

10. Safety information

Always use the blue safety key supplied to prevent swallowing. The product should not be used if there is a known allergic reaction to one or more of the material components.

If the packaging shows serious damage, the product must be checked for integrity and cleanliness before use, and if necessary must be disposed of.

11. Information for single use products

The product is intended for single use only. Reconditioning (recycling) of the product and its reuse is not permitted, as perfect functionality of the product cannot be guaranteed.

12. Further information

Should the dental professional and/or the patient become aware of serious problems arising from the use of the product, it is important that the manufacturer and the competent authority in the country in which the dental professional and/or the patient is resident are informed accordingly.

Information for the dentist/patient

Before the Titan palex® appliance is cemented into position, open the spindle (screw) by making 2-3 quarter turns in the direction of the arrow to test the mobility. Then turn back to the original position.

Turn the Titan palex® screw only in the direction of the arrow. Opening and closing the screw several times during treatment can cause it to loosen and no longer function properly.

The finished Titan palex® appliance is cemented into position with splints in the usual manner. Follow the instructions from the cement manufacturer.

Following this, the screw is turned four times 90° (quarter turn) using the safety key (REF 611-120-00, Fig. 8) supplied for this purpose. One full 360° turn of the spindle = 0.80 mm expansion.

Following instruction, the patient should complete two quarter turns (2 x 90°) in the morning and two quarter turns in the evening until the desired expansion is achieved. Patients: Please contact the dentist who is treating you if you have any further questions.

Note: Always use the blue safety key (Fig. 8) supplied to avoid accidental swallowing.

13. Product range

For the complete range of Titan palex® screws, please see our orthodontics catalog or visit www.dentaurum.com.

14. Quality information

Dentaurum ensures faultless quality of its products. These recommendations are based upon Dentaurum's own experiences. The dental professional is solely responsible for the processing of the products. Responsibility for failures cannot be taken, as Dentaurum has no influence on the processing on site.

14. Explanation of symbols used on the label



Please refer to the label. These Instructions for use and additional information can be found at www.dentaurum.com (Explanation of symbols REF 989-313-00).

The safety key is designed to take a maximum force of 35 N \pm 3.5 kg. Please note that the force exerted on the safety key wire should always be exerted on the closed side of the wire clasp so that the clasp cannot loosen from the axis. Improper use may lead to overload and consequently to failure of the safety key, thus potentially excluding any guarantee and liability. Regular visits are recommended to monitor progress.

The Titan palex® appliance is secured against unwanted reversing, after the desired degree of expansion is achieved, by fitting a ligature or blocking out with acrylic. The appliance should remain in the mouth for approximately 2-3 months for stabilization purposes.

A retention plate should be worn following removal of the appliance.



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➤ For more information on our products, please visit www.dentaurum.com

Date of information: 2022-07

Subject to modifications

US

Instructions for use



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Titan • palex®
Maxi - 12
Screw

D
DENTAURUM
USA

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Phone 800.523.3946 | Fax 800.553.6389 | www.dentaurum.com | info@dentaurum-us.com

D
DENTAURUM
USA

Dear customer,

Thank you for choosing a quality product from Dentaureum. Please read these instructions for use to ensure you use this product in a safe and simple way and that you and your patients gain full benefit. In case of questions or ideas, please contact your local representative.

1. Manufacturer

Dentaureum GmbH & Co. KG | Turnstr. 31 | 75228 Ispringen | Germany

2. General device description

The Titan palex® screw (Hygienic Rapid Expansion Screw) is a special expansion screw for rapid palatal expansion. The retention legs of this titanium RPE screw are welded onto titanium cap splints (Fig. 1). Alternatively they can also be polymerized into Orthocryl® acrylic splints (Fig. 2). The appliance with the titanium or acrylic splints is cemented in the conventional manner. Follow the instructions from the cement manufacturer.

3. Intended purpose

Used for rapid palatal expansion with a fixed appliance.

4. Intended users

All products are intended for dental professionals only.

5. Indications

In case of transverse under-development of the upper jaw.

6. Contraindications

Warnings are found on the respective product labels. Also see 9. Composition.

7. Patient target group

All patients for whom a fixed appliance with an expansion screw can be placed as part of orthodontic treatment.

8.1. Fabricating a Titan palex® appliance

The retention legs can be lasered onto individually cast titanium cap splints or polymerized into Orthocryl® acrylic splints.

The Titan palex® screw should be "suspended" at least 1 mm – 2 mm above the palatal vault/gingiva (Fig. 3) and its dorsal side should be in line with the mesio-palatal cusps of the first molars. In order to avoid leverage, the screws must be situated parallel to the occlusal plane. The Titan palex® screw is positioned so that it may be turned in a dorsal direction (Figs. 1 - 3) in order to make the task of inserting the safety key and activating the screw easier.

8.2. Tips for working with Titan palex® screws

In order to bend the retention legs of the Titan palex® screw gently and easily, we recommend using the universal bending key (REF 611-122-00, Fig. 6) without the aid of additional pliers (lever principle). If the universal bending key is not available, the retention legs must be stabilized during bending by holding the expansion screw body with a pair of sturdy pliers, e.g. wire bending pliers Maxi, Premium Line (REF 013-522-00), in order to prevent the retention legs from fracturing (Fig. 5).

For the weld connection to be durable, the retention legs of the Titan palex® screw must be welded to the cap splint, (Figs. 1 and 3), for example using the welding unit desktop Compact (REF 090-578-50). As an average value for titanium, the initial laser setting on the unit is as follows: 230 volt, 2.0 ms – 2.3 ms, 0.8 mm. The use of a shielding gas is indispensable during the welding process. When using or adding new material to reinforce the welding area, we recommend rematitan® wire, ø 0.40 mm (REF 528-039-50, Fig. 7).

9. Composition

The Titan palex® screws are made of the following materials: DIN 3.7165 and DIN 3.7035. The material composition is included in the orthodontics materials list; please refer to the orthodontics catalog or www.dentaureum.com. The SSCP is available at <https://ec.europa.eu/tools/eudamed> and www.dentaureum.com.

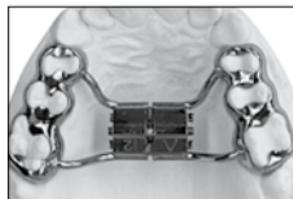


Fig. 1



Fig. 2



Fig. 3

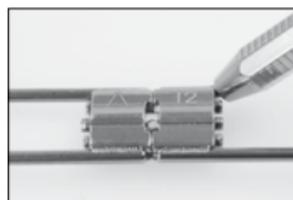


Fig. 4

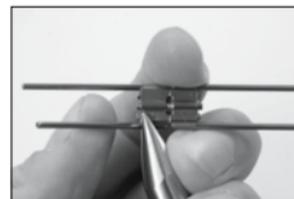


Fig. 5



Fig. 6
Universal bending tool
REF 611-122-00



Fig. 7
rematitan® wire, ø 0,40 mm
REF 528-039-50

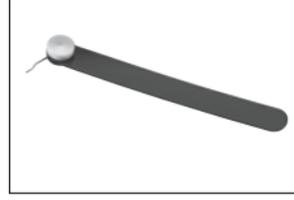


Fig. 8
Safety key
REF 611-120-00