

1. Foreword

Valid from: 25.08.2025

- 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 Explorer distal socket interface is a semi-finished part which can be laminated into the distal section of a prosthetic socket. It is provided with a Nut (M12x1.5 or ½-20” thread) which allows to connect terminal devices that are provided with a screw (M12x1.5 or ½-20” thread).

Our role is limited to supplying the distal socket interface as a non-finished component. The medical personnel 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 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 distal interface does not deform, for example, when you work with high temperatures or high pressures applied to the distal interface.

Notes on using the connector






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




4. Approach

Material needed

Distal interface	1x assembly material set (content: Nut cap, Nut M12x1.5 or ½-20”)
Additional materials needed on behalf of medical personnel	Sealing compound / wax

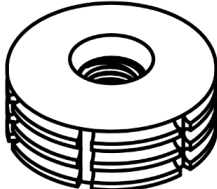
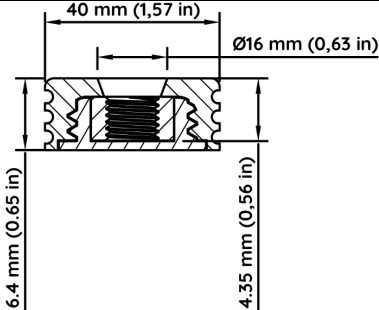
Example to illustrate how to use the distal interface

<p><u>Preparation of the positive model</u></p> <ul style="list-style-type: none"> • Create a positive model of the stump and add the length compensation. Consider the size of the module and the socket interface. • Make sure that the distal part is an aligned flat surface in the size of the socket interface. 	
<p><u>Preparation of the distal socket interface</u></p> <ul style="list-style-type: none"> • Make sure the threading of the socket interface is according to the threading of the used modules. • Seal the distal socket interface so that no resin can enter the screw thread. 	
<p><u>Application of the socket interface</u></p> <ul style="list-style-type: none"> • Mount the socket interface to the model and check for alignment and length compensation • It is critical that this component is precisely aligned as it dictates the orientation and connection of the entire prosthesis. 	
<p><u>Application of carbon fibres</u></p> <ul style="list-style-type: none"> • Place the first layer of unidirectional carbon fibre around the model and around the socket interface. • The circumferential grooves on the 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. 	
<p><u>Application of textile covers</u></p> <ul style="list-style-type: none"> • Add layers of fabric and secure each of them around the socket interface using a tie or band. 	

<p><u>Resin Impregnation</u></p> <ul style="list-style-type: none"> • Impregnate the resin with a vacuum bag and let it cure 	
<p><u>Final Cleaning</u></p> <ul style="list-style-type: none"> • Grind free the distal socket interface and clean the residual wax • Confirm the functionality by connecting an Explorer module using an Explorer Ring STD. • If inserting or operating the module is difficult, further cleaning of the socket interface is required. • Smoothen the grinding locations to prevent sharp edges. • Apply adapted cushioning and a closing mechanism. 	
<p><u>Completion</u></p> <ul style="list-style-type: none"> • Smoothen the grinding locations to prevent sharp edges. 	

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

5. Technical data

<p>General</p>	
<p>Drawing</p>	
<p>Dimensions</p>	
<p>Net weight</p>	<p>Between approx. 28 g / 1 oz</p>

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 socket component
Material of the Nut	Stainless steel A2
Dimensions of the threading	Metric: M12x1.5 Inch: ½-20"

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 GmbH (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

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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):

https://25462115.fs1.hubspotusercontent-eu1.net/hubfs/25462115/mac4_GmbH_Explorer/Product_Experience_Report_EN.pdf