




5A60=* Varos

 Instructions for use (user)	4
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Document: 647H901 Version: 10

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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).
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- 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).
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Изданията на настоящата инструкция за употреба на други езици са налични онлайн или могат да бъдат поръчани безплатно под формата на печатен екземпляр (вижте страница 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）。

Basic UDI-DI: 406441100000000005A60G7

INFORMATION

Date of last update: 2024-01-04

- ▶ 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 "5A60=* Varos" is referred to simply as the product/socket below.

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 product consists of the following components:



1. Outer socket shell (lateral)
2. Inner socket shell (medial)
3. Boa cables
4. Connection adapter with magnetic bottom shell (not visible)
5. Boa dials

2.2 Function

The product is a trans-femoral socket with a modular structure. The product connects the residual limb to the knee joint. The product can be adapted to the volume of the residual limb while it is being worn.

3 Intended use

3.1 Indications for use

The product is to be used solely for the prosthetic treatment of the lower limbs. The product is to be used for the treatment of trans-femoral amputations.

3.2 Area of application

Our components perform optimally when paired with appropriate components based upon weight and mobility grades identifiable by our MOBIS classification information and which have appropriate modular connectors.



The product is recommended for mobility grade 1 (indoor walker), mobility grade 2 (restricted outdoor walker), mobility grade 3 (unrestricted outdoor walker) and mobility grade 4 (unrestricted outdoor walker with particularly high demands).

Size	S	SC	M	MC	L
Max. body weight [kg]	100	100	100	100	125

3.3 Conditions of use

The product was developed for everyday use and must not be used for unusual activities. These unusual activities include, for example, sports that require continuous high walking speeds (running ...) or extreme sports (free climbing, parachuting, paragliding, etc.).

The product is intended **exclusively** for use on **one** user.

3.4 Indications




- For unilateral or bilateral amputation
- For users with a normal weight bearing residual limb of conical or cylindrical shape
- For users with or without daily volume fluctuations of the residual limb
- For users whose residual limb length and residual limb circumference are in the specified range (see the instructions for use for the 6Y200=* Varos liner).

3.5 Contraindications


- Skin changes in the fitting area (e.g. open sores, skin diseases)
- Sensory disorders on the residual limb
- Pronounced atrophic scars or very bulgy residual limb

4 Safety


4.1 Explanation of warning symbols

 WARNING	Warning regarding possible serious risks of accident or injury.
 CAUTION	Warning regarding possible risks of accident or injury.
 NOTICE	Warning regarding possible technical damage.

4.2 Structure of the safety instructions

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

 WARNING
Non-observance of safety notices
Personal injury/damage to the product due to using the product in certain situations.
▶ Observe the safety notices and the stated precautions in this accompanying document.

⚠ CAUTION

Risk of pinching when inserting the liner into the socket

Injury due to powerful magnetic attraction between the magnetic cap of the matching 6Y200=* Varos liner and the magnetic bottom shell of the product.

- ▶ When inserting the liner into the socket, ensure that no fingers/body parts are between the liner and socket.

⚠ CAUTION

Independent user manipulation of system components

Falling due to breakage of load-bearing components or malfunction of the product.

- ▶ Manipulations to the product other than the tasks described in these instructions for use are not permitted.
- ▶ The product and any damaged components may only be repaired or replaced by qualified personnel.

⚠ CAUTION

Remaining in areas outside the allowable temperature range

Falling due to breakage of load-bearing components or malfunction of the product.

- ▶ Avoid remaining in areas with temperatures outside of the permissible range (see page 9).

⚠ CAUTION

Use of a damaged product

Falling due to breakage of load-bearing components or malfunction of the product.

- ▶ Regularly check the socket, Boa cable, Boa dials, socket brim pad and fabric or plastic adhesive strips for wear or damage.
- ▶ If components are damaged or a Boa cable is torn, the socket has to be repaired by qualified personnel.

⚠ CAUTION

Risk of pinching when closing the socket shells

Injury due to pinching of body parts.

- ▶ When closing the socket shells, ensure that fingers and other body parts are not in this area.

⚠ CAUTION

Mechanical overloading of the product

Falling due to breakage of load-bearing components or malfunction of the product.

- ▶ Do not subject the product to excessively strong mechanical vibrations or impacts.
- ▶ Check the product for visible damage before each use.

⚠ CAUTION

Overloading due to unusual activities

Falling due to the breakage of load-bearing components or malfunction.

- ▶ Careful handling of the product and its components not only increases their service life but, above all, ensures your personal safety!
- ▶ If the product and its components have been subjected to extreme loads (e.g. due to a fall, etc.), the product must be inspected for damage immediately by qualified personnel.

⚠ CAUTION

Contact of the product with embers or fire

Injuries due to contact with molten material.

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

⚠ CAUTION

Storage of the product in direct sunlight

- > Falling due to the breakage of load-bearing components caused by plastic parts of the product becoming brittle due to UV exposure.
- > Discolouration of plastic parts.
- ▶ Avoid storing the product in direct sunlight.

⚠ CAUTION

Signs of wear on system components

Falling due to breakage of load-bearing components or malfunction of the product.

- ▶ Annual safety inspections have to be carried out in the interest of your own safety and in order to maintain operational reliability.

⚠ CAUTION

Improper care/disinfection of the product

Skin irritation, formation of eczema or infections due to contamination with germs.

- ▶ Clean the product regularly with a damp cloth and mild soap (e.g. 453H10=1 Ottobock DermaClean).
- ▶ Disinfect the inner side of the product when needed with a colourless, conventional, medical disinfectant.
- ▶ For hygienic reasons, only use the product on yourself.

5 Scope of Delivery and Accessories

Scope of Delivery

- 1 pc. 5A60=* Varos (socket)
- 1 pc. Instructions for use (user)

Accessories

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

- 1 pc. 6Y200=* Varos liner

6 Use



Note the 6Y200=* Varos liner 647G1239=all_INT instructions for use (user)

⚠ WARNING

Use of the product near active implanted systems

The product's magnetic field can interfere with active implanted systems (e.g. pacemakers, defibrillators etc.).

- ▶ When using the product in the immediate vicinity of active implanted systems, ensure that the minimum distances stipulated by the manufacturer of the implant are observed.

- ▶ Make sure to observe any operating conditions and safety instructions stipulated by the manufacturer of the implant.

⚠ CAUTION

Metallic objects or particles adhering to the magnetic cap

- > Falling due to lack of suspension on the prosthetic socket.
- > Damage to the product.
- ▶ Before putting on the liner, check for metallic objects or particles on the magnetic cap and remove any that are present.

6.1 Putting on the liner and socket

Putting on the liner

- 1) Check the liner and magnetic cap for damage.
- 2) Turn the liner inside out and apply it to the end of the residual limb.
- 3) Apply the liner to the end of the residual limb and check the alignment of the liner at the same time.

INFORMATION: The orientation thread on the inner side of the liner has to be centred on the front of the transfemoral residual limb. The liner's two seams have to be positioned on the sides of the transfemoral residual limb.

- 4) Unroll the liner onto the residual limb so that it has no wrinkles or air pockets, without shifting the soft tissue.
- 5) Check the fit and the alignment of the liner.
- 6) In a standing position (or position with the residual limb nearly extended), unroll the liner part-way and roll it back up again to release possible skin tension.

Putting on the socket

- 1) To open, pull the Boa dials away from the prosthetic socket.
- 2) Open the socket by pulling the shells apart.
- 3) Sit on the front edge of a chair.
- 4) Pull the socket over the residual limb.

INFORMATION: In doing so, note the alignment of the toes and the position of the lower leg so the desired level of exterior foot rotation is given while standing and walking. If the exterior foot rotation is not correct, take the socket off again (at least, the magnetic cap has to be released from the bottom of the socket) and put it back on in a changed position.

- The magnetic bottom shell of the socket and the magnetic cap of the liner attract each other when they are brought close together. A clicking sound is heard, indicating the proper connection of the socket and liner.
- 5) Push the Boa dials towards the socket.
 - 6) Turn the Boa dials clockwise.
- The Boa cables are tightened and the socket is closed.

INFORMATION: Position the outer socket shell (lateral) under the inner socket shell (medial).

- 7) Tighten the Boa dials as needed.

6.2 Taking off the socket and liner

- 1) Pull the Boa dials away from the socket.
- 2) Pull the outer socket shell (lateral) to the outside.
If plastic adhesive strips are used in the lateral socket shell, pull until there is no longer any contact between the plastic adhesive strips and textile cover of the liner.

- 3) Push the socket off the residual limb.
In doing so, preferably grasp the socket brim of the lateral socket shell with one hand and the socket brim of the medial socket shell with the other hand.
- 4) Unroll and remove the liner from the residual limb.

7 Cleaning

- 1) Clean the product with a damp cloth and mild soap (e.g. Ottobock 453H10=1 Derma Clean) when needed.
- 2) Dry the product with a lint-free cloth and allow it to air dry fully.
The socket brim pad can be removed for cleaning.
- 1) Clean the socket brim pad with water and mild soap (e.g. 453H10=1-N Ottobock Derma Clean) when needed.
- 2) Dry the socket brim pad with a lint-free cloth and allow it to air dry fully.
- 3) After it is completely dried, attach the socket brim pad to the medial socket shell again.

8 Maintenance

- ▶ A visual inspection and functional test of the prosthetic components should be performed after the first 30 days of use.
- ▶ Perform annual safety inspections (visual inspection for damage and wear and tear, functional test).

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 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.

9.3 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>

10 Technical data

Ambient conditions	
Transport in original packaging	-25 °C/-13 °F to +70 °C/+158 °F
Storage in original packaging	-25 °C/-13 °F to +50 °C/+122 °F Max. 90% relative humidity, non-condensing
Storage and transport without packaging	-25 °C/-13 °F to +50 °C/+122 °F Max. 90% relative humidity, non-condensing

Ambient conditions	
Operation	-10 °C/+14 °F to +40 °C/+104 °F Max. 90% relative humidity, non-condensing
Water resistance	Fresh water, mild soap
Not waterproof	Salt water, chlorine water

General information	
Reference number	5A60=*
Lifetime	3 years 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	Contact with fresh water and mild soap is permitted. Not designed for chlorinated water or salt water.
Product weight (not shortened) (size S / SC / M / MC / L in g)	1260 / 1310 / 1320 / 1450 / 1490
Magnetic bottom shell material	INOX (stainless steel)
Connection adapter material	Anodised aluminium
Medial and lateral bar material	Carbon fibre reinforced polyamide PA12
Medial and lateral socket shell material	Polyamide PA12
Clamping piece material	Coated die-cast zinc
Slot nut material	Stainless steel
Socket brim pad material	EVA blend

11 Appendix

11.1 Symbols Used



Declaration of conformity according to the applicable European directives



Manufacturer



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



Medical device



Article number



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