

## 1. Foreword

Valid from: 03.03.2026

- Read this document carefully before using the product.
- Follow the warnings and instructions for assembly carefully to avoid product damage.
- Medical personnel should assemble the product.
- Contact the manufacturer if you have any questions about the product (e.g., commissioning, use, maintenance, unexpected operation, or incidents).
- Keep this document in a safe place.

These instructions for assembly provide you with important information on the use, adjustment, and handling of the provided component(s).

## 2. Product

### Product service description

The Lumo Distal Interface is a semi-finished part that can be laminated into the distal section of a prosthetic socket. It allows connecting Lumo Spacers and the Lumo Module Connector.

Macu4's role is limited to supplying the Lumo Distal Interface as a semi-finished component. The professional who is using the semi-finished component is solely responsible for the integration of this component with other materials or parts, the assembly of the complete prosthetic device, and its clinical evaluation and fitting for the end user. In this capacity, the medical personnel acts as the Legal Manufacturer of the final medical device under applicable medical device regulations and assumes full responsibility for regulatory compliance, safety, and performance of the finished device.



### **CAUTION**

## 3. Warnings

FAILURE TO HEED THESE WARNINGS OR TO FOLLOW THE INSTRUCTIONS FOR ASSEMBLY COULD RESULT IN MALFUNCTION OF THE PRODUCT OR PHYSICAL INJURY. IN THE EVENT OF INJURY, SEEK MEDICAL ATTENTION PROMPTLY.

### Notes on unpacking the supplied component

Only open the packaging at the indicated locations with care so that the component inside is not damaged. Inspect the delivered component and be sure that it is undamaged.

### Notes on the lamination process

Make sure that the Lumo Distal Interface does not deform, for example, when you work with high temperatures or high pressures applied to the Lumo Distal Interface.

MAKE SURE THAT YOU DO NOT ADD EXTRA LAYERS OF MATERIAL ONTO OR INTO THE DISTAL AREA OF THE LUMO DISTAL INTERFACE (SEE CHAPTER 5). THIS WOULD AFFECT COMPATIBILITY WITH OTHER COMPONENTS.

### Notes on using the connector

Make sure that you do not weaken the Lumo Distal Interface, for example, when you decide to use cutting or abrasive processes.

### NOTES ON MAGNETS IN THE COMPONENTS

THE PRODUCT CONTAINS MAGNETS (SEE CHAPTER 5), KEEP THE COMPONENT AT LEAST 15 CM / 6 IN AWAY FROM E.G. PACEMAKERS OR DEFIBRILLATORS. IF THE MAGNET COATING IS DAMAGED, STOP USING THE PRODUCT IMMEDIATELY.

#### 4. Approach

##### Material needed

Lumo Distal Interface	Lumo Distal Interface with Lumo Adapter Pin
Additional equipment required (not provided)	Protective/sealing material for the distal area

##### **Example to illustrate how to use the Lumo Distal Interface**

###### Preparation of the positive model

- Create a positive model of the stump and add the required length compensation. Consider the length of the module and the socket connector.

###### Preparation of the Lumo Distal Interface

- Make sure that no material will enter the distal area of the Lumo Distal Interface. Use of protective/sealing material if required.

###### Application of the Lumo Distal Interface

- Mount the Lumo Distal Interface to the model and control alignment and length compensation. It is critical that this component is precisely aligned, as it dictates the orientation and connection of the other components.

###### Application of carbon fibers

- Place the first layer of unidirectional carbon fibre around the model and Lumo Distal Interface.
- The circumferential grooves on the Lumo Distal Interface ensure reliable mechanical anchoring in the laminate.
- The carbon is optimally pressed into the grooves by tightly wrapping two or more cords around it. This results in a form-fit and secure integration.

###### Application of textile covers

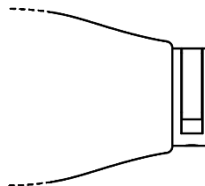
- Add layers of fabric and secure each of them around the socket connector using a tie or band.

###### Resin Impregnation

- Impregnate the resin with a vacuum bag and let it cure.

###### Final Cleaning

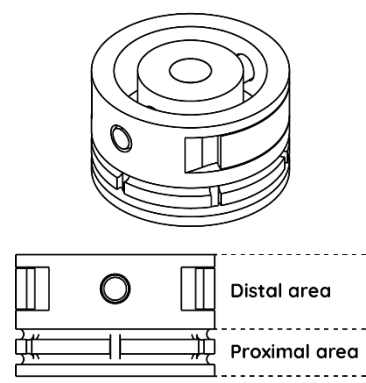
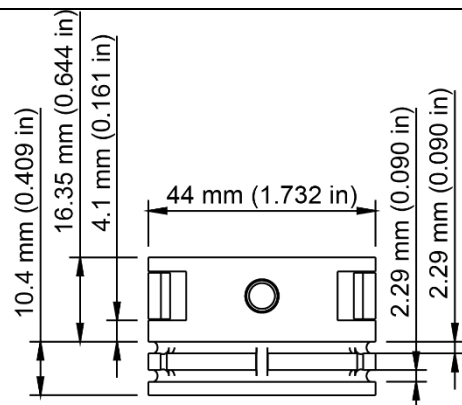
- Clean the distal part of the Lumo Distal Interface.
- Confirm the functionality by connecting a Lumo Spacer or Module Connector.
- If inserting or operating the element is difficult, further cleaning is required.
- Apply adapted cushioning and a closing mechanism.



Note: The illustrations provided are for indicative purposes only and may not be to scale.

**Please refer to the Instructions for Use of the Lumo System for further indications.**

## 5. Technical data

General	
Drawing	
Dimensions	
Net weight	approx. 25 g / 0.88 oz
Material of printed component	Module body: PA2200, coloured with DM standard colour (DyeMansion)
Magnet element	Material: Neodymium-iron-boron (NdFeB), grade 52, Nickel-copper-nickel coating. Dimensions: Ø 9 mm (0.35 in) × 3 mm (0.12 in), tolerance ±0.1 mm (± 0.004 in)
Lifetime of the 3D printed component	2 years at an average of 120 minutes per day of daily use on the 3D printed socket component

## 6. Legal notice

### Limitation or exclusion of liability

Failure to follow these instructions for use, care, maintenance, handling, storage, etc., of this product, or the use of this product in any component combination other than those approved by macu4 AG (hereinafter referred to as “Macu”) constitutes misuse of the product and invalidates any and all warranties, express or implied, in their entirety as to any consequences of such misuse. In the event of such misuse, Macu disclaims liability for any adverse consequences to the maximum extent allowed by law. Any opening, disassembly, or repair of the products may only be carried out by Macu or with Macu’s written permission.

### Manufacturer of the semi-finished component

Macu4 AG, Rämistrasse 3, 8001 Zürich, Switzerland

### Trademark

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absence of explicit identification of the trademarks used in this document does not imply that a designation is free of third-party rights.

**7. Environmental conditions**

Conditions	
During transport	<ul style="list-style-type: none"><li>• Protect from direct sunlight (UV radiation)</li><li>• Temperature shall be 0 °C to +35 °C / 32 °F to 95 °F</li></ul>

**8. Allergic reactions**

THIS PRODUCT IS FORMULATED FOR GENERAL SKIN COMPATIBILITY. HOWEVER, ALLERGIC REACTIONS MAY OCCUR IN SOME INDIVIDUALS, PARTICULARLY THOSE WITH A HISTORY OF SKIN ALLERGIES OR SENSITIVITY. THE PRODUCT COMPONENTS MUST NOT BE USED IF THE INDIVIDUAL HAS A KNOWN ALLERGY OR HAS PREVIOUSLY EXPERIENCED A REACTION TO ANY OF THE MATERIALS USED IN THIS PRODUCT. DISCONTINUE USE IMMEDIATELY AND SEEK MEDICAL ADVICE IF REDNESS, ITCHING, RASH, SWELLING, OR IRRITATION OCCURS. INDIVIDUALS WITH SENSITIVE SKIN SHOULD REVIEW THE FULL LIST OF MATERIALS AND, IF NECESSARY, PERFORM A PATCH TEST BEFORE FIRST USE. FOR DETAILED INFORMATION ON THE MATERIALS USED IN SPECIFIC PRODUCTS, PLEASE CONTACT MACU. THE TECHNICAL DATA SECTION PROVIDES GENERAL INFORMATION ON MATERIAL USAGE ONLY.

**9. Returns**

If you suspect or believe there is a problem with the semi-finished component, please first read this manual carefully before contacting [support@macu4.com](mailto:support@macu4.com).

Please use the Product Experience Report (PER): [https://25462115.fs1.hubspotusercontent-eu1.net/hubfs/25462115/mac4\\_AG\\_Lumo/Product%20Experience%20Report\\_P03\\_EN.pdf](https://25462115.fs1.hubspotusercontent-eu1.net/hubfs/25462115/mac4_AG_Lumo/Product%20Experience%20Report_P03_EN.pdf)