

bioretec

better healing – better life

Bioretec

***bioresorbable medical
implants company***

CEO Timo Lehtonen

*Health Technology and
Pharmaceutical Developer Night*

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Bioretec in brief:

- **Globally operating company that develops and manufactures bioresorbable orthopedic implants**
 - HQ and production in Tampere Finland and subsidiary in Austria
 - Headcount 28 with >200 manpower years of experience from bioresorbable implants
 - Publicly listed in Nasdaq Helsinki First North marketplace

7
registered
product
families

~240
orthopedical
products

~40
countries
around
the world

~400 000
sold
products



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

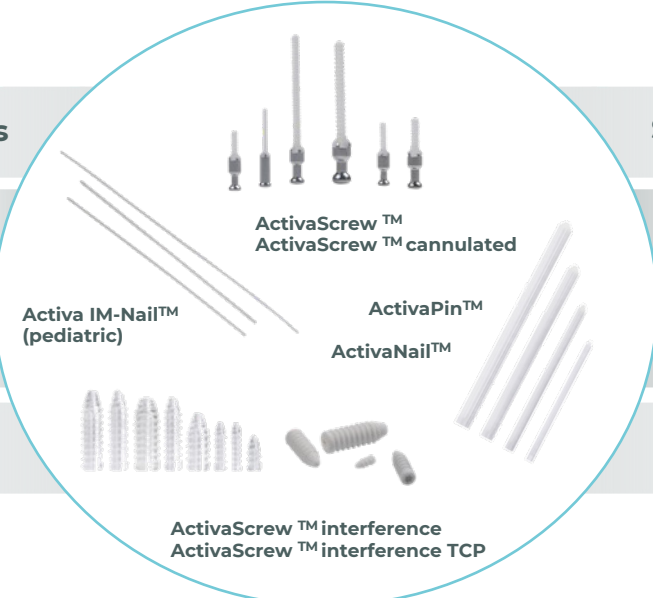


Society

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

Bioretec's current **Activa** biopolymer implant product line provides the **know-how and foundation** to launch **RemeOs™**

Commercially available **Activa** products



No adverse events

For non-load bearing applications

No need for removal surgery

Designed products for pediatrics

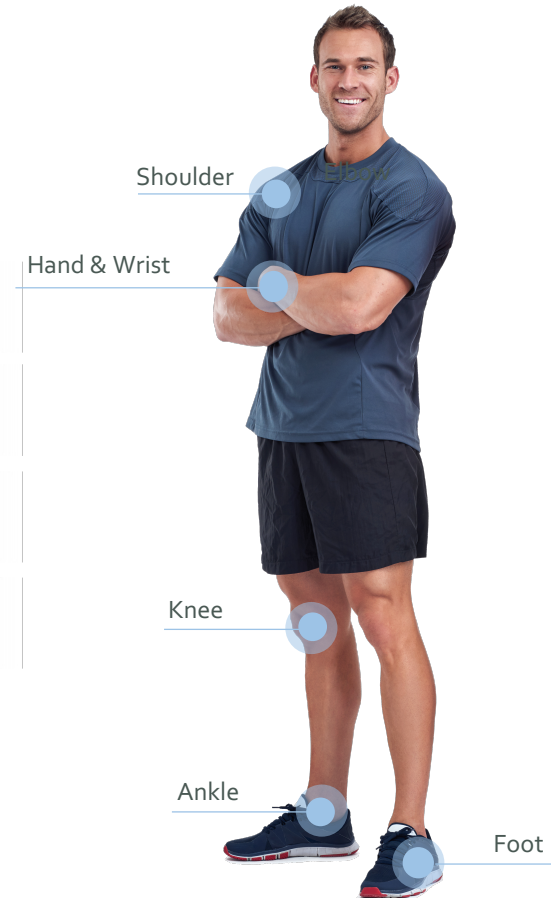
Self-reinforcement technology

Strength retention 8 weeks

Fully biocompatible

Resorbs safely in app. 2 years

✓ **Manufactured by Self-reinforced bioabsorbable polymer (PLGA¹)**



The **benefits** of the RemeOs™ product family based on the **innovative bioresorbable metal**

Our new **RemeOs™** product line will be available in **2023**



Common surgical techniques

No stress shielding

No need for removal surgery

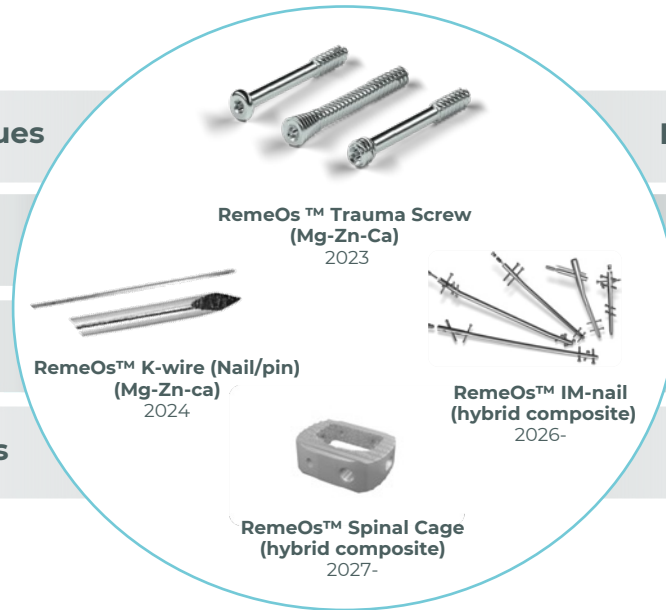
Reduces overall costs

From natural elements Mg-Zn-Ca

Has metallic properties

Enhances bone healing

Resorbs safely in app. 2 – 3 years



Manufactured from RemeOs™ alloy¹ and patented hybrid composite²

First product group to be commercialized is **RemeOs™ – Trauma screws**

- **RemeOs™ bioresorbable alloy is based on fully natural material composition¹**
 - Calcium 0.5 - 0.7 wt.-%, Zinc 0.4 – 0.7 wt.-% and the rest being Magnesium
- **RemeOs™ trauma screw product line contains 4 types of screws for fracture fixation:**
 - Cannulated fully threaded compression screw
 - Cannulated partially threaded compression screw
 - Cannulated LAG screw
 - LAG screw
- **Safety and efficacy proven in preclinical and clinical studies**
 - Safety and efficacy verified in clinical trial - 3 years follow-up confirming complete degradation and disappearance with High resolution CT



Diameters: 2.0 – 4.0mm (0.5mm increments)

Lengths: 8 – 50mm (2mm increments)

¹ Rare earth elements (set of 17 soft heavy metals), also called the rare-earth metals (REE) or the lanthanides (though yttrium and scandium are usually included as rare-earths) have shown in vitro negative effects like promoting apoptosis, as well as other short and long term negative biological effects.

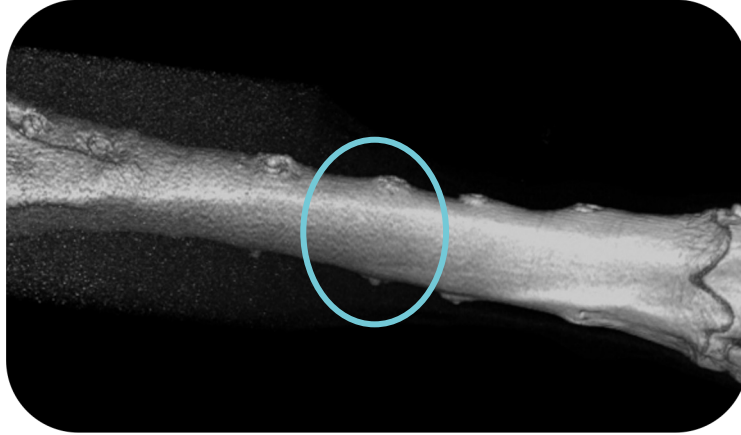
² Final anatomical locations, indications, designs and sizes of RemeOs™ products depend on regulatory approval in connection with marketing authorization

Bioactivity and Enhanced **bone growth** verified in vivo

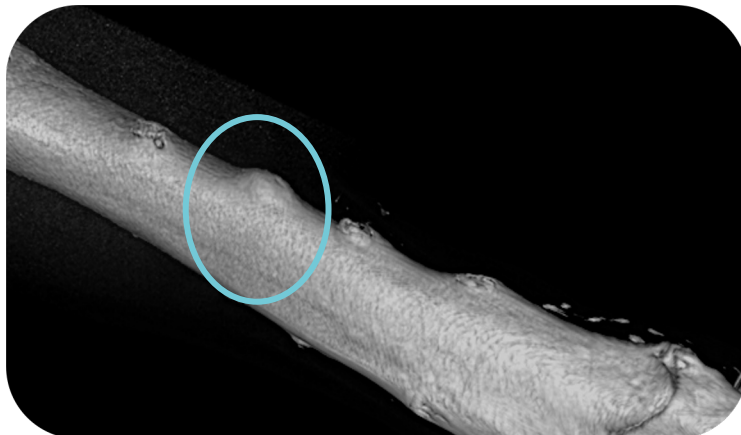
RemeOs:

Titanium:

6 weeks



12 weeks



RemeOs™
Trauma screws vs.
Titanium screws
analyzed by
Micro-CT in sheep

Our bioresorbable products meet the **growth drivers of the market...**



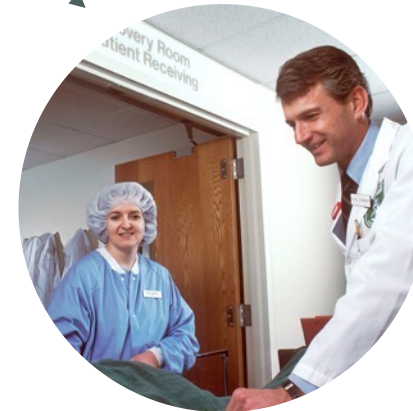
The share of the elderly population is increasing



The number of trauma is increasing



Lack of operation room and healthcare professional capacity



Growing demand for advanced orthopedic implants



Value Based Healthcare¹

Status update of the year 2022

RemeOs™ product line:

- **US/FDA DE Novo:**
 - De Novo application submitted in May 2022
 - Supplement of the De Novo application to be completed by the end of 2022
 - **Expected approval in April 2023**
- **EU/CE-mark**
 - The CE-mark application submitted in December 2021
 - We are still waiting for the feedback from the Notified Body on main sections of the submitted application
 - **Expected approval in 2023**
- **RemeOs™ K-wire (Nail/pin) clinical trial study site contracting on-going**
- **Hybrid composite patent has been approved in Europe**
 - Patented material is utilized in future RemeOs™ IM-nail and spinal Cage product lines

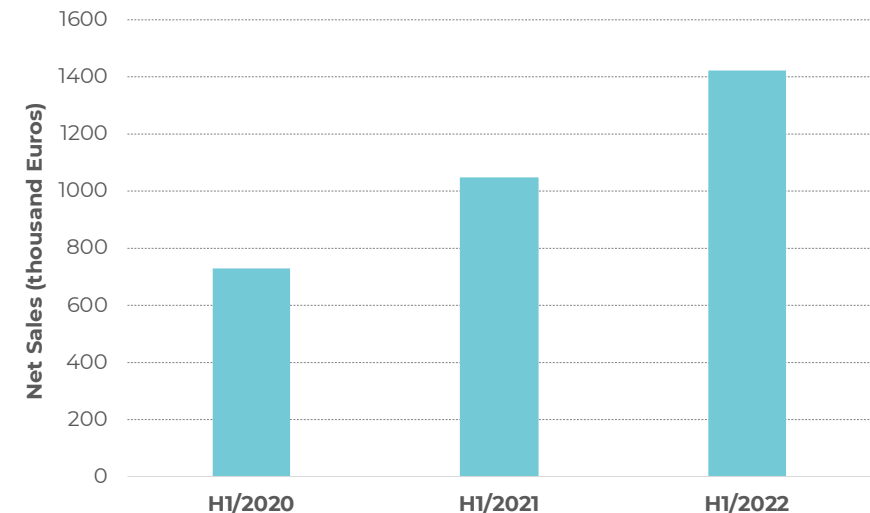
Activa product line:

Activa Sales Growth

+34% 2020 → 2021

+36% H1 / 2021 → H1 / 2022

Net Sales H1/2020 - H1/2022



RemeOs™ commercialization activities for the year 2023

Both US and EU commercialization plan follows the industry best practice through KOL's, education and training to create product awareness



1-3. Key Opinion Leader Community engagement on-going

4. Regulatory approvals on-going in US and EU

5. Preparations on-going for product introduction in EU and US. Key hospitals for launch identified in US together with experienced local S&M advisors

6-8. Strong presence in forthcoming orthopedic key conferences (ACFAS, AAOS, EPOS, EFFORT)

Main R&D activities for the year 2023

RemeOs™ Trauma screw:

- Finalization of the third-year follow-up study.

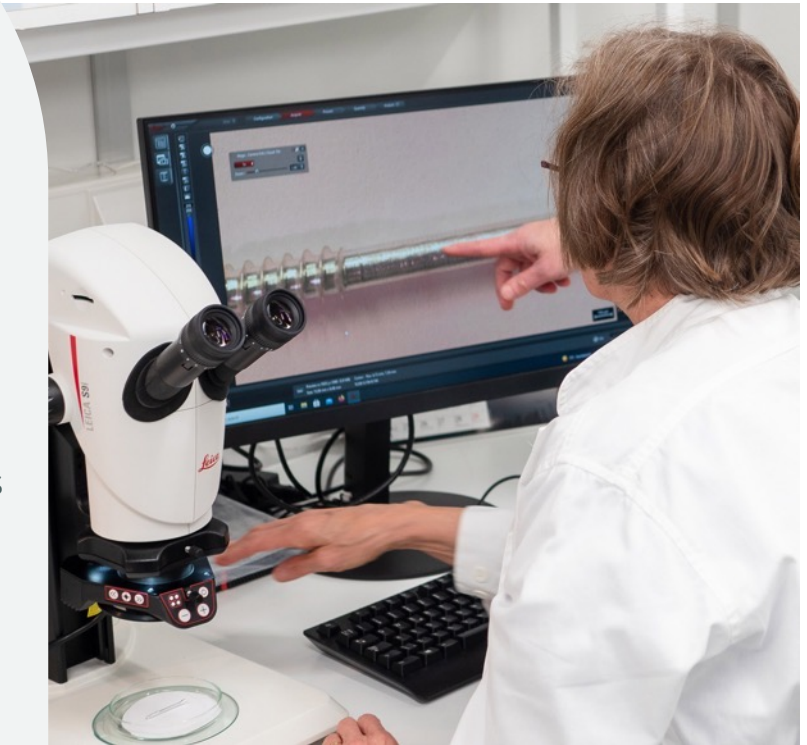
RemeOs™ K-wire (Nail/pin)

- Receive the first interim results from the First in Human clinical trial of the RemeOs™ Nail

Activa IM-Nail™

- Continuation of the Post-Market Clinical Follow-up study (PMCF) of the Activa pediatric IM- nail in forearm fractures in several European countries (62 % completed)
- Continuation of an investigator initiated clinical trial focusing on children's wrist (distal radius) fractures (70% completed)

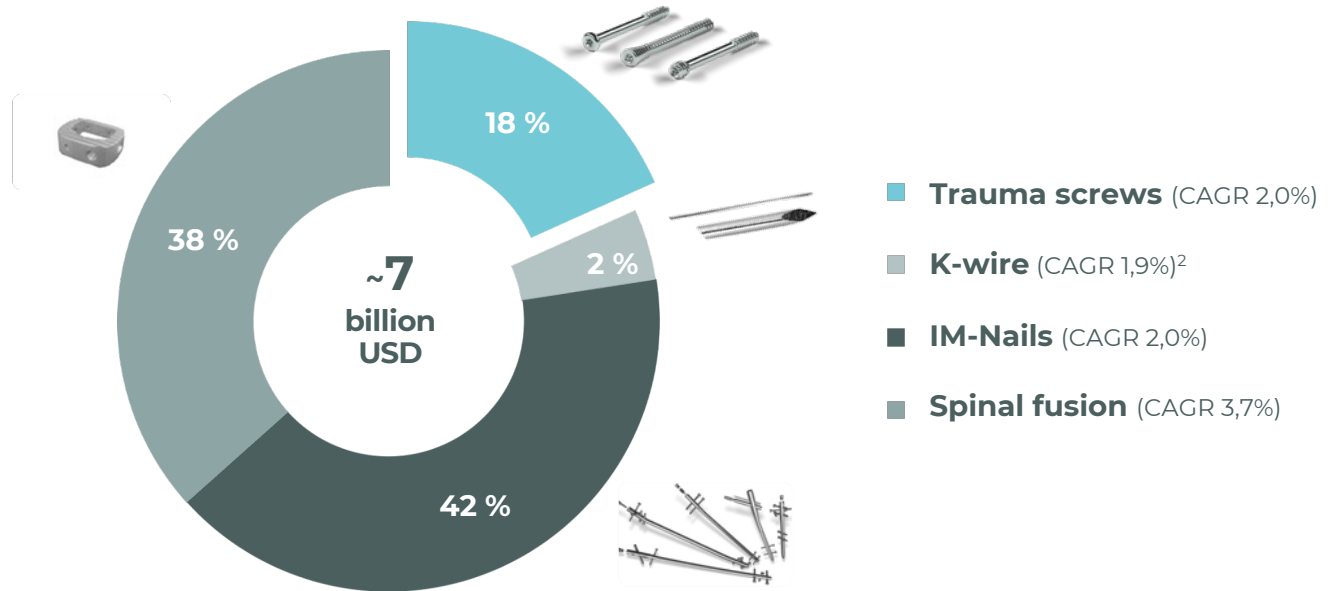
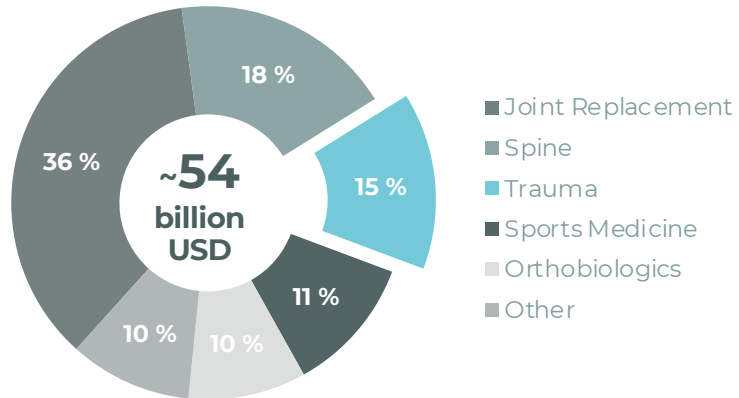
IM-nail and spinal cage development based on hybrid composite



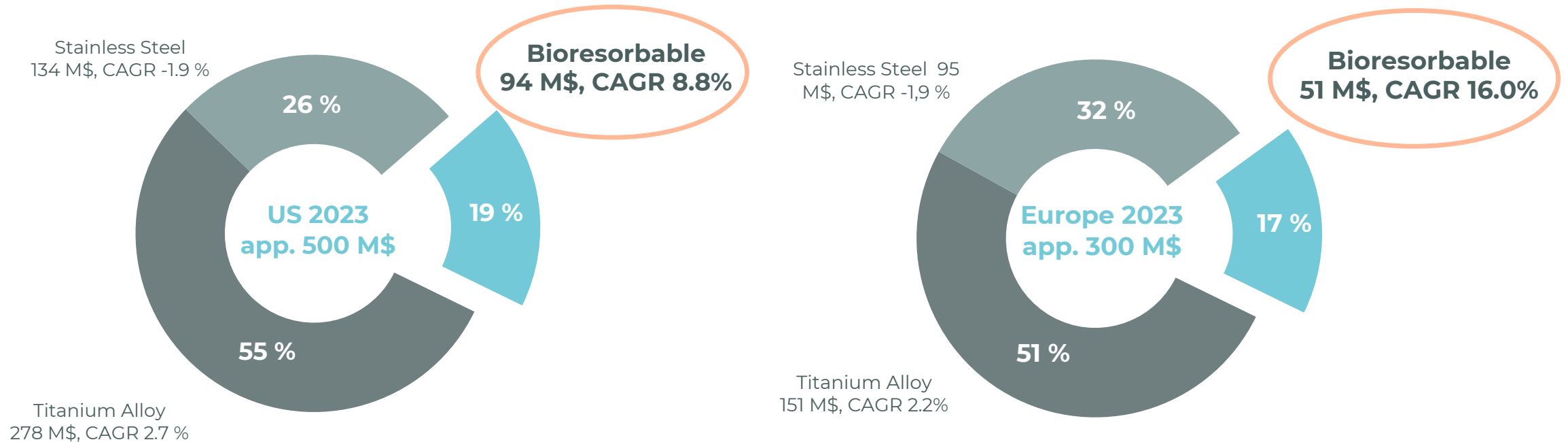
Global Orthopedic Market 2022 is recovering from Covid-19 pandemic

“ Our goal is to be the **first in the US market** with bioresorbable metal implants . RemeOs products open up to Bioretec an addressable global market for orthopedic products worth app. **USD 7 billion** , of which more than **65%** accounted by the US market. ”

Global Orthopaedics Product Markets 2021



Bioresorbable trauma screws are estimated for 2023 to be **USD 145 million rapidly growing market** in US and Europe



The bioresorbable trauma screw usage is expected to **grow significantly faster** than traditional non-resorbable trauma screws

Thank you !

Financial calendar for 2023
will be released during
December 2022

www.bioretec.com

