bioretec

better healing – better life

Investor Presentation

Disclaimer

IMPORTANT INFORMATION

This presentation includes forward-looking statements. The words "believe", "expect", "anticipate", "intend", "may", "plan", "estimate", "will", "should", "could", "aim", "target", "might", or, in each case, their negative, or any similar expressions identify certain of these forward-looking statements. Others can be identified from the context in which the statements are made. By their nature, forward-looking statements are subject to assumptions, risks and uncertainties. Although Bioretec believes that the expectations reflected in these forward-looking statements are reasonable, actual results may differ, even materially, from those expressed or implied by these forward-looking statements. Bioretec expects presentation participants and readers of this presentation not to place undue reliance on such statements.

Bioretec publishes inside information according to the European Market Abuse Regulation (MAR) and the rules of Nasdaq First North Growth Market Finland.

Nothing in this presentation constitutes, and this presentation may not be used in connection with, any offer of securities.

Danske Bank A/S, Finland Branch (the “Financial Adviser”) has not independently verified the contents hereof. The Financial Adviser is acting only for the Company and will not be responsible to anyone other than the Company for providing the protections afforded to clients of the Financial Adviser.

Investor call 7th October 2024

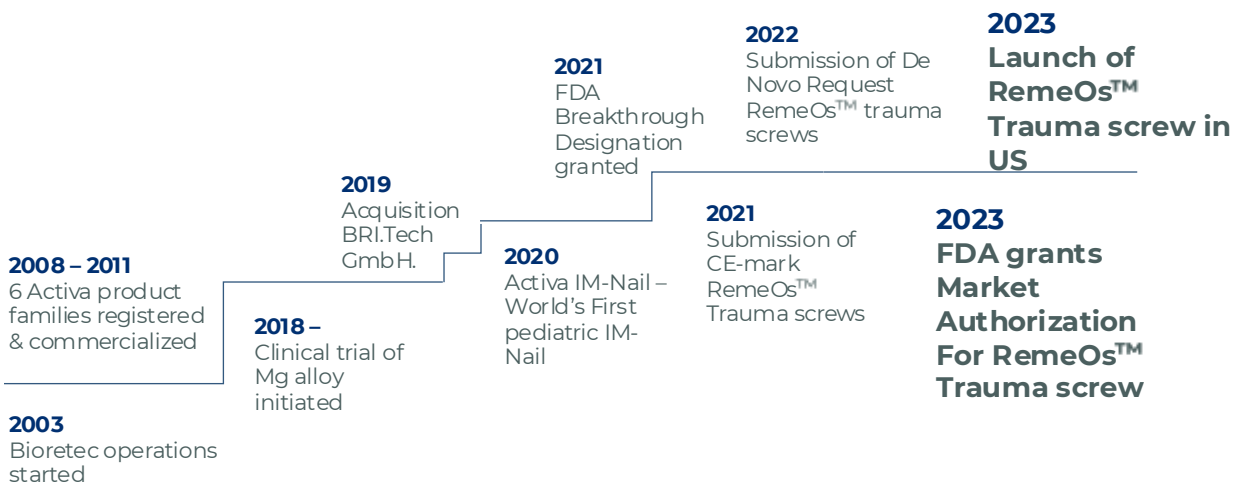
Alan Donze
Chief Executive Officer

Timo Lehtonen
Chief Technology Officer

Bioretec in brief:

A globally operating company that develops, manufactures, and sells absorbable orthopedic implants

- HQ and production in Tampere, Finland, and a subsidiaries in Austria and the U.S.
- Publicly listed in Nasdaq First North Growth Market Finland



~ 4 M€ 2023 Revenue

~ 40 countries around the world

8 registered product families

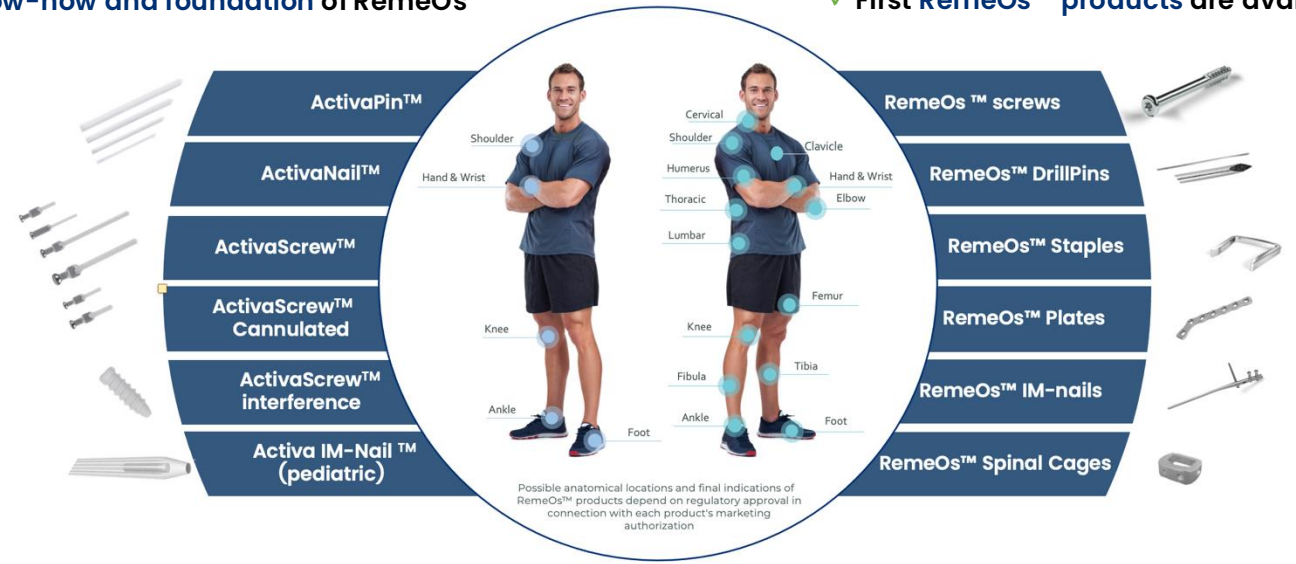
Our Products: Absorbable orthopedic implants

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

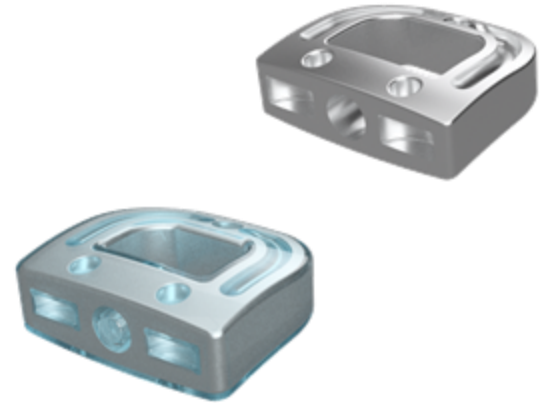


*Mg alloy with Ca 0.55 w-% and Zn 0.45 w-%

Value Increase Opportunity

Rationale and milestones leading to strategic pivoting to accelerate RemeOs™ Spinal Interbody Cage

- Product Concept Development
- FDA Breakthrough Device Designation
- Successful Patenting
- Industrial Manufacturing Advancements
- Entering the functional performance testing
- FDA Interaction for Faster Market Entry



RemeOs™

Purity and Strength in Healing

What is Spinal Interbody Fusion

Spinal fusion is the most common spinal surgery

… for connecting two vertebrae, one or more levels

… connecting them prevents movement between them

… preventing movement helps to prevent pain

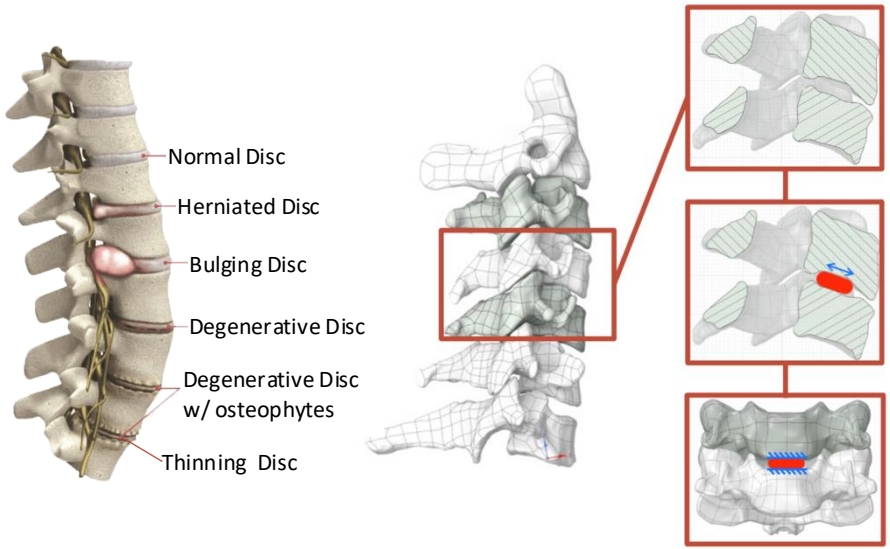
During spinal fusion

… the diseased disc is removed between vertebrae

… a surgeon places in the opening a spinal interbody cage

… **spinal cage** typically has a hole in the center filled with bone grafts

… the bone grows around and through the hole of the cage, fusing the vertebrae.

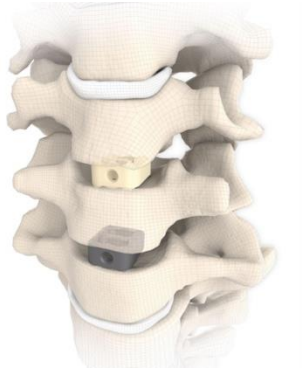


Interbody Spinal Cage

Interbody Spinal Cage is designed to be inserted between the vertebrae in the spine to maintain or restore the height of the intervertebral disc space after the removal of a damaged or degenerated disc.

The key features and purposes of interbody spinal cages:

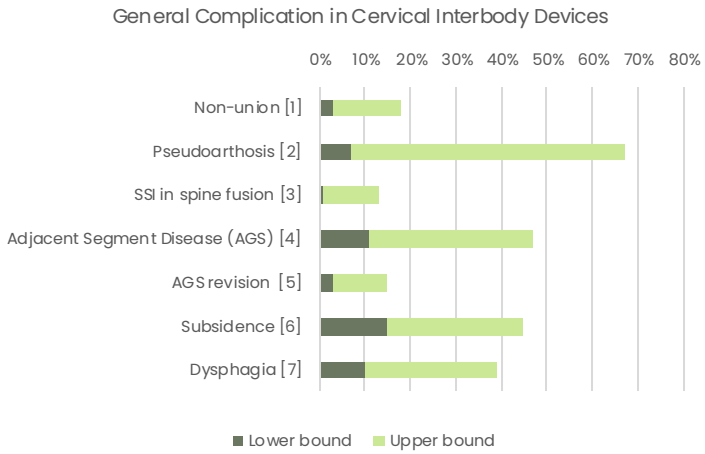
1. **Function:** The primary purpose of the cage is to provide structural support to the spine, stabilize the affected vertebral segments, and promote the fusion of the bones over time.
2. **Material:** Interbody cages typically made from titanium, PEEK, or a combination of them as machined, injection molded and 3D printed
3. **Design:** Cages come in various shapes and sizes, to fit different anatomical requirements. Some cages have porous surfaces or integrated features to encourage bone growth into and around the cage.
4. **Types: I**nterbody cages are typically divided by anatomical location, including:
    1. Cervical Interbody Cages
    2. Thoraic Interbody Cages
    3. Thoraco lumbar Cages
    4. Lumbar Interbody Cages



Clinical challenges of current cages

Complications Related to non-bioactive materials and Stress Shielding

- **Non-union/Pseudarthrosis:** Non-union remains a prime cause of failure in cervical fusion. It is usually defined as absence of interbody bone fusion at 1 year or non-progression of the bone callus. Pseudarthrosis refers to the formation of a false bone due to improper healing
- **Cage Subsidence:** As the bone density decreases, the implant may sink into the bone, leading to loss of intervertebral height and mechanical stability.
- **Adjacent Segment Disease**: Increased load on adjacent segments due to altered biomechanics can lead to degeneration of nearby vertebrae.
- **Bone Resorption**: Reduced mechanical loading on the bone can stimulate osteoclastic activity, leading to bone resorption and potential osteopenia around the implant. Weakened bone surrounding the implant may be more susceptible to fractures under normal physiological loads
- **Dysphagia (Difficulty Swallowing):** Fusion hardware obstructing the proper movement of the structures involved in swallowing. Sometimes post-surgical inflammation, infection, and scarring can also contribute to dysphagia.



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

Definition of Stress Shielding: Stress shielding occurs when the mechanical load is transferred from the bone to an implant that is significantly stiffer than the surrounding bone. This can lead to reduced bone density in the areas surrounding the implant.
Xu et al. BMC Musculoskeletal Disorders (2023) 24:876

Clinical challenges of current cages

Medical state	Complications related to non-bioactive materials (in simple terms)	Outcome to patient	RemeOs™ Spinal Cage
Non-union/Pseudarthrosis	Bones are not fusing properly	Patient not healing properly High pain Numbness Muscle weakness Limited ability to move Additional medical operation Daily activities limited Paralysis Opioid abuse	Alloy forms new bone and will significantly improve healing
Cage Subsidence	Titanium implant sinks to the bone		Equals to normal bone strength and stiffness – no sinking should materialise
Adjacent segment disease	Adjacent vertebrae degeneration		Bone strength and natural implant absorption
Bone resorption	Bones are weakened due to titanium fracturing the bone		Normal mechanical load, no weakening of bones
Dysphagia	Difficulty in swallowing	Patient has difficulties to eat or drink, additionally inflammation and infection	Implant will disappear from the body and form new bone

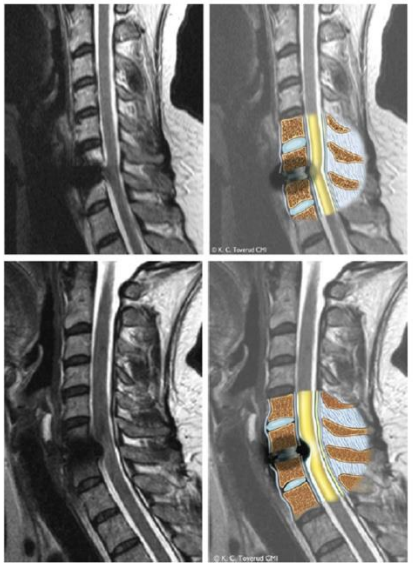
Source: Bioretec research and materials.

Clinical challenges of current cages

Other Complications Related to current golden standard

- **MRI compatibility and artifacts**: The presence of titanium cages can make it challenging to accurately assess the spinal area for complications or for the presence of tumors or cancerous lesions. Artifacts caused by the titanium can obscure or mimic lesions, potentially complicating the interpretation of MRI scans.

- **Surgical site infections (SSIs):** The second most frequently cited hospital-acquired infection in the United States and lead to significant morbidity, prolonged hospitalization, increased medical costs, and overall compromised patient outcomes. In particular, SSIs following spine fusion surgery can be devastating, requiring surgical debridement(s) and prolonged intravenous antibiotics, and. at times, leading to significant long-term disability.



Eur Spine J (2013) 22:2296–2302

Source: Bioretec research and materials.

RemeOs™ Interbody Spinal Cage

RemeOs™ interbody spinal cage

… An advanced absorbable interbody spinal cage designed to **enhance bone growth, stability and reduce infection rates**

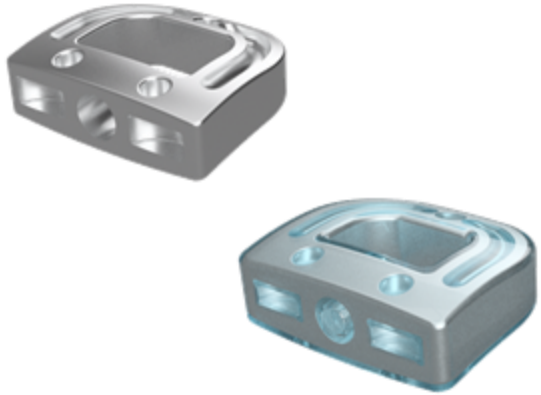
… Fosters effective **biological interaction** and fixation of bone tissue, facilitating osteointegration and the formation of a robust bony fusion around the device

… Optimized mechanical properties (elastic modulus, compression strength) that **closely match cortical bone**, mitigating the risk of complications derived from permanent metallic counterparts

… Engineered to **maintain appropriate intervertebral height** until bony fusion gains structural integrity

… Facilitates **natural load transfer** to developing bony fusion, reducing risks associated with permanent materials

… Fulfills the demand for **bone bridge formation** without leaving permanent foreign materials in the spine, enabling **artifact-free imaging** (MRI, X-ray, CT)



Source: Bioretec research and materials.

The key design features and functions

Hybrid Composite Core-Shell Structure with **Roughened** Upper and Lower Faces

… **Core** is Osteopromotive RemeOs alloy

… **Shell** is Osteostimulative composite treated with antimicrobial bioglass.

… The shell is engineered to slow the degradation of the magnesium alloy core, **prolonging mechanical stability**.

… Hybrid composite material provides **essential structural support** to the spine during the critical healing period

… Optimized degradation rates through careful selection of biopolymer components to **manage the release of hydrogen** by-products from the magnesium alloy.

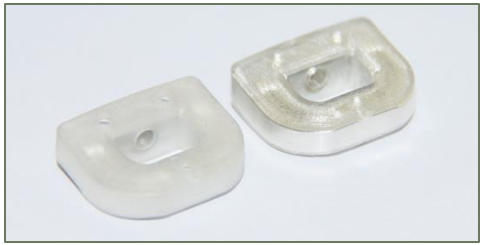
… The bioactive glass roughened surface **prevents microbial layer formation** around the cage, a common issue with traditional permanent materials, reducing infection risks

… Textured design **minimizes subsidence** into the vertebral planes and **prevents migration** prior to osteointegration.

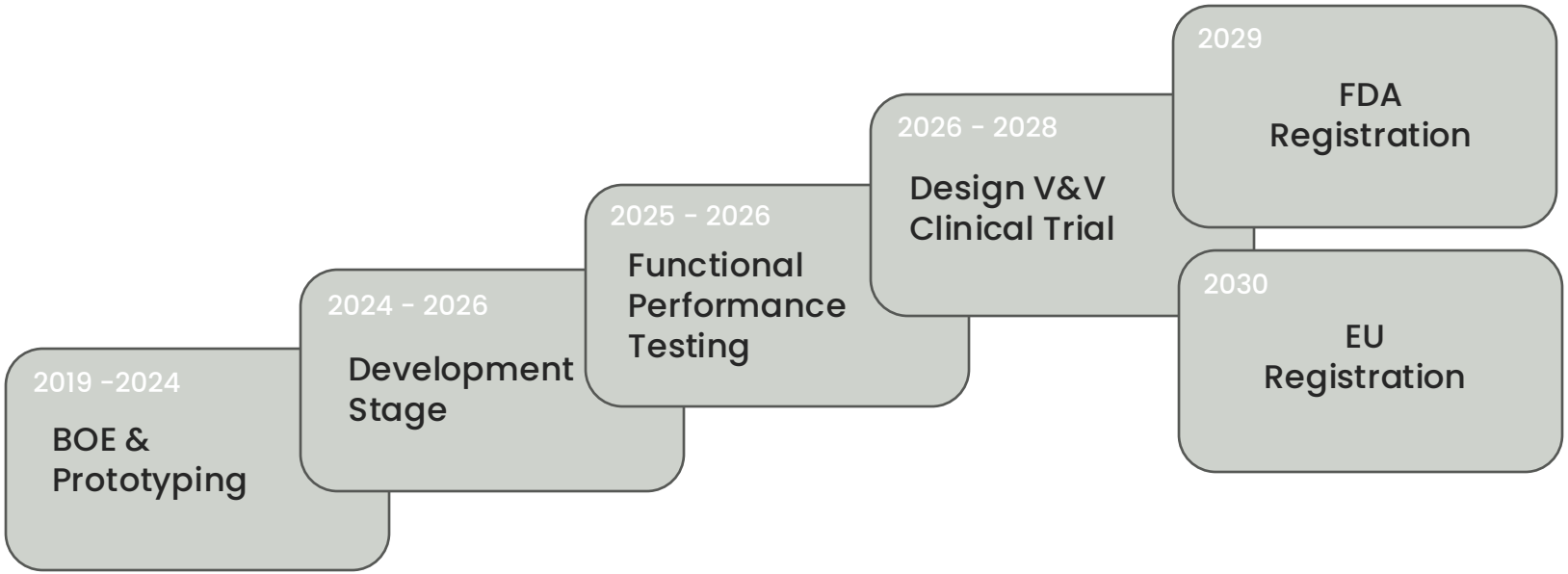
… Reacts with physiological fluids to **form hydroxyapatite layers** during absorption, **promoting cell adhesion** and differentiation, leading to **new endosteal bone mass formation**.

… Gradually degrades over time and made magnetic-free materials, ensuring no interference with future treatments

… All materials are currently in clinical use, biocompatible and are known to promote bone growth



Development Pathway to Registration



BOE = Business Opportunity Evaluation
V&V = Verification and Validation

FDA granted Breakthrough Designation

Degenerative disc disease (DDD) is an irreversible and debilitating disease that has a substantial impact on day-to-day functioning. Spinal fusion -related complications can cause (Failed Back Surgery Syndrome) FBSS and consequences leading to long-term or chronic use of medication such as opioids. It has been reported that disc degeneration is common in over 50% of middle-aged individuals.

FDA granted Breakthrough designation for this unmet clinical need to bone growth enhancing RemeOs™ Interbody Spinal Cage

The criteria for granting are:

1. *Provides for more effective treatment of an irreversibly debilitating human disease or conditions*
2. *Device meets at least one of four criteria for addressing an unmet need.*
   - *A: Device represents a breakthrough technology.*
   - *B: No approved or cleared alternatives exist.*
   - *C: Device offers significant advantages over existing approved or cleared alternatives.*
   - *D: Availability is in the best interest of patients*

RemeOs™ Interbody Spinal Cage Design and Data Development Plan met all criteria

Source: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program

Market Drivers & Restraints

Driving Factors

Rising incidence of spinal disorders:

- Increasing prevalence of spinal conditions contributes to a growing demand for surgical interventions
- Cervical interbody fusion cages play a crucial role in stabilizing the spine and facilitating fusion, offering an effective solution for patients experiencing spinal conditions

Advancements in surgical techniques and reimbursement policies:

- Innovations such as minimally invasive procedures and navigational technologies have enhanced the precision and efficiency of spine surgeries, yielding reduced surgical trauma and faster patient recovery.
- Reimbursement policies focused on reducing the total cost of care in surgical procedures play a significant role in the growth of this segment.

Limiting Factors

Regulatory Landscape:

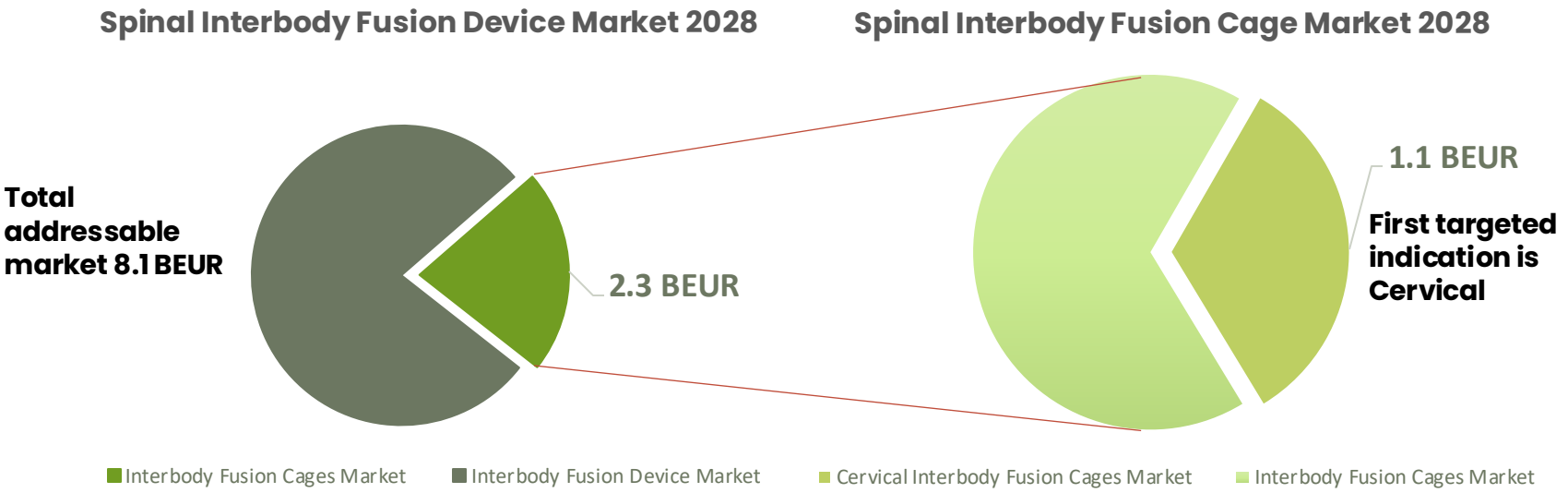
- Industry-level delays in regulatory processes can impact approval and launch timing
- Stringent regulatory requirements and approval processes are required for medical devices.
- Compliance impacts the pace of new technologies in the market

Crowded Landscape:

- Incumbent players offer only “me too” products in their extensive product portfolios and partnerships

Source: https://www.grandviewresearch.com/industry-analysis/spinal-fusion-device-market

Markets & Competitor Landscape



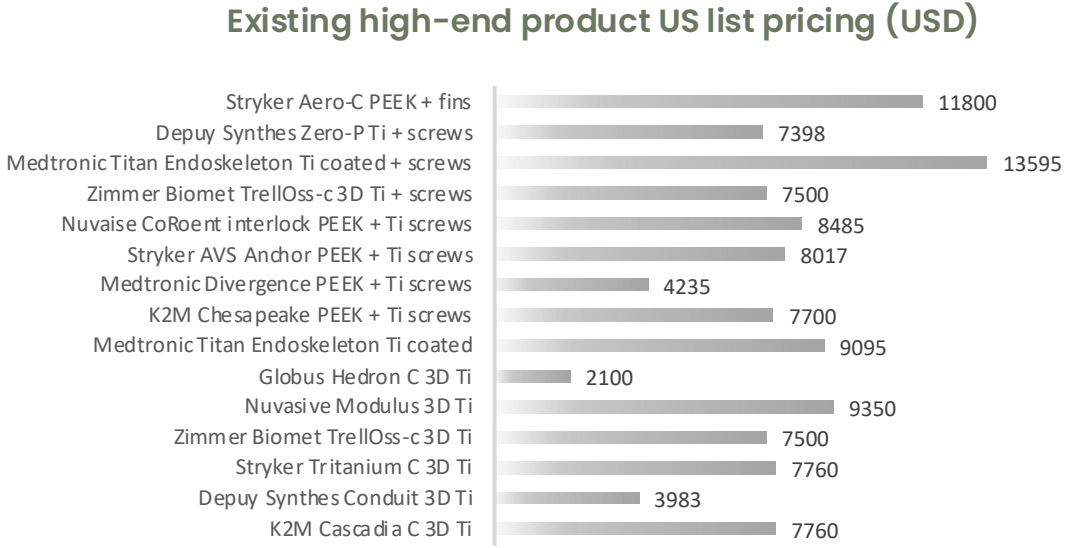
Top players in the market: Stryker, DePuy Synthes, Medtronic, Orthofix Medical Inc. Globus/NuVasive, Inc., Zimmer Biomet, Seaspine

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

Cervical Interbody Cage Pricing

… Spinal Interbody Cages are high-margin complex products belonging to higher risk category than trauma products

… without the locking mechanism (screws), the cages are often accompanied by a Cervical plate and screws.



Cervical Spine Research society 2020
Prof. Ahmed Nassr, Mayo Clinic
Economic update on material Technology
Contribution of prices: DePuy Synthes, Medtronic(Titan), Globus, Stryker/K2M, Zimmer/Biomet, Nuvasive

Current Clinical Challenges vs. Solutions Provided by RemeOs™

Challenges with current solutions		Solutions offered by RemeOs
Non-union and Pseudarthrosis	⟷	Enhanced Bone Healing and Fusion Rate
Stress Shielding, non-union, adjacent level degeneration and Subsidence	⟷	Optimized mechanical properties matching cortical properties
Erosion during the lifetime of the product	⟷	Use of known Biocompatible natural Materials
Long-term effects, permanent	⟷	Time-Engineered Absorption Characteristics
Incidence of Surgery-Related Complications	⟷	Surface roughened with bioglass with known antimicrobial properties
Artifacts in MRI	⟷	Radiolucency for Improved Imaging
Failed Back Surgery Syndrome (FBSS)		Better clinical outcome, less surgeries, less medication, improved quality of life

Source: Bioretec research and materials.

bioretec

better healing – better life