GAUNTLET IMMOBILIZATION SPLINT

GEBRUIKSAANWIJZINGEN - INSTRUCTIONS D'UTILISATION
INSTRUCTIONS FOR USE - GEBRAUCHSANWEISUNGEN

Listed with

Material: ORFIT® COLORS NS 2 mm micro perfo

***Indicaties**: Ontsteking van polsgewricht - polsverstuiking - fractuur van handbeentjes - styloïditis - carpaal tunnel syndroom - reuma (functie-orthese)*
***Indications**: Arthrite radio-cubito-carpienne - entorse du poignet - styloidite radiale - syndrome du canal carpien*
***Indications**: Acute wrist arthritis - wrist sprain - radial styloiditis - carpal tunnel syndrome*
***Indikationen**: Akute Handgelenk-Arthritis - Handgelenk-Verstauchung - Styloiditis Radii - Carpaltunnel Syndrom*

Dit product is vervaardigd uit een lage temperatuur thermoplastisch materiaal dat direct op de patiënt kan worden gevormd.
Lees eerst aandachtig de gebruiksaanwijzingen (ref. nr. 31052) van het hierboven aangeduide basisproduct en neem de voorzorgsmaatregelen in acht die daarbij horen.

Dit spalkpatroon is NIET GESCHIKT voor volgende toepassingen:
- acute polsfracturen
- Südeck dystrofie
- langdurig en agressief gebruik

Deze gebruiksaanwijzingen werden opgesteld in de geest van de Europese Richtlijn 93/42/EEG betreffende medische hulpmiddelen. Het is verboden veranderingen aan te brengen in deze tekst zonder voorafgaande toestemming van ORFIT Industries.
Indien u bijkomende exemplaren wenst, neem dan contact op met de verdeler in uw land of stuur een faxbericht naar (+32) (0)3 326 14 15 of een e-mailbericht naar welcome@orfit.com.

Ce produit est fabriqué dans un matériel thermoformable à basse température, qui est formé directement sur le patient.
Lisez d'abord attentivement les instructions d'utilisation (ref. no. 31052) pour le produit de base mentionné ci-dessus et respectez les précautions d'usage y référant.

Ce patron n'est PAS INDIQUE pour les cas suivants:
- fractures aiguës du poignet
- algo neuro dystrophie
- emploi agressif et prolongé

Ces instructions d'utilisation ont été rédigées dans l'esprit de la Directive Européenne 93/42/CEE concernant les aides techniques médicales. Il est interdit d'apporter des modifications à ce texte sauf accord préalable d'ORFIT Industries.
Si vous souhaitez des exemplaires supplémentaires, prenez contact avec notre distributeur dans votre pays ou envoyez votre demande par fax (+32) 3.326.14.15 ou par e-mail à welcome@orfit.com.

This product is made of a Low Temperature Thermoplastic material and can be moulded directly on the patient. Before starting, read the instructions for use (ref. No. 31052) of the basic product mentioned above and take all the necessary precautionary measures.

This pattern is NOT SUITABLE for the following applications:
- acute fractures of wrist
- reflex sympathetic dystrophy (RSD)
- prolonged and aggressive use

These instructions were made up in accordance with the European Directive 93/42/EEC for Medical Devices. It is prohibited to make alterations to this text without prior approval from ORFIT Industries.

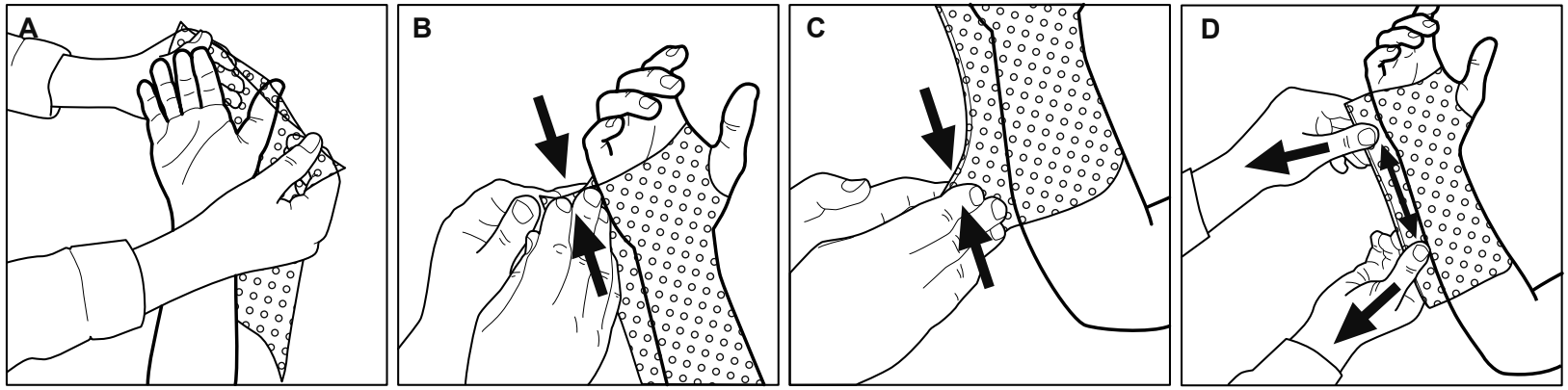
For additional copies, please contact your local distributor or send a fax to
(+32) (0)3 326 14 15 or an e-mail to welcome@orfit.com.

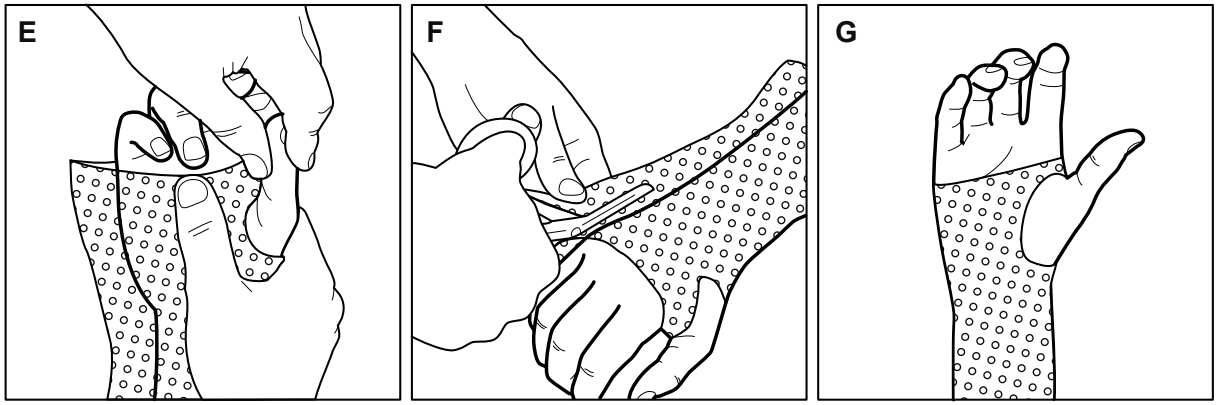
Dieses Produkt ist aus ein Niedrigtemperatur Thermoplast hergestellt und darf unmittelbar auf den Patienten angelegt werden.
Lesen Sie zuerst andächtig die Gebrauchsanweisungen (Ref. Nr. 31052) die zu dem o.e. Basisprodukt gehören und nehmen Sie die notwendigen Sicherheitsmaßnahmen.

Dieses Dessin EIGNET SICH NICHT für die nachstehenden Indikationen:
- akute Handgelenkfrakturen
- Südecksche Dystrophie
- langfristigen und aggressiven Gebrauch

Diese Gebrauchsanweisungen wurden im Geiste der Europäischen Richtlinie 93/42/EWG für medische Hilfemittel aufgestellt. Es ist verboten den Tekst zu änderen, ohne vorhergehende Zustimmung von ORFIT Industries.
Falls Sie mehrere Exemplare wünschen, bitte nehmen Sie Kontakt auf mit dem Verteiler in Ihrem Land, oder schicken Sie uns einen Faxbericht nach der Nummer (+32) (0)3 326 14 15 oder einen e-mail Bericht nach der Adresse welcome@orfit.com.

Ref.: 35830-35831-35832 – version 1 – last update: 18/10/2013 – revision date: 18/10/2015





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ORFIT® COLORS NS - 2.0 mm - micro perforated					precuts
Description	Size	Art. No.			
		Ocean Blue	Atomic Blue	Sonic Silver	Dominant Black
Gauntlet Immobilization Splint	S	35830B/NS	35830MB/NS	35830MG/NS	35830Z/NS
	M	35831B/NS	35831MB/NS	35831MG/NS	35831Z/NS
	L	35832B/NS	35832MB/NS	35832MG/NS	35832Z/NS

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2110 Wijnegem, Belgium

ORFIT® COLORS NS

INSTRUCTIONS FOR USE

A. GENERAL PRODUCT INFORMATION

ORFIT® COLORS NS is a low temperature thermoplastic sheet material for the production of orthoses, external immobilisation devices and rehabilitation aids.
ORFIT® COLORS NS is applied directly to the patient once it is activated.

! ***ORFIT® COLORS NS is not suitable for internal use. It may not be used on open wounds or in the mouth.***

B. PRODUCT RANGE

ORFIT® COLORS NS is available in sheets of 450 x 600 mm, in different colours, thicknesses and perforation types.

	Art. no.	Colour	Thickness in mm	Perforation type
	8133PU.1/NS 8133PU.2/NS	violet	2.0	non perforated micro perforated
	8133GR.1/NS 8133GR.2/NS	hot green	2.0	non perforated micro perforated
	8133Z.1/NS 8133Z.2/NS	dominant black	2.0	non perforated micro perforated
	8133R.1/NS 8133R.2/NS	dynamic red	2.0	non perforated micro perforated
	8133B.1/NS 8133B.2/NS	ocean blue	2.0	non perforated micro perforated
	8133FP.1/NS 8133FP.2/NS	bright pink	2.0	non perforated micro perforated
METALLIC COLOURS	8133MG.1/NS 8133MG.2/NS 8134MG.1/NS 8134MG.4/NS	sonic silver	2.0 3.4	non perforated micro perforated non perforated mini perforated
	8133MB.1/NS 8133MB.2/NS 8134MB.1/NS 8134MB.4/NS	atomic blue	2.0 3.4	non perforated micro perforated non perforated mini perforated
	8133GO.1/NS 8133GO.2/NS 8134GO.1/NS 8134GO.4/NS	gold	2.0 3.4	non perforated micro perforated non perforated mini perforated

C. PRECAUTIONS BEFORE USE

1. Make sure the workplace is well-ventilated to avoid overheating.
2. The necessary tools should in no way put the patient at risk.
3. Encourage the patient to assume a comfortable position and ensure that you yourself are in an easy working position.

D. TECHNICAL ACTIVATION

1. ORFIT® COLORS NS is softened by heating at a minimum temperature of 65°C (149°F). Possible activation sources are: water bath, heat gun, heating plate, hot air oven. The activation time depends on the heat source and varies from 2 to 5 minutes.
2. When using a Suspan water bath, it is recommended to soften the water by adding a spoonful of liquid soap.
   When using a heat gun, do not exceed 250°C (482°F) to avoid breakdown of the material.
   When using a heating plate or an oven, the hot surface must be covered with a Teflon film.

! ***3. Please note: temperatures of 65°C (149°F) or more can also be reached in the patient's daily life. Think of a closed car in the summer, the surface of a hot radiator, a sauna or the proximity of an open fireplace.***

4. High temperatures up to a maximum of 120°C (248°F) do not damage ORFIT® COLORS NS, but are not user-friendly. High temperatures are allowed provided that the activation time is reduced accordingly and that the product is sufficiently rubbed with talcum powder. Wear gloves and do not apply ORFIT® COLORS NS directly to the patient at these high activation temperatures.

! ***5. Never use an open flame to activate ORFIT® COLORS NS.***

E. WORKING PROPERTIES

Cutting

1. Draw the splint pattern on the ORFIT® COLORS NS sheet using a marker.
2. Cut the pattern out roughly with a suitable pair of scissors, or use a cutter. When using a cutter, carve a straight line and break the sheet in two.

! ***Be careful of possible cuts when using a cutter; always keep the assisting hand away from the cutting line.***

3. Heat the ORFIT® COLORS NS sheet until it is formable but not yet stretchable and cut the precise splint pattern with a pair of scissors.

Applying

1. Activate the ORFIT® COLORS NS pattern until it is completely soft. Take it out of the water and let its surface cool and dry on a towel for a few seconds.
   Make sure that the temperature of the activated material will not burn the patient.

! ***ORFIT® COLORS NS is:***
- ***not adhesive at all when wet heated, or when dry heated and extra powdered with talcum.***
- ***slightly adhesive when dry heated at a low temperature.***
- ***fully adhesive when dry heated at a high temperature. However the bonding is never permanent and will pop apart once the material has hardened.***

2. Several application techniques are possible:
   - gravity technique: the material forms itself under gravity.
   - closed technique: mould the material around the limb and overlap the edges.
   - bandaging technique: secure the splint by means of a bandage.

! ***As with all thermoplastics, take advantage of the stretch and the elasticity of ORFIT® COLORS NS while moulding but be aware that it may tear if overstretched.***

3. In case of accidental bonding, let ORFIT® COLORS NS harden completely so that parts that are stuck can be separated. Reactivation in hot water is then safe again.
4. Remove the splint from the patient when ORFIT® COLORS NS is sufficiently hard.
   Excessive material can be trimmed before complete hardening. To do so, use a suitable pair of bandage scissors.
   The cooling time can be shortened by means of cold air, a cold bandage or a cold spray.
5. To attach fastening straps and secure hinges, outriggers or other accessories to the splint, the NS film must be REMOVED locally. It can be scratched off with a knife using rough sandpaper or with a grinding tool. Avoid encrusting the film into the splinting material by back and forth movements. The film can also be softened using acetone or rubbing alcohol and then wiped off. Use hot dry heat to make the spots sticky.

F. FINISHING

There are several ways to give the edges of a ORFIT® COLORS NS splint a smooth and even finish:
- local reheating and rubbing with a wet finger,
- after hardening, edge finishing can be done by means of a deburring knife,
- grinding by using a suitable polishing wheel at a low speed.

G. MAINTENANCE AND WASTE MANAGEMENT

Orthoses made of ORFIT® COLORS NS should be cleaned daily. Use lukewarm water and liquid soap, biological detergent or toothpaste, and rinse well.

! ***Never use solvents. Avoid acid detergents.***

Sterilisation of ORFIT® COLORS NS orthoses in an autoclave is impossible.
Disinfection is possible with alcohol, quaternary ammonium or a solution of commercial disinfecting soaps (HAC®, Sterilium®, etc.).

! ***Avoid prolonged contact with detergents and acids which may affect the NS film.***

After use, an orthosis can be disposed of with normal household waste without harming the environment. ORFIT® COLORS NS is biodegradable.

H. ADVICE FOR THE PATIENT

! ***Give the patient sufficient information about the exact use of the orthosis and about the possible constraints of the splint.***

I. STORAGE

- ORFIT® COLORS NS should be stored vertically, if supported and horizontally if not.
- Stock should be kept in a dark, cool, dry place at a temperature of min. 10°C (50°F) and max. 30°C (86°F) and in the original packaging.
- Once removed from the packaging, left-overs should be placed back in the packaging for storage to avoid adhesion of the NS film and biodegradation.

Low temperature thermoplastics can only be kept for a limited period of time and must be protected as much as possible from light, heat and humidity. The material ages in relation to storage circumstances. When aged, it becomes brittle and often very stretchy when activated.

J. GENERAL SAFETY ADVICE

! * ***ORFIT® COLORS NS is not suitable for internal use. It may not be used on open wounds or in the mouth.***
! * ***Never use an open flame to activate ORFIT® COLORS NS.***
! * ***To make orthoses and rehabilitation aids, ORFIT® COLORS NS may only be used by qualified health professionals.***

K. ADDITIONAL INFORMATION

For additional information such as product brochures, Material Safety Data Sheets and regulatory information, please visit our website www.orfit.com.

These instructions are written in accordance with the European Directive 93/42/EEC for Medical Devices. It is prohibited to make alterations to this text without prior approval from ORFIT Industries.

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