Instruction for use
INNOTERE 3D Scaffold – custom-made device

Description
INNOTERE 3D Scaffold - custom-made device - is a synthetic, porous, biocompatible, osteoconductive and bioresorbable bone substitute material for filling non-infected and non-load-bearing bone defects. INNOTERE 3D Scaffold - custom-made device - is an effective alternative to other bone substitute materials supporting the bone healing process with comparable residual risk for the patient.

Composition
INNOTERE 3D Scaffold - custom-made device - is a porous, mineral bone substitute material of synthetic calcium and phosphate salts with a calcium-to-phosphate ratio of approx. 1.5. The calcium phosphate phases are present with 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 - custom-made device - 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 purpose
INNOTERE 3D Scaffold - custom-made device - is a synthetic, porous bone substitute material for filling non-infected bone defects.

Indications for use
INNOTERE 3D Scaffold - custom-made device - is intended for filling or reconstructing non-load-bearing bone defects or for filling bone defects that have been sufficiently stabilised by appropriate means.

Particular indications are:
- 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 - custom-made device - is an implantable product and designed for single surgically invasive use.
The INNOTERE 3D Scaffold - custom-made device - 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 - custom-made device - 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 - custom-made device - 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 - custom-made device -. The defect size determines the number of units to be used.

Contraindications
INNOTERE 3D Scaffold - custom-made device - **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 - custom-made device - 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

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 - custom-made device - is MRI safe since it is a non-metallic, non-conducting and non-magnetic bone substitute material. INNOTERE 3D Scaffold - custom-made device - is radiopaque.

Precautions and warnings
The use of INNOTERE 3D Scaffold - custom-made device - is restricted to specialists who are familiar with handling bone substitute materials, the appropriate surgical techniques and the treatment of bone defects from their training.
INNOTERE 3D Scaffold - custom-made device - is intended for use on a single person for a single procedure. Multiple applications pose a risk of infection.
INNOTERE 3D Scaffold - custom-made device - 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 - custom-made device - 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 - custom-made device - 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 - custom-made device - and the surrounding bone. If a complete defect filling with INNOTERE 3D Scaffold - custom-made device - 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 - custom-made device - 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 - custom-made device - does not affect the intended purpose.
INNOTERE 3D Scaffold - custom-made device - 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 - custom-made device - is resorbed by biological processes and replaced by the body's own bone. INNOTERE 3D Scaffold - custom-made device - 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.

Implant removal
If implant removal becomes necessary, a complete removal must be ensured and thorough debridement of the adjoining bone surfaces is essential to produce new well vascularized bone interfaces. Conventional surgical tools that are part of the standard equipment in the operating theatre can be used to remove bone substitute material. Following debridement, the defect can be filled with autologous bone, allogenic materials or osteoconductive 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 - custom-made device - does not require specific storage conditions. It is recommended to store INNOTERE 3D Scaffold - custom-made device - in a dry place at room temperature. Do not use if the sterile packaging is damaged or unintentionally opened before use.

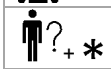
Sterilisation procedure
INNOTERE 3D Scaffold - custom-made device - is a sterile medical device. It is sterilised using gamma radiation. Due to the risk of infection transmission and/or the potential impairment of product performance, INNOTERE 3D Scaffold - custom-made device - must not be cleaned or resterilized. INNOTERE 3D Scaffold - custom-made device - 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.
This instructions for use is also provided electronically through the website www.innotere.de/downloads.
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

Symbols

	Patient number
	Batch code
	Use-by date
	Manufacturer
	Quantity
	Do not use if sterile barrier system of the product or its packaging is damaged
	Medical device
	Sterilized using irradiation
	Do not resterilize
	Do not re-use
	Consult instructions for use
	Caution, consult accompanying documents
	MR safe
	Double sterile barrier system
	Patient record
	Indication of the healthcare institution
	Patient name / Patient ID + Date of birth
	Date of implantation

Dated: 2023/01