Dear doctor, we are honored that you have chosen this innovative new product from Tiger Dental.

To ensure the safe and effective use of this product, you must carefully read and adhere to this user manual.

The user manual covers all necessary safety instructions but cannot describe all possible circumstances. For this reason, you may find further user notices online at tigerdental.com under the "Know-how" link. Our customer service is available for any additional questions.

The continual development of our products indicates our company's commitment to innovation. Accordingly, after several clinical uses, we recommend you carefully review the accompanying user manual (this can be found online under the "Downloads" link at tigerdental.com).

1. Manufacturer

Tiger Dental, Belruptstrasse 59, 6900 Bregenz, Austria

2. Product description

TopStop direct is a variably adjustable connection between a mini anchor screw placed in the anterior palate and the Goshgarian lock on the band around the first molar.

The TopStop direct consists of a double internal wire with retentive notches (TopClip strong) and a slotted tube on the end of which a wire with notches for better adhesion is situated (Fig. 1).

3. Areas of application

Indication: Anchorage of molars, also ideal retention after previous distalization with TopJet Distalizer. Can be used on one or both sides.

4. Mounting the TopStop direct

- 1. Measure off the distance "L" between the head of the mini anchor screw and the access to the Goshgarian lock.
- 2. Shorten the internal wire of the TopStop direct and the notched outer tube so that the two pushed together are about 4–5 mm shorter than the distance "L" measured in the mouth (Fig. 2+3).
- 3. Lowering by one notch of the outer tube leads to some difficulty of movement of the notched internal wire, although it does not limit the ability to slide. Both parts of the TopStop direct should be secured with dental silk before inserting into the mouth. The TopStop can then be held securely at any time or removed from the mouth.
- 4. If necessary, the end of the tube can be bent before use in order to determine the direction of the TopStop direct. To push the C-Clip onto the head of the mini anchor screw without stress, this must also be bent (Fig. 4).







3 Shortening

4 Bending the C-Clip and the end of the tube



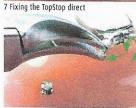


6 Pushing up the C-Clip (Clip on)





8 Separating the TopStop direct

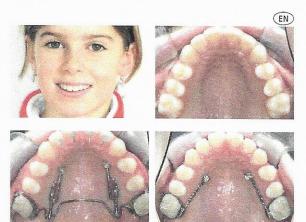




9 Pulling out with the Weingart pliers

10 Pushing off the C-Clip (Clip off)

- After pushing the end of the wire into the Goshgarian lock, the internal wire can be pulled out so that the C-Clip can be pushed up on the head of the screw (Fig. 5+6).
- 6. Finally, apply light-curing resin between the C-Clip and the head of the screw (e.g. Triad® Gel), leading to a rigid, stable connection between the Goshgarian lock and the mini anchor screw by means of the notches on the internal wire. This produces a reliable anchorage (Fig. 7).



Sophie, 13 years. After distalization of the two molars to create space in the upper jaw in the area of the lateral teeth. The molars are firmly anchored using the TopStop direct, after which the holes are closed from a mesial to distal direction using fixed treatment technology.

5. Removal of the TopStop direct

Removal of the TopStop direct is performed either with cutting pliers or by separating the middle part with a small cutting disc. A diamond wheel can also be used for this. Prior to this, the anterior and posterior ends must be secured with knotted dental silk (Fig. 8).

Afterwards, the posterior end can be pushed out of the Goshgarian lock from the back using the Weingart pliers and pulled out by turning (Fig. 9). The Weingart pliers can then be used at the posterior end of the screw head and at the end of the C-Clip with the other line. The clip is pushed off the screw head with light pressure (Fig. 10).

10. Description of the used symobols of ÖNORM EN ISO 15223-1

6. Notices for Single-use Products

This product is nearly ready to use out of the box, but is not sterile and should not be used more than once. The reprocessing of this once used product (recycling) and its reapplication to the patient is strictly prohib-

7. Safety Instructions

This operating and installation manual contains tips and recommendations, but does not release you from personal responsibility! The use of this product is allowed only by orthodontists and dentists according to MDD 93/42/EEC. The user must comply with the provisions of the Medical Devices Directive and any other applicable laws and regulations.

⚠ This product contains nickel.

8. References of Quality

Tiger Dental assures the user a flawless quality of its products. The content of this manual is based on experience. The user is responsible for the processing of the products themselves. Tiger Dental is not liable for erroneous results or processing by the user that occure in the absence of influence of Tiger Dental. Although this product is a mature product, improvements and changes can be made, which may not be documented in the present manual. Similarly, we are not liable for printing errors.

9. Package contents

- TopStop direct, 2 pcs/pkg

C € 0483

Notified body

Manufacturer

LOT

Lot / Batch number

REF

Reference / Article number



Non sterile



Do not reuse



Consult instructions for use



Caution

