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Instruction manual
for STERILE Albus WITAR Implants „AWI“
3908 3910 3912 4508 4510 4512 5008 5010 5012 6008 394010 394012
3908R 3910R 3912R 4508R 4510R 4512R 5008R 5010R 5012R 6008R 394010R 394012R
5008Z 5010Z 5012Z 5008ZR 5010ZR 5012ZR

1.Description of the system
The AWI Implants consist of a single-phase (One-part 394010 und 394012 were developed for lower front teeth) and two-phase (Two-part 3908, 3910, 3912, 4508, 4510, 4512, 5008, 5010, 5012, 6008, 3908R, 3910R, 3912R, 4508R, 4510R, 4512R, 5008R, 5010R, 5012R, 6008R, 394010R, 394012R, 5008Z, 5010Z, 5012Z, 5008ZR, 5010ZR, 5012ZR.
have been developed for upper anterior and posterior teeth and lower posterior teeth)systems. The AWI dental implants are made of TZP zirconia ceramic (Tetragonal Zirconia Polycrystal Bioceramics according to ISO 13356). These implants are made of one piece. At one end there is a thread (screw thread) that is placed in the bone and at the other end there is a head (abutment) or an internal thread for inclusion of the an abutment, which the dental prosthesis is attached to. After insertion, the inner lumen of the two-part AWI implant is closed with an enclosed sterile cover screw made of PEEK plastic. After the osseointegration, the cover screw is removed for prosthetic restoration; the abutment is screwed in and cemented with glass ionomer cement. The thread is not coated and might have different surface roughness. All AWI implants heal transgigivally into the jawbone. Implants have been certified according to the European Directive (directive 93/42/EEC, appendix II, classification IIb). The implant is essentially a replacement for a natural root. This zirconia ceramic product is designed for surgical insertion into the bone of the upper or lower jaw arch as a support for dental prothesis in order to restore patient's chewing function as an artificial tooth. These instruction manual is not sufficient for immediate use of dental implants. It is recommended to do a training course with an expert who is experienced in this system before using dental implants. Implants may only be placed by dentists, doctors or surgeons, who have received specific training and have advanced experience in oral surgery, gum treatment, implantology and dental prosthetics. This is particularly important because the surgical implantation technique is complicated. The marking of information includes numbers and letters like AWI 3908: the following numbers stand for the diameter of the implant (3,9mm), the length of the implant (8mm). For AWI 394010: the diameter of the implant (3,9), diameter of the shoulder area (4 mm), the length of the implant (10 mm).

2. General operation/use
The implant is packed in a double sterile packaging and must be stored carefully in a closed protective packaging. Before unpacking the implant, check if the entire packaging is not damaged. If the transparent film is damaged, the sterility of the implant is no longer guaranteed. The transparent films can be opened only immediately before use. Damaged or previously implanted endoprostheses may not be reused.

3. Handling of sterile packaging
The dust must be cleaned of the sterile packaging before opening it.
After the folding box (according to EN 1041) is opened, the stickers, instruction manual and the transparent film are removed. The outer transparent film is opened and the implant, which is packed in the inner transparent film, is prepared for the surgery. The manufacturer is only liable for implants that were implanted immediately after removal of the original packaging.
Non-sterile implants must always be disposed of.
! Attention ! Implants that have fallen down can disintegrate due to internal stresses. In general, the implant must not be grinded, otherwise it might break.

4. Packaging and sterility
The sterilization process consists of an autoclave run, controlled by bioindicators (validated process) and a random check of the autoclaved endoprostheses using a sterility test (Direct feeding of two-layer medium for identification of aerobic and anaerobic germs). The implant is double-welded in autoclavable foil, packed and sealed in a folding box, so that the implant is protected against external factors and sterility of 4 years according to EN 868 is guaranteed.
Implants must be protected from moisture and sunlight, stored in original packaging in a clean and dry place. If the inner packaging is damp, damaged or was accidentally opened, the implant must not be used. Implants must never be reused or re-sterilized.

5. Documentation
The enclosed 3 stickers are used to identify the implant for practice, hospital, health insurance and patients to ensure that the implant can be traced back to the manufacturer. The key of the identification number is structured as follows: 1.-3. position - Type and size of the implant according to table
4.-7.position - serial number
8.-9.position - the year of manufacture

6.Indications
The patient should have no local or systemic contraindications; he should have normal healing ability, good oral hygiene and sufficiently healthy bones.
AWI dental implants are surgically inserted in the upper and lower jaw,to replace missing teeth. They serve as attachment points for dental protheses and are particularly suitable for patients suffering from metal incompatibilities and associated diseases. Suitable for implants connected by bridge or splint. AWI implants must be placed at tissue level.

7. Contraindications
Dental implants should not be placed to patients with health problems or diseases as well as those who suffer from physical or psychological condition that would discourage oral surgery. Relative contraindications: previously irradiated bone, diabetes, anti-coagulant treatment, hemodynamic problems, nocturnal teeth grinding, parafunctional habits, poor bone anatomy, heavy smoking, uncontrolled dental inflammation, malocclusion, Jaw joint problems, Diseases in the oral cavity, Pregnancy. AWI implants are not suitable for indications where there is a risk of excessive bending moments (Bridges with more than one connecting link, Krone/Brücke mit Anhänger). AWI implants are not suitable for bone level position. Contraindications: the bone is not completely healed,(Restostitis/NICO), untreated periodontitis, poor oral hygiene, untreated tooth and bone area, crown length is longer than the osseointegrated section of the implant thread, Cantilever bridges /- crowns (mesial or distal), connection between a natural tooth and an implant.
-Local contraindications: insufficient quality or quantity of bone, remaining roots, localized gums disease and any pathology in adjacent teeth.

side effects, interactions and complications of dental implants
-Temporary complaints: pain, swelling, phonetic difficulties and gingivitis.
-Permanent complaints: non-integration of the implant, chronic pain associated with the implant, permanent sensitivity, dysesthesia, bone loss in the bone crest, local or systemic infection, oronasal or oroantral fistulas, inflammation or pain, temporary or long-term damage to adjacent teeth, implant fracture, fracture of prostheses, aesthetic problems, damage of the nerve tissue, mobility of the implant, implant failure, gingival hyperplasia, bone or gum necrosis and radiological dilution.
Instructions: Dental implants are designed for surgical implantation in the upper and lower jaw, to support prostheses and replace missing or damaged teeth. There are different types of implants for different anatomies, dimensions and indications. Implant thread has a rough surface with osteoinductive properties. Implants without coating are particularly suitable for patients who suffer from periodontitis, are prone to it or smoke.
Warnings: Anatomical and general medical conditions can have negative effect on the performance of dental implants. If the external stress to the implant is beyond its functional capacity, it may result in excessive bone loss or fracture of the implant. The doctor must inform the patient about the following risks: poor bone quality, poor oral hygiene, ailments such as blood diseases or untreated hormone disorders, alcohol or drug abuse, All AWI implants must be protected from stress during the healing phase.

8. Notes on the OP – Techniques and principles of planning the treatment
In the process of planning the treatment, interdisciplinary examination of the oral cavity is required. Among other things, it may involve: occlusal position, periodontal ligament, aesthetics, quality and quantity of bone, arrangement of teeth, anatomy and pathologies of adjacent teeth. For this purpose, the following supplementary examinations are carried out: periapical X-ray images, panoramic X-ray images, DVT-CT images, teleradiograpgic images, dental scanner, photos, work models, diagnostic waxing, radiological splint and surgical manual. Having considered the instructions of the implant and the plan of the treatment, a dentist or a surgeon has to identify the most suitable type and lenght of the implant.The oral cavity must be completely disinfected. In each case, it is necessary to determine the best type of the implant. A surgical manual (protocol) is necessary to ensure that the implant is placed in the exact position with the exact angle.Mistakes in the process of planning the treatment can possibly lead to the failure of the implant.

9. Operation
Standard surgical procedures for dental implantation must be followed. The location of the implant must be prepared according to the treatment plan and surgical manual (protocol). The main aim of the implantation is to achieve the primary stability of the implant. Standard drilling systems can be used to prepare the location for the implant. The location of the implant should be prepared in such a way that the implant can be inserted in a position so that the fitting of the implant (shoulder) is at the same level as the fitting of dental protheses. After the preparation of the location for the implant, the implant must be screwed into the bone with a special wrench. The stump of the implant must not reach the bite

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position of its antagonist in order to avoid premature pressure and the failure of the implant. If the implant moves after the implantation or has a weak primary stability, a rigid splint must be placed between the implant and the adjacent teeth or implants.

10. Important information about our implants

Dental protheses must be made entirely of ceramics and without metal. It is necessary to have good occlusion and disocclusion. The dental protheses must be slightly in infraocclusion in order to compensate the elasticity of the periodontal membrane of the adjacent teeth. It is important to avoid lateral occlusion so that the implant does not have to bear an excessive pressure, which can result into the fracture of the implant or damage it. A dentist and a laboratory technician must be specially trained and considerably experienced in dealing with all ceramic dental protheses. Implants must not be connected to natural teeth. The connection between two implants must not be larger than a bridge of three units. The cement must be compatible with fully ceramic dental protheses.

Endoprostheses, which are permanent implants, are desined to replace natural parts of the body. The following information must be observed before using implants:

a. The appropriate type of the implant is extremely important.

The success of the procedure largely depends on the appropriate type and size of the implant. The choice of the size and shape of the implant is limited by the shape and size of the human bone. For this reason, stress capacity is also limited. Implants are not suitable for bearing the unrestricted load. Endoprostheses require a particularly accurate implantation and support in the bone. Their stress should be limited to normal functional load. Exceptional loads, especially those caused by impact and shock forces, can break the ceramics.

b. The correct handling of the implant is extremely important.

Under no circumstances should the implant be knocked with hard objects during the operation.

The maximum torque for the insertion of the implants must not exceed 35Ncm. Only appropriate instruments may be used for the insertion of the implant. This and similar operations can damage the structure of the zirconium oxide ceramic as well as hidden material, which can cause the fracture of the implant.

c. Any implants may not be reused or sterilized on the site

Even if the implant looks undamaged, the internal material will be damaged. Implants that have not been sterilized must not be re-sterilized, because it can cause hairline cracks. We point out explicitly that only brand-new, originally packed implants of the latest design should be used.

d. The post treatment is also very important.

11. Duration of healing of the wound

The duration of implant integration into the bone is very individual and depends on the treatment, and must be individually customized. It may take up to four months. During the healing period, special attention must be paid to oral hygiene and occlusion. The implant must not be exposed to lateral pressure which can result in movement and failure of the implant. The healing period may take longer as a result of poor bone quality, bone regeneration or the immediate filling of a position after tooth extraction. After the operation, the implant must be checked regularly by X-ray in order to detect any risk of implant failure. Dental implants must not hold a temporary removable prostheses before bone integration. All dental prostheses must be temporarily cemented and they must not touch the bite position of their antagonist.

GRAPHIC SYMBOLS:

	DATE OF MANUFACTURE		DATE OF EXPIRY
	MANUFACTURER		
STERILE	STERILISATION BY STEAM OR DRY HEAT	LOT	BATCH DESCRIPTION
	FOR SINGLE USE ONLY	CE 0483	CE MARKING NB NO. 0483
	ATTENTION, NOTE ACCOMPANYING DOCUMENTS	REF	PURCHASE ORDER NUMBER
	DO NOT RESTERILISE		DO NOT USE CONTENTS IF THE PACKAGE IS DAMAGED

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