CERAFORM®

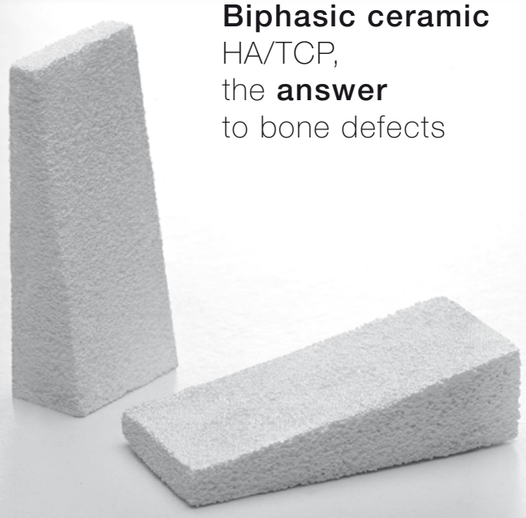
Synthetic Bone Substitute

Teknimed

CERAFORM®

CERAFORM® is a biocompatible and safe synthetic biphasic ceramic made of hydroxyapatite (HA) and beta tricalcium phosphate (β-TCP).

Hydroxyapatite $Ca_{10}(PO_4)_6(OH)_2$ is a calcium phosphate similar to the mineral phase of bone tissue. Tricalcium phosphate $Ca_3(PO_4)_2$, more soluble than HA, improves the resorption kinetics of CERAFORM®.



Biphasic ceramic
HA/TCP,
the **answer**
to bone defects

SYNTHETIC
- Free from organic phase
- No immunological risk

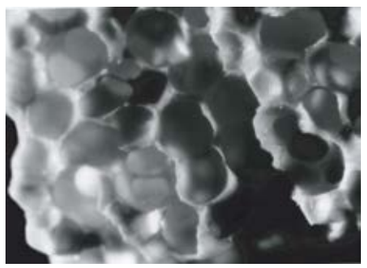
ABSORBABLE
- Absorbed after a minimum of 2 years[1,2,3]

BIOCOMPATIBLE
- Compliant to ISO 10993-1[4]

1. El-Adl G, Ali AM. Does bone marrow affect the radiological outcome when added to biphasic ceramic graft in treatment of benign bone lesions? Eur J Orthop Surg Traumatol. 2013 Jan;23(1):13-20. doi: 10.1007/s00590-012-0943-x. Epub 2012 Jan 22.
2. P. Botez, P. Sirbu, L. Simion, Fl. Munteanu, I. Antoniac. Application of a biphasic macroporous synthetic bone substitutes CERAFORM®: clinical and histological results. Eur J Orthop Surg Traumatol (2009) 19:387–395.
3. El-Adl G, Mostafa MF, Enan A, Ashraf M. Biphasic ceramic bone substitute mixed with autogenous bone marrow in the treatment of cavitary benign bone lesions. Acta Orthop Belg. 2009 Feb;75(1):110-8.
4. Biological Risk Assessment Report CERAFORM® 095/3/PERB

Characteristics

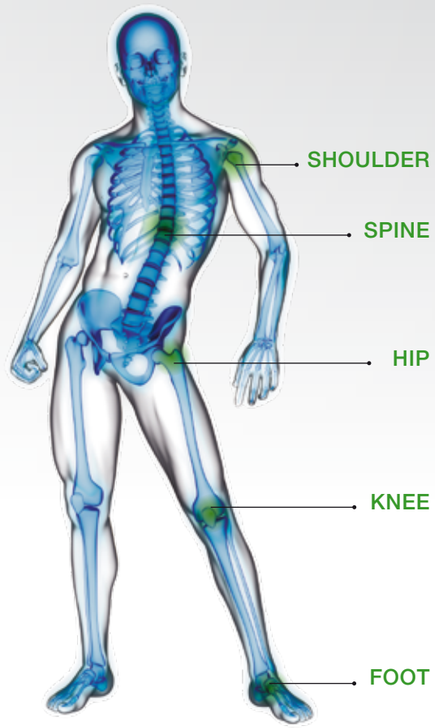
- 65% HA / 35% β-TCP
- Pores size 150-400 µm
- Interconnected porosity
- 60-85% porosity



Indications

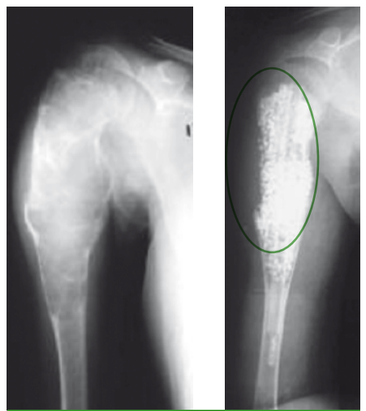
CERAFORM® **is indicated for the filling of bone defects due to bone injury (such as tumour, trauma, disease), or surgical procedure (such as arthrodesis, osteotomy).**

- Granules are indicated for use in tumoral or benign bone cysts (shoulder, hip, knee, foot), fractures (shoulder, knee), osteotomies (knee), and spine fusion procedures,
- Sticks are indicated for use in fractures (knee, shoulder),
- Wedges are indicated for use in fractures (knee, shoulder).



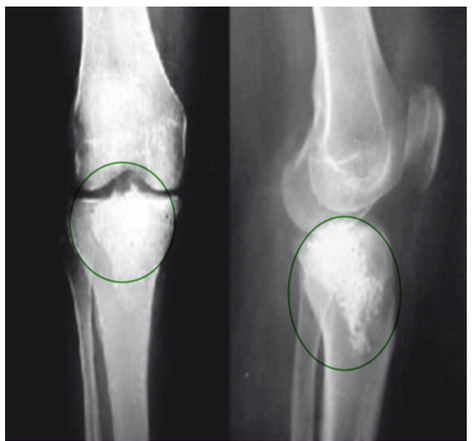
Clinical cases :

Case N° 1



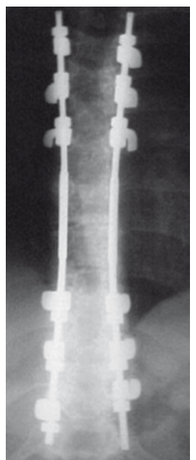
Proximal humeral aneurysmal bone cyst.

Case N° 2



Aneurysmal epiphyseal bone cyst (tibia)

Case N° 3



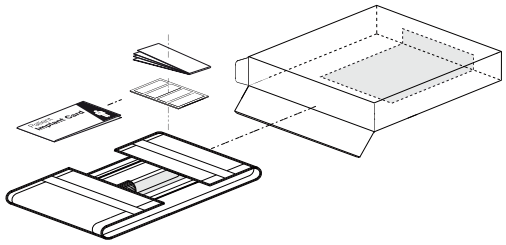
Spine fusion

Case N°1 :
El-Adl et al. – 2009 - Acta Orthop. Belg., 2009, 75, 110-118
Cases N°2 & 3 :
Botez et al. – 2009 - Eur J Orthop Surg Traumatol, 2009, 19:387–395

CERAFORM®

Storage & Products

CERAFORM® must be stored, unopened, in its original packaging.
No specific conditions are necessary for the storage.



The calcium phosphate used in ceramic production is manufactured and controlled by TEKNIMED and complies with ISO 13779-1, ASTM F1088 and ASTM F1185 standards.
CERAFORM® is sterilized by radiation at a minimum dose of 25 kGy.
Single use. Do not re-sterilize.
For any further information, please refer to the IFU.

SHAPES	REF.
Granules - 3x3x3 mm - 5 cc	T804402
Granules - 3x3x3 mm - 10 cc	T804405
Granules - 3x3x3 mm - 15 cc	T804407
Granules - 3x3x3 mm - 20 cc	T804410
Granules - 3x3x3 mm - 30 cc	T804415
Granules - 6x6x6 mm - 15cc	T804507
Granules - 6x6x6 mm - 30cc	T804515

SHAPES	REF.
Wedge - 8°	T803008
Wedge - 10°	T803010
Wedge - 12°	T803012
Sticks (x5) - 5x5x20 mm - 2.5 cc	T807104

bsi. ISO 13485 Medical Devices Quality Management

Class III

CE 2797

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