



EN

Ti-System

CE 0483
consisting of:
• Titanium foil
• Titanium pins

CE
Instruments:
• Tool Holder
• Titan-Aufsatz
• Schraubendreher
• SteriBox

INSTRUCTIONS FOR USE

1. Purpose
This medical device system is used to provide temporary rigid cover for augmentation material, especially in the dental, oral and maxillofacial region. Here the fix for the fixed titanium foil to remain in place depends on the specific objective, on the local conditions and on the general condition of the patient.

2. Description and indications

The target group of the medical device system consists of patients with bone defects to be regenerated and patients after implantation of augmentation material.

In these patients, use of the titanium foil and titanium pins can prevent ingrowth of soft tissue into the implant area, promoting bone regeneration.

In most cases bone regeneration using the titanium foil will take, depending on the defect size, 2-6 months.

3. Adverse Events

So far, no adverse events have been reported.

4. Tissue Compatibility, Interactions

There are no data available that would suggest tissue incompatibility of components of the Ti-System.

5. General Safety Notes

Application of the Ti-System is reserved to qualified experts.

The entire Ti-System is supplied non-sterile and must be sterilized accordingly before each use (see ARI Directive).

The titanium foils and titanium pins are intended for single use only. Unused pins remaining in the SteriBox can be reused after passing through a complete cleaning and sterilization cycle.

6. Further Information
• Use only System tool!
• Documentation labels are enclosed with the foils and pins.

7. Product Characteristics
The starting material for the implantable parts of the Ti-System is titanium (of a grade) specified for surgical use. The titanium foils are cleaned and packaged into a foil pouch.
The titanium pins (3-mm titanium pins (yellow)) are recommended for hard, 5-mm titanium pins (blue) for soft tissue. The pins are sterilized in a foil pouch.
In addition, for application and removal of the titanium foils and titanium pins, the following instruments are to be used:
• Tool Holder
• Titan-Aufsatz
• Schraubendreher
• SteriBox

The multi-coloured surface of the electro-passivated titanium foil may exhibit production-related colour variations, which however do not affect biocompatibility.

8. Restrictions of Use
• Unsterile or tissue-resistant conditions such as decreased blood clotting (inhibited coagulation), known defects in wound healing or bone regeneration, infection and inflammation in the area of the wound and bone regeneration, tobacco and alcohol abuse, immunosuppressive therapies, infection and inflammation in the area of intended use, poor oral hygiene.

9. Mode of Application

Preparation:
Titanium foils

The titanium foils (either 20 µm or 40 µm) are prepared by removing from the foil pouch and cleaning with isopropanol 70% or ethanol 70% in a titanium bath.

The cleaned titanium foils are to be sterilized, arranged vertically in a suitable container without foil pouch.

Titanium pins

The titanium pins are prepared by removing from the foil pouch and cleaning with isopropanol 70% or ethanol 70% in an ultrasonic bath.

The cleaned titanium pins are sterilized in the likewise cleaned SteriBox.

To load the SteriBox, the cleaned titanium pins into the appropriate slots. Then close the SteriBox with the swing cover (so the titanium pins cannot fall out of the SteriBox or slip anymore) and sterilize it.

10. Instruments

Before use or application, all the components of the Ti-System must be cleaned, disinfected and sterilized in accordance with a validated procedure for surgical instruments.

11. Documentation

Documentation 029203

Documentation 0101040

12. Instructions for use

These instructions for use are intended for the opening and closing of the titanium foil and titanium pins.

The titanium foil and titanium pins are to be cleaned and sterilized according to the instructions for use.

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