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CE

DynamicArm 12K100N

1 Foreword

English

INFORMATION

Date of last update: 2024-09-25

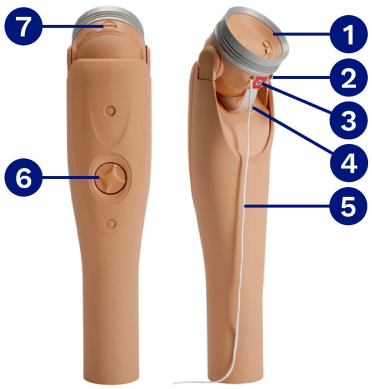
- ► Please read this document carefully before using the product and observe the safety notices.
- ► Instruct the user in the safe use of the product.
- ► Please contact the manufacturer if you have questions about the product or in case of problems.
- ► Report each serious incident related to the product to the manufacturer and to the relevant authority in your country. This is particularly important when there is a decline in the health state.
- ► Please keep this document for your records.

The product "DynamicArm 12K100N=*" is referred to as the product/elbow joint below.

These instructions for use provide you with important information on the use, adaptation and handling of the product.

2 Product description

2.1 Design



1. Easy Plug
2. On/Off switch
3. Band clamp
4. Charging receptacle
5. Switch cable (mechanical unlocking mechanism)
6. Handwheel
7. Humeral rotation feature adjusting screw

2.2 Function

The elbow joint is controlled myoelectrically and driven by an electric motor. It supports the user in everyday tasks in combination with other prosthetic components (see page 4).

The product uses an integrated Li-Ion battery as the energy source. The "ElbowSoft 646C42=V*" software is used for the user-specific adjustment of the product.

The product can be locked and unlocked in any position, even under load, by activating the switch cable. Even when it is switched off or the rechargeable battery is drained.

The product can lift a load of up to 5 kg. The joint locks automatically when the load is exceeded.

The product has a load capacity of up to 177 N in the locked state with a forearm lever length of 305 mm. The lock will slip under higher loads.

2.2.1 Definition of terms

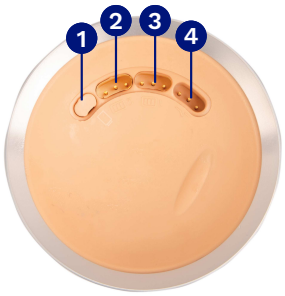
AFB (Automatic Forearm Balance)

AFB is a mechanical flexion aid. It stores energy when the arm is extended and uses it to minimise the force required for flexion. The level of support can be adjusted to the weight of the prosthetic forearm and clothing with a handwheel.

Humeral rotation feature

The humeral rotation feature is an upper arm rotation joint with bilateral stops. It is used for rotation of the forearm. The resistance of the humeral rotation feature can be changed using the adjusting screw.

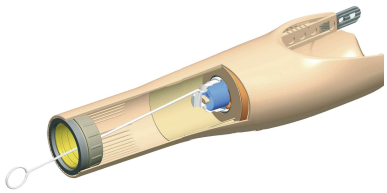
Easy Plug



1. Optional switch
2. Electrode
3. Electrode
4. Optional switch

Easy Plug is a plug connection for myoelectrically controlled prostheses that is integrated in the elbow joint.
The connecting cables of the electrodes and optional switches are connected to the Easy Plug. Its interior cable routing minimises the risk of cable breaks.

Forearm cable



The forearm cable establishes the electrical connection between the product, electric wrist rotator and System Electric Hand or System Electric Greifer.
On delivery, the forearm cable is rolled up in the forearm of the elbow joint. After the forearm has been cut to its final length, the forearm cable can be pulled out.

Lock

The elbow joint is unlocked and locked using an electronically controlled locking drive. This is actuated as a function of the operating situation, the applied load and the control signal generated by the user.

Mechanical unlocking

The elbow joint can be manually unlocked and locked with a slight pull on the switch cable. This function is also available when the product is switched off or the rechargeable battery is drained. In this way, the forearm can be brought into the desired position. Mechanical unlocking is also possible under load.

On/Off switch

The ON/OFF switch 1 is activated/deactivated by pressing it.
A signal sounds and the product briefly vibrates once when it is turned on. It is recommended to turn the product off during longer passive breaks. This increases the period of use before charging the battery.

2.3 Combination possibilities

- bebionic hand EQD 8E70=*
- bebionic hand Flex 8E72=*
- 8E38=9, 8E39=9, 8E41=9 MyoHand VariPlus Speed
- 8E38=8, 8E39=8 Sensor Hand Speed
- 8E3*=9* System Electric Greifer DMC VariPlus
- Battery
- 10S17 Electric wrist rotator
- 13E200=* electrode
- 13E202=* suction socket electrode
- 757L24 DynamicArm battery charger
- Pressure switch 9X37
- 9X25 Rocker switch
- Cable pull switch 9X18
- Linear control element 9X50
- 4-stage control element 9X51
- Linear control element 9X52
- 4-stage control element 9X53

3 Intended use

3.1 Indications for use

The product is to be used solely for upper limb exoprosthetic fittings.

3.2 Conditions of use

The product is suitable for users with unilateral or bilateral upper arm amputations.

The product was developed for everyday use and must not be used for unusual activities. These activities include, for example, sports/extreme sports with high strain on the wrist and/or shocks such as push-ups, downhill racing, mountain biking, free climbing, paragliding, etc.

The product is intended **exclusively** for use on one user. Use of the product by a further person is prohibited by the manufacturer.

3.3 Contraindications

- All conditions which contradict or go beyond the specifications listed in the sections on "Safety" (see page 5) and "Intended use" (see page 5).

3.4 Qualification

Treatment may only be carried out by trained, qualified personnel.

4 Safety

4.1 Explanation of warning symbols

⚠ WARNING	Warning regarding possible serious risks of accident or injury.
⚠ CAUTION	Warning regarding possible risks of accident or injury.
NOTICE	Warning regarding possible technical damage.

4.2 General safety instructions

⚠ CAUTION

Electrode lifting off

Injury due to unexpected product behaviour as a result of uncontrolled activation of the prosthesis component.

► Inform the user that uncontrolled movement of the prosthesis component may occur if the electrode is lifted off.

⚠ CAUTION

Damage to connecting cable due to kinking or small radii

Risk of injury due to unexpected product behaviour as a result of a malfunction.

► Replace the connecting cable immediately if it is damaged.

► Make sure there are no tight angles or kinks when installing the connecting cables.

⚠ CAUTION

Incorrect donning and doffing of the prosthesis

Risk of injury due to sudden flexion of the prosthesis.

► Switch off the prosthesis before donning or doffing.

► The prosthesis must always be flexed for donning and doffing.

⚠ CAUTION

Incorrect electrode settings due to muscle fatigue

Injury due to faulty control or malfunction of the product.

► Allow the user to rest during the adjustment of the electrodes.

⚠ CAUTION

Risk of pinching in the joint flexion area

Injuries due to pinching of body parts.

► Ensure that fingers and other body parts are not in this area when bending the joint.

⚠ CAUTION

Independent user manipulation of system components

Injury due to faulty control or malfunction of the product.

► Manipulations to the product other than the tasks described in these instructions for use are not permitted.

► The battery may only be handled by Ottobock authorised, qualified personnel (no replacement by the user).

► The product and any damaged components may only be opened and repaired by authorised, qualified Ottobock personnel.

⚠ CAUTION

Insufficient skin contact of the electrodes

Injury due to faulty control or malfunction of the product

► The electrodes are to be placed on intact skin only and with as much skin contact as possible.

► In the case of strong interference from electronic devices, the position of the electrodes should be checked and changed if necessary.

► If interference cannot be eliminated, please contact the Ottobock branch responsible for your country.

► The user must rest during the adjustment of the electrodes. Muscle fatigue leads to inconsistent results, and therefore the therapist will tend to establish electrode settings that are excessively sensitive.

⚠ CAUTION

Unintentional unlocking of the terminal device

Risk of injury due to releasing the terminal device from the forearm (e.g. while carrying objects).

► When using a quick-disconnect wrist unit, position the terminal device so that slight twisting does not release the terminal device from the forearm.

⚠ CAUTION

Improper handling

Injury due to loss of product functionality.

► Instruct the user in the proper use of the product.

⚠ CAUTION

Injury due to incorrect adjustment of the product.

Loosening of the components.

► In case of a product with a quick-disconnect wrist, position the terminal device before use so that a slight turn cannot disconnect the terminal device from the prosthesis.

⚠ CAUTION

Signs of wear and tear on the product components

Injury due to faulty control or malfunction of the product

► In the interest of patient safety and in order to maintain operating reliability and protect the warranty, the specified service intervals must be observed (see the section "Maintenance").

⚠ CAUTION

Use of inappropriate components

Risk of injury due to malfunction of the product.

► Operate the product only with components recommended by the manufacturer. You can find the list of components in the “Combination possibilities” section (see page 4).

► Operate the product only with accessories that have been recommended by the manufacturer. You can find the list of components in the “Scope of delivery” section (see page 7).

NOTICE

Damage to the battery

Damage to the battery due to using both connection options.

► Only use one of the two connections for the battery (connection on the forearm cable or Easy Plug connection).

NOTICE

Coating, gluing or painting the prosthesis

Damage or fracture due to chemical processes.

► The prosthesis must not be coated, glued or painted.

NOTICE

Improper product care

Damage to the product due to the use of incorrect cleaning agents.

► Clean the product only as described in the section "Cleaning and care" (see page 18).

5 Scope of delivery

- 4 pcs. mounting brackets
- 1 pc. DynamicArm 12K100N=*
- 1 pc. Lamination protection cover (hollow ball)
- 1 pc. Lamination protection cover (disc with arrow)
- 1 pc. 10S1=40 lamination ring
- 1 pc. Instructions for use (qualified personnel)
- 1 pc. instructions for use (user)
- 1 pc. hook
- 1 pc. clamp ring
- 1 pc. battery charger 757L24
- 4 pcs. oval head self-tapping screw
- 1 pc. O-ring
- 1 pc. electric wrist rotator dummy
- 1 pc. foam cover
- 1 pc. cable guide
- 1 pc. cable lock
- 1 pc. service pass
- 1 pc. Technical information (qualified personnel)

6 Preparing the product for use

6.1 Shortening the forearm

INFORMATION

Wrap the elbow area with plastic wrap to prevent swarf from entering it during cutting.

6.1.1 Adjusting the forearm length and using the 10S17 electric wrist rotator

INFORMATION

The forearm length is measured from the distal end of the lamination ring to the middle of the elbow axis.

Insert used	DynamicArm forearm length
Coupling piece	187 – 305 mm
Electric wrist rotator	213 – 305 mm

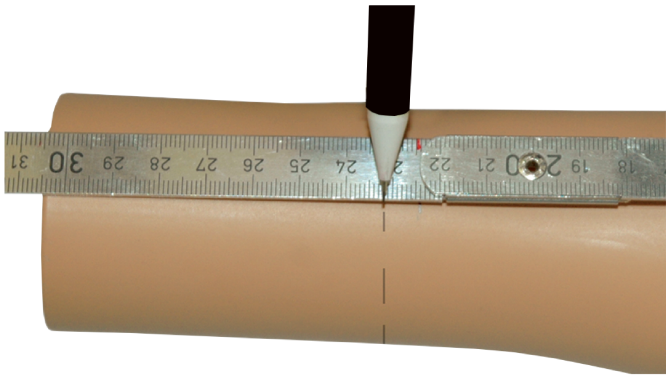
6.1.2 Cutting to length

NOTICE

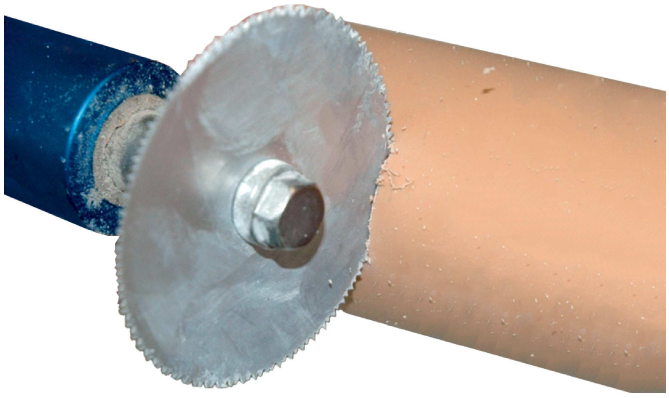
Do not pull the foam or cable protection sleeve out of the forearm under any circumstances before the forearm is cut to length and before the lamination ring is glued in! This reduces the usable length of the forearm!

If the cables were pulled out anyway, they have to be pushed back into the forearm and secured with the foam disc before performing further work. The resulting reduced usable length is as follows:

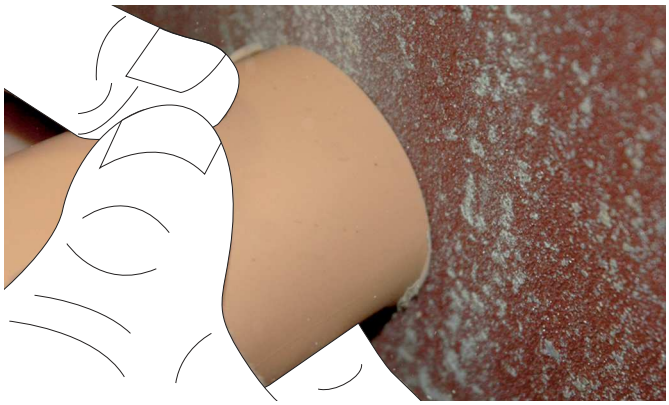
- To a minimum of 207 mm when using the 10S4 coupling piece.
- To a minimum of 230 mm when using the 10S17 electric wrist rotator.



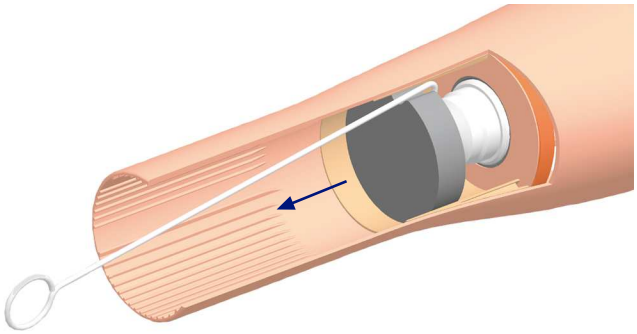
1) Mark the length of the prosthesis so it is approximately 1 cm shorter than the user's other arm.



2) Shorten the forearm to the marked length.

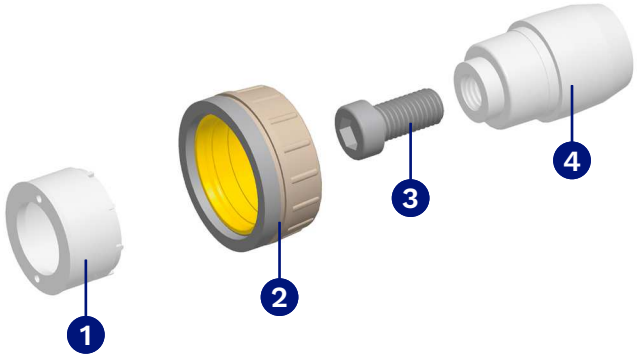


3) Sand all sides of the cut edge at a right angle. Deburr inner and outer sanded edges.



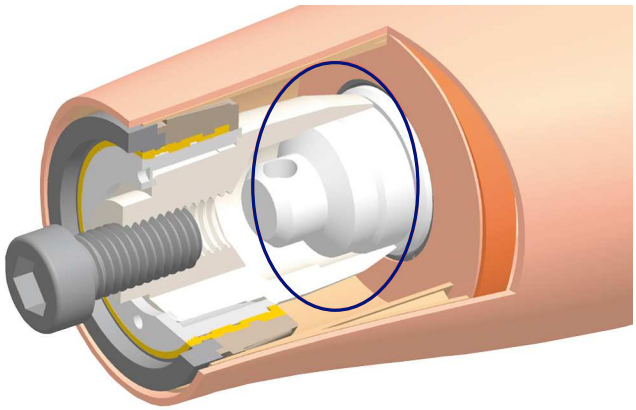
4) Use the hook to remove the foam cover.

6.2 Gluing in the lamination ring with quick-disconnect wrist



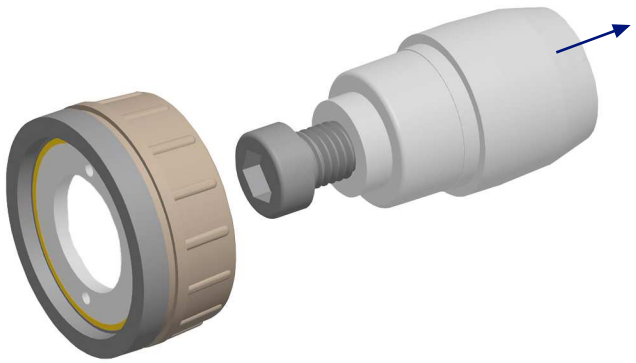
1. Lamination cover
2. Lamination ring with quick-disconnect wrist
3. Hexagon socket screw
4. Electric wrist rotator dummy

Optional: 10S17 electric wrist rotator for forearm length of 213 mm to 225 mm



► Make sure the 10S17 electric wrist rotator dummy is pushed over the cable protection sleeve. This ensures correct axial alignment of the lamination ring.

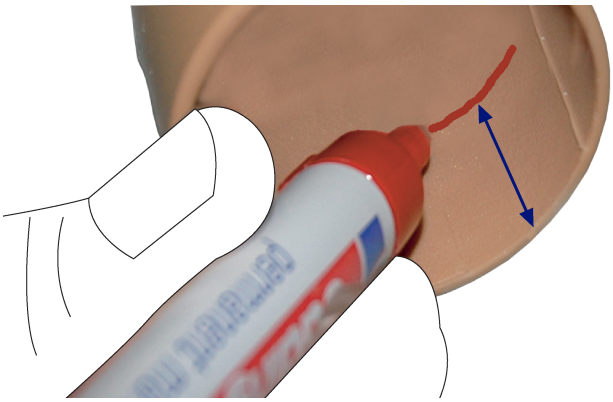
Optional: 10S4 coupling piece for forearm lengths of 187 mm to 225 mm



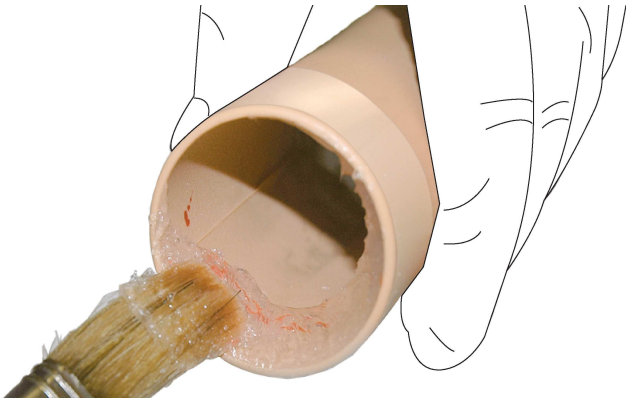
► Pull the 10S17 electric wrist rotator dummy back and out of the lamination ring. The lamination ring cover has to remain in the lamination ring.

The lamination ring with quick-disconnect wrist has to be glued in after the forearm has been cut to length.

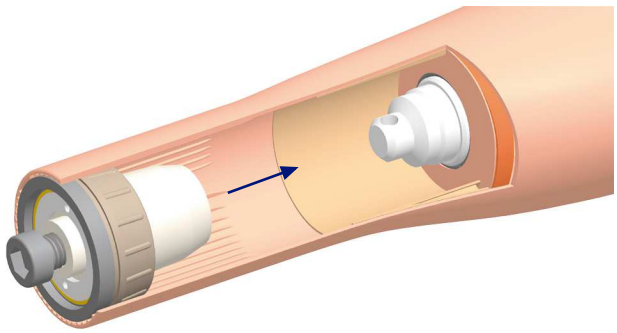
1) Measure the height of the lamination ring.



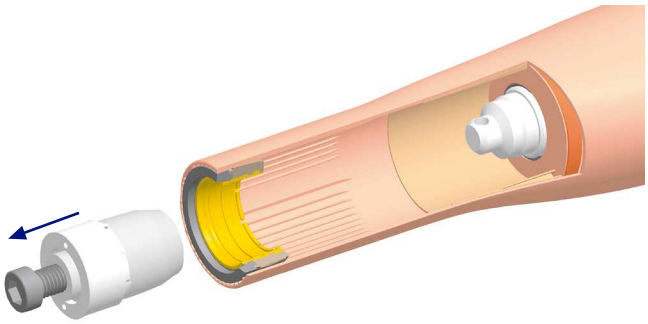
2) Mark this measurement on the inside of the forearm.
3) Mix 636K18=1 Orthocryl sealing resin compact adhesive and 2 % 617H14 hardener paste.
4) Cover the outside of the forearm with 627B4 polyethylene adhesive tape to avoid soiling it while gluing.



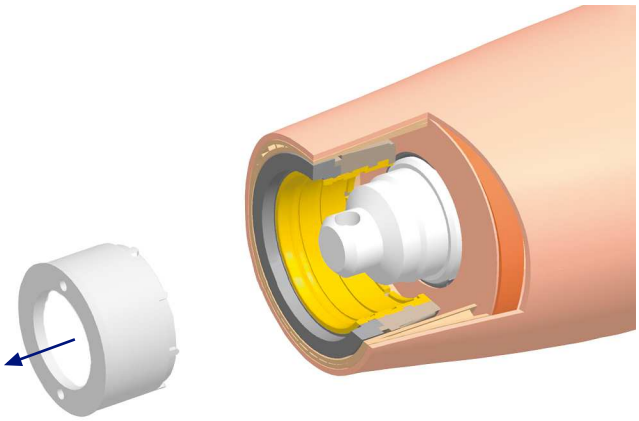
5) Using a paintbrush, apply the resin to the marked area and to the outside of the lamination ring.



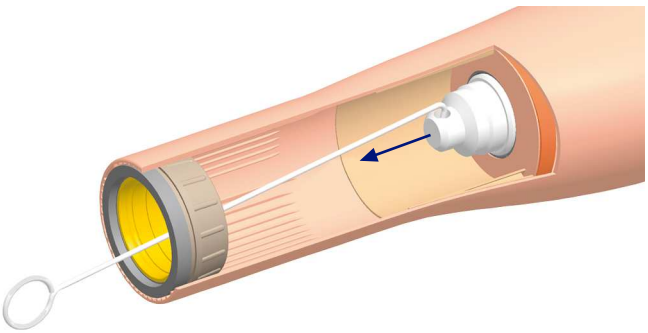
6) Insert the lamination ring and lamination ring cover. The lamination ring must be flush with the socket!
7) Allow the adhesive to cure.



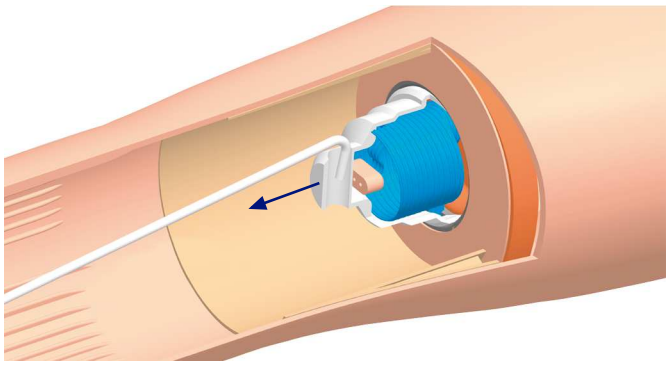
8) Pull out the 10S17 electric wrist rotator dummy with the lamination ring cover on the hexagon socket screw.



9) **OPTIONAL:** Pull out the lamination ring cover.



10) Remove the cable protection sleeve using the hook.

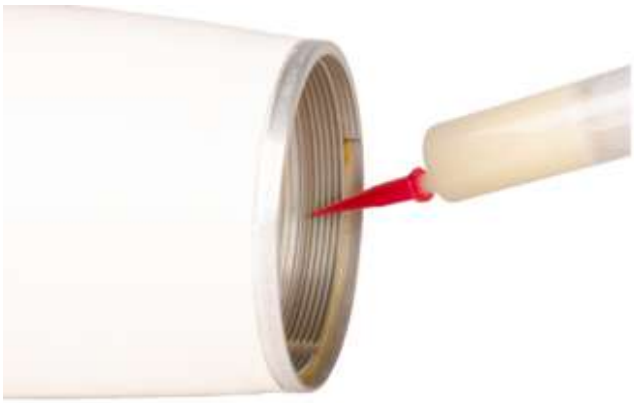


11) The cables are rolled up inside the cable protection sleeve. When removing the cable protection sleeve, the cables are pulled out of the forearm.

6.3 Checking the symmetry

1) Connect prosthetic components to the forearm.
2) Check the symmetry using the 743L20=230 Ottobock LaserLine.

6.4 Sealing the prosthesis



1) After laminating the lamination ring, clean the thread.
2) Lubricate the groove, inner edges and thread of the lamination ring with 633F30 special grease.

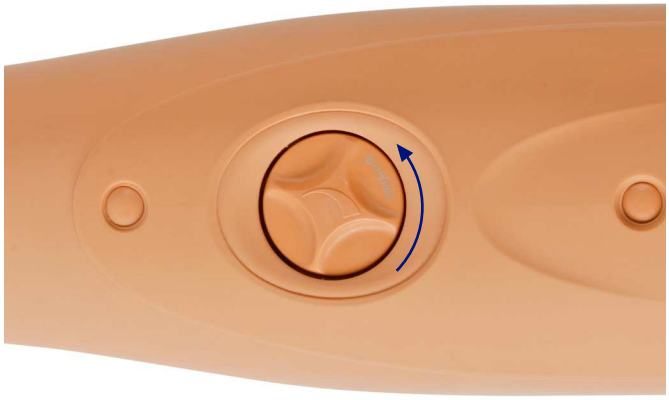
6.5 Installing the Easy Plug

1) Slide the Easy Plug with the connected cables into the greased lamination ring. It has to engage completely!
   INFORMATION: It is clearly audible when the Easy Plug engages.

2) Check that the Easy Plug engages properly.
   INFORMATION: The circuit board and the edge of the lamination ring are parallel to each other.

6.6 Installing the elbow joint

1) Do not remove the two cover caps!
2) Screw the elbow joint into the upper arm socket.
   INFORMATION: The opposite application of the adjusting screw and the threaded recess makes it easier to screw it in.



3) Set the flexion assist to minimum using the hand-wheel.

4) Extend the elbow joint and lock it with the switch cable.

5) Unscrew the hexagon socket screw.

6) Lift and remove the red mounting clamp.
INFORMATION: The lifter strap must not be removed from the elbow ball. Fixing the lifter strap in place (e. g. with a haemostat) is no longer necessary.

7) Slide the band clamp under the lamination ring.

8) Screw in the hexagon socket screw.

6.7 Installing the switch cable on the upper arm socket

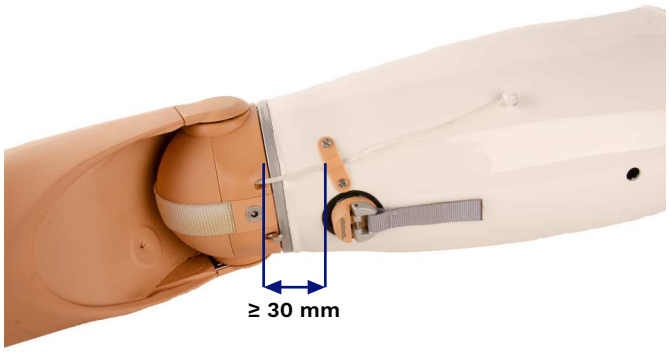
⚠ CAUTION

Removing the switch cable

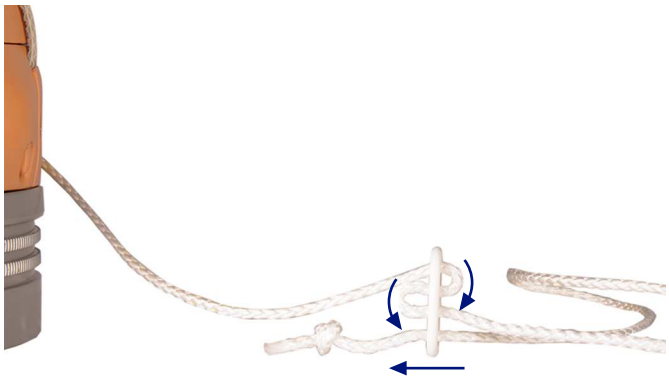
Risk of injury due to malfunction of the product.

► The switch cable is to be used for emergency operation only. For safety reasons, it must not be removed! If the product is switched off or defective or the rechargeable battery is drained, the elbow joint cannot be locked or unlocked without the switch cable.

1) Bring the forearm into neutral position.
2) Affix the cable guide to the socket with cap screws (at least approx. 30 mm distance to the lamination ring).
   INFORMATION: Rotate the socket in and out up to the stop. Ensure that the switch cable does not tighten.



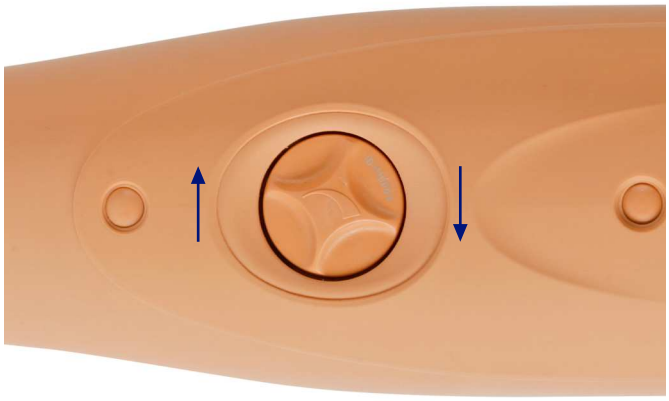
Complete the following additional steps to finish the switch cable:



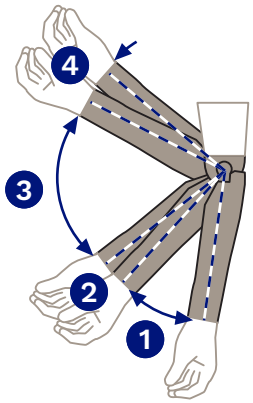
1) Thread the switch cable through the cable lock.
2) Secure the end of the switch cable with a knot.
3) Tighten the switch cable and make a loop.

6.8 Adjusting the flexion assist

Complete the following steps to set the flexion assist:



1) Flex the arm.
2) Use the handwheel to set the desired flexion assist.
   INFORMATION: The support level can be adjusted to the weight of the clothing and the hand weight.



Position 1
Low support to allow the arm to swing freely while walking.

Position 2
Support increases progressively when flexing the arm and decreases during extension.

Position 3
Support remains constant. If set correctly, the weight of the forearm is balanced by the flexion assist and the forearm “floats”.

Position 4
Low support before flexion stop.

6.9 Adjusting the humeral rotation feature

The humeral rotation feature has a bilateral stop of ±80°. The resistance of the humeral rotation feature can be adjusted using the external adjusting screw.

1) Increase the resistance by turning it clockwise.
2) Reduce the resistance by turning it counter-clockwise.

6.10 Connecting the electric wrist rotator

There are numbers for the plug contacts on the plastic housing of the electric wrist rotator. These numbers serve as orientation for connecting the cables.

1) Connect the motor cable to one of the two no. 3 contacts.
2) Connect the two-pole cable to one of the two no. 3 contacts.
3) Connect the three-pole cable to the no. 2 contact. One of the three-pole cables is marked with a coloured dot.
   INFORMATION: If the two three-pole cables are interchanged when connecting them, no function of the System Electric Hand or System Electric Greifer is possible.

4) To secure the coaxial plug, insert the lock ring into the groove of the lamination ring using tweezers.
5) Then install the electric wrist rotator in the lamination ring.

6.11 Connecting the coupling piece

1) One of the two three-pole cables is marked with a coloured dot (arrow). The two cables must not be interchanged!
INFORMATION: The two-pole motor cable must not be connected to the coaxial plug.

2) Install the plastic screw to secure the two cables.
3) Push the coaxial plug in to the stop and rotate it until the stop noticeably engages.
4) Install the lock ring in the lamination ring.

7 Handling

7.1 Charging the battery

INFORMATION
Please observe the corresponding instructions for use of the charging equipment.

7.2 Data transfer between the product and the PC

Product settings using the adjustment software can only be made via Bluetooth data transfer. For this purpose, a Bluetooth wireless connection must be established between the product and the PC using the “60X5=* BionicLink PC” Bluetooth adapter. The installation and use of the “60X5=* BionicLink PC” adapter are described in the instructions for use included with the adapter.

7.3 “646C42=V1.6 ElbowSoft” software

INFORMATION
Observe the corresponding instructions for use for the installation/removal of “646C42=V1.6 ElbowSoft”.

7.3.1 Calibration

INFORMATION
Calibration takes place in the course of the initial fitting, after adapting a new or modified socket, after each repair and after each service.
The elbow joint cannot be adjusted if the calibration process has not been completed yet.

The flexion angle of the product is approx. 15 – 145°. The effective flexion angle is determined on the user by the shape and size of the prosthetic socket and by clothing. The flexion angle has to be determined through the calibration process and stored in the product.

1) Mount the product on the socket.

2) Switch on the product.
3) Start the “ElbowSoft 646C42=V1.6” software.
4) For the subsequent steps, see the corresponding instructions for use.

8 Cleaning and Care

1) Clean the product with a damp cloth and mild soap (e.g. 453H10=1-N Ottobock Derma Clean) when needed. Make sure that no liquids get into the product and product components.
2) Dry the product with a lint-free cloth and allow it to air dry fully.

9 Maintenance

Regular maintenance (service inspections) every 24 months is mandatory in the interest of patient safety, in order to maintain operating reliability, to protect the extended warranty and to maintain basic safety.

The product is required for maintenance 4 weeks before, up to a maximum of 3 months after the due date.

Components required for maintenance or repair:

The product, battery charger and power supply unit.

Use the service packaging to send the components requiring inspection.

10 Legal information

All legal conditions are subject to the respective national laws of the country of use and may vary accordingly.

10.1 Liability

The manufacturer will only assume liability if the product is used in accordance with the descriptions and instructions provided in this document. The manufacturer will not assume liability for damage caused by disregarding the information in this document, particularly due to improper use or unauthorised modification of the product.

10.2 Trademarks

All product names mentioned in this document are subject without restriction to the respective applicable trademark laws and are the property of the respective owners.

All brands, trade names or company names may be registered trademarks and are the property of the respective owners.

Should trademarks used in this document fail to be explicitly identified as such, this does not justify the conclusion that the denotation in question is free of third-party rights.

10.3 CE conformity

Otto Bock Healthcare Products GmbH hereby declares that the product is in compliance with applicable European requirements for medical devices.

The product meets the requirements of the RoHS Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic devices.

This product meets the requirements of the 2014/53/EU directive.

The full text of the regulations and requirements is available at the following Internet address: http://www.ottobock.com/conformity

10.4 Local Legal Information

Legal information that applies **exclusively** to specific countries is written in the official language of the respective country of use in this chapter.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

1) This device may not cause harmful interference, and

2) This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

—Reorient or relocate the receiving antenna.

—Increase the separation between the equipment and receiver.

—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

—Consult the dealer or an experienced radio/ TV technician for help.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Caution: Exposure to Radio Frequency Radiation.

This device must not be co-located or operating in conjunction with any other antenna or transmitter.

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s)..

Operation is subject to the following two conditions:

(1) This device may not cause interference.

(2) This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:

(1) L'appareil ne doit pas produire de brouillage;

(2) L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Caution: Exposure to Radio Frequency Radiation.

The installer of this radio equipment must ensure that the antenna is located or pointed such that it does not emit RF field in excess of Health Canada limits for the general population.

Caution: Federal law (USA) restricts this device to sale by or on the order of a practitioner licensed by law of the State in which he/she practices to use or order the use of the device.

11 Technical data

Ambient conditions	
Storage (with and without packaging)	+5 °C/+41 °F to +40 °C/+104 °F Max. 93% relative humidity, non-condensing
Transport (with and without packaging)	-20 °C/-4 °F to +60 °C/+140 °F Max. 93% relative humidity, non-condensing
Charging temperature	+5 °C/+41 °F to +40 °C/+104 °F
Operation	+5 °C/+41 °F to +45 °C/+113 °F Max. 93% relative humidity, non-condensing

General	
Reference number	12K100N=*
Weight (dependent on forearm length)	approx. 1000 g
Max. lifting force	50 N
Flexion angle	approx. 15° – 145°
Expected lifetime given compliance with the recommended maintenance intervals	6 years

Rechargeable battery of the product	
Battery type	Li-ion
Output voltage	approx. 11.1 V
Charging voltage	approx. 4.2 V
Capacity	1880 mAh
Dimensions of battery cells	approx. 49.5 x 52 x 43.5 mm
	500

Rechargeable battery of the product	
Charging cycles (charging and discharging cycles) after which at least 80 % of the original battery capacity remains available	
Weight	approx. 118 g
Charging time until battery is fully charged	4.0 h

Power supply	
Reference number	757L24
Storage (with and without packaging)	-25 °C/-13 °F to +70 °C/+158 °F 10% to 95% relative humidity
Transport (with and without packaging)	-25 °C/-13 °F to +70 °C/+158 °F 10% to 95% relative humidity
Operation	-25 °C/-13 °F to +40 °C/+104 °F Max. 95% relative humidity, non-condensing
Input voltage	90 V~ to 264 V~
Mains frequency	47 Hz to 63 Hz

12 Appendices

12.1 Symbols Used

CE — Declaration of conformity according to the applicable European directives

Manufacturer

FC — Compliance with the requirements according to "FCC Part 15" (USA)

In some jurisdictions it is not permissible to dispose of these products with unsorted household waste. Disposal that is not in accordance with the regulations of your country may have a detrimental impact on health and the environment. Please observe the instructions of your national authority pertaining to return and collection.

Compliance with the requirements under the "Radiocommunications Act" (AUS)

SN — Serial number (YYYY WW NNN)
YYYY – year of manufacture
WW – week of manufacture
NNN – sequential number

Non-ionising radiation

MD — Medical device

REF — Article number

12.2 Operating states/error signals

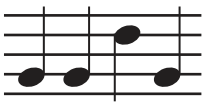
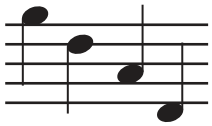
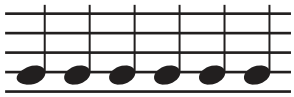
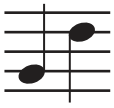
12.2.1 Warnings/error signals

Beep signal	Vibration signal	Error	Required action
1 x long	1 x	Critical error (e.g. a sensor is not operational)	Switch the product off and on again. Connect the battery charger while the product is switched on. Contact Ottobock Service if the error has not been resolved.
1 x long	5 x	Severe error (e.g. temperature of the lifting motor too high)	
2 x	1 x	Malfunction (e.g. incompatible component connected)	

12.2.2 Signals for operating states

INFORMATION

It is possible that only individual or several components can no longer be controlled.

Sound sequence		Event	Elbow joint	Electric wrist rotator	Hand/Greifer
	Low, low, high, low	The product has been switched on.	Function is present	Function is present	Function is present
	Very high, high, low, very low	Decreasing battery charge level.	No function	Function is present	Function is present
	6 x low	Battery charger was connected during operation.	No function	No function	No function
	Low, high	Prosthetic component is being controlled.	Function of the prosthetic component in question is not possible.		

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