

**CE**

**3F2=0**

**EN** Instructions for use (qualified personnel) ..... 3



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# 1 Foreword

## INFORMATION

Date of last update: 2024-06-05

- ▶ Please read this document carefully before using the product and observe the safety notices.
- ▶ Instruct the user in the safe use of the product.
- ▶ Please contact the manufacturer if you have questions about the product or in case of problems.
- ▶ Report any serious incident related to the product, in particular any deterioration of health, to the manufacturer and the competent authority in your country.

The product "3F2=0 functional cosmesis Genium X4" is referred to as the "product/functional cosmesis" in the following.

The component "functional shank" is referred to as "foam/shank foam/shank" in the following.

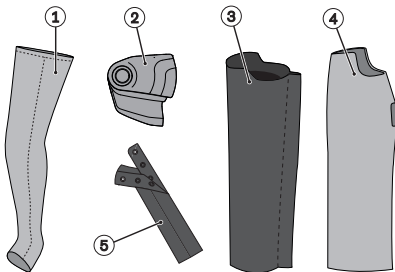
These instructions for use provide you with important information on the use, adaptation and handling of the product and its components.

Put the product and components into service only in accordance with the information contained in the accompanying documents supplied.

## 2 Product description

### 2.1 Design

The functional cosmesis consists of the following components:

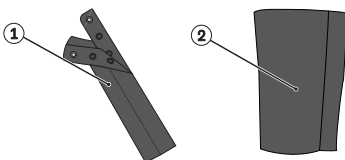


1. 99B122=\* functional stocking (not included in the scope of delivery)
2. Functional knee part consisting of the upper knee part and the lower knee part. These two parts can be separated.
3. Textile finish
4. Functional shank
5. Magnetic closure

### 3D13=1 Thigh kit/magnetic closure(optional)

A transitional element (thigh connection) with moulding and shaping characteristics should be used as a socket connection to ensure that the knee part is fitted to the transfemoral socket in an optimal manner. To enable the patient to remove this "thigh connection", it should be provided with a textile finish and a magnetic closure like the "functional shank."

The following components are parts of the 3D13=1 thigh kit/magnetic closure and are therefore not included in the scope of delivery of the functional cosmesis:



1. Magnetic closure
2. Textile finish

## 2.2 Combination possibilities

This product can be combined with the following Ottobock components:

### Knee Joint Combination Possibilities

- 3B5-4=P Genium X4 (with pyramid) or 3B5-4=ST Genium X4 (with threaded connector)

### Prosthetic Foot Combination Possibilities

- 1C10 Terion
- 1C30-1 Trias
- 1C31 Trias
- 1C40 C-Walk
- 1C50 Taleo
- 1C51 Taleo Vertical Shock
- 1C52 Taleo Harmony
- 1C53 Taleo Low Profile
- 1C56 Taleo Adjust
- Taleo side flex: 1C58
- 1C60 Triton
- 1C61 Triton Vertical Shock
- 1C62 Triton Harmony
- 1C63 Triton Low Profile
- 1C64 Triton Heavy Duty
- 1C68 Triton side flex
- 1C70 Evanto
- 1D35 Dynamic Motion
- 1E56 Axtion
- 1E57 Lo Rider
- F11 Maverick Xtreme
- F21 Maverick Xtreme AT
- F22 Maverick Comfort AT
- F23 Maverick Vertical Shock

### Limited compatibility with prosthetic feet

Combination with the following prosthetic feet will detract from the product's appearance in all cases. There are no restrictions in terms of functionality.

- 1A1-2 Empower
- 1B1 Meridium
- 1B1-2 Meridium
- 1E95 Challenger

### Limited use of the 4R57\* rotation adapter

When this rotation adapter is used, a check must be carried out to verify whether rotation is possible over the entire flexion angle range. Collisions between the rotation adapter and the functional knee part or knee joint have to be excluded by tilting and/or using suitable flexion stops.

If the socket collides with the upper knee part, this has to be removed.

## 3 Intended use

### 3.1 Indications for use

The product is intended exclusively for lower limb exoprosthetic fittings.

This product gives the Genium X4 3B5-4=P or Genium X4 3B5-4=ST mechatronic knee joints a (physiological) appearance similar to an anthropomorphic look. External influences on the knee joint are alleviated as well.

### 3.2 Conditions of use

The product is intended exclusively for wearers of the 3B5-4=P Genium X4 or 3B5-4=ST Genium X4 prosthetic knee joints.

The product is intended **exclusively** for use on **one** patient. Use of the product by another person is not approved by the manufacturer.

The product was developed for everyday use and must not be used for unusual activities such as extreme sports (free climbing, paragliding, etc.).

The product has to be removed before showering, swimming and other activities in water.

### 3.3 Contraindications

All conditions which contradict or go beyond the specifications listed in the section on "Safety" and "Indications for use".

### 3.4 Qualification

Only qualified personnel (such as an O&P professional) who are familiar with how to use the various techniques, materials, tools and machines may prepare the product for use.

However, patients may only be fitted with the product by qualified personnel authorised by Ottobock after completing the corresponding training for the 3B5-4=P/3B5-4=ST Genium X4 mechatronic knee joints.

## 4 Safety

Ottobock developed this product according to applicable standards and rules and tested it multiple times. In order for you to enjoy the product, we need your help. Only by complying with the following instructions can we guarantee safe treatment and operation.

### 4.1 Meaning of warning levels

**CAUTION!** Failure to follow the instructions can lead to accidents and injuries.

### 4.2 Before treatment

#### **CAUTION! Possibility of falling**

- ▶ Observe the alignment and assembly instructions.
- ▶ Only combine the product with the components mentioned in the chapter on possible combinations.
- ▶ Check the settings of the prosthesis in combination with the product.

### 4.3 During treatment

#### **CAUTION! Possibility of falling**

- ▶ Check that the user can hear the operating state signals and set the corresponding volume.
- ▶ Warnings/error signals are always emitted at the highest volume. The volume of the warnings/error signals cannot be changed.
- ▶ At maximum flexion under full load, it is essential to maintain a minimum distance of 6 mm between the lower leg and the thigh.
- ▶ If the minimum distance of 3 mm (5 mm when using a functional cosmesis) is not met, a flexion stop has to be installed. If a flexion stop has already been installed, it has to be replaced with the next larger flexion stop. If the largest flexion stop is already installed, please contact Ottobock Customer Service.

#### **CAUTION! Possible injuries (e.g. burns) and damage to the product**

- ▶ Do not use a hot air gun.

## 5 Scope of delivery, accessories, spare parts

### 5.1 Scope of delivery

- 1 pc. functional shank
- 1 pc. functional knee part
- 1 pc. textile finish
- 1 pc. magnetic closure (two-part)
- 1 pc. Instructions for use (qualified personnel)
- 1 pc. instructions for use (user)

### 5.2 Accessories

The following components are not included in the scope of delivery and must be ordered separately:

- 1 pc. 99B122=\* functional stocking

The following components can be ordered separately as needed:

- 1 pc. 3D13=1 thigh kit/magnetic closure

### 5.3 Spare parts

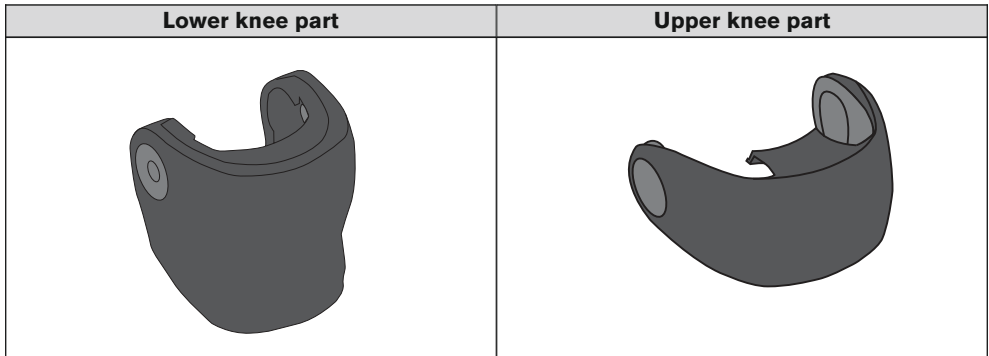
- 3D10=1 functional upper knee part
- 3D11=1 functional shank
- 3D12=1 textile finish

## 6 Preparing the product for use

### 6.1 Required tools

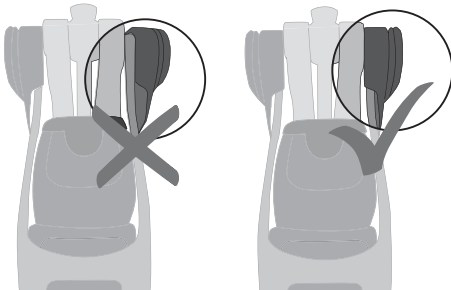
- Adhesive tape
- Contact adhesive (e.g. 636N9, 636W17)
- 743E7=L Folding rule
- Wood saw or knife
- Scissors
- 710D20 torque wrench
- Allen key size 4
- Protective goggles
- Dust mask
- Heat protection gloves
- Pins with metal heads or glass heads (heat-resistant)
- Towel
- 99B25 Nylon stockinette

### 6.2 Elements of the functional knee part

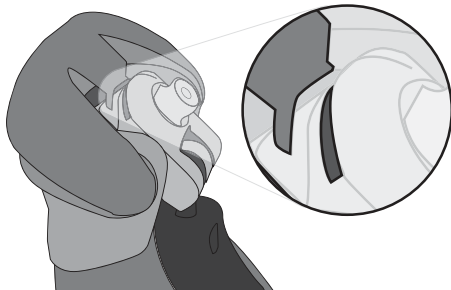


### 6.3 Assembling the functional knee part

Complete the following steps to assemble the functional knee part:



- 1) Put the functional knee part onto the frame of the knee joint.  
Ensure that the lower knee part fits flush with the knee joint. The retainers have to engage exactly in the frame.



- 2) Swing the upper knee part up and allow the spring to engage in the groove on the knee head.
- 3) If the socket collides with the upper knee part, the upper knee part can be taken off and the functional cosmesis can be worn with only the lower knee part.



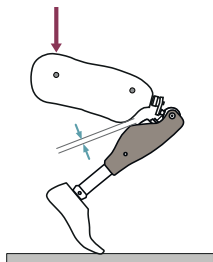
## 6.4 Disassembling the functional knee part

- 1) Pull apart the functional knee part in the rear area of the frame.
- 2) Take off the functional knee part.

## 6.5 Checking the clearance between the prosthetic socket and knee joint

Before starting fabrication of the functional cosmesis, verify that the distance from the socket to the knee joint is not less than the minimum under load at maximum flexion. Damage to the hydraulics, frame, electronics housing etc. may occur if the distance from the socket to the knee joint is insufficient.

Compressing the foam is permissible, provided the alignment recommendations for the knee joint are followed.



- 1) Place the prosthesis, without the functional shank applied, on the workbench and flex the knee joint.
- 2) Check the available distance between the knee joint and socket.
- 3) The distance should be at least 6 mm.
- 4) Then grasp the upper front area of the socket with both hands and put a substantial load on the socket.
- 5) Check the available distance between the knee joint and socket again.  
→ The distance under this load should still be at least 5 mm.

**INFORMATION: If the value falls short of this distance, a flexion stop has to be installed or an existing flexion stop has to be replaced with a larger flexion stop. If the largest flexion stop is already installed, please contact Ottobock Customer Service.**

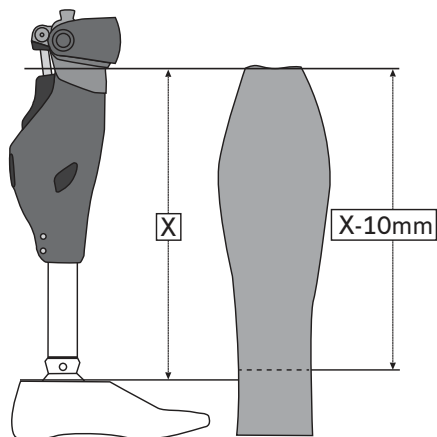
## 6.6 Finishing the functional shank

### INFORMATION

The inner textile reinforcement changes the cutting characteristics of the shank.

### 6.6.1 Shortening the functional shank

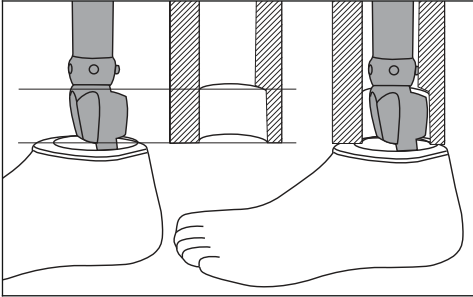
Complete the following steps to shorten the shank:



- 1) Move the prosthesis to full extension.
- 2) Measure from the bottom edge of the upper knee part to the top edge of the foot connection plate (length X).
- 3) Reduce the measured length by 10 mm because the foot shifts the foam up as it moves.
- 4) Transfer the measurement to the shank.  
**INFORMATION: Measure from the top to the bottom on the shank.**
- 5) Cut off the shank at the marked location.  
**INFORMATION: Note the foot position for an optimum fitting result.**
- 6) Make the set screws accessible and assemble the prosthetic foot.

### 6.6.2 Adapting to feet with a large build height

For prosthetic feet with a high build height, e.g. Triton 1C60, carry out the following steps:



- 1) Remove the prosthetic foot.
- 2) Check whether the foam cover fits over the connection of the prosthetic foot.
- 3) If the opening in the foam cover does not fit, sand the foam cover on the inside at the structural height of the foot (see illustration).

**INFORMATION: The textile reinforcement can be sanded off in the foot area.**

### 6.6.3 Sanding the functional shank

#### Information for sanding the shank

- Streaks, colour differences and small air pockets (up to 1 cm) in the shank are concealed by the textile finish and the functional stocking. These differences, which are due to production reasons, do not affect the function of the product and therefore do not constitute grounds for complaints.

#### Sanding the functional shank

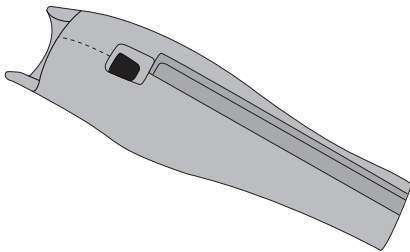
- 1) Wrap the knee joint with household plastic wrap.
- 2) Protect the footshell with adhesive tape.
- 3) Sand the shank so it protrudes slightly over the footshell around the circumference in the ankle area.

The slight oversize is offset when the foam is later compressed by the textile finish.

**CAUTION! Wear protective goggles and a dust mask during processing.**

- 4) Sand the shank to the desired contour.
- 5) Mark the posterior centre of the shank in the longitudinal direction.
- 6) Below the opening for the charging receptacle, sand a recess (groove) to the right of the centre to hold the magnetic closure (25 mm wide). This helps give the prosthesis an inconspicuous appearance.

**CAUTION! The black textile reinforcement must not be visible when the groove is sanded. There must always be a wall thickness of the foam to prevent the magnetic closure from interfering with the tube adapter sensor.**



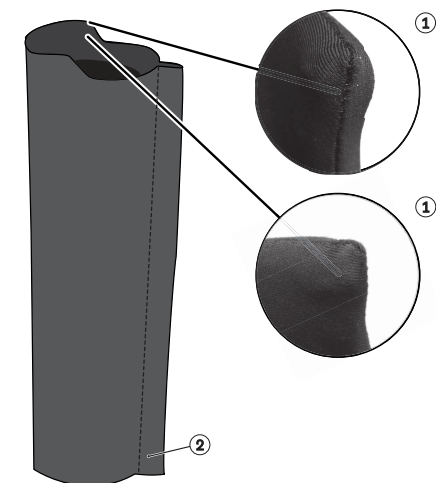
#### INFORMATION

##### Textile reinforcement is only taken into account in the area of the tube adapter

The textile reinforcement does not have to be taken into account in the area of the prosthetic foot (up to the pyramid receiver of the tube adapter), since the sensor is located above the black ring in the tube adapter.

### 6.7 Applying the textile finish

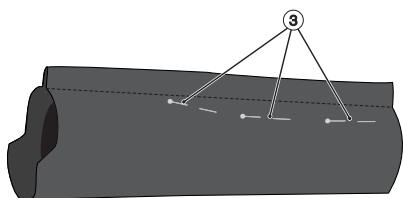
Complete the following steps to apply the textile finish:



- 1) Pull the textile finish with the interior dot coating (glue dots) over the previously sanded shank so it fits without wrinkles.

**INFORMATION: The seam allowance (2) faces outwards and runs centrally at the back.**

- 2) Insert the upper end of the shank into the prepared form-fitting pockets of the textile finish (1). Secure the inner area of the upper edge ahead of time using a hand sealing iron, e.g., 756E1=\*



- 3) Mark the excess width of the textile finish with pins (3). The textile finish should be taut against the foam.

**INFORMATION: Due to subsequent heating, only pins with metal or glass heads may be used.**

### Shortening the textile finish on the bottom

- 1) Trim any excess material so there is still enough material left to adhere to the lower edge of the foam shank. Fold the remaining material over the edge and use pins to secure it on the bottom of the foam.
- 2) Stuff the shank with a towel to stabilise it, without stretching the shank.
- 3) Pull a nylon stockinette over the shank as well and knot it to prevent the towel from falling out of the shank.

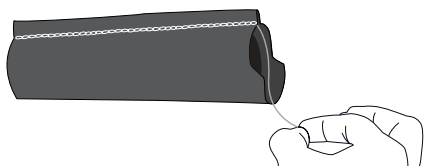
**INFORMATION: The adhesive layer is activated by heat and pressure. For this reason, ensure good compression.**

- 4) Heat the shank in the convection oven for about 10 minutes at 180 °C. An infrared oven can also be used. The differences between the two types of furnaces are shown in the table at the end of this chapter.

**INFORMATION: To prevent contact heat, place the shank on a textile underlay.**

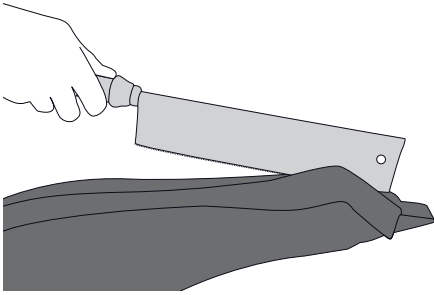
- 5) Take the shank out of the oven and let it cool for about 15 minutes.

**INFORMATION: For better adhesion, use a heat protection glove to press the hot textile finish onto the shank.**



- 6) Take off the nylon stockinette; remove the towel and pins.
- 7) Pull the **red thread** of the seam.  
→ The seam separates and the seam allowance unfolds.

- 8) Use a suitable tool (saw or knife, etc.) to cut open the functional shank along the centre of the resulting gap.



Oven	Temperature	Time	Storage	Notices
Hot air	180 °C	approx. 10 minutes	hanging	–
Infrared	140 °C	approx. 3 minutes Turn the shank over after half the time.	hanging horizontally	<ul style="list-style-type: none"> <li>• Due to the shape of the shank and the resulting poorer heat distribution, more reworking is required.</li> <li>• Observe the instructions for use of the oven</li> </ul>

Fault profile	Cause	Correction
The textile finish did not adhere to the foam in some areas after it was removed from the oven	Glue dots of the textile finish not fully activated (melted)	Iron in corresponding areas (e.g. hand sealing iron coated with Tefon 756E1=*).

### Gluing the textile finish

- 1) Glue the projecting seam allowance along the cut edge on both sides with contact adhesive (e.g. 636N9, 636W17).

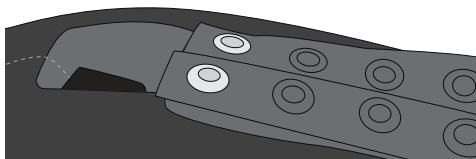
**INFORMATION: Note the setting time of the contact adhesive depending on the application thickness and temperature.**

- 2) Cut away the excess fabric ends.

### 6.7.1 Integrating the magnetic closure of the functional shank

Complete the following steps to attach the magnetic closure:

- 1) Put the foam leg onto the knee joint with the attached prosthetic foot.
- 2) Transfer the length of the recess (groove) to the magnetic closure and shorten it if necessary. The magnetic closure does not have to be attached over the overall length of the shank.
- 3) Align the grey interlock button with the cutout for the charging receptacle.



- 4) Apply contact adhesive to the two sides of the magnetic closure.
  - 5) Press the cut edges of the foam shank together so they are flush and glue on the magnetic closure. The row of magnets lies in the groove.
- INFORMATION: Note the setting time of the contact adhesive depending on the application thickness and temperature.**
- 6) Check adhesive surfaces and adhesion of the magnetic closure and re-glue if necessary.

## 6.8 Fabricating the thigh connection (optional)

### INFORMATION

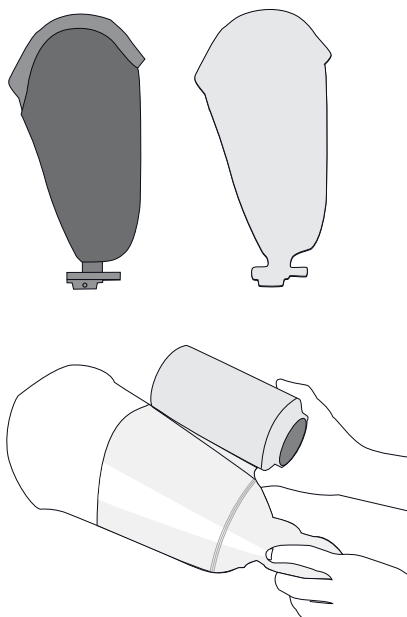
The "3D13=1 thigh kit/magnetic closure" accessory is required to fabricate the thigh connection. This accessory includes the textile finish for the thigh part and the magnetic closure.

### Verification at maximum flexion

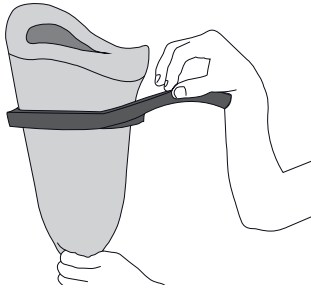
Before fabricating the thigh connection, you must verify that the distance from the socket to the knee joint was not less than the minimum under load at maximum flexion (see page 9). Damage to the hydraulics, frame, electronics housing etc. may occur if the distance from the socket to the knee joint is insufficient.

Compressing the foam is permissible, provided the alignment recommendations for the knee joint are followed.

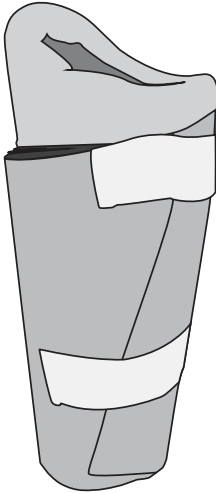
### Fabricating the thigh connection



- 1) Pull a stitched nylon stockinette over the socket and the corresponding adapter. This makes it easier to remove the foamed thigh part from the socket at a later time.
- 2) Wrap the area to be foamed, including the adapter, with household plastic wrap.
- 3) Pull on another nylon stockinette. This will join during foaming and then serve as a textile reinforcement, as with the functional shank.



- 4) Wrap the upper end of the socket with three layers of foam adhesive tape. This serves as an upper limit during casting with soft foam.



- 5) Wrap the socket with trolene and shape it into a cone.
- 6) Foam the cone.
- 7) Sand the foamed thigh part to the required individual shape.

If a rotation adapter is installed, expose the release button of the rotation adapter so it is still easy to operate.

- 8) Remove the foamed thigh part and shorten it to the desired length.

**INFORMATION: Ensure that the function of the knee part is not impaired during shortening.**

- 9) Pull the textile finish for the thigh with the interior dot coating (glue dots) over the thigh part so it fits without wrinkles.

**INFORMATION: The seam allowance faces outwards.**

- 10) The steps to apply the textile finish to the thigh are identical to those for applying the textile finish to the shank (see page 10).

## 6.9 Finishing the functional cosmesis

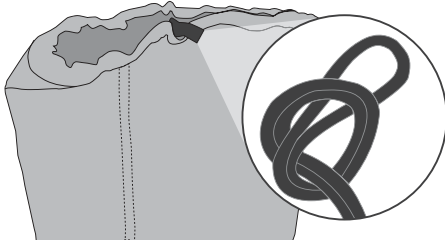
- Perform the prosthetic alignment and assemble the functional shank.

## 6.10 Putting on the functional stocking

Complete the following steps to put on the functional stocking:

- 1) Fold the slip-resistant anti-slip strips (upper end and lower end) for donning over to the outside.
- 2) Pull the functional stocking up over the functional cosmesis.

**INFORMATION: Adjust how far you pull the functional stocking up according to the patient's needs so that the use of the joint is not noticeably impaired. Secure the functional stocking to the socket while the joint is flexed.**



- 3) Depending on the thigh circumference, pull and tie the drawstring on the thigh tighter.
- 4) Fold the slip-resistant anti-slip strips (upper end and lower end) over to the inside.

## 7 Cleaning and Care

We recommend cleaning the product and components at least once per week or directly after contact with liquids. Otherwise, an impaired function and/or appearance cannot be excluded.

### INFORMATION

The penetration of dirt and humidity into the product leads to a loss of comfort.

### 7.1 Cleaning the functional cosmesis

- 1) Clean the product with a damp, soft cloth and then set it upright to dry. Spread the shank as you do so.
- 2) Disinfect the plastic parts of the product by wiping with a common household disinfectant.

### 7.2 Cleaning the functional stocking

### INFORMATION

The functional cosmesis can be worn without the functional stocking for a short time while the functional stocking is being cleaned and dried.

Wash the product at 30 °C/86 °F in a washing machine using standard mild detergent. Using a laundry bag for washing is recommended to protect the product.

**Setting:** Gentle cycle (for delicates).

To ensure good socket adhesion of the anti-slip strips on the inside, wipe them with a damp cloth as needed.

### INFORMATION

Note the washing symbols on the label.

### 7.3 Cleaning the thigh connection

Clean the product with a damp, soft cloth and then let it dry.

### 7.4 Cleaning the functional knee part

#### 7.4.1 Manual cleaning

- 1) Clean with a soft, damp cloth.
- 2) Dry with a soft cloth.
- 3) Allow to air dry in order to remove residual moisture.
- 4) Disinfect by wiping with a surface disinfectant (e.g. DescoSept) and drying.

#### 7.4.2 Cleaning in the dishwasher

The following points have to be observed for cleaning in the dishwasher:

- Rinse dishes first to remove food scraps and any food residue likely to leave strong stains.

- Place the functional knee part in the top rack.
- Use a short wash cycle with a water temperature below 60 °C.

## 8 Disposal

The product and all its components must be disposed of properly in accordance with the respective national environmental regulations.

## 9 Legal information

### 9.1 Liability

The manufacturer will only assume liability if the product is used in accordance with the descriptions and instructions provided in this document. The manufacturer will not assume liability for damage caused by disregarding the information in this document, particularly due to improper use or unauthorised modification of the product.

### 9.2 CE conformity

This product and all its components comply with the relevant European requirements for medical devices.

The full text of the regulations and requirements is available at the following Internet address: <http://www.ottobock.com/conformity>

### 9.3 Trademarks

All product names mentioned in this document are subject without restriction to the respective applicable trademark laws and are the property of the respective owners.

All brands, trade names or company names may be registered trademarks and are the property of the respective owners.

Should trademarks used in this document fail to be explicitly identified as such, this does not justify the conclusion that the denotation in question is free of third-party rights.

## 10 Technical data

Environmental conditions	
Transport in original packaging	-25 °C/-13 °F to +75 °C/+167 °F Max. 90% relative humidity, non-condensing
Storage in the original packaging (≤3 months)	+5 °C/+41 °F to +40 °C/+104 °F Max. 85% relative humidity, non-condensing
Long-term storage in the original packaging (>3 months)	+5 °C/+41 °F to +20 °C/+68 °F Max. 93% relative humidity, non-condensing
Transport and storage between applications (without packaging)	-25 °C/-13 °F to +70 °C/+158 °F Max. 90% relative humidity, non-condensing
Operation	-5 °C/+23 °F to +45 °C/+113 °F 5% to 90% relative humidity, non-condensing

Functional cosmesis	
Reference number	3F2=0
Lifetime	2 years The lifetime decreases or increases depending on the individual level of use. The maximum lifetime – which depends on the level of use – can only be achieved when the instructions for use are observed.
Water resistance	Not waterproof



<b>Functional cosmesis</b>	
Weight of the functional cosmesis (without adaptations)	Approx. 915 g (without functional stocking) Approx. 975-1005 g (with functional stocking)
Weight of the functional knee part	Approx. 130 g
Weight of the functional shank	Approx. 725 g
Weight of the textile finish	Approx. 32 g
Weight of the magnetic closure	Approx. 28 g

<b>Functional stocking</b>	
Reference number	99B122=*
Lifetime	6 months Wear and tear part that is subject to natural wear. The lifetime decreases or increases depending on the individual level of use. The maximum lifetime – which depends on the level of use – can only be achieved when the instructions for use are observed.
Water resistance	Machine washable, repels splashed water
Weight	70-90 g

<b>Thigh kit/magnetic closure</b>	
Reference number	3D13=1
Lifetime	2 years The lifetime decreases or increases depending on the individual level of use. The maximum lifetime – which depends on the level of use – can only be achieved when the instructions for use are observed.
Weight of the textile finish	Approx. 26 g
Weight of the magnetic closure	Approx. 28 g

## 11 Appendix

### 11.1 Symbols Used



Declaration of conformity according to the applicable European directives



Manufacturer



Lot number (10)PPPP YYYY WW  
PPPP – plant  
YYYY – year of manufacture  
WW – week of manufacture



Please note the instructions for use



Article number



Medical device



Global Trade Item Number



Unique device identifier



Gentle cycle at 30°



Do not dry clean



Do not tumble dry



Do not bleach



Do not iron

Not made with  
natural rubber latex.

Natural rubber latex was not used as a material





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