Activa IM-Nail™

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Absorbable self-reinforced poly (L-lactide-co-glycolide) with TCP (β-tricalcium phosphate) marker

Activa IM-Nail™ opened a new chapter in orthopaedics with the introduction of the world's first fully absorbable elastic nail for pediatric forearm intramedullary nailing. Activa IM-Nail™ implants are manufactured with self-reinforced technique to provide improved mechanical properties and malleabilty. Additionally, it utilizes Bioretec´s patented Self-Locking SL™ technologies. Activa IM-Nail™ implants gradually lose their strength, however, maintaining their function for at least 8 weeks. Complete absorption takes place within approximately two years, thus eliminating the need for implant removal surgery. Activa IM-Nail™ is specially designed for Pediatric use.

Patient Benefits

In pediatric patients, conventional metal implants are often removed as they interfere with bone growth.

Unlike conventional metal implants, which are often left protruding through the skin for eventual removal—potentially causing irritation and infections—absorbable implants eliminate these short-term risks. Furthermore, they eliminate the need for removal surgery, mitigating long-term complications.

Properly used, in the presence of appropriate casting for 4-6 weeks, the implants maintain accurate alignment of the fractured bones after surgical procedure. As the operated, fractured bones gain strength during healing, the implants gradually lose their strength, maintaining the function for at least 8 weeks.

Complete absorption occurs within approximately two years, offering a patient-friendly solution that supports bone healing without the drawbacks of traditional implants. Eliminates the need of implant removal surgery and associated general complications related anesthesia and surgical operations with pediatric patients.

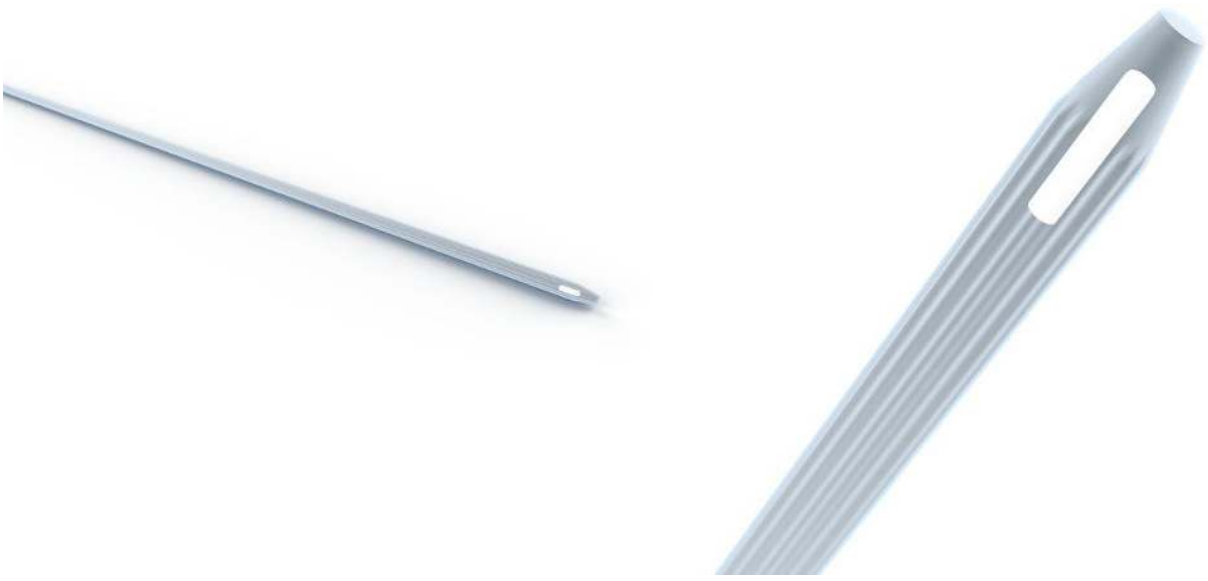
Professional Benefits

Activa IM-Nail™ offers an economical solution for hospitals and society, as the unnecessary removal operation, rehabilitation and costs related will be avoided. The insertion technique respects traditional intramedullary nailing methods.

The mechanical strength of the Activa IM-Nail™ together with cast immobilization enables stabilization of the fracture. Activa IM-Nail™ has a capacity to maintain alignment of the fracture line for at least 8 weeks to support to the healing tissue until it has achieved its original function. Therefore, Activa IM-Nail™ continues to support the healing even after the cast removal at week 4 or later.

The osteoconductive tricalcium-phosphate marker in the tip of Activa IM-Nail™ allows mini-invasive navigation with enhanced implant visibility in the x-ray. Activa IM-Nail™ can be trimmed (lenght) to be suitable also for more distal diaphyseal intramedullary radius and ulna fracture fixations.

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Overview

- For the intramedullary nailing of diaphyseal forearm fractures in pediatric patients.
- Material is safe and fully absorbable PLGA 85L/15G with an x-ray positive β-tricalcium phosphate (TCP) tip for navigation.
- Activa IM-Nail™ has the strength characteristic of the Activa portfolio and exploits Bioretec´s patented Self-Locking SL™ technology. This technology increases the implant´s diameter 1-2 % in bone´s hydrolytic environment.
- Activa IM-Nail™ maintains its function for at least 8 weeks, which supports healing well after cast removal.
- Patented grooved surface design improves the rotational stability.
- The structure of the nail allows it to be inserted at a point that does not disturb the growth plate.
- Activa IM-Nail™ is indicated for patients from 3 to under 13 years with appropriate immobilization. The age limit depends on the biological development of the child.
- Eliminates the need for implant removal surgery and associated general complications related to anesthesia and surgical operations with pediatric patients.

Specific Indication Examples



Activa IM-Nail™ is intended for intramedullary nailing of diaphyseal forearm fractures (radius or ulna or both) in pediatric patients in the presence of appropriate immobilization.

In diaphyseal forearm fractures the Activa IM-Nail™ is indicated for the patients from 3 years to under 13 years, but the age limits depend on the biological development of the child.

Features / Unique Selling Points

No skin irritation, as the implant is cut to the desired length, flush with the cortex.

Traditional implants´ long-term complications can be avoided: interference with the growing skeleton, the release of metallic ions.

Patented grooved design.

Individual sterile packages for every implant.

Instruments are similar to traditional ESIN.

Self-Locking SL™ technology makes the implant diameter expand 1-2 %.

Implants combine safe and absorbable PLGA + TCP with Bioretec's unique self-reinforcement technologies.

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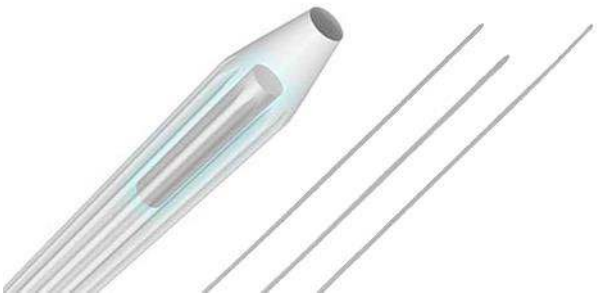
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Product codes

B-ANIM-20200 Activa IM-Nail™ 2.0 x 200 mm
B-ANIM-20300 Activa IM-Nail™ 2.0 x 300 mm
B-ANIM-20400 Activa IM-Nail™ 2.0 x 400 mm

B-ANIM-27200 Activa IM-Nail™ 2.7 x 200 mm
B-ANIM-27300 Activa IM-Nail™ 2.7 x 300 mm
B-ANIM-27400 Activa IM-Nail™ 2.7 x 400 mm

B-ANIM-32200 Activa IM-Nail™ 3.2 x 200 mm
B-ANIM-32300 Activa IM-Nail™ 3.2 x 300 mm
B-ANIM-32400 Activa IM-Nail™ 3.2 x 400 mm



Instrumentation options

Product Code	Description
B-INIM-4000	Inserter for intramedullary nail
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



Instruments are delivered unsterile

Product properties

- Material: Activa IM-Nail™ is made out of the self-reinforced PLGA (poly-L-lactide-co-glycolide polymer) and has a tricalcium phosphate (β-TCP) x-ray marker in the tip.
- Certificates: Activa IM-Nail™ is CE approved.
- Product measures: Activa IM-Nail™ is available in diameters 2.0, 2.7 and 3.2 mm and lengths 200, 300 and 400 mm.

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Product Information and Availability Notice

Please refer to the package labelling and Instructions For Use to identify the intended use, indications and surgical technique for additional information.

Registrations for Bioretec implants vary by market and specific product design, including but not limited to authorizations from the FDA in the United States and CE marking in Europe. For more information, please contact Bioretec customer service.

For orders and more information, contact sales@bioretec.com
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