This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of key aspects of DTI abutment safety and clinical performance.

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

Contents

1 Device Description and General Information

1.1 Trade name of the device

DTI Abutment

1.1.1 Product Name

- STRAIGHT ABUTMENT
- ANGLED ABUTMENT
- ANATOMICAL STRAIGHT ABUTMENT
- ANATOMICAL ANGLED ABUTMENT
- Ti-BASE STRAIGHT ABUTMENT
- Ti-BASE ANGLED ABUTMENT
- BALL ABUTMENT
- TELESCOPIC ABUTMENT
- MULTI UNIT STRAIGHT ABUTMENT
- MULTI UNIT ANGLED ABUTMENT
- MULTI UNIT TITANIUM ABUTMENT
- LOCATOR ABUTMENT
- PREMILL ABUTMENT
- PEEK ABUTMENT
- UNIVERSAL ABUTMENT
- UCLA ABUTMENT
- HEALING ABUTMENT
- SINUS WIDE HEALING ABUTMENT

1.1.2 Product Sizes

- **Straight Abutment;**

Ultra Mini; Diameter: Ø3.0 / GH: 1, 2, 3, 4, 5 / H: 5.5

Mini; Diameter: Ø4.5 / GH: 1, 2, 3, 4, 5 / H: 5.5

; Diameter: Ø5.0 / GH: 1, 2, 3, 4, 5 / H: 5.5

; Diameter: Ø5.5 / GH: 1, 2, 3, 4, 5 / H: 5.5

; Diameter: Ø5.5 / GH: 1, 2, 3, 4, 5 / H: 7.0

; Diameter: Ø6.0 / GH: 1, 2, 3, 4, 5 / H: 5.5

Standard; Diameter: Ø4.5 / GH: 1, 2, 3, 4, 5 / H: 5.5

; Diameter: Ø5.0 / GH: 1, 2, 3, 4, 5 / H: 4.0

; Diameter: Ø5.0 / GH: 1, 2, 3, 4, 5 / H: 5.5

; Diameter: Ø5.0 / GH: 1, 2, 3, 4, 5 / H: 7.0

- **Angled Abutment**

Ultra Mini; Diameter: Ø3.0 / GH: 2 / Type X / Angled: 15

Mini; Diameter: Ø4.3 / GH: 2, 4 / Type: X, Y / Angled: 15, 25

Standart; Diameter: Ø4.5 / GH: 2, 4 / Type: X, Y / Angled: 15, 25

; Diameter: Ø5.5 / GH: 2, 4 / Type: X, Y / Angled: 15, 25

- **Anatomical Straight Abutment**

Ultra Mini; Diameter: Ø3.0 / GH: 1, 2, 3, 4, 5 / H: 5.5

Mini; Diameter: Ø4.5 / GH: 1, 2, 3, 4, 5 / H: 5.5

Standard; Diameter: Ø4.5 / GH: 1, 2, 3, 4, 5 / H: 5.5

; Diameter: Ø5.0 / GH: 1, 2, 3, 4, 5 / H: 5.5

- **Anatomical Angled Abutment**

Ultra Mini; Diameter: Ø3.0 / GH: 2 / Type X / Angled: 15

Mini; Diameter: Ø4.3 / GH: 2, 4 / Type: X, Y / Angled: 15, 25

; Diameter: Ø4.5 / GH: 2, 4 / Type: X, Y / Angled: 15, 25

; Diameter: Ø5.5 / GH: 2, 4 / Type: X, Y / Angled: 15, 25

Standard; Diameter: Ø4.5 / GH: 2, 4 / Type: X, Y / Angled: 15, 25

; Diameter: Ø5.5 / GH: 2, 4 / Type: X, Y / Angled: 15, 25

- **Ti-Base Straight Abutment**

Ultra Mini: GH: 0.6, 1.5, 2.5 / Hex: Hex, Non-Hex / S/L: S

Mini: GH: 0.6, 1.5, 2.5 / Hex: Hex, Non-Hex / S/L: S

Standard; GH: 0.6, 1.5, 2.5 / Hex: Hex, Non-Hex / S/L: S, L

- **Ti-Base Angled Abutment**

Mini: GH: 1.5, 2.5 / Hex: Hex, Non-Hex / S/L: S, L

Standard; GH:1.5, 2.5 / Hex: Hex, Non-Hex / S/L: S, L

- **Ball Attachment**

Ultra Mini; Diameter: Ø3.0 / GH: 1, 2, 3, 4, 5

Mini; Diameter: Ø3.5 / GH: 1, 2, 3, 4, 5

Standard; Diameter: Ø3.5 / GH: 1, 2, 3, 4, 5

- **Telescopic Abutment**

Ultra Mini

Mini

Standard

- **Multi Unit Straight Abutment**

Mini; GH: 1, 3, 5

Standard; GH: 1, 3, 5

- **Multi Unit Angled Abutment**

Mini; GH: 1, 3, 5 / Angled: 20, 35

Standard; GH: 1, 3, 5 / Angled: 20, 35

- **Multi Unit Titanium Abutment**

Hex: Hex, Non-Hex

- **Locator Abutment**

Ultra Mini; Diameter: GH: 1, 2, 3, 4, 5

Mini; Diameter: GH: 1, 2, 3, 4, 5

Standard; Diameter: GH: 1, 2, 3, 4, 5

- **Premill Abutment**

Ultra Mini; Diameter: GH: A, B, C, D, E

Mini; Diameter: GH: A, B, C, D, E

Standard; Diameter: GH: A, B, C, D, E

- **PEEK Abutment**

Ultra Mini : Hex, Non-Hex

Mini : Hex, Non-Hex

Standard : Hex, Non-Hex

- **Universal Abutment**

Ultra Mini : Hex, Non-Hex

Mini : Hex, Non-Hex

Standard : Hex, Non-Hex

- **UCLA Abutment**

Mini : Hex, Non-Hex

Standartd: Hex, Non-Hex

- **HEALING ABUTMENT**

Ultra Mini; Diameter: Ø3.0 / GH: 1, 2, 3 / H: 3.0

; Diameter: Ø3.0 / GH: 1, 2, 3/ H: 5.0

; Diameter: Ø3.0 / GH: 1, 2, 3 / H: 7.0

Mini; Diameter: Ø4.5 / GH: 1, 2, 3 / H: 3.0

; Diameter: Ø4.5 / GH: 1, 2, 3 / H: 5.0

; Diameter: Ø4.5 / GH: 1, 2, 3 / H: 7.0

; Diameter: Ø5.0 / GH: 1, 2, 3 / H: 3.0

; Diameter: Ø5.0 / GH: 1, 2, 3 / H: 5.0

; Diameter: Ø5.0 / GH: 1, 2, 3 / H: 7.0

; Diameter: Ø5.5 / GH: 1, 2, 3 / H: 3.0

; Diameter: Ø5.5 / GH: 1, 2, 3 / H: 5.0

; Diameter: Ø5.5 / GH: 1, 2, 3 / H: 7.0

; Diameter: Ø6.0 / GH: 1, 2, 3 / H: 3.0

; Diameter: Ø6.0 / GH: 1, 2, 3 / H: 5.0

; Diameter: Ø6.0 / GH: 1, 2, 3 / H: 7.0

Standard; Diameter: Ø4.5 / GH: 1, 2, 3 / H: 3.0

; Diameter: Ø4.5 / GH: 1, 2, 3 / H: 5.0

; Diameter: Ø4.5 / GH: 1, 2, 3 / H: 7.0

; Diameter: Ø5.5 / GH: 1, 2, 3 / H: 3.0

; Diameter: Ø5.5 / GH: 1, 2, 3 / H: 5.0

; Diameter: Ø5.5 / GH: 1, 2, 3 / H: 7.0

- **SINUS WIDE HEALING ABUTMENT**

Ultra Mini

Mini

Standard

1.2 Manufacturer 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

868067149TRAV9

1.5 Classification of Device

Medical Device Directive Annex 9-Rule 8:

Based on rule 8 of the relevant legislation, DTI ABUTMENT has been 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 Use of the Device

2.1 Intended of Use

DTI Abutments are designed for use on the upper or lower jaw and are used to support dental restorations to restore chewing function.

Abutments combined with two-stage implants are used as the basis for fixing dental restorations in both jaws. Restorations can be made by replacing a single tooth with fixed dentures, using fixed dentures.

2.2 Indications and target populations

2.2.1 Indications

DTI Abutments are prefabricated prosthetic components attached directly to an endosseous dental implant and are indicated for use to support prosthetic rehabilitation.

2.2.2 Target populations

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

2.3 Contraindications or limitations

The abutment is suitable for patients outside these contraindications.
- Patients who are medically unsuitable for an oral surgical procedure.
- Patients whose adequate size, number, or desired positions of implants cannot be achieved to safely support functional or ultimately parafunctional loads.
- Patients who are allergic or hypersensitive to titanium, PEEK (Polyetheretherketone), POM(Polyoxymethylene), material.

3 Description of the Device

3.1 Description of the device

44879: Dental implant superstructure, permanent.

DESCRIPTION: A prefabricated device that is added to or forms the superstructure on dental implants to assist the mimic preparations of the natural tooth. This device is used during dental implant restorative processes and creates a permanent intermediate fixation level between the dental implant and the final restoration (eg bridge, single tooth, denture). This device can be used for cemented or screw-retained restorations and typically consists of a foot, foot screws, and rollers. The device can be found in different shapes and designs (eg ball or stick) and can be made of many different materials (eg titanium, plastic, gold alloy).

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

3.2 Variant, reference and explanation of differences

According to their variants, the raw material differs in terms of their design and surface properties.

3.3 Accessories to be used with the device

- Implants
- Suitable drills

3.4 Other devices

Instruments and auxiliary equipment used 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 considered to be 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

The use of non-sterile devices may lead to tissue infections or infectious diseases. Before using the product, it should be used after sterilization according to the conditions specified by the manufacturer.

The product should not be used by patients who are allergic to its raw material.

The abutment should be selected in accordance with the area to be used and should be compatible with the implant to which it will be attached.

The Abutment System has not been evaluated for safety and compatibility in the MR environment. Not tested for heating, displacement, or image artifact in the MR environment. The safety of the Abutment System in the MR environment is unknown. Scanning a patient with this device may result in patient injury.

4.3 FSCA summary other relevant safety (if any)

There are no Field Safety Corrective Actions (FSCA) or Field Safety Notices (FSN) for any DTI product.

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

Summary of the latest approved PMCF plan for the device the planned currently valid PMCF includes four general PMCF activities: scientific literature review, customer complaint assessment, and two proactive customer surveys. The next scientific update Literature review is scheduled for 2021 based on the calculation of the review period.

If any risks, complications or unexpected device failures are detected and how they will occur, provided that no unexpected events occur and the devices in question are working as intended, all PMCF activities performed show in the 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 may be obtained from a variety of sources, including use and use in physicians' 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, particularly those involving a lack of osseointegration or overload restoration. The clinical data collected revealed that restorations could be made, and the patient's chewing function was restored, with the benefits outweighing any risks.

5.3 Ongoing or planned post-market clinical follow-up

Clinical evaluations will be made to identify new or previously unidentified risks that will cause a change in the benefit/risk ratio. Additionally, reviews will review changes in the latest technology.

6 Possible methods of diagnosis or treatment

Fixed Prostheses can be used.

7 Recommended profile and training for users

Dental implant surgery requires appropriate and adequate training. Experienced implant users as well as new clinicians are always strongly advised to receive specific training before embarking on a new treatment modality.

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	(ISO 10993-10:2010) 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	Medical Devices- Information to be supplied by the manufacturer
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