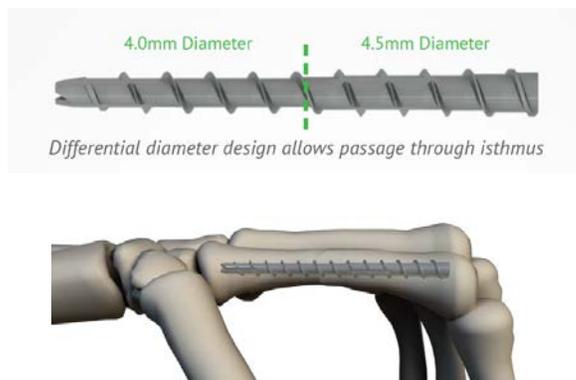


INnate™ Intramedullary Threaded Nail for Metacarpal Fractures

INnate™ Product Overview

ExsoMed's INnate Implant introduces an innovative category of fixation in treating metacarpal fractures by allowing rigid fixation through a percutaneous technique.

INnate™ is a minimally invasive, intramedullary threaded nail for fixation of metacarpal fractures. The 4.5mm stainless steel implant is available in multiple lengths to address metacarpal fractures of all varieties: 35, 40, 45, 50, 55, 65, 75mm. The INnate diameter is specifically designed to provide rigid, intramedullary fixation and immobilization of fractures. The non-compression design of the nail is intended to provide stabilization without compression, to avoid common over-compression of comminuted fractures.



INnate™ Comparable Analysis

The following memorandum provides a rationale why the ExsoMed intramedullary threaded nail is unique for addressing metacarpal fractures and does not provide the same purpose as a headless compression screw or compression-oriented plate solutions.

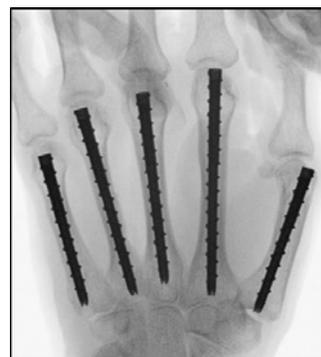
Mechanical Differentiation

By way of background, compression screws typically possess a continuously variable thread pitch to ensure each screw rotation threads new bone along the screw's entire length. As each successive individual thread advances faster than the trailing thread counterpart, the conical shape becomes seated into bone. This radial expansion of the screw threads, combined with their axial advancement, creates the ability to reduce and compress bone fragments. By allowing each thread along the entire length of the screw to aid in reduction and compression, compression can be maintained. Generally, mechanical studies show that headless compression screws provide the greatest push-out force, highest amount of retained compression after cyclic loading, and highest resistance to torsional loading.

By way of contrast, the ExsoMed INnate implant is an intramedullary threaded nail for fixation of metacarpal fractures and other small bone indications. The product is intended to provide a non-compression design that will immobilize rigidly but avoid compression (or shortening) of fractures, similar to headless compression screws. This same rationale can also be applied to various plate fixation solutions.

Technique Differentiation

Unlike headless compression screws and plate solutions, the INnate implant is inserted through a percutaneous, minimally invasive technique into the metacarpal head. This cannulated insertion technique allows minimal impact to soft tissue and articular cartilage upon insertion. The variety of lengths from 35mm – 75mm offers a solution long enough to be equivalent to a plate while also providing longer options than current compression screws on the market.



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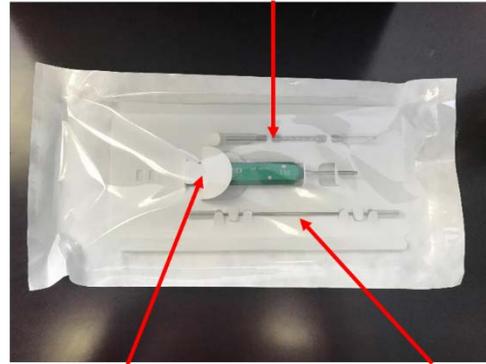
Delivery System Differentiation

The INnate system comes sterile packed and consists of a disposable instrument kit and individually packed implants (with a variety of options). This kit system lowers procedural cost without the management of trays especially when considering tray delivery options by most screw and plate companies.

INnate Implant (1)



3.4 Cannulated Drill (1)



Cannulated T10 Driver (1)

0.045" x 6" Guide Wires,
Single Trocar (2)

Post-Operative Care Comparison

When compared to occasional plating solutions post-operative protocols, surgeons believe that motion therapy may lead to accelerated healing and earlier functional restoration of hand motion.

“My patients are returning within 10-14 days with no pain, full motion asking to get back to work. It’s pretty unreal.”

Dr. Marissa Rae Matarrese
Champlain Valley Physicians
Plattsburgh, NY



In summary, the plate solutions can be modified to deliver less compression and may be a better proxy for comparison but neither headless compression screws nor compression plates provide a compression-free solution necessary for providing rigid stability.

Finally, there is the minimally-invasive time-saving (labor saving) consideration that facilities more and more frequently factor into their procurement algorithm. The ExsoMed INnate cannulated insertion technique offers surgeons and facilities a fast, simplified approach designed to decrease surgical time in the operating room.

