7. Composition

The composition is included in the materials list. Refer to the catalog or www.dentaurum.com.

8. 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.

9. Information on 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.

10. Availability

Description	straight legs	bent legs	Quantity
palex® click Mini - 7 (Expansion 7 mm)	602-830-11 602-830-51 602-830-01	602-831-11 602-831-51 602-831-01	1 piece 10 pieces 50 pieces
palex® click	602-832-11		1 piece
Medium - 10	602-832-51		10 pieces
(Expansion 10 mm)	602-832-01		50 pieces
palex® click	602-834-11	602-835-11	1 piece
Maxi - 12	602-834-51	602-835-51	10 pieces
(Expansion 12 mm)	602-834-01	602-835-01	50 pieces

Packages (1 piece): with safety key Packages (10 pieces / 50 pieces): without safety key

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Safety key	611-120-00	10 pieces
Universal bending tool	611-122-00	1 piece

11. With reference to our quality standards

Dentaurum ensures a faultless quality of the products manufactured by us. These recommendations are based upon our own experiences. The user himself is responsible for the processing of the products. Responsibility for failures cannot be taken, as we have no influence on the processing on site.

12. Explanation of symbols used on the label

REF Order number

Batch description LOT

(6 0483 CF Mark MP Class 2

Instructions for use available i → www.dentaurum.de in the internet

Not for reuse

Codablock barcode

Matrix code

Green dot 0

Date of information: 01/15 Subject to modifications

Our orthodontic technicians are available to answer any questions you may have regarding our products:

Customer Service

Phone 800 523 3946

sales@dentaurum-us.com

Additional information regarding Dentaurum products can be found in the internet.

www.dentaurum.com

Date of information:

01/15









Instructions for use





Dear Customer

Thank you for choosing this high-quality product from Dentaurum.

In order to achieve the best results with this product, it is important to carefully study and follow these instructions for use.

The written instructions cannot cover all possible situations that can occur during use. For this reason, our hotline is available to answer any other questions or concerns that may arise.

Due to constant developments, we recommend, even when using the same products regularly, that you study the enclosed current instructions for use or refer to our website at www.dentaurum.com.

1. Manufacturer

Dentaurum GmbH & Co. KG Turnstraße 31 · 75228 Ispringen · Germany

2. General product description

The palex® click screw (hygienic rapid expansion screw) is a special expansion screw with a patented locking device (Fig. 1) that prevents unwanted turning back during quick mid-palatal suture separation. The retention legs of the palatal expansion screw are welded or soldered onto preformed metal bands or cap splints. Alternatively, they can be polymerized into acrylic splints. The bands or splints are cemented in the usual way.

3. Area of application

Used for rapid palatal expansion with a fixed appliance.

4. Fabricating a palex® click appliance using the example of preformed bands

Preformed bands are fitted on the maxillary left and right 1st bicuspids and left and right 1st molars. These bands are transferred to a dental stone model using an impression or fitted to a dental stone model. The legs of the palex® click screw are then bent to fit the bands so that they can be soldered or welded into place (Fig. 2 + 4).

To prevent the legs from breaking during bending, we recommend using our universal bending tool (REF 611-122-00, Fig. 5). If one is not available, hold the legs against the body of the expansion screw, using strong flat pliers (Fig. 6).

The palex® click screw should "float" freely at least 1-2 mm above the palate roof/gingiva (Fig. 3). Its posterior side should form a straight line with the mesio palatal cusps of the 1st molars. To avoid any leverage effect, be sure that the occlusal level is parallel.

5. Information on use of palex® click screws

To increase strength, the bands can be joined on the buccal and/or lingual side with a piece of 1.0 mm remaloy® wire (REF 528-100-00). Laser weld or solder these wires above the legs. The palatal strengthening wire should project slightly beyond the bands and be supported by the adjacent teeth to allow better distribution of expansion forces.

Easy, problem-free bending of the retention legs of palex® click screws can be accomplished with the universal bending tool (REF 611-122-00), without the use of additional pliers (leverage principle).

To prevent the legs from breaking during bending, they should be held against the body of the expansion screw using strong flat pliers e.g. Maxi wire-bending pliers (REF 013-522-00).

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

6. Note for doctor and patient

Before the palex[®] click appliance is cemented into position, turn the spindle (screw) slightly (½ turn) 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

Following this, the screw is turned four times by 90° using the key supplied for this purpose. One full 360° turn of the spindle = 0.8 mm expansion.

The patient should turn the screw twice through 90° (¼ turn) both in the morning and evening (according to your instructions) until the desired expansion is achieved. When the planned activation step is reached (¼ turn) a distinct "click" can be felt and heard.

Important: use only the blue safety key supplied, as this cannot accidentally be swallowed.

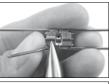
Regular visits are recommended to monitor progress.

In addition to the safeguard against unwanted turning back, we recommend securing the palex® click appliance by fitting a ligature or a blockout with composite after the desired expansion is reached. For stabilization the appliance should remain in the mouth for approximately 2-3 months.

A retainer should be worn following removal of the palex® click appliance.



Fig. 5



F:-



Universal bending tool



Fig. 4

Fig. 2



Safety key REF 611-120-00

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Fia. 3