

# Incidence and risk of Nail Breakage in patients implanted with the DePuy Synthes TFN-ADVANCED™ Proximal Femoral Nailing System (TFNA)

**First published:** 26/03/2020

**Last updated:** 16/01/2023

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/50577>

### EU PAS number

EUPAS34300

### Study ID

50577

### DARWIN EU® study

No

## Study countries

☐ United States

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## Study description

This is a retrospective cohort study of patients with femur fracture undergoing surgical repair with a cephalomedullary nail system in an inpatient setting. An overall cohort of patients implanted with cephalomedullary nails will be identified between January 2010 (in alignment with FDA approval date of Zimmer Natural Nail) and September 2019 or most recent data. A subset of the overall cohort implanted with TFNA, Stryker Gamma3, or Zimmer Natural Nail between February 2014 (in alignment with FDA approval date of TFNA) and September 2019 or most recent data will be identified to meet some of the objectives including the primary objective. The identified patients will be longitudinally followed for pre-specified time intervals until they experience the endpoint of interest (co-occurring diagnosis of breakdown of internal device AND procedure for femur fracture repair or device removal from femur) or a censoring event (end of hospital participation in PHD, end of risk window, end of study), whichever occurs first. Our rationale for requiring BOTH a diagnosis of breakdown of internal device AND a procedure for femur fracture repair or device removal from femur is due to the ICD-9/10 diagnosis codes for breakdown of internal device which are not specific to the cephalomedullary nails. Presence of a co-occurring procedure to repair a fractured femur or remove a device from the femur helps ensure that the device breakage refers to the device of interest. The graphic below provides a visual representation of the study design.

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## Study status

Finalised

## Research institutions and networks

# Institutions

## Johnson & Johnson

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

## Contact details

### Study institution contact

Anna Wallace

Study contact

[AWalla13@its.jnj.com](mailto:AWalla13@its.jnj.com)

### Primary lead investigator

Anna Wallace

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 23/03/2020

Actual: 23/03/2020

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### Study start date

Planned: 26/03/2020

Actual: 26/03/2020

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### **Date of final study report**

Planned: 31/12/2020

Actual: 02/11/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Johnson & Johnson

## Study protocol

[RWE19\\_SAF\\_013 TFNA Protocol\\_Final 2 .pdf](#)(628.04 KB)

## Regulatory

### **Was the study required by a regulatory body?**

No

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### **Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To estimate the incidence rate and the relative risk of nail breakage among patients implanted with the DePuy Synthes TFNA Proximal Nailing System compared to patients implanted with selected nails designed to provide cephalomedullary support to a proximal femoral fracture, the Stryker Gamma3 Nail System or Zimmer Natural Nail System.

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Retrospective study

## Study drug and medical condition

## **Medical condition to be studied**

Femur fracture

## **Population studied**

### **Short description of the study population**

Study population included patients with femur fracture undergoing surgical repair with a cephalomedullary nail system in an inpatient setting identified from the Premier healthcare database from January 2010 to September 2019.

Inclusion Criteria: Cephalomedullary Nail Overall Cohort

- >21 years\*, AND
- have an ICD-9/10 procedure code for femur fracture repair with internal fixation device, AND
- be treated surgically with a TFN, TFNA, Stryker Gamma3 or Zimmer Natural Nail cephalomedullary nail in an inpatient setting between January 1, 2010, and September 30, 2019 or most recent data (index procedure)

Inclusion Criteria: Cephalomedullary Nail Sub-cohort

- >21 years\*, AND
- have an ICD-9/10 procedure code for femur fracture repair with internal fixation device, AND
- be treated surgically with TFNA, Stryker Gamma 3 or Zimmer Natural Nail cephalomedullary nail in an inpatient setting between February 1, 2014 and September 30, 2019 or most recent data (index procedure)

\*Age 21 and older was selected to be in alignment with the TFNA indication, which is for the treatment of fractures in adults and adolescents in which the growth plates have fused.

Exclusion Criteria: Cephalomedullary Nail Overall Cohort & Cephalomedullary Nail Sub cohort

- Missing age or sex on index date
  - Presence of nail breakage ICD9/10 diagnosis code on index date
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### **Age groups**

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

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### **Special population of interest**

Other

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### **Special population of interest, other**

Patients with femur fracture

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### **Estimated number of subjects**

12000

## **Study design details**

### **Outcomes**

Nail breakage, defined as  $\geq 1$  ICD-9/10 diagnosis code for breakdown of internal device AND  $\geq 1$  ICD-9/10 procedure code for femur fracture repair or device removal from femur co-occurring within the same inpatient hospitalization with admission date between index date + 1 day and index date + 18 months

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## Data analysis plan

Descriptive statistics on baseline characteristics with comparison between exposure groups, Unadjusted incidence rate for nail breakage, Multivariate Cox Regression to determine HRs with 95% CI, Sensitivity analyses

## Documents

### Study publications

[Wallace A, Amis J, Cafri G, Coplan P, Wood J. Comparative Safety of the TFN-ADV...](#)

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## Data management

## Data sources

### Data source(s), other

Premier Healthcare Database

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### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications



**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No