INSTRUCTIONS FOR USE FOR THE AB DENTAL DEVICES IMPLANT SYSTEM

DISCLAIMER: AB Dental Devices' products are intended for use only by certified dentists and authorized personnel with specific implant training.

CAUTION

Federal (USA) law restricts the sale of this device to, or on the order of a licensed physician or dentist.
AB Dental Devices implants are used for two-stage and one-piece implantation processes. The implants are made of Titanium alloy. AB Dental Devices implants are delivered in sterile, sealed containers. They are intended to be used only with AB Dental Devices products: Instruments and prosthetics accessories that are compatible to each implant platform. If these conditions are not met, the manufacturer will refuse to accept responsibility.
Product availability may vary between countries according to regulation approvals.

INTENDED USE

AB Dental Implants are dental implants intended to be used in the upper or lower jaw bone for anchoring and providing support to tooth replacements, such as artificial teeth, in order to restore chewing function.
AB Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
Two Stage Implants: I2, I22, I5, I55, I6BI, I10, I5C, I10C.
One Stage: I6, I6b, I6B, I7.
One Stage & One-Piece 3.0 mm diameter implants: I6, I6B are intended for placement at the mandibular central and lateral incisors and maxillary and lateral incisors. Indicated also for denture stabilization using multiple implants.
One stage & One-Piece 2.4 mm diameter implants for temporary use or long-term use: I6, I6b, are intended for immediate splint stability and long-term fixation of new or existing crown, bridge and prosthesis.

Patient Target

The products are intended for women or men over the age of 18 years old.

CONTRAINDICATIONS

Customary contraindications associated with implant materials used in oral surgery should be observed.
First, the patient's general health and suitability for oral surgery must be assessed by the general practitioner.
Insufficient bone, complicated grafting surgery.
Smoking, poor oral hygiene, drug use, alcohol use.
Illnesses like diabetes, malnutrition, hemophilia, autoimmune disorders.
Involuntary tooth grinding during sleep, Bruxism.

GENERAL DISEASES AND MEDICATIONS

Cardiovascular disorders associated with high endocarditic risk (SBE); Coronary insufficiency; Blood dyscrasias; Immunodeficiency, AIDS; Cancers and radiation of the facial region in the past five years; Respiratory disease; Thyroid or parathyroid disease; Patients with nodular enlargements, or inexplicable lumps on the head or neck region; Bone metabolism disorders; Diabetes; Hypertension above 170/110 mmHg; Drug abuse, alcoholism; Titanium hypersensitivity; Patients on corticosteroids, anticoagulants, anticonvulsive, and immunosuppressant therapy; Patients with abnormal values for creatine, BUN or serum calcium; Hemophilia; Granulocytopenia; Steroid use; Prophylactic antibiotics; Ehlers-Danlos syndrome; Renal failure; Organ transplantation; Fibrous dysplasia.

RELATIVE CONTRAINDICATIONS

Mild psychological disorders, aggression, smoking, use of chewing tobacco; Practitioner has reason to believe that the patient will not comply with post-operative instruction.

TEMPORARY CONTRAINDICATIONS

Lactating or pregnant women; Children with undeveloped bones.

LOCAL CONTRAINDICATIONS

Inadequate bone mass; Residual infections and inflammations occurring around implant; Poor oral hygiene; Hypersensitivity to components of the implant; Periodontal diseases.

SURGICAL RECORD

Mandatory initial diagnosis: Patient's medical history, Biological observations, Radiographic evaluation (CT scan intra-oral X-rays, pan-oral), Clinical examination of patient's: hygiene, teeth, occlusion, periodontium, etc.

SURGICAL AND RESTORATION PROCEDURES SURGERY

The hard and soft tissues must be carefully managed, to ensure Osseo-integration. The site must be prepared with extreme precision. Any ancillary instruments used must be properly sterilized. The surgical procedure requires drilling speeds from 1200 rpm for the pilot drill to 200 rpm for the final drill. Physiological saline must irrigate the area, while the graduate diameter drill increment sequence must be strictly adhered to. Thermal trauma will be reduced if these procedures are followed.
The implant size (height and width) is chosen according to preliminary X-rays. There must be a 2-mm margin from anatomical obstacles and maximum bone height.
The implants are provided sterile.
Implants are not to be re-sterilized.
Implants are for single use only.
All devices should be placed in a sterile surgical field/tray during surgery.
The shelf life of the devices is six years or five years (for India only).

GUIDE TO CHOOSING THE PROPER IMPLANT

After making a preliminary diagnosis, an X-ray and/or CT, in conjunction with a transparency that displays the necessary measurements, should be used to determine the dimensions of the implant suitable for the site in question.
It is the dentist reasonability to choose the most appropriate implant type and size and to fit the specific site drill protocol accordingly.
As a general rule, the widest and longest implant suitable for a particular site (density and dimensions of bone, dimensions of gums) should be used, in order for rehabilitation to be most effective. Another general rule is that implant and abutment combinations offer the greatest range of rehabilitation options. The use of the Integrated Implant offers some advantages that appeal to certain patients and are appropriate for them. The choice of an integrated implant/abutment (one-piece) requires immediate loading and rehabilitation and cementing of the restoration device. There is no affixing of the abutment by screw, and no choice as to the structure of the abutment. That choice is made beforehand. In a two-stage implantation, if there is a need for immediate loading, the conical implant, which has good retention from the outset, should be used. Below are some more specific guidelines for various situations.
In the front, single-rooted teeth and in the upper teeth between tooth 14 to tooth 17 and between tooth 24 to tooth 27, where the sinus cavity is found, wide conical implants are recommended in order to reduce pressure on the base of the sinus. When the bone is very wide, and the sinus cavity is distant, any implant can be used. When the bone is narrow, a wide implant should not be used.

RECOMENDED DRILLING PROCEDURE FOR ALL IMPLANTS

Following appropriate surgical exposure of the bony surface, the position for the implant placement should be determined and a marking guide hole should be made using our marking drill, taken down into the cortical bone to the level of the neck beneath the drill cutting head. Do not attempt to drill deeper with the marking drill. Using the guide hole for position, the color-coded drill will be utilized to drill the osteotomy to the desired depth. The color coding on the drills indicates their diameter. The drill protocol for all implants starts with Ø2.0 mm drill. In case preferred, for small diameter implant smaller diameter drills can be use. The drills are used in graduated order to slowly increase the diameter of the osteotomy until the desired diameter is reached. This will allow safe progression and decrease trauma to the surrounding bony structures. The accurate depth of the osteotomy is determined by the length of each particular implant and is indicated by the depth lines around each drill, in order to allow good position of the implant in the bone so that its proximal end is flush with the alveolar ridge.
Procedure recommended by AB Dental should not replace the dentist/surgeon's judgment and experience.
Final drill color (for hard bone) should correspond to Implant's Tube Cap color.

RECOMMENDED FINAL STRAIGHT/STEP DRILL PROTOCOL

Implant Diameter [mm]	2.4	3	3.3	3.5	3.75	4.2	4.5	5 Conical Platform	5	6
Drill Diameter Soft Bone [mm] (*3)	Ø2	Ø2	Ø2.5	Ø2.8	Ø2.8 (*1)	Ø3.2 (*1)	Ø3.65 (*1)	Ø3.65 (*1)	Ø4 (*1)	Ø5.0 (*1)
Drill Diameter Hard Bone [mm] (*3)	Ø2	Ø2.5 (*1)	Ø2.8 (*1)	Ø3.2	Ø3.2 (*1)	Ø3.65 (*1)	Ø4 (*1)	Ø4 (*1)	Ø4.5 (*2)	Ø5.5 (*2)

(*1) Optional Cortical plate drilling with next diameter straight drill in case needed.
(*2) Optional Cortical plate drilling with Counter Sink in case needed.
(*3) For step-drills the large drill diameter.

RECOMMENDED FINAL CONICAL STOPPER DRILL PROTOCOL

Implant Diameter [mm]	2.4	3	3.3	3.5	3.75	4.2	4.5	5 Conical Platform	5
Drill Diameter Soft Bone [mm]	Ø2.2	Ø2.2	Ø2.7	Ø2.7	Ø3.3	Ø3.2	Ø3.7	Ø3.7	Ø4
Drill Diameter Hard Bone [mm]	Ø2.2	Ø2.7	Ø3.3	Ø3.3	Ø3.2	Ø3.7	Ø4	Ø4	Ø4.5

INTERNAL CONNECTIONS (STANDARD, NARROW AND CONICAL PLATFORMS) IMPLANTATION PROTOCOL

After the implant is removed from its double wrapping its sterility should be maintained. For package with implant carrier the implant should be screwed manually via the carrier, extract the carrier and follow insertion of the implant inside the osteotomy by implant drivers as required.
Important: Do not exceed 30Ncm when using the implant carrier to insert the implant!
For package without carrier the implant is taken form the package using implant driver and screwed inside the osteotomy as required. The recommended position for perfect restoration is achieved by reaching the exact height, with one of the hexagon's faces tangential to the external jaw arc. Implant driver assist the visualization of the Hexagon faces. Complete the screwing motion with a torque up to 50Ncm. In case of immediate loading the recommended insertion torque is at least 35Ncm.

One can close the implant top with a cover screw, stitch, and wait for recovery, or load immediately by installing the proper abutment, and stitch tissue around. Remove the cover screw or healing cap prior to restoration in two-piece implants.

STORAGE

The implants should be kept in their original packaging. The products should be stored in a clean environment, away from direct sunlight. The implant should not be used after the expiration date on the package. Do not store implants near dangerous or toxic materials.

WARNINGS

Implant surgery is a highly complex procedure and practitioners are advised to take the necessary courses that train implant surgery. Improper implant techniques may result in implant failure and loss of bone.
AB Dental Devices implants are intended to be used only according to the recommended protocol with AB Dental Devices drills.
Implants placed at large angles may lead to implant failure. Bone loss, infection and movement of the implant may indicate that the implant is failing. If any of these is observed, the problem should be treated or the implant removed, as soon as possible.
Implants are for single use only, re-use of an implant is prohibited and can cause serious contamination and cross contamination.
Important: Do not exceed 30Ncm when using the implant carrier to insert the implant!

SIDE EFFECTS

Risks include: Immediate anesthetic surgical risks, psychiatric risks, medical threats to long-term retention, long-term effects on health and other complications. Complications may include: delayed healing, edema, hemorrhage, dehiscence, paresthesia, hematoma, allergic reaction, inflammation, perforation of the sinus, nerve damage, speech problems and gingivitis.
Long-term problems may include: nerve damage, bone loss, hyperplasia, local or systemic bacterial infection, endocarditis, long-term pain and fractures of the bone, the implant or the teeth.
The following organ systems that might be affected:
Cardiovascular: coronary heart disease, arrhythmias; Respiratory: chronic pulmonary disease; Renal: chronic renal failure; Endocrine: diabetes, thyroid disease, pituitary and adrenal disorders; Hematologic: anemia, leukemia, blood clotting disorders; Musculoskeletal: arthritis, osteoporosis; Neurologic: stroke, palsy, mental retardation.

CHANGES IN PERFORMANCE

It is the responsibility of the clinician to inform the patient on the side effects, contra-indications and any change in implant's performance.
If any of the side effects occur, it is the responsibility of the patient to seek a professional clinician immediately.

PRECAUTIONS

Adequate palpation and visual inspection of the future implant site must be carried out in order to determine if there is sufficient quality and volume of bone for placing an implant. After implant failure, the quality and volume of residual bone must be evaluated. The implant is supplied in sterile packaging. Do not re-sterilize. An opened, damaged, or defective package should be returned to the supplier for free replacement.

The use of an implant does not require the use of any unusual preoperative antibiotic prophylaxis. In the case of unexpected pain, the surgeon must be contacted immediately. Physical exertion should be avoided following surgery. Patients must be informed that the implant is a metallic device and may affect the performance of MRI apparatus.

MR SAFETY INFORMATION

AB Dental Implants have not been evaluated for safety and compatibility in the MR environment.
It has not been tested for heating, migration, or image artifact in the MR environment. The safety of AB Dental Implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

HYGIENE AND MAINTENANCE

The quality of oral hygiene directly affects the long-term success of the implant. The patient should be instructed on the use of the proper tools and the maintenance of oral hygiene for preserving implant health and should visit a dental professional for periodic check-ups and regular cleaning.

GUARANTEE

AB Dental Devices undertakes after sale, to replace any implant or restoration component bearing the name AB Dental Devices. This guarantee does not cover the surgical accessories or tools used with the implant. AB Dental Devices stipulates that to be covered by this guarantee, AB Dental Devices implants must be implanted according to the protocols and procedures described in this manual. The practitioner must undergo formal training in implant surgery. AB Dental Devices cannot be responsible for anybody or material damages whatsoever. This guarantee ensures that if necessary, the company will replace the damaged implant or cover the expenses of purchasing the replacement.
It is important for the surgeon to take note of the batch number of the implant, should there be any warrant for replacement/return implant.

DISPOSAL

Contaminated or no longer usable implants must be disposed/discarded according to local authority regulations and environmental requirements. In case contaminated implants need to be returned to AB Dental Devices, please follow the company return policy.

NOTE

Issues that arise in relation to the implant should be reported together with the related implant to the AB Dental Devices' representative.
In case that any serious incident occurs in relation with the implants, the user and/or patient should report to AB Dental Devices and to the competent authority of the Member State in which the serious incident occurs.
The implant card should be provided by the dentist/surgeon to the patient.

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	Use by date
	Do not re-use
	Caution Indicated the need to consult the instructions for use for important cautionary
CE	**CE marking of conformity**
LOT	**Batch code** Lot number
REF	**Catalog number**
eIFU	**Consult instructions for use: www.ab-dent.com/ifu**
	Date of manufacture
	Manufacturer
Rx only	**Subject to prescription**
MD	**Medical Device**
	Keep away from sunlight
STERILE R	**Sterilized using irradiation**
	Do not use if package is damaged
EC REP	**Authorized representative in the European Community**

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