ActivaScrew[™]

Contact

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

Advanced absorbable screw for upper extremities, ankle and foot fixation of bone fractures, osteotomies, arthrodeses, bone grafts and osteochondral fractures in the presence of appropriate immobilization with patented Auto-Compression[™] technology. ActivaScrew[™] 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 ActivaScrew™ implant is designed for use in the upper extremities, ankle and foot to support successful bone healing in the fixation of 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. ActivaScrew™ material facilitates bone healing and is absorbed in approximately two years.

Professional Benefits

ActivaScrew™ implants are available in fully threaded design with various diameters and lengths, featuring patented Auto-Compression™ technology. These features provide excellent compression and fixation stability, keeping the bone sections securely in place after implantation. Its self-reinforced structure offers enhanced support, with the diameter increasing and length decreasing by 1–2% from its initial dimensions, ensuring a reliable fixation. In the case where the screw head is needed, ActivaScrew™ implants can be cut appropriate length for example with a high temperature cautery or cutting tools.

- ActivaScrew[™] is compatible with AO standard instrumentation
- ActivaScrew[™] implants are sterile packaged to ensure ease of use and maintain aseptic conditions during surgical procedures.

ActivaScrew™





bioretec Markets: OUS

ActivaScrew[™]

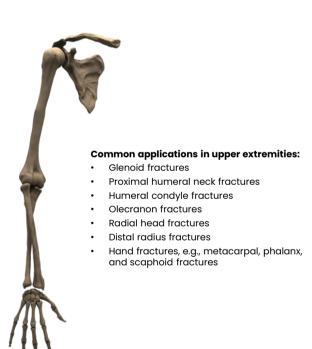
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Overview

- For fixation of bone fractures, osteotomies, arthrodeses, bone grafts and osteochondral fractures in the presence of appropriate immobilization.
- ActivaScrew[™] 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.
- ActivaScrew[™] material facilitates bone healing and is absorbed in approximately two years. It is made of PLGA 85/15.
- ActivaScrew[™] implants utilizes Bioretec´s patented Auto-Compression[™] technology which reduces the risk of unstable fixation. This technology provides additional compression to the fracture for 8 weeks for proper fixation over the healing period. In hydrolytic conditions, its diameter will expand, and length will decrease 1-2 % to produce the compression.

Specific Indication Examples





Common applications in lower extremities:

- Tibial condyle fracture
- Ankle fractures, e.g. malleolar fracture and syndesmotic injury
- Talar fractures
- · Calcaneal fractures
- Fractures of the tarsals, metatarsals, and other fractures of the foot
- Fixation of metatarsal and phalangeal osteotomies (i.e., Akin, Scarf, Chevron, Weil) e.g., Hallux Valgus and Hammer Toe Correction
- Arthrodesis e.g., talocrural arthrodesis, subtalar arthrodesis, Lapidus arthrodesis, 1st MTP arthrodesis, Interphalangeal (IP) arthrodesis

Features / Unique Selling Points

Easy insertion with removable metallic insertion adapter.

Single sterile packed. Excellent also in pediatric orthopaedics.

ActivaScrew™ implants are available in fully threaded design with various diameters and lengths, featuring patented Auto-Compression™ technology.

Self-reinforced structure provides additional strength, stiffness and malleability.

Auto-Compression™ technology for additional compression and fixation stability. bioretec Markets: OUS

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Product Codes

B-AS-2020 ActivaScrew™ 2.0 x 20 mm	B-AS-4535 ActivaScrew™ 4.5 x 35 mm	
	B-AS-4540 ActivaScrew™ 4.5 x 40 mm	
B-AS-2712 ActivaScrew™ 2.7 x 12 mm	B-AS-4545 ActivaScrew™ 4.5 x 45 mm	
B-AS-2714 ActivaScrew™ 2.7 x 14 mm	B-AS-4550 ActivaScrew™ 4.5 x 50 mm	
B-AS-2716 ActivaScrew™ 2.7 x 16 mm	B-AS-4555 ActivaScrew™ 4.5 x 55 mm	финициппи ф
B-AS-2718 ActivaScrew™ 2.7 x 18 mm	B-AS-4560 ActivaScrew™ 4.5 x 60 mm	
B-AS-2720 ActivaScrew™ 2.7 x 20 mm	B-AS-4570 ActivaScrew™ 4.5 x 70 mm	
B-AS-2724 ActivaScrew™ 2.7 x 24 mm	B-AS-4590 ActivaScrew™ 4.5 x 90 mm	
B-AS-3516 ActivaScrew™ 3.5 x 16 mm		
B-AS-3520 ActivaScrew™ 3.5 x 20 mm		ammmmmmid
B-AS-3524 ActivaScrew™ 3.5 x 24 mm		
B-AS-3528 ActivaScrew™ 3.5 x 28 mm		
B-AS-3532 ActivaScrew™ 3.5 x 32 mm		
B-AS-3536 ActivaScrew™ 3.5 x 36 mm		
B-AS-3540 ActivaScrew™ 3.5 x 40 mm		Θ m m m m m m m Θ
B-AS-3550 ActivaScrew™ 3.5 x 50 mm		7

Instrumentation Options

Product Code B-ISS-1000	Description Instrument set, for ActivaScrew™	pcs / package	
set includes following reusable instruments:			
B-IS-2000	Drill bit Ø1.5 mm, for 2.0 mm screws, quick coupling	1	
B-IS-2700	Drill bit Ø2.0 mm, for 2.7 mm screws, quick coupling	1	
B-IS-3500	Drill bit Ø2.5mm, for 3.5 mm screws, quick coupling	1	
B-IS-4500	Drill bit Ø3.2 mm, for 4.5 mm screws up to length 90 mm, quick coupling	1	
B-IS-4510	Drill bit Ø3.2 mm, for 4.5 mm screws up to length 70 mm, quick coupling	1	
B-IS-2001	Tap Ø2.0 mm, for 2.0 mm screws	1	
B-IS-2701	Tap Ø2.7 mm, for 2.7 mm screws	1	
B-IS-3501	Tap Ø3.5 mm, for 3.5 mm screws	1	
B-IS-4501	Tap Ø4.5 mm, for 4.5 mm screws up to length 90 mm	1	
B-IS-4511	Tap Ø4.5 mm, for 4.5 mm screws up to length 45 mm	1	
B-IS-2005	Double drill sleeve Ø1.5/2.0 mm, for 2.0mm screws	1	
B-IS-2705	Double drill sleeve Ø2.0/2.7 mm, for 2.7mm screws	1	
B-IS-3505	Double drill sleeve Ø2.5/3.5 mm, for 3.5mm screws	1	
B-IS-4505	Double drill sleeve Ø3.2/4.5 mm, for 4.5mm screws	1	
B-IS-2004	Countersink, for 2.0 mm screws	1	
B-IS-3504	Countersink, for 2.7/3.5 mm screws	1	
B-IS-4504	Countersink, for 4.5mm screws	1	
B-IS-9020	Depth gauge, for 2.0/2.7/3.5 mm screws	1	
B-IS-9021	Depth gauge, for 4.5 mm screws	1	
B-IS-9032	HEX shaft (2.5mm) with quick coupling for 2.0/2.7/3.5mm screws	1	
B-IS-9033	HEX shaft, for 4.5mm screws	1	
B-IS-3503	Holding sleeve, for 2.0/2.7/3.5mm screws	1	
B-IS-4503	Holding sleeve, for 4.5mm screws	1	
B-ISC-9013	Large handle, cannulated, quick coupling	1	
B-IS-9012	Small handle, quick coupling	1	
B-IS-9010	T-handle, quick coupling	1	
B-IS-9000	Sterilization tray, for ActivaScrew™ instruments	1	
Instruments are delivered unsterile.			

Product Properties

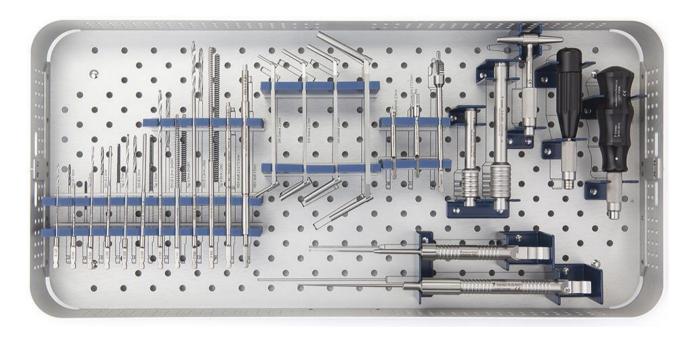
- Material: ActivaScrew[™] is made of PLGA 85/15, which safely absorbs in the body in approximately two years. The material has a long
 history of medical use and is proven to be safe in various scientific clinical studies and by real-world evidence.
- Certificates: ActivaScrew[™] is FDA cleared and CE approved.
- Product measures: ActivaScrew™ is available fully threaded in diameters 2.0, 2.7, 3.5 and 4.5 mm and lengths 20 90 mm.

ActivaScrewTM

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Reusable ActivaScrew™ Instrument Set B-ISS-1000



ActivaScrew[™] Adapter Detachment



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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.