

ORTH \odot easy[®] Pin System



Instructions for use, warnings and precautions

To be observed by medical users and patients.

The instructions must be read carefully prior to clinical use of the implants!

DESCRIPTION

The FORESTADENT OrthoEasy® anchorage system offers easy and safe application of orthodontic anchorage through implantation of self-cutting and self-drilling implant screws. The products are manufactured under compliance with high quality standards. These instructions include the main notes on use and warnings to achieve safe application of the product. Please note that it is not possible to describe all possible situations for application. We therefore ask you to clarify individual detailed questions with our team in case of unclear situations. Please read these instructions carefully for safe application.

GENERAL DESCRIPTION

Orthodontic implants serve for the anchorage of orthodontic appliances in the treatment of malpositioning of teeth, jaws and the masticatory apparatus. The screws are implanted under surgical conditions and remain in the patient's mouth until the achieved end of treatment/partial treatment. They are equipped with a self-drilling and self-cutting thread.

Dimensions according to DIN 13997

Thread diameter of the implantable thread section	1,7 mm
Height/diameter of the gingival neck, tapered transition to the thread head	h = 1,5 mm / \varnothing 2 mm
Outer diameter of the head d4	3 mm
Head height k1	2,5 mm
Cross slot h/w	.022" (0,56 mm) x 1,5 mm
Key width/shape	3 mm/8 octagon

The system includes different thread lengths which are colour-coded with a titanium coating. The head of the OrthoEasy® Pins is equipped with a cross slot for attaching orthodontic appliances. The head of the OrthoEasy® Pal includes a fit for the OrthoEasy® Pal Abutment and an internal thread (M 1.7 x 2.2) for mounting the abutment. The geometry of the head is designed for the safe use with the original accessories of our accessory programme.

OrthoEasy® Pin and OrthoEasy® Pal are made of Ti-6Al-4V (Ti Grade 5, ASTM 136 DIN EN ISO 5832-3), a material approved for implant dentistry.

Ref.-No.	Description	CE 0297	Colour
1101A2306	OrthoEasy® Pin .022"/1,7 x 6 mm	CE 0297	Rose
1101A2308	OrthoEasy® Pin .022"/1,7 x 8 mm	CE 0297	Pink
1101A2310	OrthoEasy® Pin .022"/1,7 x 10 mm	CE 0297	Gold
1201A2308	OrthoEasy® Pal 1,7 x 8 mm	CE 0297	Green

For the correct placement and alignment of the OrthoEasy® Pin you require an octagonal blade from the OrthoEasy® accessory programme. The octagonal blade is labelled with a red ring marking. Two black laser markings are applied to the head of the octagonal blade which are to be aligned with the slot of the OrthoEasy® Pin. This lets the user see the position of the slot during insertion (see Figure 1).

Note: this does not apply to the OrthoEasy® Pal.

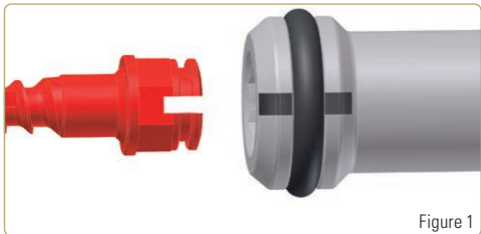


Figure 1

PRODUCT DESCRIPTION ORTHOEASY® PAL

OrthoEasy® Pal is intended for orthodontic anchorage in the palatal anterior region. They need to be placed pairs, as this is the only way they are blocked against torsion stress. They are made of titanium (Ti-6Al-4V – Grade 5), are equipped with a self-drilling and self-cutting thread and can be loaded immediately after insertion.

No alignment of the blade marking is necessary for the OrthoEasy® Pal as it is not equipped with a slot.

INDICATION

OrthoEasy® Pins can be used for closing gaps in Class-I occlusions, distalisation and mesialisation of teeth, uprighting molars, intrusion of teeth, sliding mechanics in Class II, avoiding protrusion of incisors, oligodontic therapy as well as changes on the position of teeth as part of pre-prosthetic treatment. The OrthoEasy® Pal system was

developed specifically for use in the palatal region and the corresponding orthodontic tasks, such as, for example, distalisation, mesialisation, intrusion of molars as well as palatal suture expansion under inclusion of the corresponding complementary FORESTADENT products.

CONTRAINDICATION

As a rule, skeletal anchorage as part of orthodontic treatment, is performed on systemic healthy patients. This is not directly comparable with dental implantology. However, the same general contraindications for dental/surgical interventions apply to the selection of patients. Among others these include: infections and inflammation in the oral cavity (i.e. periodontal disease, gingivitis), reduced blood coagulation, (congenital or acquired coagulation disorders), acute and chronic infections of the surgical site (soft tissue infections, inflamed, bacterial bone diseases, osteomyelitis), severe metabolic disorders (for example, severe, not or poorly adjusted diabetes mellitus; disorders of calcium metabolism), treatment with steroids and other medications interacting with calcium metabolism, immunosuppressant therapy such as, for example, chemo and irradiation therapy; endocrinologically caused bone diseases, insufficient local bone volume (also the proximity of endangered structures such as the nervus mandibularis, arteria sublingualis, sinus maxillaris etc.), insufficient soft tissue cover, lacking occlusion and/or articulation as well as too little interocclusal distance, psychiatric disorders, pain syndromes, poor oral hygiene and lacking willingness with regard

to overall oral rehabilitation, lacking patient compliance. Relative contraindications apply to patients with bruxism, allergies, alcohol or nicotine abuse.

SIDE EFFECTS

There are hardly any reports on side effects such as swelling, bleeding or pain following the insertion of orthodontic mini screws. Individual cases of a feeling of pressure or tension have been reported, however, these generally subside on the day following insertion.

PROTECTIVE MEASURES AND GENERAL SAFETY WARNINGS

The OrthoEasy® mini screws may only be used by orthodontists, dentists and physicians which are familiar with dental surgery, including diagnosis and pre-operative planning. This includes knowledge about the indications and general rules for dental/surgical actions and compliance with the regulations on occupational safety and accident prevention.

These instructions for use alone are not sufficient to ensure appropriate application in the case of users inexperienced in implant procedures. OrthoEasy® mini screws may only be used in perfect condition. All parts used in the mouth of the patient must be safeguarded against swallowing and aspiration. Abstain from application, if there are uncertainties on topics mentioned here, until they have been clarified completely. Generally, we recommend introductory training through an experienced user or attending one of our training

courses. As the application of the product is performed outside the control of the distributor, any liability for caused damages is excluded. The responsibility lies exclusively with the user.

INSTRUCTIONS ON APPLICATION

The OrthoEasy® system must be used exclusively with original FORESTADENT instruments and accessories. These were matched to each other in development and production. Using products of other manufacturers may lead to unforeseeable risks and is therefore not recommended. We, or our authorised dealers, are at your service for further information on this issue.

The OrthoEasy® Pal mounting screws (Item No. 1299-1003) are equipped with a lock which holds the screw on the OrthoEasy® Pal blade (Item No. 1299-1006). To ensure the function of this lock, it should only be used once. Due to the built-in locking function of the mounting screws, it can happen that the OrthoEasy® Pal blade cants in the screw after screwing in at 10 Ncm. This can be loosened easily again by careful movement to and fro. For this reason, the OrthoEasy® Pal blade is subject to a certain amount of wear.

Before use, you should therefore check whether the mounting screws are still safely attached to the blade. If this is not the case, they should be replaced immediately. Check regularly whether the OrthoEasy® Pal mounting screws have become loose and re-tighten these again if required with 10 Ncm.

SUITABLE INSERTION SITES FOR ORTHOEASY® PIN AND ORTHOEASY® PAL MINI SCREWS

The OrthoEasy® Pin can be inserted vestibular, palatal in the maxilla or the alveolar ridge. In the mandible, insertion should only be vestibular, as a rule in the centre of the alveolar ridge. Insertion should not be performed in the area of the flexible mucosa, on the lingual side of the mandible or in the proximity of extraction wounds, and tooth follicles. The OrthoEasy® Pal is designed specifically for palatal application and is used in pairs. The bone volume must be sufficient for an insertion length of 8 mm to avoid perforation of the opposite side.

Selection of the mini screw as well as the insertion site must be performed on the basis of an X-ray check. Here, the bone volume, planned loading, position of nerves and vessels as well as the patient's dental structures need to be taken into account. When using under-sized screws in relation to the occurring forces, this can lead to the loss or breaking of the screw. The length of the screw must be selected such, that perforation of the opposite side is excluded.

INSERTION PROCEDURE

- For selection of the insertion site see above, whereby subsequent loading should be at right angles to the longitudinal axis of the implant as far as possible.
- Careful cleaning, disinfection and sterilisation of the OrthoEasy® mini screws and the instruments necessary for the intervention (see point CLEANING AND DISINFECTION).

- Local anaesthetic.
- Generally speaking, pilot drilling is not required. However, this may prove useful in terms of bone strength and thickness. If required, pre-drill with pilot drill in case of compact bone.
- Place screw in the insertion instrument.
- Screw into bone with smooth motion, avoid canting. Maximum torque 20 Ncm. In case of automated insertion, limit the torque and speed to 30 to 50 rpm. Irrigate the OrthoEasy® mini screw continuously with sterile saline solution during the entire insertion procedure (manual or automated). This serves cooling and avoiding deposits. In the case of the OrthoEasy® Pin, observe the alignment of the slot by observing the marking on the blade.
- As a rule, the OrthoEasy® mini screws can be loaded immediately in case of sufficient primary stability. If you do not want to incorporate the pins immediately into treatment, you should cover these in the interests of improved convenience and hygiene. Please use the Pal Abutment (Item No. 1299-1004) for the OrthoEasy® Pal. Apply the OrthoEasy® Pins either with an Ortho Smooth Ring (Item No. 657-0002) or some light-curing bonding agent and chamfer.

Placement of a connecting element into the slot of the implant for connecting with orthodontic elements (brackets, bands, etc.) or attach coupling elements and fixate with a light-curing bonding agent. Maximum loading is 2 N (approx. 200 g). At the beginning of treatment, it is recommended to restrict the transfer of force to approx. 1 N, 100 g for the first 2 months.

PROCEDURE FOR REMOVAL

- Local anaesthetic.
- Removing the connected appliances.
- Unscrew the mini screw either manually with the handle or automated, and set torque and speed as for insertion.

PRECAUTIONS AND WARNINGS FOR THE USER

To ensure safe use of OrthoEasy[®] mini screws, you, as a user, should be familiar with the requirements for such interventions and ideally have gained appropriate experience or have completed appropriate training.

Every patient needs to be informed about the planned intervention according to legal requirements. Informing your patients about hygiene and the technique are a major part of the treatment success. Protect your patients. Safeguard the mini screws and small instruments during intraoral use to avoid aspiration or swallowing. Check the instruments and mini screws for possible damage prior to use.

OrthoEasy[®] mini screws are intended for single use. Screws that have already been used should under no circumstances be re-used. Only place and remove the OrthoEasy[®] mini screws with the intended instruments.

Excessive force during screwing in can lead to the screw not being stable. Please observe the torque limits and, in case of automated insertion, the speed.

Ensure that sterilised screws do not come into contact with the patient's lips after removal from the rack or the packaging, or become otherwise contaminated.

STORAGE

OrthoEasy® mini screws and instruments must be stored in a dry and dust-protected place. The original packaging protects the products against damage and soiling. If the packaging is damaged, check the products carefully for damage and, if required, reject them.

Prior to cleaning, disinfection and sterilisation, the OrthoEasy® mini screws and instruments must be removed from the packaging and placed in a suitable sterilisation container (i.e. Item No.. 1199-0000 – OrthoEasy® Rack).

CLEANING AND DISINFECTION

All FORESTADENT products are supplied NON-STERILE.

These need to be sterilised in a validated process according to DIN EN ISO 17665-1 prior to use. Please observe the relevant national regulations. This activity may only be performed by qualified personnel and trained for this purpose.

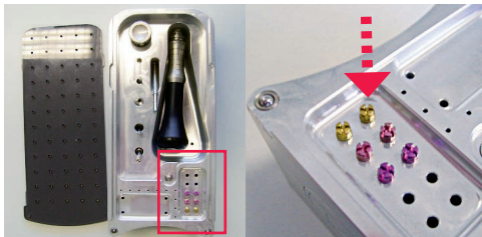
PRE-CLEANING OF INSTRUMENTS AND BLADES

Place the instruments in an alkaline cleaning bath for the prescribed exposure time such that they are sufficiently covered and the instru-

ments do not touch each other. Rinse all cavities in the instruments using a disposable syringe (minimum volume 5 ml) prior to and after the exposure time. Then remove the forceps and instruments from the cleaning bath and rinse thoroughly with water. Then inspect visually whether the instruments have been cleaned successfully.

CLEANING OF INSTRUMENTS, BLADES AND IMPLANTS

Prior to further cleaning, disinfection and sterilisation, the OrthoEasy® screws and instruments must be removed from the packaging and placed in a suitable sterilisation container (for example Item No. 1199-0000 – OrthoEasy® Rack).



DISINFECTION OF INSTRUMENTS, BLADES AND IMPLANTS

Automated disinfection, alkaline cleaning/disinfection, if required with ultrasonic treatment, (i.e. pre-rinsing, alkaline cleaning (pH > 10, at increased temperature of at least 55 °C, interim rinsing, followed by thermal disinfection/post-rinsing).

STERILISATION OF INSTRUMENTS, BLADES AND IMPLANTS

Please observe the manufacturer's instructions for your sterilisation equipment with regard to duration, temperature, pressure and post-drying time.

The following parameters were validated for the fractionated steam sterilisation method:

- Parameters for the fractionated steam sterilisation method.
- Temperature: 133° – 135° C (270° – 275° F) 3x pre-vacuum.
- Standard cycle 15 minutes (min. 6 minutes).
- Post-drying time 8 minutes.

FORESTADENT will not be responsible for correct sterilisation by the user.

PRECAUTIONS AND WARNINGS FOR PATIENTS

Comprehensible information of your patients about hygiene and the technique are a major part of the treatment success. Surgical information must refer to the possible risks of damage to roots or nerves, bleeding, pain or the premature loss of the mini screw.

You should also inform the patient that inappropriate manipulation of the mini screw or the appliance can lead to loosening and loss. Regular follow-ups, as prescribed by the treating physician, must be kept. Should side effects, changes or pain occur, the treating physician should be visited immediately.

Accessories	Item No.
OrthoEasy® Rack	1199-0000
OrthoEasy® Screwdriver, Handle	1199-0002 1199-0003
OrthoEasy® Pin	
OrthoEasy® Blade for Screwdriver	1199-0006 1199-0015
OrthoEasy® Blade Angled Handpiece	1199-0007 1199-0008
OrthoEasy® Pal	
OrthoEasy® Pal Blade	1299-1006
OrthoEasy® Smart Drive	1299-1007
OrthoEasy® Pal Impression Cap (laboratory)	1299-1005
OrthoEasy® Pal Abutment	1299-1004
OrthoEasy® Pal Mounting Screw	1299-1003
OrthoEasy® Pilot Drill 1 mm x 4 mm	1199-1040

CE 0297 Conformity according to 93/42 EEC



Observe instructions for use



Do not re-use



Observe accompanying documents



Company address

REF

Order number

LOT

Batch number



Non-sterile



GERMAN PRECISION IN ORTHODONTICS

Bernhard Förster GmbH

Westliche Karl-Friedrich-Straße 151 · 75172 Pforzheim · Germany

Phone +49 (0) 7231 459-0 · Fax +49 (0) 7231 459-102

info@forestadent.com · www.forestadent.com