MANUFACTURING GUIDELINES

TRANS-TIBIAL PROSTHESIS

Physical Rehabilitation Programme

ICRC

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All photographs: ICRC/PRP

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Foreword

The ICRC polypropylene technology

Since its inception in 1979, the ICRC's Physical Rehabilitation Programme has promoted the use of technology that is appropriate to the specific contexts in which the organization operates, i.e., countries affected by war and low-income or developing countries.

The technology must also be tailored to meet the needs of the physically disabled in the countries concerned.

The technology adopted must therefore be:

- durable, comfortable, easy for patients to use and maintain;
- easy for technicians to learn, use and repair;
- standardized but compatible with the climate in different regions of the world;
- low-cost but modern and consistent with internationally accepted standards;
- easily available.

The choice of technology is of great importance for promoting sustainable physical rehabilitation services.

For all these reasons, the ICRC preferred to develop its own technique instead of buying ready-made orthopaedic components, which are generally too expensive and unsuited to the contexts in which the organization works. The cost of the materials used in ICRC prosthetic and orthotic devices is lower than that of the materials used in appliances assembled from commercial ready-made components.

When the ICRC launched its physical rehabilitation programmes back in 1979, locally available materials such as wood, leather and metal were used, and orthopaedic components were manufactured locally. In the early 1990s the ICRC started the process of standardizing the techniques used in its various projects around the world, for the sake of harmonization between the projects, but more importantly to improve the quality of services to patients.

Polypropylene (PP) was introduced into ICRC projects in 1988 for the manufacture of prosthetic sockets. The first polypropylene knee-joint was produced in Cambodia in 1991; other components such as various alignment systems were first developed in Colombia and gradually improved. In parallel, a durable foot, made initially of polypropylene and EthylVinylAcetate (EVA), and now of polypropylene and polyurethane, replaced the traditional wooden/rubber foot.

In 1998, after careful consideration, it was decided to scale down local component production in order to focus on patient care and training of personnel at country level.

Objective of the manuals

The ICRC's "Manufacturing Guidelines" are designed to provide the information necessary for production of high-quality assistive devices.

The main aims of these informative manuals are as follows:

- To promote and enhance standardization of ICRC polypropylene technology;
- To provide support for training in the use of this technology;
- To promote good practice.

This is another step forward in the effort to ensure that patients have access to high-quality services.

ICRC
Assistance Division/Health Unit
Physical Rehabilitation Programme

Introduction

The aim of this document is to describe a method for manufacturing **trans-tibial (TT) prostheses** using the ICRC's polypropylene technology as applied in ICRC projects worldwide.

The casting, rectification and alignment methods used correspond to international prosthetic and orthotic (P&O) standards of practice and are therefore not described in these ICRC manufacturing guidelines.

1 RAW MATERIALS AND COMPONENTS

For short and medium stump, adult

The alignment system and foot components are available in adult and child sizes.

- Description:

1 Convex ankle

2 Two concave cylinders

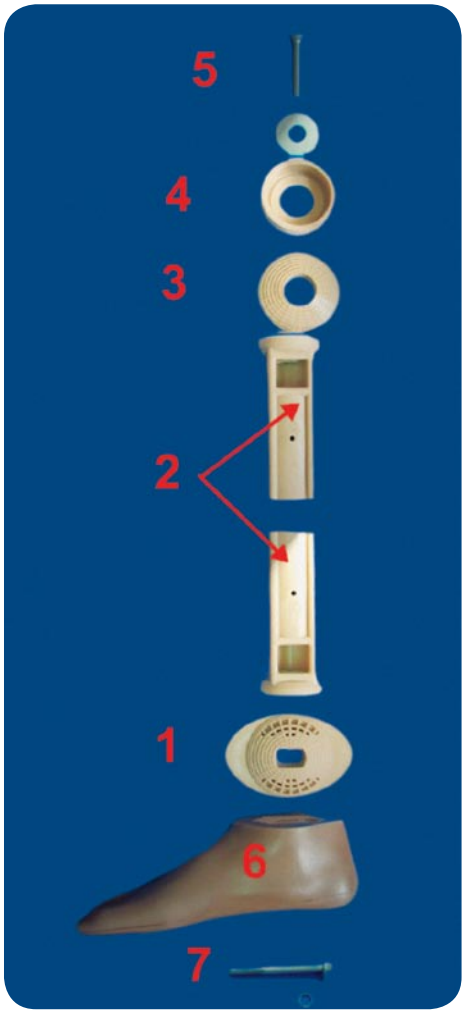
3 Convex disc

4 Cylindrical TT cup

5 Flat steel washer and countersunk head bolt

6 Solid Ankle Cushion Heel (SACH) foot

7 Hexagonal head bolt and lock washer



For long stump

The alignment system and foot components are available only in adult size.

- Description:

  1 Concave ankle

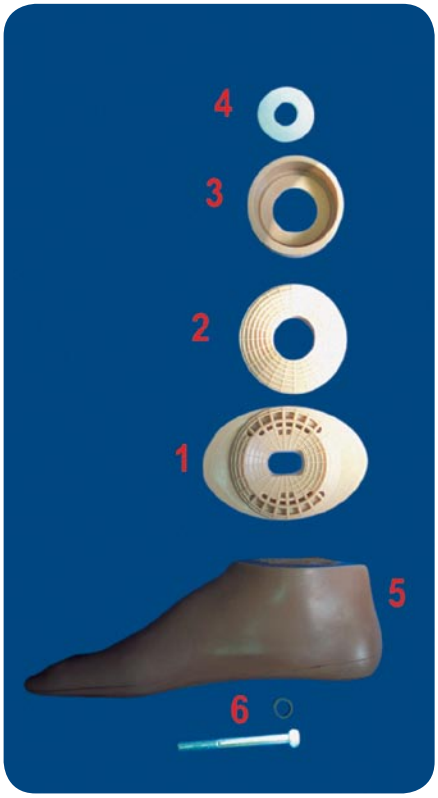
  2 Convex disc

  3 Cylindrical TT cup

  4 Flat steel washer

  5 Solid Ankle Cushion Heel (SACH) foot

  6 Countersunk head M10 bolt and the lock washer



Socket design

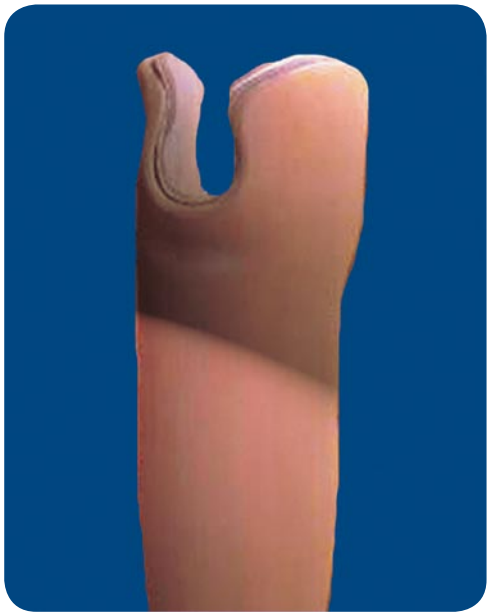
- **PTB** (patellar-tendon-bearing) socket secured with a cuff suspension. The suspension can be adjusted.

  In case of medio-lateral instability of the knee or for a strong hyperextension, a thigh corset with sidebars is suitable.

  This can be made with or without a soft liner.

- **PTB-SC** (supra-condylar)

  Should be made with a soft liner.

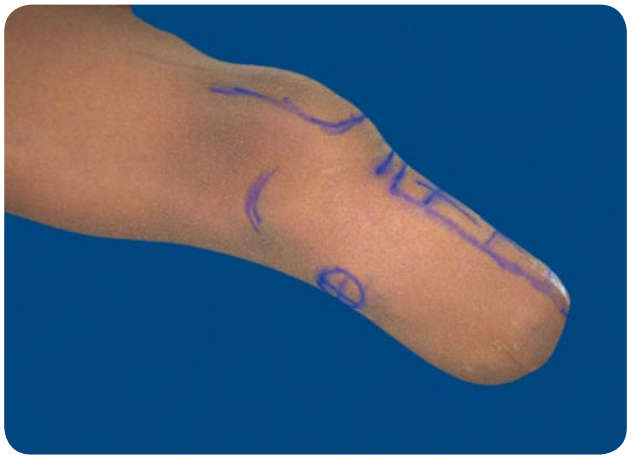


- **PTB-SCSP** (supra-condylar, supra-patellar)

  Must be made with a soft liner.

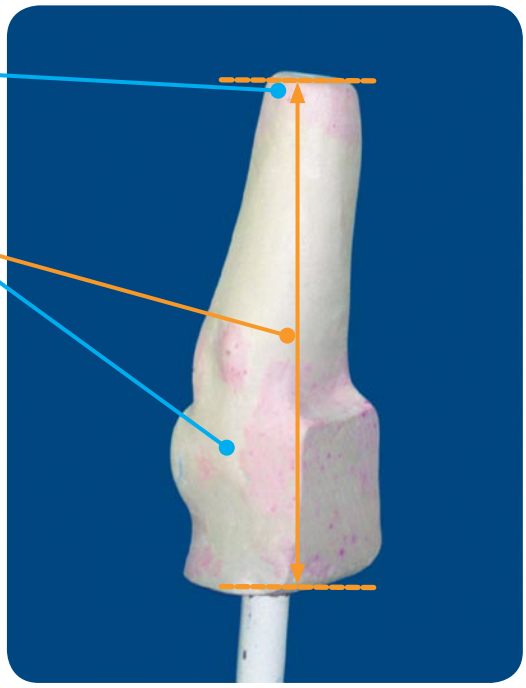
2 MEASUREMENTS AND SOFT SOCKET MANUFACTURE

- The patient is assessed, a prescription is made, measurements are taken and moulding and rectification are performed according to best P&O practice.



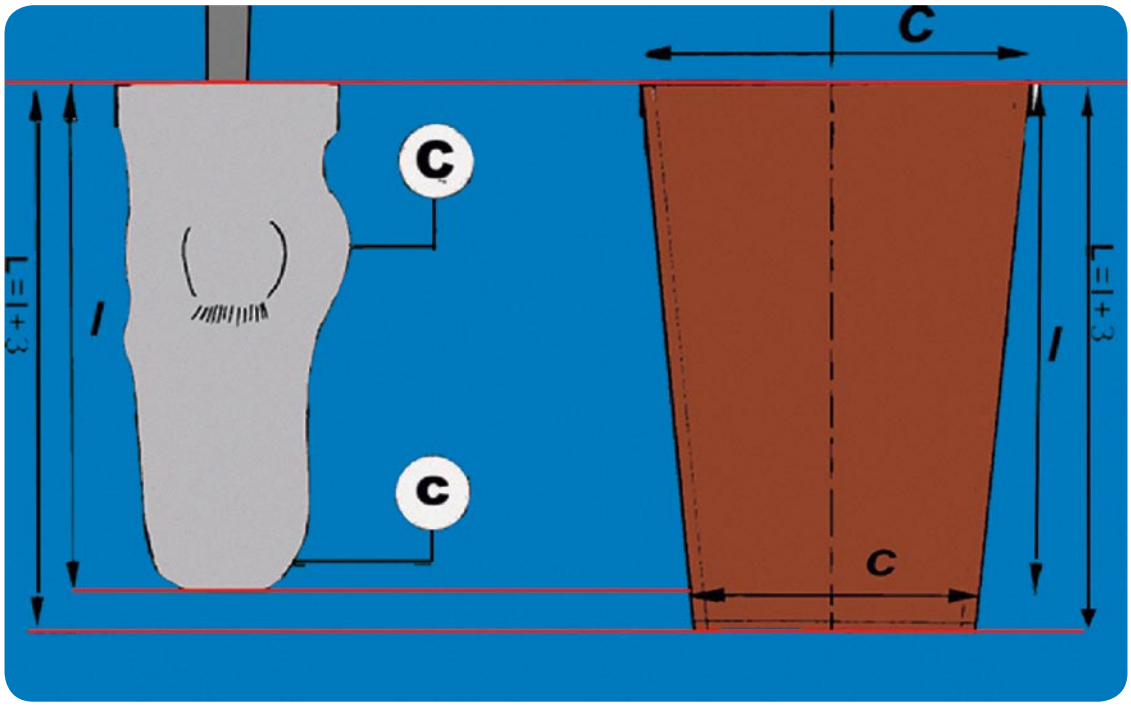
Soft liner manufacture

- Measure the plaster mould. Note the:
  - smallest circumference;
  - largest circumerence;
  - length.

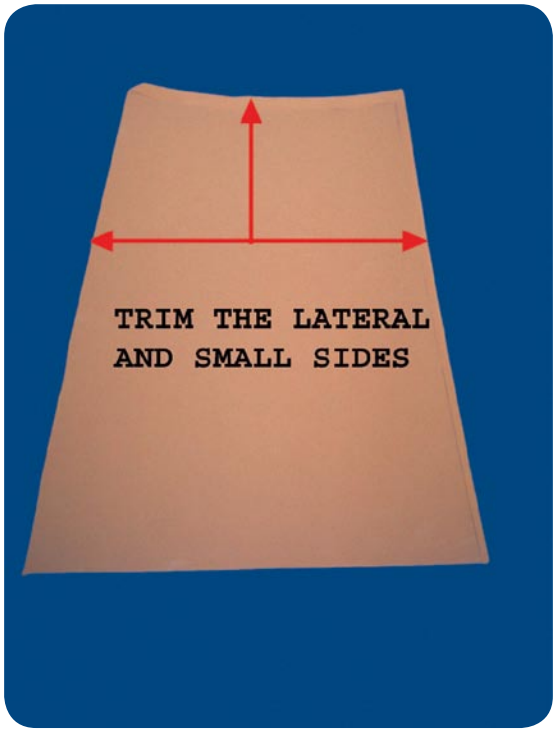


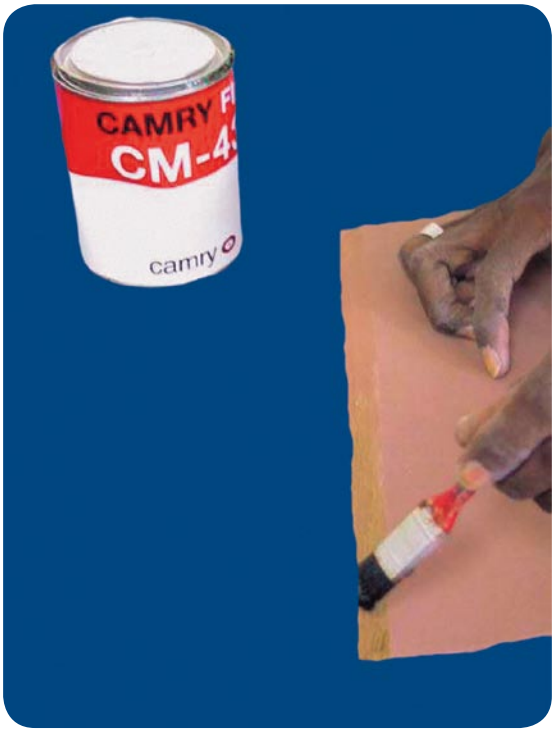
- Draw a trapezoid on a sheet of 6 mm EVA according to the measurements taken but adding 3 cm to the length on the short side of the trapezoid.

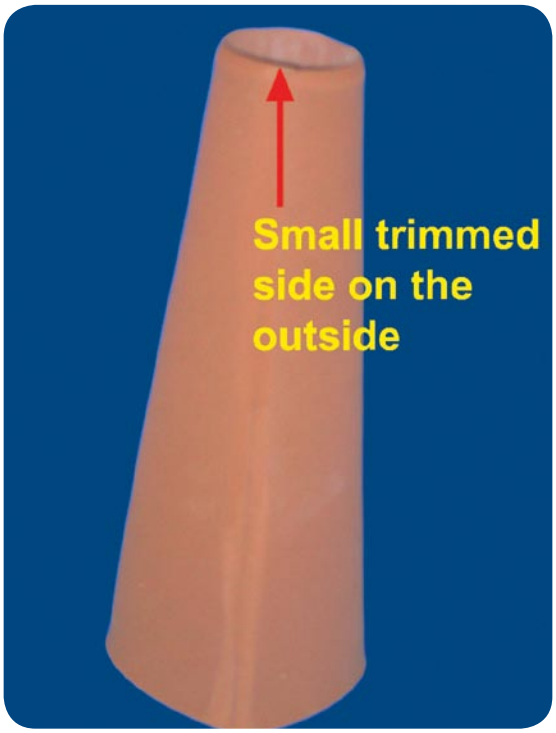
  Cut the EVA and skive the lateral and the distal sides (about 12 mm).



- Apply glue on both skived sides and form a cone. Keep the trimmed distal side on the outside of the cone and leave it free of glue.







Apply talcum powder inside the cone and on the plaster model.

Thermoforming is done using the vacuum pump, on a vertical suction hose.

Heat the EVA cone in the oven at 120°C.

- Pull the EVA cone over the plaster mould, keeping the glued line on the posterior side, until the trimmed distal side coincides with the tip of the plaster mould.

  Cover the mould with a plastic bag, close it securely below the mould with an elastic strap and switch on the vacuum pump.

- Allow the soft liner to cool down for few minutes.

  Remove the plastic bag.

  Prepare a piece of 6 mm EVA to cover the bottom edge.

  Apply glue to the trimmed edge and the cover cap.

  Heat the cap in the oven and mould it on the socket.

  Cut off the extra EVA and grind till smooth.

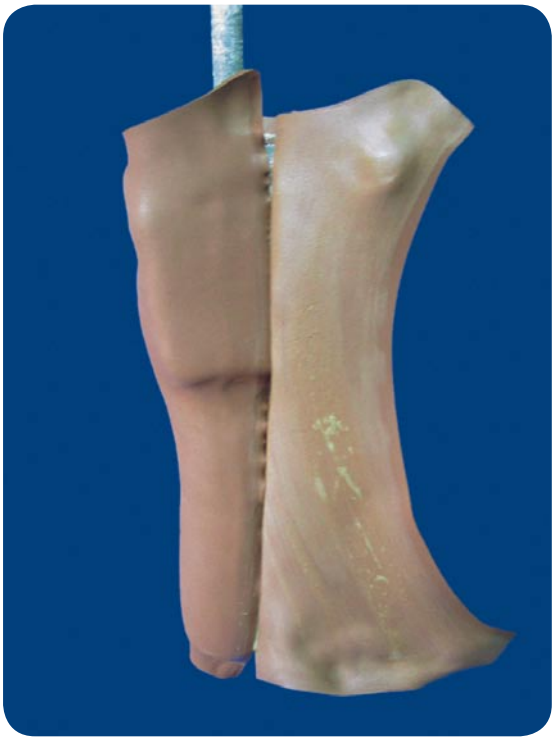
  Add padding above the medial condyle and other areas if required.

- Cover the soft socket with a tubular cotton stocking and glue.

- Prepare a sheet of 3 mm EVA to cover the cotton.

  Skive one side of the EVA, apply glue to the entire surface of the EVA including the skived side, and place it in the oven at 120°C.

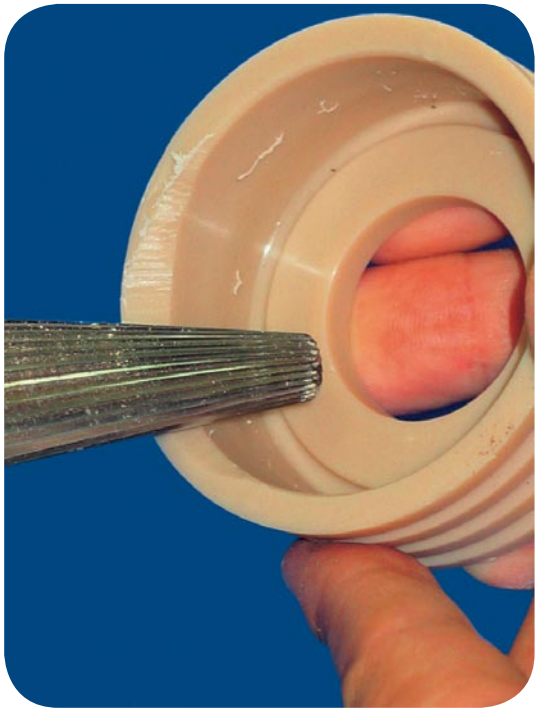
  Cover the soft liner, starting from the posterior side. Remove the excess EVA and grind the posterior side and the distal part till smooth.



- Lastly, cover the distal part with a 3 mm or 6 mm EVA “cap” and grind till smooth.

3 TRANS-TIBIAL CUP ALIGNMENT AND SOCKET MANUFACTURE

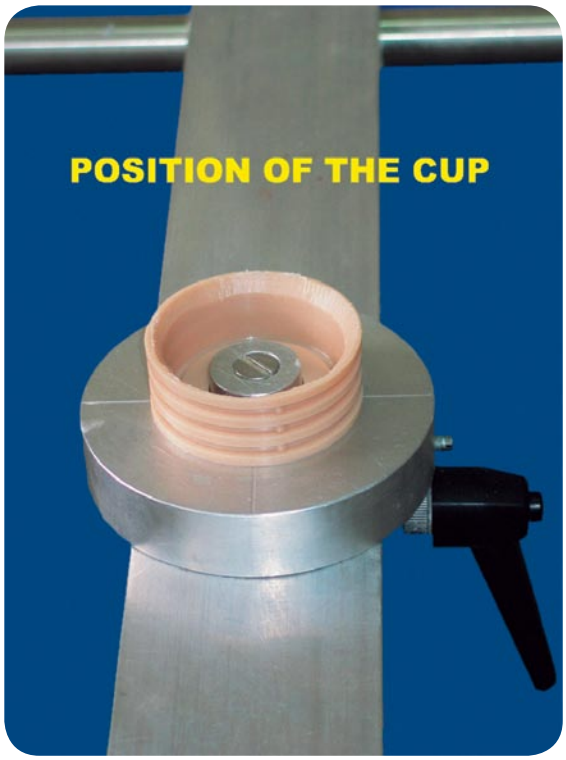
- Grind the edge of the socket cup.



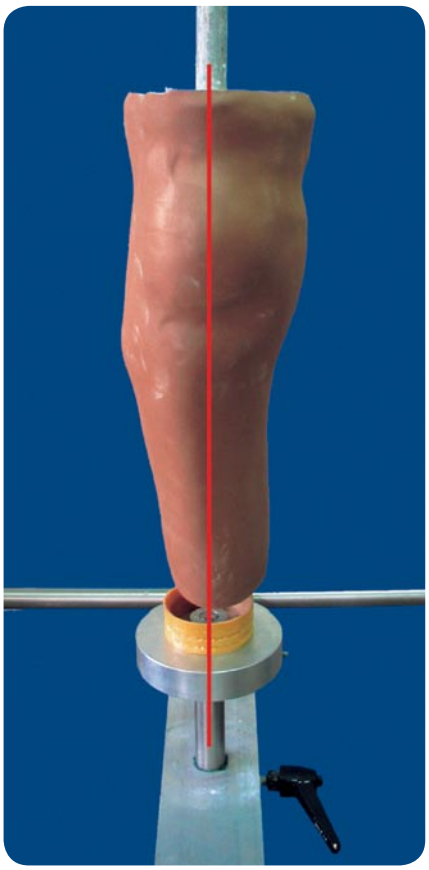
Alignment of the trans-tibial cup

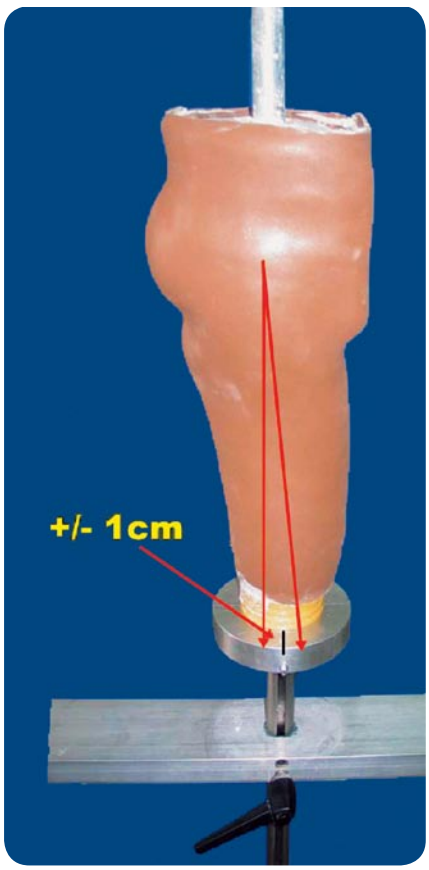
- Fix the nail at the bottom of the mould, where the cup will be attached.

  Place the TT mould on the CR alignment jig; align according to the instructions on the use of the jig (separate manual). Perform the alignment in accordance with the measurement card. Fix the cup to the socket with plaster.

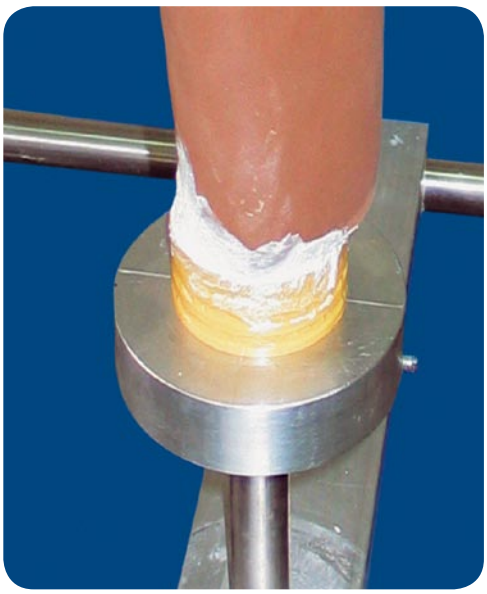


- From the middle of the condyle, the plumb line should pass about 1 cm in front of the cup axis.

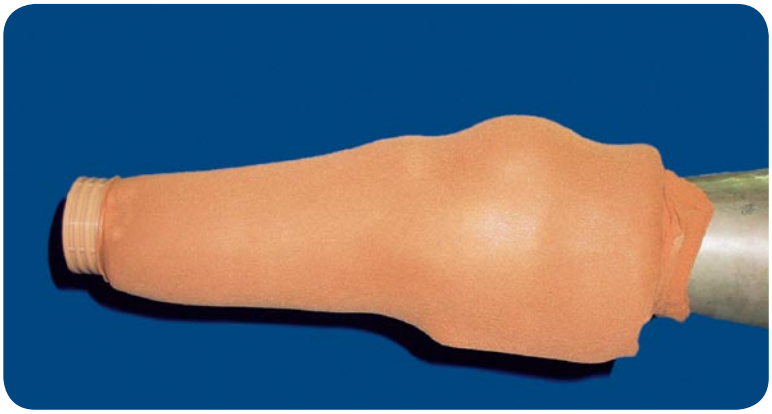




- When the plaster has set, smooth it.



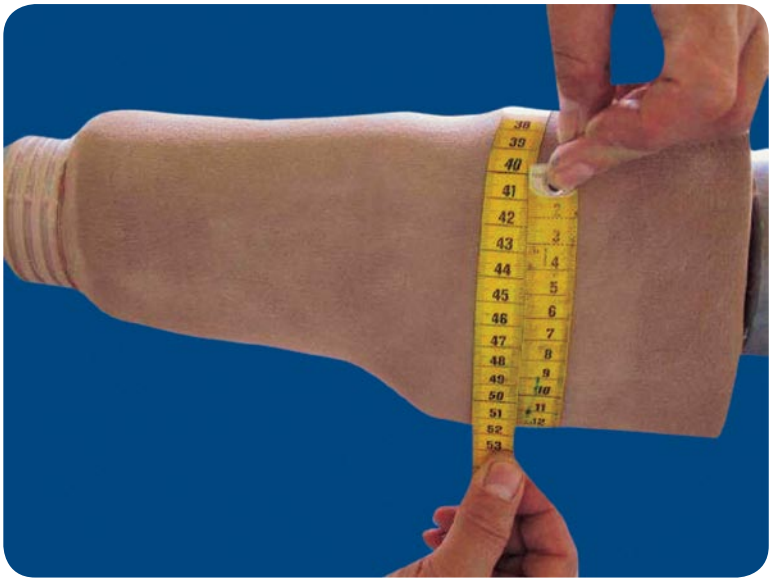
- Cover the soft liner with a nylon or cotton stocking. Remove the nylon covering the cup.



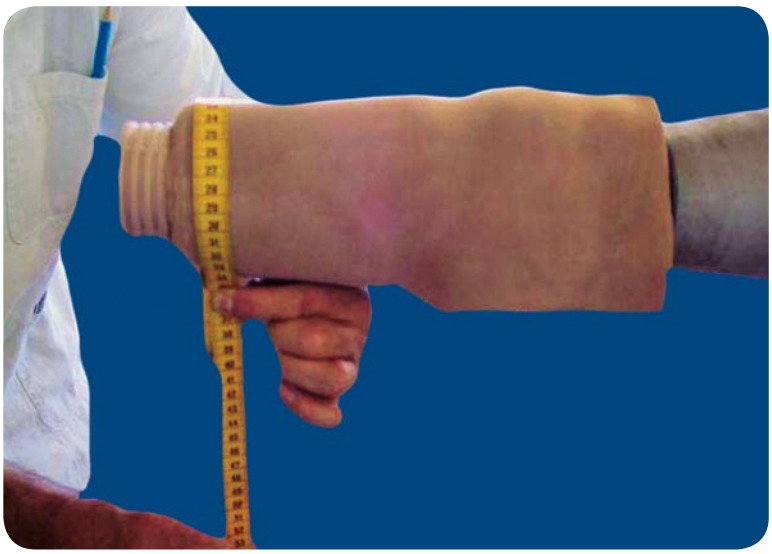
Manufacture of the socket (4 mm polypropylene)

Measurements

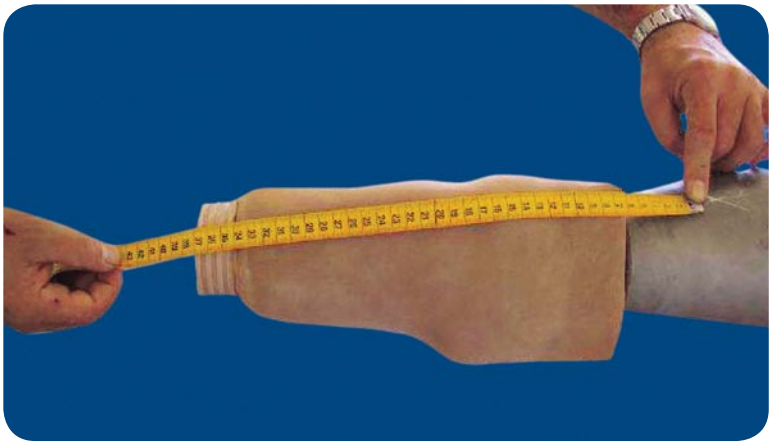
- Add 15 cm to the measurement taken at patella level.



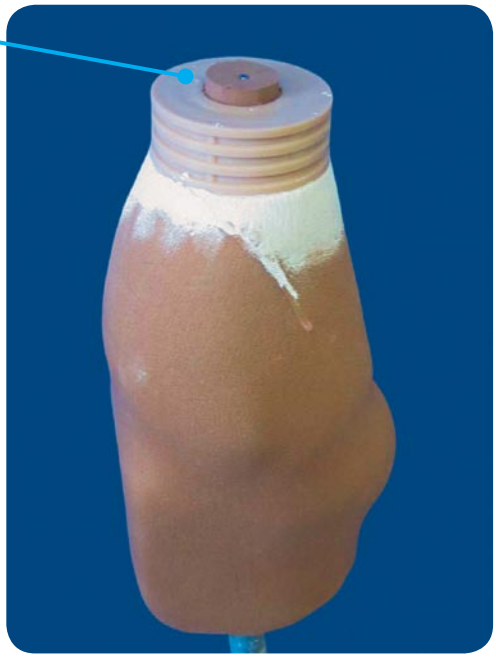
- Add 15 cm to the measurement taken at the distal part.



- Add 15 cm to the measured length of the socket.

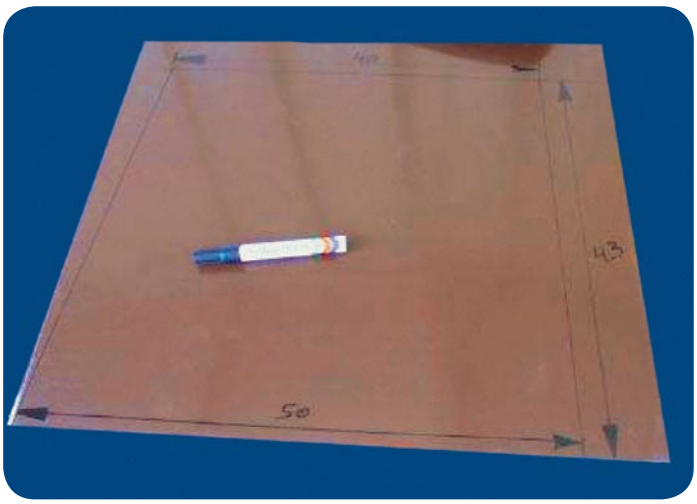


- Fix a round piece of EVA (12 + 6 mm) with a nail inside the opening of the cup.



- Cut a sheet of 4 mm PP corresponding to these measurements. Clean the PP sheet and the Teflon in the oven with thinner.

  Put the PP in the oven at 180°C .

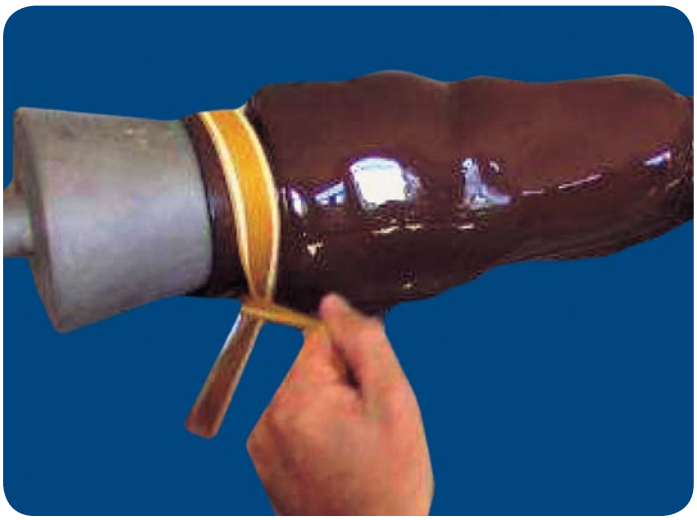


- Switch on the vacuum pump; drape the PP around the socket.

  Welding seam position:
  - for PP cosmetic: lateral or medial
  - for EVA cosmetic: posterior

  Cut off the excess PP while it is still hot.

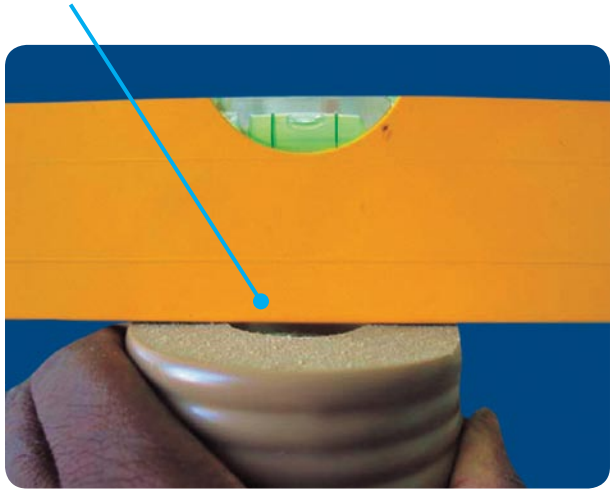
  Leave the vacuum on until the PP cools down.



- Cut the PP according to the trim lines, remove the plaster without damaging the socket liner and PP socket, and grind the welding seam down to 3 mm.

- Once the plaster is removed, use a screwdriver to remove the piece of EVA.

- Grind the distal part and check that the surface is flat.



For maximum strength, keep a minimum PP thickness of 2 to 3 mm under the cup.

4 BUILDING UP THE PROSTHESIS AND BENCH ALIGNMENT

Steps to follow:

- Ankle-foot build-up and alignment;
- Socket build-up;
- Adjustment of length and welding of concave cylinder butt;
- Final bench alignment.

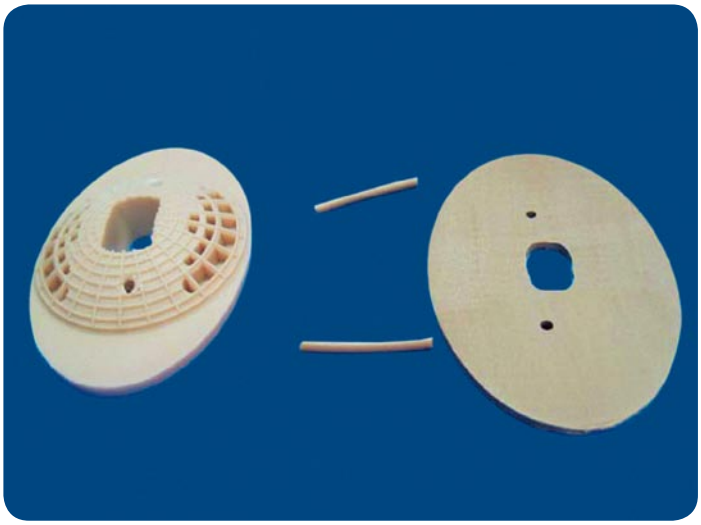
The foot, the convex ankle and the concave cylinder are attached together.

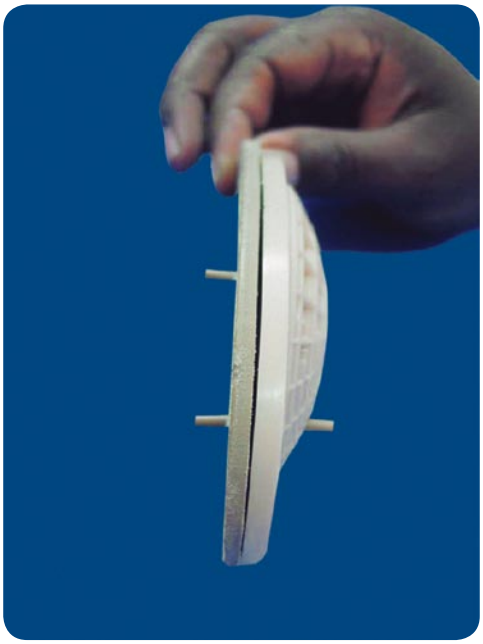
The window in the concave cylinder must be anterior.

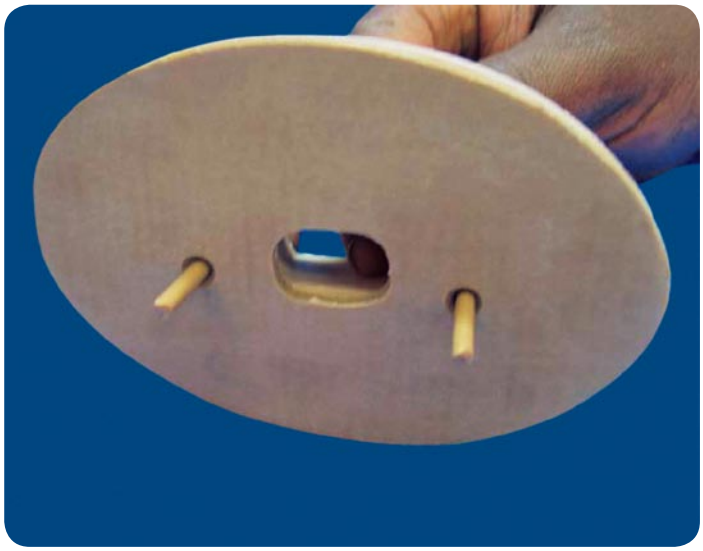
Ankle-foot alignment

An extra 4 mm plate must be attached to the convex ankle. Drill two holes as shown on the illustration below and fix the two components together with a PP welding rod. **This will prevent breakage of the foot bolt.**

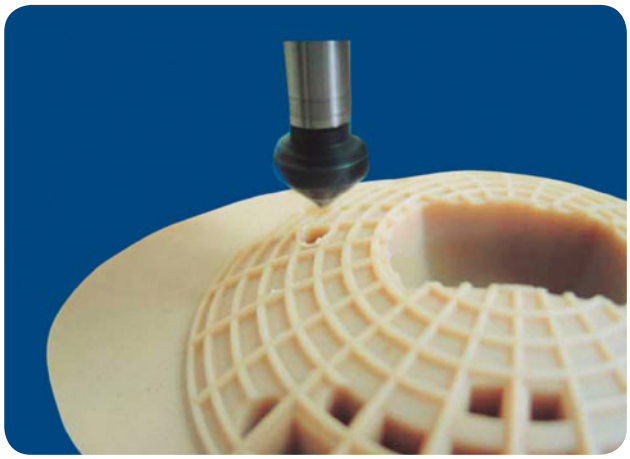
Components

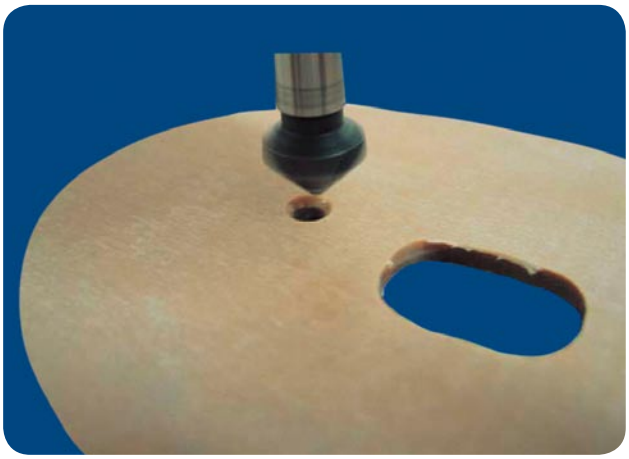


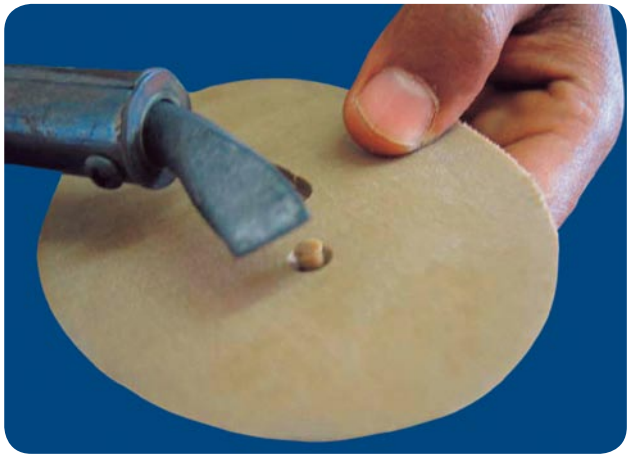


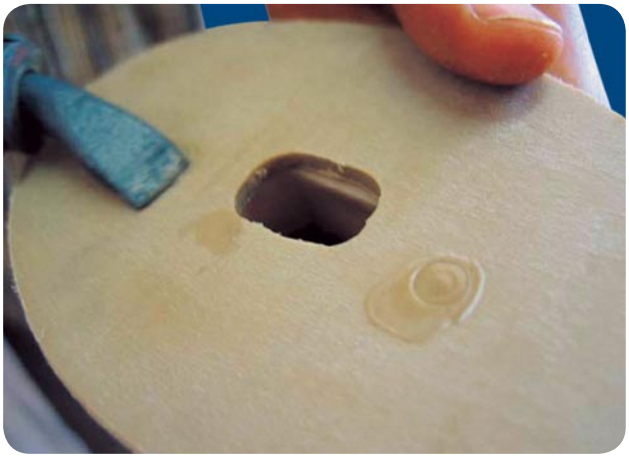


Preparation before fixation









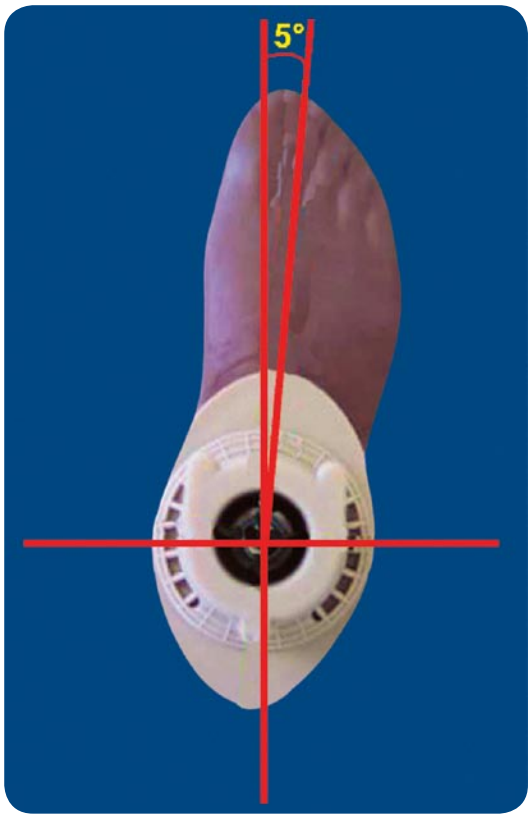
Attach the concave cylinder (with the opening in front) to the foot and the convex ankle.

The heel height is adjusted according to the patient's shoe; the concave cylinder **must be perpendicular to the ground**.

The foot has a heel height of 10 mm (maximum heel height: 15 to 20 mm).

- **The ankle alignment system allows antero-posterior movements (flexion, extension).**
- **This alignment system is used to adjust the angulation of the prosthesis according to heel height.**
- **In any event, the concave cylinder must remain perpendicular to the ground.**

- The foot is adjusted in 5° to 8° external rotations.



- Check the alignment once again with the patient's shoe on the foot.

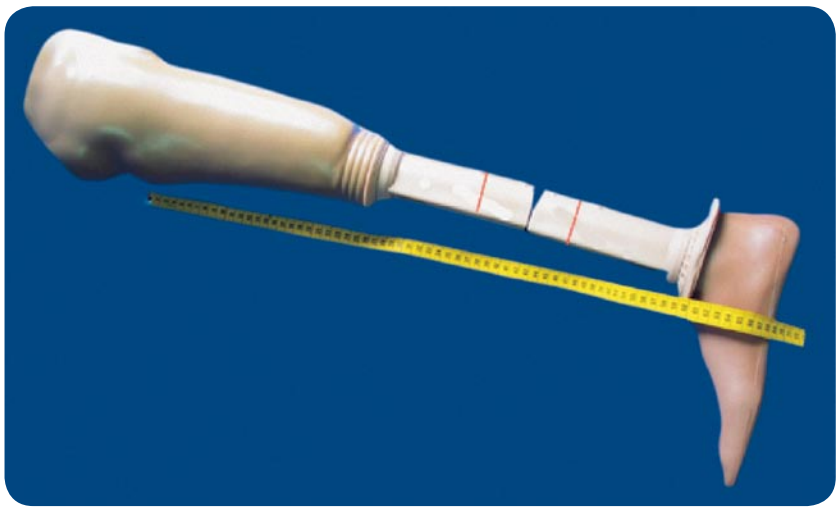
- The socket is attached to the concave cylinder with the convex disc in between.

- The opening in the concave cylinder remains in front. The alignment system is in neutral position for the first fitting.

- Adjust the length according to the measurements taken on the patient.

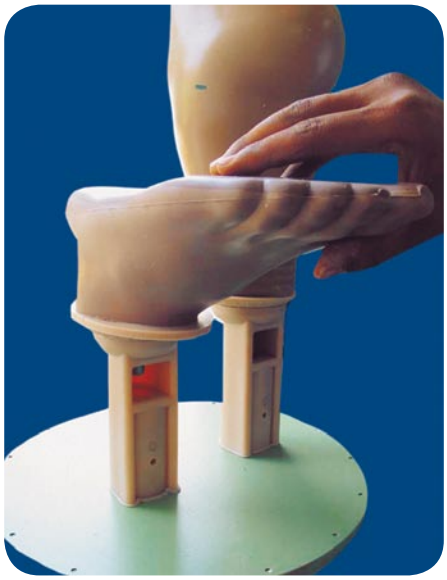
  Mark the concave cylinder and saw off the excess.

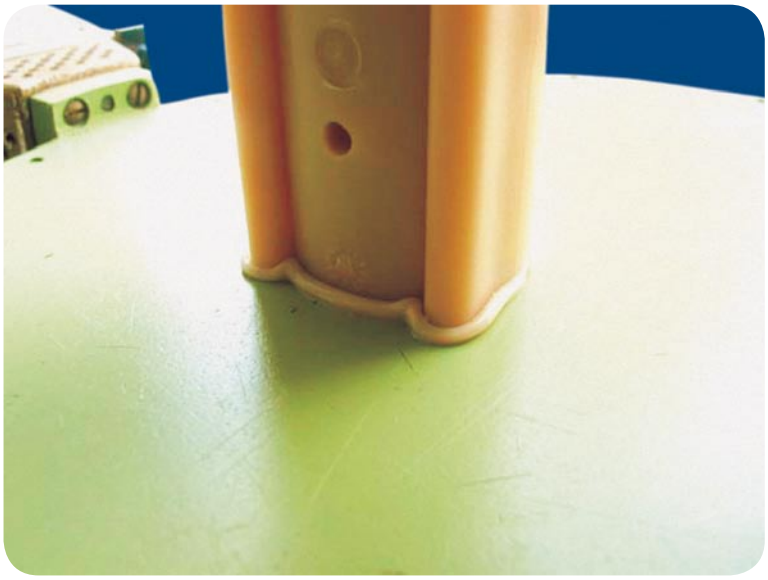
  Cut the concave cylinder at an angle of 90°.



- Set the temperature of the mirror welder between 185° and 200°C.

- Hold the concave cylinders on the mirror welder until a roll of melted PP forms.

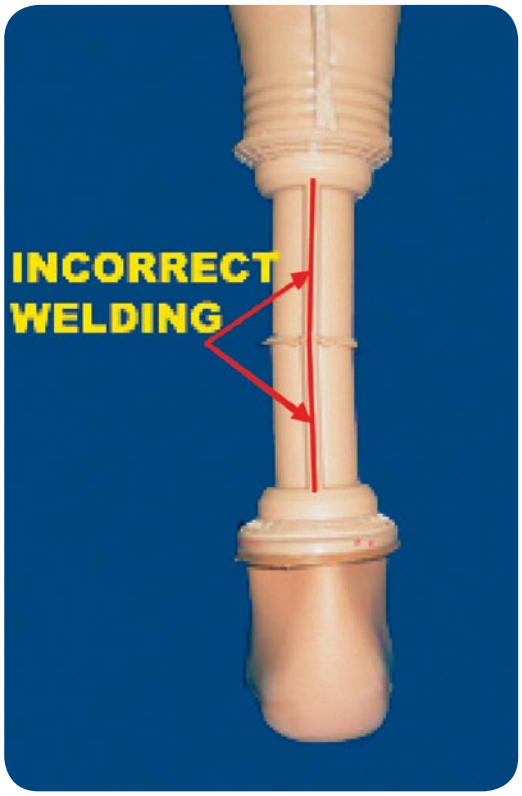


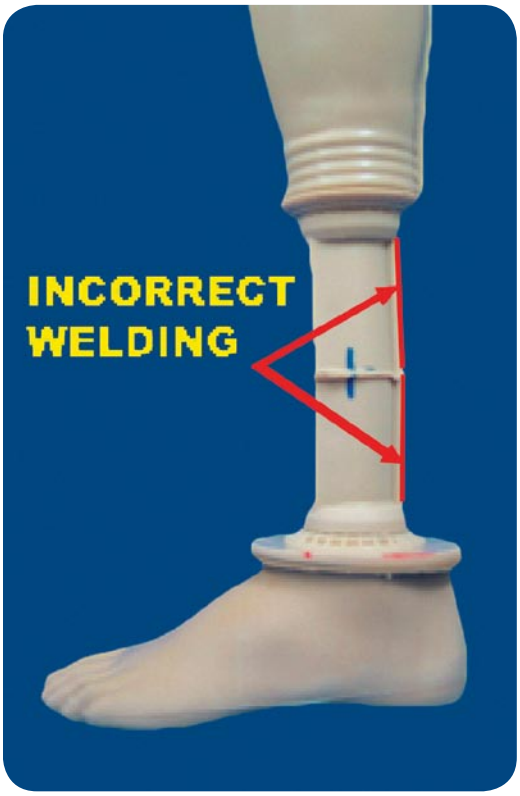


- Carefully bring the cylinders together and apply slight pressure.

Concave cylinders correctly welded

Concave cylinders incorrectly welded



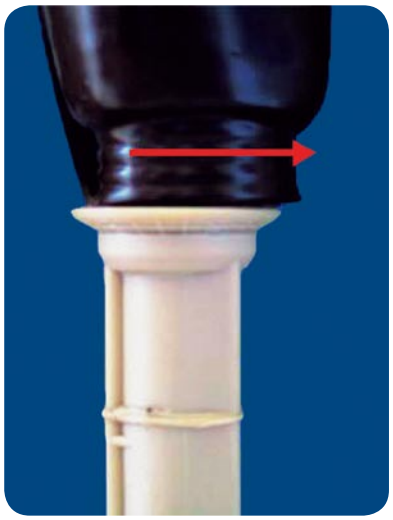


Socket alignment

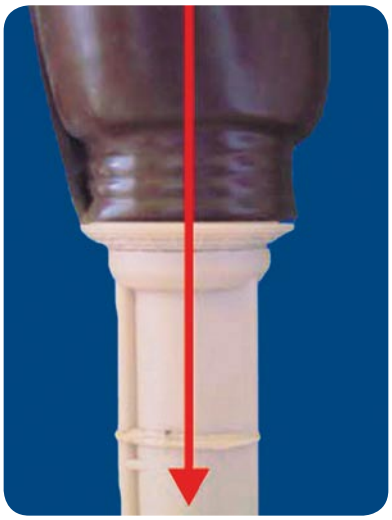
The socket is connected to a concave cylinder with a convex disk in between. The connection is secured by a countersunk head bolt and flat washer inside the socket, with the T-nut inside the concave cylinder.

Shifting can occur in all directions: anterior, posterior, medial, lateral and combined movements, with a range of 10 mm in all directions

Anterior shifting

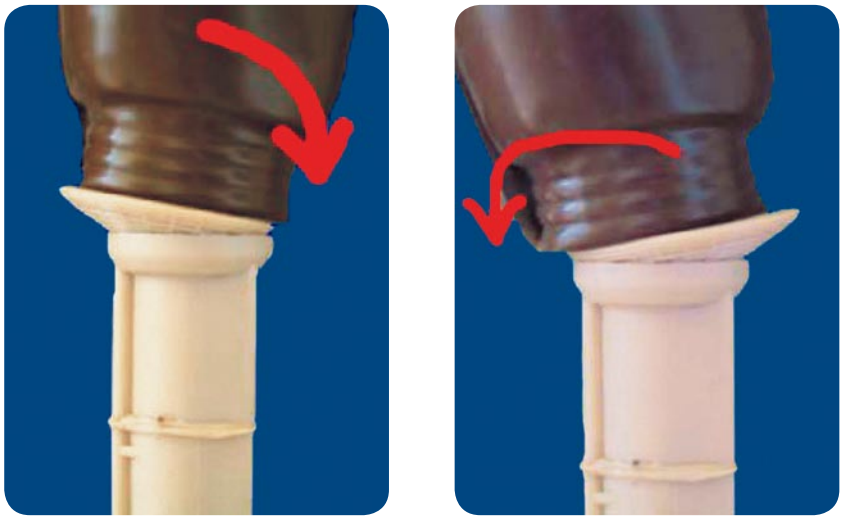


Initial position



Posterior shifting

- The alignment system also allows flexion, extension, abduction, adduction and rotation.



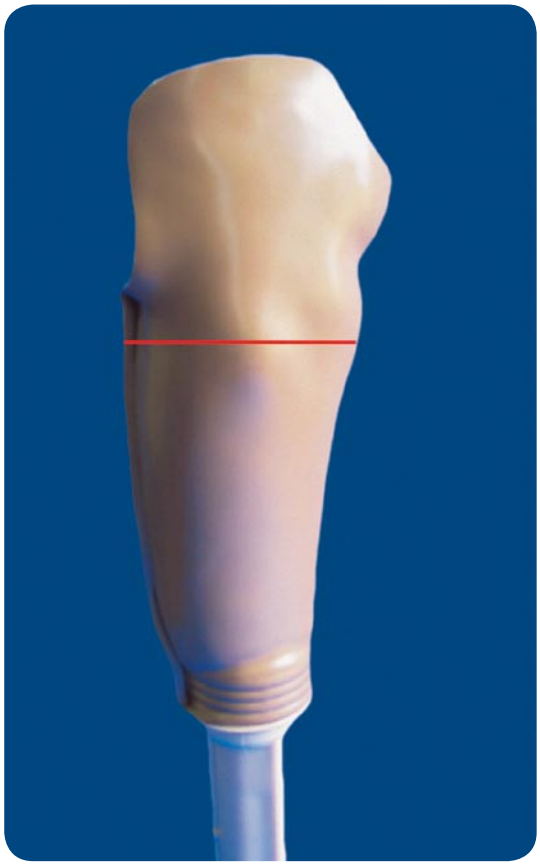
- Bench alignment is performed according to P&O practice and adjusted during fitting and during the gait training period.

▾ Before the cosmetic is made, all the components must be welded together.

5 POLYPROPYLENE COSMETIC MANUFACTURE

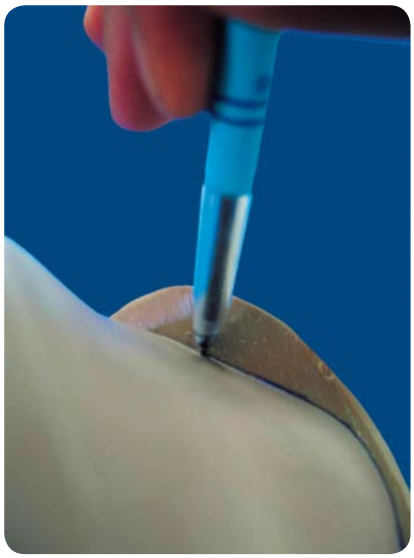
There are two ways of manufacturing a PP cosmetic.

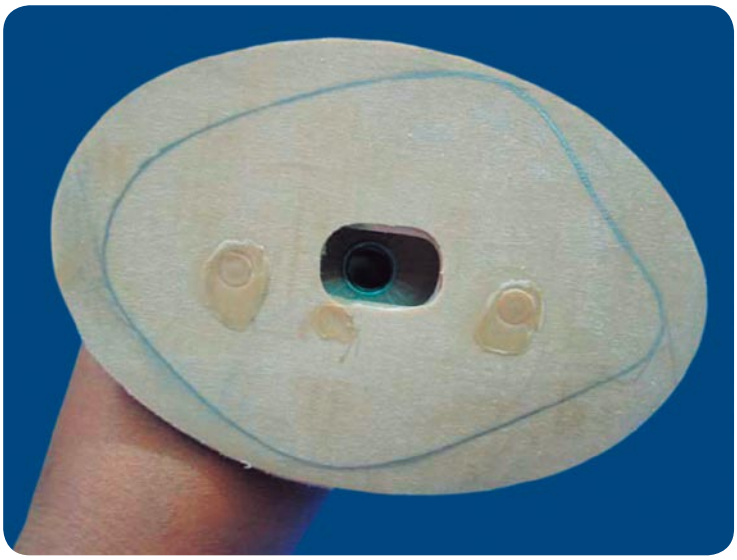
5.1 Cosmetic with upper part of socket removed



Adjustment of ankle part

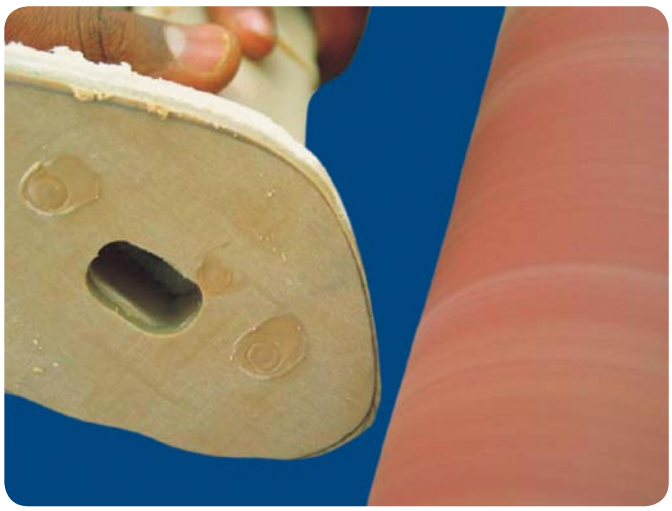
- Draw a line following the shape of the foot, then disassemble the foot.





- Check your mark and grind it carefully.

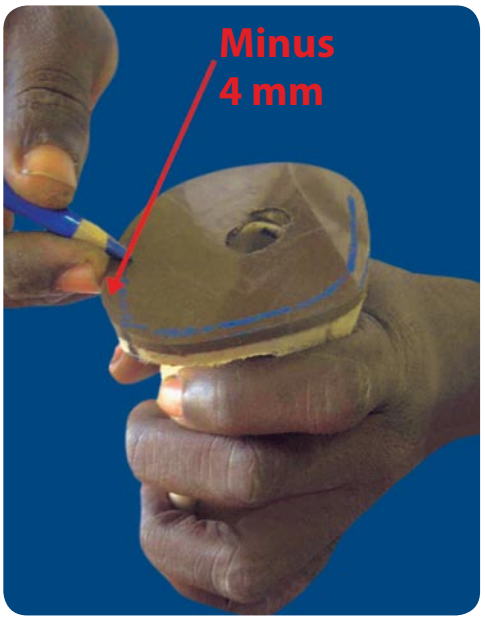
  Check once more against the foot.



- Stick adhesive tape on the foot and draw a line with a permanent marker on the top of the convex ankle and on the tape.

- Disassemble the foot and draw a line all around the plate 4 mm from the edge.

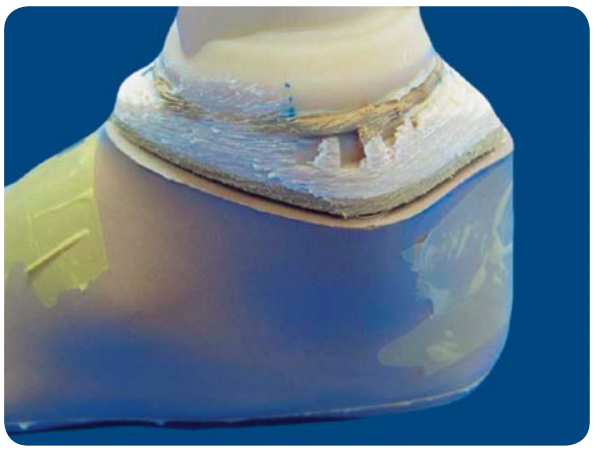
  Grind the edge carefully.



- Check again with the foot.

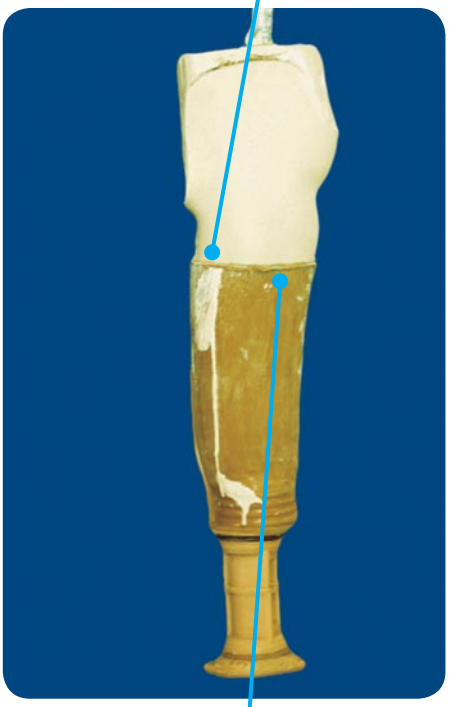
  Weld the two plates together, first using the welding iron to make a groove and then welding with the hot-air welding gun.

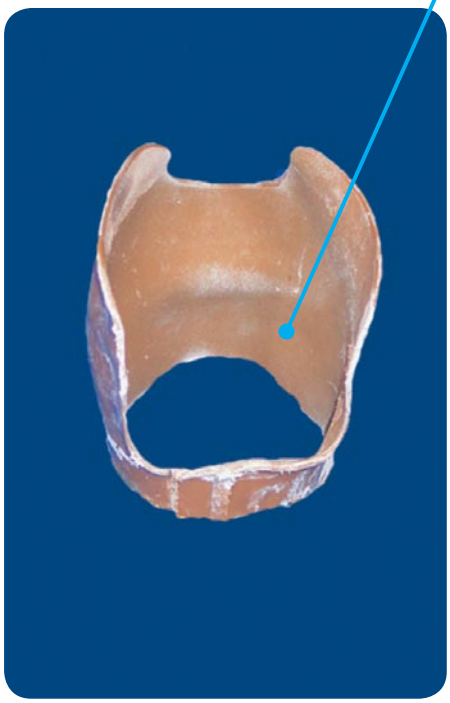
  Grind again carefully.



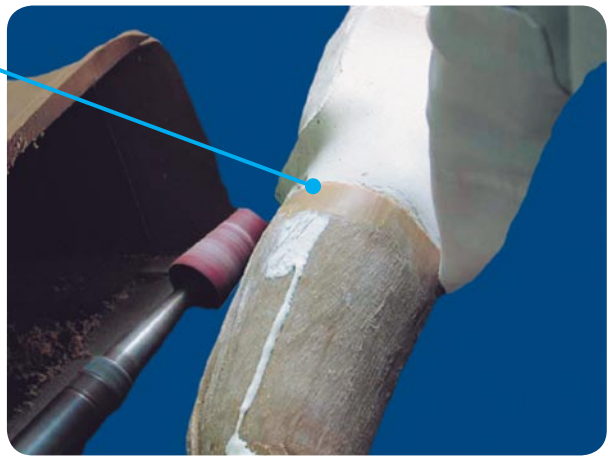
Manufacture of cosmetic shell

- Cut across the prosthesis below the level of the hamstring tendons and remove the upper part.

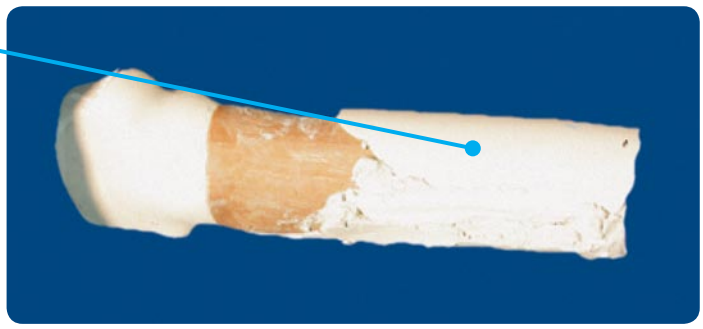




- Skive the PP edge carefully.



- Add plaster to shape the shank.



- Reduce the circumference of the shank by 3 cm to allow for the thickness of the 4 mm PP sheet.

  Smooth the plaster.

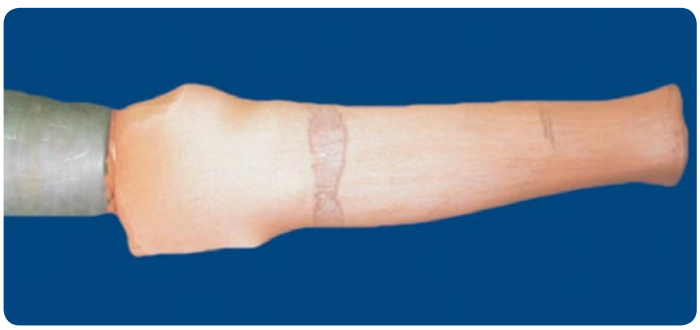
  Leave the ankle edge free of plaster for the final welding.

- Fix the 4 mm PP reinforcement plate at the popliteal level with 2 nails.

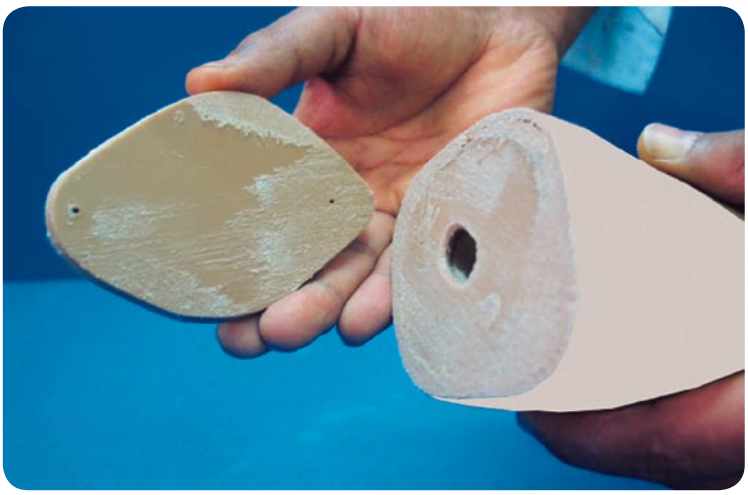
- Draw a nylon or cotton stocking over the plaster.

  Add talcum powder.

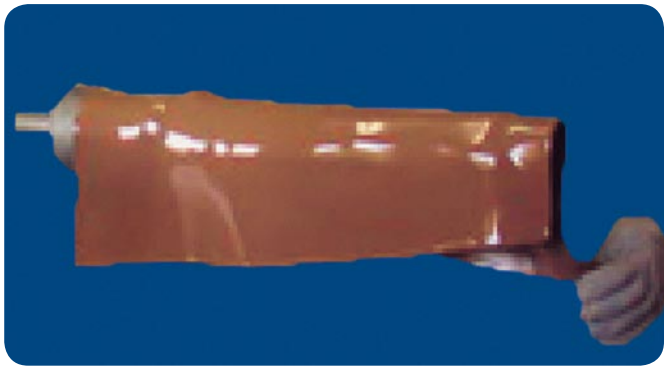
  Heat the 4 mm PP sheet in the oven at 180° C.



- Glue or nail 5 mm PP under the ankle plate to compensate for retraction of the PP after opening.

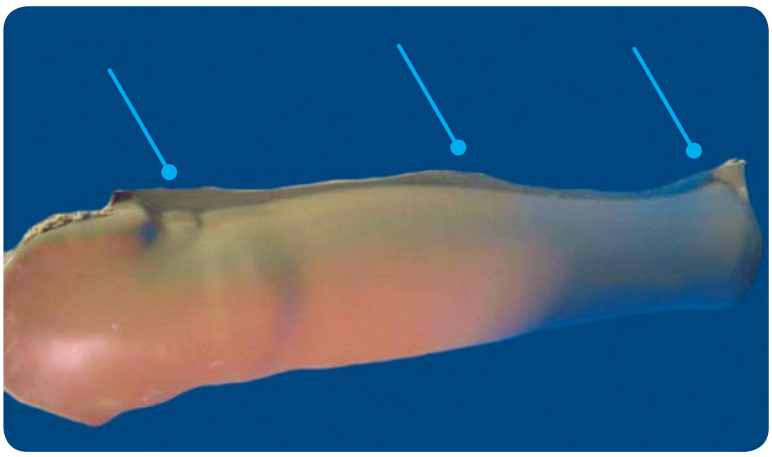


- Drape the PP under vacuum.

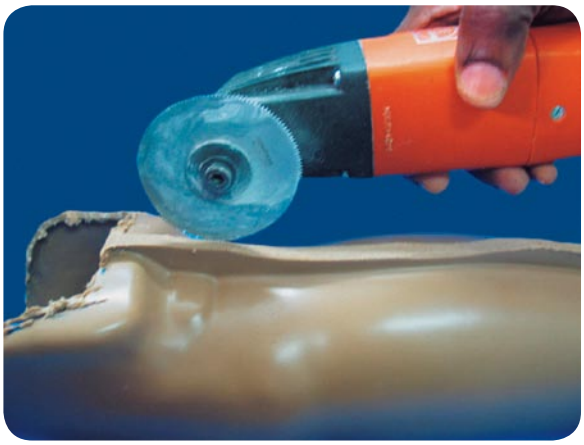


- Cut off the excess PP at the welding seam. Keep the vacuum on until the plastic cools down.

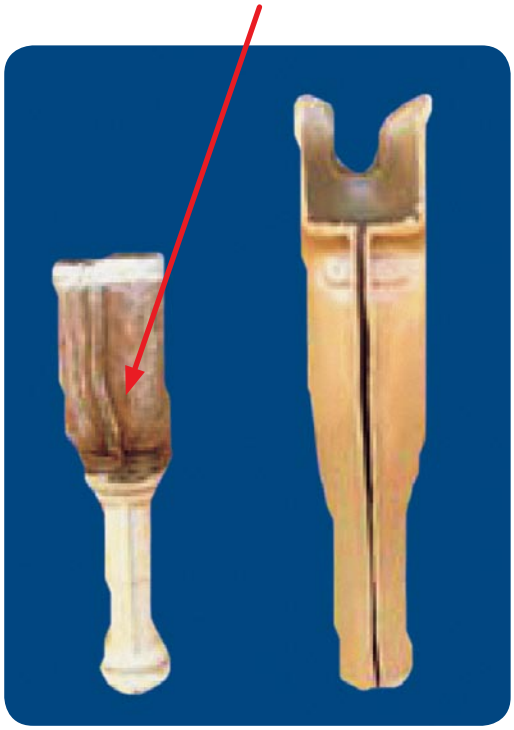
- Grind the posterior seam down to 2 to 3 mm. In three places, leave a wider overlap of PP for holding the prosthesis during welding.



- Open the seam carefully with an oscillating saw to avoid breakage.

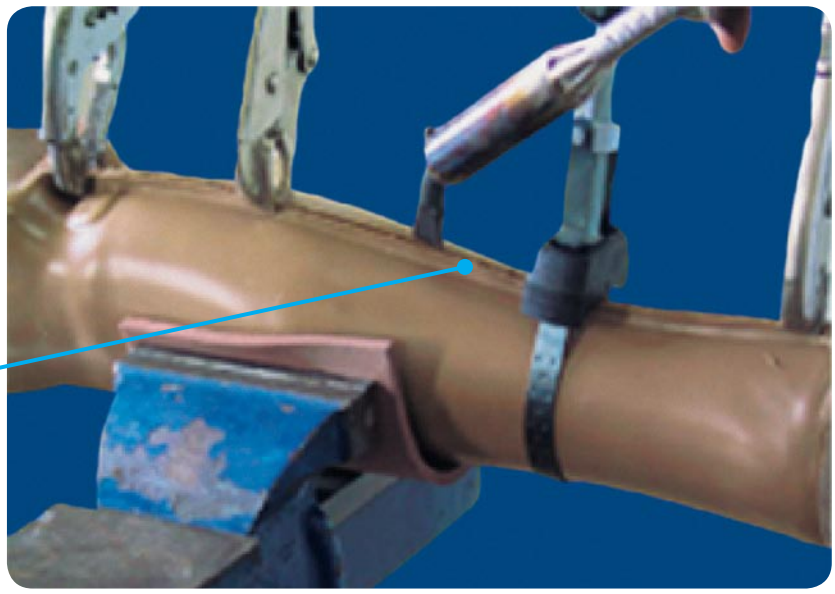


- Remove the PP shell from the prosthesis and remove the plaster. Clean the prosthesis thoroughly to ensure that no pieces of plaster remain. Put the prosthesis back into the shell.

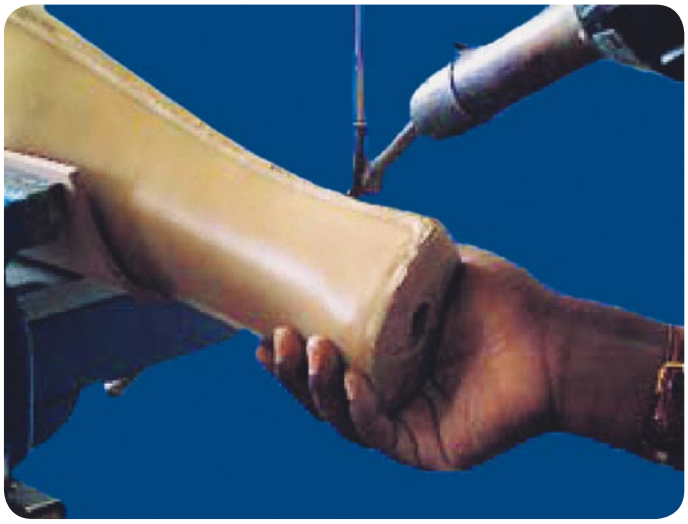


- Hold the prosthesis in a parallel vice with EVA or rubber protection between the vice jaws and the cosmetic shell. Close the two sides of the posterior seam with lock grips and/or other suitable tools.

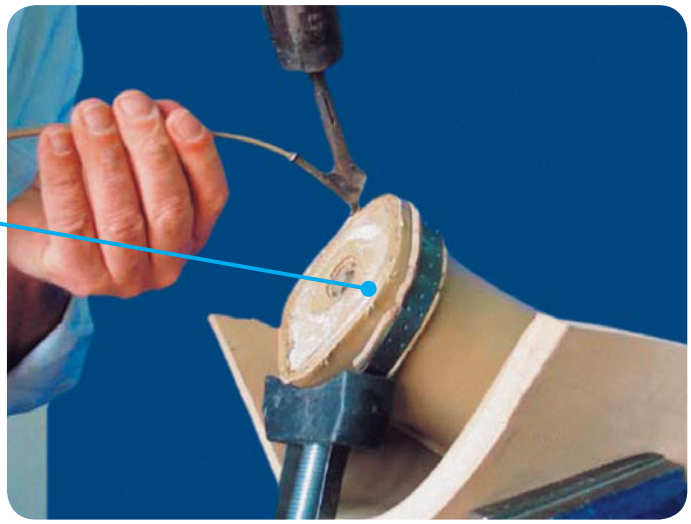
  Before welding, make V-shaped indentations along the seam with a welding iron.



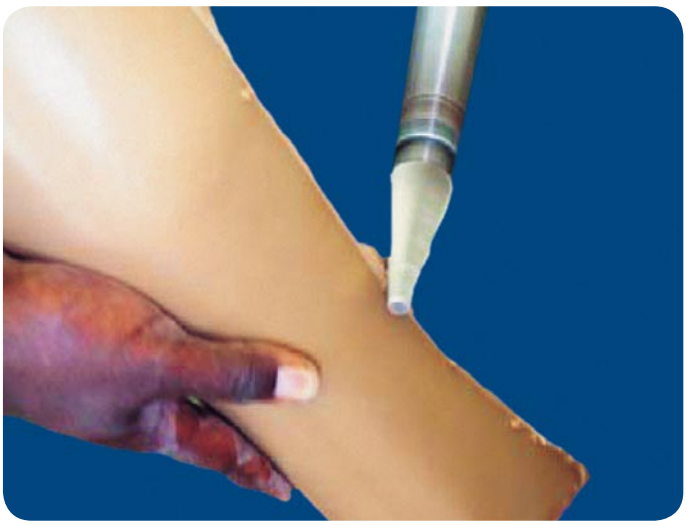
- The final welding is done with a hot-air welding gun and a 4 mm PP welding rod.



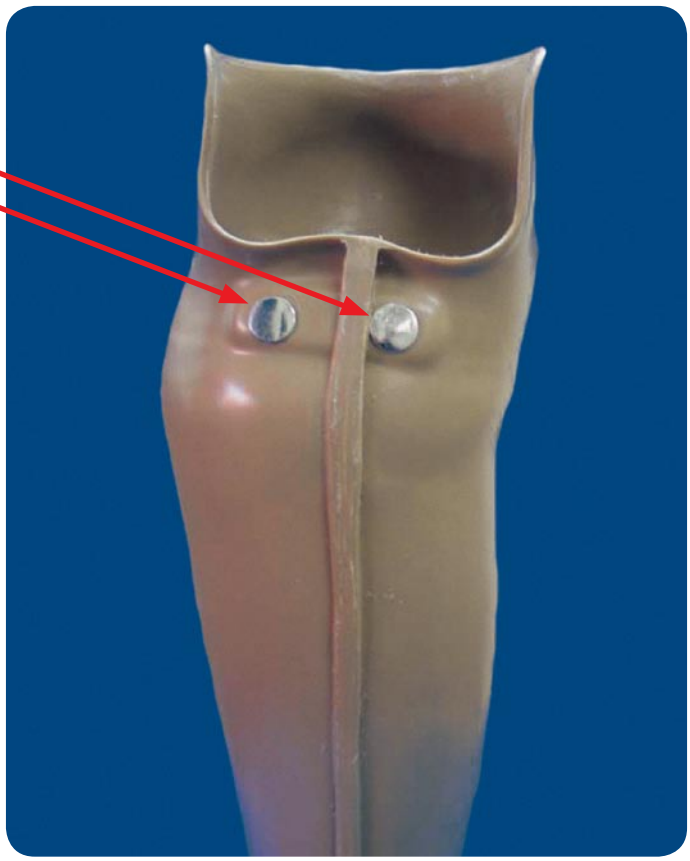
- Weld the ankle to the shell. After welding, carefully flatten the ankle surface.



- Polish with a rasp and/or a sharp piece of glass.



- Attach the 4 mm PP reinforcement to the shell with tubular rivets.

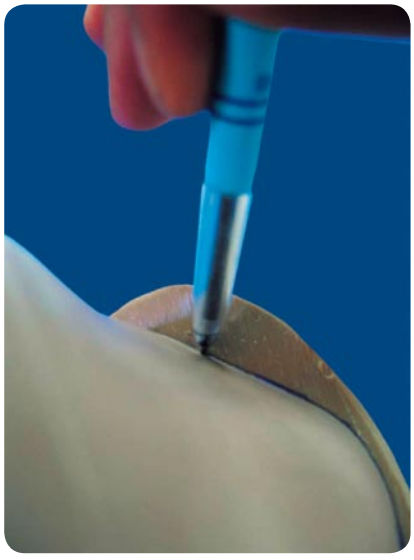


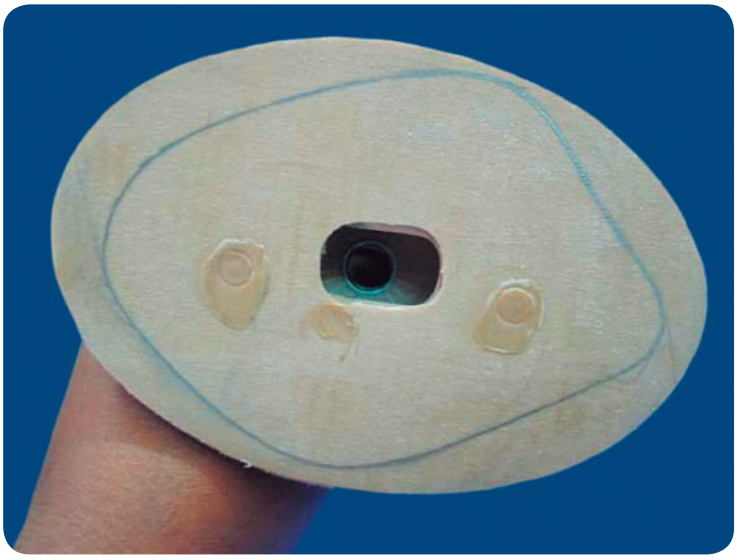
The last step is to fix the foot on the prosthesis.

5.2 Cosmetic with complete PP socket

Adjustment of ankle part

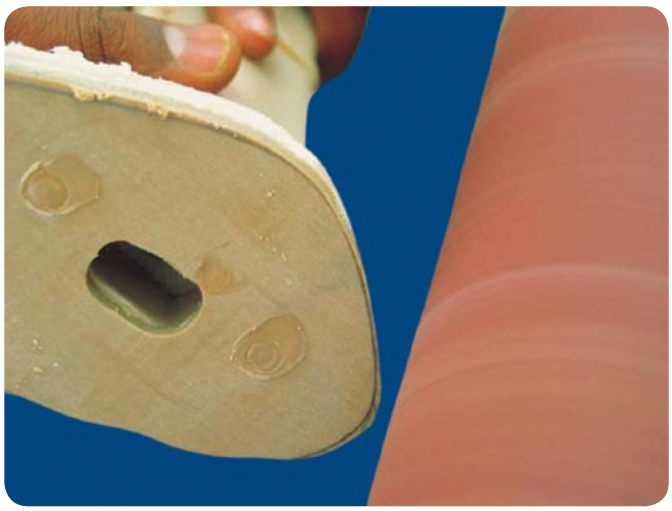
- Draw a line following the shape of the foot, then disassemble the foot.





- Check your mark and grind it carefully.

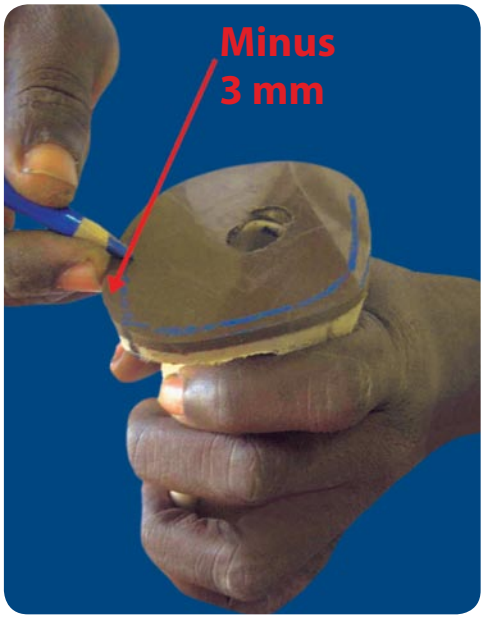
  Check once more against the foot.



- Stick adhesive tape on the foot and draw a line with a permanent marker on the top of the convex ankle and on the tape.

- Disassemble the foot and draw a line all around the plate 3 mm from the edge.

  Grind the edge carefully.

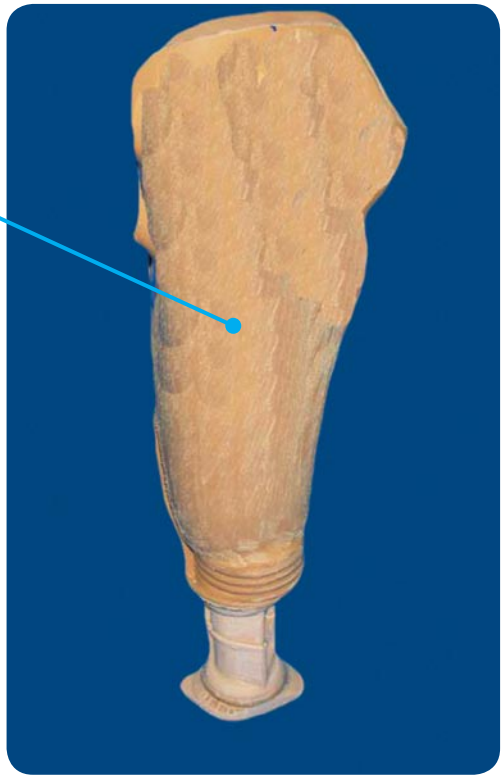


- Check again with the foot.

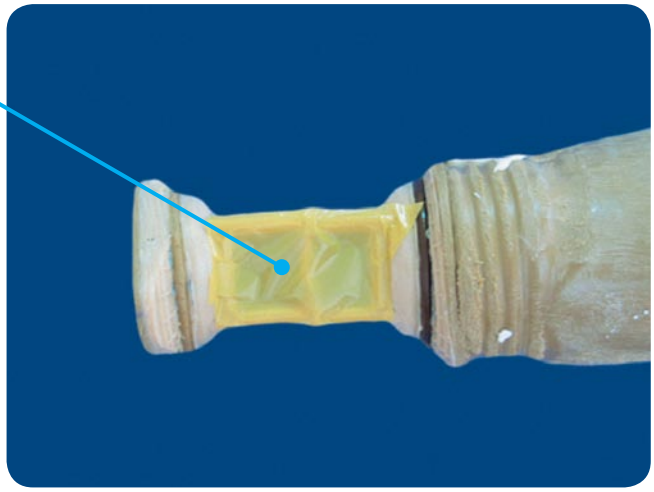
  Once a good fit has been achieved, weld the two plates together: first make a groove with the welding iron and then weld with the hot-air welding gun.

  Grind again carefully.

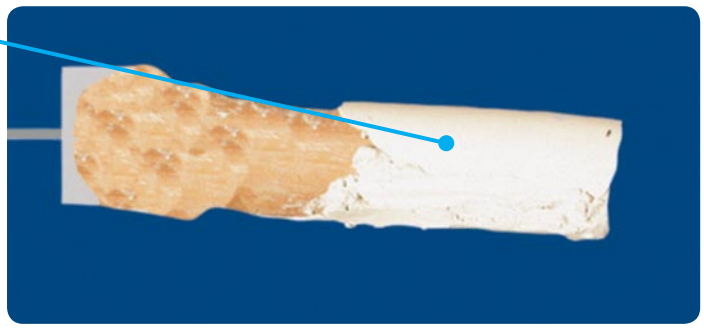
- Roughen the surface of the socket.



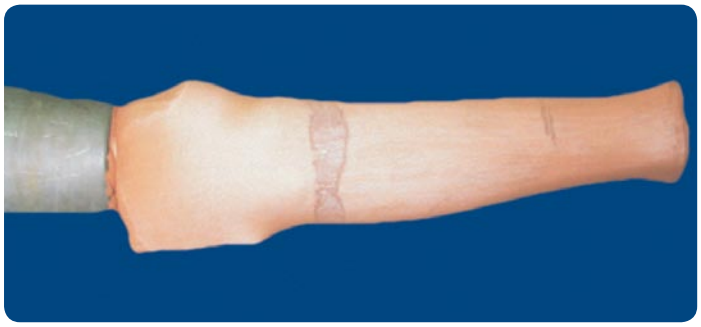
- Cover the concave cylinders with adhesive tape.



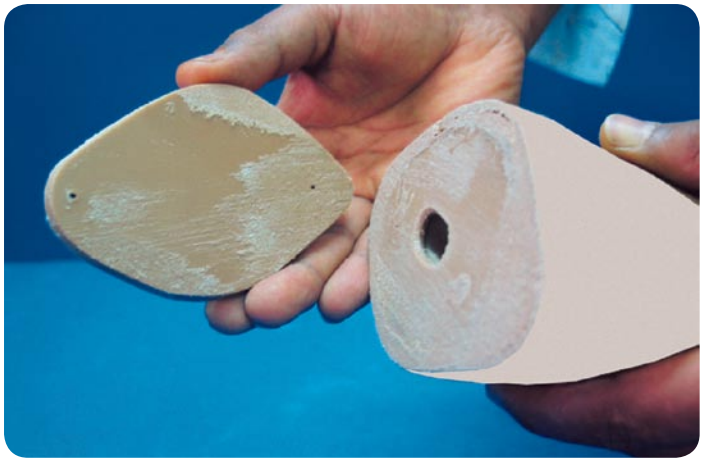
- Shape the shank with plaster.



- Draw a nylon or cotton stocking over the prosthesis.

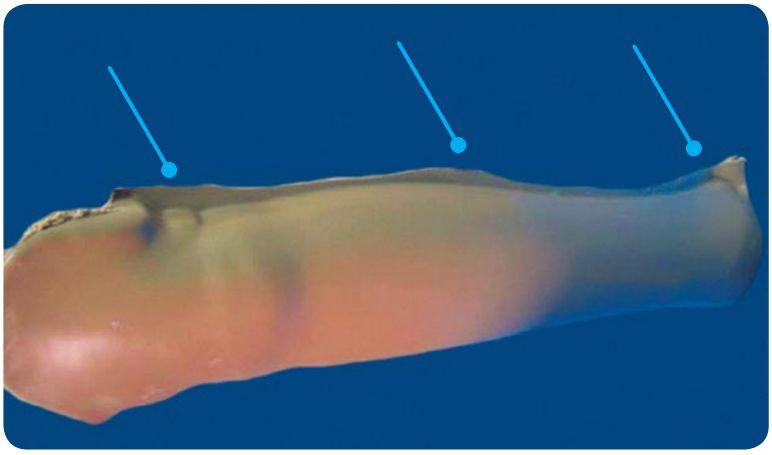


- Glue or nail 5 mm PP under the ankle plate to compensate for shrinkage of the PP after thermoforming.



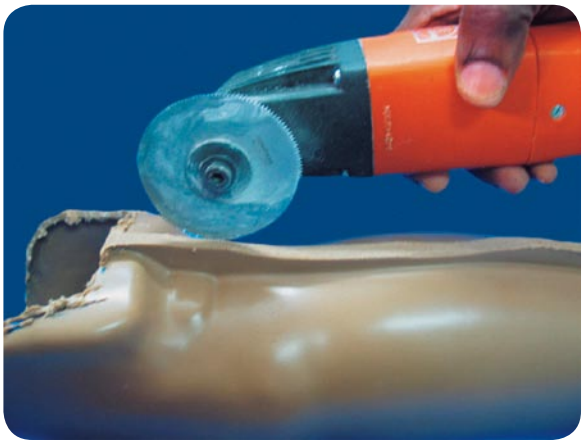
- Drape a sheet of 3 mm PP around the mould under vacuum.

- Grind the posterior seam down to 2 to 3 mm. In three places, leave a wider overlap of PP for holding the prosthesis during welding.



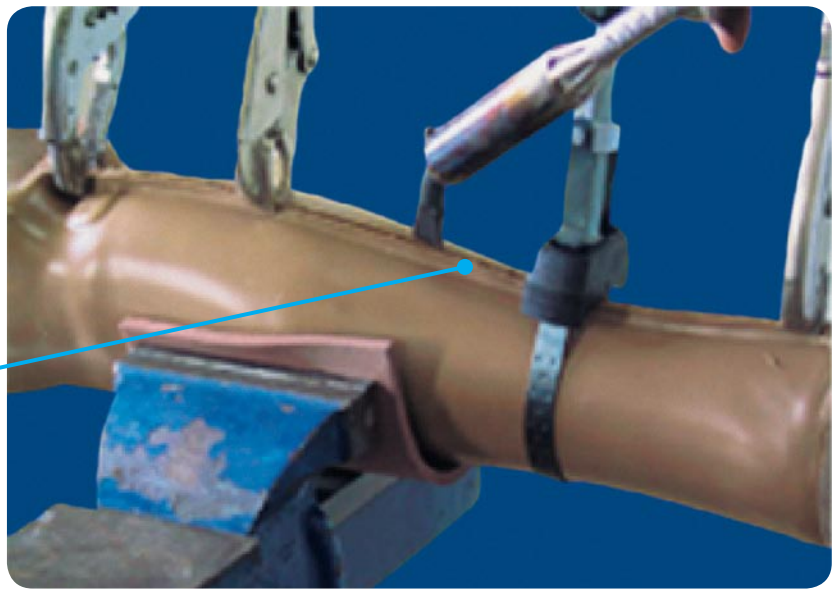
- Open the seam carefully with an oscillating saw to avoid breakage.

- Remove the PP shell from the prosthesis and remove the plaster. Clean the prosthesis thoroughly to ensure that no pieces of plaster remain.

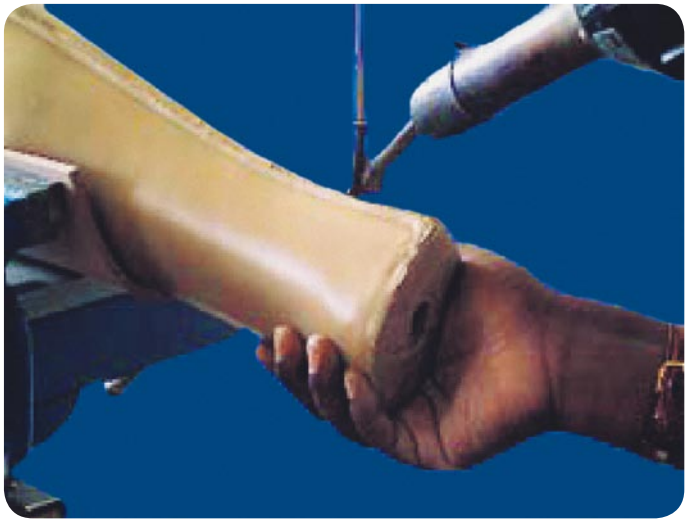


- Hold the prosthesis in a parallel vice with EVA or rubber protection between the vice jaws and the cosmetic shell. Close the two sides of the posterior seam with lock grips and/or other suitable tools.

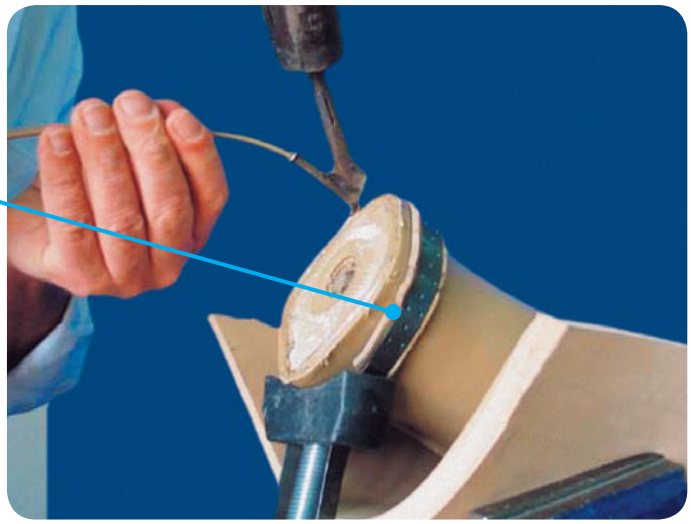
  Before welding, make V-shaped indentations along the seam with a welding iron.



- The final welding is done with a hot-air welding gun and a 4 mm PP welding rod.

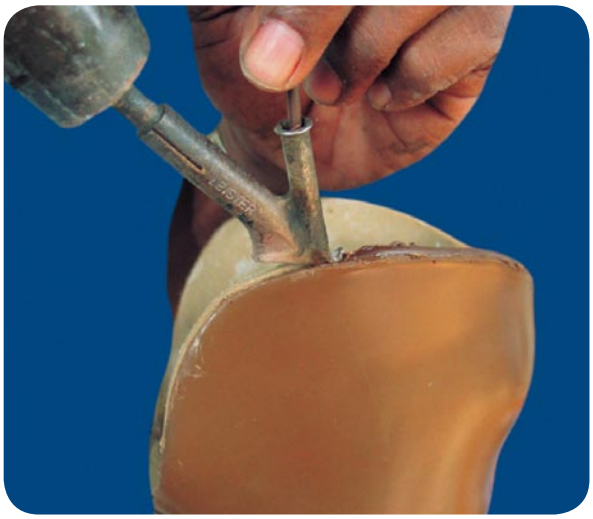


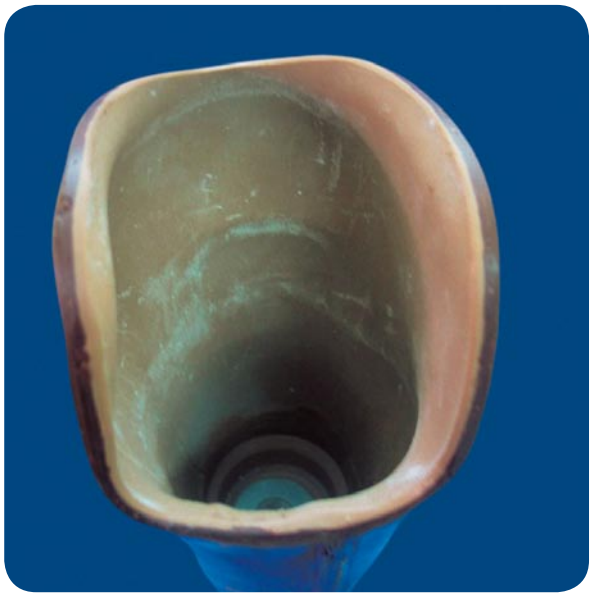
- Weld the ankle to the shell. After welding, carefully flatten the ankle surface.



- Grind the seam down to 2 to 3 mm. Polish with a rasp or a piece of glass.

- Weld the proximal part of the prosthesis.



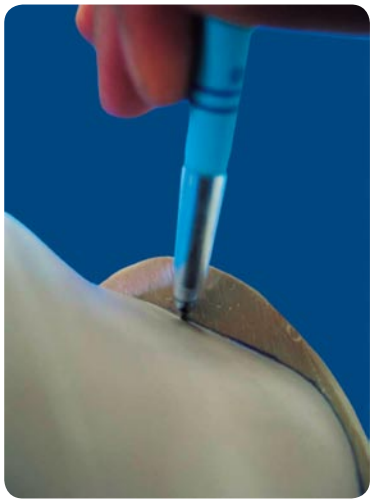


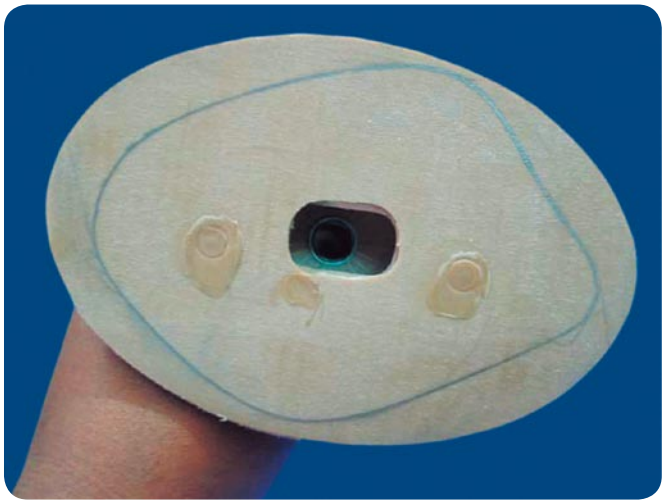
The last step is to fix the foot back on the prosthesis. Check the flatness of the ankle.

6 EVA COSMETIC MANUFACTURE

Adjustment of ankle part

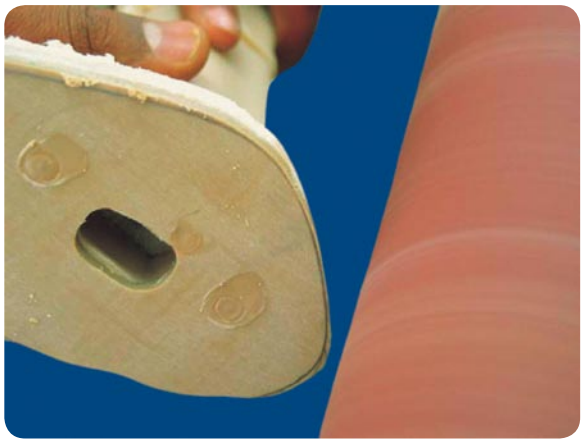
- Draw a line following the shape of the foot, then disassemble the foot.





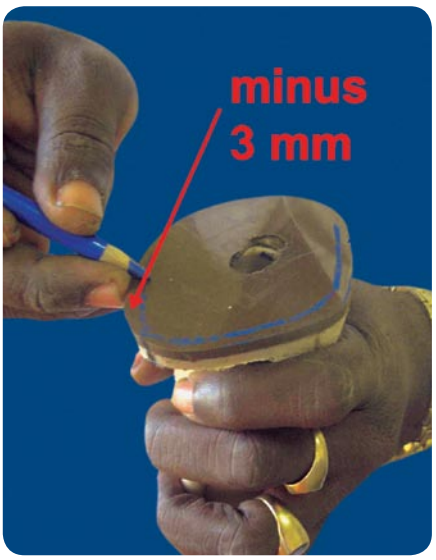
- Check your mark and grind it carefully.

  Check once more against the foot.

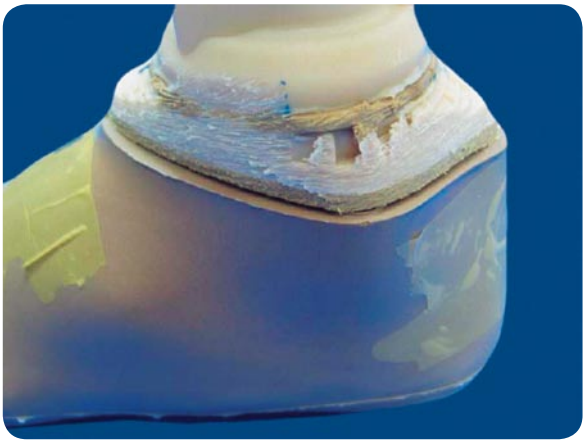


- Stick adhesive tape on the foot and draw a line with a permanent marker on the top of the convex ankle and on the tape.

- Dismantle the foot and draw a line all around the plate, 3 mm from the edge.

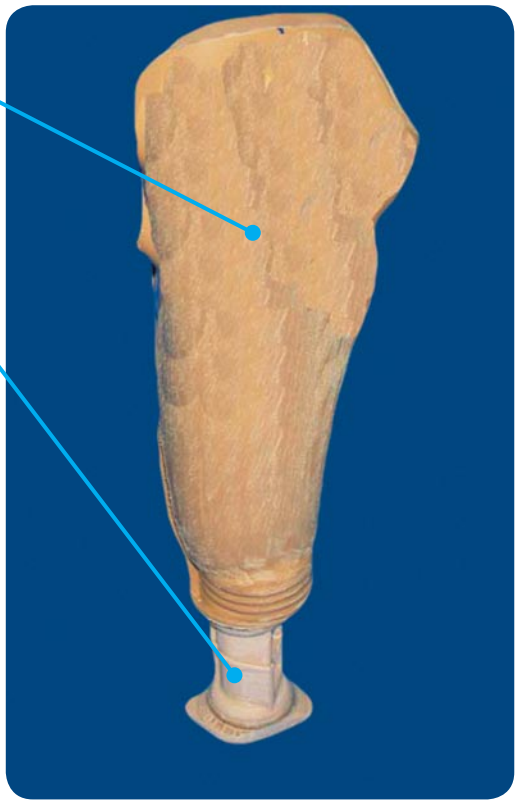


- Grind the edge carefully.



- Roughen the surface of the socket.

  For heavy patients, reinforce the concave cylinders with a 3 mm PP sheet.

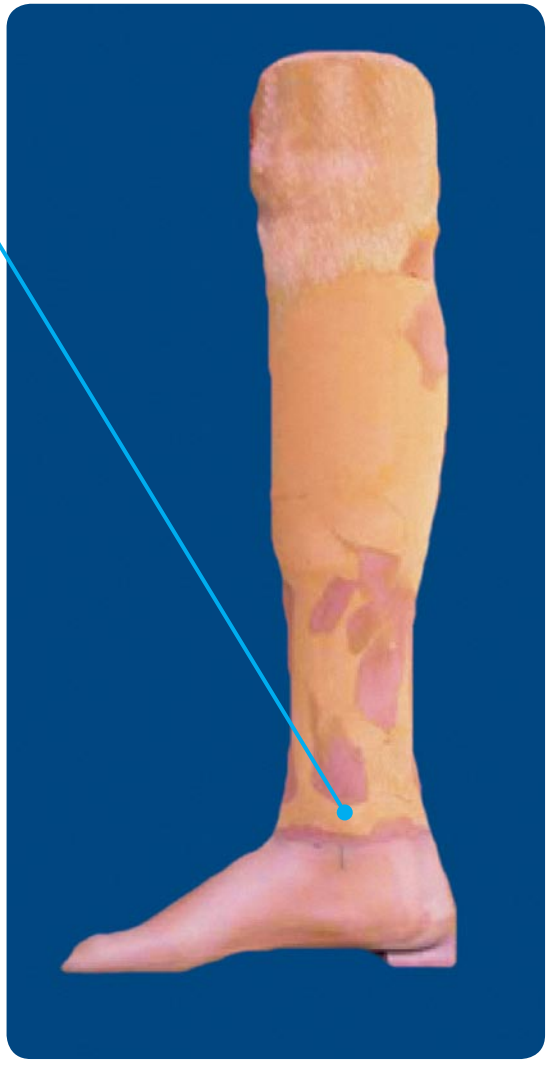


- Glue layers of EVA on the prosthesis.

- Shape to match the sound leg.

  Leave the ankle plate free of EVA for the final cosmetic.

  Bear in mind the fact that an additional layer of 3 mm EVA will cover the entire prosthesis, and that this will increase the circumference of the prosthesis by about 1 cm. At this stage, check your circumferences by comparing them with the measurements noted on the patient's technical card, and reduce the size by 1 cm all over.

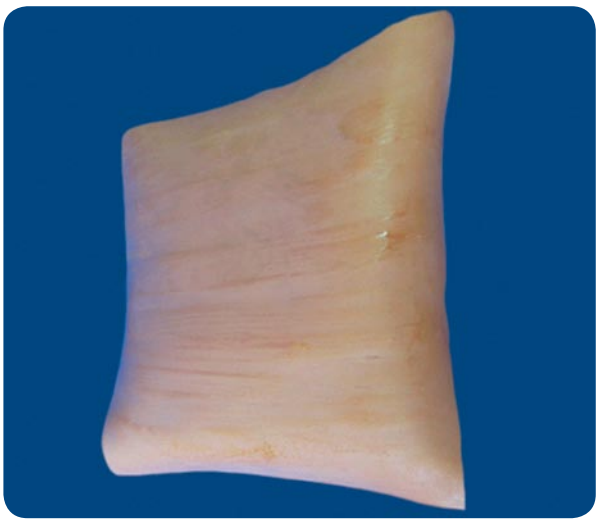


- Cut a sheet of 3 mm EVA according to the circumferences measured, but longer than the measurements.

  Skive the side that will be glued on top of the foot.

  Skive one long side of the EVA sheet and apply glue to that part.

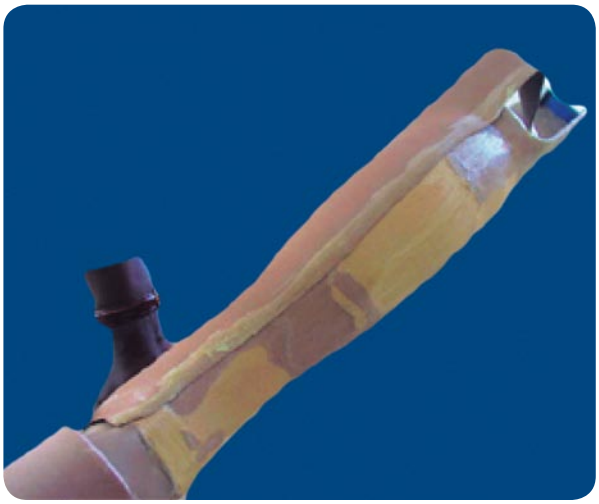
  Turn the EVA sheet over, and cover this reverse side with glue.



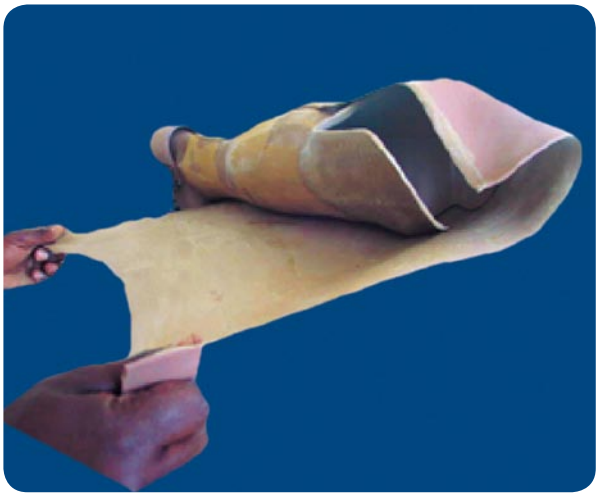
- Apply glue to the entire prosthesis (except the foot).

  Heat the 3 mm EVA sheet in the oven at 120°C for a few seconds until it becomes very flexible. Do not overheat the EVA or you may accidentally make print marks on it during manipulation.

  Take the 3 mm EVA sheet out of the oven and glue it over the prosthesis, starting by gluing the skived edge along the posterior side of the prosthesis.



- Then start gluing the 3 mm EVA sheet on the prosthesis by revolving the prosthesis on it, applying constant tension on the EVA to avoid air bubbles and folds.



- The last step is to remove the excess EVA and to grind the seam and the proximal trim line of the prosthesis smoothly.

Reference list of materials

Components: Trans-tibial module, child

ICRC Code	Description	Specification	Unit of Measure
Trans-tibial module, child			
0CPOMODUTTC	Countersunk head bolt Flat washer, steel Trans-tibial cup Convex disc Concave cylinder with M8 T-nut Convex ankle	M8 x 60 mm D40 x d10 x H2.5 mm D70 x H26 mm dia. 22 mm	1 piece 1 piece 1 piece 1 piece 2 pieces 1 piece

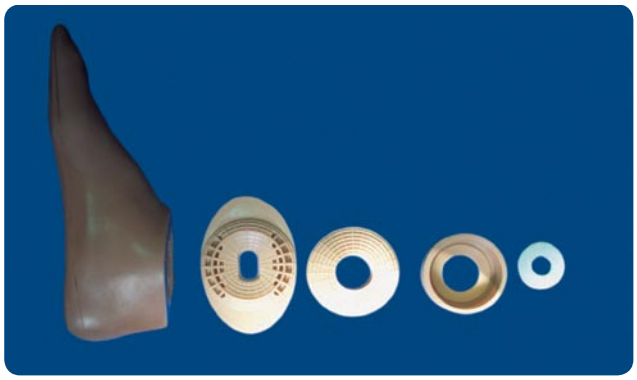
Weight per unit of measurement: 285 grams • Quantity per box: 25 sets • Box size: L40 x l30 x H44 cm

Components: Trans-tibial module, adult

ICRC Code	Description	Specification	Unit of Measure
Trans-tibial module, adult			
0CPOMODUTTA	Countersunk head bolt Flat washer, steel Trans-tibial cup Convex disc Concave cylinder with T-nut M8 Convex ankle	M10 x 60 mm D44 x d15 x H3 mm D70 x H26 mm dia. 25 mm	1 piece 1 piece 1 piece 1 piece 2 pieces 1 piece

Weight per unit of measurement: 490 grams • Quantity per box: 25 sets • Box size: L40 x l30 x H44 cm

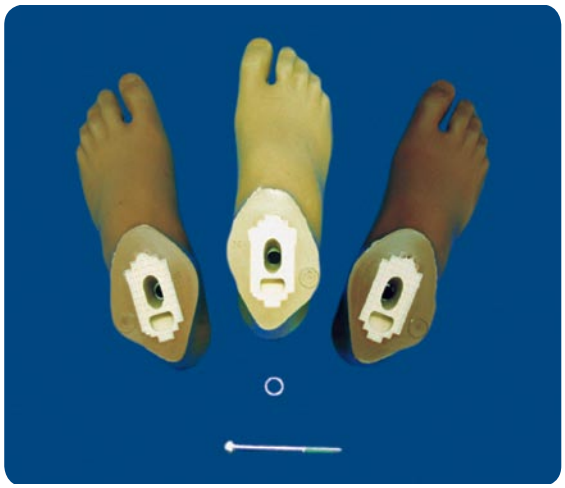
Components: Trans-tibial module, long stump prosthesis



ICRC Code	Description	Specification	Unit of Measure
Trans-tibial module, long stump prosthesis			
OCPOMODUTTLA	Flat washer, steel Trans-tibial cup Convex disc Concave ankle	D44 x d15 x H3 mm D70 x H26 mm	1 piece 1 piece 1 piece 1 piece

Weight per unit of measurement: 130 grams • Quantity per packet: 1 piece

Components: Feet for prosthesis



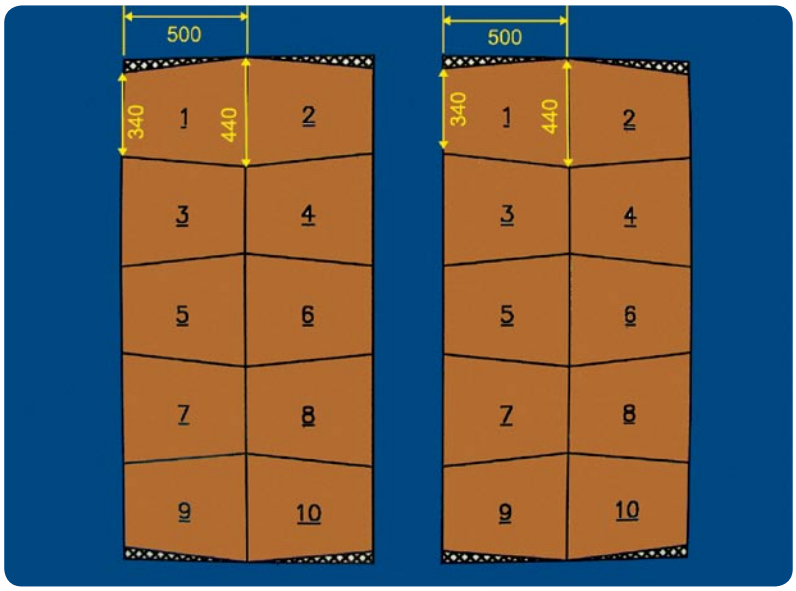
ICRC Code	Description	Specification
Feet for prosthesis		
OCPOFOOT...	Foot 22 – 28 cm, left and right, olive and terra colours	Heel, 10 mm
When ordering feet from 22 to 28 cm, change the number in the ICRC code and description. ▸ With all the adult feet a M10 bolt and a M10 lock washer are included. ▸ Weight per unit: (size 25) 605 grams • Quantity per box: 25 pcs. • Box L40 x l30 x H44 cm		
OCPOFOOT...	Foot 14 -21 cm, left and right, olive and terra colours	Heel, 10 mm
When ordering feet from 14 to 21 cm, change the number in the ICRC code and description. ▸ With all child feet a M8 bolt and a M10 lock washer are included. ▸ Weight per unit: (size 19) 340 grams. • Quantity per packet: 1 pc.		

PP, EVA and other consumables

Designation	Used for
Materials	
POP bandage 15 cm	Cast-taking
POP powder	Positive mould
Contact glue	Soft socket
Soap (demoulding agent)	Positive mould
Talcum powder	Thermoforming
Vaseline	Cast-taking
Nails	Positive mould
Colorant for plaster	Positive mould
Cotton/nylon stockinet dia. 8 or 10 cm	Cast taking and soft socket
Cotton stockinet or sock	Stump sock
Welding rod PP dia. 4 mm	Welding components
Polypropylene 4 mm	Hard socket
EVA 3 mm	Soft socket
EVA 6 mm	Soft socket
Polypropylene cosmetic	
Polypropylene 3 or 4 mm	Cosmetic shell
Welding rod dia. 4 mm	Welding cosmetic shell
Plaster powder	Cosmetic shape
Adhesive tape	
Tubular rivets (2)	Posterior reinforcement
EVA cosmetic	
EVA 3 mm; 6 mm; 12 mm	
Contact glue	

Standard cuts of polypropylene sheets for lower-limb prostheses

Polypropylene sheet: 2000 mm x 1000 mm



Trans-tibial socket 4 mm **Trans-tibial cosmetic 3 mm or 4 mm**

MISSION

The International Committee of the Red Cross (ICRC) is an impartial, neutral and independent organization whose exclusively humanitarian mission is to protect the lives and dignity of victims of war and internal violence and to provide them with assistance. It directs and coordinates the international relief activities conducted by the Movement in situations of conflict. It also endeavours to prevent suffering by promoting and strengthening humanitarian law and universal humanitarian principles. Established in 1863, the ICRC is at the origin of the International Red Cross and Red Crescent Movement.

Acknowledgements:

Jean François Gallay
Leo Gasser
Pierre Gauthier
Frank Joumier
Jacques Lepetit
Bernard Matagne
Joel Nininger
Guy Nury
Peter Poetsma
Hmayak Tarakhchyan

and all prosthetists-orthotists who have worked in ICRC-assisted physical rehabilitation centres.

ICRC

0868/002 09/2006 200