

Fig. 10 palex®

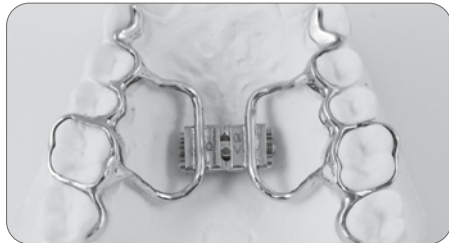


Fig. 11 palex® neo



Fig. 12

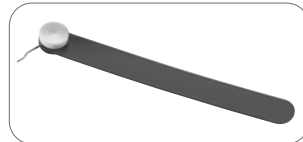


Fig. 13 Safety Key REF 611-120-00

- 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
info@dentaurum-us.com

Date of information: 2024-04

Subject to modifications

CE 0483

The palex®/palex® neo 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.



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.

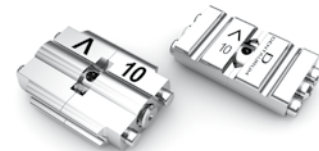
Note: Always use only the blue safety key supplied to prevent swallowing!

The safety key is designed to take a maximum force of 35 N \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 palex® neo expansion screw has, due to its construction, no active stop (indent in pin offers passive stop). If the palex® neo expansion screw is turned too far, the spindle loses its function and the screw is held in position by the pins. It is then no longer possible to turn the palex® neo expansion screw back.

US



palex®
 palex® neo

Instructions for use

Screw without retention legs

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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

palex® and palex® neo screws without retention legs (hygienic rapid expansion screw, Figs. 1–2) are special screws used for fast palatal expansion. The body of the RPE screw is welded onto individual retention legs, connectors or cap splints which have been either cast or produced by the SLM method in metal. The appliances are cemented or fixed to the tomas®-pin as usual. Follow the instructions from the cement manufacturer.

3. Intended purpose

Used for fast 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 a palex®/palex® neo appliance with individualized retention legs and cap splints

The following steps should be followed to fabricate individualized retention legs and cap splints by casting or by the SLM method (Figs. 3 – 5). Individualized cap splints are fitted on the first premolars in the maxilla and the first molars, each left and right (Figs. 10 – 11).

The retention legs are connected to the palex®/palex® neo screw in such a way that two weld seams form along the lateral or the upper groove (Figs. 8 – 9). The palex®/palex® neo screw should be “suspended” at least 1 mm – 2 mm above the palatal vault/gingiva (Figs. 6–7) 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®/palex® neo screw is positioned so that it may be turned in a dorsal direction in order to make the task of inserting the safety key (Fig. 13) and activating the screw easier.

8.2. Tips for working with palex®/palex® neo screws without retention legs

For the connection to be durable, the individualized retention legs must be welded onto the groove of the palex®/palex® neo screw body (Figs. 8–9), for example using the desktop Compact welding unit (REF 090-578-50). As an average value for NiCr, the initial laser setting on the unit is as follows: 240 volt, 4 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 the NiCr welding wire, ø 0.50 mm (REF 528-220-00, Fig. 12).

9. Composition

The palex® and palex® neo screws are made of the following materials: DIN 1.4301, DIN 1.4305 and DIN 1.4310. 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.

10. Safety information

Always use only the blue safety key (Fig. 13) 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.

13. Notes on disposal

When disposing of the product, please adhere to the national regulations that are valid for your region and - if available - the details outlined in the safety data sheets.

14. Product range

For the complete range of palex®/palex® neo screws, please see our orthodontics catalog or visit www.dentaureum.com.

15. Quality information

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

16. Explanation of symbols used on the label



Please refer to the label. These instructions for use and additional information can be found at www.dentaureum.com/ifu (explanation of symbols REF 989-313-00).

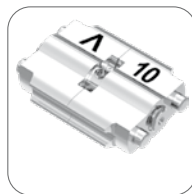


Fig. 1 palex®



Fig. 2 palex® neo

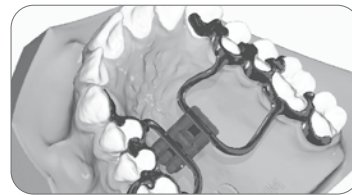


Fig. 3 palex® neo



Fig. 4 palex®



Fig. 5 palex® neo



Fig. 6 palex®



Fig. 7 palex® neo



Fig. 8 palex®



Fig. 9 palex® neo