

Michelangelo Hand with Axon-Bus system

Fabricating a Transradial Prosthesis

Technical Information 3.3.4

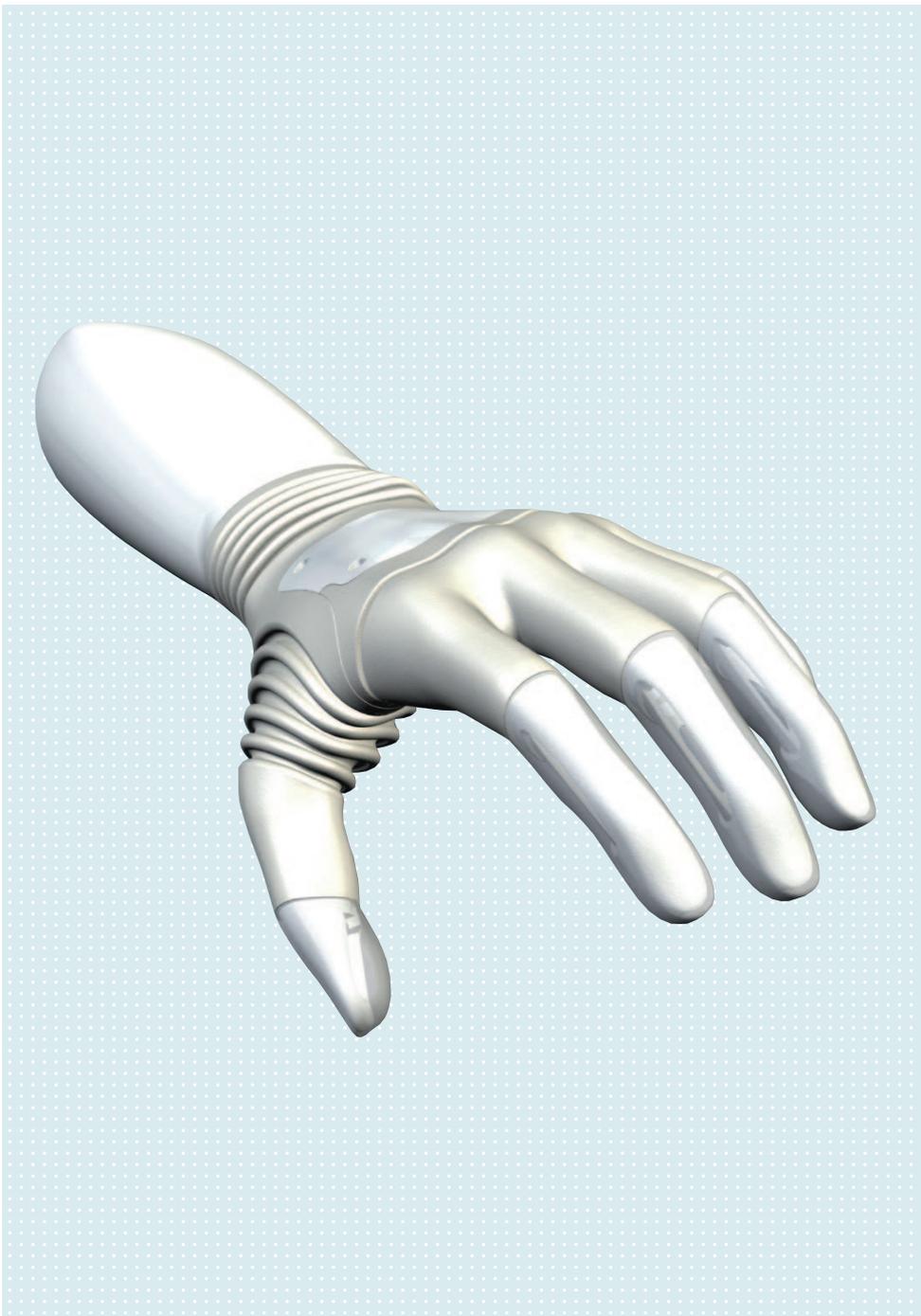


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1 Information about this document

INFORMATION

Date of the last update: 2012-05-07

2 Taking Measurements on the Patient

2.1 Description

Examining and measuring the limbs is essential in order to successfully fabricate a socket. Take the measurements in the specified order and enter the results in the measurement form.

2.2 Tools

Measurement form	in PDF format for downloading
Grease Pen	645C2=*
Folding Ruler	743E7=P
Self-Retracting Tape Measure	743B4
Callipers	743S20
Crosshair Laser	743L5
Goniometre	662M4

2.3 Measuring

2.3.1 Measuring the sound limb



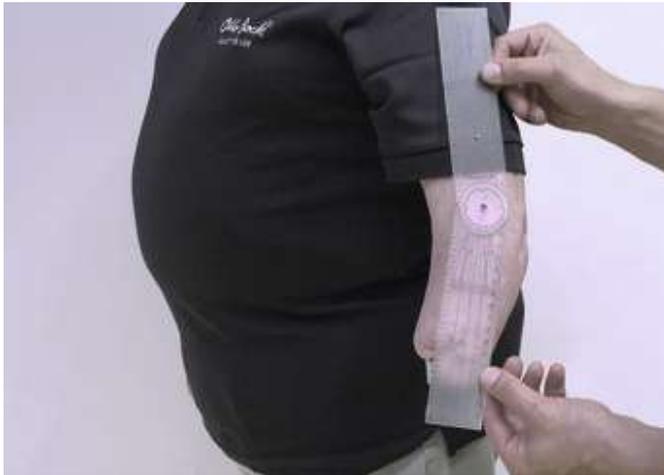
Use the grease pen to mark the centre of the olecranon.



Measure from the olecranon to the tip of the middle finger. Enter the measurements of the sound side in the measurement form:

2.3.2 Measuring the amputated limb

When measuring the residual limb, three circumference measurements and one M/L measurement are taken as reference measurements for modelling. The measurements must be entered in the corresponding measurement form.



INFORMATION

Measurements are taken with a residual limb flexion of 15°.



Using a grease pen, mark the measured length from the residual limb end to the centre of the olecranon at 30 mm, 60 mm and 90 mm.

INFORMATION

Ensure that the circumference measurements are distributed evenly and according to the residual limb length.



Measure the residual limb circumference at the three marked positions and enter the results in the measurement form.



Measure the length from the centre of the olecranon to the end of the residual limb and enter the value in the measurement form.



Measure the M-L distance using callipers and enter the result in the measurement form.

- Proximal above the epicondyles



- Directly on the epicondyles



- On the future electrode surfaces



Slide the Michelangelo dummy alignment tool over the residual limb to check for excess length. With the help of the crosshair laser, transfer the forearm length from the sound side to the residual limb side (reference measurement).

2.4 Verification of Results



The completed measurement form.

3 Determining the Correct Electrode Position

3.1 Description

This step serves to determine the electrode position.

INFORMATION

Only use the 13E202=* suction socket electrode!

3.2 Tools

Grease Pen	645C2=*
PAULA Software with MyoBoy	646C48=*

3.3 Materials

Electrode cable	13E129=G*
Suction Socket Electrode	13E202=*

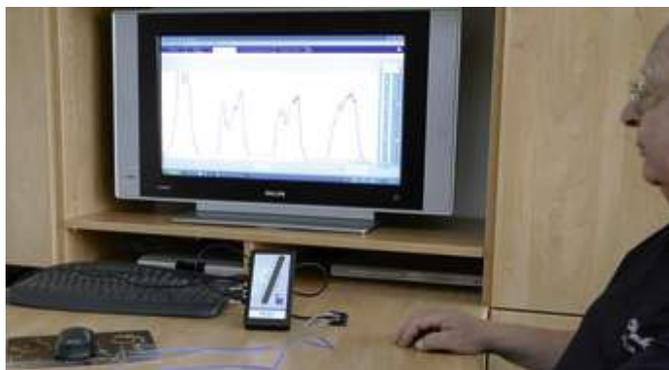
3.4 Determining Electrode Positions



With bilateral contraction, palpate the muscle belly.



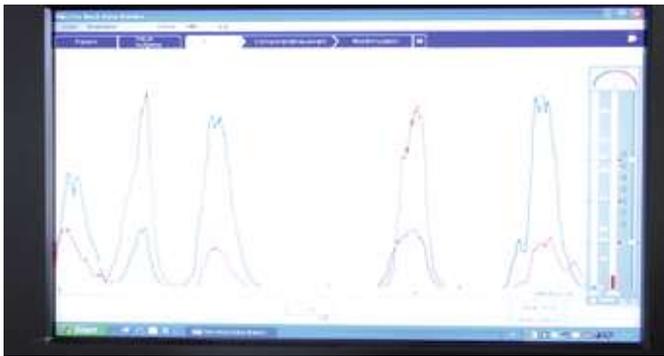
Apply the suction socket electrode parallel to the muscle fibres.



Check the muscle activity on both sides (extensor and flexor). In order to do so, conduct the MyoTest to determine the optimum electrode position with the Myo-Boy and PAULA on the patient. If necessary, move the electrodes and check again.



Attach both suction socket electrodes.



Check for optimum signal separation on the PC and change the electrode positions if required.



Mark the electrode positions on the skin.



4 Plaster Cast on the Patient

4.1 Description

The plaster cast must be taken carefully in order to ensure a good socket fit. Prominent bone structures and the flexion of the residual limb must be taken into account when fabricating the plaster negative. The finished plaster negative is used to fabricate the plaster positive.

4.2 Tools

Grease Pen	645C2=*
Plaster Cast Scissors	719G2
Latex Gloves or Latex-Free Gloves	641H12 or 641H9=2
Tape Measure	743B4
Knife	718H5
Water Basin	754W5=1
Crosshair Laser	743L5
Michelangelo Dummy Alignment Tool	

4.3 Materials

1x 4 - 6 layers of Cellona plaster languette 12 cm	699G3=12
2 x elastic plaster bandages, 10 cm	699G1=10
Easy-Proth Arm Donning Sheath	OC1560=TR
Cellona Plaster Languette, width: 8 cm	699G3=8
Plaster/Compression Sock	641T10=M
Plastering Apron	641S1
Plastering Shoes	627B5=25
Plaster Parting Liquid	85F1

INFORMATION

Select plaster bandages on a patient-specific basis depending on the length of the residual limb.

4.4 Preparing the Residual Limb



Examine the residual limb clinically to locate prominent bone structures.

- Olecranon
- Bone ends
- Medial and lateral epicondyles

INFORMATION

Ensure sufficient compression for the initial fitting. For example, apply post-operative bandaging, a silicone liner or occupational therapy for this purpose.



Simulate the condyle cage, test for pressure sensitivity.



Check the physiological range of motion.



Check load tolerance of the end of the residual limb.



Check the load bearing capacity of the residual limb against a resistance.



If necessary, apply a "load relief pad" made of neoprene cellular rubber band to pressure-sensitive areas.

INFORMATION

Put on the 641S1 Plastering Apron and 627B5=25 Plastering Shoes to protect the patient.



Depending on the volume and length, prepare 4 - 6 layers of circular longuette using 12 cm/15 cm wide Cellaona.



Fold the longuette down the middle.



Mark the flexion cut-out to a sufficient depth; the epicondyles must be fully covered.



Prepare the flexion cut-out.



Measure off the width of the condyle cage.



Establish the depth of the extension cut-out (approx. $\frac{1}{2}$ the length of the flexion cut-out).



Prepare the extension cut-out.



The completed languette.



Check on the patient:

- Flexion cut-out
- Condyle overlap
- Olecranon embedding



Fill the condyle cage with plaster waste as reinforcement.



Prepare the flexion crease pull-in strap.

1. Measure off 10 cm Cellona to the circumference of the residual limb and fold midway in longitudinal direction.
2. Slightly cut in the flexion cut-out.



The completed longuette with 12 cm/15 cm elastic plaster bandage.

4.5 Fabricating the Plaster Negative



Slip the dry stockinette over the residual limb. While doing so note the following:

- Isolating the skin is not necessary.
- Apply the distal seam of the stockinette to the residual limb side.
- The writing on the stockinette must be on the outside.
- Check the fit and compression of the stockinette and stitch down if required.



Mark the medial epicondyle.



Mark the lateral epicondyle.



Mark the olecranon.



Mark the electrode positions.



Mark the flexion crease and flexion cut-out.

Also establish the proximal socket edge and mark it. While doing so note the following:

- Dorsal: mark one thumb width proximal above the olecranon.
- Lateral and medial: mark one thumb width proximal above the epicondyles.
- Ventral: mark according to the flexion crease.



INFORMATION

On the flexion crease, mark the centre line as orientation for the longitudinal direction of the residual limb.

CAUTION

Use latex gloves for plaster work on the patient.



Soak the longuette and apply it to the residual limb precisely (residual limb approx. 45° flexion).



Mould the flexion cut-out.



Form the olecranon embedding and the extension cut-out.
Residual limb position approx. 45° flexion. Ensure that the patient keeps the residual limb fully relaxed!



Under slight tension, apply the soaked elastic bandage alternating between "figure 8" and circular wrapping. Only unroll half the plaster bandage!



Under slight tension, draw the pull-in strap into the proximal flexion area. Unwrap the remaining elastic bandage as described above.



Now passively bring the residual limb to 90° of flexion (patient does not contract!).
Mould the edge of the negative as far as possible.
As the plaster is setting, palpitate and form the condyle brace.



With the extended index finger, mould the flexion cut-out perpendicular to the residual limb axis.



The electrode support surfaces must be moulded flat.



Bring the residual limb to max. flexion and max. extension.



The cured negative.



Carefully trim the socket edge on the patient.



Check the range of motion and, if necessary, trim the socket edge again.



Mark the flexion crease.



Use a crosshair laser to mark the residual limb alignment on the plaster negative in the frontal and sagittal plane.



Slide the prefabricated Thermolyn Soft outer sheath onto the plaster negative and check the range of motion in various planes.



Using the thumb, draw soft tissue out of the socket. With the residual limb flexed, carefully pull off the plaster negative.



Finish the socket edge.



Measure the reinforcing longuette and soak it in water.



Apply the reinforcing longuette, mould and smooth.



Mark the positions of the electrodes, olecranon and epicondyles.



Transfer the electrode positions to the outside, cut open the electrode openings, open the distal end.



INFORMATION

Cut an additional "expansion joint" on the flexion cut-out if required.



Carefully widen the plaster negative.

4.6 Fitting the Plaster Negative



Apply the plaster negative with the Easy-Proth Arm donning sheath. Fully insert the residual limb into the socket; gradually and carefully pull out the donning sheath.

INFORMATION

Observe the correct position while donning. Use the marked plumb lines as a reference.



Check the fit, volume and electrode positioning.



Transfer the electrode positions marked on the skin to the plaster negative.



CAUTION

Caution: To protect the skin, insert a piece of Trolene between the skin and the plaster negative.



Draw the expansion joint closed with stockinette.



Check the range of motion for:

- Maximum flexion



- Maximum extension



- Rotational stability

Mark the trim line for correction if required.



Check the end load capacity of the residual limb.



Check the condyle load capacity.



Check the load bearing capacity of the residual limb.

5 Fabricating the Plaster Positive

5.1 Description

The plaster positive is used to fabricate the test socket. The marked points are transferred from the plaster negative to the plaster positive.

5.2 Tools

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
Wax Pen	645C2=2
Wet Sanding Paper 400	General workshop supplies
Water Basin	754W5=1
Plaster Mixing Bowl	754B1
Plaster Spatula	756G2=*

5.3 Materials

Alabaster Modelling Plaster	699G4=25
Cellona Plaster Bandages, 15 cm width	699G3=15
Plaster Parting Liquid	85F1
Plastering Rod	General workshop supplies

5.4 Preparing the Plaster Positive



Check the markings and touch them up if required.



Seal the openings.



Extend the plaster negative with 4 – 5 layers of plaster longuette. The negative should be moulded 3 – 4 cm longer than the epicondyles.



Isolate the plaster negative with 85F1 Plaster Parting Liquid.



Fill the plaster negative with plaster, avoiding air inclusions in the material.

Position the plastering rod according to the residual limb alignment.



Cut the plaster longuette on the proximal side and remove it.



Use a grease pen to transfer the marked residual limb direction from the plaster negative to the plaster positive.



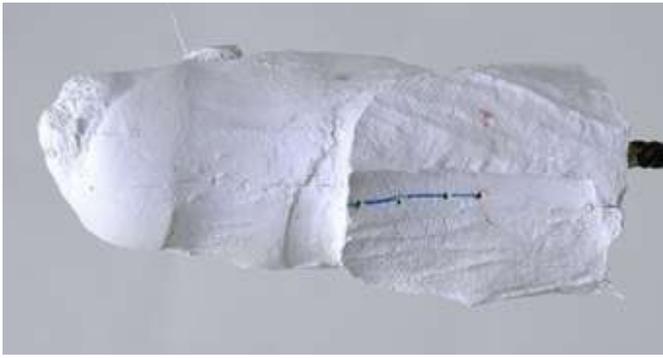
Puncture with a pointed object.



Unpack the plaster model layer by layer.



Transfer the electrode positions and apply centre holes so that the electrode positions are not lost during moulding.



Ensure that the marked olecranon, epicondyle and residual limb alignment points are retained.



Flatten the electrode positions, watching for bony epicondyles.

Use the electrode dummy to check the position and application.



Mark the condyle cage bilaterally.



Deepen by approx. 3 – 5 mm and scrape out in a rounded form.



Check the circumference measurements at 30 mm, 60 mm and 90 mm. In case of deviations, rework the plaster accordingly.

INFORMATION

First remove plaster. When the measurements are OK, begin applying plaster to the bony areas.



Mark the bony areas and extend in the proximal direction to increase the range of motion.

Apply plaster to increase the range of motion in the flexion direction for the olecranon and epicondyles.



Extend the plaster model by approx. 3 – 5 mm as required.



In the distal area, flatten the base for the component holder. Observe the residual limb direction (alignment direction).

Flatten the pull-in tube.



Remove a small amount of material from the flexion crease. For volume compensation, apply plaster where the muscle is contracted.

5.5 Smoothing the Plaster Positive



Smooth the proximal edge of the model to achieve a uniform socket edge.



Smooth the plaster model with wet sanding paper.

INFORMATION

First soak the wet sanding paper in water.

Use a dry 699G3 Plaster Bandage to seal any air bubbles or uneven areas.



Use a grease pen to mark the centre holes for the suction socket electrode dummies.



Mark the residual limb alignment.

5.6 Verification of Results



The completed plaster positive.

6 Fabricating the Inner Test Socket

6.1 Description

The test socket is fabricated to verify proper fit and correctly position the component holder.

6.2 Tools

Grease Pen	645C2=*
Phillips Screwdriver	710H5=*
Knife	718H5
Vacuum Forming Plate (Small)	755X22=260
Vacuum Forming Tool for Arm Prostheses	711M53
Temperature-Resistant Glove	641H13
Polishing Wheel	749Z12=160x16
Leather Cutter	719L1

6.3 Materials

Dummy Set for Pull-in Tube	99B83=21
Dummy Set for Component Holder	Included in scope of delivery of 757B500
Plaster Parting Liquid	85F1
Nylon Tube Sock	99B25
Thermolyn Soft transparent - material thickness: 8 – 10 cm (depending on residual limb length)	616T53*

6.4 Preparation for Vacuum Forming



Position the plaster positive on the vacuum forming plate.



Establish the position of the component holder base and pull-in tube.

INFORMATION

The angle of the component holder must correspond to the forearm angle.



Mark the position of the component holder base.



Mark the position of the pull-in tube.



Use a wood screw to secure the inner tube of the 99B83=* Dummy Set on the plaster positive in the alignment direction.



Pull a 99B25 Nylon Tube Sock soaked in plaster parting liquid over the plaster positive to allow for vacuum formation.



Apply the outer tube dummy.



Secure the component holder base with two nails.



Press in the blue pin to protect the thread.



Secure the suction socket electrode dummies on the plaster positive. Observe the electrode positions defined in the MyoTest.

INFORMATION

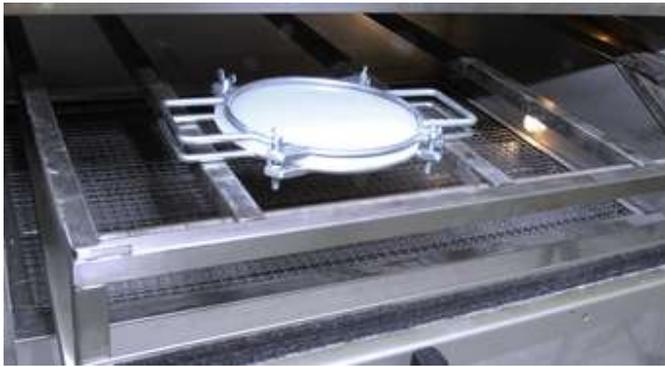
The electrode dummies must be fixed on the nylon stockinette.

The potentiometers must be aligned proximally.

6.5 Vacuum Forming



Remove both protective films from the Thermolyn Soft transparent, thickness 8 – 10 mm, and clamp the Thermolyn sheet in the vacuum forming plate.



Then heat at 160°C in an oven until the material sags by 2/3 of the length of the positive.

CAUTION

Use the 641H13 Heat-Resistant Glove to avoid injuries. Use the small vacuum forming plate.



Put the vacuum forming plate with the heated ThermoLyn Soft material over the plaster positive.



Apply a low vacuum and after vacuum forming, massage the material to the contours of the plaster positive. Pull away wrinkles in the direction of the flexion cut-out or remove them with a massaging movement.



Once the ThermoLyn Soft material is wrinkle-free on the plaster positive, apply maximum vacuum. Mould on major structures such as the flexion cut-out, olecranon and pull-in tube dummy. Allow the ThermoLyn Soft material to cool.

6.6 Completing the Test Socket



Cut away material over the component holder base until the blue marking appears.
Remove the blue pin.



Cut open the course of the socket edge on the proximal side.



Grind away material over the suction socket electrode dummies and the valve tube.



Next remove the dummies and the plaster.



Mark the course of the socket edge.



Trim the socket edge including additional material with the help of a leather cutter.



Grind the socket edge.



Polish the edges.

6.7 Verification of Results



The prepared test inner socket.

6.8 Trial Fitting on the Patient:



Apply the inner socket using the Easy-Proth donning sheath. Observe correct residual limb alignment while doing so.



Check the fit and volume for:

- Maximum flexion



- Maximum extension



- End load of the residual limb



- Condyle load



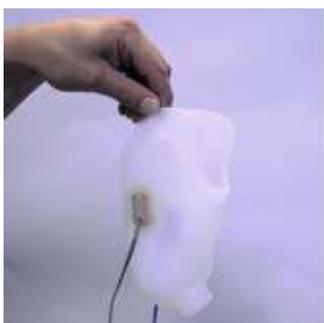
- Load bearing capacity of the prosthesis



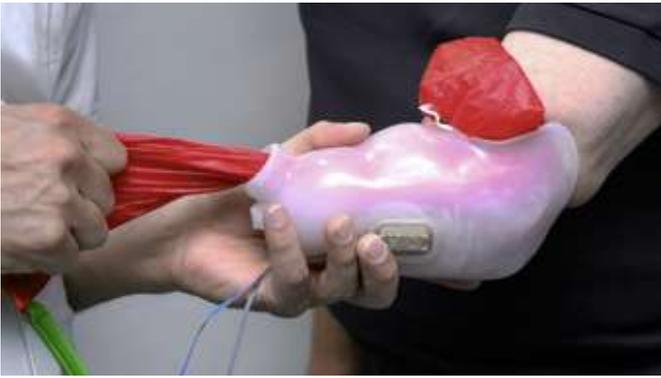
Check the position and application of the electrodes.



Mark any required corrections and optimise the test socket accordingly.



Apply the test socket and integrate the suction socket electrodes with electrode cables.



Apply the inner socket using the Easy-Proth donning sheath.



Conduct the MyoTest using the MyoBoy to verify electrode functionality.

7 Fabricating the Outer Test Socket

7.1 Tools

Hand Drill	General workshop supplies
Felt-Tip Pen	General workshop supplies
Component Holder Unit	Included in scope of delivery of 757B500
Folding Ruler	743B4
Knife	718H5
Conical Drill 14	726W9=*
Conical Drill 30	726W9=*
Allen Wrench	709S15=2
Twist Drills 4/5/8 mm	724S1=4/5/8
Hot Air Gun	756E11=*
Leather Cutter	719L1
Temperature-Resistant Glove	641H13

7.2 Materials

2x Electrode Cable	13E129=G*
2x Suction Socket Electrodes	13E202=*
8x M4 Screws	503F3
8x Setting Nuts	29C5=M4X9
Elastic Cord/Band	General workshop supplies
AxonEnergy Integral	757B500
AxonMaster	13E500
Drilling Template for Charging Receptacle	Included in scope of delivery of 757B500
Cyamet Quick-Drying Adhesive	636K11
AxonWrist	10V500=2*
Edding Permanent	General office supplies
Pull-in Tube	99B13=21
Plastering Rod	General workshop supplies
Component holder for battery and AxonMaster	Included in scope of delivery of 757B500
Michelangelo Hand	8E500
Perlon Stockinette 8 cm	623T3=8
PVA Adhesive Tape	627B40
PVC Bag	99B71=*
Silicone Grease	633F11
Easy-Proth Donning Sheath	OC1560=TR
Electrode Dummies	Included in the scope of delivery of 13E202=*
Plaster Parting Agent Cream	640Z5=*
Modelling Clay	636K6
Linen Adhesive Tape	627B1=*
Bonding Agent	617H46

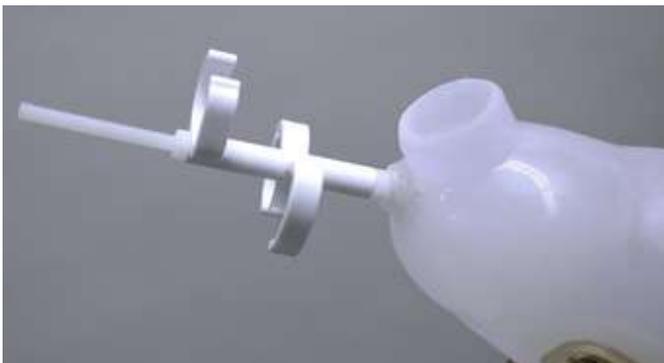
7.3 Preparing the Outer Test Socket



Screw the threaded nylon rod into the component base. Slide on the plastic washer and thread on the nut.



First slide on the dual component holder, then the single component holder.



Slide on the plastic washer and thread on the nut. Use the spacer for the component holder if necessary.



Using an elastic band, attach the dummies of the AxonEnergy Integral and AxonMaster to the component holder.

Change the height of the component holder by turning the two nuts.



Trim off the protruding threaded nylon rod.



Fit the Thermolyn Soft inner socket on the patient and mark the olecranon.



Position the Thermolyn Soft outer socket on the measured forearm length and mark the proximal course of the socket edge.
Observe the marked olecranon position.



Then trim using the leather cutter.

NOTICE

Do not trim the distal end of the outer socket.



Grind the socket edge and taper it to zero.



Slide the Michelangelo dummy onto the distal hand adapter.



Slide the distal hand adapter onto the Thermolyn Soft outer socket.



Slide the Thermolyn Soft outer socket onto the donned inner socket. Check the prosthesis length of the Michelangelo dummy and adjust it if necessary.



Check the prosthesis alignment and the prosthesis fit in various planes of movement and adjust if necessary (shorten, change angles etc.).



Then attach the Michelangelo dummy to the outer socket using PVC adhesive tape.

INFORMATION

If necessary, use PVC adhesive tape to join the Thermolyn Soft outer socket to the inner socket in the area of the proximal socket edge.

7.4 Finishing the Outer Test Socket



Remove the PVC adhesive tape on the proximal side and transfer the socket position to the inner socket.



Mark the centre line for orientation.



Separate the inner and outer socket.



Remove the component dummies and the component holder. Next remove the inner socket and dismantle the suction socket electrodes.



Use linen adhesive tape to cover the electrode openings from the inside.



Use modelling clay to close the valve tube opening in the inner socket.



Close the flexion cut-out and dorsal socket opening with linen adhesive tape and/or plaster longuette.



Apply plaster parting agent cream to the inside of the inner socket.



Check the M-L measurement.



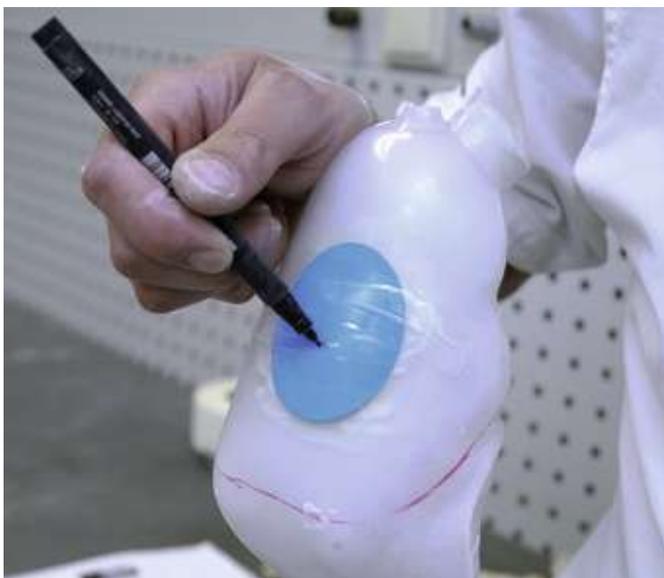
Mix plaster and pour it into the isolated inner socket.
Insert the plastering rod for fixation.
Let the plaster cure.

INFORMATION

Table salt can be applied to allow the plaster to cure more quickly.



Remove the linen adhesive tape from the plaster model after it has cured.



Insert the suction socket electrode dummies and secure them using PVC adhesive tape.



Clamp the plaster model in the vice and warm the proximal course of the socket edge on the Thermolyn Soft outer socket with hot air.



Slide the warmed Thermolyn Soft outer socket onto the inner socket and mould it into place.

In the first step, use the heat-resistant gloves to press on the socket edge.

In the second step, apply firm pressure with an elastic bandage.

Then secure with adhesive tape.

Allow the Thermolyn Soft material to cool. Next remove the elastic bandage.



Mark 2 holes to attach the outer socket on the ventral and dorsal side, respectively.



Bore through the markings (\varnothing 4 mm).



Bore the position of the electrode potentiometers (\varnothing 8 mm).



Slide the Thermolyn Soft outer socket from the inner socket. Next remove the plaster from the inner socket.



Bore out the mounting holes in the inner socket (\varnothing 5 mm).



Insert the 99B13=21 Pull-In Tube into the inner socket. If required, trim the pull-in tube but leave an additional length allowance.

INFORMATION

The pull-in tube can be ordered in various colours.



Insert the setting nut (M4) into the inner socket.



Join the inner socket and Thermolyn Soft outer socket with setting nuts.

Note that the length of the screws must be individually adapted.



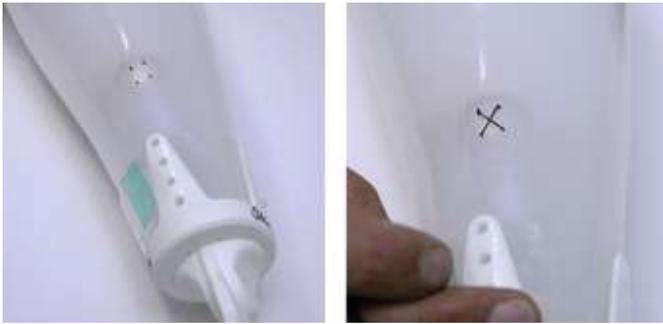
Insert the magnetic centring aid into the pull-in tube.



Position the opposite pole of the magnetic centring aid on the Thermolyn Soft outer socket (use magnetic orientation).



Use a pen to mark the 4 positions of the centring.



Joining these position points delivers the exact centre point.



Remove the centring aid.
Unscrew the inner socket and outer socket from each other.



Pre-drill the centre point position of the valve tube (ø 4 mm).



Use a conical drill to pre-drill the marked position (ø 14 mm).



Then mark the conical drill (ø 30 mm) at the height where the diameter is 24 mm. This step ensures drilling for a proper fit.



Drill the hole for the pull-in tube accordingly.



Insert the pull-in tube into the inner socket and check for an optimum fit with the pull-in tube. To do so, screw together the inner and outer socket.



Mark the excess length at the level where it is flush with the outer socket and grind to trim.



Transfer the contour of the charging receptacle dummy to the Thermolyn Soft outer socket.





Unscrew the inner and outer socket from each other.
Bore out the charging receptacle opening with a conical drill (\varnothing 14 mm).



Cut out the contour of the charging receptacle opening and check the fit with the charging receptacle dummy.



Drill 4 holes (\varnothing 5 mm) into the Thermolyn Soft outer socket to attach the distal hand adapter. Then remove the PVC adhesive tape.



Insert the setting nuts into the Thermolyn Soft outer socket and screw together with the distal hand adapter.

7.5 Wiring the Components in the Test Socket



Use electrode cable to fasten the suction socket electrodes in the inner socket and insert the 99B13=21 Pull-in Tube into the inner socket.



Use 636K11 Cyamet Quick-Drying Adhesive to secure the 99B13=21 Pull-in Tube.



Then seal with bonding agent to protect the electronic components.



Screw the threaded nylon rod into the component base. Slide on the plastic washer and thread on the nut.



First slide on the dual component holder and then the single component holder. Slide on the plastic washer and thread on the nut. Use the spacer for the component holder if necessary.



Seal the plug connections 1 and 2 on the AxonMaster with silicone grease.

INFORMATION

The silicone grease seals the plug connection as protection against moisture.



Connect the electrode cables to the AxonMaster. Observe the correct assignment of the plug connections.

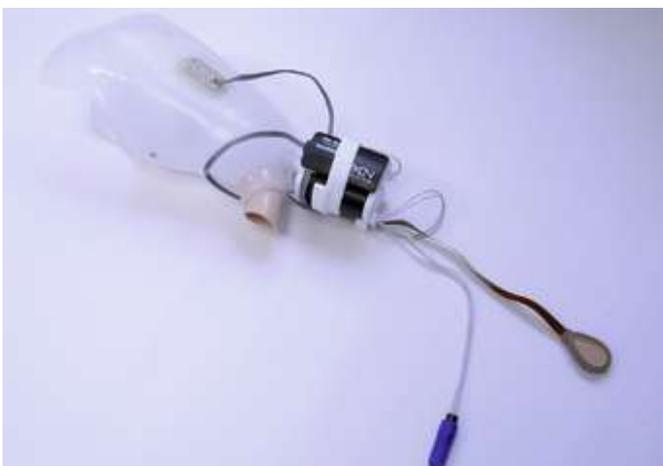
- Plug connection 1 -> close
- Plug connection 2 -> open



Seal the plug connection on the AxonEnergy Integral with silicone grease and connect with the 3-pin plug on the AxonMaster.

INFORMATION

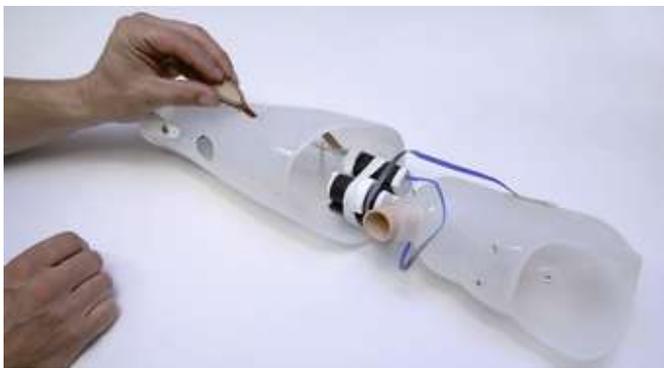
The silicone grease seals the plug connection as protection against moisture.



Position the AxonEnergy Integral and AxonMaster on the component holder and use an elastic band to secure them as a compact unit.



Remove the Michelangelo dummy from the distal hand adapter.



Insert the charging receptacle through the charging receptacle opening of the Thermolyn Soft outer socket.

INFORMATION

When disassembling or assembling the outer and inner test socket, first remove the charging receptacle.



Place the inner socket into the Thermolyn Soft outer socket. It is essential to ensure that the components and the cable are not damaged. In case of volume problems, rework the Thermolyn Soft outer socket. Use setting nuts to join the inner socket to the Thermolyn Soft outer socket.

Thread the hand connecting cable through the distal hand adapter.



Use silicone grease to seal the plug connection.



Join the 10V500=2* AxonWrist to the hand connecting cable.



Screw connect the 10V500=2* AxonWrist to the distal hand adapter.



Attach the Michelangelo Hand.

7.6 Verification of Results



Fit the prosthesis with the Michelangelo Hand on the patient.



Switch on the prosthesis and verify the functionality of the Michelangelo Hand.



Check the range of motion of the prosthesis.



NOTICE

If the trial prosthesis is to be used as an interim prosthesis, the prosthetic glove must be applied over the Michelangelo Hand. Observe the instructions for use provided for the prosthetic glove and the process for putting it on and taking it off described in the same.

8 Fabricating the Definitive Inner Socket

8.1 Tools

Twist Drill	724S1=10
Grease Pen	645C2=*
Phillips Screwdriver	710H5=*
Tape Measure	743B4
Oscillating Saw	756B12=110/230
Modelling Clay	636K6
Half-Round Rasp	716Y3
Vacuum Forming Plate (Small)	755X22=260
Vacuum Forming Tool	711M53
Temperature-Resistant Glove	641H13
Wet Sanding Paper 400	General workshop supplies

8.2 Materials

Alabaster Modelling Plaster	699G4=25
Dummy Set for Pull-in Tube	99B83=21
Lamination Template for Inner Socket	Included in the scope of delivery of 13E202=*
Plaster Parting Liquid	85F1
Plaster Longuette	699G3=12
Hardener for Rigid Foam	617P21
Rigid Foam 200	617H12
Lamination Dummy, Charging Receptacle	Included in scope of delivery of 757B500
Nylon Tube Sock	99B25
PVA Adhesive Tape	627B40
PVC Bag	99B71=*
ThermoLyn Soft, Skin-coloured 10 mm	616T69=10
Parting Agent	617F8=*

8.3 Preparation for Vacuum Forming



Remove the Michelangelo Hand from the AxonWrist.



Loosen the screws on the AxonWrist and remove the wrist unit. Disconnect the plug connection.



Unscrew the inner and outer socket from each other. Ensure that the charging receptacle is not damaged.



Remove the charging receptacle.



Remove the suction socket electrodes.



Remove the component holder including all components from the inner socket.

NOTICE

Do not remove the distal hand adapter. Store the Axon-Bus components in a safe place.



Use adhesive tape to close the holes for the setting nuts and the electrode openings from the inside. Seal the pull-in tube cut-out with modelling clay.



Insert the electrode dummies and secure with adhesive tape from the outside.



Apply a plaster longuette to extend the socket model proximally. Do not change the M-L measurement in doing so. Check with callipers for verification.



Apply parting agent cream to the test socket.



Fill the test socket with plaster. In doing so, observe the correct alignment of the plastering rod. Let the plaster cure.



Cut open and remove the plaster longuette.



Cut open the test socket ventrally with the oscillating saw and remove it from the plaster.



Smooth the plaster positive.



Slide the test socket back onto the plaster positive.



Transfer the electrode positions, the valve position and the position of the component holder.





In order to transfer the position of the outer test socket onto the definitive socket, colour-mark the four mounting holes in the proximal course of the socket edge on the plaster model.



Use a wood screw to secure the inner tube of the 99B83=* Dummy Set on the plaster positive in the alignment direction.



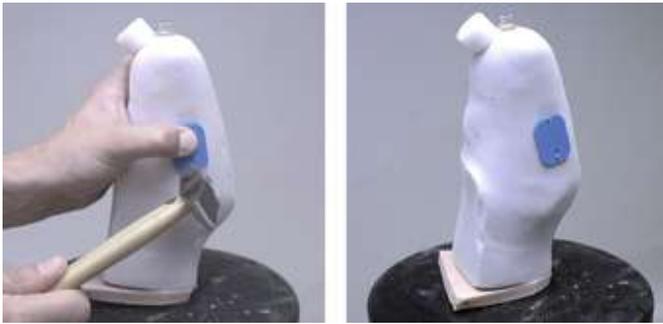
Pull a 99B25 Nylon Tube Sock soaked in plaster parting liquid over the plaster positive to allow for vacuum formation.



Apply the outer tube dummy.



Secure the component holder base with two nails. Press in the blue pin to protect the thread.



Use nails to secure the suction socket electrode dummies on the plaster positive. Ensure precise positioning.
Align the potentiometer proximally.

8.4 Vacuum Forming



Remove the two protective films of the 616T69=10 Thermolyn Soft. Clamp the Thermolyn Soft material in the vacuum forming plate.



Then heat in an oven at 160°C until the material sags by 2/3 of the length of the plaster positive.

CAUTION

Use the 641H13 Heat-Resistant Glove to avoid injuries. Use a small vacuum forming plate.



Put the vacuum forming plate with the heated Thermolyn Soft material over the plaster positive. Set a low vacuum and after vacuum forming, massage the material over the contours of the plaster positive. Pull away wrinkles in the direction of the flexion cut-out or remove them with a massaging movement.

Once the ThermoLyn Soft material is located wrinkle-free on the plaster positive, apply maximum vacuum.



Mould on major structures such as the flexion cut-out, the olecranon and the dummy of the pull-in tube.

The completed vacuum-formed inner socket.

9 Foaming and Grinding the Definitive Outer Socket

9.1 Description

Finishing the Outer Socket Transfer from the test socket to the definitive outer socket.

9.2 Foaming and Grinding the Definitive Outer Socket



Use an oscillating saw to proximally cut open the cooled ThermoLyn Soft.



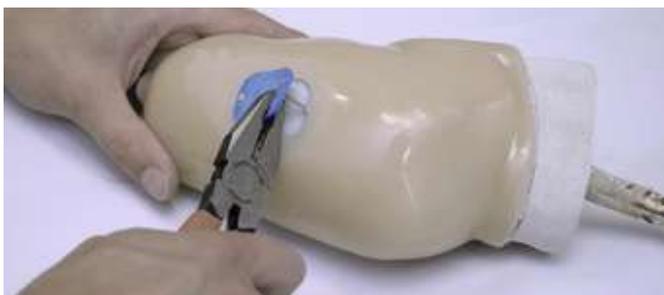
Cut away material over the component holder base until the blue marking appears.
Remove the blue pin.



Grind away material to reveal the dummies of the valve tube and remove both tube dummies.



Grind away the material from the nails of the lamination template of the suction socket electrodes and remove them.
In the lamination template area, sand the ThermoLyn Soft flush.



Remove the lamination template for the inner socket. For this purpose, drill a hole (4 mm) in the lamination template. Use a screwdriver or similar tool to pry out the lamination template.



Insert the 13E204 Lamination Template for the outer socket and position it with PVC adhesive tape.



Fill the hole for the pull-in tube with modelling clay.



Secure the inner socket in the vacuum pipe and powder with 453H2=1 Special Lubricant.



Heat the 99B71=60x11x4 PVC Film with a hot air gun and slide it over the inner socket.



Tie off the PVC film distally above the valve tube and proximally at the vacuum pipe. Next extract air and apply vacuum.



Cover the outer socket holes with Coroplast.



Apply 617F8 Parting Agent to the inside of the distal hand adapter and allow to dry.



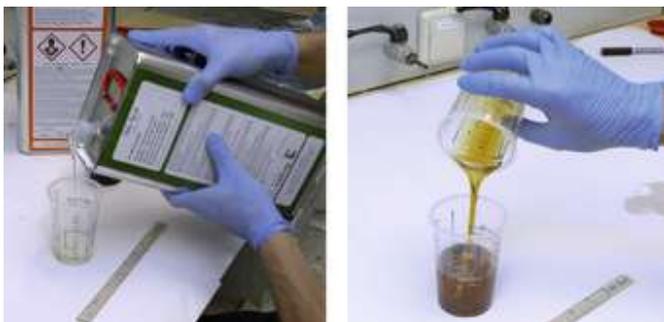
Use a grease pen to transfer the marked holes for the mounting screws to the PVC film.



Position the outer socket on the inner socket and attach with adhesive tape on the proximal side.

NOTICE

Observe the coloured positioning points to check the alignment of the residual limb.



Mix the 617H12=0.865 Pedilen Rigid Foam 200 and the 617H37=0.865 Hardener (process according to Instructions for Use).



Fill the Thermolyn Soft outer socket with rigid foam 200 and allow to cure.



Once the rigid foam has cured, trim excess material in the distal area so it is flush. Then loosen the screws in the hand adapter.



Mark the A-P alignment of the hand adapter on the rigid foam to transfer the position to the lamination ring. Then remove the hand adapter.



Mark the ventral side of the Thermolyn Soft outer socket, cut it open and pull it off the inner socket.

NOTICE

Ensure the inner socket is not damaged during cutting.





Position the lamination ring on the rigid foam and mark the outline.



Remove the lamination ring and separate the rigid foam from the inner socket. Next remove the PVC bag.



Mark the contour of the charging receptacle. Fit the charging receptacle dummy into the foam.



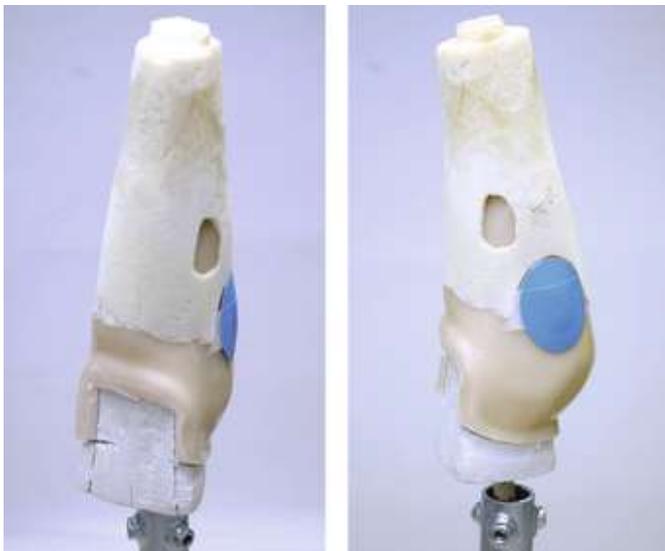
Grind the entire rigid foam component for a positive fit. Observe the distal marking of the lamination ring while doing so.



Mark the electrode dummy cut-outs and cut them out completely (full-surface contact in the lamination resin socket).



Thin the proximal foam edge.



Check the shape of the foam model against the inner socket.



Position the charging receptacle dummy in the rigid foam and secure it with modelling clay or 636K8=* Plasta Tape. The dummy should project from the foam by approx. 1 mm.



Grind the distal area of the rigid foam until flush.



Drill the hole (\varnothing 10 mm) approx. 10 mm deep in the distal side of the rigid foam.

10 Laminating the Outer Socket

10.1 Description

Fabricating the definitive outer socket.

10.2 Materials

Elastic Cord	General workshop supplies
Colour	617Z2=*
Hardener	617P37=*
Lamination Ring	10S500=*
Lamination Dummy for Lamination Ring	Included in scope of delivery of the lamination ring
Lamination Resin Orthocryl 80:20	617H19=*
Nylon Tube Sock	99B25
Perlon Stockinette	623T3=*
PVA Bag	99B81=*
Double-Sided Adhesive Tape	633D5=*
Silicone Grease	633F11
Special Lubricant	453H2=1
Linen Adhesive Tape	627B1=*
PVA Adhesive Tape	627B40

10.3 Preparation for Lamination



Fill the threaded bores with 636K8=* Plasta Tape and 633F11 Silicone Grease.
Apply the lamination cover.



Fill the inside of the lamination ring with silicone grease.



Assemble the lamination cover and lamination ring.



To protect the PVA bag, seal the proximal end of the plaster model with linen adhesive tape.



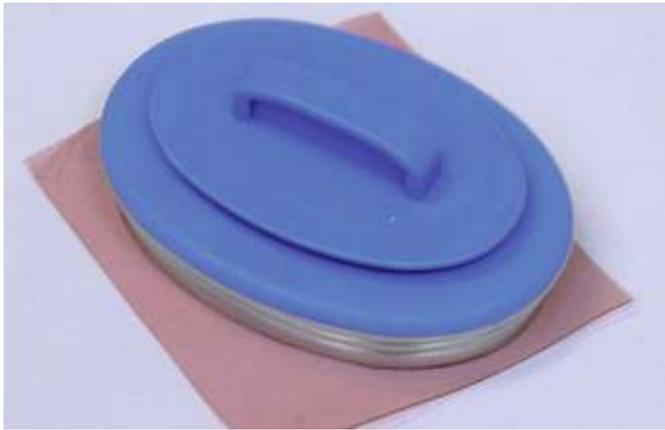
Slide the rigid foam component on the inner socket model and powder with 453H2=1 Special Lubricant.



Soak the PVA bag, pull it over the foam core and tie off the distal end.



Press the distal knot into the 10 mm bore and cover with PVA adhesive tape.



Apply double-sided adhesive tape to the lamination ring.



Position the lamination ring on the PVA bag.



Cut off 2 layers of perlon stockinette. First only apply 1 layer and tie off in the proximal groove.



For extra reinforcement, the carbon fibre mesh is bonded onto the perlon stockinette as a frame structure. The carbon fibre reinforcement is applied in a circular fashion, respectively at the proximal and distal socket edge.



Carbon fibre is applied as connecting strips on the medial and lateral sides, respectively.



INFORMATION

Carbon fibre must not be applied in the area of the AxonMaster in order to avoid interfering with the transfer of data via Bluetooth. Use the template supplied for this purpose.



Pull the 2nd layer of perlon stockinette downwards.



Cut off another 2 layers of perlon stockinette in double length and turn them inside-out. Tie off the 3rd layer in the proximal groove as well, and pull the fourth layer downwards.

10.4 Laminating the Socket



Pull on the soaked PVA Bag.



Mix 617H19 Orthocryl® Lamination Resin with 617P37 Hardener Powder. Add colour paste as desired and fill the resin mixture into the bag. Next tie off the bag and switch on the vacuum so that the resin mixture permeates the reinforcing mesh.



Once the resin mixture is evenly distributed, tie off the film in the groove of the lamination cover.

INFORMATION

Turn the socket so that the resin bag is at the lowest point. This allows air to escape in the proximal direction. To distribute the resin, powder the film with 453H2=1 Special Lubricant.



Press the contour of the charging receptacle template into the still soft laminate so that both centre punches are marked out.

Allow the resin mixture to cure.

11 Finishing the Outer Socket

11.1 Description

Making the component recesses in the outer socket.

11.2 Tools

Twist Drill	724S1=5
Felt-Tip Pen	General workshop supplies
Hot Air Gun	756E11=*
Tape Measure	743B4
Conical Drill 30 mm	726W9=*
Scissors	719S7

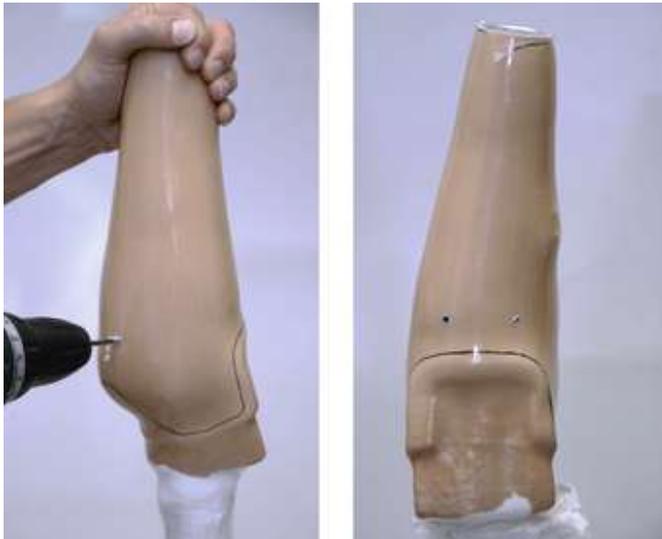
11.3 Processing the Socket Edge



Remove the outer film and cut into the distal lamination cover. Then remove the lamination cover.



Mark the proximal socket edge and the mounting bores.



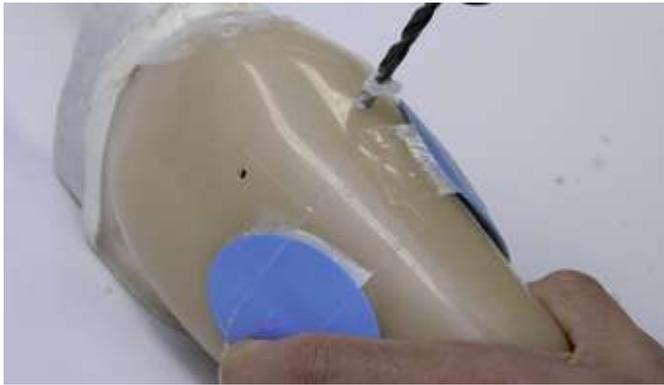
Drill the marked drilling points (\varnothing 4 mm).



Cut open the perlon stockinette and trim the laminate of the outer socket using a knife.



Pull off the outer socket.



Drill the holes for the inner socket (\varnothing 5 mm).



Remove the foam from the outer socket. In order to do so, either use a hammer to tap out the rigid foam from the distal end or thin out the rigid foam from the inside using a ball cutter.



Grind and deburr the marked proximal course of the socket edge.

11.4 Recess for the Charging Receptacle



Burn through the marks for the charging receptacle and electrodes.



Mark and drill the contour of the charging receptacle (tapered cutter).



Grind the contour.



Check with the template.

12 Assembling the Outer and Inner Socket

12.1 Description

Final assembly of all components in the inner and outer socket.

12.2 Tools

Magnetic Centring Aid	
Conical Drill 14 mm	726W9=*
Conical Drill 30 mm	726W9=*
Twist drill 4 mm	724S1=4

12.3 Materials

Cyamet Quick-Drying Adhesive	636K11
Pull-in Tube	99B13=*
Bonding Agent	617H46
Setting Nut	29C5=M4x9

12.4 Preparing the Outer and Inner Socket for Assembly



Remove the plaster.



Grind the inner socket at the proximal socket edge.



Insert the valve tube into the inner socket.



Attach the setting nuts in the inner socket.



Screw together the outer and inner socket.



Insert the magnetic centring aid into the pull-in tube.



Position the opposite pole of the magnetic centring aid on the outer socket. Use the magnetic alignment for this purpose.



Use a pen to mark the 4 positions of the centring.



Joining these position points delivers the exact centre point.



Unscrew the inner and outer socket from each other.



Pre-drill the centre point position of the valve tube (\varnothing 4 mm).



Use a conical drill to pre-drill the marked position (ø 14 mm).



Mark the conical drill (ø 30 mm) at the height where the diameter is 24 mm. This step ensures drilling for a proper fit.



Drill the hole for the pull-in tube accordingly. Verify optimum fit with the pull-in tube.



Drill the holes for the electrode potentiometer (\varnothing 8 mm).



Insert the inner socket into the outer socket and screw them together. Insert the 99B13=* Pull-in Tube into the inner socket, mark the pull-in tube and grind off the excess length flush with the outer socket.

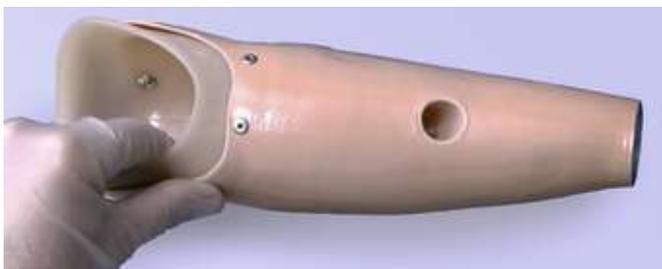


Use 636K11 Cyamet Quick-Drying Adhesive to fixate the pull-in tube.



Then seal with bonding agent to protect the electronic components.

12.5 Verification of Results



The completed screw-connected outer and inner socket.

13 Final Assembly and Wiring the Components

13.1 Mounting the Component Holder and Installing the Components

To mount the component holder and install the components, please proceed as described in section "Wiring the Components in the Test Socket" (see Page 56).

NOTICE

Glue the suction socket electrodes in place with bonding agent.

13.2 Assembling the Charging Receptacle and Wrist Unit with the Michelangelo Hand



Push the charging receptacle from the inside through the corresponding opening in the outer socket.



Slide the inner socket into the outer socket. It is essential to ensure that the components and cables are not damaged. Screw together the inner socket and outer socket and trim the screws.

NOTICE

When assembling/disassembling the inner and outer socket, first remove the charging receptacle.



Thread the hand connecting cable through the lamination ring and connect to the 10V500=2* AxonWrist.



Screw together the 10V500=2* AxonWrist with the lamination ring and connect the 8E500=* Michelangelo Hand.

13.3 Verification of Results



Don the AxonSkin Natural onto the Michelangelo Hand. Observe the instructions for use provided for the prosthetic glove and the process for putting it on and taking it off described in the same.



Perform a function check on the patient.



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