

Bioretec

The first to market a new generation of bioresorbable metal implants in the USA

Briefing for investors, analysts and media

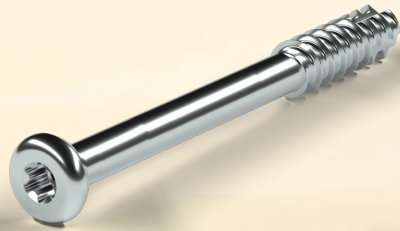
30 March 2023

better healing – better life

In this release the term (bio)resorbable is interchangeable with (bio)absorbable and (bio)degradable



RemeOs™ is the first and only bioresorbable metal trauma screw in the US market



Bioretec's goal is to produce **bioresorbable implants to improve patients' quality of life** and produce significant benefits...



Patients

- ...No need for removal surgery
- ...The risks of complications are reduced.



Surgeons

- ...Only value-creating care measures
- ...No risks associated with removal surgeries



Society

-More efficient use of health care resources
- ... Reduce the total cost of care

FDA confirmed benefits of RemeOs™ trauma screw and material



Excellent biocompatibility

= Safe

Bioactive, osteopromotive properties

= Enhanced bone growth

Rapid bone ingrowth, regeneration, and replacement

= Makes removal operations redundant

Strength retention tailored to match the bone healing

= Carries the load over the healing period

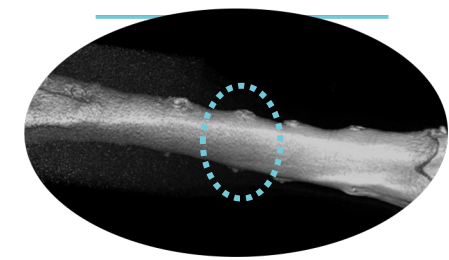
Fixation strength comparable with conventional metal implants

= No screw loosening due to gas evolution

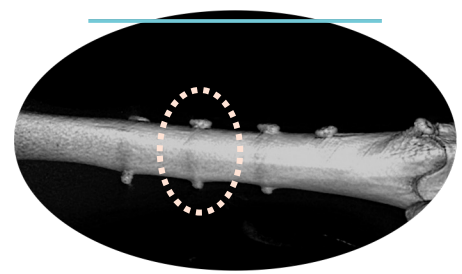
Easy insertion and use, comparable to conventional metal implants

= Common surgical techniques

RemeOs™



Titanium



The RemeOs™ bioresorbable metal is composed of natural elements found in the human body **Magnesium (Mg), Calcium (Ca) and Zinc (Zn)**

De Novo decision – a predicate for Bioretect for the expansion to other indications



PRE-OP



WEEK 12



WEEK 130



FDA's decision to grant this De Novo request identifies this as a new type of device classification:

Absorbable metallic bone fixation fastener

The First RemeOs™ indication is for the Ankle and Foot area and FDA RemeOs™ Trauma Screw approval is for ¹

- RemeOs™ Screw LAG Solid is intended for the use in traumatic and orthopedic surgery for the fixation of bone fractures (osteosynthesis) and for the fixation after osteotomies, e.g., for the correction of deformities or malalignments. The absorbable implants serve as temporary fixation and stabilization by osteosynthesis of bone fractures and osteotomies until bony fusion has occurred. The RemeOs™ Screw LAG Solid is intended to be used for skeletally mature adults. The RemeOs™ Screw LAG Solid is indicated for the fixation of the medial malleolus.

The Breakthrough Device Designation program continues for the expansion of the RemeOs™ products and indications in cooperation with the FDA

- De Novo Request approval opens a less burdensome regulatory pathway (510k) for the next RemeOs™ indications and product lines

Fast growing and sizeable market available for the first indication of RemeOs™ trauma screws

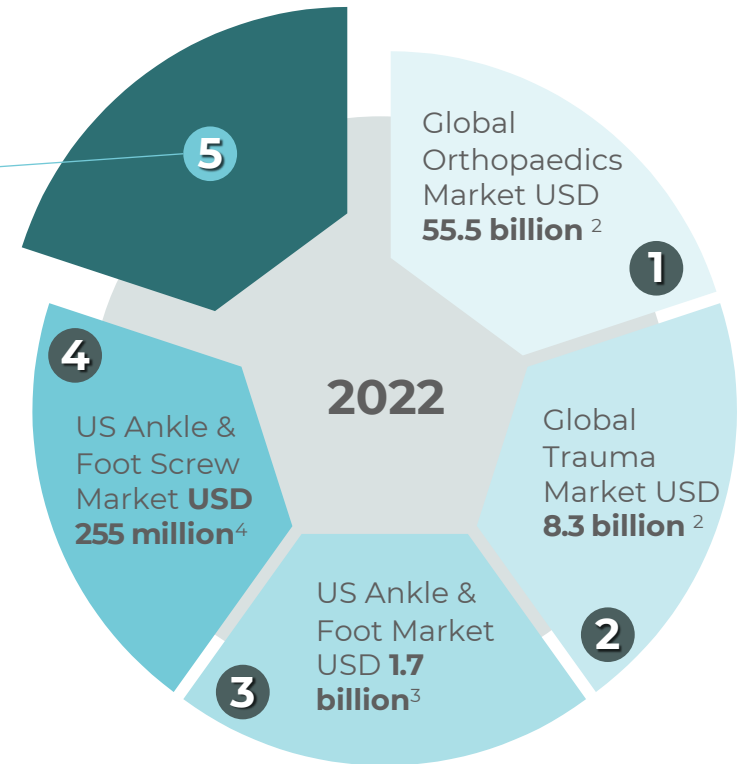
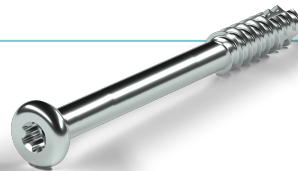


The Ankle and Foot devices market is likely to witness lucrative market opportunities on account of the use of bioresorbable implants and the emergence of technological advancements.¹



US Ankle & Foot addressable market Is USD 180 million in 2022⁵

The U.S. Ankle and Foot market is estimated to grow **(CAGR) by 7.3%** per the year 2022-2027³.



Bioretec estimate is based on the following sources of market forecasts:

¹ <https://www.futuremarketinsights.com/reports/foot-and-ankle-devices-market>

² Orthoworld: The Orthopaedic Industry Annual Report 2022 ja Orthopedic Market 2022 Projections & 2023 Outlook.

³ <https://www.marketdataforecast.com/market-reports/north-america-foot-and-ankle-devices-market>

⁴ GlobalData Report 2020, Trauma Fixation (Orthopedic Devices)

⁵ Ankle Fractures. [Updated 2022 Aug 15]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls

FDA market authorization - next steps

- **Next steps and strategic focus:**

- Launch the RemeOs™ trauma screws in the US in collaboration with hospitals and clinical professionals specialized in ankle fractures.
- Sales are expected to grow gradually as US clinics gain confidence in the breakthrough technology

- **The Breakthrough device program continues**

- The market authorization opens a regulatory path for the next RemeOs™ product lines covering a wide array of indications



Q&As

Participants:

Timo Lehtonen, CEO

Johanna Salko, CFO



Thank You!

More information:

www.bioretec.com

www.bioretec.com/investors

www.bioretec.com/products

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