Protocol No.: CEA2020-26SM

A Prospective Multi-Center, Randomized Controlled Pre-Market Clinical Trial to Evaluate the Safety and Efficacy of JuggerStitch™ Meniscal Repair Device on Arthroscopic Meniscal Repair

Investigational Medical Device: JuggerStitch™ Meniscal Repair Device

Specifications for Intended Use: See Appendix 7

Protocol Version No. and Date: V1.2, 25 February 2022

Lead Clinical Trial Institution / Principal Investigator: Huashan Hospital Affiliated to Fudan University / Prof. Shiyi Chen Prof. Hongyun Li

Clinical Trial Institutions/Investigators: See "List of Clinical Trial Institutions and Investigators"

Sponsor: Zimmer (Shanghai) Medical International Trading Co., Ltd

Contract Research Organization (CRO): EBTM (Beijing) Co., Ltd.

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List of Abbreviations

Abbreviation	English Full Name
AE	Adverse Event
FAS	Full Analysis Set
GCP	Good Clinical Practice
ICRS	International Cartilage Repair Society
IKDC	International Knee Documentation Committee
MRI	Magnetic Resonance Imaging
PEEK	Polyetheretherketone
PET	Polyethylene Terephthalate
PPS	Per-Protocol Set
SAE	Serious Adverse Event
SS	Safety Set
UHMWPE	Ultra-High Molecular Weight Polyethylene
VAS	Visual Analogue Scale

Protocol Synopsis

Clinical Trial Title	A Prospective Multi-Center, Randomized Controlled Pre-Market Clinical Trial to Evaluate the Safety and Efficacy of JuggerStitch™ Meniscal Repair Device on Arthroscopic Meniscal Repair
Protocol Number	CEA2020-26SM
Investigational Device	JuggerStitch™ Meniscal Repair Device (Herein after referred to as JuggerStitch™)
Phase of Clinical Trial	Pre-market
Clinical Trial Design	Prospective, multi-Center, randomized controlled pre-market clinical trial
Control Device	Fast-Fix 360 Meniscal Repair System (Herein after referred to as Fast-Fix 360)
Number of Clinical Trial Institutions	5 clinical sites
Sample Size	94 subjects, 47 cases in investigational group and 47 cases in control group
Indications	Repair of Meniscal Tears
Primary Objective of the Clinical Trial	To evaluate the clinical safety and efficacy of the JuggerStitch™ Meniscal Repair Device on arthroscopic meniscal repair by comparing with Fast-Fix 360 Meniscal Repair System.
Primary Endpoint	Lysholm Knee Score at postoperative 6 months
Secondary Endpoints	(1) Immediate device success rate postoperatively; (2) Lysholm Knee Score at postoperative 3 months and 12 months; (3) Tegner Activity Score at postoperative 3 months, 6 months and 12 months; (4) Visual analogue scale (VAS) score for pain at postoperative 3 months, 6 months and 12 months; (5) Meniscus healing evaluated by Magnetic Resonance Imaging (MRI) scans at postoperative 6 months and 12 months; (6) Device-related adverse event rate.
Inclusion Criteria	(1) 18~60 years old (18 and 60 inclusive); (2) Patient who are scheduled for meniscal repair with a vertical longitudinal full-thickness tears (e.g. bucket-handle) in the red-red and red-white zones; (3) Patients who can understand all risks and benefits described in the informed consent form (ICF), and are willing to comply with the guidance for rehabilitation, and the follow-up visits specified in the clinical trial protocol, and voluntarily participate in the trial and sign the ICF;
Exclusion Criteria	(1) Patient has meniscal tears in the avascular zone of meniscus; (2) Meniscal tears not suitable for repair because of the degree of damage (marked irregularity and complex tearing) to the meniscus body including degenerative, radial, horizontal cleavage, flap and root tears; (3) Patient with multiple ligament injuries of the affected knee joint; (4) Patient with adhesion of the affected knee joint; (5) Patient is planned to accept intraoperative or postoperative intra - articular injection;

	(6) Articular surface cartilage injury of the targeted knee assessed by the International Cartilage Repair Society (ICRs) is grade 3-4; (7) Kellgren-Lawrence grades of documented radiographic evidence of Osteoarthritis (OA) in the affected knee is ≥III. (8) Instability or valgus/varus deformity(＞5°) of the affected knee; (9) Patient has acute or chronic, local or systemic infections; (10) Patient with metabolic diseases; (11) Abnormal liver and kidney function (creatinine 3 times higher than the upper limit of normal value or alanine aminotransferase or aspartate aminotransferase 3 times higher than the upper limit of normal value) before operation; (12) History of operation in the affected knee; (13) Acute myocardial infarction or stroke occurred within 6 months before operation; (14) Patients are known allergy to any material (polyethylene, polypropylene, polyester, polyetheretherketone) of the implants; (15) Patient is pregnant or known to be pregnant; (16) Other circumstances that the researchers believe that may affect the efficacy and safety evaluation of the investigated medical devices; (17) Patients are currently participating in other clinical trials.
Clinical Trial Procedure	**1. Process of Informed Consent** Patients will be subjected to the informed consent process performed by the investigators, and those who agree to participate in this clinical trial will sign an ICF. **2. Subject Screening (-14 DAY~0 DAY)** **The following data will be collected and assessed during the period of subject screening:** (1) Collect demographics/history: gender, date of birth, height, weight, history of knee joint related diseases, and injury location; (2) Assessment of vital signs: including pulse and blood pressure. (3) Specialized Physical Examinations used for the diagnosis of knee meniscus injury, including joint line tenderness, knee motion, and stability assessment including Anterior Drawer Test, Lachamn test, Lever Sign, Bohler Sign; (4) Laboratory tests: including blood routine, blood biochemistry (liver function, kidney function, and blood glucose level), blood/urine HCG test. (5) X-ray assessment including anteroposterior and lateral views of plain radiographs and full-length weight-bearing radiographs of the lower extremity for using to evaluate fracture, degenerative changes of the knee and episome; (6) MRI assessment on the affected knee to determine the type and extent of meniscus injury;

(7) Record pre-operative Lysholm Knee Score, Tegner Activity Score and VAS of the index knee joint.

3. Arthroscopy Exploration and Surgery

(1) Anesthesia and position: After the subject is under epidural, lumbar or general anesthesia, take a supine position according to the investigator's habitual surgical operation procedures, and take on a routine tourniquet to the roof of the index knee joint.
(2) Surgical incision: Operate according to the standard operating procedure of arthroscopic surgery, and choose the subpatellar and medial lateral approach to the knee joint.
(3) Exploration: Explore from the suprapatellar bursa, patellofemoral joint, medial compartment, medial malleolus fossa, lateral compartment, posterior medial compartment to posterior lateral compartment, conduct preoperative physical examination and MRI to assess the location of the meniscus tear and determine the repairability of the injury.
(4) Check inclusion and exclusion criteria, and randomization: Investigator to check if patient is qualified based on arthroscopy exploration result. For the patients who meet all inclusion criteria but none of the exclusion criteria, log in to the central random system to obtain the subject screening code; Patients randomized to the investigational group will be planned to perform surgery using JuggerStitch™, and patients randomized to the control group will be planned to use Fast-Fix 360 (Control Product); Subjects who do not meet the inclusion criteria or meet any of the exclusion criteria will be considered as a screening failure.
(5) Surgical procedures: during the treatment of meniscus injury, for the combined articular loose body, the loose body should be removed and clean the joint. According to the injury location of meniscus, the probe will be used to determine and select the appropriate meniscal repair system.
(6) Record the details of medical devices used (model, lot number and quantity, performance evaluation), the treatment of combined injuries;
(7) Record concomitant medications during the surgery (painkillers and anesthetics by the anesthesiologist excluded);
(8) Record the device deficiency;
(9) Monitor and record adverse events during operation and at postoperative.

4. Postoperative rehabilitation and follow-up visits

(1) Postoperative treatment: subjects are recommended to use the elastic bandage round limb, appropriate massage to prevent blood clots. After being awake anesthesia, nurse will provide guidance on quadriceps isometric contraction and the straight leg-raising training. See Appendix 9 Postoperative Rehabilitation Guidance.
(2) Subjects will be followed up in clinical visits at postoperative 3 months, 6 months and 12 months, and Lysholm Knee Score, Tegner Activity

	Score, and VAS will be obtained at each follow-up visit to assess the recovery of knee joint. (3) MRI of the knee joint will be performed at postoperative 6 months and 12 months to evaluate the recovery of meniscus. (4) Monitor and record clinical adverse events during each follow-up period for data evaluation and analysis. (5) Record the use of analgesic drugs at discharge and during each follow-up period (name of drug, start/discontinuation date, and daily dose). **5. MRI Central Laboratory** This study will establish an independent MRI imaging central laboratory, which will be responsible for instructing each sub-center how to collect and transmit MRI image data, and evaluate the MRI results of all subjects at postoperative 6 and 12 months continuously and independently.
Follow-up Visits for the Clinical Trial	**Follow-up window:** (1) 3 months postoperatively ± 15 days: clinical visit (2) 6 months postoperatively ±30 days: clinical visit (3) 12 months postoperatively ±30 days: clinical visit
Clinical Trial Schedule	Duration of subject recruitment: 6 months Duration of subject follow up: 12 months

1. Information of Sponsor

Name: Zimmer (Shanghai) Medical International Trading Co., Ltd

Address: Floor 19/21, Changfang International Plaza, No. 555 Loushanguan Road, Changning District, Shanghai

Contact: 021-22206116

Qualifications: Enterprise business license

2. Information of Contract Research Organization (CRO)

Name: EBTM (Beijing) Co., Ltd.

Address: Bldg 4-2301, No.89, JianGuo Rd, Chaoyang District, Beijing, China

Contact: 010-85888779

Qualifications: Enterprise business license

3. List of Clinical Trial Institutions and Investigators

Number of the Clinical Trial Institution	Name of the Clinical Trial Institution	Principal Investigator	Contact Information
01	Huashan Hospital Affiliated to Fudan University	Pro. Shiyi Chen Prof. Hongyun Li	021-52889999
02	Hunan Provincial People's Hospital	Pro. Jing Wang	021-58752345
03	The First Affiliated Hospital of Jinan University (Guangzhou Overseas Chinese Hospital)	Pro. Xiaofei Zheng	0731-83929035
04	The First Affiliated Hospital of Nanchang University	Pro. Zhizeng Gao	020-38688888
05	Wuhan Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology	Pro. Fengjin Guo	022-60911000

4. Objective and Content of the Clinical Trial

4.1 General background on the diagnosis and treatment of meniscus tears

The objective of this clinical study is to evaluate the clinical safety and efficacy of the JuggerStitch™ meniscal repair device on arthroscopic meniscal repair by comparing with Fast-Fix 360 Meniscal Repair System.

Meniscus is an important part of the knee joint and plays a key role to support its physiological function. Meniscus of knee joint is a cartilage structure, comprised of both sides, including the lateral meniscus shows the shape in O-ring, cover the lateral tibial plateau of 80% ~ 85%, and the medial meniscus is in C shape covering the 60% ~ 65% of the medial tibia platform [1].The meniscus increases the depth of the articular surfaces, compensates for mismatches between articular surfaces, and its ring-parallel peripherals provide important meniscal biological functions, including increase contact area of the joint and disperse the load of the articular cartilage when the knee joint is in bearing, so as to reduce the contact stress, absorb the impact force, enhance the dynamic stability of the joint and provide proprioception. In addition, in the process of flexion and extension of the joint, the meniscus can allow the conversion of forces in different directions [2]. Normal meniscus is a fibrous cartilage structure composed of collagen (90% ~ 95% type I collagen), fibrocartilage, proteoglycan, elastin and water. Cells in all areas of the meniscus have similar healing potential, while the repair ability of different damaged areas of the meniscus is mainly determined by its blood supply. Blood comes mainly from meniscus peripheral meniscal inside and outside and popliteal artery branch of capillary bundle, depending on its blood supply, the meniscus is divided into the red zone, red and white zone, and white zone, capillary goes through the 10% ~ 30% of the medial meniscus, and 10% ~ 25% of the lateral meniscus, this part is called the red zone under the arthroscope. There is no blood supply in the central part of the meniscus, known as the white area, and it depends on the infiltration of joint fluid for nutrition, so it lacks the ability of repair and regeneration after injury [3].

Knee meniscus injury can be caused by trauma, degeneration or congenital anomalies. In young patients, damage associated with sports (especially football, basketball, baseball, and skiing) is the most common causes of meniscus injury, accounts for more than a third of all cases [4]. Based on a systematic evaluation of the epidemiological characteristics of exercise-induced meniscal tears conducted by Yang Yuan [5], the prevalence of meniscus tears in sports injuries was 5%, including 8% in the lateral meniscus, and 7% in the medial meniscus. According to O 'Connor's Method, the types of meniscus injuries can be divided into longitudinal tear, horizontal tear, oblique tear, radial tear, valvular tear and degenerative meniscus tear [6], among which longitudinal tear is more common. Treatment for traumatic meniscus tears include repair, in situ preservation or partial meniscectomy. Repair and in situ preservation are the most favorable treatment options. Total meniscus resection or subtotal meniscus resection can lead to secondary cartilage damage and degeneration, and is rarely used now [7]. Meniscus repair has the advantage of reducing long-term osteoarthritis, improving activity level and improving patient satisfaction [8,9].

Meniscus tear is often due to external force, the medial side of the meniscus by the rotational pressure between the femur and the tibia, causing meniscus tear. Generally, the greater the degree of knee flexion, the more backward the position of meniscus tear. After the meniscus fracture, a small part will enter into the joint, which will seriously affect the activity of the knee joint and hinder the normal flexion and extension of the joint. Therefore, there will be significant swelling and pain in the joint of the patient, and the patient will have obvious difficulties in ascending and descending, squatting, running, jumping and other movements. Meniscus tears are common in young people, and the mechanism of injury is associated with sudden joint rotation and violent movement. The success of meniscus repair is related to injury type, injury size, location, blood supply, repair technique and concomitant lesions. The best target of meniscus repair is full-layer longitudinal tear located in the red area of meniscus with good blood supply and the red-white junction area. Meniscus repair can be done in three main ways: inside-out, outside-in or all-inside repair. As the awareness for meniscal preservation has risen, a number of devices that allow for an all-inside procedure to be performed which avoids the need for further incisions, reduces the risk of neurovascular injury and faster operating times. New technologies keep emerging and obtain satisfactory efficacy, and the main repair devices include meniscus nail, suture and new combined devices [10]. In an early study, Gill et al. [11] achieved good results in 32 patients who underwent total meniscal repair, with only 3 (9.4%) requiring further meniscal surgery. Zhang Hongtao et al. [12] performed total internal suture for 59 patients with meniscus injury, followed up for an average of (15.0±2.3) months, with a clinical recovery rate of 89% and a meniscus recovery rate of 91% by MRI.

With the development of minimally invasive arthroscopic techniques and the innovation of suture instruments, meniscus tears can be repaired with complete intraarticular suture under arthroscopy. One all suture meniscus repair system developed

by Zimmer Biomet is a new minimally invasive repair system, which is made of soft material, less interference and trauma to surrounding tissues; The unique design of the two soft anchors improves meniscus tissue preservation through the knotless, self-locking suture ring connection technology, while the operation is simple and the repair site is strongly controlled.

4.2 General background on the diagnosis and treatment of meniscus tears

The investigational device JuggerStitch™ is a kind of all inside meniscal repair system. The device is composed of a suture device and various auxiliary tools. The device includes soft anchors and none absorbable sutures, and the other components mainly include the tip, rod, handle, and protective sleeve of the suture device, the suture is made of ultra-high molecular weight polyethylene (UHMWPE) and polypropylene. The investigational device JuggerStitch™ Meniscal Repair Device (Herein after referred to as JuggerStitch™) belongs to all-inside devices. The primary benefits of the JuggerStitch™ device are the strong, knotless, all-suture implant and the low-profile insertion device. It is intended to repair vertical and longitudinal full-thickness tears (e.g. barrel handle tears) in red-red or red-white areas of the meniscus.

Traditional meniscal knotting and fixation devices often use rigid plastic anchors and surface junctions, which may lead to complications including cartilage damage and synovitis, displacement and fragmentation, as well as soft tissue stimulation [10]. In order to avoid these complications related to rigid devices and allow more controllable tension, JuggerStitch™ adopts an all-suture design with two soft anchors passing through without knots. Self-locking suture ring connection improves meniscus tissue retention, enhances Surgeon's control over the repair site, and makes the operation easier than the sliding knot locking implant.

An internal study initiated by the manufacturer investigates the effect of tissue models on the biomechanical results of meniscal fixation for soft anchors and hard polymer anchors using the JuggerStitch™ device and the Ultra FAST-FIX device [13]. All 9 of the JuggerStitch™ implants passed cyclical testing with porcine menisci compared to 78% (7 of 9) of Ultra FAST-FIX implants. Cyclic displacement values for the samples that passed the cyclic load test were similar for the JuggerStitch™ and the Ultra FAST-FIX in porcine tissue and cadaveric tissue under the loads introduced in this study. Surviving samples were then tested to failure. Both implants saw similar load to failure results in cadaveric tissue. However, JuggerStitch™ devices experienced a statistically significantly higher load to failure in porcine tissue. These results demonstrate that the knotless, all-suture design of the JuggerStitch™ does not compromise the strength of the device in comparison to a traditional knotted device with hard anchor fixation.

The purpose of this clinical trial is to collect data on the safety and efficacy of JuggerStitch™ in the Chinese population to support its registration application in China. Since there is no soft anchor product for meniscus suture in China, the Fast-Fix 360 meniscal repair system (Herein after referred to as Fast-Fix 360), which is one of the most recognized products in all inside meniscal repair device, was selected as the control device. This device is composed of the implants and auxiliary tool, the implants including suture and two fixed rod, auxiliary tools include insert (including the handle and lever) and depth limit and shear line, from no coating non absorbable suture is made from UHMWPE and PP monofilament, fixed bar/anchors is polyether ether ketone (Polyetheretherketone, PEEK) material, suitable for use as suture closure device in percutaneous or arthroscopic soft tissue repair surgery, mainly used for meniscus repair and meniscus allograft surgery.

Fast-Fix series products are the representative products of all suture technology of knee joint, which belong to innovative rapid fixation device. It has been used in clinical practice for 15 years, and has achieved good clinical performance in meniscus repair. Postoperative knee function of patients is significantly improved, and postoperative Lysholm Knee Score is 83.45~92.3 on average, the postoperative Tegner Activity Score can reach an average of 5.7~6.3 points [15-19] (the average score of healthy level is 5.7 points [14]). Samuelsen et al. [20] compared and analyzed the effect of all suture repair (Fast-Fix 360, 20 cases) and Ethibond (20 cases) in the treatment of meniscus barrel hilt-like tear by retrospective collection of electronic medical record system data. The overall survival time without re-tear was 4.4 (2.5-7.4) years. There was no significant difference in KM survival rate between Fast-fix 360 and Ethibon. Postoperative knee function was significantly

improved in both groups, functional scores such as IKDC score and Tegner activity level showed no difference between two groups, and the average number of implanted Fast-Fix 360 suture devices was 5.1±1.3. Ethibond was 10.9±3.2, and the number of implants in Fast-Fix 360 group was significantly reduced ($P < 0.01$). Ardizzone et al. [6] conducted a systematic review to analyze the safety and effectiveness of Fast-Fix and other all inside meniscus repair devices in the treatment of bucket handle tear of meniscus. A total of 15 studies involving 763 patients were included in the analysis. The average follow-up period was 13.0 (5.0-32.4) months. The repair failure was defined as the need for reoperation after meniscus repair. The overall failure rate was 29.3%, and the failure rate of Fast-Fix was 22.4%, The failure rates of other devices were 27.1%, 42.9% and 45.2% for meniscus arrow, Biofix arrow and Rapidloc, respectively. Fast-Fix had obvious advantages.

In this clinical trial, a randomized controlled trial design was used to study the clinical safety and effectiveness of JuggerStitch™ in the repair of meniscal tears.

4.3 The characteristics, structure composition, principle, mechanism and scope of the investigation products

4.3.1 Characteristics of the investigational product

JuggerStitch™ is made of soft material with little interference and trauma to surrounding tissues. The unique design, in which the two soft anchors are connected by a knotless, self-locking suture ring improves meniscal tissue retention and enhances the Surgeon's control over the repair site, compared to implants that use a sliding knot to lock the repair site.

4.3.2 Structure composition, principle, mechanism and scope of the investigation product

JuggerStitch™ consists of a suture instrument and various auxiliary tools. The pre-installed implant consists of a soft anchor and non-absorbable suture. The remaining components include the suture needle, rod, handle, and protective sleeve.

JuggerStitch™ is made of ULTRA-high molecular weight polyethylene polypropylene (UHMWPE), the suture needle is made of 631 stainless steel, and the rod is made of 304 stainless steel.4.3.3 Scope for trial

This clinical trial is intended to evaluate the clinical efficacy and safety of the JuggerStitch™ in repair of meniscal tears.

4.3.3 Management of investigational products

4.3.3.1 Storage of the investigational medical device

JuggerStitch™ is supplied in sterile packaging, and its outer packaging can ensure that the device remains sterile during the shelf life. The investigational medical device shall be stored in a room without corrosive gas at ambient temperature.

4.3.3.2 Management of the investigational medical device

A strict registration system shall be established for the storage and distribution of the investigational medical devices. The sponsor or its entrusted personnel shall send the investigational medical devices directly to the study centers. The study centers shall establish complete procedures for the receipt of investigational medical devices, and record the date of receipt, quantity, batch number/serial number, expiration date with the signatures of personnel responsible for the handover and device administrators. Each study center shall have designated personnel to act as the administrator of the investigational medical device and establish a specialized "Record Form for Use of Medical Devices", in which the subject's initials, date of use and serial number shall be registered and the device label shall be attached.

4.3.3.3 Recycling/destruction of the remnant investigational medical devices

After the completion of the trial, the sponsor or its entrusted personnel will collect all unused investigational medical devices, and the sponsor is responsible for the recycling/destruction of the unused investigational medical devices.4.4. Indications, Contraindications and Warnings

4.4.1 Indications

JuggerStitch™ Meniscal Repair Device is indicated for the repair of vertical longitudinal full thickness tears (e.g. bucket-handle) in the red-red and red-white zones. The device is not to be used for meniscal tears in the avascular zone of the meniscus.

4.4..2 Contraindications

(1) Infection.
(2) Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
(3) Meniscal tears not suitable for repair because of the degree of damage (marked irregularity and complex tearing) to the meniscus body including degenerative, radial, horizontal cleavage and flap tears.

4.4.3 Warnings

Biomet Sports Medicine internal fixation devices provide the surgeon with a means to aid in the management of meniscal tears. While these devices are generally successful in attaining these goals, they cannot be expected to replace normal healthy soft tissue or withstand the stress placed upon the device by full or partial weight bearing or load bearing, particularly in the presence of incomplete healing. Therefore, it is important that immobilization (use of external support, walking aids, braces, etc.) of the treatment site be maintained until healing has occurred. Surgical implants are subject to repeated stresses in use, which can result in fracture or damage to the implant. Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the implant. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but also must be aware of the mechanical and polymeric aspects of the surgical implants and the surgical technique.

(1) Correct selection of the implant is extremely important. The potential for success in soft tissue fixation is increased by the selection of the proper type of implant. While proper selection can help minimize risks, the device is not designed to withstand the unsupported stress of full weight bearing, load bearing or excessive activity.
(2) The implants can loosen or be damaged when subjected to increased loading associated with inadequate healing. If healing is delayed, or does not occur, the implant or the procedure may fail. Loads produced by weight bearing and activity levels may dictate the longevity of the implant.
(3) Inadequate fixation at the time of surgery can increase the risk of loosening and migration of the device or tissue supported by the device.
(4) Care is to be taken to assure adequate fixation of the meniscal tissue at the time of surgery. Failure to achieve adequate fixation through improper positioning or placement of the device can contribute to a subsequent undesirable result.
(5) The use of appropriate immobilization and postoperative management is indicated as part of treatment until healing has occurred.
(6) Correct handling of suture is extremely important. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.
(7) DO NOT USE if there is loss of sterility of the device.
(8) DO NOT USE opened or damaged devices. Use only devices that are packaged in unopened and undamaged containers. Do not use excessive force when inserting the device. Excessive force may cause damage to the device and/or adversely affect its performance.
(9) Adequately instruct the patient. Postoperative care is important. The patient's ability and willingness to follow instructions is one of the most important aspects of successful soft tissue management.

- Patients affected with senility, mental illness, alcoholism, and drug abuse may be at a higher risk of device or procedure failure. These patients may ignore instructions and activity restrictions.
- The patient is to be instructed in the use of external supports, walking aids, and braces that are intended to immobilize the repair site and limit weight bearing or load bearing.
- The patient is to be made fully aware and warned that the device does not replace normal healthy tissue, and that the device can break, or be damaged as a result of stress, activity, load bearing, or weight bearing.
- The patient is to be made aware and warned in advance of general surgical risks, possible adverse effects, and to follow the instructions of the treating physician.
- The patient is to be advised of the need for regular postoperative follow-up examination as long as the device remains implanted. Noncompliance with postoperative instructions could lead to failure of the device, which could require additional surgery and device removal.

(10) Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat with implants that have been, even momentarily, placed in a different patient.

(11) Device is single use only. After use, the device may be a potential biohazard. Reuse of devices labeled for single-use may result in product contamination, patient infection and/or failure of the device to perform as intended.

(12) Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.

5. Objective and Content of Clinical Trial

5.1 Objective

The clinical safety and efficacy of the JuggerStitch™ in repair of meniscal tears are assessed by comparing the clinical data of the Fast-Fix 360.

5.2 Content

This trial was a prospective, multicenter, randomized controlled clinical trial to evaluate the clinical safety and efficacy of JuggerStitch™ all-suture meniscus suture system for arthroscopic repair of meniscus tears.

5.2.1 Primary Endpoints

Lysholm Knee Score at postoperative 6 months.

5.2.1 Secondary Endpoints

(1) Immediate device success rate postoperatively;

(2) Lysholm Knee Score at postoperative 3 months and 12 months;

(3) Tegner Activity Score at postoperative 3 months, 6 months and 12 months;

(4) Visual analogue scale (VAS) score for pain at postoperative 3 months, 6 months and 12 months;

(5) Meniscus healing evaluated by Magnetic Resonance Imaging (MRI) scans at postoperative 6 months and 12 months;

(6) Device-related adverse event rate.

6. Overall Design

6.1 Study Design

6.1.1 Objective of the trial

6.1.2 Selection of clinical trial methods and the rationale

A prospective multi-center, randomized controlled design is adopted in this trial, and the 12-month postoperative Lysholm Knee Score is used as the primary endpoint indicator to verify the 12-month postoperative improvement in knee function. The secondary endpoint evaluation indicator is the immediate device success rate of the surgery, which is used to evaluate the immediate surgical effect of the investigational medical device for repairing meniscal tears.
The Lysholm Knee Score at postoperative 1 month, 3 months and 6 months, and Tegner Activity Score and VAS score of the index knee joint at postoperative 1 month, 3 months, 6 months and 12 months are used to evaluate the improvement in knee function;

MRI will be performed at postoperative 12 months to evaluate the recovery status during the trial, and the medical device-related adverse events during the clinical trial period are used to evaluate the safety of the device.
Meniscal tears mainly affect the knee function, resulting in pain and limited mobility. Lysholm Knee Score, Tegner Activity Score and VAS score for pain are commonly used clinical evaluation indicators of knee function after meniscal tears. These indicators not only quantitatively score the various functions of knee joint, but also cover the quantitative scores of subject's subjective feelings, which more objectively reflect the function of knee joint. In addition, MRI analysis at the shoulder joint during the 12-month follow-up periods make the results of clinical trials more objective and reliable.

6.1.3 Measures to reduce and avoid bias

(1) The investigators participating in this study will receive training on the clinical trial protocol and the operating procedure for the investigational medical device, and strictly abide by the inclusion and exclusion criteria.
(2) The sponsor will assign a qualified clinical trial monitor to monitor the study center, make quality control and monitoring records, and communicate with the investigators in time about the problems found during the monitoring.
(3) Interventions will be performed on the subjects according to the randomization results obtained by the central randomization system.
(4) Multi-center clinical study design is adopted to make the results more objective and reliable, and avoid data bias in single-center clinical study.
(5) The subjects with good protocol compliance will be included as far as possible, and the subject's follow-up, withdrawal and dropout will be controlled during the clinical study period.
(6) Fixed efficacy assessors will be arranged before and after treatment, who will receive training on strict efficacy assessment criteria to prevent detection bias.
(7) To reduce data loss, data analysis will also be performed on subjects who withdraw from treatment.

6.1.4 Diagnosis and treatment method of the investigational medical device

(1) Anesthesia and position: After the subject is under epidural or lumbar anesthesia, take a supine position according to the investigator's habitual surgical operation procedures, and take on a routine tourniquet to the roof of the index knee joint.
(2) Surgical incision: Operate according to the standard operating procedure of arthroscopic surgery, and choose the subpatellar and medial lateral approach to the knee joint.
(3) Exploration: Explore from the suprapatellar bursa, patellofemoral joint, medial compartment, medial malleolus fossa, lateral compartment, posterior medial compartment to posterior lateral compartment, conduct preoperative physical examination and MRI to assess the location of the meniscus tear and determine the repairability of the injury.

(4) The investigator will then recheck whether the subjects meet the eligibility criteria, subjects who does not meet all inclusion criteria or meet any of the exclusion criteria will be deemed to screening failure under arthroscopy.

(5) Surgical procedures: during the treatment of meniscus injury, for the combined articular loose body, the loose body should be removed and clean the joint. According to the injury location of meniscus, the probe will be used to determine and select the appropriate meniscal repair system.

The Surgical Techniques for JuggerStitch ™:

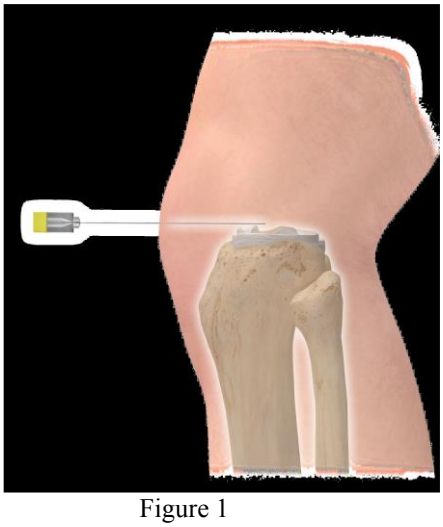


Figure 1

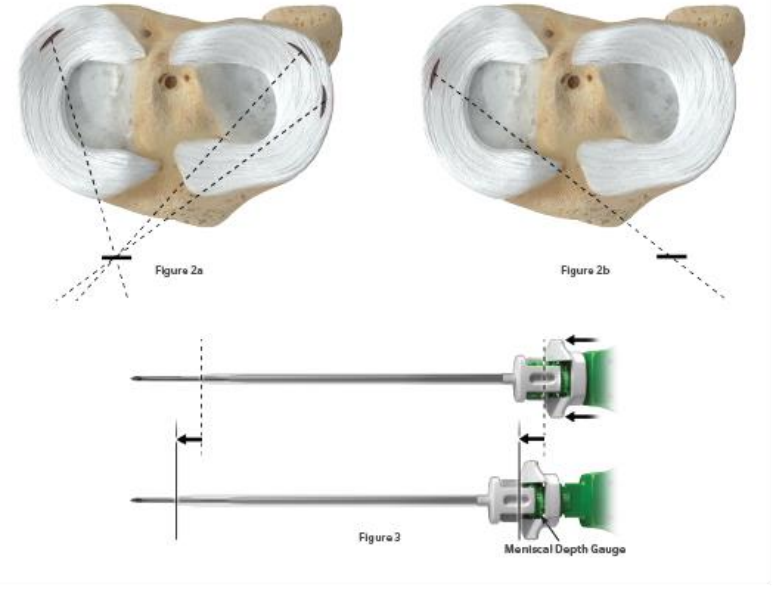
Step 1: Diagnostic Arthroscopy

Assess the location of the meniscal tear and determine the reparability of the lesion. Determine optimum medial portal placement using an 18-gauge spinal needle and direct arthroscopic visualization to create a medial working portal. Appropriate position is achieved when the needle enters just above the anterior medial meniscus parallel to the tibial joint surface (Figure 1).

Avoid placing the portal too superior or inferior and ensure the medial portal is large enough to readily pass the inserter and suture cutter.

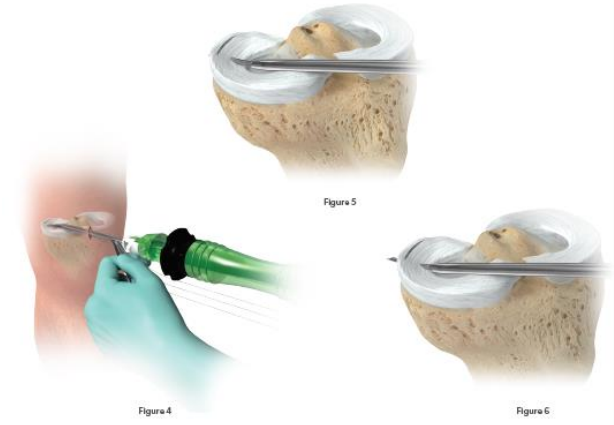
For mid-body tears of the medial meniscus, the scope should be switched to the medial portal, and the lateral portal should be assessed by inserting the half pipe into the lateral portal. Should the half pipe not enter the joint just above the anterior lateral meniscus parallel to the tibial surface, the lateral portal should be expanded or a new lateral portal should be created.

Step 2: Decide on Proper Approach



Both straight and curved needle options are available to optimize implant positioning for repair. Utilize a probe through the medial portal to help determine whether a straight or curved needle is optimal. Posterior horn tears, whether medial or lateral, should be approached from the medial portal (Figure 2a). Approach the mid-body tears from the contralateral portal (Figure 2b). If the needle depth needs to be adjusted, push down on the white depth control slider in a forward motion to decrease the needle length exposed (Figure 3).

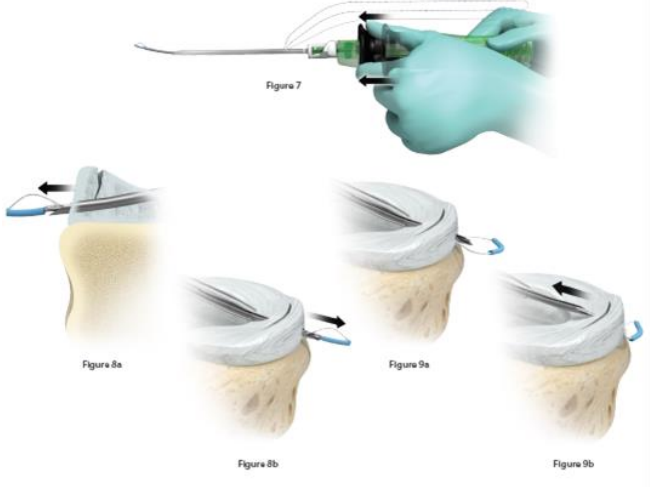
Step 3: Position the JuggerStitch™ Meniscal Repair Device



Advance the half pipe cannula sled through the designated portal to the meniscus. Advance the JuggerStitch™ into the joint by sliding the sharp point against the half pipe cannula sled. This procedure is designed to limit catching the device on soft tissue. Retract the half pipe cannula sled from the joint space once the JuggerStitch™ has been successfully inserted into the joint space (Figure 4). Using the needle, enter the surface of the meniscus with the tip of the needle (Figure 5). Advance the needle until the clear depth limiting tube contacts the surface of the meniscus (Figure 6).

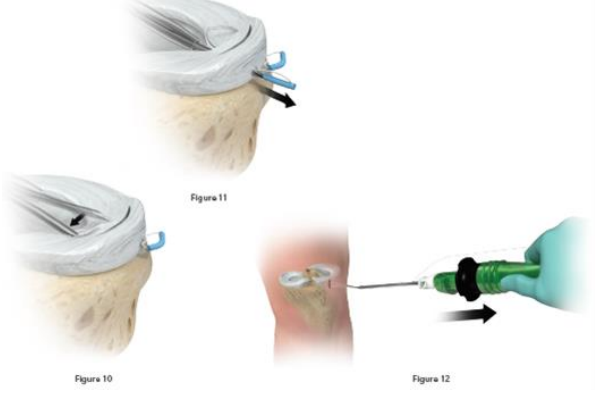
Alternative Technique: When inserting anchors using curved-tip inserter on the superior surface of the meniscus, keep the curved tip pointed inferiorly when penetrating the surface of the meniscus. Once penetrated, rotate the inserter 180 degrees and advance the needle until the clear depth limiting tube contacts the surface of the meniscus

Step 4: Deploy the First Anchor



Once the JuggerStitch™ depth limiter is in contact with the anterior surface of the meniscus, use two hands, one to hold the handle while the other advances the black button (Figure 7). Fully advance the black button to deploy the first anchor. (Figures 8a and 8b). Fully retract the black button and subsequently pull the needle tip gently out of the meniscus (Figure 9a and 9b).

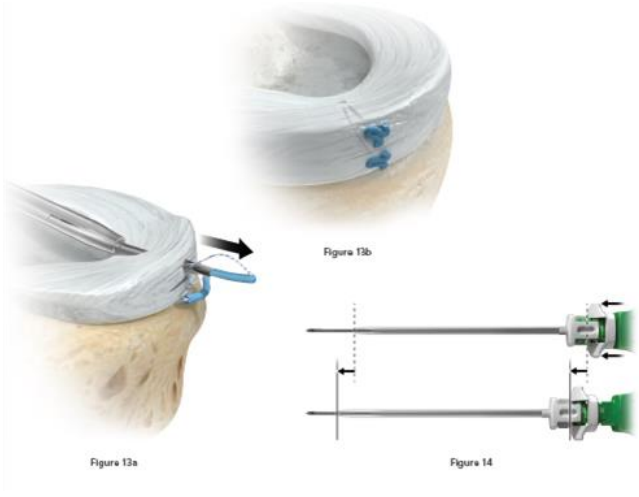
Step 5: Deploy the Second Anchor



Reposition the needle tip at the desired location and advance the needle tip as described previously (Figure 10). Once the depth gage contacts the surface of the meniscus, advance the black button forward to deploy the second anchor (Figure 11). Fully retract the black button and then completely remove the meniscal inserter from the joint (Figure 12).

Pearl: Always work towards the scope. Insert the first anchor away from the scope lens of view and insert
the second anchor closer to the lens and field of view.

Pearl: Do not remove the device from the joint between anchors as this could create a tissue bridge.



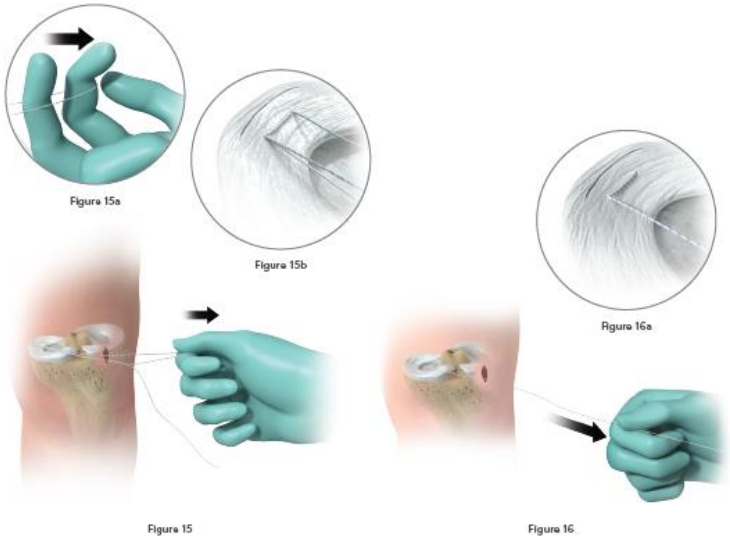
Step 6: Vertical Mattress Technique

Insert the first anchor on the inferior meniscal rim. Then, insert the second anchor superior to the tear on the meniscal rim. Anchors placed in the superior meniscus may require less deployment depth compared to anchors placed in the inferior meniscus because the superior meniscus is typically less thick than the inferior meniscus (Figure 13).

To lessen the needle depth for the superior position, push down on the white depth control slider in a forward motion to decrease the depth of the needle until desired measurement is reached (Figure 14).

Step 7: Tension the Suture

After retracting the JuggerStitch™ from the joint, a suture loop and a single strand will remain protruding from the portal.

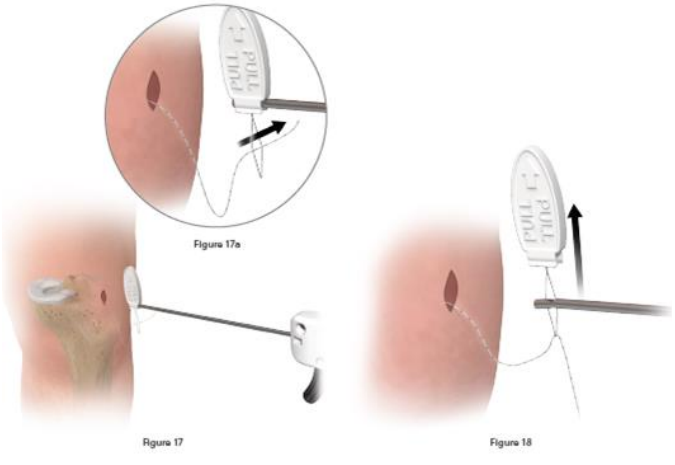


Pull the blue/white side of the loop with multiple short tugs using the index and middle finger to set the anchors at the repair site (Figures 15 & 15a). The anchor is fully set once the blue/white portion of the suture loop no longer moves. Confirm under visualization of the scope at the repair site (Figure 15b).

Next, pull the white single strand to reduce the large loop down to the surface of the meniscus. Pull on the strand until tension on the second loop matches the tension of the first loop (Figure 16 & 16a). At this time, if desired, a probe may be utilized to check the repair site for

Step 8: Cut the Suture

Place JuggerStitch™ 2-0 MaxBraid™ suture through kite (Figures 17 & 17a).



Once suture is through kite, use white pull tab to pull suture through the eyelet of the suture cutter (Figure 18). Please note that when reloading suture through the suture cutter to always load suture in this direction.

appropriate tension.

Surgical Technique for Fast-Fix 360:

Step 1: Determine the Depth of Pin

Use the meniscus depth probe to determine the desired depth. Place the tip of the probe at the meniscus-synovial junction and determine the width of the meniscus at the desired delivery needle entry point. For average sized knees, a depth of 14mm is usually sufficient, and this length can be adjusted either externally or internally on the probe. The laser marks on the tips also serve as a reference. As shown in figure 19.

Figure 19 Fast-Fix 360 Probe

Step 2: Insertion of suture needle

Insert Fast-Fix360 needle into the joint through the appropriate arthroscopic approach. Easy insertion by using slotted casing. As shown in figure 20.

Figure 20 Needle Insertion

Step 3: Deploy the First Anchor

Place the first anchor (T1) on the capsular side of the tear. Insert the FastFix360 needle into the capsule or tear any remaining meniscus tissue on the side of the capsule. Keep the conveying needle in the appropriate position and push the expansion slider forward to expand T1; The correct deployment of the implant is accompanied by a clicking sound. For better suture management and to prevent removal of the second implant (T2), release the unfurl slider and slowly pull the needle out of the meniscus, keeping the needle within the grossed socket and the arthroscopic field of view. As shown in figure 21-23.

Figure 21 Insert Needle into the Meniscus Tissue

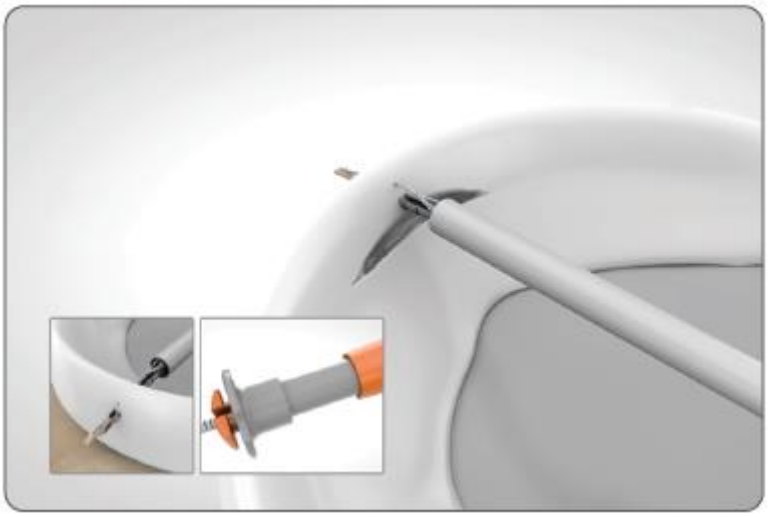


Figure 22 Deploy the first implant T1

Figure 23 Unfold the first Anchor T1

Step 4: Deploy the Second Anchor T2

Place the slotted casing on the internal meniscus fragment at the desired entry point (if required). The entry point of the second (T2) anchor should be at least 5mm away from the tear. Propel the insertion of needle until the depth of penetration limiter touches the meniscus surface (Figure 24). With the needle

insertion in place, push the unroll slider forward to deploy T2. As with T1, proper deployment of T2 is accompanied by a "click" sound. After the T2 is deployed, slowly remove the conveying needle from the connector. Tighten the thread to make the knot tight. Slide the pusher/suture cutter onto the knot to cut off excess stitches and complete the suture. As shown in figure 24-26.

Figure 24 Deploy the Second Anchor T2

Figure 25 Unfold the Second Anchor T2

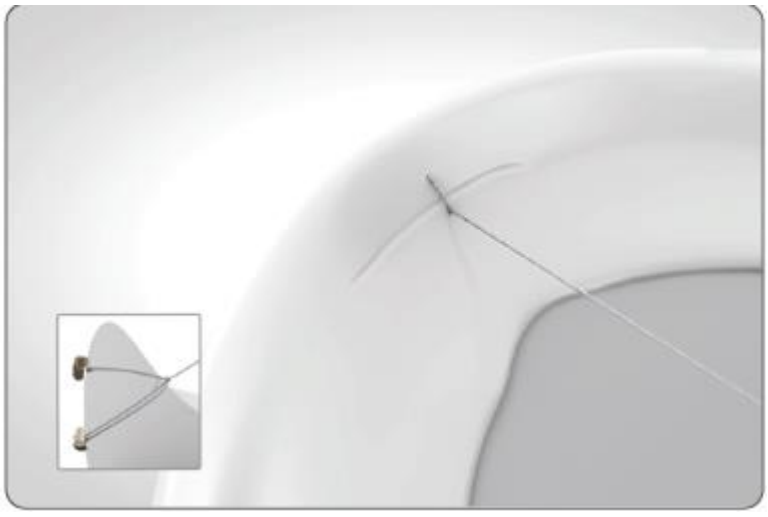


Figure 26 Tension the Suture

The fixed position of the anchors and the number of devices used are determined according to the type of injury, and the details of the use of the anchors and the repair of combined injuries are recorded.

Probe to confirm that the meniscus is well fixed, the soft anchor and suture are stable, rinse the incision, check the instrument dressing is correct, suture the incision, bandage.

6.1.5 Selection of subjects

6.1.5.1 Inclusion criteria of subjects

(1) 18~60 years old (18 and 60 inclusive);
(2) Patient who are scheduled for meniscal repair with a vertical longitudinal full-thickness tears (e.g. bucket-handle) in the red-red and red-white zones;
(3) Patients who can understand all risks and benefits described in the informed consent form (ICF), and are willing to comply with the guidance for rehabilitation, and the follow-up visits specified in the clinical trial protocol, and voluntarily participate in the trial and sign the ICF;

6.1.5.2 Exclusion criteria of subjects

(1) Patient has meniscal tears in the avascular zone of meniscus;
(2) Meniscal tears not suitable for repair because of the degree of damage (marked irregularity and complex tearing) to the meniscus body including degenerative, radial, horizontal cleavage, flap and root tears;
(3) Patient with multiple ligament injuries of the affected knee joint;
(4) Patient with adhesion of the affected knee joint;
(5) Patient is planned to accept intraoperative or postoperative intra - articular injection is planned;
(6) Articular surface cartilage injury of the targeted knee assessed by the International Cartilage Repair Society (ICRs) is grade 3-4;
(7) Kellgren-Lawrence grades of documented radiographic evidence of osteoarthritis (OA) in the affected knee is ≥III.
(8) Instability or valgus/varus deformity(＞5o) of the affected knee;
(9) Patient has acute or chronic, local or systemic infections;
(10) Patient with metabolic diseases;
(11) Abnormal liver and kidney function (Creatinine 3 times higher than the upper limit of normal value or alanine aminotransferase or aspartate aminotransferase 3 times higher than the upper limit of normal value) before operation;
(12) History of operation in the affected knee;
(13) Acute myocardial infarction or stroke occurred within 6 months before operation;
(14) Patients are known allergy to any material (polyethylene, polypropylene, polyester, polyetheretherketone) of the implants;
(15) Patient is pregnant or known to be pregnant;
(16) Other circumstances that the researchers believe that may affect the efficacy and safety evaluation of the investigated medical devices;
(17) Patients are currently participating in other clinical trials.

6.1.5.3 Criteria and procedure for suspending the trial/treatment

The clinical trial suspension means that the clinical trial does not end according to the protocol, but all trials are stopped midway. The purpose of terminating the clinical trial is to protect the rights and interests of the subjects and ensure the quality of the clinical trial. Except for Item 5 below, the Sponsor and the Investigator shall jointly negotiate whether to terminate the study:

(1) If serious safety problems occur during the clinical trial, the clinical trial should be terminated in time;
(2) If the product is found to be of no clinical value during the clinical trial, the clinical trial should be terminated;
(3) It is difficult to evaluate the effect of the product because there is a major error in the clinical study scheme in the process of clinical trial; Or the program in the implementation of serious deviation, continue, it is difficult to evaluate the effect of the product should be terminated clinical trial;
(4) The Sponsor requests termination (for financial reasons, etc.)
(5) The National Medical Products Administration (NMPA) ordered the termination of the clinical trial for some reason.

After the termination of the study, the investigator shall continue to provide appropriate treatment to the subjects from the perspective of protecting their rights and interests, and shall inform the subjects in detail of the treatment and treatment they have received during the study period. Subjects' data can still be used to evaluate product safety.

6.1.5.4 Enrollment duration

The first subject is scheduled to be enrolled in December 2021, and the total enrollment time limit is set to 6 months.

6.1.5.5 Expected overall duration of the clinical trial and the rationale

The expected overall duration of the clinical trial is 18 months, calculated from the first subject enrolled in the group. The recruitment time is set to 6 months, and the postoperative follow-up time is 12 months.

6.1.5.6 Expected duration of each subject’s participation

The patients will be hospitalized for 2-5 days, and followed up for 12 months after discharge.

6.1.5.7 Number of subjects required for the clinical trial

47 patients will be included in the investigational group and the control group, respectively. A total of 94 subjects will be included in this clinical trial.

6.1.6 Efficacy evaluation approach

6.1.6.1 Description of efficacy parameters

Primary evaluation: Difference of Lysholm Knee Score from baseline to postoperative 6 months;
Secondary evaluation: Significant improvement in follow-upTegner Activity Score and VAS Score for pain compared with the preoperative ones, is used as the basis for evaluating the efficacy of the investigational medical device.

6.1.6.2 Method and time selection for evaluating, recording and analyzing efficacy parameters

The subject’s Lysholm Knee Score, Tegner Activity Score and VAS will be recorded at preoperative and at postoperative 3 months, 6 months and 12 months, respectively. The soft tissue will get healed around postoperative 6 weeks, and the rehabilitation program allows active exercise after postoperative 1 day. Follow-up visit will be started at postoperative 3 months, and knee function scores were performed at each follow-up point to evaluate the recovery of knee function of the subjects, and MRI will be performed at postoperative 6 and 12 months to evaluate meniscus repair.

6.1.7 Safety evaluation approach

6.1.7.1 Description of safety parameters

Safety parameters include all adverse events that occur during surgery and follow-up period, surgery-related adverse events, and device-related adverse events (MRI results at postoperative 12 months will be analyzed separately in the form of a list). See the Evaluation and Report of Adverse Events for details.

6.1.7.2 Method and time selection for evaluating, recording and analyzing safety parameters

The adverse events that occur during surgery and at postoperative 1 month, 3 months, 6 months and 12 months will be recorded in detail, and evaluated and reported in accordance with the Evaluation and Report Procedure of Adverse Events.

6.2 Trial procedure

6.2.1 Trial flow chart

For details of the trial procedure, see the following trial procedure and trial flow chart.

Trial procedure

Assessment	Enrollment and Treatment			Follow Up Visit		
	Baseline	Operation	Post-operation~Discharged	3months	6 months	12 months
Window Period	-14~0d	0d		±15d	±30d	±30 d
Subject Informed Consent	X					
Subject screening registration	X					
Eligibility	X					
Demographics	X					
Physical Examination	X					
Routine Blood	X					
Erythrocyte Sedimentation Rate	X					
Blood Coagulation	X					
Blood/Urine HCG	X					
Electrocardiogram	X					
Lysholm Knee Score	X			X	X	X
Tegner Activity Score	X			X	X	X
VAS	X		X	X	X	X
X-Ray（Knee）	X					

MRI （Knee）	X				X	X
Arthroscopic Exploration		X				
Randomization		X				
Operation		X				
Trial Completion	←		As required (Early Termination)			→
Adverse Events	←		As required			→

Notes:

- Examinations on Routine Blood Erythrocyte Sedimentation Rate, Blood Coagulation, Electrocardiogram and X-ray in 14 days prior to the date of surgery (0d) during the screening period are acceptable for baseline assessment.
- Data on Magnetic Resonance Imaging (MRI) in 1 month prior to the date of informed consent is acceptable for baseline assessment.
- During the screening period, the available examination results from standard of care evaluation are acceptable for baseline assessment. After the informed consent form is completed, baseline examination data will be collected for assessing the inclusion and exclusion criteria by investigators.

6.2.2 Trial procedure

6.2.2.1 Acquisition of the signed informed consent form from subjects

The investigator or his designated personnel will explain to the patient (potential subject) the detailed information related to the investigational medical device and the clinical trial, inform the patient of the possible benefits as well as the known and foreseeable risks, and obtain the signed and dated informed consent form from the patient or his guardian. The investigator must also sign his name and date on the informed consent form.

6.2.2.2 Process of Informed Consent

Patients will be subjected to the informed consent process performed by the investigators, and those who agree to participate in this clinical trial will sign an ICF.

6.2.2.3 Subject Screening

The following data will be collected and assessed during the period of subject screening:

(1) Collect demographics/history: gender, date of birth, height, weight, history of knee joint related diseases, and injury location;
(2) Assessment of vital signs: including pulse and blood pressure.
(3) Specialized Physical Examinations used for the diagnosis of knee meniscus injury, including joint line tenderness, knee motion, and stability assessment including Anterior Drawer Test, Lachamn test, Lever Sign, Bohler Sign;
(4) Laboratory tests assessment: including blood routine, blood biochemistry (liver function, kidney function, and blood glucose level), blood/urine HCG test.
(5) X-ray assessment including anteroposterior and lateral views of plain radiographs and full-length weight-bearing radiographs of the lower extremity for using to evaluate fracture, degenerative changes of the knee and episome;

(6) MRI assessment on the affected knee to determine the type and extent of meniscus injury;
(7) Record pre-operative Lysholm Knee Score, Tegner Activity Score and VAS of the index knee joint.

8.2.2.4 Arthroscopy Exploration and Surgery

(1) Anesthesia and position: After the subject is under epidural, lumbar or general anesthesia, take a supine position according to the investigator's habitual surgical operation procedures, and take on a routine tourniquet to the roof of the index knee joint.
(2) Surgical incision: Operate according to the standard operating procedure of arthroscopic surgery, and choose the subpatellar and medial lateral approach to the knee joint.
(3) Exploration: Explore from the suprapatellar bursa, patellofemoral joint, medial compartment, medial malleolus fossa, lateral compartment, posterior medial compartment to posterior lateral compartment, conduct preoperative physical examination and MRI to assess the location of the meniscus tear and determine the repairability of the injury.
(4) Check inclusion and exclusion criteria, and randomization: Investigator to check if patient is qualified based on arthroscopy exploration result. For the patients who meet all inclusion criteria but none of the exclusion criteria, log in to the central random system to obtain the subject screening code; Patients randomized to the investigational group will be planned to perform surgery using JuggerStitch™, and patients randomized to the control group will be planned to use Fast-Fix 360 (Control Product); Subjects who do not meet the inclusion criteria or meet any of the exclusion criteria will be considered as a screening failure.
(5) Surgical procedures: during the treatment of meniscus injury, for the combined articular loose body, the loose body should be removed and clean the joint. According to the injury location of meniscus, the probe will be used to determine and select the appropriate meniscal repair system.
(6) Record the details of medical devices used (model, batch number and quantity, performance evaluation), the treatment of combined injuries;
(7) Record concomitant medications during the surgery (painkillers and anesthetics by the anesthesiologist excluded));
(8) Record the device deficiency;
(9) Monitor and record adverse events during operation and at postoperative.

8.2.2.5 Postoperative rehabilitation and follow-up visits

(1) Postoperative treatment: subjects are recommended to use the elastic bandage round limb, appropriate massage to prevent blood clots. After being awake anesthesia, nurse will provide guidance on quadriceps isometric contraction and the straight leg-raising training. See Appendix 9 Postoperative Rehabilitation Guidance.
(2) Subjects will be followed up in clinical visits at postoperative 3 months, 6 months and 12 months, and Lysholm Knee Score, Tegner Activity Score, and VAS will be obtained at each follow-up visit to assess the recovery of knee joint.
(3) MRI of the knee joint will be performed at postoperative 6 months and 12 months to evaluate the recovery of meniscus.
(4) Monitor and record clinical adverse events during each follow-up period for data evaluation and analysis.
(5) Record the use of analgesic drugs at discharge and during each follow-up period (name of drug, start/discontinuation date, and daily dose).

8.2.2.5 Specifications for use of the investigational medical device

(1) The correct choice of the type of investigational medical device can minimize the risk of failure of the investigational medical device.
(2) Meniscal tears not suitable for repair because of the degree of damage (marked irregularity and complex tearing) to the meniscus body including degenerative, radial, horizontal cleavage and flap tears;
(3) Ensure that the meniscal tissue is properly fixed during surgery. Incorrect fixation of the soft tissue may lead to serious postoperative consequences.
(4) Proper handling of sutures is very important. Avoid compression or curling injuries caused by the use of surgical instruments such as tweezers or needle holders.
(5) Excessive force shall be avoided when implanting the investigational medical device to prevent damage to the surrounding tissues or the investigational medical device.
(6) Properly use the investigational medical device and accessories.
(7) Use proper fixation devices and follow correct postoperative rehabilitation requirements in the early postoperative period. Incorrect rehabilitation activities in the early postoperative period may lead to failure of the device.

8.3 Monitoring plan

The sponsor shall appoint monitors to regularly monitor the clinical trial institutions participating in this clinical trial to ensure that the clinical trial is carried out in accordance with the trial protocol, the ethics committee's requirements and relevant regulations. The monitor's visit plan is as follows:

(1) Kick-off meeting of clinical trial institutions: It is carried out after obtaining the approval from the ethics committee and the signing of the clinical trial contract. Its purpose is to ensure that the investigators and their teams receive necessary trainings, fully understand the clinical trial protocol and other project documents, and ensure that all clinical documents and samples are in place prior to the kick-off meeting.
(2) First subject enrollment visit of clinical trial institutions: The visit is carried out as soon as possible after the first subject of the clinical trial institution is enrolled. Its purpose is to ensure that the enrolled subjects meet the inclusion criteria of the clinical trial and all the required tests are completed, and to confirm that the investigators and their teams fully understand the requirements of the clinical trial, and find and deal with the existing problems in advance.
(3) Regular monitoring visit of clinical trial institutions: It is carried out after the kick-off meeting and before the end of the clinical trial. The monitoring visit of clinical trial institutions will be carried out every two weeks within the first 2 months of the enrollment period, and once a month thereafter. Its purpose is to ensure that all the enrolled subjects meet the inclusion criteria of the clinical trial, the required tests are completed, and the enrolled subjects are treated smoothly. The data in the case report form and the source data are 100% checked to ensure that thorough settlement of adverse events, and follow-up and treatment of the existing problems. Any changes to the monitoring plan shall be approved by the sponsor in advance.
(4) Clinical trial close-out visit: It is carried out after all subjects have completed the follow-up, the clinical trial report summary has been formulated and all the existing problems have been properly addressed. Its purpose is to ensure that the investigators and clinical trial institutions fully understand the requirements for clinical trial archiving and the inspections on clinical trials possibly carried out by regulatory authorities.
(5) The monitor will complete the monitoring visit report after each monitoring visit.

7. Statistics Considerations

7.1 Statistical hypothesis testing, statistical method selection and statistical analysis

7.1.1 Statistical hypothesis testing

This trial is intended to adopt a prospective, multi-center, randomized controlled design, and its comparison type is a non-inferiority trial. The primary evaluation indicator is set as the difference of Lysholm Knee Score for knee function at 6 months postoperatively.

7.1.2 Statistical analysis method

SAS® 9.40 statistical software is used for statistical analysis.
Two-sided tests are used in all statistical tests (unless otherwise specified), and a *P* value of less than 0.05 will be considered as statistically significant.

Descriptive analysis:
The count data are described by frequency and percentage; the measurement data are described by mean, standard deviation, median, maximum, minimum, and the 25th and 75th percentiles.

Baseline demographic analysis:
Summarize the subject number in each clinical sites, list the loss visit cases. Present the size of different data sets in each group, case distribution in each clinical sites, comparison of total shedding rate and detailed list of incomplete causes. Demographic characteristics (age, gender, etc.), relevant medical history and treatment history of the subjects will be described, and age, gender and other characteristics of the two groups will be compared to measure the comparability of the two groups.
Demographic analysis will be based on full Data Set (FAS)

Primary Efficacy analysis:
The efficacy indicators will be analyzed by PPS and FAS.
Statistical analysis of the primary endpoint:
H0: $\pi 1-\pi 2 \leq -\triangle$;
H1: $\pi 1-\pi 2 > -\triangle$
The difference of Lysholm Knee Score at postoperative 6 months from baseline will be compared between the two groups using covariance analysis model, and the modified LS means and 95% confidence interval (CI) of the difference between the two groups at postoperative 6 months from baseline will be estimated. If the lower limit of 95% confidence interval is greater than the non-inferiority margin, the research hypothesis will be established. To investigate the consistency among centers, a covariance analysis model containing interaction terms between centers and groups will be considered on the basis of the above covariance analysis model, and the significance of interaction terms will be judged at the level of 0.10.

Secondary Efficacy analysis:
The secondary efficacy indicators will be analyzed by PPS and FAS.
Statistical description and inference of data will select suitable descriptive indicators and hypothesis testing methods according to the characteristics of data.
Statistical analysis method for safety:
The incidence of adverse events such as pain, device loosening or detachment, and retear occurring during surgery, as well as immediately, at 3 months, 6 months and 12 months postoperatively will be counted.

The type and frequency of adverse events, and their relationship with the investigational medical device will be described. Cases where the clinical trial is suspended due to adverse events and severe or serious adverse events will be specifically noted.

7.2 Calculation of sample size

7.2.1 Total sample size

The clinical trial hypothesis is based on several publications [22-26], the difference between Lysholm Knee Score at baseline and postoperative 6 months was 30. It is assumed that the difference between Lysholm Knee Score at baseline and postoperative 6 months after arthroscopic meniscus repair will be 34 for both the experimental group and the control group, the standard deviation is set to 8.00, and the non-inferiority margin is set to 5.1 under 15% of the difference, and the test level α is set to one-sided 0.025 and β to 0.2. Based on the above assumptions, the sample size of each group is 40. Considering that the clinical dropout rate in the clinical trial process was 15%, it was recommended to include 94 subjects in this trial. The calculation formula and required parameters for sample size are as follows:

$$n_T = n_C = \frac{2\left(Z_{1-\alpha/2} + Z_{1-\beta}\right)^2 \sigma^2}{(|D| - \Delta)^2}$$

where, α= Expected standard deviation of control group；|D|= Pooled variance of the test group and the control group, Δ= Non-inferiority test margin.

7.2.2 Number of clinical trial cases for each disease and the rationale

Meniscal injury of knee joint will be included in this clinical trial as treatment indications, which is in line with the application scope of the JuggerStitch™, and can evaluate the safety and effectiveness for the repair of meniscal tears. The number of sample size is determined by statistical calculation with reference to the clinical study data of the control device.

7.2.3 Minimum and maximum subjects for each clinical trial institution in the multi-center clinical trial and the rationale

This trial will be carried out simultaneously in multiple clinical trial institutions, using a centrally randomized, competitive enrollment design. In principle, the number of cases enrolled in each center will be distributed as evenly as possible to ensure sufficient center representativeness. However, considering the feasibility and the progress of enrollment, the number of cases in each participating institution will be adjusted according to the actual situation to ensure the balance of the size of enrollment of each center as far as possible. For a certain center, the final size of enrollment shall not exceed 50% of the total number of cases.

7.3 Level of Significance and Power

The statistical test level α is set to one-sided 0.025, and the power of test 1-β is set to 80%.

7.4 Expected dropout rate

The expected dropout rate is not greater than 20%.

7.5 Pass/fail Criteria To Be Applied To The Results

The pass or fail of test results is determined from a statistical point of view, which is equivalent to verifying the initial hypothesis testing. For this trial, the primary evaluation indicator is difference of Lysholm Knee Score at baseline and postoperative 6 months, and the test type is a non-inferiority test. If the lower 95% confidence interval of the difference in 6-month Lysholm Knee Score between the baseline and postoperative 6 months in the investigational group and the control group is greater than -8 (the preset non-inferiority margin), it is indicated that the non-inferiority conclusion is valid, and it can be considered that the clinical trial successfully verifies that the JuggerStitch™ can meet the requirements of clinical

application, indicating that the clinical trial results are passed; on the contrary, the non-inferiority conclusion is not valid and the clinical trial results are failed.

7.6 Termination Criteria On Statistical Grounds

This section does not apply as there is no interim analysis and evaluation in this trial.

7.7 Statistical methods for all data, together with missing, unused or incorrect data (including dropouts and withdrawals) and processing methods for unreasonable data

All subjects shall be included in the analysis of primary indicators, and the data from the full analysis set and the per-protocol set shall be selected respectively for the analysis. When the analysis conclusions of the above two data sets are consistent, the credibility of the study results can be enhanced.
For any missing data that may appear during the study process, all analyses will be based on the actual data obtained. Any filling in the missing primary endpoint indicators will be addressed in the statistical analysis plan.
Incorrect and unreasonable data will be dealt with in the data cleansing process prior to statistical analysis.
For dropouts and withdrawals from the trial, the information of these patients will still be included in the final statistical analysis. All specific reasons for dropouts and withdrawals will be explained in detail in the statistical report.

7.8 Procedure for reporting deviations from the original statistical plan

The statistical analysis plan needs to be confirmed by the sponsor, coordinating investigators, data management and statistical analysis personnel, and finalized prior to database locking. Before finalization, the initial analysis plan can be modified according to the actual situation in the trial process. Any change to the original statistical analysis plan due to the changes in the protocol shall be confirmed again by the sponsor, coordinating investigators, data management and statistical analysis personnel, and the change shall be made in strict compliance with the clinical trial operating rules and procedures. In principle, no change will be made to the main analysis principles, methods, and analysis sets, and all changes (if any) shall be recorded.

7.9 Selection criteria for subjects included in the analysis and the rationale

Full Analysis Set (FAS): A set of subjects determined according to the Intention To Treat principle, which refers to a data set composed of all subjects who have signed an informed consent form and used the investigational medical device. For subjects whose primary efficacy evaluation is not observed, different strategies will be adopted to intercept the missing data.

Per-Protocol Set (PPS): refers to a subset of treatment population who have all finished the trial and have no severe deviation from the protocol (i.e., violations of subjects of the clinical trial against the inclusion criteria or exclusion criteria).

Safety Set (SS): refers to the set of all subjects who have signed an informed consent form, used the investigational medical device, and have at least one safety evaluation result.
Efficacy analysis will be performed based on the Full Analysis Set and Per-Protocol Set. All demographic analysis at baseline will be performed based on the Full Analysis Set, and the safety evaluation will be performed on the Safety Set.

7.10 Special information excluded for verification of the hypothesis and the rationale (if applicable)

Not applicable.

8. Monitoring Plan

Sponsor will appoint Monitors to regularly monitor the clinical trial institutions participating in the clinical trial to ensure that the clinical trial is conducted in accordance with the study protocol, ethics committee requirements and relevant regulations. The Monitors' monitoring plan is as follows:

(1) Site initiation visit in each clinical trial institution: it will be held after the approval of the Ethics Committee and the signing of the clinical trial agreement The purpose is to ensure that investigators and study teams obtain necessary training, fully understand the clinical trial plan and other study documents, and ensure that the documents and clinical supplies required for clinical trials are in place before the site initiation visit.
(2) Monitoring visit of first patient enrolment in each clinical institution: The visit will be conducted as soon as possible after the first subject is enrolled in the clinical trial institution. The purpose is to ensure that the enrolled subjects met the inclusion criteria of the clinical trial, that all required examinations are completed, that the investigators and their study team fully understand the requirements of the clinical trial, and that issues are discovered and dealt with in advance.
(3) Routine monitoring visit in each clinical institution: After the initiation to the end of the clinical trial, monitoring visits will be conducted every two weeks for the first two months of the enrollment period, and once a month thereafter, to ensure that all the enrolled subjects meet the inclusion criteria of the clinical trial, complete the required examinations, and receive smooth treatment of the enrolled subjects. Verify 100% of data in case report form and source data to ensure proper management of adverse events, follow up and resolve existing issues. Any change in the monitoring plan shall be approved by Sponsor in advance.
(4) Site Close Visit: after all subjects have completed follow-up visits, clinical trial report and all existing problems have been properly resolved. The purpose of which is to ensure that investigators and clinical trial institutions fully understand the requirements of clinical trial archiving and the possible auditors of clinical trials by regulatory authorities.
(5) Monitor will complete the monitoring report after each monitoring visit.

9. Data Management

(1) Database setup

In this trial, an electronic data capture system is proposed to be used to establish the database, which conforms to the *Technical Guideline for Electronic Data Capture for Clinical Trials*. Each center has its own account and password, and the investigators of each center shall properly keep the account information.

(2) Data entry

Before the official use of the database, the data management department shall draft the instructions for use of the database, and provide the investigators with training on the use of the database. The monitors shall complete the training for the investigators and keep the training records before the formal input of information.

(3) Data verification

The project manager and statistician shall attend the meeting to discuss the draft version of data verification plan, and all contents of the meeting must be recorded.

The data verification plan shall focus on the following items: inclusion and exclusion criteria, logicality and consistency verification, missing items verification, time window verification, protocol deviation

verification, baseline data verification, medication as well as adverse events and serious adverse events during hospitalization and follow-up periods.

(4) Data query

The data query comes from medical and procedure verifications; all data queries must be verified against the corresponding case report form. Those that cannot be verified by a computer program shall be subject to manual verification, which must include all data points.

The monitor shall resolve each batch of electronic data queries according to the schedule and feed them back to the data management department.

(5) Database locking and transfer

The database shall be locked if the following conditions are met:

All queries are resolved and data updated; the statistical analysis plan is finalized.

The database locking document shall be signed after all the previous conditions are met. The clinical data specialist shall transfer the final database to the statistician for statistical analysis after the database is locked.

10. Feasibility Analysis

10.1 Feasibility analysis of success

JuggerStitch™ is made of all-soft material, which has little interference and trauma to surrounding tissues. Under unique in design, the two soft anchors are connected by a knot-free, self-locking suture ring. Compared to implants that use sliding knots to lock the repair site, the technique improves meniscal tissue retention and the surgeon's control over the repair site. The operation is simple with complete suture and no knot. Compared with the existing mainstream products, the mechanical properties are more than 60% higher, and the success rate of surgery can be greatly improved.

Meanwhile, JuggerStitch™ has been launched in the United States and has a certain clinical application basis in the United States. No serious safety events, such as serious adverse reactions and device deficiencies have been found since the device was launched. Due to the low risk of injury of the medical device used in this trial, subject compliance is high and the possibility of case drop is low.

All the clinical trial institutions participating in this clinical trial are authoritative entities in the field of orthopedics or sports medicine in China, and have medical equipment and resources that can meet the requirements of this clinical trial; all participants have high level of medical literacy and professional qualifications, which provides professional technical support for the design and implementation of this clinical trial protocol. At the same time, since the investigational medical device has been marketed abroad, and this clinical trial is to verify its safety and efficacy to provide support for marketing and registration in China, this clinical trial is expected to have quite high probability of success.

10.2 Feasibility analysis of failure

10.2.1 Analysis of risk factors regarding the investigational medical device

This clinical trial is to implant the investigational medical device through the arthroscopic shoulder surgery, and the potential adverse events (AEs) possibly related to the surgery include infection, deep vein thrombosis, brachial plexus spasm, cardiogenic shock, severe respiratory depression, and articular cartilage injuries, etc. after implantation of the investigational medical device, adverse events may occur, including nonunion or delayed union of bone, damage to implant or implant rupture, implant migration or loosening, rejection of the body to the implant, pain or paresthesia due to the presence of the implant, osteonecrosis, poor healing, bone cyst formation, and secondary cartilage injuries. However, these risks have been specified in the ICF, and the subjects participating in this study will not have additional risks due to the

treatment or receive other additional auxiliary tests or treatments. Moreover, this investigational medical device is a marketed product approved by the US FDA and has been applied for clinical use in the US for over 2 years. No SAEs definitely or possibly related to the device have occurred during its use.

10.2.2 Analysis of the risk of investigator-related bias in the clinical trial

The investigators participating in this clinical trial will be properly trained, and the clinical trial procedures and treatment as well as the collection of follow-up data will be implemented in compliance with the requirements of relevant standards. In addition, the clinical trial institutions conducting this clinical trial are all excellent teams in sports medicine in China, with excellent experience and techniques in clinical treatment and surgery. As such, the risk of failure caused by investigators is low.

10.2.3 Analysis of risks regarding the subjects

Since the investigational medical device has high requirements for early postoperative rehabilitation exercise, the early engagement of the subjects in postoperative rehabilitation exercise may lead to failure of the investigational medical device and AEs. At the same time, the excessive withdrawal of subjects due to the failure of the investigational medical device and AEs may also lead to the failure of the clinical trial. The investigational medical device is designed to be an innovative soft anchor, with small damage caused at implantation. The control device (Fast-Fix 360) is also a product that has been marketed abroad for many years and has been applied for clinical use in China for a certain number of years. Considering this, the subjects are expected to have good compliance, and the medical staff participating in the study will provide appropriate education on the precautions for postoperative rehabilitation for the subjects. As a result, the subjects are less likely to withdraw from the trial due to the failure of the investigational medical device postoperatively.

11. Quality Control of the Clinical Trial

(1) Qualification of clinical study personnel

Investigators participating in the clinical trial must have the professional expertise, qualifications and abilities in conducting clinical studies, and pass the qualification review. The personnel requirements shall be relatively constant.

(2) Training of clinical study personnel

The monitoring entity of this clinical study will be responsible for training the investigators and relevant staff from various clinical study institutions involved in this study before the initiation of this clinical study on the protocol and the conduct of this clinical study, to ensure that the personnel for the clinical study have adequate understanding and knowledge of the overall situation of the study, protocol, case report form, etc.

(3) Monitoring

Authorized clinical monitors with professional experience in clinical studies will visit clinical study institutions on a regular basis according to the monitoring plan to verify their compliance with the protocol and regulatory requirements, and to conduct raw data verification.

(4) Inspection and audit

The medical products regulatory authorities and the sponsor may entrust inspectors/auditors to conduct systematic inspection/audit on the activities and documents related to this clinical trial so as to evaluate whether the trial is conducted in accordance with the clinical trial protocol, SOP and relevant regulatory requirements, and whether the data of the trial is recorded authentically, accurately and completely in a timely manner.

12. Ethical Issues of the Clinical Trial and Informed Consent

12.1 Ethical considerations

Informed consent of the subjects is a protective measure for the subjects. Before the start of the clinical trial, investigators must have explained the details of this clinical trial to the subjects or their guardians to allow them fully understand and obtain the informed consent. The clinical trial cannot be started until the ICF is signed. If any important updated information related to the investigational medical device is found during the clinical trial, the ICF must be revised accordingly in writing and submitted to the ethics committee. After re-approval, the clinical trial may continue only after the reacquisition of the subjects' informed consent.

12.2 Approval of the clinical trial protocol

This clinical trial must follow the *Good Clinical Practice for Medical Devices*. Before the clinical trial, investigators must submit the clinical trial protocol, ICF and other relevant documents to the medical ethics committee of the hospital where the entity responsible for the clinical trial is located. The clinical trial can only be started after the approval of the ethics committee. Any change to the study protocol can only be implemented after the approval of the ethics committee.

12.3 Informed consent process and text of the ICF

12.3.1 Informed consent process

During the screening of subjects, investigators must explain to the subjects or their guardians the details of this clinical trial, including the content, risks of the clinical trial and subjects' rights and interests, elaborate the contents of the ICF, and seek the patients' opinions on their willingness to participate in the clinical trial. The benefits and risks of this trial must be fully explained to ensure that the patients participating in the trial have undergone adequate informed consent process.

Incapacitated subjects may also enter the clinical trial if the ethics committee agrees in principle and the investigators believe that the subjects' participation in the clinical trial is in their own interests. However, the ICF shall be signed by their guardians and dated before the trial.

When neither the subjects nor their guardians are able to read, a witness shall be present during the informed consent process. After detailed explanation of the ICF, the witness will read the ICF and determine that its content is consistent with the orally informed content. Then the witness will sign and date the ICF with the verbal consent of the subjects or their guardians. However, it shall be noted that the signature of the witness and that of the investigator(s) shall be on the same day.

12.3.2 Text of the ICF

The ICF will mainly include the following contents:

(1) Introduction of the clinical trial project: project name, investigator, sponsor, version number or date of preparation; clarification of the purpose of the clinical trial; description of the process of the trial; statement of the time and duration of the subject's participation; the number and process of follow-up visits.
(2) Description of the possible benefits, discomforts and risks of participation in this clinical trial.
(3) Other alternative treatments for the conditions involved in the clinical trial.
(4) Confidentiality of the clinical trial.
(5) Clarification of the rights of subjects.
(6) Explanation of the measures to deal with the injury caused to the subjects by the investigational medical device.

(7) Subject statement.

13. Provisions on Reporting of AEs and DDs

13.1 Adverse event (AE)

13.1.1 Definition of AE

Adverse Event (AE):

An adverse event is any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in participants, users or other persons, whether or not related to the investigational medical device.

Note 1: This definition includes events related to the investigational medical device or the comparator.

Note 2: This definition includes events related to the procedures involved.

Note 3: For users or other persons, this definition is restricted to events related to investigational medical devices.

Serious Adverse Event (SAE):

A Serious Adverse Event is any adverse event that:

a. led to death.
b. led to serious deterioration in the health of the participant, that either resulted in:
    1. a life-threatening illness or injury, or
    2. a permanent impairment of a body structure or a body function, or
    3. in-patient or prolonged hospitalization, or
    4. medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function.
c. led to fetal distress, fetal death or a congenital abnormality or birth defect.

Note: Planned hospitalization for a pre-existing condition, or a procedure required by the protocol, without serious deterioration in health, is not considered a serious adverse event.

Adverse Device Effect (ADE):

An Adverse Device Effect is an adverse event related to the use of an investigational medical device.

Note 1: This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment implantation, installation, or operation, or any malfunction of the medical device.

Note 2: This definition includes any event resulting from use error or from intentional misuse of the medical device.

Serious Adverse Device Effect (SADE):

A Serious Adverse Device Effect is an adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.

Device Deficiency

A Device Deficiency is defined as an inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance.

Note: Device Deficiencies include malfunctions, use errors, and inadequate labeling.

It is important to document in the study also all device deficiencies that could have led to a medical occurrence but did not lead to an adverse event.

The AEs that may occur during this clinical trial include:

1. AEs possibly related to the surgery

Surgery-related events are divided into general surgical complications, anesthesia-related complications, articular cartilage injuries, postoperative haemarthrosis and peripheral nerve injury, etc.

1） General surgical complications include postoperative infection, deep vein thrombosis, etc.
2） Anesthesia-related complications mainly include brachial plexus spasm, cardiogenic shock, and severe respiratory depression, etc.
3） Headache caused by intraoperative controlled hypotension and neurological deficits caused by cerebral ischemia secondary to hypoperfusion.
4） Articular cartilage injuries are the most common complication of arthroscopic surgery. Cartilage injuries are difficult to repair, so the instrument used may not be forcefully inserted into the joint space or scratched on the surface of the cartilage during arthroscopy and arthroscopic surgery. Instead, the surgical operation shall be performed under direct visualization.
5） Postoperative haemarthrosis is a common postoperative complication, manifested as swelling and pain in the shoulder joint, and bloody fluid after arthrocentesis.
6） Postoperative paresthesia or paralysis of the nerves around the shoulder.
7） Intraoperative or postoperative fracture, and/or postoperative pain.

2. AEs possibly related to the investigational medical device

1） Infection can lead to failure of the procedure.
2） Neurovascular injuries can occur due to surgical trauma.
3） Bending, fracture, loosening, rubbing, and migration of the implant may occur as a result of excessive activity, trauma, or load bearing.
4） Implantation of foreign materials can result in an inflammatory response or allergic reaction.
5） Inadequate healing, which may lead to breakage of the implant or failure of the graft material.
6） Pain, discomfort, or abnormal sensation due to the presence of the device.
7） Necrosis of bone or tissue.

3. Other AEs that occur during the trial.

13.1.2 Intensity of Symptoms

For AEs, the severity or changes in severity shall be recorded at each follow-up visit. The following definitions of severity can be applied:

- ***Mild:***

  The participant is aware of the sign or symptom, but finds it easily tolerated. The event is of little concern to the participant and/or little clinical significance. The event is not expected to have any effect on the participant's overall health or well-being.

- ***Moderate:***

The participant has discomfort enough to cause interference with or a change in usual activities. The event is of some concern to the participant's health or well-being and may require medical intervention and/or close follow-up.

- ***Severe:***
  The event interferes considerable with the participant's usual activities. The event is of definite concern to the participant and/or poses substantial risk to the participant's health or well-being. The event is likely to require medical intervention and/or close follow-up and may be incapacitating or life threatening. Hospitalization and treatment may be required.

Note: The term "severe" refers to the intensity of the event and can be used with any event, without regard to whether or not it meets the criteria for being classified as "serious" or "unanticipated". For example, a participant can have a severe headache, but it is not a serious event.

13.1.3 Outcomes between AEs and the surgery or investigational medical device

Outcome Definitions

The outcome is in relationship to the Adverse Event, not the treatment rendered for the event (if any).

- *Resolved:* The adverse event has been resolved and/or no further treatment is required to treat the reported condition or illness.
- *Tolerated:* The adverse event will most likely never be resolved. The participant "tolerates" the illness or condition as a matter of life.
- *Pending:* Treatment or diagnostic studies were prescribed for the adverse event and the outcome of the adverse event is not yet known.
- *Study Withdrawal:* Due to the adverse event, the participant was withdrawn from the study.
- *Device Removal:* The adverse event resulted in the removal of a study device.
- *Reoperation of Affected Joint:* The adverse event resulted in reoperation of the study joint, but the reoperation did not include removal of a study device.
- *Death:* The outcome indicates the participant died as a direct result of the reported adverse event.

13.1.4 Recording of AEs

Investigators must record in detail all AEs (signs and symptoms) that have occurred in the study on the corresponding CRFs, including those reported by the patients voluntarily or observed during or after the treatment.
The records of the AEs shall describe the following:
(1) Name.
(2) Date of occurrence.
(3) Date of resolution/relief (duration).
(4) Determination of the severity of the AE.
(5) Investigators must make judgment on the possible causality between the AEs and the investigational device or surgery.
(6) Actions taken (if any).
(7) Outcome.

13.3 Device deficiencies (DDs)

Device Deficiency

A Device Deficiency is defined as an inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance.

Note: Device Deficiencies include malfunctions, use errors, and inadequate labeling.

It is important to document in the study also all device deficiencies that could have led to a medical occurrence but did not lead to an adverse event.

13.4 Safety Management – Medical Events/Adverse Events

Adverse events are required to be reported on the **Adverse Event Report Form**. The completed **Adverse Event Report Form** must be submitted to the Sponsor in a timely manner. The Investigator or Designee will also promptly provide the Sponsor with any additional requested information required for the Sponsor to comply with regulatory requirements. If applicable per their reporting requirements, the Investigator or Designee will also report applicable adverse event(s) to their EC.

The following definitions are from ISO 14155:2011.

Reporting and Documentation of Adverse Events and Adverse Device Effects

Adverse Events and Adverse Device Effects (Table 1) have to be documented on the Adverse Event Report form over the whole time of the investigation including information on the date of onset, treatment and resolution, as well as assessment of both the seriousness and the relationship to the study device. Adverse Events that are deemed unrelated to the investigational device, the study protocol or procedure by the investigator will not be reported or followed. Further, the outcome of complications has to be documented and any changes in outcome are to be updated during the course of the study. In case of early termination of the study, further follow-up of the patient shall proceed according to the hospital's standard procedure.

Reporting and Documentation of Serious Adverse Events, Serious Adverse Device Effects, and Device Deficiencies

Serious Adverse Events and **Serious Adverse Device Effects** have to be **reported to the Sponsor as soon as possible**. The incidence has to be documented on the **Adverse Event Report form** over the whole time of the investigation including information on the date of onset, treatment and resolution, as well as assessment of both the seriousness and the relationship to the study device based on the evaluation of the investigator. The outcome of such complications has to be documented and any changes in outcome have to be updated during the course of the study. In case of early termination of the study, further follow-up of the study participant shall proceed according to the hospital's standard procedure.

Device Deficiencies that did not lead to an adverse event but **could have led** to a medical occurrence if suitable actions had not been taken, if intervention had not been made or if circumstances had been less fortunate shall be **reported to the Sponsor as soon as possible**, as well.

The **Investigator** is responsible for reporting all SAEs, SADEs and Device Deficiencies that could have led to a SADE to the Ethics Committee.

The contact information is as follows:

- Name of the sponsor: ZIMMER (Shanghai) Medical International Trading Co., Ltd.
- Address of the sponsor: Floor 19/21, Changfang International Plaza, No. 555 Loushanguan Road, Changning District, Shanghai
- Contact of the sponsor: Lijie Wang

- Contact information of the sponsor: 021-22206116

14. Deviations from and Amendments to the Clinical Investigation Plan

14.1 Protocol Deviation

(1) Subjects who fail to meet any of the inclusion criteria, or meet any of the exclusion criteria are included in the clinical trial.
(2) The subjects do not sign the ICF as required; the subjects only sign the ICF after participation in the trial.
(3) Test or examinations for safety indicators, primary efficacy indicators or key secondary efficacy indicators are not conducted as required in the protocol.
(4) The subjects fail to come for follow-up within the time window specified in the protocol.
(5) Loss to follow-up.
(6) Serious adverse events are not reported or reported in time.
(7) Any serious violation of the GCP principles in the implementation of the protocol, such as improper process of obtaining informed consent, etc.

14.2 Protocol Amendments

Neither the investigator nor the sponsor shall carry out any behavior that deviates from or changes the protocol without the mutual consent of both the investigator and the sponsor. And the revised clinical trial protocol shall be reviewed by the ethics committee with comments provided based on the revised content. Amendments to the protocol will be submitted to the corresponding ethics committees and regulatory authorities in accordance with relevant regulatory requirements.

15. Direct Access to Source Documents

The source documents of this trial include the medical records of subjects, ICFs, subject screening and enrollment log, subject identification code form, medical documents of subjects (such as physical examination reports and chemical test reports, etc.), and usage record form of the investigational medical devices, etc.
The source data of this trial include: name, date of birth, gender, trial identification code of subjects; protocol number, name and model of the investigational medical device; start date for trial screening or enrollment; date of use of the investigational medical device and model; investigator's signature; SAEs and their handling; laboratory specimen collection date, results and report date; physical examination results and report date; monitor's signature.
The monitors, auditors, ethics committees related to the trial and the regulatory authorities may have direct access to these source documents and source data to verify the procedures or data of the trial while conforming to the provisions on confidentiality, and such access is authorized by subjects through signing the written ICF.

16. Finance and Insurance

Refer to the statement in the contract signed between the clinical trial institution and the sponsor.

17. Clinical Study Report

After the end of the clinical trial, the investigator of each participating site should issue a signed and dated clinical trial summary respectively, which should be submitted to the leading clinical trial institution after reviewed, dated and stamped by the medical device clinical trial management department of such site;

The principal investigator of the leading clinical trial institution should complete a signed and dated clinical trial report according to the summaries, which should then be submitted to the sponsor after reviewed, dated and stamped by the medical device clinical trial management department of the leading clinical trial institution. The clinical trial report should include:

(1) General information
(2) Summary
(3) Introduction
(4) Objective of the clinical trial
(5) Method of the clinical trial
(6) Content of the clinical trial
(7) General clinical data
(8) Investigational medical device and control medical device/control diagnosis and treatment method
(9) Statistical analysis method and evaluation method used
(10) Clinical evaluation criteria
(11) Organizational structure of the clinical trial
(12) Ethical compliance statement
(13) Results of the clinical trial
(14) AEs found in the clinical trial and their handling
(15) Analysis and discussion of clinical trial results, especially for indications, scope of application, contraindications and precautions
(16) Conclusion of the clinical trial
(17) Problems and suggestions for improvement
(18) List of trial personnel
(19) Other matters to be addressed
(20) Opinions of the investigator and clinical trial management department of the clinical trial institution;

18. Confidentiality

The investigator will maintain all personal data of the subjects in a special place and keep it strictly confidential without disclosure. Only the initials and case numbers of the subjects will appear in the report.

The results of the trial are for research purposes only. Except for that, the personal data of the subjects participating in the trial will be kept confidential.

The materials provided by the sponsor to the investigators (including this clinical trial protocol) are nonpublic information and should be kept confidential.

19. Publication Policy

The results of this clinical trial may be published and disclosed as scientific literature. All data on this clinical trial are considered confidential, and proprietary to the sponsor. The investigators may not publish and use the data from this clinical trial for data disclosure without the written permission of the sponsor.

20. Responsibilities of Each Party

20.1 Responsibilities of the sponsor

(1) The sponsor should be responsible for sponsoring, applying for, organizing, and monitoring the clinical trial, as well as for its authenticity and reliability.
(2) The sponsor should be responsible for organizing the preparation and modification of the investigator's brochure, clinical trial protocol, ICF, CRF, relevant standard operating procedures and other relevant documents, and responsible for carrying out training necessary for the conduct of the clinical trial.
(3) The sponsor should select clinical trial institutions and investigators from the qualified medical device clinical trial institutions based on the characteristics of the investigational medical device, and should provide the clinical trial institutions and investigators with the latest investigator's brochure and other relevant documents for them to decide whether they can undertake this clinical trial before signing the clinical trial agreement with the clinical trial institution.
(4) During the clinical trial, the sponsor should make modifications to the investigator's brochure and other relevant documents in a timely manner if aware of any important information that affects the clinical trial, and should submit the modifications to the ethics committee for approval through the medical device clinical trial management department of the clinical trial institution.
(5) The sponsor should reach a written agreement with the clinical trial institutions and the investigators on relevant details of the clinical trial.
(6) The sponsor should be responsible for the safety of the investigational medical device in the clinical trial.
(7) The sponsor should notify the medical device clinical trial management department of all clinical trial institutions within 5 days, with reasons explained in writing in case of a decision to suspend or terminate the clinical trial.
(8) The sponsor should ensure that all investigators for conduct of the clinical trial strictly follow the clinical trial protocol, and should point out the problem and urge for corrections if it is found that the clinical trial institutions and investigators fail to comply with relevant laws and regulations, the SOPs and this clinical trial protocol; if there is serious noncompliance or such condition remains uncorrected, the sponsor should terminate the trial and report to the medical products regulatory authority at the level of province, autonomous region, and municipality where the clinical trial institution is located as well as the National Medical Products Administration.
(9) The sponsor should bear the treatment cost for the subjects who have suffered from injuries or deaths related to the clinical trial as well as the corresponding economic compensation, except that the damage is caused by the fault of the medical institutions and their medical staff in the diagnosis and treatment operations.
(10) The sponsor should be responsible for the monitoring and audit of the clinical trial.
(11) For SAEs and MDDs that may lead to SAEs, the sponsor, after being notified, should report to the medical products regulatory authority where the trial is filed and the competent health authority at the same level within 5 working days, and should at the same time, notify other clinical trial institutions and investigators participating in the clinical trial, who should notify their respective ethics committee in a timely manner through the medical device clinical trial management department of their respective clinical trial institution.
(12) The sponsor should ensure that the clinical data in the electronic clinical database or remote electronic clinical data system is controlled and authentic, and create complete verification documents.

(13) The sponsor should ensure that the CRF is rigorously and reasonably designed to allow the coordinating investigators to obtain all data of the clinical trial institution in the respective sub-site.

20.2 Responsibilities of the clinical trial institutions and investigators

(1) Before accepting the clinical trial project, the clinical trial institutions should evaluate their relevant resources to decide whether to accept the clinical trial project based on the characteristics of the investigational medical device.
(2) The clinical trial institutions should properly keep the clinical trial records and essential documents as agreed with the sponsor.
(3) Investigators in charge of the clinical trial should have corresponding qualifications.
(4) Before the start of the clinical trial, the medical device clinical trial management department of the clinical trial institutions should cooperate with the sponsor to submit an application to the ethics committee as well as other relevant documents as required.
(5) Investigators should ensure that the relevant staff involved in the trial are familiar with the principles, scope of application, product performance, handling methods, installation requirements and technical indicators of the investigational medical device, understand the pre-clinical study data and safety data of the investigational medical device, and master the prevention and emergency treatment methods for the risks that may arise from the clinical trial.
(6) Investigators should ensure that the investigational medical device is only used for the subjects of this clinical trial, without charging any fees.
(7) Investigators should strictly follow the clinical trial protocol, and should not deviate from or substantially change the protocol without the approval of the sponsor and the ethics committee, or without the approval of the National Medical Products Administration as required. However, reporting may be made subsequently in writing if the subjects are faced with immediate hazards and other emergencies that require immediate mitigation.
(8) Investigators should be responsible for recruiting subjects, and performing informed consent with the subjects or their guardians.
(9) Investigators or other personnel involved in the trial should not force or otherwise improperly induce the subjects to participate in the trial.
(10) When an unexpected AE of the investigational medical device is discovered in the clinical trial, the investigators should work with the sponsor to modify the relevant content of the ICF, and submit to the ethics committee for review in accordance with relevant working procedures, and should ask the affected subjects or their guardians to confirm and re-sign the modified ICF after obtaining approval.
(11) Investigators should be responsible for making medical decisions related to the clinical trial, and in the event of AEs related to the clinical trial, the clinical trial institutions and investigators should ensure that the subjects are provided with adequate and timely treatment and management.
(12) In the event of SAEs in the clinical trial, investigators should take appropriate measures to treat the subjects immediately, and at the same time, report in writing to the medical device clinical trial management department of their respective clinical trial institution, which should then notify the sponsor in writing. Adverse events are required to be reported on the Adverse Event Report Form. The completed Adverse Event Report Form must be submitted to the Sponsor in a timely manner. The Investigator or Designee will also promptly provide the Sponsor with any additional requested information required for the Sponsor to comply with regulatory requirements. If applicable per their reporting requirements, the Investigator or Designee will also report applicable adverse event(s) to their EC. The Investigator is responsible for reporting all SAEs, SADEs and Device Deficiencies that could have led to a SADE to the Ethics Committee.
(13) Investigators should record all AEs that occur and MDDs discovered during the clinical trial, and work with the sponsor to analyze the cause of the events to prepare a written analysis report where opinions

on continuation, suspension or termination of the trial should be proposed, to submit to the ethics committee for review through the medical device clinical trial management department of the respective clinical trial institution.

(14) Investigators should ensure that the clinical trial data is recorded into the CRF accurately, completely, clearly and in a timely manner.

(15) The clinical trial institutions and investigators should ensure that the data, documents and records formed during the clinical trial are authentic, accurate, clear and secure.

(16) The clinical trial institutions and investigators should accept the monitoring and audit of the sponsor as well as the supervision of the ethics committee, and provide all necessary records related to the trial.

(17) The clinical trial institutions and investigators should notify the subjects, and ensure that the subjects are properly treated and followed up, and should report as required and provide detailed written explanations if the clinical trial needs to be suspended or terminated since it is found that the risks exceed the potential benefits, or sufficient results have been obtained for determining the safety and efficacy of the investigational medical device.

(18) The clinical trial institutions and investigators should report to the medical products regulatory authority at the level of province, autonomous region, or municipality where the sponsor is located or the National Medical Products Administration if it is found that the sponsor has violated relevant regulations or requests to change the trial data or conclusions.

(19) At the end of the clinical trial, investigators should ensure that all records and reports are completed, and submit the necessary clinical data as required to their respective clinical trial institution.

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22. Investigator's Statement

I agree:

1. To conduct this clinical trial in strict accordance with the Declaration of Helsinki, the current laws and regulations in China and the requirements of this clinical trial protocol.
2. To accurately record all required data in the CRF and complete the clinical trial report on time.
3. To use the investigational medical device only for this clinical trial, and to completely and accurately record the receipt and use of the investigational medical device during the clinical trial and preserve the records.
4. To allow the monitors, auditors authorized or dispatched by the sponsor and the regulatory authorities to conduct monitoring, audit and inspection on the clinical trial.
5. To strictly fulfill the terms of the clinical trial contract/agreement signed between the parties concerned.

I have read through the clinical trial protocol, including the statement above, and I agree with all the contents.

Investigator's opinion Signature (seal) MM-DD-YYYY

23. Protocol Approval Page

Opinion of the medical device clinical trial institution (Seal) MM-DD-YYYY

Sponsor’s opinion: (Seal) MM-DD-YYYY

Appendix 1 Lysholm Knee Score [1]

Items and Scoring Scale	Score
1. Limp	
I have no limp when I walk	5
I have a slight or periodical limp when I walk	3
I have a severe and constant limp when I walk	0
2. Using cane or crutches	
I do not use a cane or crutches	5
I use a cane or crutches with some weight-bearing	2
Putting weight on my hurt leg is impossible	0
3. Locking sensation in the knee	
I have no locking and no catching sensation in my knee	15
I have catching sensation but no locking sensation in my knee	10
My knee locks occasionally	6
My knee locks frequently	2
My knee feels locked at this moment	0
4. Giving way sensation from the knee	
My knee gives way	25
My knee rarely gives way, only during athletics or vigorous activity	20
My knee frequently gives way during athletics or other vigorous activity. In turn,	15
I am unable to participate in these activities.	10
My knee frequently gives way during daily activities.	5
My knee often gives way during daily activities.	0
My knee gives way every step I take.	
5. Pain	
I have on pain in my knee	25
I have intermittent or slight pain in my knee during vigorous	20
I have marked pain in my knee during vigorous activities	15
I have marked pain in my knee during or after walking more than 1 mile	10
I have marked pain in my knee during or after walking less than 1 mile	5
I have constant pain in my pain	0
6. Swelling	
I have swelling in my knee	10
I have swelling in my knee only after vigorous activities	6
I have swelling in my knee only after ordinary activities	2
I have swelling constantly in my knee	0
7. Climbing stairs	
I have no problems climbing stairs	10
I have slight problems climbing stairs	6
I can climb stairs only one at a time	2
Climbing stairs is impossible for me	0
8. Squatting	
I have no problems squatting	5
I have slight problems squatting	4
I cannot squat beyond a 90 degree bend my knee	1
Squatting is impossible because of my knee	0

[1] Tegner Y, Lysholm J. Rating systems in the evaluation of knee ligament injuries. Clin Orthop Relat Res. 1985; 198:43–9.

Appendix 2 Immediate device success rate

Device success rate refers to the successful suturing of the injured site without any additional instruments (except matching surgical tools) during the operation.

Device Success Rate= Number of successfully implanted anchors/Total number of implanted anchors ×100%

Appendix 3 Tegner Activity Score [1]

Please indicate in the spaces below the HIGHEST level of activity that you participated in BEFORE YOUR INJURY and the highest level you are able to participate in CURRENTLY.	Score
Competitive sports-soccer, football, rugby (national elite)	Level 10
Competitive sports-soccer, football, rugby (lower divisions), ice hockey, wresting, gymnastics, basketball	Level 9
Competitive sports-racquetball or bandy, squash or badminton, track and field athletics (jumping, etc.), down-hilling skiing	Level 8
Competitive sports-tennis, running, motorcars speedway, handball Recreational sports-soccer, football, rugby, bandy, ice hockey, basketball, squash, racquetball, running	Level 7
Recreational sports- tennis and badminton, handball, racquetball, down-hill skiing, jogging at least 5 times per week	Level 6
Work- heavy labor (construction, etc.) Competitive sports- cycling, cross-country skiing, Recreational sports- jogging on uneven ground at least twice weekly	Level 5
Work- moderately heavy labor (e.g. truck driving, etc.)	Level 4
Work- light labor (nursing, etc.)	Level 3
Work- light labor Walking on uneven ground possible, but impossible to back pack or hike	Level 2
Work- sedentary (secretarial, etc.)	Level 1
Sick leave or disability pension because of knee problems	Level 0

[1] Y Tegner and J Lysolm. Rating Systems in the Evaluation of Knee Ligament Injuries. Clinical Orthopedics and Related Research. Vol. 198: 43-49, 1985.

Appendix 3 VAS [1]

The degree of pain is judged on a scale of 0-10cm. 0 meant no pain, the degree of pain increased with the increase of the value, and 10 meant unbearable pain.

[1] Pincus T, Bergman M, Sokka T,et al. Visual analog scales in formats other than a 10 centimeter horizontal line to assess pain and other clinical data. J Rheumatol 2008;35(8):1550–1558.

Appendix 5 International Cartilage Repair Society, ICRS [1]

Grade	Arthroscopic appearance
Grade I	there are softening and swelling of the cartilage
Grade II	there are fragmentation and fissuring in an area half an inch or less in diameter
Grade III	there are fragmentation and fissuring an area more than half an inch in diameter is involved
Grade IV	there is erosion of cartilage down to bone

[1] Outerbridge RE. The etiology of chondromalacia patellae. J Bone Joint Surg Br 1961;43B:752e67

Appendix 6 Kellgren Lawrence Classification for Knee Osteoarthritis [1]

Grade	X-ray Findings
Grade 0	No lesion (Normal)
Grade I	Slight formation of osteophytes on joint margin
Grade II	Formation of osteophytes on joint margin but not involve joint space
Grade III	Moderate narrowing of joint space
Grade IV	Narrowing of joint space associated with sclerosis of subchondral bone

[1] Kellgren JH, Lawrence J. The epidemiology of chronic rheumatism. In: Atlas of Standard Radiographs of Arthritis, Volume II. Oxford, UK: Blackwell Scientific; 1963.

Appendix 7 Lists of Investigational Products

REF	Description	Materials	Standards
110024772	JuggerStitch Meniscal Device Straight Implant	PET / ABS / PTFR / Stainless Steel / Copolyester / PEB AX / UHMEWP / PP	ASTM F138 ASTM F899
110024773	JuggerStitch Meniscal Device Curved Implant	PET / ABS / PTFR / Stainless Steel / Copolyester / PEB AX / UHMEWP / PP	ASTM F138 ASTM F899
110027358	JuggerStitch Meniscal Device Half Pipe Cannula Sled	Stainless Steel	ASTM F899
110031679	JuggerStitch Meniscal Device Straight Implant	ABS / PC / Stainless Steel	/

Appendix 8 Specialized Physical Examinations

Lachman Test:

Patient is in supine or prone position with knee flexion of 30°. Surgeon to ho ld the distal lateral femur with one hand and the medial upper tibia with the other hand. The direction of force shall be anterior and posterior of the tibia, the result is positive when compared with the healthy side. For example, significant anterior tibia movement is considered as anterior cruciate ligament or posterior cruciate ligament injury.

The Anterior Drawer Test, ADT:

Patient is in supine position with lower extremity bend at 90 and hip flexion at 45, foot are put on the examining table, surgeon sit on the foot, place thumbs in front of patient's knees, with the remaining four fingers behind the knees, pull the tibia forward, two thumbs feelings on both sides of the tibia forward relative to the migration of the femur, to be compared with the contralateral, if the tibia moved forward, it means that ADT test is positive, which suggests the injury of anterior cruciate ligament injury.

Valgus Stress Test:

Patient is in supine position, unbend the knee joint, surgeon put one hand in the lateral femoral condyle, place the other hand on the ankle and apply gentle valgus stress, if medial pain is extremely suggests medial collateral ligament injury in the knee joint. Repeat the test with knee flexion of 90°, the healthy side should be compared during the examination, positive extension indicates combined injury of medial collateral ligament, anterior cruciate ligament, posterior oblique ligament and posterior medial joint capsule, positive flexion at 30° indicates independent medial collateral ligament injury.

Varus Stress Test:

Similar to the valgus stress test, also needs to be examined when the knee joint is completely unbent and flexion at 30°, and the affected side should be compared during the exa mination. If the varus stress instability occurs in both the unbent and flexion positions, it indicates the injury of the posterior cruciate ligament and the lateral collateral ligament complex.

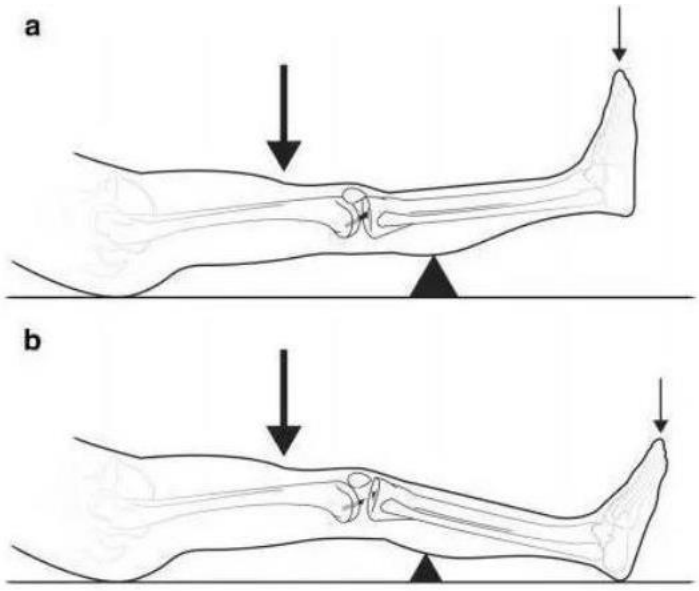
McMurray Test:

Patient is in supine position and the knee joint is in flexion completely, surgeon holds ankle with one hand and rotates lower leg with another supporting knee, if the meniscus is uneasy, it may pop, pain and pop when internal rotation, indicating that there is a problem with the external meniscus. It occurs in external rotation indicating a problem with the medial meniscus. If there is pain/pop in the knee position, it is associated with the posterior corner of the meniscus. If there is pain/popping as the knee extension Angle increases, there is a problem with the front corner.

The "Lever Sign":

a. Lever negative force diagram, use the fist as a fulcrum on patient's calf and with the other hand press down on quadriceps (large arrow), the ACL counteracts the downward weight of the foot (little arrows);

b. Lever positive force diagram, use the fist as a fulcrum on the calf and the other hand to press down on the quadriceps (large arrow), the torn ACL does not counteract the downward force of gravity on the foot, which remains on the examination table (small arrows).


a
b

Appendix 9 Postoperative Rehabilitation Guidance

Postoperative Rehabilitation for Meniscus suture

Principles of rehabilitation exercise: Painless, Cold Compress, Slow Movement

Muscle strengthening:

1） Within 3 weeks:
   a. Move the instep up and down to contract the leg muscles (ankle pump) ;
   b. Tighten the thigh muscles while the knee is straightened, for 5-10 seconds ;
   c. Raise the straight leg 30 to 50 degrees, for 5-10 seconds;

2） Weeks 4~8
   a. Start riding a stationary bike on flat ground;
   b. Straight leg elevations (sandbags can be gradually added to increase the load);
   c. Tighten the big leg muscles at different angles;
   d. Elastic belt exercises;
   e. Up and down the steps;
   f. Half-squat with your back against the wall

3） After 2 months
   a. Resistance to joint extension and flexion can be achieved on the comprehensive rehabilitation training device, and the resistance amount can be specifically set.
   b. Gait exercise;
   c. Hydrotherapy

ROM exercise:

1） Knee flexion:
   a. within 0-4 weeks: less than 90
   b. within 4-6 weeks: less than 90-120
   c. Step by step return to normal after 6 weeks
2） Flexible patella (inside, upper side, lower side)
3） Avoid squats within 3 months postoperatively
4） Avoid knee joint emergency stop, sudden change of direction, axial movement to prevent retear of meniscus within 6 months postoperatively

Weight-bearing, Walking:

0-6 weeks: Walking on two crutches, partial weight bearing, gradual transition;
Standard to walk without crutches: no swelling, basically normal flexion and extension, walk painlessly, follow with surgeon’s guidance.

Cold Compress:

Within 1 week: every 2 to 3 hours, about 5 to 6 times a day, no need when sleeping at night;
After 1 week: according to the degree of swelling, the number of times can be appropriately reduced, about 2-3 days;
Recovery phase: Immediately after each activity training session; 10 for 15 minutes every time.

Appendix 10 MRI Classification for Meniscus Tear after Arthroscopy Repair [1]

Grade	Standard
Grade 0	Normal
Grade I	There were focal globular or elliptical signal enhancement shadows in the meniscus, which did not reach the articular surface.
Grade II	The high signal in the meniscus is horizontal and linear, which extends to the capsular margin of the meniscus joint.
Grade III	High signal in the meniscus reaches the articular surface of the meniscus

[1] Crues JV, Mink J, Levy TL, et al. Meniscal tears of the knee: accuracy of MR imaging. Radiology. 1987 Aug;164(2):445-8.