Instructions for Use for Medartis TTS −Titanium Trauma Splint

I. General Instructions

These instructions for use do not include all of the information necessary for use of the products. Additional information on the products (e.g. surgical technique and instructions for cleaning, disinfection, sterilization, inspection and maintenance) can be found on the internet at www.medartis.com/documentation/instructions-for-use. They can also be requested from your local Medartis territory consultant or distribution partner. All instructions provided in this document and in the corresponding user information must be followed.

The TTS tooth splint may only be accepted when the manufacturer's label and packaging are undamaged and unopened at the time of delivery. If this is not the case, the rejected goods must be returned to Medartis AG, Basel/Switzerland or to the relevant Medartis territory consultant or distribution partner within ten working days.

II. Scope

The TTS tooth splint is covered by these instructions for use.

III. Product Description

Product Materials

The TTS tooth splint is manufactured from a biocompatible material. All materials are standard implant and instrument materials for use in medical devices for orthopedics, traumatology, and general surgery.

Product	Material	Standard
TTS tooth splint	Pure titanium TiCP	ASTM F67

Color Coding Concept

The colors of the TTS tooth splints have no impact on material properties or geometry. The colors can be chosen for esthetical reasons.

Intended Purpose

The TTS tooth splint is used for the treatment of traumatized or replanted teeth.

Indications and Contraindications

Indications and contraindications for the TTS tooth splint can be found in the corresponding surgical technique under www.medartis.com/documentation/instructions-for-use.

Intended User / Patient Target Group

The products may only be used by health care professionals, e.g. dentists, surgeons, radiologists, operating room staff and individuals involved in preparation of the device who hold the relevant qualifications.
Medartis, as the manufacturer, recommends that the user reads all available documents (e.g. surgical techniques, instructions for cleaning, disinfection, sterilization, inspection and maintenance) before first use and contacts other users who have practical experience with this type of treatment. The user must be familiar with the state-of-the-art and splint function. Responsibility for proper selection of patients rests with the surgeon, based on the specific indications and contraindications and on patient-related factors (e.g. activity, occupation, mental health and age).

Intended Performance

The available clinical data confirmed good clinical performance and safety outcomes of the TTS tooth splint, when they are used according to the user information. This was in line with or superior to the state of the art.

IV. Side Effects / Possible Complications

TTS tooth splint related possible complications

- Irritation or inflammation of the inner part of the lip
- Irritation or inflammation of the gingiva
- Inadequate composite fixation of the TTS tooth splint (e.g. due to insufficient drying/bonding) may result in loosening of the TTS tooth splint, which entails the risk of swallowing and aspiration of the product
- Transient speech impairment
- Use of excessive amounts of composite may cause hygiene problems

Trauma related possible complications

- Post-traumatic external root resorption
- Pulp necrosis requiring root-canal treatment
- Pulp canal calcification
- Replacement-related root resorption
- Infection-related root resorption
- Pulp obliteration
- Facial recession of the gingiva

The manufacturer is not responsible for any complications arising from incorrect diagnosis or choice of incorrect product.

V. Warnings

- The product may only be used by medical personnel who hold the relevant qualifications.
- Medartis, as manufacturer, recommends that the user reads all available documents before first use and contacts other users who have practical experience with this type of treatment.
- The TTS tooth splint is intended for one single application in a single patient.
- Never use products that have been damaged by transport, improper handling, or in any other way!
- Intraoral appliances must be secured against aspiration.
- Necessary care must be observed for storage and use of the splint:
  - Damages (e.g. from improper cutting or bending) to and/or scratches on the splint can substantially impair the strength of the product and lead to premature breakage.
  - Repeatedly bending the splint in opposite directions may cause the splint to break.

For application-specific warnings related to the TTS tooth splint, it is mandatory to consult the surgical technique (www.medartis.com/documentation/instructions-for-use).

VI. Cautions

- The TTS tooth splint has been developed and manufactured for a specific purpose and may not be modified by the user in another way than stated in the surgical technique.

For application-specific cautions related to the TTS tooth splint, it is mandatory to consult the surgical technique (www.medartis.com/documentation/instructions-for-use).

VII. General Important Information

Clinical Benefits

The most important clinical benefit of the TTS tooth splint is that it allows treatment of the clinical conditions stated in the intended purpose and indications. These are often mildly to severely invalidating clinical conditions, and their treatment or alleviation is strongly beneficial to the patients.
In consideration of patient's clinical condition and medical history, the treating physician shall ensure that the use of the TTS tooth splint can be justified based on a patient-specific benefit/risk assessment. Based on the clinical evaluation and risk analysis, all residual risks are deemed acceptable when weighed against the benefits to the patient based on current knowledge/the state of the art.

Selecting the Appropriate Product

Medartis, as the manufacturer, does not recommend a specific procedure for a specific patient. The treating dentist is solely responsible for choosing the appropriate treatment procedure and customizing an appropriate TTS tooth splint for the individual case. The follow-up treatment as well as the decision when to remove the splint is the responsibility of the user.
The treating dentist must beforehand become thoroughly familiarized with the procedure, for example by:

- Carefully studying all the product documentation
- Carefully reviewing the current professional literature
- Consulting with colleagues experienced in this field and with the use of the TTS tooth splint
- Practice in handling and applying the TTS tooth splint and follow-up treatment

Removal of the Product

Generally, the TTS tooth splint is designed for temporary fixation of traumatized/replanted teeth until the periodontium has sufficiently healed. Prolonged and rigid splinting may lead to adverse effects such as ankylosis or resorption. Splinting periods should be in accordance with clinical and radiological findings. The recommended splinting period is 2−4 weeks at most.

Follow-up Care

The treating dentist has to instruct the patient on appropriate hygiene procedures according to standard dental practice. Depending on the clinical and radiological findings, the treating dentist must advice the patient on possible restrictions regarding solid foods or sports following standard dental practice.

Information on MR Marking

Conditionally MR safe

Non-clinical tests under worst case conditions show that all Medartis implants/splints are MR conditional.

Magnetically Induced Torque and Displacement According to ASTM F2213-06 and ASTM F2052-06e1
Non-clinical tests in a 3T MRI system under worst case conditions have shown that no relevant torque and displacement of Medartis products were observed at a maximum spatial gradient of 12 T/m.

Image Artifacts According to ASTM F2119-07
Non-clinical tests in a 1.5T MRI system showed image artifacts extending up to 29 mm away from the implant during a gradient echo pulse sequence.

Radio-Frequency Induced Heating According to ASTM F2182-11a
Electromagnetic and thermal simulations combined with non-clinical tests demonstrated maximum temperature rises of 13.1°C (1.5T) and 4.2°C (3T) after 15 minutes of continuous scanning (Normal Operating Mode, whole body absorption rate (SAR) of 2.1 W/kg).

Since the above results were obtained through non-clinical tests,the actual in vivo temperature increase will depend on a variety of factors beyond the SAR and the scan duration. Therefore, note the following:
- Do not scan patients with impaired thermo regulation, temperature or pain sensation.
- Reduce the SAR as much as possible, as reducing the SAR strongly reduces the temperature increase caused by RF heating.
- Use an external cooling/ventilation system to help reduce the body temperature .

VIII. Cleaning, Disinfection and Sterilization of Non-Sterile Products

The TTS tooth splint which is delivered **NON-STERILE** must be cleaned, disinfected and sterilized before use. All packaging must be removed before preparation.
Thorough cleaning and disinfection are essential for effective sterilization. The TTS tooth splint is intended for one single application in a single patient. Splints that were used in a patient and removed, have to be discarded following the local requirements. Application of an already used splint may compromise the structural integrity of the product and/or lead to device failure which may result in patient injury. Furthermore, application of a splint that has already been used may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury of the patient or user.
Splints that have not come into direct contact with a patient may be reprocessed. Splints that have come into direct contact with blood or other bodily fluids or show visual contamination must be cleaned and disinfected separately.
It is your responsibility to ensure that the TTS tooth splint is completely sterile when used, to use device- and product-specific procedures for cleaning/disinfection and sterilization that are sufficiently validated, to regularly service and inspect the employed devices (disinfector, sterilizer), and to ensure that the validated and/or manufacturer's recommended parameters are maintained for each cycle.
The statutory regulations applicable in your country and the hospital's hygiene requirements must also be observed. This applies in particular to the various instructions for effectively deactivating prions.

Detailed instructions for processing/reprocessing of medical devices are described in the brochure "Instructions for Cleaning, Disinfection, Sterilization, Inspection and Maintenance of Medartis Products" and can be downloaded from www.medartis.com/documentation/instructions-for-use.

IX. Complaints and Adverse Events

Any complaint or adverse event that has occurred in relation to the device should be reported to the manufacturer and the respective national competent authority of the state in which the user and/or patient is established.

X. References

The following user documentation on the products is additionally available online and can be found under the following link: www.medartis.com/documentation/instructions-for-use.
- Surgical technique
- Instructions for cleaning, disinfection, sterilization, inspection and maintenance

For additional information contact your local Medartis territory consultant, distribution partner or the manufacturer directly under the given address.

XI. Symbols

	Consult instructions for use
	Article number / Reference number
	Lot number / Batch code
	Non-sterile
	Single-use product. Do not reuse The product is intended for one single application in a single patient. Application of an already used product may compromise the structural integrity of the device and/or lead to device failure, which may result in patient injury.
	Do not use if packaging is damaged
	Medical device
 YYYY-MM-DD	Manufacturer Date of manufacture
	Conditionally MR safe
	Authorized representative in the European Community / European Union
	Importer
	Applies only to EC risk class I devices in sterile condition, I devices with a measuring function, I reusable surgical instruments, IIa and IIb devices.

This document is subject to continuous revision. the most current version is always available online at www.medartis.com/documentation/instructions-for-use.

Medartis AG
Hochbergerstrasse 60E
4057 Basel/Switzerland
Phone +41 61 633 34 34
Fax +41 61 633 34 00
info@medartis.com
www.medartis.com

Importer EU
Medartis GmbH
Am Gansacker 10
79224 Umkirch/Germany

Medartis GmbH
Am Gansacker 10
79224 Umkirch/Germany

Sponsor Details Australia & New Zealand
Medartis Australia & New Zealand Pty Ltd.
64 Brooks Street
Fortitude Valley QLD, 4006

Disclaimer: This information is intended to demonstrate the Medartis portfolio of medical devices. A surgeon must always rely on her or his own professional clinical judgement when deciding whether to use a particular product when treating a particular patient. Medartis is not giving any medical advice. The devices may not be available in all countries due to registration and/or medical practices. For further questions, please contact your Medartis representative (www.medartis.com). This information contains CE-marked products.
For US only: Federal law restricts this device to sale by or on the order of a physician.