A Prospective Study Evaluating Trochanteric Fixation Nail Advanced (TFNA) in a Chinese Patient Population

SHORT TITLE: The CHINA TFNA Study

Name of device	Proximal femoral nailing system
Model	See appendix C and D
Protocol number	DPS201502
Version	C
Version Date	8 Jan 2019
Study type	Clinical trial
Leading site	Beijing JiShuitan Hospital
sponsor	Johnson & Johnson Medical Shanghai

The Approval Sheet：

Short title： China TFNA Study

Protocol number：DPS-201502

Version date：8 Jan 2019

The signature of the following team indicates the protocol, including the study design, statistical method, study procedure, regulation requirement, quality control and so on, have been internally approved within Johnson & Johnson before submission to ethics committees.

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CHANGE LOG

Version No.	Version Date	Description of Change
C	8 Jan 2019	According to hospital actual practice, the required visit window for visit 3 has been changed：from 4-14 days changed to 1-14 days after surgery
B	10 Apr 2018	Augmentation removed per CMDE request in CTA letter
A	3 Feb 2016	Original Version

Investigator Signature Page：

Study Title： The CHINA TFNA Study

Project No.: DPS 2015-02

Version Date: 8 Jan 2019

I have read this protocol and/or amendment and appendices and agree to adhere to the requirements. I will provide copies of this protocol and all pertinent information to the study personnel under my supervision. I will discuss this material with them and ensure they are fully informed regarding the device and the conduct of the study.

I will implement the study in compliance with the protocol, GCP, the ethical principles outlined in Declaration of Helsinki and all applicable laws and regulations.

_____ _____

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Synopsis

Study Title	A Prospective Study Evaluating Trochanteric Fixation Nail Advanced (TFNA) in a Chinese Patient Population
Study objective:	The primary objective of this study is to evaluate whether fracture union rate, evaluated 24 weeks after proximal femur fracture, for the investigational TFNA intramedullary nail is non-inferior to that for currently available control product PFNA-II in patients with proximal femur fractures.
Country	China
No. of clinical sites	Up to 15
No. of Patients	188 patients enrolled
Duration of subject participation	Enrollment of 188 subjects is anticipated to require approximately 8-10 months. Each subject will undergo six months of clinical and radiographic follow-up. Total study duration is approximately 16 months.
Study Design	The Trochanteric Fixation Nail Advanced (TFNA) is an implant designed to treat proximal femur fractures and is currently in use in several regions worldwide (e.g., US, Europe). TFNA is manufactured using a titanium-molybdenum alloy (TiMo) that has not been used for a similar clinical application within China. The purpose of this study is to evaluate TFNA to support registration of the product in China. The study is a prospective, multicenter, controlled, two-arm, randomized, non-inferiority study comparing the 24-week fracture union rate for proximal femur fractures treated with intramedullary nails using investigational devices (TFNA) compared to control devices (Proximal Femoral Nail Antirotation, PFNA-II), under a 10% non-inferiority margin. The study population will include 188 patients with proximal femur fracture undergoing internal fixation using an intramedullary nail. Subjects will be randomized in a 1:1 ratio to receive either the investigational TFNA devices (n=94) or to the control PFNA-II devices (n=94). The primary endpoint (fracture union) will be assessed by clinical and radiographic follow-up at 24 weeks. An independent reviewer will evaluate radiographs for evidence of fracture healing and implant integrity. Secondary endpoints will include safety and efficacy outcomes, radiographic outcomes and adverse events.

Study Components	• TFNA as the investigational product for this study, including: o Short nails available in various diameters (Ø9, Ø10, Ø 11, Ø12 mm), lengths (170, 200, or 235 mm) and CCD angle (125°, 130°and 135°). The 235 mm short nail is available for left and right sides. o Long nails available in various diameters (Ø9, Ø10, Ø 11, Ø12, Ø14mm), lengths (260-480mm in 20mm increments) and CCD angle (125°, 130°and 135°). All long nails are available for left and right sides. o Head elements are available in blade and screw (both are 70-130 mm in length, available in 5mm increments) o Locking screws (4.2mm diameter and available in lengths from 26-80mm (2mm increments) or 80-100mm (5mm increments) o End caps available in 0, 5, 10 and 15mm lengths • PFNA-II as control product for this study, including: o Short nails available in various diameters (Ø9, Ø10, Ø 11, Ø12 mm), lengths (170, 200, or 240 mm) and CCD angle (125°and 130°). The 240 mm short nail is available for left and right sides. o Long nails available in various diameters (Ø9 and Ø10mm), lengths (260-340mm in 20mm increments and 340-420mm in 40mm increments) and CCD angle (125°and 130°). All long nails are available for left and right sides. o Head elements are available in blade (70-120 mm in length, available in 5mm increments) o Locking screws (4mm diameter and available in lengths from 16-60mm (2mm increments), 60-80mm (4mm increments) or 80-100mm (5mm increments) o End caps available in 0, 5, 10 and 15mm lengths
Study Period	2018-2021
Inclusion Criteria	**Subjects will be included if ALL of the following inclusion criteria apply:** 1) Age ≥18 years 2) Patients with unilateral proximal femur fractures that will be

	treated with intramedullary nail internal fixation 3) According to AO fracture classification, subjects with following fracture types: a. Pertrochanteric (31-A1 and 31-A2) b. Intertrochanteric (31-A3) c. Trochanteric area (31-A1/A2/A3) with diaphyseal extension 4) Subject must be comfortable with speaking and understanding questions and responses in an available translated language for patient reported outcomes (PROs)
Exclusion Criteria:	**Subjects will be excluded if ANY of the following exclusion criteria apply:** 1) Subject does not provide voluntary consent to participate in the study 2) The subject is a woman who is pregnant or lactating 3) Fractures where the operative treatment will occur more than three weeks after the primary injury 4) Patients with femoral head fractures and femoral neck fractures (AO classification 31-B and 31-C) 5) Pathological fracture (e.g., primary or metastatic tumor) 6) Serious soft tissue injury, judged by the investigator, will impact the union of the fracture, combined vascular injury, and combined osteofascial compartment syndrome 7) Multiple systemic injuries judged by researchers not suitable for enrollment, or orthopaedic fractures in other bones at three or more sites 8) Revision surgeries (for example, due to malunion, nonunion or infection) 9) Concurrent medical conditions judged by researchers not suitable for enrollment, such as: diabetes, metabolic bone disease, post-polio syndrome, poor bone quality, prior history of poor fracture healing, etc 10) Patients with anaesthetic and surgical contraindications 11) Patients known to be allergic to implant components 12) Patients who are currently using chemotherapeutics or accepting radiotherapy, use systematically corticosteroid hormone or growth factor, or long-term use sedative hypnotics (continuous use over 3 months) or non-steroidal

	anti-inflammatory drugs (continuous use over 3 months) 13) Intemperance judged by researchers not suitable for enrollment (e.g., excessive daily drinking or smoking, drug abuse); 14) Patients participated into other clinical trial in the previous 3 months; 15) Patients with bad compliance judged by researchers and cannot complete the test according to test scheme, such as schizophrenia and dementia.
Endpoints	**Primary Endpoint:** The primary endpoint is fracture union at 24 weeks postoperatively. Fracture union success is a composite endpoint; in order for an individual subject's surgery implanted with TFNA or PFNA-II to be considered successful he/she must satisfy all of the following criteria: 1. No focal tenderness or lengthwise percussion pain, or abnormal movement 2. The frontal/lateral X-ray examination shows the vague or no fracture gap, or the continuous callus passing across the fracture line 3. No deformation or breakage is found in the test product The fracture union rate for the investigational group will be shown to be non-inferior to the fracture union rate of the control group using a 10% non-inferiority margin and a one-sided 2.5% alpha. The sample size has been established to provide 80% power to demonstrate non-inferiority if the fracture union rates in the patient population are greater than 95%, and approximately the same when treated with TFNA or PFNA-II. **Secondary Endpoints:** • Adverse events (type and frequency) for all adverse events will be compared for the investigational and control groups • 24-week revision rate where revision is defined as *removal of any component for any reason.* • 24-week reoperation rate is defined as secondary surgery at the fracture site(s) for any reason • Clinical Outcomes ■ SF-12 ■ Harris Hip Score

	■ EQ-5D • Radiographs: incidence of complications such as loosening or cut-out that require reoperation or revision

TIME AND EVENT SCHEDULE

	Enrollment		Follow-up			
Event/Visit	FU1: Pre-Op	FU2: Surgery	FU3: 1 week	FU4: 6 weeks	FU5: 12 weeks	FU6: 24 weeks
Required Timing	-90 to 0 days from day of surgery	0	1 to 14 days after surgery	±2 weeks	±2 weeks	±4 weeks
The signing of the informed consent form	X					
Inclusion/Exclusion criteria	X					
Demographic data and medical history enquiry	X					
Concise patient self-rated health measurement scale (SF-12v2)	X				X	X
EQ5D	X				X	X
Harris Hip Score					X	X
Subject history	X					
Urine pregnancy test[1]	X					
Frontal and lateral X-ray of fracture sites	X		X	X	X	X
Surgical reduction and intramedullary nail fixation		X				
Surgeon's evaluation on product operability during operation		X				
Wound healing assessment [2]			X			
Local physical examination	X		X	X	X	X
Concomitant drugs[3]	X	X	X	X	X	X
Adverse event		X[4]	X	X	X	X
Serious adverse event		X[4]	X	X	X	X
Blood chemistry	X	X[5]				

1. Urine pregnancy tests: women of childbearing age only.
2. Wound healing condition is assessed until wound healing.
3. Concomitant Drug Table should include only pain killers and anti-osteoporosis drugs.
4. Adverse events and serious adverse events should be recorded starting at the time of patient randomization.
5.Second Laboratory Test analyses performed during post-op recovery phase per site standard of care. The results closer to the time of surgery will be recorded.

1.0. INTRODUCTION

1.1. Background and Rationale

Proximal femoral fractures are common where the incidence is increasing with possible correlation to the aging population [1]. Trochanteric fractures make up 55% of proximal femoral fractures and occur predominantly in elderly patients [2]. Trochanteric fractures most commonly are caused by low-energy trauma, usually in combination with osteoporosis [1]. Due to the patients' high age and comorbidities, fractures of the proximal femur are often life-threatening. In the first postoperative year, mortality rates account for 11% to 30% of cases [1, 3]. In young patients on the other hand, trochanteric fractures are typically associated with high-energy trauma and/or other injuries [2].

Trochanteric fractures by definition are extracapsular where the vascularity of the femoral head is rarely compromised [2]. Although various fracture classification systems exist [4], the Müller AO Classification of Fracture is one of the most commonly used fracture classification system. It divides trochanteric fractures (31-A) into three groups: 31-A1 are simple and stable pertrochanteric fractures, 31-A2 are unstable pertrochanteric fractures with medial comminution including a fractured lesser trochanter, and 31-A3 are unstable intertrochanteric fractures with or without medial comminution (reverse oblique fracture type) [2, 4]. In general, instability is determined by the presence of a zone of comminution of the medial cortex and posterolateral instability [4].

Operative treatment is the standard of care in trochanteric fractures (31-A), leading to good clinical results in the majority of cases [2]. Trochanteric fractures are often treated with intramedullary devices such as trochanteric nails [1]. The classical surgical approach is a straight lateral incision, splitting the iliotibial tract, and gently elevating the vastus lateralis muscle [2]. The entry point is located in the area of the tip of the greater trochanter. Nail insertion and locking of the nail is a well-known procedure that is standard for most medullary nailing systems. After internal fixation, mobilization of a compliant and otherwise healthy patient starts on the first postoperative day using a walking frame or crutches [2]. Fracture healing of the proximal femur should then be completed within three months [2]; for patients with ipsilateral femoral shaft fractures healing times may be longer [5].

Intramedullary implants have proven clinical outcomes based on the results of global studies conducted outside of China. The data is reflective of many patients worldwide. Both the investigational (TFNA) and control devices (PFNA-II) currently are used clinically worldwide including regions such as North America and Europe. PFNA-II currently is available for clinical use in China. The investigational device (TFNA) is manufactured using a titanium-molybdenum alloy (TiMo) that has not been used for a similar clinical application (i.e., intramedullary nail) within China. In order to meet Chinese registration requirements, the purpose of this study will be to examine the clinical results of TFNA

compared to a device manufactured from titanium aluminum nitride (TAN) that is already approved and used clinically in China (PFNA-II). A comparative study inside China also could account for possible differences in patient population, surgical technique, and/or rehabilitation practices (if any). In summary, the purpose of this study is to conduct a randomized controlled trial of Chinese patients with proximal femur fractures who are treated with TFNA versus PFNA-II.

1.2. Investigational Device Description

1.2.1 TFNA

The investigational device is the Trochanteric Fixation Nail Advanced (TFNA; see Figure 1).

Figure 1. Synthes Trochanteric Fixation Nail Advanced (TFNA)

The TFNA nails are cannulated for insertion over a guide wire. A proximal bend of 5° towards lateral allows for an insertion point close to the tip of the greater trochanter. The nail is inserted through the standard lateral surgical approach, which is a straight lateral incision, splitting the iliotibial tract, and gently elevating the vastus lateralis muscle [2]. The entry point is located in the area of the tip of the greater trochanter. Nail insertion and locking of the nail is a well-known procedure that is standard for most medullary nailing systems.

Due to the anatomy of the femur, all nails except for the shortest two lengths are specific for left and right use. The nails are curved in the sagittal plane. The radius of the TFNA follows the anteroposterior curvature of the femur. The TFNA nails are available in different diameters and lengths to match the geometry of the medullary canal. They involve three different caput-collum-diaphyseal (CCD) angles to match the patients'

anatomy. Moreover, the nails are tapered distally to reduce potential stress risers at the distal end of the nail, as secondary fracture around the implant is a typical complication of trochanteric nailing [6, 7].

Distal locking options include one oval locking hole for short nails and three distal locking options for long nails (proximal & distal round locking hole, middle oval locking hole). Both short and long nails incorporate an oval hole allowing for static and dynamic locking. Secondary dynamization is a well-known procedure that reduces the stress exerted by the locking nail [8], leads to greater contact pressure at the fracture site [8], and shortens mean time to union [9]. The method therefore is suitable for fractures with a high risk of delayed healing [2].

An internal locking mechanism prevents the head element from rotating. Sliding may be locked as an option. Highly comminuted fractures may be a good candidate for locked fixation. As an option, the proximal fragment can be re-approximated with a specific intraoperative compression feature, which is a standard feature seen in many proximal femoral nailing devices (e.g. PFNA or Stryker Gamma3).

The head elements for TFNA are available as a helical blade or femoral neck screw; each has potential advantages that may be beneficial in the individual clinical case. For example, the helical blade leads to bone compaction around the implant [2, 10], which could biomechanically improve implant anchorage and fixation [11, 12]. The femoral neck screw may have a positive influence on intraoperative reduction by diminishing the postoperative fracture gap providing compression of the bone fragments [13].Both types of head elements are within the state of art (e.g., PFNA or Stryker Gamma 3), where preferably the surgeon selects the head element for the individual clinical case.

1.2.2 Comparison of TFNA and PFNA-II

The control device is Proximal Femoral Nail Antirotation II (PFNA-II). PFNA-II and TFNA have the same indications and can be used for treatment of pertrochanteric, intertrochanteric, high subtrochanteric fractures (Type 31-A). Both implants are contraindicated for treatment of femoral neck fractures. The overall design of both implants is that same in that they include a head element (TFNA: helical blade or screw; PFNA-II: screw) and distal locking screws. Both are manufactured from titanium alloys (TFNA: Titanium Molybdenum alloy; PFNA-II: Titanium Aluminum Niobium alloy).

1.3. Summary of Available Clinical Data

1.3.1 Intramedullary nails as treatment for extracapsular hip fractures

Recent meta-analyses show good clinical outcomes for intramedullary nail fixation of proximal femur fractures. For example, Queally et al. [14] evaluated 17 randomized trials

comparing different cephalocondylic nail designs. The trials involved a total of 2,130 adults (predominantly female and older people) and mainly unstable trochanteric fractures. Key findings are described below.

Queally et al. [14] summarized 10 studies that included mortality outcomes with one year of follow up. In these trials, mortality after implantation of an intramedullary nail in patients with extracapsular fractures ranged from 0% to 24%.

Fracture union rate also was evaluated by Queally et al. [14], where they reported 12 studies that included summaries of fracture union rate. The number of subjects ranged from 15 to 213 subjects, and all studies included intramedullary nails. Fracture union rate ranged from 90% to 100% in these studies. This was in alignment with a recent book chapter that summarized fracture union rates from select studies using reamed or unreamed antegrade or retrograde nails, where the fracture union rate ranged from 92% to 100% [15]. It is noted that the method for determining fracture union was rarely reported.

Queally et al. [14] summarized Harris Hip Scores (HHS) reported in eight RCTs with a minimum of 12 months follow up. Mean HHS ranged from 65 to 96 points in these studies.

Potential complications associated with implantation of intramedullary nails also were reviewed by Queally et al. [14], summarized in Table 2.

Table 2. Summary of fracture healing complications included in a recent meta-analysis [14] evaluating intramedullary nails used as treatment for extracapsular hip fractures.

Complication	No. studies	No. subjects	Range of complication rates
Cut out	17	2099	0.0% - 7.5%
Distal interlocking problem	1	113	3.5% - 3.6%
Failure of distal locking	1	215	0.9% - 3.8%
Femoral shaft fracture	2	295	0.0% - 5.0%
Fixation failure	2	173	3.3% - 22.6%
Implant breakage	5	895	0.0% - 3.3%
Infection (deep)	9	1236	0.0% - 6.5%
Infection (superficial)	8	1157	0.0% - 10.0%
Infection (unspecified)	4	473	0.0% - 5.9%
Joint penetration	1	215	0.0% - 2.9%
Later femur fracture	8	1197	0.0% - 3.2%
Lateral greater trochanter fracture	1	113	1.8% - 10.5%
Migration	4	903	0.0% - 9.1%
Nail breakage	1	215	0.9% - 1.0%

Nonunion / pseudoarthrosis	13	1587	0.0% - 9.7%
Operative fracture of femur	9	1334	0.0% - 3.6%
Periprosthetic fracture	2	295	0.0% - 2.5%
Proximal end of nail penetrating trochanter	1	113	1.8% - 7.1%
Reoperation	15	1934	0.0% - 47.1%
Technical complications of fixation	2	160	2.4% - 7.5%

The available data from the meta-analysis support the use of intramedullary nails to treat extracapsular, proximal femur fractures. In these studies, intramedullary nails made from different materials and by various manufacturers performed similarly in trials conducted globally. These data provide a good reference for estimating the performance of TFNA and PFNA-II in the study described here.

1.3.3 Summary of PFNA-II as treatment for extracapsular hip fractures

A recent literature review that included peer-reviewed literature published between 2007 and 2015, nine English language articles were identified that summarized clinical results for PFNA-II, the control device for this clinical study. The level of evidence included one RCT, one case controlled study, six uncontrolled case series, and one case report (Table 3). A total of 880 subjects were represented in these nine studies.

Table 3: summary of level of evidence for PFNA-II papers

Level of evidence	Type of study	Reference(s)	Number of PFNA-II subjects
1	Randomized controlled trial	[16]	47
4	Case control	[17]	50
4	Uncontrolled case series	[18] [19] [20] [21] [22] [23]	127 158 40 118 163 176
4	Case report	[24]	1

Fracture union rate was reported in three of the studies, where satisfactory fracture union was achieved in all 389 subjects [17, 22, 23]. It is noted that the method for determining fracture union was rarely reported. Harris Hip Score (HHS) was reported in two studies [21, 22], which was 85.6 ±17.5 after 15 months follow up in 163 subjects and 86.19 ±6.53 after 12 months follow up in 118 subjects, respectively.

Complications for PFNA-II in the reported literature were similar to those reported for other

intramedullary nails. Table 4 summarizes the complications reported by Zhang et al. [16] during the RCT of patients with extracapsular hip fractures treated with PFNA-II and the InterTan nail.

Table 4. Complication rates reported by Zhang et al. 2013 [16] for intramedullary nail fixation of proximal femur fracture (also summarized by Queally et al. 2014 [14]).

Complication	InterTan Nail	PFNA-II
Cut out	0.0%	4.3%
Distal interlocking problem	3.5%	3.6%
Infection (deep)	4.3%	2.2%
Infection (superficial)	6.4%	4.3%
Later femur fracture	0.0%	2.2%
Lateral greater trochanter fracture	10.5%	1.8%
Migration	0.0%	8.7%
Operative fracture of femur	1.8%	3.6%
Proximal end of nail penetrating trochanter	1.8%	7.1%
Reoperation	4.3%	6.5%

2.0 BENEFITS/RISKS

Intramedullary nails are widely accepted as state of the art for treatment of extracapsular proximal femur fractures (for example, [2, 25]). The below sections describe the expected benefits and risks of the investigational device (TFNA). Overall, the risk-benefit ratio for TFNA is expected to be similar compared to that for the control device (PFNA-II).

2.1. Benefits

The TFNA implant system is intended for the treatment of proximal femur and combinations of proximal and shaft fractures of the femur. Compared to conservative e care, operative treatment of hip fractures is more likely to result in fracture healing without leg shortening, a shorter hospital stay and possible increase in return of patients back to their original residence [26]. In this study, study subjects will be monitored closely during the 24-week follow-up period by the investigators who will use radiographic, functional and patient reported evaluations. The knowledge gained from the data produced in this study may benefit future patients.

2.2. Risks

Any surgical procedure poses a potential risk and the procedures undertaken as part of this clinical investigation are no exception. There are known risks associated with the method of anesthesia (general, epidural, local). In addition to these there are risks

associated with a surgical procedure that involves a device. The risks that are associated with the study devices are similar to those of any intramedullary nail. The following complications have been reported and are consistent with the IFU. Please refer to the device Instructions for Use (IFU) which are included in the implant packaging and are also available upon request. The adverse events identified below are to be reported as AEs.

Compared with PFNA-II, there is no additional risk associated with the investigational device (TFNA). The following is a summary of the most commonly reported adverse events and complications in intramedullary nail fixation of proximal femur fractures[1]:

- Damage to vital organs: Damage to vital organs may occur when a guide wire is accidentally advanced during implant insertion, when the opening instrument modifies the placement of the guide wire, or when the guide wire is captured by the drill cannulation and advanced inadvertently.
- Embolism: Bony and fat embolism may e.g. occur due to increased medullary pressure with improper nail insertion technique, like using an oversized nail. Air embolism may occur when the cannula is inadvertently filled with air.
- Soft tissue damage: Major soft tissue damage may result from a variety of different conditions: Accidental static locking of the head element when dynamic locking is required, improper measurement technique for head element due to user error, incorrect final placement of head element, etc.
- Malunion / nonunion: Malunion / nonunion may occur due to implant breakage because of inappropriate strain by the patient.
- Neurovascular damage: Major neurovascular damage may be consequence of blocking at the blade / impactor interface leading to displacement of the blade in the femoral head.
- Postoperative bone fracture: Major postoperative bone fracture may be consequence of undesired position of the head element in the femoral head.
- Adverse soft tissue reaction: Major adverse soft tissue reaction may be a consequence of the use of materials with unknown biocompatibility in conjunction with implant and instrument materials.

[1] Cement augmentation will not be made available for this clinical study. Therefore, any risks related to the augmentation procedure or cement are not captured in this list.

- Injury to user: Injury to user may be associated with the risks associated with cleaning and sterilization of instruments.
- Surgical delay: Moderate surgical delay may be associated with a variety of different conditions which may include: Distal locking screw targeting and insertion; General instrument breakage; General technique guide comprehension; Head element removal for example the risk of having cement in the implant-instrument interface of the head element; Head element targeting and insertion; Nail insertion and Nail removal.
- Pain: Pain may be associated with the risk of implant stiffness or end cap protruding above the cortex.
- Poor joint mechanics: Poor joint mechanics may be associated with the risk of guide wire penetrating joint surface during insertion.
- Infection: Infection may be associated with the risk of sterilization process does not adequately sterilize device or packaging does not provide adequate protection for the device

3.0 STUDY OBJECTIVES

3.1. Intended Use and Indication

The intended use for TFNA is the following:

Intended Use: intended for the treatment of proximal femur and combinations of proximal and shaft fractures of the femur.

The indications of the TFNA are:

Short Nails (lengths 170 mm, 200 mm, 235 mm)
- Pertrochanteric fractures (31-A1 and 31-A2)
- Intertrochanteric fractures (31-A3)
- 235 mm nails are additionally indicated for high subtrochanteric fractures

Long Nails (lengths 260 mm – 480 mm)
- Pertrochanteric fractures (31-A1 and 31-A2)
- Intertrochanteric fractures (31-A3)
- Fractures of the trochanteric area (31-A1/A2/A3) with diaphyseal extension

- Combined fractures of the trochanteric area (31-A1/A2/A3) and the femoral shaft (32-A/B/C)
- Pathological fractures, including prophylactic use
- Malunions
- Nonunions

3.2. Objective

The primary objective of this study is to evaluate whether fracture union rate, evaluated 24 weeks after proximal femur fracture, for the investigational TFNA intramedullary nail is non-inferior to that for currently available control product PFNA-II in patients with proximal femur fractures.

4.0 STUDY DESIGN

This is a prospective, multicenter, randomized, controlled, two-arm, non-inferiority study which will be conducted in China, comparing the safety and the effectiveness of two intramedullary nails (the investigational group is TFNA and the control group is PFNA-II). Patients enrolled at each site will be randomized in a ratio of 1:1, i.e. one patient assigned to surgery implanted with TFNA for each patient assigned to PFNA-II. Separate block randomization schedules within each site will be used to ensure equal distribution of treatment and control patients. Up to 15 centers will be approved to participate in this study.

Patient will be clinically followed after surgery at 1, 6, 12 and 24 weeks. The data up to and including 24 week follow up visit will be used in determining the primary safety and effectiveness of the TFNA.

5.0 ENDPOINTS

5.1. Primary Endpoint

The primary endpoint is fracture union at 24 weeks postoperatively. Fracture union success is a composite endpoint; in order for an individual subject's surgery implanted with TFNA or PFNA-II to be considered successful he/she must satisfy all of the following criteria at 24 weeks:

1. No focal tenderness or lengthwise percussion pain, or abnormal movement
2. The frontal/lateral X-ray examination shows the vague or no fracture gap, or the continuous callus passing across the fracture line
3. No deformation or breakage is found in the test product

The primary endpoint analysis will be to demonstrate that the investigational device (TFNA) is non-inferior to the control device (PFNA-II) based the fracture union rate at the 24 week follow-up visit. Non-inferiority test will be conducted based on a one-sided 97.5% confidence interval for the difference in the fracture union rates at 24 weeks between the investigational and control groups.

5.2. Secondary Endpoints

The following secondary endpoints will be evaluated:

- Adverse events (type and frequency) for all adverse events will be compared for the investigational and control groups
- 24-week revision rate where revision is defined as removal of any component for any reason.
- 24-week reoperation rate is defined as secondary surgery at the fracture site(s) for any reason
- Clinical Outcomes
    - SF-12
    - Harris Hip Score
    - EQ-5D
- Radiographs: incidence of complications such as loosening or cut-out that require reoperation or revision

5.3 Safety

An overall summary of adverse events (AE) will be provided, including for each group the number and the percent of subjects with all AE, all serious AE, all related AE, and all AE by severity. In addition, all adverse events, serious, and non-serious adverse events will be summarized and tabulated by preferred term, both overall and by severity, by time period of onset, and by operative site

6.0 STUDY POPULATION

6.1. Subject Selection

The study will include 188 subjects with proximal femur fracture on a single limb requiring intervention that meet eligibility criteria and agree to participate in the study.

Subjects must meet ALL inclusion criteria and NO exclusion criteria.

6.2. Inclusion Criteria

Subjects will be included if ALL of the following inclusion criteria apply:

1) Age ≥18 years

2) Patients with unilateral proximal femur fractures that will be treated with intramedullary nail internal fixation

3) According to AO fracture classification, subjects with following fracture type:
   a. Pertrochanteric (31-A1 and 31-A2)
   b. Intertrochanteric (31-A3)
   c. Trochanteric area (31-A1/A2/A3) with diaphyseal extension

4) Subject must be comfortable with speaking and understanding questions and responses in an available translated language for patient reported outcomes (PROs)

6.3 Exclusion Criteria

Subjects will be excluded if ANY of the following exclusion criteria apply:

1) Subject does not provide voluntary consent to participate in the study

2) The subject is a woman who is pregnant or lactating

3) Fractures where the operative treatment will occur more than three weeks after the primary injury

4) Patients with femoral head fractures and femoral neck fractures (AO classification 31-B and 31-C)

5) Pathological fracture (e.g., primary or metastatic tumor)

6) Serious soft tissue injury, judged by the investigator, will impact the union of the fracture, combined vascular injury, and combined osteofascial compartment syndrome

7) Multiple systemic injuries judged by researchers not suitable for enrollment, or orthopaedic fractures in other bones at three or more sites

8) Revision surgeries (for example, due to malunion, nonunion or infection)

9) Concurrent medical conditions judged by researchers not suitable for enrollment, such as: diabetes, metabolic bone disease, post-polio syndrome, poor bone quality, prior history of poor fracture healing, etc

10) Patients with anaesthetic and surgical contraindications

11) Patients known to be allergic to implant components

12) Patients who are currently using chemotherapeutics or accepting radiotherapy, use systematically corticosteroid hormone or growth factor, or long-term use sedative hypnotics (continuous use over 3 months) or non-steroidal anti-inflammatory drugs (continuous use over 3 months)

13) Intemperance judged by researchers not suitable for enrollment (e.g., excessive daily drinking or smoking, drug abuse);

14) Patients participated into other clinical trial in the previous 3 months;

15) Patients with bad compliance judged by researchers and cannot complete the test according to test scheme, such as schizophrenia and dementia.

7.0 STUDY PROCEDURES

7.1. Screening and Baseline Period

7.1.1. Patient Screening

A qualified member of the Institution's research team assigned to the study team will review the patient's medical history to screen for study eligibility. All patients meeting all inclusion criteria and no exclusion criteria will be invited to participate in the study.

7.1.2. Informed Consent

All potential patients must be consented prior to performing any study specific procedures. Once the Investigator has determined the patient's eligibility for the study, the background of the proposed study and the benefits and risks of the procedures and study must be explained to the patient. Only those patients who sign the site's Ethics Committee (EC) approved informed consent prior to participation are eligible to be in the study. Failure to provide written informed consent renders the patient ineligible for the study.

7.1.3. Screening and Baseline Assessments

To be performed for all patients prior to the procedure to ascertain eligibility:

1. Medical history
2. Inclusion and exclusion criteria
3. Physical Exam

7.1.4. Patient Enrollment

Sites will be required to maintain a record of patients screened for the study meeting general inclusion criteria who have signed the approved informed consent document.

Randomization will occur if the patient meets all inclusion criteria and does not meet any exclusion criteria.

Subjects who do not continue to meet eligibility criteria at this point are considered screening failures. The Investigator will document screening failures on the screening failure log, including reasons for failures. Once randomization is complete and a treatment arm is assigned, crossover between treatment arms will be considered as a major protocol violation.

If for some reason an enrolled subject does not receive a study device during their surgery he/she will be withdrawn postoperatively. This will be noted upon the end of study form.

Thus, patients will be considered enrolled into the study after:

1. The patient has met all of the inclusion and none of the exclusion criteria, and
2. Signed informed consent has been obtained.

7.1.5. Randomization and Treatment Assignment

Each patient will be assigned a unique patient identification number at screening that will be used to identify the patient throughout the study. Eligible patients will be randomized to study treatment or control group using a centralized computer-generated randomization system.

The study will be comprised of two (2) treatment groups: an investigational group (TFNA) and a control group (PFNA-II). Enrolled patients who meet inclusion and exclusion criteria will be randomized prior to the study procedure. Individual subjects will be randomized to one of two groups (TFNA or PFNA-II) in a 1:1 ratio. The plan is to accrue 94 subjects for each of the two groups.

7.2. Procedure

7.2.1. Instructions for Use

Preparation, handling and the implantation procedure must be performed in accordance with the Instructions for Use (IFU) provided within the implant packaging. An instrumentation system will be available for both investigational and control treatments. The surgeon should refer to the appropriate surgical technique manual for details on the use of the instrument system and implantation of the devices.

7.3. Post-Procedure

Subjects should be managed in accordance with institutional standards following the enrollment procedure including in-hospital and physiotherapy. Blood chemistry also will be documented. All adverse events (serious and non-serious) occurring during post-

operative hospitalization will be reported. Concomitant medications (prescription and non-prescription) will be collected.

7.4. Follow-up Period

For each clinic visit there is a required timeline for the visit, as shown in the Time & Events Table. For each of these visits, the data described in Table 8 must be collected.

Table 8. Time and events schedule

	Enrollment		Follow-up			
Event/Visit	FU 1: Pre-Op	FU2: Surgery	FU3: 1 week	FU4: 6 weeks	FU5: 12 weeks	FU6: 24 weeks
Required Timing	-90 to 0 days from day of surgery	0	1 to 14 days after surgery	±2 weeks	±2 weeks	±4 weeks
The signing of the informed consent form	X					
Inclusion/Exclusion criteria	X					
Demographic data and medical history enquiry	X					
Concise patient self-rated health measurement scale (SF-12v2)	X				X	X
EQ5D	X				X	X
Harris Hip Score					X	X
Subject history	X					
Urine pregnancy test[1]	X					
Frontal and lateral X-ray of fracture sites	X		X	X	X	X
Surgical reduction and intramedullary nail fixation		X				
Surgeon's evaluation on product operability during operation		X				
Wound healing assessment [2]			X			
Local physical examination	X		X	X	X	X
Concomitant drugs[3]	X	X	X	X	X	X
Adverse event		X[4]	X	X	X	X
Serious adverse event		X[4]	X	X	X	X
Blood chemistry	X	X[5]				

1. Urine pregnancy tests: women of childbearing age only.

2. Wound healing condition is assessed until wound healing.

3. Concomitant Drug Table should include only pain killers and anti-osteoporosis drugs.

4. Adverse events and serious adverse events should be recorded starting at the time of patient randomization.

5. Second Laboratory Test analyses performed during post-op recovery phase per site standard of care. The results closer to the time of surgery will be recorded.

Unscheduled Visits

If in between protocol required visits/telephone contacts, the site study team learns of any interventional treatment that a subject has undergone or study-related reportable adverse events, as defined in Section 8.0, the relevant information will be captured on the appropriate CRFs. All diagnostic radiographic films will be reviewed by the independent radiographic reviewer. All relevant source documentation required to assess the event will be maintained in the subject files and all relevant documentation required for event adjudication will be provided as requested by the Sponsor.

Clinical follow-up

The Investigator will be required to document clinical assessment in the medical and research source documents.

7.5. Blinding Procedures

Many medical records (source documents) documenting the patient's operative procedure, hospital stay and follow-up visits will not be blinded because implant labels identifying the implanted stems will be provided. As is common in device trials, it will not be possible to blind surgeon investigators or study staff because each group will be implanted with a different implant system, each of which is easily distinguished and has its own instrument set. Blinding of the independent radiographic reviewers and study staff also is not feasible because of small differences in design features that may be distinguished postoperatively (e.g., radiographs).

Blinding practices for this study will include the following:

Patients: Patients will be informed of the 1:1 randomization between the two devices, but will remain blinded as to which implant they actually received until after they have completed all study follow-up.

Implanting surgeon: It is not possible to blind the implanting physician due to his/her contact with the product labeling and IFU.

Independent Radiographic Reviewer (IRR): The IRR will not be blinded to the device implanted due to small differences that may be apparent in the radiographic images.

Medical Records: All medical records (source documents) documenting the implant procedure through hospital discharge and all follow-ups will not be blinded because implant labels identifying the implanted stems will be provided.

Monitors: Monitors will not be blinded because the detachable labels provided with the product identify the product and may be used in the study device accountability records and patient research file for the purpose of device accountability and source document validation.

8.0 ADVERSE EVENT REPORTING

Adverse events are reported using two case report forms: Adverse Event and Serious Adverse Event. Adverse events will be collected starting at the time the patient is randomized and throughout the study, including during the hospital stay, any follow up visits and during any unscheduled patient contact or visits. The definitions and details are provided in the following sections.

Data Collection Requirements

Adverse Event Type	Adverse Event Form	Serious Adverse Event Form
Non-Serious Adverse Event	Complete entire form	DO NOT COMPLETE
Serious Adverse Event	DO NOT COMPLETE	Complete entire form

8.1. Anticipated Adverse Events

There are immediate post-operative events that are changes from the baseline condition of the Subject, but are expected events resulting from the surgery. If these events occur, they should be recorded in the Subject's medical record and reported forward as AEs to the study sponsor.

8.2 Adverse Events

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.

At each evaluation of the subject enrolled in a clinical investigation, the investigator determines whether any adverse events (AE) have occurred, and determines their relationship to the study devices or procedure.

All adverse events, study device malfunctions and other product issues must be recorded in the medical records and entered into CRFs.

8.3 Serious Adverse Events

Serious Adverse Events (SAEs) are defined as any adverse event that:

a) led to death,

b) led to serious deterioration in the health of the subject, that either resulted in

1) a life-threatening illness or injury, or

2) a permanent impairment of a body structure or a body function, or

3) in-patient or prolonged hospitalization, or

4) medical or surgical intervention to prevent life-threatening illness or injury or permanent

impairment to a body structure or a body function,

c) led to foetal distress, foetal death or a congenital abnormality or birth defect

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

The investigator must submit to sponsor and CFDA (or designee) any Unanticipated Adverse Device Effects (UADE) and SAEs occurring during the study within 24 hours after being notified of the event and provide additional information if required by sponsor.

All SAEs need to be followed until the event is resolved (with or without sequelae). The medical monitor of this study will decide if more follow-up information is needed in case the event is not resolved or stable at study completion.

The investigator notifies his/her EC of all SAEs and UADEs occurred at his/her site (and any additional information as required by Ethics Committee). The investigator notifies competent authority of all SAEs and UADEs that occurred at his/her site in accordance with local regulation requirements.

The sponsor will report to all participating clinical investigators all UADEs and deaths within 5 working days after the sponsor first receives notice of the effect and/or event. The sponsor will submit every year (unless otherwise indicated by the Ethics Committee or recommended by the local regulations to all participating clinical investigators an update of all study devices related, site reported and adjudicated SAEs. A letter summarizing the study status, enrollment figures, any safety concerns as well as any recommendation from the steering committee will accompany the updates.

Event reporting to relevant competent authorities will occur by the sponsor in a manner and timing in accordance with local regulation requirements.

8.4. Duration of Follow-up after Adverse Events

The Investigator should ensure that adequate medical care is provided to any subject for any adverse events, including clinically significant laboratory values, related to the study.

All adverse events related to the subject's participation in the study should be followed until the condition has resolved, or in the case of permanent impairment until the condition stabilizes and clinical outcome has been ascertained.

8.5. Reporting an Adverse Event

Adverse events are reported from the start time of the index procedure until the subject's study participation has ended (i.e. revision, completion of study or withdrawal of consent). All AEs must be followed until the AE has resolved, stabilized, or the study has been completed.

The Investigator will record the nature, severity, treatment and outcome of the AE, and will

determine the relationship to the investigational products, medications or any protocol mandated procedures involved in the clinical study.

The following categories of adverse event severity are to be used:

Mild:	Awareness of sign or symptom that does not interfere with the subject's usual activity or is transient, resolved without treatment and with no sequelae,
Moderate:	Interferes, but does not hinder, the subject's usual activity and may require treatment,
Severe	Symptom(s) causing severe discomfort and significant impact on the subject's usual activity and requires treatment or intervention.

The causal relationship should be rated as follows:

Unrelated:	The event is definitely not associated with product application
Unlikely:	The temporal sequence between product application and the event is such that the relationship is unlikely,
Possible:	The temporal sequence between product application and the event is such that the relationship is not unlikely or the subject's condition or concomitant therapy could have caused the AE,
Probable:	The temporal sequence is relevant or the event abates upon product application completion or the event cannot be reasonably explained by the patient's condition,
Related:	The temporal sequence is relevant and the event abates upon product application completion or reappearance of the event on repeat product application (re-challenge).

Adverse events will be reported by the investigator to the Sponsor via the CRF.

9.0 EARLY DISCONTINUATION

9.1 Reasons for Early Discontinuation

Possible reasons for early discontinuation may include, but are not limited to the following:

- Withdrawal of consent: Subject decides to withdraw from the study. This decision must be an "independent decision" that is documented in the patient study files;
- Physician discretion: The Investigator may choose to withdraw a subject from the

study if there are safety concerns;

- Adverse event: Adverse event or serious adverse event may not lead to subject discontinuation from the study. When the investigator decided to discontinue the subject, subject must be followed until the adverse event resolves or until a stable clinical endpoint is reached;
- Death;
- Early study termination: The sponsor can decide to discontinue the study prematurely for various reasons.
- Lost to follow-up: All subjects should be encouraged to return for all scheduled clinical follow-ups, and to provide appropriate contact information to accommodate completion of required telephone follow-ups. If a subject is unable to return for mandatory clinical visits, 3 separate telephone calls should be made to attempt to bring the subject back into the clinic and/or obtain safety information and assess implant status. All attempts at contact should be documented in the source documents. If the subject does not respond to 3 telephone calls, the Investigator must send a registered letter to the subject. If the subject does not respond to the registered letter and further contact is not made, then the subject will be considered to have missed the scheduled visit. If the aforementioned contact efforts are unsuccessful over two study intervals the subject will be considered lost to follow-up and an End of Study case report form (CRF 9) must be completed.

9.2. Subject Early Discontinuation

Every subject should be encouraged to remain in the study until they have completed the protocol-required 24-week follow-up period. If the subject discontinues prematurely from the study, the reason for discontinuation must be documented in the source documents and site files, and submitted via CRF.

Subjects who have discontinued prematurely will be included in the analysis of results; however new subjects may not be enrolled to replace these subjects.

9.3. Study Early Discontinuation

The sponsor reserves the right to temporarily suspend or prematurely discontinue this study either at a single site, multiple sites, or at all sites at any time for reasons including, but not limited to, safety or ethical issues, inaccurate or incomplete data recording, non-compliance, or unsatisfactory enrollment with respect to quality or quantity

If the study is prematurely terminated or suspended, the sponsor or its representatives will inform the investigators/institutions, and the regulatory authority(ies) of the termination or suspension and the reason(s) for the termination or suspension, in accordance with applicable regulatory requirement(s). The EC should also be informed and provided with

reason(s) for the termination or suspension by the sponsor or by the investigator/institution, as specified by the applicable regulatory requirement(s). In addition, arrangements will be made for the return of all unused investigational products and other material in accordance with sponsor procedure for the study.

10.0 STATISTICAL METHODS SECTION

10.1. Study Design

See section 4.0.

10.2. Treatment Assignment

See section 7.1.5.

10.3. Levels of Significance

A two-sided alpha of 0.05 will be used for statistical testing and confidence intervals unless otherwise stated. There will be no adjustment to p-values or alpha levels for testing the primary and the secondary endpoints.

10.4. Interval Windows

The required visit windows are presented in Table 8 of Section 7.4, Time and Event Schedule. The required pre-operative window will be from 90 days prior to surgery and day of the surgery, and 1 week, 6 weeks, 12 weeks and 24 week required post-operative intervals are defined as follows for analysis purposes:

	Study interval windows (days or weeks, as indicated)				
Pre-Op	**Day of surgery**	**1 week**	**6 week**	**12 week**	**24 week**
-90 to 0 days	**Day 0**	**1 to 14 days after surgery**	**±2 weeks**	**±2 weeks**	**±4 weeks**

10.5. Handling of Missing Data

All primary and secondary efficacy endpoint analyses will utilize actual subject data which are collected during the course of study. No data will be imputed during analysis of the primary endpoint.

To evaluate the potential effects of missing data, sensitivity analyses of the primary endpoint will be conducted based on the Per Protocol population, which is defined in Section 10.8. The effect of missing data will be evaluated using a last observation carried forward (LOCF) approach for all subjects, i.e. to replace missing values with the last

observed values. In this LOCF sensitivity analysis, the last observed value will be non-union unless it was definitively determined to be a successful union.

10.6. Primary and Secondary Endpoints

See sections 5.1 and 5.2.

10.7. Hypotheses

The primary endpoint analysis will be to demonstrate that the investigational device (TFNA) is non-inferior to the control device (PFNA-II) based on the fracture union rates at the 24 week follow-up visit. Non-inferiority test will be conducted based on a one-sided 97.5% confidence interval for the difference in the fracture union rate at 24 weeks between the investigational and control groups.

The primary hypothesis is that, at 24 weeks after surgery, the investigational device (TFNA) is non-inferior to the control device (PFNA-II) based on the individual patient fracture union rate. Non-inferiority is defined by a test with a two sided 5% type I error and a 10% "margin of non-inferiority".

The study's null and alternative hypotheses are as follows:

$$H_o : \mathrm{P}_{\mathrm{PFNA\text{-}II}} - \mathrm{P}_{\mathrm{TFNA}} \geq 10\%$$
$$H_a : \mathrm{P}_{\mathrm{PFNA\text{-}II}} - \mathrm{P}_{\mathrm{TFNA}} < 10\%$$

where $\mathrm{P}_{\mathrm{PFNA\text{-}II}}$ represents the fracture union rate among those receiving PFNA-II implant and $\mathrm{P}_{\mathrm{TFNA}}$ denotes the fracture union rate among the recipients of TFNA.

Decision Criterion: The decision will be made to reject the null hypothesis H_o and conclude the alternative hypothesis H_a if the one-sided 97.5% confidence interval for the difference in the fracture union rates between the investigational and the control groups is less than the margin of non-inferiority, 10%.

10.8. Analysis Sets

All subjects who met the inclusion and exclusion criteria will be eligible for enrollment and will be randomized to either the investigational (TFNA) or the control (PFNA-II) group. The following two analysis sets have been defined for this study:

1) **<u>Intent-to-Treat (ITT) Population</u>**

This analysis set includes all subjects randomized and implanted with a protocol specified implant, TFNA or PFNA-II. It includes the patients who were treated and withdrew prior to

week 24 due to various reasons. If a patient is randomized to one treatment group, but receives the other group for any reasons, the patient is considered to be part of the treatment group as received. This analysis set will be the primary one for the secondary safety analysis.

2) Per Protocol Population

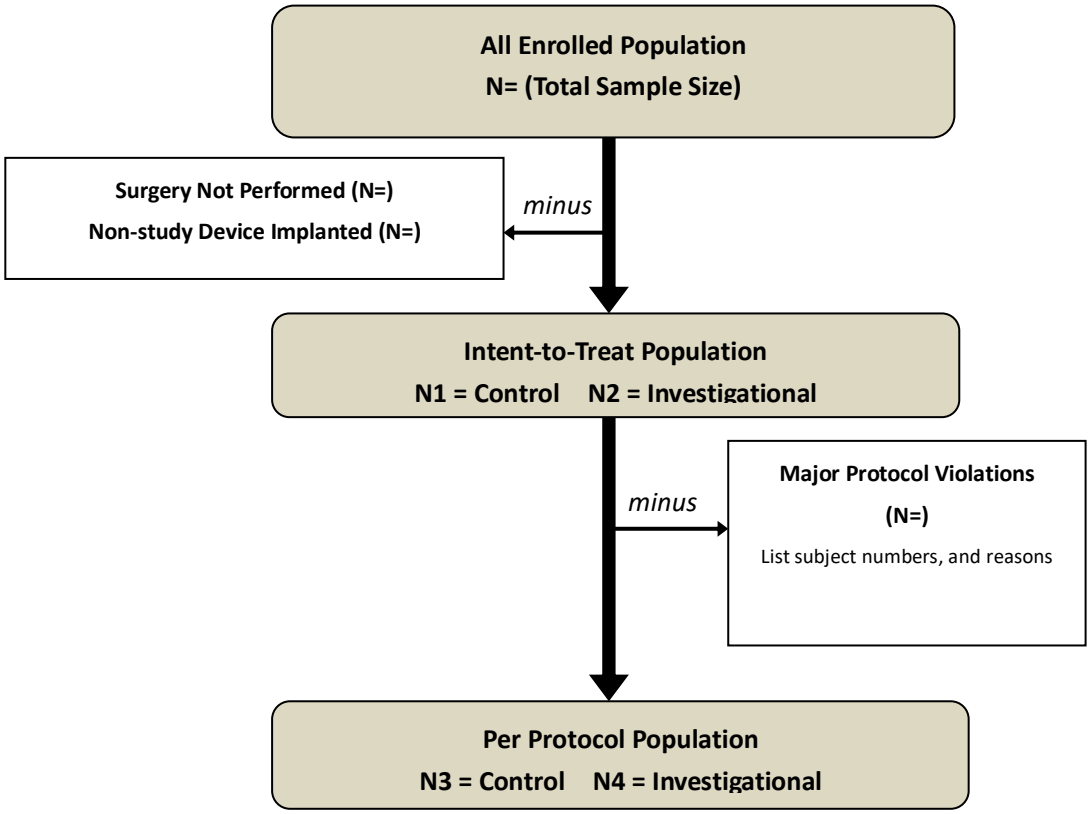
The Per Protocol Population will consist of the subset of the ITT Population who complete 24 weeks of follow-up with no major protocol deviations (including but not limited to: failure to satisfy all inclusion/exclusion criteria, failure to adhere to all protocol-required restrictions and prohibitions, receipt of prohibited concomitant procedures or therapies, and non-compliance to protocol-specific procedures) as determined by a review of subject data.

This PP population will be the analysis set for conducting the primary and secondary effectiveness endpoint analyses.

Separately from these two populations, any subjects who are enrolled into the study but who do not receive one of the study devices will be summarized separately. This summary will include demographics and reasons for not receiving a study device.

The figure below illustrates these populations:

Figure 2: Analysis Set Flow Diagram



10.9. Sample Size Justification

The sample size calculation is determined based on the primary endpoint using PROC POWER in SAS software version 9.3. It assumes that the fracture union rate at 24 weeks after surgery in the TFNA group would be equivalent to that of the PFNA-II group, and a common fracture union rate is approximately 95% or greater based on the literature review (see Section 1. 3.1). With a non-inferiority margin of 0.10 and a power of 80%, this implies a sample size of 75 for the TFNA and of 75 for PFNA-II surgery groups, respectively. The sample size will be increased to 188 (94 per group) to accommodate potential 20% attrition (see Section 1.3).

The sample size applies to patients enrolled, randomized, and actually treated. Some patients who enroll in a study and are randomized may not be ultimately treated for various reasons. Patient enrollment and randomization will continue until the proposed sample size for treated patients is complete.

10.10. Analysis Plan

10.10.1 General Consideration

All statistical processing will be performed using SAS® Version 9.3 or higher, unless otherwise noted.

Summary tables will be provided for subject demographics and baseline variables for the Intent-to-Treat (ITT) and Per Protocol (PP) Population. The outcomes of the primary effectiveness endpoint will be summarized based on pooled data from all sites for the PP population. In addition, the primary endpoint data will be presented by investigator/site.

Descriptive statistics for continuous variables will include number of subjects, mean, standard deviation, median, minimum, and maximum. Descriptive statistics for dichotomous/categorical variables will include number and percent of subjects.

A 2-sided alpha of 0.05 will be used for statistical testing and confidence intervals unless otherwise noted. Detail on the level of significance for testing the primary endpoint analysis is addressed in Section 10.3 (Levels of Significance).

10.10.2 Subject Disposition

All Subjects who are screened or enrolled (consented) into the study will be accounted for in Subject Disposition, overall and by study site.

10.10.3 Data Management

Individual subject data which are collected during the course of this trial will be entered into an appropriate database. A data management team will be assigned to review the

data as it is being collected and any unexpected or missing data points will generate queries which will be forwarded to the site for resolution. The study will be closed and the data will be analyzed after all subjects have had an opportunity to complete their 24 week follow-up evaluation.

10.10.4 Demographic Characteristics/Pre-Operative Profile

Demographics and operative summaries will be presented and compared between the two treatment groups for the ITT and PP population. The two-sample T test and Fisher's Exact test will be used to determine the comparability of baseline characteristics between the two treatment groups (TFNA vs PFNA-II).

10.10.5 Analysis of the primary endpoint

In accordance with ICH guidance E9([2])the primary endpoint analysis will be based on the Per-Protocol set of patients for a comparison of the fracture union rates at Week 24 between TFNA and PFNA-II. Only patients in this analysis set with a known outcome for the primary endpoint will be analyzed.

The null hypothesis (TFNA is inferior to PFNA-II) will be rejected, and TFNA will be considered non-inferior to PFNA-II if the exact 97.5% upper one-sided confidence bound for the difference in fracture union rates between PFNA-II and TFNA at 24 weeks is less than non-inferiority margin, 10.0%.

Two sub-components of the primary endpoint at 24 weeks (radiographic outcome, and no deformation or breakage) will be compared between the two treatment groups.

Radiographic outcome, i.e. front/lateral X-ray films, will be assessed by the independent radiographic reviewer to determine if there are vague or fracture gap or continuous callus passing across the fracture line. The radiographic outcome will be summarized and compared at each follow up visit between the two treatment groups using Fishers exact test.

Similarly, the independent radiographic reviewer will also determine whether deformation or breakage of the implant has occurred. This outcome will be summarized between the two treatment groups at each follow up visit, as well.

10.10.6 Analysis of secondary endpoints

The outcomes of the secondary efficacy endpoints will be summarized for the two

[2] E9 Statistical principles for clinical trials. International Conference on harmonization of Technical Requirements for Registration of Pharmaceutical for Human use, 1998.

treatment groups. SF-12 scores will be summarized for both treatment groups at baseline and each follow up visit. In addition, the change from baseline to each follow-up visit will be summarized by treatment group. Similarly, Harris Hip score and the change from baseline to each follow up visit will be summarized for the two treatment groups.

Furthermore, comparison of EQ-5D Scores in each of the five dimensions between the two treatment groups at 24 weeks will be conducted using a chi-square test. Finally, the incidence of complications such as loosening or cut-out in radiographic outcome will be summarized at each follow up visit between the two treatment groups.

Adverse events (type and frequency) will be compared between the investigational and the control groups. Moreover, the revision rates for 24 weeks will be summarized between two groups.

A two-sample t-test will used to compare the continuous variables at each follow up visit between the two treatment groups, a paired t-test will be used to compare the difference in continuous secondary endpoints between baseline and each follow up visit within a treatment group. Fishers exact test will be utilized for the categorical variable comparisons.

The primary endpoint and the secondary efficacy analysis will be conducted based on PP population. Sensitivity analysis for the primary endpoint will be conducted on the PP population. Secondary safety endpoint analyses will be conducted on the ITT population.

10.11. Plans for Interim Analysis

No interim analysis is planned for this study for the purpose of stopping the study early.

10.12. Reporting

After all subjects have completed the primary endpoint (24 week follow-up visit), a clinical study report will be provided to CFDA for review.

11.0 STUDY MANAGEMENT AND ADMINISTRATION

11.1. Investigator and Sponsor Responsibility

11.1.1. Investigator Responsibility

The investigator shall ensure that all work and services described herein, or incidental to those described herein, shall be conducted in accordance with the highest standards of medical and clinical research practice. The investigator shall perform his/her

responsibilities as outlined in ISO 14155-1, ICH-GCP (E6) and the Declaration of Helsinki. The investigator will provide current copies of the study protocol to all sub-investigators or other site personnel responsible for study conduct and assure that all study personnel are qualified and trained to perform their duties.

The investigator will provide any interim progress reports, safety reports as required by local or country specific regulations as well as end of study notification in the required timelines to the EC.

The investigator will provide the sponsor or designee with copies of all EC actions regarding the study.

11.1.2. Sponsor Responsibility

The sponsor has the overall responsibility for the conduct of the study, including assurance that the study meets the regulatory requirements of international regulatory agencies governing the conduct of the study in all countries where participating centers are located. The sponsor will ensure compliance to Chinese and international regulations and guidelines including ISO 14155-1, ICH-GCP and the Declaration of Helsinki in the conduct of the study.

The sponsor is responsible for ensuring EC and regulatory authority approvals are obtained prior to the shipping of devices, ensuring proper clinical site monitoring, ensuring subject informed consent is obtained, providing quality data that satisfies regulations and informing the investigators, ECs and regulatory authorities of unanticipated adverse device effects, withdrawal of EC or other regulatory approval, current investigators list (where required) and relevant safety issues in accordance with international and local guidelines, and deviations from the protocol as appropriate. The sponsor will prepare written safety reports, progress reports and a final clinical study report.

Required insurance coverage will be handled by the sponsor according to local regulations.

11.2 Selection, Monitoring and Close-out

11.2.1. Selection

The primary requirements of site and investigator selection and continued participation in this study are adequate experience in the relevant field of study and all study procedures, commitment to safety, consistency in adherence to the protocol, and subject volume consistent with protocol timeline. The sponsor and its designees will select qualified investigators, ship investigational devices only to participating investigators, obtain signed study agreements, and provide the investigators with the information necessary to conduct the study, and any amendments or updates to study information specific to the conduct of the study.

11.2.2. Monitoring

The monitoring for this study will be conducted by sponsor or sponsor designee in all centers. The study will be monitored to assure the following:

- The rights and well-being of subjects are protected;
- The study is conducted according to Good Clinical Practices (ICH-GCP), ISO 14155-1, the Declaration of Helsinki and country specific regulations;
- The protocol and applicable amendments are followed;
- The data recorded are accurately represented according to source document verification.

Periodic monitoring visits will be performed at all active investigational sites throughout the clinical study to assure that the investigator obligations are fulfilled. These visits will assure that the facilities are still acceptable; the study protocol and any amendments are being followed, the EC has been notified of protocol changes as required, complete records are being maintained, appropriate and timely reports have been made to the sponsor and the EC, device and device inventory are controlled and the investigator is carrying out all agreed activities.

11.2.3. Close-out

Upon completion of the clinical study (when all subjects enrolled have completed the follow-up visits and the CRFs and queries have been completed), the sponsor or designee will notify the site of closeout and a study closeout visit will be performed.

During the close-out visit, all unused study materials will be collected and returned to the sponsor or destroyed on site. The monitor and the investigator will ensure that the investigator's site files are up to date and complete, and that any outstanding issues from previous visits have been resolved. Other issues which will be reviewed at this visit include: discussing retention of study files, possibility of site audits, publication policy, and notifying the EC of study closure.

A study close-out visit may be scheduled prior to completion of the clinical study if for any reason the site has not enrolled any subjects and is terminated from further participation in the study by the sponsor. In this case the sponsor will provide instructions to the investigator regarding EC notification of status of site participation in the study and final documentation required by the sponsor.

11.3. Required Documents

The following documents must be minimally submitted to the sponsor, or designee prior to subject enrollment:

- Confidentiality Agreement;
- Signed Protocol Signature page;

- A recent signed and dated Curriculum Vitae (CV) for the Principal and sub-investigator(s). This CV should clearly show the site study staff's qualifications and experience;
- A copy of the written confirmation of the EC regarding approval of the protocol including version number and date, subject information sheet and informed consent including version and date and other adjunctive subject material including health questionnaires;
- A current list of EC members, including name, title, occupation and any institutional affiliation of each member. If the EC members list is not available, a statement mentioning that the EC is working in accordance to ICH-GCP should be provided;
- A signed study contract must be in place;

11.3.1. Source Documents

Regulations require that investigators maintain information in the study subject's medical records (= source documents) which corroborate data collected on the CRF. In order to comply with these regulatory requirements, the following information will be maintained and made available as required by monitors and/or regulatory inspectors:

- Medical history/physical condition of the study subject before involvement in the study sufficient to verify protocol entry criteria;
- Medical record documenting the informed consent process;
- Description of device implantation procedure;
- All examination results and follow-up;
- Dated and signed printouts or reports of examinations (e.g., radiographs);
- Description of adverse events and follow-up of the adverse events (event description, severity, onset date, duration, relation to study device, study procedure, outcome and treatment for adverse event and concomitant medication at the time of the adverse event);
- Study subject's condition upon completion of or withdrawal from the study.

Subject's source documents minimally contain but are not limited to the above list.

11.3.2. Source Data Verification

The sponsor expects that, during the monitoring visits, the study coordinator and/or investigator will be available, the original source documentation will be available, and a suitable environment will be provided for review of study-related documents. Any

discrepancies will be noted, discussed with the investigator or designee and resolved.

11.3.3. Case Report Forms (CRFs)

A Case Report Form will be completed by the investigator or its designee for each subject enrolled in the study. All required subject data must be recorded in the CRF. The CRF cannot be used as source documentation. The study monitor(s) will review completed CRFs at the site to verify source data accuracy. All CRF corrections are to be made by an investigator or other authorized study site personnel. The investigator/ sub-investigator must sign and date the specified section of the CRF to confirm that he/she has reviewed the data and that the data are complete and accurate.

The investigator should complete CRFs as soon as possible after subject enrollment or follow-up visit. This will enable timely monitoring visits.

Any study-related patient-reported outcomes will be completed by the study subject.

11.3.4. Archiving and Data Retention

All study records, reports and source documents that support the CRFs must be retained by the responsible investigator according to regulation requirements following notification by the sponsor or designee that all investigations have been completed, and will further be retained in accordance with local and international guidelines as identified in the clinical study agreement.

This documentation must be accessible upon request by international regulatory authorities and the sponsor (or designee). The sponsor, or designee, must approve archiving or transfer of the documentation for relocation purposes of premises, in writing, prior to the actual file transfer. The investigator must notify the sponsor, in writing, of transfer location, duration, and the procedure for accessing study documentation. The investigator must contact the sponsor, or designee, before the destruction of any records and reports pertaining to the study to ensure they no longer need to be retained.

If the investigator retires, relocates, or for other reasons withdraws from assuming primary responsibility for keeping the study records, custody per written notice must be submitted to the sponsor, or designee, indicating the name and address of the person accepting primary responsibility.

11.3.5. Audit and Inspection

In the event that audits are initiated by the sponsor (or its designee), or national/international regulatory authorities, the investigator allows access to the original medical records and provides all requested information. In the event that audits are initiated by a regulatory authority, the investigator will immediately notify the sponsor.

12. ETHICS AND REGULATORY REQUIREMENTS

12.1. Ethics Committees

The protocol, informed consent form and other applicable study-related documents must be submitted to the appropriate EC and written approval must be obtained and submitted to the sponsor, or designee, prior to enrolling any subjects.

The investigator will promptly report to the EC any change in the designation of Principal investigator role and all unanticipated problems involving risks to human subjects and will not make any changes in the research plan without EC approval, except when necessary to eliminate immediate hazards to human subjects. Those amendments involving significant risk or change require EC approval and written documentation of this approval must be submitted to the sponsor or designee.

12.2. Informed consent

Each subject (or a legally authorized representative) must sign and date the EC approved Informed Consent (and other locally required documents) after the nature of the study has been fully explained, and prior to performance of any study-related activity or procedure, that is not standard of care.

The voluntary process of obtaining written informed consent confirms the subject's willingness to participate in the study. All aspects of the study must be explained to the subject prior to signing the informed consent. The Investigator and/or designee must clearly document the process of obtaining informed consent in the subject clinical record. It is the Investigator's responsibility to ensure that the informed consent process is performed in accordance with ICH-GCP, ISO 14155, EC requirements and country specific regulations.

12.3. Subject Confidentiality

Subject confidentiality will be maintained throughout the clinical study in a way that ensures the information can always be tracked back to the source data. For this purpose, a unique subject identification code (site number and subject number) will be used that allows identification of all data reported for each subject.

Data relating to the study might be made available to third parties (for example in case of an audit performed by regulatory authorities) provided the data are treated confidentially and that the subject's privacy is guaranteed.

12.4. Protocol Amendments

As appropriate, the sponsor or designee will submit changes in the protocol to the investigators, the appropriate regulatory authorities and ethics committees. Ethics Committee approval and Regulatory Authority approval are required for all substantial amendments prior to implementation of any changes to study procedures.

An amendment is regarded substantial when they are likely to have a significant impact on:

- The safety or physical or mental integrity of the subjects;
- Scientific value of the trial;
- Conduct or management of the trial;
- Quality or safety of an investigational medical product used in the trial.

12.5. Protocol Deviations

A protocol deviation is defined as a divergence from a specific element of a protocol (e.g., missed test or procedure, visit out of window, non-adherence to inclusion/exclusion criteria).

Investigators are required to obtain prior approval from the medical monitor before initiating deviations from protocol, except where necessary to protect the life or physical well-being of a subject in an emergency. Such approval will be documented in writing and maintained in study files. Prior approval is generally not expected in situations where unforeseen circumstances are beyond the investigator's control, (e.g., subject did not attend scheduled follow-up visit, blood sample lost by laboratory, etc.); however, the event is still considered a deviation.

Deviations shall be reported to the sponsor regardless of whether medically justifiable, preapproved by the medical monitor, or taken to protect the subject in an emergency. Subject specific deviations will be reported in the CRFs. Investigators will also adhere to procedures for reporting study deviations to their EC in accordance with their specific EC reporting policies and procedures.

Regulations (ISO 14155, ICH-GCP) require that investigators maintain accurate, complete and current records, including documents showing the dates and reasons for each deviation from the protocol.

13. DEVICES

13.1. Investigational Device Accountability

All received investigational devices will be inventoried and accounted for throughout the study on an ongoing basis: the investigator and/or trained designee will maintain adequate records of the receipt, use, disposition and return of the investigational devices. These investigational devices must be kept in a secure location with restricted access and stored according to the conditions outlined in the IFU. In all circumstances, the investigational device is intended for use by the investigator or sub-investigator for subjects consented for participation in this clinical study only.

An accountability log will be used by each site to acknowledge receipt of all investigational devices and to record the disposition of all investigational devices on an ongoing basis throughout the course of the study. Detailed written instructions regarding this device accountability process will be provided by sponsor and explained thoroughly during the site initiation visit. The responsible monitor will review the investigational device accountability at each monitoring visit.

In addition, the following paper study documents must be maintained as well:

- Packing slips provided with each investigational device shipment (signed and dated);
- Accountability records of each subject that received an investigational device (this may include source documents and/or package labels of investigational/commercial products used);
- All forms documenting the investigational devices return process;
- All shipment-related forms.

13.2. Return of Study Devices

All unopened and unused (e.g., expired), opened and unused, damaged, mislabeled or malfunctioning investigational devices must be returned to the sponsor. The appropriate form(s) must be completed and the device must be returned by courier to an address specified by the sponsor. Furthermore, the reason for each returned investigational device has to be reflected in the accountability system as well.

Detailed instructions for return will be provided separately by sponsor and explained thoroughly during the site initiation visit.

13.3. Device Complaint

Device Complaints consist of the following:

- The study device is damaged;
- The study device is mislabeled;
- The study device is malfunctioning.

A Device Malfunction is the failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marketed.

It is important that all malfunctioning ***investigational*** devices are returned to the ***sponsor*** per instructions provided in the Study Manual and the return process will be explained thoroughly during the site initiation visit. In case of any device complaints, the site must

notify the sponsor as soon as possible. In case of a device malfunction, the investigator will report the relevant information regarding the device malfunction in the appropriate CRF in addition to notifying the sponsor.

Should a device malfunction occur within the ***control*** group, the site must notify the study ***monitor*** as soon as possible. The monitor will then coordinate appropriate communications and product return to JJMC QC per sponsor timelines.

APPENDIX A: DEFINITIONS

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.

DEVICE RELATED ADVERSE EVENT

A device related adverse event is defined as any adverse event, for which a causal relationship between the device and the event is at least a reasonable possibility, i.e., the relationship cannot be excluded.

Device Malfunction: The failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marketed.

Device Misuse: A misused device (one that is used by the Investigator in a manner that is contradictory to the Instructions for Use) will not be considered a malfunction.

OUTCOMES IN CASE REPORT FORMS

Harris Hip Score: The Harris Hip Score was developed for the assessment of the results of hip surgery, and is intended to evaluate various hip disabilities and methods of treatment in an adult population. The original version was published in 1969 [27]. The domains covered are pain, function, absence of deformity, and range of motion. The pain domain measures pain severity and its effect on activities and need for pain medication. The HHS is a clinician-based outcome measure administered by a qualified health care professional, such as a physician or a physical therapist. Possible scores range from 0 to 100, with higher scores reflecting better clinical outcome.

SF-12: The Short Form-12 was designed to measure general health status from the patient's point of view. The SF-12 includes 8 concepts commonly represented in health surveys: physical functioning, role functioning physical, bodily pain, general health, vitality, social functioning, role functioning emotional, and mental health. It contains 12 items from the SF-36 and provides an efficient way to measure the same health concepts relevant across age, disease, and treatment groups. Most patients can complete the SF-12 in less than 3 minutes without assistance.

EuroQoL (Quality of Life)-5 Dimensions (EQ5D): The EQ5D is a patient reported outcome. It provides a simple descriptive profile and single index value for health status. This health-related, quality of life survey consists of five dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) each of which can take one of five responses. The responses record five levels of severity (no problems/slight problems/moderate problems/severe problems/extreme problems) within a particular EQ-5D dimension.

PROTOCOL DEVIATION

A protocol deviation is defined as an incident where the Investigator or site personnel did not conduct the study according to the investigational plan, protocol or the Investigator agreement.

Major deviation: Any deviation from patient inclusion and exclusion criteria or patient informed consent procedures.

Minor deviation: Deviation from a protocol requirement such as incomplete/inadequate patient testing procedures, follow-ups performed outside specified time windows, etc.

SERIOUS ADVERSE EVENT

A **Serious Adverse Event (SAE)** is any untoward event that:

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

NOTE Planned hospitalization for a pre-existing condition, or a procedure required by the

CIP, without serious deterioration in health, is not considered a serious adverse event.

UNANTICIPATED ADVERSE DEVICE EFFECT (UADE)

An Unanticipated Adverse Device Effect (UADE) is defined as any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

APPENDIX B: REFERENCED PUBLISHED LITERATURE AND JOINT REGISTRIES

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investigation. Clin Biomech (Bristol, Avon), 2009. 24(1): p. 59-64.

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APPENDIX C: DEVICE PART CODES AND SPECIFICATIONS – TFNA

Table C.1. TFNA Implants

1	04.037.912S	TFNA Femoral Nail Ø 9mm, 125°, L 170mm
2	04.037.913S	TFNA Femoral NailØ 9mm, 125°, L 200mm
3	04.037.914S	TFNA Femoral Nail Ø 9mm, right, 125°, L 235mm
4	04.037.915S	TFNA Femoral Nail Ø 9mm, left, 125°, L 235mm
5	04.037.916S	TFNA Femoral Nail Ø 9mm, right, 125°, L 260mm
6	04.037.917S	TFNA Femoral Nail Ø 9mm, left, 125°, L 260mm
7	04.037.918S	TFNA Femoral Nail Ø 9mm, right, 125°, L 280mm
8	04.037.919S	TFNA Femoral Nail Ø 9mm, left, 125°, L 280mm
9	04.037.920S	TFNA Femoral Nail Ø 9mm, right, 125°, L 300mm
10	04.037.921S	TFNA Femoral Nail Ø 9mm, left, 125°, L 300mm
11	04.037.922S	TFNA Femoral Nail Ø 9mm, right, 125°, L 320mm
12	04.037.923S	TFNA Femoral Nail Ø 9mm, left, 125°, L 320mm
13	04.037.924S	TFNA Femoral Nail Ø 9mm, right, 125°, L 340mm
14	04.037.925S	TFNA Femoral Nail Ø 9mm, left, 125°, L 340mm
15	04.037.926S	TFNA Femoral Nail Ø 9mm, right, 125°, L 360mm
16	04.037.927S	TFNA Femoral Nail Ø 9mm, left, 125°, L 360mm
17	04.037.928S	TFNA Femoral Nail Ø 9mm, right, 125°, L 380mm
18	04.037.929S	TFNA Femoral Nail Ø 9mm, left, 125°, L 380mm
19	04.037.930S	TFNA Femoral Nail Ø 9mm, right, 125°, L 400mm
20	04.037.931S	TFNA Femoral Nail Ø 9mm, left, 125°, L 400mm
21	04.037.932S	TFNA Femoral Nail Ø 9mm, right, 125°, L 420mm
22	04.037.933S	TFNA Femoral Nail Ø 9mm, left, 125°, L 420mm

23	04.037.934S	TFNA Femoral Nail Ø 9mm, right, 125°, L 440mm
24	04.037.935S	TFNA Femoral Nail Ø 9mm, left, 125°, L 440mm
25	04.037.936S	TFNA Femoral Nail Ø 9mm, right, 125°, L 460mm
26	04.037.937S	TFNA Femoral Nail Ø 9mm, left, 125°, L 460mm
27	04.037.938S	TFNA Femoral Nail Ø 9mm, right, 125°, L 480mm
28	04.037.939S	TFNA Femoral Nail Ø 9mm, left, 125°, L 480mm
29	04.037.942S	TFNA Femoral Nail Ø 9mm, 130°, L 170mm
30	04.037.943S	TFNA Femoral Nail Ø 9mm, 130°, L 200mm
31	04.037.944S	TFNA Femoral Nail Ø 9mm, right, 130°, L 235mm
32	04.037.945S	TFNA Femoral Nail Ø 9mm, left, 130°, L 235mm
33	04.037.946S	TFNA Femoral Nail Ø 9mm, right, 130°, L 260mm
34	04.037.947S	TFNA Femoral Nail Ø 9mm, left, 130°, L 260mm
35	04.037.948S	TFNA Femoral Nail Ø 9mm, right, 130°, L 280mm
36	04.037.949S	TFNA Femoral Nail Ø 9mm, left, 130°, L 280mm
37	04.037.950S	TFNA Femoral Nail Ø 9mm, right, 130°, L 300mm
38	04.037.951S	TFNA Femoral Nail Ø 9mm, left, 130°, L 300mm
39	04.037.952S	TFNA Femoral Nail Ø 9mm, right, 130°, L 320mm
40	04.037.953S	TFNA Femoral Nail Ø 9mm, left, 130°, L 320mm
41	04.037.954S	TFNA Femoral Nail Ø 9mm, right, 130°, L 340mm
42	04.037.955S	TFNA Femoral Nail Ø 9mm, left, 130°, L 340mm
43	04.037.956S	TFNA Femoral Nail Ø 9mm, right, 130°, L 360mm
44	04.037.957S	TFNA Femoral Nail Ø 9mm, left, 130°, L 360mm
45	04.037.958S	TFNA Femoral Nail Ø 9mm, right, 130°, L 380mm
46	04.037.959S	TFNA Femoral Nail Ø 9mm, left, 130°, L 380mm
47	04.037.960S	TFNA Femoral Nail Ø 9mm, right, 130°, L 400mm
48	04.037.961S	TFNA Femoral Nail Ø 9mm, left, 130°, L 400mm
49	04.037.962S	TFNA Femoral Nail Ø 9mm, right, 130°, L 420mm
50	04.037.963S	TFNA Femoral Nail Ø 9mm, left, 130°, L 420mm
51	04.037.964S	TFNA Femoral Nail Ø 9mm, right, 130°, L 440mm
52	04.037.965S	TFNA Femoral Nail Ø 9mm, left, 130°, L 440mm
53	04.037.966S	TFNA Femoral Nail Ø 9mm, right, 130°, L 460mm
54	04.037.967S	TFNA Femoral Nail Ø 9mm, left, 130°, L 460mm
55	04.037.968S	TFNA Femoral Nail Ø 9mm, right, 130°, L 480mm
56	04.037.969S	TFNA Femoral Nail Ø 9mm, left, 130°, L 480mm
57	04.037.972S	TFNA Femoral Nail Ø 9mm, 135°, L 170mm
58	04.037.973S	TFNA Femoral Nail Ø 9mm, 135°, L 200mm
59	04.037.974S	TFNA Femoral Nail Ø 9mm, right, 135°, L 235mm
60	04.037.975S	TFNA Femoral Nail Ø 9mm, left, 135°, L 235mm
61	04.037.012S	TFNA Femoral Nail Ø 10mm, 125°, L 170mm

62	04.037.013S	TFNA Femoral Nail Ø 10mm, 125°, L 200mm
63	04.037.014S	TFNA Femoral Nail Ø 10mm, right, 125°, L 235mm
64	04.037.015S	TFNA Femoral Nail Ø 10mm, left, 125°, L 235mm
65	04.037.016S	TFNA Femoral Nail Ø 10mm, right, 125°, L 260mm
66	04.037.017S	TFNA Femoral Nail Ø 10mm, left, 125°, L 260mm
67	04.037.018S	TFNA Femoral Nail Ø 10mm, right, 125°, L 280mm
68	04.037.019S	TFNA Femoral Nail Ø 10mm, left, 125°, L 280mm
69	04.037.020S	TFNA Femoral Nail Ø 10mm, right, 125°, L 300mm
70	04.037.021S	TFNA Femoral Nail Ø 10mm, left, 125°, L 300mm
71	04.037.022S	TFNA Femoral Nail Ø 10mm, right, 125°, L 320mm
72	04.037.023S	TFNA Femoral Nail Ø 10mm, left, 125°, L 320mm
73	04.037.024S	TFNA Femoral Nail Ø 10mm, right, 125°, L 340mm
74	04.037.025S	TFNA Femoral Nail Ø 10mm, left, 125°, L 340mm
75	04.037.026S	TFNA Femoral Nail Ø 10mm, right, 125°, L 360mm
76	04.037.027S	TFNA Femoral Nail Ø 10mm, left, 125°, L 360mm
77	04.037.028S	TFNA Femoral Nail Ø 10mm, right, 125°, L 380mm
78	04.037.029S	TFNA Femoral Nail Ø 10mm, left, 125°, L 380mm
79	04.037.030S	TFNA Femoral Nail Ø 10mm, right, 125°, L 400mm
80	04.037.031S	TFNA Femoral Nail Ø 10mm, left, 125°, L 400mm
81	04.037.032S	TFNA Femoral Nail Ø 10mm, right, 125°, L 420mm
82	04.037.033S	TFNA Femoral Nail Ø 10mm, left, 125°, L 420mm
83	04.037.034S	TFNA Femoral Nail Ø 10mm, right, 125°, L 440mm
84	04.037.035S	TFNA Femoral Nail Ø 10mm, left, 125°, L 440mm
85	04.037.036S	TFNA Femoral Nail Ø 10mm, right, 125°, L 460mm
86	04.037.037S	TFNA Femoral Nail Ø 10mm, left, 125°, L 460mm
87	04.037.038S	TFNA Femoral Nail Ø 10mm, right, 125°, L 480mm
88	04.037.039S	TFNA Femoral Nail Ø 10mm, left, 125°, L 480mm
89	04.037.042S	TFNA Femoral Nail Ø 10mm, 130°, L 170mm
90	04.037.043S	TFNA Femoral Nail Ø 10mm, 130°, L 200mm
91	04.037.044S	TFNA Femoral Nail Ø 10mm, right, 130°, L 235mm
92	04.037.045S	TFNA Femoral Nail Ø 10mm, left, 130°, L 235mm
93	04.037.046S	TFNA Femoral Nail Ø 10mm, right, 130°, L 260mm
94	04.037.047S	TFNA Femoral Nail Ø 10mm, left, 130°, L 260mm
95	04.037.048S	TFNA Femoral Nail Ø 10mm, right, 130°, L 280mm
96	04.037.049S	TFNA Femoral Nail Ø 10mm, left, 130°, L 280mm
97	04.037.050S	TFNA Femoral Nail Ø 10mm, right, 130°, L 300mm
98	04.037.051S	TFNA Femoral Nail Ø 10mm, left, 130°, L 300mm
99	04.037.052S	TFNA Femoral Nail Ø 10mm, right, 130°, L 320mm
100	04.037.053S	TFNA Femoral Nail Ø 10mm, left, 130°, L 320mm

101	04.037.054S	TFNA Femoral Nail Ø 10mm, right, 130°, L 340mm
102	04.037.055S	TFNA Femoral Nail Ø 10mm, left, 130°, L 340mm
103	04.037.056S	TFNA Femoral Nail Ø 10mm, right, 130°, L 360mm
104	04.037.057S	TFNA Femoral Nail Ø 10mm, left, 130°, L 360mm
105	04.037.058S	TFNA Femoral Nail Ø 10mm, right, 130°, L 380mm
106	04.037.059S	TFNA Femoral Nail Ø 10mm, left, 130°, L 380mm
107	04.037.060S	TFNA Femoral Nail Ø 10mm, right, 130°, L 400mm
108	04.037.061S	TFNA Femoral Nail Ø 10mm, left, 130°, L 400mm
109	04.037.062S	TFNA Femoral Nail Ø 10mm, right, 130°, L 420mm
110	04.037.063S	TFNA Femoral Nail Ø 10mm, left, 130°, L 420mm
111	04.037.064S	TFNA Femoral Nail Ø 10mm, right, 130°, L 440mm
112	04.037.065S	TFNA Femoral Nail Ø 10mm, left, 130°, L 440mm
113	04.037.066S	TFNA Femoral Nail Ø 10mm, right, 130°, L 460mm
114	04.037.067S	TFNA Femoral Nail Ø 10mm, left, 130°, L 460mm
115	04.037.068S	TFNA Femoral Nail Ø 10mm, right, 130°, L 480mm
116	04.037.069S	TFNA Femoral Nail Ø 10mm, left, 130°, L 480mm
117	04.037.072S	TFNA Femoral Nail Ø 10mm, 135°, L 170mm
118	04.037.073S	TFNA Femoral Nail Ø 10mm, 135°, L 200mm
119	04.037.074S	TFNA Femoral Nail Ø 10mm, right, 135°, L 235mm
120	04.037.075S	TFNA Femoral Nail Ø 10mm, left, 135°, L 235mm
121	04.037.112S	TFNA Femoral Nail Ø 11mm, 125°, L 170mm
122	04.037.113S	TFNA Femoral Nail Ø 11mm, 125°, L 200mm
123	04.037.114S	TFNA Femoral Nail Ø 11mm, right, 125°, L 235mm
124	04.037.115S	TFNA Femoral Nail Ø 11mm, left, 125°, L 235mm
125	04.037.120S	TFNA Femoral Nail Ø 11mm, right, 125°, L 300mm
126	04.037.121S	TFNA Femoral Nail Ø 11mm, left, 125°, L 300mm
127	04.037.122S	TFNA Femoral Nail Ø 11mm, right, 125°, L 320mm
128	04.037.123S	TFNA Femoral Nail Ø 11mm, left, 125°, L 320mm
129	04.037.124S	TFNA Femoral Nail Ø 11mm, right, 125°, L 340mm
130	04.037.125S	TFNA Femoral Nail Ø 11mm, left, 125°, L 340mm
131	04.037.126S	TFNA Femoral Nail Ø 11mm, right, 125°, L 360mm
132	04.037.127S	TFNA Femoral Nail Ø 11mm, left, 125°, L 360mm
133	04.037.128S	TFNA Femoral Nail Ø 11mm, right, 125°, L 380mm
134	04.037.129S	TFNA Femoral Nail Ø 11mm, left, 125°, L 380mm
135	04.037.130S	TFNA Femoral Nail Ø 11mm, right, 125°, L 400mm
136	04.037.131S	TFNA Femoral Nail Ø 11mm, left, 125°, L 400mm
137	04.037.132S	TFNA Femoral Nail Ø 11mm, right, 125°, L 420mm
138	04.037.133S	TFNA Femoral Nail Ø 11mm, left, 125°, L 420mm
139	04.037.134S	TFNA Femoral Nail Ø 11mm, right, 125°, L 440mm

140	04.037.135S	TFNA Femoral Nail Ø 11mm, left, 125°, L 440mm
141	04.037.136S	TFNA Femoral Nail Ø 11mm, right, 125°, L 460mm
142	04.037.137S	TFNA Femoral Nail Ø 11mm, left, 125°, L 460mm
143	04.037.138S	TFNA Femoral Nail Ø 11mm, right, 125°, L 480mm
144	04.037.139S	TFNA Femoral Nail Ø 11mm, left, 125°, L 480mm
145	04.037.142S	TFNA Femoral Nail Ø 11mm, 130°, L 170mm
146	04.037.143S	TFNA Femoral Nail Ø 11mm, 130°, L 200mm
147	04.037.144S	TFNA Femoral Nail Ø 11mm, right, 130°, L 235mm
148	04.037.145S	TFNA Femoral Nail Ø 11mm, left, 130°, L 235mm
149	04.037.150S	TFNA Femoral Nail Ø 11mm, right, 130°, L 300mm
150	04.037.151S	TFNA Femoral Nail Ø 11mm, left, 130°, L 300mm
151	04.037.152S	TFNA Femoral Nail Ø 11mm, right, 130°, L 320mm
152	04.037.153S	TFNA Femoral Nail Ø 11mm, left, 130°, L 320mm
153	04.037.154S	TFNA Femoral Nail Ø 11mm, right, 130°, L 340mm
154	04.037.155S	TFNA Femoral Nail Ø 11mm, left, 130°, L 340mm
155	04.037.156S	TFNA Femoral Nail Ø 11mm, right, 130°, L 360mm
156	04.037.157S	TFNA Femoral Nail Ø 11mm, left, 130°, L 360mm
157	04.037.158S	TFNA Femoral Nail Ø 11mm, right, 130°, L 380mm
158	04.037.159S	TFNA Femoral Nail Ø 11mm, left, 130°, L 380mm
159	04.037.160S	TFNA Femoral Nail Ø 11mm, right, 130°, L 400mm
160	04.037.161S	TFNA Femoral Nail Ø 11mm, left, 130°, L 400mm
161	04.037.162S	TFNA Femoral Nail Ø 11mm, right, 130°, L 420mm
162	04.037.163S	TFNA Femoral Nail Ø 11mm, left, 130°, L 420mm
163	04.037.164S	TFNA Femoral Nail Ø 11mm, right, 130°, L 440mm
164	04.037.165S	TFNA Femoral Nail Ø 11mm, left, 130°, L 440mm
165	04.037.166S	TFNA Femoral Nail Ø 11mm, right, 130°, L 460mm
166	04.037.167S	TFNA Femoral Nail Ø 11mm, left, 130°, L 460mm
167	04.037.168S	TFNA Femoral Nail Ø 11mm, right, 130°, L 480mm
168	04.037.169S	TFNA Femoral Nail Ø 11mm, left, 130°, L 480mm
169	04.037.172S	TFNA Femoral Nail Ø 11mm, 135°, L 170mm
170	04.037.173S	TFNA Femoral Nail Ø 11mm, 135°, L 200mm
171	04.037.174S	TFNA Femoral Nail Ø 11mm, right, 135°, L 235mm
172	04.037.175S	TFNA Femoral Nail Ø 11mm, left, 135°, L 235mm
173	04.037.180S	TFNA Femoral Nail Ø 11mm, right, 135°, L 300mm
174	04.037.181S	TFNA Femoral Nail Ø 11mm, left, 135°, L 300mm
175	04.037.182S	TFNA Femoral Nail Ø 11mm, right, 135°, L 320mm
176	04.037.183S	TFNA Femoral Nail Ø 11mm, left, 135°, L 320mm
177	04.037.184S	TFNA Femoral Nail Ø 11mm, right, 135°, L 340mm
178	04.037.185S	TFNA Femoral Nail Ø 11mm, left, 135°, L 340mm

179	04.037.186S	TFNA Femoral Nail Ø 11mm, right, 135°, L 360mm
180	04.037.187S	TFNA Femoral Nail Ø 11mm, left, 135°, L 360mm
181	04.037.188S	TFNA Femoral Nail Ø 11mm, right, 135°, L 380mm
182	04.037.189S	TFNA Femoral Nail Ø 11mm, left, 135°, L 380mm
183	04.037.190S	TFNA Femoral Nail Ø 11mm, right, 135°, L 400mm
184	04.037.191S	TFNA Femoral Nail Ø 11mm, left, 135°, L 400mm
185	04.037.192S	TFNA Femoral Nail Ø 11mm, right, 135°, L 420mm
186	04.037.193S	TFNA Femoral Nail Ø 11mm, left, 135°, L 420mm
187	04.037.194S	TFNA Femoral Nail Ø 11mm, right, 135°, L 440mm
188	04.037.195S	TFNA Femoral Nail Ø 11mm, left, 135°, L 440mm
189	04.037.196S	TFNA Femoral Nail Ø 11mm, right, 135°, L 460mm
190	04.037.197S	TFNA Femoral Nail Ø 11mm, left, 135°, L 460mm
191	04.037.198S	TFNA Femoral Nail Ø 11mm, right, 135°, L 480mm
192	04.037.199S	TFNA Femoral Nail Ø 11mm, left, 135°, L 480mm
193	04.037.212S	TFNA Femoral Nail Ø 12mm, 125°, L 170mm
194	04.037.213S	TFNA Femoral Nail Ø 12mm, 125°, L 200mm
195	04.037.214S	TFNA Femoral Nail Ø 12mm, right, 125°, L 235mm
196	04.037.215S	TFNA Femoral Nail Ø 12mm, left, 125°, L 235mm
197	04.037.220S	TFNA Femoral Nail Ø 12mm, right, 125°, L 300mm
198	04.037.221S	TFNA Femoral Nail Ø 12mm, left, 125°, L 300mm
199	04.037.222S	TFNA Femoral Nail Ø 12mm, right, 125°, L 320mm
200	04.037.223S	TFNA Femoral Nail Ø 12mm, left, 125°, L 320mm
201	04.037.224S	TFNA Femoral Nail Ø 12mm, right, 125°, L 340mm
202	04.037.225S	TFNA Femoral Nail Ø 12mm, left, 125°, L 340mm
203	04.037.226S	TFNA Femoral Nail Ø 12mm, right, 125°, L 360mm
204	04.037.227S	TFNA Femoral Nail Ø 12mm, left, 125°, L 360mm
205	04.037.228S	TFNA Femoral Nail Ø 12mm, right, 125°, L 380mm
206	04.037.229S	TFNA Femoral Nail Ø 12mm, left, 125°, L 380mm
207	04.037.230S	TFNA Femoral Nail Ø 12mm, right, 125°, L 400mm
208	04.037.231S	TFNA Femoral Nail Ø 12mm, left, 125°, L 400mm
209	04.037.232S	TFNA Femoral Nail Ø 12mm, right, 125°, L 420mm
210	04.037.233S	TFNA Femoral Nail Ø 12mm, left, 125°, L 420mm
211	04.037.234S	TFNA Femoral Nail Ø 12mm, right, 125°, L 440mm
212	04.037.235S	TFNA Femoral Nail Ø 12mm, left, 125°, L 440mm
213	04.037.236S	TFNA Femoral Nail Ø 12mm, right, 125°, L 460mm
214	04.037.237S	TFNA Femoral Nail Ø 12mm, left, 125°, L 460mm
215	04.037.238S	TFNA Femoral Nail Ø 12mm, right, 125°, L 480mm
216	04.037.239S	TFNA Femoral Nail Ø 12mm, left, 125°, L 480mm
217	04.037.242S	TFNA Femoral Nail Ø 12mm, 130°, L 170mm

218	04.037.243S	TFNA Femoral Nail Ø 12mm, 130°, L 200mm
219	04.037.244S	TFNA Femoral Nail Ø 12mm, right, 130°, L 235mm
220	04.037.245S	TFNA Femoral Nail Ø 12mm, left, 130°, L 235mm
221	04.037.250S	TFNA Femoral Nail Ø 12mm, right, 130°, L 300mm
222	04.037.251S	TFNA Femoral Nail Ø 12mm, left, 130°, L 300mm
223	04.037.252S	TFNA Femoral Nail Ø 12mm, right, 130°, L 320mm
224	04.037.253S	TFNA Femoral Nail Ø 12mm, left, 130°, L 320mm
225	04.037.254S	TFNA Femoral Nail Ø 12mm, right, 130°, L 340mm
226	04.037.255S	TFNA Femoral Nail Ø 12mm, left, 130°, L 340mm
227	04.037.256S	TFNA Femoral Nail Ø 12mm, right, 130°, L 360mm
228	04.037.257S	TFNA Femoral Nail Ø 12mm, left, 130°, L 360mm
229	04.037.258S	TFNA Femoral Nail Ø 12mm, right, 130°, L 380mm
230	04.037.259S	TFNA Femoral Nail Ø 12mm, left, 130°, L 380mm
231	04.037.260S	TFNA Femoral Nail Ø 12mm, right, 130°, L 400mm
232	04.037.261S	TFNA Femoral Nail Ø 12mm, left, 130°, L 400mm
233	04.037.262S	TFNA Femoral Nail Ø 12mm, right, 130°, L 420mm
234	04.037.263S	TFNA Femoral Nail Ø 12mm, left, 130°, L 420mm
235	04.037.264S	TFNA Femoral Nail Ø 12mm, right, 130°, L 440mm
236	04.037.265S	TFNA Femoral Nail Ø 12mm, left, 130°, L 440mm
237	04.037.266S	TFNA Femoral Nail Ø 12mm, right, 130°, L 460mm
238	04.037.267S	TFNA Femoral Nail Ø 12mm, left, 130°, L 460mm
239	04.037.268S	TFNA Femoral Nail Ø 12mm, right, 130°, L 480mm
240	04.037.269S	TFNA Femoral Nail Ø 12mm, left, 130°, L 480mm
241	04.037.272S	TFNA Femoral Nail Ø 12mm, 135°, L 170mm
242	04.037.273S	TFNA Femoral Nail Ø 12mm, 135°, L 200mm
243	04.037.274S	TFNA Femoral Nail Ø 12mm, right, 135°, L 235mm
244	04.037.275S	TFNA Femoral Nail Ø 12mm, left, 135°, L 235mm
245	04.037.450S	TFNA Femoral Nail Ø 14mm, right, 130°, L 300mm
246	04.037.451S	TFNA Femoral Nail Ø 14mm, left, 130°, L 300mm
247	04.037.452S	TFNA Femoral Nail Ø 14mm, right, 130°, L 320mm
248	04.037.453S	TFNA Femoral Nail Ø 14mm, left, 130°, L 320mm
249	04.037.454S	TFNA Femoral Nail Ø 14mm, right, 130°, L 340mm
250	04.037.455S	TFNA Femoral Nail Ø 14mm, left, 130°, L 340mm
251	04.037.456S	TFNA Femoral Nail Ø 14mm, right, 130°, L 360mm
252	04.037.457S	TFNA Femoral Nail Ø 14mm, left, 130°, L 360mm
253	04.037.458S	TFNA Femoral Nail Ø 14mm, right, 130°, L 380mm
254	04.037.459S	TFNA Femoral Nail Ø 14mm, left, 130°, L 380mm
255	04.037.460S	TFNA Femoral Nail Ø 14mm, right, 130°, L 400mm
256	04.037.461S	TFNA Femoral Nail Ø 14mm, left, 130°, L 400mm

257	04.037.462S	TFNA Femoral Nail Ø 14mm, right, 130°, L 420mm
258	04.037.463S	TFNA Femoral Nail Ø 14mm, left, 130°, L 420mm
259	04.037.464S	TFNA Femoral Nail Ø 14mm, right, 130°, L 440mm
260	04.037.465S	TFNA Femoral Nail Ø 14mm, left, 130°, L 440mm
261	04.037.466S	TFNA Femoral Nail Ø 14mm, right, 130°, L 460mm
262	04.037.467S	TFNA Femoral Nail Ø 14mm, left, 130°, L 460mm
263	04.037.468S	TFNA Femoral Nail Ø 14mm, right, 130°, L 480mm
264	04.037.469S	TFNA Femoral Nail Ø 14mm, left, 130°, L 480mm
265	04.038.170S	TFNA Screw, perforated, L 70mm
266	04.038.175S	TFNA Screw, perforated, L 75mm
267	04.038.180S	TFNA Screw, perforated, L 80mm
268	04.038.185S	TFNA Screw, perforated, L 85mm
269	04.038.190S	TFNA Screw, perforated, L 90mm
270	04.038.195S	TFNA Screw, perforated, L 95mm
271	04.038.200S	TFNA Screw, perforated, L 100mm
272	04.038.205S	TFNA Screw, perforated, L 105mm
273	04.038.210S	TFNA Screw, perforated, L 110mm
274	04.038.215S	TFNA Screw, perforated, L 115mm
275	04.038.220S	TFNA Screw, perforated, L 120mm
276	04.038.225S	TFNA Screw, perforated, L 125mm
277	04.038.230S	TFNA Screw, perforated, L 130mm
278	04.038.370S	TFNA Helical Blade, perforated, L 70mm
279	04.038.375S	TFNA Helical Blade, perforated, L 75mm
280	04.038.380S	TFNA Helical Blade, perforated, L 80mm
281	04.038.385S	TFNA Helical Blade, perforated, L 85mm
282	04.038.390S	TFNA Helical Blade, perforated, L 90mm
283	04.038.395S	TFNA Helical Blade, perforated, L 95mm
284	04.038.400S	TFNA Helical Blade, perforated, L 100mm
285	04.038.405S	TFNA Helical Blade, perforated, L 105mm
286	04.038.410S	TFNA Helical Blade, perforated, L 110mm
287	04.038.415S	TFNA Helical Blade, perforated, L 115mm
288	04.038.420S	TFNA Helical Blade, perforated, L 120mm
289	04.038.425S	TFNA Helical Blade, perforated, L 125mm
290	04.038.430S	TFNA Helical Blade, perforated, L 130mm
291	04.038.000S	TFNA End Cap, extension 0mm
292	04.038.005S	TFNA End Cap, extension 5mm
293	04.038.010S	TFNA End Cap, extension 10mm
294	04.038.015S	TFNA End Cap, extension 15mm
295	459.260	Locking Bolt Ø 4.9mm, self-tapp., L 26mm

296	459.280	Locking Bolt Ø 4.9mm, self-tapp., L 28mm
297	459.300	Locking Bolt Ø 4.9mm, self-tapp., L 30mm
298	459.320	Locking Bolt Ø 4.9mm, self-tapp., L 32mm
299	459.340	Locking Bolt Ø 4.9mm, self-tapp., L 34mm
300	459.360	Locking Bolt Ø 4.9mm, self-tapp., L 36mm
301	459.380	Locking Bolt Ø 4.9mm, self-tapp., L 38mm
302	459.400	Locking Bolt Ø 4.9mm, self-tapp., L 40mm
303	459.420	Locking Bolt Ø 4.9mm, self-tapp., L 42mm
304	459.440	Locking Bolt Ø 4.9mm, self-tapp., L 44mm
305	459.460	Locking Bolt Ø 4.9mm, self-tapp., L 46mm
306	459.480	Locking Bolt Ø 4.9mm, self-tapp., L 48mm
307	459.500	Locking Bolt Ø 4.9mm, self-tapp., L 50mm
308	459.520	Locking Bolt Ø 4.9mm, self-tapp., L 52mm
309	459.540	Locking Bolt Ø 4.9mm, self-tapp., L 54mm
310	459.560	Locking Bolt Ø 4.9mm, self-tapp., L 56mm
311	459.580	Locking Bolt Ø 4.9mm, self-tapp., L 58mm
312	459.600	Locking Bolt Ø 4.9mm, self-tapp., L 60mm
313	459.640	Locking Bolt Ø 4.9mm, self-tapp., L 64mm
314	459.680	Locking Bolt Ø 4.9mm, self-tapp., L 68mm
315	459.720	Locking Bolt Ø 4.9mm, self-tapp., L 72mm
316	459.760	Locking Bolt Ø 4.9mm, self-tapp., L 76mm
317	459.800	Locking Bolt Ø 4.9mm, self-tapp., L 80mm
318	459.850	Locking Bolt Ø 4.9mm, self-tapp., L 85mm
319	459.900	Locking Bolt Ø 4.9mm, self-tapp., L 90mm
320	459.950	Locking Bolt Ø 4.9mm, self-tapp., L 95mm
321	459.960	Locking Bolt Ø 4.9mm, self-tapp., L 100mm
322	04.005.516S	Locking Screw Ø 5.0mm, L 26mm, f/Medullary Nails
323	04.005.518S	Locking Screw Ø 5.0mm, L 28mm, f/Medullary Nails
324	04.005.520S	Locking Screw Ø 5.0mm, L 30mm, f/Medullary Nails
325	04.005.522S	Locking Screw Ø 5.0mm, L 32mm, f/Medullary Nails
326	04.005.524S	Locking Screw Ø 5.0mm, L 34mm, f/Medullary Nails
327	04.005.526S	Locking Screw Ø 5.0mm, L 36mm, f/Medullary Nails
328	04.005.528S	Locking Screw Ø 5.0mm, L 38mm, f/Medullary Nails
329	04.005.530S	Locking Screw Ø 5.0mm, L 40mm, f/Medullary Nails
330	04.005.532S	Locking Screw Ø 5.0mm, L 42mm, f/Medullary Nails
331	04.005.534S	Locking Screw Ø 5.0mm, L 44mm, f/Medullary Nails
332	04.005.536S	Locking Screw Ø 5.0mm, L 46mm, f/Medullary Nails
333	04.005.538S	Locking Screw Ø 5.0mm, L 48mm, f/Medullary Nails
334	04.005.540S	Locking Screw Ø 5.0mm, L 50mm, f/Medullary Nails

335	04.005.542S	Locking Screw Ø 5.0mm, L 52mm, f/Medullary Nails
336	04.005.544S	Locking Screw Ø 5.0mm, L 54mm, f/Medullary Nails
337	04.005.546S	Locking Screw Ø 5.0mm, L 56mm, f/Medullary Nails
338	04.005.548S	Locking Screw Ø 5.0mm, L 58mm, f/Medullary Nails
339	04.005.550S	Locking Screw Ø 5.0mm, L 60mm, f/Medullary Nails
340	04.005.552S	Locking Screw Ø 5.0mm, L 62mm, f/Medullary Nails
341	04.005.554S	Locking Screw Ø 5.0mm, L 64mm, f/Medullary Nails
342	04.005.558S	Locking Screw Ø 5.0mm, L 68mm, f/Medullary Nails
343	04.005.560S	Locking Screw Ø 5.0mm, L 70mm, f/Medullary Nails
344	04.005.562S	Locking Screw Ø 5.0mm, L 72mm, f/Medullary Nails
345	04.005.564S	Locking Screw Ø 5.0mm, L 74mm, f/Medullary Nails
346	04.005.566S	Locking Screw Ø 5.0mm, L 76mm, f/Medullary Nails
347	04.005.568S	Locking Screw Ø 5.0mm, L 78mm, f/Medullary Nails
348	04.005.570S	Locking Screw Ø 5.0mm, L 80mm, f/Medullary Nails
349	04.005.575S	Locking Screw Ø 5.0mm, L 85mm, f/Medullary Nails
350	04.005.580S	Locking Screw Ø 5.0mm, L 90mm, f/Medullary Nails
351	04.005.585S	Locking Screw Ø 5.0mm, L 95mm, f/Medullary Nails
352	04.005.590S	Locking Screw Ø 5.0mm, L 100mm, f/Medullary Nails
353	04.005.516	Locking Screw Stardrive® Ø 5.0mm, L 26mm
354	04.005.518	Locking Screw Stardrive® Ø 5.0mm, L 28mm
355	04.005.520	Locking Screw Stardrive® Ø 5.0mm, L 30mm
356	04.005.522	Locking Screw Stardrive® Ø 5.0mm, L 32mm
357	04.005.524	Locking Screw Stardrive® Ø 5.0mm, L 34mm
358	04.005.526	Locking Screw Stardrive® Ø 5.0mm, L 36mm
359	04.005.528	Locking Screw Stardrive® Ø 5.0mm, L 38mm
360	04.005.530	Locking Screw Stardrive® Ø 5.0mm, L 40mm
361	04.005.532	Locking Screw Stardrive® Ø 5.0mm, L 42mm
362	04.005.534	Locking Screw Stardrive® Ø 5.0mm, L 44mm
363	04.005.536	Locking Screw Stardrive® Ø 5.0mm, L 46mm
364	04.005.538	Locking Screw Stardrive® Ø 5.0mm, L 48mm
365	04.005.540	Locking Screw Stardrive® Ø 5.0mm, L 50mm
366	04.005.542	Locking Screw Stardrive® Ø 5.0mm, L 52mm
367	04.005.544	Locking Screw Stardrive® Ø 5.0mm, L 54mm
368	04.005.546	Locking Screw Stardrive® Ø 5.0mm, L 56mm
369	04.005.548	Locking Screw Stardrive® Ø 5.0mm, L 58mm
370	04.005.550	Locking Screw Stardrive® Ø 5.0mm, L 60mm
371	04.005.552	Locking Screw Stardrive® Ø 5.0mm, L 62mm
372	04.005.554	Locking Screw Stardrive® Ø 5.0mm, L 64mm
373	04.005.556	Locking Screw Stardrive® Ø 5.0mm, L 66mm

374	04.005.558	Locking Screw Stardrive® Ø 5.0mm, L 68mm
375	04.005.560	Locking Screw Stardrive® Ø 5.0mm, L 70mm
376	04.005.562	Locking Screw Stardrive® Ø 5.0mm, L 72mm
377	04.005.564	Locking Screw Stardrive® Ø 5.0mm, L 74mm
378	04.005.566	Locking Screw Stardrive® Ø 5.0mm, L 76mm
379	04.005.568	Locking Screw Stardrive® Ø 5.0mm, L 78mm
380	04.005.570	Locking Screw Stardrive® Ø 5.0mm, L 80mm
381	04.005.575	Locking Screw Stardrive® Ø 5.0mm, L 85mm
382	04.005.580	Locking Screw Stardrive® Ø 5.0mm, L 90mm
383	04.005.585	Locking Screw Stardrive® Ø 5.0mm, L 95mm
384	04.005.590	Locking Screw Stardrive® Ø 5.0mm, L 100mm
385	459.260S	Locking Bolt Ø 4.9mm, self-tapp., L 26mm
386	459.280S	Locking Bolt Ø 4.9mm, self-tapp., L 28mm
387	459.300S	Locking Bolt Ø 4.9mm, self-tapp., L 30mm
388	459.320S	Locking Bolt Ø 4.9mm, self-tapp., L 32mm
389	459.340S	Locking Bolt Ø 4.9mm, self-tapp., L 34mm
390	459.360S	Locking Bolt Ø 4.9mm, self-tapp., L 36mm
391	459.380S	Locking Bolt Ø 4.9mm, self-tapp., L 38mm
392	459.400S	Locking Bolt Ø 4.9mm, self-tapp., L 40mm
393	459.420S	Locking Bolt Ø 4.9mm, self-tapp., L 42mm
394	459.440S	Locking Bolt Ø 4.9mm, self-tapp., L 44mm
395	459.460S	Locking Bolt Ø 4.9mm, self-tapp., L 46mm
396	459.480S	Locking Bolt Ø 4.9mm, self-tapp., L 48mm
397	459.500S	Locking Bolt Ø 4.9mm, self-tapp., L 50mm
398	459.520S	Locking Bolt Ø 4.9mm, self-tapp., L 52mm
399	459.540S	Locking Bolt Ø 4.9mm, self-tapp., L 54mm
400	459.560S	Locking Bolt Ø 4.9mm, self-tapp., L 56mm
401	459.580S	Locking Bolt Ø 4.9mm, self-tapp., L 58mm
402	459.600S	Locking Bolt Ø 4.9mm, self-tapp., L 60mm
403	459.640S	Locking Bolt Ø 4.9mm, self-tapp., L 64mm
404	459.680S	Locking Bolt Ø 4.9mm, self-tapp., L 68mm
405	459.720S	Locking Bolt Ø 4.9mm, self-tapp., L 72mm
406	459.760S	Locking Bolt Ø 4.9mm, self-tapp., L 76mm
407	459.800S	Locking Bolt Ø 4.9mm, self-tapp., L 80mm
408	459.850S	Locking Bolt Ø 4.9mm, self-tapp., L 85mm
409	459.900S	Locking Bolt Ø 4.9mm, self-tapp., L 90mm
410	459.950S	Locking Bolt Ø 4.9mm, self-tapp., L 95mm
411	459.960S	Locking Bolt Ø 4.9mm, self-tapp., L 100mm

APPENDIX D: DEVICE PART CODES AND SPECIFICATIONS – PFNA-II

Table D.1 Implants

Part number	Description
473.800S	PFNA-II Ø 9.0mm, 125°, L 240mm
473.801S	PFNA-II Ø 10.0mm, 125°, L 240mm
473.802S	PFNA-II Ø 11.0mm, 125°, L 240mm
473.803S	PFNA-II Ø 12.0mm, 125°, L 240mm
473.804S	PFNA-II Ø 9.0mm, 130°, L 240mm
473.805S	PFNA-II Ø 10.0mm, 130°, L 240mm
473.806S	PFNA-II Ø 11.0mm, 130°, L 240mm
473.807S	PFNA-II Ø 12.0mm, 130°, L 240mm
472.110S	PFNA-II Ø 9.0mm, small, 125°, L 200mm
472.111S	PFNA-II Ø 10.0mm, small, 125°, L 200mm
472.112S	PFNA-II Ø 11.0mm, small, 125°, L 200mm
472.113S	PFNA-II Ø 12.0mm, small, 125°, L 200mm
472.114S	PFNA-II Ø 9.0mm, small, 130°, L 200mm
472.115S	PFNA-II Ø 10.0mm, small, 130°, L 200mm
472.116S	PFNA-II Ø 11.0mm, small, 130°, L 200mm
472.117S	PFNA-II Ø 12.0mm, small, 130°, L 200mm
472.100S	PFNA-II Ø 9.0mm, extra-small, 125°, L 170mm
472.101S	PFNA-II Ø 10.0mm, extra-small, 125°, L 170mm
472.102S	PFNA-II Ø 11.0mm, extra-small, 125°, L 170mm
472.103S	PFNA-II Ø 12.0mm, extra-small, 125°, L 170mm
472.104S	PFNA-II Ø 9.0mm, extra-small, 130°, L 170mm
472.105S	PFNA-II Ø 10.0mm, extra-small, 130°, L 170mm
472.106S	PFNA-II Ø 11.0mm, extra-small, 130°, L 170mm
472.107S	PFNA-II Ø 12.0mm, extra-small, 130°, L 170mm
473.023S	PFNA-II Ø 10.0mm left, 125°, L 300mm
473.025S	PFNA-II Ø 10.0mm left, 125°, L 340mm
473.027S	PFNA-II Ø 10.0mm left, 125°, L 380mm
473.029S	PFNA-II Ø 10.0mm left, 125°, L 420mm
473.031S	PFNA-II Ø 9.0mm left, 125°, L 300mm
473.033S	PFNA-II Ø 9.0mm left, 125°, L 340mm
473.050S	PFNA-II Ø 10.0mm, long left, 125°, L 260mm

473.052S	PFNA-II Ø 10.0mm, long left, 125°, L 280mm
473.054S	PFNA-II Ø 10.0mm, long left, 125°, L 320mm
473.070S	PFNA-II Ø 9.0mm, long left, 125°, L 260mm
473.072S	PFNA-II Ø 9.0mm, long left, 125°, L 280mm
473.074S	PFNA-II Ø 9.0mm, long left, 125°, L 320mm
473.024S	PFNA-II Ø 10.0mm left, 130°, L 300mm
473.026S	PFNA-II Ø 10.0mm left, 130°, L 340mm
473.028S	PFNA-II Ø 10.0mm left, 130°, L 380mm
473.030S	PFNA-II Ø 10.0mm left, 130°, L 420mm
473.032S	PFNA-II Ø 9.0mm left, 130°, L 300mm
473.034S	PFNA-II Ø 9.0mm left, 130°, L 340mm
473.051S	PFNA-II Ø 10.0mm, long left, 130°, L 260mm
473.053S	PFNA-II Ø 10.0mm, long left, 130°, L 280mm
473.055S	PFNA-II Ø 10.0mm, long left, 130°, L 320mm
473.071S	PFNA-II Ø 9.0mm, long left, 130°, L 260mm
473.073S	PFNA-II Ø 9.0mm, long left, 130°, L 280mm
473.075S	PFNA-II Ø 9.0mm, long left, 130°, L 320mm
473.015S	PFNA-II Ø 10.0mm right, 125°, L 300mm
473.017S	PFNA-II Ø 10.0mm right, 125°, L 340mm
473.019S	PFNA-II Ø 10.0mm right, 125°, L 380mm
473.021S	PFNA-II Ø 10.0mm right, 125°, L 420mm
473.035S	PFNA-II Ø 9.0mm right, 125°, L 300mm
473.037S	PFNA-II Ø 9.0mm right, 125°, L 340mm
473.040S	PFNA-II Ø 10.0mm, long right, 125°, L 260mm
473.042S	PFNA-II Ø 10.0mm, long right, 125°, L 280mm
473.044S	PFNA-II Ø 10.0mm, long right, 125°, L 320mm
473.060S	PFNA-II Ø 9.0mm, long right, 125°, L 260mm
473.062S	PFNA-II Ø 9.0mm, long right, 125°, L 280mm
473.064S	PFNA-II Ø 9.0mm, long right, 125°, L 320mm
473.016S	PFNA-II Ø 10.0mm right, 130°, L 300mm
473.018S	PFNA-II Ø 10.0mm right, 130°, L 340mm
473.020S	PFNA-II Ø 10.0mm right, 130°, L 380mm
473.022S	PFNA-II Ø 10.0mm right, 130°, L 420mm
473.036S	PFNA-II Ø 9.0mm right, 130°, L 300mm
473.038S	PFNA-II Ø 9.0mm right, 130°, L 340mm
473.041S	PFNA-II Ø 10.0mm, long right, 130°, L 260mm
473.043S	PFNA-II Ø 10.0mm, long right, 130°, L 280mm
473.045S	PFNA-II Ø 10.0mm, long right, 130°, L 320mm
473.061S	PFNA-II Ø 9.0mm, long right, 130°, L 260mm

473.063S	PFNA-II Ø 9.0mm, long right, 130°, L 280mm
473.065S	PFNA-II Ø 9.0mm, long right, 130°, L 320mm
456.759S	PFNA-II Blade, length 75 mm, Titanium Alloy (TAN), sterile
456.760S	PFNA-II Blade, length 80 mm, Titanium Alloy (TAN), sterile
456.761S	PFNA-II Blade, length 85 mm, Titanium Alloy (TAN), sterile
456.762S	PFNA-II Blade, length 90 mm, Titanium Alloy (TAN), sterile
456.763S	PFNA-II Blade, length 95 mm, Titanium Alloy (TAN), sterile
456.764S	PFNA-II Blade, length 100 mm, Titanium Alloy (TAN), sterile
456.765S	PFNA-II Blade, length 105 mm, Titanium Alloy (TAN), sterile
456.766S	PFNA-II Blade, length 110 mm, Titanium Alloy (TAN), sterile
456.767S	PFNA-II Blade, length 115 mm, Titanium Alloy (TAN), sterile
456.768S	PFNA-II Blade, length 120 mm, Titanium Alloy (TAN), sterile
04.027.050S	PFNA-II Blade, length 75 mm, Titanium Alloy (TAN), sterile
04.027.051S	PFNA-II Blade, length 80 mm, Titanium Alloy (TAN), sterile
04.027.052S	PFNA-II Blade, length 85 mm, Titanium Alloy (TAN), sterile
04.027.053S	PFNA-II Blade, length 90 mm, Titanium Alloy (TAN), sterile
04.027.054S	PFNA-II Blade, length 95 mm, Titanium Alloy (TAN), sterile
04.027.055S	PFNA-II Blade, length 100 mm, Titanium Alloy (TAN), sterile
04.027.056S	PFNA-II Blade, length 105 mm, Titanium Alloy (TAN), sterile
04.027.057S	PFNA-II Blade, length 110 mm, Titanium Alloy (TAN), sterile
04.027.058S	PFNA-II Blade, length 115 mm, Titanium Alloy (TAN), sterile
04.027.059S	PFNA-II Blade, length 120 mm, Titanium Alloy (TAN), sterile
473.170S	PFNA-II End Cap, extension 0 mm, Titanium Alloy (TAN), sterile
473.171S	PFNA-II End Cap, extension 5 mm, Titanium Alloy (TAN), sterile
473.172S	PFNA-II End Cap, extension 10 mm, Titanium Alloy (TAN), sterile
473.173S	PFNA-II End Cap, extension 15 mm, Titanium Alloy (TAN), sterile
04.027.005S	PFNA-II End Cap, extension 0 mm, Titanium Alloy (TAN), sterile
04.027.006S	PFNA-II End Cap, extension 5 mm, Titanium Alloy (TAN), sterile
04.027.007S	PFNA-II End Cap, extension 10 mm, Titanium Alloy (TAN), sterile
04.027.008S	PFNA-II End Cap, extension 15 mm, Titanium Alloy (TAN), sterile
459.260	Locking Bolt Ø 4.9 mm, self-tapping, length 26 mm, Titanium Alloy (TAN), green
459.280	Locking Bolt Ø 4.9 mm, self-tapping, length 28 mm, Titanium Alloy (TAN), green
459.300	Locking Bolt Ø 4.9 mm, self-tapping, length 30 mm, Titanium Alloy (TAN), green
459.320	Locking Bolt Ø 4.9 mm, self-tapping, length 32 mm, Titanium Alloy (TAN), green
459.340	Locking Bolt Ø 4.9 mm, self-tapping, length 34 mm, Titanium Alloy (TAN), green

459.360	Locking Bolt Ø 4.9 mm, self-tapping, length 36 mm, Titanium Alloy (TAN), green
459.380	Locking Bolt Ø 4.9 mm, self-tapping, length 38 mm, Titanium Alloy (TAN), green
459.400	Locking Bolt Ø 4.9 mm, self-tapping, length 40 mm, Titanium Alloy (TAN), green
459.420	Locking Bolt Ø 4.9 mm, self-tapping, length 42 mm, Titanium Alloy (TAN), green
459.440	Locking Bolt Ø 4.9 mm, self-tapping, length 44 mm, Titanium Alloy (TAN), green
459.460	Locking Bolt Ø 4.9 mm, self-tapping, length 46 mm, Titanium Alloy (TAN), green
459.480	Locking Bolt Ø 4.9 mm, self-tapping, length 48 mm, Titanium Alloy (TAN), green
459.500	Locking Bolt Ø 4.9 mm, self-tapping, length 50 mm, Titanium Alloy (TAN), green
459.520	Locking Bolt Ø 4.9 mm, self-tapping, length 52 mm, Titanium Alloy (TAN), green
459.540	Locking Bolt Ø 4.9 mm, self-tapping, length 54 mm, Titanium Alloy (TAN), green
459.560	Locking Bolt Ø 4.9 mm, self-tapping, length 56 mm, Titanium Alloy (TAN), green
459.580	Locking Bolt Ø 4.9 mm, self-tapping, length 58 mm, Titanium Alloy (TAN), green
459.600	Locking Bolt Ø 4.9 mm, self-tapping, length 60 mm, Titanium Alloy (TAN), green
459.640	Locking Bolt Ø 4.9 mm, self-tapping, length 64 mm, Titanium Alloy (TAN), green
459.680	Locking Bolt Ø 4.9 mm, self-tapping, length 68 mm, Titanium Alloy (TAN), green
459.720	Locking Bolt Ø 4.9 mm, self-tapping, length 72 mm, Titanium Alloy (TAN), green
459.760	Locking Bolt Ø 4.9 mm, self-tapping, length 76 mm, Titanium Alloy (TAN), green
459.800	Locking Bolt Ø 4.9 mm, self-tapping, length 80 mm, Titanium Alloy (TAN), green
459.850	Locking Bolt Ø 4.9 mm, self-tapping, length 85 mm, Titanium Alloy (TAN), green
459.900	Locking Bolt Ø 4.9 mm, self-tapping, length 90 mm, Titanium Alloy (TAN), green
459.950	Locking Bolt Ø 4.9 mm, self-tapping, length 95 mm, Titanium Alloy (TAN), green
459.960	Locking Bolt Ø 4.9 mm, self-tapping, length 100 mm, Titanium Alloy (TAN), green
459.260S	Locking Bolt Ø 4.9 mm, self-tapping, length 26 mm, Titanium Alloy (TAN), green, sterile

459.280S	Locking Bolt Ø 4.9 mm, self-tapping, length 28 mm, Titanium Alloy (TAN), green, sterile
459.300S	Locking Bolt Ø 4.9 mm, self-tapping, length 30 mm, Titanium Alloy (TAN), green, sterile
459.320S	Locking Bolt Ø 4.9 mm, self-tapping, length 32 mm, Titanium Alloy (TAN), green, sterile
459.340S	Locking Bolt Ø 4.9 mm, self-tapping, length 34 mm, Titanium Alloy (TAN), green, sterile
459.360S	Locking Bolt Ø 4.9 mm, self-tapping, length 36 mm, Titanium Alloy (TAN), green, sterile
459.380S	Locking Bolt Ø 4.9 mm, self-tapping, length 38 mm, Titanium Alloy (TAN), green, sterile
459.400S	Locking Bolt Ø 4.9 mm, self-tapping, length 40 mm, Titanium Alloy (TAN), green, sterile
459.420S	Locking Bolt Ø 4.9 mm, self-tapping, length 42 mm, Titanium Alloy (TAN), green, sterile
459.440S	Locking Bolt Ø 4.9 mm, self-tapping, length 44 mm, Titanium Alloy (TAN), green, sterile
459.460S	Locking Bolt Ø 4.9 mm, self-tapping, length 46 mm, Titanium Alloy (TAN), green, sterile
459.480S	Locking Bolt Ø 4.9 mm, self-tapping, length 48 mm, Titanium Alloy (TAN), green, sterile
459.500S	Locking Bolt Ø 4.9 mm, self-tapping, length 50 mm, Titanium Alloy (TAN), green, sterile
459.520S	Locking Bolt Ø 4.9 mm, self-tapping, length 52 mm, Titanium Alloy (TAN), green, sterile
459.540S	Locking Bolt Ø 4.9 mm, self-tapping, length 54 mm, Titanium Alloy (TAN), green, sterile
459.560S	Locking Bolt Ø 4.9 mm, self-tapping, length 56 mm, Titanium Alloy (TAN), green, sterile
459.580S	Locking Bolt Ø 4.9 mm, self-tapping, length 58 mm, Titanium Alloy (TAN), green, sterile
459.600S	Locking Bolt Ø 4.9 mm, self-tapping, length 60 mm, Titanium Alloy (TAN), green, sterile
459.640S	Locking Bolt Ø 4.9 mm, self-tapping, length 64 mm, Titanium Alloy (TAN), green, sterile
459.680S	Locking Bolt Ø 4.9 mm, self-tapping, length 68 mm, Titanium Alloy (TAN), green, sterile

459.720S	Locking Bolt Ø 4.9 mm, self-tapping, length 72 mm, Titanium Alloy (TAN), green, sterile
459.760S	Locking Bolt Ø 4.9 mm, self-tapping, length 76 mm, Titanium Alloy (TAN), green, sterile
459.800S	Locking Bolt Ø 4.9 mm, self-tapping, length 80 mm, Titanium Alloy (TAN), green, sterile
459.850S	Locking Bolt Ø 4.9 mm, self-tapping, length 85 mm, Titanium Alloy (TAN), green, sterile
459.900S	Locking Bolt Ø 4.9 mm, self-tapping, length 90 mm, Titanium Alloy (TAN), green, sterile
459.950S	Locking Bolt Ø 4.9 mm, self-tapping, length 95 mm, Titanium Alloy (TAN), green, sterile
459.960S	Locking Bolt Ø 4.9 mm, self-tapping, length 100 mm, Titanium Alloy (TAN), green, sterile
458.926	Locking Screw Ø 5.0 mm, self-tapping, length 26 mm, Titanium Alloy (TAN)
458.928	Locking Screw Ø 5.0 mm, self-tapping, length 28 mm, Titanium Alloy (TAN)
458.930	Locking Screw Ø 5.0 mm, self-tapping, length 30 mm, Titanium Alloy (TAN)
458.932	Locking Screw Ø 5.0 mm, self-tapping, length 32 mm, Titanium Alloy (TAN)
458.934	Locking Screw Ø 5.0 mm, self-tapping, length 34 mm, Titanium Alloy (TAN)
458.936	Locking Screw Ø 5.0 mm, self-tapping, length 36 mm, Titanium Alloy (TAN)
458.938	Locking Screw Ø 5.0 mm, self-tapping, length 38 mm, Titanium Alloy (TAN)
458.940	Locking Screw Ø 5.0 mm, self-tapping, length 40 mm, Titanium Alloy (TAN)
458.942	Locking Screw Ø 5.0 mm, self-tapping, length 42 mm, Titanium Alloy (TAN)
458.944	Locking Screw Ø 5.0 mm, self-tapping, length 44 mm, Titanium Alloy (TAN)
458.946	Locking Screw Ø 5.0 mm, self-tapping, length 46 mm, Titanium Alloy (TAN)
458.948	Locking Screw Ø 5.0 mm, self-tapping, length 48 mm, Titanium Alloy (TAN)
458.950	Locking Screw Ø 5.0 mm, self-tapping, length 50 mm, Titanium Alloy (TAN)
458.952	Locking Screw Ø 5.0 mm, self-tapping, length 52 mm, Titanium Alloy (TAN)
458.954	Locking Screw Ø 5.0 mm, self-tapping, length 54 mm, Titanium Alloy (TAN)
458.956	Locking Screw Ø 5.0 mm, self-tapping, length 56 mm, Titanium Alloy (TAN)
458.958	Locking Screw Ø 5.0 mm, self-tapping, length 58 mm, Titanium Alloy (TAN)
458.960	Locking Screw Ø 5.0 mm, self-tapping, length 60 mm, Titanium Alloy (TAN)
458.964	Locking Screw Ø 5.0 mm, self-tapping, length 64 mm, Titanium Alloy (TAN)
458.968	Locking Screw Ø 5.0 mm, self-tapping, length 68 mm, Titanium Alloy (TAN)
458.972	Locking Screw Ø 5.0 mm, self-tapping, length 72 mm, Titanium Alloy (TAN)
458.976	Locking Screw Ø 5.0 mm, self-tapping, length 76 mm, Titanium Alloy (TAN)
458.980	Locking Screw Ø 5.0 mm, self-tapping, length 80 mm, Titanium Alloy (TAN)
458.985	Locking Screw Ø 5.0 mm, self-tapping, length 85 mm, Titanium Alloy (TAN)
458.990	Locking Screw Ø 5.0 mm, self-tapping, length 90 mm, Titanium Alloy (TAN)

458.995	Locking Screw Ø 5.0 mm, self-tapping, length 95 mm, Titanium Alloy (TAN)
458.999	Locking Screw Ø 5.0 mm, self-tapping, length 100 mm, Titanium Alloy (TAN)
04.005.516	Locking Screw Stardrive® Ø 5.0 mm, length 26 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.518	Locking Screw Stardrive® Ø 5.0 mm, length 28 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.520	Locking Screw Stardrive® Ø 5.0 mm, length 30 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.522	Locking Screw Stardrive® Ø 5.0 mm, length 32 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.524	Locking Screw Stardrive® Ø 5.0 mm, length 34 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.526	Locking Screw Stardrive® Ø 5.0 mm, length 36 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.528	Locking Screw Stardrive® Ø 5.0 mm, length 38 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.530	Locking Screw Stardrive® Ø 5.0 mm, length 40 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.532	Locking Screw Stardrive® Ø 5.0 mm, length 42 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.534	Locking Screw Stardrive® Ø 5.0 mm, length 44 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.536	Locking Screw Stardrive® Ø 5.0 mm, length 46 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.538	Locking Screw Stardrive® Ø 5.0 mm, length 48 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.540	Locking Screw Stardrive® Ø 5.0 mm, length 50 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.542	Locking Screw Stardrive® Ø 5.0 mm, length 52 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.544	Locking Screw Stardrive® Ø 5.0 mm, length 54 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.546	Locking Screw Stardrive® Ø 5.0 mm, length 56 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.548	Locking Screw Stardrive® Ø 5.0 mm, length 58 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.550	Locking Screw Stardrive® Ø 5.0 mm, length 60 mm, for Medullary Nails, Titanium Alloy (TAN), light green

04.005.552	Locking Screw Stardrive® Ø 5.0 mm, length 62 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.554	Locking Screw Stardrive® Ø 5.0 mm, length 64 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.556	Locking Screw Stardrive® Ø 5.0 mm, length 66 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.558	Locking Screw Stardrive® Ø 5.0 mm, length 68 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.560	Locking Screw Stardrive® Ø 5.0 mm, length 70 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.562	Locking Screw Stardrive® Ø 5.0 mm, length 72 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.564	Locking Screw Stardrive® Ø 5.0 mm, length 74 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.566	Locking Screw Stardrive® Ø 5.0 mm, length 76 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.568	Locking Screw Stardrive® Ø 5.0 mm, length 78 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.570	Locking Screw Stardrive® Ø 5.0 mm, length 80 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.575	Locking Screw Stardrive® Ø 5.0 mm, length 85 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.580	Locking Screw Stardrive® Ø 5.0 mm, length 90 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.585	Locking Screw Stardrive® Ø 5.0 mm, length 95 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.590	Locking Screw Stardrive® Ø 5.0 mm, length 100 mm, for Medullary Nails, Titanium Alloy (TAN), light green
04.005.516S	Locking Screw Stardrive® Ø 5.0 mm, length 26 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.518S	Locking Screw Stardrive® Ø 5.0 mm, length 28 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.520S	Locking Screw Stardrive® Ø 5.0 mm, length 30 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.522S	Locking Screw Stardrive® Ø 5.0 mm, length 32 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.524S	Locking Screw Stardrive® Ø 5.0 mm, length 34 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile

04.005.526S	Locking Screw Stardrive® Ø 5.0 mm, length 36 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.528S	Locking Screw Stardrive® Ø 5.0 mm, length 38 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.530S	Locking Screw Stardrive® Ø 5.0 mm, length 40 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.532S	Locking Screw Stardrive® Ø 5.0 mm, length 42 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.534S	Locking Screw Stardrive® Ø 5.0 mm, length 44 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.536S	Locking Screw Stardrive® Ø 5.0 mm, length 46 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.538S	Locking Screw Stardrive® Ø 5.0 mm, length 48 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.540S	Locking Screw Stardrive® Ø 5.0 mm, length 50 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.542S	Locking Screw Stardrive® Ø 5.0 mm, length 52 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.544S	Locking Screw Stardrive® Ø 5.0 mm, length 54 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.546S	Locking Screw Stardrive® Ø 5.0 mm, length 56 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.548S	Locking Screw Stardrive® Ø 5.0 mm, length 58 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.550S	Locking Screw Stardrive® Ø 5.0 mm, length 60 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.552S	Locking Screw Stardrive® Ø 5.0 mm, length 62 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.554S	Locking Screw Stardrive® Ø 5.0 mm, length 64 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.556S	Locking Screw Stardrive® Ø 5.0 mm, length 66 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.558S	Locking Screw Stardrive® Ø 5.0 mm, length 68 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.560S	Locking Screw Stardrive® Ø 5.0 mm, length 70 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.562S	Locking Screw Stardrive® Ø 5.0 mm, length 72 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile

04.005.564S	Locking Screw Stardrive® Ø 5.0 mm, length 74 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.566S	Locking Screw Stardrive® Ø 5.0 mm, length 76 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.568S	Locking Screw Stardrive® Ø 5.0 mm, length 78 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.570S	Locking Screw Stardrive® Ø 5.0 mm, length 80 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.575S	Locking Screw Stardrive® Ø 5.0 mm, length 85 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.580S	Locking Screw Stardrive® Ø 5.0 mm, length 90 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.585S	Locking Screw Stardrive® Ø 5.0 mm, length 95 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile
04.005.590S	Locking Screw Stardrive® Ø 5.0 mm, length 100 mm, for Medullary Nails, Titanium Alloy (TAN), light green, sterile

APPENDIX E: ABBREVIATIONS

Abbreviation	Terms
GCP	Good Clinical Practice
CRF	Case Report Form
SF-12	Short Form - 12
IRB	Institutional Review Board
EC	Ethics Committee
ERB	Ethics Review Board
BMI	Body Mass Index
IFU	Instructions for Use
AE	Adverse Event
SAE	Serious Adverse Event
UADE	Unanticipated Device Effect
ICH-GCP	International Conference on Harmonization – Good Clinical Practices
CV	Curriculum Vitae
HHS	Harris Hip Score
EQ5D	EuroQoL (Quality of Life)-5 Dimensions