



BONESUPPORT

Capital Markets Day 2023

November 28th

Introduction

Emil Billbäck, CEO





Focus: Innovation

Moderator: Charlotte Stjerngren, CORD

13:30 - 14:10	Strategic update - Emil Billbäck
14:10 - 14:45	Clinical update – Dr Michael Diefenbeck
14:45 - 15:00	Q&A
15:00 - 15:20	Coffee break
15:20 - 16:00	Clinical experience (incl Q&A) – Dr Stephen Quinnan
	Moderated by: Charlotte S and Michael D
16:00 - 16:30	Financial status and outlook – Emil Billbäck and Håkan Johansson

Speaker list:

Emil Billbäck, CEO BONESUPPORT Håkan Johansson, CFO BONESUPPORT Dr Michael Diefenbeck, Chief Medical Officer, EVP Medical & Clinical Affairs

Digital:

Dr Stephen Quinnan, Orthopedic Surgeon, Paley Orthopedics & Spine institute

Addition Bonesupport on-site:

Annelie Aava-Vikner, EVP Global Marketing
Dr. Michael Wrang- Mortensen, EVP R&D and Operations



BONESUPPORT Capital Markets Day, November 28th 2023

Capital Markets Day in Sept 2019 focused on:

- New strategy
- Reorganized European sales team
- Regulatory pathways

Capital Markets Day in Sept 2022 focused on CERAMENT G roll-out in US:

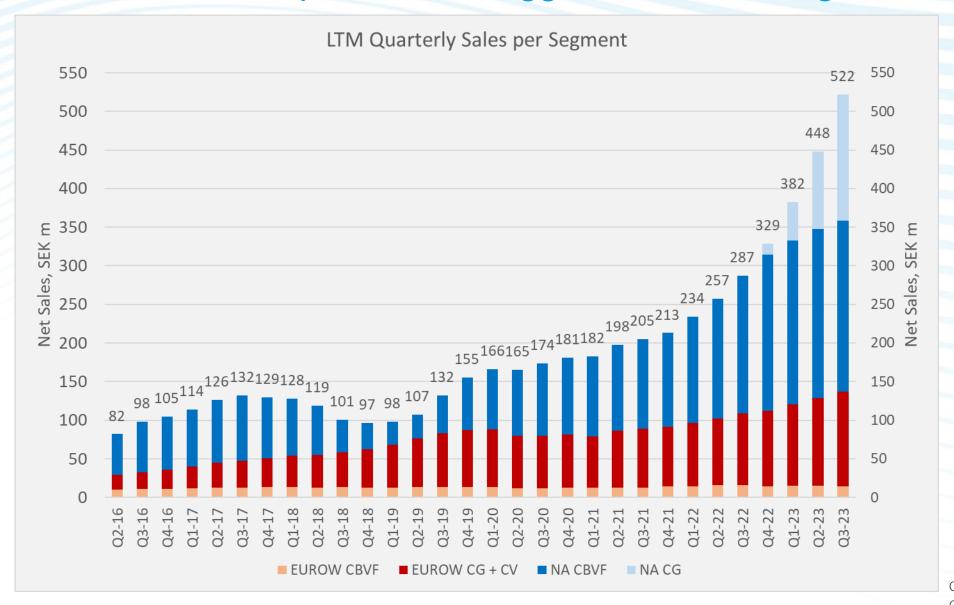
- Medical Education
- Booster program
- CPO and IDN contracts

Focus for today's Capital Markets Day is innovation and business development:

- New indication: Spinal fusions
 - Market description and clinical relevance
- Introduction of CERAMENT V in the US
- Experience from CERAMENT G in the US
- Clinical update

Accelerated market penetration. Biggest Q-over-Q net growth





Incremental, Q-over-Q LTM growth:

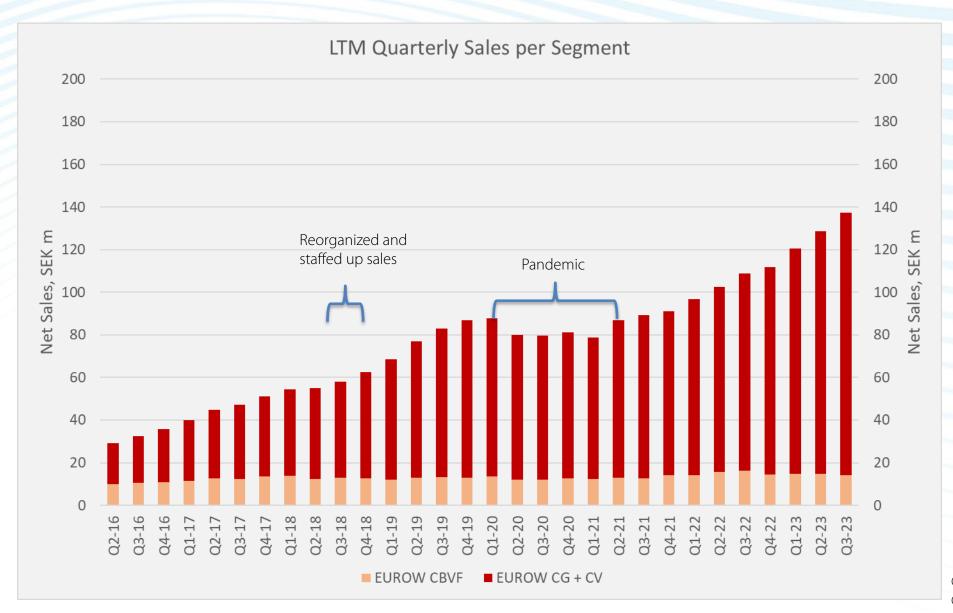
Q3-22 30 MSEK Q4-22 42 MSEK Q1-23 53 MSEK Q2-23 66 mSEK

Q3-23 74 mSEK

CBVF= CERAMENT Bone Void Filler CG = CERAMENT G (Gentamicin) CV = CERAMENT V (Vancomyciin)

EUROW - Steady and strong market penetration





Q3 LTM 2023 growing with:

+27% versus Q3 2022

(Ax: growth with 33%)

+54,2% versus Q3 2021

(Ax: growth with 80%)

Sales FTE direct markets: 26

Direct sales per head Q3 LTM: 400 k€

CBVF= CERAMENT Bone Void Filler CG = CERAMENT G (Gentamicin) CV = CERAMENT V (Vancomycin)





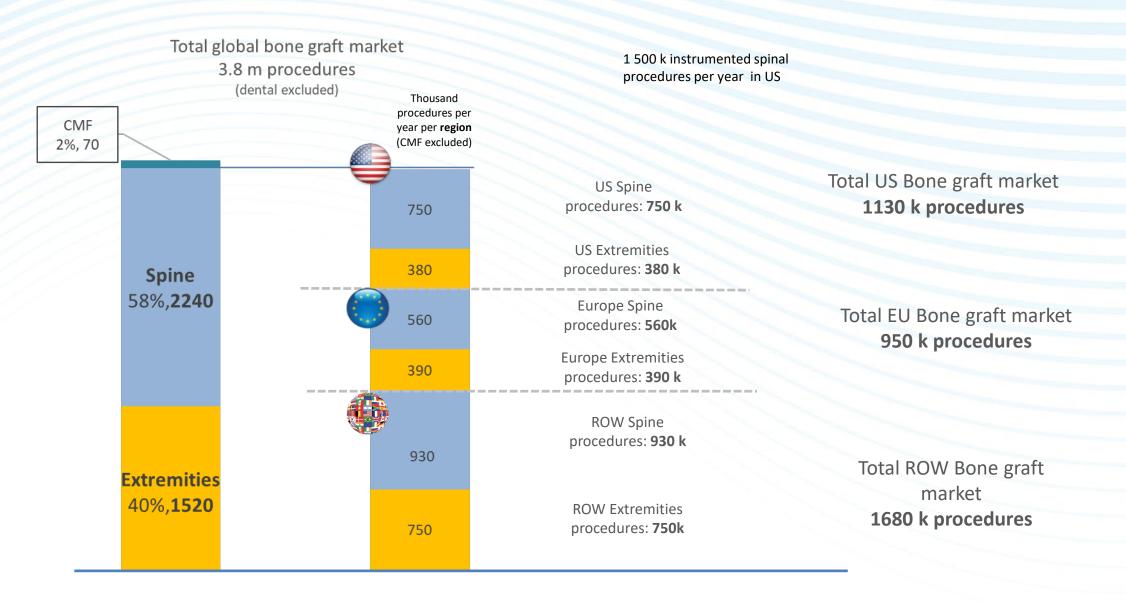
BONESUPPORTCapital Markets Day 2023

November 28th

Emil Billbäck, CEO

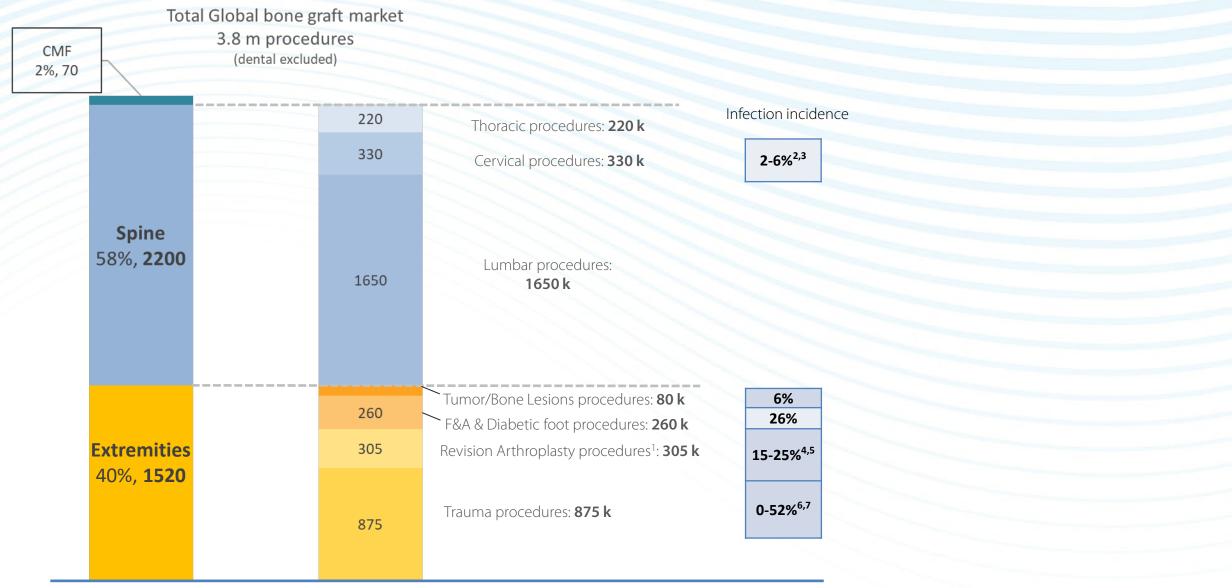


Overview Total Bone Graft Market – Segment and Geography split



Overview Total Graft Market – Segment and sub-segment split

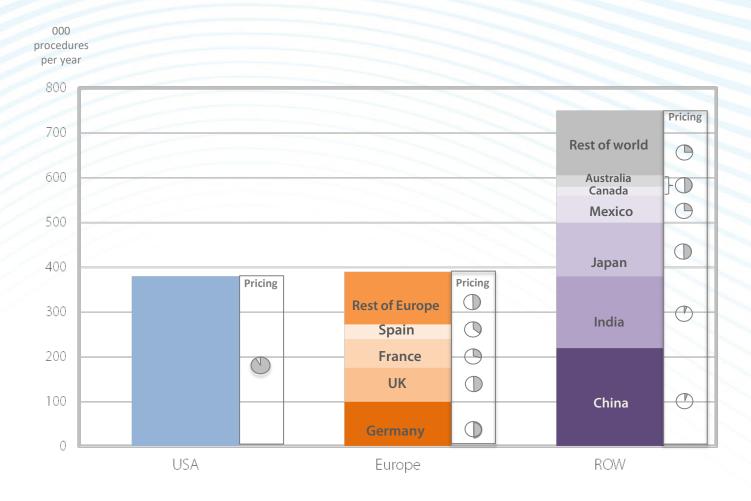




1.3000 k Arthroplasty procedures in the world. Approximately 10% leads to a revision, which has been defined as primary addressable market for CERAMENT 2.Edmiston, C., Leaper, D., Chitnis, A., Holy, C., & Chen, B. (2023). Risk and economic burden of surgical site infection following spinal fusion in adults. Infection Control & Hospital Epidemiology, 44(1), 88-95. doi:10.1017/ice.2022.32 3. Chahoud et al. Surgical site infections following spine surgery: eliminating the controversies in the diagnosis Infectious Agents and Disease Volume 1 - 2014 | https://doi.org/10.3389/fmed.2014.00007 4. Lum ZC, Shieh AK, Dorr LD. Why total knees fail-A modern perspective review. World J Orthop 2018; 9(4): 60-64 [PMID: 29686970 DOI: 10.5312/wjo.v9.i4.60] 5. Karachalios et al. Total hip arthroplasty: Survival and modes of failure. EFORT Open Reviews, 3(5), 232-239 doi.org/10.1302/2058-5241.3.170068 6. Gustilo RB et al. Problems in the management of type III (severe) open fractures: a new classification of type III open fractures. J Trauma. [Internet]. 1984; 24: 742–746. 7. Jahangir N, Niazi N, Aljawadi A, et al. The use of adjuvant local antibiotic hydroxyapatite biocomposite in the management of open Gustilo Anderson type IIIB fractures. A prospective review. Journal of orthopaedics. 2019;16(3):278-282.



Extremities split on Geographies - Procedures



USA

- Most developed market in the world
- Strong developing trend for synthetic bone grafts
- Allografts (incl DBM) holds larger share
- 000 Procedures per mil. inhabitants: 1,2

Europe

- Defined as: see ref below¹
- Representing a population of 470 m
- High share of autograft being used for bone repair and grafting.
 DBM less represented (5% of grafts)
- 000 Procedures per mil. inhabitants: 0,7-1,0

Rest of the World

- Countries highlighted represent six largest market values
- Very diverse treatment methods
- 000 Procedures per mil. inhabitants: 0,2 (India) 1,0 (Australia)



CERAMENT market penetration (LTM) in extremities

Europe

- Total Europe number of **Procedures** (extremities) 390 k → Total Europe market share CERAMENT: 2.4%
- Total Europe number of **Procedures** synthetics (extremities) 132 k \rightarrow Total Europe market share CERAMENT: 7.0%
- Core markets¹:
 - Market share Core¹ markets: 3.6 %
 - Market share Core¹ markets Synthetics: 10,7%
 - Market share Core¹ markets, infection management (treatment/recurrence and prevention): 8.3 %

US

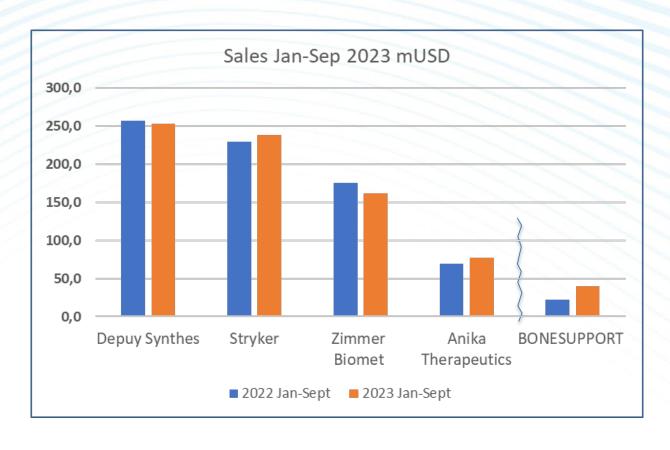
- Total US number of **Procedures** (extremities) 380 k \rightarrow Total US market share CERAMENT: 2.9%
- Total US number of Procedures synthetics (extremities) 103 k → Total US market share CERAMENT: 10.7%
- Total US market CERAMENT G in infection management (treatment/recurrence and prevention): 2,0%

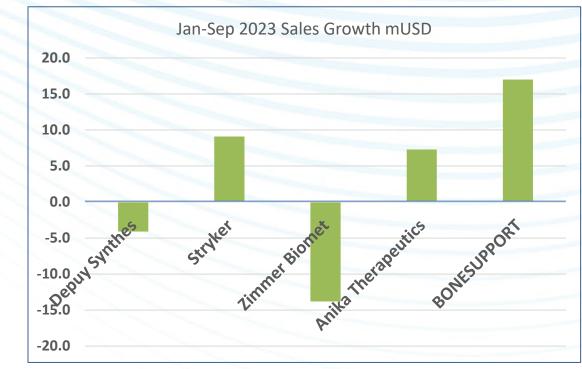


CERAMENT is outgrowing all major Orthobiologics companies



Sales of Orthobiologics Jan-Sept, 2023







Trends in Orthobiologics

- Surgical volumes back to normal (pre-pandemic levels) in the US, not yet in Europe. Mainly due to staff shortage
- Orthobiologics benefit from highly favorable patient demographics.
- Trend towards synthetic bone graft substitutes procedures vs traditional autograft and/or allograft
- National Volume-Based Procurement in China disrupted orthopedic sales. Implant prices have drastically decreased and companies as ZimVie have left the Chinese market.
- Increase of procedures taking place in Ambulatory Surgical Centers (US) which means that more of the elective surgery is going to take place in an outpatient setting, increasing the need to focus on outpatient reimbursement and funding.
- Slow adoption of instrumentation technologies & robotics. Only 11% of cases in joint replacement is using robotics and only 3% in spine. Meaning less impact of bundle solutions from big orthopedic companies then earlier anticipated.
- New MDR regulation is driving more efforts in European go-to-market model and product life cycle management. Market access also limited by health care provider's and other decision maker's availability





BONESUPPORTMajor initiatives

- 1. Overview
- 2. Spine market entry
- 3. CERAMENT V for US

CERAMENT - The versatile platform for building bone

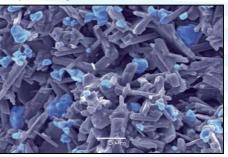


What makes CERAMENT unique?

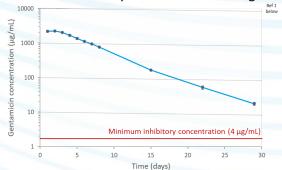
Proprietary technology platform that facilitates natural bone healing:

- Purpose engineered ceramic bio-composite
- Mimics natural healing
- Resorbs at pace of bone healing
- Builds a highly porous micro-scaffold that enables bone remodeling
- Predictable and engineered antibiotic elution
- Unique application properties reduces dead space

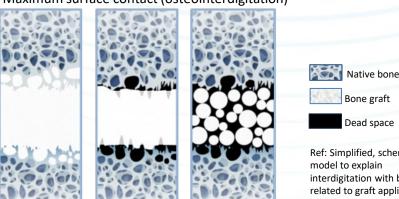
Purpose engineered



More than 30 days antibiotic elution significantly above MIC



Maximum surface contact (osteointerdigitation)



Putty

Beads (up to 50% dead space)

Spinal fusion – Indication overview



The main reason for fusion surgery of the spine is to stabilize the spinal column and reduce pain caused by certain spinal conditions.

Fusion surgery involves joining two or more vertebrae together to create a solid bony bridge, with the purpose to eliminate motion between the fused vertebrae.

Pathogenesis for indicating spinal fusion:

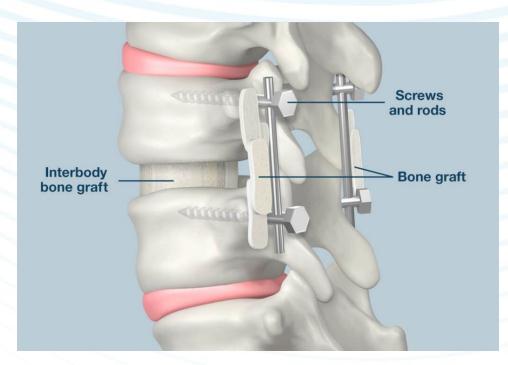
Spinal Instability: Fusion surgery is often performed when there is excessive motion between vertebrae, which can result from conditions such as degenerative disc disease, spondylolisthesis (vertebral slippage), or spinal fractures.

Disc Herniation: When a spinal disc bulges or ruptures, it can compress nearby nerves and cause pain. Fusion surgery may be considered if the disc is severely damaged and other conservative treatments have failed to provide relief.

Spinal Deformities: Conditions like scoliosis (abnormal sideways curvature of the spine) or kyphosis (excessive forward curvature) can lead to pain and functional limitations. Fusion surgery can be performed to correct the deformity and stabilize the spine.

Spinal Tumors or Infections: In some cases, fusion surgery may be necessary to remove tumors or treat spinal infections. Fusion helps restore stability after the affected vertebrae are removed.

Spinal Trauma: Severe spinal injuries, such as fractures or dislocations, may require fusion surgery to stabilize the spine and prevent further damage.



General categories of fusion:

- Posterolateral fusion (PLF)
- Interbody fusion

CERAMENT entry into US spinal fusion



Background:

750 k spinal fusion procedures are performed each year in the US.

Failure rate is 15-20%¹ (fusion not achieved)

2-6%² of spinal fusions procedures develop a surgical site infection

Standard of Care:

- Use of bone graft to create cortical bone "bridge" between vertebrae
- Off-label local antibiotics preventively applied in 40%³ of procedures

Status:

CERAMENT BVF is FDA market-authorized for Posterolateral Fusion (PLF).

Application will be made for label extension into interbody fusion

Clinical data exists on CERAMENT BVF showing excellent bone remodeling in vertebrae repair

First pre-clinical (animal) study has shown spinal fusion for CERAMENT BVF

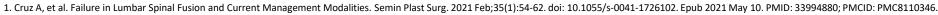
Additional data to be generated during 2024

Regulatory:

Label extension through 510(k) submission for CERAMENT BVF to get full (Interbody fusion in addition to the Posterolateral fusion) market authorization

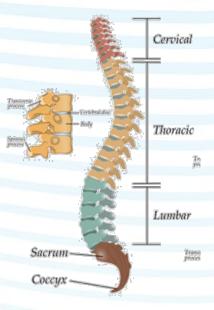
Timing:

Submission filing to FDA for full market authorization (BVF) **2024 Q4**Antibiotic eluting CERAMENT for spinal fusion; timing to be developed



2. Edmiston et al. Risk and economic burden of surgical site infection following spinal fusion in adults." Infection control and hospital epidemiology vol. 44,1 (2023): 88-95. doi:10.1017/ice.2022.32

3. Dodson et al. The effect of prophylactic vancomycin powder on infections following spinal surgeries: a systematic review; DOI: 10.3171/2018.10.FOCUS18470.



750 k procedures annually:

325 k Cervical fusion procedures

85 k Thoracic fusion procedures

340 k Lumbar fusion procedures

82% of Lumbar fusions are made with interbody procedure

CERAMENT entry into US spinal fusion

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Bone repair needs contact¹



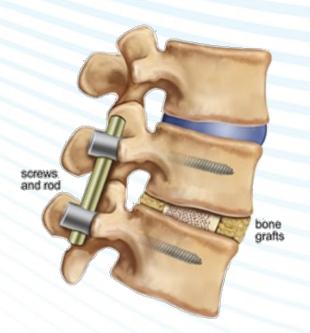
CERAMENT PU



Putty



Beads (up to 50% dead space)



Interbody fusion

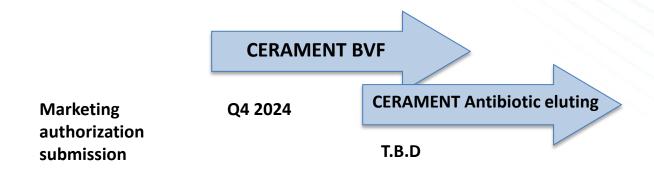


Interbody fusion cage

Lumbar Spinal Fusion Surgery | Spine-health



- Very attractive and adjacent therapeutic area, with 2,2 m procedures a year (extremities are 1,5 m), with several synergies and leverage from the proven CERAMENT platform. Focus on the 750 k procedure / year US market
- The clinicians are:
 - -Orthopedic spine surgeons
 - -Interventional radiologists
 - -Spine neurologists
- BONESUPPORT is bringing a well proven, clinically validated and versatile platform for bone repair
- Go-to-market model will follow the successful roll-out of CERAMENT BVF and CERAMENT G within extremities indications
- Good knowledge and experience within the company
- Go to market in 2 waves :





CERAMENT V for bone infection (extremities) in the USA market

Background:

CERAMENT G is available in the US since Oct 2022.

Gentamicin is very potent and with no material side effects shown, when administered locally. There are patients with **specific resistant microbials** as well as patients with several co-morbidities and **polymicrobial infection** that could benefit from a combination of antibiotics.

BONESUPPORT aims at providing a solution to this need without the surgeon having to revert to off-label mixing.

In **15 -20%** of the cases it could be beneficial to <u>combine</u> CERAMENT G and CERAMENT V. In **5 -10%** of the cases Vancomycin will be more suitable than Gentamicin

Standard of Care:

Systemic antibiotics + off-label antibiotic mixing

Status:

Breakthrough device status achieved by FDA on October 16.

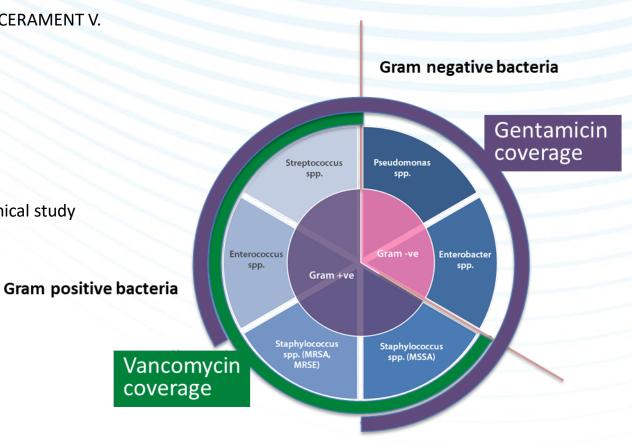
Real world clinical data exists. Assumption is no need for supplementary clinical study

Regulatory:

De Novo submission

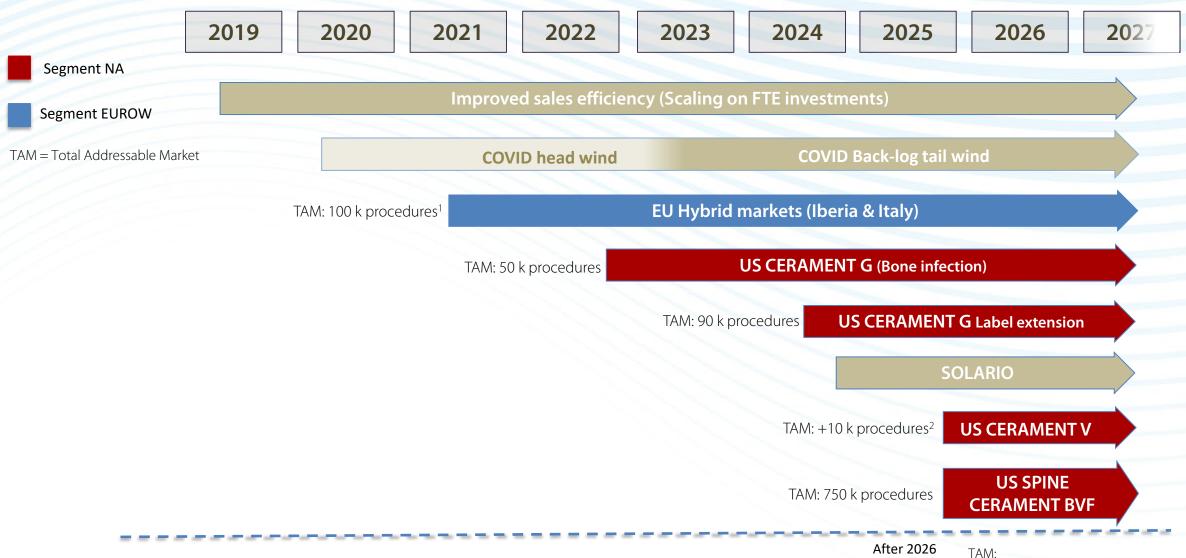
Timing (preliminary):

Submission filing to FDA Q1 2025



Strong business momentum, with additional vectors for growth





Addressable market defined as bone grafting extremities market Spain, Portugal and Italy

70 k procedures France (2027) 120 k procedures Japan

CG and CV SPINE US 345 k procedures³

Addressable market defined as 15%-20% use in addition to CERAMENT G

Not incremental. Included in the 750 k procedures for total spinal fusion. Local antibiotics is used (off-label) in 40% of the US spinal fusion procedures + 45 k treatment





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Emil Billbäck, CEO



Bonesupport Capital Markets Day, Nov 28th 2023

Expect strong continued growth momentum in the current business:

Sales in 2024 will be above 40%¹

- Preparations for entry into spinal fusion
 - FDA market authorization submission Q4 2024

- Preparations for market introduction of CERAMENT V in the US
 - FDA market authorization submission Q1 2025





BONESUPPORT Capital Market Day November 28th, 2023

Clinical update

Michael Diefenbeck MD, PhD
Chief Medical Officer

Introduction:

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Michael Diefenbeck, MD, PhD Orthopaedic Surgeon

Chief Medical Officer, BONESUPPORT AB since April 2017

EVP Clinical and Medical Affairs since Jul 2018

Honorary Consultant, Nuffield Orthopaedic Centre, Oxford University Hospitals, NHS in 2016

Founder of "Scientific Consulting in Orthopeadic Surgery and Traumatology", Hamburg in 2014

Clinical positions at:

- Schön Klinik Hamburg Eilbek, Bone infection unit, Consultant for orthopaedic surgery, 2012-14
- University Hospital Jena, 2006-12
- BG Kliniken Bergmannstrost Halle/Saale, 2004-06
- BG Unfallklinik Murnau, 2000 03













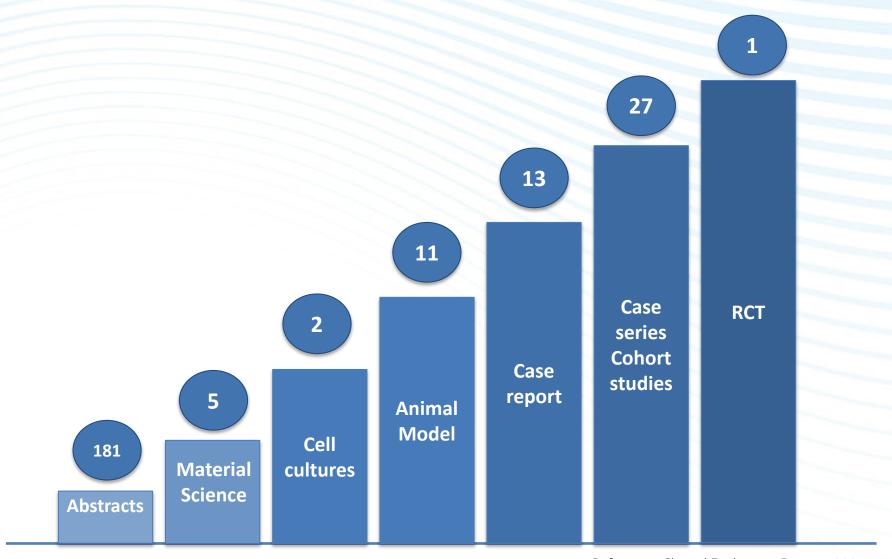
Agenda



- New clinical evidence in key indications
- Antibiotic Stewardship
- CERAMENT's primary mode of action: Remodelling into bone
- CERAMENT and the future: Spinal fusion and bone active substances

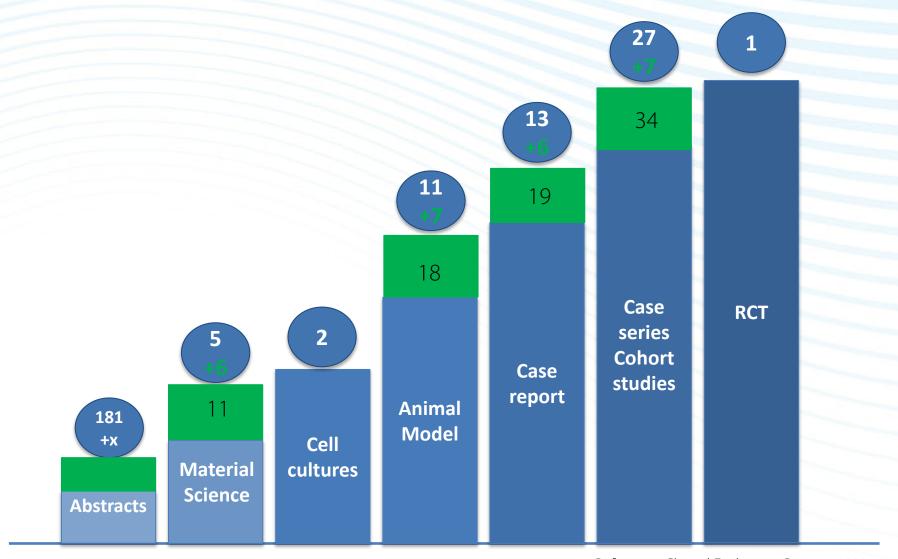
More clinical evidence for CERAMENT than any other grafting therapy





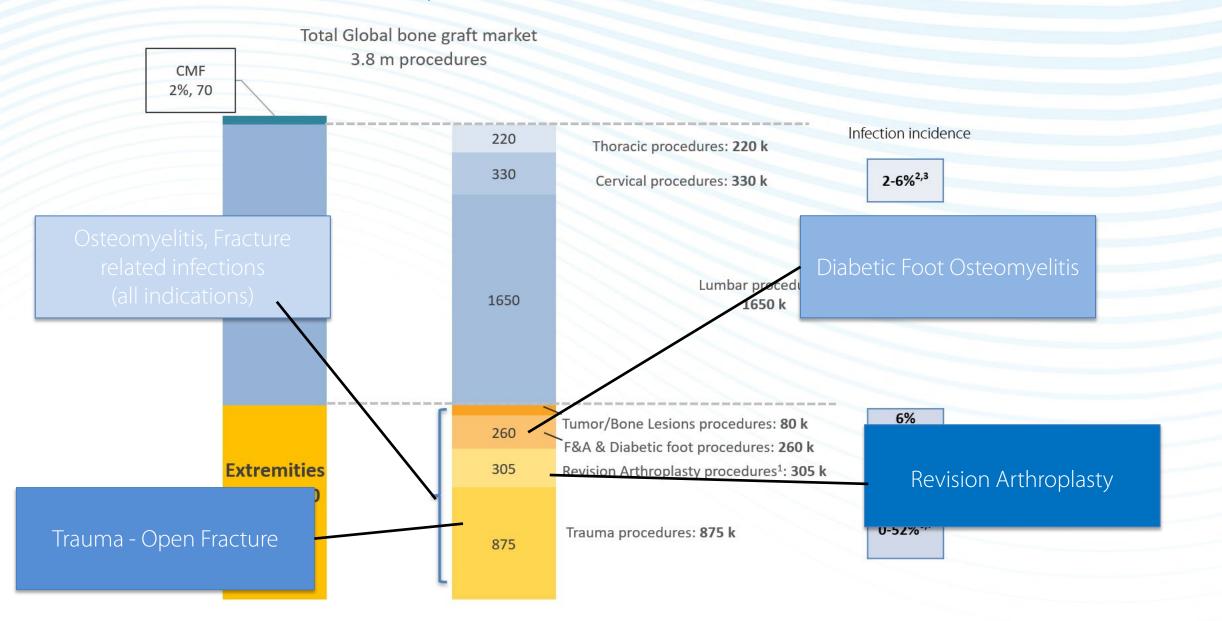
More clinical evidence for CERAMENT than any other grafting therapy







New clinical evidence in key indications



Diabetic Foot Osteomyelitis a hard-to-treat indication

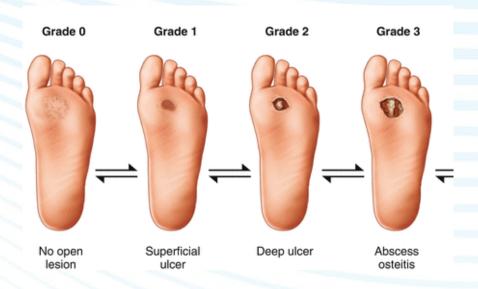


Diabetic Foot Osteomyelitis

Diabetic Foot Osteomyelitis (DFO) is mostly a consequence of a soft tissue infection (e. g. Diabetic foot ulcer) that spreads into the bone, first involving the cortex and then the marrow

The typical sequence is usually:

- Deformity of the foot (shortening of tendons)
- Lack of protective sensation (no pain)
- Superficial foot ulcer / contamination
- Deep foot ulcer with infection
- Bone infection / Osteitis / Diabetic Foot Osteomyelitis
- ...
- Amputation





Diabetic Foot Osteomyelitis a hard-to-treat indication



Diabetic Foot Osteomyelitis





Article

Evaluation of Adjuvant Antibiotic Loaded Injectable Bio-Composite Material in Diabetic Foot Osteomyelitis and Charcot Foot Reconstruction

Venu Kavarthapu ^{1,*} , Jasdeep Giddie ¹, Varun Kommalapati ¹, Joanne Casey ², Maureen Bates ² and Prashanth Vas ²

Design: Retrospective case series

Indication: Diabetic Foot Osteomyelitis and Charcot Foot

Patients: 53 (17 DFO and 37 Charcot foot)

Treatment: One stage debridement and CERAMENT® (Group 1) or one stage (Group 2a; 19) or two stage

(Group 2b; 18) Charcot foot reconstruction with CERAMENT®

Product: CERAMENT® V was used in 39% and CERAMENT® G in 65 % (2 patients both)

Follow-up: Mean 30 months [12 – 98 months]

Results: Group 1: 15/19 pat : Complete eradication of infection in 87%,

2 persisting ulcers, cons. therapy

Group 2: 100% primary ulcer resolution,100% limb salvage

and 76% bony union rate. Five patients required reoperations due to problems with bone union.

Two deep infections needing revision surgery (2b)

Benchmark: Diabetic Foot Osteomyelitis

Standard of care: Amputation rate up to 24%¹

Revision arthroplasty



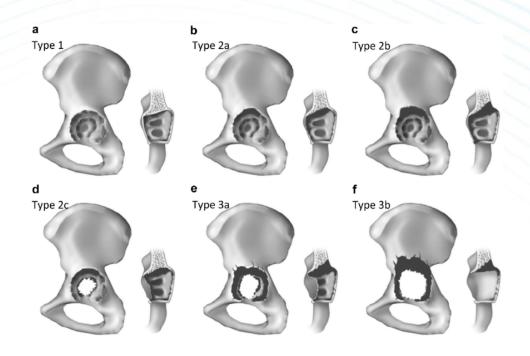
Revision Arthroplasty

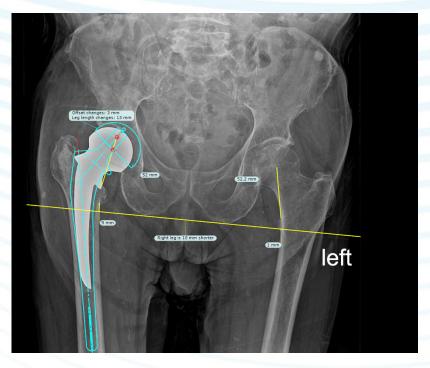
Revision arthroplasty is to be performed when a primary joint replacement fails.

Reasons for failure are infection, aseptic loosening, recurrent dislocation or fracture.

There are 3 million arthroplasty a year, and 10% goes into revision.

At revision there is often significant bone loss, which needs to be addressed.





Paprosky classification of acetabular defects^{1, 2}

¹⁾ Paprosky WG et al. Acetabular defect classification and surgical reconstruction in revision arthroplasty. A 6-year follow-up evaluation. J Arthroplasty. 1994 Feb;9(1):33-44.

²⁾ Honcharuk E, Kayiaros S, Rubin LE. The direct anterior approach for acetabular augmentation in primary total hip arthroplasty. Arthroplast Today. 2017 May 12;4(1):33-39.

Revision arthroplasty



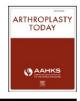
Revision
Arthroplasty



Contents lists available at ScienceDirect

Arthroplasty Today

journal homepage: http://www.arthroplastytoday.org/



Original Research

Alternating Layers of Morselized Allograft and Injectable Ceramic Bone Graft Substitute in Acetabular Reconstruction: A Novel

'Sandwich' Technique Rajesh Malhotra, MS, FRCS, FACS, All India Institute of Medical Sciences, New Delhi, Delhi,

India

Published: 2023

Patients: 24 pat.

Treatment: Bone defect filling with CERAMENT G and allograft

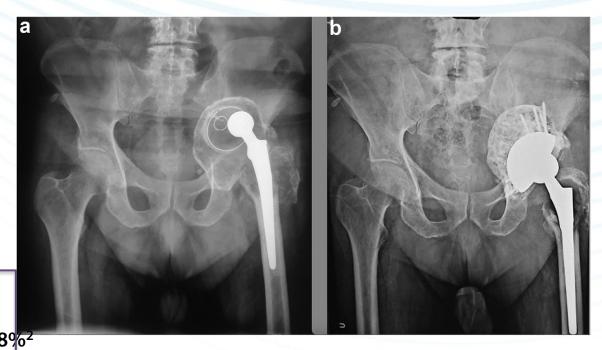
Follow-up: 60 and 82 months

Results:

- Consolidation of the bone graft was seen in all the 24 cases within a range of 96 to 165 days
- With revision of the component as end point, the survivorship was 100% at 82 months
- Infection free: 100%Follow-up rate 100%

Benchmark:





- 1) Edmiston CE Jr et al. Longitudinal Rates, Patient Risk Factors, and Economic Impact of Superficial and Deep Incisional Surgical Site Infection After Primary and Revision Total Hip Arthroplasty: A U.S. Retrospective Commercial Claims Database Analysis. Surg Infect (Larchmt). 2023 May;24(4):366-375.
- 2) Pelt Ceet al. Early outcomes after revision total hip arthroplasty with a modern modular femoral revision stem in 65 consecutive cases. Arthroplast Today. 2018 Nov 17;5(1):106-112.

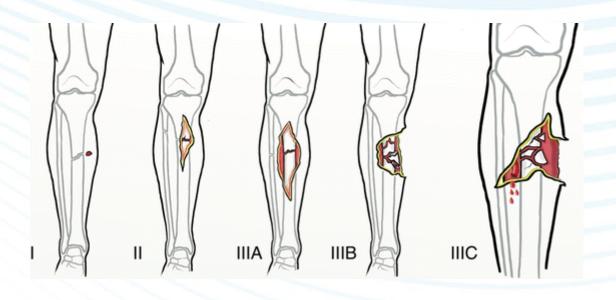
Trauma: Open Fracture

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Trauma - Open Fracture

- Open fracture is a fracture with an open wound or break in the skin near the site of the broken bone
- Most often caused by a fragment of bone breaking through the skin at the moment of injury
- Once the skin is broken, bacteria from dirt and other contaminants can enter the wound, potentially causing an infection at the site of injury

Gustilo type	Definition
	Open fracture, clean wound, wound <1 cm in length
II	Open fracture, wound >1 cm in length without extensive soft-tissue damage, flaps, avulsions
III	Open fracture with extensive soft-tissue laceration, damage, or loss or an open segmental fracture. This type also includes open fractures caused by farm injuries, fractures requiring vascular repair, or fractures that have been open for 8 h prior to treatment
IIIA	Type III fracture with adequate periosteal coverage of the fracture bone despite the extensive soft-tissue laceration or damage
IIIB	Type III fracture with extensive soft-tissue loss and periosteal stripping and bone damage. Usually associated with massive contamination. Will often need further soft-tissue coverage procedure (i.e. free or rotational flap)
IIIC	Type III fracture associated with an arterial injury requiring repair, irrespective of degree of soft-tissue injury.



New publication on IIIb open fractures with mean 55 months follow-up



Trauma - Open Fracture

Long-Term Follow-Up of Open Gustilo-Anderson IIIB Fractures Treated With an Adjuvant Local Antibiotic Hydroxyapatite Bio-Composite

Joshua A. Henry ¹, Almigdad Ali ¹, Ibrahim H. Elkhidir ², Adam Reid ³, Jason Wong ³, Anand Pillai ¹

- 1. Department of Trauma and Orthopaedics, Wythenshawe Hospital, Manchester Foundation Trust, Manchester, GBR
- 2. Department of Medicine, University of Khartoum, Khartoum, SDN 3. Department of Plastic Surgery, Wythenshawe Hospital, Manchester Foundation Trust, Manchester, GBR

Corresponding author: Joshua A. Henry, jhenry89@gmail.com

Published: 2023 Patients: 81

Treatment: Filling of fracture defects with CERAMENT G Follow-up: min. 11 months (mean **55 months** [11-110 m])

Results:

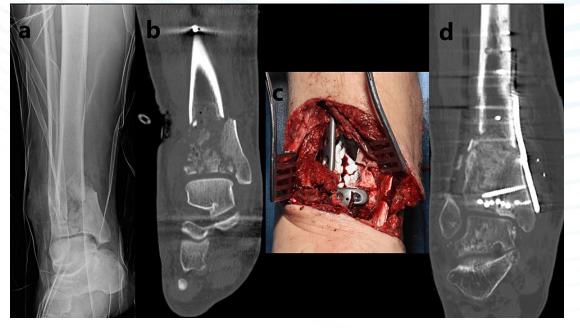
Infection rate: 3.7%

Union rate: **96%**

Limb salvage rate: 96.3%

Benchmark: Trauma: Open fracture

Standard of care: Infection rate average 15%¹



Osteomyelitis (OM)



Osteomyeliti

- McNally et al. (2016) definition: bone infection, with minimum of 6 months symptoms, with clinical and radiological features accompanied by at least one of the following:
 - The presence of a sinus, an abscess or intraoperative pus
 - Supportive histology
 - Or two or more microbiological cultures with indistinguishable organisms
- May present as recurrent or intermittent disease
- Vast majority is posttraumatic after fracture and internal fixation
 - → OM is usually a subset of Fracture Related Infections (FRI)

Benchmark Osteomyelitis: PMMA beads

Two-stage surgery (min two interventions, min two hospital stays)

Infection rate (published data): 13.3%¹ Meta analysis (published data): 13.2%²



CERAMENT G in osteomyelitis with mean 6 year follow-up



Osteomyelitis



■ GENERAL ORTHOPAEDICS

Mid- to long-term results of singlestage surgery for patients with chronic osteomyelitis using a bioabsorbable gentamicin-loaded ceramic carrier

M. A. McNally, J. Y. Ferguson, M. Scarborough, A. Ramsden,

D. A. Stubbs, B. L. Atkins **Aims**

Excision of chronic osteomyelitic bone creates a dead space which must be managed to avoid early recurrence of infection. Systemic antibiotics cannot penetrate this space in high

Published: 2022

Patients: 100 pat

Treatment: Debridement and dead-space management

with CERAMENT G

Follow-up: min. **4.4 years** (mean **6.05 years** [4.4-8.4y]

Recurrence of infection: **6%** (6/100 pat)

Pathologic fractures: **3%** (all within the first 11 months)

Mortality: 5 pat. (infection free)

Lost to Follow-up 4 pat.; Follow-up rate 96%

Benchmark
Osteomyelitis:

PMMA beads 13.2%







CERAMENT G in osteomyelitis with mean 6 year follow-up



Osteomyelitis

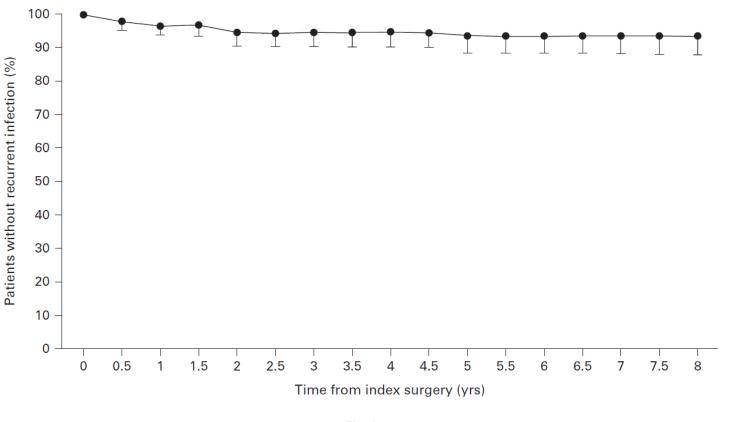


Fig. 4

Kaplan-Meier graph of survival until eight years after surgery.

"At final follow-up, six patients (six bones) had recurrent infection; thus 94% were infection-free. Three infections recurred in the first year, two in the second year, and one 4.5 years postoperatively.

Benchmark
Osteomyelitis:
PMMA beads 86%

SOLARIO – a randomized trial on 500 patients



STUDY PROTOCOL

Open Access

Short or Long Antibiotic Regimes in Orthopaedics (SOLARIO): a randomised controlled open-label non-inferiority trial of duration of systemic antibiotics in adults with orthopaedic infection treated operatively with local antibiotic therapy



Maria Dudareva¹, Michelle Kümin², Werner Vach³, Klaus Kaier⁴, Jamie Ferguson¹, Martin McNally^{1†} and Matthew Scarborough^{1†}

Title: Short Or Long Antibiotic Regimes In Orthopaedics (SOLARIO)

Design: Randomized, multi-centre, non-inferiority study

Indication: Infections of the musculoskeletal system (cOM, FRI, PJI)

Patients: 500 pat, LPI August 2023, planned LPO August 2024

Treatment: Debridement and dead-space management with an approved antibiotic eluting device plus systemic antibiotic

treatment. Comparison of a short course of systemic antibiotics (1 week or less) to a long course of systemic

antibiotics (4 weeks or more).

Hospital: 19 clinical sites

Follow-up: 12 months

Endpoint: Primary: Treatment success defined by an "clinical endpoint committee" according to the recorded data

Consequence: Change of the Standard of Care (SOC) for musculoskeletal infections to the combination of an antibiotic eluting

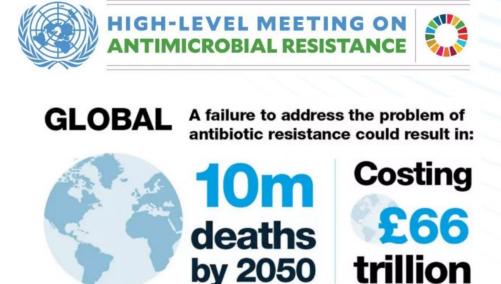
device plus systemic antibiotic treatment for only one week (in stead of four or more)



Antibiotic stewardship is the effort to measure and improve how antibiotics are prescribed by clinicians and used by patients.

Improving antibiotic prescribing and use is critical to

- Effectively treat infections
- Protect patients from harms caused by unnecessary antibiotic and
- Combat antibiotic resistance.





Effectively treat infections

- The right drug:
- At the right dosage (concentration):
- At the right time:
- With a good clinical outcome:

Protect patients from harms caused by unnecessary antibiotic use:

- Systemic side effects:
- Compliance / Does the pat. take the tablets?

Combat antibiotic resistance: Do local antibiotics cause antibiotic resistance in bacteria?

- In vitro: Bidossi et al. :
- In vivo: Young et al.:



Effectively treat infections

- The right drug:
- At the right dosage (concentration):
- At the right time:
- With a good clinical outcome:

CERAMENT G offers

Active against gram-positive and gram-negative bacteria

High local concentration (burst elution)

Right after debridement, available for 28 days above MIC

Infection free: 94% of pat. at 6.04 years (mean)

Protect patients from harms caused by unnecessary antibiotic use:

Systemic side effects:
 No systemic side effects of locally implanted CERAMENT G

Compliance / Does the pat. take the tablets? CERAMENT is implanted, no worries of compliance

Combat antibiotic resistance: Do local antibiotics cause antibiotic resistance in bacteria?

- In vitro: Bidossi et al.: Did not lead to stable or transient adaptations in either of the tested bacterial strains
- In vivo: Young et al.: Treatment of orthopaedic infection with local antibiotics was not associated with the emergence of antimicrobial resistance



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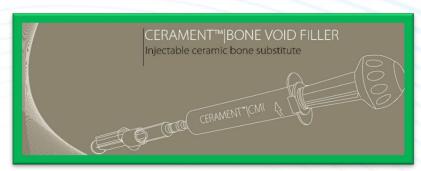
CERAMENT is optimal Antibiotic Stewardship



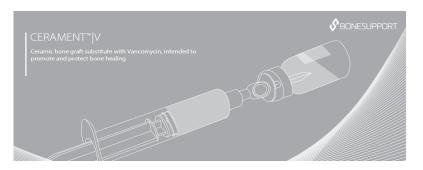


Primary mode of action: Remodelling into bone









Key features:

Remodelling to bone

Remodelling to bone

+

Elution of Gentamicin

Remodelling to bone

+

Elution of Vancomycin



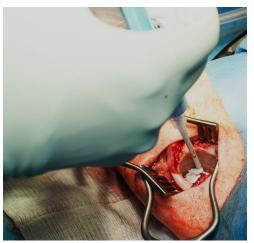


APMIS 127: 53-63

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Establishment and effects of allograft and synthetic bone graft substitute treatment of a critical size metaphyseal bone defect model in the sheep femur

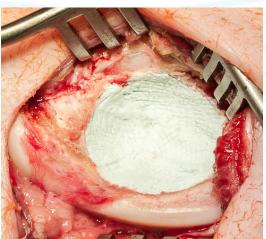
WERNER HETTWER, 1 PETER F. HORSTMANN, 1 SABINE BISCHOFF, 2 DANIEL GÜLLMAR, 3 JÜRGEN R. REICHENBACH, 3 PATRINA S. P. POH, 4 MARTIJN VAN GRIENSVEN, 4 FLORIAN GRAS 5 and MICHAEL DIEFENBECK 6,7













Material and Methods

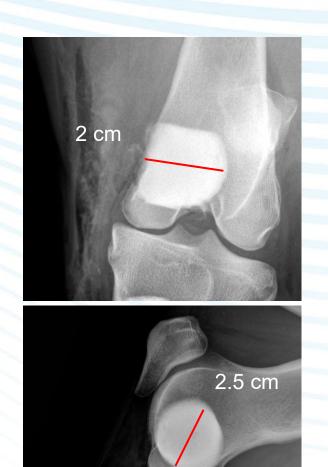
Drill hole dist. femur of sheep

> Volume: 10ml

Three months later surgery on contralateral leg

10 sheep

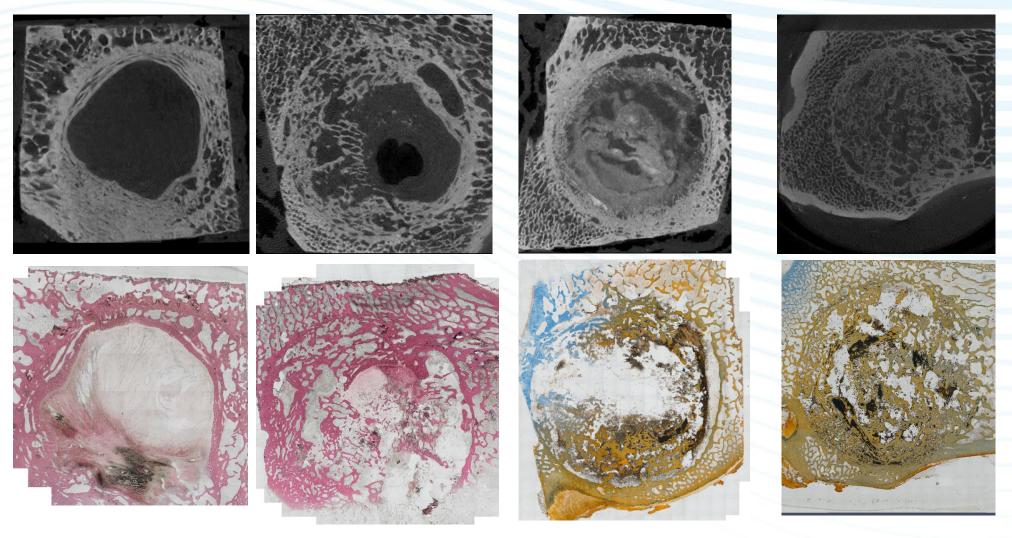
➤ Radiology, µCT, MRI, histology between 3 days and 12 months



Hettwer W et al. Establishment and effects of allograft and synthetic bone graft substitute treatment of a critical size metaphyseal bone defect model in the sheep femur. APMIS. 2019 Feb;127(2):53-63.

♦BONESUPPORT

1. Animal model: unfilled vs. allograft vs. CERAMENT



Empty, 6 months

Allograft, 6 months (Gold standard)

CERAMENT, 6 months CERAM

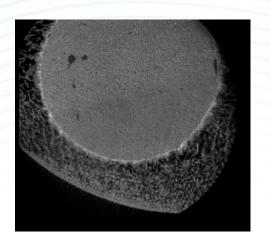
Masson Goldner

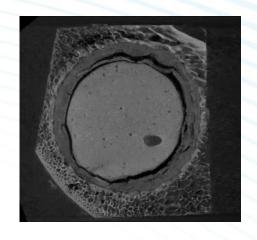
CERAMENT, 12 months

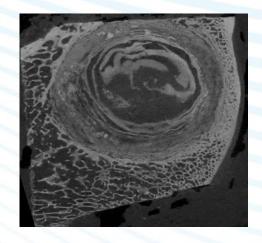
oldner BONESUPPORT, data on file

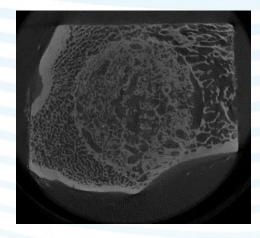


2. Animal model: CERAMENT radiological examination, Micro-CT and histology at different time points



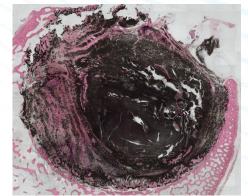


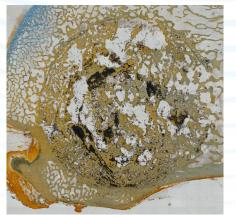












CERAMENT® 3 days

CERAMENT ® 6 weeks

CERAMENT ® 3 months

CERAMENT® 12 months



3. Level 1 Randomized Clinical Trial, CERTiFy, 135 patients

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Autologous Iliac Bone Graft Compared with Biphasic Hydroxyapatite and Calcium Sulfate Cement for the Treatment of Bone Defects in Tibial Plateau Fractures

A Prospective, Randomized, Open-Label, Multicenter Study

Alexander Hofmann, MD, PhD, Stanislav Gorbulev, PhD, Thorsten Guehring, MD, PhD, Arndt Peter Schulz, MD, PhD, Rupert Schupfner, MD, Michael Raschke, MD, PhD, Stefan Huber-Wagner, MD, PhD, and Pol Maria Rommens, MD, PhD, on behalf of the CERTiFv Study Group*



Design:

Patients:

Indication:

Treatment:

Centers:

Randomized Clinical Trial

135 (18 to 65 Y)

Tibia plateau fractures

Autologous Iliac Bone Graft vs.

CERAMENT BONE VOID FILLER

20 orthopedic trauma centers in

Germany

Outcome:

Primary:

SF-12 Physical Component Summary at 26 weeks

Co-primary:

Pain level at 26 weeks

Secondary:

SF-12 Mental Component Summary & SF-12 PCS

at 1,6 and 12 weeks

Bone-healing radiographs

Designed to show non-inferiority of CERAMENT BVF vs autograft



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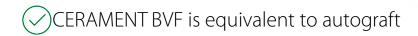
Outcome: SF-12 Physical Component Summary at 26 weeks

Primary: (>) Pain level at 26 weeks

Co-primary: SF-12 Mental Component Summary & SF-12 PCS

at 1,6 and 12 weeks

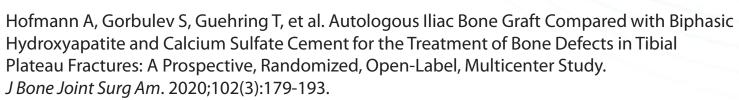
Secondary: A Bone-healing radiographs





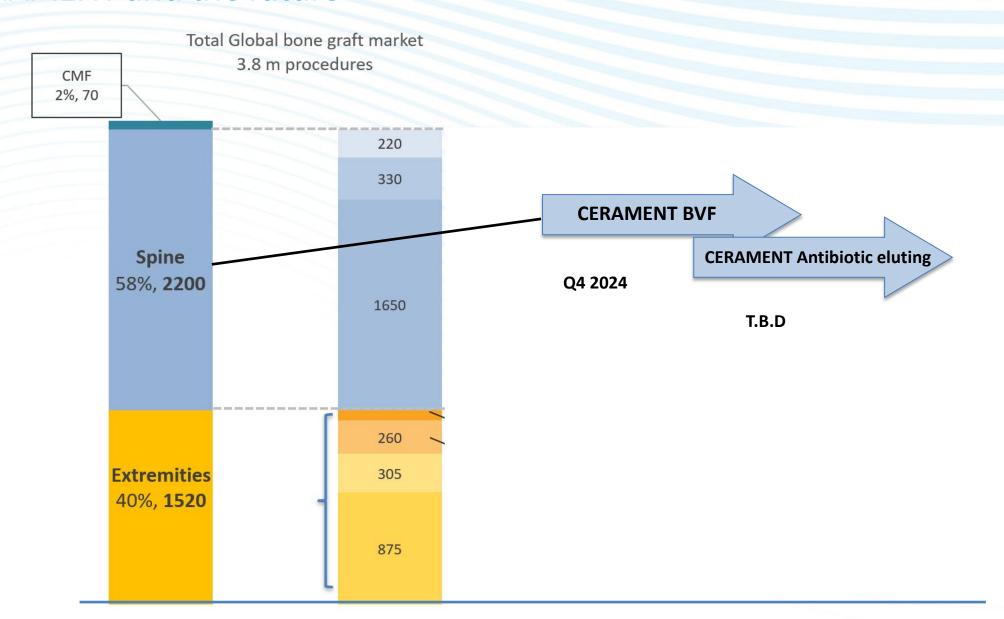
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CERAMENT and the future



CERAMENT and the future – use in spinal fusion



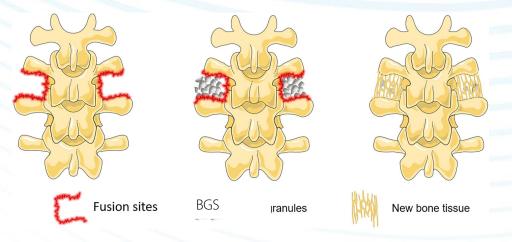
Calcium sulfate/hydroxyapatite mediated controlled co-delivery of BMP-2 and zoledronic acid enhances spinal fusion in a rat posterolateral spinal fusion model

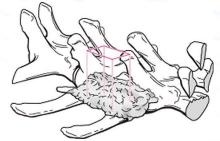
Tian X, Vater C, Raina DB, Findeisen L, Matuszewski LM, Tägil M, Lidgren L, Schaser KD, Disch KD, Zwingenberger S.

Methods: A standard posterolateral spinal fusion at L4 to L5 was performed bilaterally in rats by implanting group dependent scaffolds. At 3 weeks, 12 animals per group, and at 6 weeks 10 animals per group were euthanized for μCT, histological staining, or mechanical testing.

Groups:

Group	
1)	C BVF
2)	C BVF plus BMP-2
3)	C BVF plus systemic ZA
4)	C BVF plus local ZA
5)	C BVF plus BMP-2 plus systemic ZA
6)	C BVF plus BMP-2 plus local ZA
7)	Empty / Sham group





CERAMENT and the future – bone active substances



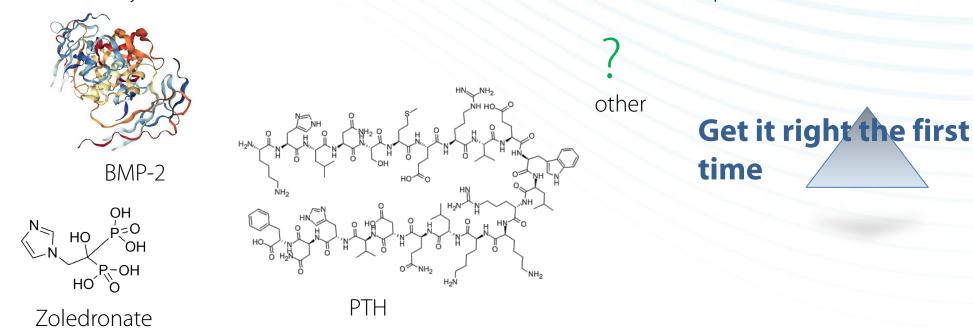
First Product	Second Product	Evidence: Animal Models	Brief outcome
BMP-2 BMP-2 plus Zoledronate (ZA) Zoledronat	C BVF	Raina DB, Matuszewski LM, Vater C, Bolte J, Isaksson H, Lidgren L, Tägil M, Zwingenberger S. A facile one-stage treatment of critical bone defects using a calcium sulfate/hydroxyapatite biomaterial providing spatiotemporal delivery of bone morphogenic protein-2 and zoledronic acid. Sci Adv. 2020 Nov 27;6(48):eabc1779.	rhBMP-2 and zoledronic acid (ZA) was combined with C BVF. The delivery of rhBMP-2 was necessary for critical defect healing and restoration of mechanical properties, but co-delivery of BMP-2 and ZA led to denser and stronger bone.
BMP-2 plus Zoledronate (ZA)	C BVF	Raina DB, Larsson D, Sezgin EA, Isaksson H, Tägil M, Lidgren L. Biomodulation of an implant for enhanced bone-implant anchorage. Acta Biomater. 2019 Sep 15;96:619-630. doi: 10.1016/j.actbio.2019.07.009. Epub 2019 Jul 10. PMID: 31301423.	A very strong effect on peri-implant bone formation was observed when a fenestrated PEEK implant was filled with C BVF plus ZA or plus a combination of rhBMP-2 + ZA. The results from the implant integration
Zoledronat (ZA)	C BVF	Raina DB, Larsson D, Sezgin EA, Isaksson H, Tägil M, Lidgren L. Biomodulation of an implant for enhanced bone-implant anchorage. Acta Biomater. 2019 Sep 15;96:619-630. doi: 10.1016/j.actbio.2019.07.009. Epub 2019 Jul 10. PMID: 31301423.	model clearly indicates that local controlled delivery of ZA alone is sufficient to enhance bone implant anchorage without the need of adding rhBMP-2.

Zoledronate(ZA) Tetracycline (TC) 18F-fluoride (18F)	C BVF	Raina DB, Liu Y, Isaksson H, Tägil M, Lidgren L. Synthetic hydroxyapatite: a recruiting platform for biologically active molecules. Acta Orthop. 2020 Apr;91(2):126-132.	Systemically administered ZA, TC and 18F seek HA acting as a recruiting moiety. The HA particles acted as a ZA-recruiting moiety and resulted in improved bone–implant anchorage
Parathormone (PTH)	CG	Freischmidt H, Armbruster J, Bonner E, Guehring T, Nurjadi D, Bechberger M, Sonntag R, Schmidmaier G, Grützner PA, Helbig L. Systemic Administration of PTH Supports Vascularization in Segmental Bone Defects Filled with Ceramic-Based Bone Graft Substitute. Cells. 2021 Aug 11;10(8):2058.	PTH alone nor the combination of CG and PTH led to the formation of a stable union. PTH induce vascularization, both as a single adjuvant treatment and in combination with CG. Systemic PTH is a potential synergistic co-treatment to CG

CERAMENT and the future – bone active substances



- So far, Zoledronate (ZA), BMP-2 and PTH have been tested together with CERAMENT
- All substances have one idea in common:
 Improve CERAMENT from an osteoconductive scaffold to an osteoinductive material
- Osteoinductive means that a substance can transfer stem cells into osteoblast, which generate bone
- CERAMENT is efficient in its current form; osteoinductive CERAMENT could be used in very challenging cases (e.g. non-unions, large bone defects, etc.)
- Only two osteoinductive products are on the market so far
- No decision yet, which substance to use for a commercial osteoinductive product



CERAMENT and the future-use in spinal fusion



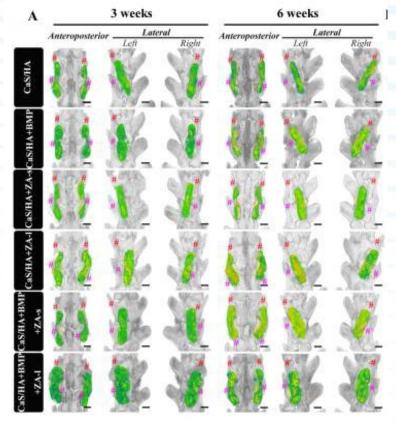
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Summary



New clinical evidence in key indications

Diabetic Foot Osteomyelitis Revision Arthroplasty

Trauma - Open Fracture

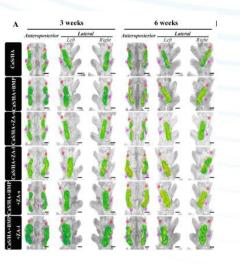
CERAMENT G is optimal Antibiotic stewardship



Proven Remodelling into bone



- CERAMENT and the future:
- Spinal fusion and Bone Active Substances







BONESUPPORTCapital Markets Day 2023

Financial status and Outlook

Håkan Johansson, CFO Emil Billbäck, CEO



Revised guidance

- The previous guidance, set at the capital markets day in Sept 2022, was established before the launch of CERAMENT G (Oct 2022) in the US
- At that time, we communicated the ambition to grow with 40% CAGR 2023-2025, in fixed currency
- 2023 has been a very strong performance year, well above expectations

Revised guidance:

Sales growth in 2024 over 40% (CER¹)

Financial overview



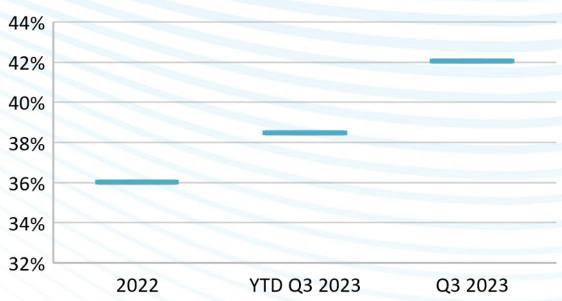
YTD Q3 2023

SEK m	YTD Q3 2022	YTD Q3 2023
Net sales	225,6	418,3
North America	143,5	310,8
EUROW	82,1	107,5
Gross Profit	203,3	382,3
Gross Margin	90,1%	91,4%
Sales commission and fees (U.S.)	-44,9	-109,7
Other operating expenses	-184,4	-229,8
EBIT	-26,1	42,8
Cash at period end	212,6	164,1

YTD Q3 2023:

- Sales growth (CER): 75%. Reported growth +85%
- Strong gross margin following favorable product mix
- Increased commercial activity impacting operating expenses
- EBIT positive from Q1 2023 and cash flow positive in Q3 2023

EBIT Conversion¹ - Incremental growth



Scalable business model:

- Gradually improved EBIT conversion from incremental sales growth confirming a strong scalability in the business model
- Scaling on existing commercial infrastructure;
 - Headroom to grow sales per FTE in EUROW
 - Strong US commercial infrastructure (380 commission-based sales reps)



		2023			202	2		2021
	Q3	Q2	Q1	Q4	Q3	Q2	Q1	Q4
SEK m								
Net Sales	158,2	140,4	119,7	103,2	84,6	74,6	66,3	61,4
North America	121,0	103,9	85,9	73,4	56,3	46,0	41,2	34,8
EUROW	37,2	36,5	33,8	29,8	28,3	28,6	25,2	26,6
Cost of sales	-12,4	-12,2	-11,4	-8,8	-7,8	-8,2	-6,3	-6,6
Gross profit	145,8	128,2	108,3	94,4	76,8	66,4	60,0	54,8
Gross margin, %	92,1%	91,3%	90,5%	91,5%	90,8%	89,0%	90,5%	89,3%
Selling expenses	-53,5	-55,0	-49,0	-46,8	-38,8	-37,4	-35,2	-35,4
Sales commissions and fees	-42,7	-37,2	-29,9	-28,1	-21,1	-16,8	-14,3	-13,9
Research and development expenses	-12,5	-14,6	-12,5	-14,8	-12,6	-13,6	-12,1	-14,4
Administrative expenses, Adj ¹	-11,9	-12,1	-11,7	-12,1	-11,3	-10,9	-10,6	-10,0
Other operating income	9,4	17,3	3,1	4,4	19,9	11,9	7,0	5,2
Other operating expenses	-10,1	-12,8	-3,7	-7,2	-17,5	-8,7	-7,3	-3,3
Operating expenses	-121,2	-114,6	-103,7	-104,5	-81,3	-75,5	-72,6	-71,8
Operating result, Adj ¹	24,6	13,7	4,6	-10,1	-4,4	-9,1	-12,5	-17,0
	2 1,0	10,7	.,0	,-	-,-		,5	27,0
Cost to sales ratio	0,77	0,82	0,87	1,01	0,96	1,01	1,09	1,17
Cash flow from operation	16,4	-38,8	-8,6	-6,5	-9,8	-23,5	-8,0	-16,7
Cash at period end	164,1	149,8	190,4	201,3	212,6	171,8	195,6	206,5

¹ Administrative expenses and Operating result before effects from the Group's incentive programs



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• Gradual gross margin improvement following the growth in the US.



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¹ Administrative expenses and Operating result before effects from the Group's incentive programs

- Gradual gross margin improvement following the growth in the US.
- Selling expenses growing following the US
 Booster program and increased momentum
 in marketing and sales promotion activities in
 both US and EUROW.



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	Q3	Q2	Q1	Q4	Q3	Q2	Q1	Q4
SEK m								
Net Sales	158,2	140,4	119,7	103,2	84,6	74,6	66,3	61,4
North America	121,0	103,9	85,9	73,4	56,3	46,0	41,2	34,8
EUROW	37,2	36,5	33,8	29,8	28,3	28,6	25,2	26,6
Cost of sales	-12,4	-12,2	-11,4	-8,8	-7,8	-8,2	-6,3	-6,6
Gross profit	145,8	128,2	108,3	94,4	76,8	66,4	60,0	54,8
Gross margin, %	92,1%	91,3%	90,5%	91,5%	90,8%	89,0%	90,5%	89,3%
Selling expenses	-53,5	-55,0	-49,0	-46,8	-38,8	-37,4	-35,2	-35,4
Sales commissions and fees	-42,7	-37,2	-29,9	-28,1	-21,1	-16,8	-14,3	-13,9
Research and development expenses	-12,5	-14,6	-12,5	-14,8	-12,6	-13,6	-12,1	-14,4
Administrative expenses, Adj ¹	-11,9	-12,1	-11,7	-12,1	-11,3	-10,9	-10,6	-10,0
Other operating income	9,4	17,3	3,1	4,4	19,9	11,9	7,0	5,2
Other operating expenses	-10,1	-12,8	-3,7	-7,2	-17,5	-8,7	-7,3	-3,3
Operating expenses	-121,2	-114,6	-103,7	-104,5	-81,3	-75,5	-72,6	-71,8
Operating result, Adj ¹	24,6	13,7	4,6	-10,1	-4,4	-9,1	-12,5	-17,0
Cost to sales ratio	0,77	0,82	0,87	1,01	0,96	1,01	1,09	1,17
Cash flow from operation	16,4	-38,8	-8,6	-6,5	-9,8	-23,5	-8,0	-16,7
Cash at period end	164,1	149,8	190,4	201,3	212,6	171,8	195,6	206,5

¹ Administrative expenses and Operating result before effects from the Group's incentive programs

- Gradual gross margin improvement following the growth in the US.
- Selling expenses growing following the US
 Booster program and increased momentum
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 both US and EUROW.
- R & D stable at an annual run rate of SEK 55 million, as a reference 15 MSEK below 2019, a year impacted by larger clinical trials.



		2023			202	2		2021
	Q3	Q2	Q1	Q4	Q3	Q2	Q1	Q4
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- Quarterly trajectory in cost to sales ratio and operating result confirms an underlying increase in operating leverage.



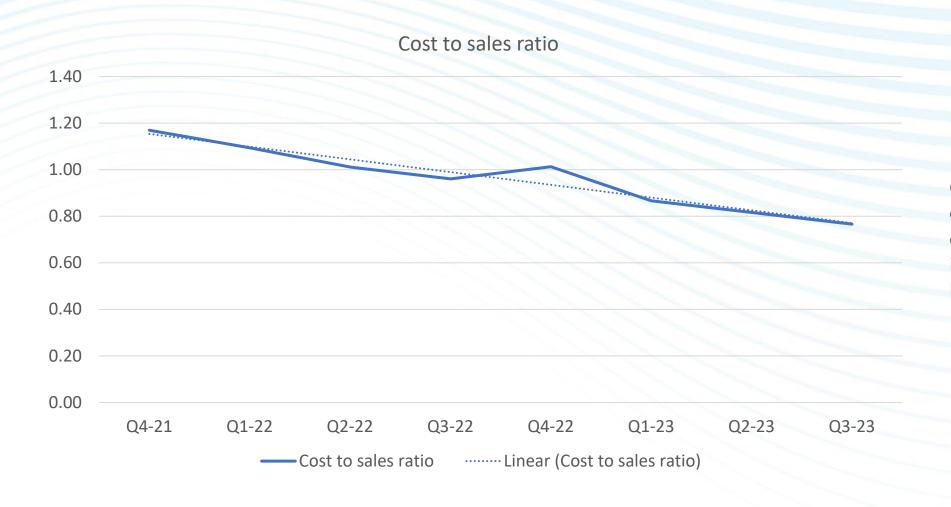
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- Quarterly trajectory in cost to sales ratio and operating result confirms an underlying increase in operating leverage.
- With current cash position and a business turning cash flow positive the business remain well funded.



Operating leverage continuously improving



Quarterly trajectory in cost to sales ratio confirms an underlying improvement in operating leverage.



Sustainability for BONESUPPORT

SUSTAINABILITY for our people

 We involve all employees and strive for integration of sustainability as a natural part of our business.

SUSTAINABILITY for our patients

• We provide solutions to global musculoskeletal healthcare challenges by ensuring access to innovative and effective products and procedures.

SUSTAINABILITY for our planet

 We take a proactive approach to sustainability by setting scienced based targets and engaging with suppliers and customers across our value chain.

BONESUPPORTs most relevant focus areas:















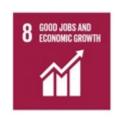
Sustainable value creation

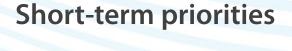
Recent achievements

- Sustainability training of ESG core team
- Extensive value chain mapping
- Business Partner Code of Conduct established
- Improved employee health benefits
- Sustainability disclosures on our website









- Join the Science Based Target Initiative (SBTi) and set science-based emission reduction targets
- Establish the company emission baseline to enable target setting for reduction
- Further strengthened ability to meet stakeholder expectations
- Prepare for future CSRD reporting





