

This report provides essential information about the safety and clinical performance of Paste-CPC. Please note that the following information is meant for patients and lay persons. It does not replace the instructions for use or the implantation card. Additionally, this report does not offer general advice for treating medical conditions. If you have any questions about your medical condition or the use of Paste-CPC or if you believe you are experiencing any side effects associated with Paste-CPC, we strongly recommend contacting your healthcare professional. We have tried to avoid using complicated medical terms, but when necessary, we have provided explanations in brackets for easier understanding.

1. General information on the product

Trade name

INNOTERE Paste-CPC
VELOX
CERASORB CPC

Name and address of manufacturer

INNOTERE GmbH
Meissner Str. 191
01445 Radebeul
Germany
Tel: +49 351 2599 9410
www.innotere.de

Year of market launch (CE-certificate)

2014

2. Application of Paste-CPC

Paste-CPC is a synthetic, self-setting bone cement to fill bone defects.

2.1 Medical treatment

Paste-CPC is intended for filling non-infected bone defects in non-load-bearing bone. If Paste-CPC is to be used in load-bearing bone, the bone must be sufficiently stabilized by suitable fixation.

Fields of application for Paste-CPC are:

- fractures of long bones (e.g. fractures of the tibia, radius and Humerus)
- bone defects after resection of benign tumours and cysts
- bone defects after removal or replacement of implants
- support for the fixation of implants (e.g. of bone screws)

2.2 Patient population

Paste-CPC is suitable for adults.

2.3 Contraindications

Paste-CPC should not be used in the following situations:

- when there is an ongoing infection at the site where Paste-CPC will be used, like a bone infection called osteomyelitis.
- for bone problems caused by cancerous tumors
- in areas where bones are still growing, like near the ends of long bones (epiphyseal plates)
- If you know you are allergic to any ingredient in Paste-CPC."

Paste-CPC should not be used in the following situations as there is not enough experience with it so far:

- for spine treatments
- for skull surgeries (cranioplasty)
- if you are pregnant or breastfeeding
- if the patient is a child; whereby a maximum volume of 3 ml Paste-CPC per surgery is known

Before using Paste-CPC, your doctor will carefully consider whether it's safe and beneficial for you in these situations:

- If you have problems with how your bone metabolism (bone metabolism disorders).
- If you have hormone-related issues (endocrinopathies).
- If you're taking medications that lower your immune system's activity (immunosuppressive therapy).
- If you're taking any drugs that affect how your bones work at the same time as using Paste-CPC.

3. Product description

Paste-CPC is a bone cement consisting mainly of calcium phosphates (see Table 1). It is introduced directly into the bone defect using a syringe with a cannula. Once placed in the bone defect, the cement gradually hardens. Over time, Paste-CPC is resorbed by the body and replaced by new bone. The time for complete resorption of Paste-CPC is variable and depends on various factors, like the volume of the injected cement and the age of the patient.

Table 1: Components of Paste-CPC

Components	Percentage %
alpha-tricalcium phosphate (α -TCP)	48.4 - 49.9
calcium hydrogen phosphate (monetite)	20.9 - 21.6
calcium carbonate (calcite)	8.1 - 8.3
tricalcium orthophosphate	3.2 - 3.3
dipotassium hydrogen phosphate (K_2HPO_4)	2.4 - 2.5
caprylic/capric triglycerides (Miglyol 812)	11.6 - 13.7
polyoxyl 35 castor oil (Kolliphor ELP)	2.1 - 2.5
cetyl phosphate (Amphisol A)	0.7 - 0.8

Paste-CPC is available in different syringe sizes and different volumina, also as a multiple package. The amount of Paste-CPC required to fill a defect depends on the type and size of the bone defect.



Paste-CPC is clearly visible on the X-ray after implantation. But as soon as the degradation process of Paste-CPC begins, the visibility decreases.

Paste-CPC does not contain any pharmaceuticals and no substances of human or animal origin.

Paste-CPC is intended for single use on a single person.

4. Risks and warnings

If you have any side effects from Paste-CPC or concerns about potential risks, please reach out to your physician. This report does not replace discussions with your healthcare provider.

4.1 Residual risks and undesirable side effects

Common side effects of surgery include bleeding, bruising (hematomas), accumulation of fluids (seromas), swelling, fever, allergic reaction, rejection, wound healing problems, infection, delayed or abnormal fracture healing (pseudarthrosis), and pain.

4.2 Precautions and warnings

The physician has the duty to inform you about possible risks before the operation. Please consult your physician if you have any questions.

- Patients with a weakened immune system (e.g. rheumatics, diabetics) as well as addicts are at increased risk of infections and implant failure.
- Paste-CPC contains a defined amount of a castor oil (polyoxyl-35 castor oil) for which very rare cases of allergic reactions and hypersensitivity reaction of the immune system (anaphylactic shock) have been described in the literature, therefore the dosage is limited to 21 ml Paste-CPC for you.
- Treatment of infections after surgery may require additional surgery to remove Paste-CPC from your body.
- The surgeon fills your bone defect completely with Paste-CPC. If complete filling of the defect is not possible, the remaining defect can be filled with the body's own bone or suitable foreign bone.
- Paste-CPC is a bone graft substitute and can only support the stability of the bone. The bone defect itself is stabilized by other implants.
- Paste-CPC must not be mixed with aqueous solutions prior to application, autologous or allogenic origin, because this may change the material properties of Paste-CPC.
- Paste-CPC is degraded (dissolved) by natural bone metabolism and replaced by your own bone. The duration of the degradation process depends on many factors, e.g. the volume of Paste-CPC and the condition of your bone. In any cases, Paste-CPC may also remain permanently in your bone.
- Paste-CPC contains a defined amount of potassium which is only successively set free and is only a fraction of the amount consumed daily with food, the physician will inform you, but the risks are very low.

5. Clinical evaluation

Paste-CPC belongs to a group of bone graft substitutes that have been successfully used in clinical applications for decades. Paste-CPC itself has been in clinical use since 2014. The preferred use of calcium phosphates for the production of bone substitute materials is derived from their close similarity to the mineral component of bone.

A comprehensive clinical evaluation report for Paste-CPC is available demonstrating the safety and clinical performance of Paste-CPC. The evidence comes from clinical data with Paste-CPC and supports the clinical benefits of Paste-CPC. No unacceptable residual risks are identified for Paste-CPC. In comparison to the state of the art, Paste-CPC has a positive benefit-risk ratio, making it a favourable choice in clinical use.

6. Therapeutic alternatives

Paste-CPC is a type of synthetic material used to replace or support bones. When treating bone issues, physician have several options:

- Using your own bone.
- Using someone else's bone.
- Using synthetic materials like hydroxyapatite or calcium sulphates.
- Combining different materials.
- Not using any substitute (for smaller issues).

The healing of a bone defect depends on many things, like how big it is, where it is, your health, and any other diseases you have. If you're thinking about these treatments, it's best to talk to your physician. They can help you decide what's right for you.