

MANUFACTURING GUIDELINES



PATELLAR TENDON-BEARING ORTHOSIS

Physical Rehabilitation Programme



ICRC



ICRC

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Table of contents

Foreword	2
Introduction	4
Choosing between two methods	4
1. Casting and rectification	5
2. PTBO with anterior-closing shell	6
2.1 EVA preparation for increased weight relief	6
2.2 Moulding of EVA	7
2.3 Orthosis trim line	8
2.4 Plastic reinforcement	9
2.5 Posterior shell	10
2.6. Anterior shell	12
2.7 Preparation for initial fitting	14
2.8 Initial fitting and finishing	17
3. PTBO with posterior-closing shell	19
3.1 EVA preparation for increased weight relief	19
3.2 Moulding of EVA	20
3.3 Orthosis trim line	21
3.4 Plastic reinforcement	22
3.5 Anterior shell	22
3.6 Posterior shell	25
3.7 Preparation for initial fitting	26
3.8 Initial fitting and finishing	27
List of manufacturing materials	28

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 two methods for producing **patellar tendon-bearing (PTB) orthoses**, working with the ICRC polypropylene technology and orthopaedic components used at the ICRC's physical rehabilitation centres.

Choosing between two methods

The following indications might help in making a choice between the two possible methods.

Anterior-closing shell	Posterior-closing shell
Weak at ankle level, especially for heavy patients or patients walking with ankle dorsiflexion.	Strong at ankle level, thus suitable for overweight patients or patients walking with ankle dorsiflexion.
Easy to fit into normal shoes.	Sometime difficult to fit into normal shoes because of the volume of the orthosis at mid-foot.

Weight relief: partial or complete?

According to the prescription and/or the pathology, the orthosis must partially or completely relieve the weight applied on the leg.

To this end, a layer of EVA is added under the foot prior to the draping of the polypropylene.

The following figures give a rough estimate of the degree of weight relief:

- No EVA: 70% of the weight on the leg and 30% on the orthosis.
- 3 mm EVA: 50% on the leg and 50% on the orthosis.
- 6 mm EVA: 30% on the leg and 70% on the orthosis.
- 12 mm EVA: 0% on the leg and 100% on the orthosis.

1**CASTING AND RECTIFICATION**

Patient assessment, casting and rectification of positive cast impressions are performed in accordance with prosthetic and orthotic (P&O) standards, taking into account the following points:

- The proximal part is manufactured like a trans-tibial prosthesis and ensures the weight-bearing function.
- The distal part is manufactured like an ankle-foot orthosis.
- There must be little or no weight borne on the leg while the cast is being taken.
- In the method involving a posterior-closing shell, the EVA used to increase weight relief is placed only under the heel, so it **affects the position of the cast** (see section 3.1, page 19).



2.1 EVA preparation for increased weight relief

Follow the procedure described below, or go on to the next section if the patient does not require additional weight relief.

- ▶ Place the plaster model on the EVA sheet and draw a line around it 1 cm wider than the foot.



- ▶ Hold the plaster model in a vice.

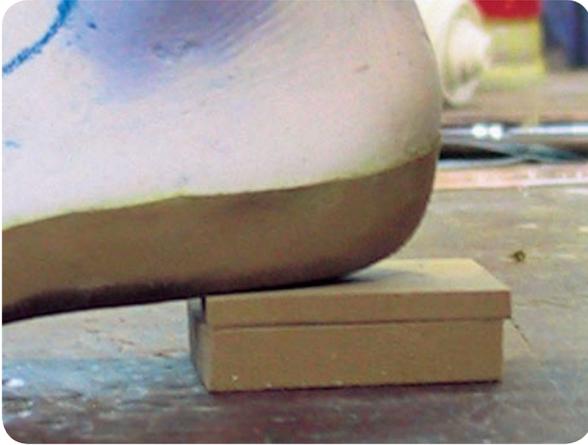
Heat the EVA at 120° for 3 to 5 minutes, depending on its thickness and on the efficiency of the oven.

Put the EVA under the foot and hold it firmly in place with an elastic bandage for one minute.



Grind the edge of the EVA until it is perfectly aligned with the shape of the plaster model.

- ▼ Glue the EVA under the plaster model.



2.2 Moulding of EVA

EVA (6 mm) can be moulded prior to draping of the polypropylene:

- to improve comfort;
- to prevent skin breakage in patients with sensation loss.

Follow the procedure described below, or go on to the next section if EVA is not required.

- ▶ Position the plaster model with the forefoot pointing downwards.

Cut a piece of EVA:

- width, knee circumference;
- length, the length of the plaster model (leg + foot);
- thickness, 6 mm.

Heat the EVA at 120° for 3 to 5 minutes, depending on the efficiency of the oven.

Drape the EVA over the plaster model manually and hold it in place until it has completely cooled.



- ▶ Cut off the excess with a cutter or a pair of scissors.

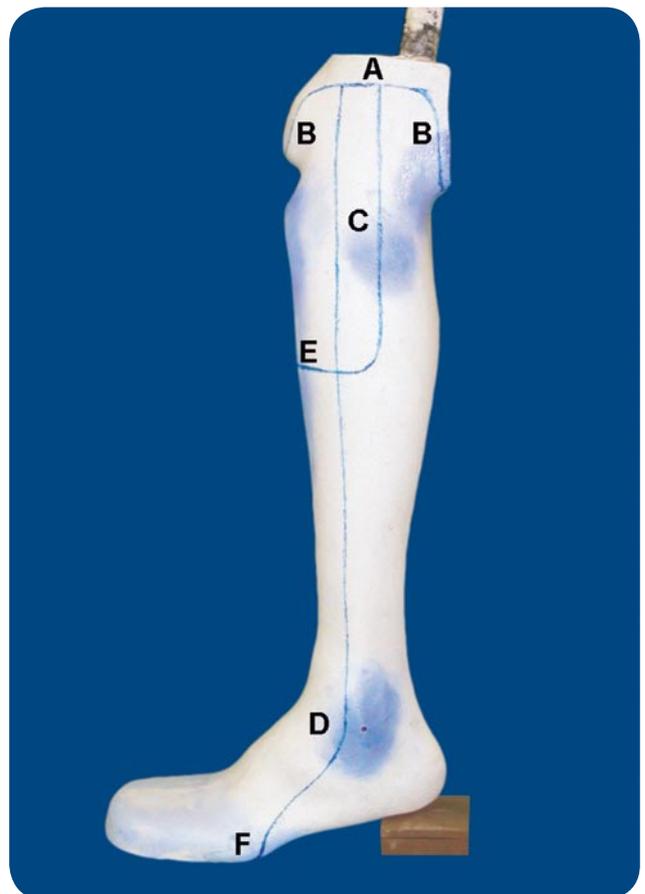
Staple the EVA onto the front of the plaster model.



2.3 Orthosis trim line

- ▶ Mark the orthosis trim line as follows:

- A** The top must be horizontal, 6 cm above the patella tendon groove.
- B** The patella and the hamstring tendons are left free.
- C** The shell overlaps the antero-posterior mid-line by 1.5 cm.
- D** At the ankle, keep the line 1 cm anterior to the top of the malleoli.
- E** The usual distal limit of the anterior shell is horizontal, at 1/3 of the length of the leg, but may be longer to provide greater protection.
- F** At the forefoot, clear the sides of the toes and the head of the metatarsus completely, passing beneath them. *This will allow the polypropylene to follow the movement of the metatarso-phalangeal joints.*



2.4 Plastic reinforcement

The orthosis may need reinforcement, especially at ankle level. If this is the case, follow one of the procedures described below; otherwise go on to the next section.

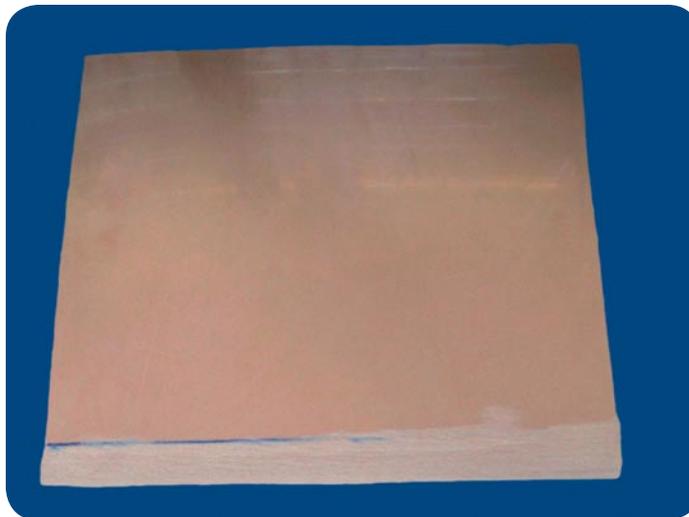
2.4.1 Double layer of polypropylene

- ▶ A second layer of polypropylene covering the ankle and the foot is moulded at the same time as the main layer.

Cut a piece of polypropylene:

- thickness, 3 mm;
- width, instep circumference;
- length, length of foot + 10 cm.

Grind the last 3 cm at the proximal end to gradually reduce the thickness of the polypropylene.



- ▶ The two layers are heated at the same time.

The reinforcement is placed on the plaster model, then the second layer is vacuum-moulded immediately afterwards to obtain a perfect seal between the two layers.



The double layer of polypropylene has the disadvantage of reducing flexibility of the forefoot in relation to the metatarso-phalangeal joint.

2.4.2 Lateral reinforcements (channels)

- ▶ Cut two bands of EVA:
 - thickness, 6 mm;
 - width, 7 mm;
 - length, 15 cm.

Pull a stocking over the plaster model.

Glue the band lightly onto the stocking.

The more anterior the position of the channel, the more the device will resist dorsiflexion of the ankle.

Reinforcements prolonged along the side of the mid-foot increase the volume of the orthosis so that it may no longer fit into the patient's shoe.



2.5 Posterior shell

2.5.1 Vacuum moulding of polypropylene

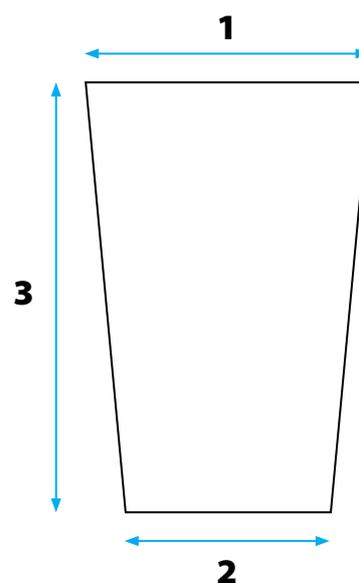
If this has not already been done, pull a stocking over the plaster model. *For maximum efficiency, the EVA used to channel the polypropylene must not be covered with a stocking.*

Dust the stocking with talcum powder.

Measurement of the polypropylene sheet:

- 1** Knee circumference + 10 cm.
- 2** Instep circumference + 10 cm.
- 3** Leg and foot length + 10 cm.

Thickness, 4 mm or 5 mm, depending on the patient's weight.



Heat the polypropylene at 180° for 20 to 25 minutes, depending on the thickness of the polypropylene and the efficiency of the oven.

Drape the polypropylene over the plaster model and stick it together along the anterior side.

Tighten the polypropylene around the suction cone with a rope or something similar.

Open the vacuum valve.

- ▶ Cut off the excess with a pair of scissors while the polypropylene is still hot.



Keep the vacuum on until the polypropylene cools down.

2.5.2 Preparation of the posterior shell

Draw the trim line on the polypropylene as explained in section 2.3 (page 8).

Cut the orthosis with an oscillating saw, following the outline.

Remove the shell gently to avoid damaging the proximal part of the plaster model, as it will be used to mould the second shell.

Remove the stocking from inside the orthosis.

Grind the trim line and smooth it.

If an EVA has been moulded, transfer the trim line to the EVA and cut off the excess with a pair of scissors.

Before moulding the second shell, keep an angle of 90° at the corner of the anterior/proximal trim line because a rounded shape would create a notch in the polypropylene of the posterior shell which might prevent proper functioning of the hinged joint.



2.6 Anterior shell

Repair the proximal part of the plaster model if necessary.

2.6.1 Moulding EVA

To improve comfort, 6 mm EVA can be moulded prior to draping of the polypropylene, whether or not the same has been done for the other shell.

Follow the procedure described below, or go on to the next section if EVA is not required.

- ▶ Cut a piece of EVA 6 mm thick and large enough to cover the proximal half of the plaster model.

Heat the EVA at 120° for 3 to 5 minutes, depending on the efficiency of the oven.

Put the EVA over the plaster model and hold it tightly in place with an elastic bandage for one minute.



- ▶ Remove the EVA and cut it, following the trim line.

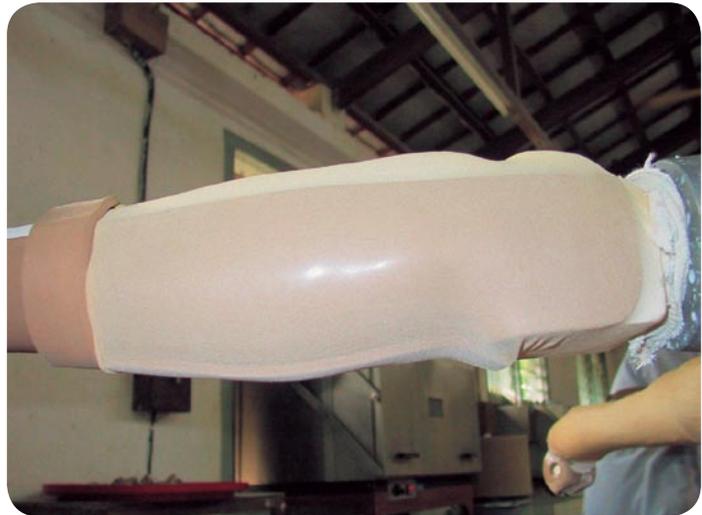
Take the polypropylene shell (with its EVA) and fix the newly moulded EVA with two staples close to the proximal/medial trim line.



2.6.2 Vacuum moulding of polypropylene on the anterior shell

- ▶ Glue a strip of EVA 6 mm thick and 3 cm wide around the middle of the plaster model. *The polypropylene draping will stop at this level, where the rope tightened around the EVA will ensure a sufficient vacuum.*

Glue another strip of EVA 6 mm thick and 3 cm wide on the middle of the first polypropylene shell at right angles to the first strip. *This will allow the polypropylene to be cut after draping without damaging the shell beneath.*



Cover with a stocking the area receiving the polypropylene. *Do not cover the strip of EVA where the rope will be tightened because the vacuum may leak through the stocking mesh.*

Place the plaster model with the forefoot pointing upwards.

Dust the stocking with talcum powder.

Cut a piece of polypropylene:

- width, knee circumference + 5 cm;
- length, half the leg length + 10 cm;
- thickness, 4 mm or 5 mm, depending on the patient's weight.

Heat the polypropylene at 180° for 15 to 20 minutes, depending on the thickness of the polypropylene and the efficiency of the oven.

- ▶ Drape the polypropylene over the plaster model and stick it together along the longitudinal strip of EVA.

Tighten the polypropylene around the suction cone.

Open the vacuum valve.

Cut off the excess with a pair of scissors while the polypropylene is still hot.



Keep the vacuum on until the polypropylene cools down.

2.6.3 Preparation of the anterior shell

Draw the trim line on the polypropylene as explained in section 2.3 (page 8).

Cut carefully along the EVA strip in the middle of the posterior shell with an oscillating saw.

Remove the posterior shell from the plaster model.

Remove the stocking from inside the orthosis and cut off the excess with a jigsaw.

Grind the trim line and smooth it.

If an EVA sheet has been moulded, transfer the trim line to the EVA and cut off the excess with a pair of scissors.



2.7 Preparation for initial fitting

2.7.1 Preparation of the hinged joint

- ▶ Secure the two shells on the plaster mould with Scotch tape.

Mark the position of the hinged joint on the lateral and medial sides:

- 4.5 cm above the patellar tendon groove;
- in the middle of the antero-posterior diameter.

Make sure that the hinged joints on both sides are at the same level.



- ▶ Drill a hole 3 mm in diameter through both shells.



- ▶ Assemble the anterior and posterior shells with 2 slotted screws and nuts 3 mm in diameter (head inside).

Cut and grind the bolt protruding from the nut.



2.7.2 Proximal strap

Use a ready-made Velcro strap 25 mm wide, or make a strap with nylon webbing or some other strong material.

- ▶ With a tubular rivet, fix the belt holding the loop on the medial side of the posterior shell, at the distal limit of the anterior shell.

The loop should be located 5 mm from the anterior shell.



- ▶ Insert the belt through the loop to measure the length.

Fix the strap with a tubular rivet on the lateral side.

Make sure the strap is perfectly horizontal before fixing it.



2.7.3 Distal strap

This strap is not always needed. The decision to install it or otherwise will depend on the capacity of the patient's shoe to hold the foot inside the orthosis.

Use a 25 mm Velcro strap.

- ▶ With a large tubular rivet, fix the belt holding the loop on the medial side, 4 cm above the malleoli.

The loop should be placed on the polypropylene and not be in contact with the patient's leg.



- ▶ Fix the strap with a large tubular rivet on the lateral side. Make sure the strap is perfectly horizontal before fixing it.

Cover the surface of the strap in contact with the patient's leg with 3 mm EVA.



2.7.4 Preparation of the EVA

If EVA is used, glue it temporarily inside the orthosis.

2.8 Initial fitting and finishing

- ▶ The patient puts on the orthosis by opening the anterior shell and sliding his/her foot through the proximal end.



The initial fitting is performed in accordance with P&O standards, taking the following points into account.

- Should the patient's leg slip through the brim, the proximal part can be padded with EVA to decrease its width.
- While the patient is standing, check the degree of weight relief.
- A heel lift on the controlateral side might be needed to accommodate the increase in length of the leg with the orthosis.

2.8.1 Finishing of the polypropylene

- ▶ Round off the corners of both anterior and posterior shells.



Carry out any modifications required on the polypropylene and smooth the trim line.

Glue the EVA completely inside the polypropylene, cut off the excess and smooth the trim line.

2.8.2 Finishing of the hinged joint

Use two copper rivets 3 mm in diameter with two brass or stainless steel washers.

Remove the 3 mm bolt on one side of each rivet.

Heat the copper rivet with a welding gun and “stamp” its head into the polypropylene of the anterior shell in order to create depressions to countersink the rivet head.



Insert the rivet, head inside, and install the washer outside.

Cut the rivet with double-action cutting pliers or side-cutting pliers so that only 2 mm protrudes from the washer.

- ▶ Place the rivet head on an anvil and hammer gently on the part of the rivet protruding from the washer in order to create a smooth, rounded shape as shown on the picture. Use a rivet set to round it off.



Do the same for the other side.

3.1 EVA preparation for increased weight relief

The EVA is placed only under the posterior part of the foot, in order to avoid an increase in volume at the mid-foot which may prevent the patient from wearing normal shoes.

Follow the procedure described below, or go on to the next section if the patient does not require additional weight relief.

- ▶ Place the metatarsal head of the plaster model at the edge of the EVA sheet and draw a line around it 1 cm wider than the foot.



- ▶ Hold the plaster model in a vice.

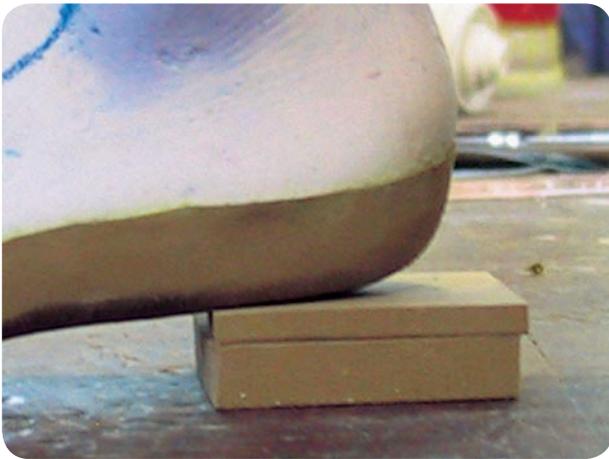
Heat the EVA at 120° for 3 to 5 minutes, depending on the thickness of the EVA and the efficiency of the oven.

Put the EVA under the posterior part of the foot and hold it firmly in place for one minute with an elastic bandage.



Grind the edge of the EVA until it is perfectly aligned, around and below, with the shape of the plaster model.

- ▶ Glue the EVA under the plaster model.



3.2 Moulding of EVA

EVA (6 mm) can be moulded prior to draping of the polypropylene to improve comfort.

Do not cover the foot, as this would create an increase of volume which might prevent the patient from wearing normal shoes.

Follow the procedure described below, or go on to the next section if EVA is not required.

Place the plaster model with the forefoot pointing upwards.

- ▶ Cut a piece of EVA:
 - width, knee circumference;
 - length, leg length;
 - thickness, 6 mm.

Heat the EVA at 120° for 3 to 5 minutes, depending on the efficiency of the oven.

Drape the EVA over the plaster model manually and hold it in place until it has cooled completely.



- ▶ Cut off the excess with a cutter or a pair of scissors.

Grind the distal trim line to gradually reduce its thickness.

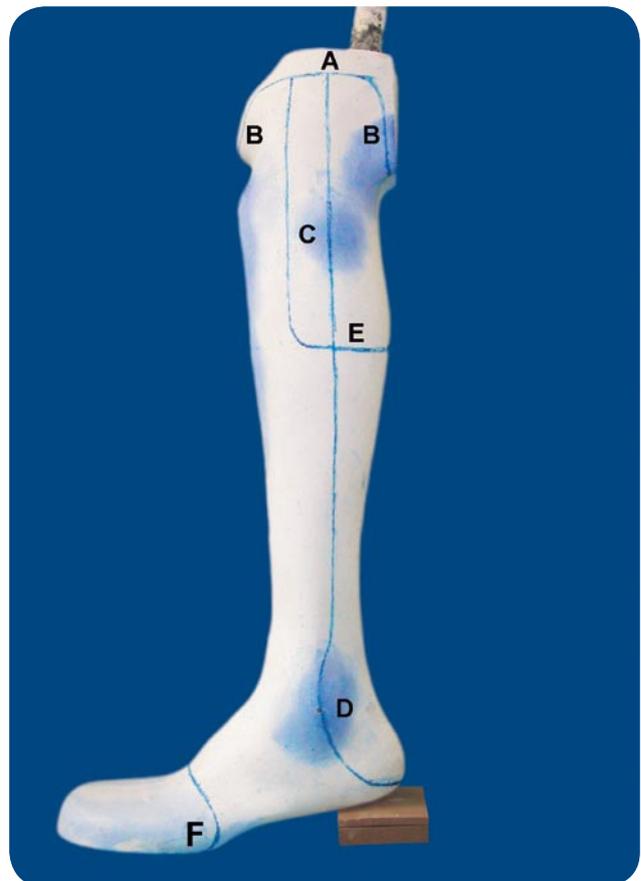
Staple the EVA onto the back of the plaster model.



3.3 Orthosis trim line

- ▶ Mark the trim line as follows:

- A** The top must be horizontal, 6 cm above the patella tendon groove.
- B** The patella and the hamstring tendons are left free.
- C** The shell overlaps the antero-posterior mid-line by 1.5 cm.
- D** At the ankle, the line must remain above the malleoli to facilitate donning.
- E** The usual distal limit of the posterior shell is horizontal, at 1/3 of the length of the leg, but it may be longer to provide greater protection.
- F** At the forefoot, clear the side and the top of the toes and the head of the metatarsus completely, passing beneath them. *This will allow the polypropylene to follow the movement of the metatarso-phalangeal joints.*



3.4 Plastic reinforcement

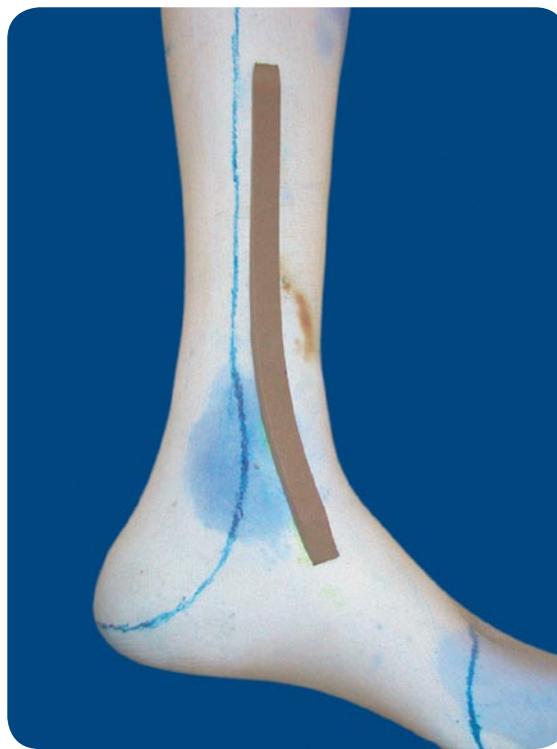
Lateral reinforcements (channels) significantly improve the strength of the orthosis. There are several ways of making these reinforcements.

- ▶ Cut two strips of EVA:
 - width 10 mm;
 - length 20 cm;
 - thickness, 6 mm.

Grind both distal and proximal ends to gradually reduce their thickness.

Glue the strips onto the plaster model, 1 cm anterior to the lateral and medial longitudinal axis.

Reinforcements prolonged along the side of the mid-foot increase the volume of the orthosis so that it may no longer fit into the patient's shoe.



3.5 Anterior shell

3.5.1 Vacuum moulding of polypropylene

The procedure described below ensures uniform thickness of the polypropylene all over the orthosis. Do not try to make a single seam on the anterior side, because the creases gathering at ankle level will make it necessary to stretch the polypropylene too thinly.

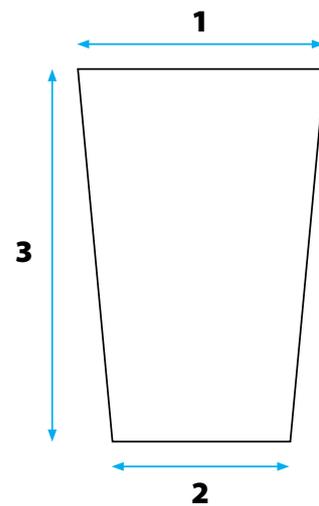
If this has not yet been done, pull a stocking over the plaster model. *For maximum efficiency the EVA used to channel the polypropylene must not be covered with a stocking.*

Dust the stocking with talcum powder.

Measurement of the polypropylene sheet:

- 1** Knee circumference + 10 cm.
- 2** Instep circumference + 10 cm.
- 3** Leg and foot length + 10 cm.

Thickness, 4 mm or 5 mm, depending on the patient's weight.



Heat the polypropylene at 180° for 20 to 25 minutes, depending on the thickness of the polypropylene and the efficiency of the oven.

Drape the polypropylene over the plaster model and stick it together along the posterior side and under the foot.

Tighten the polypropylene around the suction cone.

Open the vacuum valve.

- ▶ Cut off the excess with a pair of scissors while the polypropylene is still hot.



Keep the vacuum on until the polypropylene cools down.

3.5.2 Preparation of the anterior shell

Draw the trim line on the polypropylene as explained in section 3.3 (page 21).

Cut the orthosis with an oscillating saw, following the outline.

To remove the shell, it might be necessary to break the distal part of the plaster model below the ankle. However, care must be taken not to damage the proximal part, which is needed to mould the second shell.

Remove the stocking from inside the orthosis.

Grind the orthosis trim line and smooth it.

If an EVA has been moulded, transfer the trim line to the EVA and cut off the excess with a pair of scissors.

Before moulding the second shell, keep an angle of 90° at the corner of the posterior/proximal trim line because a rounded shape would create a notch in the polypropylene of the posterior shell which might prevent proper functioning of the hinged joint.



3.6 Posterior shell

Repair the upper half of the plaster model if necessary.

3.6.1 Moulding EVA

Follow the procedure described in section 2.6.1 (page 12).

3.6.2 Vacuum moulding of polypropylene on the posterior shell

Follow the procedure described in section 2.6.2 (page 13).

3.6.3 Preparation of the posterior shell

Draw the trim line on the polypropylene as explained in section 3.3 (page 21).

Cut carefully along the EVA strip in the middle of the anterior shell with an oscillating saw.

Remove the posterior shell from the plaster model.

Remove the stocking from inside the orthosis and cut off the excess with a jigsaw.

Grind the trim line and smooth it.

If EVA has been moulded, transfer the trim line to the EVA and cut off the excess with a pair of scissors.



3.7 Preparation for initial fitting

3.7.1 Preparation of the hinged joint

Follow the procedure described in section 2.7.1 (page 14).

3.7.2 Preparation of the straps

Follow the procedure described in section 2.7.2 (page 15) for the proximal strap, and section 2.7.3 (page 16) for the distal strap.



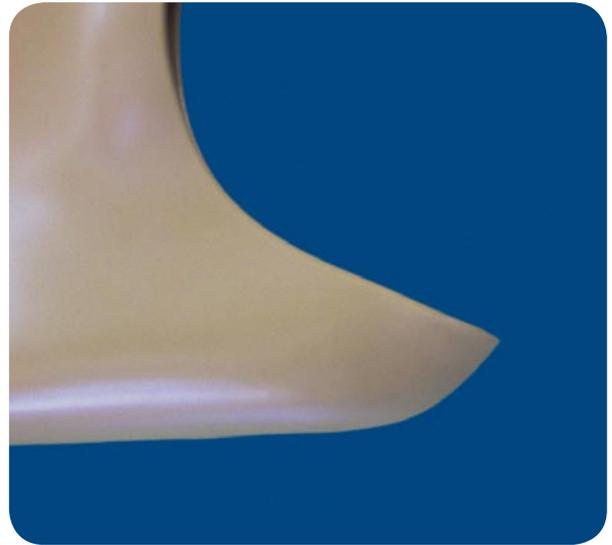
3.7.3 Preparation of EVA

If EVA is used, glue it temporarily inside the orthosis.

3.8 Initial fitting and finishing

See section 2.8 (page 17).

- ▶ It is often necessary to flare the polypropylene at the posterior part of the heel in order to facilitate donning and to avoid painful contact with the edge of the plastic.



List of manufacturing materials

ICRC Code	Description	Unit of measure	Quantity
For negative and positive cast :			
ODROSTOCOT60	Tubular stockinet, 60 cm	Cm	70
According to size: • MDREBANDP10 • MDREBANDP12 • MDREBANDP15	Plaster of Paris bandages 10, 12 or 15 cm x 3 m	Piece	3
OTOOPLASPW40	Plaster of Paris powder	Each	As required
For EVA and plastic moulding :			
If required, according to colour: • OPLAEVAFERA06 • OPLAEVAFLIV06 • OPLAEVAFKIN06	EVA 6 mm Terra, olive or beige colour	Each	As required
None	Nylon stockinet	Piece	1
According to colour and thickness: • OPLAPOLYCHOC04 • OPLAPOLYCHOC05 • OPLAPOLYLIV04 • OPLAPOLYLIV05 • OPLAPOLYSKIN04 • OPLAPOLYSKIN05	Homopolymer Terra, olive or beige colour, 4 or 5 mm thick	Each	As required
For the strap:			
OSBOSTRVP325	Strap, Velcro, PVC, with loop, brown, 300 mm x 25 mm	Piece	1
OHDWRIVET131	Rivet, tubular, 13 mm x 12 mm	Piece	2
<i>or</i>			
OSBOVSB024	Strap, Perlon webbing, 25 mm	Cm	25
None	Strap, Velcro, 25 mm	Cm	20
OSBOVSB035	Loop, 25 mm x 100 pieces	Piece	1
OHDWRIVET131	Rivet, tubular, 13 mm x 12 mm	Piece	2
For the hinged joint:			
OHDWRIVEC032	Rivet, copper, 3 mm x 20 mm	Piece	2
OHDWWASHB133	Washer, brass, 13 mm dia. x 3.1 mm thick	Piece	2

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.

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