SURGICAL TECHNIQUE

Surgical Technique for Pediatric Forearm Fixation Using Activa IM-Nail™

- Surgeons are advised to review the product specific surgical technique, including the implants, the method of application and the surgical procedure, prior to performing the surgery. Use the standards of your hospital in pre-operative care treatment.

PATIENT POSITIONING

- Position the patient supine on a standard operating table with a radiolucent arm board.
- Prepare and drape the affected limb allowing access to the elbow and wrist.

IMPLANT SELECTION

- Measure the smallest diameter of the medullary cavity of the radius and ulna.
- Select the dilator and corresponding implant whose diameter is as close as possible to, but not greater than, the smallest diameter of the medullary cavity.
- Note: For a complete listing of available sizes, please refer to the Ordering Information on the Sales Sheet.

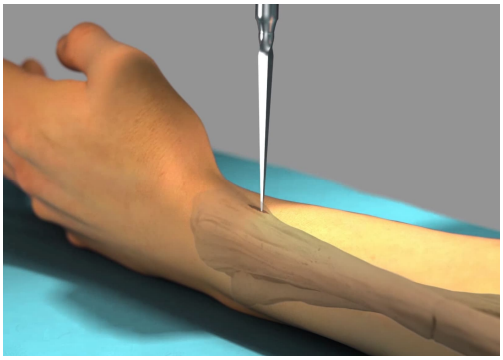
REDUCTION

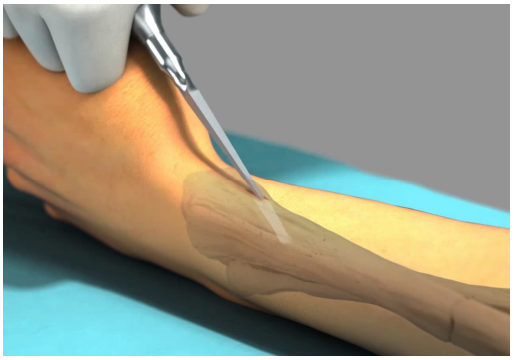
- If both the radius and the ulna require reduction, reduce and stabilize the bone that is more angulated or displaced first. I.e., if the radius is more displaced or angulated than the ulna, reduce and stabilize the radius first. If the ulna is more displaced or angulated than the radius, reduce and stabilize the ulna first..
- If an acceptable reduction cannot be achieved in a closed manner, use an mini open reduction technique. If possible, a small open incision directly over the fracture site is preferable.

INCISION

Radius

- Make a small longitudinal incision over the dorsolateral metaphyseal surface just proximal to the distal physis in the case of retrograde approach. A C-arm image can be used to aid.
- Caution: Pay attention to the dorsal branch of the superficial radial nerve.
- Make an entry portal into the cortical bone as parallel as possible to the intramedullary cavity using a bone awl or a drill bit
    1. First, place the awl or drill bit perpendicular to the cortex to make a start for the entry portal
    2. Next, slowly lower the awl or drill bit to the slightest possible angle relative to the bone shaft axis.
    3. Now advance the awl or drill bit at this angle until it reaches the medullary canal. First, use a smaller awl or drill bit and then enlarge the entry portal with a larger tool.
- Caution: If the entry portal is too small, the sharp edge of the cortical bone may catch the implant and split it during insertion. The split part may break off and be left in soft tissue causing a temporary foreign body reaction during biodegradation.



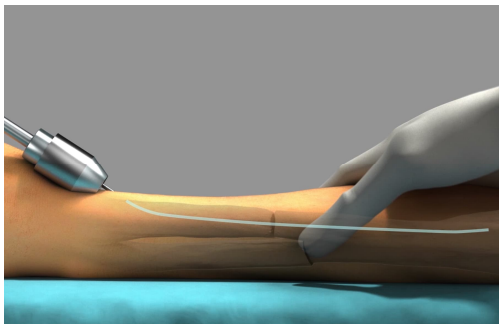


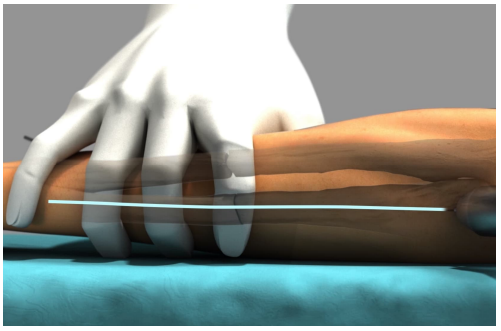
Ulna

- For the antegrade approach make a small longitudinal incision on the radial side of the proximal metaphysis. Avoid, if possible, a middle incision, due to the possibility of irritations of the skin. A C-arm image can be used to aid.
- Make an entry portal into the cortical bone using a bone awl or a drill bit (Please see above).

DILATING

- Dilate the medullary cavity through the fracture plane using an appropriate dilator for the implant.
- Leave the dilators in the bone marrow canals until it is time to insert the bioabsorbable implant. Remove and replace the dilators with the implants one by one, if both the radius and ulna will be stabilized and aligned with the bioabsorbable implants.



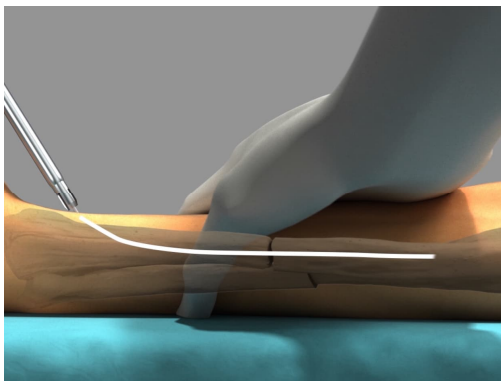


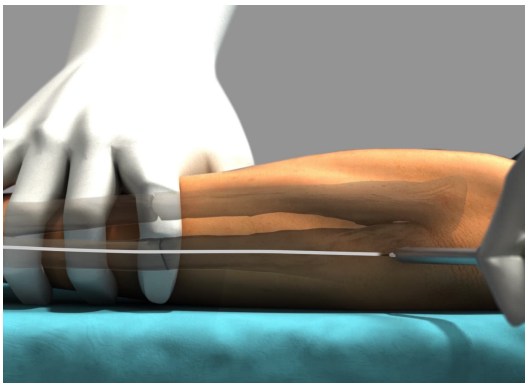
Activa IM-Nail™ diameter (mm)	**2.0**	**2.7**	**3.2**
Dilators	B-INIM-2000	B-INIM-2700	B-INIM-3200

- Caution: If the dilator is bent while dilating the intramedullary canal, do not straighten the dilator. Attempts to straighten bends may compromise the metallurgical integrity of the metal, and the instrument may subsequently break during use.

NAIL INSERTION

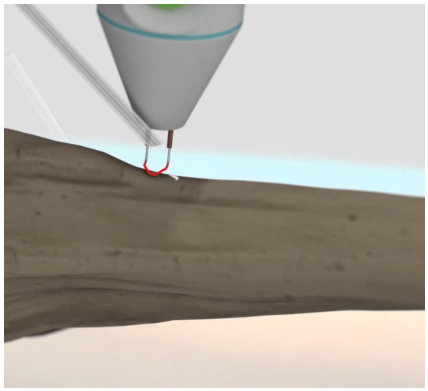
- Insert the implant using the inserter. Insert the nail into the bone marrow canal first by hand and, if resistance is felt, advance the nail by lightly tapping the instrument. Do not use rotational movements.
- If gently tapping is not adequate for insertion, the fracture alignment may be lost, and the implant may be stuck at the fracture line. Remove the implant, re-align the fractured bone, and re-dilate the medullary cavity.
- Caution: The tip of the implant with the X-ray positive TCP marker is sensitive to longitudinal impacts and can be split on the sharp edge of cortical bone at the entry portal or the fracture line, if excess force is used. Therefore, in the case that it is difficult to insert the implant into the medullary cavity and the implant must be removed for re-dilating the medullary cavity, it must be visually checked that the tip of the implant is not damaged before re-inserting it.





- Insert the Activa IM-Nail™ across the fracture by monitoring the nail position with fluoroscopy. Do not cross the physis. Caution: The X-ray positive TCP marker can be seen, but not the implant itself.

- After insertion, cut the implant using scissors, an oscillating saw, or a hot wire. Smooth the proximal end of the implant at least to the cortical level, to avoid soft tissue irritation.



- Close the wound in layers applying standard techniques.

IMMOBILIZATION

- Immobilize the forearm by cast using, e.g., an above-the-elbow cast for 2 weeks with the elbow flexed to 90 degrees and after that a short arm cast for 2-4 weeks, or an above-the-elbow dorsal plaster semicircular cast with volar support for 4-6 weeks with the elbow flexed to 90 degrees.
- Additional appropriate immobilization should be considered by the treating physician.

POSTOPERATIVE CARE

- Sports activities should be limited for 3-6 months, depending on the type of trauma.
- Provide the patient with detailed instructions for postoperative care.
- X-ray control, CT or MRI can be used to evaluate the healing of the tissue. The implant is MR Safe.

Instruments

Product code	Description
B-INIM-2000	Dilator for 2.0mm intramedullary nail
B-INIM-2700	Dilator for 2.7mm intramedullary nail
B-INIM-3200	Dilator for 3.2mm intramedullary nail
B-INIM-4000	Inserter for intramedullary nail