

This report summarizes important aspects concerning safety and clinical performance of INNOTERE 3D Scaffold. The following information is intended for patients or lay persons and does not replace the instructions for use or the implantation card. Further, it is not intended to provide the patient with general advice for the treatment of a medical problem. If you have any questions about your medical condition or treatment with INNOTERE 3D Scaffold, please contact your healthcare professional. Medical terms have been avoided for easier understanding, or are mentioned in brackets.

1. General information on the product

Trade name

INNOTERE 3D Scaffold

Name and address of manufacturer

INNOTERE GmbH
Meißner Str. 191
01445 Radebeul
Deutschland
Tel: +49 351 2599 9410
www.innotere.de

Year of market launch (CE-certificate)

2017

2. Application of INNOTERE 3D Scaffold

INNOTERE 3D Scaffold is a scaffold used to fill bone defects.

2.1 Medical treatment

INNOTERE 3D Scaffold is intended for filling bone defects in non-load-bearing bone. If INNOTERE 3D Scaffold is to be used in load-bearing bone, the bone must be sufficiently stabilized by suitable fixation.

Fields of application for INNOTERE 3D Scaffold are:

- Fractures of long bones (e.g. fractures of the radius, tibia or humerus)
- Corrections of bone malposition (osteotomy)
- Bone defects after removal or replacement of implants

2.2 Patient population

INNOTERE 3D Scaffold is suitable for adults.

2.3 Contraindications

INNOTERE 3D Scaffold must not be used on:

- Infections of the bone at the implant site (osteomyelitis)
- Bone defects due to malignant tumours
- Bone defects in the area between the shaft and the end of a bone (epiphyseal joint)
- Pregnant and breastfeeding women

The doctor will consider the use of INNOTERE 3D Scaffold especially if the following conditions are present:

- Disorders of growth processes in the bone (bone metabolism)
- Diseases of the endocrine system (endocrinopathy)
- Taking medications for the treatment of autoimmune diseases (immunosuppressants)
- Taking medications that affect bone metabolism
- Disorders of calcium metabolism (e.g. hypercalcemia)

3. Product description

INNOTERE 3D Scaffold is a porous shaped body composed mainly of calcium phosphates (see Table 1). Since hydroxyapatite is the solid component of bone, INNOTERE 3D Scaffold is easily recognized by and incorporated into bone. Over time, INNOTERE 3D Scaffold is broken down by the body and new bone is formed at the same time. The time it takes for INNOTERE 3D Scaffold to completely degrade depends on various factors, e.g. the size of the inserted scaffold as well as the age of the patient.

Table 1: Components of INNOTERE 3D Scaffold

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

INNOTERE 3D Scaffold is available in different shapes (block, cylinder and wedge) and sizes (see Figure 1). The shape and amount of INNOTERE 3D Scaffold required to fill a defect depends on the type and size of the bone defect.



Figure 1: Shapes of INNOTERE 3D Scaffold (block, cylinder, wedge)

INNOTERE 3D Scaffold is clearly visible on the X-ray after implantation. But as soon as the degradation process of INNOTERE 3D Scaffold begins, the visibility decreases.

INNOTERE 3D Scaffold does not contain any pharmaceuticals and no substances of human or animal origin.

INNOTERE 3D Scaffold is intended for single use only.

4. Risks and warnings

Please contact your doctor if you experience any side effects related to INNOTERE 3D Scaffold or if you are concerned about potential risks. This report is not a substitute for talking to your doctor.

4.1 Residual risks and side effects

Common side effects of surgery include bleeding, bruising (hematomas), accumulation of fluids (seromas), swelling, fever, wound healing problems, infection, delayed or abnormal fracture healing (pseudarthrosis), and pain.

Allergic reactions or rejections may also occur with the use of bone graft substitutes. These reactions have never been observed for INNOTERE 3D Scaffold. With the wedge-shaped products, fracture has been seen on X-ray in rare cases. However, fracture of the bone substitute material does not pose a clinical risk, as the material does not perform a load-bearing function and the bone is stabilized by other measures.

4.2 Warnings and precautions

The doctor has the duty to inform you about possible risks before the operation. Below you can read the warnings and precautions in the instructions for use of INNOTERE 3D Scaffold. Please consult your doctor if you have any questions.

- Patients with a weakened immune system (e.g. rheumatics or diabetics) as well as smokers and alcohol abusers are at increased risk of infections and implant failure.
- INNOTERE 3D Scaffold may contain very small amounts of a castor oil (polyoxyl-35 castor oil) for which very rare cases of allergic reactions and hypersensitivity reaction of the immune system (anaphylactic shock) have been described in the literature.
- Treatment of infections after surgery may require additional surgery to remove INNOTERE 3D Scaffold from your body.

- The surgeon fills your bone defect completely with INNOTERE 3D Scaffold. If complete filling of the defect is not possible, the remaining defect can be filled with the body's own bone or suitable foreign bone.
- INNOTERE 3D Scaffold is a bone substitute and can only support the stability of the bone. The bone defect itself is stabilized by other implants (e.g. plates or screws).
- In rare cases, INNOTERE 3D Scaffold may fracture in the bone defect. The fracture is visible on the X-ray image. The healing process of the bone is not negatively influenced by this.
- INNOTERE 3D Scaffold can be mixed with the body's own material during surgery, especially with blood, blood products, cells from the bone marrow (bone marrow aspirate) or through the spongy inner tissue of the bone (cancellous bone).
- INNOTERE 3D Scaffold is degraded (dissolved) by biological processes and replaced by your own bone. The duration of the degradation process depends on many factors, e.g. the size of INNOTERE 3D Scaffold and the condition of your bone. In rare cases, INNOTERE 3D Scaffold may also remain permanently in your bone.

5. Clinical evaluation

INNOTERE 3D Scaffold belongs to a group of bone graft substitutes that have been successfully used in clinical applications for decades. INNOTERE 3D Scaffold itself has been in clinical use since 2017. The preferred use of calcium phosphates for the production of bone substitute materials is derived from their close similarity to the mineral component of bone.

INNOTERE has conducted a clinical study on the use of INNOTERE 3D Scaffold (wedge shape) in a correction of bone malposition (realignment osteotomy). In this study, the bone healing and resorption of INNOTERE 3D Scaffold was investigated in comparison to the product, OSferion®. OSferion® also belongs to the group of calcium phosphate-containing bone graft substitutes and has been on the market since 1999. The aim of the study was to prove that INNOTERE 3D Scaffold is at least as good as the established product OSferion®. The study included 71 patients. The statistically validated results of the study demonstrate that the bone healing of INNOTERE 3D Scaffold is not inferior to the comparator product, OSferion®. No failure of bone healing was observed in any patient. INNOTERE 3D Scaffold was well incorporated into the bone in every case. INNOTERE 3D Scaffold is also non-inferior to the comparator product, OSferion®, in terms of resorption. Four adverse events (pain, fracture of the bone substitute, hinge fracture, wound healing disorder) and one infection were observed during the study. Except for the fracture of the bone substitute, these adverse events are not related to the use of INNOTERE 3D Scaffold, but are due to general risks of surgery.

A comprehensive clinical evaluation report is available for INNOTERE 3D Scaffold, demonstrating the safety and clinical performance of INNOTERE 3D Scaffold. The evidence for this assessment report comes from literature databases and the clinical study described, as well as feedback from clinical practice. There is sufficient evidence of clinical benefit. No unacceptable, undesirable side effects, as well as residual risks, were identified. The benefit/risk ratio can be clearly assessed for the application of the INNOTERE 3D Scaffold material.

6. Therapeutic alternatives

INNOTERE 3D Scaffold is one of the synthetic bone substitute materials for which the following therapeutic alternatives are available:

- the use of the patient's own bone (autologous bone replacement)
- the use of human foreign bone (allogenic bone substitute)
- the use of other synthetic bone substitute materials made of hydroxyapatite or other compositions (e.g. calcium sulphates)
- the combination of the above-mentioned bone substitute materials
- omission of a bone substitute material (if necessary for smaller defects)

The healing of a bone defect is influenced by many factors, such as the defect size, the anatomical location of the bone defect, the patient's health condition and underlying diseases. If you are considering alternative treatment methods, please consult your physician, as he or she can best consider your individual situation.