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

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

Contents

1 Description of the Device and General Information

1.1 Trade name of the device

Dental Drill

1.1.1 Product Name

Dental Drill

- Lance Drill
- Cortical Drill

AG Dental Drill

- AG
- AG Cortical
- AG Bone Expander

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

868067149TRDVF

1.5 Classification of Device

Medical Device Directive Annex 9 - Rule 6:

According to Rule 6, products that can be connected to active medical devices in section 2 are classified as Class IIA.

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

Dental drill is used in dental implant treatment by including the drills required in the process of dental implant placement.

2.2 Indications and target populations

2.2.1 Indications

Its use is indicated in cases where dental implants are more beneficial than conventional treatment (short edentulous arches, single tooth deficiencies, orthodontic retention) that cannot be treated with other prosthetic and surgical techniques (conditions with insufficient retention of existing teeth or tissue defects).

2.2.2 Target population

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

2.3 Contraindications or limitations

Cases where there is insufficient bone volume and/or quality. Serious internal medical problems, inadequate wound healing capacity, undeveloped maxillary and mandibular, inadequate general health status, uncooperative and unmotivated patient profile, drug and alcohol dependence, psychosis, weak immune system, uncontrollable endocrine problems, stainless steel allergy.

3 Description of the device

3.1 Description of the device

Intended of Use Surgical Drill Bits, drill bits and drill expanders are used in dental surgery with the aim of drilling a delicate hole of the appropriate depth and width in the bone of the oral cavity to facilitate the implantation of the dental instrument. These devices are made of stainless steel, can be reusable and must be attached to a motorized hood that provides rotational movement. These devices are sold in non-sterile conditions but can be sterilized by steam sterilization.

3.2 Variant, reference and explanation of differences

According to its variants, it differs in accordance with the raw material and bone.

3.3 Must be used with the device

- Implants
- Abutments

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 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 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 Aftermarket 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 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	Quality management systems - Requirements for regulatory purposes
2.	EN ISO 10993-1: 2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
3.	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
4.	EN ISO 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
5.	EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
6.	EN ISO 11140-1:2014	Sterilization of health care products — Chemical indicators — Part 1: General requirements
7.	EN ISO 20417:2021	Medical Devices- Information to be supplied buy the manufacturer
8.	EN ISO 15223-1:2021	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
9.	EN 62366-1:2015+A1:2020	Medical devices- Part 1: Application of usability engineering to medical devices
10.	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
11.	ISO 7153-1:2016	Surgical instruments -- Materials -- Part 1: Metals
12.	ISO 13504:2012	Dentistry -- General requirements for instruments and related accessories used in dental implant placement and treatment
13.	ISO 17664:2021	Processing of health care products -- Information to be provided by the medical device manufacturer for the processing of medical devices

9 Revision Record

SSCP Revision Number	Revision date	Reason for revision	Has it been approved by the notified body?
00	24-06-2022	Released 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