UNYQ°

OneFit

Firm & Flex

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Technical Guide

OneFit Firm & Flex

Product name

OneFit Firm / OneFit Flex

Product description

OneFit is a fully customized, articulated prosthetic cover designed specifically for transfemoral amputees. It provides complete coverage from the socket to the ankle, protecting all prosthetic components while allowing natural knee movement through its functional joint. OneFit is available in two durable and lightweight material options: Firm, made from robust polyamide (PA12), and Flex, crafted from a flexible, rubber-like TPA material designed for more active lifestyles. Both versions offer a perfect, made-to-measure fit that enhances comfort, aesthetics, and confidence with a wide range of customizable designs and colors.

This innovative cover not only protects mechanical and electronic parts but also offers an anatomical, natural look that blends seamlessly with the user's body. Easy to clean and water-resistant, OneFit covers enhance daily wear without compromising the functionality of the prosthesis, providing users with both practical protection and emotional support through personalization.

Main features

- **Customized fit**: Precisely shaped to each user's unique anatomy and prosthetic setup, ensuring optimal comfort and seamless integration.
- Complete articulated coverage: Envelops the entire prosthesis from socket to ankle with a functional knee joint allowing smooth, natural movement.
- Robust protection: Shields delicate prosthetic components from everyday impacts, friction, and environmental damage, and clothing from pinching and damage caused by prosthetic components
- **High-quality materials**: Manufactured using advanced durable materials Firm uses strong polyamide (PA12) and Flex uses flexible, resilient TPA—both lightweight and long-lasting.
- **Design variety:** Offers a broad palette of designs, colors, finishes (matte or gloss), and extra options, allowing users to express personal style.
- Secure attachment methods: multiple choice of reliable fixation systems such as magnets with fast-clamp, screws with c-clamp, and dual lock for stability and quick adjustment.
- Water-resistant surface: Easy-to-clean, smooth surfaces repel water, supporting hygiene and maintenance without compromising prosthetic function.
- **Lightweight and comfortable wearability:** Engineered to be light enough for daily, extended use without adding strain.



Technical Sheet

OneFit Firm & Flex

Feature	OneFit Firm (PA12)	OneFit Flex (TPA)	
Fit	Customized to each user's prosthesis and anatomy.		
Material	Rigid polyamide (PA12), a robust and durable thermoplastic with a strong, high-density structure, ideal for complex parts and waterproof applications	Flexible, shock-absorbing TPA, highly resistant to flex and wear	
Biocompatibility	Biocompatibility declaration: it meets USP Class I-VI and US FSA requirements for intact skin surface devices.		
Temperature range	-20°C to +50°C (-5°F to +125°F).		
Finish	Hard rigid surface. Matte or glossy	Soft-touch flexible surface. Matte or glossy	
mpact Resistance	High impact and abrasion resistance	Enhanced shock absorption for higher activity levels	
Design Options	20+ designs, 40+ colors, engravings and vinyl available	15+ designs, 40+ colors, some engraving available	
Compatibility	TF. most monocentric knees. Customization available for prosthesis with rotator adapters.		
Recommended Use	Everyday, moderate activity, aesthetically oriented (K2–K3 users). Remove cover before strenuous or high-impact activities to protect the finish, especially paint.	For active users (K3–K4), maximum flexibility and noise reduction for active daily routine. Remove cover during vigorous or sports-like activities to prevent damage and preserve appearance.	
Bottom part attachment (to orosthesis)	It can be chosen between these options. A combination of Magnets & C-Clamp is also available for specific cases. This preferences will be respected whenever technically feasible. • Magnets & Fast-Clamp • Screws & C-Clamp		
Upper part attachment (to socket)	It can be chosen between: 1. Two-piece coverage (front/back over the socket) 2. One-piece coverage (wraps around the front of the socket) The attachment system for the upper part will follow the client's choice for the lower part whenever possible: For two-piece coverage: • Magnets & Fast-clamp	The upper part of the cover for OneFit Flex is only available as a one-piece coverage (wraps around the front of the socket). Two-piece coverage option are not available for this product. The attachment system for the upper part will follow the client's choice for the lower part whenever possible: • Fast-Clamp • C-Clamp	
	Screws & C-Clamp For one-piece coverage: Fast-Clamp C-Clamp In all cases, an additional Dual Lock system is integrate upper part attachment is always personalized by our de requirements to ensure optimal fit and function. Client a limited to the lower part selection as explained above.	esigners based on the socket and technical	
Manufacture	Manufactured by 3D printing in Spain by the company: UNYQ Design Europe, S.L. (B21539135). Our products do not carry CE marking as they are not medical devices according to article 2 of Royal Decree 1591/2009 of 16		

Ordering process

Ordering your custom OneFit cover requires a 3D scan of the prosthesis and the patient's residual limb to ensure a precise fit.

You can place your order through one of the following convenient methods:

• Online Platform:

Access our secure online ordering platform (login required; credentials provided upon registration) to submit your order. This platform guides you through entering product details, uploading the mandatory 3D scans and photographs, and tracking your order status.

• Order form (PDF):

Download the order form PDF from our website, complete the required details, and send it, along with the necessary scans and images, via email to our team. This option offers flexibility and is suitable for clinics preferring email correspondence.

For detailed instructions, downloadable forms, and additional resources, please visit our website or scan the QR code below.. If you need assistance at any point, our team is available via phone or email to support you throughout the process

Access order forms and instructions:

unyq.com/help-center

Tips & Care

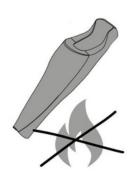




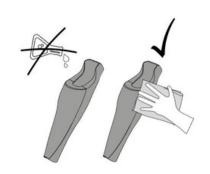


Avoid kneeling on hard surfaces.

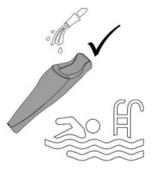
Minimize impacts with hard objects such as cars, tables, or staircases. Additionally, avoid situations where the cover might be dropped or where a fall could result in significant damage to the cover or its paint.



Keep the cover away from sharp or abrasive objects. This includes, but is not limited to, a naked flame, a heat bar, a fire gun or any other heating instrument regardless of the source of heat. The cover and paint are guaranteed to function between -20° C and 50° C (-4° F - 122° F).



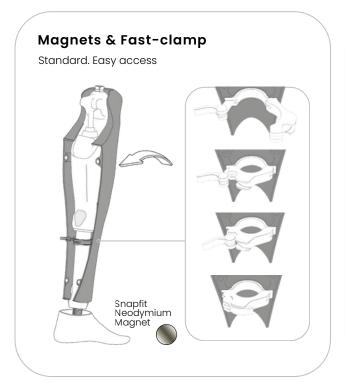
Clean the cover with a soft, damp cloth and dry it with a clean, dry cloth. Avoid using chemical cleaning products.

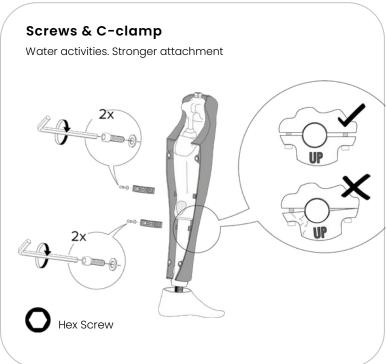


UNYQ covers are waterproof and can be used in fresh or saltwater. After water exposure, dry all metal elements (screws/inserts, magnets) thoroughly to prevent rust and extend the lifespan of your cover.

Assembly

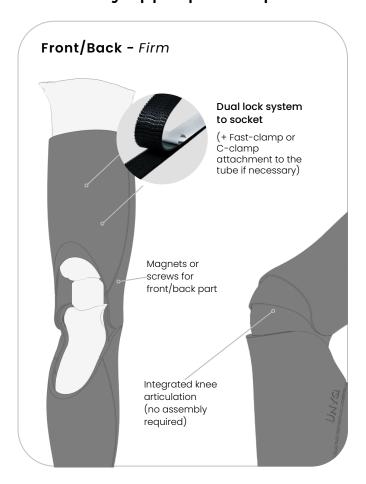
Assembly bottom part: 2 options

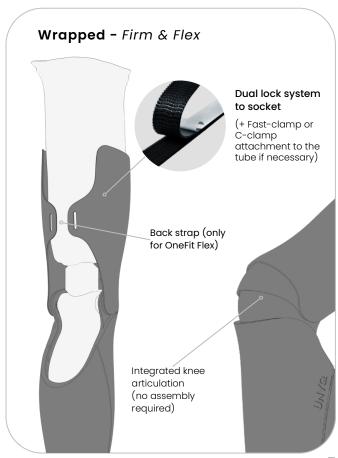




A third attachment option is also available for specific cases where the other two methods are technically not possible: choose C-Clamp to secure the front part of the cover to the tube, and magnets to connect the back part to the front part for an easy and secure closure.

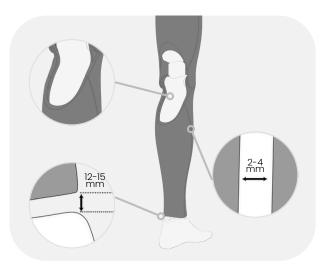
Assembly upper part: 2 options

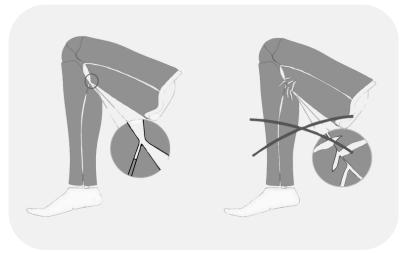




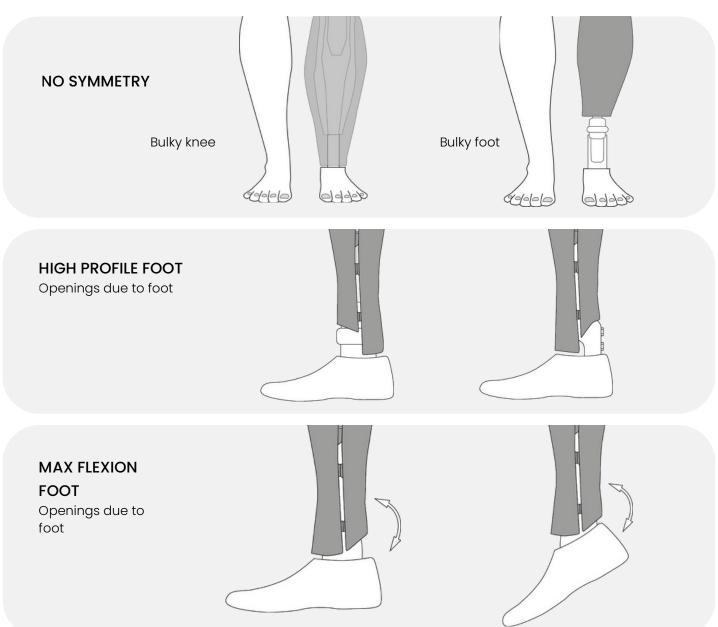
Technical specifications

General specifications



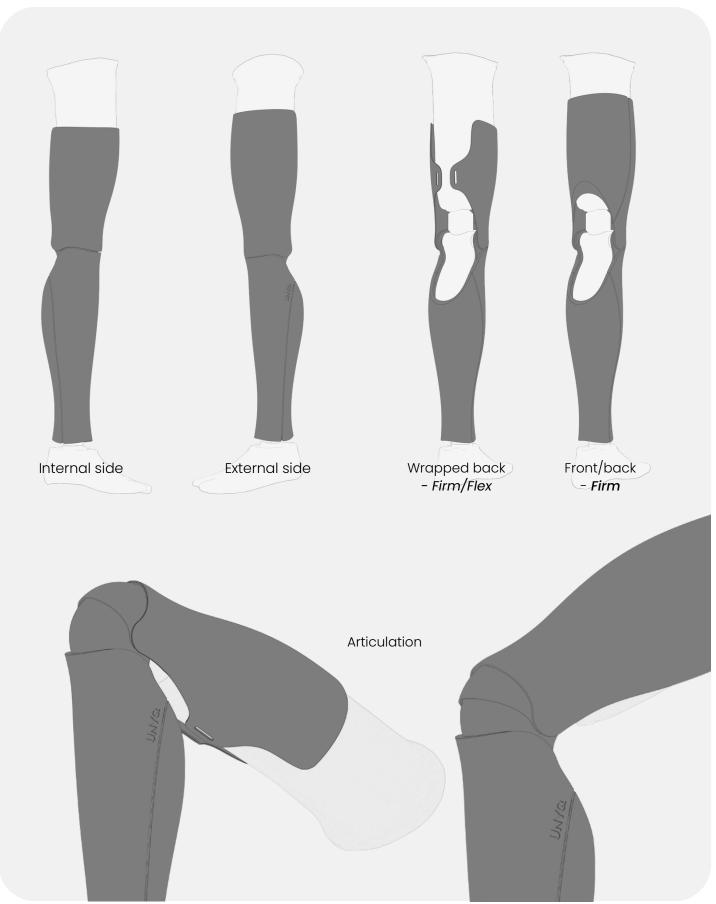


Special prosthetic components



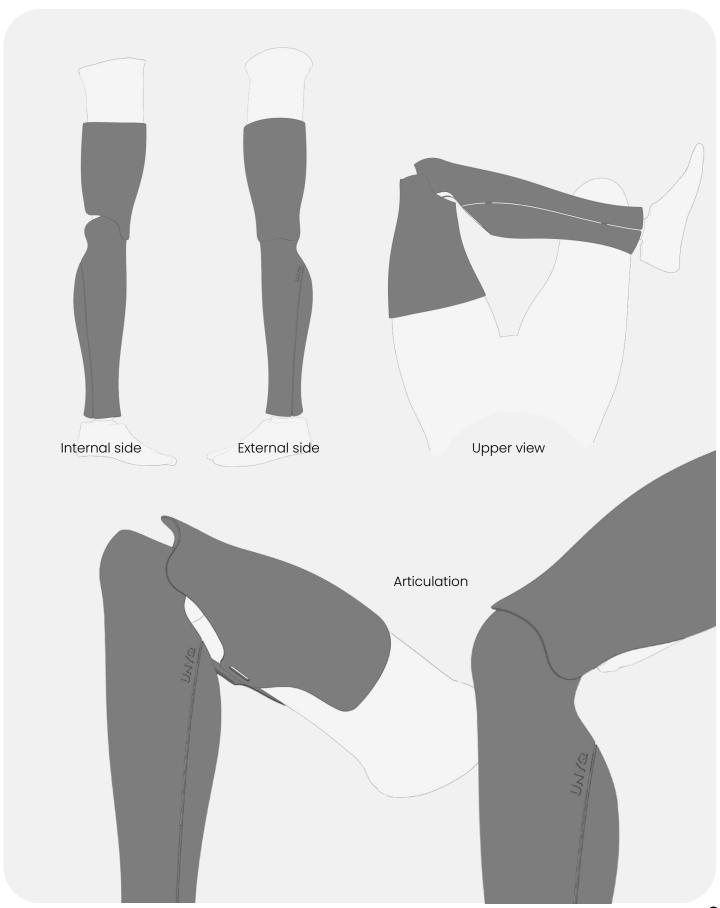
Technical specifications

For prosthesis without rotator adapter



Technical specifications

For prosthesis with rotator adapter



Warranty

General warranty information

At UNYQ, we take pride in the quality and craftsmanship of our prosthetic covers, offering a one-year warranty against defects in materials, production, and workmanship up to the point of delivery. Our covers are designed to protect your prosthetic components while enhancing your personal style, but, like any protective product, they may show signs of wear and tear with daily use.

It's important to note that damages such as scratches, paint wear, or material breakage caused by impacts, friction with abrasive surfaces (e.g., sharp objects, asphalt, or corners), or similar activities are not covered under our warranty. Painting is also excluded from warranty coverage. However, for cases outside of our warranty, we provide a repaint service to help restore your cover's appearance.

To maintain your cover in excellent condition, we recommend using it for everyday activities and avoiding high-impact situations such as sports. For added longevity, consider removing the cover during these activities. By following these guidelines, you can enjoy the durability and style of your cover for years to come.

OneFit: customized product

Our CustomFit and OneFit collections are fully personalized solutions designed to fit your prosthesis and anatomy perfectly. Since these covers are tailored specifically for each user, returns or refunds are not possible once production has started. Before manufacturing, we provide a digital preview for your approval. Any claims will only be accepted if the final product significantly deviates from the approved preview.

Any claims or concerns related to aesthetic customization, such as shape, measurements, volume, colors, or similar aspects not affecting the product's functionality, material defects, or production issues, must be reported to UNYQ within one (1) month of receiving the product. For CustomFit Flex covers, you'll benefit from enhanced impact resistance and durability, ideal for users with active lifestyles. However, while Flex covers are more resistant, they can still experience wear on the paint or surface over time. To maximize the longevity of your cover, we strongly recommend removing it during high-impact activities.

Disclaimer

1. General

- 1.1. General Liability Limitation: UNYQ prosthetic covers are designed to provide protection and enhance prosthetic aesthetics. Their optimal performance depends on proper use as outlined in the care recommendations above. UNYQ is not liable for damages resulting from modifications, misuse, negligence, falls, severe impacts, or other situations beyond its control.
- 1.2. Exclusion Conditions: Cosmetic damages such as scratches, paint wear, friction marks, and breaks caused by impacts or falls are not considered manufacturing defects and are not the responsibility of UNYQ. These are not covered by the warranty.
- 1.2.1. Changes to prosthetic components or their alignment after sending measurements, photos, or scans to UNYQ may affect the functionality and fit of the cover. Such changes are not covered by the warranty.
- 1.2.2. While we make every effort to reproduce our color chart consistently across different platforms and formats (app, website, printed materials, etc.), variations may occur due to the characteristics of individual screens or media. As a result, colors and finishes may slightly differ from the images displayed on your device.
- 1.2.3. Climatic and Chemical Conditions: It is essential to keep the products within the specified temperature range (-20° C to 50° C) and to avoid exposure to chemicals that could damage the materials.
- 1.3. Care Recommendations: Proper maintenance and cleaning are vital to preserving the product's condition. Neglecting these areas may compromise its durability.

2. Custom Covers: CustomFit & OneFit

Custom covers are specifically designed to fit the prosthesis and the end user. Therefore:

- 2.1. They are non-refundable and non-exchangeable once production has started.
- 2.2. A digital preview is provided for approval before production. Claims regarding the product's shape, anatomy, or measurements will only be accepted if there are significant differences from the approved preview. Covers made with Flex material offer greater resistance. However, it is still recommended to remove them during high-impact activities to maximize their durability.
- 2.3. Covers made with Flex material offer greater resistance. However, it is still recommended to remove them during high-impact activities to maximize their durability.
- 2.4. All UNYQ covers may present small tolerances or gaps necessary for functionality and fit.

Customer Service and Assistance

For any questions, support, or assistance with your order or product, our Customer Service team is here to help. Please contact us at:

Email: orders@unyq.com

Phone: +34 854 85 60 92 / +1 415 430 9676

If you need to make a formal complaint, you can access our Claims Form through our UNYQ App or at <u>unyq.com/claimform</u>