INNOTERE biomaterial

Instructions for use
VELOX
Revision 001

CE 0197

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Description
VELOX is a synthetic, self-setting, biocompatible, osteoconductive and bioresorbable bone graft substitute for filling non-infected and non-load bearing bone defects. VELOX is a bone substitute material to support the bone healing process. VELOX is available in 1 ml, 3x 1 ml, 3 ml, 6 ml and 12 ml.

Composition
VELOX 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 VELOX begins after application on contact with body fluids, e.g. blood and tissue fluids. VELOX 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.

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

Intended use
VELOX is a synthetic, self-setting bone graft substitute for filling non-infected bone defects.

Area of application
VELOX 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:
- metaphyseal bone defect fractures, e.g. tibia, radius and humerus fractures.
- bone defects after resection of benign tumours and cysts
- bone defects after removal or replacement of osteosynthesis implants
- to support the fixation of osteosynthesis implants (e.g. bone screws)

Use and Dosage
VELOX must not be used if the sterile packaging has been damaged or accidentally opened before use.
VELOX is a sterile ready-to-use bone graft substitute for single open surgical or minimally invasive application. In case of minimally invasive application, the filling of the bone defect must be monitored by means of suitable imaging procedures.
The amount of VELOX required for complete filling depends on the size of the defect present. Before surgery, it should be ensured that a sufficient number of packs is available. The implanted quantity of 21 ml VELOX per operation must not be exceeded for an adult, see precautions and warnings. The syringes contain the specified amount of VELOX as well as technical overfilling. The information in the following table must be observed:

Product variant	Maximum number of syringes per operation
1 ml and 3x 1 ml	15
3 ml	6
6 ml	3
12 ml	1

Only the enclosed cannula may be used for the application. It should be taken into account that a portion of VELOX, which depends on the size of the cannula, remains in the cannula (Product variants 1 ml and 3x 1 ml approx. 0.1 ml; product variants 3 ml, 6 ml and 12 ml approx. 0.7 ml) and is therefore not available for the defect filling.
VELOX can also be applied without using the enclosed cannula, which reduces the amount of force required and the loss of material.

Preparation 1 ml and 3x 1ml variant
The package contains one syringe and one cannula or three syringes and three cannulas. Remove the syringe from the packaging and remove the blue cap. If necessary, place the enclosed cannula on the syringe and apply the bone substitute material into the defect by applying slow and even pressure to the syringe plunger.

Preparation 3 ml version
The packaging contains a syringe and a cannula. Remove the syringe from the packaging and remove the blue cap. If required, place the enclosed cannula on the syringe and apply the bone substitute material to the defect by applying slow and even pressure to the syringe plunger.

Preparation 6 ml and 12 ml version
The package contains a syringe and a cannula as well as a rotary dispenser consisting of a spindle and a spindle nut. Remove the syringe and the rotary dispenser from the packaging. The spindle nut must be pushed onto the rear end of the syringe body until a distinct clicking sound is heard. Check that both sides are engaged. Now turn the spindle into the spindle nut until it rests against the plunger. Remove the blue cap from the syringe. If necessary, place the enclosed cannula on the syringe and apply the bone substitute material into the defect by slowly and evenly turning the spindle.

Setting behaviour / curing
The setting behaviour of VELOX is initiated by contact with body fluids, e.g. blood and tissue fluid, which causes the bone substitute material to set.
VELOX may only be inserted after final reduction and stabilisation of the bone defect to avoid interference with the curing process.
Since the hardening of VELOX occurs by reaction with the surrounding fluid, the strength development depends on the shape and size of the filled bone defect. The bone defect should be filled within five minutes in order to avoid disintegration of the bone substitute material that has already been applied during curing. Within 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.
After application, VELOX should not be manipulated, e.g. by dabbing, corrective measures or by testing the hardening.

Contraindications
VELOX is not to be used in the case of:
- acute or chronic infections at the implant site, e.g. osteomyelitis
- bone defects due to malignant tumours
- bone defects in the area of open epiphyseal joints
- known intolerance to any ingredient of VELOX (see composition)

VELOX is not be used in the following cases as there is no clinical experience so far:
- augmentations in the area of the spine
- cranioplasty
- pregnant or breastfeeding women
- children; whereby a dose limit of 3 ml VELOX per operation is known

VELOX is to be used only after individual risk-benefit assessment in the case of:

- bone metabolism disorders
- endocrinopathies
- immunosuppressive therapy
- concurrent therapy with drugs that affect bone metabolism

Intended patient group
Adults

Undesirable side effects
Possible product and treatment related side effects are: Swelling, seroma and haematoma formation, fever, allergic reaction, pain, fracture of the implant, wound healing disorders, rejection reaction, infection, delayed or no bone healing (pseudoarthrosis).

Interactions
Simultaneous treatment with resorption-inhibiting agents (especially bisphosphonates, non-steroidal anti-inflammatory drugs) may lead to slower resorption of the bone substitute.
Further interactions with other medical devices or medicinal products are not known, unless they directly affect bone metabolism, see contraindications.
VELOX is MRI safe as it is a non-metallic, non-conductive and non-magnetic bone graft substitute. VELOX is radiopaque.

Precautions and warnings
The use of VELOX is restricted to professionals familiar with the handling of bone graft substitutes, the relevant surgical techniques and the treatment of bone defects.
The doctor is responsible for the patient's treatment plan, including the duration and timing of clinical and radiological follow-up. The patient must follow the doctor's treatment plan. During the educational discussions, the patient must be informed about the circumstances of treatment with VELOX according to the instructions for use. The patient should be advised to contact a healthcare professional if they believe they are experiencing any side effects associated with VELOX.
VELOX is intended for single use on a single person.
VELOX may only be applied after sufficient debridement in a well-vascularised, infection-free bone bed. In addition, correct reduction and stabilisation of the fracture must be ensured. Direct contact between VELOX and the surrounding bone is only ensured if the bone defect is completely filled.
When using VELOX, leakage of the bone substitute material into adjacent soft tissue or blood vessels must be avoided. In order to prevent embolism, it must be ensured that no bone substitute material enters open venous or arterial accesses, especially when applied under pressure in defects that are enclosed on all sides.
In the case of heavily bleeding bone defects, the bleeding must first be controlled before applying VELOX. Otherwise there is a risk that the bone replacement material will be forced out again by the bleeding pressure.
VELOX can support the stabilisation of bone defects due to its mechanical properties. However, the actual stabilisation must be ensured by other measures.
VELOX must not be mixed with aqueous solutions prior to application, including those of autologous or allogeneic origin (e.g. blood), as this may change the material properties of VELOX.
VELOX is slowly resorbed in the course of natural bone metabolism and replaced by the body's own bone. Depending on the implantation conditions and the metabolic activity at the implantation site, VELOX can also remain permanently in the body as a bone-integrated material.
Treatment of postoperative infections may be complicated by the presence of an implanted foreign body and may require removal of the bone substitute. Revision surgery may be necessary due to undesirable side effects of the surgical procedure.
Especially in immunocompromised patients (e.g. rheumatics, diabetics) and addicts, it should be noted that there may be an increased risk of infection and implant failure. Such patients must be informed by the medical staff about the possible dangers before the operation.
For the component polyoxyl-35-castor oil contained in VELOX, very rare cases of allergic reactions and anaphylactic shock have been described in the literature. This is the reason for the aforementioned dosage restriction.
VELOX contains 24 mg of potassium per millilitre in the form of K_2HPO_4. In patients with severely impaired renal function, adrenal insufficiency or liver cirrhosis, lower amounts of additionally ingested potassium may increase the risk of hyperkalaemia or exacerbate existing hyperkalaemia. This also applies to patients with reduced renal potassium excretion induced by medication (e.g. heparin, ACE inhibitors, potassium-sparing diuretics, spironolactone, non-steroidal anti-inflammatory drugs, cyclosporin A). Since potassium from VELOX is only released successively and the amount contained corresponds to only a fraction of the amount ingested daily with food, only a low risk is to be assumed even in the case of severely impaired kidney function.

Removal of the bone graft substitute
If removal becomes necessary, the bone substitute should be completely removed and a thorough debridement of the adjacent bone surfaces should be performed. Common surgical tools can be used for removing. After debridement, the bone defect can be filled again with bone substitute material.

Shelf life
The product must not be used after the expiry date stated on the packaging.

Storage
VELOX must be stored at room temperature (between 5°C and 25°C).

Sterilisation procedure
VELOX is a sterile medical device. Sterilisation is carried out by gamma radiation. VELOX must not be cleaned and must not be resterilised because of the risk of infection transmission and/or possible changes in the product properties. VELOX is intended for single use only.

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

Information
The manufacturer provides an implantation card together with the product. The physician hands the implantation card and the information to be provided for the implanted product to the patient.
Users and/or patients should report any serious incident related to the device to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
The Summary Safety and Clinical Performance Report (SSCP) is published on the website of INNOTERE GmbH and can be found at the following LINK: *www.innotere.de/downloads*.
The instructions for use are also made available electronically on the website *www.innotere.de/downloads*. On request, the manufacturer will provide the instructions for use in paper form, free of charge within seven calendar days.
Please contact your supplier or the manufacturer for further information.

Responsible manufacturer
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Symbols

REF	article number
LOT	batch number
UDI	unique product identification
	use until
	manufacturer
QTY	quantity
	Do not use if the sterile barrier system of the product or its packaging is damaged.
MD	medical device
STERILE R	Radiation sterilised
5 °C 25 °C	temperature limit
	Do not re-sterilise
	Do not reuse
eIFU www.innotere.de/downloads	comply with electronic instructions for use
MR	magnetic resonance safe
	single sterile barrier system
	double sterile barrier system
	patient record
	ambulance or doctor
? + *	patient identification + date of birth
31	implantation date
www.innotere.de/downloads	website with patient information