

DynamicArm

Casting and Lamination Instructions for 12K100N=*

Technical Information 3.3.3



Date of the last update: 2015-07-15

- 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).

Contents

1 Modelling technique	2	3.3 Cutting the lower arm	15
1.1 Preparing the patient	2	3.4 Gluing in the lamination ring with quick disconnect	17
1.2 Fitting of plaster bandages	5	3.5 Verifying symmetry.....	20
1.3 Modelling the contact areas.....	6	3.6 Separating the lamination ring from the elbow bal.....	21
1.4 Fabricating the plaster positive	10	3.7 Fabricating the permanent socket	22
1.5 Vacuum forming the interim socket	11	3.8 Foaming the socket	27
2 743A27 Alignment Aid for Elbow Set-ups.....	12	4 Laminating instructions for carbon fibre sockets	31
2.1 Intended use	12	4.1 Safety instructions.....	31
2.2 Safety instructions.....	12	4.2 Preparing the foam core.....	31
2.3 Scope of delivery	12	4.3 Preparing carbon fibre tissue cloth.....	33
2.4 Description and function	12	4.4 Shape and position of the pieces	34
2.5 Liability	12	4.5 Building the socket.....	35
3 Handling.....	13	4.6 Laminating the socket.....	36
3.1 Mounting the alignment aid to the lamination ring.....	13	4.7 Finishing the socket	37
3.2 Fitting the alignment aid to the interim socket	14		

1 Modelling technique

An upper arm socket shaped by applying the plaster modelling technique introduced here, will offer the patient the following advantages:

- Best possible rotational stability
- Especially broad range of motion due to free shoulder joint
- Improved blood circulation due to full distal contact of the socket

1.1 Preparing the patient

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



Cut off the legs of the compression pantyhose.



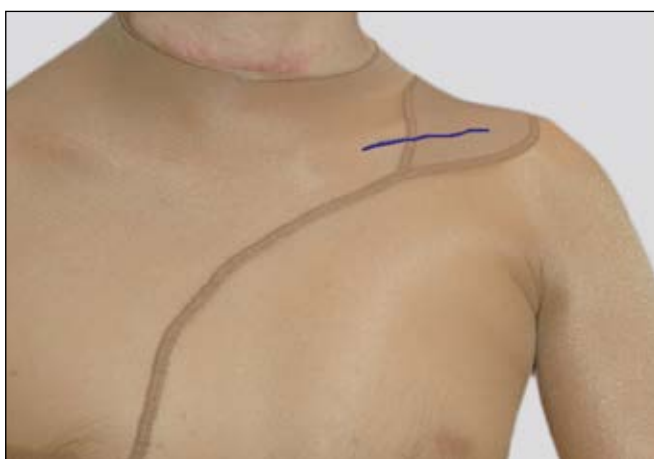
Dress the patient with the compression pantyhose and tie it off at the end of the residual limb.



Measure circumference and length and record them.

Notice:

Use a 645C1 Copy Pen to mark the compression panty hose as follows!



Mark the lower edge of the clavicle.



Mark the upper edge of the scapular spine.



Mark the socket contour of the frontal contact area.



Mark the socket contour of the side contact area.



Mark the socket contour of the rear contact area.

1.2 Fitting of plaster bandages



Prepare plaster bandages needed:

- Item1 2 Flexible plaster bandages
- Item2 7-fold longuettes for the supporter
- Item3 7-fold longuettes for the front and rear contact areas



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



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



Adjust 7-fold longuettes for the supporter.

1.3 Modelling the contact areas

During the modelling of the plaster, the patient must be in a standing position, upper arm adducted.



Notice:

Wear disposable gloves while modelling.

Have the patient wear an apron to protect against plaster splatters.



Apply Ottobock 640Z5=1 Plaster Parting Agent Cream to the axillary area.



Wrap the residual limb with two flexible plaster bandages using figure 8 loops, carefully applying steady pressure.



Shape the soft tissues from distal to proximal.

Notice:

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.



Move residual limb in a forward motion once.



Move residual limb in a backward motion once.



Model the frontal contact area.



Model the rear contact area.



Model the supporter.



Free space between supporter and contact areas at shoulder height.



Shape the dorsal groove with massaging motions.



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



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



Carefully cut through the middle of the supporter.



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.



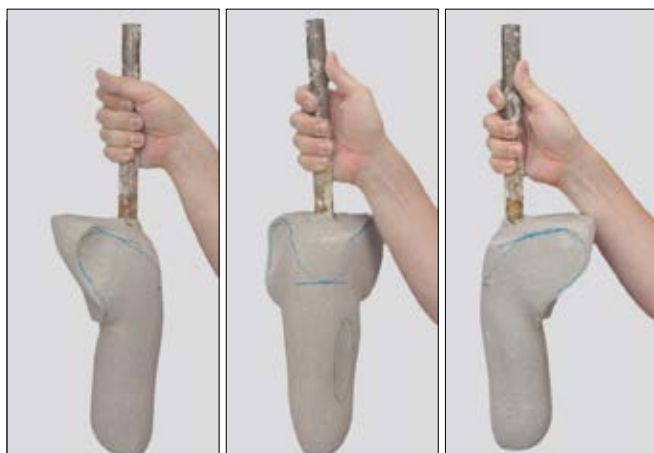
Transfer overlapping edge, and cut off the overlapping rim. Upon removing the cast, firmly reconnect the supporter using a plaster languette.



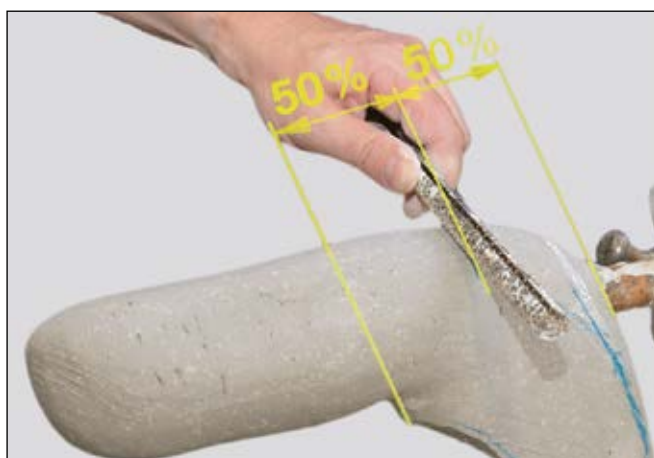
Finished plaster negative.

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

1.4 Fabricating the plaster positive



Pour plaster into the plaster negative. Due to the moisture, the lines marked in the plaster negative will transfer to the plaster positive. Upon drying, re-draw the lines on the plaster positive using 645C1 Copy Pen.



The highest point of the acromion and armpit are marked on the lateral side of the residual limb. Centre the rounded rasp between these two lines.

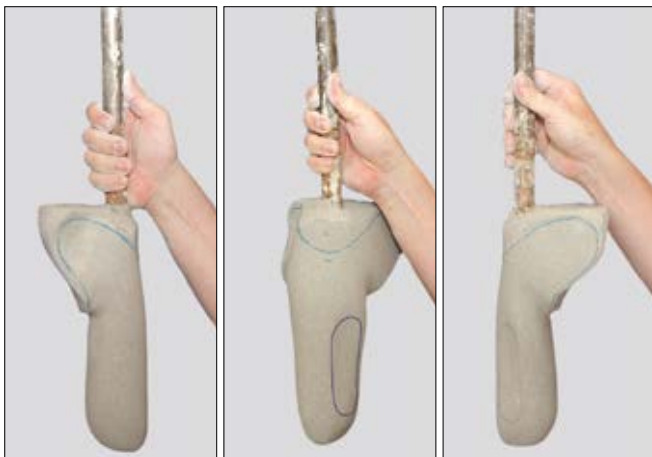


Create notch of approx. the size of the rasp's diameter (approx. 15 mm).



Then sand plaster down to the level of the rasp's diameter.

Model the plaster positive in a distal to proximal direction according to the soft tissue structure of the residual limb.



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

1.5 Vacuum forming the interim socket



Using the modelled plaster positive, the interim socket will be vacuum formed. Upon cooling, it will be sanded to shape.

See also 646T3=3.2GB Technical Information for fabricating vacuum formed sockets for myoelectrical below-elbow prostheses.

2 743A27 Alignment Aid for Elbow Set-ups

Please read these instructions carefully. Pay special attention to safety instructions!

2.1 Intended use

The 743A27 Alignment Aid for Elbow Set-ups 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 extremities.

The 743A27 Alignment Aid for Elbow Set-ups may exclusively be used for the 12K100N DynamicArm.

2.2 Safety instructions

- Before handling and processing the 617H12 Pedilen Rigid Foam 200 and the 617P21 Pedilen Hardener please read the corresponding safety data sheet.
- Deploy 743A27 Alignment Aid only in orthopaedic workshops, or during in-patient stays in rehabilitation facilities.
- Inform the patient that operating vehicles or machinery of any kind is prohibited while wearing a provisional prosthesis with 743A27 Alignment Aid for Elbow Set-ups.

2.3 Scope of delivery

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

2.4 Description and function

The 743A27 Alignment Aid for Elbow Set-ups is used to align the elbow component (DynamicArm) with the patient's interim socket and facilitates the ongoing alignment of the prosthesis until the lamination of the definitive (permanent) 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.

2.5 Liability

Ottobock can only be held liable for damages if the 743A27 Alignment Aid for Elbow Set-ups 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.

3 Handling

3.1 Mounting the alignment aid to the lamination ring



Do not remove protective foil from adhesive areas yet! Insert rods with the adhesive area pointing inwards until they stop. Secure ring and rods with screws.



Stretch ring and pull it over the lamination ring. The ring must lock into the lamination ring's lowest groove.



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

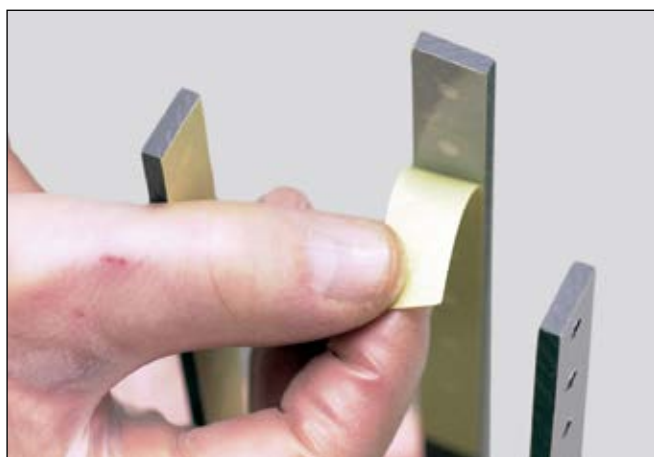
3.2 Fitting the alignment aid to the interim socket

**Notice:**

The optimal electrode positions must be determined using the 757M11 MyoBoy.

Transfer patient's measured muscle signal position to the interim socket. Transfer mounting and fixture drill holes for 13E135 Electrode Mounting Brackets to the interim socket.

Fixing 13E135 Electrode Mounting Brackets and electrodes to the interim socket using 627B2=19 Monofilament Adhesive Tape.

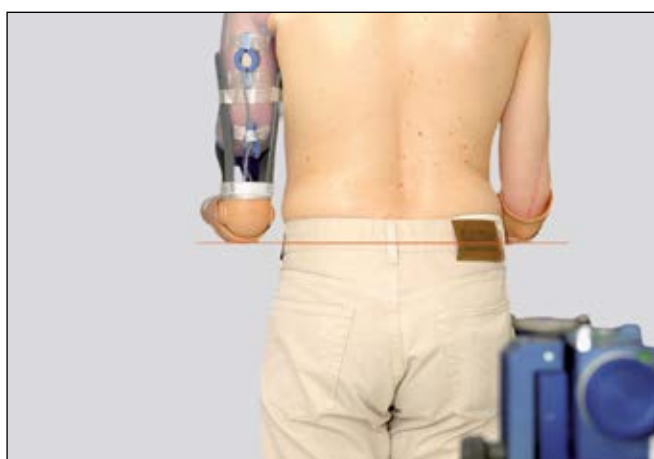


Remove the four protective foils. Adhesive areas will be exposed.



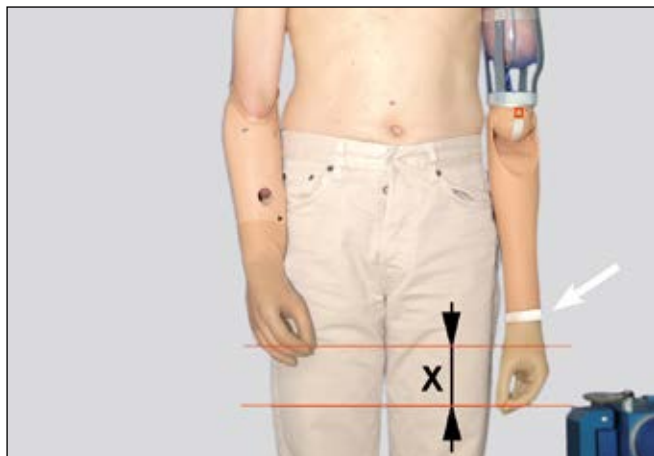
Position the DynamicArm with alignment aid over the interim socket. The socket must be free of any grease.

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.



Verify symmetry of the lower elbow ends using Ottobock 743L20=230 Laser-Line.

Using 627B2=19 Monofilament Adhesive Tape, attach the alignment aid to the interim socket permanently. This will establish stability of motion.



Attach System Electric Hand or System Electric Greifer to the lower arm using 627B2=19 Monofilament Adhesive Tape (white arrow).

Verify symmetry of the lower thumb tips using Ottobock 743L20=230 Laser-Line.

The distance to be measured is the difference between the two lower thumb tips. Document value X; it will be needed for cutting the lower arm.



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

Notice:

The distal end of the socket may reach into the elbow ball.

3.3 Cutting the lower arm

Notice:

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

3.3.1 Lower arm length and use of the 10S17 Electric Wrist Rotator

Lower arm length	10S17 Electric Wrist Rotator	Please note the minimum lower arm length when using an 10S17 Electric Wrist Rotator is 213 mm, or 187 mm without it.
305 – 213 mm	Possible	
212 – 187 mm	Not possible	

Notice:

The lower arm length is measured from distal end of the lamination ring to the elbow axis.

3.3.2 Shortening the lower arm



Attention:

Do not under any circumstances remove foam material or cable protector cap from the lower arm prior to the cutting of the lower arm and the attachment of lamination ring! Doing so will reduce the useable portion of the lower arm.

If cables were nevertheless pulled out, they have to be pushed back into the lower arm and secured with the foam cover before any further work is done on the lower arm.

This will cause the cables to take up more space inside the lower arm.

Should this be the case, please refer to the notes at the end of chapter "Lower arm length 225 mm to 187 mm without Electric Wrist Rotator" on page 18.



Mark the length to be cut from the lower arm. Mark value X (see page 15, Fig. 1) plus 1 cm.

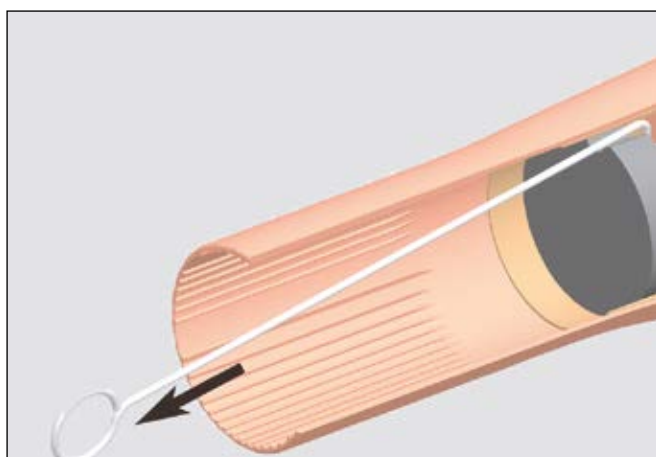
Reason: The prosthesis should be approx. 1 cm shorter than the remaining arm.



Cut lower arm using a vibro-saw.



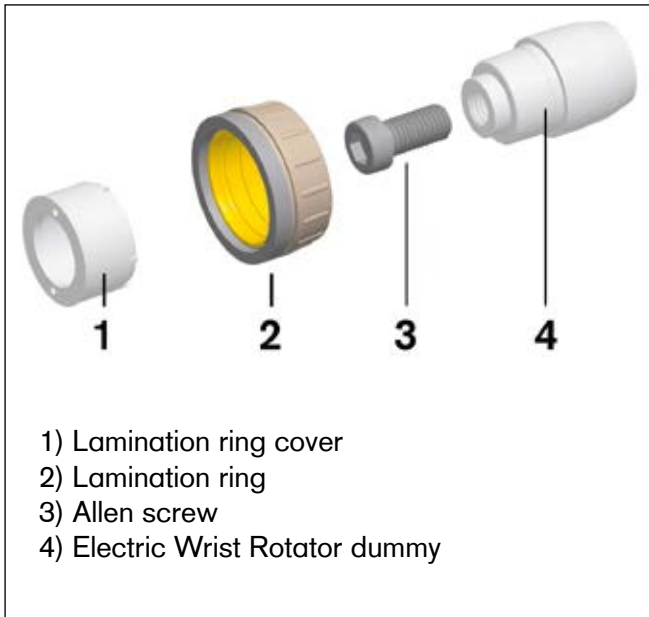
Sand the cutting edge to a right angle. Deburr inner and outer sanded edges. Round inside surface slightly.



Using the hook, remove the foam cover.

3.4 Gluing in the lamination ring with quick disconnect

The lamination ring with quick disconnect has to be glued in after cutting the lower arm. Before starting to glue it in, please read these instructions very carefully and proceed exactly in the order described.

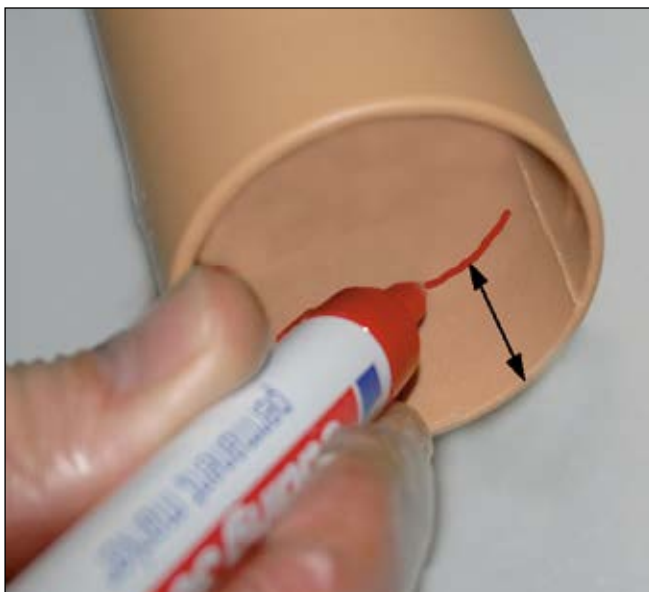


Attention:

Before processing the 636K18 Orthocryl Sealing Resin Compact Glue and the 647H14 Hardener Paste, read the corresponding safety data sheet.



Determine the height of the lamination ring.



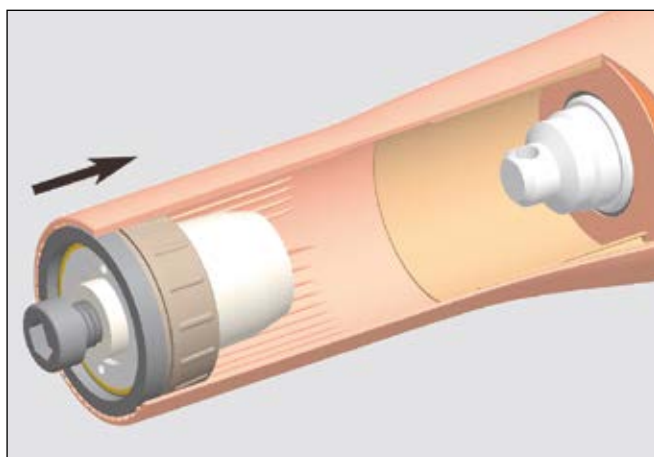
Mark this measurement on the inside of the lower arm.

Mix 636K18=1 Orthocryl Sealing Resin Compact Glue and 2% 617H14 Hardener Paste.

Tape the outside of the lower arm off using 627B4 Polyethylene Adhesive Tape to avoid soiling it while gluing.



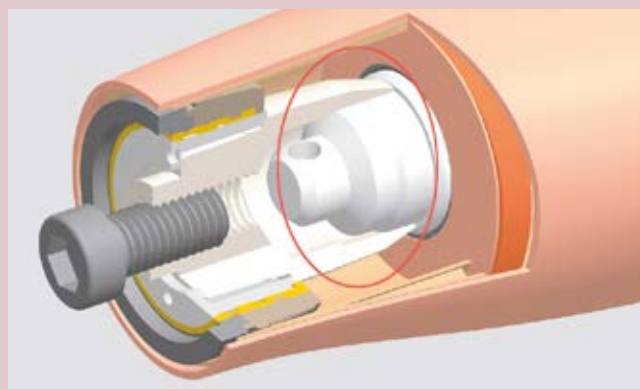
Attach lamination ring and lamination ring cover. The lamination ring must be flush with the socket! Let the adhesive joint harden.



Attach lamination ring and lamination ring cover. The lamination ring must be flush with the socket! Let the adhesive joint harden.

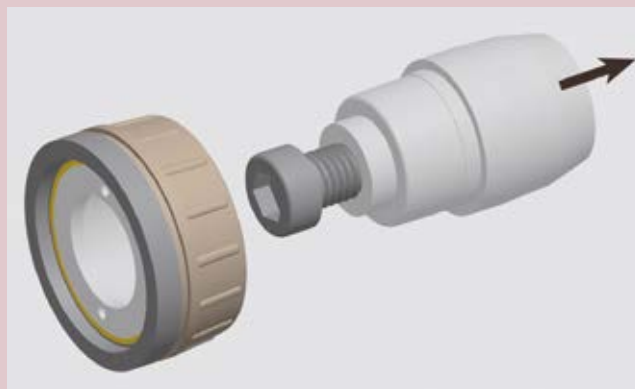
Notice:
Measure lower arm length!

For lower arm lengths from 225 mm to 213 mm with 10S17 Electric Wrist Rotator

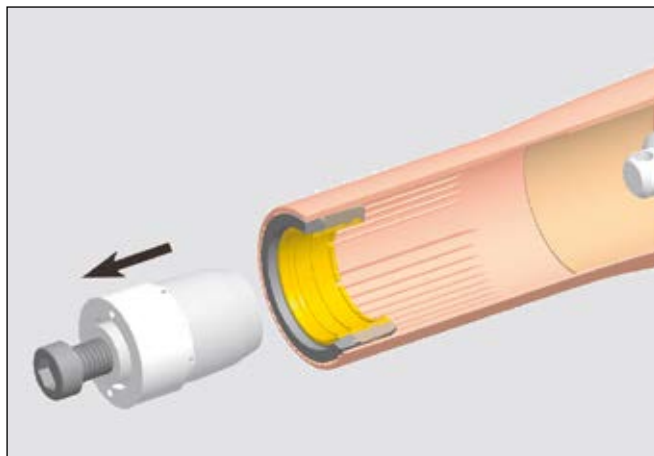


Make sure that the dummy for the 10S17 Electric Wrist Rotator is placed over the cable protector cap. This will ensure proper axial alignment of the lamination ring.

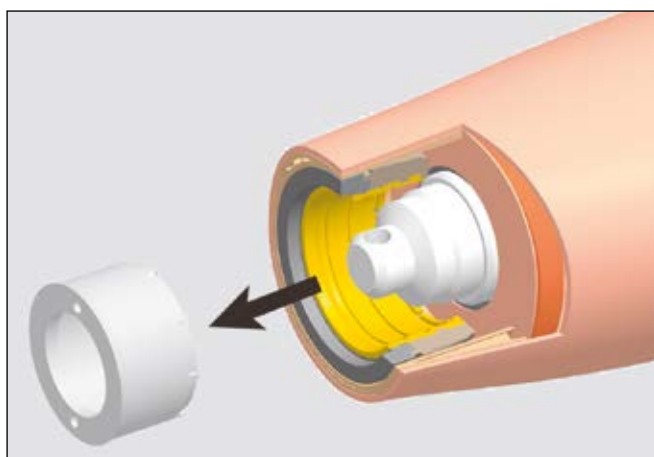
For lower arm lengths from 225 mm to 187 mm without 10S17 Electric Wrist Rotator



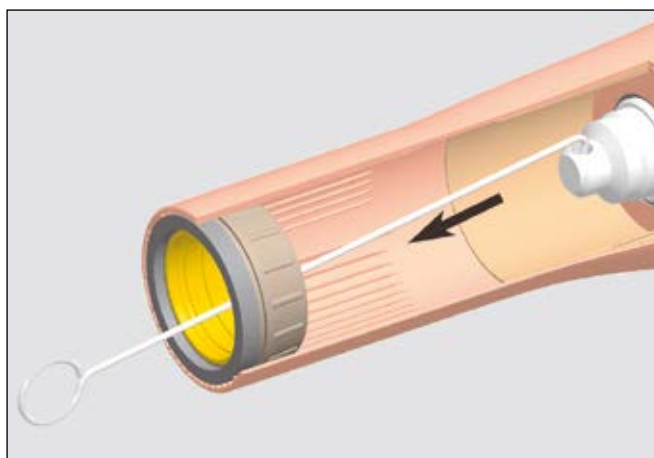
Pull dummy for the 10S17 Electric Wrist Rotator through the rear off the lamination ring. The lamination ring cover must remain inside the ring.



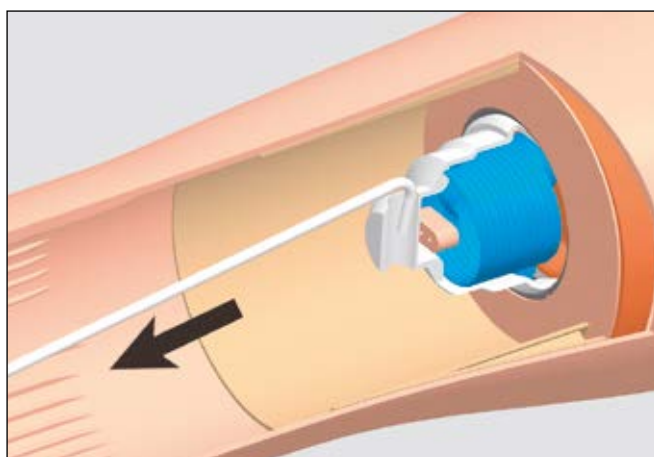
After the adhesive has hardened, either pull out the dummy for the 10S17 Electric Wrist Rotator and lamination ring cover at the Allen screw...



... or pull out lamination ring cover only.



Remove cable protector cap using the hook.



The cables are rolled up inside the cable protector cap. During removal of the cable protector cap, the cables will be pulled out of the lower arm.

**Attention!**

If the cables were pulled out prior to cutting and gluing in the lamination ring, (e.g. after a trial fitting) they must be pushed back inside the lower arm and secured using the foam cover before any further work is done.

This will cause the cables to use up more space inside the lower arm than at the time of factory delivery. The usable length of the lower arm will be reduced.

Now the lower arm may be cut to the following lengths only:

- To a minimum of 230 mm when using the 10S17 Electric Wrist Rotator.
- To a minimum of 207 mm when not using the 10S17 Electric Wrist Rotator.

Please proceed as described above when cutting and gluing in the lamination ring.

Notice:

If the foam cover has been glued in, cables may be carefully pulled through the cover's slits using a hook.

3.5 Verifying symmetry



Attach prosthesis components to the 12K100N DynamicArm.

Verify symmetry using Ottobock 743L20=230 Laser-Line.

3.6 Separating the lamination ring from the elbow bal



Before fabricating the permanent socket, the lamination ring and alignment aid must be removed from the elbow ball of the 12K100N DynamicArm.

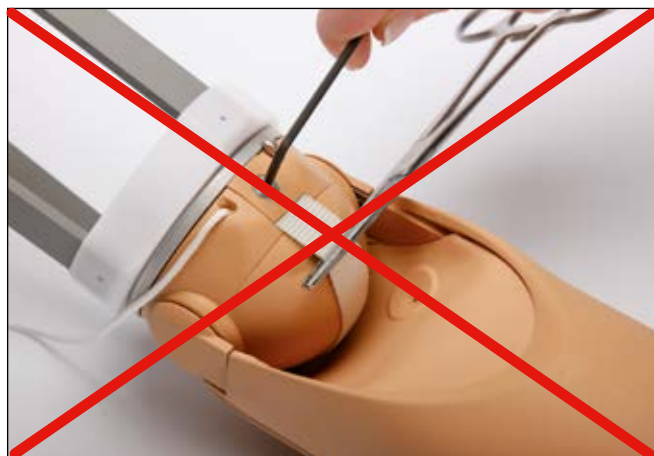
Important notice!

Set control wheel to minimum compensation. This will prevent the strap from being retracted.

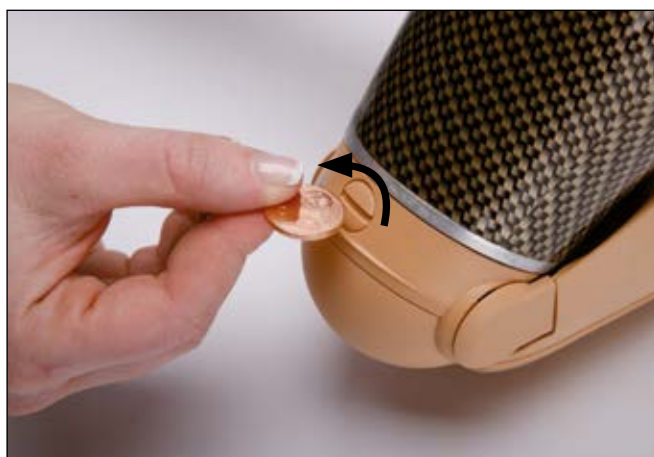


Notice:

Upon delivery, the DynamicArm is equipped with a red assembly clamp. This allows the lamination ring to be unscrewed even after assembly.



Attention: The lifter band should not be removed from the elbow ball. Fixing the lifter strap in place (e.g. with a haemostat) is no longer necessary.



Loosen the friction screw until the lamination ring and elbow ball begin to separate.

Completely unscrew the lamination ring from the elbow ball. Carefully push the electronics housing out of the lamination ring.

3.7 Fabricating the permanent socket



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



Attach the outer lamination cover.



Lengthen the interim socket using plaster bandages (left fig.).
Shape plaster bandages to the interim socket (right fig.).
Fill interim socket and cast with plaster.
Also insert the mounting rod for later clamping during the vacuum forming process.
Allow cast to dry.



Remove plaster bandages from interim socket. Adjust cast to fit the socket rim shape. 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.



Cut socket open using a vibro-saw. Remove the interim socket from the plaster model.



If necessary smooth the plaster model, and mount it onto the vacuum forming device.

Soak a 99B25 Nylon Stockinette in NWax=1 Liquid Wax and pull it over the model to allow for vacuum formation.

Mount Inner Socket Lamination Pattern together with pattern from 13E201 Electrode Accessories for vacuum formed inner sockets and attach to the positive by inserting roundhead steel nails into the drilled marker holes.



Cover the sheet of 616T69=* ThermoLyn Soft skin-coloured or 616T53=* ThermoLyn soft colourless with NWax=1 Liquid Wax. Heat ThermoLyn soft to 160° C in the oven. Switch on vacuum and vacuum form the sheet.

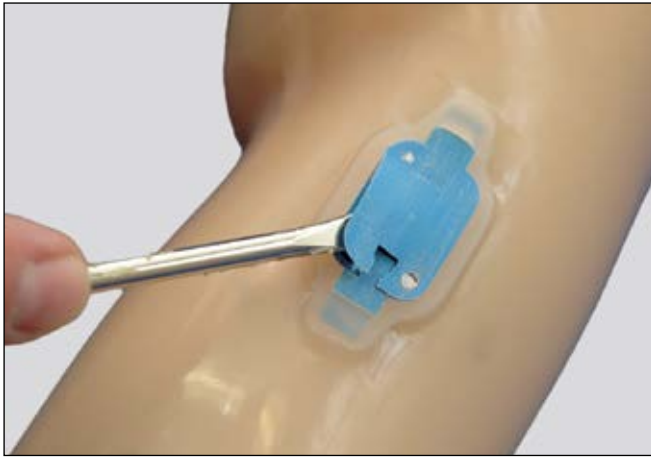
While vacuum forming, mould the sheet to the plaster positive.



In the lamination pattern area, sand ThermoLyn soft flush with the lamination pattern.



Sand free the lamination pattern's nail heads and remove the nails.



Remove the upper part of the vacuum forming pattern.



Align Outer Socket Lamination Pattern proximally (see arrow) and insert.



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



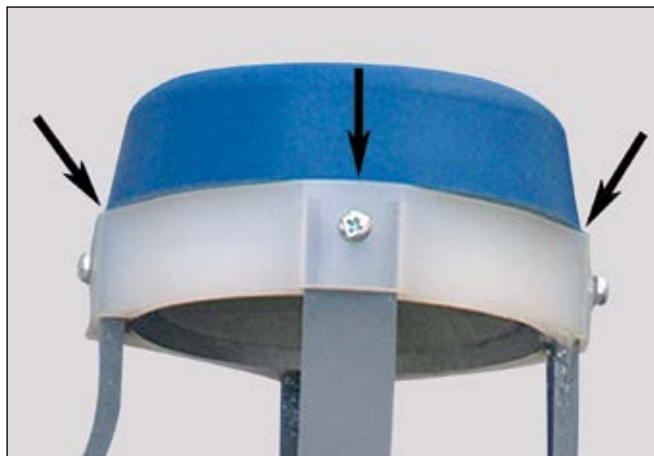
Glue on 627B5=19 Neoprene Cellular Rubber Band.



Apply 633F11 Silicone Grease to lamination cover.



Glue alignment aid to position markers. Place foam cover onto the lamination ring.



The foam cover must close flush with the lamination ring (arrows).

3.8 Foaming the socket



Attention!

Before handling and processing the 617H12 Pedilen Rigid Foam 200 and the 617P21 Pedilen Hardener, please read the corresponding safety data sheet.

Wrap 616T3=1 Trolen Sheeting conically around the permanent socket. It should overlap about 10 centimeters. Secure Trolen wrapping against rolling up using adhesive tape. The Trolen wrapping should be the same distance (approx. 2 to 3 cm) from the model all around.

Mix 617H12 Pedilen Rigid Foam and 617P21 Pedilen Hardener thoroughly as described in the enclosed processing instructions, and pour into the gap between Trolen wrapper and model.



Let rigid foam rise to about 3/4 height. Then position model horizontally. This will prevent cavities.

Remove Trolen wrapper once the curing time has elapsed.



Remove foam piece.



Remove foam cover from the lamination ring.



Remove screws.



Remove alignment aid ring and lamination ring.



Cut fixation arms to the lower edge of the lamination ring using a vibro-saw.



Remove alignment aid from the lamination ring.



Mount lamination ring with lamination cover.



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



Fixation arms will remain in the foam core. Then laminate the core.

4 Laminating instructions for carbon fibre sockets

Please read these instructions carefully. Pay special attention to safety instructions!

4.1 Safety instructions

- For your own protection wear appropriate respirator, protective gloves and goggles when cutting carbon fibre tissue or sanding the socket.
- Before processing the 617H55 C-Orthocryl Lamination Resin or 617H19 Orthocryl Lamination Resin and 617P37 Hardener read the corresponding safety data sheet.
- Ensure sufficient ventilation of working rooms and spaces.

4.2 Preparing the foam core



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.

Apply talcum powder to foam core.

Pull 99B81 PVA Bag over the foam core. Tie off PVA bag at the rod and in the distal area. Cut off excess bag in the distal area.



Switch vacuum on, and place knot into the drilled hole.



Place adhesive tape over the knot.



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



Pull over the socket positive and secure with clamp in the distal area. Pull Perlon stocking down free of wrinkles and tie off.



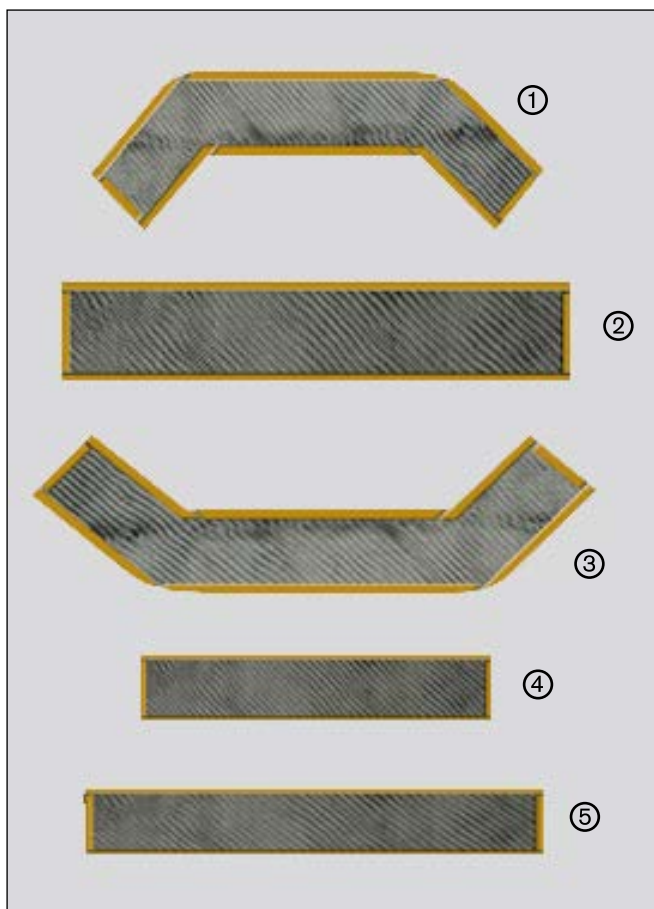
Tie 623T3=* Perlon Stockinette off in the lower groove of the lamination ring using a lace.

4.3 Preparing carbon fibre tissue cloth



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

The carbon fibre tissue cloth shapes will be determined using a paper template. Then lay the paper template on the 616G12 Carbon Fibre Tissue Cloth.



Pieces to be cut out:

Pattern #1: 4x

Pattern #2: 2x

Pattern #3: 4x

Pattern #4: 2x

Pattern #5: 2x

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

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

4.4 Shape and position of the pieces

Pattern No. 1



Positioned in the lateral area. 4 pieces

Pattern No. 2



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



Positioned in the distal area. 2 pieces

Pattern No. 3



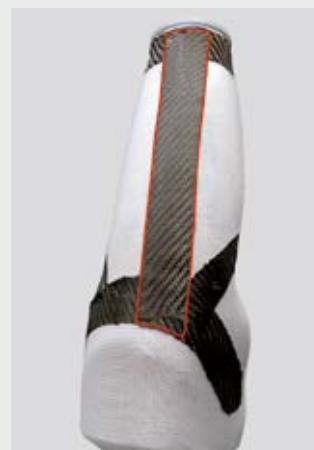
Positioned circumferentially in the proximal area. 4 pieces

Pattern No. 4



Positioned in the lateral area. 2 pieces

Pattern No. 5



Positioned in the medial area. 2 pieces

4.5 Building the socket

The following chapter shall serve as an example for a socket with five reinforcement layers.

1st layer:

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

2nd layer:

Remove clamp. Reflect 623T3=* Perlon Stockinette, pull down free of wrinkles and tie off.

Glue pieces no. 1 through 5 exactly on top of the previously glued pieces.

3rd layer:

Cut 623T3=* Perlon Stockinette to twice the length of the socket positive. Pull over the socket positive and secure with clamp in the distal area. Pull 623T3=* Perlon Stockinette down free of wrinkles and tie off.

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

Glue pieces no. 1 and 3 exactly on top of the previously glued pieces.

4th layer:

Remove clamp. Reflect 623T3=* Perlon Stockinette, and pull down free of wrinkles and tie off.

Glue pieces no. 1 and 3 exactly on top of the previously glued pieces.

5th layer:

Cut 623T3=* Perlon Stockinette to twice the length of the socket positive. Pull over the socket positive and secure with clamp in the distal area. Pull 623T3=* Perlon Stockinette down free of wrinkles and tie off.

Tie 623T3=* Perlon Stockinette off in the uppermost groove of the lamination ring using a lace. Remove clamp.



Reflect 623T3=* Perlon Stockinette, pull down free of wrinkles and tie off.

4.6 Laminating the socket



Pull 99B81 PVA Bag down free of wrinkles over the positive model, and tie off proximally. Switch on vacuum.

Mix 617H55 C-Orthocryl Lamination Resin or 617H19 Orthocryl Lamination Resin and 2% of the resin weight of 617P37 Hardener. Add 617Z2=* Resin Colour Paste as needed.



Pour lamination resin into the bag. Tie off the bag above resin level and work the resin into the reinforcement layer.



Spread lamination resin using a lace, trying to keep the wall thickness as thin as possible. In order to create a high quality socket, there must be no air bubbles inside the lamination resin.



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

Notice:

Do not twist rubber ring!
Once the lamination resin has cured, remove the PVA bag.

4.7 Finishing the socket



Remove lamination cover.



Retract inner lamination cover using pliers. Remove rigid foam.



Sand the inner and outer socket brim to shape, and smooth edges.



Finish socket as usual.



Attention!

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.

5 Trademarks

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Ottobock has a certified Quality Management System in accordance with ISO 13485.