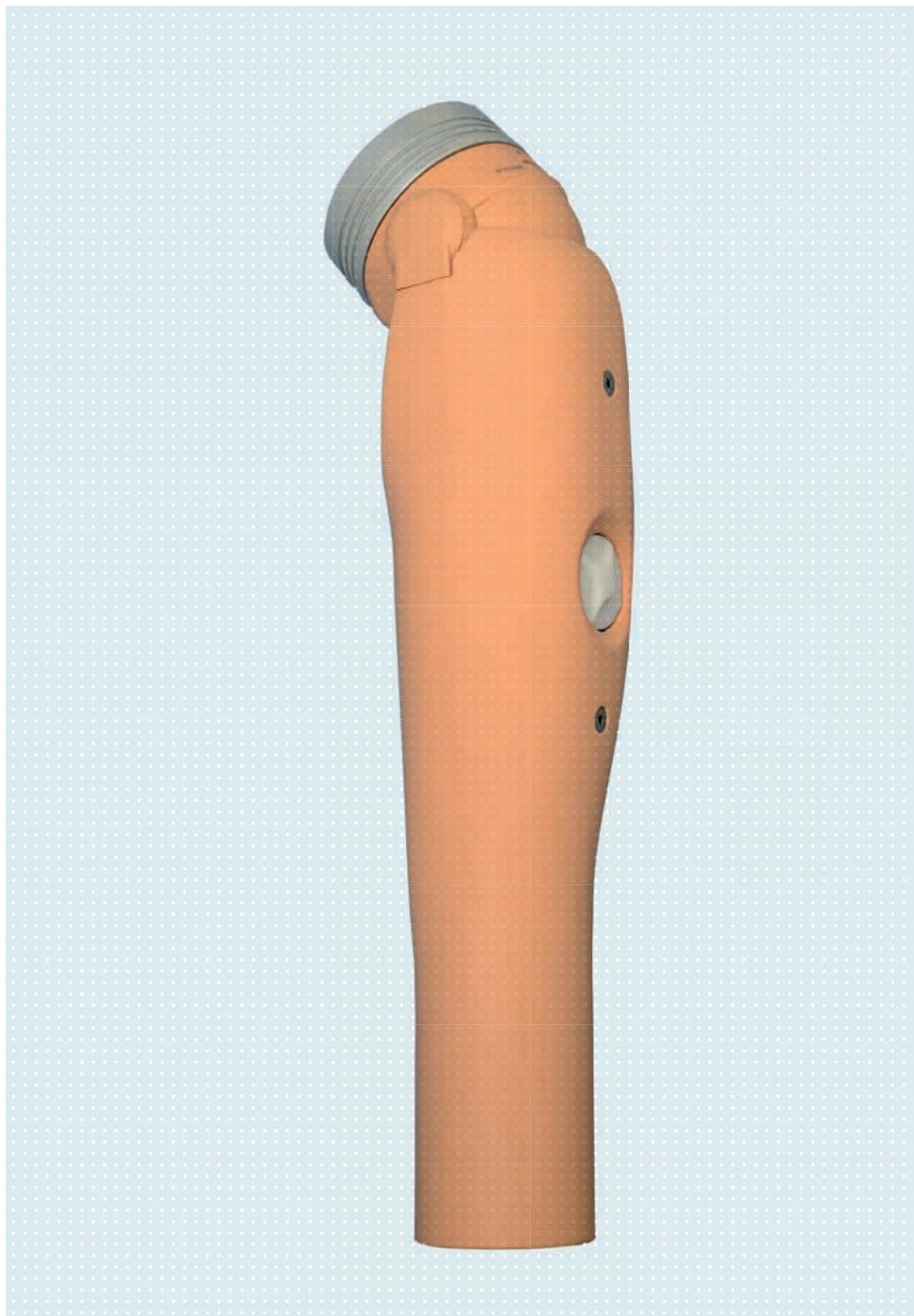


12K500=* AxonArm Hybrid

12K501=* AxonArm Ergo

Casting and Lamination Instructions

Technical Information 3.3.6



DE | INFORMATION

Zusätzlich zu der gedruckten Gebrauchsanweisung, sind auch weitere Sprachen auf CD beigelegt (siehe rückseitigen Umschlag). Auf Anfrage können Sie eine gedruckte Gebrauchsanweisung kostenlos in der jeweiligen Landessprache unter der unten angegebenen Anschrift bestellen.

EN | INFORMATION

In addition to the printed Instructions for Use, additional language versions are also included on CD (see back cover). You can order a printed version of the Instructions for Use at no charge in the respective national language at the address below.

FR | INFORMATION

Le mode d'emploi est disponible en d'autres langues sur CD en supplément de la version imprimée (voir au dos de la couverture). Vous pouvez commander gratuitement une version imprimée du mode d'emploi dans la langue de votre choix en envoyant votre demande à l'adresse indiquée ci-dessous.

ES | INFORMACIÓN

Aparte de las instrucciones de uso impresas, se incluye un CD con dichas instrucciones en otros idiomas (véase la solapa del dorso). Puede solicitar de forma gratuita unas instrucciones de uso impresas en el idioma de su país a la dirección que se indica más abajo.

IT | INFORMAZIONE

In aggiunta alle istruzioni per l'uso in formato cartaceo, il CD contiene le istruzioni anche in altre lingue (vedere il retro della copertina). Su richiesta, è possibile ordinare gratuitamente le istruzioni per l'uso in formato cartaceo nella lingua del Paese di appartenenza all'indirizzo di seguito riportato.

PT | INFORMAÇÃO

Adicionalmente ao manual de utilização impresso, encontra-se incluído um CD com mais idiomas (ver na contracapa). A pedido, é possível encomendar gratuitamente um exemplar impresso do manual de utilização no idioma respectivo junto ao endereço especificado.

NL | INFORMATIE

De gebruiksaanwijzing is behalve in gedrukte vorm ook in diverse andere talen bijgevoegd op cd (zie de achterzijde van de omslag). Een gedrukte gebruiksaanwijzing in de gewenste taal kunt u kosteloos bestellen op het hieronder vermelde adres.

SE | INFORMATION

Som komplement till den tryckta bruksanvisningen har dessutom ytterligare språk bifogats på CD (se baksidan av omslaget). Vid efterfrågan kan du utan kostnad beställa en tryckt bruksanvisning i det respektive språket under den angivna adressen.

DA | INFORMATION

Supplerende til brugsanvisningen på papir er der også vedlagt yderligere sprog på cd (se bagsiden af omslaget). På den oplyste adresse nedenfor kan du bestille en gratis brugsanvisning på papir på det pågældende sprog.

NO | INFORMASJOU

I tillegg til den trykte bruksanvisningen er flere språk vedlagt på CD (se på baksiden omslaget). På forespørsel kan du bestille en trykt bruksanvisning på det aktuelle språket gratis via adressen nedenfor.

FI | TIEDOT

Painetun käyttöohjeen lisäksi tarjoaa oheinen CD-levy käyttöön myös lisää kieliä (katso kansilehden takapuoli). Painettu käyttöohje kunkin maan omalla kielellä on pyynnöstä tilattavissa maksutta alla ilmoitetusta osoitteesta.

CZ | INFORMACE

Kromě této vytištěné verze návodu k použití jsou na přiloženém CD k dispozici také další jazykové verze překladu (viz zadní strana obalu). V případě požadavku si můžete na níže uvedené adrese zdarma objednat vytištěný návod k použití v příslušném jazyce.

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1 Foreword

INFORMATION

Last update: 2013-11-12

- Please read this document carefully.
- Follow the safety instructions and the precautions specified in this accompanying document.
- If assistance is required during the start-up, use or maintenance of the product, as well as in the event of unexpected operating behaviour or circumstances, contact the manufacturer (see manufacturer's address on the back of this accompanying document).

2 Materials and Products Used

The required materials and tools are listed in the tables below. The tables contain the materials and tools shown in the photos within this technical information.

INFORMATION

This is a recommendation for an approach that leads to a very good result when making the model.

Materials	
Designation	Reference number or article number
Compression pantyhose	Match the size to the patient
Copying Pen	645C1
Plaster Insulating Cream	640Z5=1
Monofilament Adhesive Tape	627B2=19
Michelangelo Dummy	Match to the patient's hand size
Silicone Grease	633F11
Nylon Tube Sock	99B25
Liquid Wax	NWax=1
Vacuum Forming Pattern for electrodes	13E201
ThermoLyn soft or	616T69=*
ThermoLyn soft clear	616T53=*
PVC Bag	99B71
Neoprene Cell Rubber Tape	627B5=19
Pedilen Rigid Foam 200	617H12
Pedilen Hardener	617P21
Trolen Sheeting	616T3=1
PVA Bag	99B81
Countersink Drill	D=20 mm
C-Orthocryl Lamination Resin or	617H55
Orthocryl Lamination Resin	617H19
Perlon Stockinette	623T3=*
Carbon Fibre Cloth	616G12
Double-Sided Adhesive Tape	616F10
Pigment Paste	617Z2=*

Tools	
Designation	Reference number or article number
Latex Gloves or Latex-Free Gloves	641H12 or 641H9=2
Tape Measure	743B4
Knife	718H5
Flat Rasp	716Y1
Half-Round Rasp	716Y3
Round Rasp	716Y4

Tools	
Designation	Reference number or article number
Wet Sanding Paper 400	General workshop supplies
Water Basin	754W5=1
Plaster Mixing Bowl	754B1
Plaster Spatula	756G2=*
Grinding Brush	749B1
Sanding Cone	749F8
Polishing Roller	749F7
Sanding Drum	749F6
Rasp Milling Tool	729W31/729W34
Habermann Cleaner	749Z4

Machines, equipment and accessories	
Designation	Reference number or article number
Alabaster Modelling Plaster	699G4=25
Cellona Plaster Bandage 15cm wide	699G3=15
Plastering Rod	General workshop supplies
Alignment Aid for Elbow Components	743A27
Vacuum Forming Tool	711M53
MyoBoy	757M11
Electrode Mounting Brackets	13E135
Electrode Accessories	13E201
Ottobock LaserLine	743L20=230

3 Determining the correct electrode position

3.1 Tools

Designation	Reference number or article number
Grease Pen	645C2=*
PAULA Software with MyoBoy	646C48=*
Electrode Cable	13E129=G*
Suction Socket Electrode	13E202=50/60

3.2 Determining electrode positions

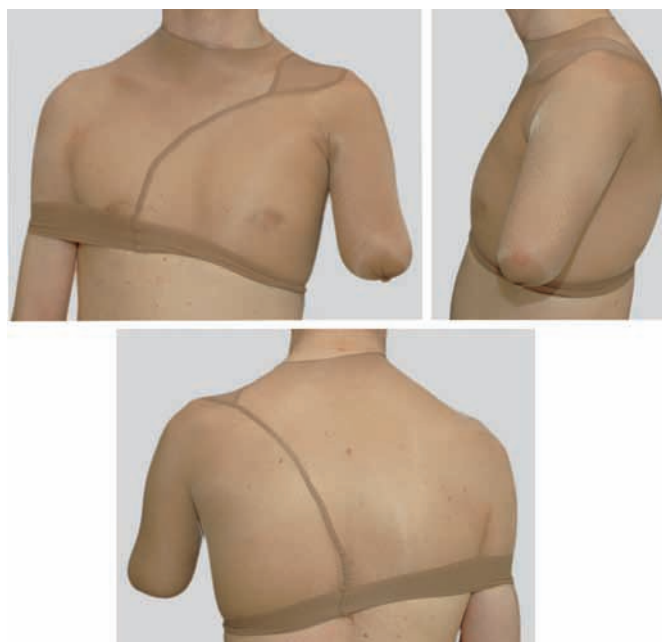
- 1) With bilateral contraction, palpitate the muscle belly.
- 2) Apply the suction socket electrodes parallel to the muscle fibres.
- 3) Check the muscle activity on both sides (extensor and flexor).
- 4) In order to do so, conduct the MyoTest to determine the optimum electrode position with the MyoBoy and PAULA on the patient.
- 5) If necessary, move the electrodes and check again.
- 6) Attach both suction socket electrodes.
- 7) Check for optimum signal separation on the PC and change the electrode positions if required.
- 8) Mark the electrode positions on the skin.

4 Preparing the patient

To shape the upper arm residual limb's soft tissues into a suitable form, a compression pantyhose will be used. This pantyhose must match the patient's size.



- 1) Cut off the legs of the compression pantyhose.

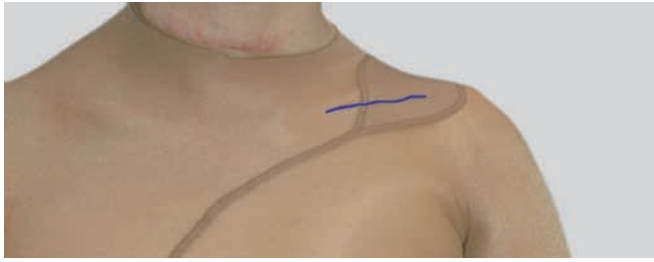


- 2) Dress the patient with the compression pantyhose and tie it off at the end of the residual limb.



- 1) Measure circumference and length and record them.

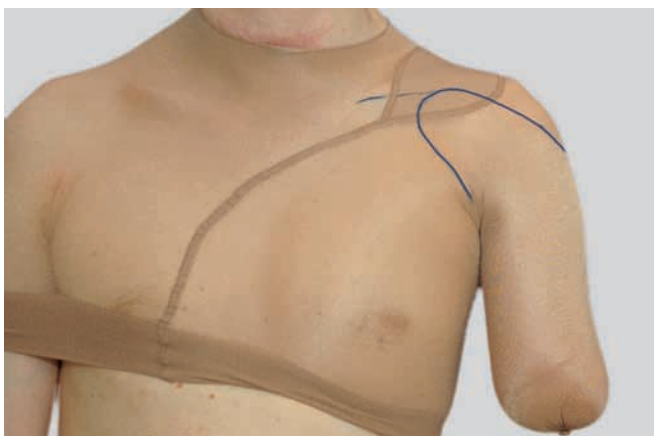
INFORMATION: Use a 645C1 Copying Pen to mark the compression pantyhose as follows.



2) Mark the lower edge of the clavicle.



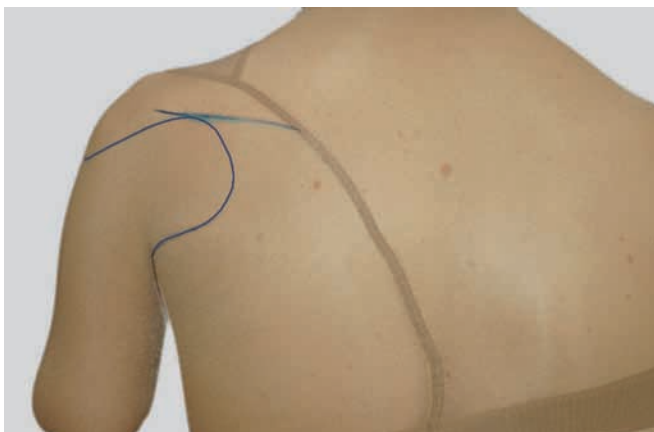
3) Mark the upper edge of the scapular spine.



4) Mark the socket contour of the frontal contact area.



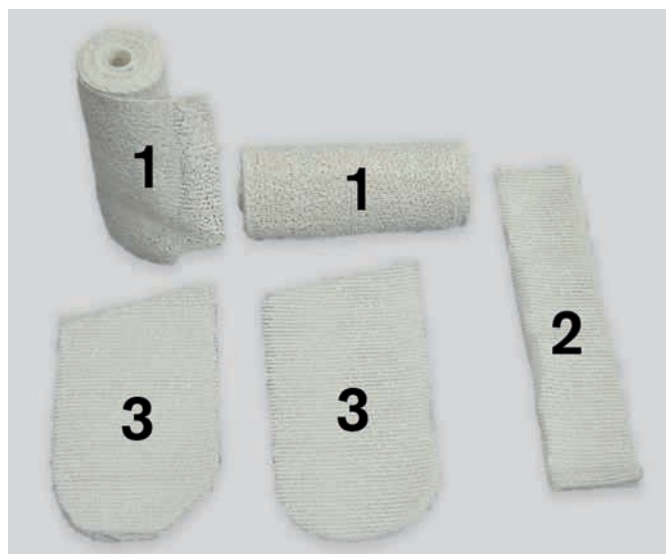
5) Mark the socket contour of the side contact area.



6) Mark the socket contour of the rear contact area.
7) Transfer the electrode position to the compression pantyhose.

5 Plaster cast on the patient

5.1 Fitting of plaster longuettes



Prepare plaster bandages needed:

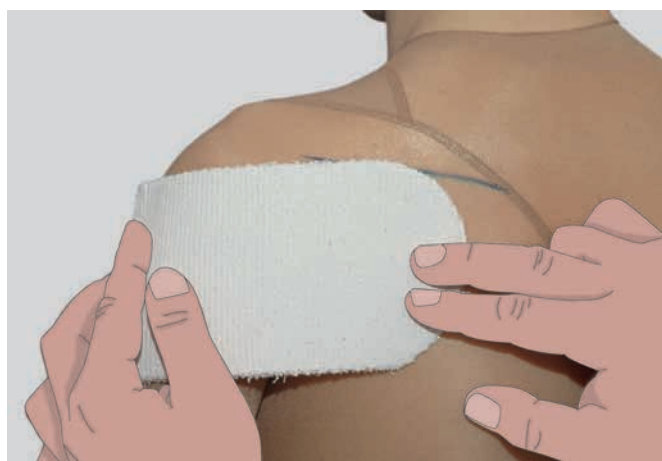
Item 1: 2 elastic plaster bandages

Item 2: 7-fold longuettes for the supporter

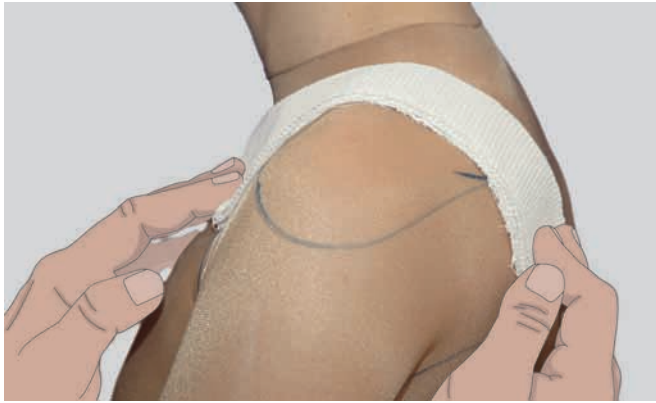
Item 3: 7-fold longuettes for the front and rear contact



- 1) Adjust 7-fold longuettes for the frontal contact area according to the marked line.



- 2) Adjust 7-fold longuettes for the rear contact area according to the marked line.



- 3) Adjust 7-fold longuettes for the supporter.

5.2 Modelling the contact areas

INFORMATION

Wear disposable gloves while working with plaster.



During the modelling of the plaster, the patient must be in a standing position, upper arm adducted. Have the patient wear an apron to protect against plaster splatters.



- 1) Apply 640Z5=1 Otto Bock Plaster Insulating Cream to the axillary area.



- 2) Wrap the residual limb with two elastic plaster bandages using figure-eight loops, carefully applying steady pressure.



- 3) Shape the soft tissues from distal to proximal.
INFORMATION: After wrapping the residual limb with plaster bandages, move the residual limb once in a forward motion and once in a backward motion. This will ensure an optimal imprint of the axillar pit in the plaster negative.



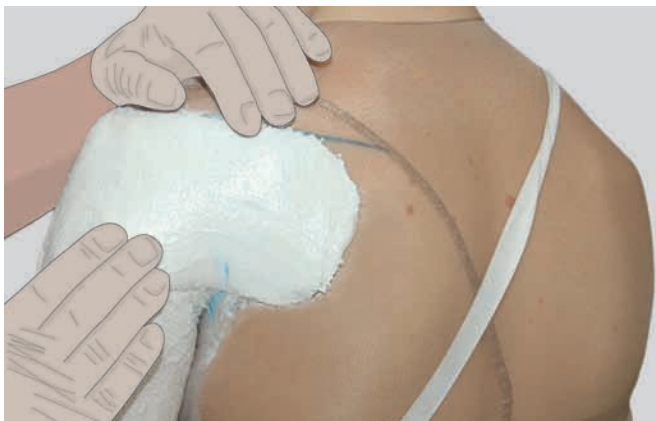
- 4) Move residual limb in a forward motion once.



- 5) Move residual limb in a backward motion once.



- 6) Model the frontal contact area.



- 7) Model the rear contact area.



- 8) Model the supporter.



- 9) Free space between supporter and contact areas at shoulder height.



- 10) Shape the dorsal groove with massaging motions.



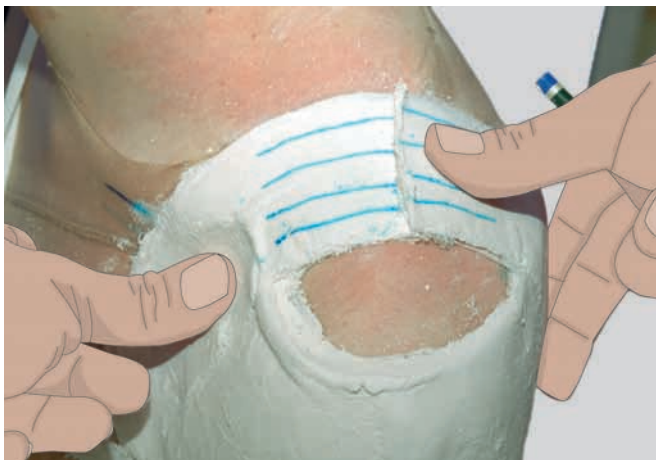
- 11) Model the contact areas until plaster is hardened.
12) Apply pressure to scapula with flat of hand, index finger positioned just below the clavicle.



- 13) Mark longitudinal lines on the supporter to allow for precise reconnection of the ends later on.



- 14) Carefully cut through the middle of the supporter.



- 15) To achieve improved guidance of the finished socket, press front and rear contact area towards each other. The compression should be comfortable for the patient.



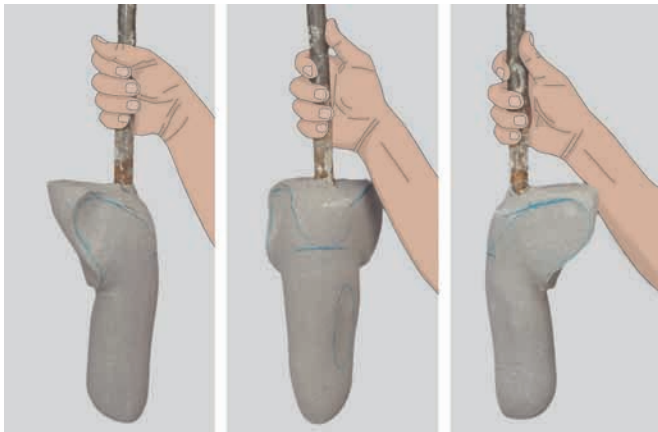
- 16) Transfer overlapping edge, and cut off the overlapping rim.

INFORMATION: Upon removing the cast, firmly reconnect the supporter using a plaster longuette.

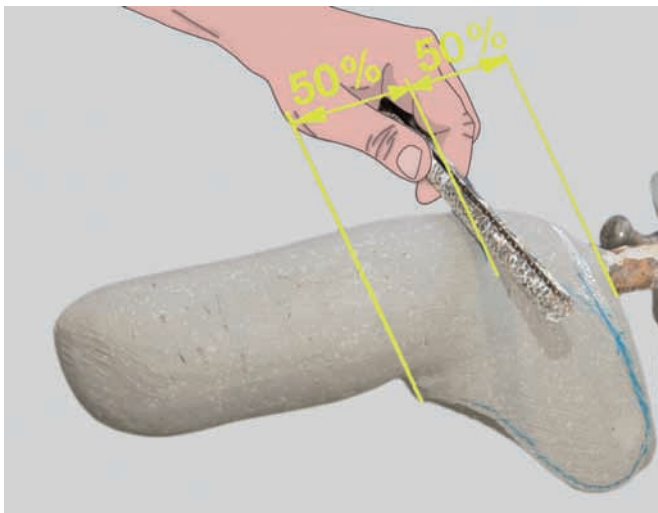


- Finished plaster negative.
- The lines marked on the compression pantyhose using the 645C1 Copying Pen are now clearly recognisable on the inside of the moist plaster negative.

6 Fabricating the plaster positive



- 1) Pour plaster into the plaster negative.
 - Due to the moisture, the lines marked in the plaster negative will transfer to the plaster positive.
- 2) Upon drying, redraw the lines on the plaster positive using the 645C1 Copying Pen.



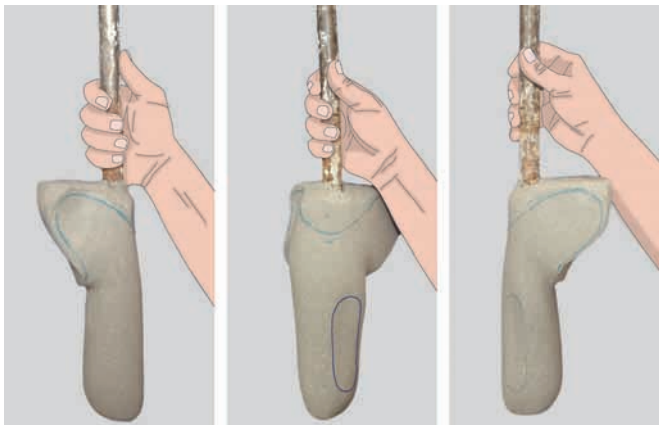
- 3) Mark the highest point of the acromion and armpit on the lateral side of the residual limb.
- 4) Centre the rounded rasp between these two lines.



- 5) Create a notch the size of the rasp diameter (approx. 15 mm).



- 6) Then sand the plaster down to the level of the rasp's diameter.
- 7) Model the plaster positive in a distal to proximal direction according to the soft tissue structure of the residual limb.



- 8) Smooth plaster positive in the distal region according to the condition of the residual limb in this area.
- 9) Now smooth plaster positive frontally and dorsally.
- 10) Shape the dorsolateral humerus groove. Depending on the proportions of the soft tissue, model a groove 3 to 10 mm in depth.
- 11) Verify and compare patient data using the plaster model.

7 Fabricating the inner check socket

7.1 Vacuum forming the interim socket



- 1) Using the modelled plaster positive, the interim socket is shaped by vacuum.
- 2) Upon cooling, it will be sanded to shape.

INFORMATION: Also see the 646T3=3.2D Technical Information for fabricating vacuum formed sockets for myoelectrical transradial prostheses.

8 743A27 Alignment Aid for Elbow Components

8.1 Intended use

The 743A27 Alignment Aid for Elbow Components is to be used exclusively as an alignment and foaming tool, as well as to support functionality training during rehabilitation for patients receiving exoprosthetic fittings of the upper limbs.

The 743A27 Alignment Aid for Elbow Components may only be used for the following products: 12K100N, 12K500, 12K501.

8.2 Safety instructions

⚠ WARNING

Operating vehicles and machinery with the interim prosthesis

- Injury due to unexpected actions of the prosthesis
- Inform the patient that operating vehicles or machinery of any kind is prohibited while wearing an interim prosthesis with the 743A27 Alignment Aid for Elbow Components.

⚠ CAUTION

Use of the alignment aid in an unsecured environment

- Injury due to faulty control or malfunction of the product.
- Deploy the 743A27 Alignment Aid only in orthopaedic workshops, or during in-patient stays in rehabilitation facilities.

⚠ CAUTION

Failure to observe the safety datasheet

- Injury due to skin and eye irritation.
- Before processing 617H12 Pedilen® Rigid Foam 200 and 617P21=* Pedilen® Hardener, please read the corresponding safety datasheet.

8.3 Scope of delivery

- 1 Ring
- 4 Rods
- 1 Foam cover
- 4 Sheet metal cylinder head screws

8.4 Description and function

The 743A27 Alignment Aid for Elbow Components is used to align an elbow component (12K100 DynamicArm, 12K500 AxonArm Hybrid, 12K501 AxonArm Ergo) with the patient's interim socket and facilitates the subsequent alignment of the prosthesis until the lamination of the definitive upper arm socket. Training with the fully aligned

interim socket during the rehabilitation phase helps the patient to learn movements from early on, thus allowing a seamless transition to the use of the prosthesis.

8.5 Liability

Ottobock can only be held liable for damages if the 743A27 Alignment Aid for Elbow Components is used under the specified conditions and in accordance with the intended use.

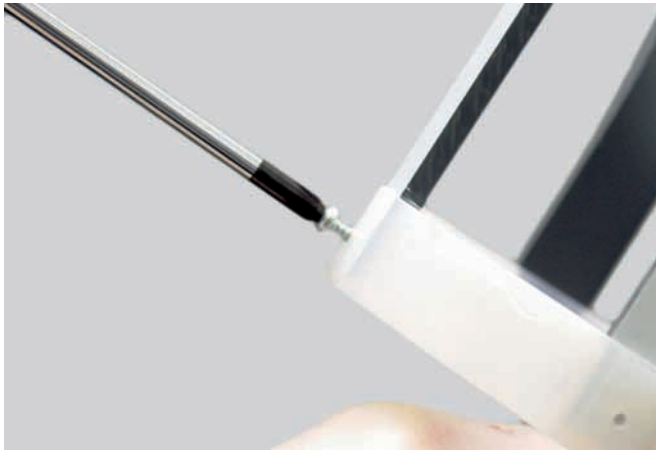
The manufacturer explicitly states that this product must only be used in component combinations authorised by Ottobock (see Instructions for Use and catalogues). Ottobock cannot be held liable for damages caused by component combinations not authorised by Ottobock.

8.6 Mounting the alignment aid to the lamination ring

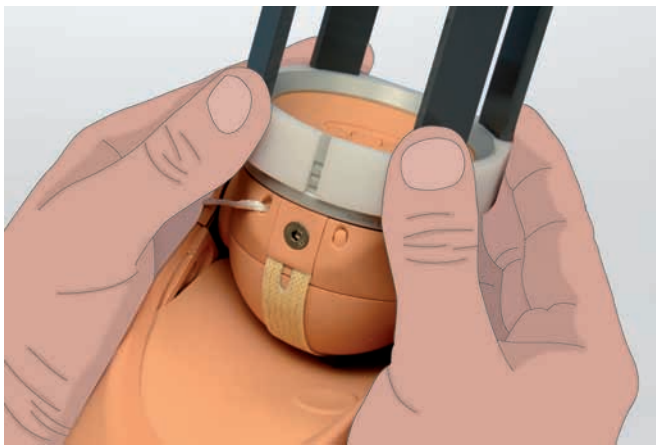
INFORMATION

Removing the protective foil

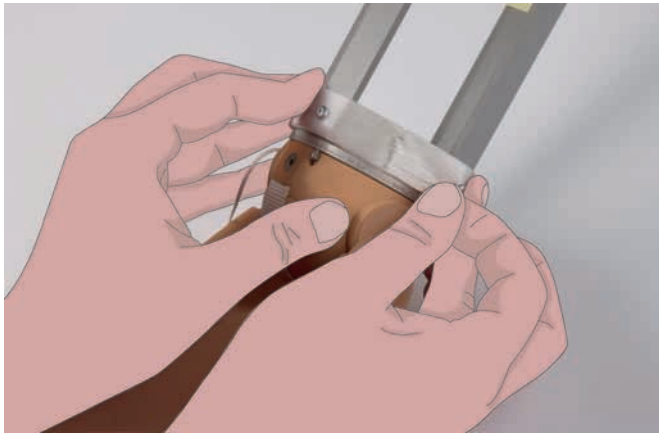
Do not remove protective foil from adhesive areas yet!



- 1) Insert rods into the ring to the stop with the adhesive area pointing inwards.
- 2) Secure the ring and rods with screws.



- 3) Stretch the ring and pull it over the lamination ring.
INFORMATION: The ring must lock into the lowest groove of the lamination ring.

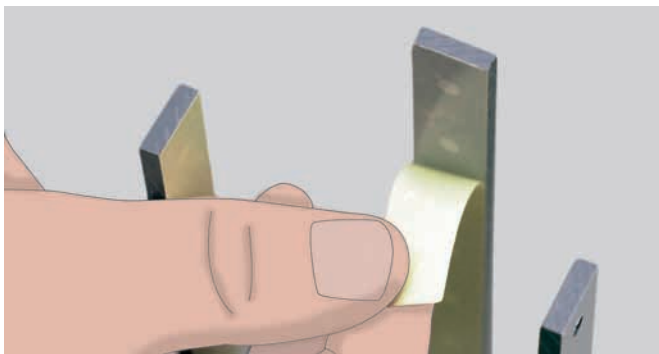


- 4) Squeeze ring tightly and tape circumferentially, using 627B2=19 Monofilament Adhesive Tape.

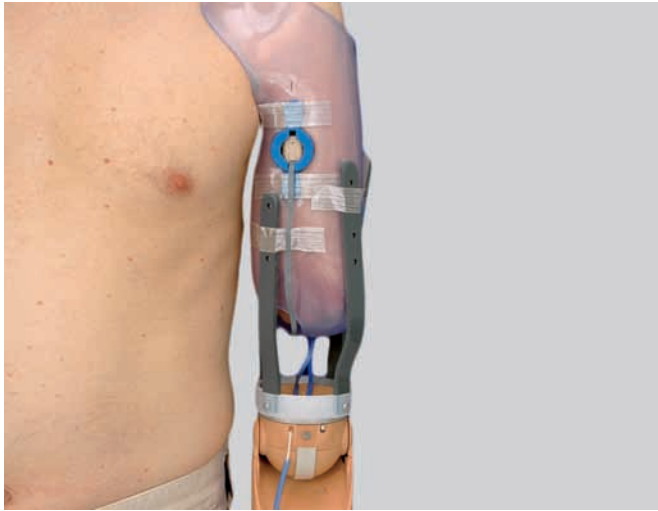
8.7 Fitting the alignment aid to the interim socket



- 1) Transfer the patient's measured muscle signal position to the interim socket.
- 2) Transfer mounting and fixture drill holes for 13E135 Electrode Mounting Brackets to the interim socket.
- 3) Attach the 13E135 Electrode Mounting Brackets and electrodes to the interim socket using 627B2=19 Monofilament Adhesive Tape.



- 4) Remove the four protective foils from the 4 rods.
→ Adhesive areas will be exposed.

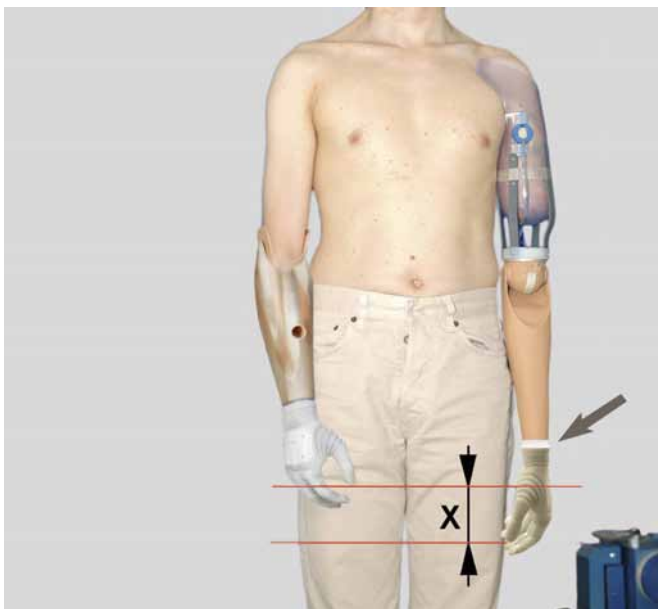


- 5) Position the AxonArm Ergo with alignment aid over the interim socket. The socket must be free of any grease.

INFORMATION: To facilitate adjustment of the alignment aid to the interim socket, the rods may be slightly warmed using a hot air gun, and reshaped as needed.

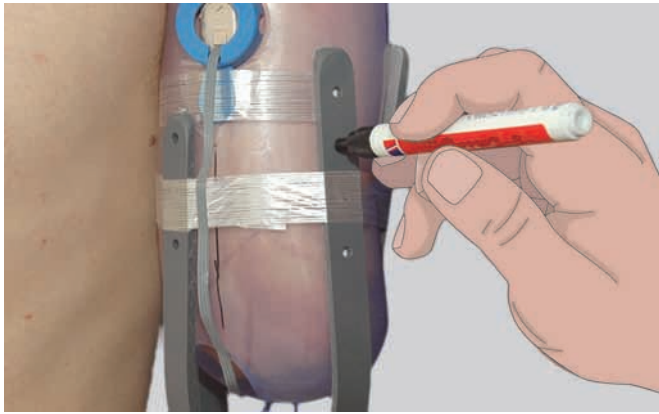


- 6) Verify symmetry of the lower elbow ends using the Ottobock 743L20=230 LaserLine.
7) Using monofilament adhesive tape, attach the alignment aid to the interim socket permanently. This will establish stability of motion.



- 8) Secure the hand prosthesis to the forearm with 627B2=19 Monofilament Adhesive Tape. See arrow.
9) Verify symmetry of the lower thumb tips using the Ottobock 743L20=230 LaserLine.
10) Measure the difference between the two thumb tips and document the value X.

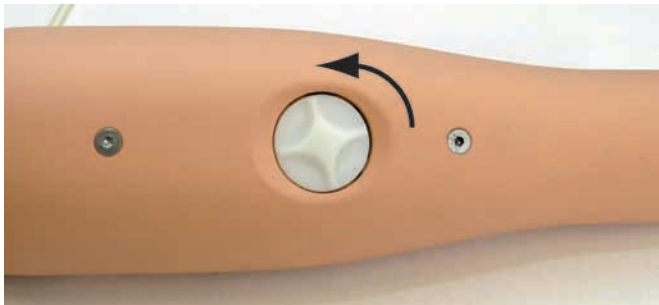
INFORMATION: This measurement is needed for cutting the forearm to length.



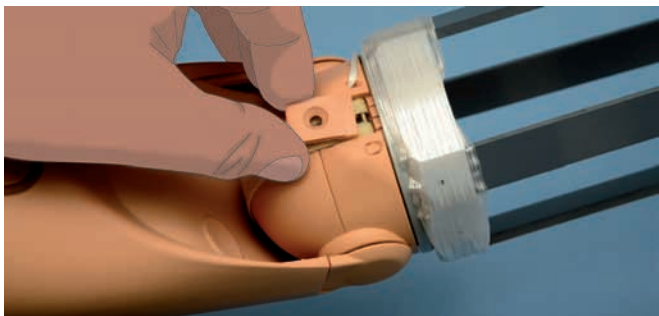
- 11) Mark the position of the alignment aid on the interim socket using a felt-tip pen.

INFORMATION: The distal end of the socket may reach into the elbow ball. However, sufficient space must be maintained for attaching the AxonMaster.

8.8 Removing the Elbow Joint



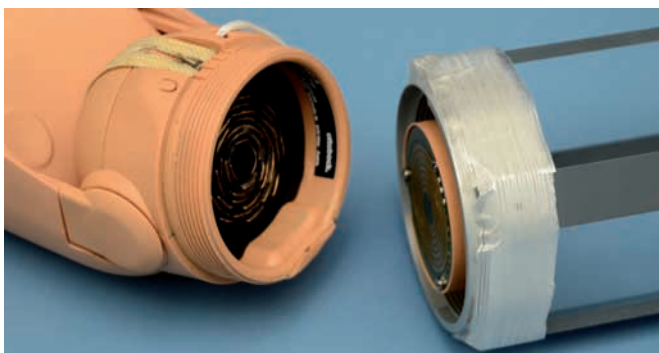
- 1) Fully flex the AxonArm.
- 2) Adjust the AFB compensation to the minimum amount with the dial.
- 3) Fully extend the AxonArm again.
- 4) Lock the elbow joint in this position to fix the removal and installation position.



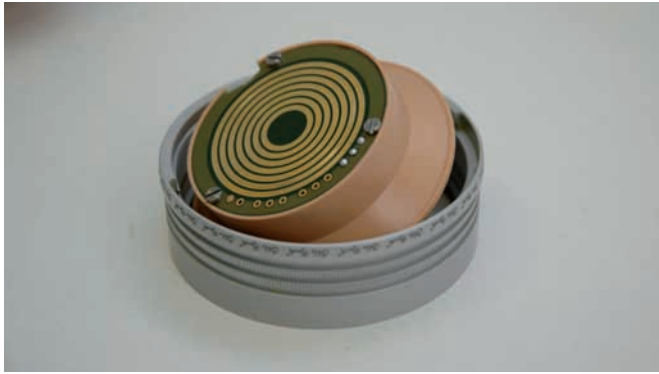
- 5) Remove the screw on the strap clamp and remove the clamp.



- 6) Loosen the humeral rotation feature to facilitate unscrewing of the lamination ring.



- 7) Unscrew the lamination ring and remove.



8) Push out the EasyPlug.



9) Pull out the belt.



10) Gently pop off both joint caps.



11) Carefully pry out the cable plugs.

12) Pull off the cable plugs.



13) Unscrew both fastening screws from the elbow joint.

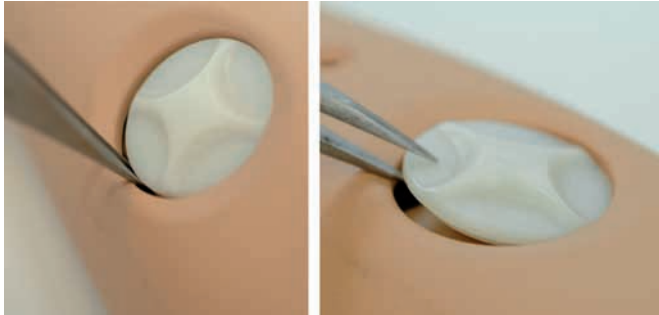


14) Carefully pull the elbow joint off the forearm.

8.9 Removing the Flexion Aid



- 1) Unscrew the two fastening screws from the forearm.



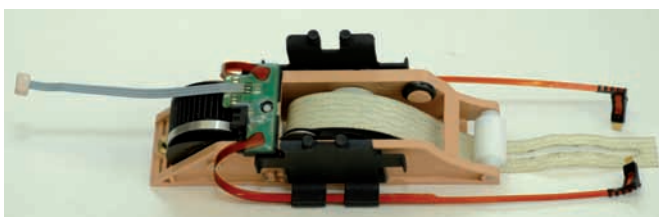
- 2) Pull off the compensation adjustment dial.



- 3) Lift the cover membrane.



- 4) Pull out the AFB flexion aid.



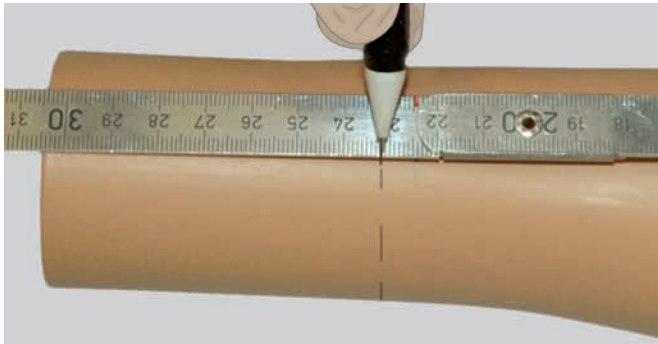
- 5) Remove the cover membrane.

8.10 Shortening the forearm

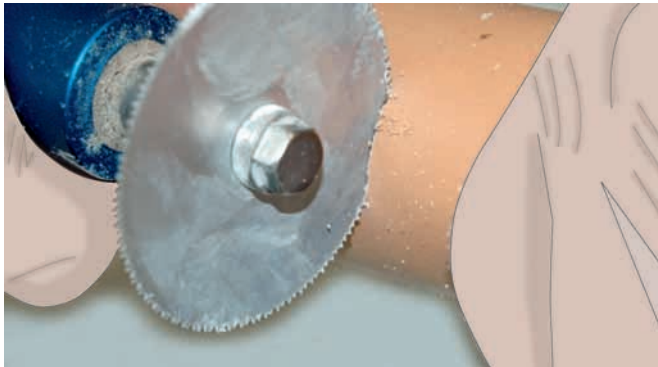
INFORMATION

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

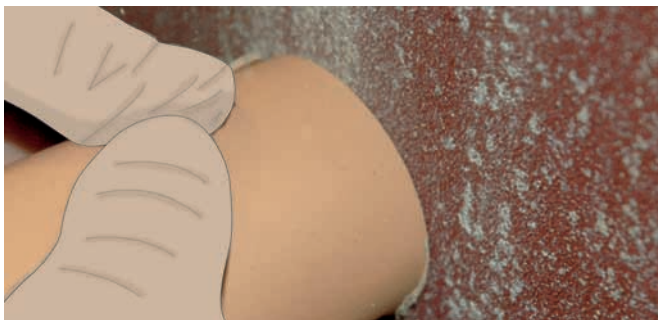
8.10.1 Shortening the Forearm



- 1) Mark the length to be cut from the forearm. The minimum length of the forearm from the joint axis is 187 mm.



- 2) Cut the forearm using a vibrating saw.



- 3) Sand all sides of the cut edge at a right angle. Smooth inner and outer sanded edges. Round the inside edge slightly.

8.11 Fastening the Flexion Control Cable (optional)

Fastening of the flexion control cable is required when a triangular upper arm bandage, e.g., 21A35=1, is to be used to lift the AxonArm.



- 1) Fasten the flexion control cable inside the marked area.



- 2) If a clamp stopper is required, use the 21A207 clamp stopper set. Please see the 647G231 Instructions for Use.

INFORMATION: Note the different area for fastening the flexion control cable to the AxonArm because the mounting hole for the charger socket restricts this area!

8.12 Gluing In the Lamination Ring



The lamination ring has to be glued in after the forearm has been cut. Before starting to glue it in, please read these instructions very carefully and proceed exactly in the order described.

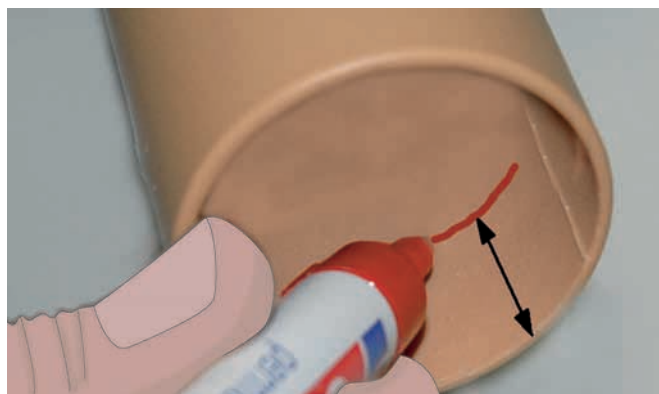
⚠ CAUTION**Failure to observe the safety datasheet**

► Injury due to skin and eye irritation.

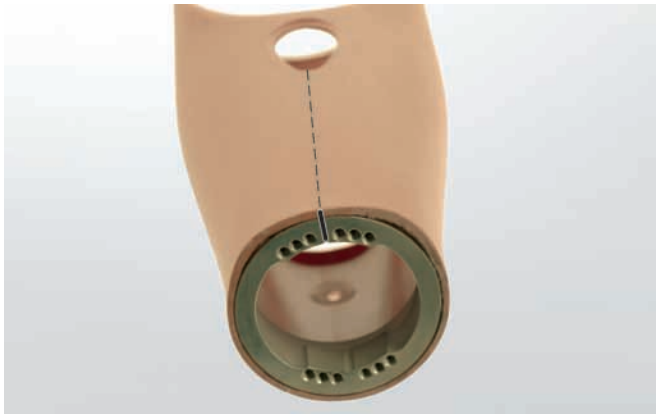
→ Before processing the 636K18=1 Orthocryl Sealing Resin Compact Adhesive and the 617H14 Hardener Paste please read the relevant safety datasheets.



- 1) Determine the height of the lamination ring.
- 2) Clean (degrease) the inside of the forearm.



- 3) Mark this measurement on the inside of the forearm.



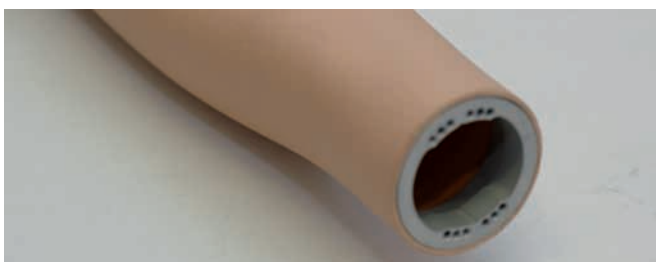
- 4) Mark the radial position on the lamination ring. The position between each set of 3 screw holes must lie on a line projected to the charging socket.
- 5) Mix Orthocryl sealing resin putty adhesive 636K18=1 and 2% hardener paste 617H14.
- 6) Cover the outside of the forearm with 627B4 polyethylene adhesive tape to avoid soiling it while gluing.



- 7) Using a paintbrush, apply the resin in a wedge shape to the marked area of the inside forearm and the outside of the lamination ring.



- 8) Align the lamination ring in a radial direction and insert it into the forearm.
→ The lamination ring must be flush with the socket!



- 9) Allow to cure according the material safety data sheet for Orthocryl sealing resin putty adhesive 636K18=1.

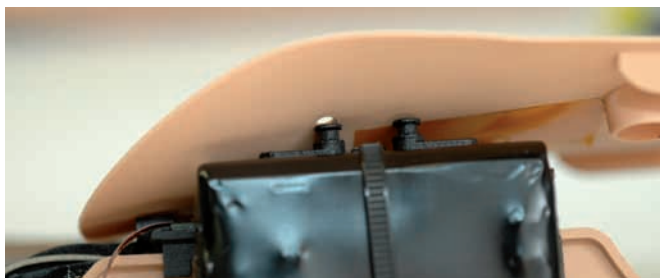
8.13 Installing the Flexion Aid



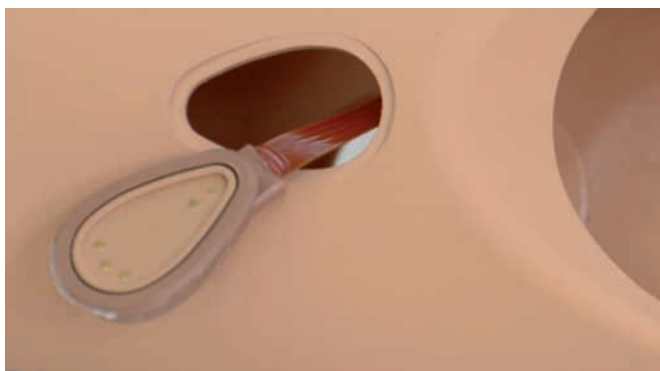
- 1) Carefully thread the two flex cables out of the groove in the battery holder.
- 2) **INFORMATION: Start with the narrow end and then pull into the final position after the cable has been completely threaded in. The flex cables must not be twisted.**



- 3) Flexion aid with installed battery pack.



- 4) Mount the cover membrane with the holes over the **front fastening pins** on the flexion aid.



- 5) Insert the charging receptacle into the hole.



- 6) Thread the connecting cable for the Axon-Bus gripping component through the forearm opening.



- 7) Insert the flexion aid into the forearm.
INFORMATION: Be careful not to pinch the cable beneath the flexion aid.



- 8) Insert the mounting screws and tighten them.
 9) Position the dial and press on.
INFORMATION: The dial must snap in audibly.



- 10) Only use bonding agent to glue in the charging receptacle.
INFORMATION: Do not use cyanoacrylate or similar substances because it will prevent the charging receptacle from being removed without being destroyed.



- 11) Keep the charging receptacle secured with adhesive tape until the bonding agent is completely cured.



- 12) Fold down the cover membrane.

8.14 Installing the Elbow Joint

⚠ CAUTION

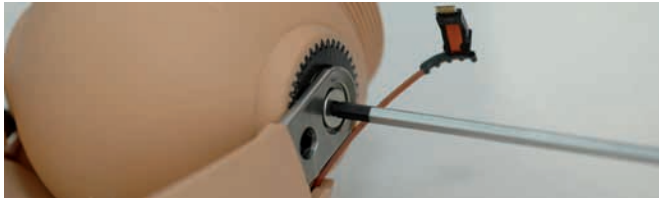
Operating the elbow joint without the cover caps

- Injury due to faulty control or malfunction of the product as a result of damage and bending of the flex cables due to missing guide.
- Never operate the elbow joint without cover caps because they serve as guides for the flex cables during flexion and extension.



- 1) Carefully push the elbow joint back on to the flat toothed disc on the forearm.

INFORMATION: Be careful of the flex cables! The cables must be guided out to the sides.



- 2) Apply Loctite 243 (thread-locking compound) to the two elbow joint fastening screws and tighten them uniformly.

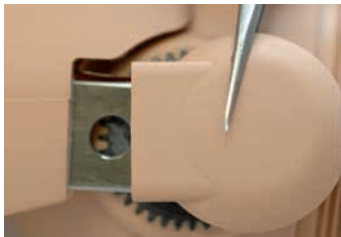


- 3) Grease the wiring connectors with 633F11 silicone grease.

- 4) Reattach both cables.

- 5) Extend the arm.

INFORMATION: Be careful of the flex cables. They must not be bent.



- 6) Position the joint cap at an angle above the cable.

- 7) Slide it along the cable and then press down to attach.

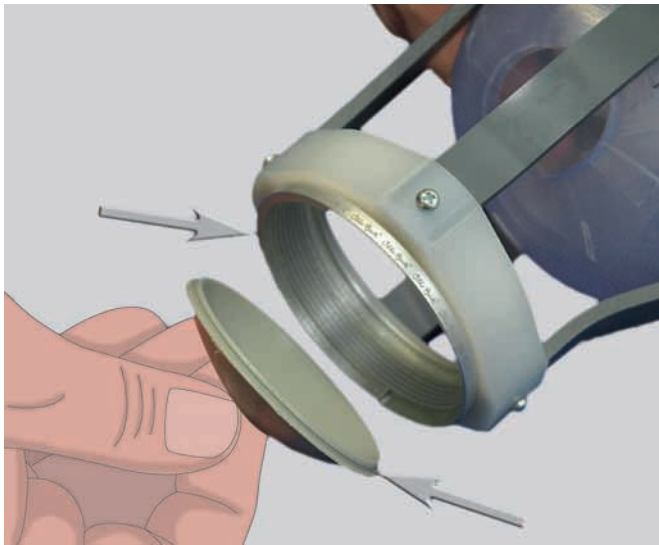
INFORMATION: This will prevent any cable damage during assembly.

8.15 Checking the Symmetry

- 1) Connect the Axon-Bus gripping component (e.g. Michelangelo Hand) to the AxonArm.
- 2) Check the symmetry with respect to the other hand (e.g. using the 743L20=230 Ottobock Laser-Line).

9 Fabricating the definitive inner socket

9.1 Fabricating the definitive socket



- 1) Grease the half shell rim (inner lamination cover) and outer rim of the lamination ring using 633F11 Silicone Grease (see arrows).
- 2) Insert the inner lamination cover.



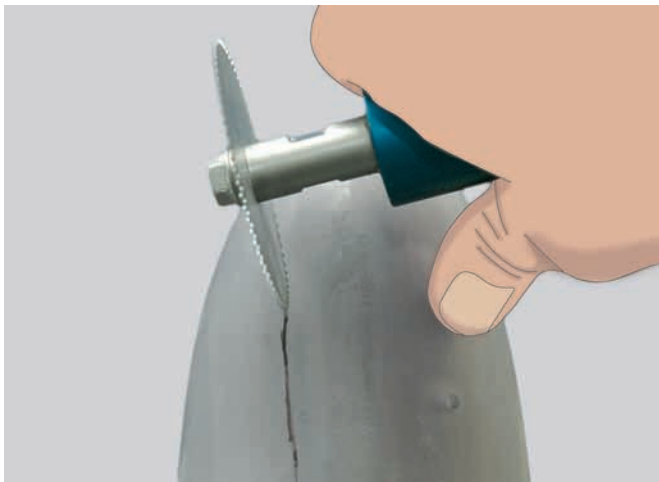
- 3) Apply the outer lamination cover.
- 4) Use linen adhesive tape to cover the electrode openings from the inside.
- 5) Use plasticine to close the valve tube opening in the inner socket.
- 6) Apply plaster insulating cream to the inside of the inner socket.



- 7) Lengthen the interim socket using plaster bandages (left fig.).
- 8) Shape plaster bandages to the interim socket (right fig.).
- 9) Mix plaster and pour it into the insulated interim socket and plaster bandages.
- 10) Insert the plastering rod for later clamping during the vacuum forming process.
- 11) Allow the plaster to dry.
INFORMATION: Table salt can be applied to allow the plaster to cure more quickly.
- 12) Remove plaster bandages from interim socket.
- 13) Adjust the cast to fit the socket rim shape.



- 14) Mark positional drill holes of the alignment aid and the electrodes on the plaster model. In order to do so, use a twist drill to drill through the interim socket.



- 15) Cut the socket open using the vibrating saw.
16) Remove the interim socket from the plaster model.



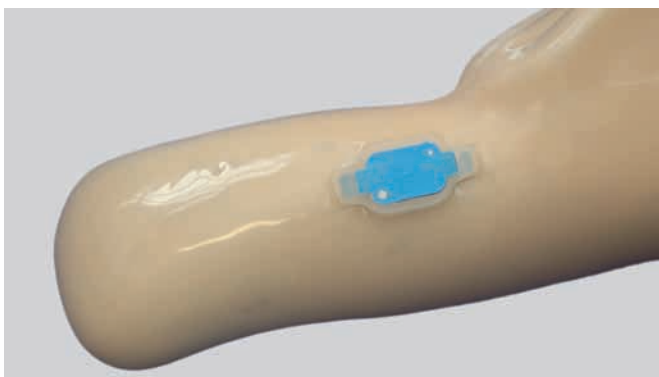
- 17) If necessary, smooth the plaster model and then mount it onto the vacuum forming device.
18) Soak a 99B25 Nylon Tube Sock in NWax=1 Liquid Wax and pull it over the model to allow for vacuum forming.
19) Install blue electrode dummies from the 13E201 Electrode Accessories. Attach to the positive by inserting roundhead steel nails into the drilled marker holes.



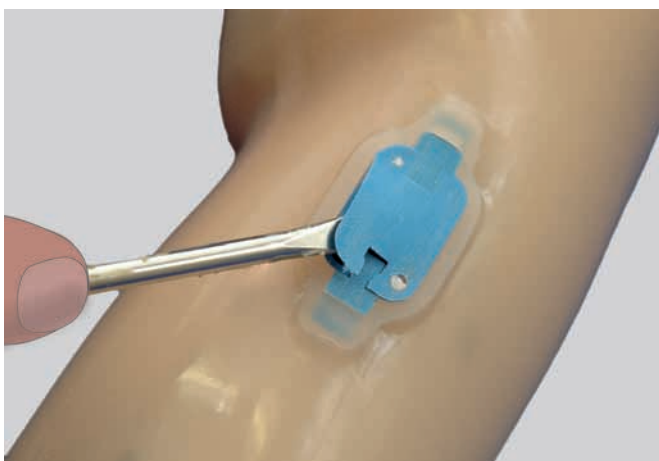
- 20) Cover the sheet of 616T69=* ThermoLyn soft skin-coloured or 616T53=* ThermoLyn soft clear with NWax=1 Liquid Wax.
- 21) Heat ThermoLyn soft to 160 °C (320 °F) in the oven.
- 22) Switch on the vacuum and vacuum form the sheet.
- 23) While vacuum forming, mould the sheet to the plaster positive.



- 24) In the casting template area, sand ThermoLyn soft flush with the casting template.



- 25) Sand free the casting template's nail heads and remove the nails.



- 26) Remove the upper part of the vacuum forming pattern.



27) Align the outer socket lamination pattern proximally (see arrow) and insert.



28) Pull a 99B71 PVC Bag over the model, tie off at the vacuum pipe and switch the vacuum on.



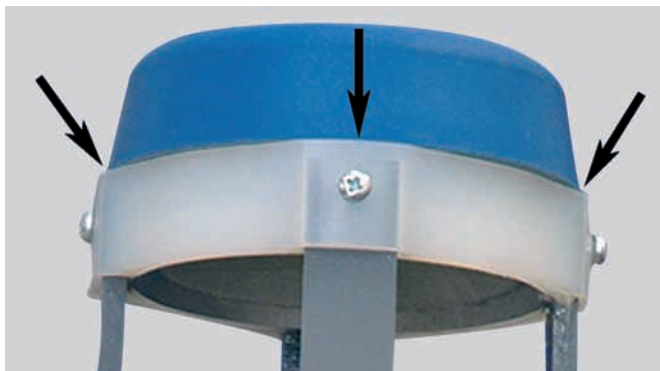
29) Glue on 627B5=19 Neoprene Cell Rubber Tape.



30) Apply 633F11 Silicone Grease to lamination cover.



31) Glue the alignment aid to the position markers.



- 32) Place the foam cover onto the lamination ring.
INFORMATION: The foam cover must close flush with the lamination ring (arrows).

10 Foaming and grinding the definitive outer socket

10.1 Foaming the socket

⚠ CAUTION

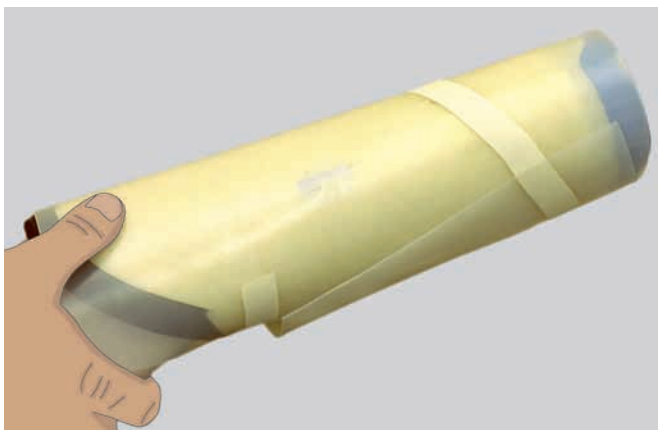
Failure to observe the safety datasheet

► Injury due to skin and eye irritation.

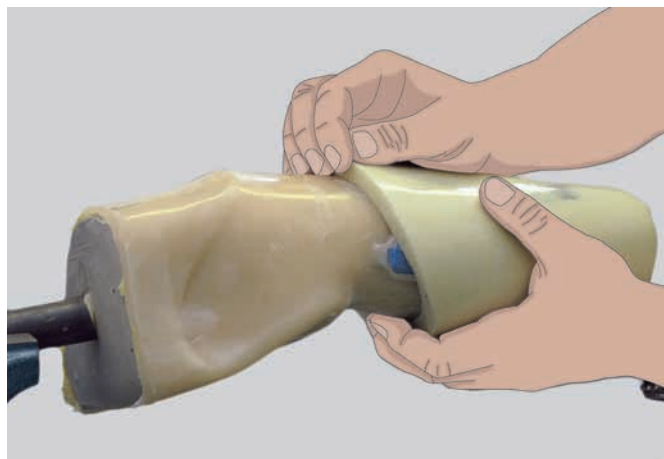
→ Before processing 617H12 Pedilen® Rigid Foam 200 and 617P21=* Pedilen® Hardener, please read the corresponding safety datasheet.



- 1) Wrap 616T3=1 Trolen Sheeting conically around the definitive socket.
It should overlap by about 10 centimetres.
Secure Trolen sheeting against rolling up using adhesive tape.
The Trolen sheeting should be the same distance (approx. 2 to 3 cm) from the model all around.
- 2) Mix 617H12 Pedilen Rigid Foam and 617P21 Pedilen Hardener thoroughly as described in the enclosed processing instructions, and pour into the gap between Trolen sheeting and model.



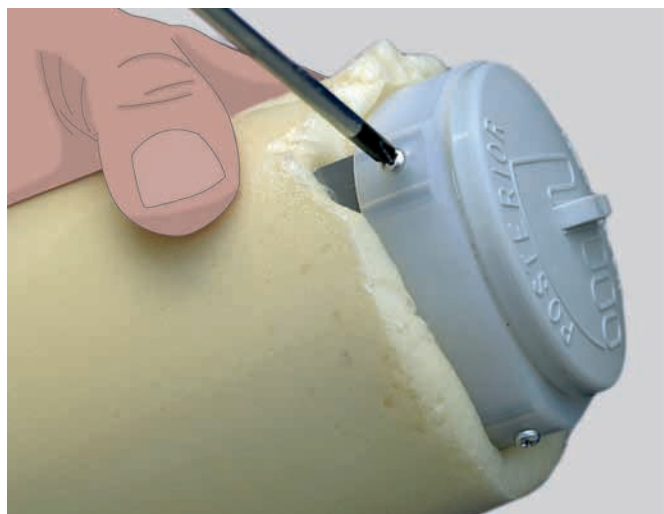
- 3) Let rigid foam rise to about $\frac{3}{4}$ height. Then position the model horizontally.
→ This will prevent cavities in the area of the lamination cover.
- 4) Remove the Trolen sheeting once the reaction time has elapsed.



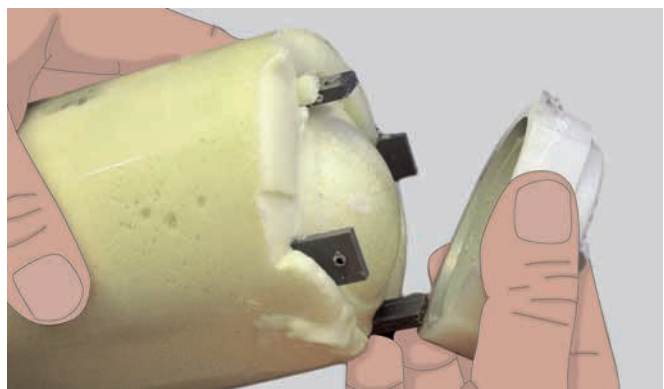
5) Remove the foam piece.



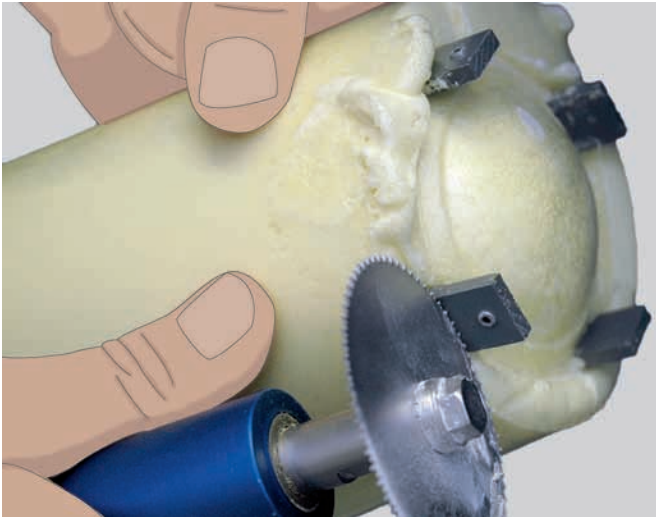
6) Remove the foam cover from the lamination ring.



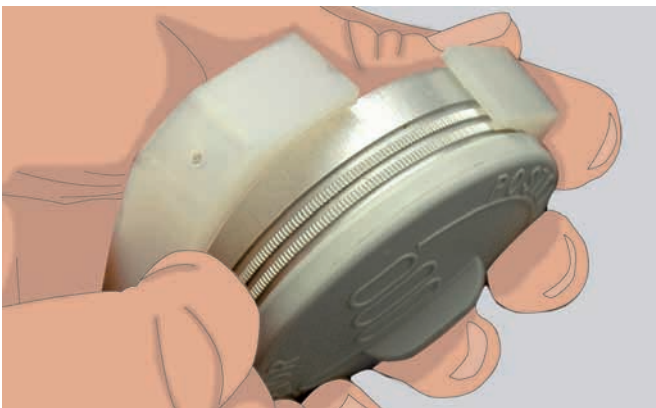
7) Remove screws.



8) Remove the alignment aid ring and lamination ring.



- 9) Cut fixation arms to the lower edge of the lamination ring using the vibrating saw.



- 10) Separate the alignment aid from the lamination ring.



- 11) Mount the lamination ring with lamination cover.



- 12) Sand the foam cone until the fixation arms of the alignment aid and the lamination ring are exposed.



13) Then laminate the foam core.

INFORMATION: The fixation arms will remain in the foam core.

11 Laminating the outer socket

11.1 Laminating instructions for carbon fibre sockets

11.1.1 Safety instructions for processing carbon

⚠ CAUTION

Working with carbon fibre cloth

- ▶ Injuries due to cutting the carbon fibre cloth and carbon dust.
- For your own protection, wear an appropriate respirator, protective gloves and goggles when cutting carbon fibre cloth or sanding the socket.

⚠ CAUTION

Failure to observe the safety datasheet

- ▶ Injury due to skin and eye irritation.
- Before processing 617H55 C-Orthocryl Lamination Resin or 617H19 Orthocryl Lamination Resin and 617P37 Hardening Powder, please read the corresponding safety datasheets.

⚠ CAUTION

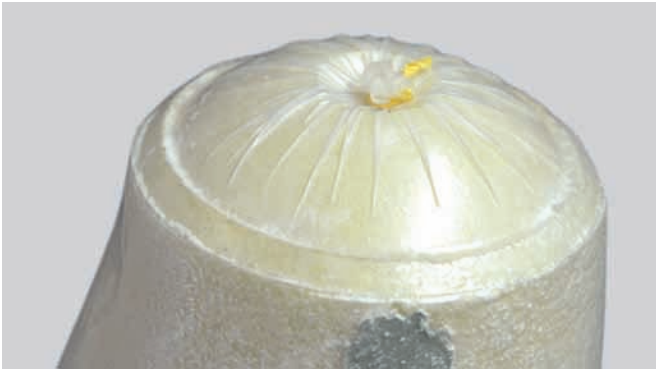
Insufficient ventilation

- ▶ Injury due to respiratory tract irritation.
- Ensure sufficient ventilation of rooms and workstations.

11.1.2 Preparing the foam core



- 1) Use a countersink drill to reduce foam core to approx. 15 mm in diameter and a depth of about 10 mm in the distal area.
- 2) Apply talcum powder to foam core.
- 3) Pull a 99B81 PVA Bag over the foam core. Tie off the PVA bag at the rod and in the distal area. Cut off the excess bag in the distal area.



- 4) Switch the vacuum on and place knot into the drilled hole.



- 5) Place adhesive tape over the knot.



- 6) Mount the lamination ring with lamination cover.
INFORMATION: Note the "ANTERIOR" and "POSTERIOR" positions!
- 7) Cut 623T3=* Perlon Stockinette to twice the length of the socket positive.



- 8) Pull over the socket positive and secure with a clamp in the distal area.
- 9) Pull Perlon stockinette down free of wrinkles and tie off.



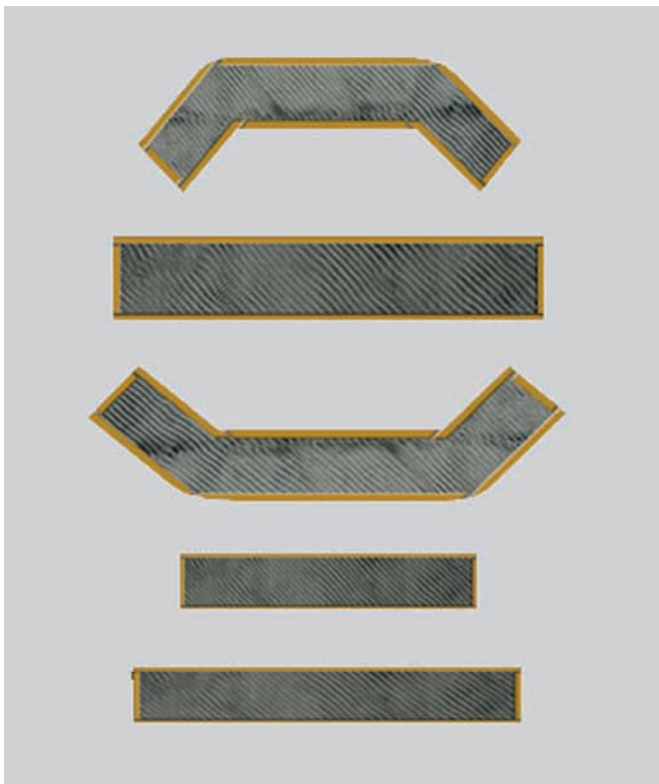
- 10) Tie 623T3=* Perlon Stockinette off in the lower groove of the lamination ring using a lace.

11.1.3 Preparing the carbon fibre cloth

To improve the stability of the socket, the layers are reinforced with pieces of 616G12 Carbon Fibre Cloth. These will have to be measured and cut according to the shape of the socket.



- 1) The carbon fibre cloth shapes are determined using a paper template.
- 2) Then transfer the contour of the paper template to the 616G12 Carbon Fibre Cloth.



- 3) Pieces to be cut out:
 No.1: 4 pieces
 No. 2: 2 pieces
 No. 3: 4 pieces
 No. 4: 2 pieces
 No. 5: 2 pieces

The approximate numbers of reinforcement layers stated above as well as their size have to be adjusted by the prosthetist according to the individual needs and requirements of each patient.

The woven structure of the carbon fibre cloth may disintegrate rather easily during cutting. Therefore, the edges of the cloth should be secured using 616F10 Double-Sided Adhesive Tape. Apply adhesive tape firmly. Then cut carbon fibre cloth and adhesive tape in the centre of the tape.

11.1.4 Shape and position of the pieces

Pattern no. 1:



Positioned in the lateral area, 4 pieces

Pattern no. 2:



Positioned in the distal area, 2 pieces



Wrap cloth around circumference to the first groove of the lamination cover.

Pattern no. 3:



Positioned circumferentially in the proximal area, 4 pieces

Pattern no. 4:



Positioned in the lateral area, 2 pieces

Pattern no. 5:



Positioned in the medial area, 2 pieces

11.1.5 Aligning the socket

The following section serves as an example for a socket with five reinforcement layers.

1st layer:

- Glue pieces no. 1 through 5 to the 623T3=* Perlön Stockinette pulled over the model.

2nd layer:

- 1) Remove the clamp.

- 2) Fold over the 623T3=* Perlon Stockinette, pull down free of wrinkles and tie off.
- 3) Glue pieces no. 1 through 5 exactly on top of the previously glued pieces.

3rd layer:

- 1) Cut 623T3=* Perlon Stockinette to twice the length of the socket positive.
- 2) Pull over the socket positive and secure with a clamp in the distal area.
- 3) Pull 623T3=* Perlon Stockinette down free of wrinkles and tie off.
- 4) Tie 623T3=* Perlon Stockinette off in the **second groove** of the lamination ring using a lace.
- 5) Glue pieces no. 1 and 3 exactly on top of the previously glued pieces.

4th layer:

- 1) Remove the clamp.
- 2) Fold over the 623T3=* Perlon Stockinette, pull down free of wrinkles and tie off.
- 3) Glue pieces no. 1 and 3 exactly on top of the previously glued pieces.

5th layer:

- 1) Cut 623T3=* Perlon Stockinette white to twice the length of the socket positive.
- 2) Pull over the socket positive and secure with a clamp in the distal area.
- 3) Pull 623T3=* Perlon Stockinette down free of wrinkles and tie off.
- 4) Tie 623T3=* Perlon Stockinette off in the **uppermost groove** of the lamination ring using a lace.
- 5) Remove the clamp.



- 6) Fold over the 623T3=* Perlon Stockinette, pull down free of wrinkles and tie off.

11.1.6 Casting the socket



- 1) Pull the PVA Bag 99B81 down over the positive model without wrinkles and tie off proximally.
- 2) Apply vacuum.
- 3) Mix 617H55 C-Orthocryl Lamination Resin or 617H19 Orthocryl Lamination Resin and 2% of the resin weight of 617P37 Hardening Powder.
- 4) Add 617Z2=* Resin Colour Paste as needed.



- 5) Pour lamination resin into the bag.
- 6) Tie off the bag above resin level and work the resin into the reinforcement layer.



- 7) Spread lamination resin using a lace, trying to keep the wall thickness as thin as possible.

INFORMATION: In order to create a high quality socket, there must be no air bubbles inside the lamination resin.



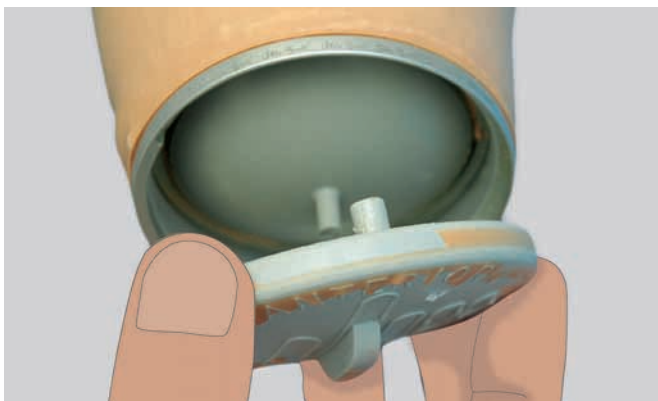
- 8) Place the rubber ring around the resin beneath the lamination protection cap as long as the laminate is still flexible.

INFORMATION: Do not twist the rubber ring!

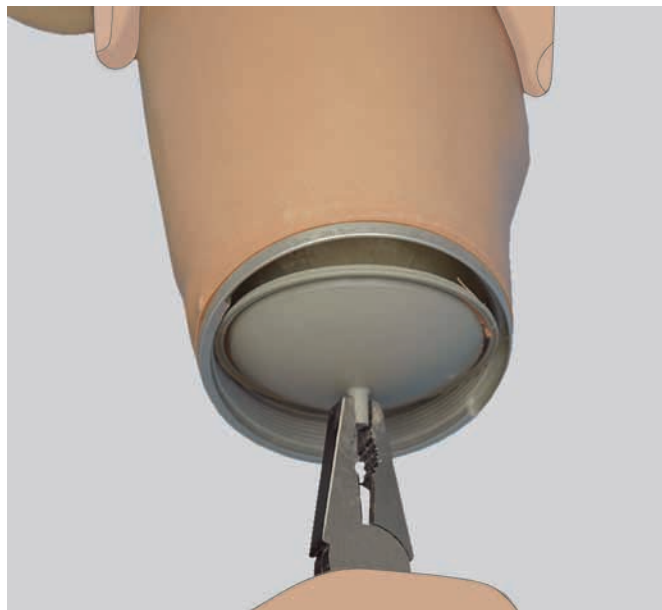
- 9) Once the lamination resin has cured, remove the PVA bag.

12 Finishing the outer socket

12.1 Finishing the socket



- 1) Remove the lamination cover.



- 2) Retract the inner lamination cover using pliers.
- 3) Remove rigid foam.



- 4) Sand the inner and outer socket brim to shape and smooth the edges.



- 5) Finish the socket as usual.

⚠ CAUTION**Damage to the electrode cables**

- ▶ Injury due to faulty control or malfunction of the product as a result of damage and bending of the electrode cables.
- When assembling the inner and outer socket, it is important to make sure that the electrode cables are not bent or pinched and that they cannot get damaged by screws.

12.2 Sealing the prosthesis

- 1) After laminating the lamination ring, remove the grease and any dirt.
- 2) Lubricate the groove, inner edge and thread of the lamination ring with 633F30 Special Grease.

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