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EN

Instructions for Use
Ligament Reconstruction System

CE 2292

Ligament Reconstruction System consists of Loop Button System, Non-absorbable Surgical Suture System, and PEEK Interference Screw. Loop Button System products is composed of titanium plate, loop and passing suture. Non-absorbable Surgical Suture contains loop suture and suture tape, with or without needle to meet various clinical demands. PEEK Interference Screw can be with or without outer sheath. The device provides the fixation of bone-to-bone or soft-tissue-to-bone via Loop button plates, non-absorbable surgical sutures, and/or interference screws It acts as a temporary internal stent to provide a stable local environment for the avulsion of the ligament, create conditions for healing. As the tissue gradually grows in, it is to provide sufficient biomechanical fixation to restore the stability of the joint.

I.Material
The device is made of Ti6Al4V, PEEK stainless steel and UHMWPE.

II.Intended Use
Ligament Reconstruction System is intended for bone-to-bone or soft tissue-to-bone fixation in orthopedic reconstruction.

III.Indication
Ligament Reconstruction System is suitable for fixation of bone-to-bone or soft tissue-to-bone in orthopedic reconstruction.
AC Loop Button: Acromioclavicular joint ligament;
CF Loop Button, Loop, G-Max Interference Screw, G-Max Pro Sheath and Screw, Tapered Interference Screw, sparse thread: Anterior cruciate ligament, Posterior cruciate ligament, Medial collateral ligament, Lateral collateral ligament;
Knotless Syndesmosis CFLoop Button: ankle ligament;
Mini CFLoop Adjustable Button: hand, foot;
Non-absorbable Surgical Suture is used in the above mentioned ligament reconstruction process.

IV. Contraindications
1. Known hypersensitivity to the implant material. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
2. Except those listed in the indications section.
3. Blood supply and previous infections which may tend to retard healing.
4. Active infection
5. Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.

V.Intended user
Intended Users shall be qualified medical personnel who have received professional training on surgical operation and relevant device information.

VI.Patient group
Patients who are meeting the surgical indications and not meeting any of the contraindications, and who are mental normally and can tolerate surgery. Products are mainly used for adults. Other population need to be evaluated by a surgeon according to the specific situation.

VII.Clinical benefits
It provides a stable local environment for soft tissue avulsion, creates conditions for healing, and provides sufficient mechanical fixation to restore joint stability.

VIII. Potential Adverse Events
1. Infections, both deep and superficial
2. Foreign body reactions
3. Redislocation resulting from a failure of the implant insertion technique
4. Osteomyelitis surrounding the loop
5. Joint stiffness
6. Neuropraxia.

IX. Warnings and Precautions
Warnings:
1.Do not use if package is damaged. Do not use if the product sterilization barrier or its packaging is compromised.
2.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.
3.It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.
4.Read these instructions completely prior to use.
5.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.
6.MRI Information: Button Plate System has not been evaluated for safety, heating, migration, or compatibility in the magnetic resonance environment.
Precautions:
1.Hazards associated with reuse of this device include, but are not limited to, patient infection and/or device malfunction.
2.Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device.
3.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.
4.Ensure the endoscopic cannulated drill bit does not breach the cortex, otherwise the fixation with the fixation device will be compromised.
5.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.
6.Careful attention must be paid to asepsis and avoidance of anatomical hazards.

X. Sterilization
The products are provided as sterile. The interference screws are sterilized with γray and others are sterilized with ethylene oxide. The validity period is 5 years.

XI. Labels

REF	Catalogue number		Manufacturer
	Date of Manufacture		Use -by date
LOT	Batch code		Do not re-use
STERILE R	Radiation Sterilization		Do not use if package is damaged
EU REP	Authorized Representative in the European Community		Caution
	Keep away from sunlight		Keep dry

	Consult instructions for use		Importer
	Medical device		Double sterile barrier system
	Humidity limitation		Temperature limit
	Ethylene Oxide Sterilization		

XII. Storage
The sterilized product should be stored in a clean environment, protected from direct sunlight and pests.
The storage temperature range of the product is 0-35 ℃ and relative humidity is under 80%.

XIII. Transportation
Avoid collision and compression during storage and transportation.

XIV.Use of Original Products
Implants and instruments are designed to be used together. The use of products from other manufacturers along with Double Medical products can involve incalculable risks, injury or corrosion of the material and misalignment of implant and instruments, impeding functionality, thereby endangering the patient, user or third parties.

XV. Handling Information
The materials used in the ligament reconstruction system are widely used in orthopedic medical applications. They are biocompatible, corrosion resistant and non-toxic in the biological environment, and can be ignored by X-ray and CT.

XVI. Surgical Technique
1.Surgical Approach
(1) Use a special locator to locate the bone tunnel drilling position, so as to establish the correct bone tunnel.
(2) Use the matching drill bit to drill the bone tunnel.
(3) Remove the drill bit and locator, and use the guide wire to pull a looped button plate through the bone tunnel and fix it.
(4) Slide another button plate into the opposite side of the cortical bone.
(5) Pull sutures until a satisfactory reduction is achieved, and the remaining sutures can then be cut off.
(6) When using interference screws, use specialized instruments to insert the interference screw into bone channel and compress the soft tissue graft for fixation.
2.Removal of Device
According to the patient's postoperative recovery effect, if adverse reactions occur, the soft tissue graft and loop button plate are removed under arthroscopy or the second operation is performed after adequate evaluation.
3.Disposal of Device
Retrieved devices are medical waste and should be handled and disposed of according to local regulations
4.More detailed operation instructions and selection of supporting instruments could be found in the Operation Manual.

XVII.Manufacturer/ Contact Information

Manufacturer:	Double Medical Technology Inc.
Legal Address:	No. 18, Shanbianhong East Road, Haicang District, 361026, Xiamen, Fujian, PEOPLE'S REPUBLIC OF CHINA
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SSCP(Summary of safety and clinical performance)	Eudamed(https://ec.europa.eu/tools/eudamed/#/screen/home) Document No.:DM-CE-P03-09

Note: If any serious incident that has occurred in relation to the device, please report to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Notified Body: UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş.

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EU REP

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