



CE

4P110=7

EN Instructions for use (user) 4



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Document: 647H941 Version: 03

<https://product-documents.ottobock.com/IFU/INT/4P110/647H941/03/O/S/F>

- 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.
- 2 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 elérhetők, vagy nyomtatott példányként ingyenesen megrendelhetők (lásd a 2. oldalt).
- 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).
- 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).
- 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).
- 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).
- 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).
- 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)。
- 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）。
- KO** | 전문 기사에게 제품의 안전한 사용법을 배우십시오.
이 사용 설명서의 다른 언어는 온라인에서 볼 수 있으며 또는 인쇄본은 무료로 주문할 수 있습니다 (2 페이지 참조).

INFORMATION

Date of last update: 2023-08-16

- ▶ Please read this document carefully before using the product and observe the safety notices.
- ▶ Consult the qualified personnel for instructions regarding the safe use of the product.
- ▶ Please contact the qualified personnel 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 qualified personnel and the competent authority in your country.

The product "4P110=7 Genium X4 Protective Cover, long" is referred to simply as the Protective Cover/product below.

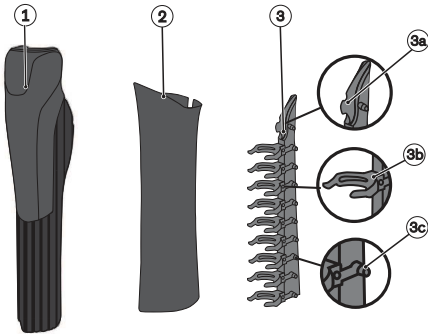
These instructions for use provide you with important information on the use, adaptation and handling of the product.

Only put the Protective Cover into use in accordance with the information provided in the accompanying documents supplied.

2 Product description

2.1 Design

The Protective Cover consists of the textile cover (1) and the tube cover. The tube cover components are the "tube sleeve" (2) and the "tube clamp" (3).



1. **Textile cover**

2. **Tube sleeve**

3. **Tube clamp**

3a. Guiding ridge

The guiding ridge at the upper end of the tube clamp prevents the tube clamp from twisting and sliding up and down the tube adapter

3b. Clamp

The clamps are parts of the tube clamp and are used to attach the tube clamp to the tube adapter

3c. Locking pin

These locking pins are used to attach the tube sleeve (2) to the tube clamp (3)

3 Intended use

3.1 Indications for use

The product is to be used **solely** for lower limb exoprosthetic fittings.

The Protective Cover provides a means of enclosing the 3B5-4=P, 3B5-4=ST mechatronic knee joints and the tube adapter to enhance their appearance and function. The Protective Cover protects the housing of the knee joint against external influences such as scratches or surface contamination. The Protective Cover is not required for the knee joint to function properly and safely. The tube cover can also be worn without the textile cover to add volume in the area of the tube adapter only.

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

The Protective Cover could fall off the knee joint due to leg movements while swimming. For this reason, the Protective Cover should be taken off the knee joint before swimming.

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, users 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

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

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

! Failure to follow the instructions can result in technical damage.

4.2 Before use

WARNING! Possible disruptions to active implantable systems (e.g. pacemaker, defibrillator, etc.)

- ▶ When the magnetic closures of the lower leg/thigh are close to active implanted systems (e.g. pacemakers), ensure that the minimum distances stipulated by the implant manufacturer are observed.
- ▶ Observe the operating conditions and safety notices stipulated by the manufacturer of the implant.

CAUTION! Possibility of falling

- ▶ Because the magnetic closure of the textile cover may interfere with the tube adapter, only use it in combination with the tube cover.

4.3 During use

CAUTION! Possibility of falling

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

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

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

4.4 After use

CAUTION! Possible skin irritation due to contact with a soiled product

- ▶ Clean the product only as described in the section "Cleaning and care".

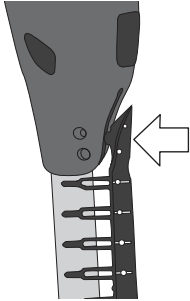
5 Scope of delivery

- 1 pc. 4P110=7 Genium X4 Protective Cover, long, consisting of:
Textile cover, tube sleeve and tube clamp
- 1 pc. Instructions for use (user)

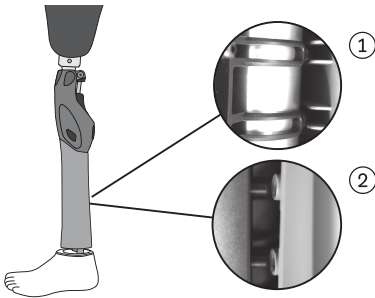
6 Handling

6.1 Putting on the Protective Cover

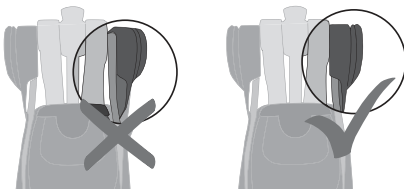
Complete the following steps to put on the Protective Cover:



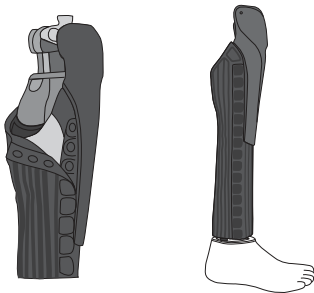
- 1) Insert the guiding ridge of the tube clamp into the tube clamp slot of the knee joint and fit the clamps on the tube adapter.



- 2) Spread open the tube sleeve, positioning it to fit the frame and the tube clamp so that each narrow extension of the clamp lies in a pair of ribs of the tube sleeve (detail 1).
- 3) Close the tube sleeve, pushing the tube sleeve onto the locking pins of the tube clamp (detail 2).



- 4) Put the Protective Cover onto the frame of the knee joint. Ensure that the Protective Cover fits flush on the knee joint. The retainers have to engage exactly in the frame.



- 5) Apply the textile cover to the knee joint and tube sleeve, and fasten the magnetic closures.

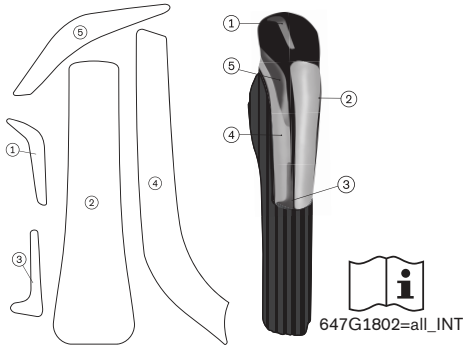
6.2 Taking off the Protective Cover

Complete the following steps to take off the Protective Cover:

- 1) Open the magnetic closure of the textile cover and remove it from the knee joint and tube sleeve.
- 2) Open the tube sleeve, spread it open and remove it from the tube adapter.
- 3) Take the tube clamp off the tube adapter.

6.3 Customising the Protective Cover

6.3.1 Laminating the Protective Cover



- 1) Select the corresponding template from the 647G1802=all_INT supplement.
- 2) Transfer the pattern to any adhesive film. Note that the supplement only shows the cuts for the right side. For the left side, the cutting part must be turned over before transferring.
- 3) Cut out the adhesive film.
- 4) Clean the Protective Cover.
- 5) Apply the adhesive film to the Protective Cover.

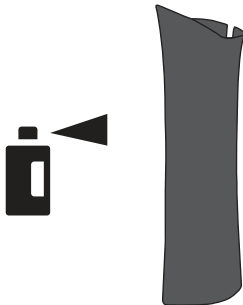
NOTICE! Do not use a hot air gun.

6.3.2 Painting the tube cover

CAUTION! Possible injury due to skin, eye and respiratory tract irritation.

- ▶ Read the corresponding safety data sheets/processing instructions prior to processing with substances for priming the surface and for painting.
- ▶ Wear appropriate protective equipment during processing.

Complete the following steps to paint the tube cover:



- 1) Clean and degrease the tube cover (e.g. with Hesse-Lignal NV 395)
- 2) Pre-treat the outer surface of the tube cover with a bonding agent for TPU/polyurethanes (e.g. Hesse-Lignal TG 5250 adhesive primer) according to the processing instructions for the bonding agent. The bonding agent being used specifies which paint can be used for painting.

INFORMATION: Follow the processing instructions for the chosen paint to obtain optimal painting results.

INFORMATION: Use paint for elastic materials to obtain the most long-lasting results possible.

7 Maintenance

- ▶ Have the product checked by the O&P professional during the regular inspection of the prosthetic components.

8 Cleaning and Care

We recommend cleaning the product at least once a week or directly after coming into contact with liquids. Otherwise, impairment of the product's function or appearance cannot be excluded.

INFORMATION

Take the product off for drying.

8.1 Cleaning the textile cover

1) Wash the textile cover 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: Easy care or delicates.

2) After washing, open the textile cover and allow it to air dry.

NOTICE! Do not use a dryer.

8.2 Cleaning the tube cover

8.2.1 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.

8.2.2 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 tube cover in the top rack.
- Use a short wash cycle with a water temperature below 60 °C.

9 Disposal

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

10 Legal information

10.1 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.

10.2 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>

10.3 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.

11 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

Genium X4 Protective Cover, long	
Reference number	4P110=7
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 cover	Approx. 280 g
Weight of the tube cover	Approx. 270 g

12 Appendices

12.1 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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