

PODOSTRIPE

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1 INTRODUCTION

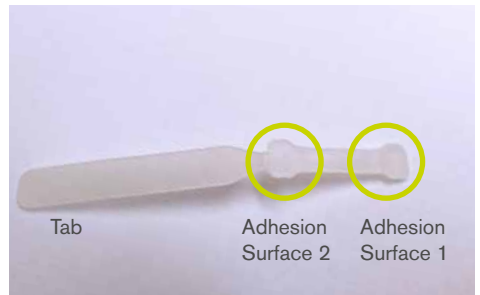
The PODOSTRIPE Glue-on Brace is a brace that can be used in nearly all cases involving deformed, painful ingrown and involute nails.

It is also suitable for the cosmetic correction of deformed nails and for use by diabetics.

The PODOSTRIPE Glue-on Brace consists of a flexible plastic strip with two adhesion Surfaces and a tab.



PODOSTRIPE from above



PODOSTRIPE from below

AIM OF THE TREATMENT

The aim of the PODOSTRIPE Glue-on Brace therapy is to establish healthy nail growth.

By lifting an ingrown nail immediately, the PODOSTRIPE brace can provide immediate pain relief and thus a spontaneous improvement in the general condition of the patient.

MODE OF ACTION

The first end of the brace is fixed to the nail. The brace is then stretched and the second end glued to the nail whilst under tension. The tension of the material causes the edges of the nail to lift up slightly. The tab is then removed.



TREATMENT DURATION

Depending of the findings, the PODOSTRIPE Glue-on Brace remains on the nail for a period of 3 to 6 weeks and is then replaced with a new brace until the desired therapeutic effect manifests.

The more frequently the brace is replaced, and thus re-activated, the faster the desired result will be obtained.

2 ATTACHING THE GLUE-ON BRACE

Please follow these instructions for use carefully when using the product.
Please observe all the safety precautions given.

NOTE

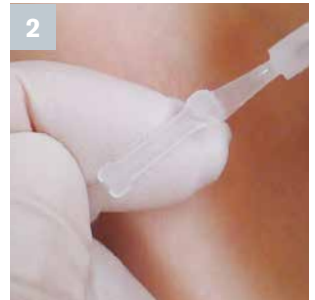
Please ensure that the nail has not become softened before the brace is applied. Intensive foot baths and the excessive application of disinfectant or callus softener on the nail should be avoided prior the use.

Also take note to protect your health when applying the brace. Wear surgical gloves and mask.

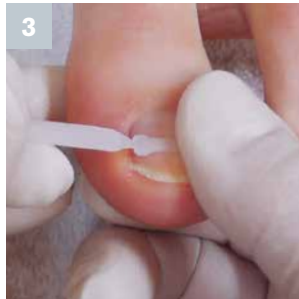
OVERVIEW



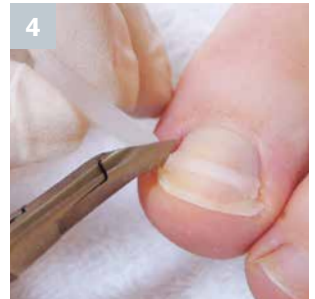
Cleaning of nail and brace



Glue on adhesion surface 1



Activate and glue on adhesion surface 2



Cut off tab

PREPARATION OF THE NAIL



Remove loose particles from the nail surface. Use a file to slightly smooth extremely rough nails or to roughen extremely smooth nails.



Clean and degrease the nail with the alcohol swab. The nail must then be dried with a swab in order to completely remove remains of the alcohol.

SELECTING THE BRACE SIZE

You should select the largest possible size. The elongation of the brace (approx. 1.3 – 2.7 mm) must be taken into account when doing so.

Brace	Elongation	Final width
13.0 mm	max 1.3 mm	14.3 mm
16.0 mm	max 2.0 mm	18.0 mm
19.0 mm	max 2.7 mm	21.7 mm



CLEANING THE BRACE

The brace must be degreased using the alcohol swab and must then be dried using a clean, dry swab in order to completely remove remains of the alcohol.



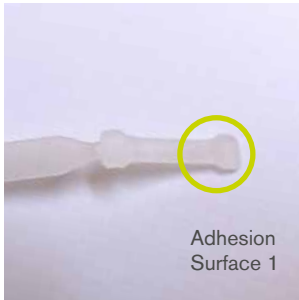
POSITIONING THE BRACE

The PODOSTRIPE brace should be positioned at the front area of the nail.

The brace should be applied as close as possible to the edge of the nail on the side that is painful or more severely ingrown.



BONDING (ADHESION SURFACE 1)



ADVICE ON USING THE GLUE

- > Use the glue sparsely; if too much glue is used, the brace will not stick to the nail.
- > Ensure that the edge and thread of the bottle stay clean. Clean with a swab if needed.
- > After tightly closing the bottle, reopen it just a little bit. This prevents the bottle and its top from sticking together.
- > It is recommended to store the glue in a horizontal position.



Gently wipe off each side of the brush to remove excess glue.



Apply a thin film of glue to adhesion Surface 1.

NOTE: Use the glue sparsely; if too much glue is used, the brace will not stick to the nail.



Position adhesion Surface 1 on the more severely ingrown side of the nail. Press the adhesion Surface of the brace onto the nail for approx. 15 seconds.

NOTE: Make sure that the brace does not move once it has been placed on the nail.

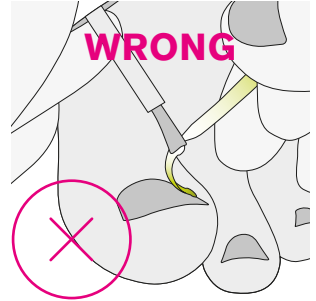
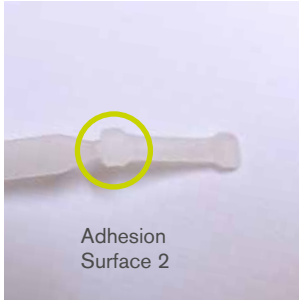


The glue must then be allowed to harden for 2 minutes.



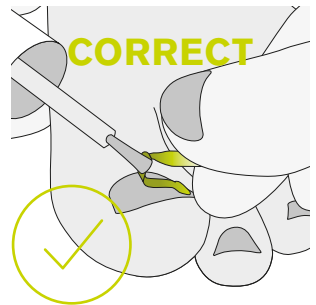
2 MIN.

ACTIVATING AND BONDING (ADHESION SURFACE 2)

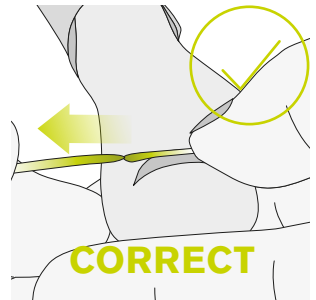
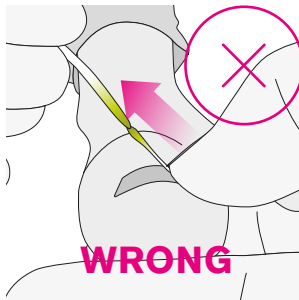


Gently wipe off each side of the brush to remove excess glue. Apply a thin film of glue to adhesion Surface 2.

NOTE: Make sure that no force is applied to the first end and that it does not become detached.



Use the force necessary to stretch the brace by 1.00 - 2.70 mm (dependent on brace width, nail thickness and the problem). The brace should be pulled parallel to the nail.



Place the stretched brace onto the nail and press down on adhesion surface 2 for 30 seconds.

NOTE: Make sure that the brace does not move once it has been placed on the nail.



The glue must then be allowed to harden for 2 minutes.



REMOVING THE TAB

Place the pincers slanted under the tab and pinch off the pad.



TREATING THE NAIL

Remove the ingrown part of the nail (using a nail splitter, ingrown nail clippers or nail drill).

- > Clean the nail fold
- > If necessary, pack
- > If necessary, patient must have the wound examined



3 REMOVING THE GLUE-ON BRACE

REMOVING THE BRACE

The brace is to be replaced with a new brace every 3 to 6 weeks until the desired therapeutic effect is achieved. To do this, the old brace must first be removed.

Lift one end of the brace by using the pincers. The second end is detached using the fingers.



4 PROBLEMS AND SOLUTIONS

THE BRACE DOES NOT GLUE WELL OR COME LOOSE

- › Adhesion surface 1 has been removed from the nail while applying adhesion surface 2
- › The brace or the nail have not been cleaned well enough
- › Too much glue has been used (so the glue is not able to dry)
- › The brace was moved while applying it to the nail
- › The nail is too porous
- › While cutting off the tab the brace has been torn off

SOLUTION

Make sure all notes of the instructions are complied properly.

The patient must be informed about the correct behavior during the treatment

THE GLUE'S BOTTLE CAN NOT BE OPENED

When wiping off the brush the bottle's thread was covered with glue and the bottle was then stored standing

SOLUTION

Try to open the bottle using a flat pliers. CAUTION: this has to be done with great care so that no glue can leak from the bottle.

Future storage as detailed described in the instructions for use (store in a horizontal position; reopen a little bit after tight closing).

5 WARNINGS

NOTE: In order to prevent accidents and injuries, please follow these instructions for use carefully and observe all the disinfection instructions and notices given!

PLEASE OBSERVE THE FOLLOWING DURING TREATMENT

- › The patient should notify the therapist immediately should sudden pain be experienced following attachment of the brace.
- › Despite immediate absence of pain the patient should avoid doing sports until the inflammation has subsided.
- › In case of hypergranulation the toe should be kept dry.

CLEANING AND CARE OF THE PINCERS

As the skin does not become broken when using the pincers with the PODOSTRIPE Glue-on Brace, disinfection and cleaning is adequate to maintain hygiene.

We recommend using a commercially available DGHM-approved (German Association for Hygiene and Microbiology) disinfectant with corrosion protective effect to disinfect the pincers. Always follow the instructions on the packaging or enclosed information leaflet regarding concentration and exposure time. Never disinfect the pincers together with instruments that already show signs of rust as this may damage the pincers too.

Rinse the pincers with distilled water following disinfection. Should the pincers exhibit visible surface contamination, they can be cleaned in an ultrasonic bath or by brushing using a soft natural bristle brush and then rinsed with water. Dry them thoroughly afterwards.

In order to keep the pincers in proper working order and presentable for a long time, commercially available instrument sprays can be used following disinfection and cleaning. To ensure that the joint area of the pincers remains free to move and slides smoothly, we recommend lubricating it with a drop of special oil for surgical instruments following cleaning and disinfection.

SAFETY NOTICES

- › Always wear surgical gloves when working!
- › The brace may not be transferred from one patient to another!

GLUE

Warning: The glue bonds skin and eyelids together in a matter of seconds.

Contains cyanoacrylate. Causes irritation to eyes, respiratory organs and skin. Avoid contact with eyes and skin. Seek medical advice immediately in case of contact with eyes or internal organs.

Avoid inhaling vapours. Do not allow glue to come into contact with wounds. Protect wounds with a film of oil or fat prior to use. Should the skin become stuck together, do not separate by force. Soak in warm soapy water for a while before gently prising apart or carefully release using acetone. Keep out of reach of children.



- › Use the glue sparingly; if too much glue is used, the brace will not stick to the nail.
- › Keep the sides and thread of the bottle clean. Clean with a swab or similar as required.
- › It is recommended to store the glue in a horizontal position.

PINCERS WARNING!

The pincers are sharp and pointed, and there is risk of injury. You should therefore use them exclusively in the area described in the instructions for use.



GENERAL NOTES

- › The patient must be informed about the treatment in a consultation session beforehand (Mechanism of action and possible unwanted side effects of the brace).
- › The patient must be called in for a check-up depending on the severity of the case
 - in severe cases, after around 1 to 3 days
 - in mild cases, after around 3 to 6 days
- › In the case of inflammation, the inflamed area must be treated and a bandage applied. A doctor must also be consulted in the case of inflammation.



Die Spange ist zum einmaligen Gebrauch bestimmt.

The brace is intended for single use.



Lesen Sie vor der ersten Anwendung diese Gebrauchsanweisung aufmerksam durch und beachten Sie alle Hinweise.

Please read the instructions for use carefully before using the product for the first time and observe all the notices.

Konformitätserklärung

Die 3TO GmbH erklärt hiermit, dass das PODOSTRIPE Nagelkorrektursystem als Medizinprodukt der Klasse I im Sinne der EG-Richtlinie 93/42/EWG, Anhang VII, auf Grund der in dieser Gebrauchsanleitung genannten Zweckbestimmung und der technischen Hinweise in der in Verkehr gebrachten Ausführung den grundlegenden Bestimmungen der EG-Richtlinie 93/42/EWG entspricht. Diese Erklärung wird abgegeben vorbehaltlich einer Änderung durch eine Rechtsverordnung des BMG gem § 14 Abs. 3 MPG.

Declaration of Conformity

3TO GmbH hereby declares that the PODOSTRIPE Glue-on Brace Nail Correction System in the form placed on the market complies with the basic provisions set out in Council Directive 93/42/EEC as a class 1 medical device in the sense of Council Directive 93/42/EEC, Annex VII, based on the stated purpose and technical notices in these instructions for use. This declaration is made subject to revision by a legislative decree issued by the BMG [German Ministry of Health] pursuant to Section 14, Paragraph 3 of the MPG [Medical Products Directive].

PODOSTRIPE

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