macu4 | Assembly Instructions

Customized Explorer socket design for socket fitting

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

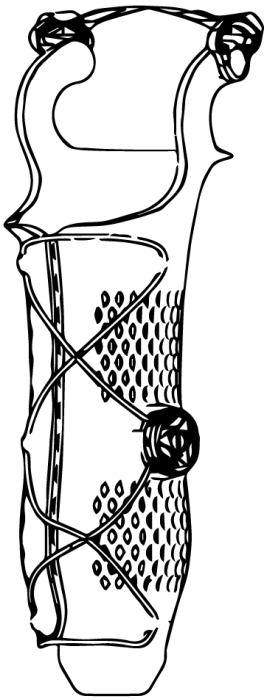
The 3D design of the Explorer Socket shell is generated exclusively on the basis of measurement data and technical specifications provided by qualified medical personnel. It can be used to fit a prosthetic socket.

Our role is limited to supplying the 3D-printed Explorer Socket shell 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.

Combination possibilities

The Explorer Socket has been tested for combination possibilities with the Explorer modules. For other combination possibilities, the specialist must check on their own responsibility whether the combination with the Explorer Socket is possible.

Design principle



Velcro Loops

Condyle Clips

Lacing system knob (here referred to as Atop)

Distal section which contains the Nut

Note: The scale is not respected compared to the other elements.

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 using the socket
Make sure that the lay user understands and is instructed by you

- does not overload the socket,
- cleans the socket after each use,
- removes visible dirt particles so that it is not restricted in its function,
- inspects the socket before each use to make sure that it does not show any visible damage

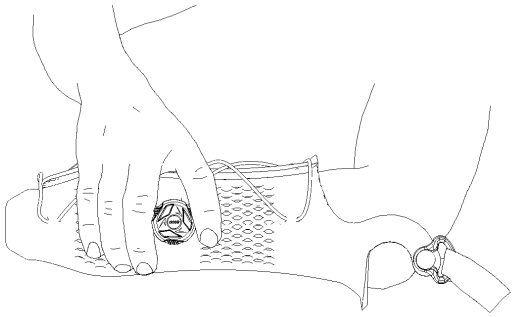
Notes on proper handling of the Socket
Improper handling may restrict the socket's function or render it inoperable.
The 3D-printed socket is made of polyamide 12; mechanical stability may be compromised if recommended environmental conditions are not observed.

Notes on using the Socket together with the Explorer Ring
Make sure that the lay user always uses the Explorer Ring EXP together with the Socket. Not using the Explorer Ring may lead to damage to the distal section of the Socket, which contains the Nut.

Notes on using the socket with protective material
Make sure that the lay user uses the socket with a protective insert, prosthetic sock, or liner. The lay user shall not use the socket if the lay user feels that it no longer fits comfortably in terms of length, circumference, or due to pressure points. If the lay user's arm has changed in shape, circumference, and/or length since custom fabrication, the fit of the socket may no longer be optimal. Be sure that the socket encloses your arm appropriately.

Notes on putting on the socket
Make sure that the lay user understands and is instructed by you

- The lacing system must be unlocked. To easier insert the arm, press the sides of the socket slightly outwards – it increases the width as needed,
- The socket must be positioned in a specific orientation on the arm,
- The Atop always points laterally.

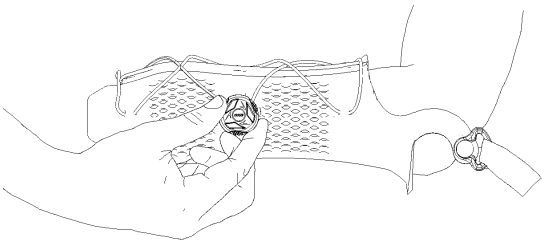


Notes on the lacing system
Make sure that the lay user understands and is instructed by you

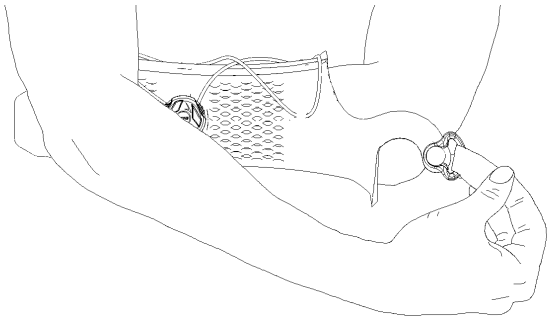
- The Atop must not become entangled with nearby objects (e.g., nets or ropes), as this may unintentionally release the Atop and loosen the socket's fit,
- The socket should not be used if the lacing system is malfunctioning (i.e., if the laces cannot be tightened or loosened),

- The system is properly functioning, including complete tightening and subsequent loosening performed by turning the Atop in the opposite direction and sequentially pulling the protruding ropes,
- Only little force is required to operate the Atop (lacing system knob). The lay user must not turn the Atop abruptly or with excessive force in either direction (clockwise to tighten or counterclockwise to loosen), as this may damage the mechanism.

Notes for putting on the socket
Both the lacing system and the locking mechanism — whether condylar clips or an internal bandage support — must be securely engaged to ensure a stable fit.



When the arm is comfortably positioned in the socket, the Atop shall be turned clockwise to tighten the lacing system. The user shall turn until the socket fits snugly on the arm. The fit of the socket on the arm should be snug but not uncomfortable.



Avoid a too-tight lacing that squeezes the tissue of the user's arm in the area of the crook of the arm. Use the Velcro to close the socket at the back and above the user's elbow. This will give a tighter fit.

Notes on the condylar clips with Velcro strap
Make sure that the lay user understands and is instructed by you:

- The condylar clips are never in contact with objects that could snag or obstruct them, such as nets or tightly woven rope structures, during activity.

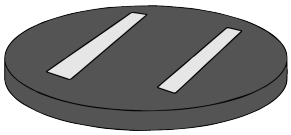
Notes on taking off the socket
Make sure that the lay user understands that both the lacing system and the locking mechanism of the condylar clips are opened or loosened. Both serve to ensure that you can easily remove the socket.

4. Assembly

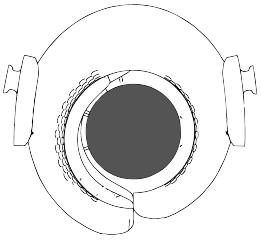
Material needed

Accompanying assembly material	1x assembly material set (content: Self-adhesive Velcro, Velour strap with Velcro, Lacing system knob, Lace (Dyneema))
	1x print template of a stencil used as cutting template for the protective material used in the proximal socket section
Additional materials needed on behalf of medical personnel	Protective material for the Socket Shell
	Any other material on a custom-based level
Required tools	Tool to cut the protective material (e.g., scissors suitable for cutting fabrics)
	Textile pencil with white lead/chalk to draw on the padding material
	Tool to cut the printout of the stencil (e.g., scissors suitable for cutting paper)
	Tool to cut the Lace (e.g., cutter)

Place protective material (distal section)
Use a padding disc to pad the distal end of the socket from the inside. Be sure that it provides the lay user with a sufficiently high wearing comfort.

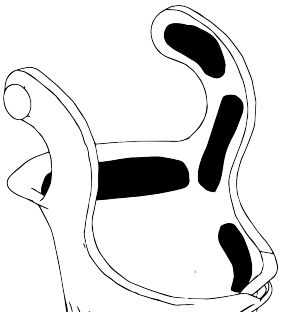


For example, attach two pieces of self-adhesive Velcro to the outer edge of the disc. Make sure that neither glue nor adhesive foil touches the center of the disc. This central area is in contact with the hexagonal opening of the Nut Cap, which covers the nut.

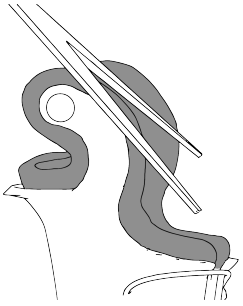


The nut's thread must remain completely free of glue, adhesive residues, or hardening resins, as these could block the thread. Position the disc inside the socket and make sure that the disc remains in the desired position.

Place self-adhesive and padding material (proximal section)

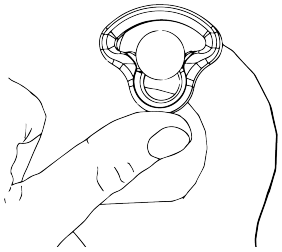


Clean the surface of grease residues. Attach the self-adhesive Velcro in the proximal part of the socket so that you can secure compatible padding material to it. If needed, cut the self-adhesive Velcro smaller.

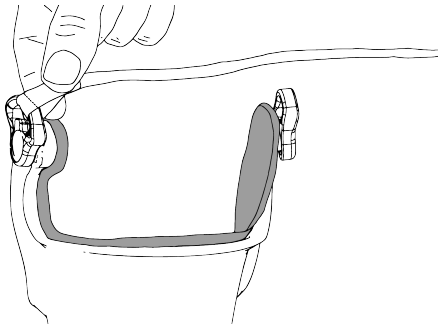


Use the cutting template of the stencil and cut the padding material accordingly. Insert it about 3 cm / 1.2 in into the socket and unfold it gradually so that it is fixed along the proximal edges and the condylar brace. Trim those areas that do not yet correspond well enough. Make sure that the material overlaps the socket edge by up to 1 cm / 0.4 in.

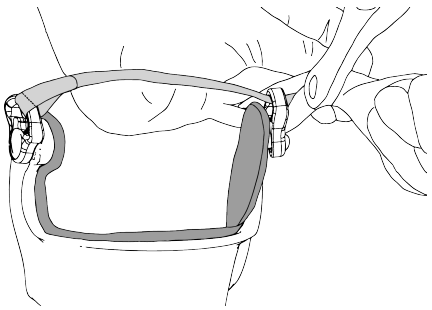
Mount the Velcro loops and Velcro strap



Press one Velcro Loop at a time onto the designated spot on the condylar brace. Occasionally, you may need to press a Velcro loop harder to slide it over the corresponding nub. Make sure that you do not overload the condyle clip. If you overload it, it can break.

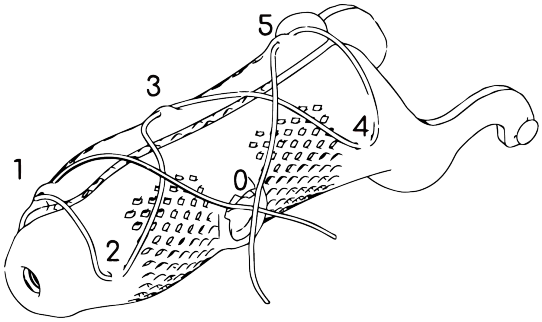


Pass the end of the Velour Strap through the Velcro Loop of the medial condyle clip towards the inside of the socket. Confirm that the Velcro is correctly in place.

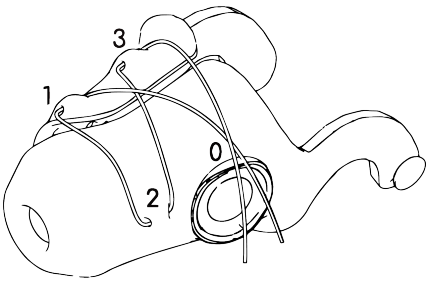


Pass the other end of the Velour Strap through the Velcro Loop of the lateral condylar brace. Cut it off directly at the level of the Velcro loop.

Mount the lace

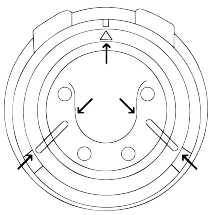


Example for a socket with 5 guide channels: Insert the string into guide channel #1. Guide the string step by step, as shown in the diagram, to the last guide channel #5. A larger socket has up to 5 guide channels. Note that the ends of the string meet at point 0.

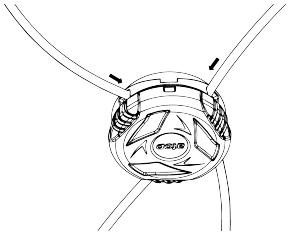


Example for a socket with 1 to 3 guide channels: Insert the string into guide channel #1. Guide the string step by step to the last guide channel #3 as shown in the diagram. A smaller socket has 1 to 3 guide channels. Note that the ends of the string meet at point 0.

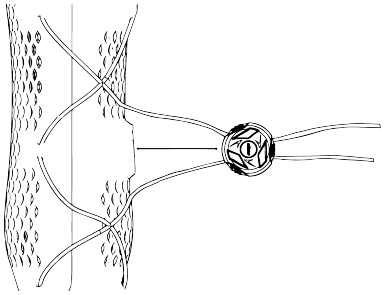
Connect the laces to the Atop



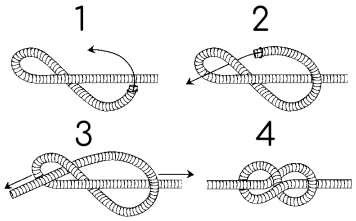
Align the cable channels of the Atop so that the two cord ends can be inserted. To make this easier, there are lines and an arrow on the bottom of the Atop.



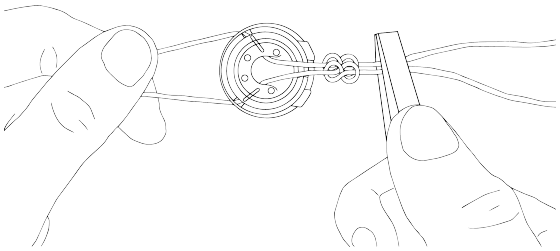
Insert one end of each cord over the outside into the respective cable duct. The cord end should come out on the inside or underside of the 'atop'. Be sure to insert the cords into the correct holes by holding the ‘atop’ against its base in the socket, checking which cord end goes to which hole.



Lay the string from guide channels #1 and #5 (in the case of a socket with 5 guide channels) to the Atop and stretch it about 7cm further each to find the place where the knot is to be made.

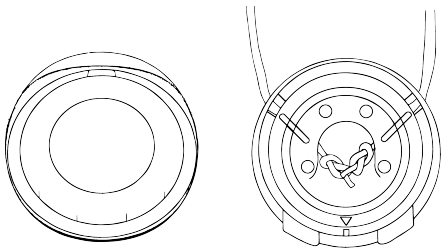


Make a figure-eight knot in each of the ends of the cord. Tighten this very tightly, e.g., with a pair of combination pliers. Choosing the right knot is important because Dyneema is very slippery, and other knots could come loose.

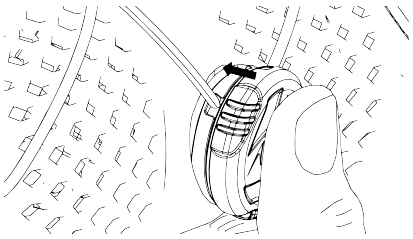


Use combination pliers to grab the respective loose ends of the Atop Laces. Use your other hand to grab the long end of the Laces sticking out of the Atop. Now tighten the two knots individually or simultaneously. Cut off the excess end of the cord.

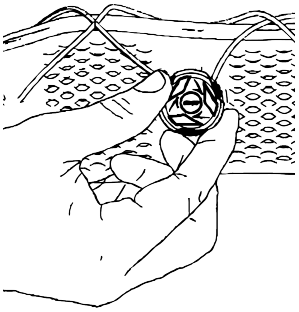
Make sure that the cut end is not too short to avoid loosening the knot. If necessary, use heat to seal the figure-eight knot.



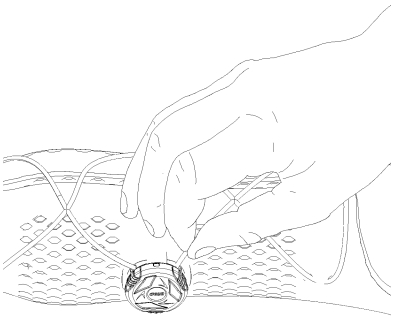
The Atop has two recesses that branch away from the Laces and one recess that points towards the laces. The Atop itself has one protruding edge on the side through which you have inserted the Laces and two protruding edges on the opposite side.



Anchor the Atop in the base position of the socket. First, push the two protruding edges of the Atop into the recesses provided. Then press the entire Atop into the atop base.



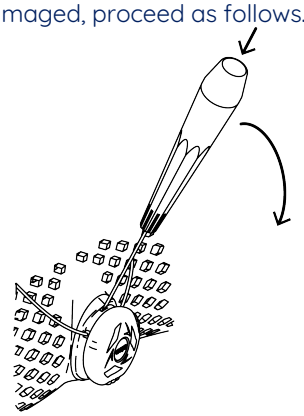
Be sure that the lacing system is working properly by turning the Atop softly to the right to tighten the lacing and then by turning softly the Atop to the left.



Pull gently on the Laces to loosen them.

Disconnect the Atop

If you need to remove the Atop, for example, if the length of the Lace should be adapted or the lacing system is damaged, proceed as follows.



- Use a flat-blade screwdriver.
  Place the tip in the hole as illustrated.
- Gently lever the screwdriver downward while applying slight inward pressure on the Atop to release it.
- The Atop should jump out.

Once the Atop is disconnected, cut the eight-knots out and remove the lace, or adjust the length. If the Atop or the lace shall be replaced, reassemble according to the previously described assembly procedure.

5. Technical data

General	
Net weight (without lacing system, screw nut, and padding materials)	Between approx. 28 g / 0.99 oz (relatively smaller socket) and 100 g / 3.53 oz (relatively larger socket)
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
Material of the Nut	Stainless steel A2
Dimensions of the threading	Metric: M12x1.5 Inch: ½-20”
Lifetime of the Atop lacing system	1 year at an average of 120 minutes per day of daily use

Maximum load forces in the coupling interface	
Axial tension and compression force	Approx. 250 N / 56.20 lbf
Bending moment around the socket axis	Approx. 5 Nm / 44.25 in-lb
Bending moment normal to the socket axis	Approx. 10 Nm / 88.50 in-lb

6. Storage of the Products

To ensure user safety and maintain the functionality of the product, please observe the following instructions:

- After use, the product must be stored in a clean, dry, and secure place — out of the reach of children, unless used under direct supervision.
- The product must be kept away from areas where it could be mixed with other objects or handled improperly.
- The product must be protected from dust, dirt, and mechanical impacts.
- Storing the product in places with strong temperature fluctuations or high humidity must be avoided.

7. Care of the Products

- Removing dirt particles: Use a soft-bristled brush to remove dirt from the spaces between the product components. Do not use water for this step.
- Clean surfaces: Wipe the component surfaces with a damp, non-scratching cloth. Use only cold or lukewarm water.
- Disinfection (if necessary): If disinfection is required, use a material specifically suitable for medical devices (risk class I, plastic materials).

- Important: Never place the component in a cleaning machine or any other appliance (washing machine, dishwasher, microwave, steamer, or similar).

8. Adverse event reporting

Any serious incident related to the device should be reported to the manufacturer. Please use the form Please use the Product Experience Report (PER) https://25462115.fs1.hubspotusercontent-eu1.net/hubfs/25462115/macu4_AG_Explorer/Product_Experience_Report_EN.pdf and send it to by email to support@macu4.com.

9. 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 18, 8001 Zurich, Switzerland

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10. Environmental conditions

Conditions	
During transport	• Protect from direct sunlight (UV radiation) • Temperature shall be 0 °C to +35 °C / 32 °F to 95 °F
During operation	• Temperature shall be 0 °C to +35 °C / 32 °F to 95 °F
When not in use (e.g., long-term storage)	• Protect from direct sunlight • Max. 70 % relative humidity

11. 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.

12. 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/macu4_AG_Explorer/Product_Experience_Report_EN.pdf