English

Instructions for Use: K3Pro®Implants

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1.Product information:
The K3Pro® Implant System is a self-contained system of endosseous implants with corresponding surgical and prosthetic parts and instruments. The K3Pro® Implant System is made of titanium grade 4. The cover screws of the K3Pro® Implant System are made of titanium grade 5. This material has been repeatedly found to be biocompatible in studies. The surface configuration has been carefully designed and should not be altered. The implants are supplied with the OsteoActive® etched surface treatment.

2. Application:
The K3Pro® implant system can be placed in the mandible or maxilla. There are different sizes to choose from, which fit into healed or fresh extraction sites. The K3Pro® implants must be placed 1-2mm subcrestally, except for the K3Pro® SHORT implants (see 8.). For information on surgical procedures, please visit our website at www.argon-medical.com or take a course on K3Pro® Implant System surgical procedures.

3. Indications:
The K3Pro® Implant System is intended for use in edentulous sites in the mandible or maxilla to support a complete denture, bar, intermediate abutment for fixed bridges, partial dentures or as a single tooth replacement. The K3Pro® Implant System is intended for placement in bone as a submucosal screw to which a permanent or temporary prosthesis can be attached.

4. Contraindications:
The K3Pro® Implant System should not be used in patients with contraindicated conditions such as blood dyscrasias, uncontrolled diabetes, hyperthyroidism, bruxism, oral infections or malignancies. The K3Pro® Implant System should also not be used in patients with contraindicated conditions such as myocardial infarction within the last year or insufficient supporting bone to allow the use of an appropriately sized implant. Implants should not be placed if the width and height of the alveolar bone is insufficient to completely surround the implants.
a) K3Pro® Short Implants are not intended to be used as single-tooth replacements, neither splinted nor unsplinted, in the anterior tooth area, premolar or molar region. They should also not be used as denture fixation with less than four (4) implants. Their use is as a fixation for bridges with a maximum of one pontic between the abutments, in conjunction with multiple implants.
b) K3Pro® Mini Implants (ø 3.0 - 3.5 mm) are not intended for single tooth replacement, either splinted or splintedless, in the premolar or molar region. They are also intended as permanent support for a prosthesis, but only when four (4) implants or more are used. They are not designed for lateral loading. Their only use is as an abutment for fixed bridges in conjunction with multiple implants.

5. Warnings
a) implant surgery is a highly specialized and complex procedure. The established techniques of oral implantology require special training. Implant courses and seminars are strongly recommended before surgery is performed. Incorrect technique can lead to implant failure and significant loss of surrounding bone. The K3Pro® Implant System should not be used in locations or situations other than those specifically indicated.
This may lead to failure of the implant with simultaneous destruction of the supporting bone. The K3Pro® Implant System may only be used with the bone drills specifically supplied for this purpose. Only dentists and oral and maxillofacial surgeons or oral surgeons are permitted to use the K3Pro® Implant System products.
b) Hygiene and disinfection: The K3Pro® Implant System is supplied sterile. If the implant package is damaged or if the implants become contaminated in any way, they should be discarded. The K3Pro® Implant System is intended for single use. Implants are delivered sterile by irradiation and should not be cleaned or sterilized.
c) MRI Safety Information: The K3Pro® Implant System has not been tested for safety and compatibility in the MRI environment. It has not been tested for heating, migration or image artifacts. Therefore, the safety of the product in the MRI environment is unknown. Scanning a patient with this product may result in patient injury.

According to currently available scientific literature, titanium can be considered to reflect the state of the art as a material. Furthermore, current evidence suggests that only minor effects are to be expected from titanium. However, the individual decision regarding the use of magnetic resonance imaging is the responsibility of the radiologist in each case."

6. Precautions:
Panoramic radiographs or X-ray should be used to determine if sufficient bone is available at the intended implant site and to locate established critical anatomic features such as the mandibular canal, mental foramen, maxillary sinuses, and adjacent teeth. Adequate reporting and direct visual inspection of the prospective implant site are also required to determine the anatomy of the available bone. A thorough clinical evaluation is essential. Proper patient motivation is necessary if the procedure is to be successful.

7. Side effects:
The following complications associated with the procedure may occur, but were not caused by the implant itself: dehiscence, delayed healing, paresthesias, edema, hematoma, infection, inflammation, and general allergic reactions.

8. Notes on the K3Pro® Short implant system:
When using K3Pro® Short implants, the implant should be placed at least 3 mm subcrestally. Clinicians should carefully monitor patients for any of the following conditions: peri-implant bone loss, changes in implant response to vibration, or radiographic changes in bone at implant contact along the implant length. If the short implant has mobility or more than 50% bone loss, the implant should be evaluated for possible removal. If the clinician chooses a short implant, clinicians should consider a two-stage surgical approach in which a short implant serves as an additional implant and is placed with the largest possible implant diameter. Allow extended periods for osseointegration and avoid immediate loading.

9. Sterile handling:
The assistant removes the sterile Tyvek blister pack from the box, carefully opens the Tyvek blister pack and allows the inner pack to fall freely onto a sterile tray. Do not contaminate the inner packaging.
The assistant or dentist grasps the K3Pro® implant container and removes the cover cap, which also contains the K3Pro® cover screw. The implant is removed from the container in the following way:
a) Implant insertion:
Grasp the container with sterile gloved fingers and insert the insertion tool into the implant while squeezing the container. The insertion tool should engage the hexagonal connection of the implant, which is also indicated on the instrument mark. If inserted correctly, the mark on the insertion tool should meet the upper part of the implant body. The implant should now be slightly tapered and allow placement into the osteotomy without having to separate the implant and instrument. The implant is now placed into the prepared osteotomy according to the surgical instructions from the K3Pro® Implant System.
b) Instrument removal:
Remove the insertion instrument from the implant by gently wiggling the insertion instrument until the conical connection disengages from the implant and the instrument can be removed.
c) Placement of the cover screw of the K3Pro® implants:
Remove the cover screw from the container cover cap using a 1.2mm Hex screwdriver and turn counterclockwise. The screwdriver has a conical tip so that the connection with the cover screw is ensured for placement.
Used correctly, there is no direct contact with the sterile component.

10. Surgical Instructions:
The implant bed is prepared according to the implant insertion length with a 2.0 mm twist drill using external irrigation. The implant bed is prepared with the step drills (3.0 - 6.0) up to the implant diameter at low speeds (40 - 50 rpm for titanium drills) without irrigation, (600-1000 rpm for steel). After completion, the instrument is center-punched to match the corresponding implant diameter.
For D1 - D2 type bone densities, the use of a tap (20 rpm) is recommended. It should be ensured that the implant length has been properly reamed and is not obstructed by bone particles. Safety can be ensured by using the bone level gauge. The K3Pro® implant is screwed into the prepared alveolus manually or by machine.

11. Recommended torques for implants:

Platform	troques (ratchet)	Max. insertion speed (handpiece-/contra-angle)
2 mm	35 N/cm2	20 U/min
3 mm/ Short	45 N/cm2	20 U/min

The implant is intended to be used as a support for a temporary or permanent prosthesis, so these should be closed with a closure of the mucosal flap during osseointegration of the endosseous implants after implant placement.

12. The K3Pro® implant system warranty and limitations:
The success of all dental implants depends on the surgical procedure, which must be performed carefully. Careful patient selection and final restorative prostheses that meet individual patient needs and remaining anatomical conditions are essential. Selection of single or multiple implants of appropriate size and configuration for the existing anatomy is also critical to success. For the above reasons, Argon strongly recommends that all dentists attend one or more endosseous dental implant courses or symposia on the use of the K3Pro® Implant System before attempting to place implants in their dental practices. Because Argon cannot control factors within the scope of services performed by the dentist, including patient selection, surgical technique and restorative techniques, Argon assumes no responsibility beyond product replacement for failures or other adverse reactions or results from its purchasers arising from or through the use of a K3Pro® Implant. The K3Pro® Implant System is manufactured from Grade 4 surgical titanium and is supplied with the OsteoActive® surface treatment and, which has been found to be highly biocompatible by biomaterials researchers in numerous animal and human studies conducted over many years.

The K3Pro® Implant System and titanium abutments are exceptionally resistant to bending and fracture. However, there is no guarantee that fracture or bending of an implant or abutment cannot or will not occur due to traumatic injury or excessive occlusal stress. For the foregoing reasons, unless otherwise expressly stated, Argon makes no warranties beyond those contained in this warranty or beyond the description contained in any invoice. This warranty is in lieu of all other warranties, expressed or implied, including merchantability and fitness for a particular purpose. Argon sells and warrants this to purchasers who are licensed dentists and who purchase implants and abutments for the purpose of their use and resale as part of the services they provide to patients. Argon does not grant any written warranty to any consumer, patient or end user and does not authorize any person to make such a written warranty on its behalf. The remedies of any purchaser from Argon (and its liabilities) shall be limited solely to the replacement or repair of a defective K3Pro® implant or abutment if such product was defective at the time of shipment and was returned to Argon for inspection, replacement or repair within six (6) months of its shipment. Argon shall not be liable to any person for incidental, consequential or other damages of any kind, whether a claim or potential claims are based on contract, negligence or tort theories.

CE **2797** Products of Argon Medical Productions & Vertriebs Gesellschaft mbH & Co. KG with CE approval meet the requirements of the Medical Devices Directive 93/42 EEC.

℞ Only Caution: According to US Federal Law, this product may only be sold directly to or on behalf of a trained medical professional.

SN	serial number		do not use if package is damaged
REF	product code		manufacturer
	read instructions for use		warning
	date of manufacturing		to be used until
	Single use only		keep dry
STERILE R	sterilization by irradiation		do not sterilize again

Rev. 10 - 4.2024