

1. Foreword

Valid from: 15.11.2025

- Read this document carefully before using the product.
- Follow carefully the warnings and instructions for assembly 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 Lynk Interface is a semi-finished part which can be integrated into a custom-made orthosis or prosthetic socket. It must be only used together with Lynk Modules.

Our role is limited to supplying the Lynk Interface as a non-finished component. The medical personnel are 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 READ 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 PROMPLY.

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 Lynk Interface does not deform, for example, when you work with high temperatures or high pressures applied to the Lynk Interface.

Make sure that no resin can enter the Lynk Interface. If resin does get inside, it may become difficult or even impossible to remove the dummies. In addition, resin contamination can affect the operation of the modules and may render the Lynk Interface unusable.

Seal not only the entry slits but the entire interior of the Lynk Interface. The sealing compound must cover the entire inside surface of the Lynk Interface. Examples for sealing compounds can be found in the next chapter under "Required material".

Notes on using the connector

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

Do not expose the Lynk Interface to heat or pressure. Excessive heat or mechanical stress can cause deformation of the Lynk Interface, which may result in an unusable end product.

Make sure that no material remains inside the Lynk Interface before using it together with a Lynk Module.

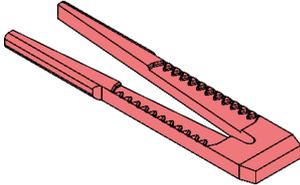
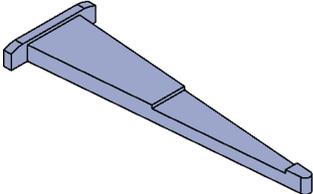
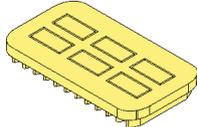
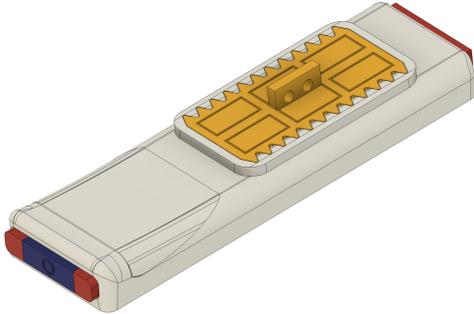
4. Approach

Required material

Interface	1x assembly material set (content: 1x Interface for lamination, 3x Interface dummies)
Additional materials needed on behalf of medical personnel	Sealing compound / wax / grease e.g. grease, silicone spray, Stick Wax

Lynk Interface Dummies

The dummies serve to protect the integrity of the Lynk Interface. There are 3 types of dummies that shall be used.

Part 1.1 – Dummy A Used to be inserted from the distal end	Part 1.2 – Dummy B Used to be inserted from the distal end into the Dummy A	Part 2 –Dummy C Used to be inserted from the top
		
Lynk Interface assembled with Dummies		

Example to illustrate how to use the component

The present steps below illustrate an example of lamination with acrylic resin and unidirectional carbon fibres. The photos are used for illustration.

Preparation of the model

- Create a plaster cast of the limb. The limb shall stand in the desired position.
- Place the first layer of foil around it.
- Create a base layer. Here, a white fabric hose is used. It serves to prevent direct skin contact with the carbon fibres.



First application of carbon fibres

- Place the first layer of unidirectional carbon fibre.
- Define the desired orientation of the Lynk Interface. An inserted plate or a Lynk module may help imagine the final result.



- Use some material such as plaster or silicone paste (Sheraduet) to create a small flat area.
- Consider that the modules have enough space to be inserted and removed from the Lynk Interface without colliding with the rest of the orthosis.

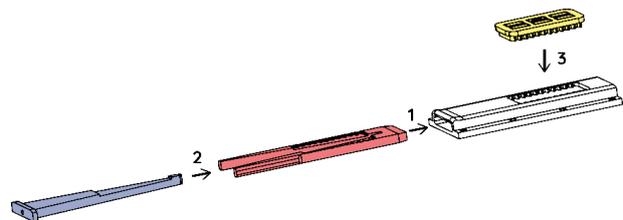


Warning: Pay attention to the direction of the orientation of the Lynk Interface. The proximal side needs to face the proximal side of the forearm model.

Usage of the Dummies

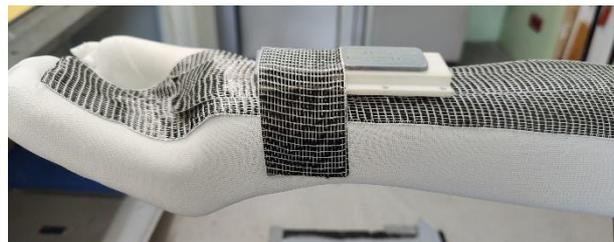
- Apply the sealing compound inside the interface, ensuring that all walls are fully covered. Cover all dummies in the sealing compound. For Dummy C, fill all cavities completely with the sealing compound. Press the dummies firmly into the Lynk Interface, following the specified insertion order, and remove any excess sealing compound that emerges from the slits.

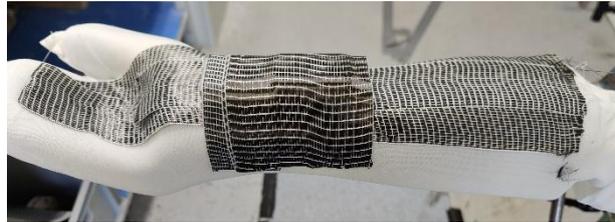
Warning: If the sealing is not done properly, resin may enter the Lynk Interface. Even small amounts of resin on the Lynk Interface walls can alter the geometry or surface properties, making it impossible to use. Ensure that all openings and internal surfaces are completely sealed before proceeding.



Second application of carbon fibres

- Apply stepwise the required layers of carbon fibres.





Usage of resin

- Pour resin between the two foils. Here, blue acrylic resin is used.



Hardening of material

- Let it harden the material. For acrylic resin, about one hour shall be considered. Please refer to the instructions for the material you are using.

Removal of dummies

- Grind free the distal opening in which Dummy A and B have been inserted and the opening for Dummy C.
- First, remove Dummy C by pulling it out.



- Remove the Dummy B. There is a small hole in the middle. Break the bottom of the hole and screw in the provided M3 screw, and pull on it.



- Remove Dummy A. It has a V-shape and this allows you to press the V-edges slightly together. This will help you to remove Dummy A. A sharp or pointy object, like a screwdriver, can be used.



Final cleaning

- Clean the Lynk Interface from residual wax. Cleaning the Lynk Interface is crucial and required to ensure compatibility with the Lynk Modules.

Testing

- Confirm the functionality by connecting a Lynk Module.
- If inserting or operating the module is too difficult, further cleaning of the channel of the Lynk Interface is required.

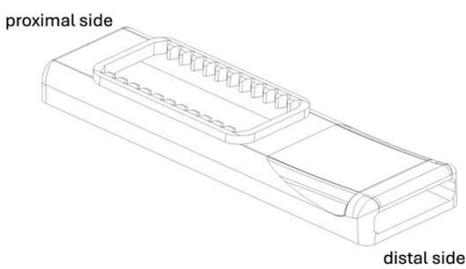
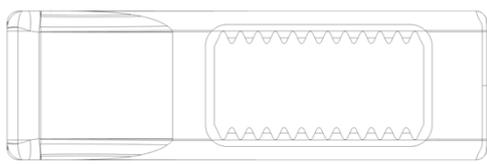


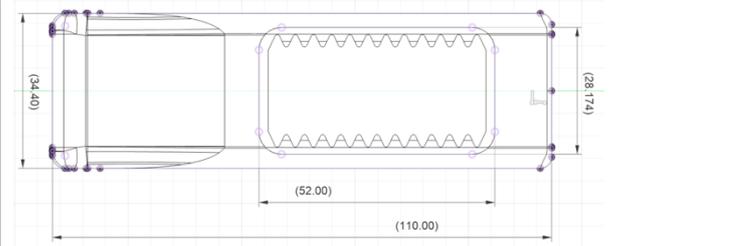
Completion

- Smoothen the grinding locations to prevent sharp edges.
- Apply adapted cushioning and a closing mechanism.



5. Technical data

General	
Drawing (overview)	 <p>proximal side</p> <p>distal side</p>
Drawing (front)	
Drawing (side)	
Drawing (top)	

Dimensions (bottom)	
Dimension (side)	
Net weight	Between approx. 30 g / 1.05 oz
Material of printed component	Module body: PA2200, coloured with DM standard colour (DyeMansion)
Lifetime of the 3D printed component	2 years at an average of 120 minutes per day of daily use on the 3D printed 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 GmbH, Bücklestrasse 3, 78467 Constance, Germany

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7. Environmental conditions

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

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. Please use the Product Experience Report (PER):

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