Safety and Performance of PEEK Anchors (DYNOMITE◇, SPYROMITE◇, RAPTORMITE◇, FOOTPRINT◇ ULTRA PK SL) in Extremities

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Sponsor Name and Address:	Smith & Nephew Orthopaedics 7135 Goodlett Farms Parkway Cordova, TN 38016 USA
Investigational Product(s)	PEEK Extremity Suture Anchors RAPTORMITE◇ 3.0 PK W/NDL, 2 0 ULTRABRA DYNOMITE◇ 2.0 PK W/NDL,1 2-0 ULTRABRAID SPYROMITE◇ 2.0 PK W/1 2-0 ULTRABRAID WH FOOTPRINT ULTRA PK 4.5 mm, SL FOOTPRINT ULTRA PK 5.5 mm, SL

1. SIGNATURES

1.1 PROTOCOL 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 "Safety and Performance of PEEK Anchors (DYNOMITE◇, SPYROMITE◇, RAPTORMITE◇, FOOTPRINT◇ ULTRA PK SL) in Extremities", version 2.0, dated 05Dec2018, and agree to abide by all provisions set forth herein. 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)

2. SIGNATURE APPROVAL

Role	Approver Name	Approver Signature	Date Approved (DD/MMM/YYYY)
Medical Writer	Esvanhnelly Podany **(Author)**	DocuSigned by: Esvanhnelly Podany Signer Name: Esvanhnelly Podany Signing Reason: I am the author of this document Signing Time: 12-Dec-2018 | 19:47 GMT E5647A006DCD4E309BB879946B4FEC0F	12-Dec-2018 | 19:47:52 GMT
Senior Vice President / Chief Medical Officer, Global R&D	Andy Weymann **(Owner)**	DocuSigned by: Signer Name: Andy Weymann Signing Reason: I approve this document Signing Time: 18-Dec-2018 | 03:40 GMT 675C45EC25704A5FB20A08674419D6D8	18-Dec-2018 | 03:40:37 GMT
Vice President Clinical, Scientific & Medical Affairs	Beate Hanson	DocuSigned by: Beate Hanson Signer Name: Beate Hanson Signing Reason: I approve this document Signing Time: 18-Dec-2018 | 19:51 GMT A491AB16277146CA9C8B8366F1B6BEA5	18-Dec-2018 | 19:51:38 GMT

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Head of Global Biostatistics or Designee	Director Biostatistics and Data Management, Global Clinical Strategy	DocuSigned by: Alan Rossington Signer Name: Alan Rossington Signing Reason: I approve this document Signing Time: 14-Dec-2018 | 10:30 GMT 556E7DBFCA8A4287A7EE3EE9B5B3ABFD
Medical Affairs Representative	Vice President Medical Affairs, Scientific & Medical Affairs	DocuSigned by: Signer Name: Luca Orlandini Signing Reason: I approve this document Signing Time: 12-Dec-2018 | 21:16 GMT FC872951AC1C4261B85EC7A7CD09ACDC

3. SYNOPSIS

Title of Study:	Safety and Performance of PEEK Anchors (DYNOMITE◇, SPYROMITE◇, RAPTORMITE◇, FOOTPRINT◇ ULTRA PK SL) in Extremities
Study Design:	Multi-center, retrospective case series
Study Type:	Post-market, clinical follow-up
Study Product:	PEEK Extremity Suture Anchors RAPTORMITE◇ 3.0 PK W/NDL, 2 0 ULTRABRA DYNOMITE◇ 2.0 PK W/NDL,1 2-0 ULTRABRAID SPYROMITE◇ 2.0 PK W/1 2-0 ULTRABRAID WH FOOTPRINT ULTRA PK 4.5 mm, SL FOOTPRINT ULTRA PK 5.5 mm, SL
Study Purpose:	Assess safety and performance post-market of the PEEK suture anchor devices to address clinical data gaps for Medical Device Regulations (MDR).
Primary Objective:	Safety and performance of the study devices in extremities over a time period of 6 months after intervention.
Secondary Objective:	Safety and performance of the study devices in extremities over a time period of 12 months after intervention.
Statistical Rationale:	The sample size for this study is determined based on the feasibility of recruitment, enrollment and follow-up considerations. The study is therefore not powered for any statistical hypothesis testing but will be able to estimate a clinical success rate of 91% with a 95% confidence interval (CI) of 80% to 100%.
Sample Size:	Minimum, n= 80 Maximum, n= 480 Enrollment distribution:

PEEK Anchor	Minimum	Maximum
RAPTORMITE◇	20	120
DYNOMITE◇ (If available)	20	120

	SPYROMITE◇ (If available)	20	120
	FOOTPRINT ULTRA PK SL (If available)	20	120
Number of Study Sites:	Up to 15 sites		
Targeted Global Regions:	United States and/or Outside United States		
Inclusion Criteria:	1. Subjects who have undergone extremity joint repair using the study devices. 2. Subjects aged 18 years and older at the time of surgery.		
Exclusion Criteria:	1. Subject is entered in another investigational drug, biologic, or device study or has been treated with an investigational product within 12 months post-operative. 2. Subjects who are < 3 months post-operative.		
Study Duration:	Twelve month follow up.		
Primary endpoint:	Clinical success rate (%) of the study devices in extremities at 6 months post-operative. Clinical success is defined as extremity repairs without signs of device failure and/or re-intervention as assessed by the surgeon.		
Secondary endpoint(s):	Clinical success rate (%) of the study devices in extremities at 12 months post-operative. Clinical success has previously been defined.		
Other exploratory endpoint(s):	Surgeon Reported Outcomes based on data collected in the subject's medical chart as standard of care at study sites. This may include but not limited to the following: • Range of Motion (ROM) • Pain assessed by Visual Analogue Scale (VAS)		
Safety Data	• All AEs, SAEs and complications including intra-operative adverse events and complications.		

	• Device related intervention. • Device deficiency. • Concomitant medications/therapy.

3.1 STUDY SCHEDULE

Table 1: Schedule of Events

Schedule of Events	Chart Review	
	6 months (182 days) post-op (+/- 90 days)	12 months (365 days) post-op (+/- 90 days)
Informed Consent	X N/A if waiver of consent approved by IRB	
Inclusion/Exclusion	X	
Demographics/Medical History	X	
Operative/Discharge Data Collection	X	
Implant Status	X	X
Pain assessed by VAS	X	X
ROM	X	X
Concomitant Medications or Therapies[1]	*	*
Serious Adverse Event (SAE)/Adverse Device Effect (ADE)/ Device Deficiency (DevD) Assessment	*	*
AE Assessment	*	*
End of Study/Subject Disposition	*	*

[1]Any concomitant medications associated with an AE, SA(D)E will be recorded.
*As Needed

4. TABLE OF CONTENTS

4.1 TABLE OF TABLES

4.2 LIST OF ABBREVIATIONS

Abbreviation	Definition
ADE	Adverse Device Effect(s)
AE	Adverse Event(s)
AOL	Activities of Daily Living
ASADE	Anticipated Serious Adverse Device Effect
CI	Confidence Interval
CRF	Case Report Form(s)
CSR	Clinical study Report
CTA	Clinical Trial Agreement
CV	Curriculum Vitae
DevD	Device Deficiency(ies)
EC	Ethics Committee
FU	Follow-Up
GCP	Good Clinical Practice
IBT	Iliotibial Band Syndrome
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
IEC	International Ethics Committee
ICMJE	International Committee of Medical Journal Editors
IFU	Instructions for Use
IP	Investigational Product
IRB	Institutional Review Board
ISF	Investigator Site File

Abbreviation	Definition
ISO	International Organization for Standardization
MEDDEV	Master Control European Medical Device Vigilance System
MDD	Medical Device Directive
NA or N/A	Not Applicable
NSAIDs	Nonsteroidal anti-inflammatory drugs
NSAE	Non-Serious Adverse Event(s)
PI	Principal Investigator
PP	Per-Protocol Population
ROM	Range of Motion
S&N	Smith & Nephew, Inc.
SADE	Serious Adverse Device Effect(s)
SAE	Serious Adverse Event(s)
SAF	Safety population
SAP	Statistical Analysis Plan
SOP	Standard Operating Procedures
SLAP	Superior Labral Tear from Anterior to Posterior
UHMWPE	Ultra-high molecular weight polyethylene
USADE	Unanticipated Serious Adverse Device Effect(s)
VAS	Visual Analog Scale

5. INTRODUCTION

5.1 BACKGROUND

Suture Anchors are small fixation devices used in surgical procedures for attaching or reattaching tendons and ligaments to bone. The size and type of anchor used depends on the patient's bone density and the procedure performed.

Suture anchors are made up of three components: the anchor - which is inserted into the bone; the eyelet – which is a hole or a loop in the anchor which the suture passes through to link the anchor to the suture; and the suture – which is attached to the anchor through the eyelet of the anchor. An anchor-receiving hole is first drilled in the bone at the desired point of tissue reattachment. A suture anchor is deployed in the hole using an appropriate installation tool. This effectively locks the suture to the bone, with the free end(s) of the suture extending out of the bone. Soft tissue is then moved into position over the hole containing the deployed suture anchor. As this is done, the free end(s) of the suture is (are) passed through or around the soft tissue so that the free end(s) of the suture reside(s) on the far (i.e., non-bone) side of the soft tissue. The suture is now used to tie the soft tissue securely to the bone.

Smith & Nephew (S&N) offers a variety of suture anchors including several polyetheretherketone (PEEK) suture anchors soft tissue to bone repair. The PEEK devices included in this review are all single use, sterile devices comprised of machined component anchor bodies that are manufactured from PEEK-OPTIMA Polymer (LT1). This material meets ISO 10993 biocompatibility requirements for implant devices, bone/tissue contact, and permanent contact. The anchor tips are molded components which are also manufactured from PEEK-OPTIMA Polymer (LT3). PEEK-OPTIMA polymers provide an ideal combination of strength, biocompatibility, revisability and inherent radiolucent characteristics. Smith & Nephew also provides a variety of reusable and

disposable instrumentation used in conjunction with the suture anchors including awls, dilators, drills, guides, obturators and wires.

5.2 STUDY PURPOSE

This is a retrospective study to evaluate intra-operative, 6 months and 12 months safety and performance of the PEEK anchors (DYNOMITE◇, SPYROMITE◇, RAPTORMITE◇, FOOTPRINT◇ ULTRA PK SL) for extremities to meet existing MDD/MEDDEV requirements.

5.3 SAFETY CONSIDERATIONS

The PEEK suture anchor family, which include the following products: DYNOMITE◇, SPYROMITE◇, RAPTORMITE◇ and FOOTPRINT◇ ULTRA PK SL, are intended for reattachment of soft tissue to bone fixation in the joint extremities such as elbow, wrist, hand, foot and ankle. Representative language of the contraindications and potential adverse events can be found in the Instructions for Use (IFU) for each product.

Table 2: Instructions for Use Reference Numbers

PEEK Suture Anchor	IFU
DYNOMITE◇	01/2017 10600401 Rev. D
SPYROMITE◇,	01/2017 10600400 Rev. D
RAPTORMITE◇	03/2017 10600402 Rev. E
FOOTPRINT◇ ULTRA PK SL	2017 10601001 REV. B

6. STUDY RELATED RISKS

6.1 STUDY POSSIBLE RISKS

As a result of participating in the study, there could be a risk of loss of protected subject information confidentiality. All applicable confidentiality standards and data protection and privacy laws will be

followed by the Sponsor to ensure that data collected is handled in confidence. Data will be coded and handled only by appropriately qualified and authorized personnel.

6.2 STUDY RELATED BENEFITS

Because the surgery and all the follow-up visits are the same as if the subject would not participate in this study, there are no additional medical benefits associated with participating in this study. The information gained from this study may help improve the treatment of people in the future that need to undergo any of the procedures included in this study.

7. OBJECTIVE(S)

7.1 PRIMARY OBJECTIVE

The primary objective of this study is to assess the safety and performance post-market of the PEEK Anchors (DYNOMITE◇, SPYROMITE◇, RAPTORMITE◇, FOOTPRINT◇ ULTRA PK SL) in extremities over a time period of 6 months after intervention.

7.2 SECONDARY OBJECTIVE

The secondary objective of this study is to assess the safety and performance post-market of the PEEK Anchors (DYNOMITE◇, SPYROMITE◇, RAPTORMITE◇, FOOTPRINT◇ ULTRA PK SL) in extremities over a time period of 12 months after intervention.

8. STUDY PRODUCT(S)

8.1 DYNOMITE◇ 2.0 PK SUTURE ANCHOR WITH NEEDLES

The Smith & Nephew DYNOMITE◇ 2.0 PK Suture Anchor with Needles is a push/tap-in fixation device intended to provide secure attachment of soft tissue to bone. The device consists of a suture anchor with attached non-absorbable suture(s) and stainless steel needles preassembled

to an insertion device. The suture anchor is provided sterile, for single use only. DYNOMITE◇ 2.0 PK Suture Anchor with Needles contains: Non-absorbable suture anchor, 2.0 mm diameter – PEEK-OPTIMA® from Invibio® (polyetheretherketone), Insertion device – stainless steel shaft with ABS and polycarbonate handle. Non-absorbable suture(s) with attached stainless steel needles.

Non-absorbable suture options:

- White – braided, uncoated, UHMW polyethylene
- White/blue – braided, uncoated, UHMW polyethylene with monofilament polypropylene cobraid
- White/black – braided, uncoated, UHMW polyethylene with monofilament nylon cobraid
- Braided, silicone, or PTFE-impregnated polyester (USP), non-absorbable

8.2 RAPTORMITE◇ 3.0 SUTURE ANCHOR WITH NEEDLES

The Smith & Nephew RAPTORMITE◇ Suture Anchor is a fixation device intended to provide secure attachment of soft tissue to bone. The device consists of a suture anchor with attached non-absorbable suture(s) and stainless steel needles preassembled to an insertion device. The suture anchor is provided sterile, for single use only. RAPTORMITE◇ 3.0 Suture Anchor with Needles contains: non-absorbable suture anchor, 3.0 mm diameter – PEEK-OPTIMA® from Invibio® (polyetheretherketone), Insertion device – stainless steel shaft with ABS and polycarbonate handle. Non-absorbable suture(s) with attached stainless steel needles. Refer to individual suture anchor product labels for suture size and type, and quantity.

Non-absorbable suture options:

- White – braided, uncoated, UHMW polyethylene
- White/blue – braided, uncoated, UHMW polyethylene with monofilament polypropylene cobraid

- White/black – braided, uncoated, UHMW polyethylene with monofilament nylon cobraid
- White/green – braided, silicone-coated, polyester (USP), non-absorbable

8.3 SPYROMITE™ 2.0 PK SUTURE ANCHOR WITH NEEDLES

The Smith & Nephew SPYROMITE◇ 2.0 PK Suture Anchor with Needles is a screw-in fixation device intended to provide secure attachment of soft tissue to bone. The device consists of a suture anchor with attached non-absorbable suture(s) and stainless steel needles preassembled to an insertion device. The suture anchor is provided sterile, for single use only. SPYROMITE◇ 2.0 PK Suture Anchor with Needles contains: Non-absorbable suture anchor, 2.0 mm diameter – PEEK-OPTIMA® from Invibio® (polyetheretherketone), Insertion device – stainless steel shaft with ABS and polycarbonate handle. Non-absorbable suture(s) with attached stainless steel needles.

Non-absorbable suture options:

- White – braided, uncoated, UHMW polyethylene
- White/blue – braided, uncoated, UHMW polyethylene with monofilament polypropylene cobraid
- White/black – braided, uncoated, UHMW polyethylene with monofilament nylon cobraid,
- Braided, silicone, or PTFE-impregnated polyester (USP), non-absorbable

8.4 FOOTPRINT ULTRA PK SL SUTURE ANCHOR

The Smith & Nephew FOOTPRINT ULTRA PK SL (PEEK-OPTIMA® from Invibio®) Suture Anchor is non-absorbable, attached to an insertion device, and available in 4.5 mm and 5.5 mm. The suture anchor is intended to provide secure reattachment of soft tissue to bone. Attachment of the soft tissue is performed by the surgeon's preferred technique.

- Non-absorbable suture options PEEK-OPTIMA® from Invibio®

- Suture (USP #2-0).
- Retention suture- braided polyester non-absorbable suture (USP #2-0).

Table 3 demonstrates the model, and product description of the devices. Refer to individual suture anchor product labels for suture size, type, and quantity.

Table 3: Product Specification, structural composition and description

Product #	72201806	72201881	72201882	72203776 72203783
Specification	RAPTORMITE◇ 3.0 PK W/NDL, 2 0 ULTRABRA	DYNOMITE◇ 2.0 PK W/NDL,1 2-0 ULTRABRAID	SPYROMITE◇ 2.0 PK W/1 2-0 ULTRABRAID WH	FOOTPRINT ULTRA PK SUTURE ANCH SL
Diagram				
Product description	3.0 mm diameter PEEK-OPTIMA® from Invibio®suture anchor	2.0 mm diameter PEEK-OPTIMA® from Invibio® suture anchor	2.0 mm diameter PEEK-OPTIMA® from Invibio® suture anchor	4.5 mm and 5.5 mm PEEK-OPTIMA® from Invibio® suture anchor

8.5 INDICATIONS FOR USE

The following Table 4 identifies the Indications for Use for the Smith & Nephew PEEK Suture Anchors.

Table 4: Summary of indications for PEEK Anchors (DYNOMITE◇, SPYROMITE◇, RAPTORMITE◇, FOOTPRINT◇ ULTRA PK SL) in extremities

	DYNOMITE◇	RAPTORMITE◇	SPYROMITE◇	FOOTPRINT◇ ULTRA PK SL
Foot & Ankle				
Hallux valgus repairs	X	X	X	X
Medial or lateral instability repairs/reconstructions	X	X	X	X
Achilles tendon repairs/reconstructions	X	X	X	X
Midfoot reconstructions	X	X	X	X
Metatarsal ligament/tendon repairs/reconstructions	X	X	X	X
Bunionectomy	X	X	X	N/A
Elbow, Wrist & Hand				
Scapholunate ligament reconstructions	X	N/A	X	N/A
Ulnar or radial collateral ligament reconstructions	X	X	X	N/A
Lateral epicondylitis repair	X	X	X	N/A
Biceps tendon reattachment	X	X	X	N/A

8.6 PRODUCT USE

All study related procedures using the PEEK suture anchors in the extremities have been performed according to the recommended surgical technique described in the labelling and the instructions for use.

8.7 SURGICAL TECHNIQUE

The operative visit of this study is retrospective. The use of the PEEK Anchors (DYNOMITE◇, SPYROMITE◇, RAPTORMITE◇, FOOTPRINT◇ ULTRA PK SL) in extremities was performed per standard of care at the participating study sites.

9. SUBJECT ENROLLMENT AND WITHDRAWAL

Investigators will screen all subjects that have undergone usage of the PEEK suture anchors in the extremities using only the existing information in the medical records.

Investigators will conduct a chart review after IRB approval has been granted. All subjects whose chart undergoes the screening process will be documented on a Screening and Enrollment Log, with the reason for exclusion noted, if applicable. The Investigator or designee must notify the Sponsor upon subject enrollment.

9.1 SUBJECT POPULATION

To minimize the potential for selection bias, Investigators will screen and subsequently enroll subjects (after fulfilling all inclusion and exclusion criteria) on whom PEEK Anchors RAPTORMITE◇, DYNOMITE◇, SPYROMITE◇ and FOOTPRINT◇ ULTRA PK SL in the extremities were implanted. Enrollment will be in sequential order based on the date of their surgical procedure with the investigational device, i.e. earliest to latest.

9.2 INCLUSION CRITERIA

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

1. Subjects who have undergone extremity joint repair using the study devices.
2. Subjects aged 18 years and older at the time of surgery.

9.3 EXCLUSION CRITERIA

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

1. Subject is entered in another investigational drug, biologic, or device study or has been treated with an investigational product within 12 months post-operative.
2. Subjects who are < 3 months post-operative.

9.4 SCREENING

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

9.5 INFORMED CONSENT

Study sites will obtain Institutional Review Board (IRB/Ethics Committee (EC)) approval for this study before any study specific activities are performed.

Due to the retrospective nature of the study, a waiver of informed consent for study participation will be requested from the IRB/EC for those subjects who meet eligibility criteria as only retrospective data set will be collected for these subjects. No prospective visits will be performed.

A waiver or alteration of the requirements for obtaining informed consent can occur under any of the following three provisions set forth by the Department of Health and Human Health Services: Research in general: an IRB may waive or alter the requirement of informed consent under 45 CFR 46.116(d), provided that the IRB finds and documents that all of the following four conditions are met:

1. the research involves no more than minimal risk to the participants;
2. the waiver or alteration will not adversely affect the rights and welfare of the participants;
3. the research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

If an IRB/EC waiver is not granted, then informed consent shall be obtained from all study subjects according to ISO 14155 guidelines and all applicable national regulations. If waiver of consent is not approved, potential subjects must be informed as to the purpose of the study and the potential risks and benefits known or that can be reasonably predicted or expected as described in the written consent form. The subject, or their legally authorized representative, will then **read**, **sign**, and **personally date** the IRB/EC approved informed consent document(s) (see below for difficulties with reading and writing). Additionally, the individual who obtains consent from the subject will sign and date the informed consent document. A copy of the signed informed consent documentation will be provided to the subject, a copy will be placed in the subject's medical record, and the original filed in the Investigator Site File (ISF).

If a subject refuses participation, no further information will be collected. Reason for exclusion should be noted on the Screening and Enrollment Log.

9.6 ENROLLMENT

For screening, only information available in the medical records will be reviewed. Once a potential subject has been identified, all inclusion criteria and none of the exclusion criteria have been met, and the informed consent process has been completed or a waiver of consent has been granted by IRB/EC, the subject will be considered enrolled and assigned a consecutive Subject

Identification (ID) number. Enrollment and assigned Subject ID will be documented on the Screening and Enrollment Log. For bilateral subjects, only one Subject ID will be assigned.

Any subject who signs an informed consent or has a waiver of informed consent and is subsequently identified as not meeting the required entry criteria is considered to be a screen failure. Demographic information must be captured in the appropriate Case Report Form (CRF) and the reason for screen failure will be documented on the Screening and Enrollment Log.

9.7 LOST TO FOLLOW-UP

A subject will be considered lost to follow-up if he/she did not return for follow-up per the study Investigator's standard of care follow-up schedule. Information will be documented on the Case Report Form (CRF).

9.8 WITHDRAWAL

9.8.1 Withdrawal from the Study

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

- At the discretion of the Investigator.
- If the Investigator or the Sponsor stops the study for any reason and decides to withdraw subject(s) from the study.

For each case, information will be documented in the source document and the Case Report Form (CRF), detailing circumstances leading to the withdrawal. Subjects who are withdrawn will not be re-entered into the study at a later date. Data collected up to the point of withdrawal may be used but no additional data for that subject may be collected.

10. STUDY DESIGN

10.1 STUDY DESIGN

This is a retrospective, multi-center, case series study to collect clinical data that will evaluate post-market PEEK Anchors RAPTORMITE°, DYNOMITE°, SPYROMITE° and FOOTPRINT° ULTRA PK SL in extremities. A minimum of 80 subjects and a maximum of 480 subjects who underwent surgery for PEEK Anchors RAPTORMITE°, DYNOMITE°, SPYROMITE° and FOOTPRINT° ULTRA PK SL in extremities are planned to be enrolled into the study after the fulfilment of all inclusion and exclusion criteria. It is also planned that any of the investigational sites will enroll a minimum of 10 subjects into the study. Data from eligible subjects will be recorded on case report forms (CRFs).

10.2 STUDY ENDPOINTS

10.2.1 Primary Endpoint

Clinical success rate (%) of the study devices in extremities at 6 months post-operative with clinical success defined as extremity repairs without signs of device failure and/or re-intervention as assessed by the surgeon.

10.2.2 Secondary Endpoints

Clinical success rate (%) of the study devices in extremities at 12 months post-operative. Clinical success has previously been defined.

10.2.3 Safety Endpoints

Safety endpoints include the collection of the following events from the subjects' medical record:

- All adverse events (AEs) and complications occurring from the time of subject enrollment until study termination or study completion including intra-operative adverse events and complications.
- Device related re-intervention.
- Device deficiency.

10.2.4 Other Endpoints

Surgeon Reported Outcomes would constitute other endpoints and may include but not be restricted to the following:

- Range of Motion (ROM)
- Pain assessed by Visual Analogue Scale (VAS)

Surgeon reported outcomes are optional and will be definitively specified in collaboration with the Investigators once sites have been identified for the conduct of the study.

11. STUDY PROCEDURES

11.1 RETROSPECTIVE DATA COLLECTION: 6 MONTHS POST-OPERATIVE (±90 DAYS)

Given the retrospective study design, data will be collected from the medical chart to the extent it is available.

1. Subject should undergo the informed consent process and sign the informed consent *only* if a waiver of consent has not been approved by the IRB.
2. Screen the subject's chart for protocol inclusion/exclusion criteria.
3. Obtain demographic information and a medical history.
4. VAS, ROM.
5. Operative Data Collection – review operative case notes.

6. Implant Status/ Disposition.
7. Document concomitant medications and/or therapies associated with an AE, SA(D)E.
8. Review the subject's chart for AEs, SAEs and Device Deficiencies, including inter-operative. AEs, SAEs and DevDs should be documented from the time of surgery through the study duration.

11.2 RETROSPECTIVE: 12 MONTHS POST-OPERATIVE (±90 DAYS)

Given the retrospective study design, data will be collected from the medical chart to the extent it is available.

1. VAS, ROM.
2. Implant Status/Disposition.
3. Document concomitant medications and/or therapies associated with an AE, SA(D)E.
4. Review the subject's chart for AEs, SAEs and Device Deficiencies including inter-operative. AEs, SAEs and DevDs should be documented from the time of surgery through the study duration.
5. Complete the End of Study CRF.

11.3 CONCOMITANT MEDICATIONS AND THERAPIES

Any concomitant medications associated with an AE, SAE or SADE will be recorded.

12. STATISTICAL DESIGN

A Statistical Analysis Plan (SAP) based on the contents of the protocol will be written and finalized prior to database lock. The SAP will account for any changes or deviations from the projected analyses in this protocol.

12.1 General

Smith & Nephew's Global Biostatistics group 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 and 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 Statistical Analysis System (SAS) version 9.3 (or later).

12.2 Analysis Populations

The following analysis populations will be used for this study:

- **Safety Population (SAF):** This includes all subjects who enroll in the study who had previously undergone repair in the extremities using any of the PEEK anchors: RAPTORMITE◇, DYNOMITE◇, SPYROMITE and FOOTPRINT◇ ULTRA PK SL.
- **Per-Protocol Population (PP):** This includes all subjects in the Safety Population, who have no significant protocol deviations and who meet all the inclusion/exclusion criteria. Deviations considered as significant will be defined and finalized prior to database lock.

12.3 Efficacy Analysis

Analysis of Primary Endpoint

The rate (%) of clinical success of all the anchor devices combined at 6 months post-operative will be summarized as a frequency and a percentage. A 95% two-sided exact CI for a single proportion will be presented using Clopper-Pearson's method (1934). The same type of analysis will be carried out for each of the anchors used in the study. These analyses will be carried out using the per protocol population as the primary analysis population with the safety population used for sensitivity analysis.

12.3.2 Analysis of Secondary Endpoints

The analysis of the following secondary endpoint will be carried out using the safety population:

- The rate (%) of clinical success of all the anchors combined at 12 months post-operative will be summarized as described for the analysis of the primary endpoint. This analysis will also be repeated for each of the anchors used in the study.

12.4 Safety Analyses

- All safety endpoints will be summarized using the safety population. The incidence of events encountered on-study will be summarized using frequencies and percentages. An overall AE table will summarize the overall AE incidence according to subjects with at least one AE; subjects with at least one AE by worst severity (mild, moderate, or severe); subjects with at least one AE by worst outcome; subjects with at least one AE that led to study discontinuation; subjects with at least one AE by relatedness to investigational device; SAEs; ADEs; ASADEs; USADEs and; SADEs as applicable. A cumulative summary by the number of adverse events encountered overall and within each classification will also be summarized. The incidence of subjects reporting device deficiencies will additionally be summarized.

- Each of the AE classifications will further be summarized by event using frequencies (n) and percentage (%) of subjects with each adverse event as well as the cumulative adverse events/episodes per classification.
- A listing of concomitant medications/therapies will be provided by subject.

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

12.5 INTERIM ANALYSES

Not applicable.

13. SAMPLE SIZE JUSTIFICATION

This study is precision-based, thus, the sample size is not based on statistical power calculations. The sample size for this study is determined based on the feasibility of recruitment, enrollment and follow-up considerations. The study is therefore not powered for any statistical hypothesis testing but to have sufficient number of subjects to be able to estimate a clinical success rate of 91% with a 95% confidence interval (CI) of 80% to 100%.

With an assumption of a 91% clinical success rate to be obtained in each of the PEEK anchors and a corresponding 95% CI between 80% and 100%, enrolling between 20 and 120 subjects for each anchor's precision analysis is expected to provide between 15.2% to >95% probability, pending that there is sufficient volume of each type of anchor available. Thus, an overall minimum of 80 and maximum of 480 subjects are to be enrolled into the study, pending that there is sufficient volume of each type of anchor available. Additionally, a minimum of 10 subjects will be enrolled at any investigational site.

14. ADVERSE EVENTS AND DEVICE DEFICIENCIES

Adverse Events (AE) related to the study implant, or procedure including Adverse Device Effects (ADE), Serious Adverse Device Effects (SADE), Unanticipated Serious Adverse Device Effect (USADE), and Device Deficiencies (DevD) occurring from the time of the surgery until revision or study completion must be recorded on the appropriate CRF and reported. If the event is known to have been previously reported to Smith & Nephew, this must be noted on the CRF. After enrollment, in addition to all adverse events related to the implant or the procedure, all serious adverse events (SAE), regardless of causality, must be recorded on the appropriate CRF and reported to the Sponsor, and IRB if necessary. Adverse events leading to a revision should be reported at all times regardless of causality.

Adverse Device Effects (ADE) occurring after study completion will be handled as product complaints reportable by the Sponsor and will not be entered into the study database.

14.1 DEFINITIONS

The categories of adverse events are shown in table 5. The definitions for each of these categories are given in the subsequent sections (see reference within the table).

Table 5: Categories of Adverse Event

	NOT DEVICE-RELATED	DEVICE- OR PROCEDURE-RELATED	
NON-SERIOUS	ADVERSE EVENT (AE) (SEE 14.1.1)	ADVERSE DEVICE EFFECT (ADE) (SEE 14.1.2)	
SERIOUS	SERIOUS ADVERSE EVENT (SAE) (SEE 14.1.3)	SERIOUS ADVERSE DEVICE EFFECT (SADE) (SEE 14.1.3)	
		ANTICIPATED	UNANTICIPATED
		ANTICIPATED SERIOUS ADVERSE DEVICE EFFECT (ASADE) (SEE 14.1.4)	UNANTICIPATED SERIOUS ADVERSE DEVICE EFFECT (USADE) (SEE 14.1.4)

14.1.1 Adverse Event (AE)

An AE is any untoward medical occurrence temporally associated with the use of an Investigational Product (IP)/Ancillary Product, whether or not considered causally related to that IP/Ancillary Product.

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

14.1.2 Adverse Device Effect (ADE)

An ADE is an adverse event that, in the opinion of the Investigator, is related to the IP or the procedure.

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

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

14.1.3 Serious Adverse Events (SAE) and Serious Adverse Device Effects (SADE)

An AE or ADE is considered a SAE or SADE if, in the view of either the Investigator or the Sponsor, it:

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

Medical and scientific judgment should be exercised in deciding whether other situations should be considered serious such as important medical events that might not be immediately life-threatening or result in death or hospitalization but might jeopardize the subject or might require

intervention to prevent one of the other outcomes listed in the definition above. Examples of such events are intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias, or convulsions that do not result in hospitalization; or development of drug dependency or drug abuse.

14.1.4 Anticipated/Unanticipated Serious Adverse Device Effect (ASADE/USADE)

An USADE is a serious ADE that meets any of the above definitions but is also considered, by the Investigator, to be caused by or related to the IP, not previously identified in nature, severity or degree in the IFU.

An Anticipated Serious Adverse Device Effect (ASADE) is a serious ADE that does not meet the criteria for a USADE.

14.1.5 Severity

The severity of every AE will be assessed by the Investigator or medically qualified site staff to whom the responsibility has been delegated and documented on the delegation of authority log. AEs should be classified as mild, moderate, or severe, regardless of whether or not the AEs 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.

14.1.6 Device Deficiency

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

14.2 Reporting Procedures

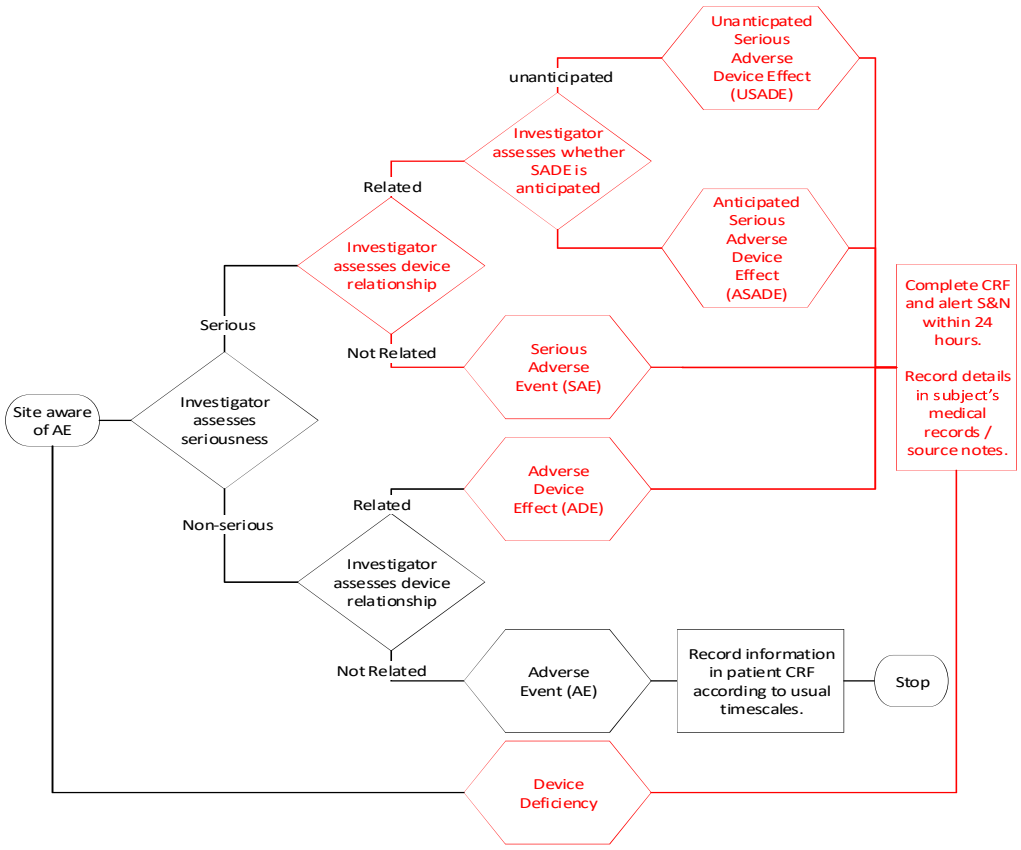
AEs of any kind and DevDs will be recorded in the applicable CRF and source notes. The Investigator will evaluate all AEs for relationship to the device and procedure, if applicable, seriousness, and severity. ADEs, SAEs, and DevDs will be submitted/entered into the CRF and reported to the Sponsor within 24 hours of the Investigator being informed about the event (Figure 1). For ADEs and DevDs, details of the product/procedure related to the event will be recorded in the CRF within 24 hours of the retrospective chart review.

All SAEs and ADEs will be reviewed by a medically qualified person appointed by the Sponsor to determine which, if any, meet criteria for expedited reporting to the regulatory authorities. The Investigator will inform the IRB of AEs according to the IRB requirements.

Depending on the nature of the AE, the Sponsor 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 the Sponsor and should be forwarded as soon as it becomes

available. In certain cases, the Sponsor also may request a letter from the Investigator that summarizes the events related to the case.

Figure 1: Evaluation and Reporting of AE and DevD



Reference the Investigator Site File Sponsor Contact Information Sheet to report SAEs, unanticipated ADEs and SADEs, anticipated SADEs, and DevDs.

14.3 FOLLOW-UP OF SUBJECTS WITH ADVERSE EVENTS

For subjects who are experiencing an ongoing unresolved AE at the time of their study completion or early discontinuation from the study, it is recommended that the investigator follow-up with the patient per standard clinical practice.

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

14.3.1 Ongoing Adverse Events at Study Discontinuation

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

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

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

15. INVESTIGATOR OBLIGATIONS

The Principal Investigator (PI) will comply with the commitments outlined in the in the Statement of Investigator and with GCP, and all applicable regulatory requirements.

16. SPONSOR AND MONITOR RESPONSIBILITIES

The Sponsor will designate a monitor to conduct the appropriate site visits at the appropriate intervals. The clinical investigation will be monitored to ensure that: the rights and wellbeing of the

subjects are protected; the reported data are accurate, complete, and verifiable from the source documents; and the study is conducted in compliance with the currently approved protocol, with GCP regulations, and with applicable regulatory requirements.

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

16.1 Site Qualification Visit

A site qualification visit may be performed by the Sponsor or qualified person designated 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.

16.2 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 Clinical Trial Agreement (CTA) and documented IRB/EC approval.

16.3 Sponsor Audits and Regulatory Inspection

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

16.4 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/IEC reporting requirements.

17. PROTOCOL AMENDMENTS

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

19. STATEMENTS OF COMPLIANCE

This clinical study will be performed in compliance with the ethical principles of the Declaration of Helsinki; International Organization for Standardization (ISO) 14155: Clinical investigation of medical devices – Good Clinical Practice (GCP); and the International Council for Harmonisation (ICH)-E6.

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.

20. END OF STUDY

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 this will be undertaken according to the Standard Operating Procedures (SOP) of the Sponsor.

21. PUBLICATION POLICY

21.1 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.

21.2 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 9 months and end 36 months after article publication. Data supplied may only be used by the researcher(s) named in the approved research proposal for the purposes of achieving the aims of the analyses specified therein. All proposals should be directed to the Sponsor. To gain access, data requestors will need to sign a data access agreement.

22. REFERENCES

1. U.S. Department of Health and Human Services (HHS) Code of Federal Regulation Title 45 Part 46 (45 CFR 46) Revised January 15, 2009
2. Clopper, CJ & Pearson ES. (1934) The use of confidence or fiducial limits illustrated in the case of the binomial. Biometrika, 26, 404–413.
3. IFU- Dynomite◇ 2.0 OK Suture Anchors with Needles, 10600401.
4. IFU-Spyromite◇ 2.0 PK Suture Anchors with Needles, 10600400.
5. IFU FOOTPRINT ULTRA PK SL Suture Anchors 10601001-B
6. PEEK SUTURE Anchors Post Market Surveillance Statement- PMS-140
7. Clinical Evaluation: *PEEK Suture Anchors* EOP:14000055

23. APPENDICES

23.1 PROTOCOL AMENDMENT VERSION 1.0 TO 2.0

23.1.1 General Purpose

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 a product (FOOTPRINT° ULTRA PK SL), increasing sample size, adding exclusion criteria, and administrative actions to clarify and/or correct typographical errors.

23.1.2 Rationale

The protocol changes below were made to include the product PEEK family FOOTPRINT° ULTRA PK SL, increase sample size to account for the additional product family, and addition of exclusion criteria so that subjects have follow-up data (as this is a retrospective study).

23.1.3 Effect on Study Status

Not applicable; this amendment is to be in effect and implemented prior to subject enrollment.

23.1.4 Details

Section	Current Text 12Sept2018 , Version 1.0	Revised Text 05Dec2018 , Version 2.0
Throughout document header	Safety and Performance of PEEK Anchors (DYNOMITE®, SPYROMITE®,RAPTOMITE Version #, Date TMP-110 – Clinical Protocol - Devices SOP-059 Clinical Protocols	THROUGHOUT PROTOCOL HEADER- Updated information to reflect additional product name FOOTPRINT® ULTRA PK SL Typo error corrected for Raptormite Version #, Date change from 12Sep2018 to 8/20/2012 Version change to 1.0 from 2.0 Added Footer: TMP-CD-05-01 – Clinical Protocol-Device – Revision A; SOP-CD-05 Clinical Protocols
Title Page	Protocol Version : 1.0 Safety and Performance of PEEK Anchors (DYNOMITE®, SPYROMITE®, RAPTOMITE®) in Extremities	Updated information to reflect version changes and addition of product family (FOOTPRINT® ULTRA PK SL) Updated: Safety and Performance of PEEK Anchors (DYNOMITE®, SPYROMITE®, RAPTORMITE®, FOOTPRINT® ULTRA PK SL) in Extremities Added Investigation products: FOOTPRINT ULTRA PK 4.5 mm, SL FOOTPRINT ULTRA PK 5.5 mm, SL

<table>
<tr><td>Section 1.1 Protocol Signature page</td><td>I have read the attached protocol entitled “Safety and Performance of PEEK Anchors (DYNOMITE◇, SPYROMITE◇, RAPTOMITE◇) in Extremities”, version 1.0, dated 11Sep2018, and agree to abide by all provisions set forth herein. I agree to comply with the Investigator’s Obligations stipulated in Section 23.1 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.</td><td>Updated version and date. Removed Investigator Obligations as this will be provided to the site separately:
I have read the attached protocol entitled “Safety and Performance of PEEK Anchors (DYNOMITE◇, SPYROMITE◇, RAPTORMITE◇, FOOTPRINT◇ ULTRA PK SL) in Extremities”, version 2.0, dated 05Dec2018, and agree to abide by all provisions set forth herein. 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.</td></tr>
<tr><td>Section 3 Protocol Synopsis</td><td>Study Product
No language in prior protocol

Sample Size:
Minimum, n= 60
Maximum, n= 120
Enrollment distribution:<table><tr><th>PEEK Anchor</th><th>Minimum</th><th>Maximum</th></tr></table></td><td>Study Product: Updated product family to reflect FOOTPRINT◇ ULTRA PK SL 4.5mm 5.5 mm:
Safety and Performance of PEEK Anchors (DYNOMITE◇, SPYROMITE◇, RAPTORMITE◇, FOOTPRINT◇ ULTRA PK SL) in Extremities

Sample Size: Increased the sample size to reflect addition of FOOTPRINT◇ ULTRA PK SL and added “if available” to reflect that there may be limited data for DYNOMITE, SPYROMITE, and FOOTPRINT ULTRA PK SL:
Minimum, n= 80
Maximum, n= 480
Enrollment distribution:</td></tr>
</table>

RAPTORMITE◇	20	40
DYNOMITE◇	20	40
SPYROMITE◇	20	40

Number of Study Sites:
Up to 6 sites

Targeted Global Regions:
United States

Exclusion Criteria:
1. Subject is entered in another investigational drug, biologic, or device study or has been treated with an investigational product within 12 months post-operative.

PEEK Anchor	Minimum	Maximum
RAPTORMITE◇	20	120
DYNOMITE◇ (If available)	20	120
SPYROMITE◇ (If available)	20	120
FOOTPRINT ULTRA PK SL (If available)	20	120

Number of Study Sites:
Increased sample size to allow for site diversity across regions:
Up to 15 sites

Targeted Global Regions:
Added OUS as an option for site selections:
United States and/or Outside United States

Exclusion criteria:
Added exclusion criteria
Subjects who are < 3 months post-operative to ensure that subjects have follow-up data:
1. Subject is entered in another investigational drug, biologic, or device study or has been treated with an investigational product within 12 months post-operative.

<table>
<tr><td></td><td>Study Duration:
The expected timeline for the study is approximately two years from first site initiation until final study report.</td><td>2. Subjects who are < 3 months post-operative.

Study Duration: Updated to clarify that charts will be abstracted with data up to 1-year post surgery:
Twelve month follow up.</td></tr>
<tr><td>Section 5.0 Introductio n</td><td>5.3 Safety Considerations

<table><tr><td>DYNOMITE◇</td><td>01/2017 10600401 Rev. D</td></tr><tr><td>SPYROMITE◇,</td><td>01/2017 10600400 Rev. D</td></tr><tr><td>RAPTORMITE◇</td><td>03/2017 10600402 Rev. E</td></tr></table></td><td>Updated overall section to reflect addition

<table><tr><td>DYNOMITE◇</td><td>01/2017 10600401 Rev. D</td></tr><tr><td>SPYROMITE◇,</td><td>01/2017 10600400 Rev. D</td></tr><tr><td>RAPTORMITE◇</td><td>03/2017 10600402 Rev. E</td></tr><tr><td>FOOTPRINT◇ ULTRA PK SL</td><td>2017 10601001 REV. B</td></tr></table>of FOOTPRINT ULTRA PK SL</td></tr>
<tr><td>Section 8 Study Products</td><td>8.4:
No language in prior protocol</td><td>Sections updated to reflect product family

8.4 Added FOOTPRINT ULTRA PK SL:
FOOTRINT ULTRA PK SL Suture Anchor
The Smith & Nephew FOOTPRINT ULTRA PK SL (PEEK-OPTIMA® from Invibio®) Suture Anchor is non-absorbable, attached to an insertion device, and</td></tr>
</table>

		available in 4.5 mm and 5.5 mm. The suture anchor is intended to provide secure reattachment of soft tissue to bone. Attachment of the soft tissue is performed by the surgeon's preferred technique. • Non-absorbable suture options PEEK-OPTIMA® from Invibio® • Suture (USP #2-0). Retention suture- braided polyester non-absorbable suture (USP #2-0).
	Table 4: Product Specification, structural composition and description	Table 3 updated to reflect addition of ULTRA FOOTPRINT PK SL: Table 3: Product Specification, structural composition and description (see table in protocol)
	Table 3: Summary of indications for PEEK Anchors (DYNOMITE®, SPYROMITE®, RAPTORMITE®) in extremities	Table 4 updated to reflect addition of FOOTPRINT ULTRA PK SL: Summary of indications for PEEK Anchors (DYNOMITE®, SPYROMITE®, RAPTORMITE®, FOOTPRINT® ULTRA PK SL) in extremities (see table in protocol)
	All study related procedures using the PEEK suture anchors in the shoulder have been performed according to the recommended surgical technique	8.6 Changed typo error to clarify study is in extremities and not shoulder: All study related procedures using the PEEK suture anchors in the extremities have been performed according to the recommended surgical technique described in the labelling and the instructions for use.

	described in the labelling and the instructions for use.	
Section 9. Subject Enrollment and Withdrawal Section 9.1 Subject Population Section 9.3 Exclusion criteria Section 9.5 Informed Consent Section 9.6 Enrollment	9. Investigators will screen all subjects that have undergone usage of the PEEK suture anchors in the shoulder using only the existing information in the medical records. 9.1: To minimize the potential for selection bias, Investigators will screen and subsequently enroll subjects (after fulfilling all inclusion and exclusion criteria) on whom PEEK Anchors RAPTORMITE®, DYNOMITE®, and SPYROMITE® in the extremities were implanted. Enrollment will be in sequential order based on the date of their surgical procedure with the investigational device, i.e. earliest to latest. 9.3: 1. Subject is entered in another investigational drug, biologic, or device study or has been treated with an investigational product within 12 months post-operative.	9. Changed typographical error to clarify study is in extremities and not shoulder: Investigators will screen all subjects that have undergone usage of the PEEK suture anchors in the extremities using only the existing information in the medical records. 9.1 Added FOOTPRINT ULTRA PK SL: To minimize the potential for selection bias, Investigators will screen and subsequently enroll subjects (after fulfilling all inclusion and exclusion criteria) on whom PEEK Anchors RAPTORMITE®, DYNOMITE®, SPYROMITE® and FOOTPRINT® ULTRA PK SL in the extremities were implanted. Enrollment will be in sequential order based on the date of their surgical procedure with the investigational device, i.e. earliest to latest. 9.3 Exclusion Criteria Administrative change: Updated to reflect synopsis change: 1. Subject is entered in another investigational drug, biologic, or device study or has been treated with an investigational product within 12 months post-operative. 2. Subjects who are < 3 months post-operative.

	9.5: Study sties will obtain Institutional Review Board (IRB) approval for this study An IRB waiver of informed consent for study participation should be requested for those subjects who meet eligibility criteria and have retrospectively completed a 6 month postoperative visit, are deceased, or are lost to follow-up, per IRB policy. If allowed, a retrospective data set will be collected on these subjects.	9.5 Informed Consent Administrative change: Updated language to clarify IRB approval to occur before study begins and ICF waiver of consent approval: Study sites will obtain Institutional Review Board (IRB/Ethics Committee (EC)) approval for this study before any study specific activities are performed. Due to the retrospective nature of the study, an waiver of informed consent for study participation will be requested from the IRB/EC for those subjects who meet eligibility criteria as only retrospective data set will be collected for these subjects. No prospective visits will be performed.
	9.6: For screening, only information in the medical records will be reviewed. Once a subject has completed the informed consent process, if required by the IRB, or a waiver of consent is granted, the subject will be considered enrolled and assigned a consecutive Subject Identification (ID) number. Enrollment and assigned Subject ID will be	9.6 Enrollment Administrative change: Updated language to clarify Enrollment process: For screening, only information available in the medical records will be reviewed. Once a potential subject has been identified, all inclusion criteria and none of the exclusion criteria have been met, and the informed consent process has been completed or a waiver of consent has been granted by IRB/EC, the subject will be considered enrolled and assigned a consecutive Subject Identification (ID) number. Enrollment and assigned Subject ID will be documented on the

	documented on the Screening and Enrollment Log. Any subject who signs an informed consent or has a waiver of informed consent and is subsequently identified not meeting the required entry criteria is considered to be a screen failure. Demographic information must be captured in the appropriate CRF and the reason for screen failure will be documented on the Screening and Enrollment Log	Screening and Enrollment Log. For bilateral subjects, only one Subject ID will be assigned. Any subject who signs an informed consent or has a waiver of informed consent and is subsequently identified as not meeting the required entry criteria is considered to be a screen failure. Demographic information must be captured in the appropriate Case Report Form (CRF) and the reason for screen failure will be documented on the Screening and Enrollment Log.
Section 10 Study Design	This is a retrospective, multi-center, case series study to collect clinical data that will evaluate post-market PEEK Anchors RAPTORMITE®, DYNOMITE®, and SPYROMITE® in extremities. A minimum of 60 subjects and a maximum of 120 subjects in the United States who underwent surgery PEEK Anchors RAPTORMITE®, DYNOMITE®, and SPYROMITE® in extremities are planned to be enrolled into the study after the fulfilment of all inclusion and exclusion criteria. It is also planned that any of the investigational sites would enroll a minimum of 10 subjects into the study. Data from eligible subjects will have their data recorded on case report forms.	Administrative changes: Updated product information and sample size to reflect inclusion of FOOTPRINT ULTRA PK SL: This is a retrospective, multi-center, case series study to collect clinical data that will evaluate post-market PEEK Anchors RAPTORMITE®, DYNOMITE®, SPYROMITE® and FOOTPRINT® ULTRA PK SL in extremities. A minimum of 80 subjects and a maximum of 480 subjects who underwent surgery for PEEK Anchors RAPTORMITE®, DYNOMITE®, SPYROMITE® and FOOTPRINT® ULTRA PK SL in extremities are planned to be enrolled into the study after the fulfilment of all inclusion and exclusion criteria. It is also planned that any of the investigational sites will enroll a minimum of 10 subjects into the study. Data from eligible subjects

		will be recorded on case report forms (CRFs).
Section 12.2 Analysis Population	**Safety Population (SAF):** This includes all subjects who enroll in the study who had previously undergone repair in the extremities using any of the PEEK anchors: RAPTORMITE◇, DYNOMITE◇, and SPYROMITE. **Per-Protocol Population (PP):** This includes all subjects in the Safety Population, who have no significant protocol deviations and who meet all the inclusion/exclusion criteria.	12.2 Administrative changes: Updated to reflect inclusion of FOOTPRINT ULTRA PK SL and clarified per protocol population: • **Safety Population (SAF):** This includes all subjects who enroll in the study who had previously undergone repair in the extremities using any of the PEEK anchors: RAPTORMITE◇, DYNOMITE◇, SPYROMITE and FOOTPRINT◇ ULTRA PK SL. • **Per-Protocol Population (PP):** This includes all subjects in the Safety Population, who have no significant protocol deviations and who meet all the inclusion/exclusion criteria. Deviations considered as significant will be defined and finalized prior to database lock.
Section 13 Sample Size Justification	The study is therefore not powered for any statistical testing but will be able to estimate a clinical success rate of 91% with a 95% confidence interval (CI) of 80% to 100%. With an assumption of a 91% clinical success rate to be obtained in each of the PEEK anchors and a corresponding 95% CI between 80% and 100%, enrolling between 20 and 40 subjects for each anchor's precision analysis	13.0 Increased sample size to account for inclusion of FOOTPRINT ULTRA PK SL: The study is therefore not powered for any statistical hypothesis testing but to have sufficient number of subjects to be able to estimate a clinical success rate of 91% with a 95% confidence interval (CI) of 80% to 100%. With an assumption of a 91% clinical success rate to be obtained in each of the PEEK anchors and a corresponding

	would provide between 15.2% to 71% probability. Thus, an overall minimum of 60 and maximum of 120 subjects would be enrolled into the study. Additionally, a minimum of 10 subjects would be enrolled at any investigational site.	95% CI between 80% and 100%, enrolling between 20 and 120 subjects for each anchor's precision analysis is expected to provide between 15.2% to >95% probability, pending that there is sufficient volume of each type of anchor available. Thus, an overall minimum of 80 and maximum of 480 subjects are to be enrolled into the study, pending that there is sufficient volume of each type of anchor available. Additionally, a minimum of 10 subjects will be enrolled at any investigational site.
Section 14.2 Reporting Procedures Section 14.3 Follow-up of Subjects with Adverse Events	14.2: For ADEs and DevDs, 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 the sponsor unless it is contaminated (e.g. used dressings must not be retained). Updates to submitted information will be recorded in the CRF within 24 hours of the information being available to the Investigator. 14.3: For subjects who are experiencing an 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	14.2 Removed language regarding pictures and retained product as it is not applicable to this retrospective chart abstraction study design: For ADEs and DevDs, details of the product/procedure related to the event will be recorded in the CRF within 24 hours of the retrospective chart review 14.3 Clarified that follow-up is not a study procedure as this study is retrospective chart abstraction only: For subjects who are experiencing an ongoing unresolved AE at the time of their study completion or early discontinuation from the study, it is recommended that the investigator

	in order to determine the outcome of the event.	follow-up with the patient per standard clinical practice.
Section 22: References	1. U.S. Department of Health and Human Services (HHS) Code of Federal Regulation Title 45 Part 46 (45 CFR 46) Revised January 15, 2009 2. Clopper, CJ & Pearson ES. (1934) The use of confidence or fiducial limits illustrated in the case of the binomial. Biometrika, 26, 404–413.	Added additional sources document references. 3. IFU- Dynomite◇ 2.0 OK Suture Anchors with Needles, 10600401. 4. IFU-Spyromite◇ 2.0 PK Suture Anchors with Needles, 10600400. 5. IFU FOOTPRINT ULTRA PK SL Suture Anchors 10601001-B 6. PEEK SUTURE Anchors Post Market Surveillance Statement-PMS-140 7. Clinical Evaluation: *PEEK Suture Anchors* EOP:14000055
Section 23 Principal Investigator Obligations	See Version 1.0 12Oct2018 below.	Removed section as this will be provided to the site separately