NITRX CLINICAL STUDY

Primary Investigator: Dr. Alexander Sah

Observational Clinical Study on Evolution NitrX

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Background

MicroPort Orthopedics, Inc. (MPO) and the site(s) would like to coordinate the collection of clinical data that may be used for regulatory and research purposes. The specific data to be collected is in the "Data Collection and Parameters." The site(s) will provide MPO with anonymized, de-identified data as requested, understanding the site's overriding obligations about patient care and patient confidentiality.

Synopsis

Study Title	Evolution NitrX Observational Study	
Study Rationale	To evaluate the safety and performance of Evolution NitrX TKA	
Study Design	Single Center observational study	
Study Sites	Dr Alexander Sah (PI)	
Sample Size	100	
Visit Schedule	subject schedule will consist of the following time points:	
Study Timeline	3 yr follow up within 2025 5 yr follow up within 2027 7 years follow up 2029 10 years follow up 2032	
Inclusion Criteria	• Subjects > 18 years of age at the time of surgery • Subjects who were implanted with the Evolution NitrX SKU #s listed below) in MicroPort Orthopedics' intended patient population listed within the Instructions for Use (IFU). • Willing and able to participate in the clinical study	
Exclusion Criteria	• Subjects without follow-up history • Subjects not meeting the inclusion criteria • Contraindications as listed in the IFU • Currently enrolled in another study that could affect the endpoints of this protocol. • Has a medical or mental health condition, as judged by the investigator, that would affect the endpoints of this protocol.	
	Objectives	Outcome Measures
Primary	Survivorship (KM)	Kaplan Meier survival rates at each time point
Secondary	PROMS	KOOS Jr
	SAE including Revisions	Track revisions and reason for revisions throughout the study

Scope

Both MPO and the site(s) agree that the site shall be the sole owner of the data and all intellectual property rights in such data. The site will grant MPO the ability to use the aggregated and/or anonymized data for regulatory and research. The opportunity for MPO and the site(s) to collaborate on further use of the data for publication or abstract submissions for medical or professional conferences may be pursued later.

Site Responsibility

The site will maintain strict confidentiality regarding any data about subjects. It will control the subjects' data as defined in relevant data protection laws or regulations applicable to the site.

The site will be responsible for obtaining approvals from an Institutional Review Board (IRB) for data collection. The site will be the sole owner of the data and all related intellectual property rights. However, the site will grant MPO the ability to use, edit, compile, and disseminate the data for regulatory and research activities. The site will not disclose any patient-identifiable information to MPO. The site will provide data on patients solely in aggregated and/or anonymized form, preventing MPO from identifying individual patients.

Data Collection and Parameters

Data Collection Plan

- 100 cases with min 10-year follow-up, implanted with Evolution NitrX, will be included in this study.
- Data collection will be prospective.
- Patient preop and intra-op information has been collected in study 20K001, and this study is a continuation of that study.
- Information regarding adverse events or revisions after surgery will be obtained from patient charts.
- IRB will be notified of the change in study collection.
- Site will ensure Informed consent does not need to be re-consented and will consult the IRB.
- Subjects will be called or have an office visit,
    - Has undergone index procedure on the operative knee with NitrX and
    - In the 20K001 study and
    - Would be willing to complete a KOOS Jr survey
- Once the survey/questionnaire is completed, the site will compile the data parameters into a data collection form provided by the MPO and send it to the MPO upon completion for analysis.

Data Parameters

The data parameters listed below will be collected anonymized before being provided to MPO.

De-Identified Subject #

- A minimum of 100 subjects with Evolution NitrX will be assigned a de-identified subject number entered into the case report form.

Data Collection and Follow-up Schedule

Data Collection	3 years	5 years	7 years	10 years
KOOS Jr	X	X	X	X
SAE including Revision	X	X	X	X

Postoperatively

- Subject Status
  - Is the subject deceased?
  - Date the subject was deceased.
- Is the subject revised?
  - Reasons for revision
  - If a revision occurs, the removed and retained components will be provided.
  - Date that the revision occurred.
- Adverse events
  - Information regarding adverse events that have occurred after surgery will be provided.

SCOPE

Table 1. Evolution NitrX Scope

Part Number	Product Name
Femoral Components	
EFSAN1PL	EVOLUTION NitrX FEM CS/CR NONPOR TiNbN COATED SZ 1 LEFT
EFSAN2PL	EVOLUTION NitrX FEM CS/CR NONPOR TiNbN COATED SZ 2 LEFT
EFSAN3PL	EVOLUTION NitrX FEM CS/CR NONPOR TiNbN COATED SZ 3 LEFT
EFSAN4PL	EVOLUTION NitrX FEM CS/CR NONPOR TiNbN COATED SZ 4 LEFT
EFSAN5PL	EVOLUTION NitrX FEM CS/CR NONPOR TiNbN COATED SZ 5 LEFT
EFSAN6PL	EVOLUTION NitrX FEM CS/CR NONPOR TiNbN COATED SZ 6 LEFT
EFSAN7PL	EVOLUTION NitrX FEM CS/CR NONPOR TiNbN COATED SZ 7 LEFT
EFSAN8PL	EVOLUTION NitrX FEM CS/CR NONPOR TiNbN COATED SZ 8 LEFT
EFSAN1PR	EVOLUTION NitrX FEM CS/CR NONPOR TiNbN COATED SZ 1 RIGHT
EFSAN2PR	EVOLUTION NitrX FEM CS/CR NONPOR TiNbN COATED SZ 2 RIGHT
EFSAN3PR	EVOLUTION NitrX FEM CS/CR NONPOR TiNbN COATED SZ 3 RIGHT
EFSAN4PR	EVOLUTION NitrX FEM CS/CR NONPOR TiNbN COATED SZ 4 RIGHT
EFSAN5PR	EVOLUTION NitrX FEM CS/CR NONPOR TiNbN COATED SZ 5 RIGHT
EFSAN6PR	EVOLUTION NitrX FEM CS/CR NONPOR TiNbN COATED SZ 6 RIGHT
EFSAN7PR	EVOLUTION NitrX FEM CS/CR NONPOR TiNbN COATED SZ 7 RIGHT
EFSAN8PR	EVOLUTION NitrX FEM CS/CR NONPOR TiNbN COATED SZ 8 RIGHT
Tibial Bases	
ETAKN1SL	EVOLUTION NitrX TIB KEELED NONPOR TiNbN COATED SZ 1 STD LEFT
ETAKN2SL	EVOLUTION NitrX TIB KEELED NONPOR TiNbN COATED SZ 2 STD LEFT
ETAKN3SL	EVOLUTION NitrX TIB KEELED NONPOR TiNbN COATED SZ 3 STD LEFT
ETAKN4SL	EVOLUTION NitrX TIB KEELED NONPOR TiNbN COATED SZ 4 STD LEFT
ETAKN5SL	EVOLUTION NitrX TIB KEELED NONPOR TiNbN COATED SZ 5 STD LEFT
ETAKN6SL	EVOLUTION NitrX TIB KEELED NONPOR TiNbN COATED SZ 6 STD LEFT
ETAKN7SL	EVOLUTION NitrX TIB KEELED NONPOR TiNbN COATED SZ 7 STD LEFT
ETAKN8SL	EVOLUTION NitrX TIB KEELED NONPOR TiNbN COATED SZ 8 STD LEFT
ETAKN1SR	EVOLUTION NitrX TIB KEELED NONPOR TiNbN COATED SZ 1 STD RIGHT
ETAKN2SR	EVOLUTION NitrX TIB KEELED NONPOR TiNbN COATED SZ 2 STD RIGHT
ETAKN3SR	EVOLUTION NitrX TIB KEELED NONPOR TiNbN COATED SZ 3 STD RIGHT
ETAKN4SR	EVOLUTION NitrX TIB KEELED NONPOR TiNbN COATED SZ 4 STD RIGHT
ETAKN5SR	EVOLUTION NitrX TIB KEELED NONPOR TiNbN COATED SZ 5 STD RIGHT
ETAKN6SR	EVOLUTION NitrX TIB KEELED NONPOR TiNbN COATED SZ 6 STD RIGHT

ETAKN7SR	EVOLUTION NitrX TIB KEELED NONPOR TiNbN COATED SZ 7 STD RIGHT
ETAKN8SR	EVOLUTION NitrX TIB KEELED NONPOR TiNbN COATED SZ 8 STD RIGHT
ETAKN2PL	EVOLUTION NitrX TIB KEELED NONPOR TiNbN COATED SZ 2 PLUS LEFT
ETAKN6PL	EVOLUTION NitrX TIB KEELED NONPOR TiNbN COATED SZ 6 PLUS LEFT
ETAKN8PL	EVOLUTION NitrX TIB KEELED NONPOR TiNbN COATED SZ 8 PLUS LEFT
ETAKN2PR	EVOLUTION NitrX TIB KEELED NONPOR TiNbN COATED SZ 2 PLUS RIGHT
ETAKN6PR	EVOLUTION NitrX TIB KEELED NONPOR TiNbN COATED SZ 6 PLUS RIGHT
ETAKN8PR	EVOLUTION NitrX TIB KEELED NONPOR TiNbN COATED SZ 8 PLUS RIGHT