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Manufactured by:
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FAIRFIX ADJUSTABLE BUTTON

CAUTION

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

SYMBOLS

	Do not reuse
	Do not resterilize
	Caution, read the accompanying documents
	Consult instructions for use
	Do not expose to sunlight
	Store in a dry place
	Do not use if package is damaged
	Use by
	Lot number
	Reference number
	Sterilized with ethylene oxide
	Sterilized by irradiation
	Manufacturer
	RX Only
	MR Conditional
	Double sterile barrier system

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ENGLISH: FAIRFIX - INSTRUCTIONS FOR USE

Important notice: the device(s) can be prescribed and implanted only by a doctor legally authorized to perform this type of surgery.

1. GENERAL

Before any surgery, the surgeon must be familiar with the sales product literature and operative technique and must carefully read these instructions for use. Patient selection is as important as implant placement or positioning. Overweight patients or unsuitable functional requirements may generate exceptional stresses and reduce the implant life. The warnings must be heeded, and the instructions for use must be strictly followed.

2. PRODUCT DESCRIPTION

FairFix – Adjustable Button

Implantable device indicated for knee ligament (i.e. ACL, PCL) reconstructive surgery for the fixation of tendons and ligaments by means of a suspensory fixation with an adjustable suture loop. The device consists of a titanium implant with a pre-assembled, non-absorbable adjustable suture loop. The implant is preloaded with a pulling suture (blue) to pull the construct through the bone tunnel and a flipping suture (white) to flip the button once the extracortical side has been reached.

FairFix Extender

Implantable device used during knee ligament (i.e. ACL, PCL) reconstruction surgery for the fixation of a sutured graft with an extracortical suspensory fixation. It has to be used in association with the FairFix Adjustable Button. It is used for large tunnel conditions (e.g. cortical blowout, revision cases, full tunnel). It consists of an elongated metal plate with a recess to house the FairFix Adjustable Button and a lateral slot to allow suture passage.

REF NO.	DESCRIPTION	IMAGE
05.05.0091	FairFix – Adjustable Button	
05.05.0092	FairFix Extender	

Material Specifications

Adjustable Loop: Ultra High Molecular Weight Polyethylene and Polyester.
Flipping and Pulling sutures: UHMWPE
FairFix Adjustable Button and FairFix Extender: Ti6Al4V ELI (ISO 5832/3)
Suture colorants: additive D&C Blue No. 6, 21CFR §74.3106

3. INTENDED USE / INDICATIONS

FairFix Adjustable Button is intended to be used during a knee ligament (i.e. anterior cruciate ligament and posterior cruciate ligament) reconstruction surgery when a Ø4.5mm tunnel is realized.

FairFix Extender is intended to be used in association with FairFix Adjustable Button during a knee ligament (i.e. anterior cruciate ligament and posterior cruciate ligament) reconstruction surgery with a Ø 6 – 11 mm tunnel.

4. CONTRAINDICATIONS

- Active infection
- Blood supply limitations and previous infections which may tend to retard healing
- Known hypersensitivity to the implant material
- Insufficient quantity or quality of bone
- Conditions which tend to limit the patient's ability of willingness to restrict activities or follow directions during the healing period
- Sensitivity to implant materials

5. WARNINGS AND PRECAUTIONS

The success of the operation depends on compliance with the operative technique supplied, and the proper use of the dedicated instruments specially designed for that range of implants. Malpositioning may reduce implant longevity and lead to early implant failure.

MRI Compatibility

FairFix Adjustable Button if used without FairFix Button Extender

Non-clinical testing has demonstrated FairFix Adjustable Button when used without FairFix Button Extender is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla
- Maximum spatial field gradient of 3,000 G/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, FairFix Adjustable Button if used without FairFix Button Extender is expected to produce a maximum temperature rise of less than 3.0°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 20.5 mm from FairFix Adjustable Button if used without FairFix Button Extender when imaged with a gradient echo pulse sequence and a 3 Tesla MR system.

FairFix Adjustable Button if used with FairFix Button Extender

The Medacta Adjustable Button used with FairFix Button Extender has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Medacta Adjustable Button used with FairFix Button Extender in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Medacta International implants

Medacta® International is not responsible for the use of its implant components in combination with a component from another manufacturer (unless otherwise specified by Medacta® International in the surgical technique), therefore we advise against such a use. The components of FairFix Adjustable Button should never be reimplanted. While an implant may appear undamaged, microscopic imperfections may occur and cause implant failure. The operating surgeon must be aware that even a very small superficial damage, caused for instance by a sharp tool or electrocautering, can have an influence on the endurance of the device and can lead to fracture.

6. RISK FACTORS

The following risk factors, individually or together, may result in poor clinical outcomes:

- Inadequate bone quality (e.g., osteoporosis, previous cruciate ligament operation)
- Systemic diseases or metabolic disorders
- History of infections or recurrent falls
- Drug dependence and abuse of alcohol and medicaments
- Mental incapacity of patient to understand the instructions of the physician and to comply with them
- Local bone tumors

7. INSTRUCTIONS FOR USE

Preoperative Phase

The surgeon should verify possible patient physical limitations and mental deficiencies and should also discuss with the patient all the details of the procedure and implant. The discussion should consider the limitations of the procedure and the constraints imposed by the selected implant. The factors which could limit the performance and stability of the implant, e.g. level of activity, should be set out to improve the patient's chances to avoid complications. The necessity to follow the postoperative instructions given by the surgeon should be fully understood by the patient. A stock of sterile implants of suitable sizes must be available and checked by the operator before surgery.

8. HANDLING

To avoid scratching or damaging the implants, these should be handled with the utmost care by qualified personnel and in an environment where conditions of hygiene are controlled. The implants should be kept in their undamaged packages.

9. SURGICAL TECHNIQUE

The surgeon should be fully familiar with the dedicated surgical technique. Supplementary information about the surgical techniques (brochure and video) and products are available on request. Careful preoperative planning, documented by X-rays, is essential.

10. POSTOPERATIVE CARE AND FOLLOW-UP

The surgeon should caution the patients to control their level of activity and avoid excessive loads on the operated limb. Moreover, the surgeon should make the patients aware of the precautions to be taken in terms of exercises, treatments and limitations on activities, any limitations reported on the label, as well as exposure to magnetic fields. The patient must be told that implants can affect the results of computer tomography (CT) or magnetic resonance imaging (MRI) scans and that MRI may result in patient injuries (please see also §5). Periodic follow-up and X-rays are recommended to make comparisons with the immediate postoperative condition and anticipate implant related complications. Excessive physical activity, and operated limb traumas may cause early failure of the implant. If the case occurs, it is necessary to place the patient under supervision, evaluate the possible progression of the deterioration, and weigh the benefit of early revision.

11. ADVERSE EVENTS AND COMPLICATIONS

Adverse events that can occur in reconstructive treatment of ligament ruptures include:

- Infection, both deep and superficial
- Allergies, mild inflammatory and foreign body reactions to implant material

Some adverse effects can ultimately lead to death.

General complications include:
- Venous thrombosis with/without pulmonary embolism
- Cardiovascular or pulmonary disturbances
- Hematomas
- Systemic allergic reactions
- Systemic pain

12. PACKAGING

The components of FairFix Adjustable Button are supplied in single-use packages, the sterilization method is indicated on the label. The expiration date must be checked on the label as well as the package integrity to ensure that sterility of the contents has not been compromised. If the package is damaged or has been previously opened, do not use the component. Do not resterilize.

13. INSTRUMENTS

Instruments are supplied non-sterile and must be cleaned and sterilized prior to use. Recommended cleaning, decontamination and sterilization instructions are provided at www.medacta.com

14. STORAGE

The packages must be stored in a cool, dry place, away from light.

15. TRADEMARKS

Medacta® is a registered trademark of Medacta International SA, Castel San Pietro, Switzerland.

The reference text is the English text

This document is intended for the US market.

Distributed by Medacta USA, Inc. 3973 Delp Street, Memphis, TN 38118 (800) 901-7836

Last update: October 2020