

ActivaNail™

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Absorbable self-reinforced biopolymer (poly L-lactide-co-glycolide copolymer, PLGA 85/15)

Advanced absorbable nail for upper and lower extremity fixation of bone fractures, osteotomies, arthrodeses, and osteochondral fractures in the presence of appropriate immobilization with patented Self-Locking SL™ technology and grooved surface design with a conical head. ActivaNail™ 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.

Patient Benefits

The ActivaNail™ implant is designed for use in the upper or lower extremities to support successful bone healing in the fixation of small fractures or correction of malalignments. Its gradual absorption into the body eliminates the need for a removal surgery, reducing patient stress and discomfort.

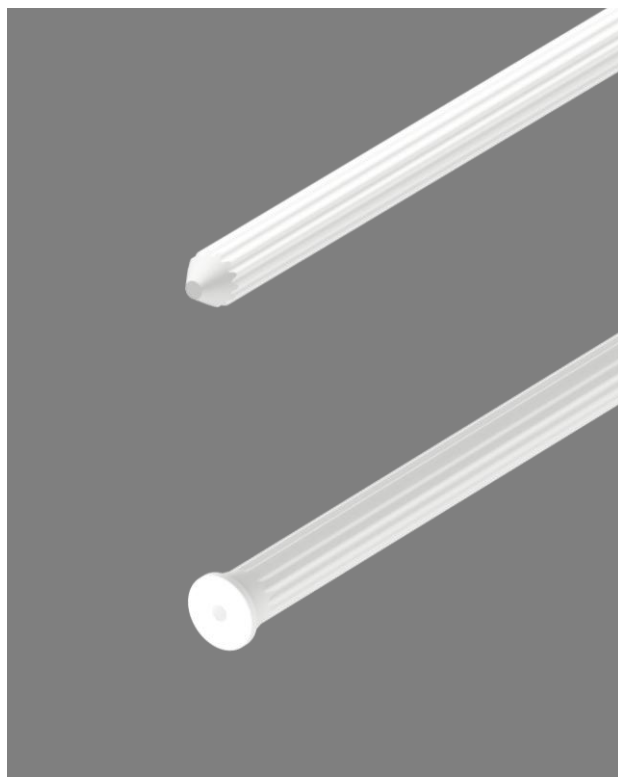
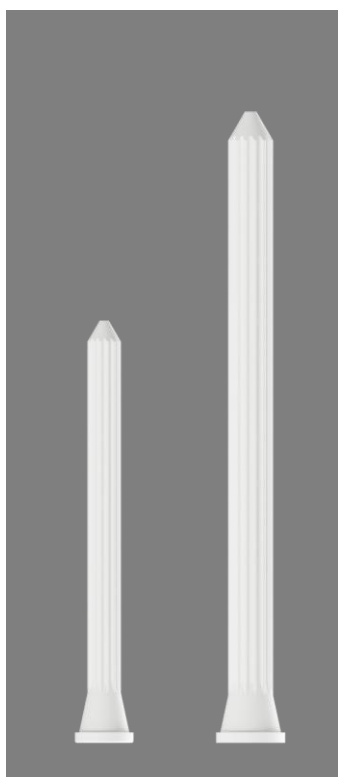
During the absorption the implant slowly transfers stress to the healing bone, assisting in the healing process. Due to the absorption, the risks of implant-related long-term complications are eliminated. ActivaNail™ material facilitates bone healing and is absorbed in approximately two years.

Professional Benefits

ActivaNail™ is available in various diameters and lengths, featuring patented Self-Locking SL™ technology and a grooved surface design for excellent fixation. These features provide excellent rotational stability, keeping the product securely in place after implantation. Its self-reinforced structure offers enhanced support, with the diameter increasing by 1–2% from its initial dimensions, ensuring a tight and reliable fit to the bone.

The use of ActivaNail™ is straightforward with Bioretec's reusable pin applicator, designed to pick up and attach the implant. This eliminates the risk of losing the pin during insertion. The insertion process can be performed using either a reusable arthroscopic or regular applicator. ActivaNail™ is sterile packaged to ensure ease of use and maintain aseptic conditions during surgical procedures.

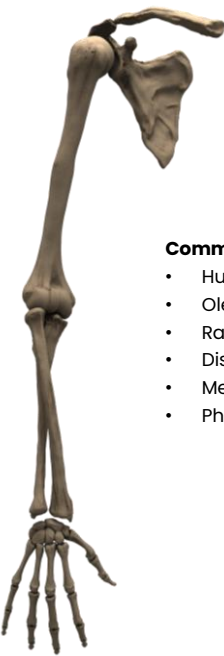
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Overview

- For fixation of bone fractures, osteotomies, arthrodesis and osteochondral fractures in the presence of appropriate immobilization.
- ActivaNail™ implant provides higher strength and stiffness created by the tailored material and the proprietary manufacturing technique.
- The material's bending modulus is closer to the value of cortical bone, which eliminates stress shielding in bone.
- ActivaNail™ material facilitates bone healing and is absorbed in approximately two years. It is made of PLGA 85/15.
- ActivaNail™ utilizes Bioretec´s patented Self-Locking SL™ technology, which reduces the risk of unstable fixation. This technology enables the implant´s diameter to expand 1-2 % in the physiological environment and fixes the implant firmly to the bone.

Specific Indication Examples



Common applications in upper extremities:

- Humeral condyle fractures
- Olecranon fractures
- Radial head fractures
- Distal radius fractures
- Metacarpal fractures
- Phalanx fractures



Common applications in lower extremities:

- Ankle fractures, e.g. malleolar fractures
- Talar fractures
- Patella fractures
- Fixation of metatarsal and phalangeal fractures and osteotomies (i.e., Akin, Scarf, Chevron, Weil) e.g., Hallux Valgus
- Arthrodesis e.g., talocrural arthrodesis, subtalar arthrodesis, 1st MTP arthrodesis, Interphalangeal (IP) arthrodesis

Features / Unique Selling Points

Absorbable, complete absorption takes two to three years.	Easy insertion also arthroscopically with reusable instrumentation, compatible with ActivaNail™.	Patented grooved design enhances the rotational stability.	Single sterile packed.	Self-reinforced structure provides additional strength, stiffness and malleability.	Additional support from the conical head design e.g. to OCD repair.
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Product Codes

- B-ANCO-1510 ActivaNail™ Conical 1.5 x 10 mm
B-ANCO-1515 ActivaNail™ Conical 1.5 x 15 mm
- B-ANCO-1520 ActivaNail™ Conical 1.5 x 20 mm
B-ANCO-1525 ActivaNail™ Conical 1.5 x 25 mm
B-ANCO-1530 ActivaNail™ Conical 1.5 x 30 mm
- B-ANCO-2015 ActivaNail™ Conical 2.0 x 15 mm
B-ANCO-2020 ActivaNail™ Conical 2.0 x 20 mm
B-ANCO-2025 ActivaNail™ Conical 2.0 x 25 mm
B-ANCO-2030 ActivaNail™ Conical 2.0 x 30 mm



Instrumentation Options

Reusable instruments for ActivaNail™:

Product Code	Description
B-IP-3200	Applicator Ø3.2 mm, reusable, for 3.2 mm pins and for 1.5/2.0/2.7/3.2 mm nails
B-IP-1502	K-Wire Ø1.5 mm, length 130 mm, for 1.5 mm pins/nails, 10 pcs.
B-IP-1501	K-Wire Ø1.6 mm, length 130 mm, for 1.5 mm pins/nails, 10 pcs
B-IP-2001	K-Wire Ø2.0 mm, length 130 mm, for 2.0 mm pins/nails, 10 pcs.
B-IP-1503	Drill bit Ø1.5 mm, for 1.5 mm pins/nails, quick coupling
B-IP-2003	Drill bit Ø2.0 mm, for 2.0 mm pins/nails, quick coupling
B-IP-4000	Applicator handle, arthroscopic, for pins and nails
B-IP-3212	Applicator tip, arthroscopic, for 1.5/2.0 mm nails
B-IP-4001	Applicator drill guide, arthroscopic, for 1.5/2.0 mm nails
B-IP-4004	Applicator housing, arthroscopic, for pins and nails
B-IP-1506	K-Wire Ø1.5 mm, length 260 mm, for 1.5 mm pins/nails
B-IP-1504	K-Wire Ø1.6 mm, length 260 mm, arthroscopic, for 1.5 mm pins/nails
B-IP-2004	K-Wire Ø2.0 mm, length 260 mm, arthroscopic, for 2.0 mm pins/nails
B-IP-4003	Sterilization tray for ActivaPin™ instruments

Instruments are delivered unsterile.

Product Properties

- Material: ActivaNail™ is made of PLGA 85/15, which safely absorbs in the body in approximately two years. The material has a long history in medical use and is proven to be safe in various scientific clinical studies and by real-world evidence.
- Certificates: ActivaNail™ is FDA cleared and CE approved.
- Product measures: ActivaNail™ is available in diameter 1.5 and lengths 10-30 mm and diameter 2.0 and lengths 15-30 mm.

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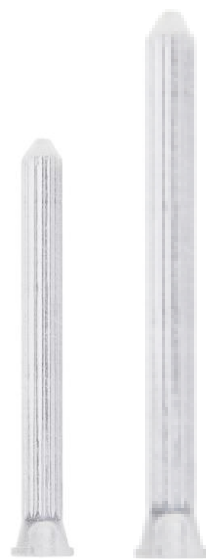
Instrument set, for ActivaPin™ B-IPS-1000



Applicator



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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 or visit www.bioretec.com.