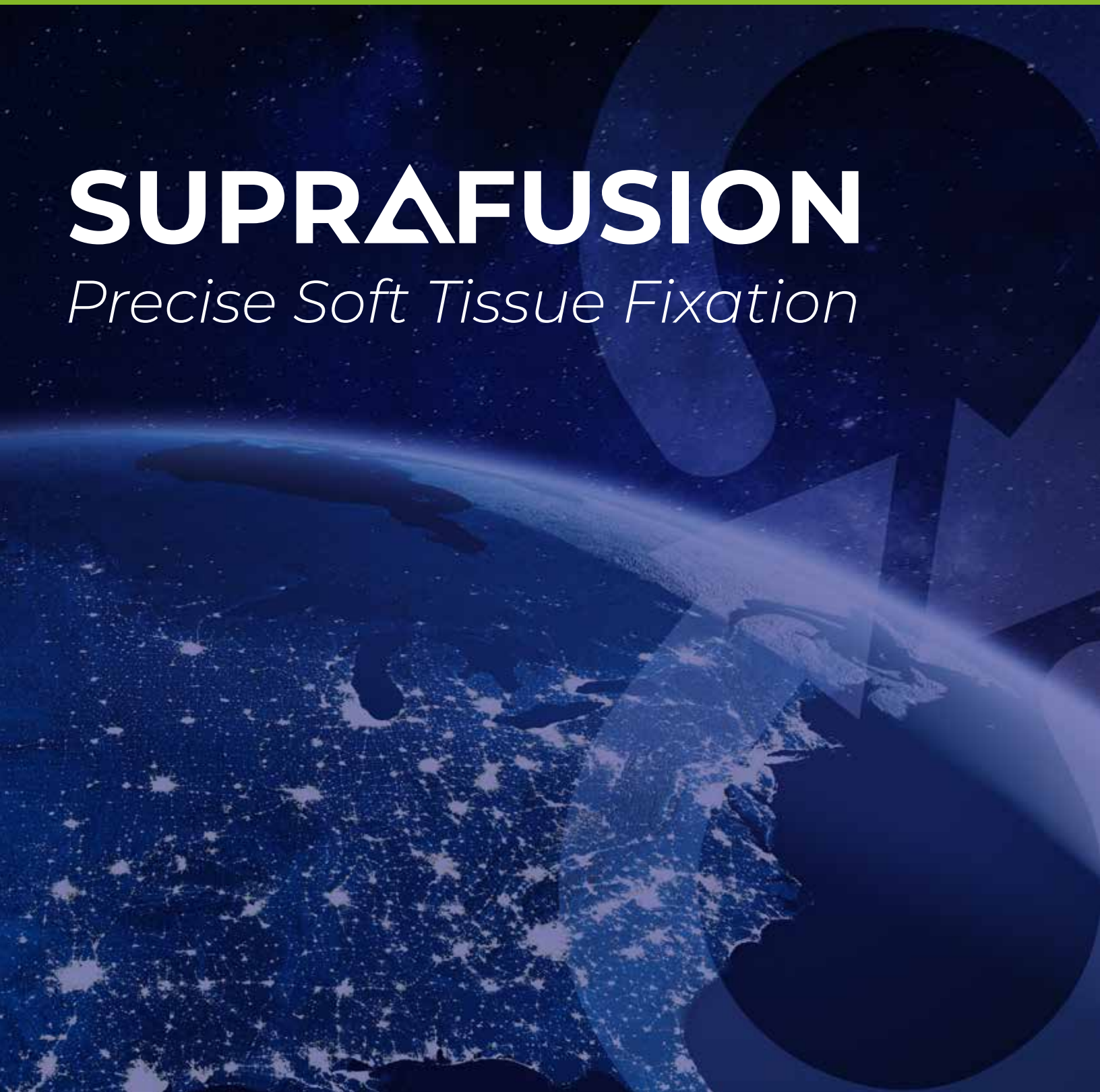
innov8ortho

www.innov8ortho.com

Value Analysis Guide



SUPRAFUSION

Precise Soft Tissue Fixation

SUPRAFUSION

Value Analysis Guide

Suprafusion Contents

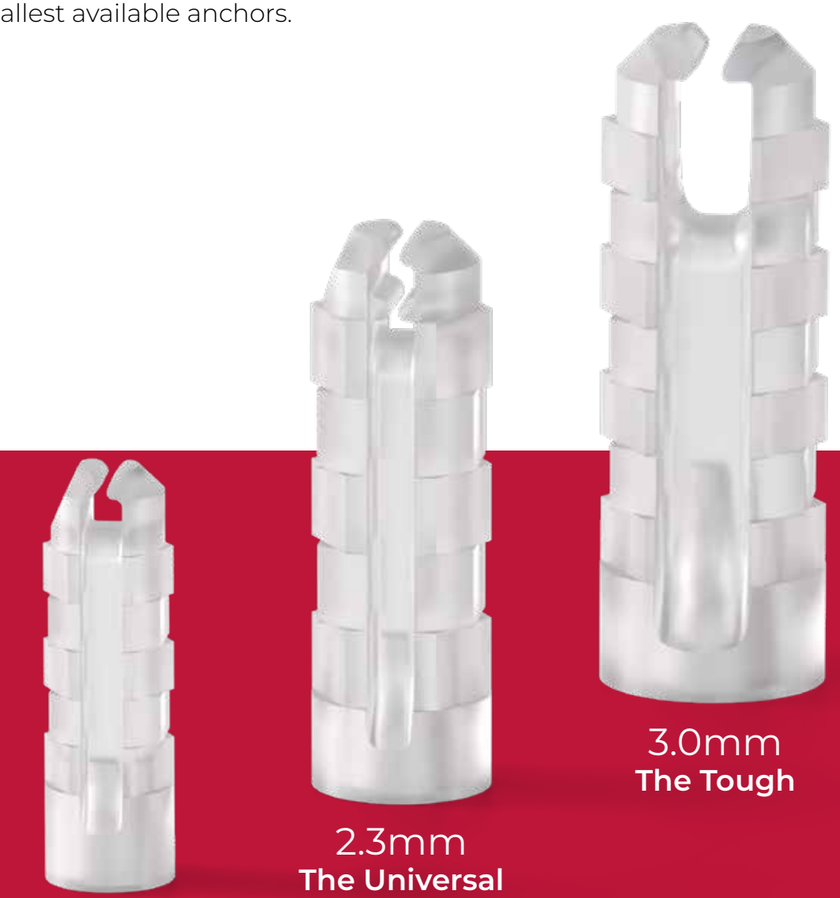
SupraFusion®

The Paradigm Shift to Surgery 3.0

The innovative SupraFusion® Technology is a surgical technique for soft-tissue to-bone fixation using ultrasonic energy.

SupraFusion® integrates the SF-Push-in Anchor into the cancellous bone within seconds. This unique bonding augments the trabecular bone, introducing a new paradigm in maximizing load capacity while minimizing bone trauma.

The SupraFusion® Technology reinforces the bone instead of compromising it, enabling precise soft tissue fixation using the smallest available anchors.



1.6mm
The Delicate

2.3mm
The Universal

3.0mm
The Tough

Design Features

Ultrasonic Design for Seamless Soft-Tissue to-Bone Fixation

Enhanced biomechanical strength and no micromotion:

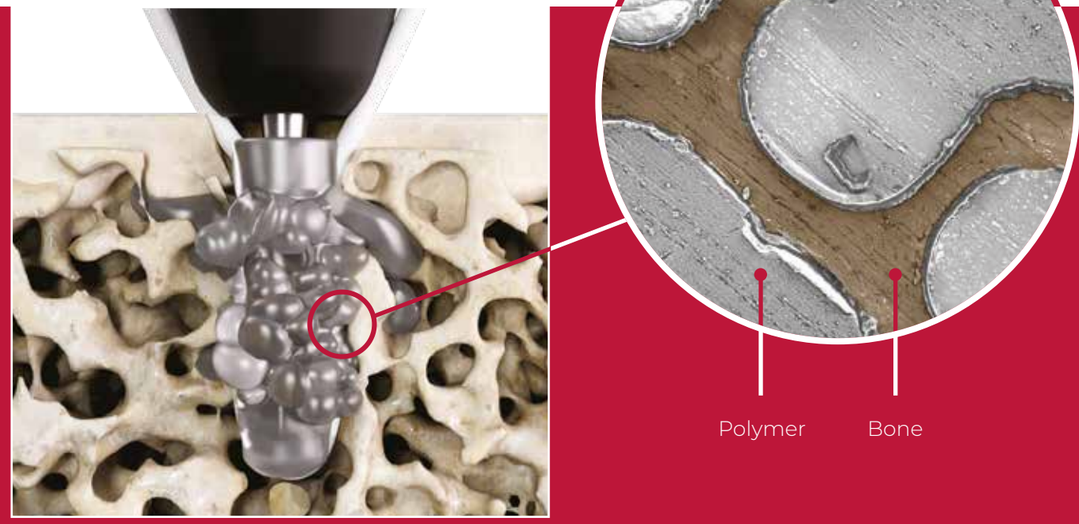
The sophisticated design of the implant surface ensures that the SF Push-in Anchor liquefies reliably in contact with bone and bonds homogeneously to the cancellous bone.

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.

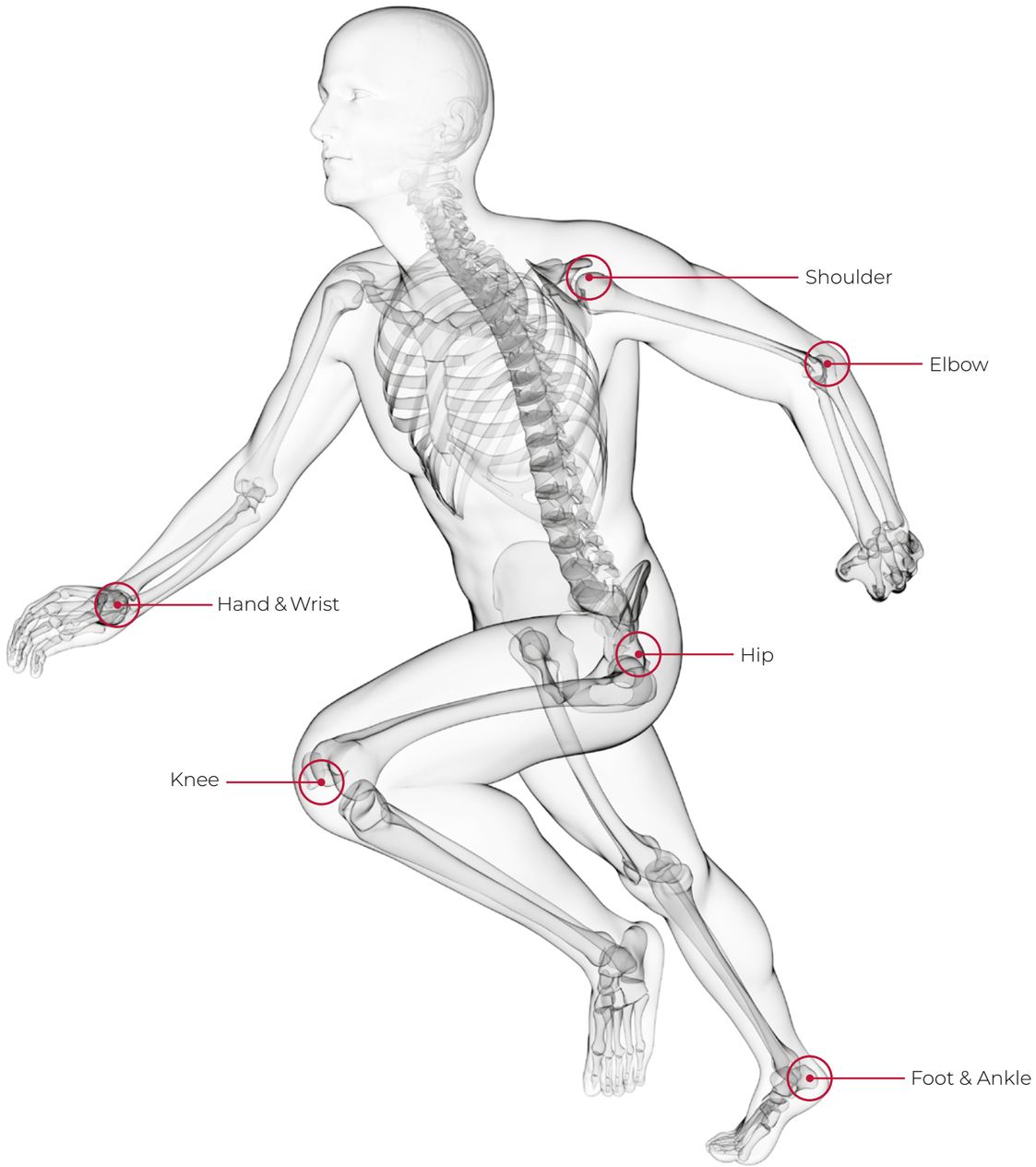
Consequently, the small footprint of the anchor provides unparalleled freedom of implant placement without compromising on fixation strength.

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



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, hip, knee, elbow, and shoulder. The SF Push-in Anchors are designed to be inserted with Ultrasonic Energy using the SupraFuser® Ultrasonic System.

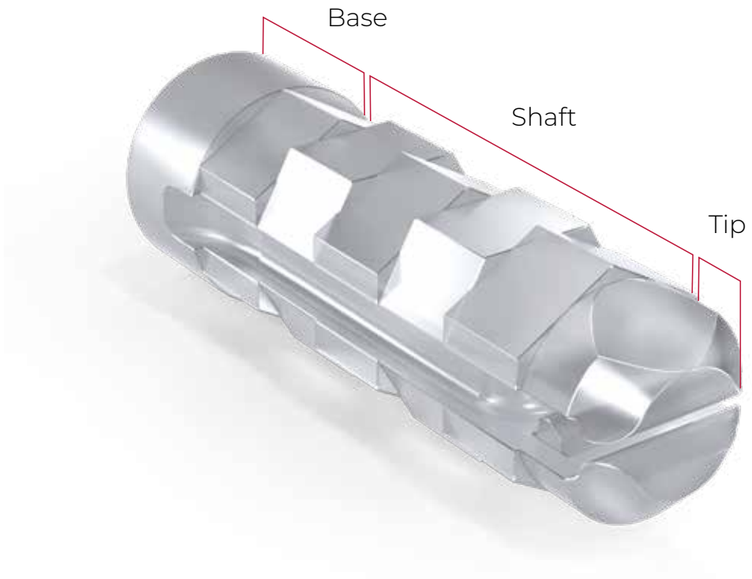


Indications

		Push-in Anchor		
Extremity	**Indication**	**1.6**	**2.3**	**3.0**
Hand & Wrist	Scapholunate Ligament Reconstruction	•	•	•
	Carpal Ligament Reconstruction	•	•	•
	Repair/Reconstruction of collateral ligaments	•	•	•
	Repair of Flexor and Extensor Tendons at the PIP, DIP & MCP joints for all digits	•	•	•
	Digital Tendon Transfers	•	•	•
	Carpometacarpal Reconstruction	•	•	•
	Triangular Fibrocartilage Complex (TFCC)		•	•
	Extensor Carpi Ulnaris Subsheat Reconstruction	•	•	•
Elbow	Ulnar or Radial Collateral Ligament Reconstruction	•	•	•
	Biceps Tendon Reattachment		•	•
	Lateral Epicondylitis Repair		•	•
Shoulder	Bankart Repair	•	•	•
	SLAP Lesion Repair	•	•	•
	Capsular Shift or Capsulolabral Reconstruction	•	•	•
	Rotator Cuff Repairs		•	•
	Biceps Tenodesis		•	•
	Acromio-Clavicular Separation Repair		•	•
	Deltoid Repair		•	•
Foot & Ankle	Lateral Stabilization	•	•	•
	Mid-foot Reconstruction	•	•	•
	Medial Stabilization	•	•	•
	Metatarsal Ligament Repair	•	•	•
	Hallux Valgus Reconstruction	•	•	•
	Digital Tendon Transfers	•	•	•
	Achilles Tendon Repair		•	•
	Hallux Varus Reconstruction			•
	Metatarsal Tendon Repair			•
	Bunionectomy		•	•
Knee	Medial Collateral Ligament Repair	•	•	•
	Lateral Collateral Ligament Repair	•	•	•
	Patellar Tendon Repair		•	•
	Iliotibial Band Tenodesis		•	•
	Posterior Oblique Ligament Repair		•	•
Hip	Acetabular Labral Repair		•	•
	Capsular Repair		•	•

Design Features

SF Push-in Anchor



Implant Base

The head is designed to transfer the ultrasonic vibration generated in the Handpiece of the SupraFuser® 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 a transverse apical “click-in” groove to position the sutures 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-tape and -thicknesses can be easily loaded.

The SF Push-in Anchors must be used with non-resorbable UHMWPE sutures or a combination of UHMWPE and polyester sutures or polyethylene terephthalate sutures.

The suture material is supplied with, or recommended sutures are outlined in the table below:

Implant size	Suture/Type Compatibility
SF Push-in Anchor 1.6	USP, #4-0 to #0
SF Push-in Anchor 2.3	USP#4-0 to #2
SF Push-in Anchor 3.0	USP #0 to #2, Tape up to size 2mm

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.

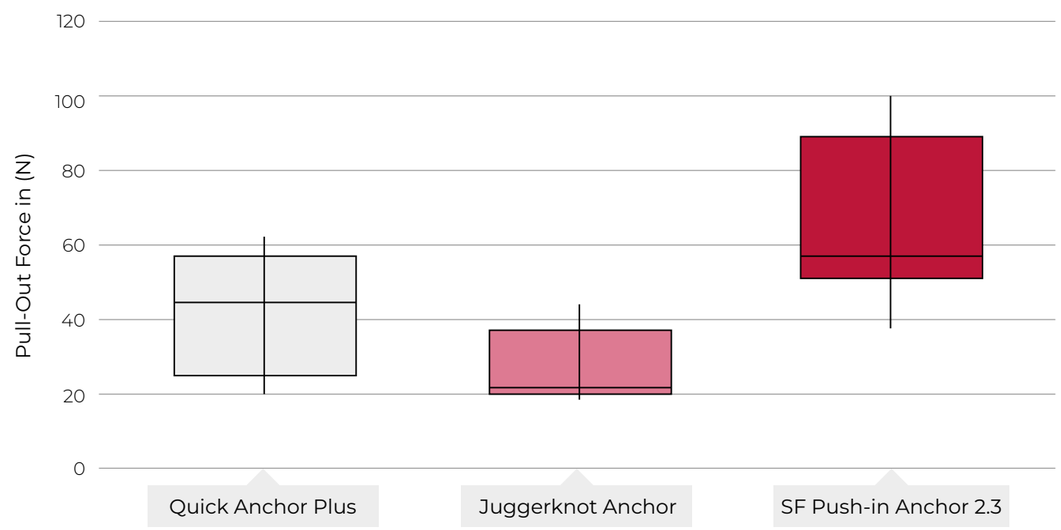
The Degradation Mechanism

- The H_2O 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_2O leads to a continuous shortening of the polymer chains (hydrolysis). The resulting L-and D-lactide molecules are converted into H_2O and CO_2 via physiological metabolic processes.

USP

Higher Pull-Out Strength in Cancellous Bone

(Ulnar Collateral Ligament Fixation)



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

Strong

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

Small

The SF Push-in Anchors are remarkably compact and optimized in their 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

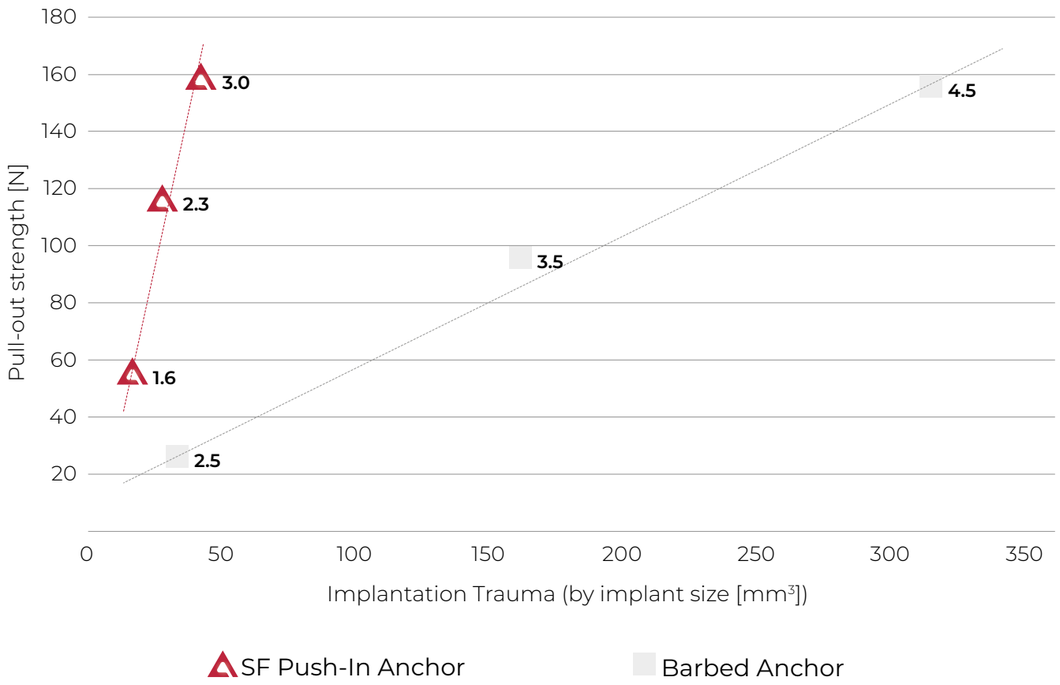
The stronger biomechanical strength combined with a smaller footprint and resorbable material provides unique surgical options in terms of anchor placement and functionality.

The SupraFusion® Paradigm Shift

Higher Performance – Lower Trauma – More Surgical Options

Augmentation of the bone by SupraFusion® provides SF Push-in Anchor with outstanding strength, so they can be much smaller without compromising on performance. This reduces the implantation trauma to a level unheard of before and enhances surgical options.

Less Trauma but Higher Strength – The SupraFusion® Paradigm Shift



Measured in sawbone, 20 pcf after 3 months simulated aging.
(Data on file at Surgical Fusion Technologies GmbH).

Surgical Steps

Instrumentation

SupraFuser® Ultrasonic System

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

The SupraFuser® 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, Stopper, Drill and Drill Guide with integrated Wrench 5.0. The system includes sutures and tapes that are provided separately.

The Drill features a drill geometry specific for the SF Push-in Anchor to ensure controlled liquefaction during ultrasonic implantation of the SF Push-in Anchor.

Each SF Push-in Anchor size has a specific drill size with identical color coding.

Drill Guide with Integrated Wrench: Prevents soft tissue from wrapping around the drill and through the drill stop prevents drilling too deep.

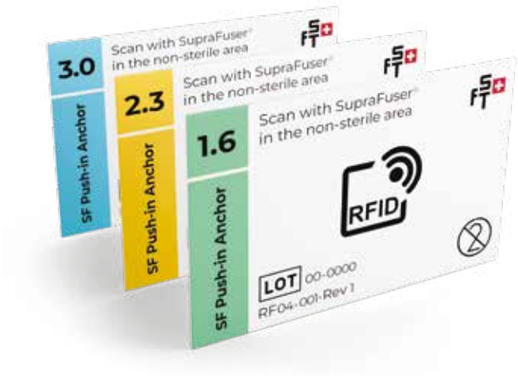
The integrated Wrench is used to tighten the Sonotrode on the Handpiece.

The Stopper provides a controlled insertion stop for the implant and prevents the implant from being inserted too deep. There are three color-coded Stoppers, one for each anchor size with identical color coding.

SupraFuser® Ultrasonic Generator: with integrated RFID reader. This ensures that every anchor size is implanted with the its optimized implant-specific ultrasonic power settings.

Handpiece with an ergonomic and user-friendly handle.

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



RFID Tag: The unique RFID Tag identifies the Anchor and provides the ultrasonic process settings specific to the respective SF Push-in Anchor. Each Implant is supplied with an RFID Tag.

Reprocessing

Tray

The specially designed Tray for the SupraFuser® Ultrasonic System and SF Push-in Anchor Portfolio is tailored for the efficient reprocessing of instruments and accessories. Each instrument and accessories has a designated Tray section and the validated protocol is outlined in the Reprocessing Guide.

The Drill is intended for single patient, multiple uses and comes non-sterile. Prior to use, it must be cleaned and sterilized using our validated methods. Additionally, the Handpiece,Stopper, Handpiece Front Cover, Sonotrode, and respective Guide/Wrench are also provided non-sterile and should be cleaned and sterilized following the validated protocols before each use.

The Handpiece, Handpiece Front Cover, Stopper, Guide/Wrench and Sonotrode have an estimated end of life of 200 reprocessing cycles.

SupraFuser® Ultrasonic System delivered with two fully equipped Trays.

April 1, 2024

Surgical Fusion Technologies GmbH
% Kelliann Payne
Regulatory Counsel
Hogan Lovells US LLP
1735 Market Street, 23rd Floor
Philadelphia, Pennsylvania 19103

Re: K240288
Trade/Device Name: SF Push- in Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: MAI, HTY, GAT
Dated: January 31, 2024
Received: February 1, 2024

Dear Kelliann Payne:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For: Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240288

Device Name

SF Push- in Anchor

Indications for Use *(Describe)*

The SF Push-in Anchor is intended to be used for suture or tissue fixation in the foot, ankle, hand, wrist, elbow, hip, knee and shoulder. The SF Push-in Anchor is designed only to be inserted with the SupraFuser Generator.

SF Push-in Anchor 1.6mm:
Hand/Wrist: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/ Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits, digital tendon transfers

Elbow: Ulnar or Radial Collateral Ligament Reconstruction

Shoulder: Bankart Repair, SLAP Lesion Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Metatarsal Ligament Repair, Hallux Valgus reconstruction, Digital Tendon Transfers, Mid-foot Reconstruction

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair

SF Push-in Anchor 2.3mm:
Hand/Wrist: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/ Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits, digital tendon transfers

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction, Lateral epicondylitis repair

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Metatarsal Ligament Repair, Hallux Valgus reconstruction, Digital Tendon Transfers, Mid-foot Reconstruction, Achilles Tendon Repair, Bunionectomy

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Hip: Acetabular labral repair, capsular repair

SF Push-in Anchor 3.0mm and 3.6mm:
Hand/Wrist: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/ Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits, digital tendon transfers

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction, lateral epicondylitis repair

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, Digital Tendon Transfers, Mid-foot Reconstruction, Metatarsal tendon repair, Bunionectomy

Knee: Medial collateral ligament repair, lateral collateral ligament repair, patellar tendon repair, posterior oblique ligament repair, and iliotibial band tenodesis

Hip: Acetabular labral repair, capsular repair

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Orders – Customer Service

Phone: 917.765.7847

Email: custsvc@innov8ortho.com

Shipping FOB Origin, Freight Prepay & Add
*Expedited shipments will be invoiced for the change associated with the expedited delivery

510 K Clearance #'s

Creed Screws K200291

Apollo AFX Plating K213005

FusionFrame K200343

Artemis PFN Nail K221489

Remit to Address

Innov8ortho, LLC

P.O. Box 154

Edgewater, NJ 07020

CORPORATE OFFICE

Innov8ortho, LLC

300 Sylvan Ave, 2nd Floor

Englewood Cliffs, NJ 07632

Email: enquiries@innov8ortho.com

Website

www.innov8ortho.com

Terms and Conditions of Sale

The following terms and conditions of sale constitute an integral part of this Innov8ortho, LLC. ("Innov8ortho") product list and are applicable to all purchase orders. All prices and terms are subject to change.

I. Acceptance of Purchase Orders
All purchase orders are subject to acceptance at Innov8ortho's customer service department located in Englewood Cliffs, NJ and will be deemed accepted only when confirmed in writing or upon Innov8ortho's commencement of performance. For convenience, customers may place purchase orders or make inquiries (between the hours of 8:30 a.m. – 5:30 p.m. EST, Monday – Friday, exclusive of all federal and state holidays) by calling 917.765.7847 or emailcustsvc@innov8ortho.com.

II. Payment Terms
Payment is due no later than 30 days from the date of the invoice.

Mail purchase order to:
Innov8ortho, LLC.
300 SYLVAN AVE, 2ND Flr
Englewood Cliff, NJ 07632

Mail payments to:
Innov8orth, LLC.
P.O. Box 154
Edgewater, NJ 07020

III. Additional Charges
All applicable excise, sales, or other taxes will be invoiced to customer and are not included in product prices.

IV. Shipping and Related Charges
Terms of sale on all purchase orders are F.O.B. shipping point. Each purchase order will incur a shipping and handling charge of $75.00. All shipments of product will be placed with the carrier for requested 2-day delivery.

Expedited Shipments: Customers requiring expedited delivery will be invoiced for the change associated with the expedited delivery.

Shipping Damage: Although Innov8ortho takes special care in the packaging of its products, damage may occur in transit. All products must, therefore, be inspected and any damage noted on the freight bill and reported to the carrier, upon receipt of product. Although Novastep's responsibility for damage ceases upon deposit with carrier, Innov8ortho may extend assistance in helping customer settle damage claims.

V. Return Goods and Related Charges
Return Authorization/Repairs: Customer must obtain a return authorization number from Innov8ortho or Innov8ortho account representative before any Innov8ortho product can be returned for repair, replacement, refund, or credit. To obtain a returnauthorization number, customer must provide Innov8ortho with (1) the Innov8orthocatalog number and quantity of Innov8ortho product to be returned; (2) the reason forthe return/repair; (3) a description of the Innov8ortho product being returned for repair;(4) the name and telephone number of a customer contact who may be called ifInnov8ortho requires further information; and (5) at least one of the following: (i) theapplicable customer purchase number, (ii) the applicable Innov8ortho invoice number,and (iii) the applicable Innov8ortho product lot or serial number. A purchase order isrequired for all repairs even in situations where there is no charge. If the Innov8orthoproduct to be repaired is covered by a written limited product warranty, a copy of theoriginal invoice must be sent with the Innov8ortho product. The cost of repair notcovered by a written limited product warranty must be paid by the customer.

Non-Returnable Products: Customer is not entitled to return nor eligible to receive repair, replacement, refund, or credit for any Innov8ortho product described below (collectively, "Non-Refundable Products"):

- Product damaged in transit;
- Product shipped in error and returned more than 30 days after the date of the applicable Innov8ortho invoice (unless such product is subject to a recall arising out of the negligent acts or omissions of Innov8ortho (a "Quality Recall);
- Non-defective product return in quantity less than Innov8ortho's original unit of sale;
- Non-defective product returned more than 90 days after date of applicable
- Innov8ortho invoice (unless part of a Qualified Recall);
- Defective product returned after expiration of applicable warranty period (unlesspart of a Qualified Recall);
- Product sold non-sterile that has been subjected to sterilization processing;
- Product sold for single use that has been re-used or re-processed;
- Product that has been altered, further manufactured, packaged, processed, abused, or misused;
- Product that has been adjusted or repaired by anyone other than by Innov8ortho or a person or entity authorized in writing by Innov8ortho; and
- Product that is a "custom" device unless such product is defective for a reason other than manufacture to customer's specifications.

Authorized Return Products and Freight Charges: With regard to those Innov8orthoproducts (other than Non-Returnable Products) for which customer has obtained areturn authorization number. Innov8ortho will accept returns for such products if theyare: (1) determined by Innov8ortho to be defective and returned within applicable warranty period; (2) no defective, in saleable condition and returned within 90 days of the corresponding Innov8ortho invoice date and represent product shipped in error by Innov8ortho (such products, collectively, "Authorized Return Products"). All Authorized Return Products must be returned freight prepaid by customer. All Authorized Return Product returned freight collect will be refused by Innov8ortho and returned to customer at its expense. Innov8ortho will, at its option, refund or credit customer for all freight charges incurred in connection with returning to Innov8ortho any Authorized Return Product.

Allowance Schedule for Authorized Return Products: For those Authorized Return Produ
that Innov8ortho has elected to provide a refund or credit, Innov8ortho will pay a refund
issue a credit to customer within 30 business days of Innov8ortho'sreceipt of the Authori
Return Product, based on the original purchase price, in accordance with following:

CONDITION	CREDIT
Defective product returned within applicable product warranty period	Full Credit*
Non-defective product returned in a saleable condition within 45 days of corresponding Innov8ortho invoice date	Full Credit*
Non- defective product returned is saleable condition within 46-90 days of corresponding Innov8ortho invoice date	Full Credit* minus 20% reprocessing charge min. $10.00 charge
Product shipped in error by Innov8ortho and returned is saleable condition within 45 days of corresponding Innov8ortho invoice date	Full Credit*
Product subject to a Qualified Recall	Full Credit*

**Less any credits issued by Innov8ortho to customer with respect to such product.*

VI. Confidentiality
*Customer will not disclose to any third party these terms and conditions, including the Produ
List, or any other information provided by Innov8ortho to customer, without Innov8ortho's wri
approval, except as may be required by law or lawful order of anyapplicable government age*

VII. Limited Product Warranty; Disclaimer and Limitation of Liability
Innov8ortho warrants to the original purchaser that each Innov8ortho product set forth in the Pro
List will be free from defects in material and workmanship for the period set forth in the labeling
the particular Innov8ortho product or, if no such period is set forth in the labeling, for a period of
(1) year from date of purchase. If Innov8ortho product proves to be so defective, such Innov8ort
product may be returned to Innov8ortho for repair, replacement, refund or credit at Innov8ortho's
option, in accordance with Innov8ortho's return goods and allowance policy. Any alteration, abu
misuse, further manufacture, packaging, processing, adjustment or repair by any person or entit
other than Innov8ortho or a person entity authorized in writing by Innov8ortho shall void this limit
product warranty ab initio. THIS LIMITED PRODUCTWARRANTY IS IN LEU OF ALL OTHER
WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY WARRANT
MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. THE LIABILITY AND REM
STATED IN THIS LIMITED PRODUCT WARRANTY WILL BE SOLE LIABILITY OF Innov8ortho A
REMIDY AVAILBLE TO CUSTOMER FOR Innov8ortho PRODUCTS WHETHER IN CONTRACT
TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, AND Innov8ortho WILL NOT BE LIABLE
TO CUSTOMER FOR ANY INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAG
ARISING OUT OF THE POSSIBILITY OR LIKELYHOOD OF SUCH DAMAGES. IN NO EVENT W
Innov8ortho BE LIABLE FOR ANY CLAIM, LOSS OR DAMAGE ARISING OUT OF OR RELATIN
TO, IN WHOLE OR IN PART, ANY PURCHASE ORDER, THERE TERMS AND CONDITIONS C
OTHERWISE, IN EXCESS OF THE AMOUNT PAID BY CUSTOMER TO Innov8ortho PURSUAN
TO THE PURCHASE ORDER TO WHICH CLAIM, LOSS OR DAMAGE RELATES.

VIII. Product Changes
All products and product specifications identified in the Product List are based upon the information available to Innov8ortho at the time of publication. Innov8ortho reserves the right discontinue any product or to change any product specifications without notice.

IX. Termination
Any customer purchase order may be terminated by Innov8ortho as follows: (1) upon 30 days written notice to customer; (2) effective immediately, if customer commits a material breach of provision of the purchase order or these terms and conditions and such breach continues for of 30 days following notice; or (3) effective immediately, if the customer files, or has filled agains petition for voluntary or involuntary bankruptcy or pursuant to any other insolvency law or make seeks to make a general assignment for the benefit of its creditors or applies for or consents to appointment of a trustee, receiver, or custodian for its or substantial part of its property.

X. Force Majeure
Innov8ortho will not be liable for its failure to perform or a delay in performance of any or due to strikes, fire, explosion, flood, riot, lock out, injunction, interruption of transportatio unavoidable accidents, acts of government or a public enemy, terrorism, inability to obtai supplies at reasonable prices, or other causes beyond its control.

XI. Choice of Law
All transactions under these terms and conditions shall be governed by and construed in accordance with the laws of the State of New York as applicable to contracts made and to performed in that state, without regard to conflicts of laws principles.

XII. General
NONE OF THE FOREGOING TERMS AND CONDITIONS MAY BE MODIFIED EXCEPT UPON NOVASTEP'S EXPRESS WRITTEN CONSENT STATING THAT IT IS AN AMENDMENT OT MODIFICATION THERETO. In the event of any inconsistency between these terms and conditi sale and those contained in any purchase order, purchase order release, confirmation, acceptai or any similar document, the terms and conditions set forth above shall prevail. These terms an conditions of sale constitute the entire understanding between Innov8ortho and customer and supersede all prior terms and conditions of sale published by Innov8ortho, in each case, related to the subject matter hereof.

K240288 – Kelliann Payne

SupraFusion Part List

ITEM NUMBER	DEVICE DESCRIPTION
SUPRAFUSION PUSH-IN ANCHOR SYSTEM	
SUPRAFUSION PUSH-IN ANCHOR SYSTEM – IMPLANT	
B04-411	SUPRAFUSION / Push-In Anchor 1.6 (single package, sterile, single use)
B04-401	SUPRAFUSION / Push-In Anchor 2.3 (single package, sterile, single use)
B04-421	SUPRAFUSION / Push-In Anchor 3.0 (single package, sterile, single use)
B04-431	SUPRAFUSION / Push-In Anchor 3.6 (single package, sterile, single use)
SUPRAFUSION PUSH-IN ANCHOR SYSTEM – SUTURES	
SF-HS390	SUPRAFUSION / USP 2/0, White/Blue, DA CT-3 22mm Taper ½c, 24”
SF-HS392	SUPRAFUSION / USP 1, White/Blue, DA CT-2 26mm Taper ½c, 24”
SF-HS1079	SUPRAFUSION / USP 2, White/Blue, DA MO-6 1/2 26mm Taper Needle, 29”
SF-HS391	SUPRAFUSION / USP 1, White, DA CT-2 26mm Taper ½c, 24”
SUPRAFUSION PUSH-IN ANCHOR SYSTEM – SINGLE-USE INSTRUMENTS	
D04-101	SUPRAFUSION / Drill Short 1.6 (single package, sterile, single use)
D04-001	SUPRAFUSION / Drill Short 2.3 (single package, sterile, single use)
D04-201	SUPRAFUSION / Drill Short 3.0 (single package, sterile, single use)
D04-301	SUPRAFUSION / Drill Short 3.6 (single package, sterile, single use)
SUPRAFUSION PUSH-IN ANCHOR SYSTEM – REUSABLE INSTRUMENTS	
S04-002	SUPRAFUSION / Sonotrode Short for all Push-in Anchors
G04-001	SUPRAFUSION / Guide and Wrench Short for all Push-in Anchors
ST04-001	SUPRAFUSION / Handpiece Front Cover Short with Insertion Stop for SF Push-in Anchor 1.6
ST04-101	SUPRAFUSION / Handpiece Front Cover Short with Insertion Stop for SF Push-in Anchor 2.3
ST04-201	SUPRAFUSION / Handpiece Front Cover Short with Insertion Stop for SF Push-in Anchor 3.0
ST04-301	SUPRAFUSION / Handpiece Front Cover Short with Insertion Stop for SF Push-in Anchor 3.6
SK04-002	SUPRAFUSION / Standard Handpiece
SUPRAFUSION PUSH-IN ANCHOR SYSTEM – ULTRASONIC GENERATOR	
SF04-005	SUPRAFUSION / SupraFuser Generator
FS04-002	SUPRAFUSION / Footswitch with Cable (3m)
NK04-003	SUPRAFUSION / Powercord US (110V)
F04-001	SUPRAFUSION / Fuse T1.0 A H 250V
H04-003	SUPRAFUSION / Handpiece
T04-003	SUPRAFUSION / SF Push-in Anchor Tray
TC04-002	SUPRAFUSION / SFT Transport Case

List of References
SupraFusion Technology

Animal Study

Langhoff J. D. et al. (2009)	An Ultrasound Assisted Anchoring Technique (BoneWelding® Technology) for Fixation of Implants to Bone – A Histological Pilot Study in Sheep. Langhoff J D, Jan M. Kuemmerle J M, Mayer J, et al. (June 11, 2009) Open Orthop J: DOI: 10.2174/1874325000903010040
Arnoldi J. et al. (2011)	In Vivo Tissue Response to Ultrasound Assisted Application of Biodegradable Pins into Cortical and Cancellous Bone Structures: A Histological and Densitometric Analysis in Rabbits. Arnoldi J, Henry P, Procter P, et al. (January 22, 2011). Journal of Biomaterials Science: DOI: 10.1163/092050611X558288
Heidenreich D. et al. (2011)	The use of BoneWelding technology in spinal surgery: an experimental study in sheep. Heidenreich D, Langhoff J D, Nuss k, et al. (April 8, 2011) Eur Spine J, Springer-Verlag: doi: 10.1007/s00586-011-1799-1

Biomechanical Study

Meyer D. C. et al. (2005)	Ultrasonically Implanted PLA Suture Anchors Are Stable in Osteopenic Bone. Meyer D C, Mayer J, Weber U, et al. (August 9), 2005Clinical Orthopaedics and Related Research, Lippincott Williams & Wilkins: DOI: 10.1097/01.blo.0000185033.32220.57
Ferguson S. J. et al. (2005)	Enhancing the Mechanical Integrity of the Implant–Bone Interface With BoneWelding® Technology: Determination of Quasi-Static Interfacial Strength and Fatigue Resistance. Ferguson S J, Weber U, Von Rechenberg B, et al. (October 6, 2005) Wiley InterScience: DOI: 10.1002/jbm.b.30427
Pilling E. et al. (2007)	An experimental study of the biomechanical stability of ultrasound activated pinned (SonicWeld Rx® + Resorb-X®) and screwed fixed (Resorb-X®) resorbable materials for osteosynthesis in the treatment of simulated craniosynostosis in sheep. Pilling E, Meissner H, Jung R, et al. (February 1, 2007) British Journal of Oral and Maxillofacial Surgery, Elsevier: doi.org/10.1016/j.bjoms.2006.12.008
Wagner M. et al. (2017)	Biomechanical in vitro comparison of suture anchors for thumb UCL repair. Wagner M, Schmölz W,· Stofferin H, et al. (September 24, 2017) Archives of Orthopaedic and Trauma Surgery, Springer-Verlag GmbH: DOI: 10.1007/s00402-018-2877-1
Güleçyüz F. M. et al. (2017)	Novel ultrasound assisted suture anchor system using the BoneWelding® technology yields a comparable primary stability in osteopenic and healthy human humeri as a benchmark anchor. Güleçyüz F M, Schröder C, Pietschmann M F, et al. (November 24, 2017) Acta Orthopaedica et Traumatologica Turcica: DOI: 10.1016/j.aott.2017.11.009

Clinical Study

Reichwein A. et al. 2009)	Clinical Experiences With Resorbable Ultrasonic-Guided, Angle-Stable Osteosynthesis in the Panfacial Region. Reichwein A, Schicho K, Moser D, et al.(June 6, 2009) J Oral Maxillofac Surg: doi.org/10.1016/j.joms.2008.12.033
Kastenberger T. et al. (2020)	Clinical results of the BoneWelding®Fiji® anchor for the treatment of Stener lesions of the thumb. Kastenberger T, Kaiser P, Schmidle G, et al. (September 30, 2020). Archives of Orthopaedic and Trauma Surgery, Springer-Verlag GmbH: DOI: 10.1007/s00402-020-03625-x

Contact

Surgical Fusion Technologies GmbH

Wagistrasse 6 | CH-8952 Schlieren / ZH | Switzerland

Tel: +41 (0) 44 204 6121 | Fax: +41 (0) 44 204 6133

E-Mail: info@surgical-fusion.com

SupraFusion - Mechanical Performance

The importance of implant-bone interface augmentation

SupraFusion Technology

SF Push-in Anchors are ultrasonically liquefiable, resorbable suture anchors to attach soft tissues to bone and are fabricated from poly-lactide (PLDLLA). These anchors utilize the SupraFusion Technology for soft tissue fixation, ensuring immediate and long-term implant stability.

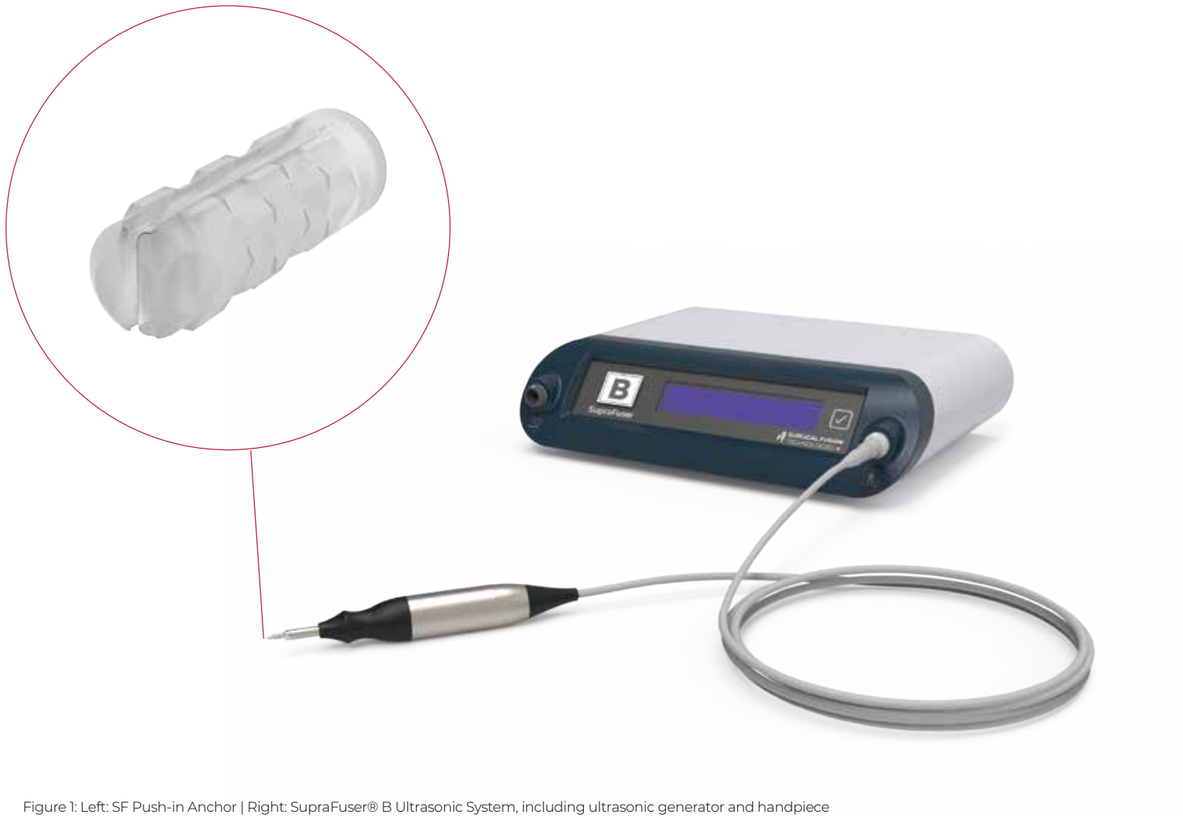
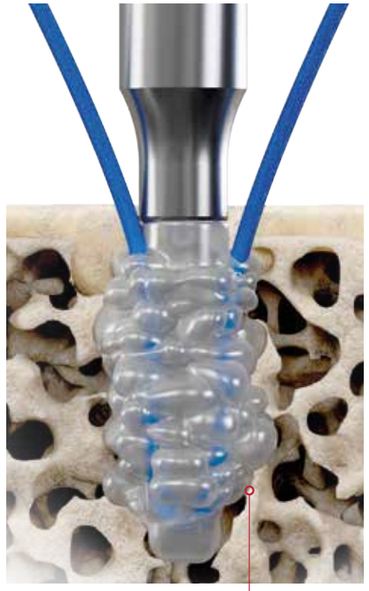


Figure 1: Left: SF Push-in Anchor | Right: SupraFuser® B Ultrasonic System, including ultrasonic generator and handpiece

Ultrasonic Implantation

Ultrasonic liquefaction of the polymer shapes the implant to bone, and by doing so, enhances fixation.



The Mechanics of Ultrasonic Implantation

The mechanical features of SF Push-in Anchors are attributed to the distinctive anchorage system created through the patented SupraFusion technology and the unique features of the SF Push-in Anchors (Figure 2).

During implant insertion, ultrasonic vibrations are applied to the implant via a handpiece. The surface of the SF Push-in Anchors melts, and the liquefied polymer infiltrates into the free space of the porous bone structure. The anchor is thus shaped to the trabecular structure rather than requiring the bone to be cut to the implant's shape (1). This creates a maximized bone-implant interface along the length of the implant (Figure 2 top). Due to this unique adaptation of the anchor to the bone's trabecular architecture, the bone at the interface to the implant is augmented, reducing localized stresses on the trabecular bone.

Consequently, the mechanical load is homogeneously distributed without cutting into the trabecular bone structure (Figure 2 right). Finite element modeling has shown that mechanical retention structures like screw threads can create a local stress increase of up to 300 % in the trabecular bone (2). Conversely, the augmented interface between bone and the SF Push-in Anchors is almost free of local peak stresses (5). This results in a stronger, more durable fixation (3).

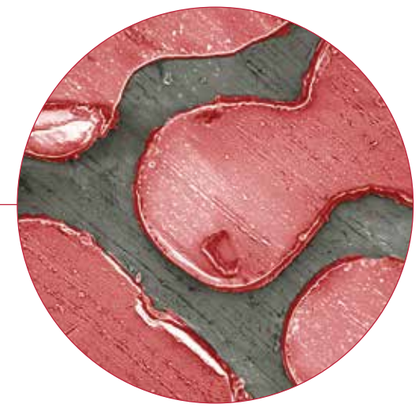


Figure 2. Augmentation of the Implant-Bone Interface by the ultrasonically liquefied polymer.

Top: A graphic representation of an SF Push-in Anchor inserted into the bone.
Right: Exemplary cross section at the implant-bone interface (sheep tibia) illustrating the augmentation by the interdigitation of the liquefied polymer with the trabecular bone.

Performance During Degradation

SF Push-in Anchors are mechanically stable for at least 12 months.

Performance

Using resorbable polymeric implants in orthopedics presents an appealing prospect by mitigating risks associated with permanent implants and it obviates the need for subsequent removal surgeries. On the other hand, premature breakdown of such implants can compromise mechanical stability before sufficient new bone growth occurs. Balancing the degradation of resorbable polymeric implants while maintaining mechanical stability is pivotal.

The degradation of PLDLLA polymers occurs within 1-3 years (4, 5) via a hydrolytic process, primarily by bulk erosion. The degradation of SF Push-in Anchors was tested my measuring modular weight over an extended period (Figure 3). After 12 months, the SF Push-in Anchors had degraded approximately 70 %, evidenced by the reduction in molecular weight. This 70 % loss through degradation should lead to decreased mechanical stability and, thus, increased risk for implant failure (4). Intriguingly, the SupraFusion Technology preserved mechanical stability for up to 12 months (Figure 4, red line). This preservation of mechanical stability can be attributed to the augmentation of the implant interface with the bone. Consequently, the ultrasonic augmentation of the interface with bone defies the initial molecular weight loss of the PLDLLA, extending the time of mechanically stable anchoring.

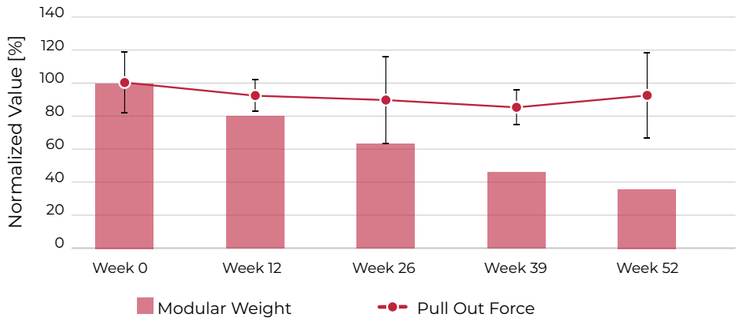


Figure 3: Reduction of molecular weight and pull-out Strength during degradation (12 months, 37°C, Sawbone (cellular rigid, 20 pcf); data on file).

Single Peak Load

Pull-out strength was higher for the SF Push-in Anchors than for mechanical press-fitted barbed anchors after both initial implantation and after 3 months (Figure 6). Upon anchor insertion, 41.5 % more force was required to pull out the SF Push-in Anchors than state-of-the-art barbed anchors. A similar result was observed 3 months after implantation, with a maximum pull-out force of 61.7 N for the SF Push-in Anchors compared to 24.8 N for the barbed anchors. Furthermore, no significant differences were observed in the pull-out force for any of the two anchor types after aging, indicating that both anchor types were mechanically stable.

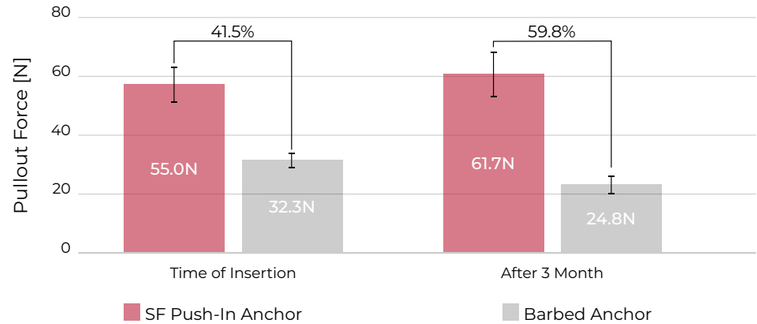
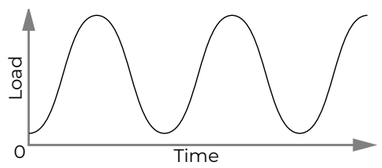


Figure 4: Comparison of Static pull-out force of SF Push-in Anchors and Barbed press-fit anchors after insertion, and after 3 months simulated degradation (testing at 37°C, Sawbone (cellular rigid, 20pcf), data on file).



Cyclinc Loading

Unlike mechanical press-fit-based anchors, SF Push-in Anchors bond to bone without exerting compression forces or cutting into the bone structure with a thread. Experimentally, this leads to significantly higher fatigue strength: in cyclic run-out testing, around 200 % higher run-out forces are measured when using SF Push-in Anchors compared to a barbed anchor (Figure 5).

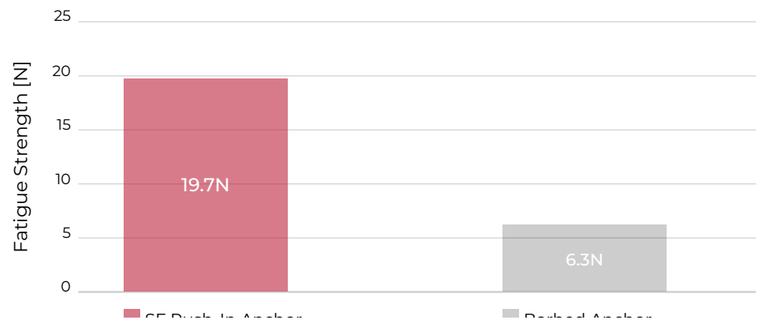


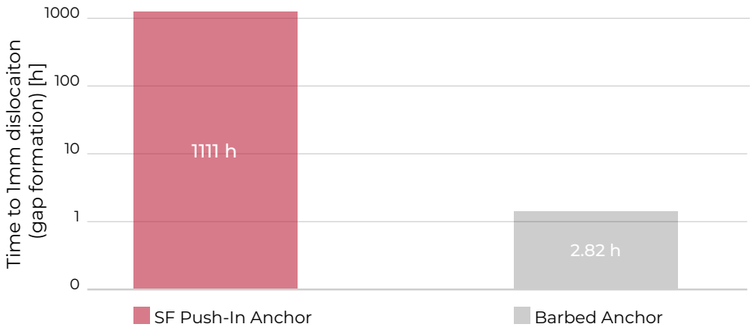
Figure 5: Cyclic loading performance ((lower run out limit (95 % confidence, acc. to ASTM 739, testing at 37°C, Sawbone (cellular rigid, 20pcf), data on file).

Top: Schematic illustration of the cyclic loading pattern.
Right: fatigue strength measured after a simulated three months degradation.

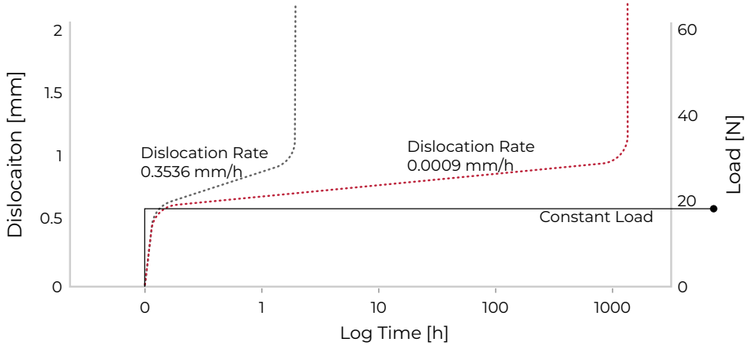
Constant Loading Test

The implant's stability to withstand constant loading to prevent gap formation or implant loosening is measured by applying a constant load until the implant fails and by measuring the dislocation behavior of the implant over time. Figure 6 illustrates the dislocation velocity of the anchor under continuous load and the resulting time to form a 1 mm gap. A notable difference in dislocation behavior was observed between the two anchoring principles, exceeding a factor of 300 in dislocation velocity. Specifically, under a given load of 20 N, reaching 1 mm dislocation (critical gap formation) is only 3 h for the barbed anchor. To achieve the same dislocation with the SF Push-in Anchor, more than 1000h under constant load is necessary.

Figures 6: Testing of resistance to constant loading (37°C, saline, 20 N pulling load, Sawbone (cellular rigid, 20pcf), data on file).



Comparative illustration of the time the anchor needs to dislocate for 1 mm (calculated from the dislocation rate).



The figure displays the dislocation of the anchor under a constant pulling load of 20 N. For illustration the mean dislocation rate in the plateau phase (also called stationary or secondary creep) is indicated for the SF Push-in Anchors (dislocation rate: 0.0009 ±0.005 mm/h) compared to the barbed anchors (dislocation rate: 0.3536 ±0.3492 mm/h)

Biomechanical Performance in Bone

To substantiate the above mentioned findings from the tests in Sawbones, the SF Push-in Anchors were compared to an all-suture anchor and a mechanically locking anchor (6). The comparison was conducted in a bone avulsion model for the fixation of the ulnar collateral ligament, in which there is no cortical bone left to support the anchoring stability.

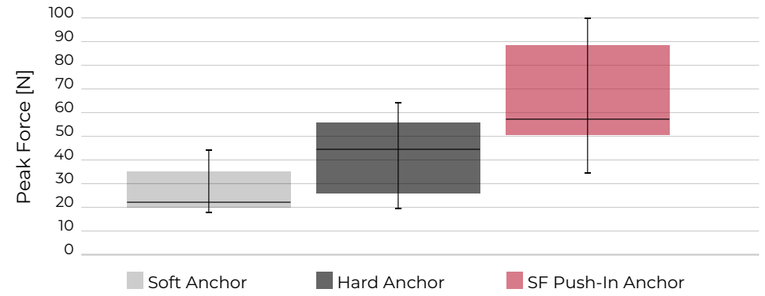


Figure 7: Box plot showing the median and quartiles of the peak force at pullout in the avulsion fracture model for soft anchors (Juggerknot soft anchor-Mini), hard anchors (Quickanchor Plus) and SF Push-in Anchors.

Following the tests conducted in Sawbone, the SF Push-in Anchors anchorage strength demonstrated exceptional performance under these conditions, exhibiting a maximum failure load of almost 200 % compared to the All Suture Anchor (p = 0.006). Interestingly, while the two mechanically locking anchors showed a clear correlation of pull-out strengths with bone mineral density (BMD), the ultrasonic augmentation of the implant bone interface appeared indifferent to bone density within the density range investigated (Table 1). This finding suggests that the inherent form-fitting nature of the SF Push-in Anchors exhibits consistent performance regardless of the bone density.

Group	**Mean age [year] (*p*=.931)**	**Mean trabecular BMD [mg/cm3] (*p*=.399)**	**Gender**
Hard Anchor	77.6 (range 58-90)	259 (SD = 96)	two female six male
Soft Anchor	79.8 (range 62-95)	210 (SD = 71)	two female six male
SF Push-in Anchor	78.0 (range 58-95)	251 (SD = 100)	two female six male

Table 1: Specimen details of the three groups.

Conclusion

SF Push-in Anchors are highly effective for attaching soft tissues to bone, offering superior stability and adaptability, particularly in challenging conditions where cortical bone is absent.

Summary

In conclusion, SF Push-in Anchors have proven to be an effective anchoring system for attachment of soft tissues to bone. SF Push-in Anchors exhibited great primary stability with superior long-term performance, compared to other anchor systems.

Compared to mechanically anchoring principles in which the implant intersects into the bone, SF Push-in Anchors follow a form-fitting principle in which the anchors model themselves into the bone architecture during ultrasonic insertion. This process augments the trabecular bone at the implant-bone interface and, overall, enhances implant stability. This is especially true for cyclic or constant long-term loading, both loading patterns being critical for soft tissue fixation.

SF Push-in Anchors emerge as a compelling anchoring system solution for attachment of soft tissues to bone, proving effective even in scenarios where cortical bone is absent (e.g. bone avulsion during ligament failure or iatrogenic). This underscores the versatility and resilience of SF Push-in Anchors as anchoring system in orthopedic applications.

References

1. Langhoff JD, Kuemmerle JM, Mayer J, Weber U, Berra M, Mueller JM, et al. An Ultrasound Assisted Anchoring Technique (BoneWelding Technology) for Fixation of Implants to Bone – A Histological Pilot Study in Sheep. Open Orthop J. 2009 Jun 11;3:40–7.

2. Ferguson S. Bone Welding Mechanical Charaterisation. An Investigation of the thermal effects and resulting interfacial strength of polymer dowels inserted in bone with ultrasonic welding. Switzerland: M.E. Müller Institute for Biomechanics. University of Bern; 2001 Jul p. 12.

3. Smit TH, Krijnen MR, van Dijk M, Wuisman PIJM. Application of polylactides in spinal cages: studies in a goat model. J Mater Sci Mater Med. 2006 Dec;17(12):1237–44.

4. Landes CA, Ballon A, Roth C. In-patient versus in vitro degradation of P(L/DL)LA and PLGA. J Biomed Mater Res B Appl Biomater. 2006 Feb;76(2):403–11.

5. Meyer DC, Mayer J, Weber U, Mueller A, Koch PP, Gerber C. Ultrasonically implanted PLA suture anchors are stable in osteopenic bone. Clin Orthop Relat Res. 2006 Jan;442:143–8.

Contact

INNOV8ORTHO, LLC

300 Sylvan Ave, 2nd Floor
Englewood Cliffs, NJ 07632
+1 (917) 765 7847
custsvc@innov8ortho.com
www. innov8ortho.com

Technology

www.supra-fusion.com
info@surgical-fusion.com

innov8ortho®

ApolloAnkle™ Fracture Plating System

Scan for more
Apollo Ankle product
information

creed™ Ortholucent Implants

Scan for more
Creed product
information

artemis Proximal Femoral Nail System

Scan for more
Artemis product
information

SUPRAFUSION

Scan for more
Suprafusion product
information

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

SF Push-in Anchor and SupraFuser® are trademarks of Surgical Fusion Technologies GmbH.
innov8ortho is the exclusive distributor of the SF Push-in Anchor Portfolio and SupraFuser® Ultrasonic System.

www.innov8ortho.com

 Ref: APO-BRO-04-23-EN

Distributed by:

Innov8ortho, LLC
300 Sylvan Ave, 2nd Floor
Englewood Cliffs, NJ 07632
custsvc@innov8ortho.com

innov8ortho®