Evidence in focus

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REGENESORB Absorbable Biocomposite Material

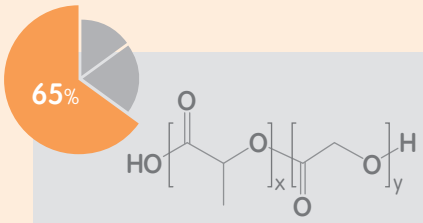
A novel formulation of materials with long histories of clinical use

Summary

REGENESORB is a bioabsorbable biocomposite material designed to remain mechanically stable for a minimum of six months before being absorbed and replaced by bone within 24 months.[1]

Material overview

REGENESORB is comprised of the copolymer PLGA (poly [l-lactide co-glycolide]; 65%) combined with two fillers, beta-tricalcium phosphate (ß-TCP; 15%) and calcium sulfate (20%), which is specific to REGENESORB. Each of these components have long histories of clinical use in implanted surgical devices.[2–4]

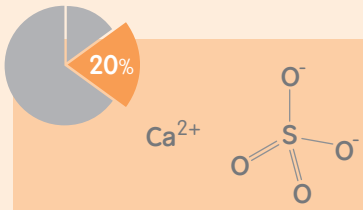


PLGA

Purpose
Responsible for providing overall structural integrity of the implant

Action
PLGA is composed of two polymers, poly l-lactic acid (PLLA) and polyglycolic acid (PGA). The absorption characteristics of PLGA are dependent on the ratio of PLLA:PGA,[5] for REGENESORB the ratio is 85:15.[1]

Time to absorbance
24 months[1]



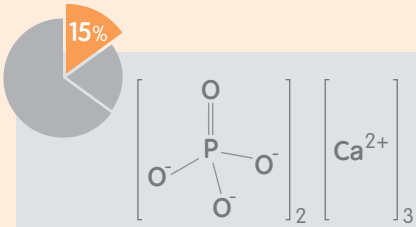
Calcium sulfate

Purpose
Promotes bone growth in the early stage of healing[6]

Action
Calcium sulfate is osteoconductive.[4,7,8] When calcium sulphate dissolves it chemically activates the cycle of bone growth, reacting with platelets to promote bone growth. The release of calcium ions activates platelets to produce local growth factors which stimulate osteogenic differentiation of mesenchymal stem cells.[9–11]

Time to absorbance
4–8 weeks[6]

Specific to REGENESORB



ß-TCP

Purpose
Acts as a scaffold for new bone ingrowth

Action
ß-TCP is a calcium phosphate filler which is osteoconductive.[7,8] Exposed calcium phosphate on the implant supports local osteoblast adhesion and new bone build up. ß-TCP has a similar compressive and tensile strength to cancellous bone.[7]

Time to absorbance
6–18 months[6]

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Preclinical testing

The purpose of biocomposite, bioabsorbable surgical implants is to provide fixation during the initial healing period and for some time after until the material is completely absorbed and replaced by new native tissue. The aim is to reduce the time of absorption and replacement, providing fast restoration of new native tissue.

REGENESORB hypothesis: The unique composition of REGENESORB will be an improvement on currently available products. REGENESORB will be replaced by bone within 24 months and work faster than implants composed of PLLA-hydroxyapatite (HA).

In preclinical studies, REGENESORB is replaced by bone within 24 months[1]

Study design

9 x 10mm interference screws moulded in REGENESORB were implanted into the distal femur or proximal tibia of sheep

Histological and micro-computer tomography analysis was conducted at 6, 12, 18 and 24 months

Results

6 months: REGENESORB screws largely intact

12 months: REGENESORB screws had begun to degrade and were partially fragmented with indications of new bone growth

18 months: REGENESORB screws degrading and evidence of new bone growth

At 24 months, REGENESORB material was absorbed and replaced by bone

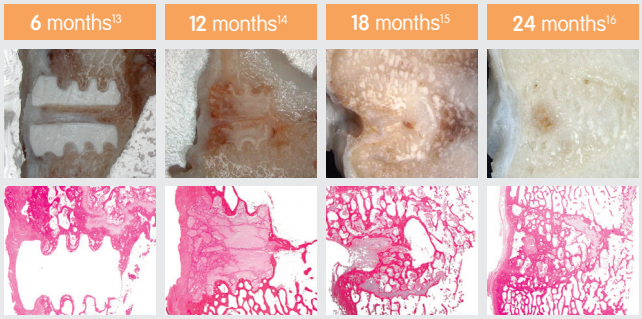

Figure 1. Absorption profile of the REGENESORB implant

In preclinical studies, REGENESORB is absorbed and replaced by bone faster than PLLA-HA[12]

Study design

REGENESORB or PLLA-HA suture anchors were implanted into the distal femur or proximal tibia of sheep

Histological and micro-CT analysis was conducted at 12 and 18 months

Results

12 months: Varying levels of degradation of REGENESORB, no degradation of PLLA-HA implant

At 18 months, REGENESORB demonstrated significant new bone fill and PLLA-HA showed no visible signs of absorption

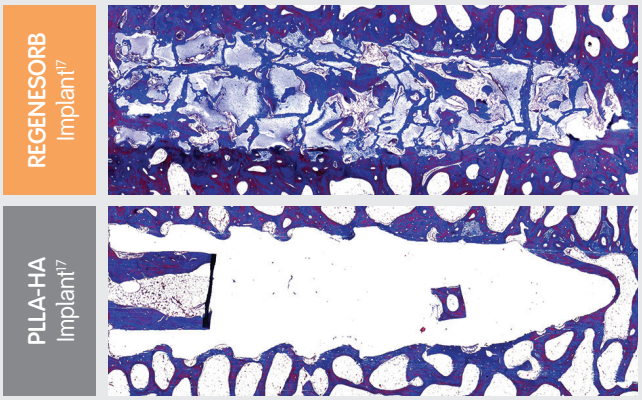

Figure 2. REGENESORB material vs PLLA-HA at 18 months

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