

Fig. 6a palex®

Information for the doctor/patient

Before cementing the palex®/palex® neo appliance into position, open the spindle (screw) by making 2–3 quarter turns in the direction of the arrow to test mobility. Then turn back to the original position.

Turn the palex®/palex® neo 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 palex®/palex® neo appliance is cemented into position in the usual manner.

Afterwards, give the spindle one full turn (4 x 90°) with the safety key supplied. One full 360° turn of the spindle = 0.8 mm expansion.

On the basis of your instructions, 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.

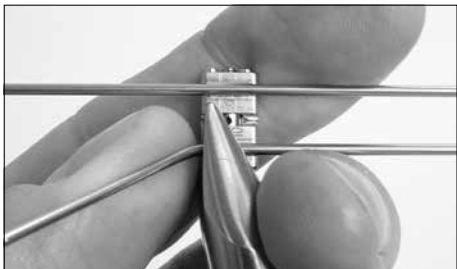


Fig. 6b palex® neo

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

The safety key is designed to take a maximum force of $35\text{ N} \triangleq 3.5\text{ kg}$. 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 screw has, due to its construction, no active stop (indent in pin offers passive stop). If the palex® neo 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 screw back.



Universal bending tool
REF 611-122-00



Safety key
REF 611-120-00

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

A retainer 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 user 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 user and/or the patient is resident is 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
info@dentaurum-us.com

Date of information: 07/21

Subject to modifications



CE 0483

palex[®]
palex[®] neo

Dear customer,

Thank you for choosing a quality product from Dentaaurum.

It is essential to read these instructions carefully and adhere to them to ensure safe, efficient use and ensure that you and your patients gain full benefit.

Instructions for use cannot describe every eventuality and possible application. In case of questions or ideas, please contact your local representative.

As our products are regularly upgraded, we recommend that you always carefully read the current Instructions for use supplied with the product and stored in the internet at www.dentaaurum.com, even though you may frequently use the same product.

1. Manufacturer

Dentaaurum GmbH & Co. KG

Turnstr. 31 | 75228 Ispringen | Germany

2. General product description/ area of application

palex® and palex® neo screws (Palatal Expansion Screw) are special screws used for rapid palatal expansion. The retention legs of this RPE screw are welded onto preformed bands or onto so-called cap splints made of metal. Alternatively they can also be polymerized into acrylic splints or anchored onto mini screws, e.g. tomas®-pin. The appliances are cemented or fixed to the tomas®-pin as usual.

3. Area of application

Used for rapid palatal expansion with a fixed appliance.

4. Fabrication of the palex® or palex® neo appliance with preformed bands

Preformed bands are fitted on the maxilla 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®/palex® neo screw are then bent to fit onto the four bands so that they can be welded into place (Fig. 2).

We recommend using the universal bending key (REF 611-122-00) to gently and easily bend the retention legs (see Fig. 5). If this is not available, the retention legs must be stabilized by holding the expansion screw body with a pair of sturdy bending pliers in order to prevent the retention legs from breaking (Fig. 6a/6b).

The palex®/palex® neo screw should be "suspended" at least 1–2 mm above the palatal vault/gingiva (see Fig. 3a/3b) and its dorsal side should be in line with the mesio-palatal cusps of the first molars.

In order to avoid leverage, it must be situated parallel to the occlusal plane.

5. Tips for working with palex®/palex® neo 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 a means of 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 (Fig. 4).

In order to bend the retention legs of the palex®/palex® neo screw easily, we recommend using the universal bending key (REF 611-122-00) without the aid of additional pliers (lever principle).

During bending, the retention legs must be stabilized by holding the expansion screw body with a pair of sturdy pliers, e.g. wire bending pliers Maxi (REF 013-522-00), in order to prevent the retention legs from breaking.



When using the soldering technique, please protect the body of the screw against excessive heat, e.g. with heat protection (REF 380-070-00).

6. Composition

The material composition is included in the orthodontics materials list; please refer to the catalog or www.dentaurum.com.

7. Safety instructions

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.

8. Information for single use products

The palex®/palex® neo screw is intended for single use only. Reconditioning a used palex®/palex® neo screw (recycling) and its reuse on a patient are not permitted.

9. Additional information

- There are no particular precautions to be taken when disposing of palex®/palex® neo screws after treatment.
- Should you have any questions, please contact your local representative.

10. Delivery program

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

11. Quality

Dentaurum ensures faultless quality of its products. These recommendations are based upon Dentaurum's own experiences. The user 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.

12. Explanation of symbols used on the label



Refer to the label. Additional information can be found at www.dentaurum.com (Explanation of symbols REF 989-313-00).



Fig. 3b palex® neo

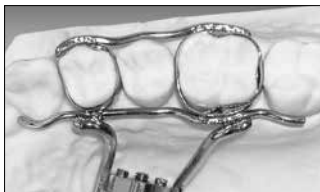


Fig. 4

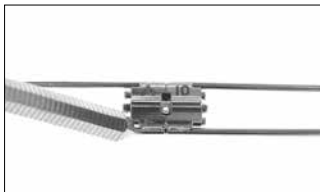


Fig. 5 palex®

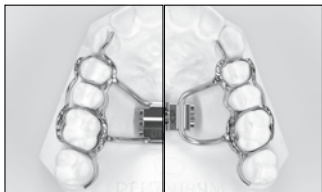


Fig. 1 palex® / palex® neo

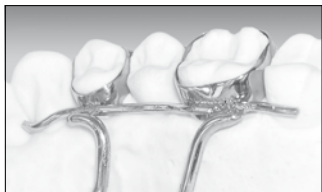


Fig. 2



Fig. 3a palex®