



GOLDSTADT



PROFESSIONAL

Instructions for Use

EN

8015202 | Instructions for use for RUCK NAIL CORRECTION GOLDSTADT professional
REV 07 | Revision status 17/11/2023





GOLDSTADT
PROFESSIONAL



Medical device
MDR 2017/745/EU Class 1



Dear Customer,

By purchasing the GOLDSTADT professional, you have chosen a product that has been developed by the best experts in the field of podiatry at RUCK.

For many years, the tried-and-tested Goldstadt brace has been an integral part of the professional podiatry repertoire. Their versatility, user-friendliness and, last but not least, their attractive appearance make them stand out from the range of different brace models.

With the GOLDSTADT professional, the Goldstadt brace is not only entering the next generation, but also a new dimension of further development. A frequently expressed customer wish becomes reality: The ready-made brace for all purposes. With 3 types each available in 5 sizes, there is a well-fitting brace for every nail. Full and half braces are available in 2 material thicknesses (0.1 and 0.15 mm). Depending on the size of the brace, it varies in width (2 or 3 mm). The full and half braces already have defined ends, so no cutting is required. This ensures that the gold plating continues right to the ends for maximum anti-inflammatory properties, while the rounded shape ensures minimum discomfort.

We sincerely thank you for the trust you have placed in our company and wish you satisfaction in your daily work with our product.

Please read these instructions for use carefully before using the device for the first time and keep them in a safe place.

Kind regards, HELLMUT RUCK GmbH

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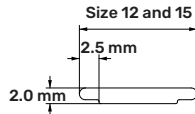
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1 Product description, product line

The GOLDSTADT professional is made of spring steel 1.4310 (chrome-nickel steel), which is widely used in the medical technology sector and especially in the dental sector. The steel has a gold plating. The brace is available in three different shapes, each in 5 sizes and different material thicknesses.

1.1 GOLDSTADT professional full brace

The "size" unit helps the user to select the brace. With the help of the RUCK NAIL CORRECTION measuring tool (item no: 2351701), the user can determine the nail width in millimetres. To securely attach a full brace, the nail width in millimetres, plus an allowance for the end hooks, is required. The smaller sizes are less wide so that the forces of the spring steel correspond to the nature of the nail.

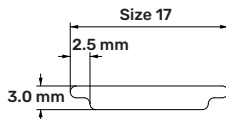


2350001 Size 12, 0.10 mm thickness

2350002 Size 15, 0.10 mm thickness

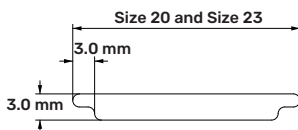
2350101 Size 12, 0.15 mm thickness

2350102 Size 15, 0.15 mm thickness



2350003 Size 17, 0.10 mm thickness

2350103 Size 17, 0.15 mm thickness



2350004 Size 20, 0.10 mm thickness

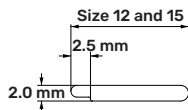
2350005 Size 23, 0.10 mm thickness

2350104 Size 20, 0.15 mm thickness

2350105 Size 23, 0.15 mm thickness

1.2 GOLDSTADT professional half brace

The "size" unit helps the user to select the brace. With the help of the RUCK NAIL CORRECTION measuring tool (item no: 2351701), the user can determine the nail width in millimetres. To attach a half brace securely, an allowance is required for the end hook. If a shorter half brace is selected, the force on the suspended side is increased. The smaller sizes are less wide so that the forces of the spring steel correspond to the nature of the nail.

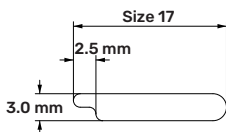


2350201 Size 12, 0.10 mm thickness

2350202 Size 15, 0.10 mm thickness

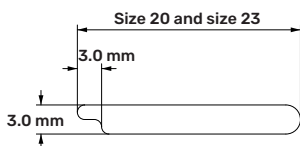
2350301 Size 12, 0.15 mm thickness

2350302 Size 15, 0.15 mm thickness



2350203 Size 17, 0.10 mm thickness

2350303 Size 17, 0.15 mm thickness



2350204 Size 20, 0.10 mm thickness

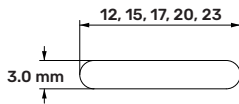
2350205 Size 23, 0.10 mm thickness

2350304 Size 20, 0.15 mm thickness

2350305 Size 23, 0.15 mm thickness

1.3 GOLDSTADT professional adhesive brace

The "size" unit helps the user to select the brace. With the help of the RUCK NAIL CORRECTION measuring tool (item no: 2351701), the user can determine the nail width in millimetres. The adhesive brace should be at least 1 mm away from the nail fold.



2350401 Size 12, 0.10 mm thickness

2350402 Size 15, 0.10 mm thickness

2350403 Size 17, 0.10 mm thickness

2350404 Size 20, 0.10 mm thickness

2350405 Size 23, 0.10 mm thickness

2 Intended purpose

The GOLDSTADT professional nail corrective brace has various applications. It is intended for the treatment of chronic nail deformities, ingrown nail tips, cornifications and pressure points in the nail area.

The brace must not be used in case of intolerance to the brace material.

The brace is a single-use product and is supplied non-sterile. A disposable product cannot be reused or resterilised. Moving the brace after the initial treatment (same patient and nail) is considered a continuation of the original treatment.

Initial treatment (disinfection/sterilisation) of the brace is possible. Depending on the skin status and the situation in which it is used, the user must decide whether treatment is necessary before use. Please refer to the HELLMUT RUCK GmbH treatment instructions for correct treatment (hellmut-ruck.uk/downloads).

3 Accessories

2351001	RUCK® INSTRUMENTS round-step pliers
2351901	RUCK® NAIL CORRECTION Cleaner
2351302	RUCK® NAIL CORRECTION Activator
2351402	RUCK® NAIL CORRECTION Adhesive
2351701	RUCK® NAIL CORRECTION Measuring tool
2313201	RUCK® INSTRUMENTS Double-ended applicator
2003301	RUCK® INSTRUMENTS Double-ended Nail Fold Instrument
5420001	peclavus® PODomed Pre-Treatment Tincture
5420101	peclavus® PODomed Post-Treatment Tincture
5420201	peclavus® PODomed AntiMYX Tincture
7441402	RUCK® DRESSINGS Nail Fold Tamponade Copoline Test Set
4116601	RUCK® NAILART-Line gel modelling brush, flat, L/W brush head: 16/0.4 cm
4116603	RUCK® NAILART-Line gel modelling brush, flat/pointed, L/W brush head: 16/0.6 cm
4116604	RUCK® NAILART-Line gel modelling brush, flat/wide, L/W brush head: 16/0.6 cm
2352001	RUCK® NAIL CORRECTION UV gel soft, clear, 15 ml
4124401UK	RUCK® UV & LED Nail Curing Lamp, 24W, white

Also available in a practical set for an easy start.

2354101UK	RUCK® NAIL CORRECTION GOLDSTADT professional adhesive brace starter set
2354001UK	RUCK® GOLDSTADT professional full and half brace starter set
2354501UK	RUCK® GOLDSTADT professional classic starter set

4 Area of use, duration of use

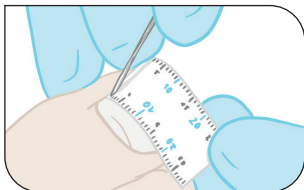
The circle of users includes podiatrists, chiropodists, doctors or related professional groups who are familiar with the application and have the necessary expertise.

In accordance with MDR 2017/745/EU class 1, the GOLDSTADT professional nail corrective brace is a non-invasive product intended for continuous use under normal conditions for a period of up to 28 days. A follow-up check must be carried out after this time. If the user does not recognise any risks, the duration of use can be extended and the product is classified as a Class 1 medical device in accordance with Rule 1 of Annex IX.

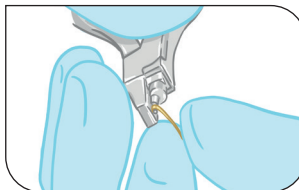
The GOLDSTADT professional brace is not intended to be combined with other products.

5 How to use

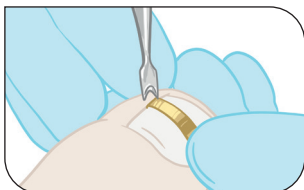
- 1** Use the measuring tool to determine the appropriate brace size.



- 2** For full and half braces: Adjust the end hooks to the nail.




- 3** Place the brace on the nail.



- 4** Cover the brace with UV gel and cure the gel.



 You can find videos showing how to use the products on our YouTube channel. Click on the link or scan the QR code.

<https://qr.de/anwendungs-videosnagelkorrektur>



6 Patient and user protection



ATTENTION: Please observe the warnings on the packaging of all products.

6.1 Potential risks for the patient

6.1.1 Risk of skin irritation/injury/inflammation and pain in the area around the nail

Choosing the right brace size and fitting and putting on the brace correctly are important prerequisites for avoiding skin irritation, skin injuries, pain and inflammation. The reactions usually occur rapidly and are quickly noticed by the patient and user. Countermeasures must be taken immediately.

6.1.2 Allergy risks

An allergic reaction of the patient to components of the brace or the adhesive cannot be ruled out. The brace is made of gold-plated spring steel. Both gold and spring steel, which is often used in medicine, have a low allergenic potential. The spring steel contains chromium and nickel. Components of the adhesive can lead to an allergic reaction in patients with an allergic tendency. A potential allergic reaction will usually be limited to local skin irritation.

6.1.3 Danger due to detachment of the nail

The selection of the correct brace size and the correct placement of the brace are important prerequisites for preventing the nail from detaching.

6.1.4 Risk of unintentional detachment of the brace

Insufficient preparation of the nail plate, inadequate fixation of the brace or incorrect positioning can lead to the brace coming off.

6.1.5 Potential infection of the nail

Infection of the nail plate due to excessive tension/activity of the brace, previous damage to the nail or lack of hygiene can lead to nail mycosis. Patient education should include necessary hygiene measures to prevent infection.

6.2 Potential risks for the user

If used as intended and protective equipment is worn, there are no risks for the user. The minimum protective equipment consists of a face mask and disposable gloves.

7 Disposal



Environmental hazard!

Incorrect disposal endangers our environment.

8 Manufacturer/contact details



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The RUCK logo, featuring the word "RUCK" in a bold, white, sans-serif font, followed by a registered trademark symbol (®). The logo is positioned on a blue background.