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-load-bearing bone defects.

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 around 1.5. The calcium phosphates are present with a microcrystalline, calcium-deficient hydroxyapatite (CDHA) and alpha-tricalcium phosphate, which are the main phase. The minor phase consists of monetite and calcite.
INNOTERE 3D Scaffold - custom-made device - has an interconnecting pore system with pore sizes of around 100-1000 µm. INNOTERE 3D Scaffold - custom-made device - does not contain any substances of animal origin, added preservatives or pharmacologically active agents.

Components with percentage (%)	
alpha-tricalium-phosphate (α-TCP)	approx. 35 ± 6
tricalcium orthophosphate (CDHA)	approx. 43 ± 9
calcium hydrogen phosphate (monetite)	approx. 18 ± 3
calcium carbonate (calcite)	approx. 4 ± 2

Intended use
INNOTERE 3D Scaffold - custom-made device - is a synthetic, porous bone substitute material for filling non-infected bone defects.

Areas of application
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.

For example, areas of application include:
- metaphyseal defect fractures, e.g. fractures of the tibia, radius and humerus
- bone defects following resection of benign tumours and cysts
- osteotomy
- bone defects in oral and maxillofacial surgery
- bone defects after removal or replacement of osteosynthesis implants
- filling of spinal cages

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.

Use
INNOTERE 3D Scaffold - custom-made device - is an implantable product and designed for 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 of 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 by means of compressed air is recommended. The fitting 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 and application
From a toxicological perspective, there is no dose limit for the implantation of INNOTERE 3D Scaffold - custom-made device. The amount of INNOTERE 3D Scaffold - custom-made device - required to fill a defect depends on the defect size.

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

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

Use during pregnancy or lactation
No clinical data for use in pregnant or lactating women is available.

Use in children or geriatric patients
No clinical data for use in children is available. There are no known reasons that would restrict use in elderly patients.

Side effects
No serious side effects attributable to the application of INNOTERE 3D Scaffold - custom-made device - are known.

Interactions
If the patient is being treated simultaneously with resorption-inhibiting substances (particularly bisphosphonates, NSAIDs – non-steroidal anti-inflammatory drugs), slower resorption of the implant material should be assumed.
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 a non-metallic, non-conducting and non-magnetic bone substitute material and therefore is designated as MRI safe.

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.
When using INNOTERE 3D Scaffold – custom-made device -, as with all surgical interventions, surgery-related risks may occur, particularly rejection reactions, pseudarthrosis, swelling, seroma and hematoma formation, pain, and wound healing disorders. Subsequent revision operations may become necessary.
Patients with weaker immune systems (e.g. those suffering from rheumatism or diabetes), smokers and alcoholics are at higher 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 prove necessary to remove the implanted material.
Any implanted foreign body can lead to allergic or inflammation reactions or fever.
INNOTERE 3D Scaffold - custom-made device - may contain very small 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.
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 aseptic conditions.
INNOTERE 3D Scaffold - custom-made device - is resorbed by biological processes and replaced by the body's own bone. Depending on the implantation conditions and the metabolic activity at the implantation site, INNOTERE 3D Scaffold - custom-made device - can also remain permanently in the body as an osseous integrated material. Any unused content of opened or damaged packages must not be used for further operations and must be discarded. Particles produced due to intra-operative shaping of the scaffold 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, allogeneic materials or osteoconductive bone substitute material.

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

Storage
No particular storage conditions must be observed. It is recommended to store INNOTERE 3D Scaffold - custom-made device - in a dry place at room temperature. As this is a sterile medical device, the packaging must be protected from damage to avoid contamination of the product itself. INNOTERE 3D Scaffolds from damaged packages must not be used.

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 must not be cleaned or resterilied. INNOTERE 3D Scaffold - custom-made device - 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
For further information, please contact your supplier or the manufacturer. 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.

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

Symbols

REF	Catalogue number
LOT	Batch code
UDI	Unique Device Identification
	Use-by date
	Manufacturer
QTY	Quantity
	Do not use if package is damaged
MD	Medical device
STERILE R	Sterilized using irradiation
	Do not resterilize
	Do not re-use
	Consult instructions for use
	Caution, consult accompanying documents

Dated: 2022/01