Summary of Safety & Clinical Performance (SSCP)
Of ITL Dental Implant System

This summary of safety and clinical performance is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the ITL Dental devices. The information, as stated below, is intended for patients or clinicians. The SSCP is not intended to give general advice on the treatment of a medical condition.

Patients: Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation.

This SSCP is not intended to replace an Implant card or the Instructions For Use which is written to provide information on the safe use of the device.

1. Device identification and general information

1.1 Device Trade Name(s):
ITL Dental Implant System, including implants, abutments, healing caps, and screws

1.2 Manufacturer's Name and Address:
Emery Enterprises, Dba ITL Dental,
31 Peters Canyon, Irvine, CA 92606, USA

1.3 ITL Dental's SRN is:
SRN- US-MF-000029053

1.4 ITL Dental Implant System Basic UDI-DI:
The basic UDI-DI is 81768602100105A

1.5 Medical device nomenclature description/text:
P010201 "Dental Implants & Accessories"

1.6 The Class of the ITL Dental Implants;
Class IIb

1.7 Year when the first certificate (CE) was issued covering the device system:
ITL Dental Received it's first CE Mark in 2016

1.8 The EU authorized representative for ITL Dental is:
EUCEREP, Ronald Dahllaan 33, 5629MC, Eindhoven, The Netherlands SRN NL-AR-000001966

1.9 The Notified Body is:
Intertek Medical Notified Body AB, NB 2862, Kista, Sweden

2.0 The intended purpose of the device and any indications, contraindications and target populations

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2.1 Intended Purpose:

The intended purpose is to replace missing, and/or compromised natural teeth including the tooth (crown), which is above the gumline, and the root which anchors to the tooth (crown).

2.2 Indications and target population:

Indication: Implants are to be placed only by dentists, doctors or operators trained in the use and placement of dental implants. Dental implants are by prescription only. The indication for the use of dental implants is the use of a crown and a titanium implant as a replacement, providing the patient with a long term complete and stable replacement for their missing/compromised teeth. The titanium alloy implants are gamma sterilized by ITL Dental prior to shipment to the dental practitioner. The implants are inserted into the patient's jawbone enabling the bone to fuse around the implant for stability. This process, called osseointegration, usually takes 3-6 months. Once the healing is complete the dental practitioner places an abutment on the implant and eventually a crown will be placed for the final restoration. The abutments and healing caps are sterilized by autoclave by the licensed dental practitioner prior to insertion into a patient's mouth. Patients may choose to have just one implant or replace as many as advised by a licensed dental practitioner who has received adequate dental restorative surgical and/or prosthetic training. The devices are considered single use.

Target Population: The intended patient group is usually adults but may include children as determined by the licensed dental practitioner.

2.3 Contraindications: Include, but are not limited to: biological hypersensitivity and/or an allergic reaction to the material (titanium alloy,) HA coating and/or surface treatment, uncontrolled diabetes, clotting disorders, anticoagulant therapy, metabolic bone disease, chemotherapy or radiation therapy, chronic periodontal inflammation, insufficient soft tissue coverage, metabolic or systemic disorders associated with wound and/or bone healing, use of pharmaceu-ticals that inhibit or alter natural bone remodeling, any disorders which inhibit a patient's ability to maintain adequate daily oral hygiene. Relative contraindications may include habits such as tobacco use, alcohol consumption, poor oral hygiene, bruxism, nail biting, pencil biting and improper tongue habits depending on severity.

3.0 A description of the device, including a reference to previous generation(s)

3.1 Description of the device/previous generation(s): ITL Dental's implant system has been on the market for over 15 years without changes and or variants. ITL Dental implants, abutments, healing caps, and screws, are single use devices. The dental implant is sold sterilized (gamma sterilization), and is surgically placed, by dentists, in the jawbone to help restore the chewing function of patients who may be missing one or more teeth. Healing abutment caps, such as the healing, or transitional healing caps, can be used as a temporary abutment during the healing period. After the healing period, also known as the osseointegration process, the healing abutment will be replaced with the permanent titanium alloy abutment. This titanium alloy abutment is connected to the implant which will provide the support for a traditional dental prosthesis such as a crown or bridge. A denture may also be secured to the dental abutment. As the implants, abutments, and healing caps are made from surgical grade titanium alloy (Ti6Al4V) generally, while the life expectancy of titanium is indefinite, once implanted, is it expected that with proper care, the implants have a life span over 10 years.

There have been no safety and performance issues that have caused any patient harm.

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4.0 Information on any residual risks and any undesirable effects, warnings and precautions

4.1 Residual Risks, Side Effects, Interactions, and Complications: The dental practitioners should pay attention to the negative and positive usage of titanium dental implants per each patient, and need to be aware of the problems that may arise after the implantation, and should be able to diagnose any issues disclosed by the patients, in spite of very rare occurrences of negative reactions.

The licensed dental practitioner must determine patient's suitability for implants by considering the patient's health. Impairments such as vascular conditions, uncontrolled diabetes, metabolic bone disease, chemo and/or radiation therapy, chronic periodontal inflammation, insufficient soft tissue, heavy smoking which could cause gum disease, and/or mouth cancer, and use of prescription medicines which may contradict the patient's ability to heal, may make a patient not eligible for dental implantation. Additionally, the patient's bone condition may be a risk factor as well as bruxing, clenching, gnawing of their teeth day or night. Other issues, such as the possibility that a patient may be allergic to the titanium alloy implant and abutment, and/or other accessories such as the stainless steel instruments used during the procedure, may jeopardize the successful implantation.

Complications/side effects associated with dental implants included, but are not limited to: temporary pain, swelling, speech impediments, and gingival infections. Longer term could be paresthesia, dyesthesia, loss of bone, infections, problem with aesthetics, nerve damage, exfoliation, hyperplasia and eczema.

4.2 Warnings which may impact the effectiveness of the implantation: Include but are not limited to: uncontrolled para-functional habits (e.g. bruxing, clenching, gnawing), insufficient height and/or width of bone, insufficient inter-arch space, intraoral infection, poor or non-compliant patient oral-hygiene. Other issues, such as the possibility that a patient may be allergic to the titanium alloy implant and abutment, and/or other accessories such as the stainless steel instruments used during the procedure, may jeopardize the successful implantation. It is important that the patient share with the dental practitioner any known allergies, illnesses, and behaviors which may impact the success of the procedure.

4.3 Summary of any field safety corrective actions: There have not been any field safety corrective action (FSCA) for any ITL Dental Product

5.0 The summary of clinical evaluation on post-market clinical follow-up (PMCF)

5.1 Summary of clinical data related to equivalent device, if applicable Any clinical data available is based on ITL Dental's devices.

5.2 Summary of clinical data from conducted investigations of the device before the CE-marking, if Applicable: There were no specific clinical investigations performed on the device prior to CE-marking.

5.3 Summary of clinical data from other sources, if applicable: Clinical data exists from a variety of sources, including use in doctor offices or clinics and use recorded in clinical articles and surveys. The clinical data within the Clinical Evaluation Report utilizes data gathered from actual ITL Dental devices. The clinical data gathered from these sources show high survival rates. There are few failures which are expected, and usually involving lack of osseointegration or overloading of the restoration. The clinical data gathered suggested the benefits outweighed any risks as final restorations were able to be constructed and the patient's chewing functions restored with high survival rates.

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5.4 An overall summary of the clinical performance and safety: Device Safety and clinical performance is important to ITL Dental who designs and manufactures the dental implants and restorative components which are part of the system, according to applicable US, EU and other applicable International standards. The titanium alloy dental implants, abutments and healing caps are fatigue tested and bio assessed which prove them to have exceptional strength and biocompatibility. ITL Dental's implant system has been on the market for over 15 years without any safety and performance issues that has caused any patient harm.

At this time, the low compliant rate regarding ITL Dental's implants, including uncoated and coated (HA) implants shows high survival rates per ITL Dental PMS studies and literature reviews. Additionally, different sizes are not significantly different from one another in terms of survival rates. Abutments, either straight or angled, have also shown high survival rates. The benefit/risk ratios are acceptable for both overall and for individual products. The biocompatibility risk of the materials used in the ITL Dental Implant System continues to be determined low due to published literature and recognized international standards, as well as decades of intended use with low complaints.

5.5 On going or planned post-market clinical follow-up: Post-market clinical follow-up plan is established to proactively collect and evaluate clinical data from the use in or on humans of a device which bears a CE marking and is placed on the market or put into service within its intended purpose. The aim of confirming the safety and performance throughout the expected lifetime of the devices includes ensuring continued acceptability of identified risks and of detecting emerging risks on the basis of factual evidence. Clinical evaluations will be performed to determine any new or previously unidentified risks that would cause a change in the benefit/risk ratio. In addition, the evaluations will review any changes to state-of-the-art. Surveys, feedback, complaints, and literature reviews continue to be the post-market clinical follow-up method.

6. **Possible diagnostic or therapeutic alternatives:** While the only way to replace a tooth root is to implant a device, it is possible that patients may chose to forgo implantation and/or choose crowns/dentures over implants. Although, leaving nothing in the place of tooth root is not a beneficial therapeutic alternative for the patient in the long run due to bone resorption. In spite of preferred alternatives, which may not provide long term solutions, with proper dental hygiene and regular checkups, as suggested by the licensed dental practitioner, it is possible that the implants could last a lifetime, which is not always the case for bridges, partials, or crowns over broken teeth, therefore implants are a reasonable and safe choice when a patient requires teeth replacements.

7. Suggested profile and training for users: The dental practitioners should take training as provided by practitioners who are qualified to perform dental implantation as well as have knowledge of implant systems. Users should pay attention to the negative and positive usage of titanium dental implants per each patient, and need to be aware of the problems that may arise after the implantation, and should be able to diagnose any issues disclosed by the patients, in spite of very rare occurrences of negative reactions. Abutments, healing caps and other ITL Dental accessories are not sold sterile and it is up to the dental practitioner to sterilize (i.e. autoclave), the devices prior to use. Implants must be stored in a dry place, at a controlled temperature, in their original packaging. Dental implants are provided in sterile vials affixed to fixture mounts. The plastic cap attached to the fixture mount is intended to be used to transport the implant to the prepared surgical site. They should be trained not to handle implant surfaces directly. Users are advised to visually inspect the package to ensure seals and contents are intact and in their original packaging prior to use.

Training should include actions during the pre-operative stage, availability of bone-height and width must be determined. Appropriate radiography should be used to determine bone availability, optimal implant location and to avoid structures such as the mandibular canal, maxillary sinuses and adjacent teeth. Training should include contraindications such as electro surgery is not advised due to the conductive nature of metallic implants. Post-surgery

requirements will be determined by the licensed dental practitioner and should be followed closely by the patient to protect from rejection, infection and/or any other negative reactions.

8. Reference to any harmonised standards and CS applied which includes standards used by ITL Dental's contract manufacturers

Standard:	Title:
ASTM F136 (2021)	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
EN 1642 (2011)	Dentistry. Medical devices for dentistry. Dental implants
EN 62366-1 (2015)	Medical devices: Part 1: Application of usability engineering to medical devices
EN ISO 10993-1 (2020)	Biological evaluation of medical devices. Evaluation and testing within a risk management process
EN ISO 11137-1 (2015)	Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11607-1 (2020)	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2 (2020)	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1 (2018)	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
EN ISO 13485 (2016)	Medical devices. Quality management systems. Requirements for regulatory purposes
EN ISO 14971 (2019)	Medical devices. Application of risk management to medical devices
EN ISO 15223-1 (2021)	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
EN ISO 20417 (2021)	Medical devices – Information to be supplied by the manufacturer
MDCG 2019-9 (2022)	Summary of safety and clinical performance – A guide for manufacturers and notified bodies
MDCG 2020-6 (2020)	Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC
MEDDEV 2.7/1 (2016)	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies
MEDDEV 2.12-1 (2013)	Guidelines on a Medical Devices Vigilance System

9. Revision history

SSCP-01 revision number	Date issued	Change description	Revision validated by the Notified Body
3.0	5/18/2023	Changed existing SSCP Rev 1 to Rev 3 to meet the guidance MDCG 2019-9	

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10.0 Devices applicable to the ITL Dental Implant System (by part number)

ITL Dental Implant System

P010201 Dental Implants (screws) /Abutments/Healing Caps Class IIb Rule 8

Internal Hex (IH) Implant

IH3210 lengths 8,10,11,13,16mm
IH3210A lengths 8,10,11,13,16 mm
IH3211 lengths 8,10,11,13,16 mm
IH3211A
IH3213
IH3213A
IH3216
IH3216A
IH328
IH328A
IH3710
IH3710A
IH3711
IH3711A
IH3713
IH3713A
IH3716
IH3716A
IH378
IH378A
IH4210
IH4210A
IH4211
IH4211A
IH4213
IH4213A
IH4216
IH4216A
IH428
IH428A
IH4710
IH4710A
IH4711
IH4711A

IH4713
IH4713A
IH4716
IH4716A
IH478
IH478A
IH5210
IH5210A
IH5211
IH5211A
IH5213
IH5213A
IH5216
IH5216A
IH528
IH528A
IH5710A
IH5710A
IH5711
IH5711A
IH5713
IH5713A
IH5716
IH5716A
IH578
IH578A

IHAW3210 IH HA Coating Implant

IHAW3210A
IHAW3211
IHAW3211A
IHAW3213
IHAW3213A
IHAW3216
IHAW3216A
IHAW328
IHAW328A
IHAW3710
IHAW3710A
IHAW3711
IHAW3711A
IHAW3713
IHAW3713A

IHAW3716
IHAW3716A
IHAW378
IHAW378A
IHAW4210
IHAW4210A
IHAW4211
IHAW4211A
IHAW4213
IHAW4213A
IHAW4216
IHAW4216A
IHAW428
IHAW428A
IHAW4710
IHAW4710A
IHAW4711
IHAW4711A
IHAW4713
IHAW4713A

IHAWP4716A IH HA Wide Implant
IHAWP478A
IHAWP5210A
IHAWP5211A
IHAWP5213A
IHAWP5216A
IHAWP528A

IHP4710 IH Narrow Implant
IHP4711
IHP4713
IHP4716
IHP478
IHP5210
IHP5211
IHP5213
IHP5216
IHP528

IHW3210 IH Wide Implant
IHW3210A

IHW3211
IHW3211A
IHW3213
IHW3213A
IHW3216
IHW3216A
IHW328
IHW328A
IHW3710
IHW3710A
IHW3711
IHW3711A
IHW3713
IHW3713A
IHW3716
IHW3716A
IHW378
IHW378A
IHW4210
IHW4210A
IHW4211
IHW4211A
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IHW428
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IHWP478
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IHWP5213
IHWP5216
IHWP528

Abutments

ACCM-1215-20 Implant Aesthetic Abutment IIb
ACCM-1225-20
ACCM-1315-30
ACCM-1325-30
ACCM-1415-40
ACCM-1425-40
ECA-6005
ECA-6015
ECA-6025

ACM-1115-10 Implant Angled Abutment IIb
ACM-1115-10P
ACM-1125-10
ACM-1215-20
ACM-1215-20P
ACM-1215-30
ACM-1215-30P
ACM-1225-20
ACM-1315-40
ACM-1315-40P
ACM-1325-30
ACM-1425-40
ACW-1115-10
ACW-1215-20

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AMS-1201 Analog 3.5P
AMU-1201 Analog for Multi Unit
AMU-1801-MLS Abutment
AMU-1811-M
AMU-1821-M
AMU-1831-M
AMU-3001-M
AMU-3011-M
AMU-3021-M
AMU-3031-M
ASM-0915 Implant Angled Abut Smooth IIb
ASM-0915LF
ASM-0925
ASM-0925LF
ASM-1115
ASM-1115LF
ASM-1125
ASM-1125F
ASM-1315
ASM-1325
AST-1115 15 D Implant Angled Abutment IIb
AST-1125
ASW-1115

AMB-1201 Implant Ball Abutments IIb
BHM-5032
BIS-0025
BMA-0020
BMA-0030
BMA-0040
BMA-0050
BMA-0920S
BMA-0930S
BMA-0940S
BMA-0950S
BMA-1820-S
BMA-1830-S
BMA-1840-S
BMA-1850-S
BMA-3020-S
BMA-3030-S
BMA-3040-S
BMA-3050-S

BMS-4010
BMS-4020
BMS-4030,
BMS 4040,
BMS 4050,
BMS 4060
BMT-0010S
BMT-0020S
BMT-0030S
BMT-0040S
BMT-0050S
BMT-0060S
BWA-1830-S
BWA-1840-S
BWT-0010S
BWT-0020S
BWT-0030S
BWT-0040S
BWT-0050S
BWT-0060-S

ECA-6005, Aes Connect Abut. 5, mmH 3.5P
ECA-6015 Aes Connect Abut 1.5 mmH 3.5P
ECA-6025 Aes Connect Abut 2.5 mmH 3.5P

EMA-0921-M MLS Implant System Abut IIb
EMA-0921-W
EMA-0931-M
EMA-0931-W
EMA-0941-M
EMA-0941-W
EMA-0951-M
EMA-1820
EMA-1831-M
EMA-1831-W
EMA-1841-M
EMA-1841-W
EMA-1851-M
EMA-1851-W
EMA-3021-W
EMA-3031-M
EMA-3031-W
EMA-3041-M
EMA-3041-W

EMA-3051-M
EMA-3051-W
EMU-0011
EMU-0021
EMU-0031
EMU-0041
EMU-0051
EMU-0910
EMU-1810
EMU-3010
EWA-1820
EWU-0011
EWU-0021
EWU-0031
EWU-0041
EWU-0051
EWU-0910
EWU-1810
EWU-3010

ITC-0010 Implant Immediate Temp Abut IIb
ITC-0020
ITC-0030
ITC-0040
ITC-0050
ITC-0060

MUC-0021 Implant MLS Connection IIb
MUC-0031
MUC-0041
MUC-0051

SCCM-1220 Implant Straight Abutments IIb
SCCM-1330
SCCM-1440
SCCW-1220
SCCW-1330
SCCW-1440
SCH-8540
SCM-1110
SCM-1220
SCM-1330
SCM-1440
SCP-2580
SCS-3011

SCS-3012
SCS-3013
SCS-3095
SCSC-1720
SCT-2213
SCT-3014
SCT-3018
SCT-3023
SCU-2315
SCW-1110
SCW-1220
SCW-1330
SCW-1440
SLM-1110
SLM-1110-G
SLM-1110P
SLM-1116
SLM-1220
SLM-1220-G
SLM-1220P
SLM-1226
SLM-1330
SLM-1330-G
SLM-1330P
SLM-1336
SLW-1110
SLW-1220
SLW-1330
SMS-0040
SMS-6040
SMT-1210
SMT-1210R

STM-0910 Abutment STD 3.5p 9mmH G
STM-1110 Abutment STD 3.5p 11mmH G
STM-1120 Abutment STD 3.5p 11mmH G, T
STM-1310 Abutment STD 3.5p 13mmH G
STW-1110 Abutment STD 4.5p, 11mmH
SWS-0040 Abutment 3D scan 4.5p, R
SWS-6040 Abutment 3D scan 4.5p Hex

WCA-0920-M OLS Implant Abutments IIb
WCA-0920-W
WCA-0930-M
WCA-0930-W

WCA-0940-M
WCA-0940-W
WCA-0950-M
WCA-0950-W
WCA-1820-M
WCA-1820-W
WCA-1830-M
WCA-1830-W
WCA-1840-M
WCA-1840-W
WCA-1850-M
WCA-1850-W
WCA-3020-M
WCA-3020-W
WCA-3030-M
WCA-3030-W
WCA-3040-M
WCA-3040-W
WCA-3050-M
WCA-3050-W
WCC-0020
WCC-0030
WCC-0040
WCC-0050
WCH-4823
WCH-5628
WCM-0000
WCM-0010
WCM-0020
WCM-0030
WCM-0040
WCM-0050
WCM-0000-SPE
WCM-0010-SPE
WCM-0020-SPE
WCM-0030-SPE
WCM-0040-SPE
WCM-0050-SPE
WCM-00600-SPE
WCP-2348
WCP-2348-H
WCPS-2348-H
WCT-900

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Implant Healing Caps Class IIb

HCC-4550
HCM-3720
HCM-3720S
HCM-3730
HCM-3730S
HCM-3740
HCM-3740S
HCM-3750
HCM-3750S
HCM-3760
HCM-3760S
HCM-3770
HCM-3770S
HCM-4020
HCM-4020S
HCM-4030
HCM-4030S
HCM-4040
HCM-4040S
HCM-4050
HCM-4050S
HCM-4060
HCM-4060S
HCM-4070
HCM-4070S
HCM-5020
HCM-5020S
HCM-5030
HCM-5030S
HCM-5040
HCM-5040S
HCM-5050
HCM-5050S
HCM-5060
HCM-5060S
HCM-5070
HCM-5070S
HCW-6030
HCW-6030S
HCW-6040
HCW-6040S
HCW-6050

HCW-6050S
HCW-6060
HCW-6060S
HCW-6070
HCW-6070S
HCW-6080
HCW-6080S
HCW-6530
HCW-6530S
HCW-6550
HCW-6550S

SCA-2385 Implant Screws Class IIb
SCA-2565
SCP-2580
SCU-2315
SMU-4023
SCS-3011
SCS-3012
SCS-3013
SCS-3095 END of ITL Dental Implant devices