

21Y2=M10

EN Instructions for use





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Document: 647G2026 Version: 01

<https://product-documents.ottobock.com/IFU/INT/21Y2=M10/647G2026/01/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.
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).
- 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).

- RO** | Solicitați să fiți instruit de către personalul de specialitate în vederea utilizării în siguranță a produsului.
Alte limbi ale acestor instrucțiuni de utilizare sunt disponibile online sau o copie tipărită poate fi comandată gratuit (consultați pagina 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).
- BG** | Поискайте от специалистите да Ви запознаят с безопасното използване на продукта.
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).
- 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).

EL | Ενημερωθείτε από το τεχνικό προσωπικό για την ασφαλή χρήση του προϊόντος.
Οι οδηγίες χρήσης διατίθενται online και σε άλλες γλώσσες ή μπορείτε να παραγγείλετε δωρεάν ένα εκτυπωμένο αντίτυπο (βλ. σελίδα 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).

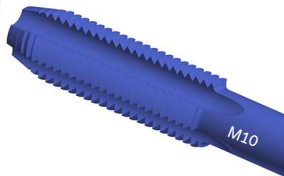
JA | 製品の安全な使用方法については、有資格担当者の指示に従ってください。
本取扱説明書のその他言語は、オンラインで入手可能ですが、印刷版も無料で注文できます (P2を参照)。

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).

Basic UDI-DI: 403276700000000021Y2V2

1



Drill and deburr a hole with a diameter of 8.5 mm.
Cut an M10 thread.

2



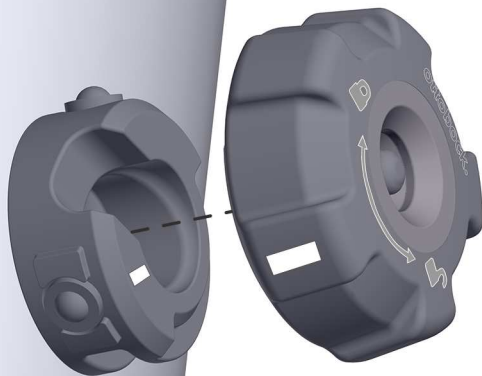
Apply adhesive to the thread.
Check socket: 617H46
Definitive socket: 636W28 or 617H46

3



Carefully screw in until the O-ring seals against the outside of the prosthetic socket.

4



Line up the markings on the cover and base.
Place the cover on the base.

5



Turned clockwise to the stop: valve locked, air can only come out

Turned anticlockwise to the stop: bypass is open, air can flow in and out

Middle position between locked and open: cover can be removed or attached

1 Product description

English

INFORMATION

Date of last update: 2024-04-04

- ▶ 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 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.

These are the instructions for use for the 21Y2=M10 outlet valve.

The outlet valve is used in combination with a sealing sleeve or a sealing liner to generate a vacuum in the prosthetic socket. This reduces friction and shear forces during the swing phase. During the stance phase, the body weight pushes the air in the prosthetic socket out of the socket via a check valve.

The outlet valve can be opened to remove the prosthetic socket or increase comfort during extended sitting.

2 Intended use

2.1 Indications for use

The product is intended exclusively for lower limb exoprosthetic fittings.

2.2 Area of application

- The product can be used for vacuum-formed and laminated prosthetic sockets.
- Only use the product in combination with a liner.

2.3 Combination possibilities

This prosthetic component is compatible with Ottobock's system of modular connectors. Functionality with components of other manufacturers that have compatible modular connectors has not been tested.

2.4 Environmental conditions

Storage and transport

Storage temperature: -20 °C to +60 °C, relative humidity: 20 % to 90 %, no mechanical vibrations or impacts

Allowable environmental conditions

Temperature during use: -10 °C to +45 °C

Chemicals/liquids: Fresh water, salt water, perspiration, urine, soapsuds, chlorine water

Moisture: Submersion: max. 1 h in 3 m depth, relative humidity: no restrictions

Solids: Dust, occasional contact with sand

Clean the product after contact with humidity/chemicals/solids, in order to avoid increased wear and tear and damage (see page 12).

Prohibited environmental conditions

Solids: Highly liquid-binding particles (e.g. talcum), continuous contact with sand

Chemicals/liquids: Acids, continuous use in liquid media

2.5 Lifetime

The manufacturer has specified a maximum lifetime of 2 years for the product.

3 General safety instructions

CAUTION! Risk of injury and risk of product damage

- ▶ To avoid damage to the product, observe the alignment and assembly instructions.

- ▶ To prevent mechanical damage, use caution when working with the product.
- ▶ Note the combination possibilities/combination exclusions in the instructions for use of the products.
- ▶ Observe the maximum lifetime of the product.
- ▶ Check the product for damage and readiness for use prior to each use.
- ▶ Do not expose the product to excessive strain (section: "Area of application" see page 10) or to prohibited environmental conditions (see page 10).
- ▶ Do not use the product if it is damaged or in a questionable condition. Take suitable measures (e.g. cleaning, repair, replacement, inspection by the manufacturer or a specialist workshop).

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

- ▶ The product may only be used by one person; reuse on another person is prohibited.
- ▶ Observe the cleaning instructions.

NOTICE! Danger of product damage and restricted functionality

- ▶ Do not allow the product to come into contact with oils, ointments or lotions containing oils or acids.

4 Scope of delivery

Quantity	Designation	Reference number
1	Instructions for use	-
1	Valve cover	21Z42=1
1	Valve base	-

5 Preparing the product for use

The outlet valve is assembled in the distal area of the prosthetic socket, offset to the posterior or lateral. The base of the outlet valve is

screwed into the prosthetic socket, and the cover is positioned on the base.

5.1 Assembling the valve

Preparing for assembly

- > **Required materials:** drill bit 8.5 mm, M10 screw tap set
- 1) Drill a hole (**8.5 mm**) in the prosthetic socket with the posterior or lateral offset in the distal area. (see fig. 1).
- 2) Carefully deburr the bore hole on the inside and the outside of the prosthetic socket. Remove chips and dust.
- 3) Cut an M10 thread into the bore (see fig. 1).
- 4) **Test assembly:** Carefully screw the valve base into the prosthetic socket until the O-ring touches the prosthetic socket.
 - **The O-ring does not lie flush:** Sand the prosthetic socket slightly flat in this area.
 - **The thread of the valve base projects into the prosthetic socket.** Carefully sand the thread a bit shorter.

Assembling the valve base

To seal the valve base, treat the thread with silicone bonding agent or special adhesive (**only for the definitive socket**) prior to assembly.

- > **Required materials:** 617H46 silicone bonding agent or 636W28 or 636W18 and 636W19 Ottobock special adhesive
- > **Prerequisite:** The thread of the valve base is clean and free of grease.
- 1) Apply a bit of silicone bonding agent or special adhesive to the thread of the valve base (see fig. 2).
- 2) Carefully screw the valve base into the prosthetic socket (see fig. 3). The O-ring has to seal on the prosthetic socket without being pushed away.
- 3) Allow the material to cure.

Assembling the valve cover

Assembly or disassembly of the valve cover is only possible in one position. Markings on the valve base and valve cover indicate the position.

- 1) Align the markings one above the other and set the valve cover onto the valve base (see fig. 4, see fig. 5).

TIP: The valve cover covers the marking on the base. Transfer the marking of the base to the prosthetic socket with a pen so it can be easily found again.

- 2) Turn (lock) the valve cover clockwise to the stop.

6 Use

NOTICE! If you turn the valve cover to the middle between “open” and “locked”, you can remove the valve cover from the base.

Open

- ▶ Turn the valve cover counter-clockwise to the stop.
- The valve is open, and air can flow into the prosthetic socket.

Locking

- ▶ Turn the valve cover clockwise to the stop.
- The valve is locked; air can only come out of the prosthetic socket.

7 Cleaning

Clean the valve if it is dirty or no longer sealed reliably.

- 1) Turn the valve cover to the middle between “open” and “locked”, and pull it off the base.
- 2) Flush the valve with compressed air or water from the underside of the valve cover.
- 3) Rinse the valve base with water or compressed air.
- 4) Align the markings on the valve base and valve cover on top of each other, and set the valve cover back on the valve base.
- 5) Turn the valve cover clockwise to the stop to lock the valve.

8 Disposal

Do not dispose of the product with unsorted household waste. Improper disposal can be harmful to health and the environment.

Observe the information provided by the responsible authorities in your country regarding return, collection and disposal procedures.

9 Maintenance

- ▶ A visual inspection and functional test of the prosthetic components should be performed after the first 30 days of use.
- ▶ During regular inspection: Inspect the prosthesis for signs of wear and check its function.
- ▶ During regular inspection: Clean the outlet valve.
- ▶ Conduct annual safety inspections.

10 Legal information

All legal conditions are subject to the respective national laws of the country of use and may vary accordingly.

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

The product meets the requirements of Regulation (EU) 2017/745 on medical devices. The CE declaration of conformity can be downloaded from the manufacturer's website.



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