ANIKA

Tactoset®

Injectable Bone Substitute

Value Analysis Committee Brochure

ANIKA
Regenerative Solutions

ANIKA

Anika is a global joint preservation company that creates and delivers meaningful advancements in early intervention orthopedic care. We partner with clinicians to understand what they need most to treat their patients and we develop minimally invasive products that restore active living for people around the world.

We are committed to leading in high opportunity spaces within orthopedics, including osteoarthritis pain management, regenerative solutions, sports medicine, and Arthrosurface.

Anika. Restore Active Living.®

Table of Contents

Tactoset Introduction

Condition overview

- Bone voids, also known as bone marrow lesions (BMLs), represent focal edema in the subchondral bone[1]
- Causes include trauma, insufficiency fractures, degenerative cartilage lesions[1]
- BMLs have been linked with significant pain, cartilage degeneration and the progression of osteoarthritis[2,3]
- Studies have shown that BMLs are associated with an increased risk of total knee replacement[3,4]

Diagnosis

- X-rays are commonly used to determine severity of osteoarthritis, however BMLs cannot be detected on X-ray[2]
- BMLs can be identified on fluid sensitive, fat suppressed magnetic resonance imaging (MRI) [1,2]
- Recognized as an area of intense signal visible on T2-weighted sequences[4]

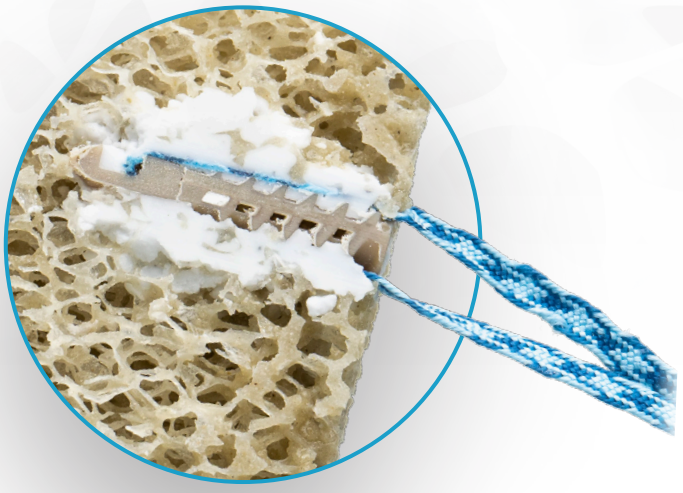
Technology overview

- Calcium phosphate injectable, self setting, osteoconductive biocompatible bone graft substitute material intended for permanent implantation[5,6]
- Indicated for filling bone voids or defects of the skeletal system that are not intrinsic to the stability of bony structure, such as surgically created osseous defects or defects created from traumatic injury to the bone[5]
- Can be mixed with autogenous bone marrow aspirate (BMA)
- Hardens post deployment to reinforce weaknesses such as those created by bone voids[6]
- Converts to a poorly crystalline hydroxyapatite at body temperature[5]
- Resorbs and is replaced by the growth of new bone during the healing process[5]

Hardware Augmentation

Augmenting with Tactoset drives surgical confidence

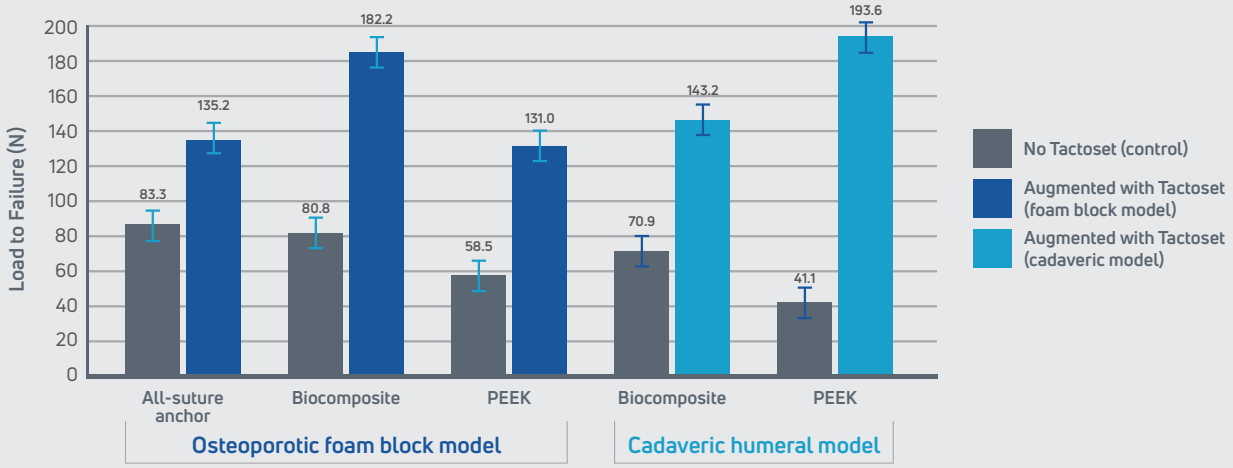
- Tactoset is indicated for augmentation of hardware such as soft tissue anchors[5]
- Increases the density of poor-quality bone caused by cysts or osteoarthritis, resulting in additional suture anchor pullout strength[11]
- Allows for placement of anchors in the ideal repair location, eliminating the need for extra anchors or complex techniques
- Augmenting anchors with Tactoset was shown to significantly increase pullout strength and stiffness in osteoporotic bone models[11]



Representation of anchor augmented with Tactoset within trabecular bone

Anchor Pullout Strength

Average load to failure significantly increased when anchors were augmented with Tactoset

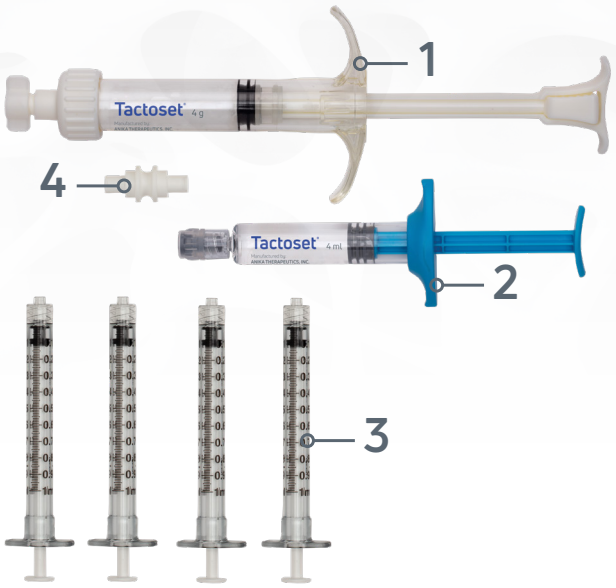


All tests results were of statistical significance.
Tactoset has been shown to double soft tissue anchor pullout at body temperature after 24 hours[11]

Components

Tactoset material set

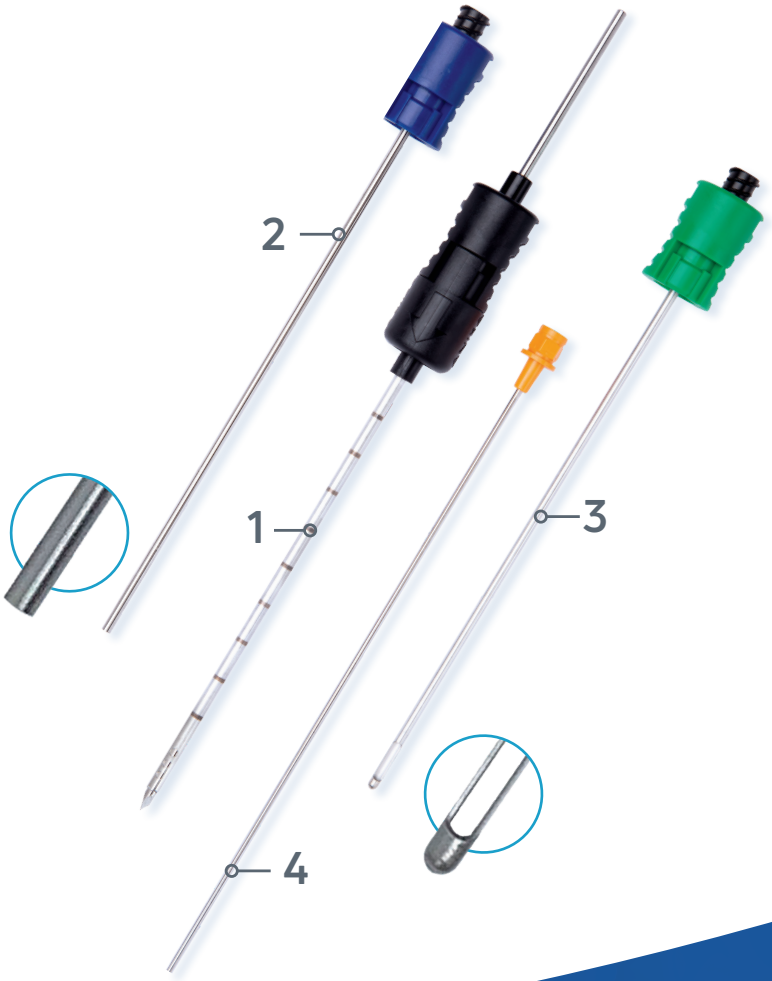
1. **Pre-filled mixing syringe**
   containing powder
2. **Glass syringe**
   containing setting solution
3. **Four 1 mL**
   Luer lock syringes
4. **Female-female**
   Luer lock connector



Anika delivery cannulas

1. **Drillable outer cannula**
   (with removable drillable stylet)
   GAUGE: 3.05 mm (11 Ga)
   LENGTH: 110 mm
2. **Inner cannula**
   for end delivery
   GAUGE: 2.41 mm (13 Ga)
   LENGTH: 134.39 mm
3. **Inner cannula**
   for side delivery
   GAUGE: 2.41 mm (13 Ga)
   LENGTH: 134.39 mm
4. **Push rod**

Anika delivery cannulas provide easier use with mini c-arm



Therapy Advantages

Tactoset supports cell-mediated regeneration of new bone as material is resorbed[5,6]

Enhanced flowability and injectability

- Contains hyaluronic acid (HA), a naturally occurring substance in the human body[7]
- HA enhances delivery of the calcium phosphate
- Highly flowable and easily injectable through minimally invasive surgery[6]
- Provides tactile feedback to confirm filling of the bone defect[6]
- Interdigitates into trabecular bone architecture to fill closed bone voids[5,6]

Closed mixing system

- Minimizes environmental exposure[6]
- Enhances ease of use: no mixing bowls; no mess[6]

Unique cannula design

- Allows surgeons to easily switch intraoperatively between side and end Tactoset delivery without having to remove and reinsert the outer cannula[6]

Product Attributes

<table>
<tr><th colspan="2">Material</th></tr>
<tr><td>Calcium phosphate</td><td>Remodels to hydroxyapatite, the mineral component of bone[6]</td></tr>
<tr><td>Hyaluronic acid</td><td>Enhances flowability and interdigitation in trabecular architecture[6]
Provides tactile feedback when injecting into the bone void[6]</td></tr>
<tr><td>Osteoconductive</td><td>Supports endogenous cell-mediated bone remodeling and growth of new bone into the bone void[5,6]</td></tr>
<tr><th colspan="2">Use</th></tr>
<tr><td>Multi-angle access cannula</td><td>Allows surgeons to easily switch intraoperatively between side and end Tactoset delivery without having to remove and reinsert the outer cannula[6]</td></tr>
<tr><td>Mix and use time</td><td>1 min mixing time; 6 min waiting time; 11 min injection time; 10 min setting time</td></tr>
<tr><td>Mixing with BMA</td><td>Indicated to be combined with autogenous bone marrow aspirate (BMA)</td></tr>
<tr><th colspan="2">Performance</th></tr>
<tr><td>Compressive strength</td><td>Compressive strength of Tactoset is similar to that of cancellous bone[6]
Tactoset
8 MPa
Cancellous bone[8]
2-12 MPa
Proximal Tibia
(Trabecular Bone)[9]
5.3 MPa
Proximal Femur
(Trabecular Bone)[10]
6.8 MPa</td></tr>
<tr><td>Reaction temperature</td><td>Non-exothermic setting reaction; no increase in local temperature or tissue necrosis[6]</td></tr>
<tr><td>Porosity (when fully cured)</td><td>50% ± 0.5%</td></tr>
<tr><td>Pullout testing</td><td>Average load to failure was over 2x greater for anchors augmented with Tactoset[11]
<table>
<tr><td rowspan="3">PEEK (4.5mm Twist PEEK)</td><td>Augmented by Tactoset in 7.5 PCF foam block model</td><td>131.0 ± 34.3 N</td></tr>
<tr><td>Augmented by Tactoset in cadaveric model</td><td>193.6 ± 63.9 N</td></tr>
<tr><td>Unaugmented (average)</td><td>49.8 ± 18.95 N</td></tr>
<tr><td rowspan="3">Biocomposite (4.5mm Twist AP)</td><td>Augmented by Tactoset in 7.5 PCF foam block model</td><td>182.2 ± 64.2 N</td></tr>
<tr><td>Augmented by Tactoset in cadaveric model</td><td>143.2 ± 28.9 N</td></tr>
<tr><td>Unaugmented (average)</td><td>75.85 ± 22.0 N</td></tr>
<tr><td rowspan="2">All-suture anchor (3.2mm Draw Tight)</td><td>Augmented by Tactoset in 7.5 PCF foam block model</td><td>135.2 ± 20.2 N</td></tr>
<tr><td>Unaugmented</td><td>83.3 ± 10.3 N</td></tr>
</table></td></tr>
</table>

Mixing Instructions

Hydration of Tactoset powder[5]

Step 1 | Unpacking

- **Open packaging** and transfer contents to the sterile field using sterile technique.
- **Loosen** stopper on each 1 mL syringe by pulling plunger rod back slightly to break seal.

Step 2 | Assembly

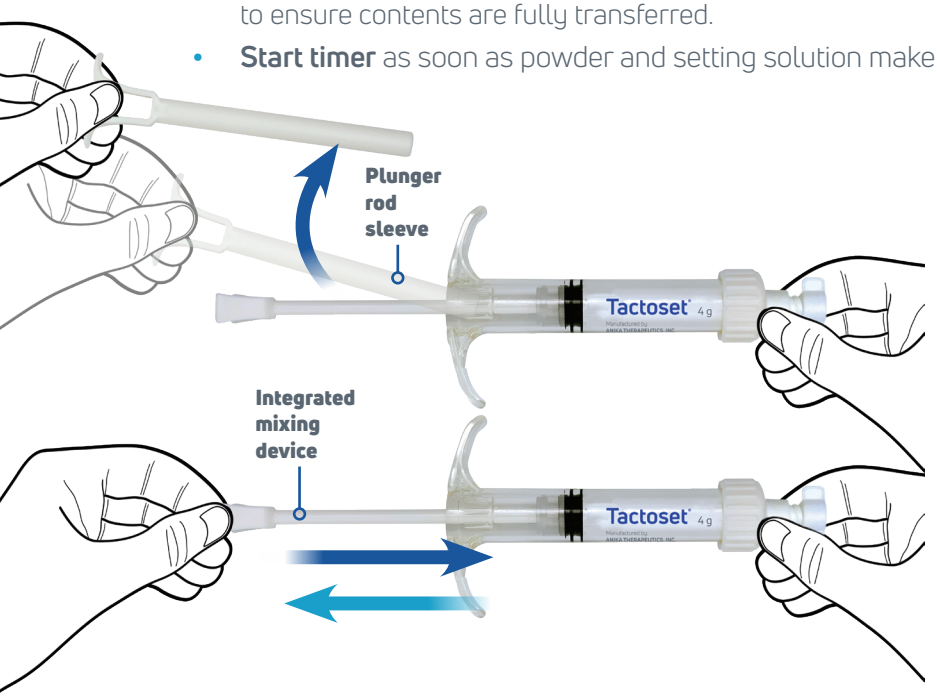
- **Remove the cap** from the prefilled mixing syringe containing the powder **(do not discard)**.
- **Remove the cap** from the glass syringe.

> ***Note:*** *If mixing with* ***BMA****, see instructions for use or visit www.anikaifu.com before proceeding to the next step.*

- Using a female-female **Luer lock connector**, attach the glass syringe containing the setting solution to the mixing syringe containing the powder.

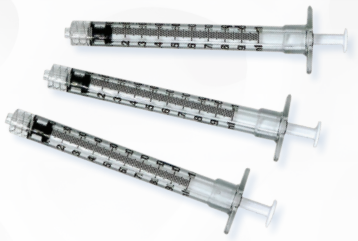
Step 3 | Mixing

- Hold the syringes vertically with the glass syringe on top. **Inject entire contents of setting solution** into the mixing syringe containing the powder. **Pull back** powder syringe plunger rod to ensure contents are fully transferred.
- **Start timer** as soon as powder and setting solution make contact.



- Remove the solution syringe and Luer lock connector (do not discard). **Recap** the mixing syringe.
- Remove the plunger rod sleeve **(do not discard)** and use the integrated mixing handle to mix the solution and powder by pressing the handle in and out of the material from top to bottom, and rotating the handle if necessary.
- **Mix for 1 minute** to ensure complete mixing.

Step 4 | Loading injection syringes



- **Reattach** the plunger rod sleeve over the integrated mixing handle
- Remove tip cap and attach a Luer lock connector to the mixing syringe. **Expel residual air** from the mixing syringe until a small drop of Tactoset is ejected.
- Attach a **1 mL Luer lock syringe**. **Hold and pull back** on the plunger rod of the 1 mL syringe to aid in transferring Tactoset material. Fill to 0.9 mL. **Do not overfill.**
- Fill and repeat as needed with remaining syringes.

> ***Note:*** *For complete product information, see instructions for use or visit www.anikaifu.com*

Timing notes

Start timer as soon as powder and setting solution make contact

Minute 0-1 | Mixing

- Mix powder and solution continuously for 1 minute

Minutes 1-7 | Fill syringes & wait

- Fill the provided 1 mL syringes to 0.9 mL
- Wait to inject until at least minute 7

Minutes 7-18 | Injection

- Inject Tactoset at desired timepoint between 7 and 18 minutes
- Check material for paste-like consistency to ensure injectability
- Inject at surgeon's desired consistency
- Apply continuous pressure when injecting
- Inspect for extrusion and remove any excess material within 2 minutes following implantation

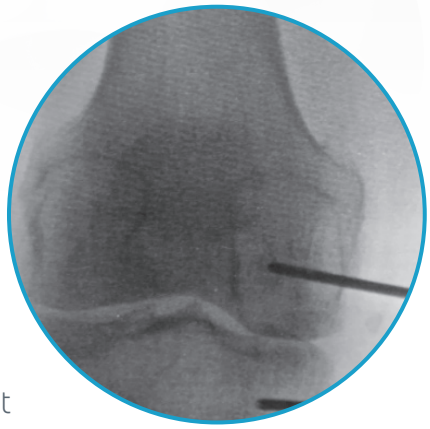
Knee Surgical Technique

Preoperative planning

- Utilize appropriate magnetic resonance imaging (MRI) sequences across all 3 planes (axial, coronal, sagittal) to identify the precise location of the bone void

Operating room setup

- Place the patient on a radiolucent table in the supine position
- Elevate the operative leg to a position that allows for unobstructed radiographic views during the procedure
- Ensure access to standard arthroscopic instruments and preoperative MRI images throughout the procedure
- Obtain appropriate fluoroscopic views to visualize the bone void
- Determine preferred trajectory to access the treatment area relative to ligamentous structures and prepare accordingly
- Based on the location of the bone void, determine whether to select a side- or end-targeted inner cannula from the Anika delivery cannulas



Intraoperative fluoroscopy image of cannula placement to treat femoral bone void

Cannula placement

- Drill the outer cannula into position under fluoroscopic guidance and confirm its positioning
- Avoid multiple drill attempts as this could result in extravasation of the material
- Once the outer cannula is in place, remove the stylet and insert the appropriate inner cannula for side- or end-targeted delivery

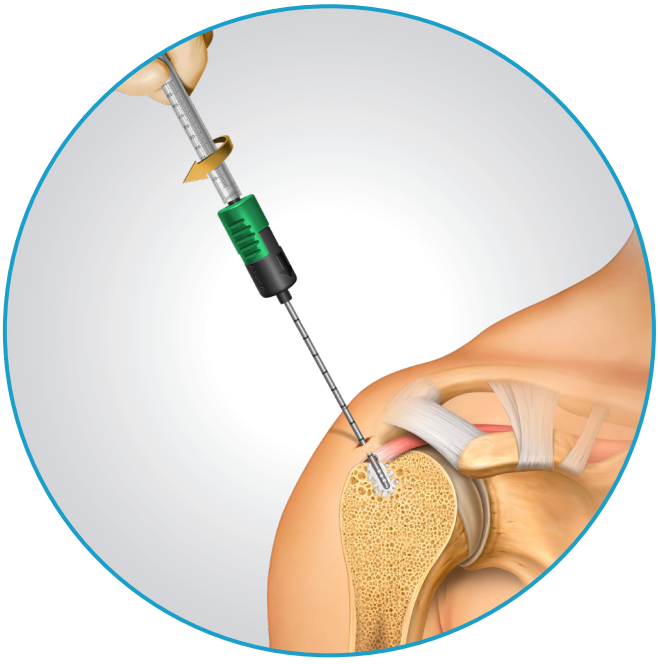
Injection technique

- Attach a 1 mL Luer lock syringe containing Tactoset and inject the material into the bone void using constant pressure and rotating the cannula if necessary
- Repeat with as many remaining 1 mL Luer lock syringes as required to fill the bone void
- Inspect for extrusion and remove any excess material within 2 minutes following implantation
- Remove the inner cannula and reinsert the stylet
- Leave the cannula in place while the material sets, approximately 10 minutes or less, after which the cannula can be removed
- Irrigate and close the incision site

Shoulder Surgical Technique

- Using a spinal needle percutaneously, identify the desired point of anchor placement most proximal to the affected bone. Take care to use a perpendicular approach in relation to the cortical surface to ensure proper drilling trajectory
- Make a small stab incision at the needle site for the 11Ga Tactoset cannula placement
- Under power, drill the 11Ga cannula to the approximate depth of the selected anchor using the laser lines as guidance. Avoid multiple drill attempts as this could result in extravasation of the material

Left shoulder, anterior view: cyst shows up as a bright white spot as seen on T2 fat-suppressed MRI



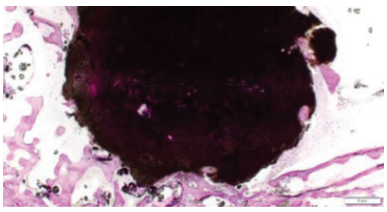
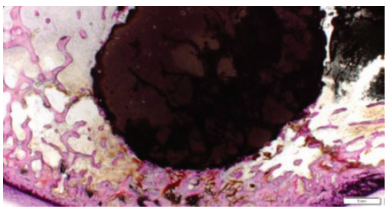
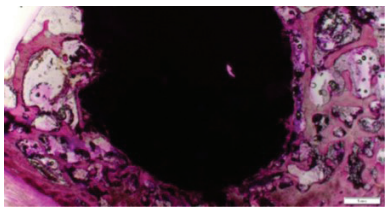
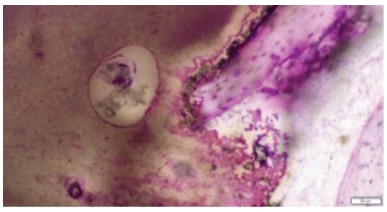
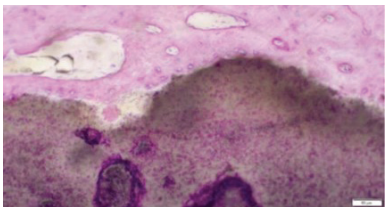
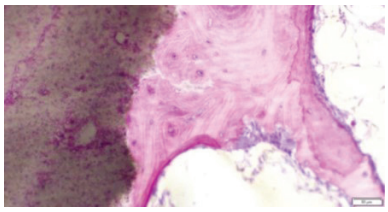
- Once the outer cannula is in place, remove the stylet and insert the appropriate inner cannula for side- or end-targeted delivery
- 7 minutes after mixing Tactoset, but prior to decorticating, inject 2-3 mL of Tactoset into the humerus
- After injection, leave the Tactoset cannula in place for 2-3 minutes prior to removing
- Complete the desired repair

Preclinical Data

Study purpose and design[6]

Evaluate the *in vivo* performance of Tactoset in a critical size defect of the distal femoral condyle in skeletally mature female New Zealand White Rabbits. Bilateral defects, 6-mm in diameter and 10-mm deep, were created in cancellous bone of the right and left femora and Tactoset was implanted.

Histology Results *PMMA Histology Tactoset*

Time 0	Time 6 weeks	Time 12 weeks
The scale bar in these images is 1 mm		
		
The implant is well placed within the defect.	Tactoset is present in the defect with new bone on-growth directly on the material. No fibrous interface was seen. No adverse reactions were noted.	Tactoset is present in the defect with new bone on-growth directky on the material. No fibrous interface was seen. No adverse reactions were noted. By 12 weeks, bone on-growth is covering much of the interface.
Images are 50 microns		
		
At Time 0, bone apposition has not occurred.	By 6 weeks, there is evidence of bone on-growth at the implant interface witout any intervening fibrous tissue layer, demonstrating the osteoconductivity of Tactoset.	At 12 weeks, there is evidence of bone on-growth at the implant interface without any intervening fibrous tissue layer, demonstrating the osteoconductivity of Tactoset.

Reimbursement

Coding guide

Potential procedure codes include:

CPT Code	Description	ASC Payment Indicator
0707T	Injection(s), bone-substitute material (eg. calcium phosphate) into subchondral bone defect (ie. bone marrow lesion, bone bruising, stress injury, microtrabecular fracture), including imaging guidance and arthroscopic assistance for joint visualization	J8
0869T	Injection(s), bone-substitute material for bone and/or soft tissue hardware fixation augmentation, including intraoperative imaging guidance, when performed	J8
23515	Open treatment of clavicular fracture, includes internal fixation, when performed	J8
23585	Open treatment of scapular fracture (body, glenoid or acromion) includes internal fixation, when performed	J8
23615	Open treatment of proximal humeral (surgical or anatomical neck) fracture, includes internal fixation, when performed, includes repair of tuberosity(s), when performed	J8
23630	Open treatment of greater humeral tuberosity fracture, with or without internal or external fixation	J8
27299	Unlisted procedure, pelvis or hip joint	IO
27509	Fracture and/or dislocation procedures on the femur (thigh region) and knee joint	J8
27599	Unlisted procedure, femur or knee	IO
27899	Unlisted procedure, leg or ankle	IO
29855	Arthroscopically aided treatment of tibial fracture, proximal (plateau); unicondylar, includes internal fixation, when performed (includes arthoscopy)	J8
29856	Arthroscopically aided treatment of tibial fracture, proximal (plateau); bicondylar, includes internal fixation, when performed (includes arthoscopy)	J8
29999	Unlisted procedure arthroscopy	IO

Reimbursement questions

Anika has partnered with reimbursement experts at MCRA to provide a dedicated hotline for reimbursement and coding questions. The Anika dedicated hotline is available via phone or email and inquiries should expect a response within 24hrs. All coding inquiries are answered by a credentialed, coding specialist.

MCRA Phone: 800-436-1377 | **MCRA Email:** USReimbursement@anika.com

IFU Details

Instructions for use

INTENDED USE / INDICATIONS

Tactoset® Injectable Bone Substitute is a synthetic, biocompatible bone graft substitute material that hardens and converts to a poorly crystalline hydroxyapatite at body temperature. It is indicated for filling bone voids or defects of the skeletal system (i.e. extremities and pelvis) that are not intrinsic to the stability of bony structure. These defects may be surgically created osseous defects or defects created from traumatic injury to the bone. The device provides an injectable, self-setting, osteoconductive bone graft substitute that resorbs and is replaced by the growth of new bone during the healing process and may be combined with autogenous bone marrow.
Tactoset® Injectable Bone Substitute can augment hardware and support bone fragments during the surgical procedure. The cured paste acts only as a temporary support media and is not intended to provide structural support during the healing process.

CONTRAINDICATIONS

Do not use this product if one or more of the following conditions are present:

- Existing acute or chronic infections, especially at the site of the operation.
- Nonviable bone.
- Areas where surrounding bone is not viable or not capable of supporting and anchoring the implant.
- Altered calcium metabolism.
- Metabolic bone disease.
- Immunologic abnormalities.
- Systemic disorders which result in poor wound healing.
- Inflammatory bone disease.
- Acute traumatic injuries with open wounds close to the defect which are likely to become infected.
- Conditions where the surgical site may be subjected to excessive impact or stresses, including those beyond the load strength of fixation hardware.

WARNINGS

- DISCARD UNUSED PORTIONS; Tactoset® Injectable Bone Substitute is a SINGLE PATIENT, SINGLE USE product.
- DO NOT RESTERILIZE; the safety and effectiveness of reused or resterilized Tactoset® Injectable Bone Substitute is unknown.
- Because Tactoset® Injectable Bone Substitute is indicated for use in defects that are not intrinsic to the stability of the bony structure, it is critical that adequate fixation be provided for unstable defects by other means.
- The safety and effectiveness for patients having received or to receive chemotherapy or radiation therapy at or near the implant site is not known.
- The safety and effectiveness when used in conjunction with other legally marketed devices having similar indications is not known.
- The safety and effectiveness for use in children or elderly patients is not known.
- The effect in patients with documented renal disease is not known.
- The effect in patients with metabolic bone disease is not known.
- The effect in patients that are pregnant/nursing is not known.
- The effect in patients with cardiovascular disease precluding elective surgery is not known.
- The effect in patients having had infection during the last 3 months is not known.
- Care must be taken to prevent the creation of emboli. Highly pressurized application of Tactoset® Injectable Bone Substitute into a tightly confined space with ready venous or arterial access is not recommended, as the potential for formation of emboli is unknown.
- Prepare Tactoset® Injectable Bone Substitute using only the specified mixing solutions; the effect of

preparing with other substances is unknown and may adversely affect product performance.
- Do not use in infected sites.
- An animal performance study comparing both Tactoset and Tactoset with Bone Marrow Aspirate (BMA) to an empty defect negative control group demonstrated low rates of new bone formation at 12 weeks. Animal study data demonstrated that more than 50% of the implant material remained at 12 weeks following implantation. Patients should be monitored to ensure adequate bone healing and minimize the risk of hardware failure.

PRECAUTIONS

- Only for use by surgeons familiar with the material, appropriate surgical techniques, and bone repair procedures.
- Use aseptic technique to minimize the risk of infection.
- Mix with the specified volume of mixing solutions; deviations will alter the consistency of the material and may adversely affect the setting reaction and the effectiveness of the implant.
- Do not disturb the material after implantation as disruption may affect the characteristics of the hardened material.
- Do not irrigate the defect site immediately after implantation; wait until the material is hard to touch (about 10 minutes at 37 °C, 98 °F).
- Fully fill the defect site to obtain maximum contact between Tactoset® Injectable Bone Substitute and host bone. Not doing so may lead to incomplete or lack of bone formation, delayed union or non-union.
- Do not overfill the defect; Over-pressurizing the device may lead to extrusion beyond the site of intended application and damage to surrounding tissue. Remove any excess material within 2 minutes following implantation.
- The insertion of fixation implants after hardening may fracture the Tactoset® Injectable Bone Substitute material.
- Follow general surgical protocol regarding use of fixation.
- Post-operative use of a closed suction drain is recommended.
- Do not administer to patients with known hypersensitivity (allergy) to hyaluronate preparations.

POSSIBLE COMPLICATIONS

Re-operation to remove or replace the implant may be required occasionally due to medical reasons or device failure; if corrective action is not taken, one or more of the following complications may occur:

- Tissue thinning over implant site.
- Tenderness/redness/edema.
- Seroma/hematoma or infection.
- Swelling/fluid collection.
- Loss of contour.
- Migration, extrusion, dehiscence, fracture and sloughing of Tactoset® Injectable Bone Substitute can occur as a result of excessive trauma or post-operative load bearing.
- Neurovascular injuries due to surgical trauma.

For complete product information, please visit www.anikaifu.com

510k Letter

U.S. FOOD & DRUG ADMINISTRATION

March 29, 2023

Anika Therapeutics. Inc.
% Mehdi Kazemzadeh-Narbat, PhD, PMP, CQA
Associate Director, Regulatory Affairs
Mcra LLC.
803 7th Street NW
Floor 3
Washington, District of Columbia 20001

Re: K223915
Trade/Device Name: Tactoset
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: December 29, 2022
Received: December 29, 2022

Dear Dr. Kazemzadeh-Narbat:

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 (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 located 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.

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

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

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Sara S. Thompson -S

Laurence D. Coyne, Ph.D.
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

Enclosure

Medical Education

Anika Medical Education's mission is to connect health care providers through meaningful education by providing them with the knowledge, skills and tools to restore active living in their patients.

Tailored programs to support practice advancement

Anika medical education programs are designed to provide clinicians with focused and flexible modalities, in-depth education on products and techniques, and interactive exchanges with other thought leaders.

Examples program includes:

- National courses and labs, lead by renowned faculty, on various orthopedic concepts.
- Visiting Surgeon Programs (VSPs) that provide surgical observation within an experts operating room.
- Surgeon to Surgeon (S2S) discussions on techniques, clinical evidence and products.
- Didactic and hands on experiences with thought leaders on current topics.
- Localized sawbones or cadaveric instruction labs designed to fit your schedule and patient needs.

Contact us at MedEd@anika.com or reach out to your Regional Director, Sales Manager or Local Anika Representative to learn about upcoming events or to schedule a one-on-one demonstration.

Services and Support

Customer Service

Anika values our customers and is committed to providing quality support services. Whether it's placing orders, answering billing questions, providing cross references or sharing other documentation, our dedicated Customer Service Specialists are available and ready to assist you.

Anika Customer Service: 1-888-721-1600

Medical Services and Support

Our Medical Services and Support center was created to assist our customers in today's evolving healthcare environment. This unique support team provides technical and clinical information on procedures involving Anika products and/or other inquiries. Our support staff consists of knowledgeable health professionals, including surgeons, prepared to answer your questions and address your resource needs.

Anika Medical Services and Support: 1-888-721-1600

Reimbursement Hotline

Anika has partnered with reimbursement experts at MCRA to provide a dedicated hotline for reimbursement and coding questions. MCRA's coding, reimbursement, and compliance experts have over 50 years of combined healthcare policy and finance services experience, and have a proven track record servicing over 250 clients nationwide. The Anika dedicated hotline is available via phone or email and inquiries should expect a response within 24hrs. All coding inquiries are answered by a credentialed, coding specialist.

Contact Information:

MCRA Phone: 800-436-1377

MCRA Email: USReimbursement@anika.com

Packaging and Ordering Information

Part Number	Description
1000040	**11Ga delivery cannula set** including: one drillable outer cannula with removable drillable stylet, one inner cannula for end delivery, one inner cannula for side delivery, one push rod
4000050	**15Ga delivery cannula set** including: one drillable outer cannula with removable drillable stylet, one push rod
6000041	**Tactoset material set** including: one prefilled mixing syringe containing Tactoset powder, one glass syringe containing Tactoset setting solution, four 1mL Luer lock syringes, one female-female Luer lock connector
6000151	**Marrow Cellution Bone Marrow Aspiration Needle set** including: one introducer needle with sharp stylet, one aspiration cannula, one 11Ga blunt stylet, one 10 mL syringe

Please note that both the Tactoset material set and one of the delivery cannula sets are needed for each procedure.

References

1. Liu JN, Shields TG, Gowd AK, Amin NH. Surgical Treatment of Insufficiency Fractures of the Knee. *Arthrosc Tech.* 2019;8(11):e1327–e1332. Published 2019 Oct 11. doi:10.1016/j.eats.2019.07.008
2. Alliston T, Hernandez CJ, Findlay DM, Felson DT, Kennedy OD. Bone marrow lesions in osteoarthritis: What lies beneath. *J Orthop Res.* 2018;36(7):1818-1825. doi:10.1002/jor.23844
3. Tanamas SK, Wluka AE, Pelletier J-P, et al. Bone marrow lesions in people with knee osteoarthritis predict progression of disease and joint replacement: a longitudinal study. *Rheumatology.* 2010;49(12):2413-2419. doi:10.1093/rheumatology/keq286
4. Scher C, Craig J, Nelson F. Bone marrow edema in the knee in osteoarthrosis and association with total knee arthroplasty within a three-year follow-up. *Skeletal Radiol.* 2008;37(7):609-617. doi:10.1007/s00256-008-0504-x
5. Tactoset Instructions for Use. Anika Therapeutics, Inc. AML 500-335.
6. Data on file, Anika Therapeutics, Inc.
7. Brandt K., Block J., Michalski J., Moreland L., Caldwell J., Lavin P. Efficacy and safety of intra-articular sodium hyaluronate in knee osteoarthritis. *Clinical Orthopaedics and Related Research* 2001;(385): 130-143.
8. Fu Q, Saiz E, Rahaman M N, Tomsia A P. Bioactive glass scaffolds for bone tissue engineering: state of the art and future perspectives. *Mater Sci Eng C Mater Biol Appl.* 2011 October 10; 31(7): 1245–1256.
9. Linde F, Hvid I. The effect of constraint on the mechanical behavior of trabecular bone specimens. *J Biomech* 1989;22(5):485–90.
10. Rohlmann A, Zilch H, Bergmann G, Kolbel R. Material properties of femoral cancellous bone in axial oading. Part I: time independent properties. *Arch Orthop Trauma Surg* 1980;97(2):95–102.
11. Diaz M, Munassi S, Teytelbaum D, Pipitone A, Baker C. An Injectable Calcium Phosphate Bone Graft Substitute Improves the Pullout Strength of Various Suture Anchor Designs in an Osteoporotic Bone Model. Arthroscopy, Sports Medicine, and Rehabilitation 2023 Jan 5; pp e1-e11. doi:10.1016/j.asmr.2023.01.010
12. Stark M, DeBernardis D, McDowell C, Ford E, McMillan S. Percutaneous Skeletal Fixation of Painful Subchondral Bone Marrow Edema Utilizing an Injectable, Synthetic, Biocompatible Hyaluronic Acid-Based Bone Graft Substitute. Arthroscopy Techniques 2020 Nov; Vol 9, No 11; pp e1645-e1650. doi:10.1016/j.eats.2020.07.005

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