

13. Product range

For the complete range of palex® click 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.

15. 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).



Information for the dentist / patient

Before the palex® click 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.

The finished palex® click appliance is cemented into position 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 supplied for this purpose. One full turn of the spindle = 0.8 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. After each step of activation (quarter turn), a clear „click“ can be perceived. Patients: Please contact the dentist who is treating you if you have any further questions.

Note: Always use only the blue safety key supplied to prevent swallowing!

The safety key is designed to take a maximum force of 35 N $\hat{=}$ 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.

We recommend securing the palex® click appliance by fitting a ligature or blocking out with acrylic after the desired expansion is reached, in spite of the feature to prevent unwanted reversing. For stabilization, the appliance should remain in the mouth for approximately 2–3 months.

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



The product should not be used if there is a known allergic reaction to one or more of the material components.

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.

- For more information on our products,
please visit www.dentaurum.com
- Our orthodontic technicians are available to answer
any questions you may have regarding our products:

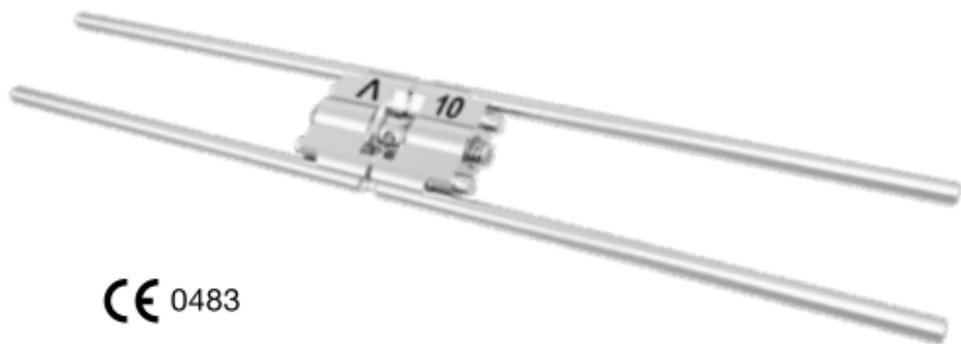
Customer Service: Phone 800 523 3946
orthodontics@dentaurum-us.com

Date of information: 2022-07

Subject to modifications

US

Instructions for use



CE 0483

palex® **click**

Screws

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DENTAURUM
USA

Dear customer,

Thank you for choosing a quality product from Dentaaurum. 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

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

2. General device description

The palex® click screw (Hygienic Rapid Expansion Screw) is a special expansion screw for rapid palatal expansion. It has a screw locking feature (Fig. 1) to prevent unwanted reversing. The retention legs of this RPE screw are welded onto preformed bands (Fig. 2) or onto cap splints made of metal. Alternatively they can also be polymerized into acrylic splints or anchored onto mini screws, e.g. tomas®-pin. The appliance is cemented or fixed to the tomas®-pin as usual. 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

Stainless steel expansion screws must not be used in patients with a nickel and/or chromium allergy. 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. Fabrication of palex® click appliance with preformed bands

Preformed bands are fitted on the upper jaw left and right first bicuspid and left and right first molars. Using an impression, these bands are either transferred to or fitted on the hard plaster model. The retention legs of the palex® click screw are then bent so that they can be welded onto the four adapted bands (Figs. 2 + 4).

The palex® click screw should be "suspended" at least 1 mm – 2 mm above the palatal vault/gingiva (cf. 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 palex® click screw is positioned so that it may be turned in a dorsal direction (Figs. 2 – 4) in order to make the task of inserting the safety key and activating the screw easier.

8.2. Tips for working with palex® click screws

The bands can be connected by means of a remaloy® wire \varnothing 1.0 mm (REF 528-100-00) on the palatal and the buccal side as reinforcement. These reinforcement wires are laser-welded above the retention legs. The palatal reinforcement wires should extend slightly over the bands and be supported by the adjacent teeth in order to distribute the expansion forces more effectively.

In order to bend the retention legs of the palex® click screws gently and easily, we recommend using the universal bending key (REF 611-122-00, Figs. 5) without the aid of additional pliers (lever principle).

If this key is not available, the retention legs must be stabilized 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 breaking (Fig 6).

9. Composition

The palex® click screws are made of the following materials: DIN 1.4301, DIN 1.4305 and DIN 1.4310. The composition is included in the materials list; please refer to the catalog or www.dentaurum.com. The SSCP is available at <https://ec.europa.eu/tools/eudamed> and www.dentaurum.com.

10. Safety information

Always use only 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.

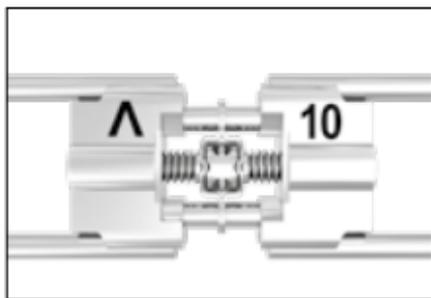


Fig. 1



Fig. 2

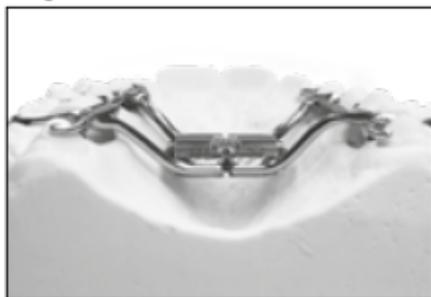


Fig. 3

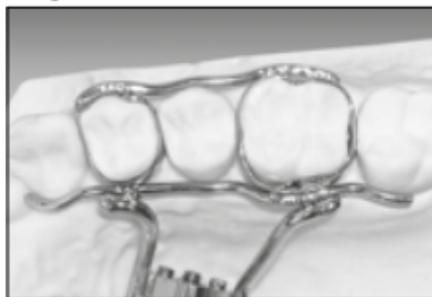


Fig. 4

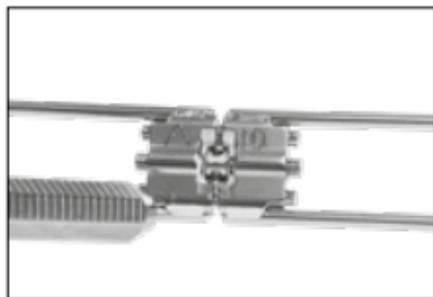


Fig. 5

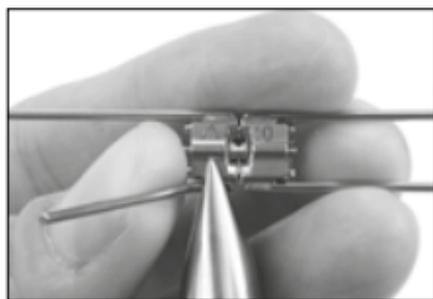
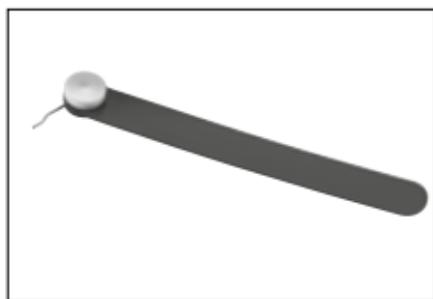


Fig. 6



Universal bending key
REF 611-122-00



Safety key
REF 611-120-00