bioretec

better healing – better life

Business Review 2024-Q3

CEO, Alan Donze

Pioneer in biodegradable orthopedic implants and reformer of surgical treatment

Bioretec is headquartered in Tampere, Finland, and has subsidiaries in Austria and in the United States.

- The company's shares are listed on Nasdaq First North Growth Market Finland.
- At the end of Q3/2024, the company employed 44 professionals

Bioretec products are sold worldwide in appr. 40 countries.

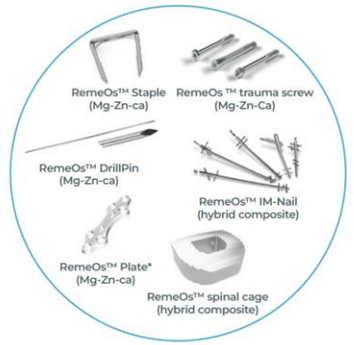
- The main target market is U.S. and the majority of Bioretec's revenue is generated from exports, with 99% coming from outside Finland in 2023.
- Bioretec's products are sold through the company's distribution network.

Product lines are built on our expertise in merging materials science and biology for active implants that promote bone growth and healing.

- RemeOs™ product line uses advanced next-generation materials based on magnesium alloy for improved implant strength and osteopromotive properties.
- Activa line includes self-reinforced biodegradable polymer products for various surgical applications.

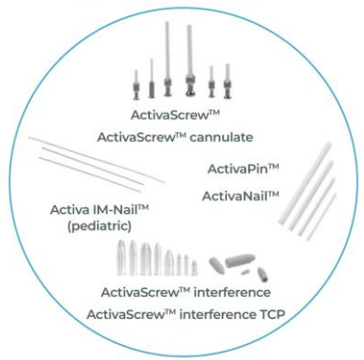
The RemeOs™ and Activa implants are designed to obviate the need for removal surgery, facilitating the healing process, reducing healthcare costs, and enhancing patient wellbeing.

RemeOs™ product pipeline



Manufactured from RemeOs™ alloy[2] and patented hybrid composite[3]

Activa product pipeline



Manufactured of self-reinforced biodegradable polymer (PLGA[1])

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

Bioretec's goal is to improve patients' quality of life and provide significant benefits to patients, the healthcare system and society

Benefits for the patient

Patient avoids:

- implant removal surgery and subsequent recovery,
- the risks of complications typically associated with it, such as nerve damage, inflammation and refracture
- hospitalization, sick leave and possible loss of income associated with the implant removal surgery.
- Because the RemeOs™products contain only natural elements essential for bone growth, the patient avoids long-term effects caused by the foreign materials in the body.

Benefits for the healthcare unit

Surgeon can:

- focus on value-added primary operations rather than on removal surgeries.
- use surgical methods, which are consistent with traditional metal implants.
- use magnetic resonance imaging (MRI) unlike with traditional titanium and steel implants.

Benefits for society

Society and the healthcare system receives:

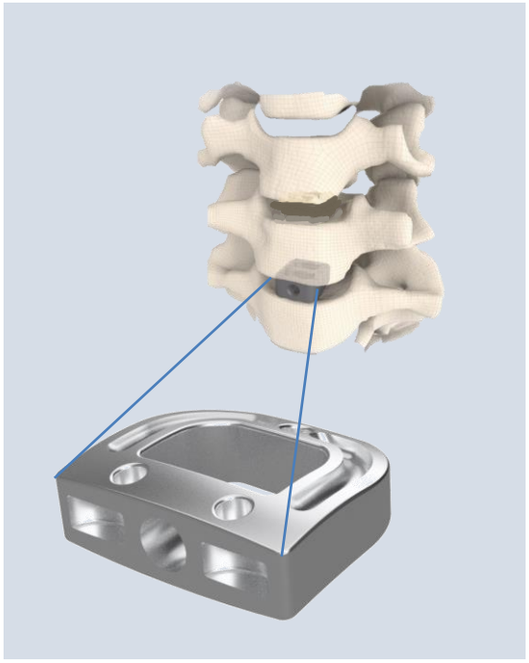
- more efficient use of resources to reduce the overall cost of operations when no removal is needed and lost productivity.
- fewer operations to reduce staffing shortages and waiting times for treatments.
- In a country the size of Germany, the implant removal costs have been calculated to be more than EUR 1 billion per year[1].

1) Source: Destatis, Robert Koch Institute, Federal Health Report, refers to year 2014

Getting ready in USA for the next phase of commercialization, delays in CE mark approval in Europe

March: FDA grants Breakthrough Device Designation status for Bioretec's RemeOs™ spinal cage

Biodegradable RemeOs™ Spinal Interbody Cage met the strict criteria set for entering the FDA's Breakthrough Device Designation program. Under the Breakthrough Devices Program, the FDA will enable an ongoing and prioritized interactive discussion between Bioretec and the authorities.



May: Strengthening the USA commercialization know-how and experience

In May the company appoints Mr. Alan Donze as the CEO. Alan has a long experience from commercialization of medical devices in USA. In June Mr. Frank Sarcone started as Vice President of Sales for the USA. Frank has an extensive back-ground in sales operations of medical devices in USA.

June: Successful clinical outcomes from U.S. controlled launch of RemeOs™ trauma screw

In June the company announced that a number of cases have been performed around the U.S. utilizing the RemeOs™ technology. The follow-up results confirmed successful implantation and fracture healing were achieved in all cases.

Q1-Q3: Delays in CE mark approval process of RemeOs™ Trauma Screw in Europe

The approval process of RemeOs™ Trauma Screw in Europe has been painfully long process, which has also affected company's sales development and sales forecasts. The approval process is in final stages and all required materials have been provided to Notified Body.

2024 Q1-Q3 in numbers
(2023 Q1-Q3 in comparison)

EUR 2.7 M
(EUR 2.4 M)
Net sales

EUR 2.1 M
(EUR 1.7 M)
Sales margin

75.9%
(73.4%)
Sales margin, % of net sales

EUR -3.2 M
(EUR -2.1 M)
EBITDA

44
(32)
Employees at end of Q3

24.2%
(27,4%)
Share of R&D spend on total costs

8 registered product families (FDA or CE-marked)

~250 implants in portfolio

Products sold in **~40** countries

>35,000 surgical operations in 2023

RemeOs™ focused launch phase completed and wider commercialization phase starting

Focused launch phase

Product confidence among leading surgeons created.

- Gathering real-world clinical evidence from Post-Market Surveillance (PMS) for Marketing and additional value dossiers for private insurance.
- Conducted in collaboration with Key Opinion Leaders (KOLs), academic centers, and clinical professionals.

Pricing base and customer purchase processes built during this phase.

- In order to qualify the product for Transitional Pass-Through payment reimbursement system a cost structure of product in surgeries needed to be established.
- Hospital approval processes are ongoing as the sales process to access Ambulatory Surgery Centers (ASC) and small private hospitals takes around 3-6 months and Integrated Delivery Networks (IDNs) 6-10 months.

100% healing rate without any complications.

- Excellent clinical results obtained during the phase.

Wider commercialization phase

Broadening the user base and product offering.

- Entering into distribution agreements with local distributors for private sector reinforces sales and marketing efforts. Spartan Medical continues to distribute products for government customers (military and veteran hospitals).
- New product variations will be added into the product portfolio (510K documentation submitted to FDA).

Transitional Pass-Through payment reimbursement system.

- Special reimbursement system available for products with Breakthrough Device Designation status. Can be applied since the cost structure of a product in surgeries has been established.
- Supports the use of products by providing special reimbursement opportunity for hospitals.

Supply chain enforcement.

- Entering into logistics agreement with third party logistics (3PL) service provider secures efficient and reliable service for customers.

Real life experiences from renowned surgeons using RemeOs™ Trauma Screw products in USA

Dr. Robert Leland

Clinical Assistant Professor in the Department of Orthopedics at the University of Colorado

"I'm thrilled to be one of the early users of the RemeOs screws and implement their use into reconstructive foot and ankle and orthopedic trauma procedures. The unique screws behave like standard metal screws during surgery and have provided reproducible results similar to standard screws but integrate into bone over time. This is one of the rare truly "new" technologies in Orthopedic Surgery that should have expanding applications over time as the implant portfolio expands. "

Dr. Animesh Agarwal

Orthopaedic surgeon and Professor of Orthopaedic Surgery at University of Texas Health Science Center San Antonio (UTHSCSA)

"The screws provide excellent fracture fixation with the advantage of not worrying about hardware removal in the future."

Dr. David Lin

DPM FACFAS, ABFAS double Board Certified Foot and Ankle surgeon

"RemeOs has allowed me to provide absorbable fixation to my patients, that I personally am comfortable with. In terms of usability, the steps for implantation compared with traditional metal is nearly identical. I have had positive results thus far and plan to continue utilizing this new technology in my practice."

Dr. Jeremy Dublon

DPM, DABPM, FACKM, Former White House Surgeon, Former FDA Medical Officer - CDRH OHT 6, Former U.S. Army Surgeon Currently practicing privately in Maryland

"RemeOs represents a new phase in orthopedic implant fixation. As a former FDA Medical Officer, I had unique perspective of evaluating new devices for market approval. What Bioretec has done with the RemeOs product, is revolutionary. There are very few products that provide such benefit to the patient while changing virtually nothing from the surgeon usability aspect. The absorbable nature, combined with osseopromotive properties, provides a biologic advantage over traditional fixation that simply cannot be ignored."

REMEOS™ IN THE EUROPEAN MARKET

Ready for launch after CE certification granted

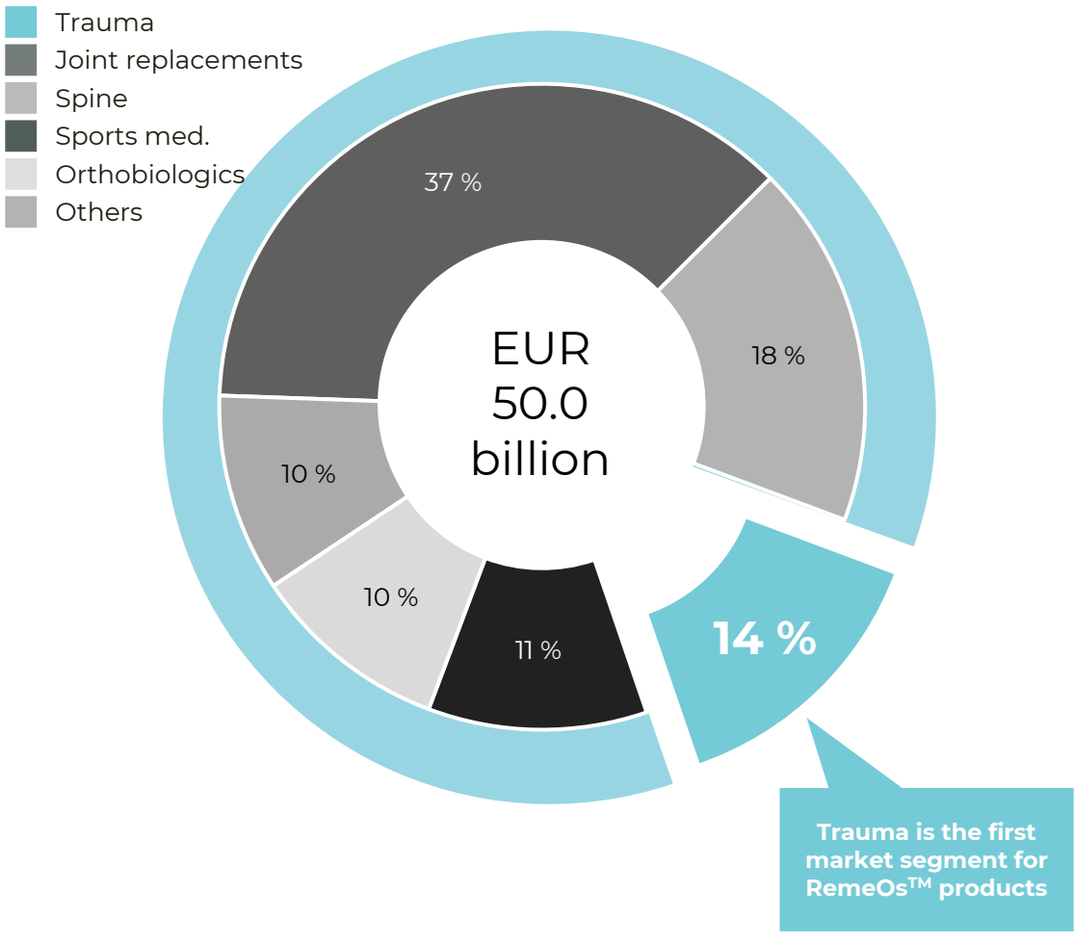
- Launch of the RemeOs™ Trauma Screws in Europe delayed due to long process handling time of Notified Body (regulatory changes from MDD to MDR have prolonged handling times of all medical devices)
- CE approval expected soon, all materials requested by Notified Body have been delivered for final review
- Product launch immediately after the CE mark received
- Established direct own sales force in Germany and Austria
- Existing distribution network will be utilized in rest of the Europe

Existing Sales & Distribution network in Europe

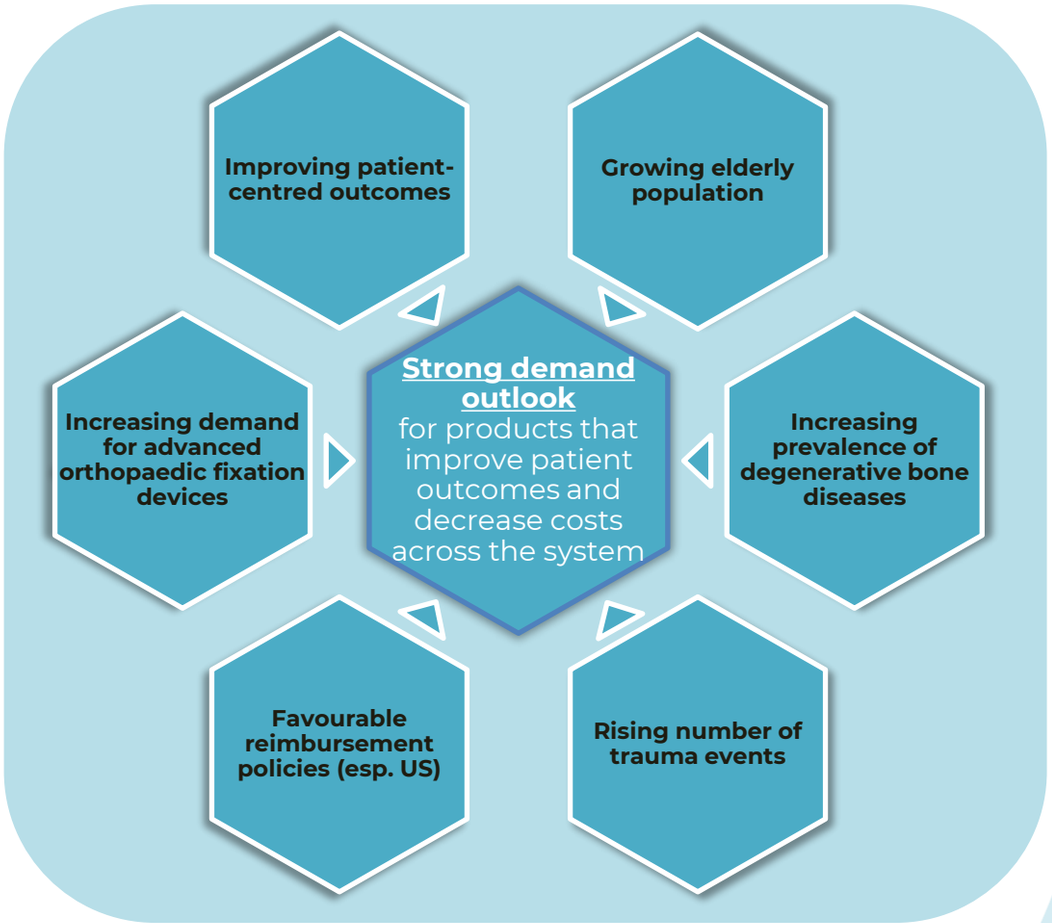
REMEOS™ TRAUMA PRODUCTS MARKET OPPORTUNITY

Ready for launch after CE certification granted

Global Orthopaedics Product Markets per indication in 2021



Growth supporting drivers for orthopaedic trauma segment



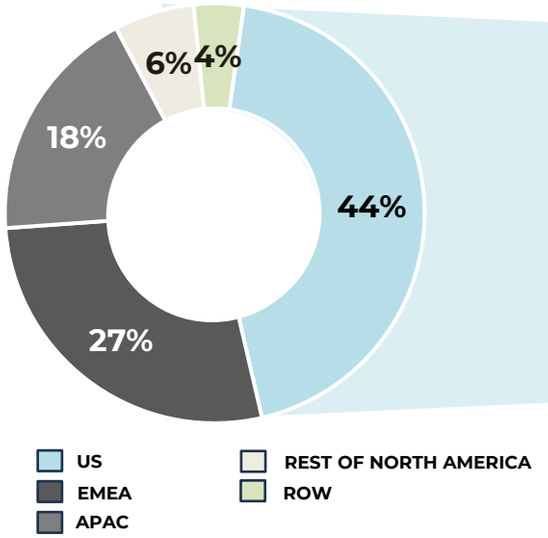
Sources: The Orthopaedic Industry Annual Report 2022, ORTHOWORLD Inc.; management estimates GlobalData, GMInsights, UN, United States Government, Willey, Michael et al. (2016) Impact of Infection on Fracture Fixation Orthopedic Clinics , Volume 47 , Issue 2 , 357 - 364

REMEOS™ TRAUMA MARKET OPPORTUNITY IN USA

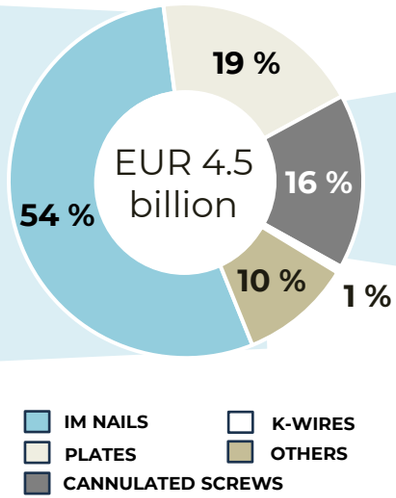
EUR 0,7 billion market opportunity only for cannulated screws in USA

First market for RemeOs™

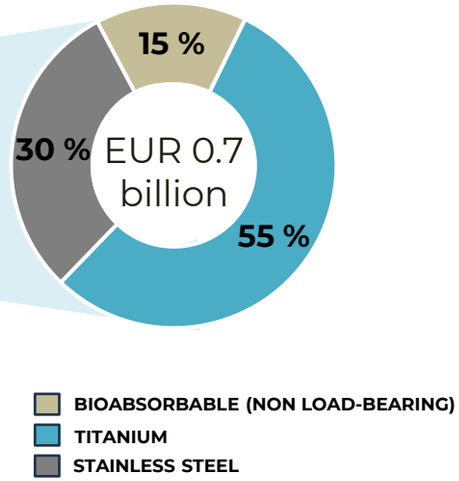
Global orthopaedic trauma product market 2021



US market for trauma fixation 2021



US Cannulated Screws by material 2021



- The market for orthopaedic trauma products consists of objects and supplies that are used internally or externally, mainly for the repair of fractures
- Fractures are typically caused by accidents, falls or injuries in sports and by various diseases
- The main products in orthopaedic trauma products are a wide variety of plates, screws, and other products that keep the broken bone in the correct position to enable and promote ossification and healing

- Sizeable market where penetration of earlier generation bioabsorbable products is low and consequently the share of traditional titanium & steel products is still high
- Represents a strong opportunity for rapid market share expansion
- RemeOs™ products can be used instead of titanium and stainless steel

Note: Please note global orthopaedic product market is based on Orthoworld sources (Industry Annual Report 2022) and global orthopaedic trauma product market is based on GlobalData sources
Source: GlobalData Report 2020, Trauma Fixation (Orthopedic Devices) - Global Market Analysis and Forecast Model

REMEOS™ SPINAL INTERBODY CAGE

Opportunity for accelerated value increase

Unique product in spinal treatment

No resorbable spinal cage product exists in the markets

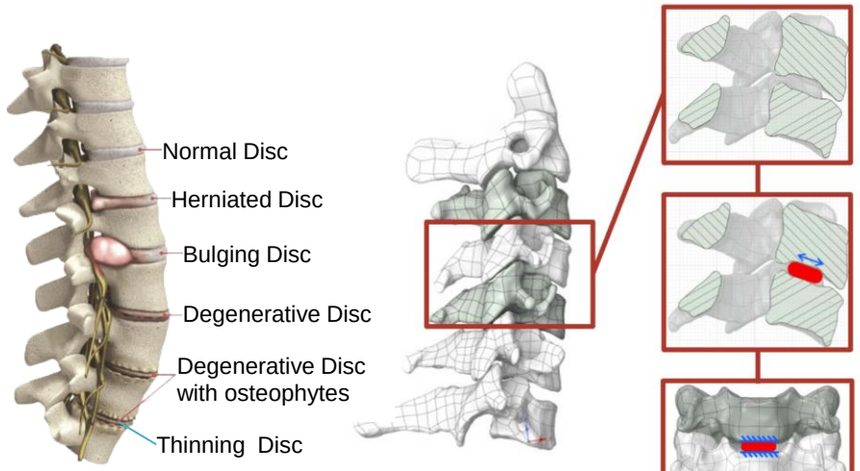
- None of the existing materials available in the markets can combine strength property requirements with resorption to fulfill the clinical requirements
- Patented hybrid composite material has shown excellent results in development stage

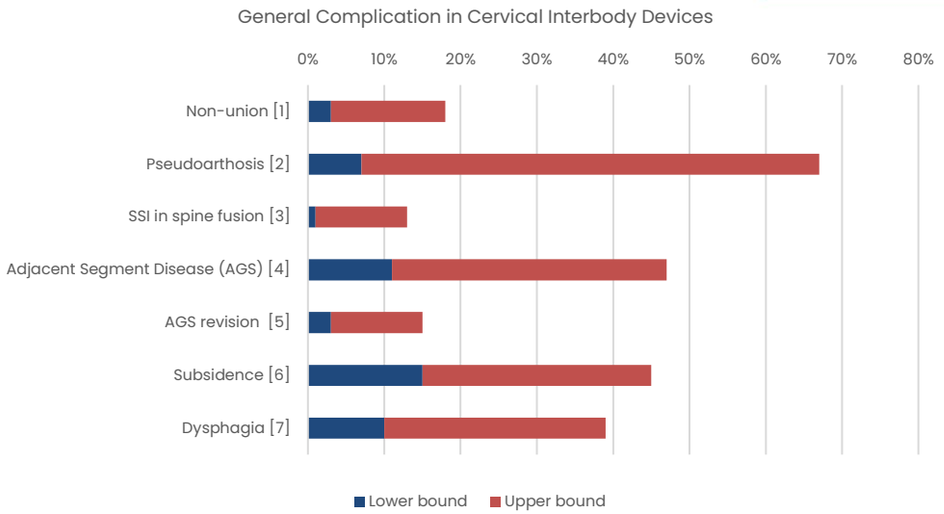
Breakthrough Device Designation status granted by the FDA for RemeOs™ spinal cage

- Validates the clinical need and innovativeness of the product concept
- Considerable complications with existing solutions.
- Provides unique opportunity for accelerated market approach

Optional business approaches

- After completion of the first animal trial in 2025 Bioretec will evaluate a **partnering option** to finalize the development and to commercialize the product with large international spine market focused company.

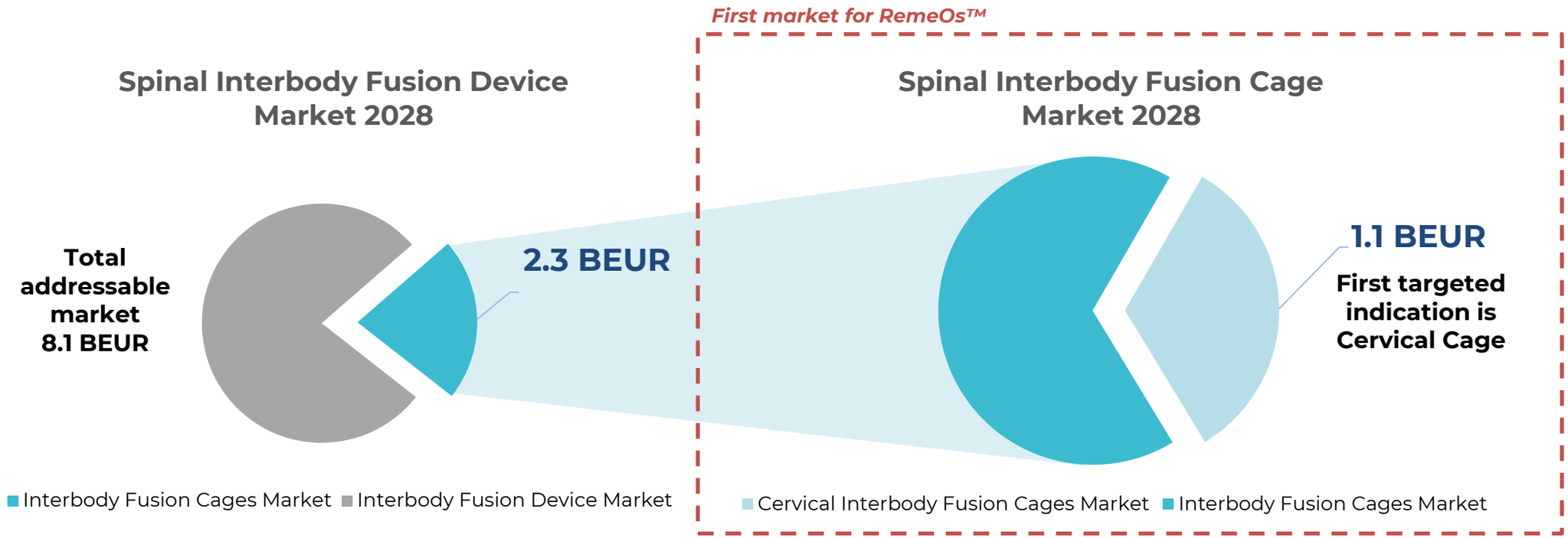




References
1 Orthopaedics & Traumatology: Surgery & Research 107 (2021) 102924
2 International Journal of Surgery Case Reports 93 (2022) 106922
3 Clinical Infectious Diseases 2011;53(7):686–692
4 Orthopaedics & Traumatology: Surgery & Research 100 (2014) 305–309
5 Orthopaedics & Traumatology: Surgery & Research 100 (2014) 305–309
6 Acta Neurochirurgica (2018) 160:873–880
7 Cureus 14(7): e26888. DOI 10.7759/cureus.26888

REMEOS™ SPINAL INTERBODY CAGE

Major market size without a resorbable solution available



Top players in the market: Stryker, DePuy Synthes, Medtronic, Orthofix Medical/SeaSpine Inc. Globus/NuVasive, Inc., Zimmer Biomet

Source:
https://www.businessresearchinsights.com/market-reports/cervical-interbody-fusion-cages-market-111868
https://www.alliedmarketresearch.com/interbody-fusion-cage-market
https://www.grandviewresearch.com/industry-analysis/spinal-fusion-device-market

SCIENTIFIC ADVISORY BOARD

Leading experts supporting throughout the lifecycle of products

SAB 2023 ANNUAL MEETING AND WORKSHOP AT TURKU, FINLAND

A key component of Bioretec's development strategy is the invaluable guidance and support of leading experts in the field. The role of Bioretec's Scientific Advisory Board (SAB) is to support Bioretec's operations throughout the life cycle of products, from early-stage concepts through product development to commercialization and continuous product support. The SAB acts as a channel to key opinion leaders, experienced surgeons who act as trendsetters in the introduction of new technologies in their areas of expertise. In addition to specific topic meetings with certain members of the team, Bioretec has regular quarterly and annual meetings with the entire SAB.

Trauma advisors

Prof. Dr. Klaus Dresing, Germany

Chairman of the SAB since 2021
Chairman of the AO Alumni Association, member of the AO Trauma International Board

Prof. Dr. Fan Liu, China

Member of the SAB since 2021
Vice President, Chief and Professor in Department of Orthopedic Surgery, Affiliated Hospital to Nantong University

Pediatric advisors

Prof. Dr. Theddy Slongo, Switzerland

Member of the SAB since 2023
Head of Pediatric Surgery and Child Traumatology, Children's Clinic, Bern

Dr. Verena Schreiber, USA

Member of the SAB since 2023
Pediatric Orthopaedic Surgeon, Nicklaus Children's Hospital Orthopedic, Sports Health, and Spine Institute in Miami

Spine advisors

Prof. Dr. Jeffrey Wang, USA

Member of the SAB since 2023
Professor of Orthopaedic Surgery and Neurosurgery, the Keck School of Medicine at the University of Southern California (USC)

Prof. Dr. Richard Assaker, France

Member of the SAB since 2023
Professor in Neurosurgery, Hopital Roger Salengro, Lille

Ankle and foot advisors

Prof. Dr. Stefan Rammelt, Germany

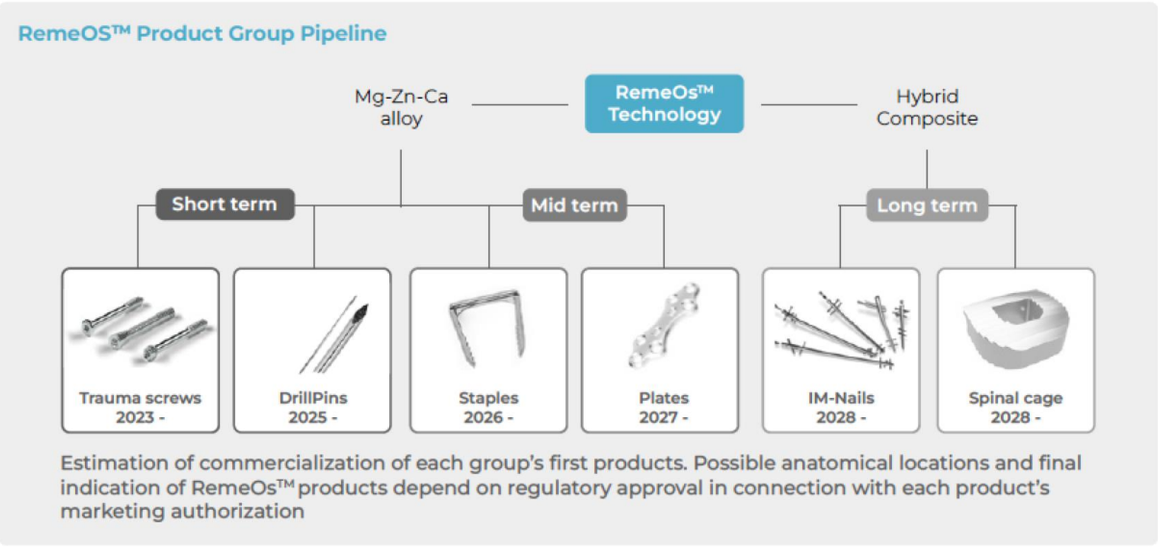
Member of the SAB since 2023
Professor of Trauma & Reconstructive Surgery, Head, Foot & Ankle Center, University Hospital, Dresden

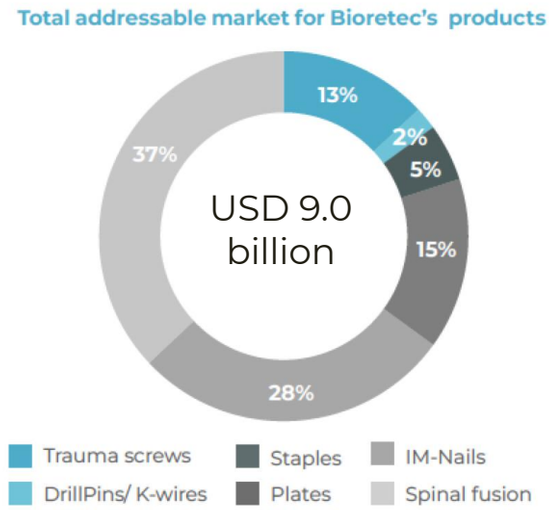
Dr. Robert Leland, USA

Member of the SAB since 2023
Clinical Assistant Professor in the Department of Orthopedics at the University of Colorado

Focus in short-term

- Starting the wider commercialization phase in the U.S., including strengthening the distribution network for civilian hospital network
- Receiving the CE mark for the RemeOs™ screws and launching the product in the EU through recently established direct sales channel in Germany and through existing distribution network in rest of the Europe
- Expansion of the RemeOs™ screw product line in the U.S. through 510K process
- Increasing the awareness, usage, and clinical experience with RemeOs™ screws in the U.S. and Europe
- Conducting preclinical and clinical trials with RemeOs™ future pipeline products, including the first animal trial with RemeOs™ spinal interbody cage





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BIORETEC AS AN INVESTMENT

1. **Attractive market** – global total addressable market of ~USD 9 billion with increasing demand for orthopaedic implants

2. **Superior solution for patient healing** – magnesium-based biodegradable implants promote bone healing and eliminate need for implant removal

3. **The first biodegradable* metal product group authorized in the US**

4. **Strong pipeline for launching additional products in coming years**
– the market authorization paves the way for next products

5. **Experienced management team executing commercialisation plan**
– supported by top-quality SAB

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

Sources: The Orthopaedic Industry Annual Report 2022, ORTHOWORLD Inc.; management estimates GlobalData, GMInsights, UN, United States Government, Willey, Michael et al. (2016) Impact of Infection on Fracture Fixation Orthopedic Clinics , Volume 47 , Issue 2 , 357 - 364

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Financial reporting in 2025

Bioretec will publish the financial reporting schedule for 2025 into the markets in December 2024.:

Financial reports will be available on the company's website, once they are published, at www.bioretec.com/investors. The company's releases can be subscribed using the form available on the website. Bioretec maintains a 30-day silent period in its investor and media contacts prior to the publication of its financial statements bulletins and half-year reports.

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Management Team on the 31st of October 2024

Alan Donze
CEO since 2024

Timo Lehtonen
CTO since 2024
(CEO between 2019-2024)

Johanna Salko
CFO since 2021

Franck Sarcone
VP, US Sales
since 2024

Rami Ojala
Sales and Marketing Director
since 2022

Esa Hallinen
Director of Operations
since 2023

Mari Ruotsalainen
Director, QA & RA
since 2018

Minna Ahlstedt-Soini
Production Director
since 2015

More detailed CV information:

https://bioretec.com/investors/investors-in-english/governance/management-team

Board of Directors on the 31st of October 2024

Tomi Numminen

Chairman of the Board of Directors since 2019, Member of the Board since 2016*

Professional board member

Michael Piccirillo

Member of the Board since 2018**

Managing Director, VALUGEN GmbH

Sarah van Hellenberg Hubar-Fisher

Member of the Board since 2021*

Healtcare industry professional, board member and venture leader

Päivi Malinen

Member of the Board since 2022* and **

Laissa Oy, Partner

Kustaa Poutiainen

Member of the Board since 2023**

President and Chairman of the Board, Stephen Industries Inc Oy

More detailed CV information:

https://bioretec.com/investors/investors-in-english/governance/board-of-directors

*. Audit committee
**. Remuneration and nomimination committee