



# ORTOGRIP

■■■■■■ PROFESSIONAL

Instructions for use

**EN**

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## Dear Customer,

with the purchase of ORTOGRIP professional, you have opted for a new brace system which, in collaboration with Elvira Osthold and a development team from RUCK, retains all the advantages of the VHO Osthold technology and clearly stands out from comparable products thanks to improved handling and greater clarity.

The ORTOGRIP professional corrective brace is based on the proven Osthold principle; a 3-part brace in which the tensile force can be precisely controlled by twisting a centre loop. The effect remains and it is much easier to use. The "brace with handle" is not only improved by the coloured plastic element, but is also much clearer thanks to the colour coding of the different models. The different roof geometry and wire thickness of the "action parts" have been specially developed for the respective requirements.

We sincerely thank you for the trust you have placed in our company and extend our best wishes for 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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## **Declaration relating to these instructions for use**

HELLMUT RUCK GmbH reserves all rights to modify and supplement these instructions for use. HELLMUT RUCK GmbH has taken great care to keep these instructions free of inaccuracies and omissions. Please contact us if you find any errors or inaccuracies. However, HELLMUT RUCK GmbH assumes no liability for mistakes in these instructions for use or consequential damage resulting from the provision of these instructions for use or their application when using the product.

These instructions for use must not be disseminated or supplemented without the express approval of HELLMUT RUCK GmbH.

The manufacturer cannot be made responsible for damage that is caused by use that deviates from the intended use or failure to comply with the safety instructions and warnings.

This product is a medical product.

**Medical product**

Directive (EU) 2017/745

## 1. Abbreviations and symbols



This symbol identifies a potential point of danger for people or for the device itself. It must be taken note of.



This symbol identifies useful advice.  
Additional information about the product and how to use it is provided here.



Observe the disposal notice



## 2. Product description, product line

The ORTOGRIP professional is made of stainless steel 1.4404 (chrome-nickel-molybdenum steel), which is widely used in the medical technology sector and especially in the dental sector. The brace consists of 2 components (brace and wire loop), which are available in different sizes and material thicknesses. The brace is available in 6 sizes with different wire thicknesses, the loop in three material thicknesses with the same geometry.

### ORTOGRIP PROFESSIONAL **braces**

<b>2340001</b>	ORTOGRIP professional brace 1, blue 0.3 mm
<b>2340002</b>	ORTOGRIP professional brace 2, green 0.35 mm
<b>2340003</b>	ORTOGRIP professional brace 3, pink 0.35 mm
<b>2340004</b>	ORTOGRIP professional brace 4, orange 0.4 mm
<b>2340005</b>	ORTOGRIP professional brace 5, yellow 0.4 mm
<b>2340006</b>	ORTOGRIP professional brace 6, white 0.5 mm

### ORTOGRIP PROFESSIONAL **loops**

<b>2340101</b>	ORTOGRIP professional loop 0.25 mm
<b>2340102</b>	ORTOGRIP professional loop 0.3 mm
<b>2340103</b>	ORTOGRIP professional loop 0.4 mm

### **3. Intended purpose**

The ORTOGRIP professional nail corrective brace has various applications. It is intended for the treatment of patients with 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 application situation, the user must decide whether treatment is necessary before use.

Please refer to the HELLMUT RUCK GmbH treatment instructions for correct treatment. These can be found in our RUCK online shop under each RUCK instrument in the "Downloads" section.

#### 4. Accessories

<b>2351001</b>	RUCK® INSTRUMENTS round-step pliers
<b>2302401</b>	RUCK® INSTRUMENTS needle-nosed pliers
<b>2306601</b>	RUCK® INSTRUMENTS wire side cutters
<b>2351901</b>	RUCK® NAIL CORRECTION Cleaner
<b>2351302</b>	RUCK® NAIL CORRECTION Activator
<b>2351402</b>	RUCK® NAIL CORRECTION Adhesive
<b>2003301</b>	RUCK® INSTRUMENTS nail fold instrument, double-ended
<b>2004001</b>	RUCK® INSTRUMENTS nail lifter, double-ended
<b>54200</b>	peclavus® Pre-Treatment Tincture
<b>54201</b>	peclavus® Post-Treatment Tincture
<b>54202</b>	peclavus® AntiMYX Tincture Silver
<b>7441402</b>	RUCK® DRESSINGS Nail fold Copoline tamponade
<b>2316601</b>	RUCK® NAIL CORRECTION Plastic for nail prostheses, powder
<b>2316701</b>	RUCK® NAIL CORRECTION Plastic for nail prostheses, liquid
<b>2351501</b>	RUCK® Silicone Mixing Vessel

**Also available in a practical set for an easy start.**

<b>2343001UK</b>	ORTOGRIP professional starter set
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## 5. User group, application duration

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

In accordance with Directive (EU) 2017/745, the ORTOGRIP 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 recognises no risks, the duration of use can be extended. The product is categorised as a Class 1 medical device in accordance with Annex VIII, Chapter III.

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

## 6. How to use

The ORTOGRIP professional corrective brace is based on the proven VHO Osthoid principle. The ORTOGRIP professional corrective brace is applied in four steps:

1. Adaptation of the brace to the nail
2. Applying the brace
3. Activating the brace by attaching the loop
4. Forming the droplet



You can find a detailed instructional video here:



Attention:  
Do observe the warnings on the packaging of all products.

## **7. Potential risks for the patient**

### **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. Particular care must be taken when fitting the end hooks to ensure that no sharp edges are created. The reactions usually occur rapidly and are quickly noticed by the patient and user. Countermeasures must be taken immediately.

### **Danger due to detachment of the nail**

The selection of the correct brace size and the correct setting of the traction/leverage forces of the brace are important prerequisites for preventing the nail from detaching.

### **Risk of 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.

## **8. Potential risks for the user**

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

## 9. Disposal



### **Environmental hazard!**

Incorrect disposal endangers our environment



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