macu4™ | Instructions for use
Lynk System

1. Foreword

Valid from: 15.08.2025

- Read this document carefully before using the product.
- Follow carefully the warnings and instructions for use to avoid injuries and product damage.
- Medical personnel should instruct the lay user on the proper and safe use of the product.
- Contact the manufacturer if you have any questions about the product (e.g., commissioning, use, maintenance, unexpected operation or incidents). You will find the contact details on the back.
- Keep this document in a safe place.

These instructions for use provide you with important information on the use, adjustment and handling of the system. **Please notice that in addition to this Instructions for use, there are several explanation videos available. See https://macu4.com/en/application-lynk.**

2. Use

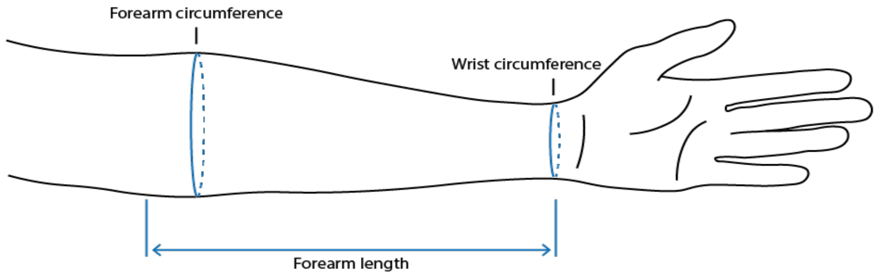
Intended Use
The Lynk System is intended for persons with partial or complete loss of function of the hand due to temporary or permanent weakened hand or hand injury, paralysis, partial hand absence or wrist disarticulation absence. By using the Lynk Cuff with the appropriate accessory, a lack of gripping dexterity, capability or force can be replaced or supported.

Indications

- The system is suitable for persons with impaired or missing gripping function.
- The Ortho-Prosthetic system can be used for people with unilateral congenital hand deficiencies or amputation immediately above the wrist (according to ISO 8548-2:2020) and, depending on the arm stump shape.
- The system is suitable for persons two years and older. An individual evaluation by the specialist is recommended to assess whether the user is physically and mentally in the condition to use the system properly.

Contraindications

- Not indicated for persons under two years of age. Exceptions: The professional (e.g. doctor, therapist, orthopaedic technician) can assess whether the user is able to use the system anyway.
- Not indicated for persons with bilateral forearm deficits. Exceptions: The specialist (e.g. doctor, therapist, orthopaedic technician) can assess whether the user is able to use the system partially despite this.
- Not for persons with mental and/or psychological conditions that would not allow for, or only partially allow for, the indicated use of the Lynk system (e.g. dementia, Alzheimer's, psychoses, and similar diseases)
- Not for persons for whom the Lynk system is expected to place too much mechanical stress on adjacent joints due to the indicated user requirements.
- Not for persons with neurological diseases in which learning movements using the Lynk system is impaired.
- Not for individuals with fresh wounds, allergies or sensitive skin on the arm.
- Not for individuals with a forearm circumference of more than 330 mm (12.99 in), a wrist circumference of less than 110 mm (4.33 in) and a forearm length of less than 140 mm 5.51 in).



Anthropometric values definition.

Combination possibilities
The system has been tested for combination possibilities of the Lynk Cuff with the different Lynk modules. When using the Lynk Cuff and to achieve an improved hold on the forearm by an additional upper arm connection, the professional has to check on his own responsibility if the combination possibility is given. When using the Lynk Interface as a semi-finished part for a self-manufactured orthosis or cuff, the specialist must check on his/her own responsibility whether it can be combined. For a cuff other than ours, the specialist must check on his/her own responsibility whether it can be combined with the Lynk modules.

CAUTION

3. Warnings

FAILURE TO HEED THESE WARNINGS OR TO FOLLOW THE INSTRUCTIONS FOR USE COULD RESULT IN MALFUNCTION OF THE DEVICE OR PHYSICAL INJURY. IN THE EVENT OF INJURY, SEEK MEDICAL ATTENTION PROMPLY.

Operating conditions
Please note that the system is intended exclusively as a medical aid. It is not suitable as a tool and must not be used for other purposes.
The system was specifically developed for everyday, sports, and leisure activities involving low to moderate physical stress. The system must not be used for exceptional activities. Such exceptional activities include, for example, sports with excessive coupling and/or impact loads (push-ups, downhill or mountain biking, etc.) or extreme sports (free climbing, paragliding, etc.).
Furthermore, the system should not be used for operating motor vehicles, heavy machinery (e.g., construction equipment), industrial machines, motor-driven work equipment, or devices with an increased risk of injury—including, but not limited to, firearms, chainsaws, or hedge trimmers
Always avoid direct contact between the product materials and food. Do not put the product in your mouth.

Operating conditions – Push Module
To achieve the highest safety level, the Push Module was tested mechanically based on the *EN ISO 11334-1:2007 Assistive products for walking manipulated by one arm - Requirements and test methods - Part 1: Elbow crutches*. According to the requirements of the above mentioned ISO, the use of the Push Module to support the walking with crutches is limited to a maximum body weight of 65kg (143.3 lb). A higher body weight in combination of the above mentioned operating condition will potentially lead to material deformation, inducing instability at the interface between the module of the crutch. Specialists should contact support@macu4.com for further information.

Operating conditions – Clic Lock Module
ALWAYS MAKE SURE THAT YOU DON'T USE THE CLIC LOCK PLUG IN ACTIVITIES THAT INVOLVE A VEHICLE SUCH AS A SCOOTER, BICYCLE, WALKER (WALKING FRAME), AND OTHER MEANS OF TRANSPORT. THE CLIC LOCK PLUG IS DESIGNED TO LOCK THE RELEASE MECHANIMS BETWEEN THE CLIC LOCK ADAPTER AND A CLIC LOCK HEAD.
ALWAYS MAKE SURE THAT THE GRIP OF THE CLIC LOCK HEAD IS NOT EXCESSIVELY TIGHT WHEN USING THE CLIC LOCK PLUG. IF THE GRIP IS TOO TIGHT, THE MODULE MAY NOT RELEASE QUICKLY ENOUGH FROM, FOR EXAMPLE, THE HANDLEBAR OR A ROD IN CASE OF EMERGENCY SITUATIONS, SUCH AS IF THE USER NEEDS TO QUICKLY DECONNECT FROM THE ROD.

Notes on unpacking the supplied components
Only open the packaging at the indicated locations with care so that the components inside are not damaged.

General
Carefully inspect your product components before use to ensure that no component is damaged. Always contact support@macu4.com and do not use the component if you suspect or believe, for example, that:

- a component is damaged.
- a component is not suitable for a specific activity.
- a module cannot be inserted easily into the Cuff or Interface insertion slot.

- a module unintentionally detaches from the Cuff or Interface insertion slot
- the Velcro or Lacing closure is not working properly or releases unintentionally.

Be sure to watch the instruction video for the component you intend to use. Incorrect use may lead to discomfort, malfunction or injury to person or property. If you do not find your activity in the provided instruction videos, please contact support@macu4.com or the professional who provided you with the system for instructions before starting the activity.

Notes on using the Cuff - General
Do not overload the Cuff. Always clean the Cuff after each use.

Notes on using the Cuff – Limited functionality
Be sure that the Cuff is well secured on your arm and that prior to usage you tested that the Cuff does not slip off your arm during situations or activities involving pulling forces. The Cuff can get damaged if the Cuff falls on the floor or hits a surface. Such incident can cause already invisible damage to the material, which may later result in material fractures.

Notes on using the Modules - General
Do not overload the Modules. Always clean the Modules after each use. Remove visible dirt particles so that Modules with flexible modes are not restricted in their function.
Do not use any component as a means to manage objects that are sharp or that could cause damage in case of loss of control (i.e. razor, drill, knives, etc.).
Don't use a Module if the diameter of the object is too large (see the specifications for each module). If the diameter of an object is too small, you can increase the diameter slightly by using a soft material around the area where you want to attach the module to the object, for example, when using the Hold Module to hold a fork.
Before using a Module, check if it is compatible with the handle (i.e. crutch handle, bike handle, etc.) or object (i.e. fork, glass, etc.), that the Module is tightly secured on the handle or the grip or the object, that you have chosen the correct orientation of the Module on the object/handle.

Notes on the CLIC STD Module
Be sure that the Clic Head is correctly placed in the Clic Adapter and that prior to usage you tested how to connect and disconnect either the module from a handle or the Clic Adapter from the Clic Head. Before using any device with the Clic Module, be sure that you can properly connect and disconnect the adapter to and from the Clic Head.
THE MODULE IS NOT SUITABLE WHEN YOU NEED TO PULL ON THE MODULE WHILE PERFORMING YOUR ACTIVITY (E.G. JUMPING WITH A SCOOTER) BECAUSE THE CLIC ADAPTER DISCONNECTS FROM THE CLIC HEAD WHEN YOU APPLY PULL FORCES.

Notes on the HOLD STD Module
Be sure that the lever of the ball joint is tightened and that the Velcro strap is correctly tightened to hold the object sufficiently and not come loose unintentionally. Do not overtighten the eccentric cam, as this may damage the material.

Notes on the HOOK STD Module
Be sure that the handle is correctly placed in the Module and that you do not exceed the maximum allowed load cases. See Chapter 11.

Notes on the PUSH STD Module
Be sure that the Module is correctly connected to the handle of the object (e.g. crutch) and that you do not exceed the maximum allowed load. See Chapter 11.
Before starting any activity, be sure that the module head (black curved handle element) is correctly attached to its module base (it should not be rotatable). If this is not the case, the screw may have loosened slightly. In this case, tighten the screw.

Notes on selection of product size

- The correct Cuff size is chosen according to the measurement instructions.

- Do not use a Cuff size that is too big for your arm. Any excessive tightening can lead to a dysfunction of the Cuff Hook(s).
- Do not use a Cuff size that is too small for your arm. It can lead to painful pressure marks and/or impede vascular flow.

Instructions for using the Cuff with the Cover or Velcro Hook closure system

- Don't use the Cuff when the protective material is missing.
- Make sure that the Velcro straps or the Lacing Knob (when using the Cover) are facing upside (posterior) on your forearm.
- Make sure that the Cuff (with or without Cover) always sits tight on your forearm. If it gets loose, tighten the Velcro or the Lacing system.

Notes on ambient conditions
Always store or use the products in accordance with the information on temperature, UV radiation and humidity given in Chapter 11. The material properties of the components may change significantly when used and stored at higher or lower temperatures than recommended, as stated in this document, and lead to discomfort, malfunction, or injury to person or property.

Notes on storage conditions
Always make sure that the components are well protected during transportation and permanent storage. Do not place weight on a component. It could deform or damage a component. In case of deformation or damage, the component can no longer be used.

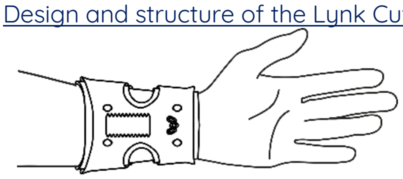
NOTES ON MAGNETS IN THE COMPONENTS
THE CUFF, VELCRO HOOK, COVER, PUSH MODULE, CLIC LOCK HEADS, AND CLIC LOCK MODULE CONTAIN MAGNETS (SEE CHAPTER 11), KEEP THE COMPONENTS RING AT LEAST 15 CM / 6 IN AWAY FROM E.G. PACEMAKERS OR DEFIBRILLATORS.

4. Use of the Components

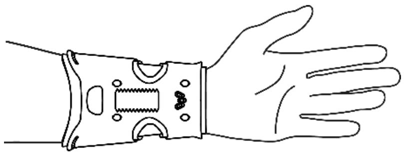
Before using the Lynk components for the first time, familiarise yourself with the instructions for use. The following chapters explain how to use the Lynk Modules together with the Lynk Cuff.

4.1. How to use the Lynk Cuff

Design and structure of the Lynk Cuff



Size: short

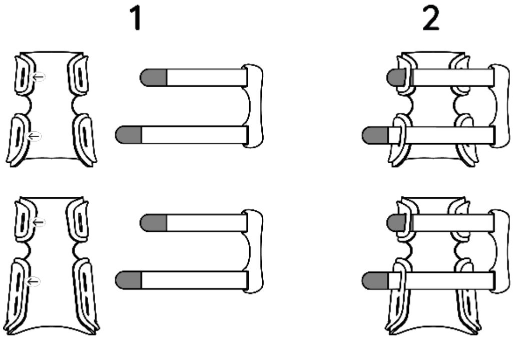


Size: Standard

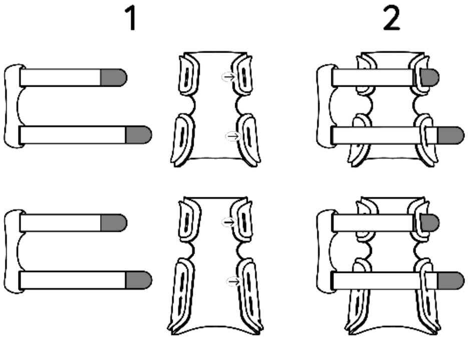
When using the Cuff for the first time
Make sure that the Cuff sits tight and cannot be moved easily. If the Cuff sits too loose on your arm, you should adapt the Velcro straps. The fit of the Cuff on the arm should be snug but not uncomfortable.

4.1.1. How to use the Lynk Cuff with the Velcro Hook (Velcro fastening system)

<u>Install the Velcro Hook</u>

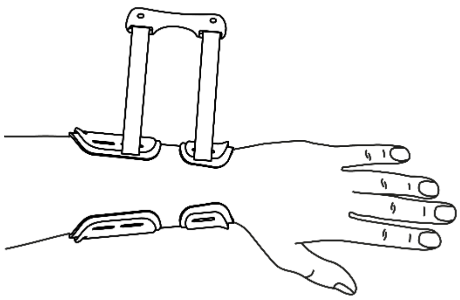


Insert Velcro Hook (arm side: left) | Carefully insert the Velcro strips into the slots on the left side.

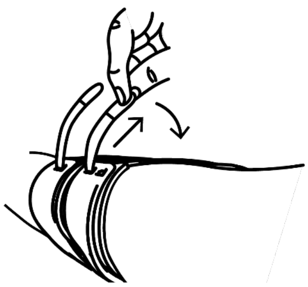


Insert Velcro Hook (arm side: right) | Carefully insert the Velcro strips into the slots on the right side.

Close the Velcro | Once the hook section of the Velcro strap has been completely fed through the slot, press it onto the loop section. This secures the Velcro strap in place and prevents it from being pulled out of the slot.

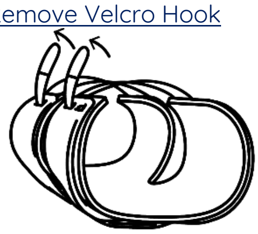


Insert your arm | You can either place the Cuff on a table and insert your arm. Or you can hold the Cuff with your other hand while inserting your arm.

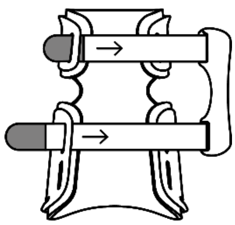


Tighten the Velcro | Open the Velcro fastener and pull the it slightly to adjust the position on the arm and close the Velcro fastener again to tighten.

<u>Remove Velcro Hook</u>



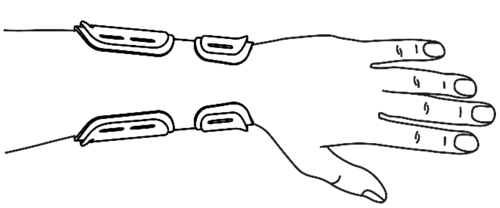
Release the Velcro | The Velcro fastening is attached to one side via slots on the cuff. You can release the Velcro fastening in this area.



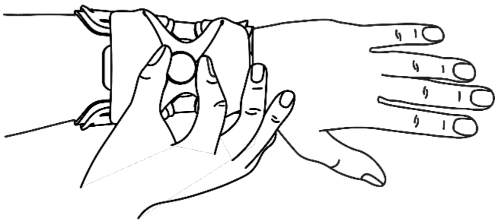
Release the Velcro | The Velcro fastening is attached to one side via slots on the cuff. You can release the Velcro fastening in this area.

4.1.2. How to use the Lynk Cuff with the Cover (Lacing System)

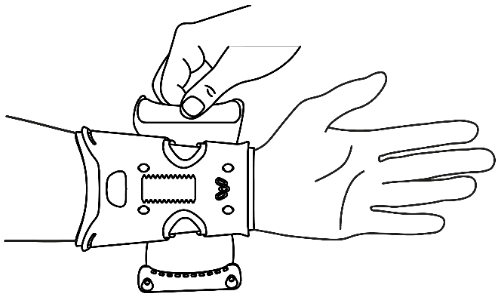
<u>When using the Cuff Cover</u>
Whenever you want to use the Cuff together with the Cuff Cover, you must remove the Velcro System.



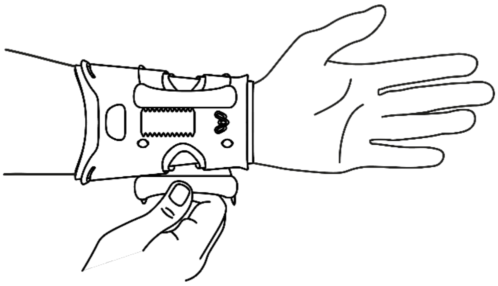
Insert your arm | You can either place the Cuff on a table and insert your arm into it. Or you can use your other hand to hold the Cuff while inserting your arm.



Prepare the cover | Take the cover and make sure that the lacing button is in the released position by pulling it slightly upwards.

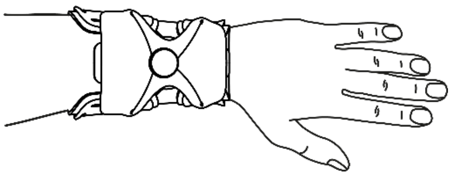


Anchor the Hooks | Place the Hook in front of the Hook Anchoring Holes. The Hook is equipped with magnets, and this will allow it to click into place.



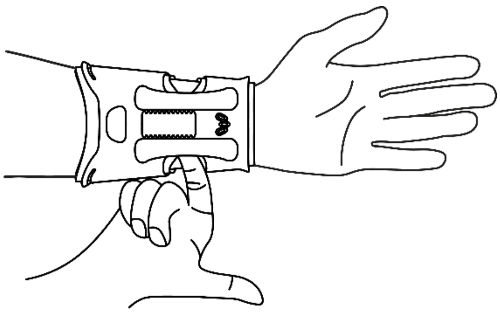
Tighten the Cuff | When both Hooks are in place, press the Lacing Knob and turn it clockwise. Turn until the Cuff fits snugly on the arm. The fit of the Cuff on the arm should be snug but not uncomfortable.

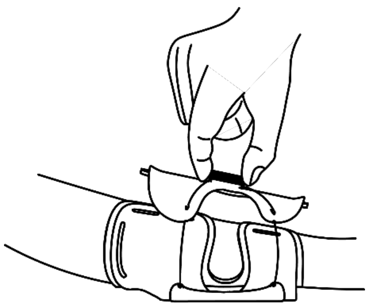
4.1.3. Final control



- Check that the Hooks are fully clicked into place.
- Make sure it is well positioned and secured by trying to move the Cuff gently. The Cuff should remain firmly in position.
- If the Cuff is not tight and can be moved, recheck the Lacing System or Velcro System.

4.1.4. How to remove the Lynk Cuff

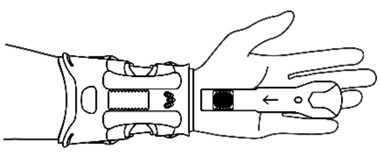




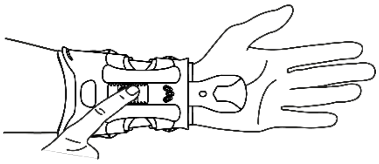
Option 1 | Applicable for both closure systems. Pull on the Hook. It shall disengage from the Cuff. If the Hook is free, you can remove the Cuff from your arm.

Option 2 | Applicable for lacing system only. Alternatively, you can first loosen the Lacing System by pulling slightly on the Knob before pulling on the Hook.

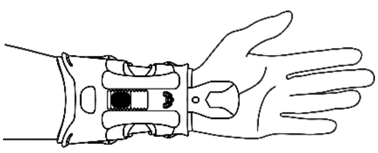
4.2. How to use a Lynk Module with the Lynk Cuff



Insert Module | Insert the module into the interface section through the slit in the cuff as shown. The button should face you so that it remains visible in the interface section. You should hear a small sound.



Change position | Press the Button of the Module to change its position in the Cuff and to adapt it to your needs and comfort. Press the Button as well when you want to remove the Module.

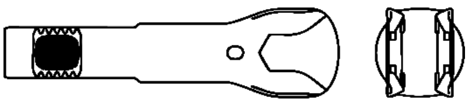


Final check | Make sure the Module is well positioned and secured by trying to move it gently. The Module should remain firmly in position.

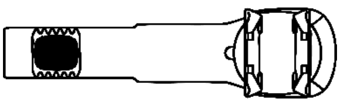
4.3. CLIC Module

4.3.1. CLIC STD Module

<u>Design and structure of the Module</u>
The Module is provided as a set of 1 Clic Adapter, 3 different Clic Lamellas and 3 different Clic Heads.

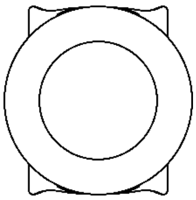


Disassembled | Module with Clic Head uncoupled from Clic Adapter (Clic Lamella is inserted into Adapter)

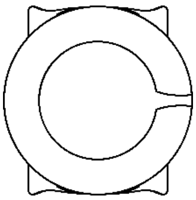


Assembled | Module with Clic Head coupled to Clic Adapter

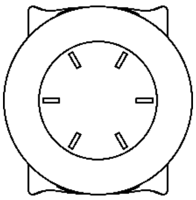
<u>Module Heads</u>
The Module is offered with different Clic Heads to support the user in a range of activities that may require different rotation levels of the Clic Head.



Clic Head 360 | Module Head providing a complete rotation, offering complete freedom.



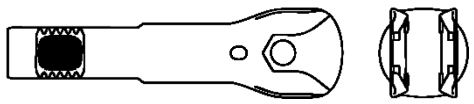
Clic Head 70 | Module Head allowing a partial rotation to prevent constraining the arm movement completely.



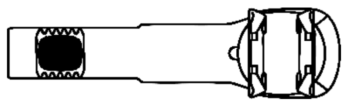
Clic Head 0 | Module Head offering no rotation but various locked positions. You can choose between different locked angles.

4.3.2. CLIC Lock Module

Design and structure of the Module
The Module is provided as a set of 1 Clic Lock Adapter, 3 different Clic Lamellas, Clic Lock Plug, Clic Lock Head 360 and Clic Lock Head 70.



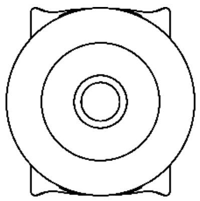
Disassembled | Module with Clic Lock Head uncoupled from Clic Lock Adapter (Clic Lamella is inserted into Adapter)



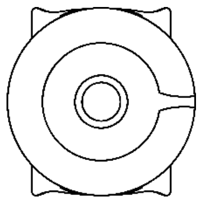
Assembled | Module with Clic Lock Head coupled to Clic Lock Adapter

Module Heads
The Module is offered with different Clic Heads to support the user in a range of activities that may require different rotation levels of the Clic Head.

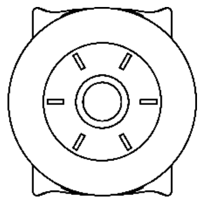
Options concerning the rotation



Clic Head 360 | Module Head providing a complete rotation, offering complete freedom.

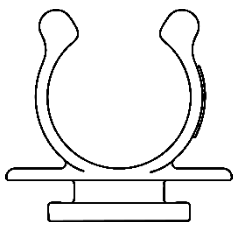


Clic Head 70 | Module Head allowing a partial rotation to prevent constraining the arm movement completely.

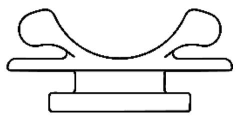


Clic Head 0 | Module Head offering no rotation but various locked positions. You can choose between different locked angles.

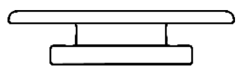
Options concerning the Head shape



Clic Lock Head STD
C-shape; used to attach to a handle or rod/bar. Same principle as for Clic STD Module Heads.

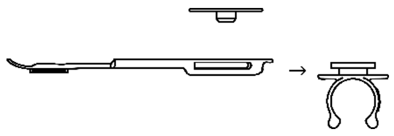


Clic Lock Head ELLIPSE
Ellipse shape; used to attach to oval shaped rods / bars or cylindrical objects of circumferences > 32 mm (1.26 in). Object can only be hold in place when additionally a cable tie or Velcro is used.

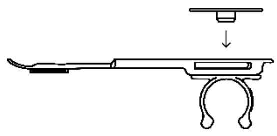


Clic Lock Head FLAT
Flat shape; used for many different needs. Option 1: a magnet disk that is glued onto the Head to hold a smartphone which is capable of wireless charging or has a magnetic cover. Option 2: Any deformable material such as SUGRU which is used to create specific shapes.

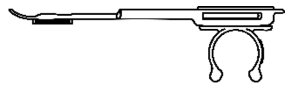
Using the Lock function



Connect a Clic Lock Head | Push the Clic Lock Adapter on the Clic Lock Head already mounted to an object.



Insert the Lock Plug | Place the Clic Lock Plug in front of the hole. The magnets will guide it into place.



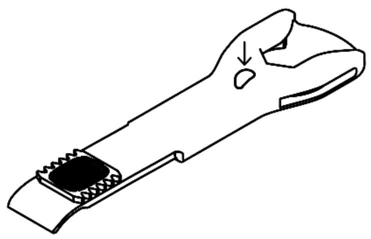
The Clic Lock Head is secured | To disconnect the Clic Lock Head, remove the Clic Lock Plug and pull the Clic Lock Adapter.

4.3.3. CLIC Lamellas

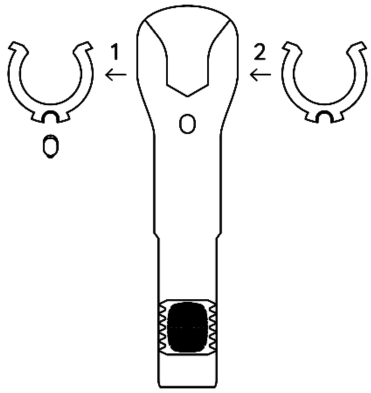
The Clic STD Module is offered with 3 different Clic Lamellas to support the user in a range of activities that may require different release forces when attaching and detaching a Clic Head. The Clic STD and Clic Lock Module is assembled with Clic Lamella 1 by default.

- **Clic Lamella I** is used for lower load forces
- **Clic Lamella II** is used for lower load forces
- **Clic Lamella III** is used for lower load forces

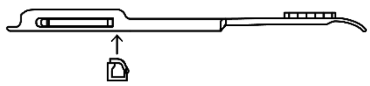
You can change the Lamella type as follows:



Remove the Pin | Press on the pin as illustrated with a small tool (no scarf tip) such as a pen onto the pin and in the direction of the Modu until the Pin is released.



Change the Lamella | Slide out the Clic Lamella on the side through the slit. Insert the new Lamella. Make sure that the pin hole remains free.



Insert the Pin | Insert the pin to secure the new Clic Lamella. If you cannot insert it with your hand, gently press a flat object (i.e. book) against the module.

4.3.4. Connect the Clic Module to a handle | Option 1

Connect the Module to a handle by pushing the clamp area of the Clic Head onto the bar. Release it by pulling. Check the fit of the Clic Module on the handlebar. If the Clic Head is too loose on the handlebar, you can add some rubber material to the handle to improve the grip. The supported diameter range of a handle is provided in Chapter 11. Always test to connect and disconnect the Clic Module to and from the handle before starting any activity.

- **Connect to handle |** Connect the Clic Module to a handle by pushing the clamp area of the Clic Head onto the bar. Find the most suitable location on the handle.
- **Disconnect from handle |** Disconnect the Clic Module from the handle by pulling it from the handle.

- **Connect Clic Adapter & Head |** Connect to the Clic Head that is fixated to the handle by pushing the Adapter slit onto the Clic Head. And releasing it by pulling on the Clic Head.

4.3.5. Use case examples with the Module

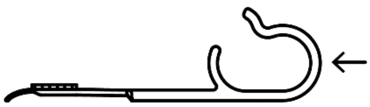
Please consult the website of macu4, where you will find specific explanation videos under the section 'Application'.

- **Using a broom |** Attach the Clic Module to a broom. Test yourself which Clic Head works best for you.
- **Using a bike |** Attach the Clic Module to the handlebar of a bike. Test yourself which Clic Head works best for you.
- **Using a scooter |** Attach the Clic Module to a broom. Test yourself which Clic Head works best for you.

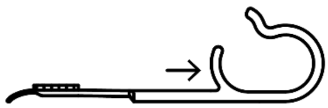
4.4. HOOK Module

<u>Design and structure of the Module</u>
The Module is provided as one single part.

View from front



View from side | The shape of the curved hook section allows objects with weight to be pulled.



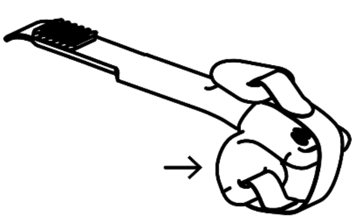
Apply pushing force | The overlapping plateau element at the other end of the curved hook section allows additional weight to be pushed.

<u>Use case examples with the Module</u>
Please consult the website of macu4, where you will find specific explanation videos under the section 'Application'. The maximum handle diameter and object weight are provided in Chapter 11.

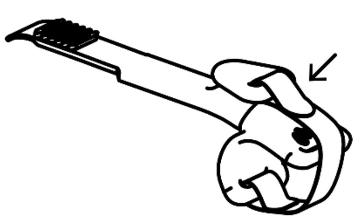
- **Holding a bag |** Insert the handle of the bag into the Hook.
- **Pulling a suitcase |** Insert the handle of the suitcase in the Hook and start pulling gently.
- **Pushing and pulling weight in the gym |** Clip your module to the Handle of the fitness equipment and simply push it. Release the Module from the bar by turning it while pulling on it softly.

4.5. Push Module

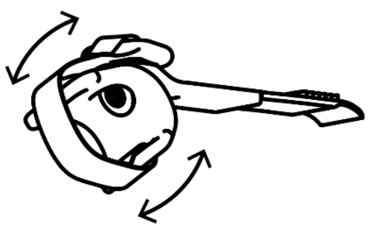
<u>Design and structure of the Module</u>
The Module is provided as one single part with a removable Velcro element.



Flexible module head | The module head is a curved grip element and is made from a flexible material to better conform to a handle.



Velcro closure | A Velcro strap is connected to the module via a slit in the head and the Velcro hook. The hook is held in position thanks to the magnets and a click-in mechanism.



Adaptable orientation | You can slightly turn the module head to the left and right to find the desired orientation for your handle.

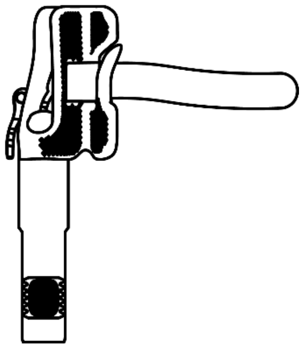
<u>Use case examples with the Module</u>
Always make sure that objects or handles are properly positioned and secured by lifting the object and shaking it gently.

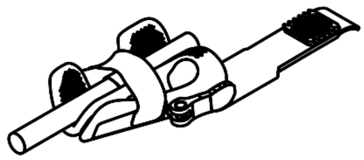
- **Using a crutch |** Make sure the Velcro strap is free and place the grip part onto the handle. Turn the Velcro strap around the handle and secure the Velcro hook in its position. If needed, shorten the length of the Velcro strap.
- **Attaching cylindric objects |** Make sure the Velcro strap is free. Press the object onto the grip part. Turn the Velcro strap around the object and secure the Velcro hook in its position. If needed, shorten the length of the Velcro strap or replace the Velcro strap with a longer one.
- **Attaching to other objects |** Use the module to fixate, for example, an arch and perform arch shooting. Proceed as described for the other used cases.

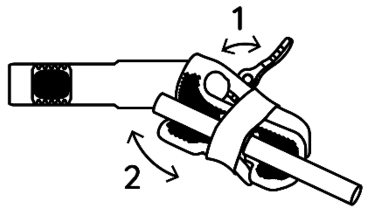
4.6. Hold Module

4.6.1. Hold STD Module

Design and structure of the Module
The Module is provided as one single part with a removable module head element.







Flexible module head | The module head is a clamp-like element and is made from a flexible material to better conform to objects.

Velcro closure | A Velcro strap is attached to the module head through a slot in the head. The strap can be wrapped around the module head and fixed in place.

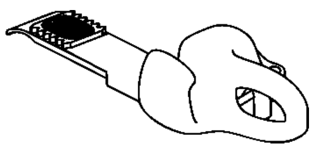
Adaptable orientation | You can turn the module head in various directions to find the desired orientation for your activity.

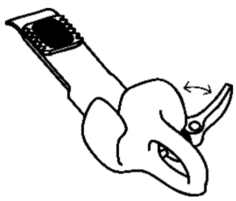
Use case examples with the Module
Always make sure that objects or handles are properly positioned and secured by lifting the object and shaking it gently. Please consult the website of macu4, where you will find specific explanation videos under the section 'Application'.

- **Kitchen accessories |** Position the kitchen aid object into the Hold Module Head. Secure its position by tightening the Velcro strap.
- **Flat objects |** Insert the flat object into the lateral slit that you find on the Hold Module Head.

4.6.2. Hold Lock Module

Design and structure of the Module
The Module is provided as one single part with a removable module head element.

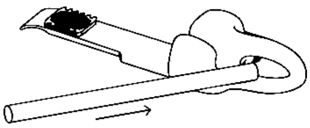




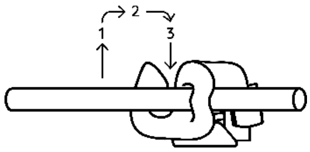
Flexible module head | The module head is a clamp-like element and is made from a

Adaptable orientation | You can turn the module head in various directions to find the desired flexible material to better conform to objects.

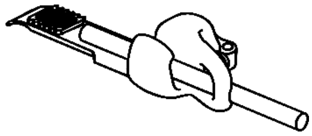
orientation for your activity by releasing the lever.



Insert the object | Insert the desired object in the hole as indicated by the arrow. Depending on the geometry of the object, it is possible to insert it from the other side.

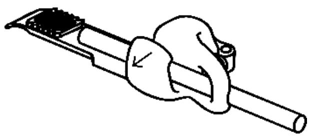


Securing the object | Follow the steps illustrated by first pulling up the object, second rotating it, and third pressing it into position.



The object is secured | To change the orientation, use the lever.

Securing the orientation of flat objects | Use the slits to prevent flat objects from rotating involuntarily.



Pull on the flexible part | The object shall release when you push on the flexible tab outwards. You can then take it out.

<u>Use case examples with the Module</u>
Always make sure that objects or handles are properly positioned and secured by lifting the object and shaking it gently.

- **Kitchen accessories |** For example a Cooking Spoon or a fork with a cylindrical handle.
- **Flat objects |** For example a fork with a flat handle.

5. Storage of the Products

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

- Store the product after use in a clean, dry, and secure place—out of the reach of children, unless used under direct supervision.
- Keep the product away from areas where it could be mixed with other objects or handled improperly.
- Protect the product from dust, dirt, and mechanical impacts.
- Avoid storing the product in places with strong temperature fluctuations or high humidity.

6. 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 product 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 macu4 medical device in a cleaning machine or any other appliance (washing machine, dishwasher, microwave, steamer, or similar).

7. Adverse event reporting

Any serious incident related to the device should be reported to the manufacturer and the competent authority of the member state where the user and/or patient is established. Please use the form Please use the Product Experience Report (PER) https://25462115.fs1.hubspotusercontent-eu1.net/hubfs/25462115/macu4_GmbH_Lynk/Product_Experience_Report_EN.pdf and send it to by email to support@macu4.com.

8. 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.

9. Conformity

The product components of the system Lynk with the Basic UDI-DI marking

Lynk Cuff	426242965P020201R4
Lynk Cover	426242965P020202R6
Lynk Clic STD	426242965P020207RG
Lynk Clic Lock	426242965P020208RJ
Lynk Hold STD	426242965P020206RE
Lynk Hold Lock	426242965P020206RE
Lynk Hook STD	426242965P020204RA
Lynk Push STD	426242965P020205RC
Lynk Hook Velcro	426242965P020209RL

meet the general safety and performance requirements according to Regulation (EU)2017/745 for medical devices and the Medical Devices Ordinance (MedDO) of 1 July 2020 (812.213).

Legal manufacturer
macu4 GmbH, Bücklestrasse 3, 78467 Constance, Germany

CE Marking Details
Macu declares that it complies with the relevant European standards for the design, manufacture and supply of orthopedic products. The products of the System meet the requirements of the European Regulation (EU)2017/745 Annex I for medical devices. Based on the classification criteria according to Annex VIII of this regulation, the Cuff has been classified as Class I and all other products as Class I "Accessories". The declaration of conformity has, therefore, been drawn up by the manufacturer under his sole responsibility in accordance with Annex IV of the Regulation. All products of the System are marked accordingly.

Trademark
All designations mentioned in this document are subject without restriction to the provisions of the applicable trademark law and the rights of the respective owners. All trademarks, trade names, or company names mentioned herein may be registered trademarks and are subject to the rights of their respective owners. The absence of explicit identification of the trademarks used in this document does not imply that a designation is free of third-party rights.

10. Symbols

The table below shows all symbols (according to ISO 15223-1:2021) used on the product and on the label.

CE Mark

CE — This symbol indicates that a manufacturer declares that the product meets all the legal requirements for CE marking and can be sold throughout the EEA.

Instructions for use.

This symbol indicates that the user must consult the instructions for use.

Manufacturer

This symbol indicates the manufacturer of the medical device.

Temperature limit

This symbol indicates the temperature limits to which the medical device can be safely exposed.

Date of manufacture

This symbol indicates when the medical device was manufactured.

Batch designation

LOT — This symbol indicates the manufacturer's batch code so that the batch or lot can be identified.

Catalogue number

REF — This symbol indicates the manufacturer's catalogue number so that the item can be identified.

Medical device

MD — This symbol indicates that the item is a medical device.

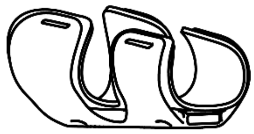
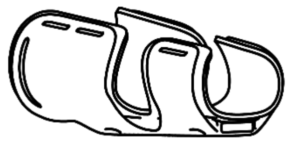
Clear device identification

UDI — This symbol identifies a carrier that contains information for unique device identification.

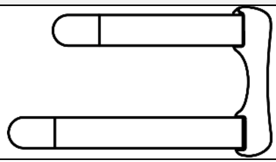
MR Unsafe

MR — This symbol indicates a medical device or other item which is known to pose hazards in all magnetic resonance (MR) environments and should not be brought into the MRI scanner room..

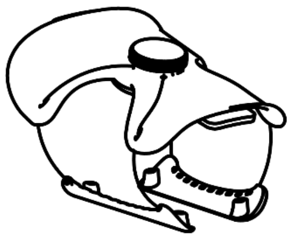
11. Technical data
11.1. CUFF

General		
Drawing	 Size: short	 Size: Standard
Dimensions (size: short)	Extra Small: 65 mm × 60 mm × 120 mm / 2.56 in × 2.36 in × 4.72 in Small: 83 mm × 61 mm × 127 mm / 3.27 in × 2.40 in × 5.00 in Medium: 93 mm × 68.5 mm × 130.5 mm / 3.66 in × 2.70 in × 5.14 in Large: 105 mm × 76.5 mm × 132 mm / 4.13 in × 3.01 in × 5.20 in	
Dimensions (size: standard)	Small: 87.5 mm × 66 mm × 158 mm / 3.44 in × 2.60 in × 6.22 in Medium: 97 mm × 72 mm × 158 mm / 3.82 in × 2.83 in × 6.22 in Large: 112 mm × 81 mm × 158 mm / 4.41 in × 3.19 in × 6.22 in	
Weight (size: short, assembled)	Extra-Small: 65 g / 2.29 oz Small: 67 g / 2.36 oz Medium: 70 g / 2.47 oz Large: 75 g / 2.65 oz	
Weight (size: standard, assembled)	Small: 75 g / 2.65 oz Medium: 80 g / 2.82 oz Large: 87 g / 3.07 oz	
Material	Cuff shell: PA2200, coloured with DM standard colour (DyeMansion) Protective material: Alcantara, Velour Velcro: Nylon Magnets: 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 component	2 years at an average of 120 minutes per day with daily use	

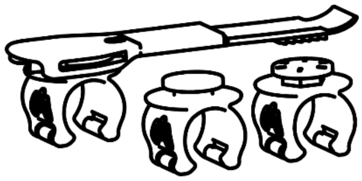
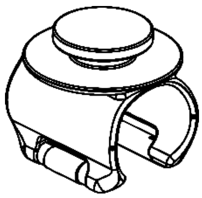
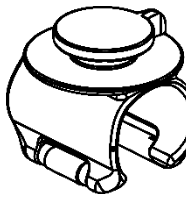
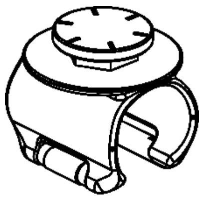
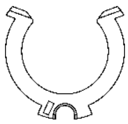
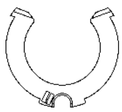
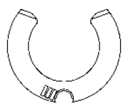
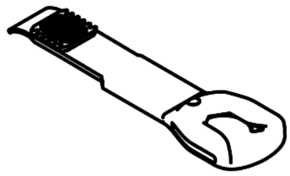
11.2. CUFF VELCRO HOOK

General	
Drawing	
Dimensions (without Velcro)	10.8 mm × 22.35 mm × 96.48 mm / 0.43 in × 0.88 in × 3.80 in
Weight (assembled)	Size A: 11.5 g / 0.41 oz Size B: 12 g / 0.42 oz Size C: 12.5 g / 0.44 oz Size D: 13 g / 0.46 oz
Material	Cuff shell: PA2200, coloured with DM standard colour (DyeMansion) Protective material: Alcantara, Velour Magnets: Neodymium-iron-boron (NdFeB), grade 45, Nickel-copper-nickel coating. Dimensions: Ø 4 mm (0.16 in) × 7 mm (0.28 in), tolerance ±0.1 mm (± 0.004 in)
Lifetime of the component	2 years at an average of 120 minutes per day with daily use

11.3. COVER

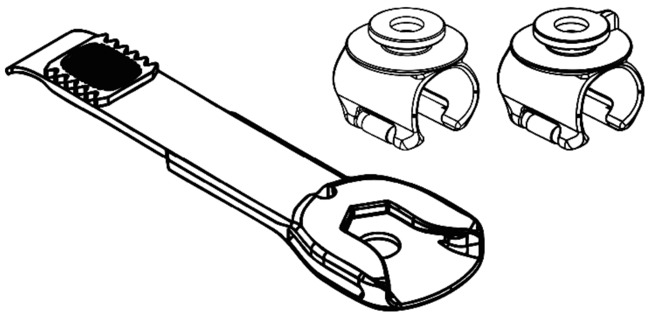
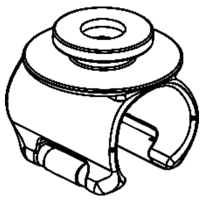
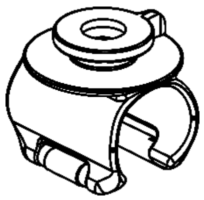
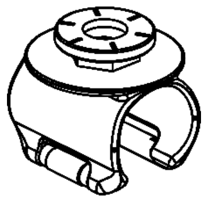
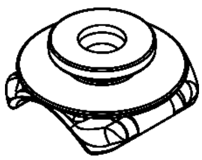
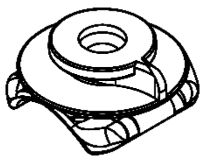
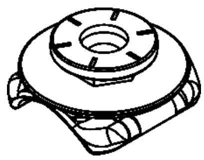
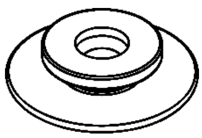
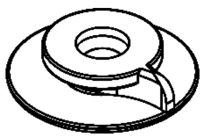
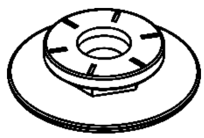
General	
Drawing	
Dimensions	Small: 83.5 mm × 39.5 mm × 131 mm / 3.29 in × 1.56 in × 5.16 in Medium: 93.5 mm × 44.5 mm × 132.5 mm / 3.68 in × 1.75 in × 5.22 in Large: 105 mm × 50mm × 134mm / 4.13 in × 1.97 in × 5.28 in
Weight (assembled)	Small: 37 g / 1.31 oz Medium: 40 g / 1.41 oz Large: 43 g / 1.52 oz
Material	Cuff shell: PA2200, coloured with DM standard colour (DyeMansion) Protective material: Alcantara, Velour Lacing System: Fitgo Magnets: Neodymium-iron-boron (NdFeB), grade 45, Nickel-copper-nickel coating. Dimensions: Ø 4 mm (0.16 in) × 7 mm (0.28 in), tolerance ±0.1 mm (± 0.004 in)
Lifetime of the component	2 years at an average of 120 minutes per day with daily use

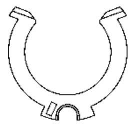
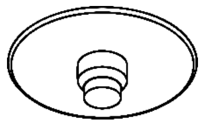
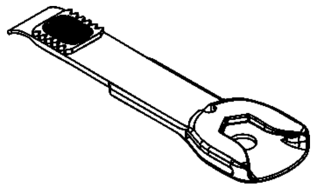
11.4. CLIC STD Module

General			
Drawing (Clic Module)			
Dimensions (Clic Module)	167 mm × 45.5 mm × 44 mm / 6.57 in × 1.79 in × 1.73 in		
Weight (Clic Module)	57 g / 2.01 oz		
Drawing (Heads only)			
	Head 360°	Head 70°	Head 0°
Dimensions (Head)	44 mm × 44 mm × 44 mm / 1.73 in × 1.73 in × 1.73 in		
Weight (Head)	11.5 g / 0.41 oz		
Drawing (Lamella)			
	Lamella soft	Lamella medium	Lamella strong
Dimensions (Lamella only)	39 mm × 35.3 mm × 3.4 mm / 1.54 in × 1.39 in × 0.13 in		
Drawing (Adapter only)			
Dimensions (Adapter only)	44 mm × 167 mm × 10 mm / 1.73 in × 6.57 in × 0.39 in		
Weight (Adapter)	23 g / 0.81 oz		
Allowed handle diameters	From 26 mm to 32 mm (1.02 in to 1.26 in)		
Material	Module body: PA2200, coloured with DM standard colour (DyeMansion)		
Lifetime of the Module	2 years at an average of 120 minutes per day with daily use		

Maximum load forces in the Module	
Maximal Pushing force (parallel to forearm)	200 N / 44.96 lbf

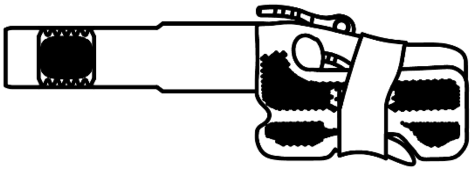
11.5. CLIC Lock Module

General			
Drawing (Clic Module)			
Dimensions (Clic Module)	167 mm × 45.5 mm × 44 mm / 6.57 in × 1.79 in × 1.73 in		
Weight (Clic Module)	48 g / 1.69 oz		
Drawing (Heads only)			
	Head 360° STD	Head 70° STD	Head 0° STD
			
	Head 360° ELLIPSE	Head 70° ELLIPSE	Head 0° ELLIPSE
			
	Head 360° FLAT	Head 70° FLAT	Head 0° FLAT
Dimensions (Head)	Head STD	43.5 mm × 44 mm × 44 mm 1.71 in × 1.73 in × 1.73 in	
	Head ELLIPSE	19.9 mm × 44 mm × 44 mm 0.78 in × 1.73 in × 1.73 in	
	Head FLAT	10.3 mm × 44 mm × 44 mm 0.41 in × 1.73 in × 1.73 in	
Weight (Head)	Head STD	11 g / 0.39 oz	

	Head ELLIPSE	10 g / 0.35 oz	
	Head FLAT	7 g / 0.25 oz	
Drawing (Lamella)			
	Lamella I		
Dimensions (Lamella only)	39 mm × 35.3 mm × 3.4 mm 1.54 in × 1.39 in × 0.13 in (differ slightly depending on the lamella)		
Drawing (Plug only)			
Dimensions (Plug only)	46 mm × 46 mm × 8.2 mm / 1.81 in × 1.81 in × 0.32 in		
Weight (Plug)	5 g / 0.18 oz		
Drawing (Adapter only)			
Dimensions (Adapter only)	44 mm × 167 mm × 10 mm / 1.73 in × 6.57 in × 0.39 in		
Weight (Adapter)	23 g / 0.81 oz		
Allowed handle diameters	From 26 mm to 32 mm (1.02 to 1.26 in)		
Material	Module body: PA2200, coloured with DM standard colour (DyeMansion) Magnets: Neodymium-iron-boron (NdFeB), grade 45, Nickel-copper-nickel coating. Dimensions: Ø 4 mm (0.16 in) × 7 mm (0.28 in), tolerance ±0.1 mm (± 0.004 in). Dimensions: Ø 9 mm (0.35 in) × 3 mm (0.12 in), tolerance ±0.1 mm (± 0.004 in)		
Lifetime of the Module	2 years at an average of 120 minutes per day with daily use		

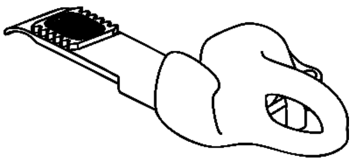
Maximum load forces in the Module	
Maximum Pushing force (parallel to forearm)	200 N / 44.96 lbf
Maximum Pulling force (parallel to forearm)	200 N / 44.96 lbf

11.6. HOLD STD Module

General	
Drawing	
Dimensions	39.5 mm × 198 mm × 59 mm * / 1.56 in × 7.80 in × 2.32 in * *Dimensions may vary depending on the orientation of the Module
Allowed diameters for cylindrical objects	From 10 mm to 85 mm (0.39 to 3.35 in) * *Dimensions may vary depending on the shape and material of the object.
Allowed thickness of flat objects	From 0.3mm to 12mm (0.01 to 0.47 in) * *Dimensions may vary depending on the shape and material of the object.
Weight	86 g / 3.03 oz
Material	Module body: PA2200, coloured with DM standard colour (DyeMansion) Module head: Ultrasint TPU01
Lifetime of the Module	2 years at an average of 120 minutes per day / daily use

Maximum conditions the Module can withstand	
Maximum object weight	3 kg / 6.61 lb
Maximum pushing force	30 N / 6.74 lbf
Maximum pulling force	30 N / 6.74 lbf

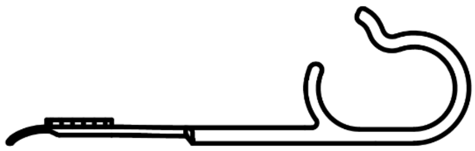
11.7. HOLD Lock Module

General	
Drawing	
Dimensions	Maximum approx. 39.5 mm × 198 mm × 59 mm / 1.56 in × 7.80 in × 2.32 in Dimensions may vary depending on the orientation of the Module

Allowed diameters for objects	Maximum 15.00 mm / 0.59 in
Weight	80 g / 2.82 oz
Material	Module body: PA2200, coloured with DM standard colour (DyeMansion) Module head: Ultrasint TPU01
Lifetime of the Module	2 years at an average of 120 minutes per day / daily use

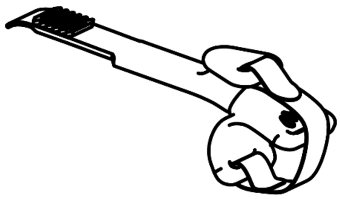
Maximum conditions the Module can withstand	
Maximum object weight	0.5 kg / 1.10 lb
Maximum pushing force	30 N / 6.74 lbf
Maximum pulling force	30 N / 6.74 lbf

11.8. HOOK Module

General	
Drawing	
Dimensions	49.2 mm × 168.8 mm × 29.1 mm / 1.94 in × 6.65 in × 1.15 in
Allowed diameters for handles	Up to 32 mm / 1.26 in
Weight	30 g / 1.06 oz
Material	PA2200, coloured with DM standard colour (DyeMansion)
Lifetime of the Module	2 years at an average of 120 minutes per day / daily use

Maximum conditions the Module can withstand	
Maximum object weight	40 kg / 88.18 lb
Maximum pushing force	200 N / 44.96 lbf
Maximum pulling force	400 N / 89.92 lbf

11.9. PUSH Module

General	
Drawing	
Dimensions	49.2 mm × 168.8 mm × 29.1 mm / 1.94 in × 6.65 in × 1.15 in
Allowed diameters for handles	From 30 mm to 40 mm (1.18 to 1.57 in) Dimensions may vary depending on the shape and material of the object.
Weight	58 g / 2.05 oz
Material	Module body: PA2200, coloured with DM standard colour (DyeMansion) Module head: Ultrasint TPU01 Magnets: Neodymium-iron-boron (NdFeB), grade 45, PTFE (PFAS) coating. Dimensions: Ø 5 mm (0.20 in) × 5 mm (0.20 in), tolerance ±0.1 mm (± 0.004 in) Neodymium-iron-boron (NdFeB), grade 35, Nickel-copper-nickel coating. Dimensions: Ø 12 mm (0.47 in) × 2 mm (0.08 in), tolerance ±0.1 mm (± 0.004 in).
Lifetime of the Module	2 years at an average of 120 minutes per day / daily use

Maximum conditions the Module can withstand	
Maximum body mass when using crutches	65 kg / 143.3 lb
Maximum pushing force	500 N / 112.4 lbf
Maximum pulling force	100 N / 22.48 lbf

11.10. 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

12. 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. DO NOT USE IF YOU HAVE A KNOWN ALLERGY OR HAVE 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.

13. Returns

If you suspect or believe there is a problem with your product, please first read this manual carefully before contacting support@macu4.com or your prosthesis manufacturer (unless you purchased the product directly from Macu). Please use the Product Experience Report (PER):
https://25462115.fs1.hubspotusercontent-eu1.net/hubfs/25462115/macu4_GmbH_Lynk/Product_Experience_Report_EN.pdf
Please provide the UDI-DI (starting with “(01) ____”) and UDI-PI (starting with “(10) ____”) of your Module when requesting warranty repairs or returns. These can be found on the product.
If you return your product to us or your prosthetist, please pack it appropriately; the original packaging in which you received your product is perfectly suitable for this purpose.