

**MJ-FLEX™**  
THE NEW METAZEAU NAIL

voice  
of  
**design**



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## 1. Introduction

The MJ-FLEX THE NEW METAIZEAU NAIL™ is an intramedullary implant system specifically designed for Elastic Stable Intramedullary Nailing (ESIN) fracture fixation.

In the ESIN technique, two elastic nails are inserted through the metaphysis into the medullary canal, advanced through the fracture site and impacted into the opposite metaphysis; this allows for flexural, axial, translational and rotational stability [1, 2]. This method achieves biomechanical stability from the “C” shape of the nail which creates six points of fixation, enabling the construct to act as an internal splint, and allowing the creation of an elastic system that resists deformation.

The method of ESIN has gained popularity and is a well recognized method for treating paediatric long bone fractures. This technique has become more widely accepted because the surgery is minimally invasive, there is no absolute indication for postoperative immobilization using casts, shorter hospital stays, early recovery of joint motion, return to physical activity, and easier metal work removal [2, 3]. In addition, aesthetics is another important aspect for patients, because the wounds are small and less conspicuous than the traditional approach for plating [2].

Furthermore, elastic intramedullary nails have recently been successfully used as a complementary treatment to external fixation for bone lengthening. They can provide several advantages such as increased stability of bone fragments, lowered healing index, reduced septic and bone complications and shorter external fixator wearing time [4, 5].

The MJ-FLEX Nail has unique features that make it different from other elastic nails on the market. The technical features of the MJ-FLEX intramedullary implant system presented here demonstrate the unique advantages and benefits that this system offers.

## 2. Intended Use and Indications for Use

### Intended Use

The MJ-FLEX System is intended for the treatment of diaphyseal fractures of long bones.

### Indications for Use

The MJ-FLEX System is indicated to treat:

- upper extremity and clavicle fractures in all patients except newborns and infants;
- lower extremity fractures in pediatric patients, except newborns and infants, where the flexibility of the implant is paramount not to disrupt the growth plate;
- lower extremity fractures in small adults where the medullary canal is narrow.

### 3. System Description

#### 3.1 A comprehensive system available in titanium alloy and stainless steel with multiple nail diameters

The MJ-FLEX System is an intramedullary implant system with different diameters and lengths to assure compatibility with the anatomy of the patient.

Nails are available in Ti6Al4V titanium alloy and stainless steel. Six sizes (from 2.5mm to 5mm) are available for the titanium alloy option and the three bigger sizes (from 4mm to 5mm) are also available in stainless steel (Table 1 and Fig. 1).

Ti6Al4V titanium alloy		Stainless steel	
Diameters (mm)	Length (mm)	Diameters (mm)	Length (mm)
2.5	400	N/A	N/A
3	400	N/A	N/A
3.5	400	N/A	N/A
4	450	4	450
4.5	450	4.5	450
5	450	5	450

Table 1



Titanium alloy and stainless steel implants combine excellent mechanical stability with elastic properties. Titanium elastic nails (TENs) are implanted more commonly than stainless steel nails due to surgeon's preference and because the biochemical properties of titanium (lower modulus of elasticity, better osseointegration, and it allows for magnetic resonance imaging) are often considered to be better [6, 7]. However, clinical studies [7, 8] suggest that the increased stiffness of stainless steel nails could be beneficial to prevent malunion. Other researchers have reported that stainless steel nails might be preferable to titanium nails in adolescents and obese children [9].

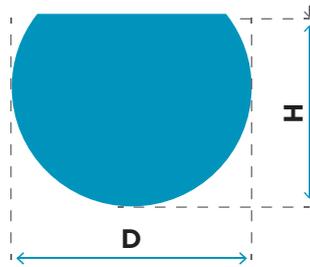
## 4. Technical Features and Advantages

### 4.1 The patented flat surface

The main innovative feature of the MJ-FLEX nails is the patented flat surface along the major axis of the nail. This section of the nail can be described by two elements (Fig. 2):

Fig. 2

**D** = the diameter of the nail  
**H** = the height



**The height and not the diameter of the MJ-FLEX nail is the correct parameter to be used for comparisons with standard cylindrical nails.**

According to  $\varnothing$  IM canal, two calculations are therefore equivalent to select the appropriate size of the nail (Table 2):

**D** =  $0.5 \times \varnothing$  IM canal  
 or  
**H** =  $0.4 \times \varnothing$  IM canal



**PRECAUTION:** The diameter of the selected nail should be no more than 50% of the width of isthmus. In case two nails with different diameters are used, the sum of the two diameters should not be more than the width of the isthmus.

$\varnothing$ IM canal	Nail size	
	D (laser marked)	H
5.0	2.5	2.0
6.0	3.0	2.4
7.0	3.5	2.8
8.0	4.0	3.2
9.0	4.5	3.6
10.0	5.0	4.0

Table 2

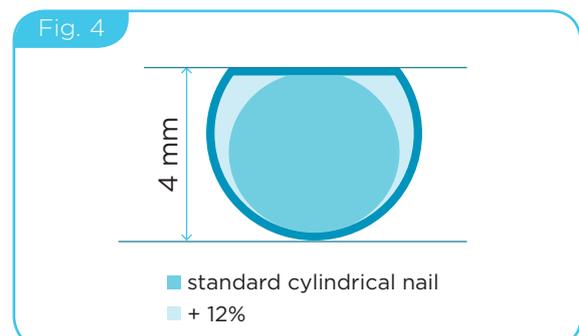
#### THIS FEATURE PROVIDES SEVERAL ADVANTAGES:

- Easy visualization of the correct plane for nail bending
- Optimal jaw-nail matching for an easier insertion (Fig. 3)
- Enables direct visual control of the alignment of the nail tip in the medullary canal and thus a smooth insertion of the nail along the medullary canal, potentially reduce X-rays exposure and operative time
- The flat surface allows optimal filling of the medullary canal. The increase in medullary canal filling is + 12% for each nail in comparison to a standard cylindrical nail (Fig. 4)
- Mechanical advantages (see also section 7 Mechanical tests)

Fig. 3



Fig. 4



Theoretical performances of one MJ-FLEX nail in comparison to a cylindrical nail:

**Average\* increase in flexural stability on the X axis**

The theoretical increase in flexural stability has been calculated with the ratio between the inertia module of the MJ-FLEX nail ( $I_{xMJ FLEX}$ ) and the inertia module of a corresponding standard cylindrical nail ( $I_{circle}$ ).

$$\left( \frac{I_{xMJ FLEX}}{I_{circle}} - 1 \right) * 100 = \mathbf{48,6\%}$$

**Average\* increase in flexural stability on the Y axis**

The theoretical increase in flexural stability has been calculated with the ratio between the inertia module of the MJ-FLEX nail ( $I_{yMJ FLEX}$ ) and the inertia module of a corresponding standard cylindrical nail ( $I_{circle}$ ).

$$\left( \frac{I_{yMJ FLEX}}{I_{circle}} - 1 \right) * 100 = \mathbf{126\%}$$

**Average\* increase torsional stability**

The theoretical increase in flexural stability has been calculated with the ratio between the polar moment of the MJ-FLEX nail ( $J_{p MJ FLEX}$ ) and the polar moment of a corresponding standard cylindrical nail ( $J_{p circle}$ ).

$$\left( \frac{J_{p MJ FLEX}}{J_{p circle}} - 1 \right) * 100 = \mathbf{87,4\%}$$

*\* Each MJ-FLEX nail size is characterized by different theoretical performances. Here average values are reported.*

**4.2 The “ship bow” tip**

The tip of the nail has a “ship bow” shape (Fig. 5) designed to allow an easy insertion and provide easy anchoring in the metaphysis and lateral stability.



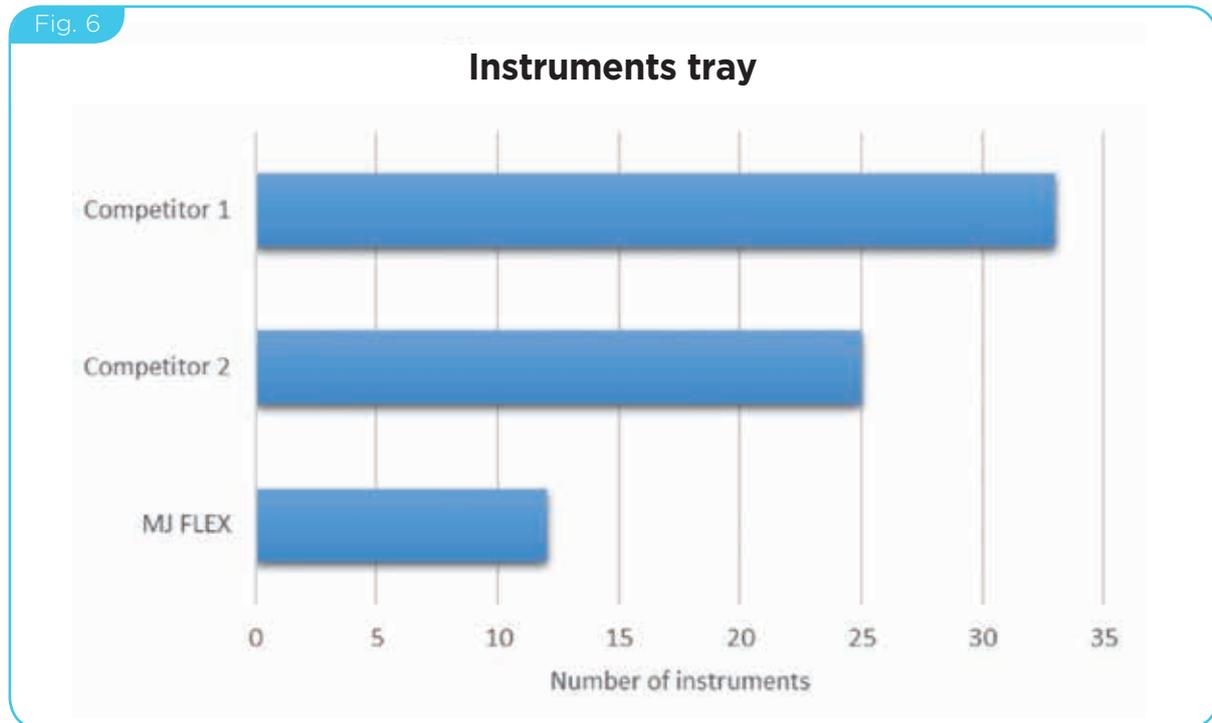
Fig. 5

## 5. Instrumentation

### 5.1 A simple and reduced instrumentation

The number of instruments needed to insert an MJ-FLEX nail is fewer in comparison to typical competitors (Fig.6). This suggests that the operative technique is simple and straightforward.

Fig. 6



## 6. MJ-FLEX System: Benefits

### Features and Benefits

- Dedicated for the treatment of diaphyseal long bones fractures in pediatric patients, except newborns and infants, and in small adults where the small size and minimally invasiveness of the device is the main priority
- The patented shape allows insertion of a strong nail to optimally fill the medullary canal
- Titanium and stainless steel options
- Strong, elastic and easy to bend
- Sterile implants
- Nails are supplied in different diameters and lengths to assure compatibility with anatomy of the patient

### Surgeon Benefits

- Developed to allow a direct visual control of the alignment of the nail tip in the medullary canal, potentially this can reduce exposure to the image intensifier during insertion of the nail and it can reduce the surgery time
- The flat surface allows to bend the nail on a proper plane
- Dedicated instrumentation for a streamlined operative technique
- A great variety of nails in several diameters both in titanium and stainless steel

### Patient Benefits

- Stability of the osteosynthesis in all planes due to the superior medullary canal filling than standard cylindrical nails
- Developed to limit x-ray exposure during insertion due to the unique shape that allows visual control of nail orientation
- A minimal invasiveness of the device

## 7. Mechanical Tests

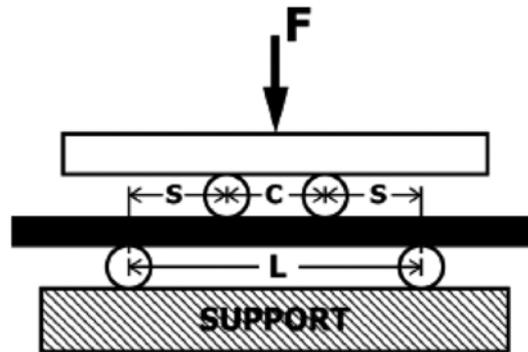
A series of mechanical tests was performed internally to characterize the MJ-FLEX System (data on file).

### 7.1 Bending stiffness

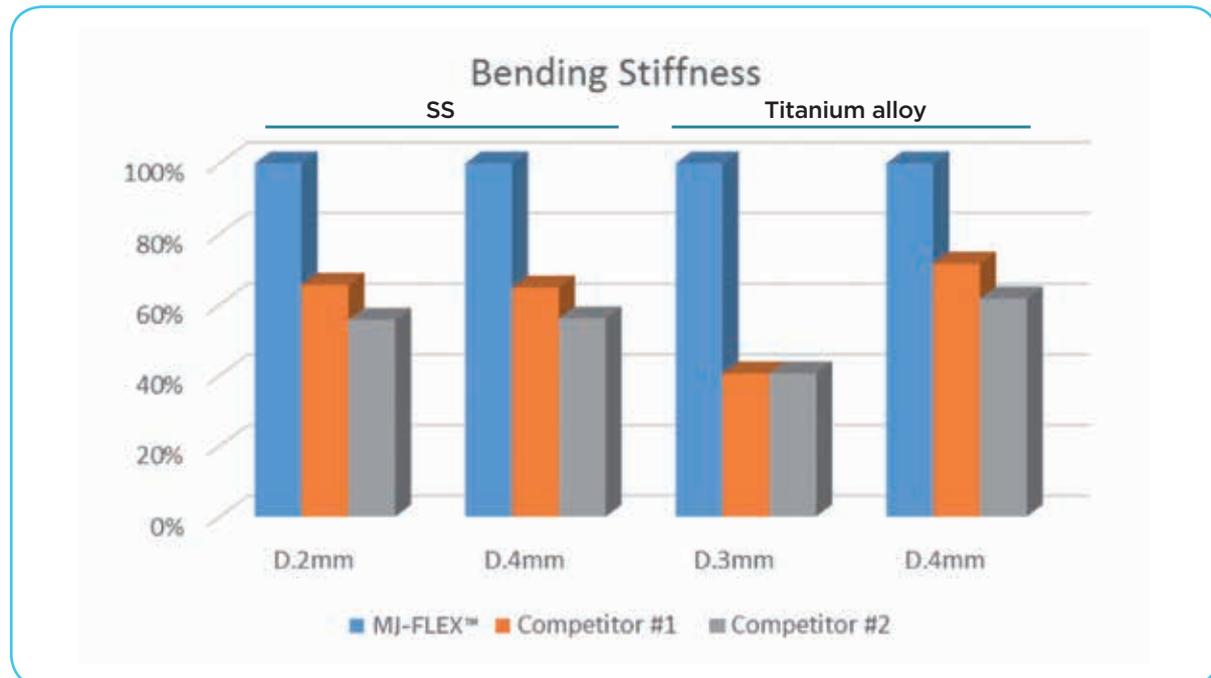
**Aim:** evaluation of bending stiffness of MJ-FLEX nail vs two main competitors.

**Set up:** the test was performed according to ASTM standard F1264. Static load was applied as shown in [Fig. 7](#).

Fig. 7



**Results:**



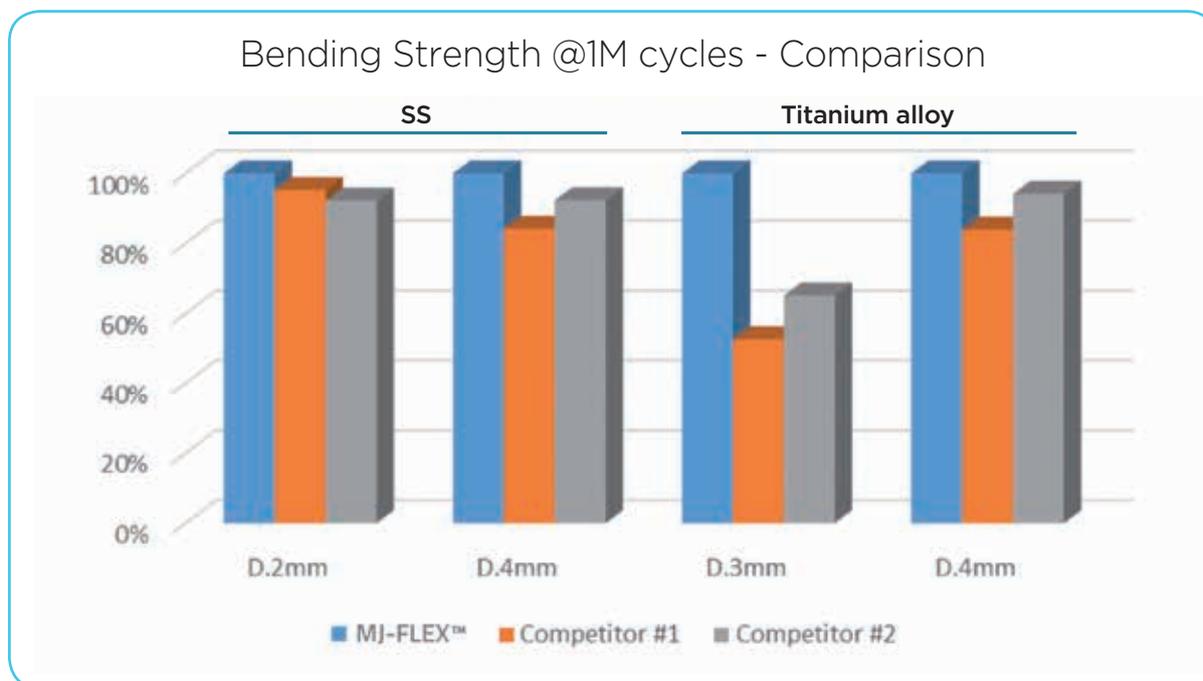
MJ-FLEX nail is characterized by a higher bending stiffness in comparison to two competitors.

## 7.2 Bending strength at 1 million cycles

**Aim:** evaluation of bending strength of MJ-FLEX nail at 1 million cycles vs two main competitors.

**Set up:** the test was performed according to ASTM standard F1264. Cyclic load was applied as shown in [Fig. 7](#).

### Results:



MJ-FLEX is characterized by an equivalent or superior bending strength when compared to two competitors.

## 8. Useful Documents

- Operative technique (MJ-1702-OPT)
- Brochure (MJ-1701-PL)

- Oral presentation:

Bah M, Suchier Y, Denis D, Metaizeau JD. Pre-clinical analysis of the performance of a new elastic stable intramedullary nail design. *Orthopedic Proceedings* Feb 2017 vol. 99-B SUPP 3 24

[http://bjjprocs.boneandjoint.org.uk/content/99-B/SUPP\\_3/24](http://bjjprocs.boneandjoint.org.uk/content/99-B/SUPP_3/24)

## 9. References

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Electronic Instructions For Use available at the website <http://ifu.orthofix.it>

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- Internet connection (56 kbps)
- Device capable to visualize PDF (ISO/IEC 32000-1) files
- Disk space: 50MB

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