This Summary of Safety and Clinical Performance (SSCP) aims to provide public access to an updated summary of the main aspects of the safety and clinical performance of DTI implants.

The SSCP is not intended to provide general advice on the treatment of a medical condition. Furthermore, this SSCP is not intended to replace the written Instructions for Use to provide information about the safe use of the device.

Contents

1 Description of the Device and General Information

1.1 Trade name of the device

DTI IMPLANT

1.1.1 Product Name

- DTI SLA IMPLANT
- DTI ACT IMPLANT
- DTI SLA UNIFORM IMPLANT
- DTI ACT UNIFORM IMPLANT
- DTI SLA AGGRESSIVE IMPLANT
- DTI ACT AGGRESSIVE IMPLANT
- DTI SLA MONO IMPLANT
- DTI SLA MONO-FLEX IMPLANT
- DTI SLA MONO-BALL IMPLANT

1.1.2 Product Sizes

- **DTI SLA/ACT IMPLANT**

Ultra Mini; Diameter: Ø3.0 / Length: 10, 11.5, 13, 15

Mini; Diameter: Ø3.5 / Length: 8.5, 10, 11.5, 13, 15

Standard; Diameter: Ø4.0, Ø 4.5, Ø 5.0 / Length: 7, 8.5, 10, 11.5, 13, 15

- **AGGRESSIVE SLA/ACT IMPLANT**

Ultra Mini; Diameter: Ø3.0 / Length: 7.0, 8.5, 10.0, 11.5, 13.0, 15.0

Kısa Mini; Diameter: Ø3.5, Ø 4.0, Ø 4.5, Ø 5.0, Ø 5.5, Ø 6.0 / Length: 5.0, 6.0

Mini; Diameter: Ø3.5, Ø 4.0, Ø 4.5, Ø 5.0 / Length: 7, 8.5, 10.0, 11.5, 13.0, 15.0

- **UNIFORM SLA/ACT IMPLANT**

Ultra Mini; Diameter: Ø3.0 / Length: 10, 11.5, 13, 15

Mini; Diameter: Ø3.5, Ø 4.0, Ø 4.5, 5.0 / Length: 7, 8.5, 10, 11.5, 13, 15

- **DTI MONO, MONO-FLEX, MONO-BALL IMPLANT**

Mono; Diameter: Ø 2.8, Ø 3.5 / Length: 10, 11.5, 13

Mono-Flex: Diameter: Ø 2.8, Ø 3.5 / Length: 10, 11.5, 13

Mono-Ball: Diameter: Ø2.8, Ø 3.5 / Length: 10, 11.5, 13

1.2 Manufacturer's Name and Address

Manufacturer Name: DTİ İMPLANT SİSTEMLERİ

Factory: Barış SB Mh. TÜBİTAK-MAM Teknoloji Serbest Bölgesi 5001 Sk. No:16 Gebze, Kocaeli, Turkey

1.3 Manufacturer's Registration Number (SRN)

TR-MF-000019662

1.4 Basic UDI-DI of the product

868067149TRIVR

1.5 Classification of Device

Medical Device Directive Annex 9-Rule 8:

Based on rule 8 of the relevant legislation, Dental Implant – DTI SLA is categorized as Class IIB

1.6 The year in which CE certification was first obtained

14.11.2012

1.7 Authorized Representative

There is no authorized representative.

1.8 Notified Body's name

Kiwa Certification Services Inc., NB 1984

2 Intended of Use of the Device

2.1 Intended use

DTI Implants are dental implants intended for use in fixing the upper or lower jawbone to restore chewing function or to support tooth replacements.

2.2 Indications and target populations

2.2.1 Indications

The DTI Implant System is designed for use in dental surgeries. It replaces the natural tooth root, which is surgically placed in the upper or lower alveolar bone. The implant can repair the injured tooth by attaching the abutment after osseointegration with the alveolar bone. The DTI Implant System is indicated for use in partially or completely edentulous mandibles and maxillas to support single or multiple unit restorations.

2.2.2 Target population

Dental implant surgery is expected to be appropriate and meet the post-implanted justifications.

2.3 Contraindications or limitations

DTI Implants are suitable for patients outside of these contraindications.

- Patients who are not ready for oral rehabilitation
- Vascular conditions
- Uncontrolled diabetes
- Coagulation disorder
- Anticoagulant therapy
- Metabolic bone disease
- Chemotherapy or radiation therapy
- Chronic periodontal inflammation
- Inadequate soft tissue cover
- Metabolic or systemic disorders due to wound and/or bone healing
- Use of pharmaceutical substances that inhibit or alter bone remodeling
- Inadequate oral hygiene and any disturbance that interferes with the patient's ability to maintain adequate daily oral hygiene; bruxism.
- Alcohol and smoking
- Drug use
- Uncontrolled parafunctional habits
- Sufficient height and/or width in the bone
- Inadequate interarch space
- Patients with autoimmune diseases
- Pregnancy and breastfeeding
- Treatment of children is not recommended until the growth is over and the pineal is closed.
- Patients who are allergic or hypersensitive to titanium.

3 Description of the device

3.1 Device Description

55849: Screw intrabody dental implant, two parts

DESCRIPTION: Sterile device made of alloplastic materials (titanium, stainless steel, ceramic) and designed to be surgically inserted into the tooth slot or the basal bone of the lower or upper jaw to provide support or holding tool for the dental prosthesis (bridge, single tooth or denture). This device consists of a threaded screw-shaped abutment component (implant body) that is inserted into the bone and a fulcrum component (implant foot) that is typically placed in the retention component after application and protrudes beyond the gum cells to support the prosthesis.

CATEGORIES: 03-Dental devices 07-Inactive implantable devices TYPE: APPLICABLE TERM

3.2 Variant, reference and explanation of differences

According to its variants, it differs in raw material and surface properties.

Implant	Raw Materials
DTI SLA IMPLANT DTI ACT IMPLANT	Titanium Grade 5
DTI SLA UNIFORM IMPLANT DTI ACT UNIFORM IMPLANT	Titanium Grade 4
DTI SLA AGGRESSIVE IMPLANT DTI ACT AGGRESSIVE IMPLANT	Titanium Grade 4
DTI SLA MONO IMPLANT DTI SLA MONO-FLEX IMPLANT DTI SLA MONO-BALL IMPLANT	Titanium Grade 5

Implant	Surface properties
DTI SLA IMPLANT DTI SLA UNIFORM IMPLANT DTI SLA AGGRESSIVE IMPLANT	SLA Sandblasted Large Grid Acid Etching
DTI ACT IMPLANT DTI ACT UNIFORM IMPLANT DTI ACT AGGRESSIVE IMPLANT	ACT Plasma
DTI SLA MONO IMPLANT DTI SLA MONO-FLEX IMPLANT DTI SLA MONO-BALL IMPLANT	SLA Sandblasted Large Grid Acid Etching

3.3 Accessories that must be used with the device

- Carrier part
- Carrier part screw
- Healing screw
- O-ring
- Abutment
- Compatible Drill

3.4 Other devices

Instruments and ancillary equipment for reusable surgery

4 Risks and warnings

4.1 Risks and side effects

Dental implants are one of the most reliable and successful surgical applications that have been performed since the 1970s. More than 95% of surgical cases continue to live their lives in a much better quality compared to the preoperative situation. After dental implantation, the pain during chewing decreases and regains its functions. Of course, like all surgical procedures, there are risks in dental implantation. 68 risks identified according to the product life cycle were evaluated by the risk management team. It has been decided that the products are safe to use. It has been proven with sufficient product basis and performance by clinical literature studies.

It is acceptable when the risks of the product are compared with the benefit to the patient.

The risk management report has been prepared by the Quality Management Representative and the risk management team to cover all stages of the risk management process according to EN 14971: 2019. The risk management report was approved after being checked by the General Manager. The report will be maintained in accordance with the Records Control Procedures.

4.2 Warnings and Precautions

DTI Implants, surgical instruments, and prosthetic components should only be used with dentists and surgeons who have training/experience in oral surgery, dentures, and biomechanical requirements, as well as with diagnosis and preoperative planning.

The implant area should be examined with radiographs, palpations and visual inspection for sufficient bone.

Determine the location of nerves and other vital structures and their proximity to the implant site before any puncture to prevent potential injuries such as permanent numbness to the lower lip and jaw.

Absolute success cannot be guaranteed. Factors such as infection, disease, and inadequate bone quality and/or quantity may cause osseointegration errors following surgery or after osseointegration.

Dental implants should not be replaced in any way. Implant mobility, bone loss, or chronic infection may indicate implant failure. Do not reuse implants. It is not recommended to reuse such a device to another patient because of the risk of cross-contamination or infection. The implant cannot be re-sterilized.

4.3 FSCA summary of other related security (if any)

There is no Field Safety Corrective Action (FSCA) or Field Safety Notification (FSN) for any DTI product.

5 Summary of Clinical Evaluation and Post-market Clinical Follow-up (PMCF)

Summary of the most recently approved PMCF plan for the device the planned currently current PMCF includes four general PMCF activities: scientific literature review, evaluation of customer complaints, and two proactive customer surveys. The next scientific update the literature review is scheduled for 2021, according to the calculation of the review period.

Provided that no unexpected events occur and that the devices in question operate as intended, if any risk, complication, or unexpected device failure is detected and how they will happen, all PMCF activities performed demonstrate in clinical safety and performance results.

5.1 Summary of clinical data on the device prior to CE certification

Not applicable. There are no clinical studies conducted prior to CE marking.

5.2 Summary of clinical data from other sources

Clinical data can be obtained from a variety of sources, including use and use in doctors' offices or clinics recorded in clinical articles. The clinical data in the Clinical Evaluation Report uses data collected from the actual DTI Implant Systems. Clinical data collected from these sources show high survival rates. There are some expected failure events, especially those involving osseointegration deficiency or overload restoration. The clinical data collected revealed that restorations of benefits outweighed any risks could be performed and the patient's chewing function was restored.

5.3 Ongoing or planned post-market clinical follow-up

Clinical evaluations will be conducted to identify new or previously unidentified risks that will cause a change in the benefit/risk ratio. In addition, the assessments will review changes in the latest technology.

6 Possible methods of diagnosis or treatment

FIXED PROSTHESIS

Fixed prostheses are known as bridges, crowns and coatings. They are prostheses that are applied when a small number of teeth are missing in the mouth and prepared in the laboratory and adhered to the teeth by reducing the supporting teeth.

CROWNS

• Teeth with excessive material loss due to decay or another reason

• Teeth that do not return color and become colored

•On the implant

• Teeth that have seen the root canal treatment as weak

• Teeth with deformities

BRIDGE

As a result of the loss of a single tooth or more than one tooth, it is the practice of reducing the neighboring teeth and filling the intermediate gaps by taking support from the special coating.

7 Recommended profile and training for users

Dental implant surgery requires proper and adequate training. Experienced implant users, as well as clinicians who are new, are strongly advised to always receive special training before starting a new treatment method.

8 Applied Standards

No	Reference	Title
1.	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
2.	EN 556-1: 2001 / AC: 2006	Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' - Part 1: Requirements for terminally sterilized medical devices
3.	EN 62366-1:2015	Medical devices. Application of usability engineering to medical devices
4.	EN 62366-2:2016	Medical devices — Part 2: Guidance on the application of usability engineering to medical devices
5.	EN ISO 10993-1: 2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
6.	EN ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
7.	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
8.	EN ISO 10993-6:2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
9.	EN ISO 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
10.	EN ISO 10993-11:2017	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
11.	EN ISO 11137-1: 2006/Amd 2:2018	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
12.	EN ISO 11137-2: 2013/Amd 1:2022	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
13.	EN ISO 11607-1:2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
14.	EN ISO 11607-2: 2019	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
15.	EN ISO 11737-1:2018 /Amd 1 :2021	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
16.	EN ISO 11737-2:2019	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
17.	EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
18.	ISO 24971:2020	Medical devices — Guidance on the application of ISO 14971
19.	EN ISO 14801: 2016	Dentistry - Implants - Dynamic loading test for endosseous dental implants
20.	EN ISO 10451:2010	Dentistry - Contents of technical file for dental implant systems
21.	EN ISO 14698-1:2003	Cleanrooms and associated controlled environments — Biocontamination control — Part 1: General principles and methods

No	Reference	Title
22.	EN ISO 14644-1:2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
23.	EN ISO 14644-2:2015	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
24.	EN ISO 20417:2021	Information supplied by the manufacturer of medical devices
25.	EN ISO 10993-18:2020 /Amd 1:2022	Biological evaluation of medical devices - Part 18: Chemical characterization of materials
26.	EN ISO 14644-3:2019	Cleanrooms and associated controlled environments - Part 3: Test methods
27.	EN ISO 14644-4:2022	Cleanrooms and associated controlled environments - Part 4: Design, construction and start-up
28.	EN ISO 14644-5:2004	Cleanrooms and associated controlled environments - Part 5: Operations
29.	EN ISO 14644-7:2004	Cleanrooms and associated controlled environments - Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)
30.	EN ISO 14644-8:2022	Cleanrooms and associated controlled environments - Part 8: Classification of air cleanliness by chemical concentration
31.	EN ISO 5832-3:2021	Implants for surgery. Metallic materials. Wrought titanium 6-aluminium 4-vanadium alloy
32.	EN ISO 15223-1 :2021	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
33.	EN ISO 17665-1: 2006	Sterilization of health care products. Moist heat. Requirements for the development, validation and routine control of a sterilization process for medical devices
34.	ISO/TS 13498: 2011	Dentistry — Torsion test of implant body/connecting part joints of endosseous dental implant systems
35.	EN 1642: 2011	Dentistry- Medical devices for dentistry - Dental implants

9 Revision Record

SSCP Revision Number	Revision Date	Reason for revision	Has it been approved by the notified body?
00	24-06-2022	Creation of the document	☐ In progress ☐ Yes Verification Language: English ☒ No
01	12.07.2023	Address change was made and the number of risks was increased. Updated the standard list	☐ In progress ☐ Yes Verification Language: English ☒ No