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Description

VETERINARY Paste-CPC is a synthetic, self-setting, biocompatible, osteoconductive and bioresorbable bone graft substitute for filling non-infected and non-load bearing bone defects. The material is applied directly into the bone defect from the syringe or with a cannula, without any further preparation. VETERINARY Paste-CPC is a bone substitute material to support the bone healing process. VETERINARY Paste-CPC is available in 1 ml, 3 ml and 12 ml. VETERINARY Paste-CPC is easy and intuitive to use thanks to its simple injectability and self-curing properties.

Composition

VETERINARY Paste-CPC is a mineral bone substitute made of synthetic calcium and phosphate salts finely dispersed in a biocompatible oil phase of short-chain triglycerides (caprylic/capric triglyceride) and two emulsifiers (polyoxyl-35-castor oil and cetyl phosphate). Caprylic/capric triglycerides and polyoxyl-35-castor oil are produced from vegetable raw materials.

The setting behaviour of VETERINARY Paste-CPC begins after application on contact with body fluids, e.g. blood and tissue fluids. VETERINARY Paste-CPC sets in situ to form a microcrystalline, calcium-deficient hydroxyapatite (CDHA) and alpha-tricalcium phosphate, which form the major phase. The minor phase consists of calcium hydrogen phosphate (monetite) and calcium carbonate (calcite). The reaction product resembles the mineral component of natural bone in its chemical composition and crystalline structure.

VETERINARY Paste-CPC contains no substances of animal origin and no added preservatives or pharmacologically active ingredients.

One milliliter of VETERINARY Paste-CPC contains approximately 24 mg of potassium in the form of K₂HPO₄ (see Dosage).

Table 1: Composition of VETERINARY 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 ₂ HPO 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

Intended use

VETERINARY Paste-CPC is a synthetic, self-setting bone graft substitute for filling non-infected bone defects in orthopedic, oral and maxillofacial veterinary surgery.

VETERINARY Paste-CPC is recommended as a bone substitute material for cementoplasty of primary osteosarcoma tumors in the load-bearing bones of the appendicular skeleton. VETERINARY Paste-CPC can also be used for other indications where bone is weakened due to disease, such as other bone tumors, metastases, traumatic or surgical injury, or for filling bone defects requiring a large volume of bone substitute material.

Cementoplasty is a low-trauma and minimally invasive surgical procedure that is performed within a short operating time and leads to a rapid recovery after surgery (compared to limb-sparing surgery and amputation).

Thanks to this surgical procedure, VETERINARY Paste-CPC strengthens the injected bone, thus preserving the function of the affected limb by clinically reducing lameness and the risk of pathological fractures. By mechanically supporting the tumor-affected bone, VETERINARY Paste-CPC also contributes to pain relief, thereby improving the animal's well-being.

Target animal species

VETERINARY Paste-CPC is intended for filling bone defects in pets and horses as a supplement to surgical procedures.

VETERINARY Paste-CPC is intended for cementoplasty of load-bearing bones of the appendicular skeleton of dogs and cats.

Area of application

VETERINARY Paste-CPC is intended for filling non-infected and non-load-bearing bone defects or for the filling of bone defects that have been sufficiently stabilised by means of suitable measures.

Fields of application are in particular:

- Bone fractures with bone defects, e.g. fractures of the tibia, ulna, femur, tarsus, carpus, coffin bone or cannon bone.
- Bone fusion at joint level - arthrodesis, e.g., carpal or tarsal joint
- Bone defects after resection of benign bone tumors or bone cysts
- Bone defects following bone resection as corrective osteotomy for angular or rotational deformity of the limbs
- Bone defects following tibial tuberosity advancement (TTA)
- Bone defects after removal or replacement of osteosynthesis implants
- Support in the fixation of osteosynthesis implants (e.g., bone screws)
- Preservation and augmentation of bone volume in oral and maxillofacial surgery (e.g., tooth extraction)

VETERINARY Paste-CPC should only be applied to well-vascularized, infection-free bone. Correct repositioning and stabilization of the fracture must be ensured by appropriate fixation.

VETERINARY Paste-CPC is intended for cementoplasty of load-bearing bones of the appendicular skeleton of dogs and cats.

Instructions for use

VETERINARY Paste-CPC is an implantable product and is intended for use in open or minimally invasive applications.



Fig. 1: VETERINARY Paste-CPC in Pre-filled syringes containing 1 ml of calcium phosphate cement



Fig. 2: VETERINARY Paste-CPC in Pre-filled syringes containing 3 ml of calcium phosphate cement

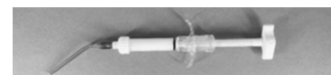


Fig. 3: VETERINARY Paste-CPC in Applicator with 12 ml calcium phosphate cement

VETERINARY Paste-CPC can be applied directly from the syringe or using one of the cannulas included in the package. The 1 ml and 3 ml packages of VETERINARY Paste-CPC contain a straight cannula, while the 12 ml package contains a curved 7G cannula. Using the cannula requires more force for application. Please note that some VETERINARY Paste-CPC will remain in the cannula and therefore will not be available for filling the defect. VETERINARY Paste-CPC can also be applied without a cannula.

The veterinarian is responsible for the patient's treatment plan, including the duration and timing of clinical and radiological follow-up. The veterinarian's treatment plan must be followed. During the pre-operative consultation, the patient's owner must be informed about the treatment conditions with VETERINARY Paste-CPC according to the instructions for use.

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Preparation 1 ml and 3 ml variant

The VETERINARY Paste-CPC packaging contains a pre-filled syringe and a straight cannula.

Open the packaging containing the syringe with VETERINARY Paste-CPC and remove the blue cap. VETERINARY Paste-CPC can then be applied directly or via a cannula into the prepared bone defect. To do this, press the syringe plunger slowly and evenly. The cannula can be shortened as needed (e.g., with Cooper scissors).

Preparation of the 12 ml variant

The VETERINARY Paste-CPC package contains a pre-filled applicator, a twist dispenser, and a curved 7G cannula. Open the package containing the applicator with VETERINARY Paste-CPC.

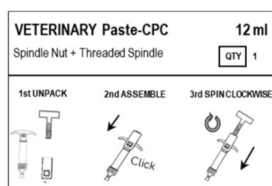


Fig. 4: Preparing the syringe with a rotary dispenser

Next, open the packaging containing the rotary dispenser (spindle nut and threaded spindle). The spindle nut must be pushed onto the rear end of the applicator until a distinct click is heard. Check that both sides of the spindle nut are locked into place. Now, turn the spindle into the spindle nut until it rests against the plunger. Remove the blue cap from the syringe. VETERINARY Paste-CPC can then be applied directly or via a cannula into the prepared bone defect by slowly turning the spindle clockwise.

Application

The amount of VETERINARY Paste-CPC required to fill the existing defect depends on the size of the defect.

To avoid delays during the operation, it should be ensured before treatment that a sufficient number of packs of VETERINARY Paste-CPC are available to completely fill the bone defect to be treated.

In minimally invasive applications, the filling of the bone defect must be monitored using suitable imaging techniques.

Setting behavior / hardening

VETERINARY Paste-CPC sets upon combination with or contact with an aqueous solution, such as bodily fluids. VETERINARY Paste-CPC can be processed indefinitely before contact with an aqueous solution.

VETERINARY Paste-CPC may only be inserted after final reduction and stabilisation of the bone defect to avoid interference with the curing process.

During oral surgery, any contact of the product with saliva should be avoided, as this could impair the product's setting/hardening properties. In this context, a gingival flap or the application of a silicone plug should be considered.

After application, VETERINARY Paste-CPC must not be manipulated (no dabbing, no corrective measures, no checking of curing, etc.).

Since the hardening of VETERINARY Paste-CPC occurs by reaction with the surrounding fluid, the strength development depends on the shape and size of the filled bone defect. Within 10 to 15 minutes, a stable outer layer is formed. In the further course, the bone substitute material hardens from the outside to the inside and reaches a compressive strength of up to 35 MPa after a few days. VETERINARY Paste-CPC sets at the implantation site over a period of several days and, when fully cured, achieves a compressive strength of up to 45 MPa.

Compressive strength

Once the setting process begins, the compressive strength of VETERINARY Paste-CPC increases continuously. Ten minutes after application, a hard outer shell forms, enclosing a pasty core. Approximately 16 to 24 hours after application, the compressive strength is equivalent to that of cancellous bone. The final compressive strength is three to four times higher than that of healthy cancellous bone and is reached after about four days, depending on the volume/geometry of the filled bone defect and the supply of body fluid.

Dosage

VETERINARY Paste-CPC is offered in the following quantities:

Contents per syringe		potassium content
1 ml	2 g	approx. 24 mg
3 ml	6 g	approx. 70 mg
12 ml	24 g	approx. 280 mg

Sterilisation procedure

VETERINARY Paste-CPC is a sterile medical device. Sterilization is achieved through gamma radiation. Due to the risk of infection transmission and/or potential impairment of product properties, VETERINARY Paste-CPC must not be cleaned or resterilized. VETERINARY Paste-CPC is intended for single use only.

Storage and shelf life

It is recommended to store VETERINARY Paste-CPC in a dry place at room temperature (between 5°C and 25°C). Storage outside this temperature range may alter the required application force and setting rate.

Short-term deviations from storage conditions during transport (maximum 5 days) have been tested for the range of -23 °C to +55 °C and do not render the product unusable.

Since this is a sterile medical device, the packaging should be protected from damage to avoid contamination of the product itself. Syringes from damaged packaging must not be used.

The expiry date is printed on the labels. The product must not be used after this date.

Additional Information

Attention! According to federal law (USA), this product may only be used by a licensed veterinarian or on their order.

For use on animals only.

Disposal

No special disposal is necessary for unopened products. For explanted or contaminated material, disposal is in accordance with hospital regulations.

Contraindications

VETERINARY Paste-CPC is **not** to be used in the case of:

- acute or chronic infections at the implantation site, e.g. osteomyelitis
- Bone defects in the area of open epiphyseal plates
- Cranioplasty
- pregnant or lactating animals
- known intolerance to an ingredient of VETERINARY Paste-CPC (see composition)

VETERINARY Paste-CPC should only be used after a strict individual benefit-risk assessment in the following cases:

- Disorders of bone metabolism
- Endocrinopathies
- immunosuppressive therapy
- simultaneous therapy with drugs that affect bone metabolism

Use during pregnancy or lactation

There are no clinical data available for use in pregnant or lactating animals. Therefore, VETERINARY Paste-CPC should not be used during pregnancy or lactation.

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Use in puppies, foals, and young animals

There are no clinically known reasons that would restrict its use in puppies, foals, and young animals.

Interactions

When used concurrently with resorption-inhibiting agents (especially bisphosphonates, NSAIDs – non-steroidal anti-inflammatory drugs), a slower resorption of the implant material is to be expected.

No other interactions with other medical devices or drugs are known, unless they directly affect bone metabolism.

VETERINARY Paste-CPC is a non-metallic, non-conductive and non-magnetic bone replacement material and is therefore classified as MRI safe.

Precautions and warnings

The use of VETERINARY Paste-CPC is restricted to professionals familiar with the handling of bone graft substitutes, the relevant surgical techniques and the treatment of bone defects. As with all surgical procedures, the use of VETERINARY Paste-CPC can carry surgery-related risks, such as rejection reactions, pseudarthrosis, swelling, seroma and hematoma formation, pain, and impaired wound healing. These may necessitate revision surgery.

Patients with weakened immune systems have a higher risk of infection and implant failure. Owners of such patients must be informed of the potential risks by medical professionals before surgery.

The treatment of postoperative infections can be complicated by the presence of an implanted foreign body and may necessitate the removal of the implant material. Conventional surgical instruments, which are part of the standard equipment in the operating room, can be used to remove the bone substitute material.

Any implanted foreign body can cause fever, allergic reactions, or inflammation. Very rare cases of allergic reactions and anaphylactic shock in humans have been reported in the literature in connection with the polyoxyl 35 castor oil component of VETERINARY Paste-CPC.

No toxic or allergic reactions were observed in dogs following local injection of Polyoxyl 35 castor oil. In patients with severely impaired renal function, adrenal insufficiency, or liver cirrhosis, the additional intake of small amounts of potassium may increase the risk of hyperkalemia or exacerbate existing hyperkalemia.

This also applies to patients with reduced renal potassium excretion due to medication (e.g., heparin, ACE inhibitors, potassium-sparing diuretics, spironolactone, nonsteroidal anti-inflammatory drugs, cyclosporine A). Since potassium is released gradually from VETERINARY Paste-CPC and the amount of potassium contained in VETERINARY Paste-CPC is only a fraction of the amount found in the daily diet, the risk is low even in cases of severely impaired renal function.

VETERINARY Paste-CPC should only be implanted after sufficient debridement of the bone defect to ensure a viable bone bed. The defect must be completely filled to establish direct bony contact between VETERINARY Paste-CPC and the surrounding bone.

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When injecting VETERINARY Paste-CPC into a bone defect, care must be taken to ensure that the material does not leak into adjacent soft tissues or blood vessels. To avoid embolisms, particular care must be taken to ensure that no material enters open veins or arteries, especially when injecting VETERINARY Paste-CPC under pressure into completely closed defects. If VETERINARY Paste-CPC is injected into a heavily bleeding bone defect, the material may be forced out by the bleeding pressure. It is recommended to control the bleeding before applying VETERINARY Paste-CPC and only proceed with filling the defect once the bleeding is under control.

Due to its mechanical properties, VETERINARY Paste-CPC can support bone stabilization, but actual stabilization must be ensured through other measures.

VETERINARY Paste-CPC must not be mixed with aqueous solutions, including those of autologous or allogeneic origin (e.g., blood), as this will lead to a change in the material properties. VETERINARY Paste-CPC is resorbed through biological processes and replaced by the body's own bone. Resorption is slow. Depending on the implantation conditions and metabolic activity at the implantation site, VETERINARY Paste-CPC can also remain permanently in the body as bone-integrated material. Unused contents of opened or damaged packaging must not be reused and must be disposed of (see Disposal).

Side effects

No side effects are known that are attributable to the use of VETERINARY Paste-CPC.






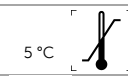




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Symbols

	Do not reuse
	Do not use if the sterile barrier system of the product or its packaging is damaged.
	Do not re-sterilise
	use until
	Sterilization by gamma irradiation
	temperature limit
	Follow the instructions for use
	single sterile barrier system
	magnetic resonance safe
	manufacturer