ActivaScrew™ Cannulated

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™ Cannulated 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™ Cannulated 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™ Cannulated material facilitates bone healing and is absorbed in approximately two years.

Professional Benefits

ActivaScrew™ Cannulated implants are available in fully and partially threaded designs 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. ActivaScrew™ Cannulated implant offers additional surgery precision, since the screw can be installed using a guide wire. 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, a fully threaded ActivaScrew™ Cannulated implants can be cut appropriate length for example with a high temperature cautery or cutting tools.

- ActivaScrew™ Cannulated implants are served with own instrumentation
- ActivaScrew™ Cannulated implant are sterile packaged to ensure ease of use and maintain aseptic conditions during surgical procedures.

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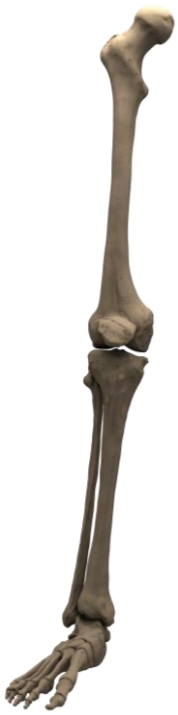
Overview

- For fixation of bone fractures, osteotomies, arthrodesis, bone grafts and osteochondral fractures of upper extremity, ankle and foot in the presence of appropriate immobilization.
- ActivaScrew™ Cannulated 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™ Cannulated material facilitates bone healing and is absorbed in approximately two years. It is made of PLGA 85/15.
- ActivaScrew™ Cannulated 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 upper extremities:

- Glenoid fractures
- Proximal humeral neck fractures
- Humeral condyle fractures
- Olecranon fractures
- Radial head fractures
- Distal radius fractures
- Hand fractures, e.g., metacarpal, phalanx, and scaphoid fractures



Common applications in lower extremities:

- 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.

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

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

Partially threaded and fully threaded cannulated implants.

Auto-Compression™ technology for additional compression and fixation stability.

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Product Codes

Fully threaded

B-ASC-3520 ActivaScrew™ Cannulated 3.5 x 20 mm
B-ASC-3524 ActivaScrew™ Cannulated 3.5 x 24 mm
B-ASC-3528 ActivaScrew™ Cannulated 3.5 x 28 mm
B-ASC-3532 ActivaScrew™ Cannulated 3.5 x 32 mm
B-ASC-3536 ActivaScrew™ Cannulated 3.5 x 36 mm
B-ASC-3540 ActivaScrew™ Cannulated 3.5 x 40 mm"

B-ASC-4035 ActivaScrew™ Cannulated 4.0 x 35 mm
B-ASC-4040 ActivaScrew™ Cannulated 4.0 x 40 mm
B-ASC-4045 ActivaScrew™ Cannulated 4.0 x 45 mm
B-ASC-4050 ActivaScrew™ Cannulated 4.0 x 50 mm
B-ASC-4055 ActivaScrew™ Cannulated 4.0 x 55 mm
B-ASC-4060 ActivaScrew™ Cannulated 4.0 x 60 mm
B-ASC-4065 ActivaScrew™ Cannulated 4.0 x 65 mm
B-ASC-4070 ActivaScrew™ Cannulated 4.0 x 70 mm
B-ASC-4080 ActivaScrew™ Cannulated 4.0 x 80 mm
B-ASC-4090 ActivaScrew™ Cannulated 4.0 x 90 mm

B-ASC-4540 ActivaScrew™ Cannulated 4.5 x 40 mm
B-ASC-4550 ActivaScrew™ Cannulated 4.5 x 50 mm
B-ASC-4560 ActivaScrew™ Cannulated 4.5 x 60 mm
B-ASC-4570 ActivaScrew™ Cannulated 4.5 x 70 mm
B-ASC-4580 ActivaScrew™ Cannulated 4.5 x 80 mm
B-ASC-4590 ActivaScrew™ Cannulated 4.5 x 90 mm

Partially threaded

B-ALC-3524 ActivaScrew™ Cannulated LAG 3.5 x 24 mm
B-ALC-3526 ActivaScrew™ Cannulated LAG 3.5 x 26 mm
B-ALC-3528 ActivaScrew™ Cannulated LAG 3.5 x 28 mm
B-ALC-3530 ActivaScrew™ Cannulated LAG 3.5 x 30 mm
B-ALC-3535 ActivaScrew™ Cannulated LAG 3.5 x 35 mm
B-ALC-3540 ActivaScrew™ Cannulated LAG 3.5 x 40 mm
B-ALC-3545 ActivaScrew™ Cannulated LAG 3.5 x 45 mm

B-ALC-4035 ActivaScrew™ Cannulated LAG 4.0 x 35 mm
B-ALC-4040 ActivaScrew™ Cannulated LAG 4.0 x 40 mm
B-ALC-4045 ActivaScrew™ Cannulated LAG 4.0 x 45 mm
B-ALC-4050 ActivaScrew™ Cannulated LAG 4.0 x 50 mm
B-ALC-4055 ActivaScrew™ Cannulated LAG 4.0 x 55 mm
B-ALC-4060 ActivaScrew™ Cannulated LAG 4.0 x 60 mm
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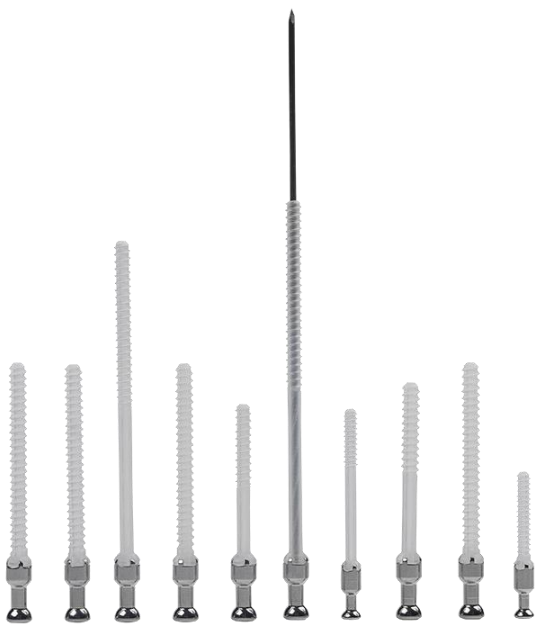

Product properties

- Material: ActivaScrew™ Cannulated 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: ActivaScrew™ Cannulated is FDA cleared and CE approved.
- Product measures: ActivaScrew™ Cannulated is available in diameters 3.5, 4.0 and 4.5 mm and lengths 20 – 90 mm.

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Instrumentation options

Product Code	Description	pcs / package
B-ISC-1000	Instrument set, for ActivaScrew™ Cannulated	1
set includes the following reusable instruments:		
B-ISC-1250	K-wire Ø1.25 mm, length 150 mm, threaded tip, for 3.5mm cannulated screws	2
B-ISC-1600	K-wire Ø1.6 mm, length 150 mm, threaded tip, for 4.0/4.5mm cannulated screws	2
B-ISC-1251	K-wire Ø1.25 mm, length 150 mm, trocar tip, for 3.5mm cannulated screws	1
B-ISC-1601	K-wire Ø1.6 mm, length 150 mm, trocar tip, for 4.0/4.5mm cannulated screws	1
B-ISC-3500	Drill bit Ø2.7 mm, for 3.5 mm cannulated screws, quick coupling	1
B-ISC-4000	Drill bit Ø3.2 mm, for 4.0 mm cannulated screws, quick coupling	1
B-ISC-4500	Drill bit Ø3.5 mm, for 4.5 mm cannulated screws, quick coupling	1
B-ISC-3501	Tap Ø3.5 mm, for 3.5 mm cannulated screws	1
B-ISC-4001	Tap Ø4.0 mm, for 4.0 mm cannulated screws	1
B-ISC-4501	Tap Ø4.5 mm, for 4.5 mm cannulated screws	1
B-ISC-9013	Large handle, cannulated, quick coupling	1
B-IS-9010	T-handle, quick coupling	1
B-ISC-9032	HEX shaft, for 3.5 mm cannulated screws	1
B-ISC-9033	HEX shaft, for 4.0/4.5 mm cannulated screws	1
B-ISC-3502	Direct driver, for 3.5 mm cannulated screws	1
B-ISC-4502	Direct driver, for 4.0/4.5 mm cannulated screws	1
B-ISC-9020	Depth gauge, for cannulated screws	1
B-IS-3503	Holding sleeve, for 2.0/2.7/3.5mm screws	1
B-ISC-4503	Holding sleeve, for 4.0/4.5mm cannulated screws	1
B-ISC-4504	Countersink, for cannulated screws	1
B-ISC-3505	Double drill sleeve Ø2.7/3.5 mm, for 3.5 mm cannulated screws	1
B-ISC-4505	Double drill sleeve Ø4.5/3.5 mm, for 4.0/4.5 mm cannulated screws	1
B-IS-6505	Protection sheath	1
B-ISC-9000	Sterilization tray, for ActivaScrew™ Cannulated instruments	1

Instruments are delivered unsterile.

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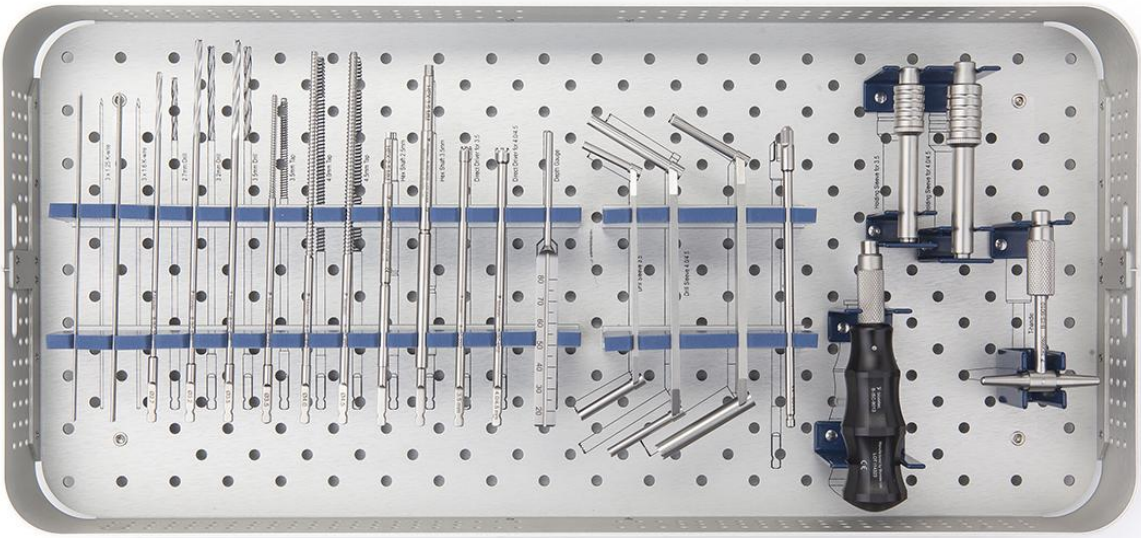
Reusable ActivaScrew™ Cannulated instrument set B-ISC-1000



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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.