For use by an Accredited Orthopaedic Surgeon only
IMPORTANT MEDICAL INFORMATION

1. ***Purpose:***

Knee Button are intended to provide the orthopedic surgeon a means of accurate suture fixation in reconstructive surgery. This system allows for endoscopic ligament reconstruction and also aid in surgical stabilization. These devices are meant to share load with the bone during the healing and regenerative phase. These devices are subjected to various mechanical forces while in use. The extent to which the device would withstand these forces is limited by the operating surgeon achieving a stable fixation construct, the use of bone graft to supplement the fixation where appropriate, the correct weight bearing regimen prescribed by the operating surgeon based on the progress of healing and the compliance of the patient.

2. ***Materials:***

The Material used for these devices are Titanium for the button which complies with the international standards in ISO 5832-3. UHMWPE Loop/ sutures complies with ASTM F2848.

3. ***Preparation:***

Before the operation, an operative plan must be drawn up by the operating surgeon, ensuring that –

- All implant components necessary are available in the required quantities
- Aseptic operating conditions are present.
- The required set of instruments is complete, operable and compatible.
- All pertinent documents related to the set of instruments and the implants being used are present and the surgeon and the operating team are, familiar with them.
- The operating surgeon is experienced in performing orthopedic reconstruction using this implant and in particular with the specific operative procedure being performed.

4. ***Indications:***

The Knee button is used fixation of bone-tendon-bone graft during orthopedic reconstruction procedure such as anterior cruciate ligament (ACL) reconstruction.

5. ***Contraindications:***

Contraindications include, but are not limited to the following:

- Acute or chronic infections in the vicinity of the joint or of a systemic nature
- Accompanying illnesses affecting the function of the joint implant
- Systemic illnesses and metabolic disturbances
- Severe osteoporosis or osteomalacia
- Severe damage to bony structures that stands in the way of stable implantation of the implant components
- Bone tumor in the area of implant anchoring
- Bony deformities, axial mal-positioning or bony conditions that rule out implantation of an artificial joint
- Obesity and overweight patients
- Expected overloading of the joint implant
- Drug abuse or alcoholism
- Lack of patient co-operation.

6. ***Possible Adverse Effects***

A listing of the possible adverse events, includes, but is not limited to the following:
Complications are seen with any method of internal fixation. Adverse reaction seen with suture include: wound dehiscence, calculi formation in urinary or biliary tract such as urine or bile occurs, infected wounds, minimal acute inflammatory tissue reaction and transitory local irritation

7. ***Warnings and Precautions:***

Pre-operative

Before surgery, the surgeon must plan the operation with a view to correct selection and sizing of the implant components and their positioning in the bone. The surgeon needs to ensure that:

- All necessary implant components are available

- Highly aseptic surgical conditions are present
- The implantation instrumentation is completely present and in good working order
- The implant is prepared and are handled with the appropriate ADLER instruments for the procedure being performed
- All informational material concerning the range of implants, instrumentation and surgical technique has been reviewed and is available and the surgeon and the surgical team are familiar with this information
- The rules of medical skill, the state of the art, and the contents of scholarly publications by medical authors are known and observed
- In uncertain preoperative situations, especially with implants already in place, prior relevant information should be obtained from the concerned manufacturer.
- Prior to use, inspect the device and ensure if it is not damaged.

Intra-operative:

- The Knee button is available with various sizes to suit the patient being treated. The various nominal sizes are explicitly marked on the packaging.
- Knee buttons has a specified technique and is clearly described in the product literature. Ensure that the technique is correctly followed.
- Hazards are associated with the reuse of the device which include patient infection or device malfunction.
- The use of metallic surgical implant provides the orthopedic surgeons with the means of accurate fixation and helps generally in the management of reconstructive surgery, these implants are intended to aid in normal healing, but are not indented to replace normal body structure or bear the weight of the body in the presence of incomplete bone/ muscle healing.
- Additional precautions include those applicable to arthroscopy. In general, careful attention must be paid to asepsis and avoidance of anatomical hazards.

Post-operative

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important:

- Detailed instructions must be given to the patient concerning the use and limitations of the implanted device. The patient must be warned that loosening, bending and/or breakage of the device are complications that may occur due to early or excessive weight bearing or muscular activity. The patient should be warned to avoid falls or sudden jolts of any nature.
- The patient must be made to understand that implants are always inferior to the function of the natural joint, and only a relative improvement of the preoperative condition can be achieved.
- The patient must be explained that implant can loosen due to overloading, wear and tear, or infection. Implant loosening can necessitate a revision operation that, under some circumstances, offers no opportunity to restore function again.
- The patient will have to submit to regular medical follow-ups.
- The patient must appreciate that the implant cannot be subjected to undue stress through extreme loading, work, and sporting activities.

8. ***SPECIAL NOTE TO USERS:***

- Implant components that have been implanted and removed must never be re-used even if they appear undamaged due to the high risk of fatigue failure due to internally accumulated material stresses.
- After use, this device maybe a potential biohazard and should be handled with accordance with accepted medical practice and applicable local and national requirements.

9. ***PACKAGING AND LABELING:***

Implant components supplied in pre-sterile condition are packed in double packaging kept inside suitable size of outer box. Sterilization is carried out using the gamma irradiation process indicated by STERILE R on the label or ETO Sterilization Process indicated by STERILE EO on the label with a suitable dose of sterilization cycle depending on the materials contained by the implant. Packaging must be carefully checked for perforation or other damage

prior to surgery. The set of instruments used for the surgery must be carefully checked for completeness and individual instruments must be inspected for functionality and absence of damage prior to surgery. The set of instruments used for the surgery must be carefully checked for completeness and individual instruments must be inspected for functionality and absence of damage prior to surgery. Implants supplied in unsterile condition are indicated by NON-STERILE or NON STERILE on the label which must be properly sterilized by suitable method prior to surgery. Metallic components may be re-sterilized using steam or ethylene oxide sterilization process. Re-sterilization of PE components is not permitted.

10. STERILISATION / RE-STERILIZATION:

Sterility and Handling:

- Correct handling of the implants prior to and during surgery is decisive for the success of surgical procedure. Implant components supplied in pre-sterile condition are individually packed in correspondingly labeled, radio sterilized (gamma sterilization, 25 kGy min.)/ ETO sterilized (Ethylene Oxide) protective packages.
- Prior to opening a sterile packed implant, verify that the package is undamaged and shows no signs of tampering, the “sterile” sticker that seals the outer box is intact, the sterility indicator button is of the right colour indicating a properly sterilized implant (red in case of Gamma Irradiation and Green in case of ETO sterilization) and that the implant is within the sterility period indicated on the label.
- Ensure that the surfaces of the implants are not damaged under any circumstances. Under no circumstances may implants that have been damaged, surgically implanted or removed again be reused.

RE-STERILIZATION:

- Re-sterilization of devices supplied in sterile form carries various risks. Various components of joint replacement prosthesis include UHMWPE parts that are known to carry a high risk of oxidative degradation if not packed and sterilized according to closely controlled and monitored conditions. Small imperfections caused on the surfaces of metallic joint replacement components are known to increase the risk of fatigue failure. Such imperfections could be caused by improper handling by untrained staff. In consideration of the above re-sterilization of joint replacement prosthesis components by user facilities is not recommended.

For non-metal components: If packaging appears to be damaged, non-metal components should not be re-sterilized and used.

For metal components only: Adler recommends that if the packaging appears to be damaged, metal components should not be re-sterilized and used. If the packaging appears to be damaged and metal components are to be used however, then the device must be cleaned and re-sterilized prior to implantation, according to the following Instructions:

Cleaning (metal components only):

If packaging of a metal component appears to be damaged and the metal component is to be used, the metal component should be cleaned prior to re-sterilization as follows:

- Use deionized, or distilled, warm (room temperature) water for soaking, cleaning and rinsing. Disassemble as appropriate. Soak soiled products for a minimum of 10 minute. For non-ceramic coated components: immerse and hand wash with a neutral pH or mild detergent. Scrub with a soft bristle brush paying close attention to threads and hard to reach areas. If product is cannulated, insert a soft nylon brush into cannula. Rinse all components immediately and thoroughly after washing. Immediately dry product. Inspect all products prior to sterilization and storage.

Recommended Steam Sterilization Cycle Parameters:

- Dynamic Air Removal (Prevacuum) Steam Cycle: 132°C (270°F) for 4 minutes or 135°C (275°F) for 3 minutes
- Gravity Displacement Steam Cycle: 132°C (270°F) for 30 Minutes and a minimum vacuum drying time of 30 minutes
- Flash Steam Cycle (Reusable Instruments only): Exposure temperature: 132°C (270°F) for 10 minutes in gravity displacement cycle or 4 minutes in a Dynamic Air Removal (Prevacuum) Cycle.

- United Kingdom Steam Cycle: 134°C for 3 minutes and a minimum vacuum drying time of 30 minutes. (Note: Sterilization evacuation and pulsing should be carried out in accordance with HTM 2010).

Containment devices should be wrapped with an approved central supply wrap (CSR) or placed in an approved reusable rigid container for sterilization. All sterilization wraps may not be approved for all cycle types. Check with manufacturer for approvals.

NOTE: This is not a recommendation as to the sterilization parameters to be followed. The adequacy of any sterilization procedure must be suitably tested. It is critical that appropriate process parameters be validated for each facility's Sterilization equipment and Product/load configuration by persons who have training and expertise in sterilization processes to substantiate the process and its reliability and reproducibility. Flash sterilization may be conducted, if applicable, according to the specific health care facility's policy.

11. ***STORAGE CONDITIONS:***

Store in dry place. Protect devices from exposure to direct sunlight, radioactive sources and rains. Do not stack devices.

12. ***IMPORTANT INFORMATION:***

The operative surgeon is responsible for carrying out the internal fixation procedure correctly and must have mastered the acknowledged updated and latest operating techniques related to the type of surgery being performed, in theory and practice. Complications due to incorrect diagnosis and operating technique and limitations of the method of treatment or lack of aseptic conditions are not the responsibility of the manufacturer.

In addition to physiotherapy and muscle training, it is the responsibility of the operating surgeon to educate the patient about the limitations of metallic implants and precautions to be followed to avoid unnecessary stresses to the implant.

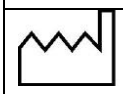
Detailed instructions must be given to the patient concerning the use and limitations of the implanted device. If partial weight bearing is required or recommended prior to bony union, the patient must be warned that loosening, bending and / or breakage of the device are complications which may occur due to early or excessive weight bearing or muscular activity. The patient should be warned to avoid falls or sudden jolts of any nature. If the patient is demented, debilitated or otherwise unable to use crutches or other supporting devices, the risk of loosening, bending and / or breakage may be increased. The patient must be made aware of this fact.

Any retrieved implant / External Fixator component should be treated in such a manner so as to render further use / re-use of the components, impossible. Used implants / External Fixator Component that appear undamaged may have internal and external defects caused through accumulated stresses while in use. Reuse of implant components or External Fixator Components predispose such components to premature failure.

Implant components from one manufacturer should not be used with those of another. In case such combinations are necessary, they would be possible only if the surgeon can ascertain that all implants being used are manufactured to correct dimensional specifications and tolerances and from chrome-nickel-molybdenum alloyed austenitic stainless-steel complying with or compatible to the relevant standards referred to above.

Manufacturing Traceability Records for the device are available for 15years after the manufacturing date mentioned on the label.

13. ***Symbols Used in IFUs, Labels and Packaging Materials***

Symbol	Definition	Symbol	Definition	Symbol	Definition
	Single use (Do not re-use)		Batch Number		Keep away from heat /sunlight and radioactive sources
	Date of Manufacture YYYY-MM		Manufactured by		Use by Date (Date of Expiry) YYYY-MM
	Caution: check for specific warnings or precautions		Do not re-sterilize		Do not use if package is opened or damaged
	Sterilized by ETO Gas Sterilization process		Consult instructions for use		Avoid moisture or water contact
	Recycle	REF:	Code Number / Part No.		To be sold only against prescription

14. ***Further information:***

For further information concerning use of these devices, please check with Adler Customer Service at the address given herein or e-mail to **adler-customer.care@adler-healthcare.com**.