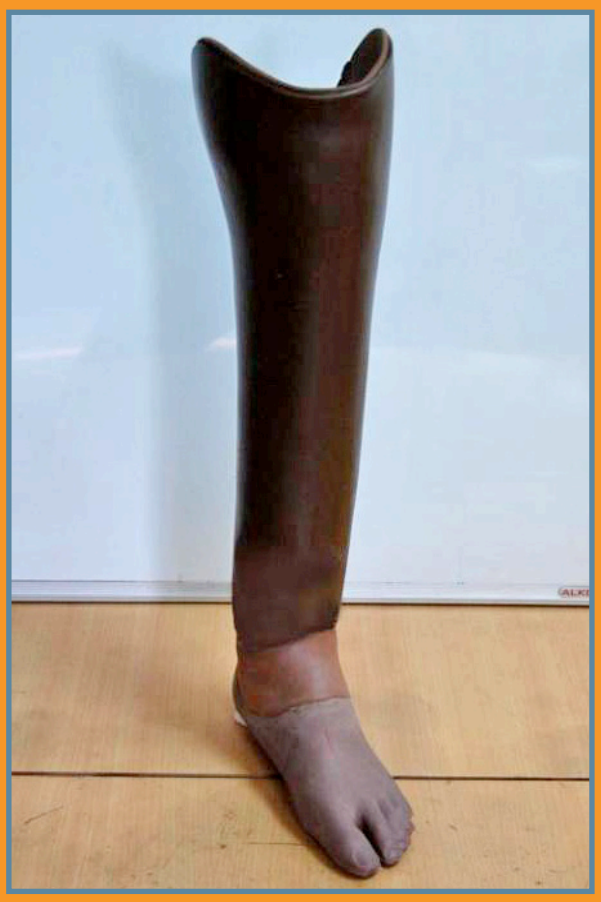
MANUFACTURING GUIDELINES



PUSH-FIT SYME PROSTHESIS

Physical Rehabilitation Programme

ICRC

ICRC

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Foreword

The ICRC's 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 adapted to the needs of the physically disabled in the countries concerned.

Therefore:
- The devices/components that are made using this technology must be durable, comfortable, and easy for patients to use and maintain
- The technology has to be simple and easy for technicians to put into practice and the devices/components easy to repair
- The technology must be standardized and the devices/components compatible with the climate in different regions of the world
- The technology must be inexpensive but modern and consistent with internationally accepted standards
- The technology must be easily available

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

For all these reasons, the ICRC decided to develop its own technology instead of buying ready-made orthopaedic components, which are generally too expensive and unsuited to the contexts in which the organization works. The materials used in the ICRC's prosthetic and orthotic (P&O) devices cost less than those used in devices assembled from ready-made components.

When the ICRC launched its physical rehabilitation programmes 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 began to standardize the techniques used in its various projects around the world, not only for the sake of consistency, but also and more importantly, to improve the quality of services for patients.

Polypropylene was first used – to manufacture prosthetic sockets – in the ICRC's projects in 1988. 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 refined. At the same time, a more durable prosthetic foot, made initially of polypropylene and ethylene vinyl acetate (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 on the training of personnel at country level.

Objectives of these *Guidelines*

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

Their main aims 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 practices

This is the latest in a series of efforts by the ICRC to ensure that patients have access to high-quality services.

ICRC
Assistance Division/Health Unit
Physical Rehabilitation Programme

Introduction

This manual describes a method of manufacturing a ***polypropylene Syme prosthesis with long-stump foot***, using the polypropylene technology employed in ICRC projects throughout the world.

The casting, rectification and alignment methods used correspond to international prosthetic and orthotic (P&O) standards and are therefore not described in the ICRC's *Manufacturing Guidelines*.

1 RAW MATERIALS AND COMPONENTS

- PP 4 mm (Low-activity patient)
- PP 5 mm (Active patient)
- EVA 3 mm
- EVA 6 mm

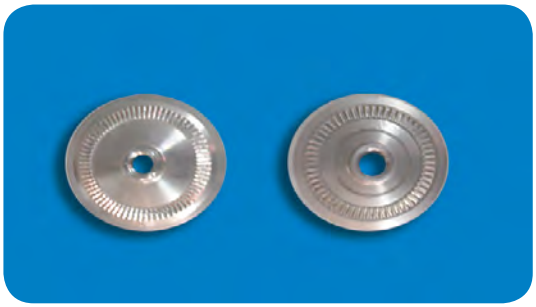
Components for Syme and Long-stump (Adults)

Long-stump foot, complete with heavy-duty nut and conical disc

Part code
Foot kit
OCPOFOOTERLS (size) L

Heavy-duty nut
EHDWNUTSTP06

Heavy-duty nut
OCPOMODUTFCB – 8 mm (Low-activity patient)
OCPOMODUTFCC – 10 mm (Active patient)



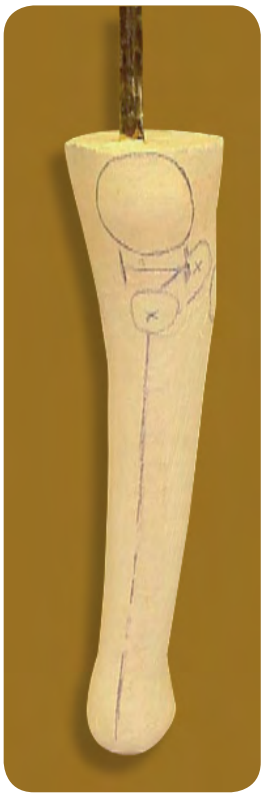
Installed before draping

Push-fit PP socket with EVA lining

Modified positive plaster model

Step 1

Alternative weight-bearing surfaces for a Syme amputation are similar to those of a PTB socket when the distal end bearing is compromised



Push-fit socket

This device consists of a cylindrical soft socket with suspension above the malleoli

2 THERMOFORMING THE SOFT LINER

Step 2

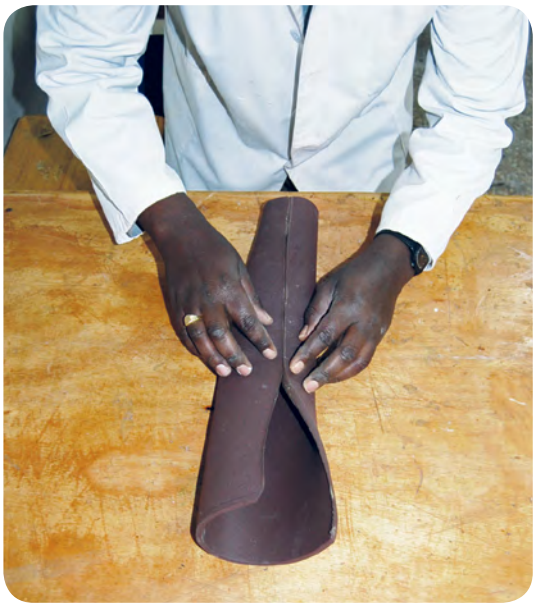
Cut 6 mm EVA sheet to conform to the shape of the positive mould with distal end cap

Skive the lateral edges and distal end (1 cm in from edge to zero at the edge)

Apply the same methods to mould EVA on a Trans-Tibial positive mould. Proceed to measure, cut and skive edges to the required size, before placing it in the oven for 5 min. Vacuum form the warm EVA over on to the mould with a plastic bag

Heat the EVA sheet until it is malleable

Create a conical liner by neatly aligning and gluing the skived edges together



Prepare the positive mould with talcum powder

Heat the cone at 120° C and drape over the positive mould; make sure the seam is in the centre of the popliteal area

Cover the mould with a plastic bag and apply the vacuum

Allow the EVA to cool

After the EVA has cooled down, remove the plastic bag

Apply contact adhesive to the skived edges of the distal end and prepare a cap (for the distal end)

Allow it to dry, and heat in the oven

Heat the cap until malleable and apply it to the distal end of the positive mould; maintain constant pressure

Grind the excess EVA to produce a smooth finish

Ensure the distal end has no seams and that it has an even finish, as the distal surface is weight-bearing

Measure the max. diameter of the malleoli

Find the same measurement proximally on the socket and mark its height

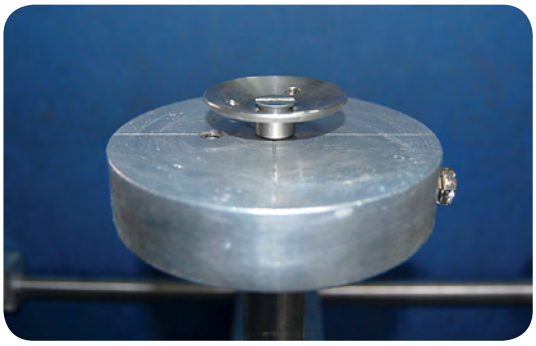
Fill the medial gap, and lateral gap on the soft socket with EVA to create a parallel sleeve at the max. diameter of the malleoli

3 ALIGNING THE HEAVY-DUTY NUT

Step 3

Fix the heavy-duty nut to the jig with a 6 mm counter sunk bolt

Install the heavy-duty nut in the centre of the jig



Install the heavy-duty nut before draping

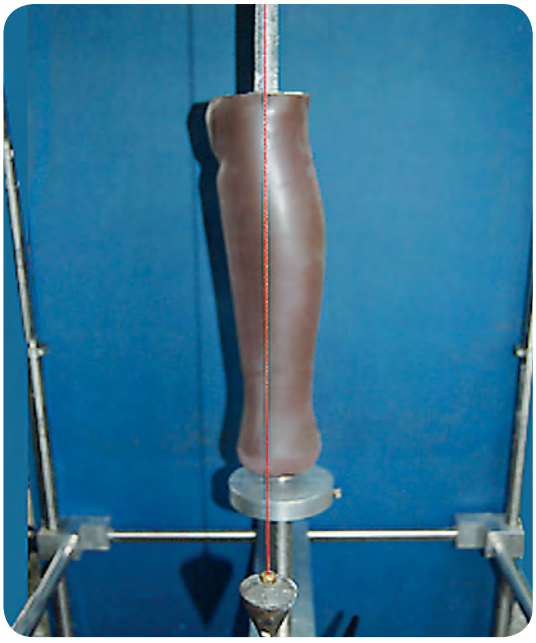
Use a standard alignment jig to make certain that the heavy-duty nut is properly aligned

Coronal plane

Align the centre of the knee with the medial aspect of the foot, with tibial adduction in accordance with P&O standards

Sagittal plane

Align the centre of the knee in flexion, in accordance with P&O standards and 10 mm anterior to the centre of the heavy-duty nut



Mark the outline of the heavy-duty nut to maintain the alignment when fixing it with a self-tapping screw

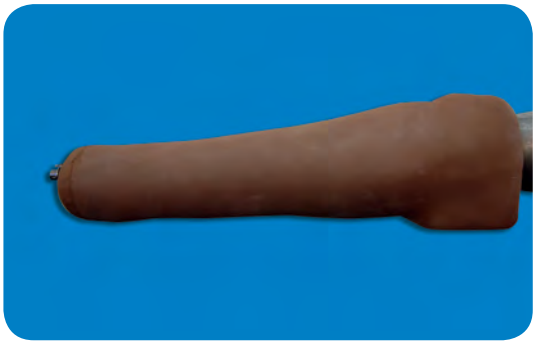
Secure the heavy-duty nut with a counter sunk screw

The mould is now ready for draping

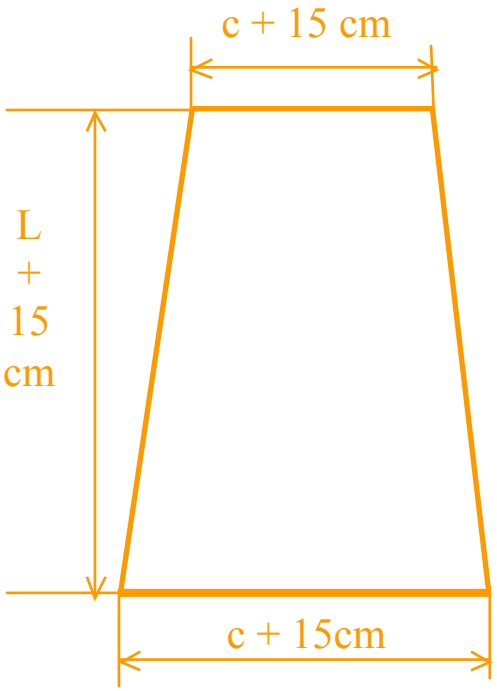
4 THERMOFORMING THE PP SOCKET

Step 4

Prepare a PP sheet (4 mm or 5 mm according to patient requirements) for thermoforming the socket



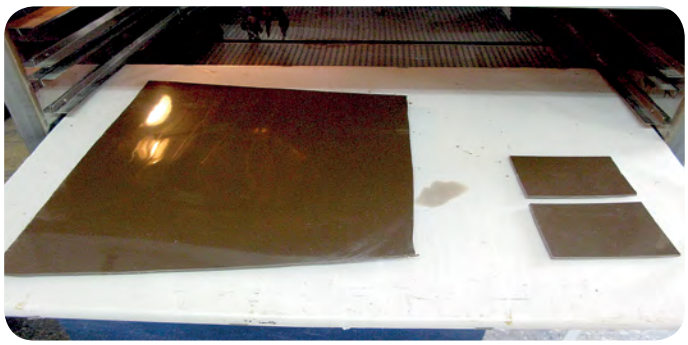
For the dimensions of the PP sheet, add 15 cm to the length and width



Prepare 2 more squares of PP (5 mm x 100 mm x 100 mm) to add to the distal end of the socket during the thermoforming process

Place the small square pieces in the oven with the large sheet of PP, as shown on the right

Place the PP sheet in the oven at 180° C



Thermoforming using the standard procedure

Drape the PP and cut off excess material

Keep the vacuum on until the plastic cools down and has regained its matt appearance

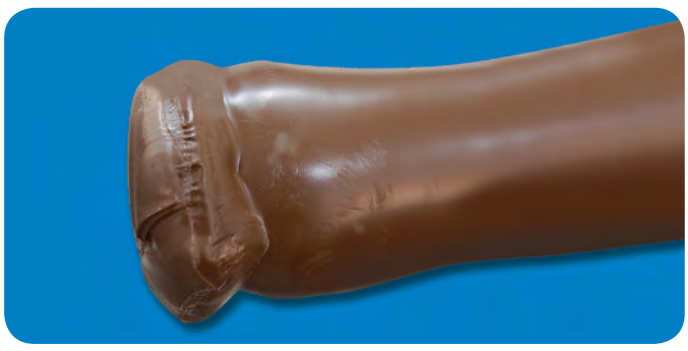
Add 10 mm of hot PP (square shapes of the same width as the mould)

Compress the distal addition as soon as excess PP has been removed

This should be done while the draped plastic is still hot

The result of adding the plastic on to the distal end of the mould can be seen in the adjacent photograph

Make sure that the two parts, i.e. the socket and the 10 mm addition, form a secure weld



Step 5

Grind the extra PP added to the distal end

If the socket is to be built directly on to the foot, round the distal end

If the socket is to be assembled with the oval disc, flatten the distal end

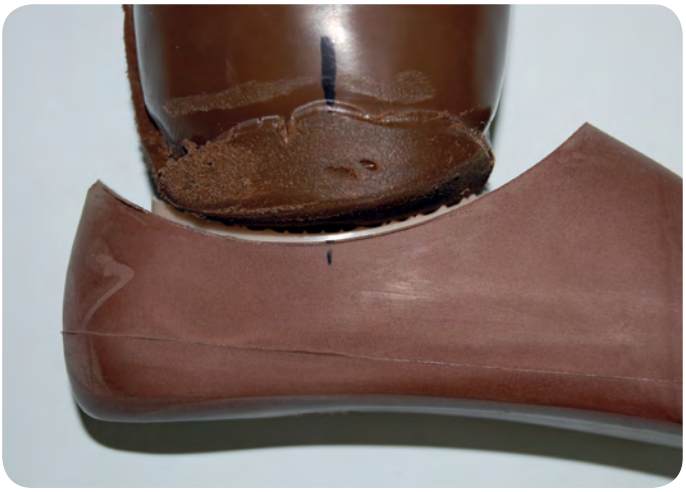
Machine the distal end to reveal the countersunk screw

Once you have revealed the countersunk screw you can remove it, knowing that you have approx. 8 mm of PP added on to the distal end

Make sure that the shape of the distal end matches the concavity of the foot

For the convex disc assembly, make sure that the distal end is flat and perpendicular to the shaft of the tibia

Convex/Concave finish



Flat finish with convex disc

Without oval disc

- Advantages: Less risk of leg-length discrepancy
- Disadvantages: Fewer adjustments, i.e. only AP tilting possible

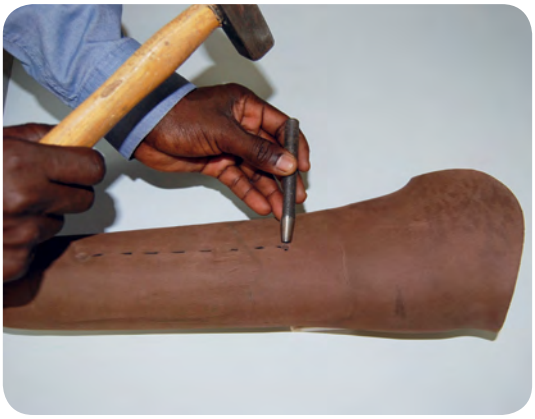
With oval disc

- Advantages: More adjustment available in tilt and shift
- Disadvantages: Prosthesis approx.10 mm longer (risk of leg-length discrepancy)

NOTE

Before fitting, cut a medial slit to make it easier to don and doff the soft liner.

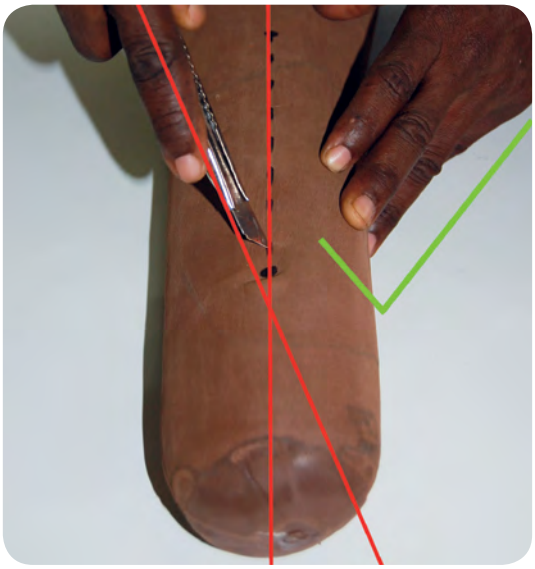
Punch a hole (approx. 3 mm in diameter) at the proximal end, at the height of the corresponding malleoli measurement; this will prevent the soft socket from tearing when donning and doffing



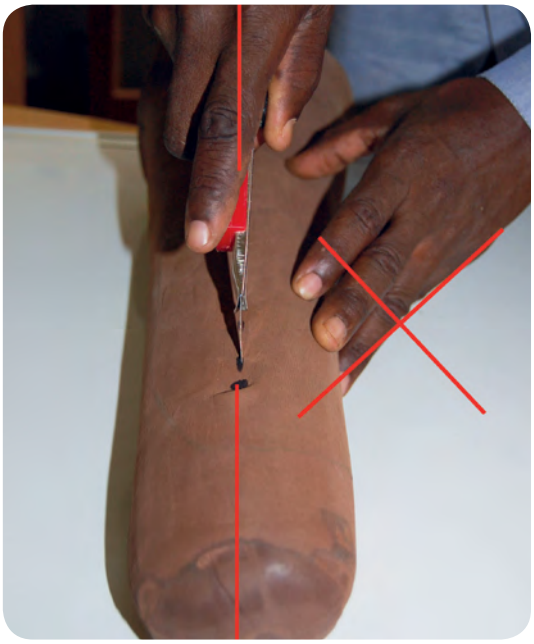
Start cutting the slit from the hole, punched in previous step, at the distal end

Cut up to the hole at the proximal end

Make sure to cut at an angle of approx. 30°, with a clean, sharp utility knife



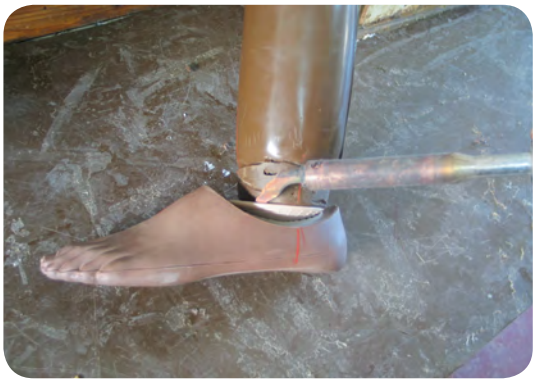
DO NOT cut liner straight as this will cause pinching of the skin when the patient is walking



6 WELDING AND COSMETIC FINISH

Step 6

Once the dynamic alignment is optimal, fasten the foot anchor bolt securely



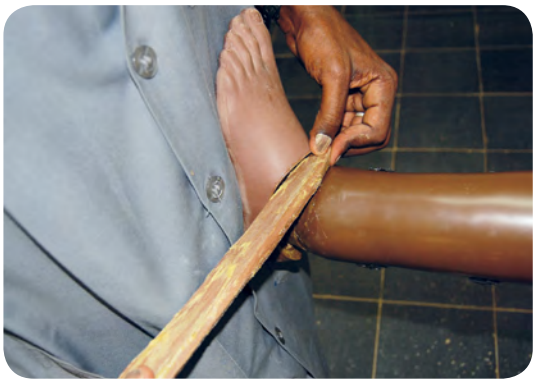
Make sure the alignment remains correct before welding

Prepare the welding surfaces with a soldering iron

Weld the components with the PP rod so that the foot is firmly attached to the socket

Cosmetic finishing

Prepare the socket for the cosmetic cover



Apply contact adhesive in the gap between foot and socket

Fill the gap between the socket and the foot with EVA

Apply adhesive to both sides of the EVA

Heat the EVA before inserting it into the gap to ensure that it fills the gap completely

Make sure that the EVA is evenly compressed into all gaps

Grind the EVA filler flush with the foot and the PP

CAUTION

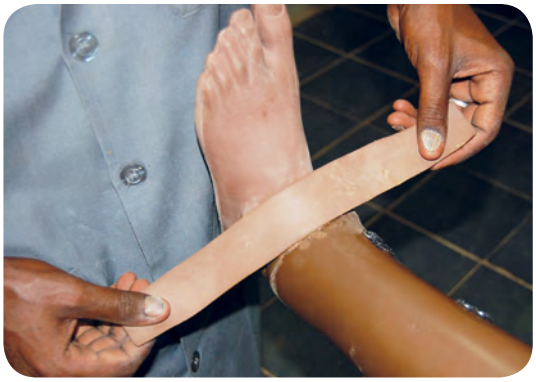
Do not grind the PP, as it will leave unsightly marks on the prosthesis and result in a poor cosmetic finish.

Use a smaller drum sander/cone: it is better for shaping and will not damage either the PP or the foot

If the shape of the filling is satisfactory, cover with a 3 mm EVA strip

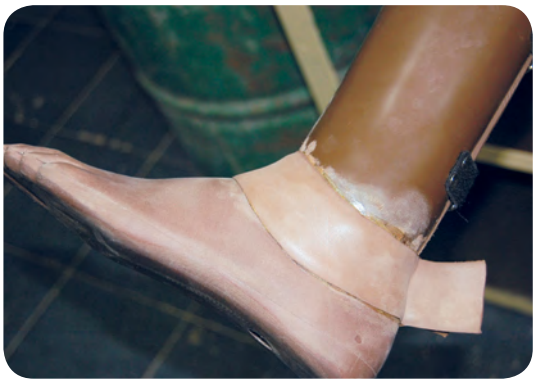
Skive the edges of the cover strip to ensure a neat, flush finish

Find the centre on the anterior aspect and wrap the finishing EVA cover around the shaped EVA filling so that the ends meet in the centre of the posterior



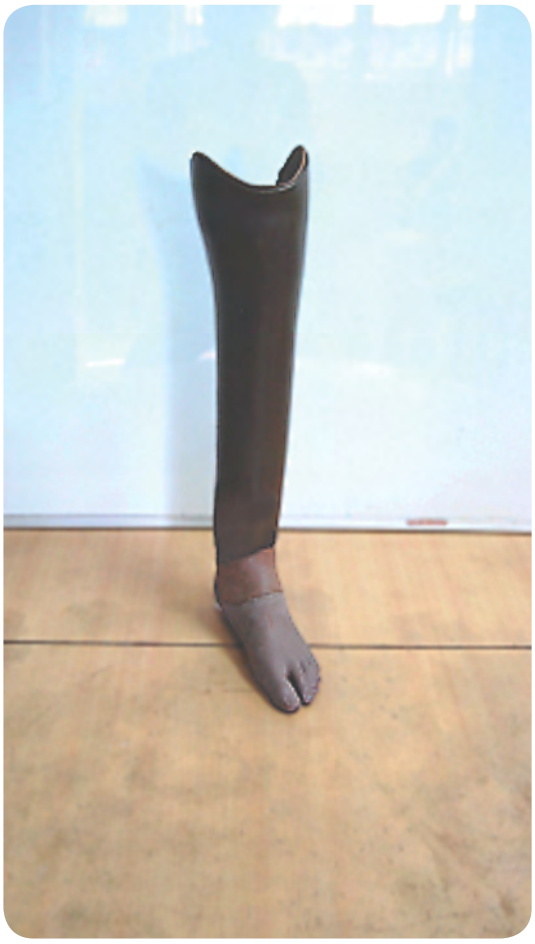
Trim the excess material for a neat finish

Polish out scuff-marks on the PP



7 FINAL PRODUCT

The prosthesis is ready for delivery



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 armed conflict and other situations of violence and to provide them with assistance. The ICRC 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 Geneva Conventions and the International Red Cross and Red Crescent Movement. It directs and coordinates the international activities conducted by the Movement in armed conflicts and other situations of violence.

ICRC

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