



CE

3F1=1/3F1=2

EN Instructions for use (user) 4



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Document: 647H914 Version: 07

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- DE** | Lassen Sie sich durch das Fachpersonal in den sicheren Gebrauch des Produkts einweisen. Weitere Sprachen dieser Gebrauchsanweisung sind online verfügbar oder können kostenlos als gedrucktes Exemplar bestellt werden (siehe Seite 2).
- EN** | Consult qualified personnel for instructions on how to use the product safely. These instructions for use are available in additional languages online or can be ordered as a printed copy free of charge (see page 2).
- FR** | Prière de demander au personnel spécialisé d'expliquer à l'utilisateur comment utiliser le produit en toute sécurité. D'autres langues de cette notice d'utilisation sont disponibles en ligne ou peuvent être commandées gratuitement en format papier (voir page 2).
- IT** | Richiedere al personale tecnico specializzato istruzioni sull'uso sicuro del prodotto. Altre lingue delle presenti istruzioni per l'uso sono disponibili online o possono essere ordinate gratuitamente su supporto cartaceo (vedere pagina 2).
- ES** | El personal técnico especializado le explicará cómo utilizar el producto de forma segura. Encontrará estas instrucciones de uso en otros idiomas en línea. También puede solicitarlo gratuitamente como ejemplar impreso (véase la página 2).
- PT** | Solicite ao pessoal técnico que o instrua no uso seguro do produto. Outros idiomas destas instruções de uso estão disponíveis online ou podem ser solicitados gratuitamente como um exemplar impresso (veja a página 2).
- NL** | Laat u door deskundig personeel uitleggen hoe u veilig met het product moet omgaan. Andere talen van deze gebruiksaanwijzing zijn online beschikbaar of kunnen gratis in gedrukte vorm worden besteld (zie pagina 2).
- SV** | Låt fackpersonal visa dig hur du använder produkten på ett säkert sätt. Den här bruksanvisningen finns tillgänglig på andra språk online och kan beställas kostnadsfritt i tryckt form (se sidan 2).
- DA** | Få faguddannet personale til at vise dig, hvordan du anvender produktet på sikker vis. Denne brugsanvisning er tilgængelig på yderligere sprog online eller kan bestilles gratis som et trykt eksemplar (se side 2).

- NO** | La fagpersonell instruerer deg i sikker bruk av produktet.
Flere språk for denne bruksanvisningen er tilgjengelige på nett, eller de kan bestilles som utskrevet eksemplar (se side 2).
- FI** | Anna ammattihenkilöstön perehdyttää itsesi tuotteen turvalliseen käyttöön.
Tämän käyttöohjeen muut kielet ovat saatavilla online tai niitä voi tilata maksutta painettuna versiona (katso sivu 2).
- PL** | Personel fachowy powinien poinstruować użytkownika na temat bezpiecznego używania produktu.
Niniejszą instrukcję używania w innych językach można przeczytać online lub zamówić bezpłatnie w wersji drukowanej (patrz strona 2).
- HU** | Kérje meg a szakszemélyzetet, hogy tanítsa meg Önt a termék biztonságos használatára.
A használati útmutató további nyelvi változatai az interneten elérhetőek, vagy nyomtatott példányként ingyenesen megrendelhetőek (lásd a 2. oldalt).
- JA** | 製品の安全な使用方法については、有資格担当者の指示に従ってください。
本取扱説明書のその他言語は、オンラインで入手可能ですが、印刷版も無料で注文できます（P2を参照）。
- CS** | Nechte se poučit odborným personálem ohledně bezpečného použití produktu.
Další jazykové verze tohoto návodu k použití jsou k dispozici online nebo je lze zdarma objednat v tištěné podobě (viz str. 2).
- HR** | Posavjetujte se sa stručnim osobljem o sigurnoj uporabi proizvoda.
Ostali jezici za ove upute za uporabu dostupni su na internetu ili se mogu besplatno naručiti u tiskanom obliku (vidi 2. stranicu).
- SL** | Strokovno osebje naj vas pouči o varni uporabi izdelka.
Ta navodila za uporabo v drugih jezikih so na voljo na spletu, lahko pa jih brezplačno naročite v tiskani obliki (glejte 2. stran).
- SK** | Nechajte sa odborným personálom zaučiť do bezpečného zaobchádzania s výrobkom.
Ďalšie jazykové mutácie tohto návodu na použitie sú dostupné online alebo si možno bezplatne objednať ich tlačенú verziu (pozri strana 2).
- TR** | Uzman personelin size ürünün güvenli kullanımı hakkında bilgi vermesini sağlayın.
Bu kullanım kılavuzundaki diğer diller online olarak mevcuttur veya ücretsiz basılı kopya olarak sipariş verilebilir (bkz. sayfa 2).
- RU** | Обратитесь к специалистам для получения инструктажа касательно безопасного и надежного применения изделия.
Текст настоящего руководства по применению на других языках доступен онлайн или может быть заказан бесплатно в печатном виде (см. стр. 2).
- ZH** | 由专业人员就产品的安全使用提供指导。
使用说明书的其他语言版本可在线获取，也可免费订购印刷版（参见第 2 页）。

Basic UDI-DI:

3F1=1: 4064411000000003F1=1K4

3F1=1-N: 4064411000000003F1=1-NT2

3F1=2: 4064411000000003F1=2K6

3F1=2-N: 4064411000000003F1=2-NT7

INFORMATION

Date of last update: 2024-03-05

- ▶ Please read this document carefully before using the product and observe the safety notices.
- ▶ Obtain instruction from the qualified personnel in the safe use of the product.
- ▶ Please contact the qualified personnel if you have questions about the product or in case of problems.
- ▶ Report each serious incident related to the product to the manufacturer and to the relevant authority in your country. This is particularly important when there is a decline in the health state.
- ▶ Please keep this document for your records.

The product "3F1=1 functional cosmesis C-Leg / 3F1=2 functional cosmesis Genium" is called the product/functional cosmesis in the following.

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

Only put the product into use 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. Functional cosmesis C-Leg (knee part) / functional cosmesis Genium (knee part) (referred to as "functional knee part" in the following)
2. Functional shank C-Leg / functional shank Genium (referred to as "functional shank" in the following)
3. Functional stocking
4. Sheath



2.2 Function

The product helps create the most natural possible appearance. The product forms the exterior finish of a prosthesis. The product is not required for the proper and safe functioning of the prosthesis.

The functional shank is shaped by the qualified personnel to create the most natural appearance possible. Streaks, colour differences and small air pockets (up to 1 cm) in the functional shank are concealed by 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.

3 Intended use

3.1 Indications for use

The product is intended exclusively for lower limb exoprosthetic fittings.

The product serves to finish the prosthesis in the sense of restoring a natural appearance that is as inconspicuous as possible.

3.2 Conditions of use

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

The product is intended exclusively for wearers of the 3C98-3/3C88-3 C-Leg, 3B1-2/3B1-2=ST Genium and 3B1-3/3B1-3=ST Genium.

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

3.3 Contraindications

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

4 Safety

4.1 Explanation of warning symbols



Warning regarding possible risks of accident or injury.



Warning regarding possible technical damage.

4.2 Structure of the safety instructions



The heading describes the source and/or the type of hazard

The introduction describes the consequences in case of failure to observe the safety instructions. Consequences are presented as follows if more than one consequence is possible:

> E.g.: Consequence 1 in case of failure to observe the hazard

> E.g.: Consequence 2 in case of failure to observe the hazard

▶ This symbol identifies activities/actions that must be observed/carried out in order to avert the hazard.

4.3 General safety instructions



Non-observance of safety instructions

Personal injury/damage to the product due to using the product in certain situations.

▶ Observe the safety instructions and the stated precautions in this accompanying document.

⚠ CAUTION

Contact of the product with embers or fire

Injuries (e.g. burns) and damage to the product.

- ▶ Keep the product away from embers and open flames.

⚠ CAUTION

Wearing the product without a functional stocking

> Injuries due to pinching of body parts.

> Damage due to articles of clothing getting pinched.

> Damage to the product.

> Loss of comfort due to the penetration of moisture into the foam.

- ▶ The product may only be worn with the functional stocking.
- ▶ The product can only be worn without the functional stocking during cleaning.

⚠ CAUTION

Skin irritation due to irregular care of the product

> Skin irritation due to contact with a soiled functional shank.

> Skin irritation due to contact with a soiled sheath.

- ▶ Clean the product only as described in the section "Cleaning and care" (Cleaning and care).
- ▶ Only wear the product with the functional stocking.

⚠ CAUTION

Thermal overload due to increased heat accumulation

Falling due to altered damping behaviour as a result of earlier switching to overheating mode.

- ▶ Observe the warnings/error signals of the prosthesis (overheating mode).

⚠ CAUTION

Influence of the product on the behaviour of the prosthesis

Change in prosthesis functionality

- ▶ Observe the safety instructions for your prosthesis.
- ▶ Have the settings of your prosthesis in combination with the product checked by the O&P professional.

⚠ CAUTION

Impaired perception of the feedback signals

Falling due to impaired perception of the feedback signals resulting from changed damping behaviour.

- ▶ The audibility of the feedback signals must be checked and the corresponding volume has to be set by the O&P professional.

NOTICE

Independent user changes or modifications made to the product

Damage to the product.

- ▶ Manipulations to the product other than the tasks described in these instructions for use are not permitted.

NOTICE

Mechanical damage to the product

Change in or loss of functionality due to damage.

- ▶ Use caution when working with the product.
- ▶ If the product is damaged, check it for proper function and readiness for use.
- ▶ Take any necessary measures (e.g. repair, replacement, inspection by the manufacturer's customer service, etc.).

NOTICE

Improper product care

Damage to the product due to the use of incorrect cleaning agents.

- ▶ Clean the product only as described in the section "Cleaning and care" (see page 8).

INFORMATION

The penetration of dirt and humidity into the product leads to a loss of comfort. Observe the safety information in the instructions for use for your prosthesis.

INFORMATION

The product can limit the range of the Bluetooth signal. Observe the safety information in the instructions for use for your prosthesis.

5 Scope of delivery

- 1 pc. 3F1=1 functional cosmesis C-Leg/3F1=2 functional cosmesis Genium
- 1 pc. Instructions for use (user)
- 1 pc. 99B120=* functional stocking

6 Handling

6.1 Putting on and taking off

Putting on the functional stocking

INFORMATION

Note the alignment of the functional stocking (zones of the functional stocking). The label in the functional stocking identifies the back of the stocking.

Complete the following steps to put on the functional stocking:



- 1) Fold over the coated ankle part of the functional stocking (coating faces out).
- 2) The functional stocking should extend approx. 1 cm beyond the footshell.
- 3) Pull the functional stocking up.
INFORMATION: Adjust how far you pull the functional stocking up according to your needs, so that your use of the joint is not noticeably impaired. To accomplish this, secure the functional stocking to the prosthetic socket, for example while the joint is flexed.
INFORMATION: Note the correct positioning of the functional zones.
- 4) For the best possible adhesion, position the end of the functional stocking directly on the socket surface if possible.

Taking off the functional stocking

Complete the following steps to take off the functional stocking:

- 1) Fold over the coated socket part of the functional stocking (coating faces out).
- 2) Pull the functional stocking down over the functional cosmesis.

INFORMATION: The functional stocking is turned inside-out.

6.2 Charging the prosthesis battery

Charging the battery with the 3F1=1 functional cosmesis C-Leg

- 1) Push the functional stocking down until the charging receptacle on the rear of the prosthesis is visible.
- 2) Open the charging receptacle cover.
- 3) Connect the charging plug to the charging receptacle of the product.

INFORMATION: Observe the instructions for use for the prosthesis.

Charging the battery with the 3F1=2 functional cosmesis Genium

INFORMATION

The inductive charger for Genium can be used after putting on the functional stocking. Exposing the charging unit is not necessary.

- ▶ Connect the inductive charger to the receiver of the charging unit on the rear of the product.

INFORMATION: Observe the instructions for use for the prosthesis.

7 Cleaning and Care

7.1 Cleaning the functional cosmesis

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

7.2 Cleaning the functional stocking

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).

INFORMATION

Note the washing symbols on the label.

INFORMATION

Drying may take between 12 and 24 hours. A second functional stocking for changing is recommended.

7.3 Care of the functional stocking

- Wipe the silicone coatings on the inside of the functional stocking with a damp cloth every three days.

8 Legal information**8.1 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.

8.2 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.

8.3 CE conformity

Otto Bock Healthcare Products GmbH hereby declares that the product is in compliance with applicable 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 Technical data

Environmental conditions	
Storage and transport in original packaging	-25 °C/-13 °F to +70 °C/+158 °F
Storage and transport without packaging	-25 °C/-13 °F to +70 °C/+158 °F Max. 93% relative humidity, non-condensing
Operation	-10 °C/+14 °F to +60 °C/+140 °F 15% to 93% relative humidity, non-condensing

General information	
Reference number	3F1=1 / 3F1=2
Service life of the functional cosmesis	2 years The service life diminishes or increases depending on the individual level of use. Only when the instructions for use are observed it is possible to achieve the maximum service life, in dependence of the level of use.

General information	
Service life of the functional stocking	6 months Wear part, subject to natural wear and tear. The service life diminishes or increases depending on the individual level of use. Only when the instructions for use are observed it is possible to achieve the maximum service life, in dependence of the level of use.
Weight of the functional cosmesis (without adaptations)	910 g

10 Appendix

10.1 Symbols Used



Manufacturer



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



Declaration of conformity according to the applicable European directives



Do not dry clean



Iron at medium temperature, max. 150°



Do not tumble dry



Gentle cycle at 30°



Do not bleach

Not made with
natural rubber latex.

Natural rubber latex was not used as a material



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