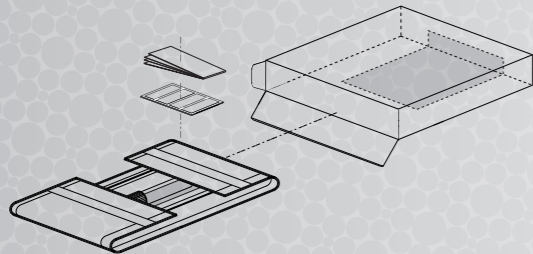


CERAFORM®

Storage

CERAFORM® must be kept, unopened, in its original packaging within a clean environment and at room temperature.



Products

The calcium phosphates used in ceramic production are manufactured and controlled by TEKNIMED and comply with ISO 13779-1, ASTM F1088-04 and ASTM F1185-03 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.

DESIGNATION	REFERENCE	DESIGNATION	REFERENCE
Granules - 3x3x3 mm - 5 cc	T804402	Wedge - 8°	T803008
Granules - 3x3x3 mm - 10 cc	T804405	Wedge - 10°	T803010
Granules - 3x3x3 mm - 15 cc	T804407	Wedge - 12°	T803012
Granules - 3x3x3 mm - 20 cc	T804410		
Granules - 3x3x3 mm - 30 cc	T804415	Sticks (x5) - 5x5x20 mm - 2.5 cc	T807104

CERAFORM®

Biphasic Bone Substitute



Classe III



Distributed by

Head offices:
8, rue du Corps Franc-Pommiès
65500 VIC en BIGORRE (France)
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Fax (33) 5 62 96 28 72

Administration and supply-chain offices:
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Sales and engineering departments:
Z.I. de Montredon - 11, rue Apollo
31240 L'UNION (France)
Tél (33) 5 34 25 10 60
Fax (33) 5 34 25 27 39

Manufactured by



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

Hydroxyapatite $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ is a calcium phosphate similar to the mineral phase of bone tissue. Tricalcium phosphate $\text{Ca}_3(\text{PO}_4)_2$, more soluble than HA, improves the resorption kinetics of CERAFORM®.

Indications

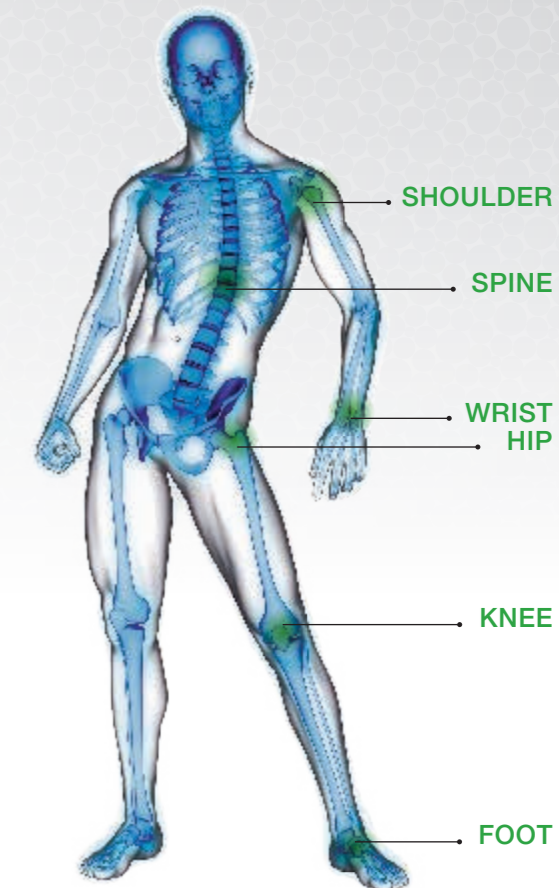
CERAFORM® is intended for application as a bone filler. It is indicated to be applied into bone void of skeletal system (extremities, pelvis, spine and in posterolateral spine fusion procedure).

Orthopaedic surgery:

- Treatment of bone defects (benign tumors or cysts, traumatic lesions)
- Reconstruction during prosthetic revision
- Arthrodesis (foot, ankle, spine, ...)
- Filling of osteotomy

Spine surgery:

- Filling cages
- Spine fusion



SYNTHETIC

Eliminates infection and immunological risks.

BIOCOMPATIBLE

No adverse biological reaction nor toxicity.

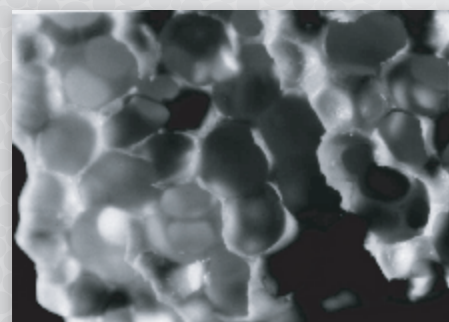
OSTEOINTEGRABLE

Perfectly integrated into the bone tissue.

Biphasic ceramic HA/TCP, an ideal answer to bone defects

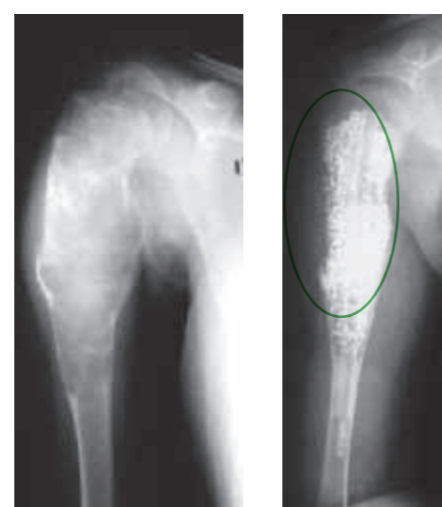
Properties

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



Clinical cases :

Case N° 1



Proximal humeral aneurysmal bone cyst in a 16-year-old patient

Case N° 2



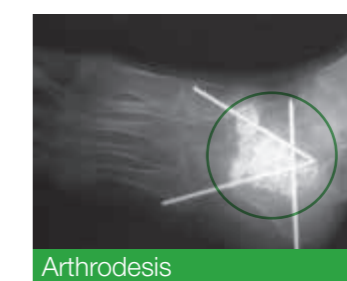
Aneurysmal epiphysal bone cyst (tibia)

Case N° 3

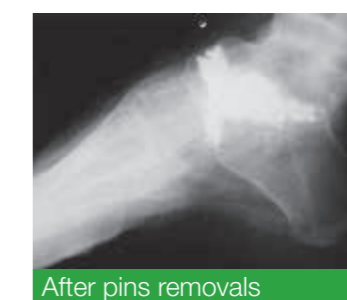


Spine fusion

Case N° 4

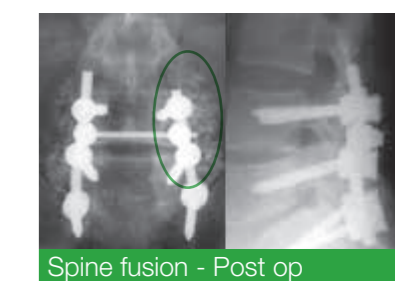


Arthrodesis

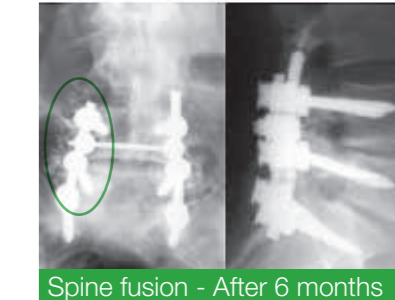


After pins removals

Case N° 5



Spine fusion - Post op



Spine fusion - After 6 months