

Symbol-Legende Icon Legend

	Achtung Attention		Europäischer Bevollmächtigter European Authorized Representative
	Artikelnummer Article number		CE-Kennzeichnung CE marking
	einzelner Patient- mehrfach anwendbar single patient- multiple use		Übersetzung Translation
	Reinigung Cleaning		Vertriebspartner Distributor
	Hersteller Manufacturer		Importeur Importeur
	Nicht bleichen Do not bleach		Keine chemische Reinigung No chemical cleaning
	Nicht bügeln Do not iron		Nicht im Trockner trocknen Do not tumble-dry

 ORTOTEK A.Ş.
Ziya Gökalp Cad. 68/21
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Tätigkeiten nach MDR, Artikel 16: 2a /
Activity according MDR, Article 16: 2a



Qualität und Funktion

Gebrauchsanweisung Instruction Manual

Karbon-Füße

F120 Chopart
F125 Chopart Plus
F130 Symes-Tech Plus
F140 Pars X3
F150 Synergy® X3 LP
F160 Synergy® X3

Carbon-Feet

F120 Chopart
F125 Chopart Plus
F130 Symes-Tech Plus
F140 Pars X3
F150 Synergy® X3 LP
F160 Synergy® X3



GA_F120-F160_Rev.1-2023-02



Please read the IFU carefully before fitting. Only correct usage will warrant the function.

1. Intended Use

The carbon prosthetic foot is the basis for the modular design of a leg prosthesis.

2. Technical Data

The carbon prosthetic feet were developed primarily for the needs of active users. They are suitable for walking on various surfaces. The carbon foot modules consist of a composite carbon fiber component, a Spectra™ sock and a foot shell. Rubber buffer to increase the stiffness of the heel for Symes-Tech Plus, Pars X3, Synergy® X3 LP, Synergy® X3.

Size:	22 – 29
Patient body weight limit:	147 kg
Heel Height:	10 mm
Foot Cover Skin Tones:	Caucasian
Patient Mobility levels:	2 – 4 (Synergy® X3 LP, Pars X3, Symes-Tech Plus, Synergy® X3)
	1 – 4 (Chopart, Chopart Plus)

REF

Order No.	Product Name	Installation Height	Attachment Type	Article No.
F120-[Size][Side][Cat.]	Chopart	approx. 9 mm without footshell	/	46031100X0Y0ZZ
F125-[Size][Side][Cat.]	Chopart Plus	approx. 10 mm without footshell	M36	46031200X0Y0ZZ
F130-[Size][Side][Cat.]	Symes-Tech Plus	22 - 25 = 38 mm 26 - 29 = 40 mm	M36	46031300X0Y0ZZ
F140-[Size][Side][Cat.]	Pars X3	22 - 25 = 63 mm 26 - 29 = 66 mm	Male Pyramid	46031400X0Y0ZZ
F150-[Size][Side][Cat.]	Synergy® X3 LP	22 - 25 = 115 mm 26 - 29 = 125 mm	Male Pyramid	46031500X0Y0ZZ
F160-[Size][Side][Cat.]	Synergy® X3	22 - 25 = 155 mm 26 - 29 = 165 mm	Male Pyramid	46031600X0Y0ZZ

X = Side: 1 = left 2 = right
Y = Hardness Category
ZZ = Size

2.1 Foot category selection table

To identify the applicable activity level, use the activity table.

Impact level			
Weight(kg)	Activity Level		
	Low	Medium	High
45 - 52	1	1	2
53 - 59	1	2	3
60 - 68	2	3	4
69 - 77	3	4	5
78 - 88	4	5	6
89 - 100	5	6	7
101 - 116	6	7	8
117 - 130	7	8	9
131 - 147	8	9	

Activity Level		
Low	Medium	High
<i>Hobby-Oriented-Athlete</i>	<i>Recreational Athlete</i>	<i>Extreme Athlete</i>
Walking	Hiking	Baseball
Biking	Jogging	Competitive Sports
Bowling	Martial Arts	Football
Camping	Skating	Power Lifting
Dancing	Skateboarding	Running
Fishing	Skiing	Snowboarding
Gardening	Tennis	Soccer
Golfing	Volleyball	Wakeboarding
Surfing	Boxing	

2.2 Service parts

2.2.1 Foot Shell

REF

Order No.	Size	Side	Article No.
E-F120-[Size][Side]	22 - 29	Right/ Left	4 603 119 0X 00 0ZZ

X = Side: 1 = Left 2 = Right
ZZ = Size

2.2.2 Spectra™ Socks

REF

Order No.	Product name	Foot	Article No.
E-F120-SS1	Spectra-Sock short	Pars X3, Symes-Tech Plus, Chopart, Chopart Plus	4 603 119 00 01 000
E-F120-SS2	Spectra-Sock long	Synergy® X3 LP, Synergy® X3	4 603 119 00 02 000

3. Indication/ Contraindication

Indication:

- Lower limb amputation

Contraindication:

- Not known

4. Side effects

There are no known side effects.

5. General Instructions



- This medical product is designed for: single patient, multiple use.
- Fitting/ service of this medical device is only allowed by a certificated orthopedic professional.
- The professional should instruct the correct use of the device to the user.
- If there is any visible damage, stop using the product.
- Do not hesitate by considering the repair and maintenance periods specified for the product.
- If there is mechanical damage to the product, check its function, or contact the manufacturer or Uniprox.
- For the highest possible safety and the longest possible service life, the recommended assembly and usage procedures must be followed.
- Do not expose the product to unacceptable environmental conditions such as mechanical shock or impact, dust, sand, excessive amounts of water, sweat, urine, fresh water, salt water or acids.
- Improper modification or use of the product is not permitted. Failure to do so may impair the function of the product, exposing the patient to risk and voiding the warranty.
- Improper modification or application to the product is not allowed. In case of nonobservance, the function of the product may be impaired, so that product liability is excluded.

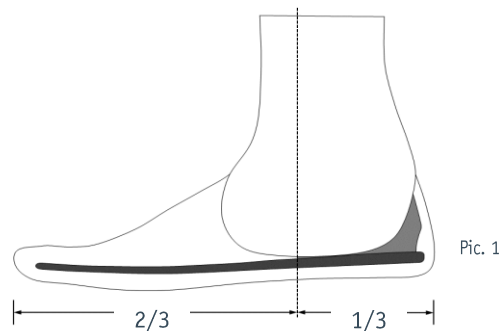
6. Installation

6.1 Before installing the prosthesis

- Plantarflex/ Dorsiflex foot to fit shoe heel height.
- Adduct/ Abduct socket to provide proper front plane angle.
- Flex or extend the socket to ensure proper sagittal plane angle.

6.2 Installation Chopart

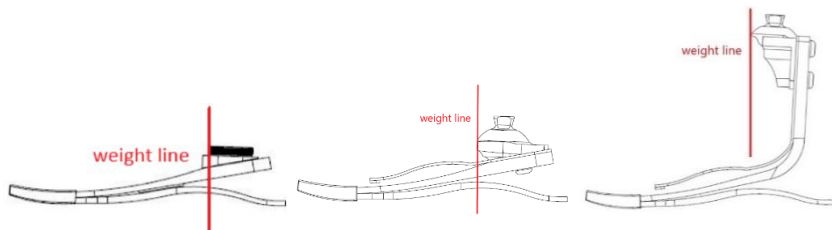
Position the socket on the sole plate as shown in the illustration, ensuring proper plantar/dorsal flexion and external rotation. The rear third of the Chopart plate must be degreased and roughened before bonding. Fix the sole plate in the rear third with suitable epoxy or PU-adhesive for the try-on. Fill the space between the socket and sole plate in the area of the rear third with adhesive. For the final finish, the connection between the socket and the Chopart plate must be covered with a sufficient amount of reinforcing material in the area of the rear third.



Pic. 1: Static structure Chopart

6.3 Installation Symes-Tech Plus, Pars X3, Synergy X3 LP and Synergy X3

Move the socket linearly to ensure that the weight line runs along the front edge of the adapter (Pic. 2)



Pic. 2

Pic. 2: Static structure (Example: Symes-Tech Plus ,Pars X3 and Synergy X3)

6.4 Dynamic Alignment

The impact energy is stored in the heel spring (except Chopart and Chopart Plus), which thus supports the rolling motion. This movement helps the main spring to store energy and release it in toe-off.

- To optimize the rolling motion from the heel to the foot, set the following variables:
 - Placement of the foot in A-P
 - Dorsiflexion/ plantarflexion
 - Heel stiffness

6.4.1 Error search and troubleshooting

Problem	Indications	Solutions
If the heel is very soft	<ul style="list-style-type: none"> The foot comes forward only with difficulty The toe feels extremely stiff 	<ul style="list-style-type: none"> Move the socket forward in relation to the foot Insert heel buffer to reinforce the heel spring
If the heel is very hard	<ul style="list-style-type: none"> Rapid knee flexion, instability Feed from the heel to the toes Feeling of lack of energy returns 	<ul style="list-style-type: none"> Move the socket backward in relation to the foot Select foot-category lower
If the foot module too hard	<ul style="list-style-type: none"> Flat point in rollover movement in slow cadences 	<ul style="list-style-type: none"> Select foot-category lower
If the foot module too soft	<ul style="list-style-type: none"> Noise at initial contact Extreme foot deflection with high effective activity 	<ul style="list-style-type: none"> Select foot-category higher

7. Maintenance and Cleaning

7.1 Maintenance

The foot should be checked after the first 30 days of use. In addition, we recommend an annual check.

Spectra™ socks should be changed at intervals appropriate to the user's activity level. Failure to inspect and replace Spectra™ socks may damage foot shells and void the warranty.

7.2 Cleaning



- Compressed air up to 2 bar
- Soap and lukewarm water
- Do not use aggressive solvents

8. CE-Conformity

The product satisfies the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council (MDR) and bears the CE mark. All major incidents related to the product needs to be informed to *Uniprox* and/or *Ortotek* as well as to the competence European Authority.

9. Warranty and Guarantee

Warranty is provided under the terms of sale and supply of Uniprox GmbH & Co. KG provided that the above conditions are met. A 3-year warranty is provided on material and manufacturing defects and a 6-month warranty is provided on foot shell.

10. Disposal

This product has no special storage regulations.

The product is disposable with standard household garbage.

Please direct any questions to:

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