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Instructions for Use—**Soft Tissue Anchoring Devices**

This document applies to All Anchors-Sterile (Listed Below) manufactured by Chetan Meditech Pvt. Ltd. (BIOTEK).

Product	Material of Construction
Anchor	Titanium Ti-6Al-4V (ISO 5832-3) OR PEEK(Poly Ether Ether Ketone as per ASTM F2026)
Micro-Fix Anchor with Biofiber Wire	Titanium Ti-6Al-4V (ISO 5832-3) and Polyethene (ISO 5834-2)
Micro-Fix II Anchor with Biofiber Wire	Titanium Ti-6Al-4V (ISO 5832-3) and Polyethene (ISO 5834-2)
Mini Vim Anchor with Biofiber Wire	Titanium Ti-6Al-4V (ISO 5832-3) and Polyethene (ISO 5834-2)
Mini Vim Anchor with Biofiber Wire with Needle	Titanium Ti-6Al-4V (ISO 5832-3) and Polyethene (ISO 5834-2) and SS 316L(ISO 5832-1)
Mini Vim II Anchor with Biofiber Wire	Titanium Ti-6Al-4V (ISO 5832-3) and Polyethene (ISO 5834-2)
Mini Vim II Anchor with Biofiber Wire with Needle	Titanium Ti-6Al-4V (ISO 5832-3) and Polyethene (ISO 5834-2) and SS 316L(ISO 5832-1)
Super-Vim Anchor with Biofiber Wire	Titanium Ti-6Al-4V (ISO 5832-3) and Polyethene (ISO 5834-2)
Super-Vim Anchor with Biofiber Wire with Needle	Titanium Ti-6Al-4V (ISO 5832-3) and Polyethene (ISO 5834-2) and SS 316L(ISO 5832-1)
Super-Vim III Anchor with Biofiber Wire	Titanium Ti-6Al-4V (ISO 5832-3) and Polyethene (ISO 5834-2)
Super-Vim III Anchor with Biofiber Wire with Needle	Titanium Ti-6Al-4V (ISO 5832-3) and Polyethene (ISO 5834-2) and SS 316L(ISO 5832-1)
RC-LOC Anchor with Biofiber Wire	PEEK(Poly Ether Ether Ketone as per ASTM F2026) and Polyethene (ISO 5834-2)
RC-LOC Knot Less Anchor with Biofiber Wire	Titanium Ti-6Al-4V (ISO 5832-3) OR PEEK(Poly Ether Ether Ketone as per ASTM F2026) and Polyethene (ISO 5834-2)
Vimfix Anchor with Biofiber Wire	PEEK(Poly Ether Ether Ketone as per ASTM F2026) and Polyethene (ISO 5834-2)
Vimfix-LR Anchor with Biofiber Wire	PEEK(Poly Ether Ether Ketone as per ASTM F2026) and Polyethene (ISO 5834-2)
Vimfix Knot Less Anchor with Biofiber Wire	Titanium Ti-6Al-4V (ISO 5832-3) OR PEEK(Poly Ether Ether Ketone as per ASTM F2026) and Polyethene (ISO 5834-2)

Device Description
BIOTEK manufactures a variety of anchors intended to aid in arthroscopic and orthopaedic reconstructive procedures requiring soft tissue fixation, due to injury or degenerative disease.

Indications for Use
Anchors (above listed) are indicated for use in soft tissue reattachment procedures in the shoulder, wrist/hand, ankle/foot, elbow, hip and knee. Specific indications are:
Shoulder Indications – Bankart repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule repair or capsulolabral reconstruction, biceps tenodesis, deltoid repair.
Wrist/Hand Indications – Scapholunate ligament reconstruction, ulnar/radial collateral ligament reconstruction.
Ankle/Foot Indications – Lateral stabilization, medial stabilization, Achilles tendon repair/reconstruction, hallux valgus reconstruction, mid- and forefoot reconstruction.
Elbow Indications – Ulnar or radial collateral ligament reconstruction, biceps tendon reconstruction
Knee Indications – Extra capsular Repair: Medial collateral ligament repair, lateral collateral ligament repair, posterior oblique ligament repair, joint capsule closure, iliotibial band tenodesis reconstruction, and patellar ligament and tendon repair, vastus medalis obliquus (VMO) muscle advancement.
Hip: Capsular repair, acetabular labral repair

Contraindications
1. Infection.
2. Patient conditions including blood supply limitations, and insufficient quantity or quality of bone or soft tissue.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
4. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.

Warnings
BIOTEK anchors provide the surgeon with a means to aid in the management of soft tissue to bone reattachment procedures. While these devices are generally successful in attaining these goals, they cannot be expected to replace normal healthy bone or withstand the stress placed upon the device by full or partial weight bearing or load bearing, particularly in the presence of nonunion, delayed union, or incomplete healing. Therefore, it is important that immobilization (use of external support, walking aids, braces, etc.) of the treatment site be maintained until healing has occurred. Surgical implants are subject to repeated stresses in use, which can result in fracture or damage to the implant. Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the service life of the implant. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but also must be aware of the mechanical and metallurgical aspects of the surgical implants.

1. Correct selection of the implant is extremely important. The potential for success in soft tissue to bone fixation is increased by the selection of the proper type of implant. While proper selection can help minimize risks, neither the device nor grafts, when used, are designed to withstand the unsupported stress of full weight bearing, load bearing or excessive activity.
2. The implants can loosen or be damaged when subjected to increased loading associated with nonunion or delayed union. If healing is delayed, or does not occur, the implant or the procedure may fail. Loads produced by weight bearing and activity levels may dictate the longevity of the implant. Excessive, unusual and/or awkward movement and/or activity, trauma and weight gain may result in premature failure of certain implants by loosening, fracture, dislocation, subluxation and/or wear.
3. Inadequate fixation at the time of surgery can increase the risk of loosening and migration of the device or tissue supported by the device. Sufficient bone quantity and quality are important to adequate fixation and success of the procedure. Bone quality must be assessed at the time of surgery. Adequate fixation in diseased bone may be more difficult. Patients with poor quality bone, such as osteoporotic bone, are at greater risk of device loosening and procedure failure.
4. Implant materials are subject to corrosion. Implanting metals and alloys subjects them to constant changing environments of salts, acids, and alkalis that can cause corrosion. Putting dissimilar metals and alloys in contact with each other can accelerate the corrosion process that may enhance fracture of implants. Every effort should be made to use compatible metals and alloys when marrying them to a common goal.
5. Care is to be taken to assure adequate soft tissue fixation at the time of surgery. Failure to achieve adequate fixation or improper positioning or placement of the device can contribute to a subsequent undesirable result.
6. The use of appropriate immobilization and postoperative management is indicated as part of the treatment until healing has occurred.
7. Correct handling of implants is extremely important. Do not modify implants. Do not notch or bend implants. Notches or scratches put in the implant during the course of surgery may contribute to breakage. Intraoperative fracture of anchors can occur if excessive force (torque) is applied while seating anchors.
8. Do not use excessive force when inserting suture anchors. Excessive force (e.g. long hard hammer blows) may cause fracture or bending of the device. Prior to insertion of the implant, predrill, awl, or tap.
9. DO NOT USE if there is a loss of sterility of the device.
10. DO NOT USE opened or damaged devices, and use only devices that are packaged in unopened or undamaged containers.
11. Ensure contact of tissue to bone when implanting. DO NOT OVERTIGHTEN the screw. Structural damage to the tissue and implant may occur if the screw is over tightened.
12. Adequately instruct the patient. Postoperative care is important. The patient's ability and willingness to follow instructions is one of the most important aspects of successful fracture management. Patients effected with senility, mental illness, alcoholism, and drug abuse may be at a higher risk of device or procedure failure. These patients may ignore instructions and activity restrictions. The patient is to be instructed in the use of external supports, walking aids, and braces that are intended to immobilize the fracture site and limit weight bearing or load bearing. The patient is to be made fully aware and warned that the device does not replace normal healthy bone, and that the device can break, bend or be damaged as a result of stress, activity, load bearing, or weight bearing. The patient is to be made aware and warned of general

surgical risks, possible adverse effects, and to follow the instructions of the treating physician. The patient is to be advised of the need for regular postoperative follow-up examinations as long as the device remains implanted.
13. Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.
Patient selection factors to be considered include: 1) need for soft tissue to bone fixation, 2) ability and willingness of the patient to follow postoperative care instructions until healing is complete, and 3) a good nutritional state of the patient.

Precautions
Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat with implants that have been, even momentarily, placed in a different patient.
Instruments are available to aid in the accurate implantation of internal fixation devices. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. BIOTEK recommends that all instruments be regularly inspected for wear and disfigurement.
All packaging, and instrument components must be removed prior to closing the surgical site.

Possible Adverse Effects
1. Non-union or delayed union, which may lead to breakage of the implant.
2. Bending or fracture of the implant.
3. Loosening or migration of the implant.
4. Metal sensitivity or allergic reaction to a foreign body.
5. Pain, discomfort, or abnormal sensation due to the presence of the device.
6. Nerve damage due to surgical trauma.
7. Necrosis of bone or tissue.
8. Inadequate healing.
9. Intraoperative or postoperative bone fracture and/or postoperative pain.

Sterility
BIOTEK anchor implants are supplied sterile, and are sterilized by Ethylene Oxide Gas (ETO). Single use only. Do not resterilize. Do not use past expiration date.

Magnetic Resonance Imaging/ Electromagnetic field/ Magnetic field
Implants made from non-ferromagnetic materials i.e. Titanium Ti-6Al-4V (ISO 5832-3) OR PEEK(Poly Ether Ether Ketone as per ASTM F2026) OR Polyethene (ISO 5834-2) are safe or 'MR conditional' according to specific conditions for patients undergoing MR procedures. However, patients who have implants made from ferromagnetic materials i.e.SS 316L(ISO 5832-1) have potential risks of loosening and migration of the implant, heating of the metal with surrounding tissues, causing thermal damage, and artifactual distortion. Patients who have implants made from ferromagnetic materials i.e.SS 316L(ISO 5832-1) are warned not to enter areas with electromagnetic or magnetic fields.

Disposal
After use, this device may be a potential biohazard and should be decontaminated before disposal and handled in accordance with accepted medical practice and applicable local and national requirements.

Warranty
This product is warranted to be free from defects in material and workmanship.

Documentation: To ensure the implant's traceability at all times, attach/mention the information (batch no., etc) given in the product label to the patient's clinical history.

For Further Information
If further information on this product is needed, please visit ***www.biotekortho.com*** or contact BIOTEK Customer Service Department., or your authorized representative. In case of any queries, please put in to the knowledge of following organization. All trademarks herein are the property of BIOTEK or its subsidiaries unless otherwise indicated.

Manufacturing unit: Chetan Meditech Pvt. Ltd. (BIOTEK), Kadi-Kalol Highway, Mehsana Dist.– 382715, Gujarat, India

Symbol Legend		
Manufacturer	Date of Manufacture	Do not use if package is damaged
Do Not Reuse	Caution	Use By
Do Not Resterilize	Sterilized Using Ethylene Oxide	By Prescription Only
Catalogue Number	Consult Instructions For Use	2265 European Conformity
EC REP CMC MEDICAL DEVICES & DRUGS S.L. Address: C/ Horacio Lengo N° 18, CP 29006, Málaga, SPAIN Ph: +34 951 214 054 info@cmcmedicaldevices.com Authorized Representative in the European Community	LOT Batch Code	