Title of Protocol:	Prospective Multi-Center Post-Market Clinical Follow-up Study to Evaluate Safety and Performance of the MICRORAPTOR™ REGENESORB™ Suture Anchor, MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor and MICRORAPTOR™ Knotless PEEK Suture Anchors (and MINITAPE Sutures) in Shoulder and Hip Arthroscopic Instability Repair
Version:	3.0
Date:	03SEP2021
Date and Version of Previous Protocol:	Version 2.0 27NOV2019
Sponsor Name and Address:	Smith & Nephew, Inc. 150 Minuteman Road Andover, MA 01810 USA
Investigational Product	MICRORAPTOR™ REGENESORB™ Suture Anchor MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor MICRORAPTOR™ Knotless PEEK Suture Anchor, including when used with the MINITAPE Suture
Protocol Author(s):	Vanessa Nifo, Clinical Study Manager Michelle Foster, Senior Biostatistician Muftau Lawal, Senior Safety Specialist Karen Schomburg, Medical Writer

1. SIGNATURES

1.1 PRINCIPAL INVESTIGATOR SIGNATURE PAGE

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

I have read the attached protocol entitled "Prospective Multi-Center Post-Market Clinical Follow-up Study to Evaluate Safety and Performance of the MICRORAPTOR™ REGENESORB™ Suture Anchor, MICRORAPTOR™ Knotless REGENESORB™™ Suture Anchor and MICRORAPTOR™ Knotless PEEK Suture Anchors (and MINITAPE Sutures) in Shoulder and Hip Arthroscopic Instability Repair", version 3.0, dated 03SEP2021, and agree to abide by all provisions set forth herein.

I agree to comply with the Investigator's Obligations stipulated in Section 24.3 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, Inc..

Name, Address, Professional Position	**Signature**	**Date Signed** (DD/MMM/YYYY)

1.2 COORDINATING INVESTIGATOR APPROVAL

☐ I have read the attached protocol entitled "Prospective Multi-Center Post-Market Clinical Follow-up Study to Evaluate Safety and Performance of the MICRORAPTOR™ REGENESORB™ Suture Anchor, MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor and MICRORAPTOR™ Knotless PEEK Suture Anchors (and MINITAPE Sutures) in Shoulder and Hip Arthroscopic Instability Repair", version 3.0, dated 03SEP2021 and agree to abide by all provisions set forth therein.

Name, Address, Professional Position	Signature and Date / DocuSign Stamp

1.3 SPONSOR APPROVAL

Name and Title	Signature and Date / DocuSign Stamp
Rachael Winter Senior Director Global Clinical Affairs (Head of Global Clinical Operations)	DocuSigned by: Rachael Winter Signer Name: Rachael Winter Signing Reason: I approve this document Signing Time: 02-Nov-2021 | 07:53:57 GMT A32F12A80F1B4490986E80ACCB7471CB
Lori Fontaine Vice President ,Global Clinical Strategy (Head of Global Clinical Strategy Sports Med/ENT)	DocuSigned by: Signer Name: Lori Fontaine Signing Reason: I approve this document Signing Time: 27-Oct-2021 | 23:36:43 BST 01CFB53A1ADE40E3B2C947E8353635A1
Alan Rossington Sr Director, Global Data Analytics Global Clinical Affairs (Head of Global Data Analytics)	DocuSigned by: Alan Rossington Signer Name: Alan Rossington Signing Reason: I approve this document Signing Time: 29-Oct-2021 | 09:32:09 BST 556E7DBFCA8A4287A7EE3EE9B5B3ABFD
Luca Orlandini Vice President Medical Affairs Global Clinical Affairs (Medical Affairs Representative)	DocuSigned by: Signer Name: Luca Orlandini Signing Reason: I approve this document Signing Time: 03-Nov-2021 | 21:28:55 GMT FC872951AC1C4261B85EC7A7CD09ACDC

1.4 PROTOCOL AMENDMENT SUMMARY OF CHANGES TABLE

DOCUMENT HISTORY		
Document	**Version**	**Date**
Original Protocol	*1.0*	*29Mar2019*
Amendment 1	*2.0*	*25NOV2019*
Amendment 2	*3.0*	*03SEP2021*

Amendment: Version 2.0 to 3.0

The protocol changes below are to update eligibility criteria to include subjects ≥ 12 years of age to participate in the study, update the eligibility criteria to align with the pending removal of the Rotator Cuff Indication for MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor and MICRORAPTOR™ Knotless PEEK Suture Anchors, update the eligibility criteria to clarify Bicep Tenodesis Indication is for the knotless anchors only, additions to align with the Sponsor's current protocol template, and administrative actions to clarify and/or correct typographical errors.

Overall Rationale for the Amendment:

The protocol changes below were made to allow enrollment of minors, to clarify indications, and align with the Sponsor's current procedures and templates.

Section # and Name	Description of Change	Brief Rationale
Throughout Protocol	Updated Sponsor Name and Branding	To align with current Sponsor branding and templates
Throughout Protocol	Updated Protocol Version and Date	To align with amendment
Throughout Protocol	Administrative updates such as section numbering and formatting	To correct prior administrative changes
Throughout Protocol	Removed reference to the 2011 year of ISO 14155	To align with current Sponsor procedures and templates
1.2 Coordinating Investigator Approval	Added Coordinating Investigator Approval signature section	To align with current Sponsor procedures and regulations
1.3 Sponsor Approval	Updated Sponsor Approval signature section	To align with current Sponsor procedures and templates
3.1 Synopsis Number of Study Sites and 6.1 Overall Design	Updated to clarify number of sites per study arm	To reduce confusion and follow-up on a prior memo submitted to IRBs
3.1 Synopsis Inclusion Criteria and 7.2 Inclusion Criteria	Updated Inclusion criterion 1 by removing the Rotator Cuff Indication and clarifying that the Bicep Tenodesis Indication only applies to the knotless anchors Updated Inclusion Criterion 2 and 3 to allow for enrollment of subjects ≥ 12 years of age at time of surgery and specified	To align with current IFUs. To allow minors to enroll in all arms of the study, but especially for the MICRORAPTOR Knotless REGENESORB Shoulder Indication due to Shoulder instability common in younger subjects.

	consenting/assenting requirements.	
3.1 Synopsis Sample Size	Updated Microraptor Regenesorb Shoulder sample size	To align with Sample size Justification
6.1 Overall Design	Updated indications by removing Rotator Cuff and clarifying that the Bicep Tenodesis only applies to the knotless anchors. Also updated sample size	To align with current IFUs.
6.2 Scientific Rationale for Study Design	Updated sample size due to sample size justification	To align with sample size justification
6.3 Allocation and Blinding	Added Allocation and Blinding section	To align with current Sponsor procedures and templates
7.2 Inclusion Criteria	Updated indications by removing Rotator Cuff and clarifying that the Bicep Tenodesis only applies to the knotless anchors	To align with Current IFU
7.4 Informed Consent	Added informed consent and assent process for Minors and Vulnerable Population	To align with change in eligibility criteria
9.1.2 Product Use and 9.1.3 Packaging and Labeling	Added sections	To align with current Sponsor template
9.2 Ancillary Products	Added section	To align with current Sponsor template and with current study practices
12. Adverse Events and Deficiencies	Updated terminology throughout section	To align with current Sponsor template
13.1 Sample Size Justification	Added sample size justification for MICRORAPTOR™ REGENESORB™ (Knotted)	To align with the updated IFU that excluded Bicep Tenodesis as an indication for MICRORAPTOR™ REGENESORB (Knotted).
13.6 Interim Analysis	Removed details	No longer needed for products
15. Sponsor and Monitor Responsibilities	Added sections regarding Site Qualification Visits, Site Initiation Visits, Interim Monitoring Visits, and Close-out Visits	To align with current Sponsor template
16. Protocol Deviations, 17. Protocol Amendments, 24.1 Appendix: Instructions for Use, and 24.2 Appendix: Equipment and Special Instructions	Added sections	To align with current Sponsor procedures and templates

Amendment: Version 1.0 to 2.0

The protocol changes below are editorial/administrative updates and do not affect the scientific intent, patient risk, or human subject protection. These changes include adding of products (MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor and MICRORAPTOR™ Knotless PEEK Suture Anchors), increasing sample size, adding a 24 month visit for the MICRORAPTOR™ Knotless REGENESORB™ arm, and administrative actions to clarify and/or correct typographical errors.

Overall Rationale for the Amendment:
The protocol changes below were made to include the MICRORAPTOR™ suture anchor product family, increase sample size to account for the additional product arms, and addition of a 24 month visit for the MICRORAPTOR™ Knotless REGENESORB™ arm.

Section # and Name	Description of Change	Brief Rationale
Document Header	Added MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor and MICRORAPTOR™ Knotless PEEK Suture Anchors (and MINITAPE sutures) to protocol title, revised version date and number	The protocol has been revised to include all three Microraptor anchors: MICRORAPTOR™ REGENESORB™ Suture Anchors, MICRORAPTOR™ Knotless REGENESORB™ Suture Anchors, and MICRORAPTOR™ Knotless PEEK Suture Anchors (and MINITAPE sutures)
Title Page	Updated information to reflect version changes and addition of MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor and MICRORAPTOR™ Knotless PEEK Suture Anchors Updated Sponsor address Updated Biostatistician information	Sponsor address has been corrected and Biostatistician has been updated.
Section 1.1 Principal Investigator Signature Page	Updated protocol version number and date	
Section 3.1 Synopsis	Updated information to reflect version changes and addition of MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor and MICRORAPTOR™ Knotless PEEK Suture Anchors; Updated sample size, number of sites, and study duration; Added rotator cuff repair to inclusion criteria #1 for knotless anchors; Revised Exclusion criteria #12;	Sample size updated to include all subjects for each anchor product. The number of sites has been increased to allow for additional investigators for each anchor product. Rotator cuff repair was added as a shoulder indication for Knotless anchors. Exclusion #12 was revised to clarify that women of childbearing potential cannot be

	Clarified secondary endpoints per study product	pregnant or breast feeding to qualify for the trial. Secondary endpoints have been updated to note that these will be analyzed by product and endpoints are clarified per subject arm.
Section 3.2 Schema	Revised 12 month visit to note that this is a follow up visit for the MICRORAPTOR™ Knotless REGENESORB™ arm and an End of Study visit for MICRORAPTOR™ REGENESORB™ and MICRORAPTOR™ Knotless PEEK arms; Added 24 month visit for MICRORAPTOR™ Knotless REGENESORB™ arm; Clarify that only 30 hip and 30 shoulder subjects will be required to complete the 24 month visit for MICRORAPTOR™ Knotless REGENESORB™ arm	MICRORAPTOR™ Knotless REGENESORB™ subjects will have a 24 month visit whereas MICRORAPTOR™ REGENESORB™ and MICRORAPTOR™ Knotless PEEK subjects will end the study at 12 months. Only 30 hip and 30 shoulder subjects from the MICRORAPTOR™ Knotless REGENESORB™ arms will be required to complete the 24 month visit.
Section 3.3 Schedule of Activities	Added MRIs for MICRORAPTOR™ Knotless REGENESORB™ arm; Added 24 month visit for MICRORAPTOR™ Knotless REGENESORB™ arm; Added notation to 12 month visit regarding study arms; Revised footnotes	MICRORAPTOR™ Knotless REGENESORB™ subjects will be required to have a pre-op, 6 month and 24 month MRI. MICRORAPTOR™ Knotless REGENESORB™ subjects will have a 24 month visit whereas MICRORAPTOR™ REGENESORB™ and MICRORAPTOR™ Knotless PEEK subjects will end the study at 12 months. Footnotes were revised to show these changes.
Section 4.1 Study Rationale Section 4.2 Background Section 4.4 Benefit/Risk Assessment	Added information on MICRORAPTOR™ Knotless REGENESORB™ Suture Anchors, MICRORAPTOR™ Knotless PEEK Suture Anchors and MINITAPE sutures	Information has been added due the inclusion of MICRORAPTOR™ Knotless REGENESORB™ Suture Anchors, MICRORAPTOR™ Knotless PEEK Suture Anchors

		and MINITAPE sutures to the protocol.
Section 5.1 Primary Objective Endpoint	Added clarification of repair failure	Define primary objective of repair failure more clearly.
Section 5.2 Secondary Objectives Endpoints	Added secondary endpoints by product; Clarification that questionnaires will be assessed by change in scores from pre-op to post-op	Secondary endpoints have been updated to note that these will be analyzed by product and endpoints are clarified per subject arm.
Section 6.1 Overall Design	Addition of MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor and MICRORAPTOR™ Knotless PEEK Suture Anchors; Updated sample size, number of sites, and study duration; Added rotator cuff repair to shoulder indications for knotless anchors; Updated schema to match section 3.2	Revised to match updates as in Section 3.1.
Section 6.2 Scientific Rationale	Addition of MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor and MICRORAPTOR™ Knotless PEEK Suture Anchors; Updated sample size and study duration	Added due to the inclusion of MICRORAPTOR™ Knotless REGENESORB™ Suture Anchors, MICRORAPTOR™ Knotless PEEK Suture Anchors and MINITAPE sutures to the protocol. Study duration updated to reflect 24 month visit for Knotless REGENESORB arms.
Section 7.2 Inclusion Criteria	Added rotator cuff repair to inclusion criteria #1 for knotless anchors	Added to reflect IFU for MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor and MICRORAPTOR™ Knotless PEEK Suture Anchor
Section 7.3 Exclusion Criteria	Addition of MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor and MICRORAPTOR™ Knotless PEEK Suture Anchors to exclusion #10; Revised exclusion criteria #12 to women who are pregnant and nursing only	Added due to the inclusion of MICRORAPTOR™ Knotless REGENESORB™ Suture Anchors and MICRORAPTOR™ Knotless PEEK Suture Anchors to the protocol. Exclusion #12 was revised to clarify that women of childbearing potential cannot be

		pregnant or breast feeding to qualify for the trial.
Section 8	Added Radiographic evaluation information for MICRORAPTOR™ REGENESORB™ and MICRORAPTOR™ Knotless PEEK Suture Anchors; Added MRI information for MICRORAPTOR™ Knotless REGENESORB™ Suture Anchors	Further clarification of measurements required per study arm. Radiographic evaluation information added for MICRORAPTOR™ REGENESORB™ and MICRORAPTOR™ Knotless PEEK Suture Anchors. MRI information added for MICRORAPTOR™ Knotless REGENESORB™ Suture Anchors.
Section 9.1 Investigational Product	Added product information for MICRORAPTOR™ Knotless REGENESORB™ Suture Anchors, MICRORAPTOR™ Knotless PEEK Suture Anchors, and MINITAPE Sutures	Information has been added due the inclusion of MICRORAPTOR™ Knotless REGENESORB™ Suture Anchors, MICRORAPTOR™ Knotless PEEK Suture Anchors and MINITAPE sutures to the protocol.
Section 11.1 Visits and Examinations	Updated Schedule of Activities to match Section 3.3	Updated to match Section 3.3.
Section 11.1.1 Visit 1	Added MRI collection per standard of care for Knotless REGENESORB™ subjects; #8 Changed to allow imaging up to 6 months prior to screening	Added MRI collection for Knotless REGENESORB™ subjects. Previous imaging (≤6 months from screening) allowed for subjects who have had recent imaging that is acceptable according to standard of care guidelines.
Section 11.1.2 Visit 2	#6 Added suture type used with Knotless PEEK and Knotless REGENESORB™ anchors, and clock-face position of anchors	Collection of suture types used for knotless anchors has been added. Clock-face position of anchor placement will now be collected.
Section 11.1.3 Visit 3	#5 Added required MRI for MICRORAPTOR™ Knotless REGENESORB™ arms	6 month MRI is required for MICRORAPTOR™ Knotless REGENESORB™ arms.
Section 11.1.4 Visit 4	Changed visit name to 12 Month Follow-up (MICRORAPTOR™	MICRORAPTOR™ Knotless REGENESORB™ subjects

	Knotless REGENESORB™ subjects) / End of Study (MICRORAPTOR™ REGENESORB™, MICRORAPTOR™ Knotless PEEK subjects); Added #8 to instruct MICRORAPTOR™ Knotless REGENESORB™ subjects to return for the month 24 visit	will have a 24 month visit whereas MICRORAPTOR™ REGENESORB™ and MICRORAPTOR™ Knotless PEEK subjects will end the study at 12 months.
Section 11.1.5 Visit 5	Added 24 month visit for MICRORAPTOR™ Knotless REGENESORB™ subjects; Notation that only 30 hip and 30 subjects are required to complete this visit	Only 30 hip and 30 shoulder subjects from the MICRORAPTOR™ Knotless REGENESORB™ arms will be required to complete the 24 month visit.
Section 12.9 Subject Pregnancy	Changed to eliminate requirement for birth control since exclusion #12 has been revised	Revised to reflect changes to exclusion #12.
Section 13.1 Sample Size Justification	Added sample size justification for MICRORAPTOR™ Knotless PEEK arm	Added due the inclusion of MICRORAPTOR™ Knotless PEEK Suture Anchors.
Section 13.2 Analysis Populations	Added Full Analysis Set; Added subgroup for MINITAPE sutures	MICRORAPTOR™ Knotless PEEK arms that include MINITAPE use will be analyzed.
Section 13.4.1 Analysis of Primary Endpoint	Added statement that for the subgroup of subjects in the shoulder and hip groups, this same type of analysis will be repeated for summarizing repair failure rate using the SAF population	Clarification that shoulder and hip subjects from each anchor product will be analyzed separately for the primary endpoint.
Section 13.4.2 Analysis of Secondary Endpoints	Added repair failure rate at 24 months and MRI analysis for MICRORAPTOR™ Knotless REGENESORB™ subjects; Added level of pain analysis and patient reported outcome score analysis for all arms	Clarification on each type of secondary endpoint analysis.
Section 13.6 Interim Analysis	Changed to only include an interim analysis for MICRORAPTOR™ Knotless REGENESORB™ arms	Only MICRORAPTOR™ Knotless REGENESORB™ arms will require an interim analysis.

2. CONTENTS

2.1 TABLE OF CONTENTS

3. PROTOCOL SUMMARY

3.1 SYNOPSIS

Title of Study:	Prospective Multi-Center Post-Market Clinical Follow-up Study to Evaluate Safety and Performance of the MICRORAPTOR™ REGENESORB™ Suture Anchor, MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor and MICRORAPTOR™ Knotless PEEK Suture Anchors (and MINITAPE Sutures) in Shoulder and Hip Arthroscopic Instability Repair
Study Design:	Prospective, multi-center, non-randomized
Study Type:	Post-market clinical follow-up (PMCF) study
Study Products:	MICRORAPTOR™ REGENESORB™ Suture Anchor MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor MICRORAPTOR™ Knotless PEEK Suture Anchor, including when used with the MINITAPE Suture
Study Purpose:	To assess safety and performance by product of MICRORAPTOR™ REGENESORB™ Suture Anchor, MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor, MICRORAPTOR™ Knotless PEEK Suture Anchor and MINITAPE Suture
Primary Objective:	To assess, by product, repair failure rate at 6 months.
Secondary Objective(s):	To assess, by product, intra-operative repair failure and post-operative repair failure rates as well as performance as assessed with patient-reported outcomes.
Safety Objective:	To assess, by product, safety with reported complications, adverse events, serious adverse events, adverse device effects, serious adverse device effects, unanticipated serious adverse device effects and device deficiencies.
Sample Size:	The sample size for this study is precision-based, and not based on statistical power considerations, thus no formal statistical hypothesis is formulated. The sample size for this study is determined based on the feasibility of recruitment, enrolment and follow-up considerations. There will be 135 (75 shoulder and 60 hip) subjects enrolled into the MICRORAPTOR™ REGENESORB™ Suture Anchor arms. There will be 120 (60 shoulder and 60 hip) subjects enrolled into the MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor arms.

<table>
<tr><td></td><td>There will be 60 (30 shoulder and 30 hip) subjects enrolled into the MICRORAPTOR™ Knotless PEEK Suture Anchor arms. At least 8 shoulder and 8 hip subjects will also include the use of MINITAPE sutures.
<table>
<tr><th>Device</th><th>Hip</th><th>Shoulder</th></tr>
<tr><td>MICRORAPTOR™ REGENESORB™</td><td>60</td><td>75</td></tr>
<tr><td>MICRORAPTOR™ Knotless REGENESORB™</td><td>60</td><td>60</td></tr>
<tr><td>MICRORAPTOR™ Knotless PEEK</td><td>30
(at least 8 with MINITAPE)</td><td>30
(at least 8 with MINITAPE)</td></tr>
<tr><td>Total</td><td>150</td><td>165</td></tr>
</table></td></tr>
<tr><td>Number of Study Sites:</td><td>Up to 18 study sites (a minimum of 3 sites for the shoulder group and a minimum of 3 sites for the hip group for each anchor product).</td></tr>
<tr><td>Targeted Global Regions:</td><td>United States</td></tr>
<tr><td>Inclusion Criteria:</td><td>• Subject requires reattachment of soft tissue to bone for one of the following indications:
MICRORAPTOR™ REGENESORB™ indications:
○ Shoulder - Capsular stabilization for: Bankart repair, Anterior shoulder instability, SLAP lesion repairs, Capsular shift or capsulolabral reconstruction
○ Hip - Acetabular labrum repair/reconstruction
MICRORAPTOR™ Knotless (REGENESORB™ or PEEK) indications:
○ Shoulder –
• Capsular stabilization for: Bankart repair, Anterior shoulder instability, SLAP lesion repairs, Capsular shift or capsulolabral reconstruction
• Biceps Tenodesis
○ Hip - Acetabular labrum repair/reconstruction
○
• Subject if ≥ 18 years of age or legally authorized representative if subject is <18 years of age has consented to participate in the study by signing the IRB approved informed consent form. If <18 years of age, subject has assented to participate in the study by signing the IRB approved assent form.
• Subject is ≥12 years of age at time of surgery.</td></tr>
</table>

	• Willing and able to make all required study visits. • Able to follow instructions.

Exclusion Criteria:	• Known hypersensitivity to the implant material. Where material sensitivity is suspected, appropriate tests should be made 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 retard healing. • The presence of infection. • Conditions which would limit the subject's ability or willingness to restrict activities or follow directions during the healing period. • Currently using tobacco products (cigarette, smokeless tobacco, e-cigarettes, vaping etc.). • Concurrent bilateral surgery. • Prior implantation with MICRORAPTOR™ REGENESORB™ Suture Anchor, MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor or MICRORAPTOR™ Knotless PEEK Suture Anchors. • Participation in the treatment period of another clinical trial within thirty (30) days of Visit 1, or during the study. • Women who are pregnant or nursing. • History of poor compliance with medical treatment. • Prior ipsilateral surgeries performed on the joint space. • Subjects with a medical or physical condition that, in the opinion of the Investigator, would preclude safe subject participation in the study.
Study Duration:	Total study timeline: 36 months Enrollment period: 12 months Follow-up period: 12 months for MICRORAPTOR™ REGENESORB™ and MICRORAPTOR™ Knotless PEEK arms; 24 months for MICRORAPTOR™ Knotless REGENESORB™ arms
Primary Endpoint:	Repair failure rate by product at 6 months.

Secondary Endpoints:	**All endpoints to be collected and analyzed BY PRODUCT** **All subjects:** • Repair failure rate at 12 months. • Change in VAS pain assessment from the pre-operative visit to each post-operative visit. **MICRORAPTOR™ REGENESORB™ and MICRORAPTOR™ Knotless PEEK subjects:** • Radiographic evaluation at 6 and 12 months (if needed to investigate root cause of failure). **MICRORAPTOR™ Knotless REGENESORB™ subjects:** • Repair failure rate at 24 months. • Radiographic evaluation at 12 months (if needed to investigate root cause of failure). • MRI to determine anchor absorption/replacement by bone at 6 months and 24 months. **Shoulder subjects:** • Change in ROWE and WOSI shoulder scores from the pre-operative visit to each post-operative visit. • Change in Constant-Murley Shoulder scale from the pre-operative visit to each post-operative visit. **Hip subjects:** • Change in Hip Outcome Score Activities of Daily Living (HOS-ADL) from the pre-operative visit to each post-operative visit. • Change in Modified Harris Hip Score from the pre-operative visit to each post-operative visit.
Safety Endpoints:	• All adverse events (AEs) and complications occurring from the time of surgical implantation until study termination or study completion including intra-operative adverse events and complications. • Device Deficiencies.

3.2 SCHEMA

Visit Type/name	Frequency / Time point
Visit 1/Pre-Operative	(≤ 30 days) Within 30 days of Visit 2
Visit 2/Operative through Discharge	Day 0 - Surgery
Visit 3/Follow-up	6 months (± 1 month) post-surgery
Visit 4/Follow-up (MICRORAPTOR™ Knotless REGENESORB™ subjects)/End of Study (MICRORAPTOR™ REGENESORB™, MICRORAPTOR™ Knotless PEEK subjects)	12 months (± 1 month) post-surgery
Visit 5/End of Study* (MICRORAPTOR™ Knotless REGENESORB™ subjects)	24 months (± 1 month) post-surgery

***For Knotless REGENESORB arms: only 30 hip and 30 shoulder subjects will be required to complete the 24 month visit.**

3.3 SCHEDULE OF ACTIVITIES

Schedule of Events	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5[1]	Unscheduled Visit
	Pre-operative (≤ 30 Days)	**Operative through Discharge Day 0**	**Follow-up 6 Months (± 1 Month)**	**Follow-up (MICRORAPTOR™ Knotless REGENESORB™ subjects) End of Study (MICRORAPTOR™ REGENESORB™/ Knotless PEEK) 12 Months (± 1 Month)**	**End of Study[1] (Knotless REGENESORB™) 24 Months (± 1 Month)**	
Informed Consent	✓					
Inclusion/Exclusion	✓					
Demographics	✓					
Medical History	✓					
Intra-op Failure (visual and surgeon assessment)		✓				
Post-op Repair Failure			✓	✓	✓	✓
Assessments **All Subjects:** Pain assessment with VAS **Shoulder:** ROWE Score WOSI Score Constant-Murley Shoulder Scale or **Hip:** HOS-ADL Score Mod. Harris Hip Score	✓		✓	✓	✓	✓
X-ray / Imaging	✓		✓[2]	✓[2]		✓[2]
MRI[3]	✓[3]		✓[3]		✓[3]	

Adverse Event Assessment		✓	✓	✓	✓	✓
Concomitant medications/therapies		✓	✓	✓	✓	✓
End of Study/Exit			✓[4]	✓	✓	✓[4]

Abbreviations: VAS, Visual Analog Scale; WOSI, Western Ontario Shoulder Instability Index; HOS-ADL, Hip Outcome Score-Activities of Daily Living

1. For MICRORAPTOR™ Knotless REGENESORB™ arms: only 30 hip and 30 shoulder subjects will be required to complete 24 month visit
2. If needed to investigate repair failure.
3. Required only for MICRORAPTOR™ Knotless REGENESORB™ Arms
4. If necessary

4. INTRODUCTION

4.1 STUDY RATIONALE

The purpose of this trial is to assess safety and performance of the MICRORAPTOR™ REGENESORB™, MICRORAPTOR™ Knotless REGENESORB™, and MICRORAPTOR™ KNOTLESS PEEK Suture Anchors. These anchors are new products and no clinical evidence is available to date.

MICRORAPTOR™ REGENESORB™ and MICRORAPTOR™ Knotless REGENESORB™ Suture Anchors

Pre-clinical testing for MICRORAPTOR™ REGENESORB™ and MICRORAPTOR™ Knotted REGENESORB™ Suture Anchor demonstrated fixation performance in worst case bone media to exceed Smith+Nephew's specification which has been derived from performance of commercially available anchors with similar size and indications for use.

MICRORAPTOR™ REGENESORB™ and MICRORAPTOR™ Knotless REGENESORB™ passed hard bone media insertion testing, cyclic load test with 500 cycles, and maintained adequate fixation strength.

Based upon pre-clinical testing and history of REGENESORB™ material for suture anchor devices we expect a clinical performance similar to existing devices.

MICRORAPTOR™ Knotless PEEK Suture Anchors

This study is being conducted to assess safety and performance of the MICRORAPTOR™ Knotless PEEK Suture Anchor. The PEEK material is nonabsorbable and well characterized for clinical implantation

MINITAPE Sutures

The MINITAPE Suture is a non-absorbable, sterile, surgical suture composed of white and/or blue UHMW polyethylene. MINITAPE is provided in braided, precut lengths intended for single use only. MINITAPE Sutures are indicated for use in approximation and/or ligation of soft tissues, including allograft tissue for orthopedic surgeries. This is a new product and no clinical evidence is available to date.

4.2 BACKGROUND

Disease/Medical Condition State

Shoulder

The shoulder is a ball and socket joint that is subject to repeated overhead movement common to routine and sports activities. Overstressing of this joint can lead to shoulder instabilities. For example the joint capsule ligament that stabilizes the shoulder joint can be loosened resulting in frequent dislocations. Other shoulder instabilities involve labral tissue tears such as SLAP (superior labrum anterior-posterior), Bankart lesions, and bicep tendonitis. Pain from the biceps tendon is usually in the front part of the shoulder and at the top of the humerus bone where it attaches to the superior labrum. Patients with biceps tendon problems may develop SLAP tear or irritation and inflammation of the biceps tendon itself. The superior labrum and biceps anchor improves 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 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.[3-6]A Bankart lesion of the shoulder is a tear of the labrum that causes instability and recurrent dislocations of the shoulder joint. This type of injury often occurs when the shoulder pops out of joint, thereby tearing the labrum. This is quite common in younger patients.

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.[7,8] Femoroacetabular impingement (FAI) is an abnormality of the structure and orientation of the hip joint, which can cause pain and early hip osteoarthrosis.[9-13] Skendzel et al.[12] 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.[12,14,15] 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. [7,8,15]

Current Treatments

Shoulder

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.[16] 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.[17]

Several techniques are utilized for SLAP tear repair, the most common consists of repairing the labrum and biceps anchor.[18] 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 patients over 40 years to patients younger, Erickson et al.[1] found similar outcomes in both populations after SLAP repair using similar suture anchors.

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.[18] 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.[18]

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.[3,4,18]

Hip

Conservative treatment, such as rest, physiotherapy, and NSAIDs, is usually the first treatment option after FAI diagnosis.[12,15,19] 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.[7,13,15] 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.[13]

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.[9,10,12] 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 (devices not reported), 13.7% were reconstructed and 7.2% were debrided.[20]

In a systematic review performed by Ayeni et al.[8], 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[8] reported mixed results comparing repair to debridement where one study reported a statistically significant advanced and the other did not. Overall, the systematic review[8] concluded the advantage of labral repair (devices not specified) over debridement in terms of short-term outcomes, decreased failure rate, and few complications.

Common complications reported in management of FAI included failures, reoperations, infection and heterotopic bone formation.[9]

Investigational Products

MICRORAPTOR™ REGENESORB™ Suture Anchor

Smith+ Nephew MICRORAPTOR™ REGENESORB™ Suture Anchor is a fixation device intended to provide secure attachment of soft tissue to bone. Most joints have a combination of soft tissues used to provide stability and joint function and these include labrum, capsule, tendon and ligament. The MICRORAPTOR™ REGENESORB™ Suture Anchor (Figure 4.2-1) is manufactured from an absorbable biocomposite material which is a polymer blend by weight containing the following components;

- polyester polymer, poly l-lactideco-glycolide (85:15% w/w) (65%w/w),
- calcium sulphate (20% w/w),
- beta-tricalcium phosphate (β-TCP) (15% w/w).

The MICRORAPTOR™ REGENESORB™ Suture Anchor consists of a suture anchor preloaded with #1 non-absorbable, braided, uncoated UHMW polyethylene suture preassembled to a flexible insertion device (Figure 4.2-2). This device is provided sterile, for single use only.

Figure 4.2-1: MICRORAPTOR REGENESORB anchor

Figure 4.2-2: Anchor inserter

Associated instrumentation to be used with the MICRORAPTOR™ REGENESORB™ Suture Anchor includes a drill, drill guides, and obturators (Figure 4.2-3).

Figure 4.2-3: MICRORAPTOR REGENESORB System

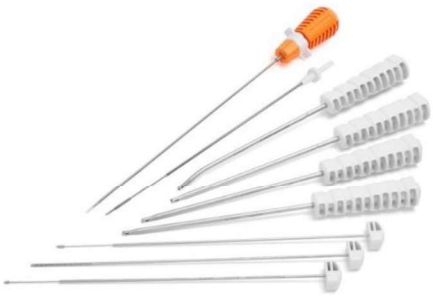


Figure 4.2-4: MICRORAPTOR REGENESORB SKU Chart (as of March 2019)

MICRORAPTOR® REGENESORB® Suture Anchor and Guide System	
Reference #	Description
MICRORAPTOR REGENESORB Suture Anchors	
72204983	MICRORAPTOR REGENESORB Suture Anchor with ONE ULTRABRAID® #1 Suture (Blue)
72204984	MICRORAPTOR REGENESORB Suture Anchor with ONE ULTRABRAID #1 Suture (Blue COBRAID)
MICRORAPTOR REGENESORB Drill Guides, Drills and Obturators	
72204988	MICRORAPTOR Drill
72204991	MICRORAPTOR Drill Guide, Crown Tip
72204992	MICRORAPTOR Drill Guide, Spike Tip
72204993	MICRORAPTOR Drill Guide, Crown Tip, Curved
72204995	MICRORAPTOR Drill Guide, Fishmouth Tip
72204999	MICRORAPTOR Obturator, Blunt Tip
72205000	MICRORAPTOR Obturator, Blunt Tip, Cannulated
72205001	MICRORAPTOR Obturator, Trocar Tip

The MICRORAPTOR™ REGENESORB™ Suture Anchors are sterilized by Ethylene Oxide. This device is considered “MR Safe” based on the following scientific rationale:

- The materials are all non-metallic; therefore a magnetically induced displacement force is not of concern.
- Heating of the materials by RF (radio frequency) fields are not of concern, due to the low electrical conductivity of the materials. All of the materials are classified as “insulators.”

MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor

MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor is fixation device, which consists of an anchor on an inserter, and a suture threader. The anchor consists of the following components: a proximal anchor body (REGENESORB™), and a non-absorbable PEEK (Polyether ether ketone) distal anchor tip (Figure 4.2-5). REGENESORB™ is an absorbable biocomposite material which is a polymer blend by weight comprised of poly l-lactideco-glycolide (85:15% w/w) (65%w/w), calcium sulphate (20% w/w) and beta-tricalcium phosphate (β-TCP) (15% w/w). The anchor is preloaded on a stainless steel inserter (Figure 4.2-6). The insertion device of the MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor is composed of an inserter handle and an inserter shaft (Figure 4.2-5, 4.2-6). The inserter device handle is manufactured with polycarbonate components. The inserter shaft is manufactured with 304 stainless steel per ASTM A908 (outer shaft), 304 stainless steel per ASTM A276 (outer shaft tip), and 17-4PH stainless steel per ASTMA564/A564M (inner shaft). This device is provided sterile, for single use only. The suture threader has nitinol wire crimped into a stainless steel tube with ABS handle (Figure 4.2-7). Figure 4.2-8 depicts the deployed MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor.

Figure 4.2-5. (left to right) proximal anchor body, distal anchor tip, inserter shaft and handle.

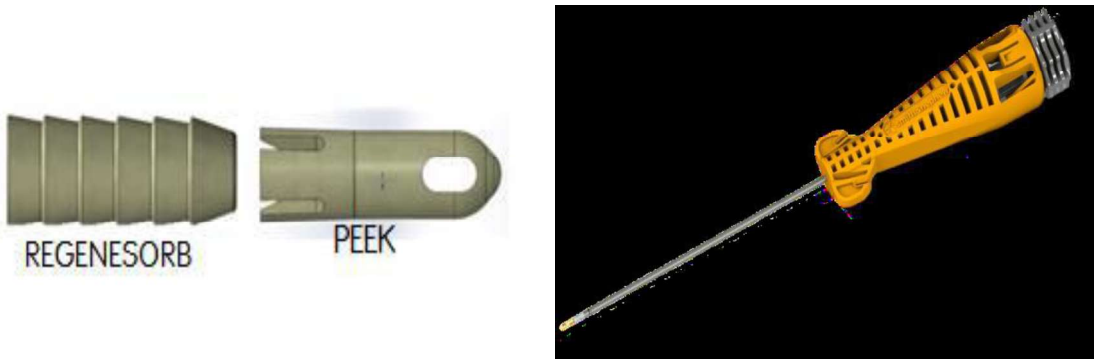


Figure 4.2-6. Inserter device shaft

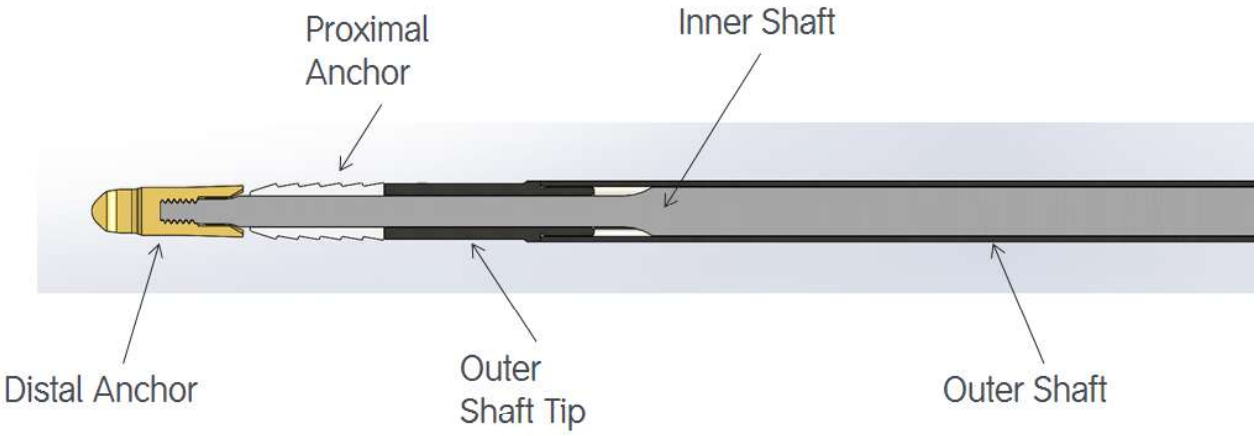


Figure 4.2-7. Suture Threader

Figure 4.2-8. Deployed MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor

The MICRORAPTOR™ Knotless REGENESORB™ Suture Anchors are sterilized by Ethylene Oxide.

This device is considered “MR Safe” based on the following scientific rationale:

- The materials are all non-metallic; therefore a magnetically induced displacement force is not of concern.
- Heating of the materials by RF (radio frequency) fields are not of concern, due to the low electrical conductivity of the materials. All of the materials are classified as “insulators.”

MICRORAPTOR™ Knotless PEEK Suture Anchor

The MICRORAPTOR™ Knotless PEEK Suture Anchor is a class IIb device, which consists of an anchor on an inserter, and a suture threader. The anchor consists of the following components: a proximal anchor body (PEEK), and a non-absorbable PEEK distal anchor tip (Figure 4.2-9). The anchor is preloaded on a stainless steel inserter (Figure 4.2-9). The insertion device of the MICRORAPTOR™ Knotless Suture Anchor is composed of an inserter handle and an inserter shaft (Figure 4.2-9, 4.2-10). The inserter device handle is manufactured with polycarbonate components. The inserter shaft is manufactured with 304 stainless steel per ASTM A908 (outer shaft), 304 stainless steel per ASTM A276 (outer shaft tip), and 17-4PHstainless steel per ASTM A564/A564M (inner shaft). This device is provided sterile, for single use only. The suture threader has nitinol wire crimped into a stainless steel tube with ABS handle (Figure 4.2-11).

Figure 4.2-9. (left to right) proximal anchor body, distal anchor tip, inserter shaft and handle.

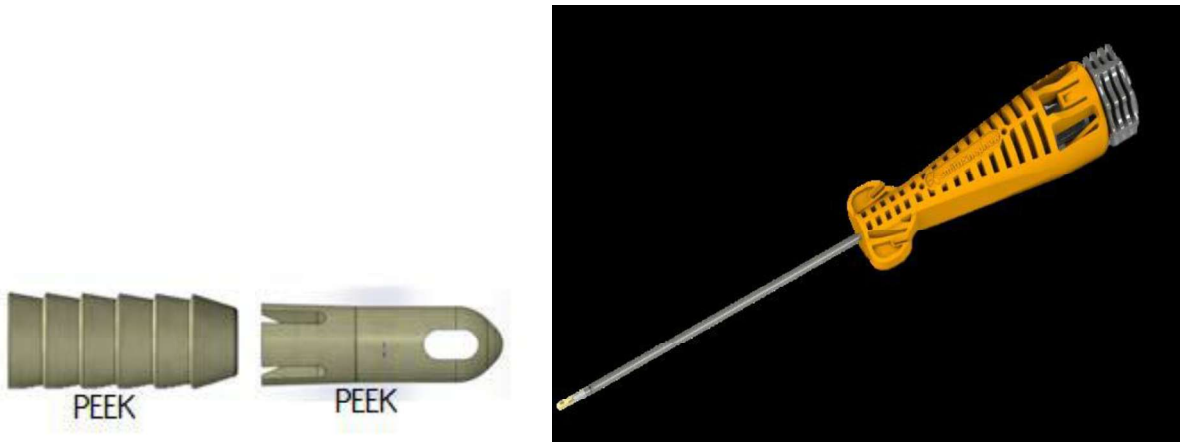


Figure 4.2-10. Inserter device shaft

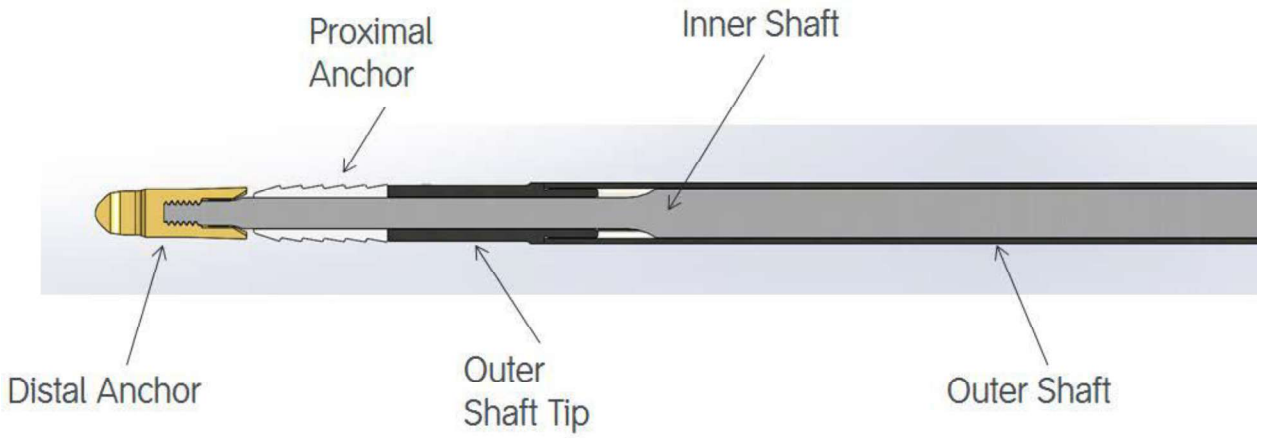


Figure 4.2-11. Suture Threader

The MICRORAPTOR™ Knotless PEEK Suture Anchors are sterilized by Ethylene Oxide. This device is considered “MR Safe” based on the following scientific rationale:

- The materials are all non-metallic; therefore a magnetically induced displacement force is not of concern.
- The materials are all non-metallic; therefore a magnetically induced torque is not of concern.
- Heating of the materials by RF (radio frequency) fields are not of concern, due to the low electrical conductivity of the materials. All of the materials are classified as "insulators."

MINITAPE Suture

The MINITAPE Suture is a non-absorbable, sterile, surgical suture composed of white and/or blue UHMW polyethylene. MINITAPE is provided in braided, precut lengths intended for single use only. MINITAPE Sutures are indicated for use in approximation and/or ligation of soft tissues, including allograft tissue for orthopedic surgeries.

4.3 LITERATURE SUMMARY

MICRORAPTOR™ REGENESORB™, MICRORAPTOR™ Knotless REGENESORB™, and MICRORAPTOR™ Knotless PEEK suture anchors are new products and there is no literature available for this device.

4.4 BENEFIT/RISK ASSESSMENT

The MICRORAPTOR™ REGENESORB™ and MICRORAPTOR™ Knotless REGENESORB™ Suture Anchors are made of a bioabsorbable biocomposite material manufactured by Smith+ Nephew comprised of the co-polymer poly (l-lactide co-glycolide), commonly abbreviated PLGA, which has been clinically used since the 1970's.[21] Combined with this polymer mixture, the REGENESORB™ material incorporates two osteoconductive fillers, calcium sulfate and Beta-tricalcium phosphate (β-TCP), each of which have long histories of safe clinical use with calcium sulfate first used in the 1890's and β-TCP since the 1920's.[22,23] Benefits of calcium sulfate include a compressive strength similar to that of cancellous bone, release of calcium ions as it is bioabsorbed,[21] and the ability to improve the rate of new bone formation as reported in the peer reviewed literature.[22,24] Based on this study and others, calcium sulfate is widely considered to be osteoconductive.[22,24,25]

Additionally, a study of the REGENESORB™ material was performed in Japan to evaluate the osteoconductivity of the Osteoraptor OS Suture Anchor after arthroscopic shoulder labral repair. The study demonstrated that 90% of anchors exhibited ossification at the anchor sites.[26] Improvements in ROWE and JSS-SIS scores were reported.

Advantages of bioabsorbable suture anchors over those made of metallic or non-absorbable polymers, include: reduced stress shielding and subsequent bone weakening due to the optimal gradual load transfer to healing tissue; decreased incidence of reoperation to remove the anchor; and the potential to be manufactured with gradual-release, osteoconductive materials or drugs. Bioabsorbable anchors can also provide easier revision, fewer concerns about tissue damage, and clearer postoperative imaging.

The MICRORAPTOR™ Knotless PEEK Suture Anchors have the same design characteristics at the MICRORAPTOR™ Knotless REGENESORB™ Suture Anchors, except it is made from

PEEK polymer, a common non-absorbable material implant. The MICRORAPTOR™ suture anchors can be used with the MINITAPE suture. MINITAPE is a smooth suture tape available in single packs or on MICRORAPTOR™ Knotless Suture Anchors.

The risk management plan for all MICRORAPTOR™ devices were reviewed and all failure modes evaluated such as implant breakage, anchor pull-out, or anchor does not absorb. The risk mitigation actions and the residual risks have been determined acceptable. Results of the risk analysis demonstrate that use of the device as intended does not adversely affect the health or safety of the patient, user or other persons.

5. OBJECTIVE(S) AND ENDPOINTS

5.1 PRIMARY OBJECTIVE AND ENDPOINT

Primary Objective:

To assess, by product, repair failure rate at 6 months post operation with the MICRORAPTOR™ REGENESORB™ device, MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor or MICRORAPTOR™ Knotless PEEK Suture Anchors.

Primary Endpoint:

The primary effectiveness endpoint is repair failure rate, (π) in the study device at 6 months post-operative by anchor product. Repair failure is to be determined by physician diagnostic of recurrent shoulder dislocation, subluxation, and patient symptoms (such as pain). In the event of suspected repair failure, magnetic resonance imaging (MRI) or CT scan will be conducted to confirm the root cause of the failure (i.e. intraarticular labrum failure or fixation repair failure) and the presence of glenoid bone loss. The focus of this study is fixation failure, so it is important to understand if the repair failure is device-related or not.

5.2 SECONDARY OBJECTIVE(S) AND ENDPOINTS

Secondary Objectives:

The secondary objective is to assess intra-operative repair failure and post-operative repair failure rates as well as performance assessed with patient-reported outcomes by anchor product.

Secondary Endpoints:

The secondary endpoints are as listed below: (All endpoints to be collected and analyzed BY PRODUCT)

All subjects:

- Repair failure rate at 12 months, as assessed by the surgeon.
- Change in VAS pain assessment from the pre-operative visit to each post-operative visit.

MICRORAPTOR™ REGENESORB™ and MICRORAPTOR™ Knotless PEEK subjects:

- Radiographic evaluation at 6 and 12 months (if needed to investigate root cause of failure).

MICRORAPTOR™ Knotless REGENESORB™ subjects:

- Repair failure rate at 24 months.
- Radiographic evaluation at 12 months (if needed to investigate root cause of failure).
- MRI to determine anchor absorption/replacement by bone at 6 months and 24 months.

Shoulder subjects:

- Change in ROWE and WOSI shoulder scores from the pre-operative visit to each post-operative visit.
- Change in Constant-Murley Shoulder scale from the pre-operative visit to each post-operative visit.

Hip subjects:

- Change in Hip Outcome Score Activities of Daily Living (HOS-ADL) from the pre-operative visit to each post-operative visit.

- Change in Modified Harris Hip Score from the pre-operative visit to each post-operative visit.

5.3 SAFETY OBJECTIVE(S) AND ENDPOINTS

Safety Objectives:

The safety objectives are to assess safety with reported adverse events (AEs), serious adverse events (SAEs), adverse device effects (ADEs), serious adverse device effects (SADEs), unanticipated serious adverse device effects (USADEs), and device deficiencies (DDs) by anchor product.

Safety Endpoints:

The safety endpoints are as listed below:

- All adverse events (AEs), serious adverse events (SAEs), device deficiencies (DDs), adverse device effects (ADEs), and serious adverse device effects (SADEs), and unanticipated serious adverse device effects (USADEs) occurring from the time of enrollment until study termination or study completion including intra-operative adverse events and complications.
- Device related intervention.

6. STUDY DESIGN

6.1 OVERALL DESIGN

This is a prospective, multi-center, PMCF study to evaluate the safety and performance of MICRORAPTOR™ Suture Anchors in a total of 315 subjects needing reattachment of soft tissue to bone as follows:

MICRORAPTOR™ REGENESORB™ suture anchors implanted in 135 subjects (75 shoulder subjects and 60 hip subjects)

MICRORAPTOR™ Knotless REGENESORB™ suture anchors implanted in 120 subjects (60 shoulder subjects and 60 hip subjects)

MICRORAPTOR™ Knotless PEEK Suture Anchors implanted in 60 subjects (30 shoulder subjects and 30 hip subjects)

For one of the following indications:

Shoulder - Capsular stabilization for Bankart repair, anterior shoulder instability, superior labrum from anterior to posterior (SLAP) lesion repairs, capsular shift or capsulolabral reconstructions; biceps tenodesis (knotless anchors only)

Hip - Acetabular labrum repair/reconstruction

Up to 18 sites (a minimum of 3 sites for the shoulder group and a minimum of 3 sites for the hip group for each anchor product) in the United States will participate in the study. Whenever possible, sites using multiple product variants in both hip and shoulder joints will be selected to decrease the number of sites (targeting less than 15 overall).

This is an open-label study with consecutive enrollment. The study will continue for 24 months from the date that the last subject received the study treatment to the date that the last subject completes 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 36 months.

Table 6.1-1: Schema

Visit Type/name	Frequency / Time point
Visit 1/Pre-Operative	(≤ 30 days) Within 30 days of Visit 2
Visit 2/Operative through Discharge	Day 0 - Surgery
Visit 3/Follow-up	6 months (± 1 month) post-surgery
Visit 4/Follow-up (MICRORAPTOR™ Knotless	12 months (± 1 month) post-surgery

REGENESORB™ subjects)/End of Study (MICRORAPTOR™ REGENESORB™, MICRORAPTOR™ Knotless PEEK subjects)	
Visit 5/End of Study* (MICRORAPTOR™ Knotless REGENESORB™ subjects)	24 months (± 1 month) post-surgery

***For Knotless REGENESORB™ arms: only 30 hip and 30 shoulder subjects will be required to complete 24 month visit.**

6.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

MICRORAPTOR™ REGENESORB™, MICRORAPTOR™ Knotless REGENESORB™, and MICRORAPTOR™ Knotless PEEK Suture Anchors are intended for the reattachment of soft tissue to bone in a variety of anatomical sites. Soft tissues, such as labrum, capsule, tendon and ligament, provide stability and joint function. When torn, the standard of care for all of these tissues is surgical repair using either an interference screw or suture anchor, each of which is intended to provide mechanical support to the re-approximated soft tissue-bone interface for the duration of the healing period. The functional healing period of the MICRORAPTOR™ REGENESORB™, MICRORAPTOR™ Knotless REGENESORB™, and MICRORAPTOR™ Knotless PEEK Suture Anchors for all indicated joints (hip and shoulder) is 12 to 13 weeks. This study is being conducted to assess safety and performance of the MICRORAPTOR™ REGENESORB™, MICRORAPTOR™ Knotless REGENESORB™, and MICRORAPTOR™ Knotless PEEK Suture Anchor devices in shoulder and hip arthroscopic instability repair procedures during the post-market phase. The data should also establish safety and performance levels deemed acceptable for the risk benefit profile of this device. Treatment of shoulder and hip arthroscopic instabilities using MICRORAPTOR™ REGENESORB™, MICRORAPTOR™ Knotless REGENESORB™, and MICRORAPTOR™ Knotless PEEK Suture Anchor devices will be performed as part of standard of care and there is no control arm. Therefore, the study is designed as a 12-month multi-center study (24 month for the

MICRORAPTOR™ Knotless REGENESORB™ arm) in patients selected based on study inclusion criteria. Sample size of the study is 315 subjects in total; 135 subjects in the MICRORAPTOR™ REGENESORB™ arm, 120 subjects in the MICRORAPTOR™ Knotless REGENESORB™ arm and 60 subjects in the MICRORAPTOR™ Knotless PEEK arm. All analyses will be done separately for each product. The primary endpoint is to assess the repair failure rate (%) at 6 months post-operative. Secondary endpoints include repair failure rate (%) at 12 month post-operative as well as performance as assessed with Patient Reported Outcomes. Safety endpoints include reporting of all complications and adverse events including device deficiencies.

6.3 ALLOCATION AND BLINDING

6.3.1 Treatment Allocation

This study is not randomized. Selection of the surgical approach will be at the discretion of the Investigator, in consultation with the subject, as appropriate. To ensure the correct number of subjects are enrolled into each arm, the Sponsor will continuously monitor enrollment and will close enrollment into the faster enrolling arm once the targeted enrollment has been reached. Enrollment into the slower enrolling arms will continue until the study is fully enrolled.

6.3.2 Blinding

This study is not blinded.

6.4 END OF STUDY DEFINITION

The end of study is defined as the date of the last subject, last visit (LSLV). Subjects will return to their normal standard of care once their participation in the study has ended.

7. STUDY POPULATION

7.1 SCREENING

Participating study sites are required to document all subjects who have signed an Informed Consent Form (ICF) and have been 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. All screening activities that occur prior to consent shall be referred to as pre-screening.

Any subject that meets the definition of a Vulnerable Subject [per International Organization for Standardization (ISO) 14155 should be reviewed, but not excluded from the study.

7.2 INCLUSION CRITERIA

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

1. Subject requires reattachment of soft tissue to bone for one of the following indications:
   - **Shoulder -** Capsular stabilization for Bankart repair, anterior shoulder instability, superior labrum from anterior to posterior (SLAP) lesion repairs, capsular shift or capsulolabral reconstructions; biceps tenodesis (knotless anchors only)
   - **Hip -** Acetabular labrum repair/reconstruction
2. Subject if ≥ 18 years of age or legally authorized representative if subject is <18 years of age has consented to participate in the study by signing the IRB approved informed consent form. If <18 years of age, subject has assented to participate in the study by signing the IRB approved assent form.
3. Subject is ≥12 years of age at time of surgery.
4. Willing and able to make all required study visits.
5. Able to follow instructions.

7.3 EXCLUSION CRITERIA

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

1. Known hypersensitivity to the implant material. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
2. Pathological conditions of bone, such as cystic changes or severe osteopenia, which would compromise secure anchor fixation.
3. Pathological conditions in the soft tissues to be attached that would impair secure fixation by suture.
4. Comminuted bone surface, which would compromise secure anchor fixation.
5. Physical conditions which would eliminate, or tend to eliminate, adequate anchor support or retard healing.
6. The presence of infection.
7. Conditions which would limit the subject's ability or willingness to restrict activities or follow directions during the healing period.
8. Currently using tobacco products (cigarette, smokeless tobacco, e-cigarettes, vaping etc.).
9. Concurrent bilateral surgery.
10. Prior MICRORAPTOR™ REGENESORB™, MICRORAPTOR™ Knotless REGENESORB™ or MICRORAPTOR™ Knotless PEEK implantation.
11. Participation in the treatment period of another clinical trial within thirty (30) days of Visit 1, or during the study.
12. Women who are pregnant or nursing.
13. History of poor compliance with medical treatment.

14.	Prior ipsilateral surgeries performed on the joint space.
15.	Subjects with a medical or physical condition that, in the opinion of the Investigator, would preclude safe subject participation in the study.

7.4 INFORMED CONSENT

Before conducting any study procedures or examinations, the purpose and nature of the study should be explained to the subject in their native language. Consent must be obtained from all study subjects using an IRB approved ICF according to ISO 14155 guidelines, Good Clinical Practice (GCP) guidelines, and all applicable national regulations. The subject shall have sufficient opportunity to consider participation in the study. A subject cannot be led to believe that they are waiving his/her rights as a subject or the liability of the Sponsor or Investigator. Before conducting any study procedures or examinations, potential subjects must be informed of the purpose of the study. The potential risks and benefits known or that can be reasonably predicted or expected as described in the ICF will be explained to the subject.

The subject will then read, sign, and date (or approve per IRB guidelines) the IRB -approved ICF. Additionally, the investigator or delegated study staff member who obtains consent from the subject will sign and date the ICF. The informed consent process will be documented in the subject's medical record and date of signed ICF recorded on the study Case Report Forms (CRFs). A copy of the signed informed consent document will be provided to the subject, a copy will be placed in the subject's study file, with the original filed in the Investigator Site File.

In the case of vulnerable subjects, the ICF must be understood and signed by the subject's legally authorized representative (parent or legal guardian). Assent to participate in the study should be obtained for subjects ≥12 years of age and <18 years of age if allowed by local regulations.

In the case of minors, the ICF must be obtained by their legally authorized representative. The

minor shall participate in the informed consent process in a way suitable for his/her age and mental maturity. Minors will receive the study information in a way adapted to their age and mental maturity from investigators or members of the investigating team who are trained or experienced in working with children. If minors express a wish or an opinion with regards to study participation this needs to be respected by the Investigator. If during the study, the minor reaches the age of 18 years (legal competence), the informed consent shall be obtained again, before the subject can continue to participate in the clinical investigation.

The PI or delegated study research staff may then complete Visit 1/Initial Visit with the subject. If a subject refuses participation, no further information will be collected. Reason for exclusion should be noted on the Screening and Enrollment Log.
ICFs will comply with the Health Information Portability Accountability Act (HIPAA) regulations.

7.5 ENROLLMENT

Subjects for whom the consent process has been completed and have received the device implant are considered enrolled.

7.6 SCREEN FAILURES

Screen failure is defined as a Subject who has signed the IC document but does not meet the eligibility criteria, was not enrolled by the Investigator for any reason, or withdraws consent for any reason prior to enrollment. A Subject may be considered a screen failure at any time prior to enrollment. End of Study CRFs will be completed for all screen failures.

8. STUDY METHODS AND MEASUREMENTS

The investigational device failure will be assessed by the surgeon at 6 months post-operative and at 12 months post-operative visits (and 24 months for the Microraptor Knotless Regenesorb arms). Criteria used for assessment of device failure and/or re-intervention will be provided by the surgeon on the designated case report form (CRF).

All subjects:

Visual Analog Scale (VAS) for pain is a continuous scale completed by the subject who is asked to place a line perpendicular to the VAS line at the point that represents their pain intensity. Using a ruler, the score is determined by measuring the distance (mm) on the 10-cm line between the “no pain” anchor and the subject's mark, providing a range of scores from 0–100. For pain intensity, the scale is most commonly anchored by “no pain” (score of 0) and “pain as bad as it could be” or “worst imaginable pain” (score of 100 [100-mm scale]).

Shoulder subjects:

ROWE score for shoulder instability is a 3-item instrument completed by the investigator or qualified, delegated study staff. Its questions address the categories of shoulder stability (0 to 50 points), motion (0 to 20 points), and function (0 to 30 points). Scores range from 0 to 100 with a score of 90-100 points indicating an excellent evaluation, 75-89 points indicating a good evaluation, 51-74 points indicating a fair evaluation, and =< 50 points indicating a poor evaluation.

Western Ontario Shoulder Instability Index (WOSI) is a subject completed instrument. Its categories include “physical symptoms” (10 items), “sports, recreation, work” (4 items), “pain” (4 items), “lifestyle” (4 items), and “emotion” (3 items), with each category scored from 0 to 100 using a visual analog scale. Overall scores range from 0 to 2100 with a score of 0 indicating better shoulder function and 2100 indicating worse shoulder function.

Constant-Murley Shoulder (CMS) scale assesses four aspects related to shoulder pathology; two subjective: pain and activities of daily living (ADL) and two objective: range of motion (ROM) and strength. The subjective components can receive up to 35 points and the objective 65, resulting in a possible maximum total score of 100 points (best function). Pain and ADL are answered by the subject; ROM and strength require a physical evaluation and are answered by the orthopaedic surgeon or the physiotherapist.

Hip subjects:

Hip Outcome Score (HOS) was designed to assess the outcome of treatment intervention for individuals with acetabular tears who may be functioning throughout a wide range of abilities. It is a subject completed measure that consists of an "Activities of Daily Living" (ADL) subscale (17 scored items) and a "Sports" subscale (9 scored items) in which the response options are presented as 5-point Likert scales. Scores for each subscale range from 0% (least function) to 100% (most function).

Modified Harris Hip Score (mHHS) is a joint specific score that is completed by both the investigator or qualified, delegated study staff and the subject and consists of 10 items covering domains of pain (1 item, 0-44 points), function (7 items, 0-47 points), functional activities, absence of deformity (1 item, 0-4 points), and hip range of motion (2 items, 0-5 points). Scores range from 0 (worse disability) to 100 (less disability).

MICRORAPTOR™ REGENESORB™ and MICRORAPTOR™ Knotless PEEK subjects:
Radiographic evaluation at 6 months and 12 months (if needed to investigate root cause of failure)

MICRORAPTOR™ Knotless REGENESORB™ subjects:
Magnetic Resonance Imaging (MRI) will be used to determine anchor absorption/replacement by bone at 6 and 24 months by measuring cyst formation (grading scale) and measuring tunnel width.

An additional MRI may be performed to investigate the root cause of a suspected failure at 12 months, or at an unscheduled visit. An independent imaging vendor will provide an imaging protocol and perform the analysis of the MRIs.

The subjects' pre-operative MRI, performed as part of their standard of care, will be collected to determine their baseline, where available.

8.1 METHODS USED TO MINIMIZE BIAS AND MAXIMIZE VALIDITY

Balanced Covariates

The inclusion/exclusion criteria will be generalizable and applicable to the widest possible subset of the population needing reattachment of soft tissue to the bone of the shoulder and/or hip. These criteria will be uniformly applied so as to enroll a cohort of subjects with similar symptoms and clinical requirements. This should maximize the applicability to as many subjects with similar baseline characteristics and help to bolster external validity.

Subject Attrition

Subject attrition due to reduction in sample size required for precision analysis has been accounted for in the sample size calculation so that the estimate of the Confidence Interval (CI) to be obtained will still be valid through the most efficient use of available subjects.

Pre-specification of Statistical Analysis

The primary outcome measure has been pre-specified as well as the type of statistical analysis to be performed to evaluate repair failure rate so as to minimize reporting bias. The precision analysis planned for the study which include construction of confidence intervals for the outcome summaries and a pre-defined range in which the 95% CI for the primary outcome are expected to fall within are designed to maximize the validity of the study results.

More detailed information on analyses to be carried out will be incorporated in the Statistical Analysis Plan (SAP) so as minimize any threats to external validity in order to yield clinically relevant estimates of effects and precision.

9. INVESTIGATIONAL PRODUCT

9.1 INVESTIGATIONAL PRODUCT

MICRORAPTOR™ REGENESORB™ Suture Anchor

The MICRORAPTOR™ REGENESORB™ Suture Anchor is a fixation device intended to provide secure attachment of soft tissue to bone. It consists of a suture anchor with attached non-absorbable suture preassembled to a flexible insertion device. The anchor is preloaded with one #1 suture. This device is provided sterile, for single use only.

MICRORAPTOR™ REGENESORB™ is made from PLGA (poly(lacticcoglycolic acid)), ß-TCP (beta tricalcium phosphate), and calcium sulfate.

MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor

The MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor is a fixation device, which consists of an anchor on an inserter, and a suture threader. The anchor consists of the following components: a proximal anchor body (REGENESORB™), and a non-absorbable PEEK (Polyether ether ketone) distal anchor tip. The anchor is preloaded on a stainless steel inserter. This device is provided sterile, for single use only.

MICRORAPTOR™ Knotless REGENESORB™ is made from PLGA (poly(lacticcoglycolic acid)), ß-
TCP (beta tricalcium phosphate), and calcium sulfate.

MICRORAPTOR™ KNOTLESS PEEK Suture Anchor

The MICRORAPTOR™ Knotless PEEK Suture Anchor is a class IIb device, which consists of an anchor on an inserter, and a suture threader. The anchor consists of the following components: a proximal anchor body (PEEK), and a non-absorbable PEEK distal anchor tip. The anchor is preloaded on a stainless steel inserter.

MINITAPE Suture

The MINITAPE Suture is a non-absorbable, sterile, surgical suture composed of white and/or blue UHMW polyethylene. MINITAPE is provided in braided, precut lengths intended for single use only. MINITAPE Sutures are indicated for use in approximation and/or ligation of soft tissues, including allograft tissue for orthopedic surgeries.

9.1.1 Product Accountability Procedures

The investigational product (IP) is not provided by Smith+Nephew (S+N) for this post-market study and no product accountability procedures will be applied.

9.1.2 Product Use

Refer to the Instructions for Use (IFU) for detailed information on contraindications, warnings, adverse reactions and precautions.

Sites that are familiar with the use of the study device will be selected or will receive training prior to enrolling any subjects per standard Smith + Nephew procedures if not familiar; no additional training is required.

9.1.3 Packaging and Labeling

Packaging and labeling will be as per commercially available and will meet regulatory requirements.

9.1.4 Surgical Technique

All study related procedures with the MICRORAPTOR™ REGENESORB™ Suture Anchor, MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor or MICRORAPTOR™ Knotless PEEK Suture Anchors (and MINITAPE Sutures) must be performed according to the recommended surgical technique described in the IFUs.

9.2 Ancillary Products

There are two ancillary products provided for the conduct of this study. All sites will be provided with at least one Manual Muscle Tester (MMT), often referred to as a dynamometer, packaged in a Pelican type storage case. MMTs are ergonomic devices used to objectively quantify muscle strength. Additionally, all sites will be provided with at least one long-arm isometric goniometer which is used to measure joint range of motion. Both devices are required to complete the Constant-Murley score at the pre-op and follow-up visits.

9.3 Concomitant Medications

9.3.1 Excluded Concomitant Medications

For this study there are no restrictions on concomitant medications. Concomitant medications used to treat AEs should be recorded on the designated CRF.

9.4 Concomitant Therapies

9.4.1 Therapies Prohibited During the Study

For this study there are no restrictions on concomitant therapies. Concomitant therapies used to treat AEs should be recorded on the designated CRF.

9.5 Intervention After the End of the Study

Following the end of study participation, subjects will return to standard medical care.

10. DISCONTINUED SUBJECTS

Discontinued subjects are those who voluntarily discontinue participation, who are withdrawn for reasons of safety, who are lost to follow-up, or who have missed study visits (refer to section 10.3 for further details). Where possible, a full End of Study 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 10.3).

10.1 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 before declaring a subject to be lost to follow-up: the subject has been contacted according to the site's policies, but no fewer than two documented phone contacts and one certified letter without response. Copies of all attempts to reach the subjects by 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.

A subject will be considered lost to follow-up if he/she does not appear for the scheduled 6 month and 12 month follow up study visits and study personnel are unable to contact the subject.

10.2 INVESTIGATOR WITHDRAWAL

The Investigator may withdraw subjects from the study for many reasons at different times of the study, including but not limited to the following:

- subject noncompliance
- 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

- concurrent illness
- Adverse Events/Adverse Device Effects
- any other significant reason identified by the Investigator

For each case, information will be obtained in the source document and the 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.

10.3 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, (if any) for withdrawal will be recorded in the CRF and source documents.

10.4 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.

11. STUDY PROCEDURES

11.1 VISITS AND EXAMINATIONS

Table 11.1.-1: Schedule of Activities

Schedule of Events	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5[1]	Unscheduled Visit
	Pre-operative (≤ 30 Days)	Operative through Discharge Day 0	Follow-up 6 Months (± 1 Month)	Follow-up (MICRORAPTOR™ Knotless REGENESORB™ subjects) End of Study (MICRORAPTOR™ REGENESORB™/ Knotless PEEK) 12 Months (± 1 Month)	End of Study[1] (Knotless REGENESORB™) 24 Months (± 1 Month)	
Informed Consent	✓					
Inclusion/Exclusion	✓					
Demographics	✓					
Medical History	✓					
Intra-op Failure (visual and surgeon assessment)		✓				
Post-op Repair Failure			✓	✓	✓	✓

Assessments **All Subjects:** Pain assessment with VAS **Shoulder:** ROWE Score WOSI Score Constant-Murley Shoulder Scale or **Hip:** HOS-ADL Score Mod. Harris Hip Score	✓		✓	✓	✓	✓
X-ray / Imaging	✓		✓[2]	✓[2]		✓[2]
MRI[3]	✓[3]		✓[3]		✓[3]	
Adverse Event Assessment		✓	✓	✓	✓	✓
Concomitant medications/therapies		✓	✓	✓	✓	✓
End of Study/Exit			✓[4]	✓	✓	✓[4]

Abbreviations: VAS, Visual Analog Scale; WOSI, Western Ontario Shoulder Instability Index; HOS-ADL, Hip Outcome Score-Activities of Daily Living

1. For Knotless REGENESORB™ arms: only 30 hip and 30 shoulder subjects will be required to complete 24 month visit
2. If needed to investigate repair failure.
3. Required only for MICRORAPTOR™ Knotless REGENESORB™ Arms
4. If necessary

None of the above listed activities are undertaken by Sponsor personnel.

11.1.1 Visit 1 / Screening/Preoperative Visit

1. Obtain written informed consent from the subject as detailed in Section 7.4

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

NOTE: Any subject who signs an informed consent/assent but fails to meet the required entry criteria is considered to be a Screen Failure. Screen Failure subjects will be assigned Subject IDs in the EDC, but their demographic information must be captured in the appropriate CRF with the reason for screen failure specified.

2. Review the subject for protocol inclusion/exclusion criteria.

3. Obtain demographic information and medical history, including information on all concomitant medications/therapies.
4. Assign the subject a study number and instruct the subject on treatment procedures.
5. Complete Screening and Enrollment Log.
6. Complete VAS pain assessment for all subjects.
7. Complete assessments for study shoulder or hip:

   Shoulder:
   - ROWE Score
   - WOSI Score
   - Constant-Murley Shoulder Scale

   Hip:
   - HOS-ADL Score
   - Mod. Harris Hip Score
8. Perform X-ray / imaging (if no prior imaging is available). Collect pre-operative MRI conducted per standard of care, where available, for Knotless REGENESORB™ subjects

   *** Imaging up to 6 months prior to screening is acceptable**
9. Complete Pre-Operative Visit CRFs
10. Subjects will be instructed to return to the treatment facility for the Treatment/Operation Visit 2 in ≤ 30 days.

11.1.2 Visit 2 / Baseline Treatment/Operation Visit

1. Query subject regarding any changes in general health.
2. Commence treatment/operation.
3. Update information in the Screening and Enrollment Log.
4. If any adverse device effects or device deficiencies are observed or reported during the surgery through discharge, they must be recorded as instructed in Section 12, Adverse Events and Device Deficiencies. Also record concomitant medications/therapies used to treat AEs.

5. Record intra-op failure (visual and surgeon assessment), if any. (Intra-op failure are AEs that need to be recorded on the AE CRFs.)
6. Record device identification information for the anchors (e.g., Unique Device Identifier, Lot Number, Serial Number, Catalogue Number), suture type used with Knotless PEEK and Knotless REGENESORB™ anchors, and clock-face position of anchors.
7. Instruct the subject on proper postoperative care/procedures.
8. Instruct the subject on follow-up procedures, including returning to the treatment facility in 6 months (± 1 month) for follow-up visit.
9. Complete Operation and Discharge Visit CRFs.

11.1.3 Visit 3 / 6 Month Follow-up Visit (± 1 Month)

1. Query subject regarding any changes in general health.
2. Record post-op repair failure, if any. (Post-op failure are AEs that need to be recorded on the AE CRFs.)
3. Complete VAS pain assessment for all subjects.
4. Complete assessments for study shoulder or hip:

   Shoulder:
   - ROWE Score
   - WOSI Score
   - Constant-Murley Shoulder Scale

   Hip:
   - HOS-ADL Score
   - Mod. Harris Hip Score
5. Collect X-ray / imaging. (If needed to investigate repair failure for REGENESORB™ and Knotless PEEK subjects).

   Perform MRI according to Imaging Protocol. (For Knotless REGENESORB™ subjects)

6. If any adverse device effects or device deficiencies are observed or reported, they must be recorded as instructed in Section 12, Adverse Events and Device Deficiencies. Also record concomitant medications/therapies used to treat AEs.
7. Instruct the subject on follow-up procedures, including returning to the treatment facility at 12 months post-operative (± 1 month) for follow-up visit.
8. Complete 6-Month Follow-up Visit (Visit 3) and/or End of Study CRFs.

11.1.4 Visit 4 / 12 Month Follow-up (MICRORAPTOR™ Knotless REGENESORB™ subjects) / End of Study (MICRORAPTOR™ REGENESORB™, MICRORAPTOR™ Knotless PEEK subjects) (± 1 Month)

1. Query subject regarding any changes in general health.
2. Record post-op repair failure, if any. (Post-op failure are AEs that need to be recorded on the AE CRFs.)
3. Complete VAS pain assessment for all subjects.
4. Complete assessments for study shoulder or hip:

   Shoulder:
   - ROWE Score
   - WOSI Score
   - Constant-Murley Shoulder Scale

   Hip:
   - HOS-ADL Score
   - Mod. Harris Hip Score
5. Collect X-ray / imaging.*

   *If needed to investigate repair failure.
6. If any adverse device effects or device deficiencies are observed or reported, they must be recorded as instructed in Section 12, Adverse Events and Device Deficiencies. Also record concomitant medications/therapies used to treat AEs.
7. Complete End of Study Visit (Visit 4) CRFs for MICRORAPTOR™ REGENESORB™ and Knotless PEEK subjects).
8. Instruct Knotless REGENESORB™ subjects on follow-up procedures, including returning to the treatment facility at 24 months post-operative (± 1 month) for follow-up visit.

11.1.5 Visit 5 / 24 Month End of Study* Visit (MICRORAPTOR™ Knotless REGENESORB™ subjects) (± 1 Month)

***Only 30 shoulder and 30 hip subjects will complete this visit**

1. Query subject regarding any changes in general health.
2. Record post-op repair failure, if any. (Post-op failure are AEs that need to be recorded on the AE CRFs.)
3. Complete VAS pain assessment.
4. Complete assessments for study shoulder or hip:

   Shoulder:
   - ROWE Score
   - WOSI Score
   - Constant-Murley Shoulder Scale

   Hip:
   - HOS-ADL Score
   - Mod. Harris Hip Score
5. Perform MRI according to Imaging Protocol.
6. If any adverse device effects or device deficiencies are observed or reported, they must be recorded as instructed in Section 12, Adverse Events and Device Deficiencies. Also record concomitant medications/therapies used to treat AEs.
7. Complete End of Study Visit (Visit 5) CRFs

11.1.6 Unscheduled Visit

An unscheduled visit is an in-office visit that occurs between the scheduled study visits and is conducted to assess subjects who are deemed to be symptomatic or require evaluation for AEs or DDs. Unscheduled examinations may be conducted at the discretion of the Investigator. All information obtained during an unscheduled visit should be recorded in the source documents and on the appropriate CRF.

1. Query subject regarding any changes in general health.
2. Record post-op repair failure, if any. (Post-op failure are AEs that need to be recorded on the AE CRFs.)
3. Complete VAS pain assessment for all subjects.
4. Complete assessments for study shoulder or hip:

   Shoulder:
   - ROWE Score
   - WOSI Score
   - Constant-Murley Shoulder Scale

   Hip:
   - HOS-ADL Score
   - Mod. Harris Hip Score
5. Collect X-ray / imaging.*

   *If needed to investigate repair failure.
6. If any adverse device effects or device deficiencies are observed or reported, they must be recorded as instructed in Section 12, Adverse Events and Device Deficiencies. Also record concomitant medications/therapies used to treat AEs.
7. If applicable, instruct the subject on follow-up procedures, including returning to the treatment facility for the next scheduled follow-up visit.
8. Complete Unscheduled Visit and/or End of Study Visit CRFs.

12. ADVERSE EVENTS AND DEVICE DEFICIENCIES

12.1 DEFINITIONS (ISO 14155)

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.

Table Error! No text of specified style in document.**.1-1: Categories of Adverse Event**

	NOT DEVICE-RELATED	**DEVICE- OR PROCEDURE- RELATED**	
Non-Serious	**Adverse Event (AE)**	**Adverse Device Effect (ADE)**	
Serious	**Serious Adverse Event (SAE)**	**Serious Adverse Device Effect (SADE) (See 12.1.3)**	
		Anticipated	**Unanticipated**
		Anticipated Serious Adverse Device Effect (ASADE)	**Unanticipated Serious Adverse Device Effect (USADE)**

12.1.1 Adverse Event

An Adverse Event (AE) is any untoward medical occurrence, unintended disease or injury or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device and whether anticipated or unanticipated.

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

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

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

AE is used both to refer to AE which do not meet the definitions of Adverse Device Effects or Serious Adverse Events 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 related to the use of an investigational medical device.

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

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

Note 3: This includes "comparator" if the comparator is a medical device.

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 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, 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 Related 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, it led to any of the following:

a) death,
b) serious deterioration in the health of the subject, users or other persons as defined by one or more of the following:
    1) a life-threatening illness or injury, or
    2) a permanent impairment of a body structure or a body function including chronic diseases, or
    3) in-patient or prolonged hospitalization, or
    4) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,
c) foetal distress, foetal death or a congenital abnormality or birth defect including physical or mental impairment

Note 1: Planned hospitalization for a pre-existing condition, or a procedure required by the study protocol, without serious deterioration in health, is not considered a serious adverse event.

12.1.4 Anticipated/Unanticipated Serious Adverse Device Effect

An Unanticipated Serious Adverse Device Effect (USADE) is a serious ADE which by its nature, incidence, severity or outcome has not been identified in the current version of the risk assessment.

Note 1: Anticipated serious adverse device effect (ASADE) is an effect which by its nature, incidence, severity or outcome has been identified in the risk assessment.

Potential Adverse Effects listed in the MICRORAPTOR IFUs include:

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

The list is inexhaustive . Please check Instructions for use for a full list of adverse effects which are known to occur (anticipated) with MICRORAPTORdevices. Adverse Effects, including those listed above , are only ASADEs if the event is considered serious as outlined in 12.1.3.

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

Note 1: DD includes malfunctions, use errors and inadequacy in the information supplied by the manufacturer including labelling.

Note 2: This definition includes device deficiencies related to the investigational medical device or the comparator.

Device deficiencies that did not lead to an adverse event but could have led to a medical occurrence

a) if either suitable action had not been taken,
b) if intervention had not been made, or
c) if circumstances had been less fortunate,

are considered Device Deficiencies with potential to cause SADE and shall be reported as specified in section 12.3.

12.2 AE CODING DICTIONARY

Coding for this study will be done per International Medical Device Regulators Forum (IMDRF) AE Terminology Annex E – Clinical signs, symptoms, and conditions.

12.3 REPORTING PROCEDURES

AE of any kind and DD will be recorded in the applicable CRF and source notes to include the date of occurrence, treatment and the details resolution. The Investigator will evaluate all AE for relationship to the device and procedure, seriousness, and severity (if applicable). DD will be evaluated for potential to cause SADE. The following timescales should be followed for the AE/DD information to be submitted/entered into the CRF and reported to the Sponsor or designee (see figure 12.3-1 and 12.3-2):

- ADE and DD – without unreasonable delay

- SAE, SADE and DD with potential to cause SADE – immediately (i.e. within 24 hours of the investigator being informed about the event)
- All other events – according to usual timescales

In addition to inputting SAE and SADE information within 24 hours of being aware of the event, the investigator should email Clinical.safety@Smith-nephew.com to alert the safety representative of the events existence and to clarify details if necessary.

For ADE and DD, date of occurrence, and 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 according to the timescales above.

All adverse events 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 regulatory agency and IRB/IEC of adverse events as per the requirements listed below:

- Unanticipated SADEs and DDs that could have led to SADE will be reported to IRB within 10 working days, or per local or central IRB requirements as applicable

All other events will be reported on a periodic/annual basis.

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 SADE, anticipated SADE, and DD.

Figure Error! No text of specified style in document.**.3-1: Evaluation and Reporting of AE**

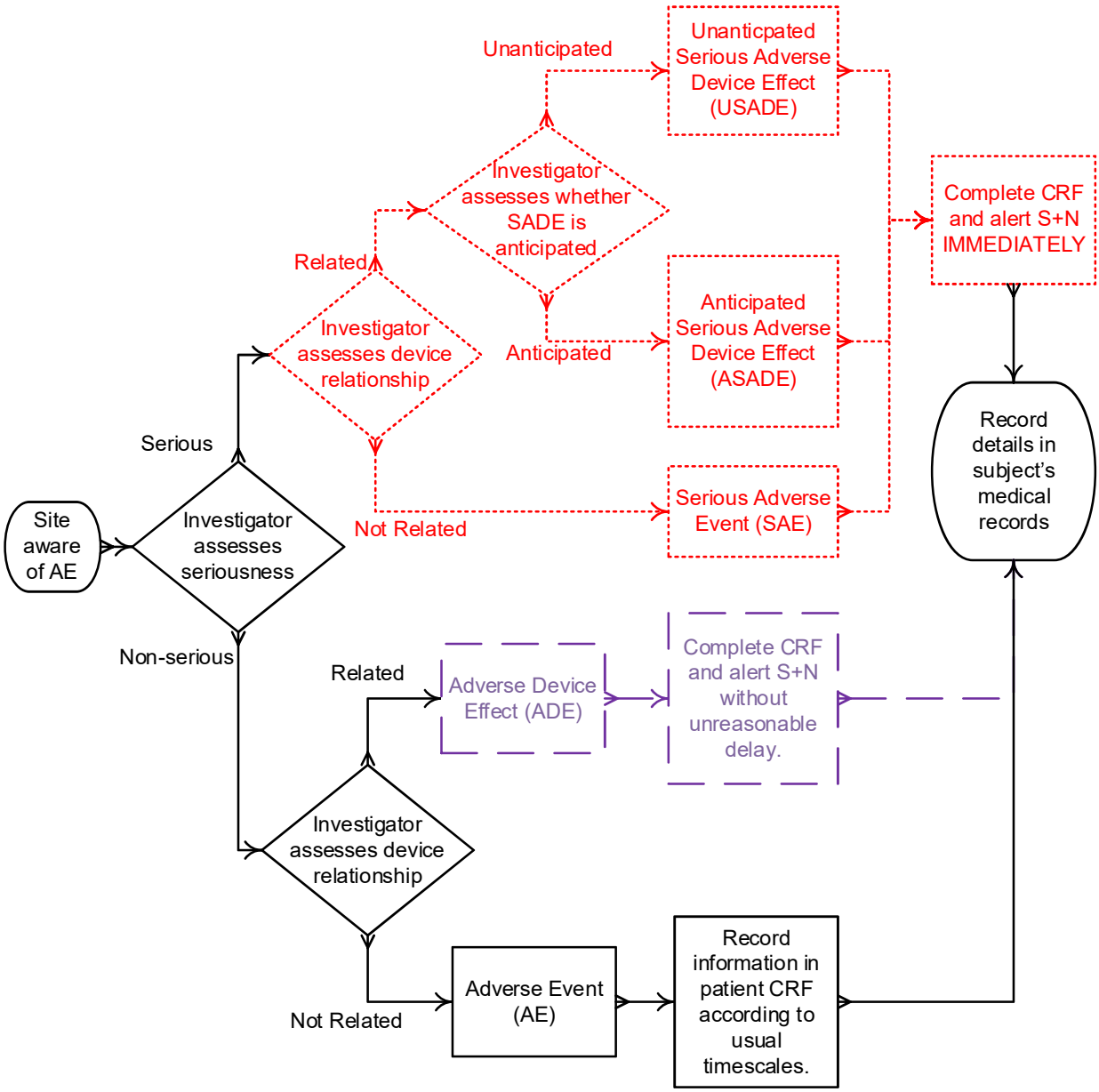
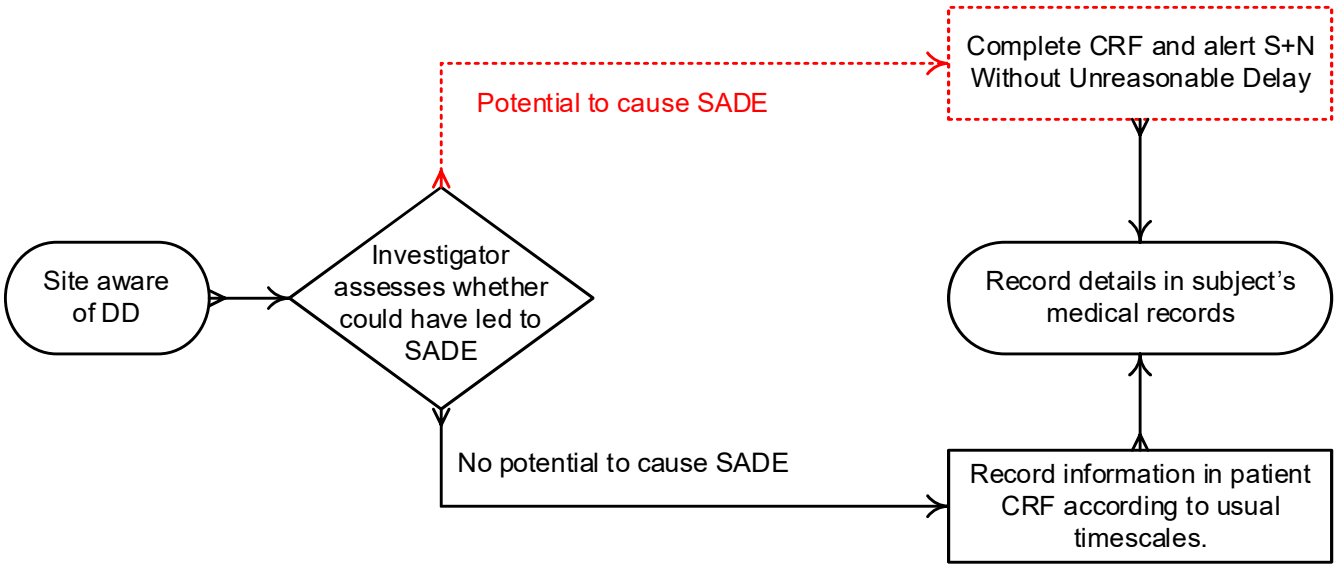


Figure Error! No text of specified style in document..**3-2: Evaluation and Reporting of DD**



12.4 UNBLINDING OF INVESTIGATIONAL PRODUCT

Not Applicable

12.5 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 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 in the CRF/Clinical Study Report.

12.5.1 Ongoing Adverse Events at Study Discontinuation

Adverse events which are **related** to a study procedure or S+N IP and are ongoing at the 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 the 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. STATISTICAL DESIGN

A Statistical Analysis Plan (SAP) will be written and finalized prior to database lock. The SAP will contain more specific details of the statistical analyses that will be carried out as well as provide information on any changes or deviations from the projected analyses in this protocol.

Smith+ Nephew's Global Biostatistics group or designee will conduct the statistical analysis for this study. Unless otherwise stated, all significance tests will be two-sided, performed at the 5% significance level. Resulting p-values will be quoted. Point estimates and their corresponding 95% two-sided confidence intervals will be generated where appropriate. Where data summaries are specified, categorical and ordinal variables will be summarized with frequencies and percentages. Continuous variables will be summarized with the following summary statistics: number of observations, mean, median, standard deviation, minimum and maximum values. All analyses will be performed in SAS 9.3 (or later).

13.1 SAMPLE SIZE JUSTIFICATION

The sample size for this study is precision-based, and not based on statistical power considerations, thus no formal statistical hypothesis is formulated. The sample size for this study is determined based on the feasibility of recruitment, enrolment and follow-up considerations.

The primary endpoint for the study upon which sample size is determined as repair failure rate in the study device at 6 months. This will be analysed per product. In the publication based on the systematic review entitled: “Is arthroscopic surgery for stabilization of chronic shoulder instability as effective as open surgery?” authored by Hobby et al.[27] the combined failure rate (from meta-analysis), in the suture anchors is 8.9% (i.e. a clinical success of 91.1%).

For the Microraptor Regenesorb arms (MICRORAPTOR™ REGENESORB™ Suture Anchor and MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor), the sample size is estimated based on assumption of attainment of a clinical success rate of 91.1% with a 95% confidence interval (CI) of 81.1% to 100% (i.e. at a precision of ± 10%). Using these assumptions, enrolling up to 60 subjects for evaluation of each shoulder and hip suture anchor would yield a probability of 96% (evaluation of combined shoulder and hip anchors using the same assumption would yield > 99% probability). Therefore, enrolment of 120 patients for the MICRORAPTOR™ REGENESORB™ Suture Anchor and enrolment of 120 patients for the MICRORAPTOR™ Knotless REGENESORB™ Suture Anchor is deemed sufficient to meet the primary objective for this study.

For the MICRORAPTOR™ Knotless PEEK arm, the same assumptions as above are used, but with precision of ±15% as this is an inert, non-resorbable Class IIb device and will be estimated based on assumption of attainment of a clinical success rate of 91.1% with a 95% confidence interval (CI) of 76.1% to 100% (i.e. at a precision of ± 15%). Using these assumptions, enrolling up to 30 subjects for evaluation of each shoulder and hip suture anchor would yield a probability

of 95% (evaluation of combined shoulder and hip anchors using the same assumption would yield > 99% probability). Therefore enrolment of 60 patients for the MICRORAPTOR™ Knotless PEEK Suture Anchor is deemed sufficient to meet the primary objective of this study.

Unfortunately, the MICRORAPTOR™ REGENESORB™ (Knotted) Suture Anchor IFU has been updated part way through the enrolment phase of this clinical study and now excludes biceps tenodesis. As a result, protocol modifications have been made to ensure the eligibility criteria aligns with the new indications for use. With this is mind and accounting for the 17 shoulder patients with biceps tenodesis enrolled in the study under protocol V2.0 (as at 15SEP2021), it is recommended to increase the total patient recruitment target to N=315 patients to ensure the study captures sufficient data on the indications per the current IFU.

Device	Hip	Shoulder
MICRORAPTOR™ REGENESORB™	60	75
MICRORAPTOR™ Knotless REGENESORB™	60	60
MICRORAPTOR™ Knotless PEEK	30 (at least 8 with MINITAPE)	30 (at least 8 with MINITAPE)
Total	**150**	**165**

13.2 ANALYSIS POPULATIONS

The following analysis populations will be used for this study:

- Safety (SAF) Population: This includes all subjects who have received the study device.
- Full Analysis Set (FAS): This includes all patients who were recruited into the study and have at least one post-baseline visit.
- Per-Protocol (PP) Population: This includes all subjects in the Full Analysis Set, who have no significant protocol deviations and who meet all the inclusion/exclusion criteria.

- A separate subgroup analysis will focus on MICRORAPTOR Knotless PEEK patients who received the MINITAPE suture.
- A separate subgroup analysis will exclude the 17 shoulder patients with biceps tenodesis enrolled in the MICRORAPTOR™ REGENESORB™ (Knotted) arm of the study under protocol V2.0.

Statistical analysis will be performed using each of the patient populations as follows: Analysis of the primary and secondary endpoints will be performed separately using both the FAS and PP populations. All safety analyses will utilize the SAF population.

13.3 BASELINE DATA

Data to be summarized at baseline includes but is not limited to all collected demographic variable such as age, gender, primary diagnosis, height, weight, Body-Mass-Index and medical history. The baseline variables will be used to describe the outcome data where necessary.

13.4 EFFICACY ANALYSIS

13.4.1 Analysis of Primary Endpoint

For each product separately, the repair failure rate at 6 months, π, will be summarized using frequency (n) and percentage (%). A 95% exact CI for a single proportion (%) will be presented using the Clopper-Pearson method.[28] This analysis will be carried out using the FAS population as the primary analysis population with the PP population used for sensitivity analysis.

13.4.2 Analysis of Secondary Endpoints

- Repair failure rate at 12 months will be summarized using frequency (n) and percentage (%). A 95% exact CI for the percentage will also be presented using the Clopper-Pearson method[28].

- Repair failure rate at 24 months (for Microraptor™ Knotless REGENESORB™ subjects) will be summarized using frequency (n) and percentage (%). A 95% exact CI for the percentage will also be presented using the Clopper-Pearson method28.
- Level of pain will be measured using a VAS scale at the pre-operative visit, 6 months post-operative, 12 months post-operative and 24 months post-operative. Descriptive summary statistics will be used to summarise the pain scores at each visit. The change from pre-operative score to each post-operative visit score will also be summarised.
- The Constant-Murley, WOSI, ROWE, HOS and mHHS PRO scores will be calculated and summarised for each visit appropriately for categorical or continuous variables. Change from pre-operative score to each post-operative visit score will be presented.
- MRI at 24 months will be used to study REGENESORB™ material resorption and replacement with new bone formation. Analysis will be conducted separately by an imaging vendor.

13.5 SAFETY ANALYSES

All safety endpoints will be summarized using the safety population.

Adverse Events

The number of subjects reporting: adverse events, serious adverse events, severe adverse events, device-related adverse events, serious device-related adverse events, unanticipated adverse events, and serious unanticipated adverse events will be summarized. In addition, for each adverse event, the following will be summarized: severity, the relationship to the investigational device, outcome and duration of the resolved adverse events and the duration of the adverse events at trial discontinuation.

Device deficiencies

The number of device deficiencies and the number of patients reporting a device deficiency will be summarised.

Additional summaries of safety endpoints, if applicable, will be described in the SAP.

13.6 INTERIM ANALYSES

There will be no interim analyses for any of the products.

14. INVESTIGATOR OBLIGATIONS

The Principal Investigator (PI) will comply with the commitments outlined in the Statement of Investigator, provided by the Sponsor, and ISO 14155 Clinical investigation of medical devices for human subjects - Good Clinical Practice (GCP), and all applicable regulatory requirements as outlined in Appendix 22.1 of this protocol.

The Principal Investigator shall ensure compliance with the protocol and 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 IRB, protocol or national regulations.

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

The sponsor and principal investigator shall maintain the clinical investigation documents as required by the applicable regulatory requirement(s). They shall take measures to prevent accidental or premature destruction of these documents. The principal investigator or sponsor

may transfer custody of records to another person/party and document the transfer at the investigation site or at the sponsor's facility.

14.1 DATA RECORDING AND RECORD RETENTION

Clinical research records shall be stored in a manner that ensures privacy, confidentiality, security, and accessibility of the records both during and after the conduct of the study. The Investigator/Institution will take measures to prevent the accidental or premature destruction of those documents. The Investigator must retain essential study documents for at least 2 years after the date the study is terminated. If the Investigator needs to dispose of the documents, the Sponsor should be contacted for approval prior to disposal or destruction. For discontinued product, the essential documents will be retained until at least 2 years have elapsed since the formal discontinuation (via notification of the Food and Drug Administration (FDA) or other regulatory agency) of clinical development of the investigational product. The investigator will retain these documents for a longer period if required by the applicable local laws.

If the responsible investigator retires, relocates, or withdraws from responsibility of keeping the study records, custody must be transferred to a person who will accept the responsibility. The Sponsor must be notified in writing of the name and address of the new custodian. Under no circumstance shall the Investigator relocate or dispose of any study documents before having obtained written approval from the Sponsor.

15. 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 and amendment(s), if applicable, with GCP regulations, and with applicable regulatory requirements.

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

15.1 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.

15.2 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 and documented IRB approval.

15.3 INTERIM MONITORING VISIT

Regular interim monitoring visits will be performed by the Sponsor or qualified person designated by the Sponsor.

15.4 SPONSOR AUDITS AND REGULATORY INSPECTION

Quality Assurance auditor(s), either 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.

15.5 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, confirm the disposition of any other ancillary items used for the study, and review regulatory

requirements regarding records retention and IRB reporting requirements. When no subjects have been included, a remote close-out visit may be conducted.

15.6 DATA MANAGEMENT AND STATISTICAL ANALYSIS

The data collected in the CRFs will be entered into a validated, 21 CFR Part 11 compliant, electronic data capture database system. Access to the electronic data capture system is controlled through Smith+Nephew procedures. The data will be subject to verification, validation and archiving according to the standard operating procedures of the Sponsor or data management vendor. The data will be analysed with reference to the analysis plan in section 13. Any deviations from the planned analysis will be documented in the final study report.

16. PROTOCOL DEVIATIONS

An Investigator must not make any changes or deviate from this protocol, except to protect the life and physical well-being of a subject in an emergency. Protocol deviations reported by the Investigator or discovered during monitoring visits will be compiled in a Protocol / GCP Deviation Log (TMP-CD-31-02 Protocol/GCP Deviation Log). Significant and/or recurrent protocol/GCP deviations will be documented by the Sponsor on a protocol deviation form (TMP-CD-31-01 Protocol/GCP Deviation) including identified root cause and, as necessary, appropriate corrective and preventive actions will be put in place and signed off by the study personnel. If it is deemed necessary full clinical CAPA will be initiated by the Sponsor.

It is not allowed to use waivers to allow planned deviation of the study protocol.

An investigator may be early terminated from the study upon identification of serious protocol deviations whereby there are concerns for patient safety or data quality (especially those not reported to the sponsor by the site). Early termination may also occur if there are repeated protocol deviations which have previously been addressed via corrective and preventative actions thereby suggesting an issue with site compliance.

The site staff must 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 IRB, protocol or national regulations. The site must report protocol deviations to the IRB per the IRB requirements.

17. PROTOCOL AMENDMENTS

Amendments should be made only in necessary cases once the study has started. Protocol amendments must be approved by the protocol signatories prior to submission to the IRB. Protocol amendments need to be approved by the IRB, according to the applicable requirements prior to implementation at the site.

18. CONFIDENTIALITY OF THE STUDY

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

19. SUBJECT PROTECTION

Data will be de-identified on forms and in the clinical database, and subjects will be identified only by a code or subject number. All information and data sent to SN or designee concerning patients or their participation in this study will be considered confidential, and confidentiality shall be observed by all parties involved at all times during the study. All data used in analysis and reports will be used without identifiable reference to the subject. All data will be secured against unauthorized access. The Investigator and investigative site will be responsible for compliance with all local privacy regulations.

20. STATEMENTS OF COMPLIANCE

The investigation was conducted in compliance with applicable requirements in the protection of human subjects' regulations in 21 CFR part 50, Good Clinical Practices, the institutional review

board's regulations in 21 CFR part 56. In compliance with the Food and Drug Administration Amendments Act of 2007 (FDAAA), this study will be listed in www.clinicaltrials.gov.

This clinical study will be performed in compliance with the ethical principles of the Declaration of Helsinki; and ISO 14155: Clinical investigation of medical devices – for human subjects - Good clinical practice.

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

21. END OF STUDY

The end of study is defined as the date of the last subject, last visit (LSLV). Subjects will return to their normal standard of care once their participation in the study has ended.

Should circumstances arise which require the termination of the entire study prior to its planned completion (e.g., safety concerns), or circumstances arise which mean the end of the participation of an individual site (e.g., departure of Investigator, non-compliance), then study termination procedures will be undertaken according to the SOPs of the Sponsor.

22. PUBLICATION POLICY

22.1 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.

22.2 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 (de-identified) 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 nine 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.

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24. APPENDICES

24.1 APPENDIX: INSTRUCTIONS FOR USE

Refer to the Instructions for Use supplied with these products.

24.2 APPENDIX: EQUIPMENT AND SPECIAL INSTRUCTIONS

Sites will be provided with a dynamometer for use in the Constant-Murley assessment. This has been labelled by Smith & Nephew and calibrated by the supplier. Dynamometers must be calibrated once per year and sites should work with the sponsor to return devise approaching calibration expiry. Calibrated replacement devices will be provided.

24.3 APPENDIX: PRINCIPAL INVESTIGATOR OBLIGATIONS (ISO14155)

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 Independent Ethics Committee (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.
        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)

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, fetus 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 acknowledgment 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. 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.

24.4 APPENDIX: LIST OF ABBREVIATIONS AND DEFINITIONS

Abbreviation	Term
ADE	Adverse Device Effect(s)
AE	Adverse Event(s)
ASADE	Anticipated Serious Adverse Device Effect(s)
CI	Confidence Interval
CRF	Case Report Form(s)
CV	Curriculum Vitae
DD	Device Deficiency(ies)
FAI	Femoroacetabular impingement
GCP	Good Clinical Practice
HIPAA	Health Information Portability Accountability Act
HOS-ADL	Hip Outcome Score-Activities of Daily Living
ICF	Informed Consent Form
IEC	Independent Ethics Committee
IFU	Instructions for Use
ISF	Investigator Site File
ISO	International Organization for Standardization
IRB	Institutional Review Board
IP	Investigational Product
mHHS	Modified Harris Hip Score
MMT	Manual Muscle Tester
PEEK	Polyether ether ketone
PI	Principal Investigator
PMCF	Post-Market Clinical Follow-up
S+N	Smith & Nephew, Inc.

Abbreviation	Term
SADE	Serious Adverse Device Effect(s)
SAE	Serious Adverse Event(s)
SAP	Statistical Analysis Plan
SLAP	Superior Labrum from Anterior to Posterior
USADE	Unanticipated Serious Adverse Device Effect(s)
VAS	Visual Analog Scale
WOSI	Western Ontario Shoulder Instability Index