Instructions for Use—**SOFT-FIX-PK** Interference Screw

This document applies to Soft-Fix-PK Interference Screw (Sterile) manufactured by Chetan Meditech Pvt. Ltd. (BIOTEK).

Device Description
The BIOTEK SOFTFIX-PK Screw is an interference screw for use in fixation of bone-tendon-bone or soft tissue grafts in anterior/posterior cruciate ligament (ACL/PCL) reconstruction procedures. The screw is for single use only.

Materials used
The SOFTFIX-PK Screw is made from PEEK(Poly Ether Ether Ketone as per ASTM F2026) and is not absorbable.

Indications for Use
The BIOTEK SOFTFIX-PK Screw is indicated for inference fixation of bone-tendon-bone or soft tissue grafts in anterior/posterior cruciate ligament (ACL/PCL) reconstruction procedures.

Product description
Refer the label on the packaging for complete specifications of the product.

General handling
Carefully store the implant in its unopened protective packing. Before unpacking check the packing for damage. If the internal packing is damaged, implant sterility cannot be guaranteed. Do not unpack the implant until immediately before use. Check the implant as specified on the packing label. Check the implant visually for damage. Never use a damaged implant. Never reuse an implant. Modular components are part of a system. Use them only in combination with the appropriate original components made by BIOTEK. For details of specified combinations, see the relevant brochures and product descriptions.

Packing
All components are packed singly, in protective sterile packing. Sterile packing is marked “STERILE”. All packing conforms to European standards and regulations. Products marked “STERILE” have been sterilized by gamma radiation of at least 25kGy (2.5Mrad) and at most 35kGy (3.5Mrad) OR Ethylene Oxide Sterilization. Inward-goods inspection is strongly recommended. Only intact packing protects the implant against outside influence and ensures sterile storage. Strictly observe the local regulations for asepsis when you remove the implant from its packing. The manufacturer or local distributor cannot accept returned implants except in their original, undamaged, and totally intact packing. If the packing seal is broken or the packing is opened improperly, the manufacturer cannot guarantee sterility and cannot be held liable. Before you open sterile packing, check the implant’s size by verification with preoperative planning.

Storage
Store the product in a dry place at room temperature. The sterilization dot must be Red (for gamma irradiation) OR Green (for ETO sterilization). On no account use the implant after its expiry date.

Preoperative planning
Preoperative planning provides information for the choice of a suitable implant and of possible combinations. Suitable instruments and additional sizes of implants should always be available.

Contraindications
- Acute or chronic local or systemic infection.
- Severe muscular, nervous, and/or vascular disorders that could endanger the limb.
- Insufficient bone substance and/or inadequate bone quality that could endanger the stable fixation of the implant.
- Conditions that would reduce the support of the screw threads, e.g., insufficient quantity or quality of bone including tumors and severe osteoporosis.
- Any concomitant illness and/or dependence that could be risk implanting function.
- Excessive bodily activities that could cause overloading of the implant.

Adverse Reactions
Complications which are seen with any method of internal fixation include failure to regain full extension or flexion, patella femoral complications, fixation complications, hardware irritation, impingement to the graft, and arthrofibrosis. Additional complications may include fixation failure, and migration of the screw.

Side effects, possible negative effects
With good preoperative planning, careful surgical technique and pre-, intra-, and postoperative observance of both the general and particular duty of care, the biological and mechanical result should be at least as good as that obtained from established systems currently in use.
Severe osteoporosis, severe malformations, local bone tumors, metabolic disorders, infections, severe falls, drug and/or alcohol abuse, overweight, and excessive vibration stress on implants can have a negative effect on the result. Possible well known effects are * Loosening and drifting of the implant. * Dislocation of the implant. * Infection. * Venous thrombosis and pulmonary embolism. * Cardiovascular Disorders. * Hematoma.
Sympathetic reactions-Before surgery, check whether the patient might be abnormally sensitive or have possible allergic reactions to the implant material, and at all cost, take these into account.

Surgical Technique
The use of the implant requires a thorough knowledge of the instruments and adequate training and experience of the implant technique.

Instructions for Use
1. Prepare the tibial and femoral tunnel in normal fashion.
2. Place the graft into position in the tunnel.
3. Choose an appropriate size SOFTFIX-PK Screw.
4. Insert a guide wire between the graft and tunnel wall.
5. Use the Screwdriver compatible for the screw. Use Biotek associated instruments (sold separately)
6. Place the SOFTFIX-PK Screw securely on the screwdriver such that the screwdriver is fully engaged. Pass the screw and driver over the guide wire and into position.
7. While applying tension to the graft, engage the screw until firmly fixed between the tunnel and the graft.
8. Do not attempt to implant this device within cartilage epiphyseal growth plates or nonosseous tissue

Notes and warnings
Always check that the components are perfectly clean, dry, and free of damages or residues. It is extremely important to tell the patient before surgery what factors could prejudice the success of the operation. Record the fact that you have told him/her this. Only adequately trained surgeons with sufficient experience of the implant technique should use this implant. Failure to observe these instructions renders any liability by the manufacturer null and void. The surgeon is solely responsible for the choice and use

of the implant. 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 patients with implants that have been placed, even if momentarily, in a different patient.

Sterility
BIOTEK's **Soft-Fix-PK Interference Screw** implants are supplied sterile, and are sterilized by exposure to a minimum dose of 25kGy (2.5Mrad) and at most 35kGy (3.5Mrad) OR Ethylene Oxide Sterilization. Single use only. Do not resterilize. Do not use past expiration date.

Magnetic Resonance Imaging
Implants made from non-ferromagnetic materials i.e. PEEK (Poly Ether Ether Ketone as per ASTM F2026) are safe or 'MR conditional' according to specific conditions for patients undergoing MR procedures.

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 Reuse	Do Not Resterilize
2265 European Conformity	STERILE R Sterilized Using Irradiation
REF Catalogue Number	STERILE EO Sterilized Using Ethylene Oxide
EC REP CMC MEDICAL DEVICES & DRUGS S.L. Address: C/ Horacio Lengo Nº 18, CP 29006, Málaga, SPAIN Ph: +34 951 214 054 info@cmcmedicaldevices.com Authorized Representative in the European Community	Consult Instructions For Use
Do not use if package is damaged	LOT Batch Code
By Prescription Only	Use By
Caution	