



bioretec

***The first to market
bioresorbable metal
implants in the USA***

Timo Lehtonen, CEO

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

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

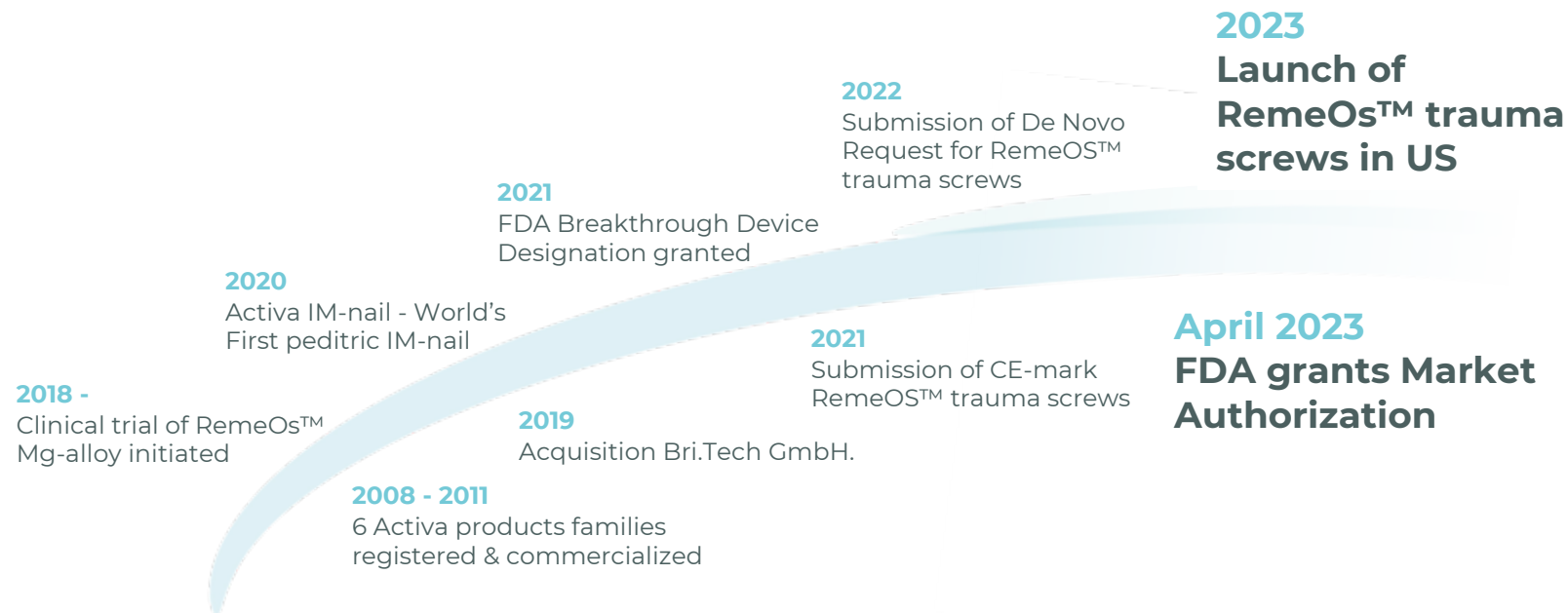


Society

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

Bioretec in brief:

- A globally operating company that **develops, manufactures, and sells bioresorbable orthopedic implants**
 - HQ and production in Tampere, Finland and a subsidiary in Austria
 - Publicly listed in Nasdaq First North Growth Market Finland



**~ 3 M€
2022 Revenue**

**~ 40 countries
around the world**

**8 registered
product families**

Our Products: **Bioresorbable orthopedic implants**

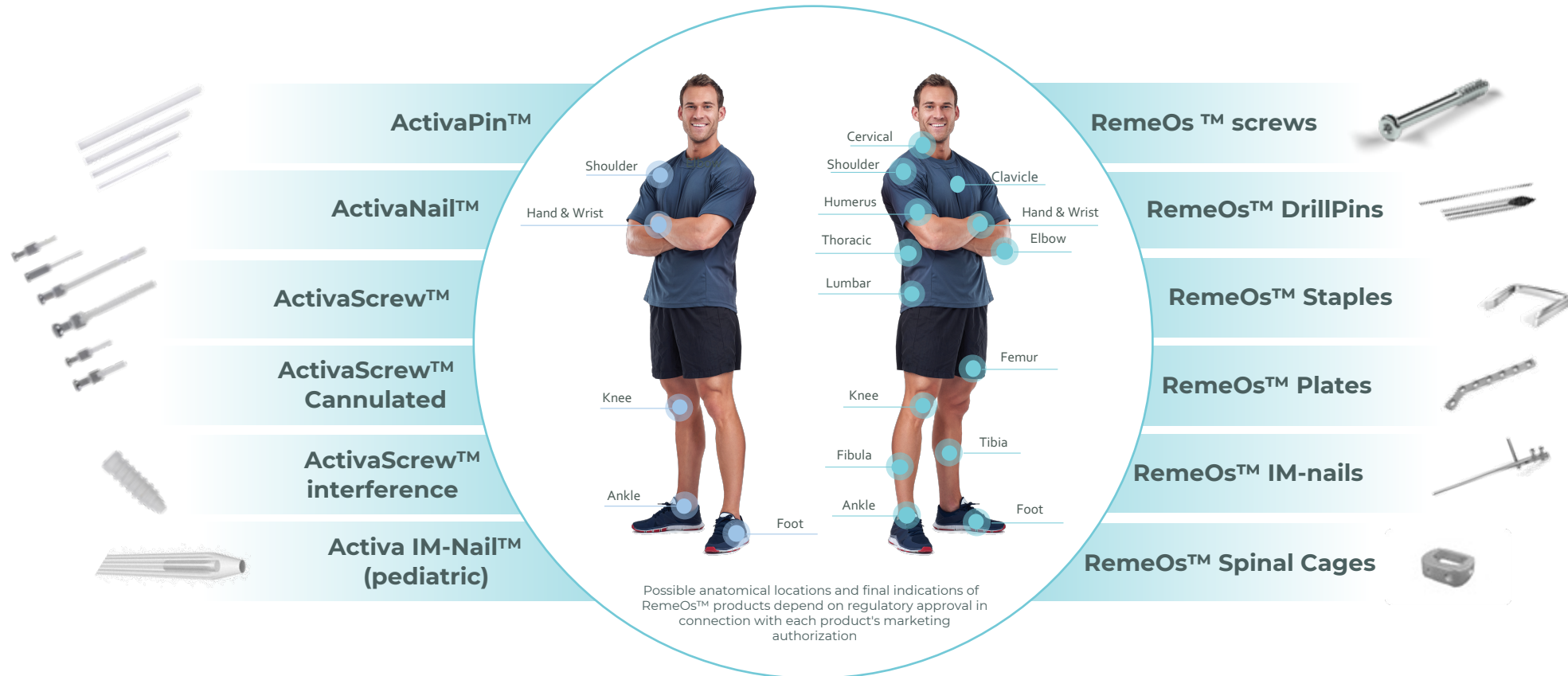
Commercially available Activa –product lines

- ✓ Based on Biopolymer (SR-PLGA)
- ✓ Currently available globally in ~40 countries
- ✓ **Basis for know-how and foundation of RemeOs™**



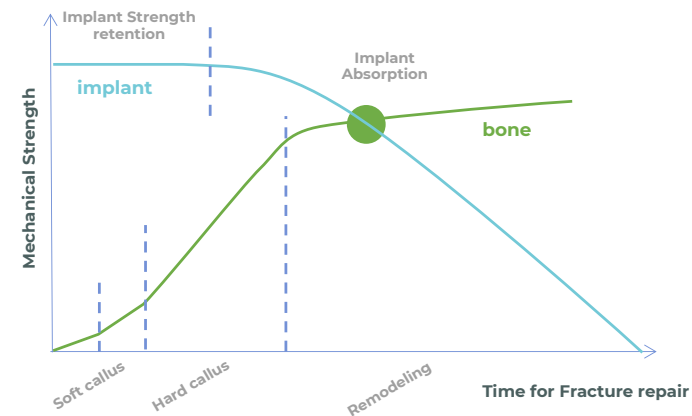
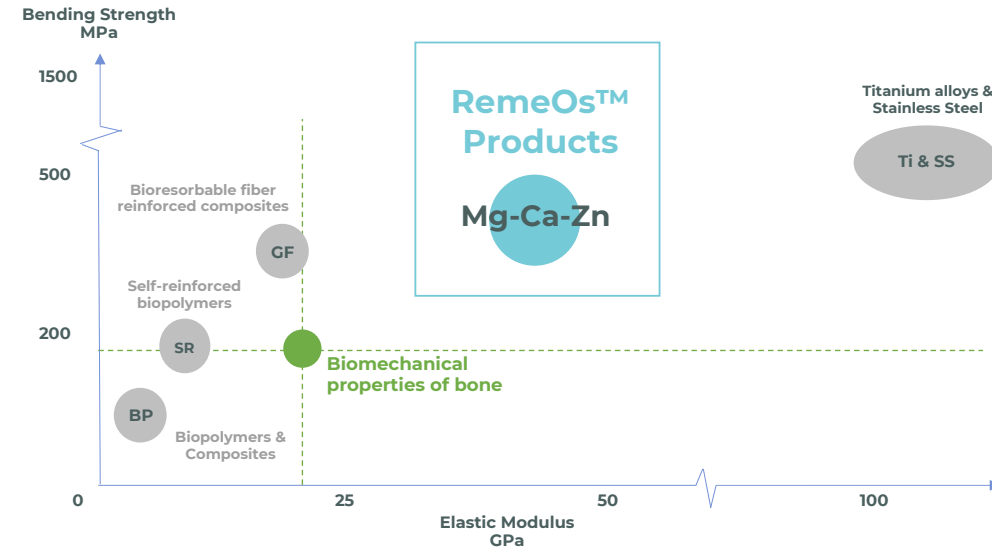
Next generation RemeOs™ -lines

- ✓ Based on Bioresorbable metal (**Mg-Zn-Ca**)
- ✓ Expanding current biopolymer indication
- ✓ **First RemeOs™ products are available now**

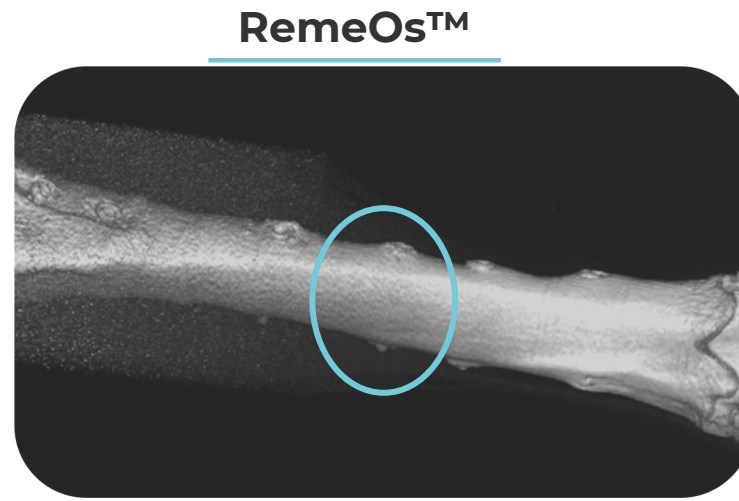
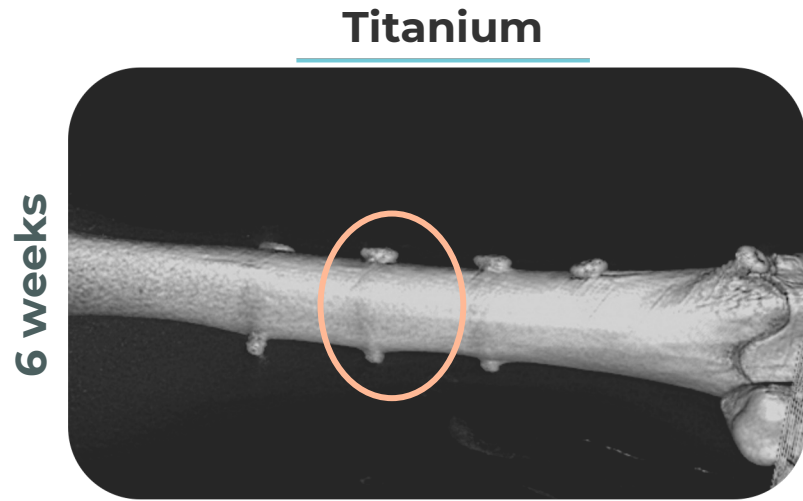


Bioretec's RemeOs™ technology is optimized to support bone healing

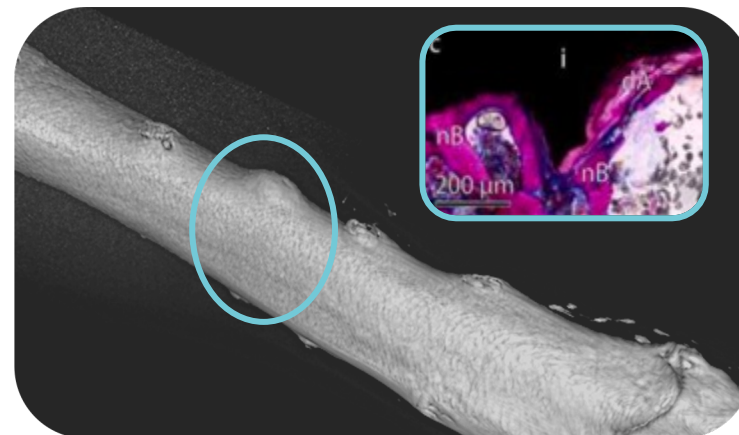
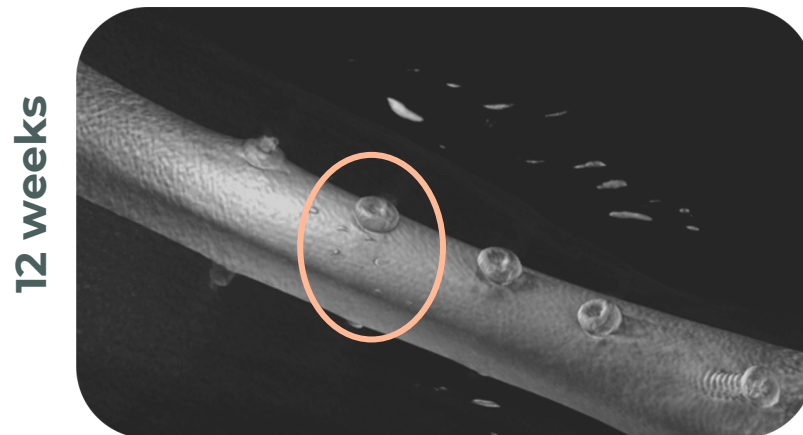
- Mg is present in large amounts in the human body and involved in many metabolic reactions and biological mechanisms as in bone growth.
 - The human body usually contains approximately 35g per 70kg body weight and the human body's daily demand for Mg is about 350 mg/day.
- It is well known that pure magnesium has poor mechanical properties, but the mechanical properties of magnesium can be effectively improved by the appropriate selection of alloying elements.
- **RemeOs™ is a Magnesium – Calcium – Zinc alloy**
 - Ca - The mechanical properties and biocompatibility can be adjusted by controlling the Ca content
 - Zn - Improves the mechanical properties and corrosion resistance of Mg alloys
 - Biomechanical properties closer to bone (cortical) than traditional metals, biopolymers and composites
 - No stress shielding
 - Bioactive and osteopromotive



RemeOs™ shows **enhanced bone growth** and **osseointegration** in contrast to Titanium



Strong new bone growth already in 6 weeks time point and in 12 weeks time point implant overgrown with new bone (blue circle)

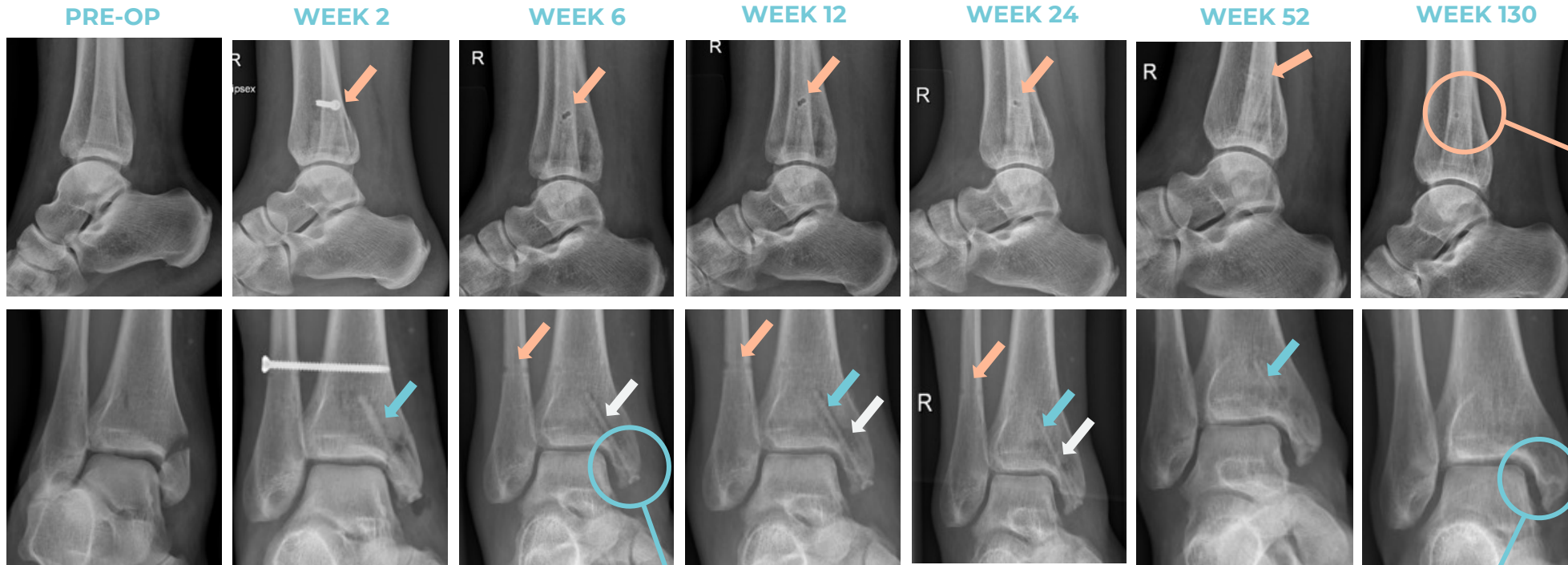


No biological activity with Titanium control group in 6 weeks or 12 weeks time point (orange circle)

Histology of an ovine tibia, 12 weeks after Mg-alloy bi-cortical implantation. Methylene-blue/basic fuchsin staining. Osteoconduction of a newly formed bone (nBpink/red color) with direct bone-implant contact was detected

Safety and Efficacy of Bioresorbable metal verified in clinical trial

Female, 47y



Removed (@ week 6) Syndesmosis screw and its removal hole (orange arrow) still visible in cortex after week 130

After 6 weeks fracture closed and fracture line not visible anymore.

Bioresorbable metal screw visible (blue arrow)
Absorption zone (white arrow)

Full absorption of the at week 130.

RemeOs™ Screw is the first and only bioresorbable metal product in the US market

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RemeOs™ Screw LAG Solid



FDA **confirmed benefits** of RemeOs™ trauma screw and material¹



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

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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

De Novo decision – The First RemeOs™ indication is for the Ankle and Foot area

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:

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.¹

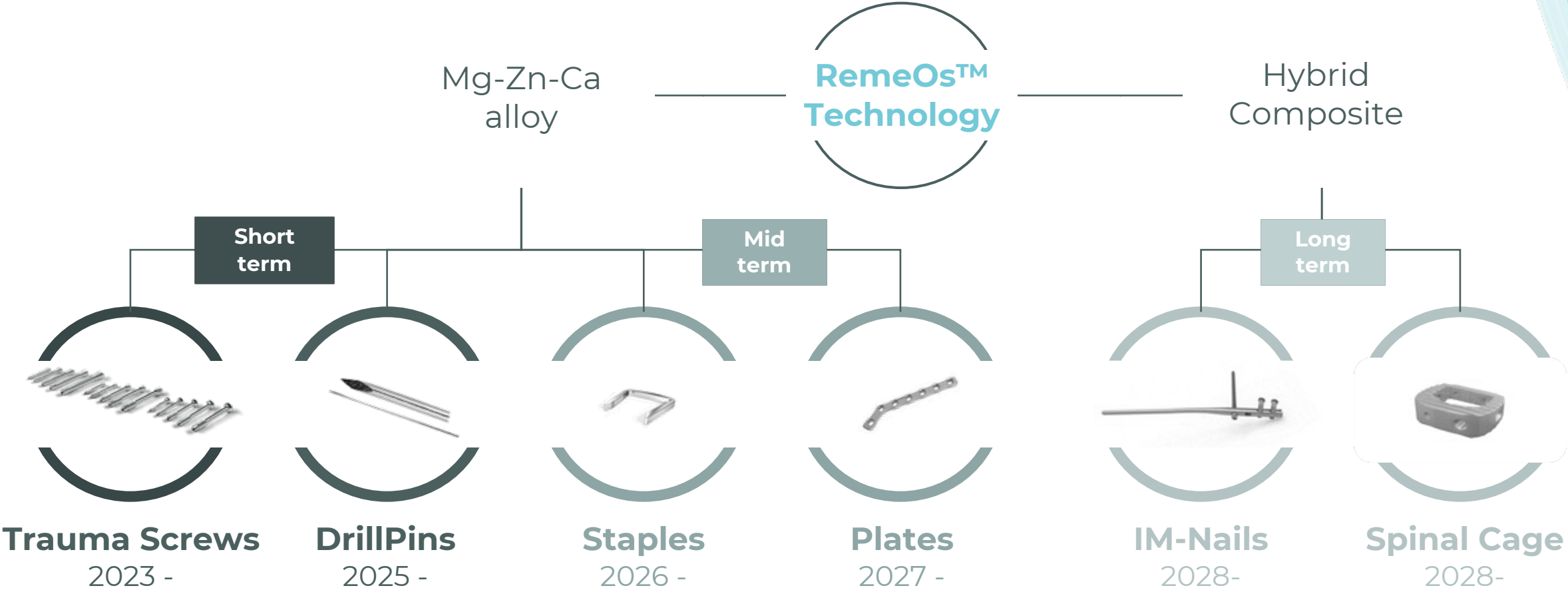


RemeOs™ trauma screws' next steps are **CE-mark approval in EU and indication expansions in US**

- **EU (CE) Market authorization** for RemeOs™ trauma screws was submitted in December 2021 and is expected during **2023**
- De Novo Request approval **opens a less burdensome regulatory pathway (510k) for the next RemeOs™ indications and product lines.**²
- Next US indications estimated to be available **in 2024**²



RemeOs™ planned **Product Group Pipeline**

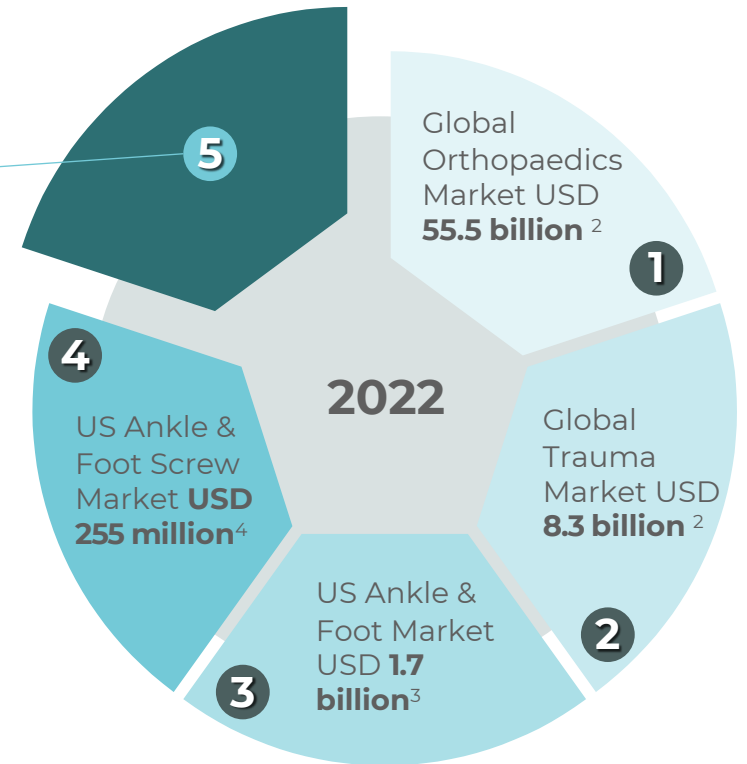


Fast growing and sizeable market available for the first indication of RemeOs™ trauma screws

The bioresorbable trauma screw usage is expected to grow significantly faster than traditional metal trauma screw materials³

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

US commercialization

- **Next steps:**
 - Launch of the RemeOs™ trauma screws will be conducted in tight collaboration with the Key Opinion Leaders (KOLs), selected clinics, and their clinical professionals specialized in ankle fractures.
 - Sales are expected to grow gradually as US clinics gain confidence in the breakthrough technology
 - Real-world clinical evidence will be gathered for PMS, indication expansion, marketing purposes, and value dossiers for private insurance companies



Key elements for controlled launch with Spartan Medical

Spartan was selected as a Nationwide sales partner with access to regional distribution networks

1. Strategic Control and Alignment:

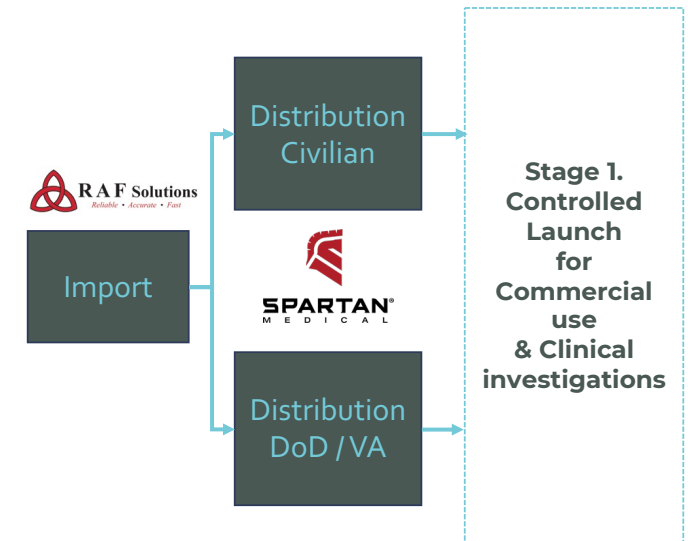
- Bioretec retains control over product positioning and initial market targeting during the crucial first 12-18 months.
 - **Civilian segment:**
 - Selected amount of academic/trauma centers handpicked by Bioretec to ensure a controlled launch.
 - **US Department of Defence and Veteran Affairs (DOD/VA) Segment:**
 - Launch leveraging Spartan's established network and status as an approved distributor for DoD/VA

2. Access to Critical Data:

- Bioretec has access to pricing structures, customer usage patterns, feedback, and engagement within relevant surgeon communities.

3. Bioretec Product specialists have proven New Market Development Expertise:

- Bioretec's product specialists take charge of distributor training and are involved in sales activities.
- Bioretec Product specialists have a track record of successfully developing new markets, showcasing their ability to drive growth in targeted sectors.
- Bioretec designs and implements the education and training program to ensure that surgeons and HCPs a comprehensive understanding of the product's benefits



The chosen strategy aims to expedite controlled market entry, optimize product launch, and set the stage for potential expansion while upholding Bioretec Strategic guidelines

Product launch in US clinics

- **Engagement is started with globally recognized academic medical centers for a controlled launch**

- Johns Hopkins Hospital – Baltimore MD
- Massachusetts General/Harvard Medical School – Boston, MA
- Rutgers University – Central NJ
- Hospital for Special Surgery – NY, NY
- University of Colorado/UCHealth – Denver, CO
- Duke University – Durham, NC

Typically, the sales process to access Single Care Facilities and small private hospitals takes around 3-6 months and INDs and public hospitals are 6-10 months

1. US KOL engagement - Leverage influencers

2. Demonstrating RemeOs™ product performance

- **1st round:** Workshop or cadaver training for KOLs and HCPs to involve selected academic medical centers

Completed

Ongoing & upcoming

- **2nd round:** Demonstration of RemeOs benefits to other decision-makers

3. Value proposition by applying performance metrics

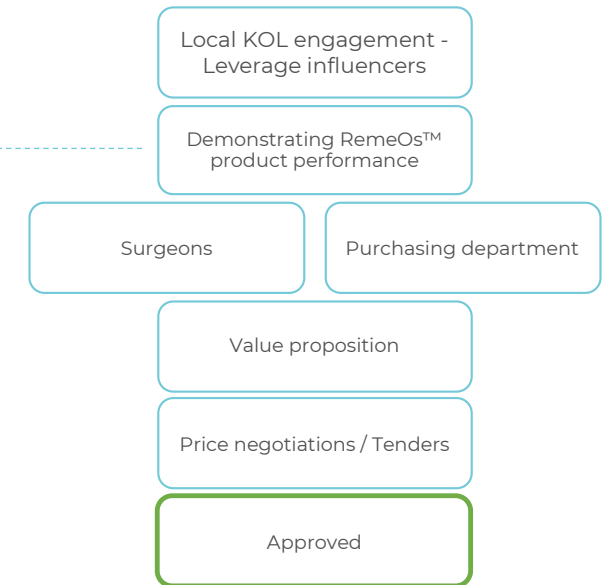
- The benefits and impact of the RemeOs™ products with the measurable performance metrics - Health economics data

4. Finding and understanding the strategic decision-making points of the buyer

- Procedure volumes, pricing, quality performance and total cost of care
- Reimbursement aspects and insurance policy

5. Engaging with the users (Surgeons) through the entire cycle of the RemeOs product

- The new product requires strong cooperation not only with the surgeon but the supporting staff, including the radiology department





SAB 2023 annual meeting and workshop at Turku, Finland 14-16.9



SAB will play an integral role in guiding the company's processes regarding **clinical product development, education and training programs, and engaging surgeon communities**

Bioretec highlights

1

Attractive market – global total addressable market of ~\$7bn with increasing demand for orthopaedic implants

2

Superior solution for patient healing – magnesium based bioresorbable implants promote bone healing and eliminate need for implant removal

3

The first bioresorbable metal product having market authorization in the US

4

Strong pipeline for launching new products and technologies in coming years

5

Experienced management team transforming orthopedic care with new cutting-edge technology – supported by top-tier SAB





bioretec

Thank You

www.Bioretec.com