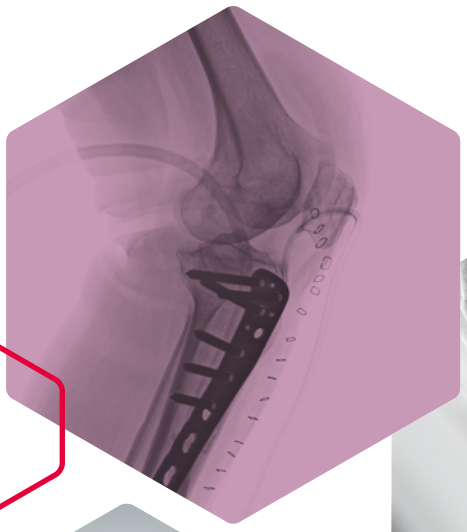
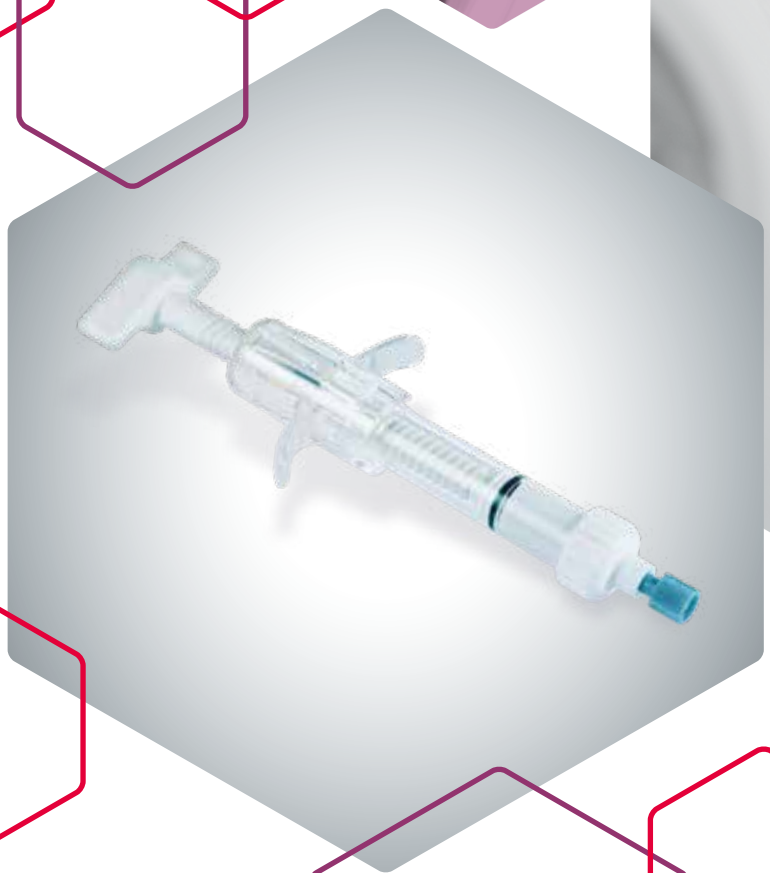
curasan

EMPOWERING FRACTURE HEALING

CERASORB® CPC

BONE VOID FILLERS





PIONEERS IN BIOSURGERY

Dear Clinician,

Bone defects are common and occur in many clinical situations including high grade open fractures with bone loss, high energy trauma, blast injuries, infection requiring debridement of bone, and resection of bone tumors or cysts.

There is a significant burden of disease associated with the management of bone defects, particularly if the bone defect is critical sized or when the planned reconstruction requires secondary surgery and autogenous bone grafting, often complicated by drawbacks such as donor site morbidity, limited graft volume, anesthesia time, need for additional surgical resources, and poor results in a significant number of patients.

A huge number of challenges can be solved with the latest addition to curasan's orthobiologic portfolio, **CERASORB® CPC** Bone Void Fillers.

CERASORB® CPC in short

- **CERASORB® CPC'S** are ready-to-use, self-setting, injectable, biodegradable bone void fillers which are indicated for filling bone defects after trauma, an elective intervention or a reconstruction.
- **CERASORB® CPC'S** are available in a 6 mL and 12 mL ready-to-use syringe and offer sophisticated solutions to treat bone defects and augment temporary osteosynthesis fixation.
- **CERASORB® CPC'S** proprietary technology provide an easy-to-use and ready-to-use, self-setting, injectable bone void filler supporting osteointegration and bone healing.
- **CERASORB® CPC'S** consist of calcium phosphates finely dispersed in a biocompatible oil phase. The final material, after the self-setting process, is microcrystalline, calcium deficient hydroxyapatite, the major constituent of bone tissue.

REASONS FOR

CERASORB® CPC

BONE VOID FILLERS

Regenerative biomaterial

- resorbed by cell-mediated processes and replaced by endogenous bone
- steady remodeling process
- radio-opaque

Precise in application

- self-setting in aqueous environment no setting in applicator syringe
- complete setting and hardening after
- contact with aqueous body fluids

Provides structural support

- highly cohesive calcium phosphate cement
- high compressive strength (up to 45 MPa)
- supports osteosynthesis by increased stability

Saves time and effort

- no mixing or preparation
- ready-to-use
- easy-to-use

Packaging, storage and transportation

- syringe is contained in a sterile double blister within a protective cardboard box
- stored at temperatures between 5° C and 25° C (room temperature recommended)
- transport validation up to 55° C.

curasan

EASY TO FOLLOW

PRODUCT HANDLING

01

02

03

04

05

06

PRODUCT ASSEMBLY & USE

01 Open and assemble

Open blister with the pre-filled syringe and the Tyvek pouch with the spindle drive (spindle nut and threaded spindle) and the PE-bag with the cannula. Push the spindle nut onto the syringe until a clear click sound is heard. Check that both sides of the spindle nut are locked.

02 Insert spindle

Insert the threaded spindle into the spindle nut.

03 Adjust threaded spindle

Screw the threaded spindle in the spindle nut until it is in direct contact with the piston.

04 Remove cap

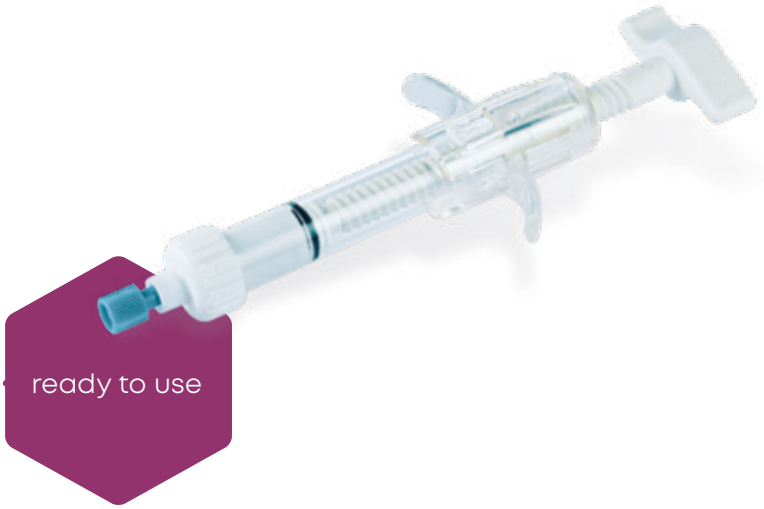
Remove the blue cap from the syringe.

05 Adjust setting

Shorten the application cannula if needed.
Attach the application cannula if necessary.

06 Application

By slowly turning the spindle clockwise, **CERASORB® CPC** can be applied to the bone defect.



curasan

PROPRIETARY TECHNOLOGY

METHOD OF ACTION

CERASORB® CPC is a synthetic composition of biomineral powders and a non-aqueous carrier liquid. The components form a cohesive, viscous bone graft substitute that transforms into a microcrystaline calcium deficient hydroxyapatite after a self-setting process.

› 01 Initial compostion (non-aqueous carrier liquid)

The non-aqueous carrier liquid (A) prevents the biomineral powders (grey) from starting a reaction process in an anhydrous environment.

› 02 Substitution (metabolization of non-aqueous carrier liquid)

As soon as **CERASORB® CPC** comes into contact with aqueous body fluids (B), the non-aqueous carrier liquid is displaced into the vascular system and metabolized. The biomineral powder is then completely covered with aqueous body fluids and the setting process of **CERASORB® CPC** is initiated.

› 03 Setting and hardening (crystallization process)

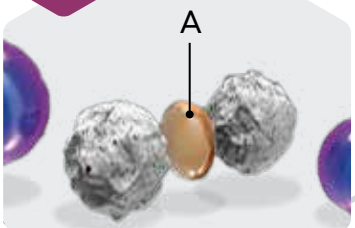
Once the crystallization process is initiated, the calcium phosphate crystals begin to interlock, increasing the mechanical strength of the bone substitute. The surface dimensional stability is achieved after 10 to 15 minutes. **CERASORB® CPC** achieves a compressive strength of up to 45 MPa once fully hardened.

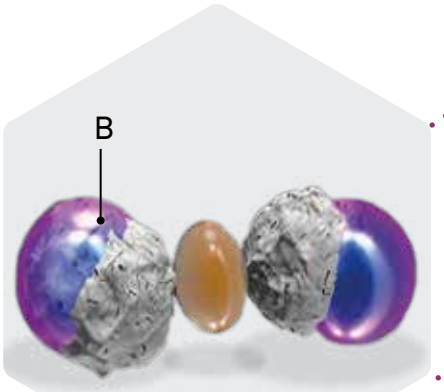
› 04 Topographic material surface of CERASORB® CPC

Since **CERASORB® CPC** does not undergo a high-temperature sintering process, the crystals form in situ and result in a specific surface that is about 100 times higher (50 m^2/gr.) than for sintered bone substitutes. A large specific surface area is essential for the settlement of osteoclasts and osteoblasts and thus for rapid bone formation.

METHOD OF ACTION

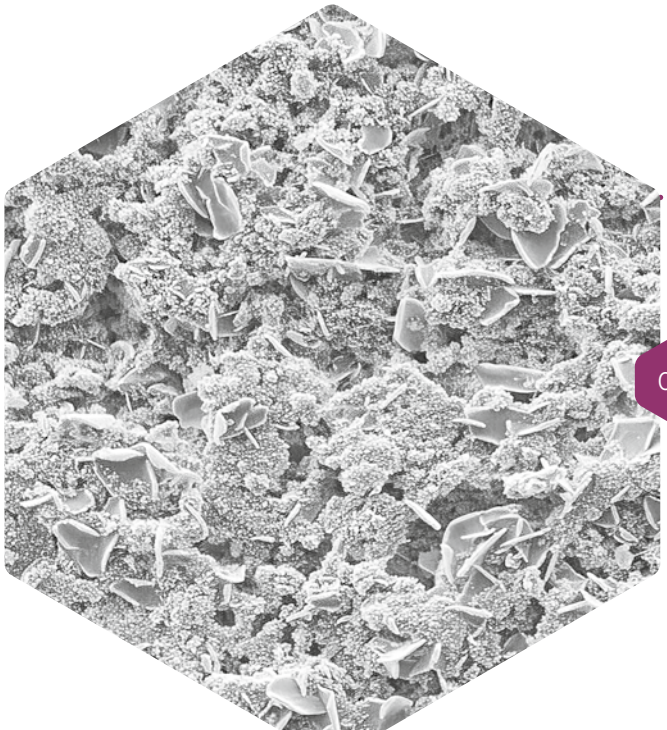
01





02

03

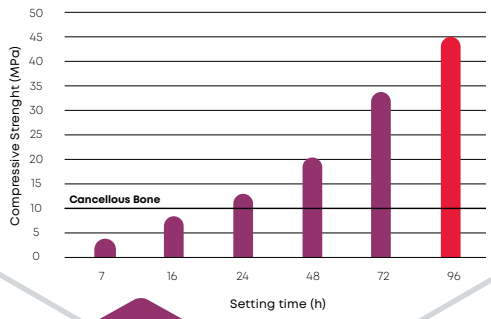


04

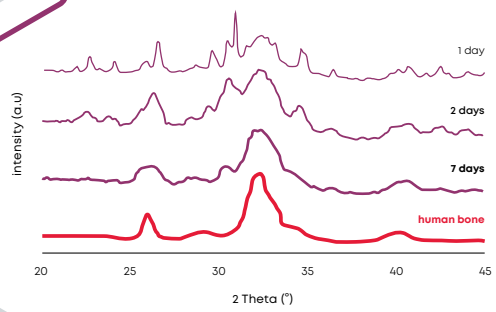
curasan

Consistency & compressive strength

Once the setting process is initiated, the compressive strength of **CERASORB® CPC** increases continuously. Just 10 minutes after injection, a hard outer shell covers the pasty core, enabling the surgeon to immediately place an osteosynthesis implant such as plates and screws. As early as 16 to 24 hours after injection, the compressive strength is similar to that of cancellous bone. Final compressive strength is achieved after about 96 hours (depending on the volume/ geometry of the filled bone defect and the supply of body fluid). At this point, the compressive strength of **CERASORB® CPC** is three to four times higher than with healthy cancellous bone.



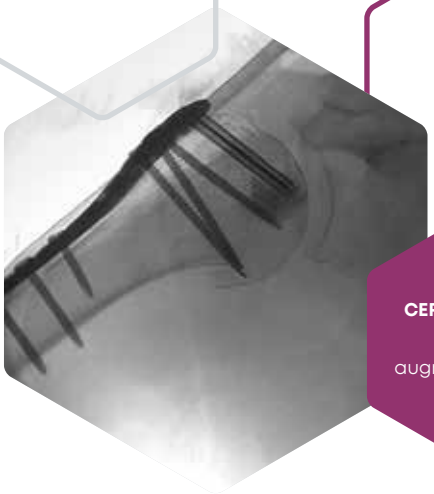
Compressive strength during the setting process of **CERASORB® CPC**.



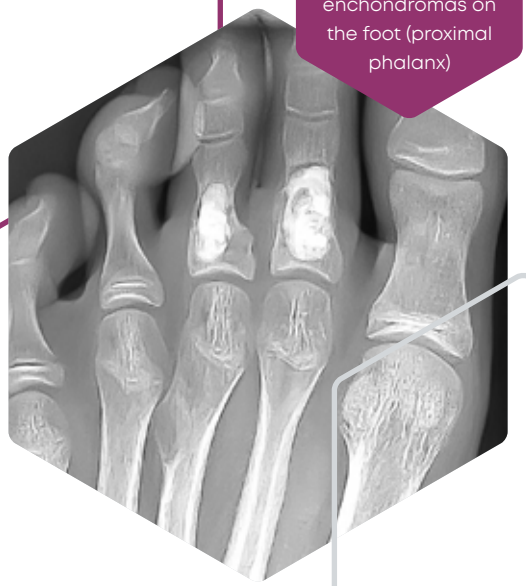
Comparison of X-ray diffraction of human bone and **CERASORB® CPC** after start of the setting reaction after one day, two days and seven days.

Phase evolution

After initiation of the crystallization process, the chemical composition of **CERASORB® CPC** adapts to the surrounding bone. By means of an X-ray diffraction analysis carried out over the complete course of the setting reaction, this reaction can be clearly verified. After about seven days, the analysis shows a continuous change to low-calcium hydroxyapatite.
The similarity between human bone (red line) and the chemical composition and crystalline structure of **CERASORB® CPC** (purple lines) is clearly evident seven days after implantation.



CERASORB® CPC on an augmented screw.



Visibility of **CERASORB® CPC** after treatment of enchondromas on the foot (proximal phalanx)

Cohesion & defect filling

The release of particles during the setting reaction of a bone substitute cement is significantly influenced by the cohesion. Accordingly, during the development of **CERASORB® CPC**, care was taken to minimize particle release to below 2% after injection in water. Thus, even in the case of screw augmentation, **CERASORB® CPC** fills the entire defect and remains completely in the bone cavity instead of flowing back along the screw from the tip to the head or leaking out under the screw head.

Radio-opacity

The high mineral density of **CERASORB® CPC** makes it more visible under the fluoroscope. This makes it easier to follow and adjust the flow of the calcium phosphate cement.

CASE REPORTS

INDICATIONS

CERASORB® CPC' S are is an orthobiological, biomineral bone cements for regenerative bone augmentation. The biodegradeable and self-setting calcium phosphate cements are indicated for filling bone defects, reinforcing temporary osteosynthesis fixation and filling or reconstructing non-load-bearing bone defects.

The scope of application includes, but is not limited to:

- metaphyseal defect fractures, (such as fractures of the tibia, radius and humerus).
- bone defects following resection (such as of benign tumors and cysts)
- bone defects after removal or replacement of osteosynthetic implants
- support for the fixation of osteosynthetic implants (such as bone screws)

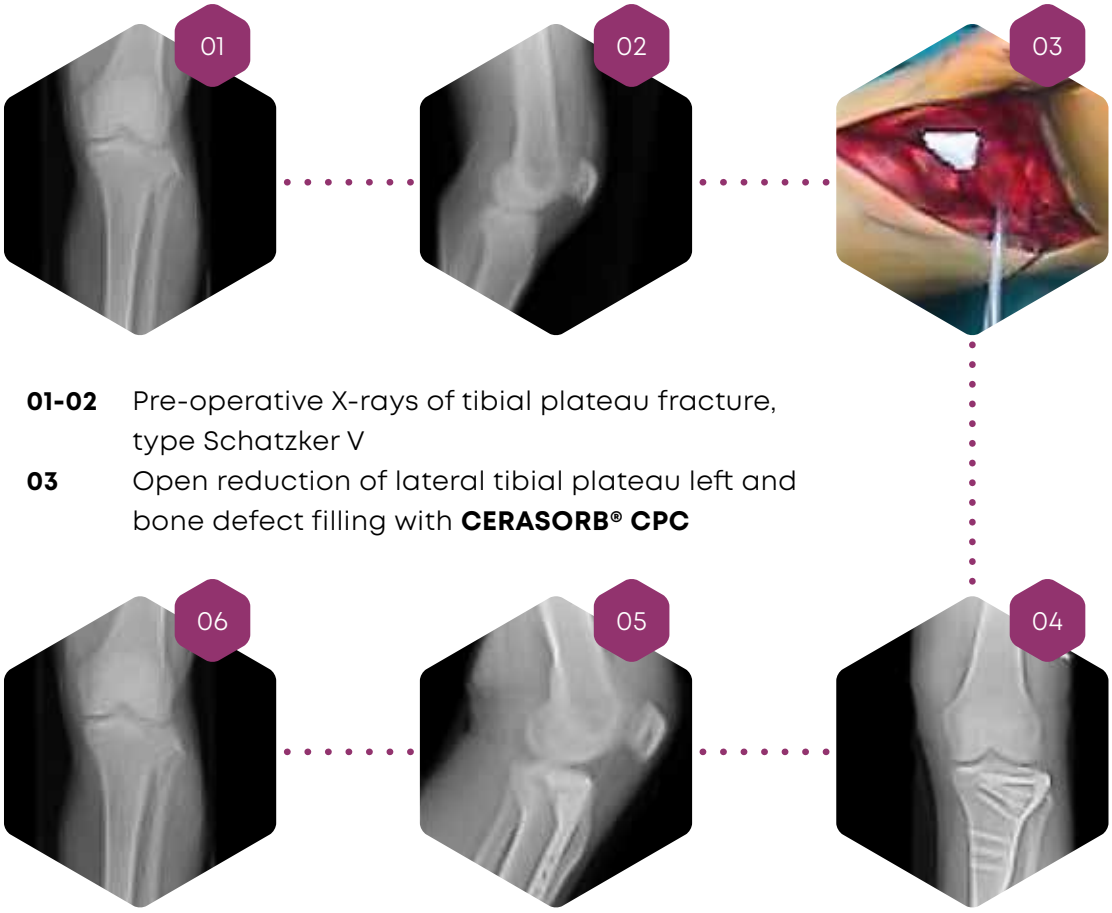
CERASORB® CPC must only be used on well-vascularized and non-infected bone sites. Correct repositioning and stabilization of fractures by means of suitable fixation must also be ensured.

(For the complete list of indications and contraindications, please refer to the current version of the Instructions for use).

curasan

Clinical case example case 1

University Hospital Regensburg, Germany. Department of Trauma Surgery
Lateral tibial plateau fracture left tibia, type Schatzker V

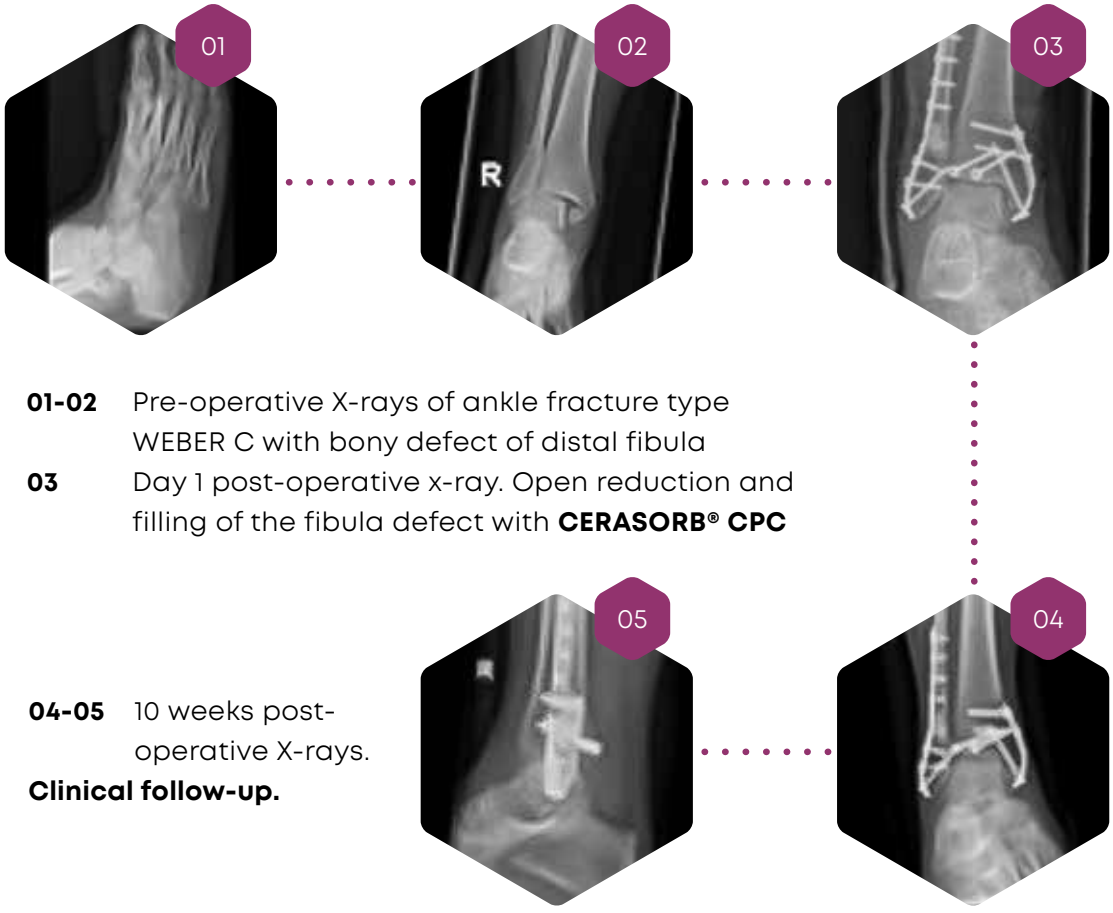


- **01-02** Pre-operative X-rays of tibial plateau fracture, type Schatzker V
- **03** Open reduction of lateral tibial plateau left and bone defect filling with **CERASORB® CPC**
- **04-05** Day 1 post-operative x-rays.
- **06** 6 months post-operative x-rays.
- **Clinical follow-up.**

- **CERASORB® CPC** was easy to handle during the operation and allowed sufficient bone defect filling.
- 6 months post-operative, X-rays showed complete fracture healing with osseous integration and initial degradation of **CERASORB® CPC**. No subsidence of the articular surface could be observed.
- **CERASORB® CPC** supports the defect through good osseous integration and is gradually replaced by the newly formed bone.

Clinical case example case 2

University Hospital Regensburg, Germany. Department of Trauma Surgery
Ankle fracture type WEBER C with bony defect of distal fibula



- **01-02** Pre-operative X-rays of ankle fracture type WEBER C with bony defect of distal fibula
- **03** Day 1 post-operative x-ray. Open reduction and filling of the fibula defect with **CERASORB® CPC**
- **04-05** 10 weeks post-operative X-rays.
- **Clinical follow-up.**

- **CERASORB® CPC** was easy to handle during the operation and allowed sufficient bone defect filling.
- 10 weeks post-operative, X-rays showed complete fracture healing with beginning of osseous integration of **CERASORB® CPC.**
- **CERASORB® CPC** supports the defect through good osseous integration and is gradually replaced by the newly formed bone.

curasan

Order information

REF. No.	Description	Content	Pack size
9100000002	CERASORB® CPC Bone Void Filler	6 mL	1
9100000003	CERASORB® CPC Bone Void Filler	12 mL	1

Further information about **CERASORB® CPC** under **www.cerasorb-cpc.com**

curasan

Head office
curasan AG
Lindigstraße 4
63801 Kleinostheim
Germany
P +49 6027 40900-0
F +49 6027 40900-29
M info@curasan.com
W www.curasan.com

Postal address
curasan AG
Ernst-Wiss-Straße 18
65933 Frankfurt am Main
Germany

curasan Inc.
1768 Heritage Center Drive,
Suite 204, Wake Forest, NC 27587
United States of America
P +1 919 941 9770
F +1 919 941 9775
www.curasaninc.com

Distribution partner

1195000001_02_2024_001