

# Project Design Specifications (PDS)

## Title

Improving Intramedullary Rod Surgical Equipment, September 15, 2005

## Team Members/Roles

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## Abstract

When longer bones such as the humerus and the femur suffer severe fractures they need assistance to heal properly. One method of repair is an intramedullary nail (IN). The nail is inserted through the proximal end of the bone and into the bone marrow. The nail is anchored in place by 4 pins, 2 proximal and 2 distal. During the surgical procedure the head of the IN is attached to an extension piece and a drill jig. The jig allows the surgeon to guide the drill through the bone at the precise locations of the holes located in the IN. However, some flex exists in the rod or the attachment to the jig. This causes the drill to sometimes miss the holes located in the IN, more often the distal holes. A new mechanism to attach the IN to the drill guide is needed to ensure surgeons can confidently drill through the bone to the holes located in the IN.

## Problem Statement

Develop a drill guide and IN that can attach securely without play, with the end goal of consistently allowing surgeons to use the drill guide to drill through the bone without missing the IN holes.

## Client Requirements:

- Develop a mechanism to lock the IN in place without play.
- Consistent drilling into the IN holes without missing.

## 1. Physical and Operational Characteristics

*a. Performance requirements:* The device must be able to accurately and consistently fit each screw through the holes in the rod. The nail must not move with respect to the jig when the forces required to get the rod in place are applied. The jig should withstand multiple uses. The nail is only used once but it must have compressive strength since it must help support the weight of the animal. It must not break or wear away during the life of the canine.

*b. Safety:* The nail must be a safe and comfortable option for canine fracture repair. It must be strong enough to prevent further injury and it must consist of materials that are not harmful in any way if implanted in a living organism. For the safety of the animal, only qualified veterinarians who understand the correct

operation of the device should use it. The equipment should only be used after being thoroughly sterilized.

*c. Accuracy and Reliability:* Current devices were estimated to fail 10% of the time. The new design should reduce the failure rate, and attempt to eliminate it.

*d. Life in Service:* The nail itself must withstand at least 12 years of compressive forces without any service, as it will be implanted in the canine. The jig may be used several times a week for several years with little to no maintenance necessary.

*e. Shelf Life:* The jig will be used for multiple surgeries over the course of its time, but will likely contain only mechanical components which will not expire. The jig and its components will be autoclaved with the surgical tools and stored in a sterile environment until its next use.

*f. Operating Environment:* Any device will be operated under standard surgical room conditions. A doctor may be able to insert the nail without assistance but will likely acquire help from an assisting physician or nurse. The time of operation may vary on the surgery but should fall in the time span of 1-2 hours. While in use the device is likely to encounter different biological contaminants, especially blood.

*g. Ergonomics:* The newly designed nails should interface with the current jig and surgical procedures. Thus, one or two people should be able to insert and secure the nail without difficulty. The new design will likely withstand higher torques than it currently does, because it should provide accurate aiming of the drill.

*h. Size:* The current jig used is approximately 18" x 6" x 3". Any additional components on the existing device should not increase this size significantly. Any size increase is restrained only by the ability of two people to operate it simply. The nails that are inserted must be able to be manufactured in the same dimensions as those currently in use (i.e. 4.0, 4.7, 6.0, and 8.0 mm in diameter and varying lengths).

*i. Weight:* The intramedullary nail should weigh no more than the current version. The extension and jig can weigh more but must still be able to be used comfortably by the surgeon, so no more than 3 lbs. The optimum weight is less than 1lb.

*j. Materials:* The nail cannot react with the internal environment of the canine. It also needs to be made with a material that can withstand weight, such as stainless steel. The extension can be made out of other materials as long as it is durable and lightweight. Materials like wood or rough metal should not be used.

*k. Aesthetics, Appearance, and Finish:* The appearance does not need to be pleasing, just practical and not difficult to use.

## **2. Production Characteristics**

a. *Quantity:* Only one prototype needs to be completed until further testing is done on it.

b. *Target Product Cost:* The cost of the product has not been determined. It will depend on how effective the prototype is at solving the problems and the amount of materials needed to make a working product.

## **3. Miscellaneous**

a. *Standards and Specifications:* As with medicine, all veterinary instruments must meet FDA approval. Due to the variance in animal size, a standard system is difficult to create.

b. *Customer:* The customer does not expect a complete and usable prototype to be created. The customer is more concerned with knowing whether a solution can be found, and creating a prototype that will test if the solution is effective.

c. *Patient-related concerns:* In the future, if such an improved intramedullary rod system is to be adapted to humans, any issues or complications which may arise through the transition should be predicted and tested.

d. *Competition:* A device, the Ti Cannulated Humeral Nail, which rectifies the aforementioned problem, has recently been released. The product, however, is only intended for human use. It is possible that a veterinary counterpart could be adapted from this system by the same counterpart.