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	Summary of Safety and Clinical Performance DESIGN I system implant system	FAR1-04 Rev 02 31/08/2026
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I. Identification of the devices and the manufacturer

Device trade name(s)	DESIGN I Implant
Manufacturer's name and address	DEEP Company ZA du bois Saint Pierre 38280 JANNEYRIAS - France
Manufacturer's SRN	FR-MF-000009485
Basic UDI-ID	3665588IMPLT201ER
Medical device nomenclature description	P01020101
Class of device	Class IIb
Year of the first CE certificate	2021
Authorized representative if applicable	N/A
Notify body's name and its single identification number	Organism : TÜV SÜD Product Service GmbH SIN : 0123

Table 1: Description of the DESIGN I implant and DEEP Company

II. Specifications for use

The specifications for use of the DESIGN I implant described below are available in the instructions for use of device : **AR-D-IUI-DES-ML-v02**, updated on 2026-01-26.

II.1. Intended use

DESIGN I implants are intended to replace the root of an absent tooth, in the mandible as in the maxilla, caused by accidental or pathological loss, extraction or agenesis, when the other medical and surgical possibilities have been considered less appropriate.

II.2. Medical indication

DESIGN Implants are used for replacing teeth both in mandible and maxilla. They must be placed in the jawbone to be integrated (osteointegration). Restorations range from a single replacement to the use of elements for overdenture applications as well as the full arch of bridgework.

II.3. Targeted population

DESIGN implants are intended for people with the absence of at least one tooth who does not have any contraindications identified in the instructions for use.

The patient population targeted by these devices is very varied (age, sex) because the causes leading to implantation can be traumatic or atraumatic. Young patients will be treated more for traumatic causes and elderly patients more for pathologies affecting bone and/or periodontal tissues

For children, the placement of implants is not recommended until the end of jaw growth has been duly established. Preoperative gum and bone deficiencies can compromise the aesthetic result or result in unfavourable implant positioning.

II.4. Contraindication

The placement of implants is not recommended in the following cases:

- Allergy or hypersensitivity to the chemical components present in the materials used and mentioned in the “Description and intended use” section ;
- Patient with the following medical risk factors: cardiovascular diseases, diabete mellitus, osteoporosis and other bone diseases requiring bisphosphonates, diseases requiring local or systemic treatments (anticoagulant, chemotherapy, radiotherapy, steroid), severe mental illnesses (e.g., dementia or schizophrenia), psychotic disorders, organ transplant patients, bleeding disorders, an immune deficiency, patients taking some pharmacological agents such as proton pump inhibitors, physical capacity not adapted to implant treatment.
- Patient with the following local contraindications : history of recurrent diseases such as dental and periodontal diseases, unfavorable occlusion for whom it is impossible to place the adequate size or number of implants, bruxism or other parafunctional habits, bad oral condition (presence of cavities or lesions near the tooth loss) and inadequate bone volume, unless an augmentation procedure can be considered
- Patient with the following behaviour : poor oral hygiene, smoking, lack of motivation or cooperation

In the elderly, implant placement is not contraindicated if they have adequate cognitive and physical abilities. For children, the placement of implants is not recommended until the end of jaw growth has been duly established. Preoperative gum and bone deficiencies can compromise the aesthetic result or result in unfavourable implant positioning. In pregnant women, implant placement is not recommended because it may be associated with taking an x-ray. There is no contraindication for breastfeeding women.

III. DESIGN I Implant description

III.1. General description

III.1.1. Design feature of the DESIGN I implant

The DESIGN I implant is an endosseous screw, made of pure grade 4B titanium in accordance with ISO 5832-2 standard. It has the following design features:

- a self-tapping apical profile;
- a double thread;
- A sandblasted surface treatment;

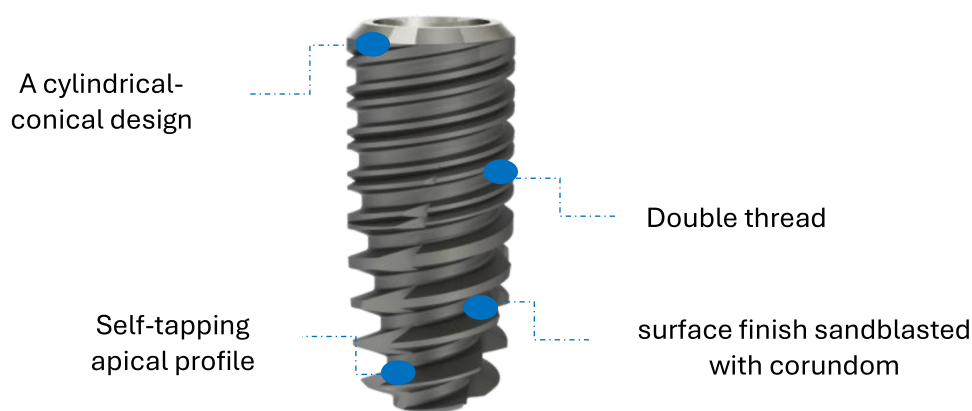


Figure 1: Representation of the DESIGN I implant features

DESIGN I are endosseous threaded dental implants belonging to the DESIGN Implant System. DESIGN Implants have the same characteristics, except their external surface treatment. DESIGN I implants are sandblasted with corundum while the DESIGN P implants are sandblasted with BCP (HA/ β -TCP) and acid/basic etched to ensure a better osseointegration.

DESIGN implants are made from pure titanium grade 4B according to ISO 5832-2 standard

Element	Mass fraction %
Nitrogen (N)	0.05 max
Carbon (C)	0.08 max
Hydrogen (H)	0.012 max
Iron (Fe)	0.5
Oxygen (O)	0.4
Titanium (Ti)	The rest

The outer surface of the DESIGN I implants are sandblasted with corundum. This process consists in projecting a jet of corundum at high pressure onto the threaded part of the implant to order to obtain a Ra roughness of 1.5 μm . This treatment surface allows to obtain a micro-textured surface.

III.1.2. Principles of operation and mode of actions

Dental implants are intended to restore the masticatory and speech function by replacing the absent root of a missing tooth. The incorporation of the implant into the alveolar bone is possible via a biological process called “**osseointegration**”. This process is defined as “direct structural and functional connection between living bone and the surface of an implant without the intervention of soft tissue” and is composed of the following step :

- 1/ Placement of dental implants in the jawbone, previously drilled, with an adequate instrument and;
- 2/ Healing period time : formation and connection between the new bone formed on the surface of the implant and the old bone induced by immune-modulated inflammatory response (see figure below). The osseointegration process lasts approximately 3 to 5 months.

III.1.3. Sterility of the implants

DESIGN I implants are sold sterile (by gamma irradiation) and must be used before the expiration date on the label. They are intended for single use only and must not be re-sterilized. Their reprocessing could alter their mechanical, chemical and/or biological properties. Their reuse could be the source of cross-contamination.

III.1.4. DESIGN I range

DESIGN I implants are available in several diameters and lengths:

		Diameter				
		3.5 mm	4 mm	4.5 mm	5 mm	5.5 mm
Length	6 mm	NA	PFD10-I10004006	PFD10-I10004506	PFD10-I10005006	PFD10-I10005506
	8 mm	PFD10-I10003508	PFD10-I10004008	PFD10-I10004508	PFD10-I10005008	PFD10-I10005508
	10 mm	PFD10-I10003510	PFD10-I10004010	PFD10-I10004510	PFD10-I10005010	PFD10-I10005510
	12 mm	PFD10-I10003512	PFD10-I10004012	PFD10-I10004512	PFD10-I10005012	PFD10-I10005512
	14 mm	PFD10-I10003514	PFD10-I10004014	PFD10-I10004514	PFD10-I10005014	PFD10-I10005514
	15 mm	NA	NA	NA	NA	PFD10-I10005515
	16 mm	PFD10-I10003516	PFD10-I10004016	PFD10-I10004516	NA	NA

Table 2: DESIGN I range

III.2. Reference to previous generations

There is no previous generation for the DESIGN implants.

III.3. Description of devices intended to be used in combination with DESIGN I implants

The dental replacement is performed during surgery in two stages:

- Implant placement to replace the root of a missing tooth by osteointegration and,
- The loading of prosthetic parts to support the overdenture and ensure its junction with the implants

The placement of implants and prosthetic surfaces is carried out using specific instruments. The combination of the three families of devices constitutes the DESIGN Implant System.

III.3.1. DESIGN Prosthetic Components

The prosthetic parts family is a set of several medical devices used in dental implantology to carry out prosthetic rehabilitations that range from replacing one single tooth to an entire arch of bridgework, as well as retentive elements for overdenture applications. [Table 3](#) presents the different products of the family and their intended use :

Prosthetic surfaces medical device	Healing abutments	Aesthetic, multi-unit, temporary abutments	Analogues	Impression copies	Castable abutments
Picture					
Intended use	To prepare gingival tissues during the healing phase	To support the overdenture and ensure its junction with the implant	To manufacture the final prosthetic device	To allow the transfer of the patient's impression to the prosthesis lab	To allow the transfer of the patient's impression to the prosthesis lab
Materials	Titanium alloy TA6V				PMMA

Table 3: Characteristics of Prosthetic Components family

The references of the DESIGN prosthetic parts are given below:

Designation	Reference
Cover screw	PFD10-I40000000
Cover screw - 2mm height	PFD10-I40030000
Straight Abutment 4 diameter - 1 mm height	PFD20-I21004010
Straight Abutment 4 diameter - 2 mm height	PFD20-I21004020
Straight Abutment 4 diameter - 3 mm height	PFD20-I21004030
Straight Abutment 4 diameter - 4 mm height	PFD20-I21004040
Straight Abutment 4 diameter - 5 mm height	PFD20-I21004050
Straight Abutment 5 diameter - 1 mm height	PFD20-I21005010
Straight Abutment 5 diameter - 2 mm height	PFD20-I21005020
Straight Abutment 5 diameter - 3 mm height	PFD20-I21005030
Straight Abutment 5 diameter - 4 mm height	PFD20-I21005040
Straight Abutment 5 diameter - 5 mm height	PFD20-I21005050
Straight Abutment 6,5 diameter - 2 mm height	PFD20-I21006520
Straight Abutment 6,5 diameter - 3 mm height	PFD20-I21006530
Straight Abutment 6,5 diameter - 4 mm height	PFD20-I21006540
Straight Abutment 6,5 diameter - 5 mm height	PFD20-I21006550
7° Angled Abutment 4 diameter - 1 mm height	PFD20-I22074010
7° Angled Abutment 4 diameter - 2 mm height	PFD20-I22074020
7° Angled Abutment 4 diameter - 3 mm height	PFD20-I22074030

Designation	Reference
7° Angled Abutment 4 diameter - 4 mm height	PFD20-I22074040
7° Angled Abutment 4 diameter - 5 mm height	PFD20-I22074050
7° Angled Abutment 5 diameter - 1 mm height	PFD20-I22075010
7° Angled Abutment 5 diameter - 2 mm height	PFD20-I22075020
7° Angled Abutment 5 diameter - 3 mm height	PFD20-I22075030
7° Angled Abutment 5 diameter - 4 mm height	PFD20-I22075040
7° Angled Abutment 5 diameter - 5 mm height	PFD20-I22075050
7° Angled Abutment 6,5 diameter - 2 mm height	PFD20-I22076520
7° Angled Abutment 6,5 diameter - 3 mm height	PFD20-I22076530
7° Angled Abutment 6,5 diameter - 4 mm height	PFD20-I22076540
7° Angled Abutment 6,5 diameter - 5 mm height	PFD20-I22076550
15° Angled Abutment 4 diameter - 1 mm height	PFD20-I22154010
15° Angled Abutment 4 diameter - 2 mm height	PFD20-I22154020
15° Angled Abutment 4 diameter - 3 mm height	PFD20-I22154030
15° Angled Abutment 4 diameter - 4 mm height	PFD20-I22154040
15° Angled Abutment 4 diameter - 5 mm height	PFD20-I22154050
15° Angled Abutment 5 diameter - 1 mm height	PFD20-I22155010
15° Angled Abutment 5 diameter - 2 mm height	PFD20-I22155020
15° Angled Abutment 5 diameter - 3 mm height	PFD20-I22155030
15° Angled Abutment 5 diameter - 4 mm height	PFD20-I22155040
15° Angled Abutment 5 diameter - 5 mm height	PFD20-I22155050
15° Angled Abutment 6,5 diameter - 2 mm height	PFD20-I22156520
15° Angled Abutment 6,5 diameter - 3 mm height	PFD20-I22156530
15° Angled Abutment 6,5 diameter - 4 mm height	PFD20-I22156540
15° Angled Abutment 6,5 diameter - 5 mm height	PFD20-I22156550
22° Angled Abutment 4 diameter - 1 mm height	PFD20-I22224010
22° Angled Abutment 4 diameter - 2mm height	PFD20-I22224020
22° Angled Abutment 4 diameter - 3mm height	PFD20-I22224030
22° Angled Abutment 5 diameter - 1 mm height	PFD20-I22225010
22° Angled Abutment 5 diameter - 2mm height	PFD20-I22225020
22° Angled Abutment 5 diameter - 3mm height	PFD20-I22225030
Healing Abutment 4 diameter - 1 mm height	PFD20-I41004010
Healing Abutment 4 diameter - 2 mm height	PFD20-I41004020
Healing Abutment 4 diameter - 3 mm height	PFD20-I41004030
Healing Abutment 4 diameter - 4 mm height	PFD20-I41004040
Healing Abutment 4 diameter - 5 mm height	PFD20-I41004050
Healing Abutment 5 diameter - 1 mm height	PFD20-I41005010
Healing Abutment 5 diameter - 2 mm height	PFD20-I41005020
Healing Abutment 5 diameter - 3 mm height	PFD20-I41005030
Healing Abutment 5 diameter - 4 mm height	PFD20-I41005040
Healing Abutment 5 diameter - 5 mm height	PFD20-I41005050
Healing Abutment 6,5 diameter - 2 mm height	PFD20-I41006520
Healing Abutment 6,5 diameter - 3 mm height	PFD20-I41006530
Healing Abutment 6,5 diameter - 4 mm height	PFD20-I41006540
Healing Abutment 6,5 diameter - 5 mm height	PFD20-I41006550
Wide multi Abutment - 1 mm height	PFD20-I31030010
Wide multi Abutment - 2 mm height	PFD20-I31030020
Wide multi Abutment - 3 mm height	PFD20-I31030030

Designation	Reference
Wide multi Abutment - 4 mm height	PFD20-I31030040
Wide multi Abutment - 5 mm height	PFD20-I31030050
Narrow multi Abutment - 1 mm height	PFD20-I31010010
Narrow multi Abutment - 2 mm height	PFD20-I31010020
Narrow multi Abutment - 3 mm height	PFD20-I31010030
Narrow multi Abutment - 5 mm height	PFD20-I31010040
Narrow multi Abutment - 5 mm height	PFD20-I31010050
17° Angled Multi-Unit Abutment - 2,5mm height	PFD20-I32170025
17° Angled Multi-Unit Abutment - 3,5mm height	PFD20-I32170035
30° Angled Multi-Unit Abutment - 3,5mm height	PFD20-I32300035
30° Angled Multi-Unit Abutment - 4,5mm height	PFD20-I32300045
Direct prosthetic screw	PFD20-I80000001
Multi prosthetic screw	PFD20-I80040001
Multi-Unit angled abutment screw	PFD20-I32000000
Wide Multi-Unit Abutment healing cap	PFD20-I43000000
Titanium Temporary Abutment	PFD20-I72000000
Titanium Temporary Wide Multi-Unit Abutment	PFD20-I72040000
Hybrid Wide Multi-Unit Abutment	PFD20-I73040000
PreMilled	PFD20-I85000021
Short Ti Base 4 diameter - 1 mm height	PFD20-I85554010
Short Ti Base 4 diameter - 2 mm height	PFD20-I85554020
Short Ti Base 4 diameter - 3 mm height	PFD20-I85554030
Short Ti Base 4 diameter - 4 mm height	PFD20-I85554040
Short Ti Base 4 diameter - 5 mm height	PFD20-I85554050
High Ti Base 4 diameter - 1 mm height	PFD20-I85654010
High Ti Base 4 diameter - 2 mm height	PFD20-I85654020
High Ti Base 4 diameter - 3 mm height	PFD20-I85654030
High Ti Base 4 diameter - 4 mm height	PFD20-I85654040
High Ti Base 4 diameter - 5 mm height	PFD20-I85654050
Short Ti Base 5 diameter - 1 mm height	PFD20-I85555010
Short Ti Base 5 diameter - 2 mm height	PFD20-I85555020
Short Ti Base 5 diameter - 3 mm height	PFD20-I85555030
Short Ti Base 5 diameter - 4 mm height	PFD20-I85555040
Short Ti Base 5 diameter - 5 mm height	PFD20-I85555050
High Ti Base 5 diameter - 1 mm height	PFD20-I85655010
High Ti Base 5 diameter - 2 mm height	PFD20-I85655020
High Ti Base 5 diameter - 3 mm height	PFD20-I85655030
High Ti Base 5 diameter - 4 mm height	PFD20-I85655040
High Ti Base 5 diameter - 5 mm height	PFD20-I85655050
Short Ti Base 6,5 diameter - 2 mm height	PFD20-I85556520
Short Ti Base 6,5 diameter - 3 mm height	PFD20-I85556530
Short Ti Base 6,5 diameter - 4 mm height	PFD20-I85556540
Short Ti Base 6,5 diameter - 5 mm height	PFD20-I85556550
High Ti Base 6,5 diameter - 2 mm height	PFD20-I85656520
High Ti Base 6,5 diameter - 3 mm height	PFD20-I85656530
High Ti Base 6,5 diameter - 4 mm height	PFD20-I85656530
High Ti Base 6,5 diameter - 5 mm height	PFD20-I85656550
Direct Castable abutments - 1 mm height	PFD20-I71004010

Designation	Reference
Direct Castable abutments - 2 mm height	PFD20-I71004020
Direct Castable abutments - 3 mm height	PFD20-I71004030
Direct Castable abutments - 4 mm height	PFD20-I71004040
Direct Castable abutments - 5 mm height	PFD20-I71004050
Multi Indexed Castable abutment	PFD20-I71000001
Short Open Tray Impression Coping	PFD20-I61010000
Long Open Tray Impression Coping	PFD20-I61030000
Short Closed Tray Impression Coping	PFD20-I62010000
Long Closed Tray Impression Coping	PFD20-I62030000
Open Tray Multi Impression Coping	PFD20-I61040000
Closed Tray Multi Impression Coping	PFD20-I62040000
Direct ScanBody	PFD20-I85000061
Multi ScanBody	PFD20-I85000062
CADCAM digital analog	PFD20-I51000001
Multi castable abutment	PFD20-I71040000
Implant analog	PFD20-I51000000

Table 4: List of references of DESIGN prosthetic surfaces that can be used with the DESIGN I Implant

III.3.2 DESIGN Ancillaries

The placement of the implants in the jawbone is carried out using specific and compatible instruments. The references of DESIGN instruments are given in the table below:

Designation	Référence
Short trocar	PFD30-I91010500
Short drill - 2mm diameter	PFD30-I91012000
Long drill - 2mm diameter	PFD30-I91032000
Long drill without stop - 2mm diameter	PFD30-I91002000
Short drill - 3,2mm diameter	PFD30-I91013200
Long drill - 3,2mm diameter	PFD30-I91033200
Long drill without stop - 3,2mm diameter	PFD30-I91003200
Short stepped drill - 2 / 3 diameter	PFD30-I91012030
Long stepped drill - 2 / 3 diameter	PFD30-I91032030
Long stepped drill without stop - 2 / 3 diameter	PFD30-I91002030
Short stepped drill - 3 / 4 diameter	PFD30-I91013040
Long stepped drill - 3 / 4 diameter	PFD30-I91033040
Long stepped drill without stop - 3 / 4 diameter	PFD30-I91003040
Short stepped drill - 4 / 5 diameter	PFD30-I91014050
Long stepped drill - 4 / 5 diameter	PFD30-I91034050
Long stepped drill without drill - 4 / 5 diameter	PFD30-I91004050
Short final drill - 3,5 mm diameter	PFD30-I91013500
Long final drill - 3,5 mm diameter	PFD30-I91033500
Long final drill without stop - 3,5 mm diameter	PFD30-I91003500
Short final drill - 4 mm diameter	PFD30-I91014000
Long final drill - 4 mm diameter	PFD30-I91034000
Long final drill without stop - 4 mm diameter	PFD30-I91004000
Short final drill - 4,5 mm diameter	PFD30-I91014500
Long final drill - 4,5 mm diameter	PFD30-I91034500
Long final drill without stop - 4,5 mm diameter	PFD30-I91004500

Designation	Référence
Short final drill - 5 mm diameter	PFD30-I91015000
Long final drill - 5 mm diameter	PFD30-I91035000
Long final drill without stop - 5 mm diameter	PFD30-I91005000
Short final drill - 5,5 mm diameter	PFD30-I91015500
Long final drill - 5,5 mm diameter	PFD30-I91035500
Long final drill without stop - 5,5 mm diameter	PFD30-I91005500
Countersink - 4 mm diameter	PFD30-I91044000
Countersink - 5 mm diameter	PFD30-I91045000
Countersink - 6,5 mm diameter	PFD30-I91046500
Contra-angle Implant Driver - Short	PFD30-I93010400
Contra-angle Implant Driver - Long	PFD30-I93030400

Table 5: List of references of DESIGN instruments that can be used with the DESIGN I Implant

IV. Risks and warning associated with the use of the DESIGN I implant

IV.1. Residual risks and undesirable effects

The risks associated with the design, production and use of DESIGN I implants have been analysed according to our internal procedures, in accordance with standard NF EN ISO 14 971:

- Identification of risks;
- Risk Assessment ;
- Implementation of means of control;
- Evaluation of the effectiveness of the means of control put in place

After risk reduction and control, residual risks called “side effects” may persist. These can still occur despite all the procedures, precautions and indications specified by DEEP Company. As dental implants are considered “Well Established Technologies” medical devices, safety data related to similar devices of DESIGN implants are included in this table.

These risks identified during risk management and the clinical evaluation through state of the art related to similar devices and reported in the associated instructions for use. All complications (occurrence included) will be confirmed by the retrospective study described in V.2.

IV.2. Warning and precautions

Warnings and precautions related to the use of the DESIGN I implant are indicated below and are available in the instructions for use of the devices.

IV.2.1. Pre-operative precautions

A careful clinical and radiological examination of the patient has to be performed prior to surgery to determine the physical and psychological status of the patient. Special attention has to be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osteointegration process (cigarette smoking, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone). In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or unfavorable jaw relationships, reappraisal of the treatment option may be considered.

IV.2.1. Per-operative precautions

Particular caution should be used when placing small diameter implant (Ø3.5 NP) in the posterior region due to the risk of prosthetic overload. Lack of adequate quantity and/or quality of remaining bone, infection and generalized diseases may be potential causes for failure of osseointegration both immediately or after the surgery. Besides the mandatory precautions for any surgery (such as asepsis), during drilling in the jaw bone, the clinician must avoid damage the nerves and vessels by referring to anatomical knowledge and preoperative radiographs. Failure to recognize actual lengths of drills relative to radiographic measurement or drilling beyond the depth intended can result in permanent injury to nerves or other vital structures. It can result in a permanent numbness to the lower lip and chin or lead to hemorrhage such as in the floor of the mouth.

Implants may be tilted up to 45° relative to the occlusal plane. When used with angulations between 30° and 45°, the following applies: The tilted implants must be splinted; a minimum of 4 implants must be used when supporting a fixed prosthesis in a fully edentulous arch.

The practitioner is advised to provide regular patient follow up and to inform about good oral hygiene.

IV.3. Other relevant aspect of safety (FSCA & FSN)

To date, there are no Field Safety Notices or Field Safety Corrective Actions for DESIGN I implants.

V. Summary of clinical evaluation and post-market clinical follow-up

V.1. Overall Summary of Clinical Performance and Safety

Overview of the clinical data

The clinical data supporting safety and performance of the DESIGN I implant have been provided by the following articles on similar devices. [Clinical data from similar devices are useful, given the well-established technology clinical pathway for dental implants.](#)

Ref	Indication / Site implantation	Similar device
Krebs 2015	Dental implant Mandible and Maxilla	Ankylos
Atieh, 2022	Dental implant Mandible and Maxilla	Ankylos
Fabbri, 2021	Dental implant Mandible and Maxilla	NobelActive
Fabbri, 2022	Dental implant Mandible and Maxilla	NobelActive
Todescan, 2023	Dental implant Maxilla	NobelActive
Yuan, 2023	Dental implant Maxilla	Nobelactive
Da Rocha, 2023	Dental implant Mandible and Maxilla	NobelActive
Blume, 2021	Dental implant Mandible and Maxilla	NobelActive
(P Weigl et al. 2024)	Single missing tooth in the maxillary lateral incisor area and the mandibular central or lateral incisor area (anterior), immediate loading. Sites: 24 fresh extraction (26.4%) and 67 healed or congenitally missing (73.6%)	NobelActive

The patient characteristics of the included studies are:

Publication	Patients (With gender data)	Gender distribution (male ♂)	Gender distribution (female ♀)	Age (Years)	Follow-up
Krebs 2015	4206	1851	2355	≤50 years: 3,758 implants; 51 to 70 years: 7,684 implants; ≥71 years: 1,257 implants	Mean 60 months Max 204 months
Atieh, 2022	Total: 162 Ankylos: NS	NS	NS	19 - 72 (Mean age 46.4 ± 11.7) Ankylos: NS	10 years
Fabbri, 2021	72	41	31	28 - 76 (53.2 ± 12.7)	1 year
Fabbri, 2022	95	41	54	23 - 86 (Mean age 58 ± 12)	1.8 ± 0.2 year
Todescan, 2023	26	11	15	Mean age 35	1 year
Yuan, 2023	22	9	13	18 - 43 (mean age 27.64 ± 7.27)	6 months
Da Rocha, 2023	Total: 51 NobelActive: NS	Total: 20 NobelActive: NS	Total: 31 NobelActive: NS	36 - 79 (Mean age 58.53) NobelActive: NS	25 months
Blume 2021	574	NS	NS	NS	NS
(P Weigl et al. 2024)	77	28 (36.4%) - 33 implants	49 (63.6%) - 58 implants	Mean 40.9 +/- 18.9	5 years (60 months) Visits at baseline, 6 months, 1, 2, 3 and 5 years
TOTAL	4495 (4221)	1953 (46.2%)	2468 (53.8%)	18 -86 years old	6 months to 23 years



Summary of Safety and Clinical Performance

DESIGN I system implant system

FAR1-04

Rev 02
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Clinical Safety

The following table shows the frequencies of adverse events identified in the literature for the DESIGN I similar devices:

Adverse events	Literature range (%) from general SOTA	Literature range (%) from Similar devices	Onset window	Expected frequency for DESIGN implants	PMS data from DESIGN	Gap
Peri-implant mucositis	40%	38,7%	Postop Day 7 to 10 years	<40%	0%	No gap
Peri-implantitis	10%	0.96% - 3.6%	Postop Day 7 to 10 years	<4%	0,005%	No gap
Implant failure/fracture	NS	0,7% - 7,8%	Postop Day 7 to 1 years	<5%	0,007%	No gap
Fracture of the implant body	0.5%	0,02% - 0,5%	Postop 6 months to 10 years	<0.5%	0%	No gap
Implant loss	NS	1,87%-5,86%	Postop Day 0 to 10 years	<6%	0,13%	No gap
Soft tissue complications	NS	0,2%	Postop Day 7 to 10 years	<0.2%	0,014%	No gap
Bone loss > 2,5 mm	5%-24%	4,78%	Postop 1 year to 10 years	<5%	0,16%	No gap
Pain	NS	3,77%	Postop Day 0 to Day 15	<4%	0%	No gap
Prosthetic complications (technical)	NS	5.6% - 23.5%	Postop 6 months to 10 years	<9%	0,01%	No gap

The values reported in the "Literature range" columns reflect the total expected incidence of each adverse event over a follow-up period of up to 10 years, based on data from literature covering both general state of the art and similar CE-marked dental implant systems. The "Onset Window" indicates the range of time post-implantation during which the event has been reported to occur or can occurs. The "expected frequency for DESIGN implants" indicates the higher frequency expected for each complication in a 10-year follow-up period.

The frequencies of adverse events identified through the PMS are all under the frequencies from the literature for DESIGN I implants. These data will be completed with PMCF safety data from the clinical investigation due to start in 2026.

Thus, at short term, DESIGN I Implants meet the claimed clinical safety.

Clinical performance and benefits

The performance of the DEEP Implant DESIGN I System product, meaning the implant associated with abutments, is the implant survival rate. The success of dental implant treatment is based on the osteointegration of the implants into the maxilla and/or the mandible and the abutment's ability to support the overdenture.

The clinical performance expected in the short and long term are as follows :

- Implant survival rate > 98 % over 1 year ;

- Implant survival rate > 95 % over 5 years ;
- Implant survival rate > 90 % over 10 years.

From PMS data for the last 2 years, DESIGN I survival rate is 99.36%. At 2 years postoperative, the clinical performance is reach.

Survival rate for DESIGN I similar devices found in the literature are presented in the following table:

Reference	Similar device	Survival rate %	FU
Krebs 2015	Ankylos	98.2% 97.3% 96.1% 94.5% 93.3%	12m 60m 120m 180m 204m
Fabbri, 2021	NobelActive	95%	1 year
Fabbri, 2022	NobelActive	95,8%	1 year
Todescan, 2023	NobelActive	100%	1 year
Yuan, 2023	NobelActive	100%	6 months
Da Rocha, 2023	NobelActive	100%	25 months
(P Weigl et al. 2024)	NobelActive	96.5%	60 months (5 years)

*Estimated by Kaplan-Meier analysis

In addition, the survival rates from the DESIGN I implants are presented in the table below from PMS survey:

Follow-up year	Survival rate
	DESIGN I implant
1 year	99,50 %
5 years	99,46%

The survival rate of DESIGN I implants is greater than 99 % over 2 years. This is in agreement with the available data found in literature (survival rate > 98 % over 1 year). These data are from the PMS activity and may overestimate the survival rate due to a possible underreporting of events. These rates will be updated when data from the ongoing PMCF studies become available.

Clinical performance is related to the clinical benefits. The evaluation of clinical benefits will make it possible to demonstrate the capacity of the DESIGN implants to achieve the intended purpose claimed by DEEP Company under the intended use claims.

The clinical benefits of the DEEP Implant System product for the patients, meaning the implant associated with abutments, are:

- Increase of oral health quality of life, measured with the clinical score OHIP (Oral Health Impact Profile)
- Satisfaction with aesthetic and function evaluated by the patient and the surgeon.

Expected lifetime is 10 years.

Clinical performance and benefits for DESIGN I implant systems will be validated by a prospective PMCF study on 220 patients with a follow-up period of 10 years, due to start in 2026.

Benefit Risk Ratio

Parameters for determining the acceptability of benefit-ratio ratio are as follows:

- Implant treatment has an advantage over existing therapeutic solutions ;
- All risks have been mitigated when appropriate and residual risks have been accepted ;
- The safety profile of DESIGN I implants is coherent and even better than those of similar devices data from literature
- Implant treatment is a viable short- and long-term alternative :
 - Implant survival rate greater than 98 % over 1 year ;
 - Implant survival rate greater than 95 % over 5 years ;
 - Implant survival rate greater than 90 % over 10 years ;
- Implant treatment increase patient quality of life. At this time, no benefit data are available for DESIGN I implants. These data will be collected through PMCF clinical investigations.

Taken together the data presented indicate a favorable benefit-risk ratio for the use of DESIGN I implant systems in comparison to established treatment options.

Moreover, in order to validate the claimed Clinical benefits and to confirm the clinical performance and safety profil of DESIGN I implant systems, a prospective PMCF study will be set up in 2026 on 220 patients with a 10-year follow-up period.

V.2. DESIGN I Post-Market Follow-up

A PMCF study is intended to be launched in the coming months with the following architecture:

Name of the PMCF study	Type of the study	Start of the study	End of the study	Number of total enrolled participants	Number of total enrolled sites
Long term assessment of DESIGN I Implant System use in patients with unitary, partial or full-arch edentulism	Prospective Multicentric Interventional Without burdensome nor invasive additional procedure	2026	2036/2037	Objective 220 patients (330 implants)	3

When more information becomes available, this section will be updated.

VI. Possible diagnostic or therapeutic alternatives

Alternatives to the use of DESIGN I implants are the use of **removal** prosthesis, fixed prosthesis or used dental implants. Main points considered in the evaluation of the benefits and risks of DESIGN I implants in comparison to current state-of-the-art treatment options as discussed above are summarized in table below:

Property	Alternative 1: Removable dental prosthesis	Alternative 2: Fixed prosthesis	Use of DESIGN implants
Indication	Partial and complete edentulism	Unitary or partial edentulism	Unitary, partial and complete edentulism
Invasiveness	Not surgically invasive	Not surgically invasive but the adjacent teeth have to be damaged	Invasive
Treatment time	Short	Short	Long
Restoration of masticatory and speech function	Masticatory function : Short and long term : poor masticatory performance caused by poor stability and lack of retention	Masticatory function : Short and long term: better masticatory performance due to improved stability and retention	Masticatory function : Short and long term: better masticatory performance due to improved stability and retention
	Speech function : Short term: adaptation more easily	Speech function : Short term: Prosthesis can affect speech articulation during first month	Speech function : Short term: implant can affect speech articulation during first month

Property	Alternative 1: Removable dental prosthesis	Alternative 2: Fixed prosthesis	Use of DESIGN implants
	Long term: poorly stability and lack retention → bad speech performance	Long term: better speech performance due to improved stability and retention	Long term: better speech performance due to improved stability and retention
Reported survival rates	No reported because removable device However, 39% of removable prostheses are no longer used after 5 years (dissatisfied patients)	Prosthesis survival rate : 94% at 5 years 89% at 10 years	Implant survival rate: > 98% over 1 year > 95% over 5 years > 90% over 10 years
Comorbidities	Using tooth-borne prostheses will induce a bone resorption, compromising any future implantation. The most common reported complications with use of removable prosthesis are caries and periodontal disease	The absence of implants in the bone means that fixed prostheses induce bone resorption beneath the prosthesis. In the long term, this resorption can affect adjacent teeth. The most common reported complications with use of fixed dental prostheses are fracture of the framework and periodontal disease	Implant-supported The bone volume is conserved (little bone recession compared to other alternatives); the aesthetic is preserved (gingiva maintained). The most frequent complication is periimplantitis.
Quality of life	Short term: normal life not disturbed Long term: Aesthetic: Complications are expected on the healthy tooth used as a support, which is subject to an aesthetic deterioration. Lower patient satisfaction Maintenance and good hygiene are necessary to ensure the long-term survival of the prosthesis	Short term: normal life not disturbed Long term: Aesthetic: Complications are expected on the healthy tooth used as a support, which is subject to an aesthetic deterioration. Lower patient satisfaction Maintenance may also be necessary following debonding.	Short term: few complications, normal life slightly disturbed postoperatively Long term: better functional and aesthetic results . Better patient satisfaction Maintenance and good hygiene is necessary to ensure the longevity of implants
Cost	Cost-effective	Cost-effective , but in the long term, may require the placement of two adjacent implants	Expensive

All complications related to dental implants has been identified, controlled and reduced as much as possible. Each residual risks has been accepted, monitored during the post-market commercialisation and is made available to the user in the instruction for use.

DESIGN Implant system is a viable solution in the short term because its survival rate is greater than 99 % over 1 year. According to the literature, for the long-term, the 10 years survival rate is >96% for the similar devices. Then, the survival rate of DESIGN Implant System is consistent with the data found in the literature.

Taken together the data presented indicate a favourable benefit-risk ratio for the use of DESIGN implant system in comparison to established treatment options.

Moreover, in order to validate the claimed Benefits and Performances, two prospective PMCF studies will be set up in 2026 (see chapter V.2.).

VII. Suggested profile and training for users

The device must be handled and / or implanted by dentists, maxillofacial surgeons, or stomatologists trained in the technique as part of their initial or continuous training and having read the instructions for use.

Some devices (prosthetic parts) must also be manipulated by dental prosthesis technicians (named prosthetist) trained in the technique in the context of their initial and continuing formation and having read the instructions for use.

VIII. Reference to any harmonized standards and CAS applied

The standards harmonized with EU directive 93/42/EEC, applicable to DESIGN I implants are shown in the table below:

Standard revision	Title	Revision	Application
Quality			
NF EN ISO 13485	Medical devices - Quality management systems – Requirements for regulatory purposes	2016	Fully
Risk management			
NF EN ISO 14971	Medical devices — Application of risk management to medical devices	2019	Fully
NF EN 62366-1	Medical devices – Part 1: Application of usability engineering to medical devices	2008	Fully
Biocompatibility			
NF EN ISO 10993-1	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	2010	Fully
ISO 10993-5	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	2009	Fully
NF EN ISO 10993-12	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	2012	Fully

Standard revision	Title	Revision	Application
NF EN ISO 10993-16	Biological evaluation of medical devices — Part 16: Toxicokinetic study design for degradation products and leachables	2009	Fully
NF EN ISO 10993-17	Biological Evaluation of Medical Devices – Part 17: Establishment of Permissible Limits for Leachables	2009	Fully
NF EN ISO 10993-18	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process	2009	Fully
Cleaning / Packaging & Sterilisation			
NF EN 1041 + A1	Information supplied by the manufacturer of medical devices	2008 + 2013	Fully
NF ISO 19227	Implants for surgery — Cleanliness of orthopedic implants — General requirements	2018	Fully
NF EN ISO 11137-1	Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	2016	Fully
NF EN ISO 11137-2	Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose	2015	Fully
NF EN ISO 11607-1	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems	2009	Fully
NF EN ISO 11607-2	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes	2006	Fully
NF EN ISO 11737-1 + AC1	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products	2006+2007	Fully
NF EN ISO 11737-2	Sterilization of health care products — Microbiological methods — Part 2: Sterility tests performed in the definition, validation and maintenance of a sterilization process	2010	Fully
NF EN ISO 15223-1	Medical devices — Symbols for use with medical device labels, labeling and information to be supplied — Part 1: General requirements	2017	Fully
Others			
NF EN 1642	Dentistry — Medical devices for dentistry — Dental implants	2013	Fully

Table 6: List of standards harmonized with the EU Directive applicable to DESIGN I Implants

	Summary of Safety and Clinical Performance DESIGN I system implant system	FAR1-04 Rev 02 31/08/2026

The standards harmonized with regulation 2017/745, applicable to DESIGN I implants are reported in the table below:

Standard revision	Title	Revision	Application
Quality			
NF EN ISO 13485+AC+A11	Medical devices - Quality management systems – Requirements for regulatory purposes	2016+2018+2021	Fully
Risk management			
NF EN ISO 14971+A11	Medical devices — Application of risk management to medical devices	2019+2021	Fully
Biocompatibility			
NF EN ISO 10993-18	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process	2020	Fully
Cleaning / Packaging & Sterilisation			
EN ISO 11137-1+A2	Sterilization of health care products - Irradiation - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	2015+2019	Fully
NF EN ISO 11137-2	Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose	2015	Fully
NF EN ISO 11737-1+A1	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products	2018+2021	Fully
EN ISO 11737-2	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	2020	Fully
NF EN ISO 11607-1	Packaging for terminally sterilized medical devices — Part 1: Requirements, for materials, sterile barrier systems and packaging systems	2020	Fully
NF EN ISO 11607-2	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes	2020	Fully
Others			
ILNAS-EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	2021	Fully

Table 7: List of standards harmonized with the MDR 2017/745 applicable to DESIGN I Implants

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