

ORTHOeasy[®] Pin System



Instruction manual

To the attention of the doctor and patients.

Quality and precision from FORESTADENT.

Thank you for choosing a quality product from FORESTADENT. This instruction manual provides you with the information you need to obtain the maximum benefit from this product for your patients and for yourself.

In the interests of our customers, we regularly update our products to take account of the latest technical developments. We therefore recommend that you always read the latest instructions through carefully before using the product, even if you are a frequent user of the product.

1. Manufacturer

FORESTADENT

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2. Summary

The FORESTADENT OrthoEasy® pin is used for skeletal anchoring during orthodontic treatment. The OrthoEasy® pin system consists of the OrthoEasy® pins and the instruments and accessories required for its insertion. The head of the OrthoEasy® pins has a 0.022" crosshead slot and is therefore suitable for attaching a wide range of orthodontic appliances.

All products are manufactured to the highest standards of quality. The OrthoEasy® pin is made from a titanium alloy (TiAl6V4 / grade 5 titanium) according to ASTM F136 (American Society for Testing and Materials). All insertion instruments are made of stainless steel according to ASTM F138.

3. Product overview, OrthoEasy® pins

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Ref.-No.	Description	Shank length	Colour
1101A2306	OrthoEasy-Pin .022"/ 1,7 x 6 mm	6 mm	Rose
1101A2308	OrthoEasy-Pin .022"/ 1,7 x 8 mm	8 mm	Pink
1101A2310	OrthoEasy-Pin .022"/ 1,7 x 10 mm	10 mm	Gold

The maximum shank diameter of all OrthoEasy® pins is 1.7 mm.

4. Indications

The Ortho Easy® pin provides temporary skeletal anchorage during the treatment of misalignment of dentition and dental arches with orthodontic appliances. In combination with the corresponding accessories, the Ortho Easy® pin can be used, for example, for the following treatments:

- Distalization and mesialization of single teeth or groups of teeth, including closing and opening gaps.
- Straightening teeth

- Intrusion and extrusion of teeth
 - Class II treatment
 - Changing the position of tooth during preprosthetic treatment
- Once the treatment is completed, the OrthoEasy® pin is removed again.

5. Contraindications

In certain cases, the OrthoEasy® pin should not be used.

General contraindications

In the presence of the following conditions or disorders, the OrthoEasy® pin should not be used:

- The patient is not in a position to undertake the steps required by the therapy.
- Reduced immune defense
- Hypersensitivity to the materials used
- Coagulopathy
- Diseases of the osseous system
- Infections

Local contraindications

- Insufficient bone quantity and quality in the intended area of insertion
- Insertion at the oral side of the mandible, in proximity to extraction wounds, deciduous teeth and tooth follicles
- unsatisfactory oral hygiene
- recurrent diseases of the mucous membrane
- Osteomyelitis, cranial radiotherapy

6. Safety precautions, important notes

The OrthoEasy® pin may only be inserted by orthodontists, dentists, oral surgeons and physicians specializing in oral, orthodontic surgery. The physician concerned is responsible for selecting the patients and planning and carrying out the treatment. Before use, the user must ensure that he or she has read this instruction manual carefully and observes its contents. When using the OrthoEasy® pins only the appropriate genuine components specified in these instructions may be used during treatment.

The OrthoEasy® pins are intended for single use only. The re-use of OrthoEasy® pins which have already been inserted (recycling) and their repeated use in patients are not permitted.

Before using the system for the first time, the practitioner is recommended to complete a suitable OrthoEasy® training course, since this instruction manual can only cover insertion and not the whole spectrum of possible treatment topics.

7. Preparing for insertion

Before the OrthoEasy® pins are used, each patient must receive a thorough examination and detailed information. During the course planning the treatment, the biomechanical concept and the ideal or the suitable insertion site is to be selected.

As packed by the manufacturer, the Ortho-Easy® pins are cleaned, disinfected, almost sterile and have a low particle count. Like the instruments, they are non-sterile. Before use, the pins must be removed from the original packaging, cleaned, disinfected and sterilized. During the entire process, from removal from the packaging to insertion, the thread of the Ortho-Easy® pins must not be touched or contaminated in any way whatsoever. For this reason, the pin may only be held by its head using sterile tweezers. Gloves must be worn whilst doing this.

Cleaning and disinfection of the instruments before first use and after each use is carried out separately from the Ortho-Easy® pins. Sterilization can be carried out together in the OrthoEasy® rack (REF. 1199-0000) (Fig. 1).



fig. 1

Cleaning

To clean the OrthoEasy® pins, use an ultrasonic cleaner. As a cleaning solution, use a 5 % solution of n-propanol (consisting of 70 % n-propanol and deionized water). This solution should be degassed for five minutes before starting the actual cleaning process. Remove the OrthoEasy® pin from its packaging and place it in the basket of the ultrasonic cleaner. Clean for 8 minutes at 25 °C. Then remove from the basket. Allow the cleaning solution to drain off the OrthoEasy® pin and the basket.

The instruments should be cleaned in the same way. The OrthoEasy handles (REF 1199-0002 und 1199-0003) must first be dismantled.

Disinfection

Disinfection is carried out with a 70 % solution of n-propanol. Place the basket in the disinfection bath for 20 minutes at room temperature. Then dry the OrthoEasy® pin for 15 minutes at room temperature. After disinfection, reassemble the dismantled instruments. The cleaning and disinfection agents should be replenished or replaced regularly according to the manufacturer's instructions.

Sterilization

Products delivered non sterile. Blister package is not designed for steam sterilization.

The dry OrthoEasy® pins can be sterilized separately. In order to sterilize each OrthoEasy® pin separately, heat seal each pin in a suitably sized plastic foil bag.

Sterilization is carried out in an autoclave. Be sure to follow the instructions for use of the autoclave. The following parameters apply to sterilization by autoclave:

Temperature: 133 – 135° C (270-275°F)

Pre-vacuum: 3 x

Holding time: 6 minutes

Pressure: 2.2 – 3.5 bar

Drying phase: 8 minutes

This device is single use only and is not to be re-sterilized once the device has been in contact with a patient or the patient's blood.

8. Inserting the OrthoEasy® pin

8.1. General remarks

When inserting the OrthoEasy® pin, the usual precautions applicable to invasive surgery must be taken, such as ensuring a sterile work area, using sterile gloves, face mask, etc. In order to perform correctly, the Ortho Easy® pins needs to be firmly anchored in the bone (primary stability) and the head must be located in the area of the attached gingiva (gingiva alveolaris, keratinized mucous membrane). Whilst using the OrthoEasy® pin as an anchorage element, it is important to ensure that the head and the surrounding soft tissue are not subjected to any detrimental physical forces (e.g. movement of the mucous membrane, effect of bands and/or the tongue, manipulation).

8.2. Selecting the insertion site

One important prerequisite for reliable skeletal anchorage is an insertion site for the OrthoEasy® pin at which the required bone quality and quantity are present. This should be determined with the aid of suitable diagnostic methods. The entire threaded section of the OrthoEasy® pins should be surrounded by at least 0.5 mm bone. The following regions may be considered as possible insertion sites:

- Maxillary – vestibular, edentulous sections of the dental arch.
- Mandibular – vestibular, edentulous sections of the dental arch and retromolar

In the case of most patients, the retromolar area in the upper arch does not fulfill the requirements for the insertion of a pin. At the current state of knowledge, it is inadvisable to insert a mini screw at the lingual side of the mandible or in the proximity of extraction wounds, tooth follicles or deciduous teeth.

If the necessary preconditions are not met at the proposed insertion site, it is not advisable to proceed with the insertion of the pin at this site. An alternative area with meets the requirements should be selected. It should also be noted that the subsequent load should as far as possible be at 90°, i.e. perpendicular to the longitudinal axis of the Ortho Easy® pins.

When choosing the length, the bone repository and the thickness of the mucous membrane in the direction of insertion play a role; in the retromolar section of the lower jaw the thickness of the mucous membrane is often more than 2 mm. The part of the miniscrew inside the bone must be at least as long as the part outside the bone. The various dimensions must be taken into account. The thickness of the bone in the planned direction of insertion determines the required length of the miniscrew:

- Bone thickness > 10mm: miniscrews with a length of up to 10mm are to be used
- Bone thickness < 10mm and > 7mm: miniscrews with a length of 8mm or 6mm are to be used
- Bone thickness > 6mm: miniscrews cannot be used.

The following guidelines can be used when selecting the length:

- in the buccal region of the top jaw: 8 mm or 10mm
- in the palatal region (depending on the region): 6, 8 or 10mm
- in the lower jaw, usually 6mm or 8mm.

8.3. The surgical procedure

The OrthoEasy® pins are inserted under a local anesthetic. It is recommended to anaesthetize only the gingiva and the periost.

If the thickness of the corticalis is ≥ 1.5 mm, use of a pilot drill $\varnothing 1$ mm, at max. 4 mm depth, is recommended in order to perforate the corticalis and the insertion site. The ideal speed is 800 r.p.m. (max. 1500 r.p.m.); ensure adequate cooling.

The insertion instrument (driver) is pressed onto the head of the OrthoEasy® pin. All drivers have two laser markings at the attachment area of the pin (Fig. 2). If this marking is aligned with the slot of the OrthoEasy® pin, its position can always be observed during insertion. This makes it possible to align the screw accurately without the need to remove the driver. The OrthoEasy® pin has a right-hand thread.

Manual insertion is carried out using the OrthoEasy® short blade 10 mm (REF 1199-0006) or the OrthoEasy® long blade 45 mm (REF 1199-0015) together with the standard handle (OrthoEasy® handle for screw driver, standard size – REF 1199-002) or in the short version (OrthoEasy® handle for screw driver, short – REF 1199-003). When inserting manually, please ensure that the insertion motions are carried out continuously and with uniform pressure. In doing so, do not exceed 30 r.p.m.

For assisted insertion, two instruments are available (OrthoEasy® blade 5 – REF 1199-0007 or OrthoEasy® blade 10 mm – REF 1199-0015). In any case the pin must be inserted with an angled handpiece applying limited torque. The torque should be limited to 20 Ncm and the speed to a maximum of 25 r.p.m. The mucous membrane is perforated with the tip of the OrthoEasy® pin. To do this, the screw is first pressed through the periosteum as far as the uppermost bone layer; only then is it screwed in. In order to avoid fracturing the OrthoEasy® pins during insertion, the maximum torque (20 Ncm) should not be exceeded. Insertion is complete at the latest when the gingival cervix of the OrthoEasy® pin rests entirely in the gingiva.

The OrthoEasy® pin can be loaded immediately after insertion by attaching the orthodontic appliance. The maximum load should not exceed 2 N (approx. 200 g).

9. Postoperative measures

It is not usually necessary to prescribe antibiotics or painkillers. The patient must be instructed in the details of dental care applicable when wearing an orthodontic appliance. The mucous membrane around the OrthoEasy® pin must be cleaned regularly. This should be performed without using an electric toothbrush. The patient must be told to avoid manipulating the pin or the orthodontic appliance in any way. The progress of treatment should be monitored at appropriate intervals and the condition of the appliance and the pin, should be inspected.

10. Removing des OrthoEasy® pins

The OrthoEasy® pins are removed when skeletal anchorage is no longer required or at the latest when the orthodontic treatment ends. In order to remove them, use one of the drivers. As a rule, no anesthetic is needed when carrying out this procedure. The wound does not require any special treatment.

11. Side effects

To date, no side effects are known which are attributable to the material of the OrthoEasy® pins. The skeletal anchorage and orthodontic treatments can have undesirable side effects which are, however, beyond the area of responsibility of the manufacturer. Within the context of his obligation to inform patients, the practitioner must inform patients of the possible side effects and document this.

12. Storage

The OrthoEasy® pin and the instruments must be stored in a dry, dust-free place. The original packaging protects the products from damage and contamination. If the packaging is damaged, the contents must be inspected for damage. If there is any doubt, the product must not be used.

13. Use of genuine products

All components of the OrthoEasy® pin system are carefully coordinated. The use of instruments from other manufacturers can lead to unpredictable risks. It is therefore recommended to use only genuine OrthoEasy® products.

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**Conformity in accordance with
93/42 EEC**



See enclosed documents



**Medical single-use product not
suitable for re-use**



**See instructions for use.
For further information see our homepage**



Manufacturer

REF

Item number

LOT

Lot number



Non Sterile

R_x

Professional use only



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