VERO™ NAIL
Trochanteric System

Veronail

voice of design

ORTHOFIX®
Orthopedics International

Orthofix approach to Evidence Based Medicine:

For years, clinical decision-making was based primarily on physician knowledge and expert opinion. Now the medical community is searching for measurable outcomes "validating" efficacy of treatments. EBM is an approach that integrates individual clinical expertise with the best available evidence when making decisions about patient treatment. (Nierengarten M.B. et al. Using Evidence Based Medicine in Orthopaedic Clinical Practice: The Why, When, and How-To Approach. Medscape Orthopaedics & Sports Medicine. 2001;5(1)).
There has been a significant growth in evidence based medicine over the last few years.

Document Objective:

This document provides a brief summary of the technical and scientific information of the design features of the Veronail trochanteric nail, how they benefit to potential users.

It discusses specific features of the product such as small nail diameter, biaxial cephalic fixation, the different cephalic and distal configurations and the design of the proximal screws and distal peg.

It also includes a glossary of terms and a bibliography of articles to consult for more information on the technical and scientific reasons for choice of these product features.

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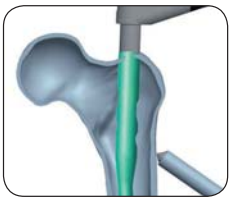
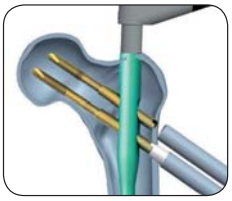
Veronail: Features summary

I. SMALL DIAMETER NAILING SYSTEM...

... Improves functional outcomes

- Small diameter nail reduces trauma during insertion
  - Smaller entrance site
  - Less medullary reaming
  - Less damage to the abductor muscles
- Small diameter of cephalic screws minimizes risk of fracturing the lateral wall
  - The integrity of the lateral wall reduces the risk of collapse
  - The result is better post-operatory mobility

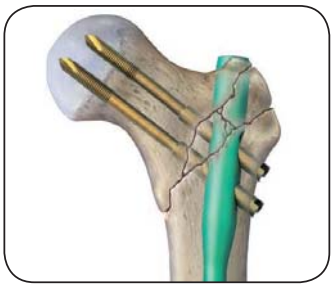




II. DUAL PROXIMAL SCREWS...

... Improve system stability

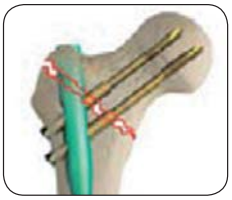
- Improve control of the fracture during the intra-operative and post-operative phases
- Improve rotational stability with respect to single axis systems
- Comparable fatigue resistance with respect to single axis systems



III. TWO PROXIMAL SCREW CONFIGURATIONS...

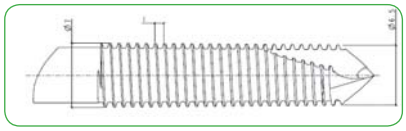
... Meet all clinical requirements and types of proximal femoral fractures

- Sliding parallel cephalic screws are recommended in cases in which the the two proximal screws cross the fracture line (fractures classifiable as 31A.1 and 31A.2 on the basis of AO)
- Convergent locked cephalic screws are recommended when the two proximal screws do not cross the fracture line (fractures classifiable as 31A.3 on the basis of AO)
- Possible to choose optimal proximal screw configuration intraoperatively.



IV. PROXIMAL LOCKING

1. Cephalic screws (parallel and convergent) Improve bone purchase



- Fine thread pitch results in:
  - Greater stability
  - Better osteointegration
  - Less invasiveness, meaning less bone removed during insertion
- Low thread profile means:
  - Optimal stress distribution at the screw/bone interface
  - Decreased osteolysis
- Conical shape of the thread means:
  - Greater stability of the system due to the radial pre-loading effect

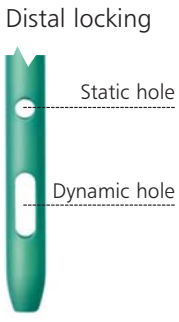
2. Parallel cephalic screws Facilitate sliding

- The barrel design optimizes sliding and permits controlled fracture compaction
- Sliding is controlled in both directions

3. Convergent cephalic screws Provide rigid strong fixation

- The convergent screws, locked to the nail, provide rigid strong fixation when required.

V. TWO DISTAL SCREW CONFIGURATIONS...



... Meet different clinical requirements depending on the type of fracture

- The nail can be locked statically or dynamically or left unlocked distally.

VI. DISTAL LOCKING

The distal peg-screw

- The unthreaded shaft increases resistance to fatigue
- The reverse/left-handed thread makes it easy to remove the peg

INDEX

1.0 DEFINITIONS

Conical shape:
characteristic description of a nail whose diameter progressively changes from the proximal end to the distal end.

Thread profile:
this describes the complete shape of a screw thread and includes the values of each geometric property.

Pitch:
distance between two crests of a thread.

Fine pitch:
if the distance between two crests is less than 1.5 mm, it is considered to be a "fine pitch".

Osteolysis:
localized loss of bone tissue, so that only its connective structure remains, due to a number of different causes. In radiographic examinations it appears as a well-defined region which is less dense than the surrounding bone tissue.

Stripping:
removal of the threads made in the bone by the self tapping or self drilling screw.

PPI (pin performance index):
ratio of insertion to extraction torque.

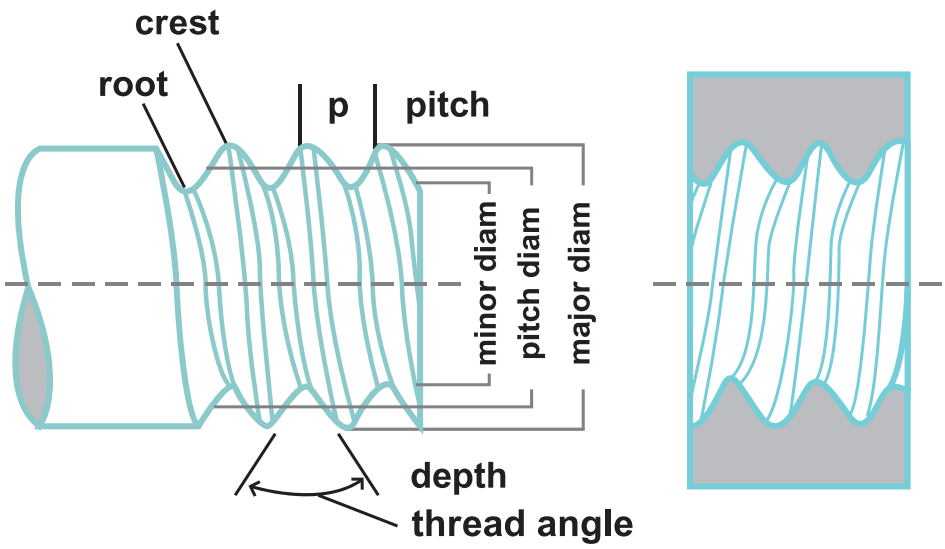


Fig.1 Detail of the thread screw

2.0 DESIGN AIMS

The Veronail was designed after considering different types of trochanteric fractures which occur in patients and the methods by which they are treated.
This device combines the advantages of intramedullary nailing with high cephalic stability achieved by a double axis system. Small proximal and distal diameter permits percutaneous insertion without reaming.

What distinguishes this system from other double axis systems is the alternative configurations of the cephalic screws, either two parallel sliding screws in a barrel anchored to the nail or two converging screws locked directly to the nail. In addition, the PORD device (Posterior Reduction Device) may be used during nail insertion to correct posterior sagging of the fracture and to maintain the reduction during fixation.

PORD is compatible with the majority of standard operating tables and is positioned underneath the patient's hip.

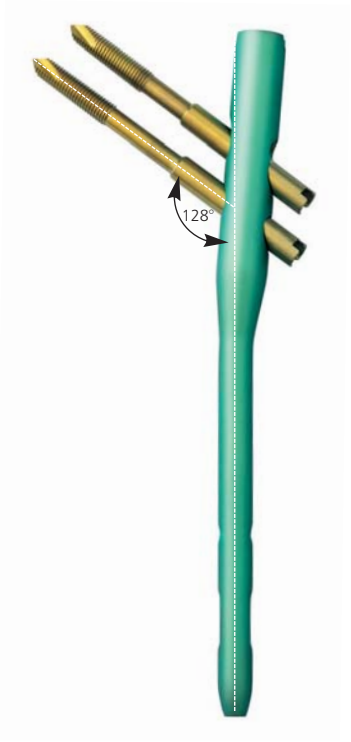


Fig.2 Parallel cephalic screws

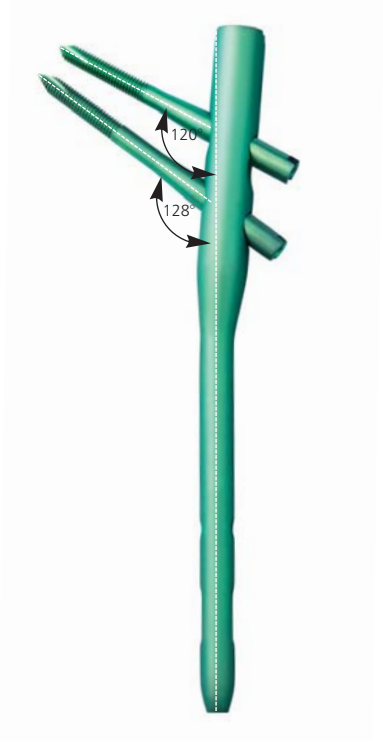


Fig.3 Converging cephalic screws

3.0 NAIL, SCREW AND PEG IMAGES AND DIMENSIONS

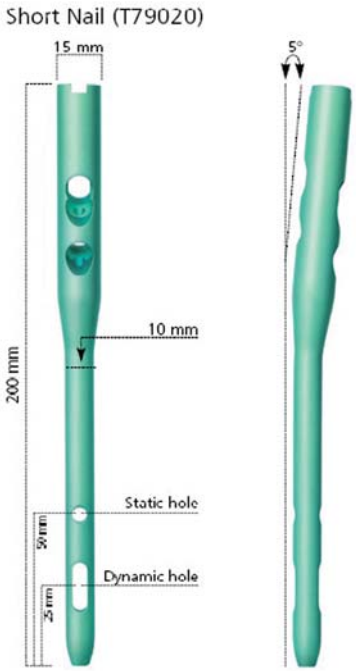


Fig.4 Short Nail

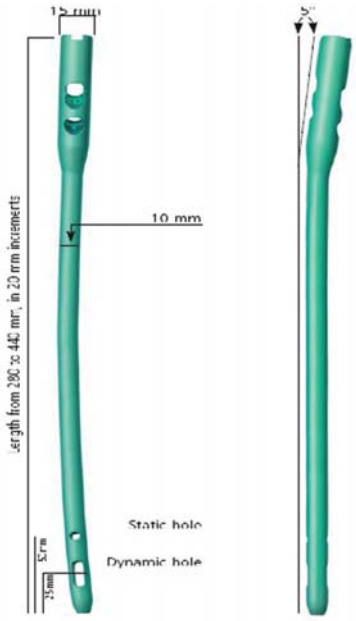


Fig.5 Long Nail

CEPHALIC SCREWS

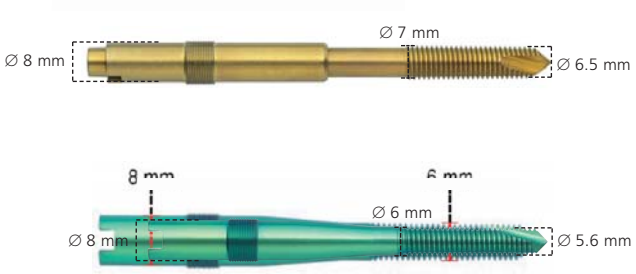


Fig.6 Cephalic Screws

DISTAL PEG

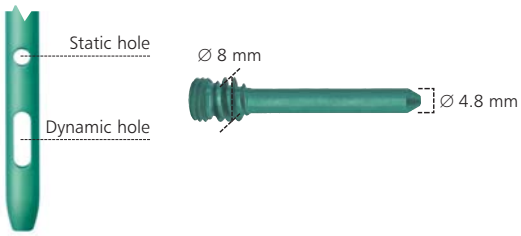


Fig.7 Distal Peg

4.0 SMALL DIAMETER NAILING SYSTEM...

... 4.1 Improves functional outcomes

4.1.1 Less trauma at the time of insertion

A small diameter nail causes less trauma during insertion.

- The surgical incision does not need to be very large, speeding up healing time.
- In the majority of patients reaming is not necessary to place the nail in the medullar canal, meaning less bone loss and less chance of damaging the gluteus medius tendon's at its insertion on the trochanter.
- The nail is placed through the abductor muscle so the smaller the diameter, the less trauma suffered by the muscle. With less damage to the muscle, there should be less effect on the patient's gait.

4.1.2 Less risk of lateral wall fracture

A small diameter cephalic screw helps to reduce trauma to the lateral wall which may cause a poor functional outcome.

- An intra- or post-operative lateral wall fracture is associated with the use of large diameter implant, such as the barrel of a DHS.

[Gotfried Y. The lateral trochanteric wall: a key element in the reconstruction of unstable pertrochanteric hip fractures. Clin Orthop Relat Res. 2004 Aug;(425):82-6.]

- Lateral wall fractures are associated with failure to recover mobility and poor functional outcome.

[Im G, Shin Y, Song Y. Potentially unstable intertrochanteric fractures. J Orthop Trauma 2005 Jan;19(1):5-9]

- Post-operative lateral wall fracture is the main indicator of the need for a second operation in intertrochanteric fractures. Data collected by Palm has revealed that 3% of patients with an intact lateral wall require reoperation, as compared to 22% of patients with a fractured lateral wall.

[Palm H, Jacobsen S, Sonne-Holm S et al. Integrity of the lateral femoral wall in intertrochanteric hip fractures: an important predictor of a reoperation. JBJS 2007; 89:470-475]

5.0 DUAL PROXIMAL SCREWS...

... 5.1 Improve system stability

5.1.1 Excellent fracture control intra-operatively through to healing

Dual proximal screws improve fracture control during the intra-operative and post-operative periods; the improved control helps maintain fixation and alignment of bone fragments.

- Intra-operative advantages: insertion of a single lag screw may cause rotation of the distal fragment by up to 30°. Use of 2 proximal screws eliminates the need for using multiple guide wires during fixation. This may extend the duration of surgery and result in a partial loss of reduction.

[Mills. Displacement of subcapital fracture during internal fixation. Aus NZJ Surgery 1989]

- Post-operative advantages: two screws provide better rotary control. The forces involved in mobilisation and ambulation may cause loss of stability, resulting in poor functioning and potential breakage of the screw. Specifically, bending may cause varus instability of the femoral head and torsion may cause head rotation.

5.1.2 More rotational stability with respect to single axis systems

Proximal fixation with a double axis maintains better rotational stability than a single axis system.

- A study conducted by Swiontkowski found that double axis fixation is associated with better rotational stability and compacting of the trochanteric fracture. The results of measurement of an intact femur were compared with those of a fractured femur treated with dual and single screw fixation.

The findings showed the benefit of the dual screw fixation:
- The intact femur has 100% rotational stability;
- Single axis fixation provides 23% of the stability of the intact fracture;
- Double axis fixation provides 60% of the stability of the intact fracture.

The study concluded that a system with multiple screws permits better control of torsional stability than a device with a single axis.

[Swiontkowski M. Torsion and bending analysis of internal fixation techniques for femoral neck fracture: the role of implant design and bone density. Journal of Orthopaedic Research, 1987.]

... 5.2 Comparable fatigue resistance with respect to single axis systems

5.2.1 Less trauma at the time of insertion

Fatigue resistance with two screws of smaller diameter is comparable to that obtained with a single large diameter screw.

The fatigue life performance with the Veronail was tested using the model published by Colombo.

[Colombo M, Raimondi M, Villa T, Quaglini V, Pietrabissa R. The biomechanics of intramedullary nailing: a protocol for laboratory testing. Journal of Mechanics in Medicine and Biology, Vol. 2, No. 1 (2001) 1-17]

The testing machine was run to 1 million cycles without failure at various levels of weight and for different types of fractures.

The Veronail results are comparable to those achieved with an intramedullary nail with a single, larger diameter screw.

6.0 TWO PROXIMAL SCREW CONFIGURATIONS...

... 6.1 Meet all clinical requirements and types of proximal femoral fractures

The Veronail nail permits two different types of cephalic configuration: two parallel sliding screws or two converging fixed screws.

The choice of the proximal configuration to be used depends on the clinical and biomechanical characteristics of the fracture and of the patient.

- Sliding parallel screws are recommended if the screws cross the fracture line (fractures classifiable as 31A.1 and 31A.2 according to AO).
- Locked converging screws are recommended if the fracture line is lower and is not crossed by the screws (fractures classifiable as 31A.3 on the basis of AO).

The nail is the same in both types of configuration, allowing the surgeon to choose the screw configuration best suited to the type of fracture even intraoperatively.

7.0 PROXIMAL LOCKING

7.1 Measurement of the cephalic screw length

To measure the length of the screws to be implanted, the Veronail operative technique involves positioning a Kirshner wire 5 to 10 mm from the articular surface. The appropriate locking screw length may be determined by inserting the screw ruler into the recess on the handle. The length of the cephalic screws is read from the position of the end of the K-wire.
After inserting the proximal screw, the K-wire is removed and the surgeon proceeds with drilling and insertion of the distal cephalic screw. This technique prevents the wire from being pulled slightly forward during drilling and considerably decreases the need for the image intensifier during the drilling phase.
Therefore proximal locking takes place in a situation of stability; during proximal screw insertion, the system is locked in place by the K-wire, during distal screw insertion the proximal cephalic screw keeps the system in the right position.

7.2 Cephalic screw design improves bone purchase

7.2.1 Fine thread pitch

In the Veronail cephalic screws the distance from the crest of one thread to the crest of the next is 1 mm.

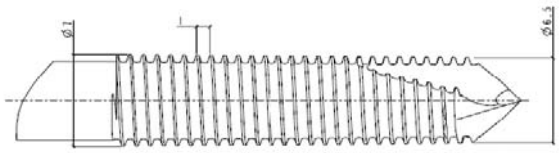


Fig.8 Thread pitch in the cephalic screw

The choice of fine pitch for the thread attenuates the stripping effect during insertion and damage to bone, reducing loss of bone mass. These two benefits promote greater osteointegration around the screw.

[Gausepohl T, Mohring R, Penning D, Koebke J. Fine thread versus coarse thread. A comparison of the maximum holding power. Injury 32 (2001) S-D-1-S-D-7]

7.2.2 Low thread profile

Choice of low thread profile translates into a 17% increase in the screw/bone contact surface thanks to the fine pitch of the thread.

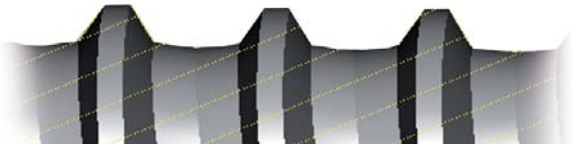
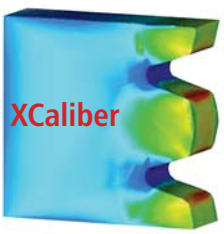
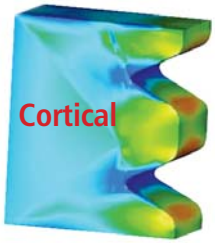


Fig.9 Cephalic screw thread profile

When screw loading occurs, this profile produces a reduction in point pressure and the optimization of stress distribution, that reduces the phenomenon of osteolysis.

- Finite Element Analysis conducted by Orthofix assessed the area of contact at the screw/bone interface in relation to different thread profiles. Compared to other designs, the XCaliber screw profile, which is the same as Veronail cephalic screws, was superior.





Thread	mm^2
Cortical Screw	18.01
XCaliber Screw	21.06

Tab.1 bone/screw contact surfaces

7.2.3 Combined effect

The low profile and fine pitch of the thread reduce the stripping effect both during insertion of the screw and under loads. These two effects attenuate the formation of micro-cracks (microscopic lesions) during insertion. The lateral wall is less affected, with extremely beneficial results for the patient. Analyses conducted by the Royal Vet College, UK (Prof. Goodship), at the Anatomy School of the University of Cologne (Prof Koebke) in vivo and ex-vivo and at St. Vincenz Hospital, Cologne (Prof D. Pennig) have confirmed this effect.

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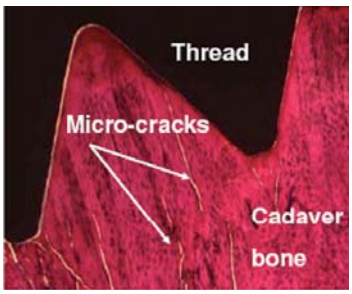


Fig.10 Histological image at the cadaver bone/screw interface

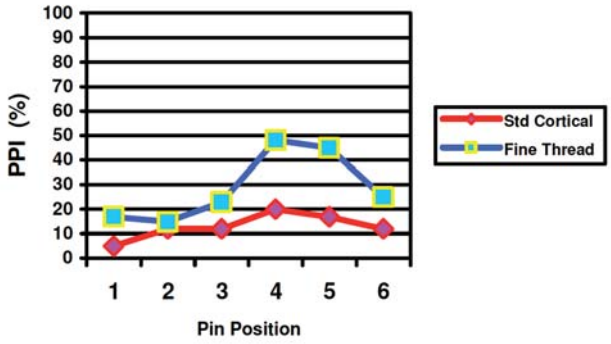
7.2.4 Conical shape

The diameter of the thread increases from the screw tip to the junction with the shank. In the parallel sliding screw the diameter varies from 6.5 to 7 mm, while in the converging screw it varies from 5.6 to 6 mm.

This conical shape produces radial pre-load: as the screw is inserted, the smaller distal end makes the initial path through the bone. As the screw advances, its diameter increases exerting radial pressure on the first cortex. This results in less osteolysis and improves the holding power of the screw.

This compression caused by the radial pre-load ensures that bone adheres perfectly to the screw profile, promoting bone integration.

- An animal study conducted by Orthofix at the Royal Vet. College (UK) compared the holding power (PPI: pin performance index) of the fine threaded conical screw to a standard cortical screw. The results revealed that the combination of these two design features (conical shape and fine thread) leads to a better PPI value with less pin loosening.



Tab.2 PPI variation in different screw positions

7.3 Parallel cephalic screws facilitate sliding

Fig.11 Parallel sliding screw

A particular feature of parallel screws is their ability to slide inside the barrel in which they are contained. First the barrel is screwed and locked onto the nail; then the screw is moved forward inside the head of the femur until it reaches the desired position.

Once the screws are in position, the screws can therefore slide distally inside the barrel, providing physiological compression at the fractures site.

- A 1998 publication demonstrated that the load on the femoral head is transformed into a sliding motion. This motion, which promotes compression and compacting of the fracture along the axis of the implant, is facilitated if the barrel is longer.

[Loch D.A. Forces required to initiate sliding in second generation intramedullary nails. J Bone Joint Surg Am. 1998 Nov;80(11):1626-31]

Intertrochanteric fracture treatment with fixed angle implants has now been almost entirely replaced by sliding screw devices, which have improved the union rate and decreased the incidence of implant failure.

- A meta analysis of 14 studies regarding 3069 patients revealed reduced risk of cut-out (4% vs 13%), non union (0.5% vs 2%), implant breakage(0.7% vs 14%) and need for reoperation (4% vs 10%) for the "sliding hip screw" as compared to the "fixed nail plate".

[Chinoy MA, Parker MJ. Fixed nail plates versus sliding hip system for the treatment of trochanteric femoral fractures: a meta analysis of 14 studies. Injury 1999 157-163]

The success of treatment also depends largely on the extent of sliding.

- A 1995 study correlated implant success or failure with the amount of sliding permitted. It resulted that fractures treated with devices permitting less than 10 mm of sliding had a failure risk 3.2 times greater.

[Gundle R, gargan MF, Simpson AHRW. How to minimize failure of fixation of unstable intertrochanteric fractures. Injury 1995 611-14]

The particular design of Veronail parallel sliding screws permits sliding of between 10 and 40 mm, depending on the length of the screw used. Furthermore screw displacement is not allowed in either direction.

7.3.1 Pitch of the barrel thread

The apparent pitch of the barrel thread is 0.5 mm. However this pitch is due to two different threads (each with a pitch of 1 mm) that are intertwined; this is technically defined as a double start thread. As result the barrel advances 1 mm into the nail per revolution. This technical solution increases the resistant section of the barrel with respect to a single thread with a pitch of 0.5 mm.

7.4 Convergent cephalic screws provide rigid strong fixation

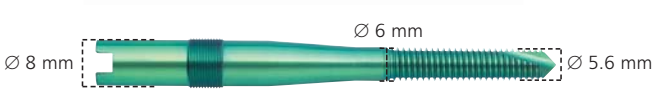


Fig.12 Convergent locked screw

The convergent screw is locked into the nail and does not slide hence providing a rigid strong fixation.
The thread part of the screw, that engages into the nail, has the same characteristics as the barrel thread of the parallel screw. As the thread pitch of the tip is 1 mm (see figure 8), the convergent screw advances 1 mm into the nail and into the bone per revolution. Thanks to this technical solution, both configurations can be used without the need for two different nails.

8. TWO DISTAL SCREW CONFIGURATIONS...

... 8.1 Meet different clinical requirements depending on the type of fracture

Locking of the distal peg-screw may be static or dynamic, depending whether it is inserted in the circumferential hole or the oval one.

Use of the most appropriate locking method on the type of fracture; Orthofix recommends inserting the peg-screw in the static hole in 31.A2 fractures and in the dynamic hole in 31.A3 fractures. In fractures classified as 31.A1 the choice of static locking is optional.

Distal locking contributes rotational stability and rigidity to the system. However, the literature reports a high rate of post-operative complications – especially diaphyseal fractures - at the tip of intramedullary nails and the hole for distal locking.

[Efstathopoulos N, Nikolaou V, Lazarettos J. Intramedullary fixation of intertrochanteric hip fractures: a comparison of two implant designs. International Orthop 2007 31:71-76.]

This problem is mitigated by use of a more elastic material, such as titanium, which provides mechanical characteristic more comparable to human bone in comparison with stainless steel.

[Heinert G, Parker MJ.Intramedullary osteosynthesis of complex proximal femoral fractures with the Targon PF nail. Injury 2007; 38(11):1294-9]

9. DISTAL LOCKING

Distal locking is achieved with a partially threaded peg-screw.

- The results of an internal test conducted by Orthofix revealed that the Veronail distal pegscrew has greater resistance to stress than a completely threaded locking screw with an external diameter of 5 mm. This is because the structure of the peg is uniform throughout its entire length. On the contrary the fully threaded screw has a resistance depending on pitch and thread profile.

Fig.13 Distal peg-screw with a diameter of 4.8 mm

Fig.14 Completely threaded distal locking screw with a diameter of 5 mm

Another characteristic of the distal peg-screw is reverse/left-handed threading on the head, permitting easy extraction if the implant is removed. The dedicated screwdriver screws onto the thread of the peg head and, if turned further in the same direction, unscrews the peg-screw from the first cortex.
The hold between the screw head and the screwdriver guarantees good system stability and easy peg extraction.

10. CONCLUSIONS

The particular features of the Veronail are the result of careful biomechanical studies of hip fractures and a long scientific and engineering research resulting in a system with a high degree of versatility which provides great stability and better recovery of pre-trauma functions.

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