

# Instructions for Use for Orthotists or Qualified/Trained Experts Sheets and Pre-Cut Soles

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CARBON THERMOPLASTIC SANDWICH

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Content	Page
1. Information	3
2. Safety Instructions	3
2.1 Classification of the Safety Instructions	3
2.2 All Instructions for a Safe Handling of CTS UNIDIREKTIONAL	4
3. Intended Use	5
4. Material Properties	5
4.1 Deformability	5
4.2 Strength and Rigidity	5
4.3 Production Tolerances	6
5. Selection of CTS Sheets and Pre-Cut Soles	6
6. Preparing the Shoe Model	7
7. Tools for Processing	7
8. Processing the Material	7
8.1 Cutting	8
8.2 Grinding	8
8.3 Adhering	8
8.4 Heating	9
8.5 Forming	9
9. Storage and Handling	10
10. Accessory Parts	10
11. Disposal	10
12. Legal Information	10




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## 1. Information

These instructions for use are addressed to orthotists or qualified/trained experts and do not contain any notes about dangers which are obvious to them. To achieve maximum safety, please instruct the patient and/or care team in the use and maintenance of the product.

## 2. Safety Instructions

### 2.1 Classification of the Safety Instructions

 <b>DANGER</b>	Important information about a possible dangerous situation which, if not avoided, leads to death or irreversible injuries.
 <b>WARNING</b>	Important information about a possible dangerous situation which, if not avoided, leads to reversible injuries that need medical treatment.
 <b>CAUTION</b>	Important information about a possible dangerous situation which, if not avoided, leads to light injuries that do not need medical treatment.
<i>NOTICE</i>	Important information about a possible situation which, if not avoided, leads to damage of the product.

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## 2.2 All Instructions for a Safe Handling of CTS UNIDIREKTIONAL

### WARNING

#### **Jeopardising the Therapy Goal Due to Excessive Load**

When reinforcing the orthosis, select the appropriate material thickness for the different orthosis areas to avoid material breakage.

### WARNING

#### **Jeopardising the Therapy Goal Due to Improper Processing**

Processing errors can lead to material breakage and/or failure of the orthosis function. Process the material as described in these instructions for use. Pay particular attention to:

- using a convection or infrared oven to heat the material,
- moulding the material before it has cooled down and
- only thermoforming the material two-dimensionally.

### WARNING

#### **Jeopardising the Therapy Goal Due to Incorrect Cutting**

Cutting errors can lead to material breakage and/or failure of the orthosis function. Cut the material as described in these instructions for use. Pay particular attention to:

- only grinding the cutting edge and not the surface of the material,
- aligning the fibres according to the loading direction and
- not removing more than 5mm of material when chamfering the pre-cut.

### 3. Intended Use

CTS UNIDIREKTIONAL has been developed exclusively for the production of sole reinforcements for reducing the deformation during rolling off.

### 4. Material Properties

#### 4.1 Deformability

The acrylic resin metcore® is used as a basis for the production of CTS UNIDIREKTIONAL. It can be used for 2D thermoforming (fig. 1) and can be adhered to metal, leather and various plastics. CTS UNIDIREKTIONAL is **unsuitable** for 3D thermoforming such as for heel-covering insoles or orthotic foot pieces (fig. 2). It is equally **unsuitable** for loads in multiple directions as is the case with bands for orthoses (fig. 3).

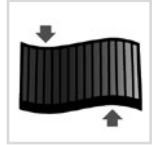


fig. 1

#### 4.2 Strength and Rigidity

CTS UNIDIREKTIONAL sheets and pre-cut soles are available in different thicknesses with different rigidities (see table). In order to increase the rigidity, you can use CTS UNIDIREKTIONAL in layers following the sandwich construction method (fig. 4). To do so, process a pre-cut sole and adhere it to the shoe sole. After that, create the next pre-cut and adhere it to the already attached pre-cut.



fig. 2



fig. 3

When producing sole reinforcements, the material is mainly thermoformed in 2D. The shoe with reinforced sole is loaded in the direction of the unidirectional fibre orientation (fig. 5).

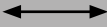


fig. 4



fig. 5

The pre-cut soles have a preproduced lengthwise fibre orientation of 0° and thus should only be loaded in this direction.

Loading Direction  Fibre Orientation	Tensile Strength	Bending Stiffness	Torsional Rigidity
0° ≡	very high	very high	low
90° ≡	very low	very low	low

The following table shows the load capacity of CTS UNIDIREKTIONAL with regards to the sole reinforcements in orthopaedic shoes. Spring steel with a material thickness of 1.5mm serves as a reference value.

Article Number		Thickness [mm]	Weight Ratio	Reinforcement	
Sheets	Pre-Cut Soles				
PL1356-XXS	-	1.2	1/7	lower rigidity	20%
PL1356-XS	SZ1250	1.6	1/6	lower rigidity	30%
PL1356-S	SZ1251	1.9	1/5	lower rigidity	40%
PL1356-M	SZ1252	2.3	1/4	standard	50%
PL1356-H	SZ1253	3.2	1/3	like spring steel	100%
PL1356-XH	-	4.0	1/2	triple rigidity	300%

### 4.3 Production Tolerances

Each pre-cut sole has an individual fabric layer structure and consequently an individual thickness. Since the fabric layer structure is subject to production tolerances, the indicated thicknesses are only reference values. The rigidity of the pre-cut is determined by the fabric layer structure. The production tolerances have minor effects on the rigidity. The production tolerances can lead to overlaps within the thickness specifications. Moreover, pre-cuts that are packed in pairs can have different thicknesses.

## 5. Selection of CTS Sheets and Pre-Cut Soles

Select the required material thickness of the carbon fibre sheets.

CTS UNIDIREKTIONAL, Carbon Fibre Sheets		
Article Number	Length x Width [mm]	Thickness [mm]
PL1356-XXS	500 x 500	1.2
PL1356-XS	500 x 500	1.6
PL1356-S	500 x 500	1.9
PL1356-M	500 x 500	2.3
PL1356-H	500 x 500	3.2
PL1356-XH	500 x 500	4.0

Determine the shoe size for the pre-cut soles and select the required material thickness. Pre-cut soles are only available in pairs.

CTS UNIDIREKTIONAL, Carbon Fibre Pre-Cut Soles		
Article Number	Shoe Size	Thickness [mm]
SZ1250-S	35-37	1.6
SZ1250-M	38-40	
SZ1250-L	41-43	
SZ1250-XL	44-46	
SZ1251-S	35-37	1.9
SZ1251-M	38-40	
SZ1251-L	41-43	
SZ1251-XL	44-46	
SZ1252-S	35-37	2.3
SZ1252-M	38-40	
SZ1252-L	41-43	
SZ1252-XL	44-46	
SZ1253-S	35-37	3.2
SZ1253-M	38-40	
SZ1253-L	41-43	
SZ1253-XL	44-46	

## 6. Preparing the Shoe Model

The pre-cut sole is usually attached after the insole, the upper and possibly the welt have already been produced onto the last (fig. 6).



fig. 6

## 7. Tools for Processing

Tool
temperature marker 160°C
band saw
jig saw
sander drum
lamellar flap grinding disc
contact adhesive
heat-resistant gloves

## 8. Processing the Material

If you are using a preproduced pre-cut sole, place it on the prepared shoe model and check the dimensions (fig. 7).



fig. 7

Adjust the pre-cut if necessary (see paragraph 8.1). For individual cuts from the sheet, make a suitable stencil. The fibre orientation has to point in the direction of the forces to be absorbed. In order for the **CTS UNIDIREKTIONAL** and the insole to adhere properly, the roughened side of the material must face the insole.

## 8.1 Cutting

For individual cuts and to adjust preproduced pre-cuts, you can modify **CTS UNIDIREKTIONAL** by cutting (fig. 8). To saw out the cuts with a band saw, ideally use a tooth pitch of 14 teeth/inch. To saw out the cuts with a jig saw, ideally use a tooth pitch of 2.5-3mm (fine woodcut).



fig. 8



fig. 9

## 8.2 Grinding

For individual cuts and to adjust preproduced pre-cuts, you can modify **CTS UNIDIREKTIONAL** by grinding (fig. 9).

- Chamfer the cut to obtain a smooth transition between the cut and the shoe base. The chamfer must not be wider than 5mm to avoid the risk of breakage (fig. 10).
- To do this, grind the cutting edge (not the surface) on a sander drum using a coarse-grained abrasive (40/60) first and a medium-grained abrasive (100/120) afterwards (fig. 11).



fig. 10



fig. 11

You can subsequently polish the edges with a lamellar flap grinding disc at low speed (fig. 12).

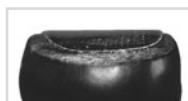


fig. 12



Respect the general safety instructions when grinding carbon fibres (extraction, breathing mask, gloves etc.).

## 8.3 Adhering

- To create a firm bond between the shoe base and the pre-cut sole, coat both surfaces with a commercial contact adhesive (fig. 13-14).
- Wait until the adhesive has dried before starting the heat treatment.



fig. 13



fig. 14



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## 8.4 Heating

- When using a convection oven or heating cabinet, set the temperature to 160°C. When using an infrared oven, set the temperature to 140°C.
- Do not use a heating plate, as the material will only be heated on one side. When heating **CTS UNIDIREKTIONAL** in a convection oven, it is **absolutely necessary** to use the temperature marker to ensure the proper processing temperature.



Always wear heat-resistant gloves when working at heating sources.

Several lines on both sides of the pre-cut indicate that the material is completely heated (fig. 15). If the lines are no longer visible on the upper side, turn the pre-cut over so that the underside faces upwards. If the lines are no longer visible there either, the correct processing temperature has been reached.



fig. 15

**CTS UNIDIREKTIONAL** can be heated several times in compliance with the processing temperature.



fig. 16



If you are using heating tubes e.g. of a VACUPRESS system (fig. 16) you must continuously observe the material and the marks on the temperature marker. Otherwise, an accurate temperature control cannot be guaranteed.

## 8.5 Forming

To prevent the material from cooling down, mould it immediately after removing it from the oven. An optimum forming result can be obtained by applying pressure against the surface e.g. with an orthopaedic press (fig. 17). After the pre-cuts have cooled down, you can design the rest of the sole structure.



fig. 17

## 9. Storage and Handling

Store **CTS UNIDIREKTIONAL** in a horizontal position at a dry place at room temperature. Avoid direct sunlight and excessive pressure as both can affect the material.

## 10. Accessory Parts

We recommend using our temperature marker to check the processing temperature.

Accessories		
Article Number	Description	Unit
ZM1001	temperature marker 160°C	piece

## 11. Disposal

Dispose of the sheets and pre-cut soles properly. The product must not be disposed of with the residual waste (fig. 18). Please comply with the applicable national laws and local regulations for the proper recycling of recyclable materials.



fig. 18

## 12. Legal Information

With the purchase of this product, our General Terms and Conditions of Business Transactions, Sales, Delivery and Payment will apply. The warranty expires, for example, if the product is mounted several times. Please note that the product is not supposed to be combined with other components or materials than with those recommended by the FIOR & GENTZ Orthosis Configurator. The combination of the product with products from other manufacturers is not permitted.

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