

MANUFACTURING GUIDELINES



ANKLE-FOOT ORTHOSIS

Physical Rehabilitation Programme

Physical Rehabilitation Programme. "Manufacturing Guidelines: Ankle-Foot Orthosis." Geneva, Switzerland: International Committee of the Red Cross, 2006. Used with permission.



ICRC



ICRC

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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 several methods for manufacturing **ankle-foot orthoses (AFO)**, working with the polypropylene technology used at the ICRC's physical rehabilitation centres.

Choosing between different designs

Without going into details, some features of different types of AFO are set out below to assist in the choice of design.

Flexible AFO

- Dorsiflexion assistance
- Poor medio-lateral stabilization of the subtalar joint

Rigid AFO

- Blocks ankle movements
- Mediolateral stabilization of the subtalar joint
- Possibility of controlling forefoot adduction/abduction

AFO with Tamarack Flexure Joint™

- Mediolateral stabilization of the subtalar joint
- Free ankle dorsiflexion
- Free or restricted ankle plantar flexion

AFO anti-talus

- Blocks ankle movements. Particularly efficient for preventing ankle dorsiflexion
- Poor mediolateral stabilization of the subtalar joint

Casting and rectification

Patient assessment, casting and rectification of positive cast impressions are performed in accordance with prosthetic and orthotic (P&O) standards.

For flexible AFO, the cast can be taken with 5 degrees of dorsiflexion so as to provide a preload and ensure some spring action.



1.1 Moulding of EVA

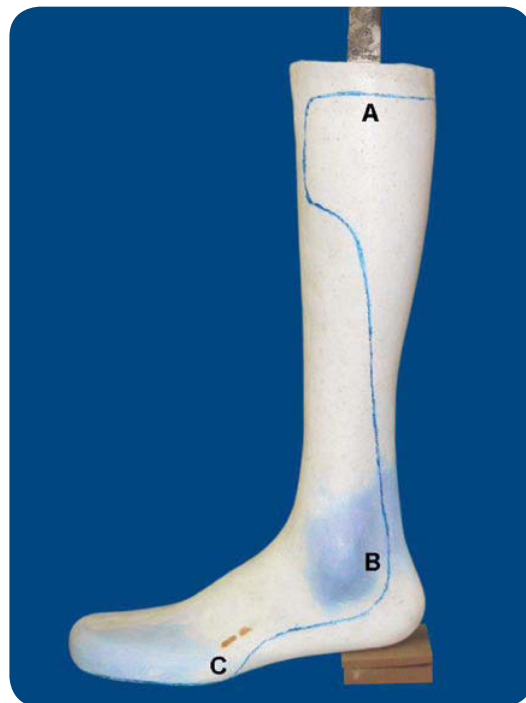
A flexible AFO does not usually require any EVA. However, in cases where it is necessary the procedure described in section 2.1 (page 8) should be followed.

1.2 Orthosis trim line

To achieve the goal of allowing dorsiflexion of the ankle while preventing passive plantar flexion, there are a number of design options.

▶ Mark the trim line as follows:

- A** The top is horizontal, 2 cm below the fibula head.
- B** At the ankle, pass 2 cm behind the tip of the malleoli to allow flexion of the polypropylene.
- C** At the forefoot, leave the sides of the toes and the head of the metatarsus completely clear and pass the trim line below them. *This will allow the polypropylene to follow the movement of the metatarso-phalangeal joints.*



Pull a stocking over the plaster model.

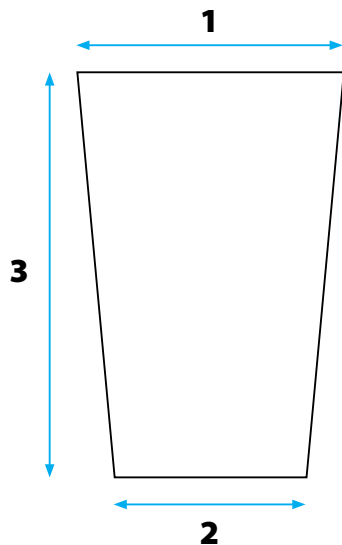
1.3 Vacuum moulding of the polypropylene

Dust the stocking with talcum powder.

Measurement of the polypropylene sheet:

- 1 Calf circumference + 10 cm.
- 2 Instep circumference + 10 cm.
- 3 Leg and foot length + 10 cm. (See next picture.)

Thickness 3 mm, 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 by means of a rope or something similar.

Open the vacuum valve.

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



Keep the vacuum on until the polypropylene cools down.

1.4 Preparation of the polypropylene shell

Draw the trim line on the polypropylene as described in section 1.2 (page 6).

Following the outline, cut the orthosis with an oscillating saw.

Remove the plastic shell from the plaster model.

Remove the stocking from inside the AFO.

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.



1.5 Preparation of the straps

For the proximal strap, follow the procedure described in section 2.6 (page 14).

A distal strap might be needed, depending on the capacity of the patient's shoe to hold the foot inside the orthosis. If this is needed, follow the procedure described in section 2.7 (page 15).

1.6 Initial fitting and finishing

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

The initial fitting is performed according to P&O standards.

Carry out the required modification on the polypropylene and smooth the trim line.

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

2 RIGID AFO

2.1 Moulding of EVA

EVA (6 mm) may be moulded prior to the draping of the polypropylene, for the following reasons:

- to improve comfort;
- to prevent skin breakage in patients with sensation loss;
- for orthoses used at night.

Follow the procedure described below or, if the case does not require EVA, go on to the next section.

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

Measurement of the EVA sheet:

- width, instep circumference;
- length, that 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 manually over the plaster model and hold it in place until it has cooled completely.



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

Staple the EVA onto the front of the plaster model.

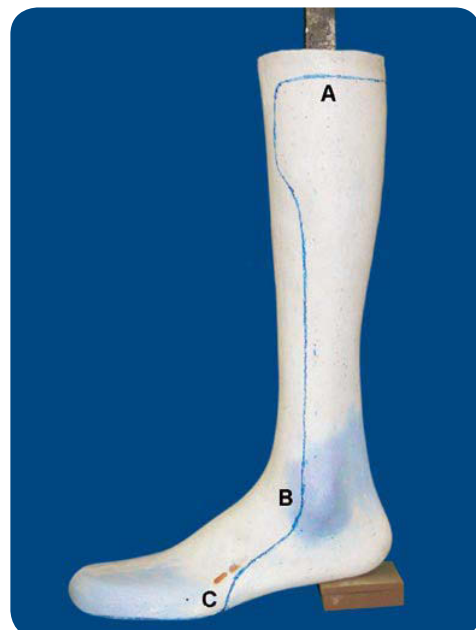


2.2 Orthosis trim line

2.2.1 "Standard" trim line

- ▶ Mark the trim line as follows:

- A** The top must be horizontal, 2 cm below the fibula head.
- B** At the ankle, pass the line 1 cm anterior to the tip of the malleoli.
- C** At the forefoot, leave the sides of the toes and the head of the metatarsus completely clear and pass the trim line below them. *This will allow the polypropylene to follow the movement of the metatarso-phalangeal joints.*

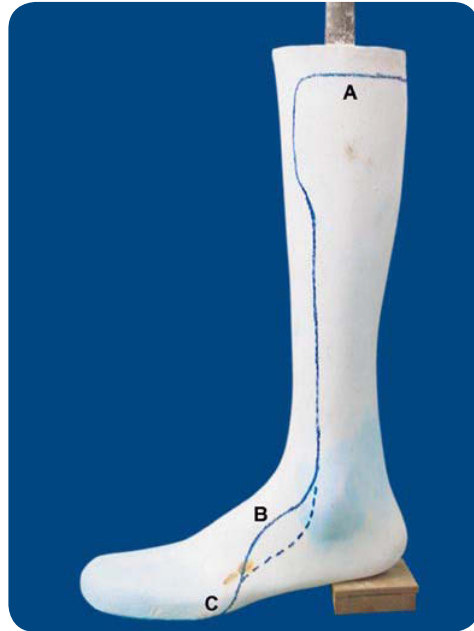


2.2.2 Trim line to correct forefoot adduction

Forefoot adduction is common in cases of clubfoot.

▶ Mark the trim line as follows:

- A** The top must be horizontal, 2 cm below the fibula head.
- B** Increase coverage of the lateral mid-foot, passing in front of the cuboid, *to enlarge the area of pressure.*
- C** At the forefoot, the line must be proximal to the 5th metatarsal head.



- D** Decrease coverage of the medial mid-foot at the navicular/malleoli, *to facilitate donning.*
- E** At the forefoot, cover the medial side of the metatarsal head and toe, *to correct forefoot adduction.*



2.2.3 Trim line to correct forefoot abduction

Forefoot abduction is often seen in cases of cerebral palsy.

▶ Mark the trim line as follows:

- A** The top must be horizontal, 2 cm below the fibula head.
- B** Decrease coverage at the level of the lateral malleoli, *to ease donning*.
- C** At the forefoot, the line must be distal to the 5th metatarsal head, *to avoid metatarsus abductus*.



- D** Increase coverage of the medial mid-foot at the level of the navicular, *to increase mid-foot support*.
- E** At the forefoot, the line must be proximal to the 1st metatarsal head.



2.3 Plastic reinforcement

The AFO may need reinforcement, especially at ankle level. If necessary, use one of the following methods; otherwise go on to the next section.

2.3.1 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, foot length + 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 to obtain a perfect seal between the two.



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

2.3.2 Channels in the polypropylene

The presence of channels in the plastic significantly improves its strength. There are several ways of making these channels.

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

Grind both distal and proximal ends to gradually reduce the thickness of the EVA.

Pull a stocking over the plaster model.

Glue the strip lightly onto the stocking.



The more anterior the position of the channel, the more the AFO 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.

2.4 Vacuum moulding of the polypropylene

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

Follow the procedure described in section 1.3 (page 6), taking into account the presence or absence of a double layer of polypropylene (section 2.3.1, page 12).

2.5 Preparation of the polypropylene shell

Draw the trim line on the polypropylene as described in section 2.2 (page 9).

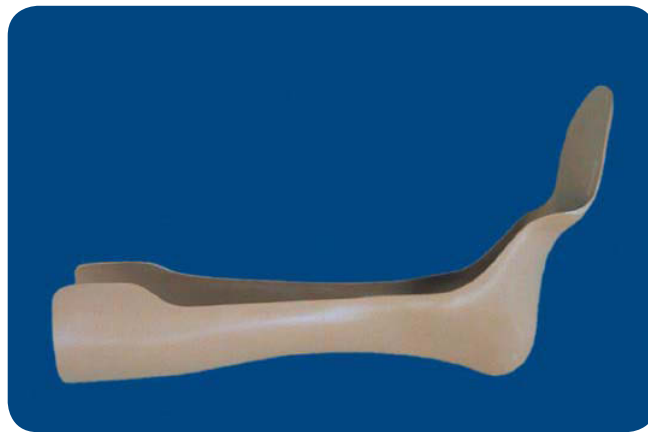
Cut the orthosis with an oscillating saw, following the outline.

Remove the plastic shell from the plaster model.

Remove the stocking from inside the AFO.

Grind the orthosis trim line and smooth it.

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



2.6 Proximal strap

Use a ready-made Velcro strap 40 mm wide, or make a strap with Perlon webbing or some other strong material.

- ▶ With a large tubular rivet, fix the belt holding the loop on the medial side, 1.5 cm below the proximal trim line.

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



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

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 Distal strap

You must choose between a distal strap and an instep strap. The latter has the advantage of holding the calcaneum firmly inside the orthosis (equinus correction).

Use a Velcro strap 25 mm wide.

- ▶ 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 over 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.



2.8 Instep strap

Use a Velcro strap 25 mm wide.

Two techniques are presented, depending on whether the back of the foot is in a neutral position or needs a valgus/varus correction.

2.8.1 Neutral position

- ▶ With a large tubular rivet, fix the belt holding the loop on the medial side, at an angle of 45° passing through the posterior distal tip of the calcaneum.

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



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

Fix the strap with a large tubular rivet on the lateral side, at the same angle of 45°.

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



2.8.2 Varus/valgus correction

The strap will pass through a slot cut in the polypropylene.

- ▶ The slot is cut on the lateral side for varus correction and on the medial side for valgus correction.

Mark the position of the slot 40 mm from the back of the foot and perpendicular to a line drawn at an angle of 45° passing through the posterior distal tip of the calcaneum.

The slot should be 30 mm long.



- ▶ Make holes along the slot axis with a drill fitted with a 4 mm bit.



- ▶ With a cutter, connect the holes with each other.

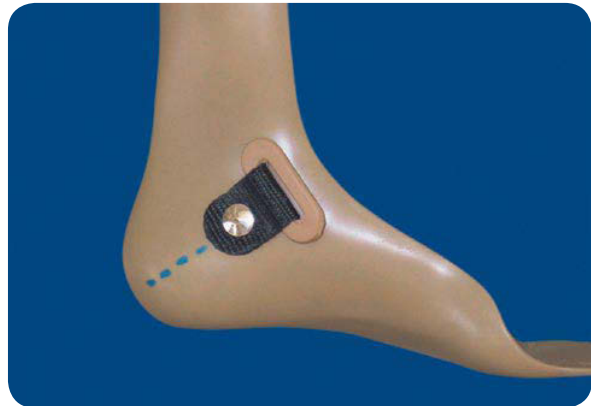
Finally, smooth the trim line with a file.



- ▶ The loop is placed on the medial side for varus correction and on the lateral side for valgus correction.

Fix the belt holding the loop with a large tubular rivet, at an angle of 45° passing through the posterior distal tip of the calcaneum.

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



- ▶ Insert the belt through the slot on one side and through the loop on the other side to measure the required length.

Fix the strap with a large tubular rivet just outside the slot.

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



2.9 Initial fitting and finishing

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

The initial fitting is performed in accordance with P&O standards.

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

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

3 AFO WITH TAMARACK FLEXURE JOINT™

3.1 Moulding of EVA

Follow the procedure described in section 2.1 (page 8), or go on to the next section if EVA is not required.

3.2 Orthosis trim line

Follow the procedure described in section 2.2.1 (page 9).

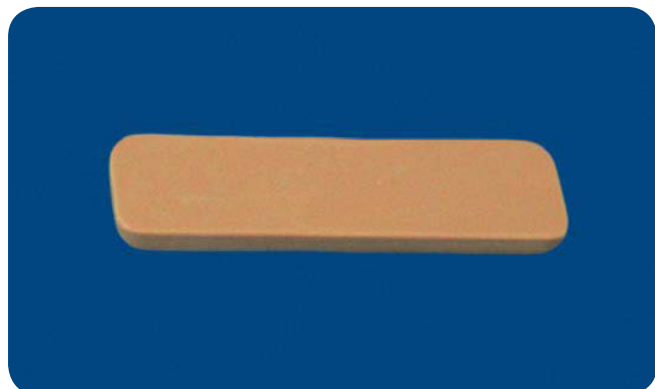
3.3 Plastic reinforcement

Posterior reinforcement for greater plantar flexion control is required when the orthosis is intended to prevent plantar flexion (not fully described below).

Follow the procedure described below, or go on to the next section if plantar flexion is left free.

A second layer of polypropylene for positioning at the level of the Achilles tendon is moulded at the same time as the main layer.

- ▶ Cut a piece of polypropylene:
 - thickness, 5 mm;
 - width, 2 cm;
 - length, 7 cm.



- ▶ First the reinforcement (heated at the same time as the polypropylene) is placed on the plaster model, then the second layer is vacuum-moulded immediately to obtain a perfect seal between the two layers.



3.4 Installation of Tamarack Flexure Joint™

On the plaster model, mark the position of the joint axis:

- laterally, at the apex of the malleoli;
- medially, slightly posterior to the distal tip of the malleoli.

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

- ▶ Use the moulding dummies to form a snugly fitting cavity for the Tamarack Flexure Joint™.

Nail them vertically onto the plaster model so that the midpoint is located on the ankle axis.



Pull a stocking (cotton stockinet is too thick) over the plaster model.

3.5 Vacuum moulding of the polypropylene

Follow the procedure described in section 1.3 (page 6), taking into account the presence or absence of a posterior reinforcement (section 3.3, page 18).

3.6 Preparation of the polypropylene shell

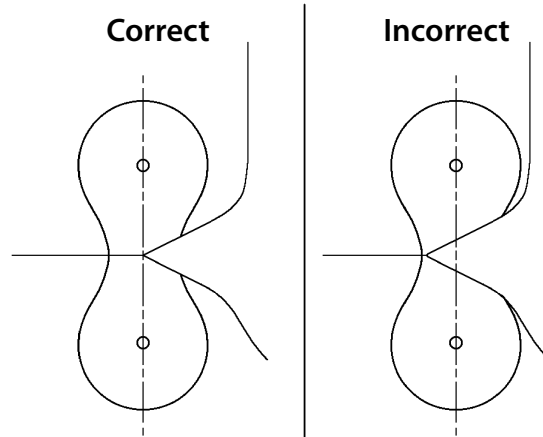
Draw the trim line on the polypropylene as explained in section 3.2 (page 18).

Cut *only* the contour of the orthosis with an oscillating saw. Do not cut along the separation between foot section and calf section.

Remove the plastic shell from the plaster model.

Extract the moulding dummies and the stocking from inside the AFO.

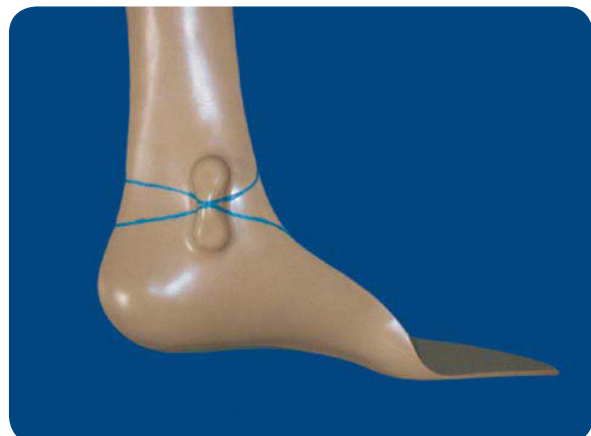
- ▶ Draw the separation line between the foot section and the calf section:
 - Mark the middle of the cavities created by the dummies.
 - Draw a “V” anterior to the midline of each cavity. Ensure that the “V” does not extend backwards past the centre of the cavity.



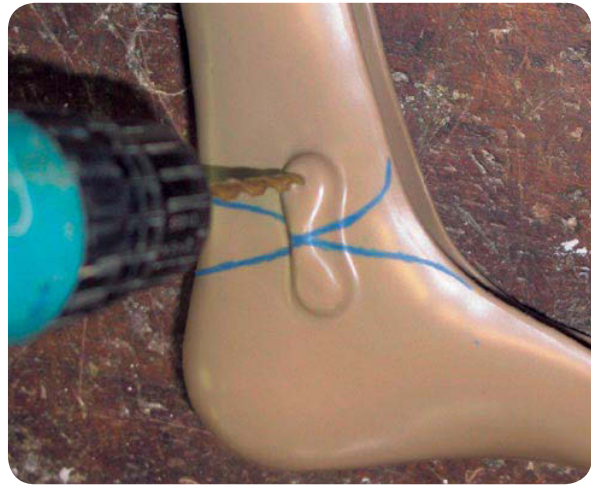
- ▶ For AFO *with plantar flexion control*, draw a horizontal line posterior to the marks joining the two sides.



- ▶ For AFO *with free plantar flexion*, draw a “V” posterior to the midline of each cavity. Ensure that the “V” does not extend forward past the centre of the cavity.

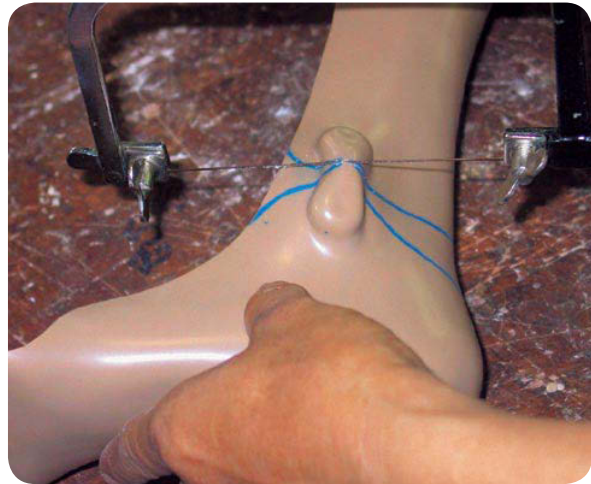


- ▶ Drill holes at the dimples left by the holes in the moulding dummies:
 - 5 mm for large size;
 - 4.5 mm for small size.



- ▶ Use a *thin-bladed* saw (1/16" blade kerf or less) to separate the foot section from the calf section.

Do not use an oscillating saw because too much material is lost along a ragged, wide cut line.



Smooth the trim line edge with a hand deburring tool or a piece of glass. *Do not grind the trim line because this will reduce flexure coverage and reduce the ability of the cavity to anchor and control the flexure effectively.*

- ▶ Insert the Tamarack Flexure Joint™ and secure with metal fasteners and anchoring screws.

Depending on the thickness of the polypropylene, it may be necessary to adjust the length of the screws if the ends protrude inside the AFO.



3.7 Preparation of the straps

For the proximal strap, follow the procedure described in section 2.6 (page 14).

In some cases the patient might need a distal strap. If so, follow the procedure described in section 2.7 (page 15).

3.8 Initial fitting and finishing

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

The initial fitting is performed in accordance with P&O standards.

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

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

Glue the flexure anchoring screws with a removable thread-locking compound (Loctite).

4

AFO ANTI-TALUS (ANTERIOR SHELL)

4.1 Moulding of EVA

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

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

Do not cover the foot, to avoid an increase of volume which may prevent the patient from wearing normal shoes.

Follow the procedure described below, or go on to the next section if the case does not require EVA.

Position the plaster model with the forefoot pointing upwards.

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

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

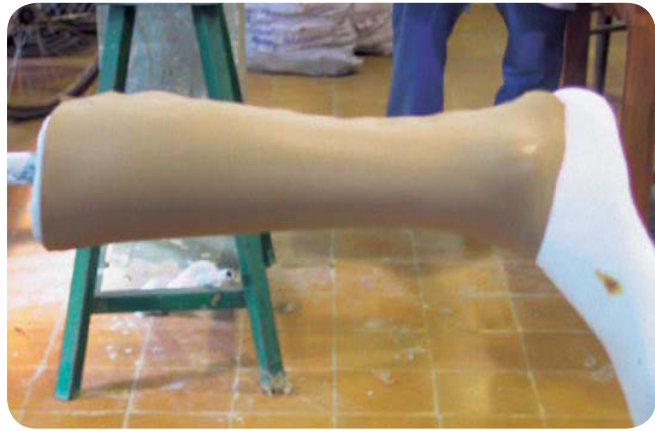
Drape the EVA over the plaster model manually and hold it in place until it has cooled completely.



- ▶ 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.



4.2 Orthosis trim line

- ▶ Mark the orthosis trim line as follows:

- A** The top must be horizontal, 2 cm below the tibial tubercle.
- B** On the leg, 1 cm posterior to the mid-line.
- C** On the ankle, at the top of the malleoli to facilitate donning.
- D** On the forefoot, clear the sides and top of the toes and the head of the metatarsus completely, passing below them. *This will allow the polypropylene to follow the movement of the metatarsophalangeal joints.*



4.3 Plastic reinforcement

The presence of channels in the plastic significantly improves its strength. There are several ways of making these channels.

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

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 axes.

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.



4.4 Vacuum moulding of the 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 the ankle will make it necessary to stretch the polypropylene too thinly.

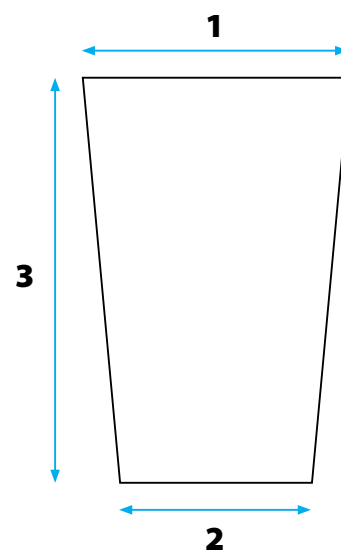
If this has not yet been done, pull a stocking over the plaster model. For maximum efficiency the EVA used to channel the polypropylene must not be covered with a stocking.

Dust the stocking with talcum powder.

Measurement of the polypropylene sheet:

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

PP 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 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.

4.5 Preparation of the polypropylene shell

Draw the trim line on the polypropylene as explained in section 4.2 (page 23).

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

Remove the plastic shell from the plaster model.

Remove the stocking from inside the AFO.

Grind the orthosis trim line and smooth it.

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

4.6 Preparation of the straps

For the proximal strap, follow the procedure described in section 2.6 (page 14).

In some cases the patient might need a distal strap. If so, follow the procedure described in section 2.7 (page 15).



4.7 Initial fitting

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

The initial fitting is performed in accordance with P&O standards.

- ▶ 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.



4.8 Finishing

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

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

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 • OPLAEVAFLIVO6 • OPLAEVAFKIN06	EVA 6 mm Terra, olive or beige colour	Each	As required
None	Nylon stockinet	Piece	1
According to colour and thickness: • OPLAPOLYCHOC03 • OPLAPOLYCHOC04 • OPLAPOLYCHOC05 • OPLAPOLYLIV03 • OPLAPOLYLIV04 • OPLAPOLYLIV05 • OPLAPOLYSKIN03 • OPLAPOLYSKIN04 • OPLAPOLYSKIN05	Homopolymer Terra, olive or beige colour 3, 4 or 5 mm thickness	Each	As required
For the TAMARACK Flexure Joint™:			
According to size: • OCPOSOOTTAL • OCPOSOOTTAS	Large size (740L) Small size (740S)	Piece	1
EHDWGLUEL243	Glue, Loctite 243, blue, threadlock, 50-ml bottle	As required	4
For the proximal strap:			
OSBOSTRVP440	Strap, Velcro, PVC, with loop, brown, 400 x 40 mm	Piece	1
OHDWRIVET131	Rivet, tubular, 13 mm x 12 mm	Piece	2
<i>or</i>			
OSBOVSB030	Strap, polyester, black, 40 mm	cm	25
None	Strap, Velcro, 40 mm	cm	20
None	Loop, 40 mm x 100 pieces	Piece	1
OHDWRIVET131	Rivet, tubular, 13 mm x 12 mm	Piece	2
For distal/instep 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	20
None	Strap, Velcro, 25 mm	cm	15
OSBOVSB035	Loop, 25 mm x 100 pieces	Piece	1
OHDWRIVET131	Rivet, tubular, 13 mm x 12 mm	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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