

10. 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. 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.

Information for the dentist/patient

Before the Variety/Variety SP 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. Turn the Variety/Variety SP 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 Variety/Variety SP 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 (REF 611-120-00, Fig. 10) supplied for this purpose. One full 360° 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. Patients: Please contact the dentist who is treating you if you have any further questions.

Note: Always use only the blue safety key supplied (Fig. 10) to prevent swallowing!

13. Product range

For the complete range of Variety/Variety SP expansion 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).

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 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 Variety/Variety SP 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.



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.

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Instructions for use



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- ➔ For more information on our products, please visit www.dentaurum.com
- ➔ Customer Service: Phone 800 523 3946
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Date of information: 2022-07

Subject to modifications

989-502-09 Printed by Dentaurum Germany 2022-07/C/RI

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USA

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

Variety/Variety SP screws without retention arms are special universal expansion screws for the lower jaw to create space and prevent tipping of the anterior and posterior teeth as well as to open and close gaps in both the upper and the lower jaw. They can also be used as distraction screws, or for early palatal expansion of the upper jaw at the beginning of the mixed dentition phase.

The body of the Variety/Variety SP expansion screw is welded to individual retention legs, connectors or cap splints which have been either cast or produced by the SLM method in metal. The appliances are cemented as usual. Follow the instructions from the cement manufacturer.

3. Intended purpose

Distalization, mesialization or gap closure by movement of a single tooth and early palatal expansion in the upper jaw.

4. Intended users

All products are intended for dental professionals only.

5. Indications

In case of transverse under-development of the upper jaw. In case of transverse under-development of the lower jaw. In rarer cases, also for sagittal tooth movements.

6. Contraindications

Palatal expansion in patients whose second mixed dentition phase is completed. 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 an appliance with a Variety/Variety SP expansion screw 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 the SLM method (Fig. 3 – 4).

Preformed bands or individualized cap splints are fitted on the lower jaw first premolars and the first molars, each left and right. The bands/cap splints are adjusted to fit on a hard plaster model or a 3D printed model.

The retention legs / cap splints are designed so that they can be welded to the expansion screw body of the Variety/Variety SP screw. The weld seam follows the groove in the screw bodies. The retention legs are connected to the Variety/Variety SP screw in such a way that the weld seams extend along the groove (cf. Figs. 5–6).

The Variety/Variety SP expansion screw should “float” freely 1 mm – 2 mm above the gingiva (Fig. 7). To avoid any leverage effect, ensure that the direction of force runs parallel to the occlusal plane.

8.2. Tips for working with Variety/Variety SP expansion screws without retention legs

For the connection to be durable, the individualized retention legs must be welded along the groove of the body of the Variety/Variety SP screw body, for example using the welding unit desktop Compact (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, \varnothing 0.50 mm (REF 528-220-00, Fig. 9).

9. Composition

The Variety/Variety SP expansion 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.



Fig. 1



Fig. 2



Fig. 3



Fig. 4



Fig. 5



Fig. 6



Fig. 7



Fig. 8



Fig. 9

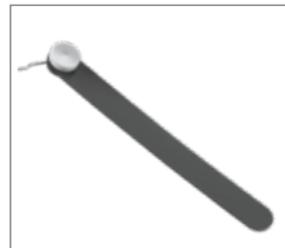


Fig. 10