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# Instructions for Use— **ONBUTTON CL** fixation device

**This document applies to "Onbutton CL fixation button with loop (Sterile)" manufactured by Chetan Meditech Pvt. Ltd. (BIOTEK)**

**Device Description**
The use of the fixation device provides the orthopedic surgeon a means of accurate suture fixation in reconstructive surgery. The fixation device allows for endoscopic ligament reconstruction without the requirement for an ancillary lateral incision.

**Materials used**
The fixation device is composed of two components: a suture loop and a fixation device. The suture portion of the fixation device is made of a UHMWPE braid (Ultra High Molecular Weight Poly Ethylene braid) (IUPAC: Polyethene) which meets ISO 5834-2. The fixation device is made of titanium alloy Titanium Ti-6Al-4V which meets ISO 5832-3

**Indications for Use**
The fixation device is used for fixation of tendons and ligaments during orthopedic reconstruction procedures such as anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) reconstruction.

**Contraindications**
- Known hypersensitivity to the implant material. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
- Insufficient quantity or quality of bone.
- Blood supply and previous infections which may tend to retard healing.
- Active infection.
- Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.

**Warnings**
- Contents are sterile unless package is opened or damaged. DO NOT RESTERILIZE. For single use only. Discard any open, unused product. Do not use after the expiration date.
- It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.
- Read these instructions completely prior to use.
- As with any foreign body, prolonged contact of this suture with salt solutions, such as those found in urinary and biliary tracts may result in calculus formation.

**Precautions**
- Prior to use, inspect the product package for signs of damage or tampering. If damaged, do not use.
- Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device.
- The use of metallic surgical implants provides the orthopedic surgeon with a means of accurate fixation and helps generally in the management of fractures and reconstructive surgery. These implants are intended as aids to normal healing, but are not intended to replace normal body structures or bear the weight of the body in the presence of incomplete bone healing.
- Ensure the endoscopic cannulated reamer does not breach the femoral cortex; otherwise the femoral fixation with the fixation device will be compromised.
- Postoperative care is important. A patient should be instructed on the limitations of the implant and should be cautioned regarding weight bearing and body stresses on the appliance prior to secure bone healing.
- Careful attention must be paid to asepsis and avoidance of anatomical hazards.

**Adverse Reactions**
Complications are those seen with any method of internal fixation. Adverse reactions associated with suture include: wound dehiscence, calculi formation in urinary or biliary tract such as bile or urine occurs, infected wounds, minimal acute inflammatory tissue reaction and transitory local irritation.

**Instructions for Use**
1. Over drill the drill bit passing pin (BAK-7036) with the 4.7 mm endoscopic cannulated reamer (BAK-7118). Measure the total femoral channel length using the graduated markings on the reamer at the moment of cortical "breakthrough", or remove the reamer and use the Onbutton Depth Gauge (BAK-7053).
2. Measure the intra-articular distance between the proximal end of the tibial tunnel and the distal end of the femoral socket. Also measure the length of the graft.
3. Determine the estimated graft insertion lengths for the tibial tunnel and femoral socket by subtracting the intra-articular distance from the total graft length and dividing the remainder in half for equal tibial and femoral insertion.
4. Select the suitable size fixation device by subtracting the estimated graft insertion length for the femoral socket from the total length of the femoral channel.

| Steps | Abbreviation | Example | Calculation |
|---|---|---|---|
| Measure total femoral channel length | FCL | 43 mm | |
| Measure graft length | GL | 50 mm | |
| Measure intra – articular distance | IAD | 20 mm | |
| Calculated estimated femoral graft insertion length (GL – IAD)/2 | FGIe | 15 mm | |
| Calculate the Loop length<br>FCL – FGI (43-15=) | CLL | 28 mm | |

There is no 28 mm loop therefore use a 25 mm or 30 mm fixation device (25<28<30).

Calculate actual graft insertion lengths and femoral socket depth prior to drilling femoral socket.

| Steps | Abbreviation | Example | Calculation |
|---|---|---|---|
| If using a shorter fixation device | EBCL | 25 mm | |
| Calculate actual femoral insertion length FCL-EBCL=FGI (43-25=18) | FGIa | 18 mm | |
| Calculate femoral socket depth FGIa+6mm (18+6=24) | FSD | 24 mm | |
| Calculate tibial graft insertion<br>GL-(IAD+FGIa)<br>[50-(20+18)]=12 | TGI | 12 mm | |
| If using a longer fixation device | EBCL | 30 mm | |
| Calculate actual femoral graft insertion length<br>FCL-EBCL=FGI<br>43-30=13 | FGIa | 13 mm | |
| Calculated femoral socket depth FGIa+6mm (13+6=19) | FSD | 19 mm | |
| Calculate tibial graft insertion<br>GL-(IAD+FGIa)<br>{50-(20+13)]=17 | TGI | 17 mm | |

5. Drill the femoral socket 6 mm deeper than the desired insertion of the graft to create a space to accommodate the turning radius of the fixation device.

**CAUTION**
Ensure the endoscopic cannulated reamer does not breach the femoral cortex. Otherwise the femoral fixation with fixation device will be compromised.

6. Pass the graft through the loop of the fixation device and then suture the tibial side.
7. Using a marker, place a line on the graft indicating the desired length of insertion, and another line 6 mm more distal to indicate the point at which the fixation device can be rotated.
8. Onbutton CL Fixation Device: The suture in the outside hole of the Onbutton CL Fixation Device acts as leading suture and passes the Onbutton CL Device/graft construct. The trailing suture in the opposite outside hole of the Onbutton CL Fixation Device rotates the Onbutton CL Fixation Device as it exits the anterolateral femoral cortex. Both sutures are passed through the eyelet of the graft passing pin (BAK-7037).
9. The graft passing pin is used for passage, piercing the quadriceps and skin proximally. The leading suture is pulled first, advancing the device/graft construct into the femoral tunnel. As the second distal marking line on the graft reaches the internal femoral aperture, the trailing suture is pulled, rotating the fixation device immediately external to the femur.
10. Tensioning the tibial side causes the graft to retreat 6 mm, locking it in place. X-ray or fluoroscopy will confirm the position of the fixation device on the anterolateral femoral cortex.

Refer to the BIOTEK ACL Reconstruction with the ONLoc Drill Guide and Onbutton CL Fixation System for more specific technique information.

**Sterility**
BIOTEK's **Onbutton CL fixation button with loop** 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**
Implants made from non-ferromagnetic materials i.e. Titanium Ti-6Al-4V (ISO 5832-3) OR Polyethene (ISO 5834-2) 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 | Caution |
| Sterilized Using Ethylene Oxide | CE 2265 European Conformity |
| Catalogue Number | Consult Instructions For Use |
| EC REP<br>CMC MEDICAL DEVICES & DRUGS S.L.<br>Address: C/ Horacio Lengo Nº 18,<br>CP 29006, Málaga, SPAIN<br>Ph: +34 951 214 054<br>info@cmcmedicaldevices.com<br>Authorized Representative in the European Community | LOT<br>Batch Code |
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| By Prescription Only | Do Not Resterilize |