



## Orthopedics

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### A Universal Pediatric Intramedullary Nail

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#### Background

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Pediatric long bones fractures are frequently stabilized with intramedullary nails. Existing nails usually come in pre-set lengths with a bent tip on the insertion end and a bulb like expansion on the other end. The bent tip allows for deflection of the nail off the inner cortex opposite the insertion side so that the nail is directed into the medullary canal. The bulb like expansion at the end allows gripping the nail when there is a need to pull it out during surgery or, if desired, at a later stage after the fracture is healed and also minimizes soft tissue irritation around the nail's tip which protrudes out of the bone into the soft tissues.

In this type of design there is a need to pre-measure the length of the nail prior to insertion. With the magnification of the radiographs, bending of the nail prior to insertion and the fracture being in a shortened position this, at times, is a difficult task. If the inserted nail is too short the nail has to be exchanged at the time of surgery to a longer nail. If the nail is too long it may be left under the skin where it may cause irritation or ulceration or it may be shortened to the appropriate length, leaving the end sharp and without the pre-made bulbous expansion. This often causes local soft tissue irritation around the nail's tip and makes removal of the nail difficult. Other existing nails are smooth along the entire nail, the nail is cut after insertion to the appropriate length and an end cap is placed at the end of the nail. This adds stability to the construct but is more complicated and does not solve the difficulty in extraction of a smooth nail.

The main problems with existing nails are :

1. When the nail is pre-made in different lengths wherein the end of the nail is designed to facilitate nail removal, insertion of a wrong size nail requires nail shortening which makes later removal difficult, or intra-operative nail exchange, risking reduction loss and prolonging the surgical procedure.
2. When the nail is smooth along its entire length removal thereof is difficult as only the nail's tip protrudes out of the bone and gripping the tip is difficult. Bending the end of the nail to allow for easier removal leaves the end of the nail superficial, often causing irritation of the soft tissues.
3. Inventory: typically, a set of nails having different diameters (usually ranging between 2.0mm to 4.0mm in increments of 0.5mm) and different lengths (ranging from 130mm to 450mm) need to be kept at the operating room, which typically sums to a total of up to fifty nails.
4. Stability: the smooth design of existing nails does not provide optimal stability of the treated fracture. Depending on the fracture anatomy shortening or malrotation may occur.

**There is an urgent need to simplify treatment procedures of broken long bones of the pediatric population.**

## **Market**

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The incidence of pediatric long bone fractures requiring intramedullary fixation is not known. Estimates from different parts of the world range from 15 to 30 annual femur fractures per 100,000 children between the ages of 6 and 12. Tibial, radial and ulnar fractures needing internal fixation with flexible nails bring the demand for these devices even higher. In addition to inferior results, the economical implication of treating these fractures in spica casts (hospital stay, loss of parental work days etc.) is very high and the current treatment of choice for many of these fractures is intramedullary nailing with flexible nails. The demand for flexible Titanium nails is high and expected to rise due to increase in population size and new markets with very high birth rates.

## **The Innovation**

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To be shared under NDA.

## **Contact**

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