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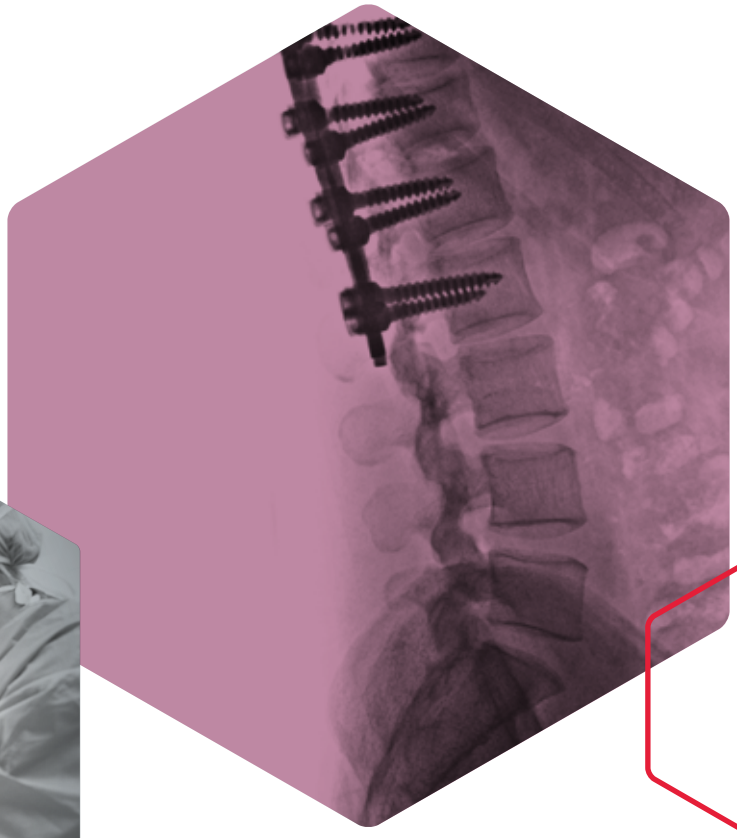
SPINE REGENERATION

CERACELL® Foam

Resorbable, pure-phase silicated
β-tricalcium phosphate + collagen matrix



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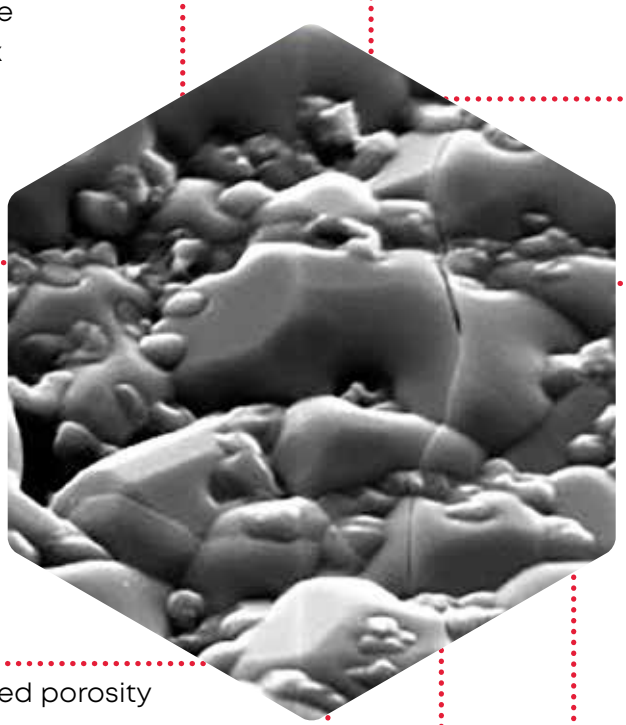
CERACELL® Foam is a resorbable β-tricalcium phosphate (β-TCP) ceramic infused with 4% sodium magnesium silicate, positioned within the interstitial sites of the TCP crystal lattice. This unique composition, combined with a collagen matrix, forms a **3-dimensional scaffold** that enhances the regenerative process. Specifically designed for the filling and bridging of degenerative or traumatic bone defects, **CERACELL® Foam** promotes improved healing and fusion. It is designed in two different variants - **mouldable and flexible** - it is tailored to meet diverse clinical needs for optimal outcomes.



Interconnected porosity allowing efficient diffusion

β-TCP + 4% silicate + collagen matrix

Optimal mechanical stability

4% Silicate consists of SiO_2, MgO, and Na_2O

Promotes effective bone regeneration while leveraging on it's interconnecting open cellular porosity and osteo-conductive properties

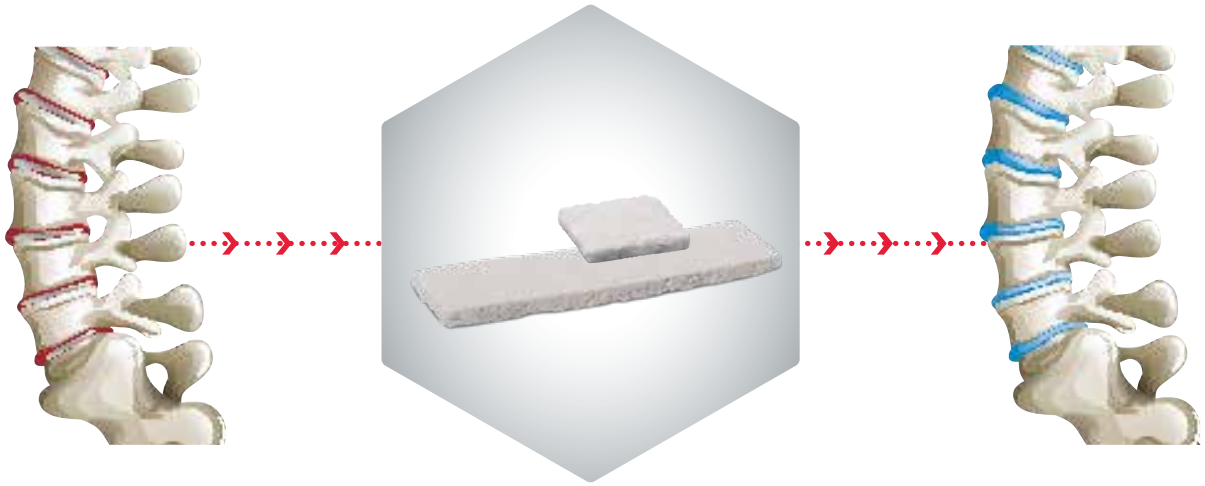
75% interconnected porosity

100% replacement of bone regeneration material by local autologous bone

High porosity enhances vascularization

Promotes 3-dimensional bone regeneration with 15% porcine collagen matrix

spine defect **CERACELL® Foam** healthy Spine



Features & Benefits

- Engineered graft designed to fully remodel into the host (autologous) bone in the appropriate physiologic timeframe.
- Superior handling with rapid hydration
- Silicate coupled with high porosity β-tricalcium phosphate to provide enhanced bone formation
- Available in mouldable and flexible (shape memory) variants to meet various clinical needs.

Indications*

- Filling and bridging of degenerative or traumatic bone defects

Why **β-TCP** outperforms **Hydroxyapatite** (HA)?

β-TCP offers superior resorbability, faster bone remodeling, and optimal integration due to its favorable calcium-to-phosphate ratio (1.5). Unlike HA, which persists in the body, **β-TCP** is fully replaced by natural bone, minimizing foreign body responses and ensuring seamless regeneration. It's the ideal choice for dynamic bone healing and regeneration.

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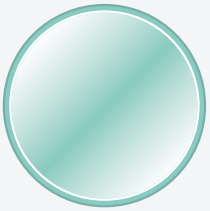
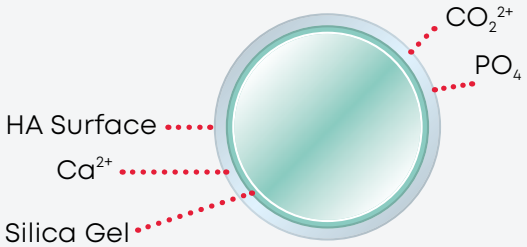
***Disclaimer:** The indications for use vary between EU and FDA regulations. Before using the product, please consult your local representative or carefully review the Instructions for Use (IFU). Ensure compliance with local regulatory requirements.

As highlighted by Ylänen (2011)[1] bioactive glass enables the controlled release of antimicrobial and antibacterial ions, effectively reducing bacterial attachment, preventing infection, and minimizing inflammation. Moreover, it enhances angiogenesis, a vital process for tissue repair. **CERACELL® Foam** combines properties of its individual components β-TCP, collagen, and silicate to improve the fulfillment of the extensive requirements for bone regeneration materials.

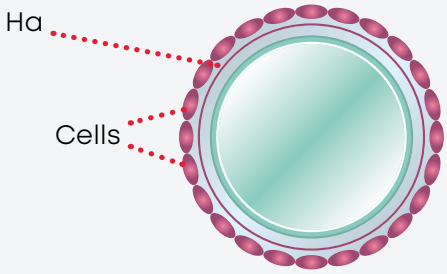
Surface reaction of bioactive glass:



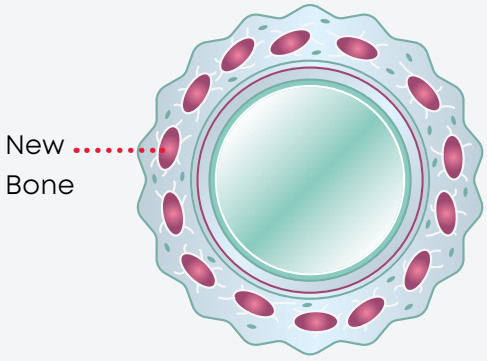
Implantation of **CERACELL® Foam** in the defect site (Bioactive glass)



On the surface, a gel-like layer is formed, and the release of ions such as Ca, PO_4, SiO_2, MgO, Na_2O begins



Calcium phosphate precipitates are crystallized into natural hydroxyapatite.



This hydroxyapatite layer stimulates osteogenesis by activating osteogenic cells.

[1] Ylänen, H. O. (2011). conclusion. In Bioactive glasses Materials, properties and applications (pp. 259–259). essay, Woodhead publishing in materials.

A Case Series of PLF Spinal Fusions with CERACELL® Foam (2023)

Author: Dr. Stephen Robbins, MD, Milwaukee, Wisconsin, USA

13 Patient Study with **CERACELL® Foam** achieving 100% Spinal Fusion

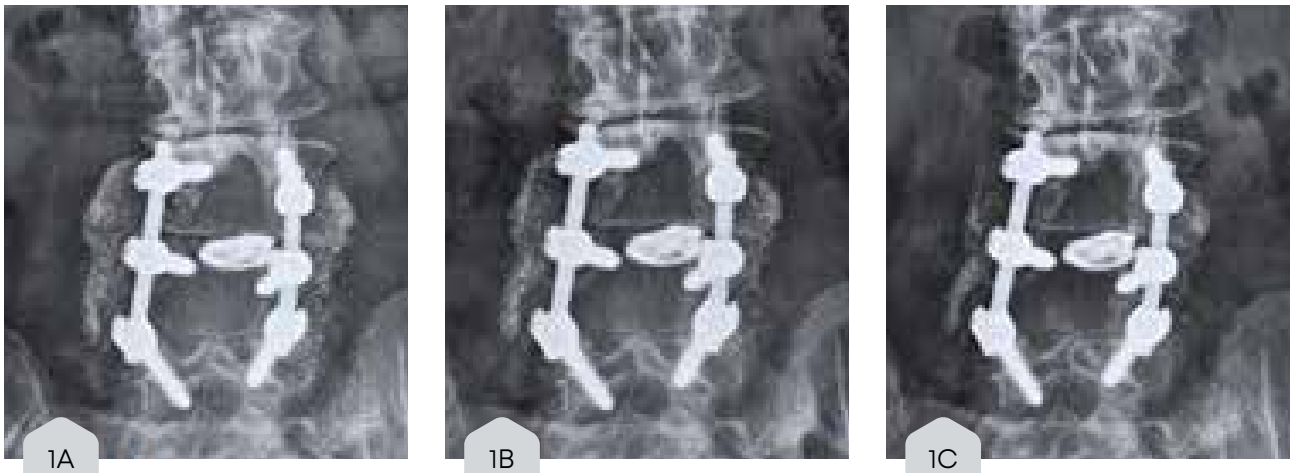
13

- **Introduction:** Amid rising rates of degenerative spinal issues, this study assesses the role of **CERACELL® Foam** in Posterolateral Lumbar Fusions (PLF). Developed with resorbable β-tricalcium phosphate and silicate, **CERACELL®** offers both mechanical stability and porosity.

- **Methods:** Thirteen patients, averaging 64 years in age, were included in the study. Prior to surgery, diagnoses of lumbar spondylosis or DDD were confirmed. The surgical protocol followed a standard posterior approach, employing radiographic techniques for precise guide wire and transpedicular screw placement. **CERACELL®** was mixed with autograft and bone marrow aspirate (BMA), and its placement was confirmed fluoroscopically.

- **Results:** Postoperative assessments showed a 100% fusion rate by a 12-month end point. New bone formation was observed primarily from the 5–12-month period, and the study reported zero complications, underscoring **CERACELL®'s** safety. formation across the fusion sites.

Case of a 68-year-old patient with a multi-level PLF



1A 1B 1C

- **1A:** Radiograph at 3 months post-operative
- **1B:** Radiograph at 6 months post-operative
- **1C:** Radiograph at 12 months post-operative

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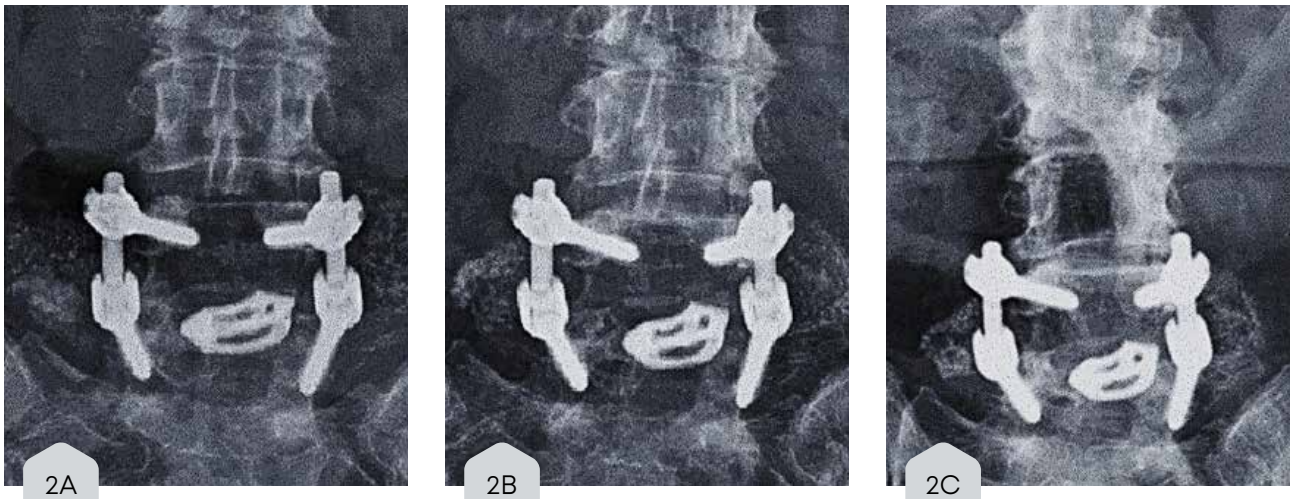
Case of a 75-year-old patient with a single PLF



2A 2B 2C

- **2A:** Radiograph at 6 weeks post-operative
- **2B:** Radiograph at 6 months post-operative
- **2C:** Radiograph at 12 months post-operative

- **Conclusion: CERACELL® Foam** proves to be a highly reliable and safe option for PLF procedures, boasting a 100% fusion rate and marked new bone formation, across the follow-up time points.

A Case Series of Spinal Fusion which responded to CERACELL® (2020)

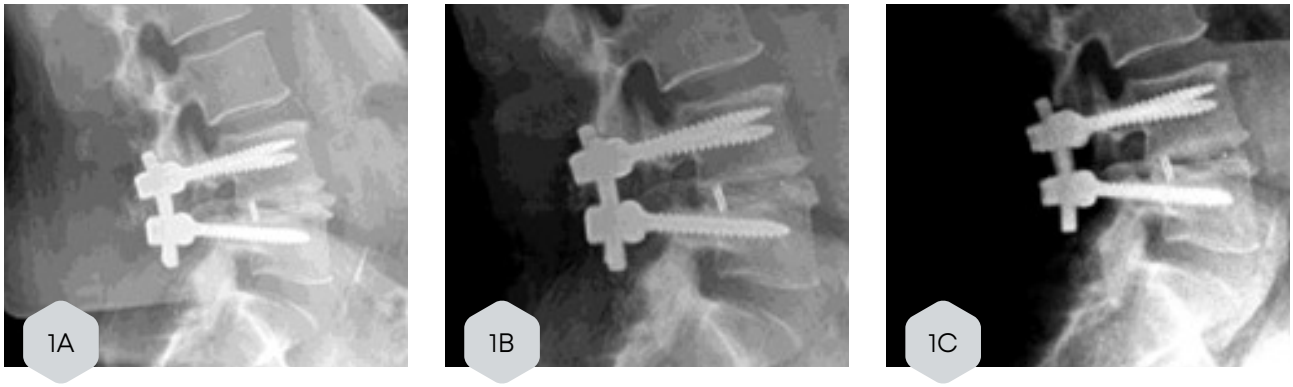
Authors: Jean Louis Benae, MD, FAANS, FICS Neurosurgeon, McKinney, Texas, USA

CERACELL® Foam Spinal Fusion study with 17 patients ranging from 37 to 61 years old 17

- **Introduction:** This case series investigates the efficacy of **CERACELL®** in spinal fusions, focusing on cervical and lumbar regions. **CERACELL®**, developed using curasan's exclusive pure-phase β-TCP technology and silicate doping, offers both mechanical stability and high porosity.

- **Methods:** The study enlisted 17 patients, aged between 37 to 61, who had advanced degenerative cervical or lumbar conditions and had not responded to conservative treatments. The surgical intervention involved a minimally invasive posterior approach, utilizing **CERACELL® Foam** mixed with bone marrow aspirate for graft placement.

- **Results:** Postoperative radiographic assessments at 1, 3, and 6 months confirmed successful arthrodesis in all cases. The evidence was based on the presence of heterotopic bone formation across the fusion sites.



Case of a 59-Year-Old Patient

- **1A:** Radiograph at 1 Month Post-Op
- **1B:** Radiograph at 3 Months Post-Op
- **1C:** Radiograph at 6 Months Post-Op

- **Conclusion: CERACELL®** consistently demonstrated its efficacy in promoting successful spinal arthrodesis, coupled with symptomatic improvement in patients. Hence, it is a reliable biological option for spinal fusions in single and multilevel cases.

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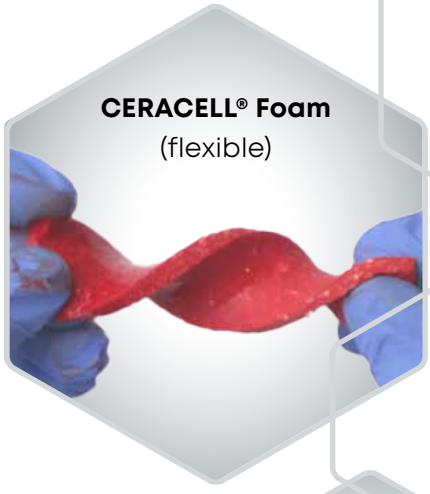


CERACELL® Foam

Key highlights:
- Best-in-class handling of the product
- Rapid hydration
- 25 years of β-TCP technology
- With added Sodium-Magnesium-Silicate, the material offers improved osteostimulatory potential, greater surface area, enhanced porosity, and accelerated bone formation.
- Collagen matrix embeds granules to achieve a 3-dimensional scaffold

Comparison of CERACELL® Foam variants:

Similarities:
- Easy to handle
- Gentle manipulation during hydration accelerates soaking, ensuring the material is quickly prepared for application.

Differences:
- **CERACELL® Foam (mouldable):** Enables plastic deformation, allowing it to be shaped and adapted to match individual defect contours.
- **CERACELL® Foam (flexible):** Features high density and elasticity, enabling the product to regain its original shape after deformation.

Summary:
- 100% fusion rate within 12-months
- Indicated in filling and bridging of degenerative or traumatic bone defects
- **CERACELL® Foam** is manufactured in two different variants: flexible and mouldable
- This high porosity enhances vascularization, surpassing the capabilities of **CERASORB®** alone.
- In contact with the vital bone, the bioactive ceramic material undergoes gradual resorption by the body over months and is simultaneously replaced by local, body-owned bone.

CERACELL® Mouldable Foam (low density)

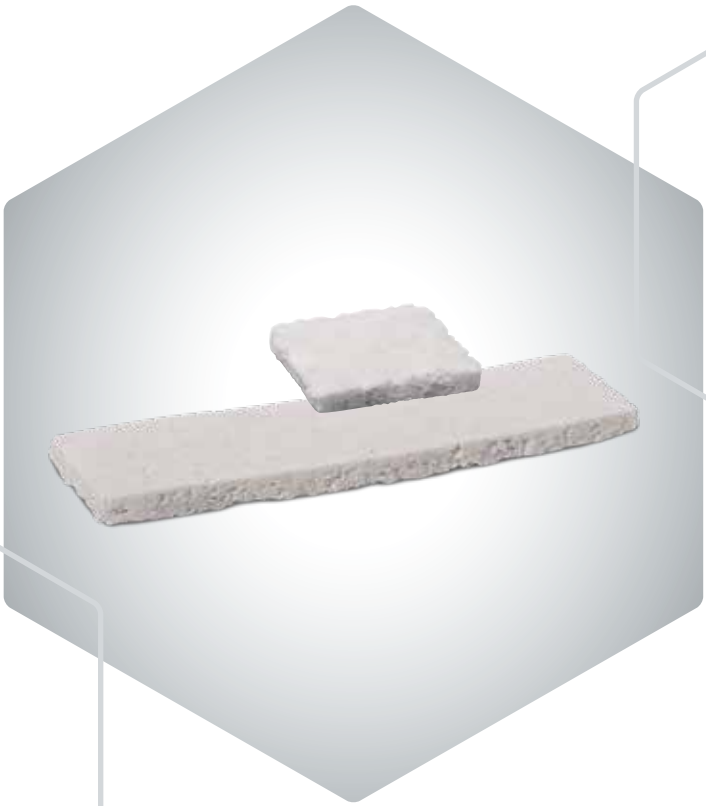
Resorbable, pure-phase silicated β-tricalcium phosphate + collagen matrix

Ref No.	Size	Content	Packsize
9001 102 041	25 x 25 x 4 mm	2.5 cc	1
9001 102 051	25 x 50 x 4 mm	5 cc	1
9001 102 061	25 x 100 x 4 mm	10 cc	1

CERACELL® Flexible Foam Strip (high density)

Resorbable, pure-phase silicated β-tricalcium phosphate + collagen matrix

Ref No.	Size	Content	Packsize
9001 102 011	25 x 50 x 4 mm	5 cc	1
9001 102 021	25 x 100 x 4 mm	10 cc	1



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