(Form source: MDCG 2019-9)

SSCP PARTS:

PART A: FOR PROFESSIONALS

PART B: FOR PATIENTS

PART A: FOR PROFESSIONALS

Healthcare Professionals

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

*The SSCP is **NOT** intended to replace the Instructions For Use (IFU) as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients. It does not intend to replace the mandatory information on implant cards or in any other mandatory documents.*

1. Device identification and general information

1.1.Device trade name:	**CeraRoot Ceramic Dental Implant**
1.2. Manufacturer; name and address:	CeraRoot S.L. Parpers, 13. 08520 Les Franqueses del Vallès. Barcelona. Catalonia. Spain www.ceraroot.com
1.3. Manufacturer's single registration number (SRN):	ES-MF-000000251
1.4. Basic UDI-DI:	84354539CREC
1.5. Medical Device nomenclature description/text:	EMDN (CND) - P01020101 Dental Implants GMDN 55848 - Screw endosteal dental implant, one-piece. MDN 1103 - Non-active dental implant and dental material: dental implant, abutment. NBOG MD0403 - Dental implants. UMDNS 16744 - Prostheses, Dental, Implantable.
1.6. Class of device:	Class IIb
1.7. Year when the device was first CE-marked:	2006
1.8. Authorised representative:	Not applicable.
1.9. NB's name and single identification number:	BSI Group The Netherlands B.V. NB No. 2797
SSCP author: **PRRC:** **(Person Responsible for Regulatory Compliance)**	Dr. Josep Oliva María José Calderón

2. Intended use of the device

2.1. Intended purpose:

The CeraRoot Ceramic Implant is suitable for oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially edentulous patients (unless specific indications and limitations are specified).

2.2. Indications and intended patient groups:

The prosthetic restorations used are single crowns, fixed partial or full dentures, which are cemented or connected to the implants through the corresponding components.
Reduced diameter implants (CeraRoot 12) are recommended for upper lateral incisors or lower incisors only.

Intended patient population: Any patient missing one or more teeth without the mentioned contraindications below. The CeraRoot dental implants are specially indicated in patients with metal allergies and chronic illness due to metal allergies.

2.3. Contraindications:

The patient should have absence of local and systemic contraindications, normal healing capacity, good oral hygiene, and presence of healthy and sufficient bone. The placement of dental implants should not be done in patients with health problems, disease or any physical or psychological condition to which an oral surgery may be contraindicated.
-Relative contraindications:
Previously irradiated bone, diabetes, anticoagulant medication, hemodynamic problems, bruxism, Para functional habits, bad bone anatomy, smokers, none controlled periodontitis, malocclusions, TMJ problems, diseases in the oral cavity, pregnancy and insufficient oral hygiene for adequate health.
- Local contraindications: insufficient bone quantity or quality, remaining of roots, localized periodontal disease, any pathology in the neighbouring teeth.
- Special contraindications: CeraRoot 12 implant is NOT suitable for applications in areas where pronounced rotation and translation movements occur, causing the implant to be subjected to large bending movements, including but not limited to: Restoration of posterior teeth in the upper or lower jaw; Single-tooth restoration of canines and central incisors in the upper or lower jaw; Any application involving retentive anchors.

3. Device description

3.1. Device description and material/substances in contact with patient tissues

CeraRoot® dental implants are made of zirconia (bioceramic according to ISO 13356). This is a one-piece implant without any connections and with three differentiated parts: the thread, the abutment, and the crown. The thread is in one end and is the endosseous part, and the opposite end is the abutment where the prosthetic restoration is cemented. The crown is the middle part of the implant and gives the emergence profile and the shoulder for the prosthetic restoration. CeraRoot® implants are certified according to the Regulation (EU) 2017/745 , Annex IX; Classification IIb). It's essentially a substitute for a natural root.
CeraRoot® dental implants are especially designed for the surgical implantation in the maxilla and mandible for the retention of fixed prosthetic devices, such as an artificial tooth, in order to restore patient aesthetics and chewing function. There are 7 different models of CeraRoot implants with different designs, actions, and indications. Each Model has 4 different lengths (8, 10, 12, and 14 mm). The CeraRoot dental implants can be used for single or multiple unit restorations in splinted or non-splinted applications. CeraRoot dental implants may be placed immediately in tooth extraction sites, providing that the initial stability requirements detailed in the surgical manual are satisfied. The CeraRoot dental implants are specially indicated in patients with metal allergies and chronic illness due to metal allergies.

3.1.1 Information about medicinal substances in the device, if any

This medical device contains NO medicinal substances.

3.1.2 Description of how the device is achieving its intended mode of action

Surgery:

Standard surgical procedures for dental implants must be followed. The implant site must be prepared according to the treatment plan and using a surgical guide. The main aim during implantation is to achieve a good primer stability of the implant of about 35 Newtons. Standard drilling systems might be used to prepare the implant site. The recommended drill sequences of diameters are stated in Table 1. The implant site should be prepared in a way that allows the implant to be inserted in a position where the shoulder of the implant is at the margin level of the final restoration.

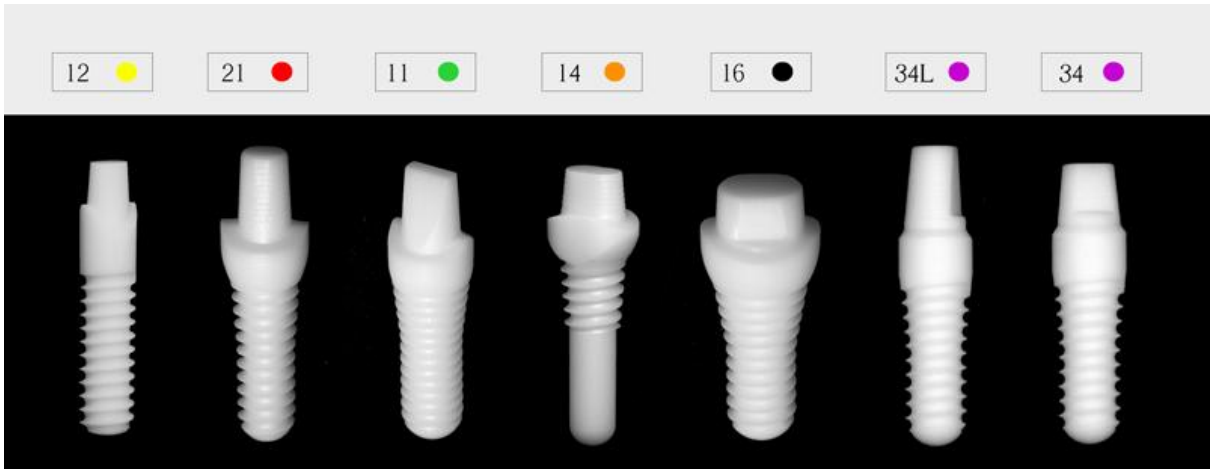
After the implant site is prepared, the implant must be screwed into the bone using the special transfer key, and taking into consideration that the concave sides of the implant scallop shoulder are the buccal-lingual sides, and the convex sides are the interproximal ones. The BICUSPID model of implant is an exception and it is a press-fit technique using a surgical hammer and a pressing instrument with a plastic or rubber end. This plastic-ended instrument must press-fit the implant into position with the hammer using axial light forces. The abutment part of the implant must not enter into occlusion with the antagonist, to avoid premature loading forces and the loss of the implant. If for any reason after implantation the implant has mobility or very low primer stability, then it is mandatory to make a rigid splint of the implant with the neighbouring teeth or implants.

3.2. A reference to previous generations or variants.

There is not a previous generation of the ceramic dental implant produced by CeraRoot S.L.

Variants:

There are **7 different models/types: CeraRoot 11, 12, 14, 16, 21, 34 & 34L** of CeraRoot implants with different designs, actions, and indications. Each Model has 3 or 4 different lengths (8, 10, 12, and 14 mm). and is identified with a colour.



3.3. Description of accessories, if any:

Accessories for surgery:

These parts include tools like implant transporters, drivers, ratchets, impactor, hammer, surgical tray, drill extender, handpiece adapter… All these devices are Class I accessories.

Accessories for prosthesis:

These parts include laboratory analogues for laboratory use, and temporary crowns and healing rings for clinical use, to cover the implant abutment during the healing phase.

3.4. Other devices and products intended to be used in combination with the device, if any:

The dental implants are intended to be used in combination with dental rotary instruments (bur, drill and countersink) that are sold separately. They are necessary for use.

4. Information on any residual risks and any undesirable effects, warnings and precautions.

4.1. Residual risks and undesirable effects.

4.1.1 Description of residual risks an undesirable effects
-Side-effects:
- Temporary complaints: pain, swelling, phonetic difficulties, gingival inflammation.
- More prolonged complaints: no integration of the implant, chronic pain associated to the implant, permanent paresthesia, disestesia, lost of bone in the bone crest, local or systemic infections, oro-nasal or oro-antral fistulas or inflammation or pain, temporal or permanent damage to neighbouring teeth, implant fracture, bone fracture, restoration fracture, aesthetic problems, damage of nerve structures, implant mobility, exfoliation of the implant, gingival hyperplasia, bone or gingival necrosis, radiological rarefactions.
- Special attention: do not exceed 35Ncm of torque during the implant insertion to avoid bone and/or implant fractures.

The risks have been identified and listed in the company FMEA risk analysis, including infection, fracture, no integration, and other risks associated with surgical treatments with sterile implantable medical devices. Subsequently the control measures were recorded as well as the effectiveness control evidence.

4.1.2 Quantitative data for the year period 2020

Total reports and complaints received	**78**
Reportable serious incidents	**0**
Implant fracture during installation	**4 (0,24%)**
Functional fracture after integration	**1 (0,06%)**
Failure before integration	**29 (1,77%)**
Failure after integration	**4 (0,24%)**
Recalls	**0**
Vigilance (FSCA,FSN)	**0**
Accessories failures	**0**
Associated drills failures	**0**
Source: CeraRoot customer complaints database.	

4.2. Warnings and precautions pertaining to the device.

4.2.1 Warnings

Products must be secured against aspiration when handled intraorally. Aspiration of products may lead to infection or unplanned physical injury.

Avoid approaching the proximity of the mandibular nerve channel during implant bed preparation and implant insertion. Nerve damage may result in anaesthesia, paresthesia and dysesthesia.

Do not exceed recommended insertion torque as this might cause bone necrosis.

No grinding of any part of the implant is allowed since the conditions of this can not be controlled by the manufacturer. If for any reason the user has to grind the implant this has to be a minor adjustment and always using fine diamond burs (red or yellow) with water refrigeration. Grinding can lead to a reduction in structural integrity of the implant material, thus causing implant fracture during normal occlusal loading. There is also the risk of bone necrosis due to excessive heat which is generated during the grinding of ceramics. Grinding of any part of the implant will void any warranties expressed or implied by CeraRoot S.L.

4.2.2. Precautions:

4.2.2.1 Clinical Use

Inadequate bone volume and/or quality might lead to insufficient primary stability and conse- quently mobility, and even loss of the implant.

Should the bone volume be insufficient to guarantee primary stability, follow a two-stage surgical approach by regenerating the bone tissue first, prior to implant insertion.

In case of very poor bone quality the removal force of the snapped transfer piece might lead to a loss of implant due to insufficient primary stability.

Avoid corrections of the vertical position using reverse rotations (counterclockwise). This may lead to a decreased primary stability.

Sterile handling is essential. Never use potentially contaminated components. Contamination may lead to infections.

Special patient conditions like diabetes, bruxism, bone metabolic disorders (e.g. osteoporosis), irradiated patients or pregnancy could lead to reduced success rates and survival rates of the implants and need therefore careful assessment by the responsible surgeon and information to the patient.

Due to the one-piece design of the CeraRoot Ceramic Implant, there is a higher risk of implant removal if the abutment is damaged or fractured. In case that the implant needs to be explanted, it should be done with a minimally invasive technique (for example removal of the buccal bone using piezosurgery technique).

Special caution is required for cantilever pontic applications, as no data are available on this treatment option.

The CeraRoot dental implants have not been evaluated for safety and compatibility in the Magnetic Resonance environment. The CeraRoot dental implants have not been tested for heating or migration in the Magnet Resonance environment. The CeraRoot dental implants are made out of ceramic and this material is known to be safe in the MR environment.

4.2.2.2 MRI (Magnetic Resonance Image safety information)

CeraRoot implants are considered MR safe and thus no warnings are included in this IFU, since the raw material is ceramic and this has no interaction with the magnetic forces associated with MR.

4.2.2.3 Storage

The implants must be stored in a dry place in the original packaging, protected from direct sunlight and at room temperature (10ºC to 35ºC). Improper storage may compromise essential material and design characteristics leading to device failure.

Do not use CeraRoot dental implants after the expiry date indicated on the packaging or if the package is damaged. Use of CeraRoot dental implants after the expiry date might lead to infections.

4.3 Other relevant aspects of safety, including a summary of any field safety corrective action, (FSCA including FSN) if applicable:

Up to the date of this SSCP there has not been any FSCA or FSN for this family of CeraRoot products.

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF):

5.1 Summary of clinical data related to equivalent devices, if applicable.
It is not applicable. The Clinical Evaluation of CeraRoot Dental Implants is not based on equivalent devices.

5.2. Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable.
Not applicable.

5.3 Summary of clinical data from other sources, if applicable.

5.3.1 Systematic literature review
The literature review has been performed in the Clinical Evaluation Report (TD-CR-A16.2-2 CER) :
"Ceramic as a material has a firm place in the replacement of teeth, showing good results also over longer periods. A very obvious advantage of ceramics as a denture material is the adaptation of the denture to the individual tooth shade. In addition, ceramics are very well tolerated, as no allergies to this material are known to date. It is particularly hard and therefore also abrasion-resistant. In addition, ceramic dentures also look closest to natural teeth and can usually only be distinguished from a dentist or dental technician. Furthermore, any available Post-Market Surveillance (PMS) data have been evaluated in order to substantiate the benefits-versus-risks profile of the investigational CeraRoot CERAMIC DENTAL IMPLANTS (see Chapter 9.5)
In summary, based upon the appraisal and analysis results reported for the potentially equivalent or at least substantially comparable devices, and considering the fact that the investigational CeraRoot CERAMIC DENTAL IMPLANTS and all related procedures represent current medical practice and a positive benefits-versus-risk profile in comparison to substantially comparable medical devices (see Chapter 9.4 and Table 7 above) and to alternative treatment options (see Chapter 9.1), the investigational CeraRoot CERAMIC DENTAL IMPLANTS is assessed to fulfill the Essential Requirements, in particular Sections 1, 3 and 6 according to Annex I of the MDD 93/42/EEC [1], respectively the analogue General Safety and Performance Requirements as specified in the MDR 2017/745 Annex I Sections 1, 6, and 8 [2]. Therefore, the CeraRoot CERAMIC DENTAL IMPLANTS under evaluation can be expected to provide the claimed technical and medical safety and performance profile, an potential undesirable clinical effects and risks seem well controlled and acceptable, when weighed against the benefits of the investigational CeraRoot CERAMIC DENTAL IMPLANTS in the replacement of missing teeth."

5.3.2 Clinically relevant information based on clinical data obtained from the implementation of the manufacturer's PMCF and PMS plans.
In summary, the first PMCF study #140110 was a multicenter retrospective study for the period 2014-2018 with 144 implants placed in 5 different countries, and the results showed a success rate of 97,23%. These results are similar to those reported for state of the art in scientific literature for ceramic dental implants, as well as for titanium dental implants, therefore a benefit-risk ratio is acceptable for the CeraRoot ceramic dental implant.

5.3.3 Analysis of clinical data from medical device registries.
We performed a search in the following online databases;

- 510(k) Premarket Notification = we conclude that the CeraRoot ceramic dental implant is the one of its kind with the longest history in the market.
- MAUDE Database = we performed a search during the Clinical Evaluation. There have not been any serious incidents reported.

5.4 An overall summary of the clinical performance and safety

5.4.1 Clinical benefits for the patient

The Clinical Evaluation Report (TD-CR.A16.2-2 CER) has described the clinical benefits for the CeraRoot ceramic dental implant as:

- Biologically unrestrictedly compatible.
- Shade corresponds to the natural tooth colour.
- High bending strength and hardness.
- Presents enhanced biocompatibility, improved mechanical properties, high radiopacity, and easy handling during abutment preparation.
- Zirconia ceramic is well tolerated by bone and soft tissues and possesses mechanical stability.
- Besides strength considerations, Y-TZP implant abutments offer enhanced biocompatibility, metal-like radiopacity for better radiographic evaluation, and ultimately reduced bacterial adhesion and plaque accumulation.
- Safety and performance data:
    - Survival rate: 98.69% after 15 years.
    - Fracture rate: 0.05% after 15 years.
- Patient satisfaction (PROMS) period 2020-2021:
    - Overall patient satisfaction: 90.91% very satisfied; 9.09 Little satisfied
    - Would you recommend the treatment?: 90.91% Yes; 9.09 Don't Know

5.4.2 Benefit risk assessment

The product Clinical Evaluation Report has described the overall conclusion and assessment of the Benefits-Versus-Risks Ratio as:

"... Based upon the answers provided to the above Analysis Questions, which are substantiated by the appraisal and analysis of extensive pertinent clinical datasets, and considering the reported potential risks and side-effects for the investigational CeraRoot CERAMIC DENTAL IMPLANTS, potentially equivalent or at least substantially comparable other devices, a positive benefits versus- risks profile can be stated for the device CeraRoot CERAMIC DENTAL IMPLANTS under evaluation,provided that it is applied in accordance with its intended use, as outlined in the Manufacturer's information materials, in particular in the Instructions for Use. The investigation at CeraRoot CERAMIC DENTAL IMPLANTS and all related treatments represent current medical practice and state of the art technologies for the treatment of patients with missing of one or several teeth (or hopeless teeth), with the replacement of teeth claimed by the Manufacturer.
Based upon the pertinent clinical data identified, appraised and analyzed in terms of MEDDEV 2.7/1 [3], it is concluded that the investigational CeraRoot CERAMIC DENTAL IMPLANTS fulfills the Essential Requirements, in particular Sections 1, 3 and 6 according to Annex I of the MDD 93/42/EEC[1], respectively the analogue General Safety and Performance Requirements as specified in the MDR 2017/745 (EU) Annex I Sections 1, 6 and 8 [2].
Therefore, the investigational CeraRoot CERAMIC DENTAL IMPLANTS can be expected to provide the claimed technical and medical safety and performance profile, and potential undesirable clinical effects and risks seem well controlled and acceptable, when weighed against the benefits of the investigational CeraRoot CERAMIC DENTAL IMPLANTS in the replacement of teeth. Therefore, a continued marketing of the CeraRoot CERAMIC DENTAL IMPLANTS can be supported without restrictions."

-Side-effects:

- Temporary complaints: pain, swelling, phonetic difficulties, gingival inflammation.
- More prolonged complaints: no integration of the implant, chronic pain associated to the implant, permanent paresthesia, disestesia, lost of bone in the bone crest, local or systemic infections, oro-nasal or oro-antral fistulas or inflammation or pain, temporal or permanent damage to neighbouring teeth, implant fracture, bone fracture, restoration fracture, aesthetic problems, damage of nerve structures, implant mobility, exfoliation of the implant, gingival hyperplasia, bone or gingival necrosis, radiological rarefactions.
- Special attention: do not exceed 35Ncm of torque during the implant insertion to avoid bone and/or implant fractures.

Warnings:

Products must be secured against aspiration when handled intraorally. Aspiration of products may lead to infection or unplanned physical injury.
Avoid approaching the proximity of the mandibular nerve channel during implant bed preparation and implant insertion. Nerve damage may result in anaesthesia, paresthesia and dysesthesia.
Do not exceed recommended insertion torque as this might cause bone necrosis.
No grinding of any part of the implant is allowed since the conditions of this can not be controlled by the manufacturer. If for any reason the user has to grind the implant this has to be a minor adjustment and always using fine diamond burs (red or yellow) with water refrigeration. Grinding can lead to a reduction in structural integrity of the implant material, thus causing implant fracture during normal occlusal loading. There is also the risk of bone necrosis due to excessive heat which is generated during the grinding of ceramics. Grinding of any part of the implant will void any warranties expressed or implied by CeraRoot S.L.

From the product Clinical Evaluation Report the following Safety and Performance data and conclusions can be extracted: Benchmarks for CeraRoot implants from PMS activities (uncontrolled clinical setting from customers. Three (3) years average 2018-2020 data) :

- CeraRoot Survival rate = 98.38 % (failure 1.62%)
- CeraRoot Fracture rate = 0.033%
- Customer product satisfaction = 96.67%
- Patient satisfaction (PROMS) period 2020-2021:
    - Overall patient satisfaction: 90.91% very satisfied; 9.09 Little satisfied
    - Would you recommend the treatment?: 90.91% Yes; 9.09 Don't Know

5.5 Ongoing or planned post-market clinical follow-up (PMCF)
The first PMCF study #140110 was a multicenter retrospective study for the period 2014-2018 with 144 implants placed in 5 different countries, and the results after 4 years observation period showed a success rate of 97,23% (success definition = absence of persisting subjective discomfort such as pain, foreign body perception and/or dysesthesia (painful sensation); Absence of recurrent peri-implant infection with suppuration; Absence of tactile implant mobility; Absence of a continuous peri-implant radiolucency)

An other longer term PMCF Study #191220 - Retrospective for the period 2005-2020 concluded:
"The success rate of **98,69% over a period of 15 years** of retrospective PMCF demonstrates that the product is comparable with the state-of-the-art titanium dental implant studies. For this reason it can be concluded that 15 years of lifetime can be expected with the CeraRoot ceramic dental implant".

Actually there is a PMCF ongoing study:
PMCF Study #200806 - Prospective from the year 2020 (1Y, 5Y, 10Y)

As per results of PMCF studies performed to date have not been detected: emerging risks, complications or unexpected device failures in CeraRoot dental implants.

6. Possible diagnostic or therapeutic alternatives
The alternative to the ceramic zirconia dental implant is the metal titanium implant or the metal titanium alloy implant.

Other alternatives without implants are:
-Fixed prosthesis on teeth: to grind and mill teeth into abutments so that a prosthetic crown or bridge can be built and cemented on top of the teeth.
-Partial denture prosthesis: plastic device with metal or plastic retention on teeth.
-Complete denture prosthesis: when there are no teeth a denture is supported on the gum and the patient can use denture glue to improve the stability in the mouth.
- No restoration (no treatment): not restoring the hopeless or missing tooth. However this involves loss of chewing function, migration of remaining teeth.

7. Suggested profile and training for users

The product is a device made of ceramic intended to be surgically placed in the bone, such as artificial teeth, of the upper or lower jaw arches to provide support for prosthetic devices, and to restore the patient's chewing function.The following instructions are not sufficient for an immediate use of CeraRoot® dental implants. To use CeraRoot® dental implants it is recommended to be trained by a professional with experience in the system. CeraRoot® implants must be placed only by dentists, doctors or surgeons that have received specific training and have advanced experience in oral surgery, periodontics, implantology and prosthodontics. This is especially important because the surgical implantation technique for CeraRoot implants is complex. CeraRoot® Training Team offers periodic training courses and practical sessions for the users.

Practitioners must have knowledge of dental implantology and instruction in the handling of the CeraRoot® product described herein ("CeraRoot® Product") for using the CeraRoot Product safely and properly in accordance with these instructions for use.

The CeraRoot® Product must be used in accordance with the instructions for use provided by the Manufacturer. It is the practitioner's responsibility to use the device in accordance with these instructions for use and to determine, if the device fits the individual patient's situation.

8. Reference to any harmonised standards and CS applied

The main applicable standards for the CeraRoot ceramic dental implants are:

Standard	Title	Edition	Compliance
EN ISO 13485	Medical devices -- Quality management systems -- Requirements for regulatory purposes.	2016	Full
EN ISO 13356	Implants for surgery -- Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP).	2015	Partial
EN ISO 14801	Dentistry -- Implants -- Dynamic fatigue test for endosseous dental implants.	2016	Full
EN 1642	Dentistry. Medical devices for dentistry. Dental Implants.	2011	Full
EN ISO 15223-1	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements.	2016	Full
ISO 20417	Medical Devices-Information to be supplied by the manufacturer.	2021	Full
EN ISO 10993-1	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.	2018	Full
EN ISO 11135	Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices.	2014 +AMD 1:2018	Full
EN 556-1	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices.	2001	Full
EN ISO 11607-1	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems.	2006 +AMD 1:2014	Full
EN ISO 11607-2	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes.	2006 +AMD 1:2014	Full
EN 62366-1	Medical Devices -- Part 1: Application of usability engineering to medical devices.	2015 A1:2020	Full
EN ISO 14155	Clinical Investigation of medical devices for human subjects - Good clinical practice.	2020	Full

9. Bibliography (scientific literature)

1. Oliva J, Oliva X, Oliva JD. One-year follow-up of first consecutive 100 zirconia dental implants in humans: a comparison of 2 different rough surfaces. Int J Oral Maxillofac Implants. 2007 May-Jun;22(3):430-5. PMID: 17622010.
2. Oliva J, Oliva X, Oliva JD. Ovoid zirconia implants: anatomic design for premolar replacement. Int J Periodontics Restorative Dent. 2008 Dec;28(6):609-15. PMID: 19146057.
3. Oliva J, Oliva X, Oliva JD. Zirconia implants and all-ceramic restorations for the esthetic replacement of the maxillary central incisors. Eur J Esthet Dent. 2008 Summer;3(2):174-85. PMID: 19655530.
4. Oliva J, Oliva X, Oliva JD. Five-year success rate of 831 consecutively placed Zirconia dental implants in humans: a comparison of three different rough surfaces. Int J Oral Maxillofac Implants. 2010 Mar-Apr;25(2):336-44. PMID: 20369093.
5. Oliva X, Oliva J, Oliva JD. Full-mouth oral rehabilitation in a titanium allergy patient using zirconium oxide dental implants and zirconium oxide restorations. A case report from an ongoing clinical study. Eur J Esthet Dent. 2010 Summer;5(2):190-203. PMID: 20589262.

10. Revision history

SSCP Revision Number	Date Issued	Description of the main changes	Revision validated by the Notified Body BSI - NB 2797
1	14/11/2020	First created	☐ Yes Validation language: Validation date: ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB).
2	10/12/2020	Eliminate "WET" (Well Established Technology)	☐ Yes Validation language: Validation date: ☐ No
3	16/12/2020	Include SRN: ES-MF-000000251	☐ Yes Validation language: Validation date: ☐ No
4	19/04/2021	Update after BSI 2nd round questions	☐ Yes Validation language: Validation date: ☐ No
5	04/05/2021	Update after BSI 2nd round questions: SSCP Patient	**X** Yes Validation language: English Validation date: 27/10/2021 ☐ No

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PART B: FOR PATIENTS

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended ***for patients or lay persons.***

A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

The SSCP is ***NOT*** *intended to give general advice on the treatment of a medical condition.*
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 (IFU) to provide information on the safe use of the device.

1. Device identification and general information

1.1.Device trade name:	**CeraRoot Ceramic Dental Implant**
1.2.Manufacturer; name and address	CeraRoot S.L. Parpers, 13. 08520 Les Franqueses del Vallès. Barcelona. Catalonia. Spain www.ceraroot.com
1.3. Manufacturer's single registration number (SRN)	ES-MF-000000251
1.4. Basic UDI-DI	84354539CREC
1.5. Year when the device was first CE-marked	2006

2. Intended use of the device

2.1. What is the device used for?

The CeraRoot dental implant is a medical device made of ceramic to be placed in the patient's jaw to restore a missing or hopeless tooth.
The implant must be placed only by medical and dental professionals with specific training.

2.2. When is the device used?

The dental implant is used to replace missing or hopeless teeth.

2.3. Who is the device meant for?

Any patient missing one or more teeth without health issues.
The CeraRoot dental implants are specially indicated in patients with metal allergies and chronic illness.

2.4. When should the device not be used?

To have implants placed, you must go through oral surgery.
So, you must be in good physical health, good oral hygiene, and have adequate bone in the jaw to support the implant.
You may not be a good candidate for dental implant surgery if you have health problems, disease, or any physical or psychological condition to which oral surgery may be contraindicated. Smoking is also contraindicated as it increases the risk of implant infection.

3. Device description

3.1. Device description and material/substances in contact with patient tissues

CeraRoot® dental implant is made of ceramic.
This is a one piece implant.
It's a substitute for a natural root.

3.1.1 Information about medicinal substances in the device, if any

CeraRoot® dental implant doesn't contain medicinal substances.

3.1.2 Description of how the device is achieving its intended mode of action

CeraRoot® dental implant is surgically placed in the bone, where it serves as the artificial root of the missing tooth.
Dental implant surgery is performed in different stages. Healing time is allowed between procedures.
The process of placing a dental implant involves multiple steps, including:

- Extraction of damaged tooth.
- Bon preparation
- Dental implant placement.
- Bone healing
- Artificial tooth placement.

3.3. Description of accessories, if any

There are surgical and prosthesis accessories to be used by professionals.

4. Risks and warnings.

Contact your healthcare professional if you feel bad after the procedure. The following may produce implant failure:

- poor oral hygiene.
- smoking
- health conditions.
- not following instructions from your health care provider.

4.1. How potential risks have been controlled or managed
The product has been cleaned and sterilized.

4.2 Remaining risks and undesirable effects
You may experience some of the typical discomforts associated with any type of dental surgery, such as:

Temporary side effects;
- Pain
- Swelling
- Speaking difficulties.

Long-term side effects.
- No integration.
- Pain.
- Nerve damage.
- Fracture of implant or bone.
- Restoration fracture.
- Aesthetic problems.
- Loose implant.
- Infection

4.3. Warnings and precautions
Please follow the instructions of maintenance provided by your dentist in order to maintain a hygienic and healthy mouth.
Please keep the Implant Card provided by your dentist.

4.3 Summary of any Field Safety Corrective Action, (FSCA including FSN) if applicable
Up to the date of this SSCP there has not been any FSCA or FSN (Field Safety Notice) for this family of CeraRoot products.

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF):

5.1. Clinical background of the device
CeraRoot® dental implant has been placed on the market since 2006 where CE-marking was first achieved as per applicable medical device regulations.
Clinical track records of safety and performance were performed accordingly as described in point 5.2.

5.2. The clinical evidence for the CE-marking
The post market studies performed by CeraRoot provide the evidence of the product for CE marking.

5.3. Safety

5.3.1 Benefit-risk assessment

The safety of the product has been considered with a benefit-risk assessment. The claimed benefit is to be used for tooth replacement for missing or damaged teeth.

5.3.2 Clinical benefits for the patient

Clinical benefits for the CeraRoot ceramic dental implant:

- Biologically compatible.
- Shade corresponds to the natural tooth colour.
- High bending strength and hardness.
- Presents enhanced biocompatibility.
- Zirconia ceramic is well tolerated by bone and soft tissues and possesses mechanical stability.
- Reduce bacterial adhesion and plaque accumulation.
- Safety and performance data:
    - Survival rate: 98.69% after 15 years.
    - Fracture rate: 0.05% after 15 years.
- Patient satisfaction (PROMS) period 2020-2021:
    - Overall patient satisfaction: 90.91% very satisfied; 9.09% Little satisfied
    - Would you recommend the treatment?: 90.91% Yes; 9.09% Don't Know

5.3.3. How the manufacturer collects information on safety and performance / clinical studies (PMCF).

CeraRoot S.L. is continuously collecting information on the safety and performance of CeraRoot dental implants placed on the market through proactive and systematic processes to collect any information, such as:

- Information concerning serious incidents.
- Records referring to non-serious incidents and data on any undesirable side-effects.
- Complaints.
- Feedback from customers.
- Information from trend reporting.
- Relevant specialist or technical literature, database, and/or registers.
- Publicly available information about similar medical devices.
- Feedback from Notified Bodies and Authorities.

5.3.4. Clinical studies (PMCF) are ongoing or planned.

Purpose:

Corroborate safety and performance of CeraRoot dental implant and demonstrate the long-term safety.

Post-market clinical follow-up (PMCF) studies:

- The first PMCF study #140110 was a multicenter retrospective study for the period 2014-2018 with 144 implants placed in 5 different countries, and the results after 4 years observation period showed a success rate of 97,23%.

- A second long term PMCF Study #191220 - Retrospective for the period 2005-2020 concluded:
  "The success rate of 98,69% over a period of 15 years of retrospective PMCF demonstrates that the product is comparable with the state-of-the-art titanium dental implant studies. For this reason, it can be concluded that 15 years of lifetime can be expected with the CeraRoot ceramic dental implant".

  -Actually, there is a PMCF ongoing study:
  PMCF Study #200806 - Prospective from the year 2020 (1Y, 5Y, 10Y)

As per results of PMCF studies performed to date have not been detected: emerging risks, complications, or unexpected device failures in CeraRoot dental implants.

6. Possible diagnostic or therapeutic alternatives

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

6.1 General description of therapeutic alternatives

The alternative to the ceramic zirconia dental implant is the metal titanium implant or the metal titanium alloy implant.

Other alternatives without implants are:

- Fixed prosthesis on teeth: a prosthetic crown or bridge.
- Partial denture prosthesis: plastic device with metal or plastic retention on teeth.
- Complete denture prosthesis.
- No restoration (no treatment): not restoring the hopeless or missing tooth. However this involves loss of chewing function, migration of remaining teeth.

7. Suggested training for users

CeraRoot® dental implant is NOT intended to be handled directly by the patient.

CeraRoot® implants must be placed only by dentists, doctors, or surgeons that have received specific training and have advanced experience in oral surgery, periodontics, implantology, and prosthodontics.

Revision History

Date	Reason	Write	Approve
01/03/2020	Created	MJ	JO
11/09/2021	Approved by Notified Body BSI for MDR	MJ	JO