**Aarhus Mini-Implant System / screw implant and anchoring system for orthodontic treatment for correction of incorrectly positioned teeth and jaws**

**Contents**



## 1.) General Information

**Before clinical use, the operating instructions must be read carefully in their entirety.**

**Implants are supplied unsterile.**

**Aarhus mini-implant screws must only be inserted by orthodontists, dentists, oral surgeons and surgeons specializing in maxillofacial surgery**

Die MEDICON eG, as the original distributor of these products, does not accept any liability for immediate or consequent damage caused by improper use or handling, especially due to non-observance of the operating instructions or inappropriate care or maintenance of the products.

Medicon Aarhus mini-implant screws are made of Ti6Al4V alloy (ASTM F136-02a). The material is biocompatible, corrosion-resistant and non-toxic in the biological milieu. It allows practically artefact-free imaging with:

- conventional x-ray radiography
- computer tomography
- MRI (Magnetic Resonance Imaging).

**Patients who have implants inserted and are undergoing an MRI must inform the staff responsible for the MRI investigation about the implants. With MRIs up to 1.5 tesla, implants Do not present any risk with regard to positional change or Heating up of tissue. The surface is chemically passive and the material is antimagnetic.**

**All standard hygienic precautions required for invasive procedures such as a sterile working environment, sterile gloves, surgical masks etc. must be taken before and during insertion of Aarhus mini-implant screws.**

## 2.) Indications

The Aarhus Mini-Implant System is designed for orthodontic treatment (anchorage of orthodontic appliances with wires, springs, rubber rings) for correction of incorrectly positioned teeth and jaws It is used for treatment of patients where anchorage is impossible in the posterior region and as required with:

- Retraction and/or intrusion of the front teeth
- Intrusion of molars and/or premolars without occluding teeth
- Mesial movements of molars where no front retraction is acceptable
- Proclination of lower incisors where no posterior anchoring units are available or where no reactive forces can be tolerated
- Space closure against absolute anchorage

## 3.) Contraindications

The Aarhus Mini-Implant System must **not** be used when the following contraindications exist:

- Patients that are unable to follw the Instructions for postoperative care. This may be caused e. g. by psychological/mental or neurological Problems of the patient.
- Patients with inadequate bone tissue, or bone tissue of insufficient Quality, and patients with circulatory Disorders of latent infections.
- Extreme material sensitivity, i. e foreign-body reaction of the patient. For this case appropriate tests must be carried out under all circum-stances prior to implantation (even When there is only a suspicion of Such condition.
- Acute Infections
- Radiotherapy in the head region and patients with tissue damaged by radiation
- Recurring diseases of the oral mucosa and poor oral hygiene

## 4.) Possible Side-Effects and Complications

- Complaints, pain, abnormal sensations or palpability of the implant.
- Material hypersensitivity of the patient due to the foreign bodies in the form of allergic reactions.
- The use of different materials may cause corrosion.
- Increased reaction of the connective tissue in the area of the implant.
- Inadequate bone formation, osteolysis, osteomyelitis, osteoporosis, inhibited revascularization or infection that may cause loosening, bending, cracking or breakage of the implants.
- Breakage, bending, migration or loosening of the implant.
- Inadequate osseointegration that could cause loosening or breakage of the implant and failure of the orthodontic treatment.
- Decrease of bone density as a result of stress shielding.

This surgical procedure may cause not only the above-mentioned side-effects and complications but also problems such as injuries to nerves, infections, pain etc., which are not necessarily caused by the implant. If complications occur, they are often the result of incorrect selection of the patient, lack of practice or lack of preoperative planning rather than caused by the implant itself.

## 5.) Selecting Aarhus Mini-Implant Screws

**Selection of the Aarhus Mini-Implant Screws is the responsibility of the maxillofacial or oral surgeon, dentist or orthodontist and must match the patient's anatomy.**



**MEDICON eG** Gänsäcker 15 78532 Tuttlingen Germany Tel.: (49) 7462 / 2009-0 Fax: (49) 7462 / 2009-50 e-mail: marketing@medicon.de sales@medicon.de homepage: http://www.medicon.de

Before using the Aarhus Mini-Implant Screws, the maxillofacial or oral surgeon, dentist or orthodontist must explain the desired course of treatment and the expected result in detail to the patient.
Selecting the incorrect implants may result in premature implant loss along with loosening, bending or breakage of the implant. Damage and scratches will reduce the strength of the product and cause premature fatigue of the implant. This will adversely affect the success of the treatment.

**6.) Handling**
Aarhus Mini-Implant Screws can be inserted in the maxilla in a vestibular of palatal position or in the alveolar ridge.
Insertion in the mandible should be vestibular only. Based on current knowledge, we advise against lingual insertion and insertion in the vicinity of extraction wounds, dental follicles and first teeth.

The following positions offer the best conditions for an insertion of the screw:
Maxilla:

- The infrazygomatica crest
- The anterior nasal spine
- The palate

Mandibula:

- The retromolar area
- The symphysis
- The alveolar process

Aarhus Mini-Implant Screws have a self-tapping thread, which makes pilot drilling unnecessary. However, it is up to the surgeon to decide whether it is better to drill a pilot hole into the cortical bone of the lower jaw. In this case select the drill and length to match the screw diameter. Drill a cavity of at least 4.0 mm with adequate cooling and at a speed of 800 – 1500 rpm.

The screw must be inserted in bone of appropriate quality only.

It is important to ensure that the screws are loaded with an appropriate orthodontic loading system immediately after insertion. If immediate therapeutic loading is not possible, an unloaded healing phase of at least three to four weeks is required.

To ensure a safe function of the Aarhus Mini-implant Screw, it must be securely anchored in the bone (primary stability) and the screw head must be placed in the region of the alveolar gingiva. When using the Aarhus Mini-Implant Screw as an anchoring element, make sure that the head and the surrounding soft tissue are not subject to any unfavourable mechanical stresses (such as movement of the mucosa, influence by bands and/or tongue, manipulations).

**Use only 50cN springs for anchorage, connected directly to the screw or to the teeth that are anchored by the screws.**

The line of force must always pass through the screw if the screw is used as direct anchorage. Forces that induce torque around the longitudinal axis of the screw (identical to the force that is required to insert or remove the screw) must be avoided. A thorough force system must be developed before insertion of the screw.

Other important information is covered in the various manuals on surgical technique.

**Aarhus Mini-Implant Screws are designed for single use only. An explanted Aarhus Mini-Implant Screw or one that has been otherwise used must not be re-inserted.**

Even if the screw appears undamaged, there may be minor defects and invisible overloading which could result in early wear and risk to the patient.

The packaging label carries a Lot no. We recommend transferring this Lot no. to the patient records as this number allows tracing the production history of the implant back to the raw material.

The implants and instruments are adapted to each other. Any useof implants and instruments from other manufactures in combination with Medicon products entails unpredictable risks, since the products are not adapted to each other. To avoid risks, only such Medicon products that are designated for combination with each other may be combined with each other.

**7.) Postoperative Care**
Periodic postoperative care and observation and also reduced physical activity after the operation and during the healing phase is very important for the success of the treatment. Implants may come loose, be displaced, bend or break as a result of overload. The supervising physician is responsible for deciding the type, duration and intensity of physical activity after the operation.
The patient must be advised that ignoring medical advice regarding the above and other areas may result in unforeseeable complications. This is particularly applicable if the patient manipulates the implant or appliance himself. Patients who are exposed to magnetic fields and/or electrical influences must be informed of the required precautions. Patients must inform medical personnel of the implant before any medical examinations.
The patient must be instructed to inform, with delay, the operating surgeon of unusual changes at the operating site. The patient must be monitored carefully if there is a manifest change in the fixation region. The surgeon must consider possible consequences, e.g. implant failure, and discuss with the patient any necessary measures for further healing.
It cannot be excluded that implants will break, loosen, corrode, migrate through tissue and cause pain.

The implants must be removed after the treatment has been completed. We can therefore only accept liability for implants up to the completion of treatment.. We do not accept any responsibility for any damage arising from implants which remain in the body after conclusion of treatment.

**8.) Application Instruments**
When inserting implants, use only those instruments specifically designed and sold for the Aarhus Mini-Implant System (see the product brochure).
The instruments intended for use of the system are subject to wear and mechanical stress even during normal use, and particularly if excessive force is used. In order to prevent failure or mechanical damage of the application instruments during surgery, they must always be checked before each use for mechanical integrity, full functional range, and possible deformation. Instruments with any damage must be discarded.


**MEDICON eG** Gänsäcker 15 78532 Tuttlingen Germany Tel.: (49) 7462 / 2009-0 Fax: (49) 7462 / 2009-50 e-mail: marketing@medicon.de sales@medicon.de homepage: http://www.medicon.de

**9.) Cleaning, Sterilization**
It is the responsibility of the user to make sure that appropriate cleaning and disinfecting methods are used.
Trained personnel must carry out cleaning along with maintenance and inspection for damage prior to the initial sterilization of new products.
The products must be cleaned, disinfected and sterilized prior to each use.

**Preparation for decontamination**
The screw implants are supplied in colour-coded screw holders (white, blue, red) and with a transparent cover and base for protection during transport and storage. The cover and base must be removed and the implants in the screw holder inserted into the implant cassette designed for the system, and the cassette lid must be closed. Remove any surface soiling resulting from use on the surfaces of the implant cassette with a disposable cloth or paper towel.
We recommend automated cleaning .

**Cleaning**
Suitable alkaline cleaners or those with a neutral pH can be used. The cleaning agent is selected depending on
the properties of the materials of the Aarhus Mini-Implant System and national directives and recommendations.

The cleaning and disinfection device (RDG) must comply with DIN EN ISO 15883-1.

1. Precleaning 1: 1 minute with demineralized cold water with no additives;
2. Draining;
3. Precleaning 2: 3 minutes with demineralized cold water with no additives;
4. Draining;
5. Cleaning: with demineralised water, heat to 55°C and wash/clean for 5 minutes, add cleaning agent at 45°C, alkaline cleaning agents, dosage 0.5%;
6. Draining;
7. Neutralisation: 3 minutes with hot water (>40°C) with neutraliser added, dosage 1 ml/l;
8. Draining
9. Final rinse: 2 minutes with hot tap water (> 40°C) (no other additives)
10. Draining

The parameter provided by the manufactures of cleaning agent with regard to concentration, temperature and exposure time must be adhered to. Automatic dosage devices must be controllable.

**Thermal Disinfection**
When using demineralized water, thermal disinfection should be carried out at temperatures from 80-95°C, with a corresponding soaking time according to the A0 approach (DIN EN ISO 15883-1).

**Drying**
Esure that the cleaning/disinfection device is programmed for an adequate drying time

**Maintenance, Inspection, and Testing**
Following cleaning and disinfection, the Aarhus Mini-Implant Screws and implant cassettes must be macroscopically clean, i.e. free of visible residue. This is checked by visual inspection. Critical areas require particularly careful checking. Any parts cleaned insufficiently must be cleaned again and must then be rinsed thoroughly.

**Sterilization**
Only cleaned and disinfected Aarhus Mini-Implant Screws may be sterilised. For sterilization, use the following sterilization procedure subject to national regulations:

- Triple fractionated vacuum method with sufficient product drying
- Autoclave in accordance with DIN EN 13060 or DIN EN 285 and validated in accordance with DIN EN 17665-1.

Sterilization time and temperature: **At least 5 minutes holding time at 134°C**

**Packaging**
The instruments must be packed in a suitable sterile barrier system. The sterile barrier system must comply with the following criteria:

- DIN EN 868 and DIN EN ISO 11607
- suitable for autoclaving (steam-permeable)
- adequate temperature resistance up to 138°C

Sterilization accessories and sterilizing packaging must conform to the package contents and the sterilization method.

**Storage**
To prevent condensation from forming, major temperature fluctuations should be avoided. Chemicals must not be stored with the Aarhus Mini-Implant Screws. Prepared sterile instruments must be stored in a suitable reusable sterilizing container in dry, dustproof, low-germ, dark and cool spaces that are vermin-proof. The approved local storage period depends on the type of sterile barrier system and the storage conditions. The operator must specify the approved storage period.

**It is the users' responsibility to validate the recommended sterilization parameters, or any other steam sterilization process than those recommended by Medicon, so that any differences regarding sterilization chambers, wrapping methods and load configurations are taken into account and the obligatory sterility assurance level (SAL) of $10^{-6}$ can be achieved.**

Please contact Medicon eG if you have further questions concerning the implants or instruments.

**CAUTION: For USA, federal law restricts this device to purchase by or on behalf of Physican or hospital.**



**MEDICON eG** Gänsäcker 15 78532 Tuttlingen Germany Tel.: (49) 7462 / 2009-0 Fax: (49) 7462 / 2009-50 e-mail: marketing@medicon.de sales@medicon.de homepage: http://www.medicon.de