Instruction for Use
INNOTERE 3D Scaffold

Revision 001

CE 0197

Attention! Always use latest revision!
www.innotere.de/downloads

Description

INNOTERE 3D Scaffold is a synthetic, porous, biocompatible, osteoconductive and bioresorbable bone substitute material for filling non-infected and non-load-bearing bone defects. INNOTERE 3D Scaffold is a bone substitute material to support the bone healing process.
INNOTERE 3D Scaffold is available in the product variants of blocks, cylinders and wedges.

Composition

INNOTERE 3D Scaffold is a porous, mineral bone substitute material of synthetic calcium and phosphate salts with a calcium-to-phosphate ratio of approx. 1.5. The main phase consists of microcrystalline, calcium-deficient hydroxyapatite (CDHA) and alpha-tricalcium phosphate (α-TCP), which are the main phase. The minor phase consists of calcium hydrogen phosphate (monetite) and calcium carbonate (calcite).
INNOTERE 3D Scaffold has an interconnecting pore system with pore sizes of 100-1000 µm.

Components	
calcium-deficient hydroxyapatite (CDHA)	≥ 75%
alpha-tricalcium phosphate (α-TCP)	
calcium hydrogen phosphate (monetite)	≤ 25%
calcium carbonate (calcite)	

Intended use

INNOTERE 3D Scaffold is a synthetic, porous bone substitute material for filling non-infected bone defects.

Area of application

INNOTERE 3D Scaffold 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 defect fractures, e.g. fractures of the tibia, radius, humerus
- osteotomy
- bone defects after removal or replacement of osteosynthesis implants

Use

INNOTERE 3D Scaffold is an implantable product and designed for single surgically invasive use.
INNOTERE 3D Scaffold must not be used if the sterile packaging has been damaged or accidentally opened before use.
The INNOTERE 3D Scaffold package contains the sterile, ready-to-use product. Intra-operative adaptation to the geometry of the defect is possible using the usual surgical instruments. This should be done carefully in order to avoid damaging the scaffold. The calcium phosphate particles released during the intra-operative shaping process might remain in the pores of the scaffold. To ensure optimal bone integration of the scaffold, removal of these particles with a sterile physiological saline solution or with compressed air is recommended. The shaping of INNOTERE 3D Scaffold must be carried out under sterile conditions.
The physician is responsible for the patient's treatment plan, including the duration and timing of the clinical and radiological follow-up. The patient must adhere to the physician's treatment plan. During the pre-operation discussion, the patient should be informed about the treatment conditions with INNOTERE 3D Scaffold according to the instructions for use.

Dosage

From a toxicological perspective, there is no limitation of the number of units for the implantation of INNOTERE 3D Scaffold. The defect size determines the selection of the product variant (block, cylinder, wedge) and the number of units to be used.
In order to avoid delays during the surgical procedure, it should be ensured prior to treatment that a sufficient number of INNOTERE 3D Scaffold packages is available, e.g. in the form of multipacks, to fill the bone defect completely.

Contraindications

INNOTERE 3D Scaffold **must not** be used in case of:

- acute or chronic infections at the implantation site, e.g. osteomyelitis
- bone defects due to malignant tumours
- bone defects in the area of open epiphyseal plates
- known disturbance of calcium metabolism, e.g. hypercalcaemia
- pregnant or breastfeeding women

INNOTERE 3D Scaffold must be used only after carefully weighing the risks and benefits in the case of:

- bone metabolism disorders
- endocrinopathies
- immunosuppressive therapy
- simultaneous treatment with medication that has an effect on bone metabolism
- children

Intended patient population

Adults

Undesirable side-effects

Product- and treatment-related side effects include: Swelling, seroma and hematoma formation, fever, allergic reaction, pain, device fracture, wound healing disorders, rejection reaction, infection, delayed and non-union (pseudarthrosis).

Interactions

Slower resorption of the implant material may occur if the patient is being treated simultaneously with resorption-inhibiting substances (particularly bisphosphonates, NSAIDs – non-steroidal anti-inflammatory drugs).
No additional interactions with other medical devices or medicinal products are known, as long as they do not have a direct effect on bone metabolism (see Contraindications).
INNOTERE 3D Scaffold is MRI safe since it is a non-metallic, non-conducting and non-magnetic bone substitute material. INNOTERE 3D Scaffold is radiopaque.

Precautions and warnings

The use of INNOTERE 3D Scaffold is restricted to specialists who are familiar with handling bone substitute materials, 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 INNOTERE 3D Scaffold 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 INNOTERE 3D Scaffold.
INNOTERE 3D Scaffold is intended for single use on a single person.
INNOTERE 3D Scaffold must be applied only to a well vascularised and non-infected bone site. The correct repositioning and stabilization of fractures is to be assured by means of appropriate fixation. A revision operation may be required because of undesirable side-effects of the surgery.
Patients with a weakened immune system (e.g. those suffering from rheumatism or diabetes) in addition to smoking and alcohol abuse increase the risk of infections and implant failure. Such patients must be informed by medical staff of the possible risks before surgery.
The treatment of post-operative infections may be hampered by the presence of an implanted foreign body and it may be necessary to remove the implanted material.
INNOTERE 3D Scaffold may contain residual amounts of polyoxyl-35-castor oil, for which very rare cases of allergic reactions and anaphylactic shock have been described in the literature.
INNOTERE 3D Scaffold must only be implanted after sufficient debridement of the bone defect in order to ensure a vital bone site. The defect must be completely filled in order to establish direct osseous contact between INNOTERE 3D Scaffold and the surrounding bone. If a complete defect filling with INNOTERE 3D

Scaffold alone is not be possible, the remaining defect sites should be filled with autologous bone or allogeneic materials.
Due to its mechanical properties, INNOTERE 3D Scaffold can support the stabilisation of bone defects, but the actual stabilisation must be ensured by other means. A radiologically visible fracture of the INNOTERE 3D Scaffold does not affect the intended purpose.
INNOTERE 3D Scaffold can be combined intra-operatively with autologous or allogeneic materials, particularly blood, blood-based products, bone marrow aspirate or autologous cancellous bone. In these cases, special care must be taken to maintain sterile conditions.
INNOTERE 3D Scaffold is resorbed by biological processes and replaced by the body's own bone. INNOTERE 3D Scaffold can also remain permanently in the body as an osseous integrated material depending on the implantation conditions and the metabolic activity at the implantation site.
Any unused contents of opened or damaged packages must not be used for further operations and discarded. Particles produced due to intra-operative shaping must not be reused.

Removal of the bone substitute material
If removal becomes necessary, the bone substitute material 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 as indicated on the product label.

Storage
INNOTERE 3D Scaffold does not require specific storage conditions. It is recommended to store INNOTERE 3D Scaffold in a dry place at room temperature. Do not use if the sterile packaging is damaged or unintentionally opened before use.

Sterilisation procedure
INNOTERE 3D Scaffold is a sterile medical device. It is sterilised using gamma radiation. Due to the risk of infection transmission and/or the potential impairment of product performance, INNOTERE 3D Scaffold must not be cleaned or resterilized. INNOTERE 3D Scaffold is intended for single use only.

Disposal
No special disposal measures are required for unopened products. Explanted or contaminated material must be disposed of in accordance with the hospital standard disposal procedure.

Information
The manufacturer provides an implant card together with the device; the health care professional shall ensure that the patient receives the implant card and the information to be supplied with an implanted device.
Users and/or patients should report any serious incident related to the product to the manufacturer and the competent authority of the Member State where the user and/or patient is established.
The Summary of Safety and Clinical Performance (SSCP) is published on the website of the manufacturer under: www.innotere.de/downloads
This instructions for use is also provided electronically through the website www.innotere.de/downloads.
The manufacturer provides a printed version of the instructions for use free of charge within seven calendar days of receipt of the request.
For further information, please contact your supplier or the manufacturer.

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

United Kingdom Responsible Person (UKRP)
Emergo Consulting (UK) Limited c/o Cr360 – UL International
Compass House, Vision Park Histon
Cambridge CB24 9BZ
England, United Kingdom
+44 (0) 1223 772 671
www.emergobyul.com

Swiss Authorized Representative (CH-REP)
confinis ch-rep ag
Hauptstrasse 16
3186 Düdingen
Switzerland
+41 (0) 26 494 84 94
www.confinis.com

Symbols

REF	Catalogue number
LOT	Batch code
UDI	Unique Device Identification
	Use-by date
	Manufacturer
QTY	Quantity
	Do not use if the sterile barrier system of the product or its packaging is damaged
MD	Medical device
STERILE R	Sterilized using irradiation
	Do not resterilize
	Do not re-use
eIFU www.innotere.de/ downloads	Consult electronical instructions for use
	Caution, consult accompanying documents
MR	MR safe
	Double sterile barrier system
	Patient record
	ambulance or doctor
	Patient identification + Date of birth
31	Date of implantation
www.innotere.de/downloads	Website with patient information