BIOABSORBABLE PINS AND SCREWS IN ORTHOPAEDICS AND TRAUMATOLOGY, ESPECIALLY FOCUSING TO PEDIATRIC FIXATION

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BIOABSORBABLE FIXATION YESTERDAY AND TODAY

1985

Bioscience Ltd. (Tampere, Finland) launched first in the world bioabsorbable pins for cancellous bone fracture fixation.

2012

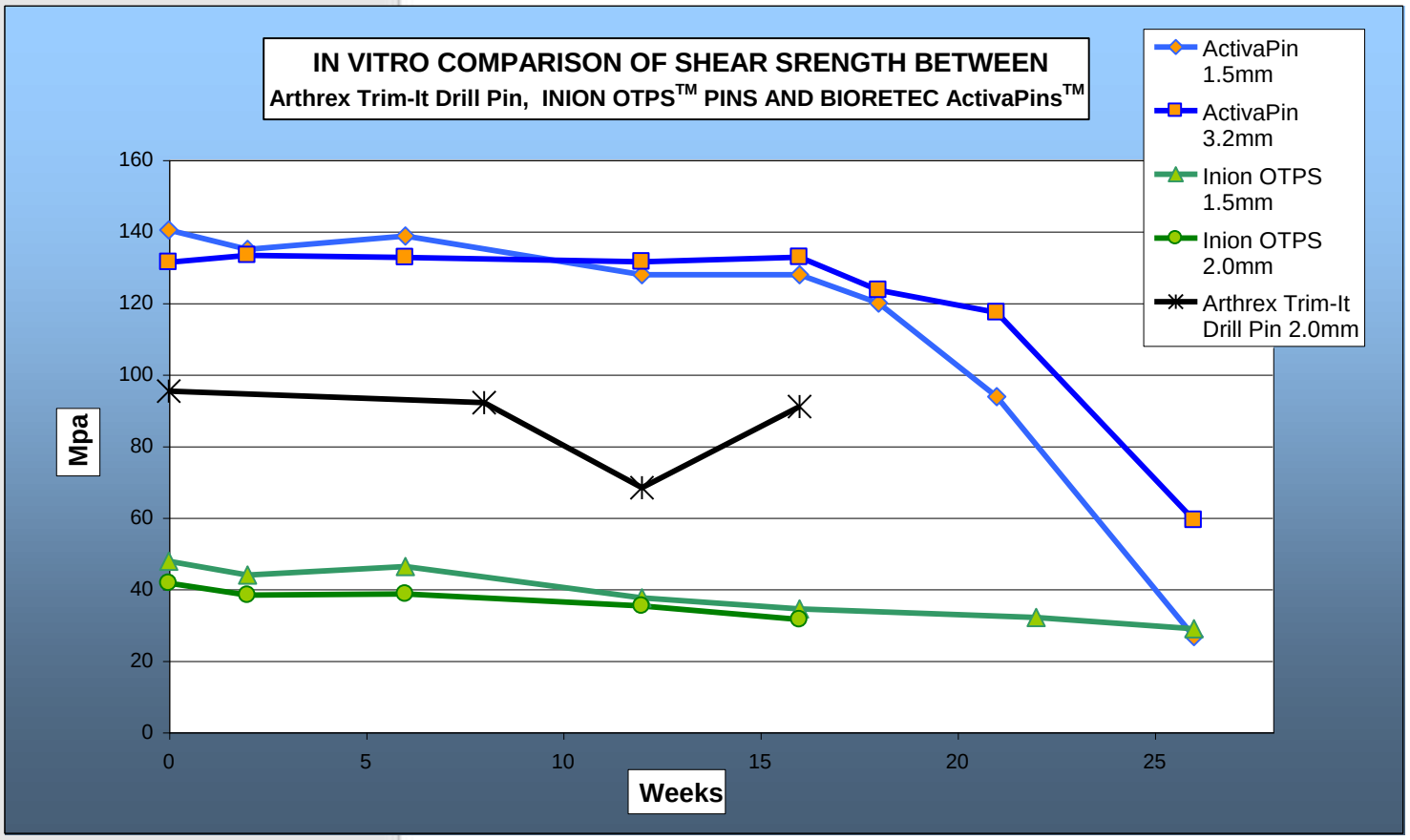
More than 20 companies deliver worldwide bioabsorbable fixation devices for musculoskeletal applications. Bioretec Ltd. (Tampere, Finland) is one of such companies.

ActivaPin™

- **The ActivaPin ™** is constructed of bioabsorbable lactic/glycolic acid copolymer (PLGA).
- ActivaPin™ offers:
  - Self-Locking SL ™ technology with its patented grooved surface design.
  - High Strength properties offers stabilized fixation, easy insertion and safe medical use.
  - The bending modulus is closer to the value of cortical bone compared to metallic implants.
  - It's designed to gradually restore the original load carrying capacity of the bone.
  - Bioabsorbable, eliminates the risk of long term complications and removal operations.
  - Completely aseptic product handling in operation theatre thanks to advanced holder&instrument concept.
- The ActivaPin™ maintains its intended function for at least 8 weeks. Complete bioabsorption takes place approximately within 2 years.
- ActivaPin™
  FDA permit to legally market July 6, 2006. K061164
  CE approval February 12, 2007.

Pat.pending: FI 20065385; EPO Patent Application 07397017.0; U.S. Patent Application 11/808,074; Patent Application FI 20075881

Comparison testing - Shear Strength - ActivaPin™



Manufacturing method and material composition of the ActivaPin™ creates high mechanical strength to the implant!

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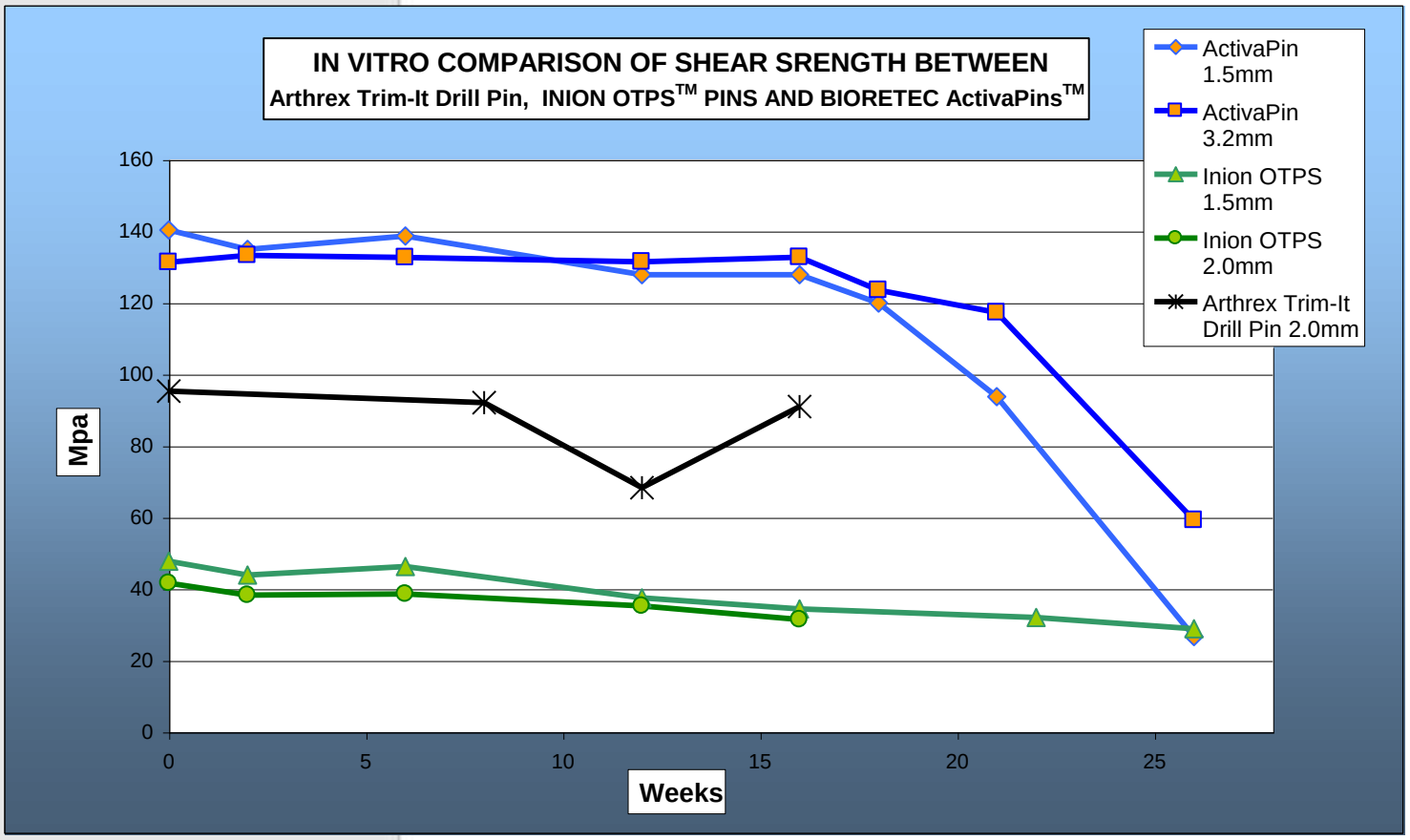
Comparison testing - Shear Strength - ActivaPin™



Manufacturing method and material composition of the ActivaPin™ creates high mechanical strength to the implant!

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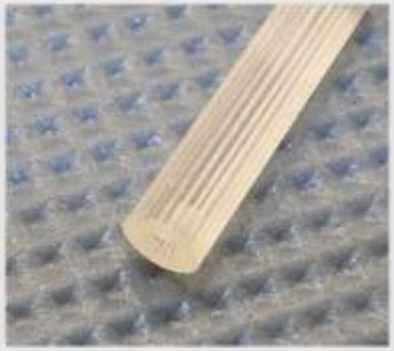
ActivaScrew ™

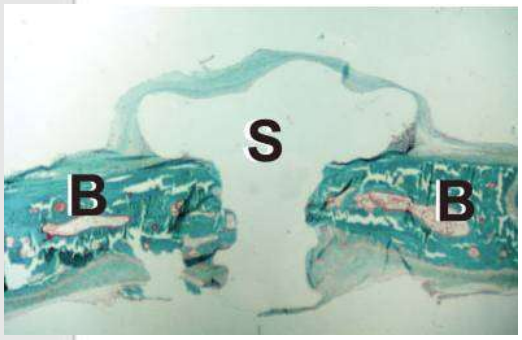
- **The ActivaScrew™** is constructed of bioabsorbable bioabsorbable lactic/glycolic acid copolymer (PLGA).
- ActivaScrew ™ offers:
  - Auto-Compression™ technology with its patented mechanical activity.
  - The ActivaScrew™ is fully compatible with AO-instrumentation. The sizing of product range follows AO-school principle.
  - High Strength properties offers stabilized fixation, easy insertion and safe medical use.
  - The bending modulus is closer to the value of cortical bone compared to metallic implants.
  - It's designed to gradually restore the original load carrying capacity of the bone.
  - Bioabsorbable, eliminates the risk of long term complications and removal operations.
  - Completely aseptic product handling in operation theatre thanks to advanced holder&instrument concept.
- The ActivaScrew™ maintains its intended function for at least 8 weeks. Complete bioabsorption takes place approximately within 2 years.
- ActivaScrew™
  - FDA permit to legally market November 22, 2006. K062980
  - CE approval May 10, 2007.

Pat.pending: EPO Patent Application 07108722.5,
U.S. Patent Application 11/802,692

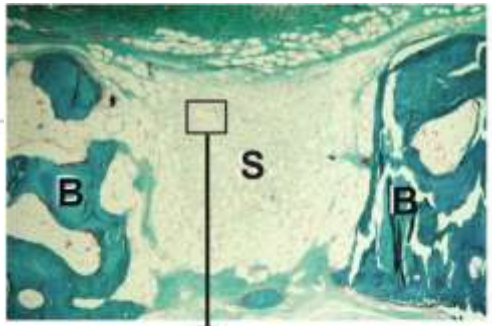
PRECLINICAL EXPERIENCE – IN VIVO DEGRADATION



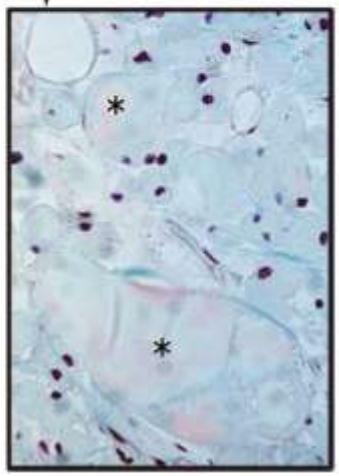
0 weeks



2 weeks

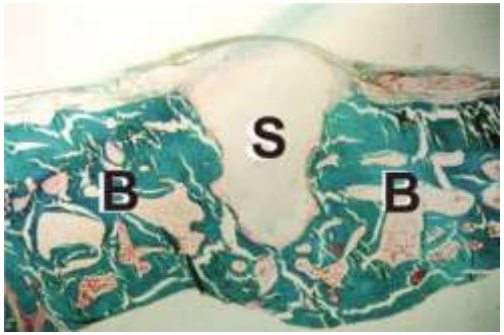


52 weeks



52 weeks

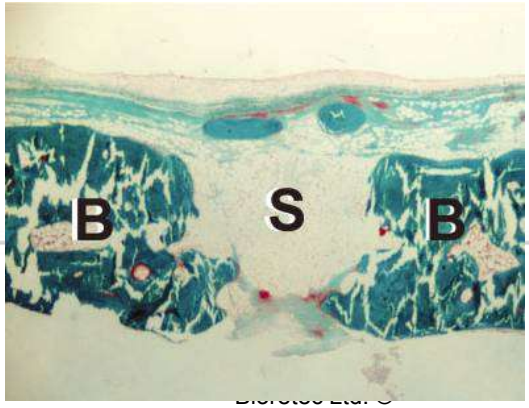
26 weeks



24 weeks

104 weeks

72 weeks



Tiainen J, Soini Y, Törmälä P, Waris T, Ashammakhi N. Self-Reinforced Polylactide/Polyglycolide 80/20 Screws Take More Than 1 ½ years to Resorb in Rabbit Cranial Bone; Journal of Biomedical Material Research, part B: Applied Biomaterials, 70B (2004) p. 49-55

POSSIBILITIES TO USE BIORETEC´S PINS IN FIXATION OF FRACTURES AND OSTEOTOMIES IN CHILDREN (**EU/US**)

ActivaPin™ with diameters 1.5 mm and 2.0 mm can be used for fixation of physeal fractures, osteotomies, arthrodeses and osteochondral fractures in children, even if the pins must be driven through the growth plate, unless the area thus destroyed by the pin tracks exceeds 3 % of the total area of the growth plate (A.Mäkelä, Doctoral Thesis, Helsinki University, 1989).

Examples of possible indications:

Fractures of the lateral humeral condyle

Fractures of the medial condyle and the medial epicondyle of humerus

Shear fractures of capitellum

Fractures of distal radius

Fractures of radial head

Fractures of radial neck

Fractures of the phalanges

Fractures of metacarpals

Fractures of metatarsal bone

Fixation of osteochondritis dissecans fragments

Fractures of the medial malleolus

The effect of the ActivaPin™ upon the healing of growth plate has not been tested clinically.

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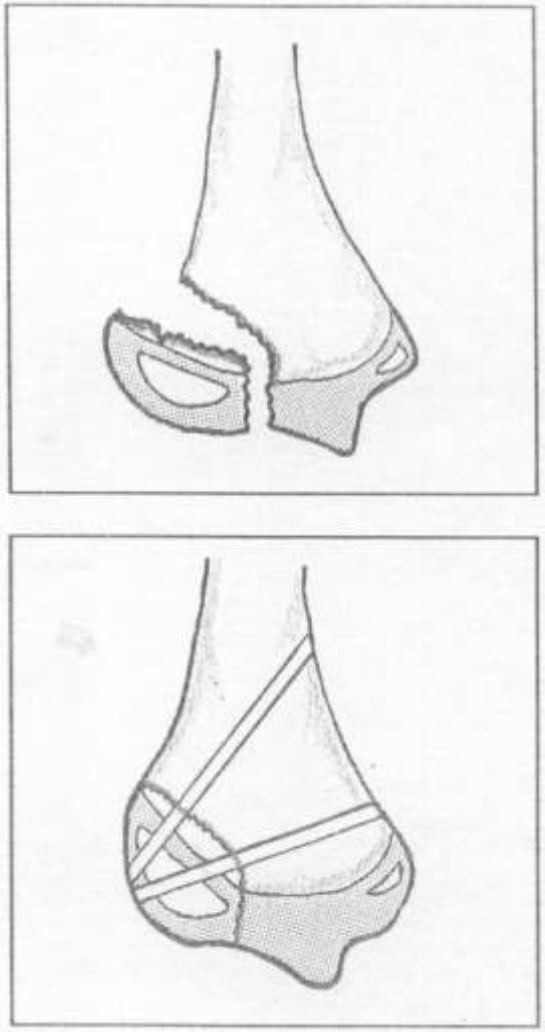
FIXATION OF FRACTURE OF THE LATERAL HUMERAL CONDYLE



POSSIBILITIES TO USE BIORETEC´S SCREWS IN FIXATION OF FRACTURES AND OSTEOTOMIES IN CHILDREN (**EU**)

ActivaScrew™ with diameters 2.0 mm, 2.7 mm, 3.5 mm and 4.5 mm can be used for fixation of cancellous bone fractures and osteotomies, arthrodeses, bone grafts and osteochondral fractures in children. Alternatively ActivaScrew™ Cannulated with diameters 3.5 mm, 4.0 mm and 4.5 mm can be used.

Screws should not be driven through the growth plate.

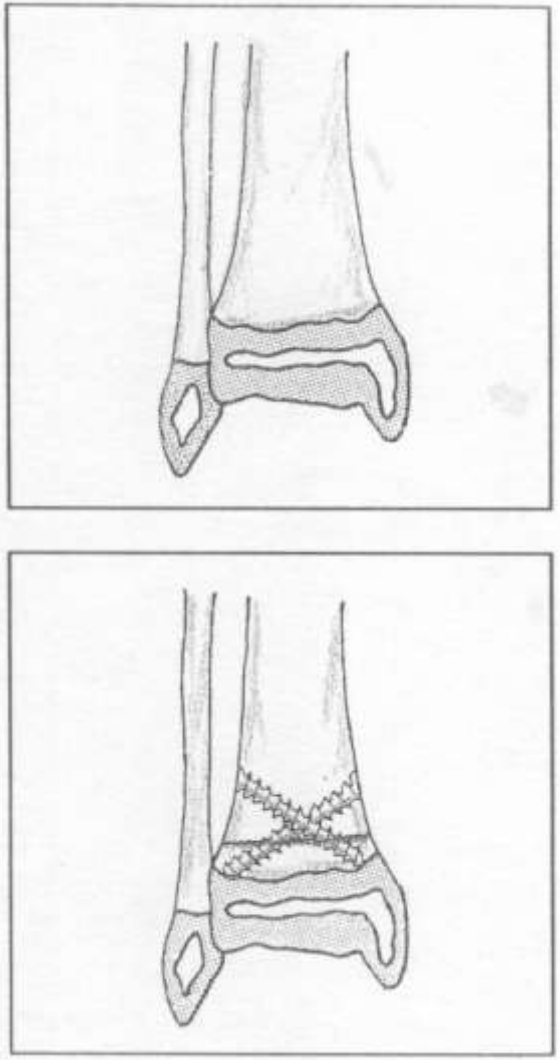
Examples of possible indications:

Talocalcaneal arthrodesis

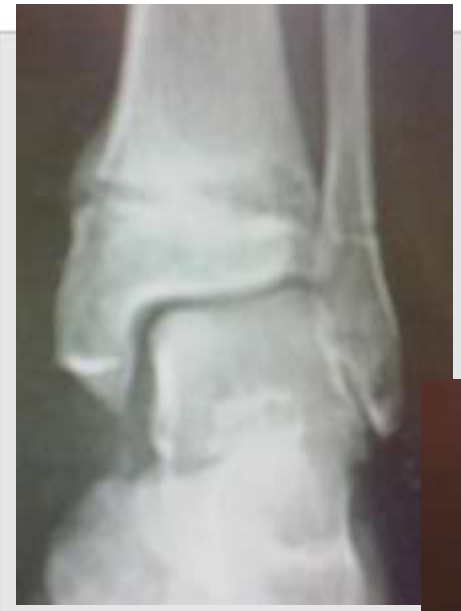
Distal tibial osteotomy

Pelvic osteotomy in the treatment of congenital hip dysplasia

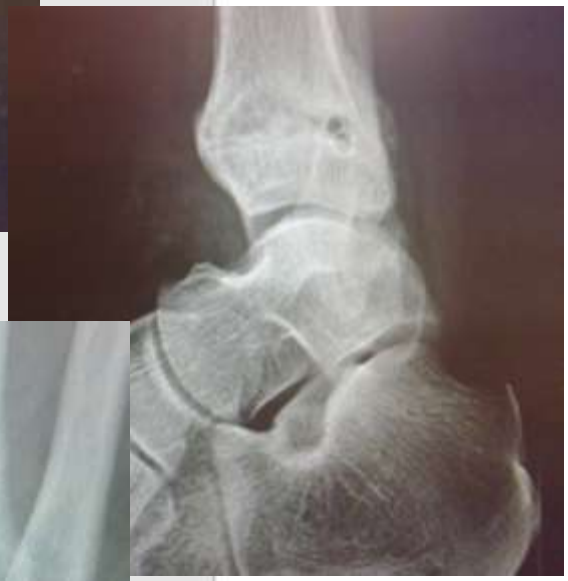
FIXATION OF DISTAL TIBIAL OSTEOTOMY

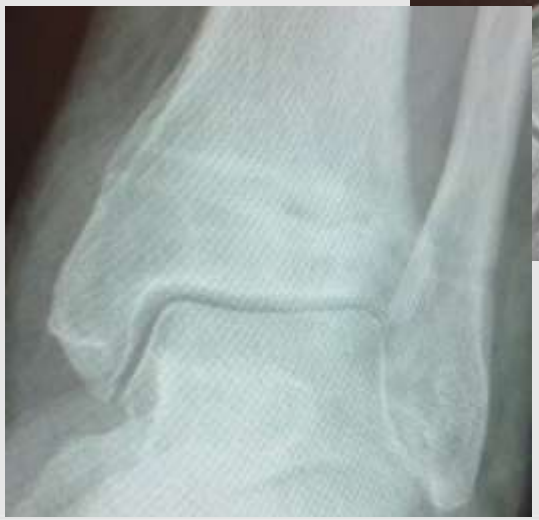


CLINICAL EXPERIENCE – FOREIGN BODY REACTIONS



26 weeks

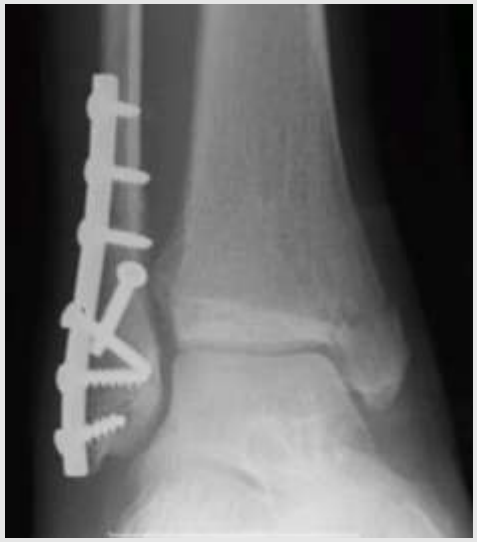




52 weeks

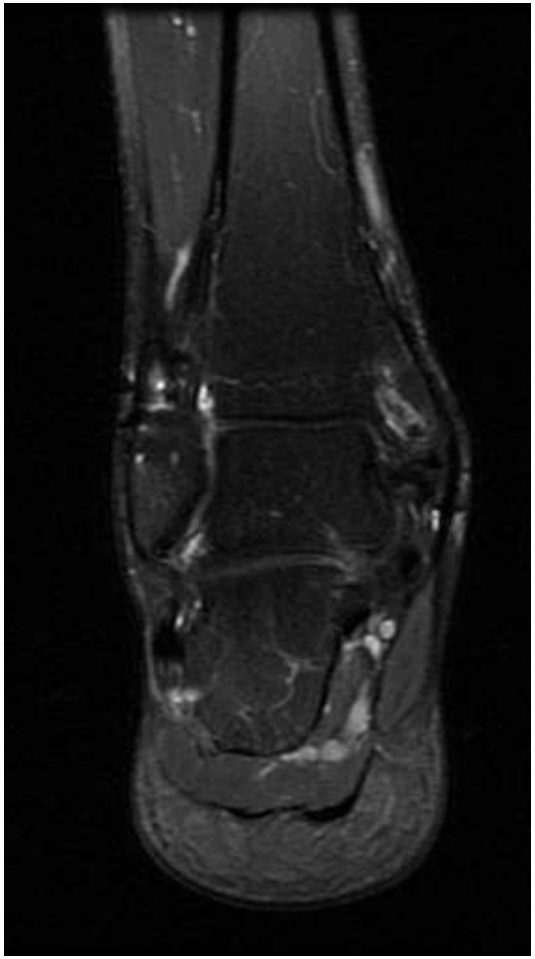
- **Clinically noticeable foreign body reactions with Bioretec products**
  - Approx. 25 000 – 30 000 patients operated since autumn 2007
  - One reaction case suspected

CLINICAL EXPERIENCE – IMPLANT HOLES

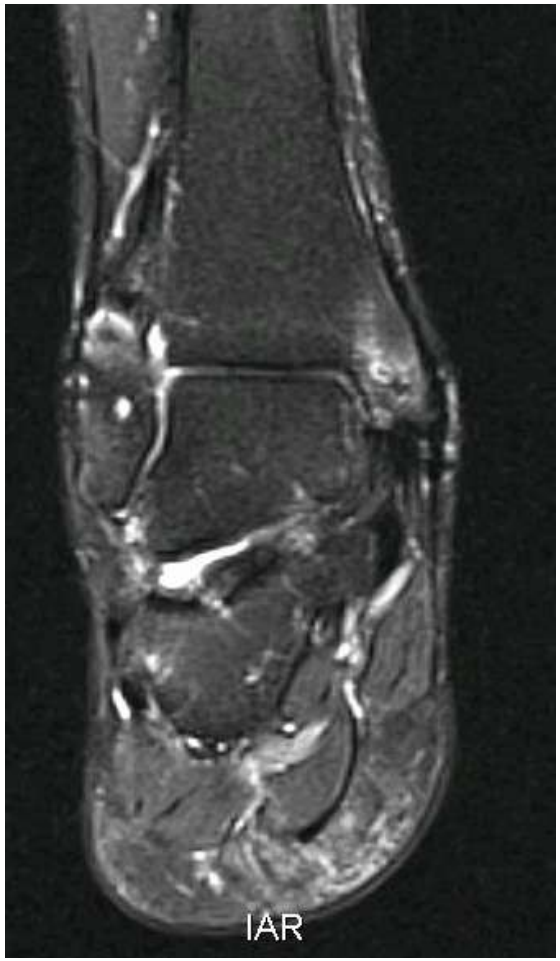


2 weeks post op X-ray.

Fixation of bimalleolar ankle fracture on lateral side with metallic harware and on the medial side with two ActivaScrew™ 4.5 mm. Metallic hardware was removed at one year because of pain and irritation. (54 Year, female)



2 Years 1 month post op MRI



4 Years 1 month post op MRI

Implants that do more – It’s Bioretec

Thank you for your interest!