

9. Product range

Description	without retention legs	Quantity
palex® click Mini – 7 (Expansion 7 mm)	602-830-13 602-830-33	1 piece 10 pieces
palex® click Medium – 10 (Expansion 10 mm)	602-832-13 602-832-33	1 piece 10 pieces
palex® click Maxi – 12 (Expansion 12 mm)	602-834-13 602-834-33 602-834-53	1 piece 10 pieces 50 pieces
Safety key	611-120-00	10 pieces

Information for the doctor/patient

Before cementing the palex® click 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. The finished palex® click appliance is cemented into position in the usual manner. Follow the instructions from the cement manufacturer. 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. After each step of activation (quarter turn), a clear „click“ can be perceived.

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 ± 3.5 kg. Please note that the force exerted on the safety key wire should always

10. Quality

Dentaureum ensures faultless quality of its products. The recommendations in these instructions are based upon Dentaureum's own experiences. The user 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.

11. Explanation of symbols used on the label



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

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 has been 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 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 gain knowledge of serious incidents 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 are informed.

US

Instructions for use



CE 0483

- ➔ For more information on our products, please visit www.dentaureum.com
- ➔ Customer Service: Phone 800 523 3946
info@dentaureum-us.com

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Subject to modifications

Germany 09/21/C/R1
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D
DENTAUREUM
USA

palex® **click**

Screw without retention legs

Dear customer

Thank you for choosing a quality product from Dentaureum.

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.dentaureum.com, even though you may frequently use the same product.

1. Manufacturer

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

2. General product description

The palex® click screw without retention legs (palatal expansion screw, Fig. 1–3) is a special expansion screw for rapid palatal expansion. It has a patented screw locking feature to prevent unwanted reversing. The body of this screw is welded onto individual retention legs, connectors and/or so-called cap splints which have been either cast or produced by the SLM method in metal. The bands or the splints are cemented into place as usual. Follow the instructions from the cement manufacturer.

3. Area of application

Used for rapid palatal expansion with a fixed appliance.

4. Fabrication of the palex® click appliance with individualized retention legs and cap splints

The following steps should be followed to manufacture individualized retention legs and cap splints by casting or by using the SLM method (Fig. 4–5).

Individualized cap splints are fitted on the first premolars in the maxilla and the first molars, each left and right (Fig. 4–7). The retention legs are connected to the palex® click screw in such a way that two weld seams extend along the lateral groove (Fig. 7).

The palex® click screw should be “suspended” at least 1–2 mm above the palatal vault / gingiva (Fig. 6) 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. In order to make the task of inserting the safety key (Fig. 10) and activating the screw easier, the palex® click screw is fitted with the direction of rotation facing towards dorsal (Fig. 6–8).

5. Tips for working with palex® click screws without retention legs

For the connection to be durable, the individualized retention legs must be welded onto the groove of the body of the palex® click screw (Fig. 7), 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 an inert gas is indispensable during the welding process.

When using or adding new material to reinforce the welding area, we recommend the NiCr welding wire, \varnothing 0,50 mm (REF 528-220-00, Fig. 9).

6. Composition

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

7. Safety instructions

Always use only the blue safety key (Fig. 10) 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 product is intended for single use only. Reconditioning of a product that has already been used (recycling) and its reuse on a patient is not permitted.

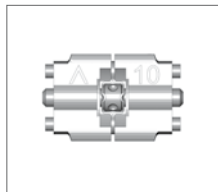


Fig. 1



Fig. 2

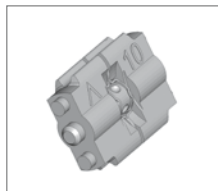


Fig. 3

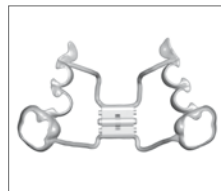


Fig. 4

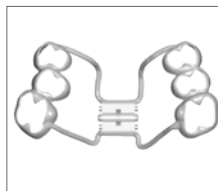


Fig. 5

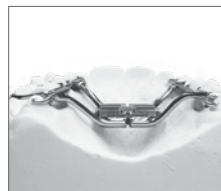


Fig. 6



Fig. 7



Fig. 8



Fig. 9

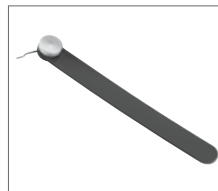


Fig. 10