Sponsor Name and Address:	Smith & Nephew Orthopaedics AG Oberneuhofstrasse 10d 6340 Baar Switzerland
Investigational	SUTUREFIX ULTRA Suture Anchor SUTUREFIX CURVED Suture Anchor
Protocol Author(s):	Fiona Schlomowitsch; Mehluli Ndlovu

1. SIGNATURES

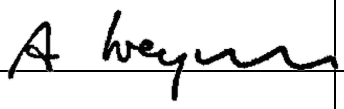
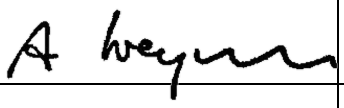
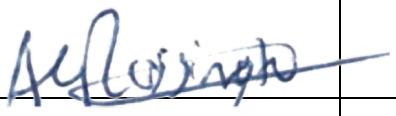
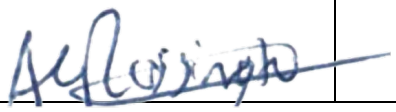
1.1 PRINCIPAL INVESTIGATOR SIGNATURE PAGE

This page will be returned to Smith & Nephew Orthopaedics AG and a copy retained at the investigational site.

I have read the attached protocol entitled I have read the attached protocol entitled", version 1.0, dated 09/MAY/2018, and agree to abide by all provisions set forth herein.
I agree to comply with the Investigator's Obligations stipulated in Section 21.4 of the protocol,
I agree to ensure that the confidential information contained in this document will not be used for any purpose other than the conduct of the described clinical investigation without the prior written consent of Smith & Nephew Orthopaedics AG

Name	**Signature**	**Date Signed** (DD/MMM/YYYY)

1.2 SPONSOR APPROVAL

Role	Approver Name	Approver Signature	Date Approved (DD/MMM/YYYY)
Head of Global Clinical Operations	Andy Weymann for Robert Eichelkraut		10/MAY/2018
Head of Global Clinical Strategy	Andy Weymann for Beate Hanson		10/MAY/2018
Head of Global Biostatistics	Alan Rossington		11/MAY/2018
Head of Global Data Sciences	Alan Rossington		11/MAY/2018

2. SYNOPSIS

Title of Study:	Prospective, Multicenter, Post-Market 1 year Clinical Follow-up Study to evaluate safety and performance of the SUTUREFIX ULTRA and SUTUREFIX CURVED Suture Anchors in shoulder and hip arthroscopic repair
Study Design:	• Prospective • Approximately 8 sites: - 4 sites for hip group - 4 sites for shoulder group • Two-arms (hip and shoulder)
Study Type:	Post-market study
Study Product:	SUTUREFIX ULTRA and SUTUREFIX CURVED Suture Anchor
Study Purpose:	Prospective, multicenter, post-market clinical follow-up to support CE Mark certification and Notified Body (BSI) for the Shoulder and Hip repair indications. Data to confirm safety and performance levels acceptable for the risk benefit profile of the devices.
Primary Objective:	To demonstrate the performance of the SUTUREFIX ULTRA and SUTUREFIX CURVED Suture Anchors in hip and shoulder for arthroscopic treatment over a time period of 6 months after arthroscopy.
Secondary Objective:	To assess safety and performance, supporting the use of SUTUREFIX ULTRA and SUTUREFIX CURVED Suture Anchors in hip and shoulder arthroscopy repair.
Statistical Rationale:	The study sample was decided based on the feasibility of recruitment, enrolment and follow-up considerations. The study is therefore not powered for any statistical testing but will be able to estimate a success rate of 86% with a 95% confidence interval (CI) [75: 97]. Previous studies suggest that the success rate among patients who have undergone any Suture Anchors for arthroscopic

	instability repair is 71-97%.
Sample Size:	A total of 80 subjects; 40 subjects for the shoulder group and 40 subjects for the hip group, will receive at least one device, SUTUREFIX ULTRA and/or SUTUREFIX CURVED Suture Anchor. A sample size of 40 subjects will estimate a success rate of 89% with a 95% confidence interval (CI) [78: 100] with 55% probability.
Number of Study Sites:	Approximately 8 sites: • 4 sites for study hip group • 4 sites for study shoulder group
Targeted Global Regions:	Europe

Inclusion Criteria:	**All subjects** 1. Subject has consented to participate in the study by signing the EC-approved informed consent form 2. Subject is ≥ 18 years of age at time of surgery 3. Subject condition meets proposed indication to SUTUREFIX ULTRA and SUTUREFIX CURVED Suture Anchor 4. Subject requiring shoulder or hip arthroscopic labral repair surgery from physical findings, subject symptoms and radiographic finding 5. Bone quality and quantity must be adequate to allow proper placement of the suture anchor 6. Able to follow instructions. 7. Willing and able to make all required study visits. **Hip subjects** 8. FAI (Femoroacetabular Impingement) **Shoulder subjects** 9. Subject with a history of recurrent dislocation/subluxation of the shoulder Hip
Exclusion Criteria:	**All subjects** 1. Participation in the treatment period of another clinical trial within thirty (30) days of Visit 1 (pre-operative) 2. Women who are pregnant, nursing, or of child-bearing potential who are not utilizing highly effective birth control measures 3. Any subject that meets the definition of a Vulnerable Subject per ISO14155:2011: individual whose willingness to volunteer in a clinical investigation could be unduly influenced by the expectation, whether justified or not, of benefits associated with participation or of retaliatory response from senior members of a hierarchy in case of refusal to participate 4. Subjects with a history of poor compliance with medical treatment 5. Contraindications or hypersensitivity to the use of the SUTUREFIX ULTRA and/or SUTUREFIX CURVED Suture Anchor, or their components (e.g. silicone, polyester). Where material sensitivity is suspected, appropriate tests should be performed and sensitivity ruled out prior to implantation 6. Prior ipsilateral surgeries performed on the joint space 7. Pathological conditions of bone, such as cystic changes or severe osteopenia, which would compromise secure anchor fixation 8. Pathological conditions in the soft tissues to be attached that would impair

	secure fixation by suture 9. Comminuted bone surface, which would compromise secure anchor fixation 10. Physical conditions which would eliminate, or tend to eliminate, adequate anchor support or impair healing 11. Epileptic history **Hip subjects** 12. Dysplasia latera/central less than 20° **Shoulder subjects** 13. Glenoid and/or humeral bone loss considered excessive by the treating orthopaedic surgeon 14. MDI: Multi-directional instability 15. Psychosomatic voluntary shoulder subluxation

Study Duration:	Study duration: 24 months Full analysis: after 12 month follow-up Enrollment period: 12 months
Primary endpoint:	• Clinical success rate, defined as subjects without signs of failure and/or re-intervention at 6 months, as assessed by the surgeon
Secondary endpoint(s):	• Clinical success rate, defined as subjects without signs of failure and/or re-intervention at 12 months, as assessed by the surgeon • Intra-operative anchor deployment success rate • Number of anchors pulled out • Use of additional anchors as a result of intra operative failure • Device-related re-intervention • Safety evaluation at all time points • Post-operative clinical success rate and performance assessed with subject reported outcomes as follows: **All subjects** • Subject pain assessed with a VAS at 6 months* and 12 months* • Subject satisfaction assessed with a VAS at 6 months* and 12 months* • EQ-5D Questionnaire at 6 months* and 12 months* **Hip subjects** • Hip Outcome Score Activities of Daily Living (HOOS-ADL) at 6 months* and 12 months* • Modified Harris Hip Score (HHS) at 6 months* and 12 months* **Shoulder subjects** • ROWE Shoulder Scores at 6 months* and 12 months* • ASES Shoulder Scores at 6 months* and 12 months* • Constant-Murley Shoulder Score at 6 months* and 12 months* * *Patient Reported Outcomes (PROs) are optional and used according to the surgeon's preference*
Safety Data	AEs, SAEs, ADEs, SADE, USADEs

STUDY SCHEMATIC (should be identical to Table 9.1.1-1)

Schedule of events (*as needed)	Visit 1	Visit 2	Visit 3 Visit	Visit 4 Telephone Call or Visit	Visit 5 Unscheduled Visit
	Pre-Operative	Operative through Discharge	6 Months (± 1 M)	12 Months (± 1 M)	
Informed Consent	√				
Inclusion/Exclusion Criteria	√				
Demographics/ Medical History	√				
Intra-operative failure as assessed by the surgeon		√			
Post-operative through Discharge		√			
Post-operative Repair failure			√	√	√
All subjects Pain assessment with VAS	√**		√**	√**	√**
Satisfaction assessment with VAS	√**		√**	√**	√**
EQ-5D questionnaire	√**		√**	√**	√**
Hip HOOS-ADL score	√**		√**	√**	√**
Mod. Harris Hip score	√**		√**	√**	√**
Shoulder ROWE Score	√**		√**	√**	√**
ASES score	√**		√**	√**	√**
Constant-Murley score	√**		√**	√**	√**
MRI / Imaging	√		√*	√*	√*
Adverse Event Assessment		√	√		
End of Study/Exit			√		

* If needed to investigate repair failure

** Patient Reported Outcomes (PROs) are optional and used according to the surgeon's preference

3. CONTENTS

3.1 TABLE OF CONTENTS

3.2 TABLE OF TABLES

3.3 TABLE OF FIGURES

3.4 LIST OF ABBREVIATIONS

Abbreviation	Definition
ADE	Adverse Device Effect(s)
AE	Adverse Event(s)
ASES	American Shoulder and Elbow Surgeons Shoulder Score
BSI	British Standards Institute
CAPA	Corrective and Preventive Action
CE	Conformité Européene
CI	Confidence Interval
CRF	Case Report Form(s)
CRO	Contract Research Organization
CT	Computed Tomography
CTA	Clinical Trial Agreement
CV	Curriculum Vitae
DevD	Device Deficiency(ies)
EQ-5D	EuroQol 5D
FAS	Full Analysis Set Population
FDA	Food and Drug Administration
FAI	Femoroacetabular Impingement
FU	Follow-Up
GCP	Good Clinical Practice
HIPAA	Health Information Portability Accountability Act
HHS	Harris Hip Score
HOOS	Hip Disability and Osteoarthritic Outcome Scores
HOOS-ADL	Hip Outcome Score Activities of Daily Living
IB	Investigator Brochure

Abbreviation	Definition
ICF	Informed Consent Form
ICH	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICMJE	International Committee of Medical Journal Editors
IEC	Independent Ethics Committee
IFU	Instructions for Use
IP	Investigational Product
IRB	Institutional Review Board
ISF	Investigator Site File
ITT	Intention to Treat population
MDI	Multi-directional Instability
MITT	Modified Intention-to-treat Population
MRI	Magnetic Resonance Imaging
NA or N/A	Not Applicable
PI	Principal Investigator
PP	Per-protocol Population
PRO	Subject Report Outcome
ROWE	ROWE Shoulder Score for Instability
S&N	Smith & Nephew
SADE	Serious Adverse Device Effect(s)
SAE	Serious Adverse Event(s)
SAF	Safety population
SAP	Statistical Analysis Plan
SD	Standard Deviation
SLAP	Superior Labrum Anterior-Posterior
USADE	Unanticipated Serious Adverse Device Effect(s)

Abbreviation	Definition
VAS	Visual Analogue Scale

4. INTRODUCTION

4.1 BACKGROUND

Shoulder

The superior labrum and biceps anchor improve joint stability by acting like a secondary stabilizer to the shoulder. Labral injuries are usually associated with anterior shoulder dislocation.[1] Diagnosis can be established through MRI by visualizing the distinct line of signal contrast that lies between the glenoid's osseous structure and the glenoid labrum.[1] SLAP (superior labrum anterior-posterior) lesions which were once mainly associated with overhead throwing athletes, are now being diagnosed in older populations.[2] SLAP Lesions are classified into 4 types based on tear stability and location. SLAP tears are a detachment of the superior glenoid labrum from anterior to posterior with or without involvement of the anchor of the long head of the biceps tendon. These tears are typically the result of traction or compression injuries or repetitive overhead activity.[3-5]

Nonoperative treatment such as physical therapy, strengthening programs, anti-inflammatories and activity modification, should be considered prior to any surgical intervention. The primary goal of conservative treatment is improvement in shoulder range of motion through posterior capsular flexibility and strengthening of the rotator cuff.[6] When conservative treatment fails to improve symptoms, surgical intervention may be required. Surgical treatments can include simple debridement, stabilization of the biceps-labrum complex through repair, or biceps tenodesis.[7]

Several techniques are utilized for SLAP tear repair, the most common consists of repairing the labrum and biceps anchor.[8] The treatment methods for SLAP repair in younger populations as compared to older populations may vary. Older populations have reported pain and stiffness after SLAP repair.[2] In a systematic review of the literature comparing the treatment in patient over 40 years to patients younger, Erickson et al.[2] found similar outcomes in both populations after SLAP repair.

Common complications associated with SLAP repair include hardware failure, glenoid osteochondrolysis, and limited range of motion. Hardware failure can include suture anchor pull out, or iatrogenic cartilage damage during instrumentation. Prominent suture knots or hardware have reportedly caused glenoid osteochondrolysis as well[8]. A scarce vascular supply to the superior labrum near the biceps where shear forces are high can contribute to SLAP repair failure as a result of lack of healing.[8]

Outcomes of SLAP repairs have been reported good throughout the literature, with reported success rates ranging from 71-97%, depending on the type of implant used.[3] Patients typically take up to 6 months to regain full motion after SLAP repairs, as stiffness is a common postoperative occurrence, which can be treated with physical therapy and/or subacromial or glenohumeral injections.[3,4,8]

Return to sport is important for many patients with shoulder injuries. Typically the criteria for patients to return to sport include no pain, normal range of motion (ROM), near normal/normal strength, normal functional ability, and patient subjectivity.[9] Usually 14-16 weeks is enough for athletes to return, however it may take as long as 9-12 months.[9] Patients may be hesitant to return to sport for fear of further injury, but those with no restrictive symptoms should be encouraged to return to full activity.[9]

The Constant score, which was developed in 1986, is also rated on a 100-point scale, of which 35 points are based on patient rating. This outcome measure is validated for shoulder arthroplasty, rotator cuff repair, adhesive capsulitis of the shoulder, and proximal humeral fractures. Like the ASES outcome score, higher Constant scores indicate better outcomes. The minimal clinically important difference for this score is not known.[10]

Hip

The labrum of the hip is a fibrocartilaginous tissue that connects to the osseous edge of the acetabulum, and deepens the acetabular socket while extending coverage of the femoral head. The labrum aids in hip stabilization, by creating negative pressure against distraction and increasing the resistance to dislocation.[11] Femoroacetabular impingement (FAI) is an abnormality of the structure and orientation of the hip joint, which can cause pain and early

hip osteoarthrosis.[12-16] Skendzel et al.[15] reported several retrospective reviews which have shown between 49-87% of all patients with a labral tear, have osseous changes consistent with FAI. Chondral injuries have been associated with labral tears and FAI.[17] [15,18] Confirmation of FAI diagnosis usually is achieved with MRI or CT, by reviewing several parameters such as α angle or head-neck offset for cam-type FAI.[11,18] Conservative treatment, such as rest, physiotherapy, and NSAIDs, is usually the first treatment option after FAI diagnosis.[15,18,19] When conservative treatment fails to improve symptoms, surgical intervention may be required. Surgical treatments include debridement, repair and reconstruction, performed either open, arthroscopically, or mini-open.[11,16,18] When labral repair is performed, suture anchors are typically placed onto the acetabular rim, ensuring they do not violate the extra-articular portion of the bone.[16]

The goal of surgical intervention is to restore normal hip mechanics and treating existing damage. Surgical options to treat FAI include Labral debridement and/or repair.[12] [13,15] In an epidemiology study published in 2017, labral pathology was the most common diagnosis at 82% of the population. Of the 1,124 tears reported, 75.3% were repaired, 13.7% were reconstructed and 7.2% were debrided.[20]

In a systematic review performed by Ayeni et al.[12], arthroscopic management of FAI resulted in postoperative improvements of modified Harris Hip scores that were greater in patients treated with repair as compared to debridement alone. Open management of FAI in the same systematic review[12] reported mixed results, with one study reporting a statistically significant advantage of labral repair over debridement while another study identified reported no differences.

Common complications reported in management of FAI included failures, reoperations, infection and heterotopic bone formation.[12]

4.2 LITERATURE SUMMARY

For this literature review, a thorough analysis of the device usage was conducted for the SUTUREFIX ULTRA Suture and SUTUREFIX CURVED Implants equivalent devices currently

on the market. Relevant literature was found pertaining to all indications of the SUTUREFIX ULTRA Suture Implant, specifically, shoulder. Good clinical outcomes were reported in the published literature. Improvements in Constant-Murley Scores as well as Flexilevel scale of shoulder function (FLEX-SF) scores were recorded.

In 2015, Agrawal and Pietrzak[21] published the first clinical study with an all-suture anchor. JuggerKnot 1.4 was used for the repair of triple labrum lesions. The mean number of anchors used in the repair was 11.5 (9-19). The study demonstrated improvement in patient outcomes, consistent healing of anchor tunnels, return to activity, and high patient satisfaction. The authors, however, stated that it is unclear whether instability rates will increase with time or there will be detrimental effects of placing more number of anchors in the shoulder. Radiographic results revealed that the JuggerKnot Soft Anchor did not hinder diagnostic imaging, and no instances of subchondral cysts or tunnel expansion were noted. The suture anchor tracts appeared to be healing with fibrous tissue.[22]

Boileau et al[22] reported the use of SUTUREFIX for Bankart repair in 76 patients, although no relevant outcomes were reported.

No complications specific to the use of the SutureFix or Juggerknot device were reported in the published literature. One patient (4.34%) fell and required revision capsular shift and labrum repair. [22]

Shoulder

Two clinical publications of the shoulder were identified in the literature which followed 76 patients treated with SutureFix and 18 patients treated with Juggerknot. [24] Mean follow up ranged from 14 to 24 months, with a maximum follow up of 24 months.

Hip

One clinical publication was identified which used the JuggerKnot device in the hip. Matsuda et al., 2015[23] performed a prospective comparative study to compare arthroscopic treatment of global versus focal pincer FAI using a JuggerKnot anchor. The global group consisted of 15 patients (18 hips) and the focal group consisted of 125 patients (129 hips) with a minimum of 2-year follow up. Labral refixation of the posterior rim was performed with a JuggerKnot anchor, it is mentioned that a curved guide was used on occasion, but the number of patients treated with curved devices was not reported.

4.3 STUDY PURPOSE

This is a prospective, multicenter study to evaluate intra-operative, 6 and 12-month safety and performance of the SUTUREFIX ULTRA and SUTUREFIX CURVED Suture Anchors for arthroscopic soft tissue repair to meet PMCF requirements for CE Mark and Notified Body (BSI) when used for any of the following indications:

Hip

- Acetabular labrum repair/reconstruction

Shoulder

- Capsular stabilization
  - Bankart repair
  - Anterior shoulder instability
  - SLAP lesion repairs
  - Capsular shift or capsulolabral reconstructions
- Rotator cuff tear repairs
- Biceps tenodesis
- Acromioclavicular separation repairs
- Deltoid repairs

4.4 SAFETY CONSIDERATIONS

The SUTUREFIX ULTRA and SUTUREFIX CURVED Anchor Systems are intended to be used for soft tissue to bone fixation in the Shoulder and Hip. Representative language of the contraindications and potential adverse effects from SUTUREFIX ULTRA and SUTUREFIX CURVED can be found in the IFU. Cleaning and Sterilization Language can be found on the Reusable Surgical Instruments IFU.

Possible Anticipated Adverse Device Effect (ADE) and anticipated Serious Adverse Device Effect (SADE) as reported in the IFU are:

- Mild inflammatory reaction
- Foreign body reaction
- Infection, both deep and superficial
- Allergic reaction
- Loss of fixation or pullout of suture anchors can occur

Investigators shall record adverse events (AEs) and observed device deficiencies, together with an assessment, in the subject's source data. Investigators are responsible for documenting AEs (AE, ADE, SAE, SADE) as described in section 12.1.1 and device deficiencies on the appropriate CRF and submitting them to the Sponsor according to the timelines described here below. At each contact with the subject, the Investigator must seek information on AEs by specific questioning and, as appropriate, by assessment of the subject. AEs must be recorded in standard English medical terminology.

Unresolved AEs should be followed by the Investigator until the events are resolved, the subject is lost to follow-up or through to the end of the study, whichever timing occurs first. Unresolved AEs at the end of the subject's participation will be monitored by the Investigator as part of the site's normal standard of care.

5. OBJECTIVE(S)

5.1 PRIMARY OBJECTIVE

The purpose of this study is to demonstrate the safety and performance of the SUTUREFIX ULTRA and SUTUREFIX CURVED Suture Anchors in hip and shoulder arthroscopic repair over a time period of 12 months after arthroscopy.

5.1.1 Primary Endpoint

To assess clinical success rate, defined as subjects without signs of failure and/or re-intervention at 6 months, as assessed by the surgeon.

5.2 SECONDARY OBJECTIVE(S)

5.2.1 Secondary Endpoints

To assess safety and performance, supporting the use of SUTUREFIX ULTRA and SUTUREFIX CURVED Suture Anchor in hip and shoulder arthroscopy repair by measuring:

- Clinical success rate, defined as subjects without signs of failure and/or re-intervention at 12 months, as assessed by the surgeon
- Intra-operative anchor deployment success rate
- Number of anchors pulled out
- Use of additional anchors as a result of intra-operative failure
- Device-related re-intervention
- Safety evaluation at all time points
- Post-operative clinical success rate and performance assessed with subject reported outcomes as follows:

All subjects:

- Subject pain assessment with VAS at 6 months* and 12 months*

- Subject satisfaction assessment with VAS at 6 months* and 12 months*
- EQ-5D Questionnaire at 6 months* and 12 months*

Hip subjects:

- Hip Outcome Score Activities of Daily Living (HOOS-ADL) at 6 months* and 12 months*
- Modified Harris Hip Score (HHS) at 6 months* and 12 months*

Shoulder subjects:

- ROWE Shoulder Scores at 6 months* and 12 months*
- ASES Shoulder Scores at 6 months* and 12 months*
- Constant-Murley Shoulder Scores at 6 months* and 12 months*

** Patient Reported Outcomes (PROs) are optional and used according to the surgeon's preference*

6. INVESTIGATIONAL PRODUCT(S)

6.1.1 Investigational Products

The SUTUREFIX Anchor is offered in multiple suture configurations including single and double loaded suture options. The delivery system of these anchors enables the suture implant to be placed in the bone in an un- deployed state. During anchor deployment, tension is applied to the repair sutures. The tension applied to the repair sutures, which are threaded through the anchor suture, cause the anchor suture to bunch up. In its deployed state the anchor has a larger nominal diameter than the hole in which it is inserted, locking it into the bone tunnel (Figure 1). The implanted suture anchor construct retains mechanical stability of the soft tissue to bone construct during the healing period. The anchors are available preloaded with either one #2 suture or two #1 sutures.

The anchor suture is composed of a single strand of #5 braided, silicone-coated, polyester, non-absorbable suture marketed under the trade name DURABRAID™. The repair suture is comprised of non-absorbable, uncoated ultra-high molecular weight polyethylene (UHMWPE) marketed under the trade name ULTRABRAID™.

Figure 1. SUTUREFIX Implant

Figure 2. SUTUREFIX ULTRA

Figure 3. SUTUREFIX ULTRA DRILL

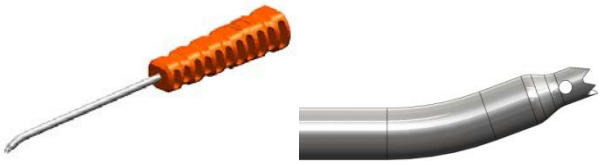
The SUTUREFIX ULTRA Suture Anchor consists of three components; an all suture based implant preloaded onto a rigid insertion device (Figure 2 and 3), hole preparation and insertion accessory instruments. The Smith & Nephew SUTUREFIX CURVED Suture Anchor utilizes the same anchor as the SUTUREFIX ULTRA (Figure 1), however it comes preassembled to a flexible insertion device (Figure 4 and 5). These devices are provided sterile, for single use only.

Figure 4. SUTUREFIX CURVED

Figure 5. SUTUREFIX CURVED DRILL

The instruments included in this file consist of single-use sterile drills (rigid and flexible), as well as reusable drill guides (straight and curved) and obturators (rigid and flexible) (examples seen below in Figures 4 and 5).

Figure 6. Straight obturator and twist drill



Figured 7. Curved Drill Guide

The devices included in this file do not contain any medicinal substances, tissues or blood products.

6.1.2 IP-Control

This is the list of study components.

SUTUREFIX ULTRA Soft Anchors and Instrumentation Systems for Shoulder

Reference #	Description
Anchors	
72203852	SUTUREFIX ULTRA Anchor 1.7 mm S with one Solid Blue (#2) ULTRABRAID[1] Suture
72203853	SUTUREFIX ULTRA Anchor 1.7 mm S with one Blue COBRAID (#2) ULTRABRAID Suture
72203854	SUTUREFIX ULTRA Anchor 1.9 mm S with two Blue, Blue COBRAID (#1) ULTRABRAID Sutures
Drills	
72203855	Twist drill 1.7 mm S
72203856	Twist drill 1.9 mm S
Guides & Obturators	
72203857	Drill Guide crown tip, Reusable, S
72203858	Drill Guide Spike tip, Reusable, S
72203859	Drill Guide Fishmouth tip, Reusable, S
72203861	Obturator, Blunt tip, Reusable, S
72203862	Obturator, Cannulated, Reusable, S
72203863	Obturator, Trocar tip, Reusable, S
Anchor Packs	
72203953	SUTUREFIX Ultra Anchor S, Box of 3 with one Drill 1.7 mm, Disposable
72203954	SUTUREFIX Ultra Anchor S, Box of 3 with one Drill 1.9 mm, Disposable
72203955	SUTUREFIX Ultra Anchor 1.7 mm S, Box of five
72203956	SUTUREFIX Ultra Anchor 1.9 mm S, Box of five
Instrumentation Kits	
72203957	Drill guide, Crown tip, Disposable; Obturator, Blunt, Disposable; 1.7 mm Drill, disposable
72203958	Drill guide, Fishmouth tip, Disposable; Obturator, Blunt, Disposable; 1.7 mm Drill, disposable
72203959	Drill guide, Spiked tip, Disposable; Obturator, Blunt, Disposable; 1.7 mm Drill, disposable
72203960	Drill guide, Crown tip, Disposable; Obturator, Blunt, Disposable; 1.9 mm Drill, disposable
72203961	Drill guide, Fishmouth tip, Disposable; Obturator, Blunt, Disposable; 1.9 mm Drill, disposable

SUTUREFIX ULTRA Soft Anchors and Instrumentation Systems for Hip

Reference #	Description
Anchors	
72203841	SUTUREFIX Ultra Anchor 1.7 mm XL with one (#2) ULTRABRAID suture (blue)
72203842	SUTUREFIX Ultra Anchor 1.7 mm XL with one (#2) ULTRABRAID suture (blue-COBRAID)
Drills	
72203843	SUTUREFIX Ultra Drill 1.7mm XL, Disposable
Guides & Obturators	
72203844	Drill Guide XL, Crown Tip
72203845	Drill Guide XL, Spike Tip
72203846	Obturator XL, Blunt tip
72203899	Obturator XL, Cannulated, Blunt Tip
Knot Pusher	
72203850	ELITE[1] Knot Pusher XL

6.1.3 Ancillary Products

No ancillary products are to be provided.

6.2 Product Use

SUTUREFIX ULTRA and CURVED Suture Anchors are intended for the secure fixation of soft tissue to bone and should be used according to IFU. The non-absorbable suture will remain in the tissue permanently.

Surgeons selected to participate in this study will be experienced with implanting SUTUREFIX ULTRA Suture Anchor and SUTUREFIX CURVED Suture Anchor and no additional training is required.

6.3 Packaging and Labelling

Packaging and labelling will be prepared to meet regulatory requirements.

Commercial products are being used and the standard device procurement and management will be used per site process.

Packaging integrity needs to be confirmed prior to surgery and recorded in the CRF.

6.4 IP/ Ancillary Products and Study Supplies Accountability Procedures

This is a post-market follow-up study. Only commercial available devices are implanted by the hospitals or clinics. All products received regulatory clearance in the countries where the study takes place. Therefore no device accountability is applicable.

6.5 Surgical Technique

All study related procedures with the SUTUREFIX Ultra Suture Anchor and SUTUREFIX Curved Suture Anchor must be performed according to the recommended surgical technique described

in the protocol or in a separate instructional document and product labelling (e.g. IFU and package insert) as applicable.

7. SUBJECT ENROLLMENT AND WITHDRAWAL

7.1 SUBJECT POPULATION

In this study a minimum of 80 subjects will be enrolled, 40 subjects for each group, hip and shoulder. The subjects will be treated with the study device(s) for hip or shoulder instability.

7.2 INCLUSION CRITERIA

Subjects will be considered qualified for enrollment if they meet the following criteria:

1. Subject has consented to participate in the study by signing the EC-approved informed consent form
2. Subject is 18 years of age at time of surgery.
3. Subject condition meets proposed indication to SUTUREFIX ULTRA and SUTUREFIX CURVED Suture Anchor
4. Subject requiring shoulder or hip arthroscopic labral repair surgery from physical findings, subject symptoms and radiographic finding
5. Bone quality and quantity must be adequate to allow proper placement of the anchor
6. Able to follow instructions.
7. Willing and able to make all required study visits.

Hip subjects

8. FAI (Femoroacetabular Impingement)

Shoulder subjects

9. Subject with a history of recurrent dislocation/subluxation of the shoulder

7.3 EXCLUSION CRITERIA

Any one (1) of the following criteria will disqualify a potential subject from participation in the study:

	All subjects
1.	Participation in the treatment period of another clinical trial within thirty (30) days of Visit 1 (pre-operative)
2	Women who are pregnant, nursing, or of child-bearing potential who are not utilizing highly effective birth control measures
3.	Any subject that meets the definition of a Vulnerable Subject per ISO14155:2011: individual whose willingness to volunteer in a clinical investigation could be unduly influenced by the expectation, whether justified or not, of benefits associated with participation or of retaliatory response from senior members of a hierarchy in case of refusal to participate
4.	Subjects with a history of poor compliance with medical treatment
5.	Contraindications or hypersensitivity to the use of the SUTUREFIX ULTRA and/or SUTUREFIX CURVED Suture Anchor, or their components (e.g. silicone, polyester). Where material sensitivity is suspected, appropriate tests should be performed and sensitivity ruled out prior to implantation
6.	Prior ipsilateral surgeries performed on the joint space

8. Pathological conditions of bone, such as cystic changes or severe osteopenia, which would compromise secure anchor fixation
9. Pathological conditions in the soft tissues to be attached that would impair secure fixation by suture
10. Comminuted bone surface, which would compromise secure anchor fixation

    Physical conditions which would eliminate, or tend to eliminate, adequate anchor support in impair healing
11. Epileptic history

Hip subjects

12. Dysplasia latera/central less than 20°

Shoulder subjects

13. Glenoid and/or humeral bone loss considered excessive by the treating orthopaedic surgeon
14. MDI: Multi-directional instability
15. Psychosomatic voluntary shoulder subluxation

7.4 SCREENING

To eliminate the potential for selection bias, Investigators should consecutively pre-screen all subjects undergoing arthroscopic instability repair with SUTUREFIX ULTRA Suture Anchor and/or SUTUREFIX CURVED Suture Anchor. Subjects receiving care at the investigative sites will be pre-screened as potential subjects for the study. To do so, only the existing information obtained per standard routine medical procedures will be used. No study-specific screening procedures, activities or questionnaires will be performed during pre-screening.

Participating study sites are required to document all screened subjects considered for inclusion in this study. If a subject is excluded from the study, the reasons for exclusion will be documented in the subject's source documents and noted on the Screening and Enrollment Log.

Once a subject has completed the informed consent procedure and signed an Ethics Committee approved Informed Consent Form (ICF), the PI or delegated study research staff can complete the screening process with the subject (see Section 9.1).

All screening activities which occur prior to consent shall be referred to as pre-screening.

7.5 INFORMED CONSENT

Before conducting any study procedures or examinations, the purpose and nature of the study will be explained to the subject in their native language. The ICF will be translated from English master ICF and/or adjusted to the EC requirements to the national languages of the participating European countries. The subject, or their legally authorized representative, will then **read**, **sign**, and **personally date** the IRB/IEC-approved informed consent document(s) (see below for difficulties with reading and writing). Additionally, the individual who obtains consent from the subject will sign and date the informed consent document. A copy of the signed informed consent documentation will be provided to the subject, a copy will be placed in the subject's medical record, with the original filed in the ISF.

If the subject is unable to read, the informed consent document and associated study information may be read aloud to the subject in the presence of an impartial witness. If possible the subject shall sign and personally date the Informed Consent Form (ICF). Where this is not possible, due to difficulties in writing, the subject shall provide verbal consent to participate in the study. The witness shall then personally sign and date the informed consent form, attesting that the information was accurately explained and that the informed consent was freely given.

For the site(s) in United States the HIPPA requirements will be in place.

7.6 ENROLLMENT

Once a subject has completed the informed consent procedure and signed an Ethics Committee approved Informed Consent Form (ICF) the PI or delegated study research staff can complete the screening process with the subject.

7.7 LOST TO FOLLOW-UP

Some actively enrolled subjects will not return for follow-up exams on time. Study personnel must make a reasonable effort to contact the subject and document the following contact attempts prior to declaring a subject to be lost to follow-up: the subject has been contacted according to the site's policies, but no fewer than 2 documented phone contacts and 1 certified letter without response. Copies of all attempts to reach the subjects per regular mail or email and/or the attempts to contact the subject via other means should be documented and that documentation should be kept with the subject's source documents.

7.8 WITHDRAWAL

7.8.1 Withdrawal from Treatment

Not applicable

7.8.2 Withdrawal from Study

The Investigator **may** withdraw subjects from the study for many reasons, including but not limited to the following:

- subject noncompliance (e.g. did not follow instructions)
- subject lost to follow-up
- if the Investigator or the Sponsor stops the study for any reason and decides to withdraw subject(s) from the study
- Adverse Events/

- any other significant reason identified by the Investigator

For each case, information will be obtained in the source document and the Case Report Form (CRF) detailing circumstances leading to the withdrawal.

Subjects who drop out or are withdrawn will not be re-entered into the study at a later date.

7.8.3 Subject's Withdrawal of Consent to Participate in Study

Study participation is voluntary and subjects may withdraw at any point during the study without giving their reason for doing so. Where subjects withdraw consent, the Investigator should make a reasonable effort to ascertain the reason(s), while fully respecting the subject's privacy. The reason for withdrawal will be recorded in the CRF and in source documents.

7.8.4 Use of Data Following Withdrawal

In cases where the subject withdraws consent, the data collected up to the point of withdrawal may be used but no additional data for that subject may be collected.

8. STUDY DESIGN

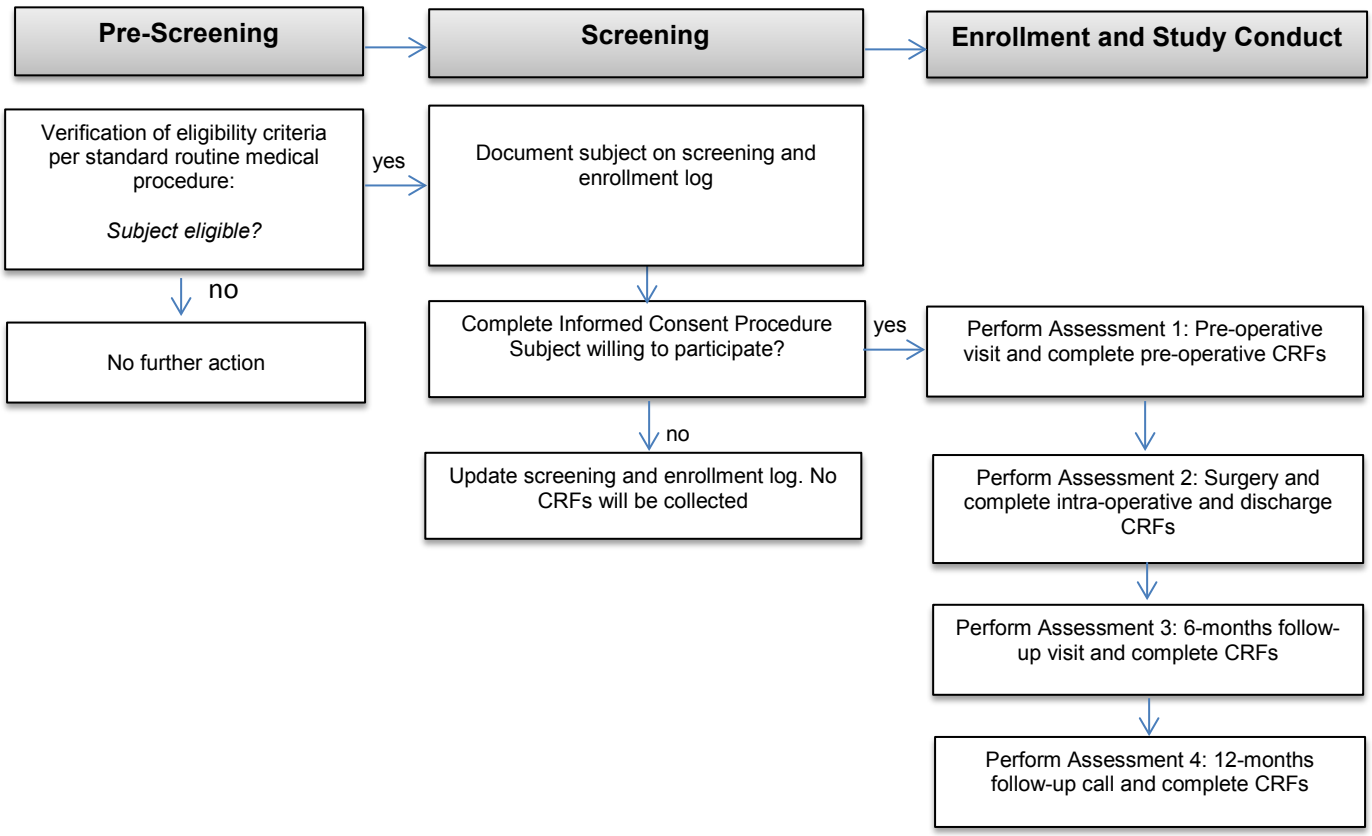
8.1 STUDY DESIGN

This is a prospective, multicenter study to evaluate the clinical and intraoperative outcomes from 80 subjects implanted with the SUTUREFIX ULTRA and/or SUTUREFIX CURVED Suture Anchors in hip or shoulder groups. Up to 8 sites (up to 4 sites for study hip group and up to 4 sites for study shoulder group) in Europe will participate in the study. Data from eligible subjects, who have provided written and informed consent for the collection of their coded data (see section 9.1.2-9.1.6) will be recorded from the subject medical file on Case Report Forms (CRFs). Follow-up clinical assessments will be performed at 6 months and 1 year post-operatively.

This is an open-label study with consecutive enrollment. The study will continue for 12 months from the date of treatment for the last subject completing the study as planned. Only subjects who meet the enrollment criteria as listed in section 7 will be enrolled into the study. The study duration is planned for 24 months.

The data will support CE Mark certification for the Shoulder and Hip repair indications. The data should confirm safety and performance levels acceptable for the risk benefit profile of this device.

Figure 8.1-1: Study Flowchart



8.2 ALLOCATION AND BLINDING

This study is an open-label study with consecutive enrolment without randomization. There is no control group. Although there are two groups one hip and one shoulder group blinding of the surgeon is not applicable due to the different indications and product specificities. The evaluator will be blinded to the treatment groups.

8.3 STUDY ENDPOINTS

8.3.1 Primary Endpoint

- Clinical success rate, defined as subjects without signs of failure and/or re-intervention at 6 months, as assessed by the surgeon

8.3.2 Secondary Endpoints

- Clinical success rate, defined as subjects without signs of failure and/or re-intervention at 12 months, as assessed by the surgeon
- Intra-operative anchor deployment success rate
- Number of anchors pulled out
- Use of additional anchors as a result of intra-operative failure
- Device-related re-intervention
- Safety evaluation at all time points
- Post-operative clinical success rate and performance assessed with subject reported outcomes as follows:

All subjects:

- Subject pain assessment with VAS at 6 months* and 12 months*
- Subject satisfaction assessment with VAS at 6 months* and 12 months*
- EQ-5D Questionnaire at 6 months* and 12 months*

Hip subjects:

- Hip Outcome Score Activities of Daily Living (HOOS-ADL) at 6 months* and 12 months*
- Modified Harris Hip Score (HHS) at 6 months* and 12 months*

Shoulder subjects:

- ROWE Shoulder Scores at 6 months* and 12 months*
- ASES Shoulder Scores at 6 months* and 12 months*
- Constant-Murley Shoulder Scores at 6 months* and 12 months*

** Patient Reported Outcomes (PROs) are optional and used according to the surgeon's preference*

8.4 METHODS USED TO MINIMIZE BIAS AND MAXIMIZE VALIDITY

The study is a prospective multi-centre non-comparative cohort study to demonstrate the performance of the SUTUREFIX ULTRA and SUTUREFIX CURVED Suture Anchors in hip and shoulder for arthroscopic treatment over a time period of 12 months after arthroscopy. The study is exploratory in nature and not powered for any statistical testing hence the results from the study will be interpreted with caution.

Biases naturally associated with exploratory non-comparative studies will be inevitable but the use of multiple recruitment centres and well defined inclusion/exclusion criteria ensures that the study is more representative of a larger population and varying backgrounds. The exploratory data analysis planned for the study which includes confidence intervals for the outcome summaries, a pre-defined confidence interval for the primary outcome and exploratory statistical models adjusting for potential confounding factors is designed to maximise the validity of the study results.

9. STUDY PROCEDURES

9.1 VISITS AND EXAMINATIONS

9.1.1 Summary

For a summary of the required procedures by visit, refer to Table 9.1-1: Study Procedures by Visit

Table 9.1.1-1: Study Procedures by Visit

Schedule of events (*as needed)	Visit 1	Visit 2	Visit 3 Visit	Visit 4 Telephone Call or Visit	Visit 5 Unscheduled Visit
	Pre-Operative	Operative through Discharge	6 Months (± 1 M)	12 Months (± 1 M)	
Informed Consent	√				
Inclusion/Exclusion Criteria	√				
Demographics/ Medical History	√				
Intra-op failure as assessed by the surgeon		√			
Operative through Discharge		√			
Post-op Repair failure			√	√	√
All subjects Pain assessment with VAS	√**		√**	√**	√**
Satisfaction assessment with VAS	√**		√**	√**	√**
EQ-5D questionnaire	√**		√**	√**	√**
Hip HOOS-ADL score	√**		√**	√**	√**
Mod. Harris Hip score	√**		√**	√**	√**
Shoulder ROWE score	√**		√**	√**	√**
ASES score	√**		√**	√**	√**

Schedule of events (*as needed)	Visit 1	Visit 2	Visit 3 Visit	Visit 4 Telephone Call or Visit	Visit 5 Unscheduled Visit
	Pre-Operative	Operative through Discharge	6 Months (± 1 M)	12 Months (± 1 M)	
Constant-Murley score	√**		√**	√**	√**
MRI / Imaging	√		√*	√*	√*
Adverse Event Assessment		√	√		
End of Study/Exit			√		

* If needed to investigate repair failure

** Patient Reported Outcomes (PROs) are optional and used according to the surgeon's preference

9.1.2 Visit 1: Pre-Operative Visit

- Obtain written informed consent from the subject as detailed in Section 7.5

----- Do not proceed until consent has been obtained -----

- Obtain demographic information and medical history, including information on all concomitant medications/therapies
- Screen the subject for protocol inclusion/exclusion criteria
- Assign the subject a study number and instruct the subject on treatment procedures
- Complete Screening and Enrollment Log
- Complete VAS-Scale for Pain for all subjects*
- Complete EQ-5D questionnaire for all subjects*
- Complete ROWE Score for shoulder*
- ASES Score for shoulder*
- Complete Constant-Murley Score for shoulder*
- Complete HOOS-ADE Score for hip*
- Complete Modified HSS Sore for hip*
- Perform MRI, only in case of repair failure
- If any adverse events are observed or reported, they must be recorded as instructed in Section 12.3, adverse events and device deficiencies
- Complete Pre-Operative Visit CRFs

**Patient Reported Outcomes (PROs) are optional and used according to the surgeon's preference.*

9.1.3 Visit 2: Operation through Discharge Visit

- Query subject regarding any changes in general health and the use of concomitant medications
- If any adverse device effects or device deficiencies are observed or reported, they must be recorded as instructed in Section 12.3 adverse events and device deficiencies
- Update information in the Screening and Enrollment Log
- Intra-operative success as assessed by the surgeon
- MRI/Images, only in case of repair failure
- Complete Operation and Discharge Visit CRFs
- Instruct the subject on follow-up procedures, including returning to the facility for FU Visit 3 in (± 1M) 6 months

9.1.4 Visit 3: 6-Month Follow-up Visit (± 1 month)

- Query subject regarding any changes in general health and the use of concomitant medications.
- If any adverse device effects or device deficiencies are observed or reported, they must be recorded as instructed in Section 12.3, adverse events and device deficiencies
- Post-operative repair failure
- Complete VAS-Scale for Pain and Satisfaction for all subjects*
- Complete EQ-5D questionnaire for all subjects*
- Complete ROWE Score for shoulder*
- ASES Score for shoulder*
- Complete Constant-Murley Score for shoulder*
- Complete HOOS-ADE Score for hip*

- Complete Modified HSS Sore for hip*
- Perform MRI/Imaging only in case of repair failure
- Complete 6-Months Follow-up Visit CRFs
- Instruct the subject on follow-up procedures, including scheduling a FU call or visit in (± 1M) 12 months

**Patient Reported Outcomes (PROs) are optional and used according to the surgeon's preference.*

9.1.5 Visit 4: 12-Months Follow-up Call or Visit (± 1 month)

- Query subject regarding any changes in general health and the use of concomitant medications.
- If any adverse device effects or device deficiencies are observed or reported, they must be recorded as instructed in Section 12.3, adverse events and device deficiencies.
- Post-operative repair failure
- Complete VAS-Scale for Pain and Satisfaction for all subjects*
- Complete EQ-5D questionnaire for all subjects*
- Complete ROWE Score for shoulder*
- ASES Score for shoulder*
- Complete Constant-Murley Score for shoulder*
- Complete HOOS-ADE Score for hip*
- Complete Modified HSS Sore for hip*
- Perform MRI/Imaging only in case of repair failure

**Patient Reported Outcomes (PROs) are optional and used according to the surgeon's preference.*

9.1.6 Unscheduled Visits

- Query subject regarding any changes in general health and the use of concomitant medications.
- Adverse device effects or device deficiencies must be recorded as instructed in Section 12.3, adverse events and device deficiencies.
  - Post-operative repair failure
- Complete VAS-Scale for Pain and Satisfaction for all subjects*
- Complete EQ-5D questionnaire for all subjects*
- Complete ROWE Score for shoulder*
- ASES Score for shoulder*
- Complete Constant-Murley Score for shoulder*
- Complete HOOS-ADE Score for hip*
- Complete Modified HSS Sore for hip*
- Perform MRI/Imaging to investigate repair failure
- Complete Unscheduled Visit CRFs

**Patient Reported Outcomes (PROs) are optional and used according to the surgeon's preference*

Unscheduled examinations may be conducted at the discretion of the Investigator with all obtained information recorded in the source documents and on the appropriate CRF.

9.1.7 Concomitant Medications and Therapies

A concomitant medication (e.g. drug, substance) and a concomitant therapy (e.g. physical therapy, TENS Unit, massage) are recorded at any time from enrollment into the study through the subject's last study visit.

9.1.7.1 *Concomitant Medications*

9.1.7.1.1 Excluded Concomitant Medications

Not applicable

9.1.7.1.2 Recording Concomitant Medications in the CRF

Concomitant medications should be recorded in the CRF with the generic name.

9.1.7.2 *Concomitant Therapies*

9.1.7.2.1 Therapies Prohibited During the Study

Not applicable

9.1.7.2.2 Recording Concomitant Therapies in the CRF

Standard concomitant therapy will be recorded in the CRF unless provided as a part of an AE treatment.

9.1.8 Discontinued Subjects

Discontinued subjects are those who voluntarily discontinue participation, who are withdrawn for reasons of safety, who are lost to follow-up, so are ineligible for further participation, refer to section 7.8 for further details. Where possible, a full Exit Visit should be completed for all subjects who discontinue the study early. Where consent is withdrawn, the date and any reason given for discontinuation should be captured, at a minimum (see Section 7.8.2).

Finally, if appropriate, the Investigator will also advise the subject of subsequent therapy and/or procedures necessary for their medical condition.

9.1.9 Subject Pregnancy

Women of child-bearing potential are not excluded from the study: as long as adequate birth control methods are being used by the subject as outlined in the protocol's exclusion criteria. However, if a woman becomes pregnant during the study, S&N must be contacted immediately once the investigator is made aware of the pregnancy and a decision will be made regarding the continuation in the study of the pregnant woman. Pregnancy is not an adverse event; however, complications related to the pregnancy may be reportable as determined on a case-by-case basis. Pregnancy-related information will be collected until the end of the pregnancy.

9.2 STUDY METHODS AND MEASUREMENTS

All subjects

- VAS for pain and satisfaction assessment*

Hip subjects

- Hip Outcome Score Activities of Daily Living (HOOS-ADL)*
- Modified Harris Hip Score (HHS) *

Shoulder subjects

- ROWE Shoulder Scores*
- ASES Shoulder Scores*
- Constant-Murley Shoulder Scores*

**Patient Reported Outcomes (PROs) are optional and used according to the surgeon's preference*

9.3 HEALTH ECONOMICS/QUALITY OF LIFE

- EQ-5D-5L

10. STATISTICAL DESIGN

The primary aim of the study is to evaluate intra-operative (6 and 12-month) safety and performance of the SUTUREFIX ULTRA and SUTUREFIX CURVED Suture Anchors for arthroscopic repair. This section of the protocol is a brief description of the analyses projected to

evaluate the aims of the study and answering the study research question. A more detailed Statistical Analysis Plan (SAP) will be written and finalized prior to database lock. The SAP will account for any changes or deviations from the projected analyses in this protocol.

10.1 GENERAL

Primary and secondary endpoints will be evaluated using listings and appropriate summary statistics. The outcomes will be summarized for the entire sample, by device implanted (SUTUREFIX ULTRA and SUTUREFIX CURVED) as well as the position, i.e. the hip or the shoulder. The summary statistics for both primary and secondary outcomes will be reported together with a 95% confidence interval where necessary to assess the degree of precision in the estimates.

Data tabulations and summarization will be presented to aid in the interpretation of the effects of clinically important variables that are disclosed. A summary of the enrolment figures by site, time point follow-up as well as the demographic and baseline variables, which include age, gender etc. will be presented. Continuous variables will be summarized using mean, median, SD, minimum, and maximum; categorical variables will be summarized as counts and percentages.

All statistical tests will be exploratory in nature as the study is not powered for any statistical testing. Appropriate parametric and/or non-parametric analyses will be chosen for statistical analysis. Test of association for the table of counts will be based on the Fisher's Exact Test unless otherwise inappropriate. The exploratory analysis of continuous variables will be done using t-test and ANOVA if appropriate. The Wilcoxon rank-sum or Kruskal-Wallis tests will be explored if the data is non-normal.

For the success/failure variable, the logistic model will be considered if needed. Associated factors will be adjusted for in unadjusted and adjusted models, if necessary (Peacock and Kerry 2007).[25] All statistical tests and models will be considered at 5% significance level. Adverse Events will be tabulated for the study duration.

All statistical analyses and calculation of confidence intervals will be performed using SAS software.

10.2 ANALYSIS POPULATIONS

All subjects who provide informed consent are considered study participants. Study populations are defined as follows:

- Full analysis set population (FAS), including all subjects who were enrolled into the study and attended at least one post-baseline assessment.
- Per-Protocol Population (PP), including all subjects in the full analysis set who have no significant protocol deviations and met the inclusion/exclusion criteria.
- Safety Population (SAF), including all subjects who have received IP.

10.3 BASELINE DATA

Data to be summarised at baseline includes all collected demographic variable such as age, gender, primary diagnosis, height, weight, BMI, medical history and co-morbid conditions. The baseline variables will be used to describe the outcome data where necessary. Continuous baseline data will be summarized using frequency, means, and standard deviations, median, minimum and maximum. Categorical variables will be summarized using counts and percentages. The percentages will be calculated based on the number of non-missing values.

10.4 EFFICACY ANALYSIS

10.4.1 Analysis of Primary Endpoint

Clinical success rate, defined as subjects without a signs of failure and/or re-intervention at 6 months, surgeon assessment:

- The frequency of the subjects without a signs of failure and/or re-intervention at 6 months together with percentage with a 95% CI will be reported. Clinical success rate for the entire sample, by device implanted (SUTUREFIX ULTRA and SUTUREFIX CURVED) as well as the position, i.e. the hip or the shoulder will be reported. A binary variable of success/failure will be used to fit a logistic model adjusting device implanted and position to estimate the odds ratio of success if data allows.

10.4.2 Analysis of Secondary Endpoint(s)

- Intra-operative anchor deployment success rate
- Number of anchors pulled out
- Use of additional anchors as a result of intra operative failure
- Device-related re-intervention

All the above variables will be categorical in nature hence frequencies together with percentages will be tabulated for the entire sample as well as by device implanted (SUTUREFIX ULTRA and SUTUREFIX CURVED) as well as the position, i.e. the hip or the shoulder will be reported.

All subjects

Clinical success rate, defined as subjects without signs of failure and/or re-intervention at 12 months; surgeon assessment

- The frequency of the subjects without a signs of failure and/or re-intervention at 12 months together with percentage with a 95% CI will be reported. Clinical success rate for the entire sample, by device implanted (SUTUREFIX ULTRA and SUTUREFIX CURVED) as well as the position, i.e. the hip or the shoulder will be reported. A binary variable of success/failure will be used to fit a logistic model adjusting device implanted and position to estimate the odds ratio of success if data allows.

- Subject pain assessed with a VAS at 6 months* and 12 months*

- Subject satisfaction assessed with a VAS at 6 months* and 12 months*
- EQ-5D Questionnaire at 6 months* and 12 months*
    - The VAS and EQ-5D-5L scores at different time points and end of study for the entire sample, by device implanted (SUTUREFIX ULTRA and SUTUREFIX CURVED) as well as the position, i.e. the hip or the shoulder will be summarized using mean, median, SD, minimum, and maximum. A one sample t-test will be used to test the difference between baseline and end of study scores. A non-parametric test will be considered if necessary.

- EQ-5D-5L

Based on the subjects responses (no problems/some or moderate problems/extreme problems) to each dimension (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) an index utility score is calculated to represent the overall EQ-5D-5L score for each subject.

The subject responses to each dimension score and the overall EQ-5D-5L index utility scores and EQ VAS scores will be summarized at baseline and all post-operative visits for the entire sample, by device type implanted and as well as the position, i.e. the hip or the shoulder.. The change in EQ-5D-5L index utility score and the change in EQ VAS score between baseline and all post-op visits will also be summarised.

EQ-5D-5L Utility scores and EQ VAS scores will be assessed using separate repeated measures ANOVA model, with the relevant score as the dependent variable for on entire sample with device implanted and position accounted for as levels in the model.

Hip subjects

- Hip Outcome Score Activities of Daily Living (HOOS-ADL) at 6 months* and 12 months*

- Modified Harris Hip Score (HHS) at 6 months* and 12 months*
    - The HOOS and HHS scores at different time points and end of study will be will be summarized for the entire sample and device implanted using median, SD, minimum, and maximum. A one sample t-test will be used to test the difference between baseline and end of study scores.

Shoulder subjects

- ROWE Shoulder Scores at 6 months* and 12 months*
- ASES Shoulder Scores at 6 months* and 12 months*
- Complete Constant-Murley Score for shoulder* at 6 months* and 12 months*
    - The ROWE and Constant-Murley Shoulder scores at different time points and end of study will be will be summarized for the entire sample and device implanted using mean, median, SD, minimum, and maximum. A one sample t-test will be used to test the difference between baseline and end of study scores. A non-parametric test will be considered if necessary.

**Patient Reported Outcomes (PROs) are optional and used according to the surgeon's preference*

10.4.3 Analysis of Other Endpoint(s)

Time to failure - intra-operative repair failure will be defined as just an event.

- If adequate data is available, Kaplan Meier survival estimate for the entire sample, by device implanted and position will be used in this study survival analyses and a Cox model will also be explored adjusting for device implanted and position.
- Available data will be summarized and summary statistics tabulated.

10.5 SAFETY ANALYSES

Adverse events

- Adverse Events (as defined in Safety Reporting Section – All adverse events will be tabulated classified by seriousness and given by frequency and percentages for the entire sample and by device implanted (SUTUREFIX ULTRA and SUTUREFIX CURVED).

10.6 INTERIM ANALYSES

No interim analysis is foreseen.

11. SAMPLE SIZE JUSTIFICATION

A systematic review by Erickson et al (2015) suggests that the variation in the success rate among patients who have undergone any Suture Anchors for arthroscopic instability repair range from 71-97%. Two studies Lafosse et al (2008) and Thal et al (2007) [26] have failure rates of 11.4% and 6.9% within a period of 2 years from surgery, giving success rates of about 87% and 93% respectively suggest that building a 11% confidence interval either side of 89% will ensure that the estimated success rate is within literature extrapolated success rates.

This study considers the SUTUREFIX ULTRA and SUTUREFIX CURVED Suture Anchors for arthroscopic repair success rate and a sample of 80 (40 per device) subjects is considered. A sample size of 40 subjects will estimate a success rate of 89% with a 95% confidence interval (CI) [78: 100] with 55% probability.

12. ADVERSE EVENTS AND DEVICE DEFICIENCIES

12.1 DEFINITIONS

The categories of adverse events are shown in table 12.1-1. The definitions for each of these categories are given in the subsequent sections (see reference within the table).

Table 12.1-1: Categories of Adverse Event

<table>
<tr><th></th><th>NOT DEVICE-RELATED</th><th colspan="2">DEVICE- OR PROCEDURE-RELATED</th></tr>
<tr><td>NON-SERIOUS</td><td>ADVERSE EVENT (AE) (SEE 12.1.1)</td><td colspan="2">ADVERSE DEVICE EFFECT (ADE) (SEE 12.1.2)</td></tr>
<tr><td rowspan="3">SERIOUS</td><td rowspan="3">SERIOUS ADVERSE EVENT (SAE) (SEE 12.1.3)</td><td colspan="2">SERIOUS ADVERSE DEVICE EFFECT (SADE) (SEE 12.1.3)</td></tr>
<tr><td>ANTICIPATED</td><td>UNANTICIPATED</td></tr>
<tr><td>ANTICIPATED SERIOUS ADVERSE DEVICE EFFECT (ASADE) (SEE 12.1.4)</td><td>UNANTICIPATED SERIOUS ADVERSE DEVICE EFFECT (USADE) (SEE 12.1.4)</td></tr>
</table>

12.1.1 Adverse Event

An Adverse Event (AE) is any untoward medical occurrence between enrollment (signed ICF obtained) and study discontinuation with the use of an IP, whether or not considered causally related to that IP.

AE is used both to refer to AE which are non-serious non-IP or procedure-related and as an umbrella term referring to adverse events of all classifications.

An AE can be any unfavorable and unintended sign (for example, an abnormal laboratory finding), symptom, or disease. For reporting purposes, emphasis is placed first and foremost on whether or not the event constitutes an untoward medical occurrence.

12.1.2 Adverse Device Effect

An Adverse Device Effect (ADE) is an adverse event that, in the opinion of the investigator, is related to the IP or the procedure.

Not Related - An AE is considered to be not related to the use of an IP or the procedure when the effect is DEFINITELY UNRELATED or UNLIKELY to have any relationship to the use of the IP or the procedure;

Related - An AE is considered to be related to the use of an IP or the procedure when there is a POSSIBLE, PROBABLE, or DEFINITE relationship between the AE and the use of the IP or the procedure.

An ADE is further categorized depending on whether the criteria in section 12.1.3 and 12.1.4 are met.

12.1.3 Serious Adverse Events and Serious Adverse Device Effects

An AE or ADE is considered a **Serious** Adverse Event (SAE) or **Serious** Adverse Device Effects (SADE) if, in the view of either the Investigator or the Sponsor, it:

- Results in death.
- Is life-threatening (*NOTE*: The term “life-threatening” in the definition of “serious” refers to an event/reaction in which the subject was at risk of death at the time of the event/reaction; it does not refer to an event/ reaction which hypothetically might have caused death if it were more severe).
- Requires in subject hospitalization or results in prolongation of existing hospitalization.
- Results in persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions.
- Is a congenital anomaly/birth defect.
- Is a medically important event or reaction.

Medical and scientific judgment should be exercised in deciding whether other situations should be considered serious such as important medical events that might not be immediately life-threatening or result in death or hospitalization but might jeopardize the subject or might require intervention to prevent one of the other outcomes listed in the definition above. Examples of such events are intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias, or convulsions that do not result in hospitalization; or development of drug dependency or drug abuse.

12.1.4 Anticipated/Unanticipated Serious Adverse Device Effect

An Unanticipated Serious Adverse Device Effect (USADE) is a serious ADE that meets any of the above definitions but is also considered, by the Investigator, to be caused by or related to the IP, not previously identified in nature, severity or degree in the IFU [28,29,30].

An Anticipated Serious Adverse Device Effect (ASADE) is a serious ADE that does not meet the criteria for a USADE [28,29,30].

12.1.5 Severity

The severity of every AE will be assessed by the PI or medically qualified site staff to whom the responsibility has been delegated and documented on the delegation of authority log. AE should be classified as mild, moderate, or severe, regardless of whether or not the AE are considered to be serious or non-serious. The classification should be based on the following definitions:

Mild - An event is mild if the subject is aware of, but can easily tolerate the sign or symptom;

Moderate - An event is moderate if the sign or symptom results in discomfort significant enough to cause interference with the subject's usual activities;

Severe - An event is severe if the sign or symptom is incapacitating and results in the subject's inability to work or engage in their usual activities.

12.1.6 Device Deficiency

A Device Deficiency (DevD) is an inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance. DevD includes malfunctions, use errors and inadequate labelling.

12.2 REPORTING PROCEDURES

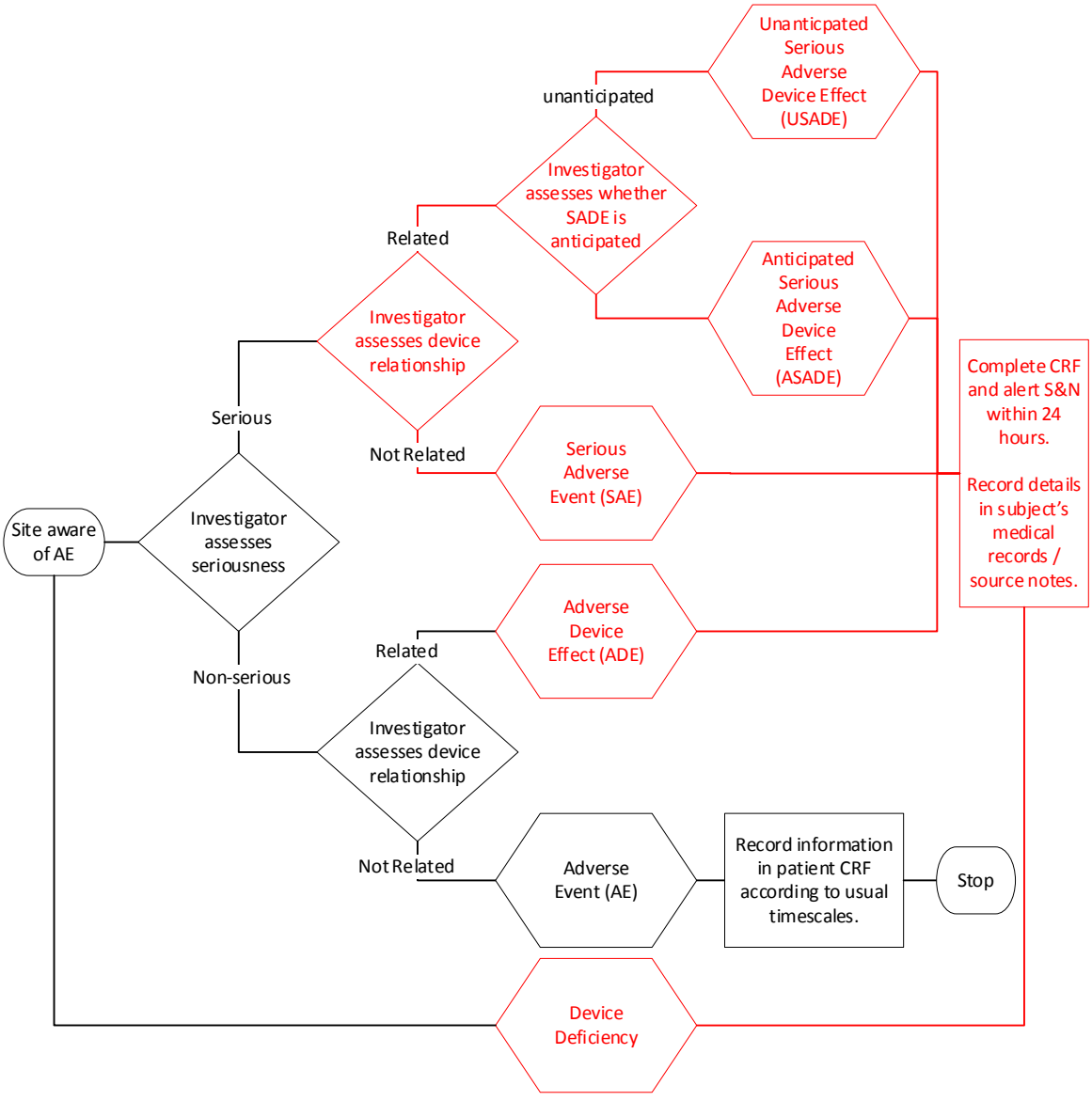
AE of any kind and DevD will be recorded in the applicable CRF and source notes. The Investigator will evaluate all AE for relationship to the device and procedure, if applicable, seriousness, and severity. ADE, SAE, and DevD will be entered into the CRF and reported to the Sponsor within 24 hours of the investigator being informed about the event (Figure 12.2-1). For ADE and DevD, details of the product/procedure related to the event will be included and where applicable, pictures taken of the device. The deficient product should be retained for return to S&N unless it is contaminated (e.g. used dressings must not be retained). Updates to submitted information will be recorded in the CRF within 24 hours of the information being available to the investigator.

All SAE and ADE will be reviewed by a medically qualified person appointed by the Sponsor to determine which, if any, meet criteria for expedited reporting to the regulatory authorities.

The investigator will inform the IRB/IEC of adverse events according to the IRB/IEC requirements.

Depending on the nature of the adverse event, S&N may request copies of the subject's medical records, Imaging, Operative notes, as well as results of any relevant laboratory tests performed or other documentation related to the AE. If the subject was hospitalized, a copy of the discharge summary may be requested by S&N and should be forwarded as soon as it becomes available. In certain cases, S&N also may request a letter from the Investigator that summarizes the events related to the case. Refer to the ISF Sponsor Contact Information Sheet to report SAE, unanticipated ADE and SADE, anticipated SADE, and DevD.

Figure 12.2-1: Evaluation and Reporting of AE and DevD



12.3 UNBLINDING OF INVESTIGATIONAL PRODUCT

Not Applicable. This is an open-label study.

12.4 FOLLOW-UP OF SUBJECTS WITH ADVERSE EVENTS

For subjects who are experiencing ongoing unresolved AE at the time of their study completion or early discontinuation from the study, it is recommended that the Investigator schedule an appropriate follow-up visit in order to determine the outcome of the event.

Any additional data must be documented and available to the Sponsor who will determine whether the data need to be documented within the CRF/Clinical Study Report.

12.4.1 Ongoing Adverse Events at Study Discontinuation

Adverse events which are **related** to a study procedure or S&N IP and are ongoing at end of subject's participation: The event should be followed until it is either resolved or until the event has become chronic and is not expected to further improve based on Investigator's review of the event.

Adverse events which are **not related** to a study procedure or S&N IP and are ongoing at end of subject's participation should be followed for 30 days after discontinuation or if the AE is resolved, whichever is sooner.

At the time of data analysis (e.g. interim or final), an evaluation of ongoing events should take place and be listed as ongoing in the safety table.

13. INVESTIGATOR OBLIGATIONS

The Principal Investigator (PI) will comply with the commitments outlined in the in the Statement of Investigator, provided by the Sponsor, and with Good Clinical Practice (GCP), and all applicable regulatory requirements as outlined in Appendix 21.4 of this protocol.

In addition, the PI will ensure that the Financial Disclosure Statements will be completed by the PI and the Sub-Investigator upon entry into the study and as any changes that affect their

financial disclosure status occur during the course of the study and up to one year after study completion.

14. SPONSOR AND MONITOR RESPONSIBILITIES

The Sponsor will designate a monitor to conduct the appropriate site visits at the appropriate intervals. The clinical investigation will be monitored to ensure that: the rights and wellbeing of the subjects are protected; the reported data are accurate, complete, and verifiable from the source documents; and the study is conducted in compliance with the currently approved protocol, with GCP regulations, and with applicable regulatory requirements.

Detailed monitoring requirements will be documented within the Clinical Monitoring Plan for this study.

14.1 CONTRACT RESEARCH ORGANIZATION

The Sponsor has engaged Contract Research Organization (CRO) to assist in conducting this study. When appropriate, the CRO is referred in study documents as “Sponsor’s agent”.

14.2 SITE QUALIFICATION VISIT

A site qualification visit may be performed by the Sponsor prior to the execution of a clinical agreement to ensure that all Investigators have the appropriate training, staff, facilities, and resources to adequately conduct the study.

14.3 SITE INITIATION VISIT

A site initiation visit to provide training on the specifics of the study, site obligations and expectations of study conduct will be performed by the Sponsor or qualified person designated by the Sponsor following the execution of the CTA (Clinical Trial Agreement) and documented IRB/IEC approval.

14.4 SPONSOR AUDITS AND REGULATORY INSPECTION

Quality Assurance auditors, whether an employee of the Sponsor or its designee, may evaluate study conduct at the study sites. These parties must have access to any and all study reports and source documentation, regardless of location and format.

14.5 CLOSE-OUT VISIT

A study close-out visit will be performed by the Sponsor or designee to retrieve and account for all remaining clinical data and to resolve outstanding queries. During study close-out, the monitor will review investigator files to ensure required documents and records are on file, and review regulatory requirements regarding records retention and IRB/IEC reporting requirements.

15. PROTOCOL AMENDMENTS

Amendments should be made only in exceptional cases once the study has started. Protocol amendments must be approved by the protocol signatories prior to submission to the IRB/IEC. Protocol amendments need to be approved by the IRB/IEC and Regulatory Authority(ies), as applicable prior to implementation at the site

16. CONFIDENTIALITY OF THE STUDY

The confidentiality of this study and associated documents is governed by the terms of the Clinical Trial Agreement (CTA).

17. STATEMENTS OF COMPLIANCE

This clinical study will be performed in compliance with the ethical principles of the Declaration of Helsinki; ISO 14155:2011 Clinical investigation of medical devices – Good Clinical Practice; ICH-E6.

This clinical study will not commence until the required approval/favorable opinion from the IRB/IEC or regulatory authority has been obtained. Any additional requirements imposed by the IRB/IEC or regulatory authority will be followed.

Public/Products Liability Insurance has been purchased by Smith & Nephew plc. Worldwide and incorporates coverage for personal injury in respect of clinical studies. The Sponsor agrees to operate in good faith and in accordance with ABHI (Association of British Healthcare Industries) guidelines regarding compensation for injury arising in the course of clinical studies.

18. END OF STUDY

The end of the study is defined by the last visit of the last subject undergoing treatment in the study.

19. PUBLICATION POLICY

19.1 PUBLICATION OF STUDY DATA

The preparation and submission for publication of manuscripts containing the study results shall be in accordance with a process determined by the Clinical Trial Agreements between the study Sponsor and participating institutions. The publication or presentation of any study results shall comply with all applicable privacy laws, including, but not limited to the Health Insurance Portability and Accountability Act of 1996.

19.2 DATA SHARING

Smith & Nephew is committed to upholding the highest ethical and legal standards involved in conducting clinical trials. Smith & Nephew therefore supports the data sharing requirements of The International Committee of Medical Journal Editors (ICMJE) published on the 6th June 2017. In accordance, Smith & Nephew will consider requests to share individual (deidentified) participant data that underlie the results of any interventional clinical trial, as presented from the 1st July 2018 within an ICMJE associated journal. Requests made by researchers who provide a

methodologically sound proposal will be considered. Requests may include data that underlie results presented in text, tables, figures and appendices, together with data dictionaries. Availability of these data will begin 9 months and end 36 months after article publication. Data supplied may only be used by the researcher(s) named in the approved research proposal for the purposes of achieving the aims of the analyses specified therein. All proposals should be directed to datasharing.gcs@smith-nephew.com. To gain access, data requestors will need to sign a data access agreement.

20. *REFERENCES*

1. **Demehri S, Hafezi-Nejad N, Fishman EK**. Advanced imaging of glenohumeral instability: the role of MRI and MDCT in providing what clinicians need to know. *Emergency radiology.* 2017;24(1):95-103.
2. **Erickson J, Lavery K, Monica J, Gatt C, Dhawan A**. Surgical treatment of symptomatic superior labrum anterior-posterior tears in patients older than 40 years: a systematic review. *Am J Sports Med.* 2015;43(5):1274-1282.
3. **Werner BC, Brockmeier SF, Miller MD**. Etiology, Diagnosis, and Management of Failed SLAP Repair. *The Journal of the American Academy of Orthopaedic Surgeons.* 2014;22(9):554-565.
4. **McCormick F, Bhatia S, Chalmers P, Gupta A, Verma N, Romeo AA**. The management of type II superior labral anterior to posterior injuries. *The Orthopedic clinics of North America.* 2014;45(1):121-128.
5. **Zlatkin MB, Sanders TG**. Magnetic resonance imaging of the glenoid labrum. *Radiologic clinics of North America.* 2013;51(2):279-297.
6. **Rossy W, Sanchez G, Sanchez A, Provencher MT**. Superior Labral Anterior-Posterior (SLAP) Tears in the Military. *Sports health.* 2016;8(6):503-506.
7. **Tayrose GA, Karas SG, Bosco J**. Biceps Tenodesis for Type II SLAP Tears. *Bulletin of the Hospital for Joint Disease (2013).* 2015;73(2):116-121.
8. **Griffin JW, Leroux TS, Romeo AA**. Management of Proximal Biceps Pathology in Overhead Athletes: What Is the Role of Biceps Tenodesis? *American journal of orthopedics (Belle Mead, N.J.).* 2017;46(1):E71-e78.
9. **Vianello R, Pannone A, Conca M, Corezzola R**. Return to Sport After Shoulder Arthroscopy. In: Volpi P, ed. *Arthroscopy and Sport Injuries: Applications in High-level Athletes*. Cham: Springer International Publishing; 2016:175-184.
10. **Smith MV, Calfee RP, Baumgarten KM, Brophy RH, Wright RW**. Upper Extremity-Specific Measures of Disability and Outcomes in Orthopaedic Surgery. *The Journal of Bone and Joint Surgery. American volume.* 2012;94(3):277-285.

11. **Mook WR, Briggs KK, Philippon MJ**. Evidence and Approach for Management of Labral Deficiency: The Role for Labral Reconstruction. *Sports medicine and arthroscopy review.* 2015;23(4):205-212.
12. **Ayeni OR, Adamich J, Farrokhyar F, et al.** Surgical management of labral tears during femoroacetabular impingement surgery: a systematic review. *Knee surgery, sports traumatology, arthroscopy : official journal of the ESSKA.* 2014;22(4):756-762.
13. **Fayad TE, Khan MA, Haddad FS**. Femoroacetabular impingement: an arthroscopic solution. *The bone & joint journal.* 2013;95-b(11 Suppl A):26-30.
14. **Kollmorgen R, Mather R**. Current Concepts in Labral Repair and Refixation: Anatomical Approach to Labral Management. *American journal of orthopedics (Belle Mead, N.J.).* 2017;46(1):42-48.
15. **Skendzel JG, Philippon MJ**. Management of labral tears of the hip in young patients. *The Orthopedic clinics of North America.* 2013;44(4):477-487.
16. **Wolff AB, Grossman J**. Management of the Acetabular Labrum. *Clinics in sports medicine.* 2016;35(3):345-360.
17. **El Bitar YF, Lindner D, Jackson TJ, Domb BG**. Joint-preserving surgical options for management of chondral injuries of the hip. *The Journal of the American Academy of Orthopaedic Surgeons.* 2014;22(1):46-56.
18. **Khan M, Bedi A, Fu F, Karlsson J, Ayeni OR, Bhandari M**. New perspectives on femoroacetabular impingement syndrome. *Nature reviews. Rheumatology.* 2016;12(5):303-310.
19. **Salata MJ, Vasileff WK**. Management of Labral and Chondral Disease in Hip Preservation Surgery. *Sports medicine and arthroscopy review.* 2015;23(4):200-204.
20. **Kivlan BR, Nho SJ, Christoforetti JJ, et al.** Multicenter Outcomes After Hip Arthroscopy: Epidemiology (MASH Study Group). What Are We Seeing in the Office, and Who Are We Choosing to Treat? *American journal of orthopedics (Belle Mead, N.J.).* 2017;46(1):35-41.
21. **Agrawal V, Pietrzak WS**. Triple labrum tears25. repaired with the JuggerKnot soft anchor: Technique and results. *Int J Shoulder Surg.* 2015;9(3):81-89.
22. **Boileau P, Gendre P, Baba M, et al.** A guided surgical approach and novel fixation method for arthroscopic Latarjet. *Journal of Shoulder and Elbow Surgery.* 2015.
23. **Matsuda DK, Gupta N, Burchette RJ, Sehgal B**. Arthroscopic surgery for global versus focal pincer femoroacetabular impingement: are the outcomes different? *Journal of Hip Preservation Surgery.* 2015:hnv010.
24. **Agrawall V, Pietrzak WS.** Triple labrum tears repaire with the JunggerKnot soft anchor: T Technique and results. *Int J Shoulder Surg.* Jul-Sep 2015;9(3):81-89
25. **Peacock JL, Kerry S.** Presenting medical statistics from proposal to publication: a step-by-step guide. Oxford University Press; 2007.
26. **Lafosse, L., Brzoska, R., Toussaint, B. and Gobezie, R., 2008.** The outcome and structural integrity of arthroscopic rotator cuff repair with use of the double-row suture anchor technique. *J Bone Joint Surg Am*, (Supplement 2 Part 2), pp.275-286.

27. **Salaffi F, Sarzi-Puttini P, Atzeni F. Best Pract Res Clin Rheumatol.** 2015 Feb;29(1):164-86. doi: 10.1016/j.berh.2015.04.023. Epub 2015 Jun 19. Review.

28. ISO 14155:2011

29 CFR 812

30. ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting

21. APPENDICES

21.1 INSTRUCTIONS FOR USE SUTUREFIX ULTRA AND SUTUREFIX CURVED

smith&nephew

SUTUREFIX Ultra
Suture Anchor

10601059-B

EC REP

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CE 0086

03/2017 10601059 Rev. B

SUTUREFIX Ultra
Suture Anchor
SUTUREFIX Ultra Fadenanker
Anclaje para suturas SUTUREFIX Ultra
Ancrage de suture SUTUREFIX Ultra
Ancora di sutura SUTUREFIX Ultra
SUTUREFIX Ultra suturankare
SUTUREFIX Ultra hechtdraadanker
Âncora de sutura SUTUREFIX Ultra
SUTUREFIX Ultra suturanker
SUTUREFIX Ultra suturanker
SUTUREFIX Ultra 봉합사 고정기

Instructions for Use
Gebrauchsanweisung
Modo de empleo
Mode d'emploi
Istruzioni per l'uso
Bruksanvisning
Gebruiksaanwijzing
Instruções de utilização
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English

SUTUREFIX Ultra Suture Anchor

STERILE EO

Device Description

The Smith & Nephew SUTUREFIX Ultra Suture Anchor is a fixation device intended to provide secure fixation of soft tissue to bone. It consists of a soft suture anchor with attached non-absorbable suture(s) preassembled onto an insertion device. The anchors are available preloaded with either one #2 suture or two #1 sutures. This device is provided sterile, for single use only.

Contents

- 1 ea. Non-absorbable suture anchor– braided, silicone coated, polyester (USP), non-absorbable
- 1 ea. Insertion device– stainless steel shaft, nitinol push rod, with polycarbonate handle
- 1 or 2 ea. Sutures–
  - Braided, uncoated, UHMW polyethylene, white and/or blue, non-absorbable
  - and/or
  - UHMW polyethylene with monofilament polypropylene colored (blue), non-absorbable
  - and/or
  - UHMW polyethylene with monofilament nylon colored (black), non-absorbable

Refer to individual suture anchor product labels for suture size, type, and quantities.

Indications for Use

The Smith & Nephew SUTUREFIX Ultra Suture Anchor is intended for the secure fixation of soft tissue to bone for the following indications:

Hip
- Hip capsule repair
  - Acetabular labrum repair/reconstruction

Shoulder
- Capsular stabilization
  - Bankart repair
  - Anterior shoulder instability
  - SLAP lesion repairs
  - Capsular shift or capsulolabral reconstructions
- Acromioclavicular separation repairs
- Deltoid repairs
- Rotator cuff tear repairs
- Biceps tenodesis

Foot and Ankle
- Hallux valgus repairs
- Medial or lateral instability repairs/reconstructions
- Achilles tendon repairs/reconstructions
- Midfoot reconstructions
- Metatarsal ligament/tendon repairs/reconstructions
- Bunionectomy

Elbow, Wrist, and Hand
- Biceps tendon reattachment
- Ulnar or radial collateral ligament reconstructions
- Lateral epicondylitis repair

Knee
- Extra-capsular repairs
  - Medial collateral ligament
  - Lateral collateral ligament
  - Posterior oblique ligament
- Patellar realignment and tendon repairs
  - Vastus medialis obliquus advancement
- Iliotibial band tenodesis

Contraindications
- Known hypersensitivity to the implant material. Where material sensitivity is suspected, appropriate tests should be performed and sensitivity ruled out prior to implantation.
- Pathological conditions of bone, such as cystic changes or severe osteopenia, which would compromise secure anchor fixation.
- Pathological conditions in the soft tissues to be attached that would impair secure fixation by suture.
- Comminuted bone surface, which would compromise secure anchor fixation.
- Physical conditions which would eliminate, or tend to eliminate, adequate anchor support or impair healing.

English

Warnings

Do not use if package is damaged. Do not use if the product sterilization barrier or its packaging is compromised.

- Contents are sterile unless package is opened or damaged. DO NOT RESTERILIZE. For single use only. Discard any open, unused product. Do not use after the expiration date.
- It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.
- Read these instructions completely prior to use.
- Only use the recommended drill bits and drill guides intended for use with the SUTUREFIX Ultra Suture Anchor. Use of other instrumentation may injure the patient, damage the instruments, or compromise fixation.
- Maintaining guide alignment throughout drilling is required to ensure drill bit integrity.
- Do not attempt to implant this device within cartilage, epiphyseal growth plates or non-osseous tissue.
- Do not resterilize or reuse anchors, sutures, and insertion devices packaged with the anchor.
- Incomplete anchor insertion may result in poor anchor performance.
- Breakage of the suture anchor can occur if the insertion site is not prepared with appropriate instrumentation prior to implantation.

Precautions

℞ U.S. Federal law restricts this device to sale by or on the order of a physician.

- Hazards associated with reuse of this device include, but are not limited to, patient infection and/or device malfunction.
- Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device.
- Postoperative care is important. Instruct the patient on the limitations of the implant and caution them regarding weight bearing and body stresses on the appliance prior to secure bone healing.
- Do not use sharp instruments to manage or control the suture.
- As with any suture anchor or suturing technique, the fixation given should be considered as only temporary, until biological attachment of tissue to bone is completed, and may not withstand weight bearing or other unsupported stresses. The suture anchor and sutures are not intended to provide indefinite biomechanical integrity.
- Implantation of the suture anchor requires preparation of the insertion site. Predrilling with the appropriate Smith & Nephew Drill Bit is the preferred method of site preparation.
- Ensure the anchor placement is aligned with the drilled hole. Proper alignment is essential for successful repair.
- Use of excessive force during insertion can cause failure of the suture anchor or insertion device.
- Bone quality must be adequate to allow proper placement of the suture anchor.
- Do not alter the implant or instrumentation, otherwise performance may be compromised.
- Once seated, do not rotate the suture anchor device in the bone as this may cause device failure.
- Postoperative range of motion is to be determined by the physician.
- After use, this device may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.

Adverse Reactions
- Mild inflammatory reaction
- Foreign body reaction
- Infection, both deep and superficial
- Allergic reaction

Instructions for Use

Note: Use the appropriate Smith & Nephew instrumentation is necessary to prepare the insertion site and maintain axial alignment between the insertion site and the SUTUREFIX Ultra Suture Anchor.

1. Select the appropriate suture anchor instrumentation length (S or XL), based on the specific indication, preferred surgical technique, and patient history.
2. Place the distal tip of the drill guide onto the bone at the desired implantation site. Drill guide placement may be aided using an optional obturator.

English

3. Hold the drill guide firmly in place and use the appropriate suture anchor drill bit to prepare the insertion site. The depth stop on the drill bit bottoms out on the handle of the drill guide when proper hole depth is reached.

   Note: The following SUTUREFIX Ultra instruments and anchors are compatible.

Drill Guide	Drill Bit	Anchor
S	1.7 mm S	1.7 mm S
XL	1.7 mm XL	1.7 mm XL
S	1.9 mm S	1.9 mm S

   Instrumentation is available in two lengths: standard (S) and extra-long (XL). Select the drill that corresponds with the guide.

4. Hold the drill guide steady, maintain alignment, and remove the drill bit from the insertion site. Verify that the drill bit is rotating forward.
5. Continue to hold the drill guide firmly in place and insert the suture anchor into the guide with the desired suture orientation. To insert the anchor:
   a. Push or tap the proximal end of the anchor handle.
   b. Continue to push or tap until the anchor handle makes contact with the drill guide handle. This positions the suture anchor to the appropriate depth below the surface of the bone.

   CAUTION: Do not rotate the suture anchor device once seated in the bone as this may cause device failure.

6. Deploy the suture anchor.
   a. Keep the drill guide in place and press the lock button on the handle to unlock the sliding ring.

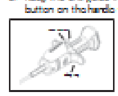

Figure 1a. Suture anchor handle (pre-deployment)

Figure 1b. Suture anchor handle (post-deployment)

   b. Deploy the anchor by pulling back on the sliding ring until a click is heard. This click confirms proper anchor deployment (Figure 1b).
   c. Unwind the suture from the now exposed suture cleat.

   CAUTION: Do not use sharp instruments to manage or control the suture.

   d. Pull back slowly on the handle to remove the insertion device from the drill guide. The anchor will remain in the bone and the suture will feed through the handle as it is removed.
   e. Discard the insertion device.

   CAUTION: After use, this device may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.

7. Reapply tension to the suture to confirm the stability of the suture anchor in the implantation site.
8. Pass the repair sutures through or around the soft tissue to be reattached using the desired suture passing techniques and devices.
9. Secure the repair of the tissue with standard knot tying techniques. When complete, cut and remove any excess suture.
10. Place additional suture anchors as required to complete the procedure.

Warranty

For single use only. This product is warranted to be free from defects in material and workmanship. Do not reuse.

For Further Information

If further information on this product is needed, contact Smith & Nephew Customer Service at +1 800 343 5717 in the U.S., or an authorized representative.

smith&nephew

SUTUREFIX® Curved Suture Anchor

10601353-B

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USA

CE

06/2017 10601636 Rev.B

SUTUREFIX® Curved Suture Anchor
SUTUREFIX gebogener Fadenanker
Anclaje curvado para suturas SUTUREFIX
Ancrage de suture incurvé SUTUREFIX
Ancora di sutura curva SUTUREFIX
SUTUREFIX Böjt suturankare
SUTUREFIX gebogen hechtdraadanker
Âncora de sutura curva SUTUREFIX
SUTUREFIX Buet suturanker
SUTUREFIX buet suturanker
SUTUREFIX 곡선형 봉합사고정기
Изогнутый шовный якорь SUTUREFIX
SUTUREFIX Kıvrık Sütür Kancası

Instructions for Use
Gebrauchsanweisung
Modo de empleo
Mode d'emploi
Istruzioni per l'uso
Bruksanvisning
Gebruiksaanwijzing
Instruções de utilização
Brugsanvisning
Bruksanvisning
사용 지침
Инструкция по применению
Kullanım Talimatları

MR

MR Magnetic resonance safe • MR-geeignet: Magnetresonanz • Seguro para procedimientos de RM (resonancia magnética) • Conforme aux normes de sécurité sur la résonance magnétique • Sicuro per la RM (risonanza magnetica) • MR-säker (magnetisk resonans) • MR-veilig (magnetische resonantie) • Seguro para RM (ressonância magnética) • MR (magnetisk resonans)-sikker • MR (magnetisk resonans)-sikker • MR (자기 공명) 안전 • MR (магнитный резонанс) – безопасно • MR (manyetik rezonans) güvenli

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English

SUTUREFIX® Curved Suture Anchor

STERILE EO MR

Device Description

The Smith & Nephew SUTUREFIX Curved Suture Anchor is a fixation device intended to provide secure fixation of soft tissue to bone. It consists of a soft suture anchor with attached non-absorbable suture(s) preassembled to a flexible insertion device. The anchors are available preloaded with either one #2 suture or two #1 sutures. This device is provided sterile, for single use only.

Contents

1 ea. Non-absorbable suture anchor – braided, silicone coated, polyester USP, non-absorbable.

1 ea. Flexible insertion device – stainless steel shaft, nitinol push rod, with polycarbonate handle

1 or 2 ea. Sutures – Braided, uncoated, UHMW polyethylene, white and/or blue, non-absorbable
and/or
UHMW polyethylene with monofilament polypropylene cobraid, blue, non-absorbable
and/or
UHMW polyethylene with monofilament nylon cobraid, black, non-absorbable

Refer to individual suture anchor product labels for suture size, type, and quantities.

Intended Use

The Smith & Nephew SUTUREFIX Curved Suture Anchors are intended for the reattachment of soft tissue to bone.

Indications for Use

The Smith & Nephew SUTUREFIX Curved Suture Anchors are intended for the secure fixation of soft tissue to bone for the following indications:

Hip

Acetabular labrum repair/reconstruction

Shoulder

- Capsular stabilization
  - Bankart repair
  - Anterior shoulder instability
  - SLAP lesion repairs
  - Capsular shift or capsulolabral reconstructions
  - Rotator cuff tear repairs
  - Biceps tenodesis

Contraindications

- Known hypersensitivity to the implant material. Where material sensitivity is suspected, appropriate tests should be performed and sensitivity ruled out prior to implantation.
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- Pathological conditions in the soft tissues to be attached that would impair secure fixation by suture.
- Comminuted bone surface, which would compromise secure anchor fixation.
- Physical conditions which would eliminate, or tend to eliminate, adequate anchor support or impair healing.

Warnings

Do not use if package is damaged. Do not use if the product sterilization barrier or its packaging is compromised.

- Contents are sterile unless package is opened or damaged. DO NOT RESTERILIZE. For single use only. Discard any open, unused product. Do not use after the expiration date.
- Prior to use, inspect the product package for structural integrity. If the seal of the outer sterile barrier is broken, or if the sterile barriers are otherwise damaged, the product should be considered non-sterile and not be used.
- It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.
- Read these instructions completely prior to use.
- Product must be stored in the original sealed pouch.
- Incomplete anchor insertion may result in the anchor not functioning as intended.
- Breakage of the flexible inserter can occur if the insertion site is not prepared with recommended Smith & Nephew curved guide & flexible drill prior to insertion.

English

- Only use the recommended flexible drill bits and curved drill guides intended for use with the SUTUREFIX® Curved Suture Anchor. Use of other instruments may injure the patient, damage the instruments, or compromise fixation.
- Maintaining guide alignment throughout drilling is required to ensure drill bit integrity.
- Do not attempt to implant this device within cartilage, epiphyseal growth plates or non-osseous tissue.
- Do not resterilize, or reuse anchors, sutures and insertion devices packaged with the SUTUREFIX Curved Suture Anchor.

Precautions

℞ U.S. Federal law restricts this device to sale by or on the order of a physician.

- Hazards associated with reuse of this device include, but are not limited to, patient infection and/or device malfunction.
- Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device.
- Postoperative care is important. Instruct the patient on the limitations of the implant and caution them regarding weight bearing and body stresses on the appliance prior to secure bone healing.
- Do not use sharp instruments to manage or control the suture.
- As with any suture anchor or suturing technique, the fixation given should be considered as only temporary until biological attachment of tissue to bone is completed, and may not withstand weight bearing or other unsupported stresses. The suture anchor and suture are not intended to provide indefinite biomechanical integrity.
- Implantation of the suture anchor requires preparation of the insertion site. Predrilling with the appropriate Smith & Nephew flexible Drill Bit is the preferred method of site preparation.
- Ensure the anchor placement is aligned with the drilled hole. Proper alignment is essential for successful repair.
- Use of excessive force during insertion can cause failure of the suture anchor or insertion device.
- Bone quality must be adequate to allow proper placement of the suture anchor.
- Do not alter the implant or instrumentation, otherwise performance may be compromised.
- Once seated, do not rotate the suture anchor device in the bone as this may cause device failure.
- Postoperative range of motion is to be determined by the physician.
- After use, this device may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.

Adverse Reactions

- Loss of fixation or pullout of suture anchors can occur
- Mild inflammatory reaction
- Foreign body reaction
- Infection, both deep and superficial
- Allergic reaction

Instructions for Use

Note: Use the appropriate Smith & Nephew instrumentation is necessary to prepare the insertion site and maintain axial alignment between the insertion site and the SUTUREFIX Curved Suture Anchor.

Note: The following SUTUREFIX Curved instruments and anchors are compatible.

Drill Guide	Drill Bit	Anchor
S	1.7 mm S	1.7 mm S
XL	1.7 mm XL	1.7 mm XL
S	1.9 mm S	1.9 mm S

Instrumentation is available in two lengths: standard (S) and extra-long (XL). Select the drill that corresponds with the guide. "S" Anchors are available in two configurations, single loaded (1.7 mm) and double loaded (1.9 mm). Select the drill that corresponds with the anchor.

1. Select the appropriate suture anchor instrumentation length (S or XL), based on the specific indication, preferred surgical technique, and patient history.
2. Place the distal tip of the curved drill guide onto the bone at the desired implantation site. Curved Drill guide placement may be aided using an optional flexible obturator.
3. Hold the curved drill guide firmly in place and use the appropriate suture anchor flexible drill bit to prepare the insertion site. Verify that the drill bit is rotating forward (clockwise) while drilling. The depth stop on the drill bit bottoms out on the handle of the drill guide when proper hole depth is reached.

   Note: For dense bone, it may be required to cycle the flexible drill in and out of the implantation site to ensure complete removal of bone.

English

4. Hold the curved drill guide steady, maintain alignment, and remove the flexible drill bit from the insertion site.

   CAUTION: Do not remove the curved drill guide from the anchor insertion site.

5. Continue to hold the curved drill guide firmly in place and insert the flexible suture anchor into the curved guide with the desired suture orientation. To insert the anchor:
   a. Push or tap the proximal end of the anchor handle.

      Note: If tapping, use multiple light taps for controlled insertion.

   b. Continue to push or tap until the anchor handle makes contact with the curved drill guide handle. This positions the suture anchor to the appropriate depth below the surface of the bone.

   CAUTION: Do not rotate the suture anchor device once seated in the bone as this may cause device failure.

6. Deploy the suture anchor.
   a. Keep the curved drill guide in place and press the lock button on the handle to unlock the sliding ring (Figure 1a).

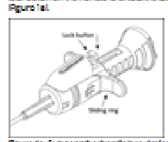


Figure 1a. Suture anchor handle (pre-deployment)

   b. Deploy the anchor by pulling back on the sliding ring until a click is heard. This click confirms proper anchor deployment (Figure 1b).

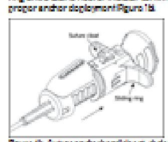


Figure 1b. Suture anchor handle (post-deployment)

   c. Unwind the suture from the now exposed suture cleat.

   CAUTION: Do not use sharp instruments to manage or control the suture.

   d. Pull back slowly on the handle to remove the insertion device from the curved drill guide. The anchor will remain in the bone and the suture will feed through the handle as it is removed.
   e. Discard the insertion device.

   CAUTION: After use, this device may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.

7. Reapply tension to the suture to confirm the stability of the suture anchor in the implantation site.
8. Pass the repair sutures through or around the soft tissue to be reattached using the desired suture passing techniques and devices.
9. Secure the repair of the tissue with standard knot tying techniques. When complete, cut and remove any excess suture.
10. Place additional suture anchors as required to complete the procedure.

Warranty

For single use only. This product is warranted to be free from defects in material and workmanship. Do not reuse.

For Further Information

If further information on this product is needed, contact Smith & Nephew Customer Service at +1 800 343 8386 in the U.S., or an authorized representative.

°Trademark of Smith & Nephew, registered U.S. Patent & Trademark Office.

21.2 PROTOCOL AMENDMENT

Not applicable, this protocol has not been amended.

21.3 QUALITY OF LIFE MEASURES EQ-5D-5L

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about ❑
I have slight problems in walking about ❑
I have moderate problems in walking about ❑
I have severe problems in walking about ❑
I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

PAIN / DISCOMFORT

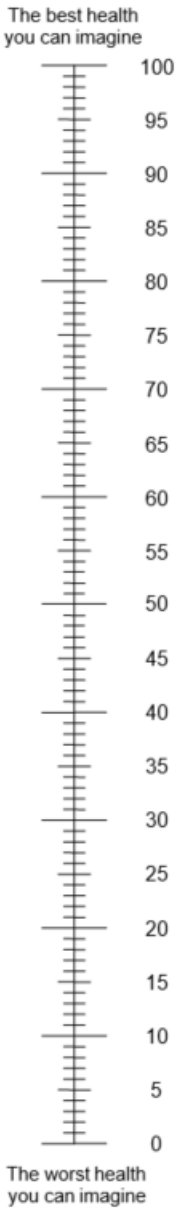
I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑
I am extremely anxious or depressed ❑

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐

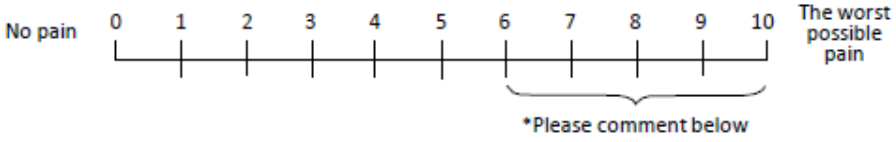


21.4 ADDITIONAL ASSESSMENTS

Patient Hip Assessments

Pain Assessment

1. Please select a number from the scale below that indicates the level of pain you are experiencing from your hip today

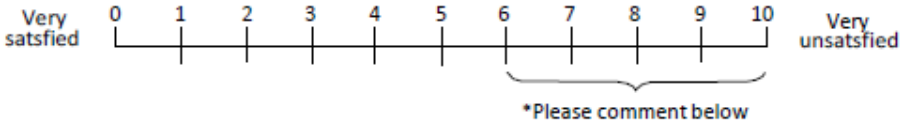


*Please provide a reason for your score _____

_____

Patient Satisfaction

2. Please select a number from the scale below that indicates your level of satisfaction with the arthroscopy repair surgery to stabilize your hip



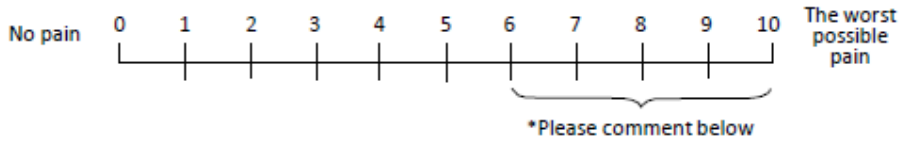
*Please provide a reason for your score _____

_____

Patient Shoulder Assessments

Pain Assessment

1. Please select a number from the scale below that indicates the level of pain you are experiencing from your shoulder today

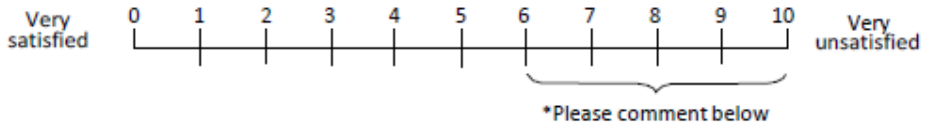


*Please provide a reason for your score _____

_____

Patient Satisfaction

2. Please select a number from the scale below that indicates your level of satisfaction with the arthroscopy repair surgery to stabilize your shoulder



*Please provide a reason for your score _____

_____

HOOS HIP SURVEY

Today's date:_____/_____/_____Date of birth:_____/_____/_____

Name:_____

INSTRUCTIONS: This survey asks for your view about your hip. This information will help us keep track of how you feel about your hip and how well you are able to do your usual activities.
Answer every question by ticking the appropriate box, only one box for each question.
If you are uncertain about how to answer a question, please give the best answer you can.

Symptoms

These questions should be answered thinking of your hip symptoms and difficulties during the **last week**.

S1. Do you feel grinding, hear clicking or any other type of noise from your hip?

Never	Rarely	Sometimes	Often	Always
☐	☐	☐	☐	☐

S2. Difficulties spreading legs wide apart

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

S3. Difficulties to stride out when walking

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Stiffness

The following questions concern the amount of joint stiffness you have experienced during the **last week** in your hip. Stiffness is a sensation of restriction or slowness in the ease with which you move your hip joint.

S4. How severe is your hip joint stiffness after first wakening in the morning?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

S5. How severe is your hip stiffness after sitting, lying or resting **later in the day**?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Pain

P1. How often is your hip painful?

Never	Monthly	Weekly	Daily	Always
☐	☐	☐	☐	☐

What amount of hip pain have you experienced the **last week** during the following activities?

P2. Straightening your hip fully

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

What amount of hip pain have you experienced the **last week** during the following activities?

P3. Bending your hip fully

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P4. Walking on a flat surface

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P5. Going up or down stairs

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P6. At night while in bed

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P7. Sitting or lying

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P8. Standing upright

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P9. Walking on a hard surface (asphalt, concrete, etc.)

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P10. Walking on an uneven surface

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Function, daily living

The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your hip.

A1. Descending stairs

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A2. Ascending stairs

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A3. Rising from sitting

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A4. Standing

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Hip dysfunction and Osteoarthritis Outcome Score (HOOS), English version LK 2.0 3

For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your hip.

A5. Bending to the floor/pick up an object

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A6. Walking on a flat surface

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A7. Getting in/out of car

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A8. Going shopping

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A9. Putting on socks/stockings

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A10. Rising from bed

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A11. Taking off socks/stockings

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A12. Lying in bed (turning over, maintaining hip position)

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A13. Getting in/out of bath

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A14. Sitting

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A15. Getting on/off toilet

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A16. Heavy domestic duties (moving heavy boxes, scrubbing floors, etc)

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A17. Light domestic duties (cooking, dusting, etc)

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Function, sports and recreational activities

The following questions concern your physical function when being active on a higher level. The questions should be answered thinking of what degree of difficulty you have experienced during the **last week** due to your hip.

SP1. Squatting

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

SP2. Running

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

SP3. Twisting/pivoting on loaded leg

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

SP4. Walking on uneven surface

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Quality of Life

Q1. How often are you aware of your hip problem?

Never	Monthly	Weekly	Daily	Constantly
☐	☐	☐	☐	☐

Q2. Have you modified your life style to avoid activities potentially damaging to your hip?

Not at all	Mildly	Moderately	Severely	Totally
☐	☐	☐	☐	☐

Q3. How much are you troubled with lack of confidence in your hip?

Not at all	Mildly	Moderately	Severely	Extremely
☐	☐	☐	☐	☐

Q4. In general, how much difficulty do you have with your hip?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Thank you very much for completing all the questions in this questionnaire.

Modified Harris Hip Score (mHHS) Calculation SOURCE WORKSHEET

Clinician Name:	
Subject ID:	___ ___ - ___ ___ ___
Subject Code:	___ ___ ___
Date (DD/MMM/YYYY):	

Instructions:
Use this Work Instruction as source documentation for the total mHHS calculation (mHHS question 12). The total mHHS is considered NULL if any question 1-8 is missing. mHHS questions 9-11 are not included in the total mHHS calculation.

Enter the actual score for questions 1-8 that correlates to the study subject's mHHS questionnaire response. To obtain the total mHHS add the actual scores from questions 1-8 then multiply by 1.1.

Question	Possible Score	Actual Score
1. Hip Pain:		
none or ignores it	44	
slight, minimal; no compromise in activities	40	
mild; following longer activities	30	
moderate; some limitations of activities	20	
marked; serious limitations of activities	10	
Disabled; no activities possible, bedridden	0	
2. Enter public transportation:		
yes, possible	1	
no, unable	0	
3. Putting on shoes and socks:		
with ease	4	
with difficulty	2	
unable	0	
4. Distance walked:		
unlimited, several hours	11	
six blocks, up to 2 km/1 mile	8	
daily shopping, up to 500 km/ .3 miles	5	
indoors only, up to 50 m/ 150 feet	2	
bed / chair / not able to walk	0	

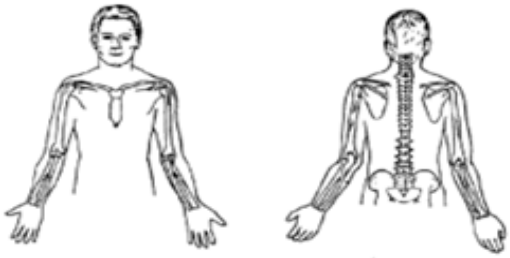
Question	Possible Score	Actual Score
5. Support:		
None	11	
single cane for long walk	7	
single cane most of the time	5	
one crutch	3	
two canes	2	
two crutches or not able to walk	0	
6. Stairs:		
foot over foot, without banister	4	
foot over foot, with banister	2	
in a manner	1	
unable	0	
7. Sitting:		
comfortably in any chair for one hour	5	
comfortably on high chair for one-half hour	3	
unable to sit comfortably	0	
8. Limp:		
none	11	
slight	8	
moderate	5	
severe	0	
Questions 1-8 Total:		
Total mHHS (Questions 1-8 Total x 1.1):		

SHOULDER ASSESSMENT FORM
AMERICAN SHOULDER AND ELBOW SURGEONS

PATIENT SELF-EVALUATION

Are you having pain in your shoulder? (circle correct answer)	Yes	No

Mark where your pain is on this diagram:



Do you have pain in your shoulder at night?	Yes	No
Do you take pain medication (aspirin, Advil, Tylenol, etc.)?	Yes	No
Do you take narcotic pain medication (codeine or stronger)?	Yes	No
How many pills do you take each day (average)?	pills	

How bad is your pain today (mark line)?

0 ——— 10

No pain at all — Pain as bad as it can be

Does your shoulder feel unstable (as if it is going to dislocate?)	Yes	No

How unstable is your shoulder (mark line)?

0 ——— 10

Very stable — Very unstable

Circle the number in the box that indicates your ability to do the following activities:
0 = **Unable** to do; 1 = **Very** difficult to do; 2 = **Somewhat** difficult; 3 = **Not** difficult

ACTIVITY		RIGHT ARM	LEFT ARM
1. Put on a coat		0 1 2 3	0 1 2 3
2. Sleep on your painful or affected side		0 1 2 3	0 1 2 3
3. Wash back/do up bra in back		0 1 2 3	0 1 2 3
4. Manage toiletting		0 1 2 3	0 1 2 3
5. Comb hair		0 1 2 3	0 1 2 3
6. Reach a high shelf		0 1 2 3	0 1 2 3
7. Lift 10 lbs. above shoulder		0 1 2 3	0 1 2 3
8. Throw a ball overhand		0 1 2 3	0 1 2 3
9. Do usual work - List:		0 1 2 3	0 1 2 3
10. Do usual sport - List:		0 1 2 3	0 1 2 3

Page 1

smith&nephew <Study Title@Master Pg> XX-XXXX-XX	**Constant Shoulder Score (CSS)**	**Subject ID:** ☐☐-☐☐☐ **Subject Code:** ☐☐☐ ☐ Left ☐ Right

INSTRUCTIONS: *Please select one answer from each of the following questions.*

During the past 4 weeks….

1. Pain

- ☐ Severe
- ☐ Moderate
- ☐ Mild
- ☐ None

2. Activity level

	Yes	No
Unaffected sleep	☐	☐
Full recreation/sport	☐	☐
Full work	☐	☐

3. Arm positioning

- ☐ Up to waist
- ☐ Up to xiphoid
- ☐ Up to neck
- ☐ Up to top of head
- ☐ Above head

4. Strength of abduction (pounds)

☐ 0	☐ 13-15
☐ 1-3	☐ 16-18
☐ 4-6	☐ 19-21
☐ 7-9	☐ 22-24
☐ 10-12	☐ >24

RANGE OF MOTION

5. Forward flexion

- ☐ 31-60 degrees
- ☐ 61-90 degrees
- ☐ 91-120 degrees
- ☐ 121-150 degrees
- ☐ 151-180 degrees

6. Lateral elevation

- ☐ 31-60 degrees
- ☐ 61-90 degrees
- ☐ 91-120 degrees
- ☐ 121-150 degrees
- ☐ 151-180 degrees

7. External rotation

- ☐ Hand behind head, elbow forward
- ☐ Hand behind head, elbow back
- ☐ Hand to top of head, elbow forward
- ☐ Hand to top of head, elbow back
- ☐ Full elevation

8. Internal rotation

- ☐ Lateral thigh
- ☐ Buttock
- ☐ Lumbosacral junction
- ☐ Waist (L3)
- ☐ T12 Vertebra
- ☐ Interscapular (T7)

Constant CR, Murley AH. A clinical method of functional assessment of the shoulder. Clin Orthop Relat Res. 1987 Jan;(214): 160-4

smith&nephew <Study Title@Master Pg> XX-XXXX-XX	**The ROWE Score for Instability**	**Subject ID:** ☐☐-☐☐☐ **Subject Code:** ☐☐☐ ☐ Left ☐ Right

INSTRUCTIONS: *Please select one answer from each of the following questions.*

Section 1 - Stability

- ☐ No recurrence, subluxation or apprehension
- ☐ Apprehension when placing arm in certain positions
- ☐ Subluxation (not requiring reduction)
- ☐ Recurrent dislocation

Section 2 - Motion

- ☐ 100% of normal ext rotation, int rotation and elevation
- ☐ 75% of normal ext rotation, int rotation and elevation
- ☐ 50% of normal ext rotation, int rotation and elevation
- ☐ 50% of normal elevation, and int rotation, no ext rotation

Section 3 - Function

- ☐ No limitation of work or sports, little or no discomfort (e.g. shoulder strong overhead, lifting, swimming, throwing, tennis
- ☐ Mild limitation and minimum discomfort
- ☐ Moderate limitation and discomfort
- ☐ Marked limitation and pain

With the permission of the Journal of Bone and Joint Surgery

21.5 PRINCIPAL INVESTIGATOR OBLIGATIONS (ISO 14155:2011)

1. General:
    a. The role of the PI is to implement and manage the day-to-day conduct of the clinical investigation as well as ensure data integrity and the rights, safety, and well-being of the subjects involved in the clinical investigation.
2. Qualification of the PI. The PI shall:
    a. be qualified by education, training, and experience to assume responsibility for the proper conduct of the clinical investigation in accordance with this International Standard; evidence of such qualifications of the PI and key members of the investigation site team shall be provided to the Sponsor through up-to-date Curriculum Vitae (CV) or other relevant documentation,
    b. be experienced in the field of application and trained in the use of the investigational device under consideration,
    c. disclose potential conflicts of interest, including financial, that interfere with the conduct of the clinical investigation or interpretation of results, and
    d. be knowledgeable with the method of obtaining informed consent.
3. Qualification of investigation site. The PI shall be able to demonstrate that the proposed investigation site:
    a. has the required number of eligible subjects needed within the agreed recruitment period, and
    b. has one or more qualified investigators, a qualified investigation site team and adequate facilities for the foreseen duration of the clinical investigation.
4. Communication with the IEC. The PI shall:
    a. provide the Sponsor with copies of any clinical-investigation-related communications between the PI and the IEC,
    b. comply with the requirements described in 4.5 of ISO 14155:2011:
        i. Submit to the IEC the following information, any amendments and any additional documentation required by the IEC: the Protocol; IB or equivalent; informed

consent form and any other written information provided to subjects; procedures for recruiting subjects and advertising materials, if any; a copy of the CV of the PI(s) for with the IEC has oversight.

ii. Provide documentation of the IECs approval/favorable opinion, identifying the documents and amendments on which the opinion was based, to the Sponsor, prior to commencing the clinical investigation.

iii. Submit the following to the IEC if required by national regulations, the protocol or IEC, whichever is more stringent:

1. SAEs
2. Requests for deviations, and reports of deviations, if the deviation affects subject's rights, safety, and well-being, or the scientific integrity of the clinical investigation. Document and report to the Sponsor and IEC a report of deviations made to protect the rights, safety, and well-being of human subjects under emergency circumstances.
3. Progress reports, including safety summary and deviations
4. Amendments to any documents already approved by the IEC.
5. If applicable, notifications of suspension or premature termination
6. If applicable, justification and request for resuming the clinical investigation after suspension.
7. Clinical investigation report or summary.

iv. As a minimum, during the clinical investigation, the following information shall be obtained in writing from the IEC prior to implementation:

1. Approval/favorable opinion of amendments
2. Approval of the request for deviations that can affect the subject's rights, safety, and well-being or scientific integrity of the clinical investigation
3. Approval for resumption of a suspended clinical investigation if applicable.

c. obtain the written and dated approval/favorable opinion of the IEC for the clinical investigation before recruiting subjects and implementing all subsequent amendments, if required,

d. promptly report any deviations from the protocol that affect the rights, safety or well-being of the subject or the scientific integrity of the clinical investigation, including those which occur under emergency circumstances, if required by the IEC, protocol or national regulations. In particular circumstances, the communication with the IEC can be performed by the Sponsor, partly or in full, in which case the Sponsor shall keep the Principal Investigator informed.

5. Informed consent process. The PI shall:

a. General:

i. Informed consent shall be obtained in writing from the subject and the process shall be documented before any procedure specific to the clinical investigation is applied to the subject; except when special circumstances for emergency treatments apply (see below)

ii. The informed consent form consists of an information form and informed consent signature form. These two forms can either be combined in one document or separated into two documents

b. Process of obtaining informed consent. The general process for obtaining informed consent shall be documented in the protocol and shall comply with the following. These requirements also apply with respect to informed consent obtained from a subject's legally authorized representative:

i. Ensure that the PI or his/her authorized designee conducts the informed consent process

ii. Include all aspects of the clinical investigation that are relevant to the subject's decision to participate throughout the clinical investigation

iii. Avoid any coercion or undue improper influence on, or inducement of, the subject to participate

iv. Not waive or appear to waive the subject's legal rights

v. Use native non-technical language that is understandable to the subject

vi. Provide ample time for the subject to read and understand the informed consent form and to consider participation in the clinical investigation

vii. Include personally dated signatures and the PI or an authorized designee responsible for conducting the informed consent process

viii. Show how informed consent will be obtained in special circumstances (see below) where the subject is unable to provide him or herself, and

ix. Ensure important new information is provided to new and existing subjects throughout the clinical investigation.

c. Special circumstances for informed consent (the following provisions are subject to national regulations):

i. Subject needing legally authorized representatives: informed consent may be given by the legally authorized representative only if a subject is unable to make the decision to participate in a clinical investigation (e.g. infant, child, or juvenile, seriously ill or unconscious subject, mentally ill person, mentally handicapped person). In such cases, the subject shall also be informed about the clinical investigation within his/her ability to understand.

ii. Subject unable to read or write: informed consent shall be obtained through a supervised oral process if a subject or legally authorized representative is unable to read or write. An independent witness shall be present throughout the process. The written informed consent form and any other information shall be read aloud and explained to the prospective subject or his/her legally authorized representative and, whenever possible, either shall sign and personally date the informed consent form. The witness also signs and personally dates the informed consent for attesting that the information was accurately explained and that the informed consent was freely given.

iii. Emergency treatments:

1. For clinical investigations involving emergency treatments, when prior informed consent of the subject is not possible because of the subject's medical condition, the informed consent of the subject's legally authorized representative, if present, shall be requested.

2. When it is not possible to obtain prior informed consent from the subject, and the subject's legally authorized representative, is not available, the subject may still be enrolled if a specific process has been described in the protocol.
3. Arrangements shall be made to inform the subject or legally authorized representative, as soon as possible, about the subject's inclusion in the clinical investigation and about all aspects of the clinical investigation.
4. The subject shall be asked to provide informed consent for continued participation as soon as his/her medical condition allows.

d. The Principal Investigator may not enroll a subject without obtaining informed consent of the subject or his/her legally authorized representative only when the following conditions are fulfilled: the prospective subject fulfils the emergency conditions and is obviously in a life-threatening situation; no sufficient clinical benefits are anticipated from the currently available treatment; there is a fair possibility that the life-threatening risk to the prospective subject can be avoided if the investigational device is used; anticipated risks are outweighed by the potential benefits of applying the investigational device ; the legally authorized representative cannot be promptly reached and informed.

e. Information provided to the subject. All information pertinent to the clinical investigation, including at least the following, shall be provided in writing and in native, non-technical language that is understandable to the subject (or the subject's legally authorized representative):
   i. Description and purpose
   ii. Potential benefits
   iii. Risks and inconveniences or the subject and, when applicable, for any embryo, foetus or nursing infant
   iv. Alternative procedures
   v. Confidentiality
   vi. Compensation
   vii. Anticipated expenses, if any, to be borne by the subject for participating in the clinical investigation

viii. Information on the role of Sponsor's representative in the clinical investigation

ix. Contact persons

x. Statement declaring that new findings or the reasons for any amendment to the protocol that affect the subject's continued participation shall be made available to the subject.

xi. Statement indicating that, upon the subject's approval, the subject's personal physician will be informed of the subject's participation in the clinical investigation

xii. Termination procedures

f. Informed consent signature shall contain the following:

i. The voluntary agreement to participate in the clinical investigation and follow the investigator's instructions

ii. A statement declaring that refusal of participation incurs no penalty for the subject

iii. A statement declaring that discontinuation at any time incurs no penalty for the subject

iv. A statement with regard to the possible consequences of withdrawal

v. An acknowledgement of the information provided and confirmation that all the subject's questions were answered

vi. A statement confirming that the subject or his/her legally authorized representative agrees to the use of the subject's relevant personal data for the purpose of the clinical investigation

vii. A statement confirming that the subject or his/her legally authorized representative agrees that Sponsor's representatives, regulatory authorities and IEC representatives will be granted direct access to the subject's medical records.

g. New information: if new information becomes available that can significantly affect a subject's future health and medical care, that information shall be provided to the subject(s) affected in written form. If relevant, all affected subjects shall be asked to confirm their continuing consent in writing.

h. ensure compliance with the applicable regulatory requirements and ethical principles for the process of obtaining informed consent, and

i. ensure and document appropriate training if an authorized designee is appointed to conduct the informed consent process.

6. Compliance with the protocol. The Principal Investigator shall:

a. indicate his/her acceptance of the protocol in writing,
b. conduct the clinical investigation in compliance with the protocol,
c. create and maintain source documents throughout the clinical investigation and make them available as requested during monitoring visits or audits,
d. ensure that the investigational device is used solely by authorized users as specified in 6.2, and in accordance with the protocol and instructions for use,
e. propose to the Sponsor any appropriate modification(s) of the protocol or investigational device or of the use of the investigational device,
f. refrain from implementing any modifications to the protocol without agreement from the Sponsor, IEC and regulatory authorities, if required,
g. document and explain any deviation from the approved protocol that occurred during the course of the clinical investigation,
h. ensure that an adequate investigation site team and facilities exist and are maintained and documented during the clinical investigation,
i. ensure that maintenance and calibration of the equipment relevant for the assessment of the clinical investigation is appropriately performed and documented, where applicable,
j. ensure the accuracy, completeness, legibility and timeliness of the data reported to the Sponsor in the CRF and in all required reports,
k. maintain the device accountability records,
l. allow and support the Sponsor to perform monitoring and auditing activities,
m. be accessible to the monitor and respond to questions during monitoring visits,
n. allow and support regulatory authorities and the IEC when performing auditing activities,
o. ensure that all clinical-investigation-related records are retained as required taking measures to prevent accidental or premature destruction, and

p. review and sign the clinical investigation report, as applicable.

7. Medical care of subjects. The Principal Investigator shall

   a. provide adequate medical care to a subject during and after a subject's participation in a clinical investigation in the case of adverse events,
   b. inform the subject of the nature and possible cause of any adverse events experienced,
   c. provide the subject with the necessary instructions on proper use, handling, storage, and return of the investigational device, when it is used or operated by the subject,
   d. inform the subject of any new significant findings occurring during the clinical investigation, including the need for additional medical care that may be required,
   e. provide the subject with well-defined procedures for possible emergency situations related to the clinical investigation, and make the necessary arrangements for emergency treatment, including decoding procedures for blinded/masked clinical investigations, as needed,
   f. ensure that clinical records are clearly marked to indicate that the subject is enrolled in a particular clinical investigation,
   g. if appropriate, subjects enrolled in the clinical investigation shall be provided with some means of showing their participation in the clinical investigation, together with identification and compliance information for concomitant treatment measures (contact address and telephone numbers shall be provided),
   h. inform, with the subject's approval or when required by national regulations, the subject's personal physician about the subject's participation in the clinical investigation, and
   i. make all reasonable efforts to ascertain the reason(s) for a subject's premature withdrawal from the clinical investigation while fully respecting the subject's rights.

8. Safety reporting. The Principal Investigator shall:

   a. record every adverse event and observed device deficiency, together with an assessment,

b. report to the Sponsor, without unjustified delay, all serious adverse events and device deficiencies that could have led to a serious adverse device effect; this information shall be promptly followed by detailed written reports, as specified in the protocol,
c. c) report to the IEC serious adverse events and device deficiencies that could have led to a serious adverse device effect, if required by the national regulations or protocol or by the IEC,
d. report to regulatory authorities serious adverse events and device deficiencies that could have led to a serious adverse device effect, as required by the national regulations, and
e. supply the Sponsor, upon Sponsor's request, with any additional information related to the safety reporting of a particular event.