EN INSTRUCTIONS FOR USE — ARDS DENTAL IMPLANTS

Indications

The product labelling and Instructions for Use (IFU) are provided in the official languages required by the Member States where the product is intended to be marketed, in accordance with Regulation (EU) 2017/745, Annex I, Chapter III, Section 23.1(d). ARDS ensures compliance with local language requirements for each country of distribution. It can also be seen on the website at https://www.ardsimplants.com/ifu

ARDS implants are sterile, single-use Titanium alloy. ARDS dental implants are indicated for use in surgical and restorative applications for placement in the bone of the upper and lower jaw to provide support for prosthetic devices in order to restore the patient's chewing function. ARDS dental implants are indicated for one-stage and two-stage surgeries. The implantation surgical procedure is performed in dental clinic by dentists experienced in dental implantology.

Intended Purpose

ARDS Dental implants are intended to replace missing tooth/teeth in either jaw for supporting prosthetic devices that may aid in restoring the patient's chewing function. The procedure can be accomplished in a one-stage or two-stage surgical operation. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading. ARDS dental implants are indicated for one-stage and two-stage surgery.

Dental implants are intended for:

- Single or multiple tooth replacement
- Full-arch restorations
- Immediate or delayed loading, depending on primary stability and clinical judgment

Note

Check the packaging before use. If the tube is “mouthless” or with carrier according to the label on the box before open it.

Before use, it is necessary to ascertain if the patient has sufficient alveolar bone width to support the implant. In addition, careful evaluation of the nerves, vital blood vessels, maxillary sinus, and soft tissue spaces relative to the proposed implant site, should be performed before implantation.

Caution

Federal law (US) restricts this device to sale by or on the order of a physician.

Warnings:

- ARDS Implants should be placed and restored only by practitioners who are licensed and trained to perform these procedures.
- Reprocessing the implants may result in biocontamination and degraded performance.
- ARDS Implants should be used with ARDS superstructures only.
- Sterile products should not be used if they are damaged or have already been opened.
- Implants are supplied sterile and sterile implants are for single use only.
- Do not Re-Sterilize. Damaged or surgically removed implants shall not be used under any circumstances. Reprocessing or Re-sterilization may affect mechanical properties or microbiological safety.
- Reprocessing the Implant may result in biocontamination, degraded performance or loss of function.
- Small diameter single implants and angled abutments are not recommended for molar region of the mouth.
- Sterile implants must not be used after the expiration date printed on the product label.
- Sterile implants must not be used if the package has been damaged or previously opened.
- A minimum of 30 Ncm insertion torque is necessary for implants to achieve osseointegration.
- The ARDS Implants has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artefact in the MR environment. The safety of ARDS Implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Reportable Events: Any serious incident that has occurred in relation to the dental implant should be reported to ARDS and the competent authority of the Member State in which the user is established.

Contraindications

Dental implantation is a surgery operation. Any contraindication that applies to surgery operations applies to patients subject to a dental implant operation, such as:

- Debilitating or uncontrolled disease.
- Pregnancy, hemophilia, granulocytopenia or other bleeding problems, steroid use, prophylactic antibiotics, brittle diabetes, Ehlers-Danlos syndrome.
- Osteoradionecrosis, renal failure, organ transplantation, anticoagulation therapy, unexplained hypersensitivity, fibrous dysplasia, regional enteritis.
- Lack of adequate training of practitioner. Conditions, diseases, or treatment that severely compromise healing, e.g., including radiation therapy.
- Psychiatric disorders that interfere with patient understanding and compliance with necessary procedures.
- Unrealistic patient expectations. Unattainable prosthodontic reconstruction. Inability of patient to manage oral hygiene.
- Patient hypersensitivity to specific components of the implants.

Absolute contraindication to implantation:

This implies the presence of diseases and certain conditions of the body when surgery is an obvious health risk, as well as when there are non-treatable diseases that make it impossible to achieve positive results of implantation. These include:

- Chronic diseases in the stage of decompensation (weakened immune system, serious internal medical problems, etc.)
- Systemic disorders of coagulation (bone metabolism disturbances)

- Uncontrolled bleeding disorders.
- Immunodeficiency, HIV and any other seropositive infection.
- Psychological diseases (uncooperative or unmotivated patient)
- Drug or alcohol abuse
- Allergies or hypersensitivity to chemical ingredients of materials used: grade 5 or 23 titanium

Relative contraindication or risk factors:

Surgical intervention represents an obvious health risk. However, relative contraindications are only diseases that create certain difficulties for achieving the predicted result, statistically reduce the effectiveness of implantation and can lead to unsuccessful treatment.

Risk factors include unfavorable anatomical conditions that require additional surgical interventions or non-standard approaches to treatment, as well as lifestyle, patients age, intellectual level and emotional status, acute and chronic diseases, and pathologies in which homeostasis can be stabilized or compensated, changes in the organs and systems of the body due to modern methods of treatment. These include:

- Acute inflammatory diseases and acute viral infections
- Chronic infectious diseases (tuberculosis, actinomycosis, etc.)
- Chronic diseases in the stage of compensation
- High risk of bacteremia (patients with prosthetic heart valves and endured bacterial endocarditis, rheumatism).
- Patients who only recently suffered heart attack or stroke.
- Pregnancy and lactation.
- Tobacco abuse
- Treatment with drugs that worsen the regeneration of tissues (hormonal, radiation and chemotherapy, the use of immunosuppressants, etc.).
- Young people under the age of 18 years
- Osteopathies are diseases that adversely affect osteogenesis.
- Osteoporosis - reduction of total bone tissue.
- Osteomalacia - inadequate mineralization of the organic bone matrix with a normal skeletal mass and bone volume
- Diseases that disrupt osteogenesis: thyroid gland diseases, parathyroid gland diseases, diabetes mellitus, pituitary diseases, adrenal gland pathology, blood diseases.
- Alcoholism and drug addiction cause not only mental changes, but also a number of somatic disorders affecting osteogenesis.
- System diseases of connective tissue: systemic lupus erythematosus, dermatomyositis, Sjögren's syndrome, a group of congenital systemic connective tissue diseases inherited by autosomal dominant type: various types of congenital dysplasia and dysostosis.
- Application of medications reducing blood clotting by patients
- Pathological conditions of maxillofacial area and oral cavity: leukoplakia, stomatitis, caries, xerostomia, periodontitis, macroglossia, malocclusion, temporomandibular joint diseases, gingivitis, periimplantitis, bruxism and unsatisfactory oral hygiene.

Treatment of these diseases should be carried out in parallel with implantation, or implantation can be regarded as one of the ways of treatment.

In case implantation was performed in conditions of absolute contraindications, the manufacturer does not accept any warranty requirements.

Related Superstructures do not have stand-alone contraindications, so all contraindications that prohibit the use of a dental implant prohibit the use of the abutments and superstructures as well. The contraindications of the related abutment and superstructures are always connected to that of the dental implants.

The device should not be used in patients with known allergies or hypersensitivity to any of the materials used in the implant or abutment, such as titanium or its alloys.

Risks

Short-term risks associated with the use of these products include: anesthetic and surgical risks, psychological and psychiatric risks, pain, gingivitis, speech problems.

Long-term risks include: nerve damage, bone loss, local or systemic bacterial infections, infectious endocarditis.

The following table lists the organ systems that may be affected together with the associated risks:

Organ System	Effect
Cardiovascular	Arrhythmias, coronary heart disease, cardiovascular failure
Respiratory	Chronic obstructive pulmonary disease
Gastrointestinal	Hepatitis, malabsorption, inflammatory bowel disease
Genitourinary	Chronic renal failure
Musculoskeletal	Arthritis, osteoporosis
Hematological	Anemia, leukemia, blood clotting disorders
Endocrine	Diabetes, thyroid diseases, pituitary and adrenal disorders

Changes in Performance

It is the clinician's responsibility to inform the patient about the precautions, side effects, and contraindications should the performance of the implant be in question. It is the responsibility of the patient to seek medical care if any of the side effects occur.

Surgical Procedure

Drilling

Irrigate the area with surgical saline. To avoid trauma to adjacent structures such as sinuses, mental foramina, and mandibular

canals perform a radiographic exam of the proposed implant area.

All drilling procedures should be performed at a maximum of 850 RPM with copious irrigation, using a physiodispenser and cool sterile saline solution. The use of sharp drills, sufficient irrigation, an in-and-out drilling motion, short cutting cycles, waiting for the bone to cool, and use of pilot drills in successively increasing sizes are essential.

Carefully manage the hard and soft tissue to ensure osseointegration. To prevent thermal trauma, use drilling speeds of 850 rpm for the first drill and 850 rpm for the second. Irrigate the area with surgical saline. To avoid trauma to adjacent structures such as sinuses, mental foramina and mandibular canals, perform a radiographic exam of the proposed implant area. Indications for Ø3.0mm, Ø3.3mm implants: these implants exhibit lower mechanical strength values than Ø3.75mm, Ø4.2mm, Ø5.0mm, Ø6.0mm to get primary stability.

The insertion torque: 30-60 Ncm insertion torque

Recommendations for device selection

Select the implant based on the clinical indication (single-tooth, partial-arch or full-arch rehabilitation), the available bone volume and quality (clinical examination and CBCT/X-ray), the insertion site (maxilla/mandible, anterior/posterior) and the planned loading protocol. Choose diameter and length to fit the residual ridge while keeping safe distances to anatomical structures; prefer wider/longer fixtures where bone permits for primary stability. Select the connection (internal hex, conical NP, or one-piece) and the matching abutment according to the prosthetic plan.

Properties and features

ARDS implants are root-form endosseous fixtures made of titanium Grade 5 / Grade 23 (Ti-6Al-4V / ELI, ASTM F136) with an SLA (sandblasted, large-grit, acid-etched) surface promoting osseointegration. Families: CLASSIC, CIT, SMART, PREMIUM, PSI and conical/one-piece variants; diameters ≈ Ø3.0–6.0 mm, lengths ≈ 6–20 mm; self-tapping buttress thread. Single-use, supplied sterile.

Mode of action

The implant is placed into a prepared osteotomy in alveolar bone. During healing (typically 3–6 months) the titanium surface integrates with the surrounding bone (osseointegration), forming a stable anchorage; an abutment is then connected to support the prosthetic restoration, transmitting functional loads to the bone.

Description of the clinical benefit

The implant restores function and esthetics of missing teeth: it re-establishes masticatory function and speech, improves appearance and quality of life, preserves alveolar bone through functional loading, and avoids preparation of adjacent natural teeth required by conventional bridges.

Clinical aspects of combinations with other devices

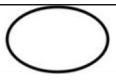
Use ARDS implants only with ARDS abutments, superstructures and surgical instruments validated for compatibility. Tighten prosthetic screws to the specified torque. Components from other manufacturers must not be used. Adjunctive procedures (bone grafting, sinus elevation) should follow accepted clinical protocols by trained clinicians.

Models and Dimensions

Model	Description	Diameters	Lengths	Basic UDI
C	CLASSIC Hex - Spiral conical implant with internal hexagon connection and double thread	3.0/3.3/3.75/4.2/5.0/6.0 mm 3.75/4.2/5.0/6.0 mm	8/10/11.5/13/16 mm 6 mm	729011576C8D
CC	CLASSIC Conical - Spiral conical implant with internal conical connection and double thread	3.0/3.3/3.75/4.2/5.0/6.0 mm 3.75/4.2/5.0/6.0 mm	8/10/11.5/13/16 mm 6 mm	729011576CCS8
S	SMART Hex - Internal hex implant with double thread at the upper part that changes to one thread at the lower part	3.75/4.2/4.5 mm	8/10/11.5/13/16 mm	729011576S9D
SC	SMART Conical - Conical connection implant with double thread at the upper part that changes to one thread at the lower part	3.75/4.2/4.5 mm	8/10/11.5/13/16 mm	729011576SCTQ
N3	SMART Narrow - External hex implant for narrow crest or narrow space between teeth	3.0 mm	10/11.5/13 mm	729011576N3SB
N	ONE PIECE - External hex implant for narrow crest or narrow space between teeth	3.0/3.3/3.75/4.2/5.0 mm	10/11.5/13/16 mm	729011576N93
PSI	PSI Hex - Spiral conical implant with clean top and internal hexagon connection and double thread	3.3/3.75/4.2/5.0 mm	8/10/11.5/13/16/18 mm	729011576PSILX
PSC	PSI Conical - Spiral conical implant with clean top and internal hexagon connection and double thread	3.3/3.75/4.2/4.5/5.5 mm	8/10/11.5/13/16/18 mm	729011576PSCLK
P	PREMIUM - Spiral implant with clean top and internal hexagon connection and double thread	3.3/3.75/4.2/5.0/6.0 mm 3.75/4.2 mm	8/10/11.5/13/16 mm 18/20/22/25 mm	729011576P97
CI3	CIT Narrow - External hex implant for narrow crest or narrow space between teeth	3.0 mm	10/11.5/13 mm	729011576CI3GN
CIT	CIT Hex - Conical internal hex implant with a short parallel upper part. Self-tapping with buttress thread.	3.3/3.75/4.2/5.0/6.0 mm 3.75/4.2/5.0/6.0 mm	8/10/11.5/13/16/18/20 mm 6 mm	729011576CISL
CIC	CIT Conical - Conical-connection conical implant with a short parallel upper part. Self-tapping with buttress thread.	3.3/3.75/4.2/5.0/6.0 mm	8/10/11.5/13/16/18/20 mm	729011576CICHL

On-the-Device Labeling

The IFU contain information about substances that are subjected to label requirements according to Section 10.4.5 of EU MDR

	Catalogue number		Regulatory compliance
	Batch code / Lot number		Consult instructions for use
	Quantity		Consult electronic instructions for use
	Use by date		Do not resterilize
	Do not re-use		Do not use if package is damaged and consult instructions for use
	Sterilized using irradiation		Manufactured by
	Importer		Date of manufacture + and country of manufacture
	Temperature limit 15°C to 25°C		Distributor
	Unique Device Identifier		Authorized representative in the European Community
	Keep dry		Single sterile barrier system
	MR Unsafe		Keep away from sunlight
	This product may be dispensed only by prescription of a licensed practitioner		Caution
			Do not reuse open packaging

Sterilization Method

The implant sets are sent to Gamma Radiation at Sor Van Ltd, ISRAEL.

Shelf life

Implants shelf life is up to 5 years. See expiry date / use-by date on the label.

Condition for use, Transportation and Storage

The implant sets will be transported only in the original package and inside a good hard cover package. If the original package is damaged do not use it. The product must be stored in a dry place, away from sunlight, water and sources of heat. It should be stored at room temperature 15°C to 25°C.

Disclaimer: this instruction provides the information necessary to use the device in a safe and efficient manner. Please read thoroughly and understand the instruction before operating the system. If any part of this manual is not clear, contact ARDS for clarifications.

Properties of Products

The implants and abutments are constructed of a Titanium alloy.

Important warning

Lack of adequate training of practitioner is a major risk factor for the success of the implant procedure and might endanger patient health.

No implantation shall, therefore, be performed without prior adequate training by a certified institute.

Reuse can cause infections, bone resorption, hard and soft tissue damage and/or implant failure.

Implants success and osseointegration was found to be directly related to the cleanness of the implants' surface, lack of any biological or other contamination on the surface and level of sterility.

Reportable Events: Any serious incident that has occurred in relation to the dental implant should be reported to the Company and the competent authority of the Member State in which the user is established.

According to Article 32 of EU MDR, you can find links to safety and clinical performance at the EUDAMED website or at the ARDS office by email.

Implant card uses

An FRM-7.5.3.00.02 Implant Card (IC) is supplied with this product as required by Regulation (EU) 2017/745.

After implantation, the healthcare provider must complete the card with the relevant patient and product information, and provide it to the patient.

The patient should be instructed to retain the card and present it during any future medical consultations or procedures.

Limited warranty

Preservation and storage precautions, packaging, sterility, surgical precautions, prosthetic precautions, possible undesirable side effects.

Limited Warranty: In case of implant failure, ARDS undertakes to replace such implant unit, free of charge, subject to the following conditions:

A written notice of such failure is submitted to ARDS, not later than within 6 months of the first sign indicating such failure, accompanied by a follow-up report in the form issued by ARDS, the relevant X-Ray and the failed implant. This is the complete warranty for the implant by ARDS, setting forth your exclusive remedies respecting thereto.

For more details on the indications and handling of the ARDS dental implants system, please refer to ARDS literature (catalogue, user guide, research, etc.).

Manufacturer

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