EN

Instructions for Use
Suture Anchor System

CE 2292

Suture Anchor System is composed of an anchor, a suture (with or without suture needles), and an inserter, which fixes the anchor in the bone, and passes through the soft tissues such as tendons and ligaments through its own suture to fix it on the attachment point of the anchor, that is, the bone surface, so that the soft tissue and bone can be reconnected to provide anatomical reduction. The anchor system includes Ti suture anchors, PEEK suture anchors, all- suture anchors, and non-absorbable surgical sutures.

I.Material
This product is made of titanium alloy,PEEK , stainless steel and UHMWPE.

II.Intended Purpose
Suture Anchor System is intended for connection and fixation of bone and soft tissue.

III.Indication
Shoulder: Bankart repair, SLAP repair, acromioclavicular separation repair, rotator cuff tear repair, capsule transfer or labrum reconstruction, biceps tenodesis, deltoid repair.
Elbow: Biceps tendon reduction, tennis elbow repair, ulnar or radial collateral ligament reconstruction.
Wrist: Scapholunate ligament reconstruction,ulnar or radial collatera ligament reconstruction, finger tendon transfer, and finger joint tendon repair.
Hip: joint capsule repair, acetabular labrum repair.
Knees: anterior cruciate ligament repair, medial collateral ligament repair, lateral collateral ligament repair, patellar tendon repair, posterior oblique ligament repair, and iliotibial band tenodesis.
Foot and ankle: repair/reconstruction of medial or lateral instability, hallux valgus reconstruction, midfoot reconstruction, metatarsal ligament/tendon repair/reconstruction, Achilles tendon repair/reconstruction.

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.Surgical procedures other than those listed in the indications section.
3.Pathological conditions of bone, such as cystic changes or severe osteopenia, which would compromise secure anchor fixation.
4.Pathological conditions in the soft tissue to be attached that would impair secure fixation by suture.
5.Comminuted bone surface, which would compromise secure anchor fixation.
6.Physical conditions which would eliminate, or tend to eliminate adequate implant support or retard healing, i.e., blood supply limitations, active or previous infections, etc.
7.The use of this device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients who are skeletally immature. The use of this device and the placement of implants must not bridge, disturb, or disrupt the growth plate.
8.Conditions such as senility, mental illness, or alcoholism, which may impact the patient's ability or willingness to restrict activities or comply with physician instructions 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 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
Suture Anchor System is used to connect and fix bones and soft tissues to achieve soft tissue suture repair, with an expected healing rate of no less than 96.6%.

VIII. Potential Adverse Events
1.Mild inflammatory reaction
2.Foreign body reaction
3.Infection, both deep and superficial
4.Allergic reaction
5.Suture fracture
6.Anchor looseness
7.Re-tear
8.Non-union

IX. Warnings and Precautions
Warnings:
1.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.
2.It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.
3.Read these instructions carefully and completely prior to use.
4.Pre-operative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the device, are important considerations in the successful utilization of this device. The appropriate Double Medical delivery system is required for proper implantation of the device.
5.Patient should be advised that product materials may cause allergic reactions including but not limited to, foreign body reaction, tissue irritation/inflammation or other allergic reactions. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
6.Product must be stored in the original sealed bag.
7.Incomplete anchor insertion may result in poor anchor performance.
8.Breakage of the suture anchors can occur if insertion sites are not prepared with appropriate instrumentation prior to implantation.
9.Do not attempt to implant this device within cartilage epiphyseal growth plates or non-osseous tissue.
10.Prior to use, inspect the drill bit to ensure it is not damage. Do not use a damaged drill bit.
11.Ensure the anchors are properly seated on driver tips prior to and during implantation.
12.Avoid excessive impaction during anchor insertion as this could lead to inserter damage and/or breakage. If insertion resistance is encountered, do not impact harder. Replace the implant and repeat the drilling/insertion process.
13.Do not bend, apply excessive torque, or twist the inserter handle during and after insertion as damage to the implant or incomplete insertion may result. Do not deploy a bent or damaged implant.
14.Do not insert an implant into a bone hole where an existing implant is present. This may cause the previously placed implant to extrude out of the bone.
15.Ti Suture Anchor only: All metallic implant devices used for this surgical procedure should have the same metallurgical composition.
16.Merit MWT Ti Suture Anchor only: Alter insertion, pause momentarily to allow the titanium alloy wire component to regain its preformed are shape. Nominal tension should then be applied on the suture lengths to set the anchor. Do not use excessive tension or overload the anchor. This could lead to device pull-out or suture breakage.
17.All-Suture anchor only:

- Do not attempt to drill an anchor out of the bone hole. Should a placed anchor need to be abandoned, trim the suture ends flush with the bone to avoid potential tissue irritation.
- Avoid lateral loading while inserting All-Suture Anchors.
- Maintain proper alignment during insertion of anchors and disengagement of drivers.
- Do not use the inserter to probe the tissue or bone as damage may occur to the device resulting in potential patient injury.

18.Do not resterilize or reuse anchors, sutures, and screw drivers.
19.After use, this device may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.
20.Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Device removal should be followed by adequate postoperative management.
21.Suture Anchor System has been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.
Precautions:
1.Prior to use, check the package to ensure it is not damaged or tampered. Do not use the device if the package is damaged.

2.Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device.
3.Do not use sharp instruments to manage or control the suture. Avoid crushing or crimping damage to the suture from the use of surgical instruments such as forceps or needle holders.
4.If the bone is hard, a pre-drilled hole is required at the insertion site to reduce the potential risk of torsion. Pre-drilling with a suitable drill bit is the preferred method for site preparation. Drilling in very hard bone may require cycling the drill while maintaining consistent alignment of the drill guide.
5.Ensure that the anchor is aligned with the drill hole. Proper alignment is one of the necessary conditions for a successful restoration.
6.Use of excessive force during insertion can cause failure of the suture anchor or driver device. A two-finger AO technique should be used to insert the anchor.
7.As in all suture anchor or suturing techniques, until biological attachment of tissue to bone is complete, the fixation should be considered temporary and may not withstand weight bearing or other unsupported stresses. The suture is not intended to provide indefinite biomechanical integrity. The fixation provided by this device should be protected. The postoperative regimen prescribed by the physician should be strictly followed to avoid adverse stresses applied to the device.
8.Do not implant the anchor in poor quality bone or where bone quantity is limited. Bone quality must be adequate to allow proper placement of suture anchor. Incomplete insertion or poor bone quality may result in implant pullout or suture breakage.
9.Do not alter implant or instrumentation or performance may be compromised.
10.Detailed instructions on the use and limitations of the device should be given to the patient. The patient should be told to follow the surgeon's protocol for postoperative management..
11.To avoid damaging needle points and swage area, grasp the needles in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping may cause needles to lose strength and become less resistant to bending and breaking. Use caution when handling needles to avoid inadvertent needle sticks. Discard used needles according to an approved hospital procedure.
12.Surgeons must apply their professional judgment when determining the appropriate suture- anchor type and size based on the specific indication, preferred surgical technique, and patient history.
13.TowerLock/HelicalLock Suture Anchor only:

- Insert the driver into the bone socket until the anchor body makes contact with the bone. Preview and adjust suture tension, if necessary. Tension will not increase during final advancement of the anchor body.
- Ensure that the anchor body is in full contact with the bone before advancing the anchor body into the prepared bone socket.

14.Under insertion of the device may leave the proximal end of the implant protruding beyond the cortical bone, which could potentially cause soft tissue irritation and/or pain post-operatively.
15.When implanting the Suture Anchor, it is necessary to use the appropriate matching instrumentation of Double Medical to prepare the insertion site. If the specification and model of the Suture Anchor do not match the instrumentation, it will result in the failure to complete the surgery, poor fixation performance or Suture Anchor breakage.

X. Sterilization

The product is provided as sterile. It is sterilized with ethylene oxide, and 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 EO	Sterilized using ethylene oxide		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
MD	Medical device		Double sterile barrier system
	Humidity limitation		Temperature limit

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 Suture Anchor 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.Using the appropriate drill bit and drill guide, prepare the anchor insertion site. Either predrilling or use of a punch-type device is recommended for site preparation, depending on the bone quality. Predrilling is recommended if the quality of the bone is unknown.
2.Using routine sterile technique, remove the preloaded suture anchor with attached inserter device from the packaging.
3.Establish axial alignment of suture anchors and drilling holes. While stabilizing the insertion site, using the two-finger AO technique, the anchor was placed at the bottom of the bone tunnel by rotating the anchor clockwise with the inserter or by tapping the inserter, and the nail body was fixed in the bone tunnel.
4.Disengage the suture anchor from the inserter.
5.Discard the inserter.
6.The suture and soft tissue were sutured and knotted to complete the reconnection and fixation of soft tissue and bone
7.More detailed operation instructions and selection of supporting instruments could be found in the 《Operation Manual》.If necessary, please download the Operation Manual from the website: www.double-medical.com.

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
Telephone Number:	+86 592 6087101
SSCP(Summary of safety and clinical performance)	Eudamed(https://ec.europa.eu/tools/eudamed/#/screen/home) Document No.:DM-CE-P01-09
e-IFU	https://www.doublemedicalgp.com

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.
Address： Mutlukent Mahallesi 2073 Sokak No:10 Umitkoy-CANKAYA
Ankara

EU REP **Shanghai International Holding Corp. GmbH(Europe)**
Eiffestrasse 80, 20537 Hamburg, Germany

Revision Date: 2026.04.27