

S1

S1 Sprunggelenkorthese nach Hellersen

S1 Ankle Joint Orthosis – According to Hellersen



DE

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Der Inhalt dieser Produktbeilage wird regelmäßig aktualisiert und ist beim Einsatz des Produktes unbedingt zu beachten.
Informationen finden Sie auch auf unserer Website: www.fior-gentz.de

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This manual is regularly updated and should be strictly followed.
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1. Declaration of Conformity

We declare that our medical devices as well as our accessories for medical devices are in conformity with the requirements of the Medical Devices Directive 93/42/EEC. Regarding these tests, all FIOR & GENTZ products have the CE marking.

2. Warranty

The warranty applies only if the product is used under the described conditions and for the intended purpose. Furthermore, we do not accept a multi-use of the product. Other than that, we refer to our General Terms and Conditions of Business Transactions, Sales, Delivery and Payment.

3. Safety Information

This manual is addressed to orthopaedic technicians. That is why the content basically confines to features of the product. It does not contain any notes about dangers which are obvious to orthopaedic technicians.

For getting a maximum of safety, please show the patient and/or the care team how to use and maintain the product correctly. Enclosed to this manual you will find a patient information which has to be given to the patient and/or the care team.

For information reasons and for the safety of your patients, please note all information provided in this manual including notes, tables and illustrations. Please note especially the safety instructions indicated by ATTENTION! CAUTION! WARNING! and DANGER! which are listed and explained in the following paragraph. Ignoring this information may lead to patient injuries and property damage.

4. Safety Instructions

4.1 Classification of the Safety Instructions



DANGER!

➔ *Important information about a possible dangerous situation which, if not avoided, leads to death or irreversible injuries.*



WARNING!

➔ *Important information about a possible dangerous situation which, if not avoided, leads to reversible injuries that need medical treatment.*



CAUTION!

➔ *Important information about a possible dangerous situation which, if not avoided, leads to light injuries that do not need medical treatment.*




ATTENTION!

➔ *Important information about a possible situation which, if not avoided, leads to damage of the product.*

4.2 Structure of the Safety Instructions

The following example demonstrates the structure of the safety instructions:

Attention symbol	Signal word	ATTENTION!
	Type of danger	<i>Mechanical load is too high!</i>
	Possible consequences for components	➔ <i>Wear of the joint parts.</i>
	Possible consequences for the patient	➔ <i>Maintenance intervals shorten.</i>
	Measures	Explain the patient the correct use of the system joint and possible dangers.

4.3 All Instructions for a Safe Handling of the S1 Ankle Joint Orthosis

There is detailed information to some of the safety instructions in the course of this manual. Respect the following safety instructions to avoid patient injuries and property damage.



WARNING!

Size of orthosis is choosen too large!

➔ *Delay of healing process.*

Choose the right orthosis size.



WARNING!

Size of orthosis is choosen too small!

➔ *Pressure points and impaired blood flow.*

Choose the right orthosis size.



WARNING!

Orthosis is not adapted to the patient's foot!

➔ *Pressure points and possible delay of healing process.*

Adapt the orthosis to the patient's foot.



WARNING!

Orthosis is put on incorrectly!

➔ *Pressure points and possible loss of fixing function.*

Put the orthosis on as described in the manual.



CAUTION!

Orthosis is not cleaned after wearing it in salt water!

➔ *Corrosion of rivet joints.*

➔ *Skin irritations and impairment of wound healing.*

Explain the patient the correct use of the orthosis and possible dangers.



ATTENTION!

Material is overheated!

➔ *Material loses strength and can burn.*

➔ *Treatment goal might not be achieved.*

Heat the material as described in the manual.

5. Application

The S1 ankle joint orthosis is exclusively for use for orthotic fittings of the foot.

6. Scope of Delivery


The scope of delivery includes the following articles (fig. 1):

Description	Quantity
S1 ankle joint orthosis	1




Fig. 1

7. Choosing the Right Orthosis Size



WARNING!
Size of orthosis is choosen too large!
➔ *Delay of healing process.*
Choose the right orthosis size.



WARNING!
Size of orthosis is choosen too small!
➔ *Pressure points and impaired blood flow.*
Choose the right orthosis size.

Determine the shoe size and choose the appropriate orthosis size.

Article number	Sizes	Shoe size	Leg
SO1000-S/L	Small	34-37	Left
SO1000-S/R	Small	34-37	Right
SO1000-M/L	Medium	38-40	Left
SO1000-M/R	Medium	38-40	Right
SO1000-L/L	Large	41-43	Left
SO1000-L/R	Large	41-43	Right
SO1000-XL/L	X-Large	44-46	Left
SO1000-XL/R	X-Large	44-46	Right

8. Shoe Recommendation

We recommend to wear the S1 with the FLENSBURG shoe. It enables comfortable walking with the orthosis due to its rocker bottom sole (fig. 2) and it is easy to put on due to hook and loop fasteners (fig. 3).

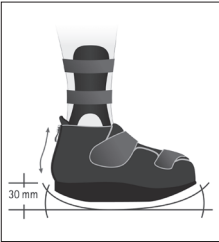


Fig. 2



Fig. 3

9. Tools for Adapting the S1 Ankle Joint Orthosis

Tool
Rivet snap
Hammer
Hot-air gun
Scissors

10. Adapting the S1 Ankle Joint Orthosis



WARNING!

Orthosis is not adapted to the patient's foot!
➔ *Pressure points and possible delay of healing process.*
Adapt the orthosis to the patient's foot.

To ensure an optimal fit of the S1, adapt the orthosis to the patient's foot.

10.1 Static Fitting

1. After choosing the right size (see paragraph 7), adapt the S1 to the patient's foot. For this purpose, attach the orthosis to the patient's foot using the hook and loop fastener. We recommend the patient to wear socks.
2. Check all edge lines as well as the fit of the S1. Adapt positions that do not fit positively to the patient's foot by thermoforming (see paragraph 10.2).
3. After thermoforming the orthosis, put it on the patient's foot again and check its fit.

10.2 Thermoforming



ATTENTION!

Material is overheated!
➔ *Material loses strength and can burn.*
➔ *Treatment goal might not be achieved.*
Heat the material as described in the manual.

The S1 is made of high quality thermoformable plastics. If the S1 does not fit positively on the foot, the material can be adapted to it by thermoforming.

1. Heat the plastic surface of the S1 with a hot-air gun to about 150°C. Keep a distance of 3-5cm between material and source of heat (fig. 4). Now, form the heated material extensively (fig. 5).
2. Before putting the S1 on the patient's foot again, let the material cool down completely.

Note:

Remove the orthosis from the patient's foot before heating it. Do thermoforming only in sufficiently ventilated rooms or under extraction systems.



Fig. 4

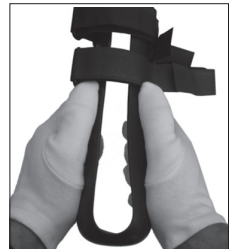


Fig. 5

11. Putting on the S1 Ankle Joint Orthosis



WARNING!

Orthosis is put on incorrectly!

➔ *Pressure points and possible loss of fixing function.*

Put the orthosis on as described in the manual.

1. The S1 is put on when seated. When putting it on, make sure that the heel is pulled in to the very back.
 - **Correct** position of the heel (fig. 6)
 - **Incorrect** position of the heel (fig. 7)
2. Close the four hook and loop fasteners as follows:
 - upper front hook and loop fastener (fig. 8)
 - lower front hook and loop fastener (fig. 9)
 - upper back hook and loop fastener (fig. 10)
 - lower back hook and loop fastener (fig. 11)



Fig. 6



Fig. 7

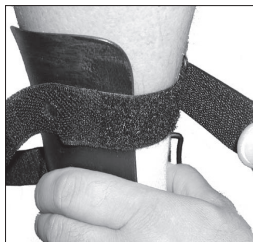


Fig. 8



Fig. 9



Fig. 10



Fig. 11

3. The hook and loop fasteners have to be tight fitted but they must not apply pressure to the muscles and soft parts.
4. To take off the S1 the patient simply has to open the front hook and loop fastener.
5. If hook and loop fasteners protrude, cut them to prevent the patient from stumbling. Cut the edges into a half moon shape to eliminate sharp edges and corners that can cause skin injuries (fig. 12).



Fig. 12

12. Cleaning



CAUTION!

Orthosis is not cleaned after wearing it in salt water!

➔ *Corrosion of rivet joints.*

➔ *Skin irritations and impairment of wound healing.*

Explain the patient the correct use of the orthosis and possible dangers.

The durability of the S1 ankle joint orthosis requires a proper handling. Clean the orthosis and the hook and loop fastener regularly with a gentle detergent. After wearing the S1 in salt water, rinse it with clear water.

13. Spare Parts (see table and fig. 13)

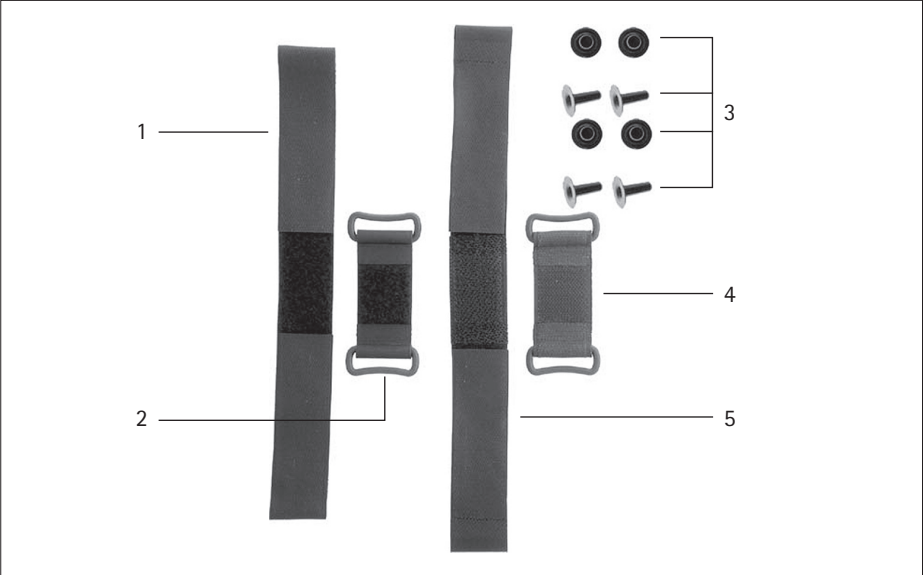


Fig. 13

Item	Article number	Description
1	KV3004-L450	Hook and loop fastener, strap 30mm wide, 420mm long
2	KV3004	Hook and loop fastener with 2 loops, 30mm wide, 70mm long
3	NI2094-L09	Lower part for compression rivet 4 x 9mm
3	NI2194-L04	Upper part for compression rivet 4 x 4mm
4	KV3104	Elastic hook and loop fastener with 2 loops, 30mm wide, 70mm long
5	KV3104-L500	Hook and loop fastener with elastic centre, 30mm wide, 470mm long

14. Informationen für die Versorgungsdokumentation/Information for the Patient's Documentation

Hinweis/Note:

Bitte heften Sie diese Produktbeilage zu Ihrer Versorgungsdokumentation!

Insert this manual in your patient's documentation!

Patientendaten/Patient's Data

Name: Name:	
Straße: Street:	
PLZ, Wohnort: Zip code, city:	
Telefon privat: Home telephone:	
Telefon geschäftlich: Telephone at work:	
Kostenträger: Insurance:	
Mitgliedsnummer: Insurance No.:	
Behandelnder Arzt: Attending physician:	
Diagnose: Diagnosis:	

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