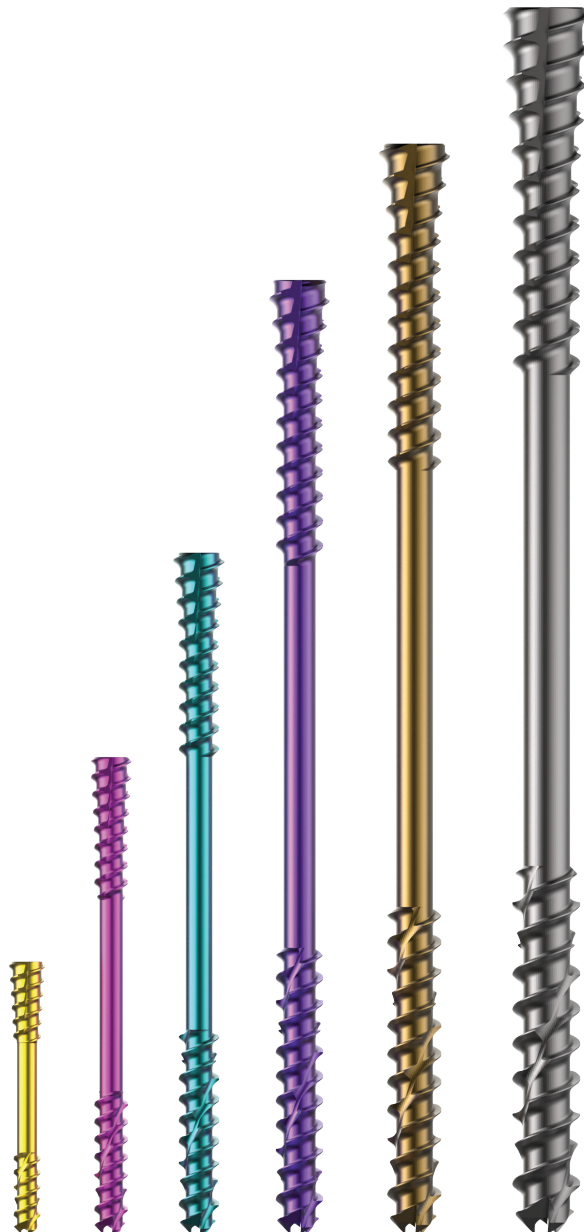


NX Nail

Design Rationale



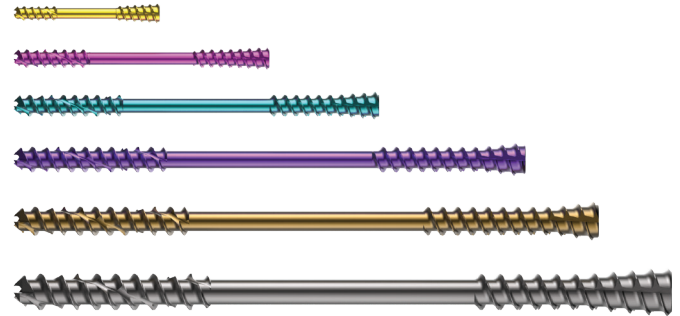
NX Nail

Design Rationale

The NX Nail is a second-generation extremity nail designed for extra-articular fracture fixation.

Key features include:

- A high precision, multi start, self-cutting, leading tip.
- A diaphysealised non-threaded shaft.
- An anatomically contoured compaction tapered head.



Design Philosophy

The philosophy behind the nail is based on the AO principals of fracture management. As most extra-articular fractures of the hand and foot involve the shaft, the NX Nail is designed to maintain length, whilst restoring version and controlling angulation. The role of the implant is to rigidly fix the head and base fragments of the bone in space while crossing the fracture and, or any comminution to act as a strut.

The NX Nail construct acts as a physiological splint, designed to withstand normal loads and to facilitate rapid return to normal activity. The leading tip and tapered head are engineered to have increased engagement with the proximal and distal fragments. These implant features stabilise the key structures of the bone in the anatomical position supporting restoration of native biomechanics.

Benefits

In modern trauma management, extremity nails have been positioned as a gold standard solution for the treatment of extra-articular fractures. The implants have unprecedented strength compared to traditional alternatives and facilitate a minimally invasive technique which is simple, easy to learn and has a short operative time (most cases taking 15 to 20 minutes). In addition to the technical benefits there are significant advantages both clinically and for the patient. Long term, large volume studies of intramedullary fixation in the hand and foot have demonstrated the lowest complication rates for any treatment option¹ with patients often able to immediately return to normal duties with significantly reduce morbidity.



How It Works

Compaction Taper

The primary feature of the NX Nail is the patented tapered head which has been designed from statistical shape models to be anatomically contoured and facilitate increased bone engagement and distal fragment control.

As one of the considerations of using an extremity nail is to maintain length, modern designs are non-compressive, and as such need to realise stability in new ways. The NX Nail achieves this goal with the compaction taper.

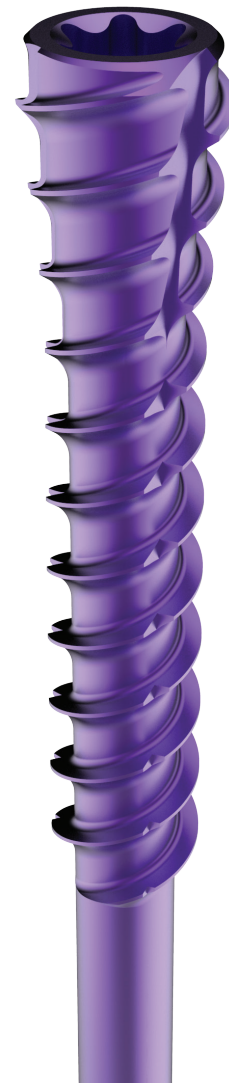
Taking advantage of the mismatch between the leading nail and the widened diameter of the tapered head, the NX Nail is engineered to circumferentially displace bone during insertion. Throughout this process the implant is designed to compact the often cavernous cancellous bone against the subcortical ridge and metaphyseal shelf, to increase the relative density of the bone mantle and generate hoop stresses.

The hoop stresses created through compaction results in a 360° high force interference engagement with the nail and the bone, as well as a tight interconnection between the fine pitch buttress threads of the implant. This mode of fixation has been designed for optimised stability with 33% more engagement than first generation implants.² The improved stability is considered suitable for extreme nailing and management of comminution.

Diaphysealised Shaft

A distinguishing feature of second generation nails is the smooth diaphysealised midsection, which is engineered in consideration of the narrow isthmus, natural bow and viscoelastic properties of bones to decrease irritation and optimise the biological potential. When loaded, bones bend due to the forces applied. In long bones, including those of the hand and foot, this motion is predominantly seen and facilitated within the bow of the isthmus. In addition to the dynamic mechanical function, the intramedullary space of the shaft has a biological role. Within this cavity, in normal bones a significant portion of vascular perfusion transverses the space. This blood flow plays a major role in normal homeostasis and in some cases, when obstructed could have an influence on fracture healing.

In implants that don't consider the bio-mechanical role of the diaphysis, some designs have threads which can be seen to come in contact with the cortex. In these situations, the thread can both obstruct the natural perfusion and create stress risers along the shaft. Whilst the impact of these shortcomings is not yet defined, in the weight bearing bones of the leg, similar irritation has been associated with both anterior thigh pain, pathological fracture and non-union.

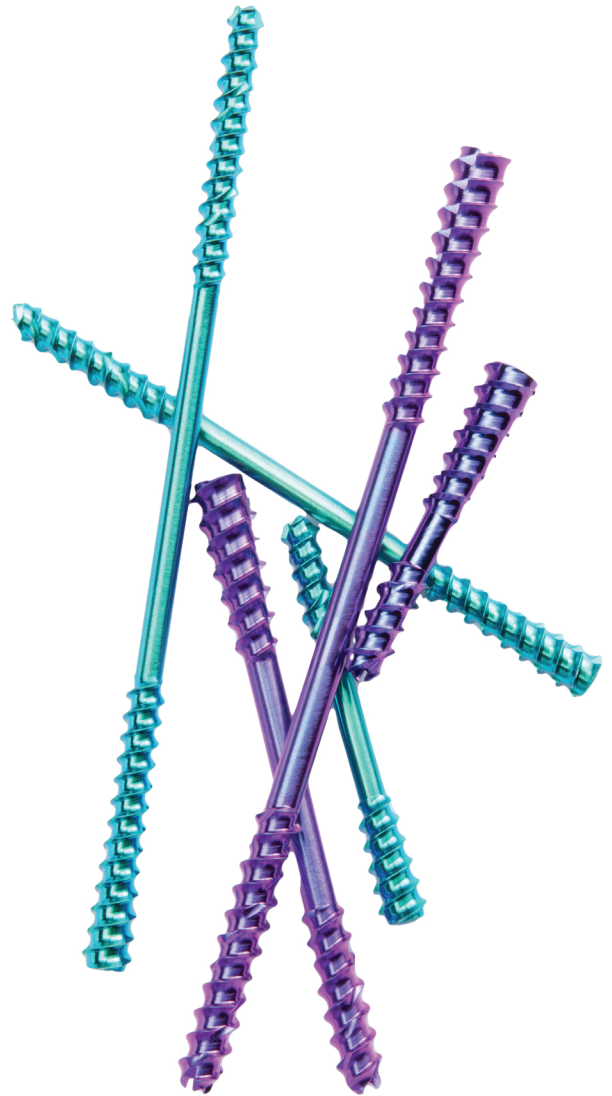


Why This Matters

While significant advances have been seen with the use of intramedullary fixation in the hand and foot, the new features of second generation designs offer further benefits. Whilst earlier implants were dependent on either sub-cortical purchase or diaphyseal stuffing to splint fractures, new implants are engineered to provide increased engagement and fragment control to facilitate rigid stability and true fixation.

With these elements, the NX Nail is strong, simple to use and provides advantages over many traditional alternatives. The fine pitch of the leading tip has been shown to firmly engage the base of bones such as the metacarpal, whilst the compaction taper is able to generate a strong fixation even in soft cancellous bone seen within the head.

Unlike other options the NX Nail is extremely versatile. There is no need for isthmus stuffing, maximising the implant length to increase the amount of thread or to achieve subcortical engagement. When using the NX Nail, all that is needed is to select an implant long enough to cross the fracture and wide enough that the surgeon is satisfied with the head purchase.



REFERENCES

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2. Internal Data on file.



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