MBlock

ADJUSTABLE BUTTON

Modification date: 02/11/2020
Ref: MGMBKUSNO, Version A

Rx ONLY Caution: Federal Law (USA) restricts this device to sale, distribution and use by or on the order of a physician

Do not re-sterilize

Do not re-use

Use by

Date of manufacture

REF Catalogue number

LOT Batch code

Caution, see instruction for use

STERILE R Sterilized using irradiation

Do not use if package is damaged

Manufacturer

DISTRIBUTED BY

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INSTRUCTIONS FOR USE

MBlock Adjustable Loop USA
MBlock BTB Adjustable Loop USA

Adjustable fixation system for ligament reconstruction

FOREWORD
The users acknowledge having read the present instructions for use and subscribe to its terms and conditions that are deemed legally binding.

COMPOSITION
Button-plate: Ti-6Al-4V ELI (in accordance with ASTM F-136)
Braided loop: 60% UHMWPE / 40% PET
Traction thread: Co-braid UHMWPE/ PP tracer strand
Flip thread: PET

DESCRIPTION
The device is proposed in the following variants:
- MBlock Adjustable Loop USA: comprises a titanium button-plate, and an adjustable nonabsorbable braided loop. The system is preloaded with traction and flip threads, and is designed to be used with a soft tissue graft.
- MBlock BTB Adjustable Loop USA: comprises a titanium button-plate, and an adjustable nonabsorbable braided loop. The system is preloaded with traction and flip threads, as well as a temporary splice suture, and is designed to be used with a bone-tendon-bone graft.
Standard models are used for cortical tunnels with a diameter of 4.5 mm; XL models are used for cortical tunnels with a diameter between 5 and 10 mm.
The implants are supplied sterile, individually packaged, ready to use.

INDICATIONS/ PERFORMANCE
The MBlock device is designed to be used as cortical fixation for ACL reconstruction.

CONTRAINDICATIONS
• Any known allergy or hypersensitivity to implant materials. When sensitivity to a material is suspected, appropriate tests must be done to check that no sensitivity is detected prior to implantation.
• Insufficient bone quantity or quality. Note: The efficacy of the MBlock implant is directly linked to the quality of the bone in which the implant is inserted.
• Insufficient blood supply and recent infections that could delay healing.
• Active infection.
• Conditions that limit the ability or willingness of the patient to slow down his/her activities or follow recommendations during the healing period.
• This medical device could be contraindicated for patients with insufficient bone density. Physicians must carefully evaluate bone quality before performing orthopedic surgery on patients who have not yet reached full skeletal maturity. The implant and fixation devices must not overlap, hinder or damage the growth plates.
• Do not use for surgeries other than those indicated.

COMPLICATIONS AND POSSIBLE SIDE-EFFECTS
• Postoperative pain
• Loss of extension
• Fluid in the tunnels
• Graft failure
• Knee instability or popping
• Tunnel enlargement
• Migration of fixation system and tissue interposition

SURGICAL PRECAUTIONS
The MBlock implant must be placed by a qualified surgeon as it requires extensive knowledge in anatomy, biomechanics, and musculoskeletal reconstruction. The surgeon must inform the patient of the need to temporarily limit his/her physical activities and of the precautions that must be taken following implant placement.

INSTRUCTIONS FOR USE
REFER TO THE SURGICAL PROCEDURE FOR MBlock IMPLANTS.

SINGLE USE
Any implant that might have been contaminated (through contact with a biological tissue) must not be re-treated and must be discarded. An explanted metal implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

MRI SAFETY
The MBlock device has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artefact in the MR environment. The safety of MBlock in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

RECOMMENDATIONS FOR DEVICES SUPPLIED STERILE
The MBlock implants have been Gamma-sterilized (dose 25 kGy). Check the sterility expiry date before use. SBM declines any responsibility regarding the use of products beyond their expiration date. We also recommend you check the integrity of the packaging. Sterility is valid only if the packaging shows no sign of deterioration.

PACKAGING
All the information required by law can be found on the box or label attached to the packaging. The integrity of the package must not be compromised.

STORAGE CONDITIONS
No special storage conditions are necessary.

GUARANTEE
The manufacturer's guarantee applies only when the device is used under normal conditions as defined in the present instructions for use.

REPORTING AN ADVERSE EVENT
Any authorized distributor or professional user dissatisfied with the service provided by SBM and/or the quality, labeling, reliability, safety, efficacy, and/or the performance of SBM products shall notify the SBM representative or distributor. The representative or distributor shall notify the SBM Quality Manager of said complaint without delay, by filling out an Adverse Event Report Form. The Adverse Event Report Form must at least include the following information: the product description, the catalogue number, the batch number, the nature of complaint or detailed description of the adverse event, and the consequences for the patient and/or the user. Any technical data that could contribute to future investigations (type of implant, X-rays, etc.) shall be appended to the form. The manufacturer must immediately be informed by telephone or fax of any adverse event related to a device malfunction or degradation, or an inadequacy in the instructions for use, having led to the deterioration in the health of a patient or user.

DISPOSAL
The device must be disposed of observing the precautions that apply to operating room waste, in accordance with applicable regulations.

SBM cannot be held liable for any incident resulting from failure to comply with the principles described in the present instructions for use.