Rehab Impulse™

MANUFACTURING GUIDELINES

Polypropylene Thermoforming for Prosthetics-Orthotics



Promoting Independent Lifestyle

rehabimpulse.org

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Foreword

The polypropylene (PP) technology

This technology was created by the International Committee of the Red Cross (ICRC) in 1979. Its use is appropriate to specific contexts i.e., countries affected by war and low-income or developing countries.

The technology has been tailored to meet the needs of the physically disabled in the countries concerned.

The features of this technology are:
- Freedom from the transport and storage restrictions of other materials and no shelf-life constraints;
- Durable, comfortable, easy for service users to use and maintain;
- Its hard cosmetic shell helps the device maintain a good appearance throughout its life;
- Easy for P&O technicians to learn, use and repair;
- Standardized but compatible with the environment in different regions of the world;
- Low-cost but modern and consistent with internationally accepted standards (ISO-certified and CE-marked);
- Does not require expensive machines, tools, and a large setup;
- Easily available.

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

The Rehab'Impulse Brand – owned by ICRC, made by Alfaset

The ICRC registered the Rehab'Impulse trademark in 2019 with the aim of developing a brand identity for its technology. The Rehab'Impulse brand remains under the ownership of ICRC, while the components are manufactured in Switzerland by the Alfaset Foundation, a social enterprise employing persons with disabilities.

Objectives of the manuals

The "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 good practice.
- To provide support for training in the use of this technology.
- To promote and enhance Rehab'Impulse technology.

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

Rehab Impulse™

Introduction

This document describes the process of **thermoforming (draping)** polypropylene sheets on a positive plaster model – the basic technological operation involved in manufacturing prosthetic and orthotic devices using polypropylene technology.

The thermoforming operation requires a proper technique and know-how, to achieve good results, it is important to pay close attention to a number of details.

The features of a good orthopedic device made of polypropylene – not only durability but also those linked with the initial shape of a positive plaster model – depend entirely on the proper thermoforming technique being used.

An external cosmetic cover determines the look of a prosthesis. In some cases, the polypropylene can also take some load (exoskeleton weight-bearing or KAFO[1] with ischial seat). If this is the case, there are some specific points to consider.

The thermoforming operation is, therefore, not just about wrapping the plaster positive model with a heated polypropylene sheet. It is actually rather a delicate operation and has a major impact on the final quality of the prosthesis or orthosis.

Before getting into the details of the thermoforming operation itself, section 1 of this document clarifies a few points, including:

- Characteristics of the polypropylene raw material
- Heating temperature and duration
- Installing a vacuum device
- Preparing the positive plaster model.

[1] Knee Ankle Foot Orthosis

1. General points

1.1 Polypropylene characteristics and use

Polypropylene (PP) is a thermoplastic. That means the material softens when heated.

One of the characteristics of thermoplastic is its high dilation coefficient or coefficient of thermal expansion (CTE). The dilation coefficient is the length increase (dilation) that the material experiences when its temperature is raised. All materials have an increase in length when heated – this is the result of an increase in the distance between the molecules – but the increase is much more significant in plastics than in wood or metal, for example.

The opposite effect of high dilation is high contraction. Obviously, materials that expand when heated tend to contract when cooled. This characteristic is very significant and should be taken into account for successful thermoforming.

The pictures below show the scale of PP contraction during the cooling process. Here, the PP was cut as soon as its rigidity was sufficient for cutting. Once it was completely cool, the distance between the two edges was almost 8 mm (Fig. 1). The length retraction of the socket if it is allowed to fully cool, is about 5 mm (Fig 2).



Fig 1

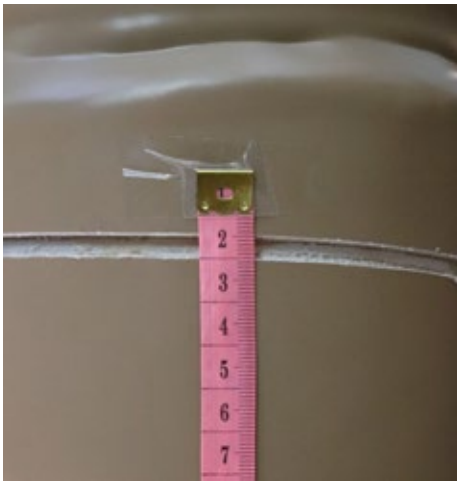

Fig 2

The consequences of PP's tendency to contract applies to the PP sheet in all directions: not only can it change the length of the sheet, but also the shape of the orthopedic device. This is not noticeable during PP heating or moulding, but can be observed during or after cooling.

Consequences for the dimensions of the PP devices

Once the positive model made of Plaster of Paris (POP) is removed, whether it is a PP socket, a PP orthosis shell, or a PP cosmetic cover, these will be slightly smaller than their original shapes. You have to anticipate this.

Consequences for the shape of orthopedic devices

1 **Convex forms** (Fig 3)
The plaster's incompressibility will oppose PP shrinkage during cooling.
Part of the shrinkage will be compensated by permanent mechanical PP lengthening and another part by the PP's elasticity. This elastic lengthening will disappear once the POP model is removed, and final dimensions will be slightly smaller.

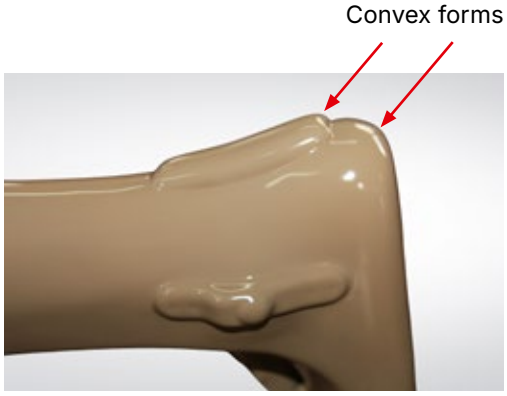

Fig 3 Thermoforming of AFO with ankle joints

2 **Concave forms**
As cooling shrinkage exerts heavy forces on the PP in all directions, concave forms will tend to reduce. Internal PP tensions mean that the PP will try to span the shortest distance between the nearest convex points of the positive plaster model (represented in Fig 4 by the dotted line).
This force will tend to delaminate the PP socket from the positive cast and decrease the positive's concave forms in the direction indicated by the two arrows.

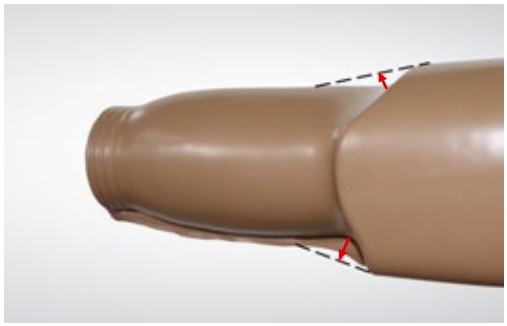

Fig 4 Thermoforming of a TF socket

All concave areas of the shape are concerned; these are actually the most crucial areas for a well-fitting prosthesis/orthosis. The main ones are:

For Trans-Femoral (TF) prosthesis quadrilateral sockets:
- Ischial seat
- Inguinal area (Scarpa's triangle)

For Trans-Tibial (TT) prosthesis sockets:
- Patella tendon bar
- Popliteal area
- Supracondylar suspension areas

For Trans-Humeral (TH) prosthesis sockets:
- Scapula suspension areas

For Trans-Radial (TR) prosthesis sockets:
- Epicondylar suspension areas

For Knee-Ankle-Foot Orthosis (KAFO) shells:
- Ischial seat (when there is one)
- Plantar arch

For Ankle-Foot Orthosis (AFO) shells:
- Plantar arch

For Elbow and/or Wrist-Hand Orthosis (E/WHO) shells:
- Hand palm areas

In order to avoid drastic changes and minimize the impact of retracting forces during cooling, we recommend shaping the positive model's proximal part so that it is slightly conical from the proximal end outwards to the distal end (the opposite is more often the case). That way, after cutting, the PP will retract easily as it cools without being hindered by the shape of the positive model.

In Fig 5 the positive model's proximal shape is slightly conical from the proximal end reducing towards to the distal end (green lines = correct). If the shape was conical in the opposite direction (red dotted lines = incorrect), the PP would not be able to retract properly during cooling, which would lead to deformations of the socket's concave areas.

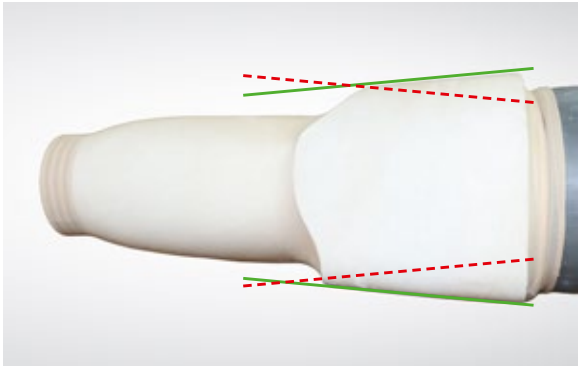

Fig 5

1.2 Heating PP

The essential factors for successful thermoforming are:

a) Heating temperature
b) Heating duration
c) Temperature homogeneity in the oven (Fig 6)
d) Teflon lining condition



Fig 6

a) Heating temperature

This depends on the type of polymer used. There are actually two different polypropylene-based plastics that are widely used in prosthetics and orthotics:

- Homopolymer: A polymer whose chain consists of macro-molecules (monomers) with identical composition and structure. This is the type that is generally the most seen in the low-resourced contexts Rehab'Impulse technology is used.
- Copolymer: A polymer whose chain consists of macro-molecules (monomers) with different composition and structure making it more flexible and less brittle in cold environments.

Two points to bear in mind concerning heating:

- **Internal oven temperature should not exceed the proper level.**

Operators sometimes increase the temperature to >200°C to shorten the heating time. This is not advised because polypropylene, like all thermoforming plastics, has low heat conductivity and needs time for the internal temperature of the sheet to reach the same temperature as the surface. If the oven is too hot, the surface of the PP sheet quickly reaches moulding temperature, but the internal temperature is not high enough. The end result will be poor.

- **The temperature controller display may not be accurate.**

Usually, the temperature controller is properly calibrated by the oven manufacturer and does not need to be adjusted. However, you should check the actual temperature inside the oven with a special thermometer (Fig 7) from time to time and then adjust the controller if necessary.



Fig 7

Convection and Infrared ovens

Two types of ovens are commonly used for thermoforming polypropylene: convection ovens (Fig 8) and infrared (IR) ovens (Fig 9).

Convection ovens are the traditional type. They heat the air within the oven chamber, and the heated air then warms the polypropylene sheet by convection. Because the entire chamber must reach the required temperature before the material can be heated effectively, convection ovens are typically left running throughout the working day.



Fig 8

Infrared (IR) ovens heat the polypropylene directly using infrared radiation rather than heating the air inside the oven. As a result, they reach operating conditions much more quickly and only need to be switched on when a sheet is to be heated. This makes IR ovens more energy efficient and economical to operate.

Most infrared ovens also allow heating times for different material thicknesses to be programmed and stored, enabling quick and consistent selection during routine thermoforming.

Whatever type of oven is used, it's important to have it calibrated annually.



Fig 9

b) Heating temperature and duration

This depends on the thickness of the PP sheet and the type of oven used (convection or infrared).

Tip:
The pigment used to colour raw polypropylene can actually affect the plastic properties of the sheets. As a result, there may be slight differences in pliability between the three colours (beige, olive and terra) during thermoforming and welding. You may have to adjust the time in the oven for thermoforming or the heat gun temperature for welding accordingly.

Recommended duration according to material thickness

Homopolymer Polypropylene sheet Thickness	Convection Oven (180° C – 200° C)	Infrared Oven (180° C – 200° C)
3 mm	10 – 15 minutes	5 – 8 minutes
4 mm	12 – 18 minutes	6 – 10 minutes
5 mm	15 – 20 minutes	8 – 12 minutes

c) Temperature homogeneity in the oven

Experience has shown that some ovens do not heat evenly and the heat is not well distributed inside the oven. To check whether your oven heats evenly, observe a large sheet of PP during heating: the appearance of the whole surface should change (colour and shine).

The three factors that most frequently disrupt temperature homogeneity are:
- Oven door seal faults – you can easily detect and rectify these defects yourself;
- Imbalance between lower and upper heating elements (or between different segments of the same heating element) - check for faulty or non-functioning heating elements and replace if required;
- Frequent door opening – technicians often test PP readiness by opening the oven door and checking it manually by touching the edge of the sheet, but this should be kept to a minimum because the oven temperature drops drastically, affecting the continuity of PP heating.

d) Teflon liner condition (Fig 10)

The oven tray should be covered with Teflon sheeting (non-stick temperature-resistant material) that stops polypropylene sticking to the metal oven tray while it is heating in the oven. Oven manufacturers usually supply ovens with these liners fixed on the tray and ready to use.

Check the condition of the Teflon – the surface must be clean and free of holes etc. If you discover such defects, change the Teflon liner to prevent damage to the PP sheet, tray or oven.



Fig 10

1.3 Installing suction cones and a vacuum device

Conducting regular thermoforming operations successfully and comfortably depends on proper installation and availability of a good-quality vacuum system, as well as a suitable working environment in the thermoforming area (typical set-up shown on Fig 11).

For more information, refer to the ICRC reference book *"Physical Rehabilitation Centre – Architectural Programming Handbook"* [2] (Fig 12).



Fig 11



Fig 12

Special enveloping cones are used to hold the positive plaster models. They make it easy to keep the positive plaster models in place and ensure efficient suction during the thermoforming operation.

There are three sizes of cones:

- Large size for large positive plaster models (e.g. TF, KAFO) (Fig 13)
- Medium size for average positive plaster models (e.g. TT, adult AFO) (Fig 14)
- Small size for small positive plaster models (e.g. Trans-Radial (TR) or orthoses for children)

To protect vacuum cones and maintain suction quality, it is absolutely forbidden to use any cutting device over the cones that could damage them (e.g. oscillating saw, knife).

For an ergonomic working position, the height of the cone's axis should be between 1.00 and 1.15 m from the ground.

Match the cone size and the positive model size as much as possible:

- Smaller positive plaster models on the smaller cones
- Medium/average positive plaster models on the medium cones
- Large positive plaster models on the large cones

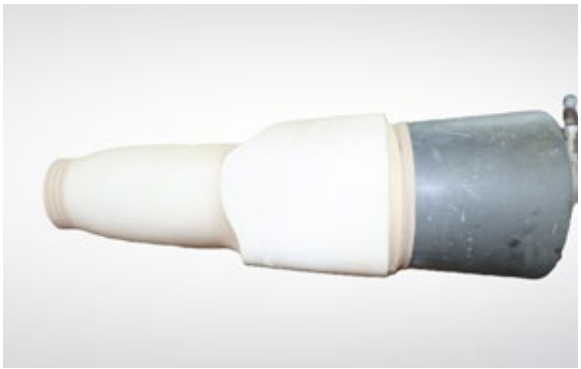

Fig 13



Fig 14

[2] Physical Rehabilitation Centre - Architectural Programming Handbook https://www.icrc.org/en/publication/4133-physical-rehabilitation-centres-architectural-programming-handbook

Vacuum devices contain various elements that must be checked regularly without fail:

Water-based vacuum pump (Fig 15)

Make sure the pump is always clean without dust. Maintain the right water level of the water tank (between the “min” and “max” marks on the tank). Check every three months and fill up if the level is at “min” or below. Replace the water at least once a year. In cold environments, add antifreeze to the water. Measure and control the vacuum level of the manometer.



Fig 15

Electrical vacuum pump (Fig 16)

Make sure the pump is always clean without dust.

Regular checks (every 2 weeks):

- Air filter
- Engine oil level
- The hose that is connected between the vacuum pump and the suction cones to ensure that there is no water inside coming from the wet positive plaster models.
- Measure and control the vacuum level of the manometer.



Fig 16

All the equipment mentioned can be ordered from the Rehab’Impulse catalogue.

1.4 PP sheet dimensions

For a successful thermoforming operation, follow the guidelines below for cutting PP sheets.

Trans-Tibial Prostheses
The diagram adjacent shows an example of the dimensions that should be taken from the positive model (Fig 17). Here, the dimensions are:

- **a** Circumference at the femoral condyles (biggest dimension)
- **b** Length of the positive plaster model
- **c** Circumference at the distal part of the positive plaster model (smallest dimension)

The dimensions of the corresponding PP sheet should be as shown in the diagram below (Fig 19).

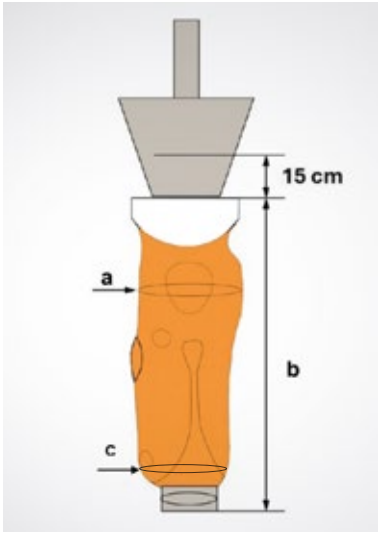

Fig 17

Trans-Femoral Prostheses:
The diagram adjacent shows an example of the dimensions that should be taken from the positive model (Fig 18). Here, the dimensions are:

- **a** Largest circumference at the proximal part of the positive plaster model (biggest dimension)
- **b** Length of the positive plaster model
- **c** Circumference at the distal part of the positive plaster model (smallest dimension)

The dimensions of the corresponding PP sheet should be as follows (Fig 19).

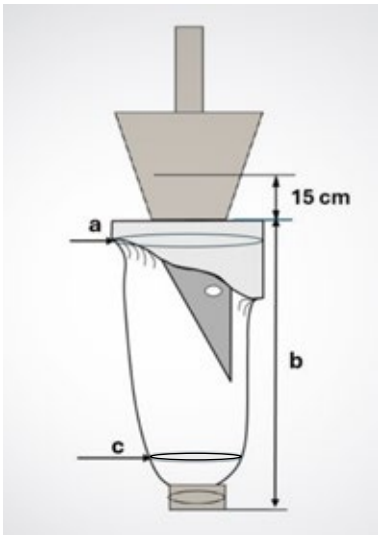

Fig 18

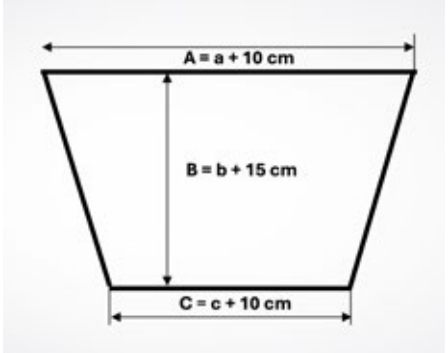

Fig 19

Practice has shown that pieces with the same dimensions (i.e. patterns) may frequently be used for the same operations, especially for sockets of Trans-Tibial and Trans-Femoral prostheses. That means it is possible to cut the entire sheet into standard pieces. This helps organize work and minimize waste to improve efficiency. However, pre-cut pieces can be used only if their dimensions are within the guidelines given in Fig 20 and Fig 21. If not, a PP blank with the correct dimensions must be cut specially (see relevant Manufacturing Guidelines).

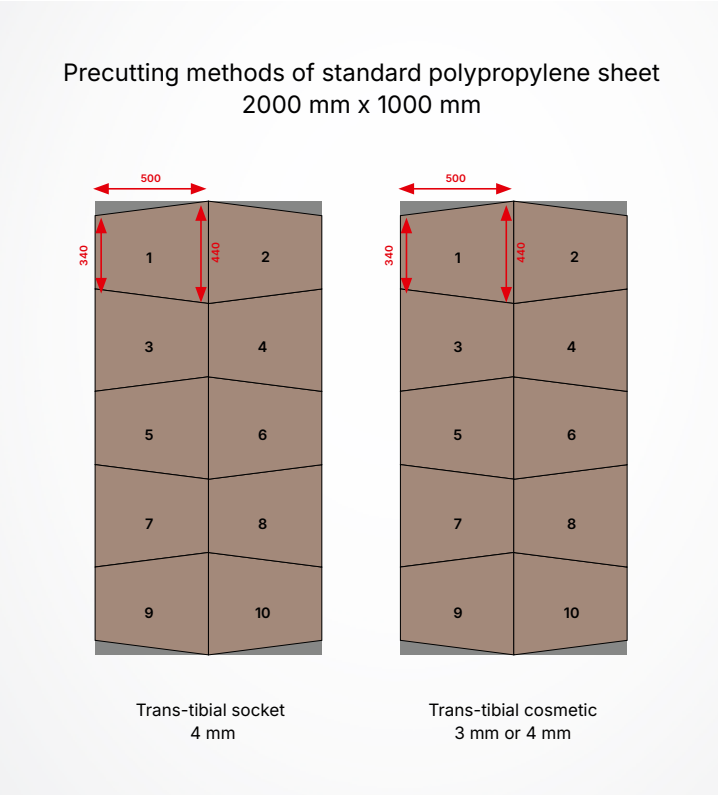

Fig 20

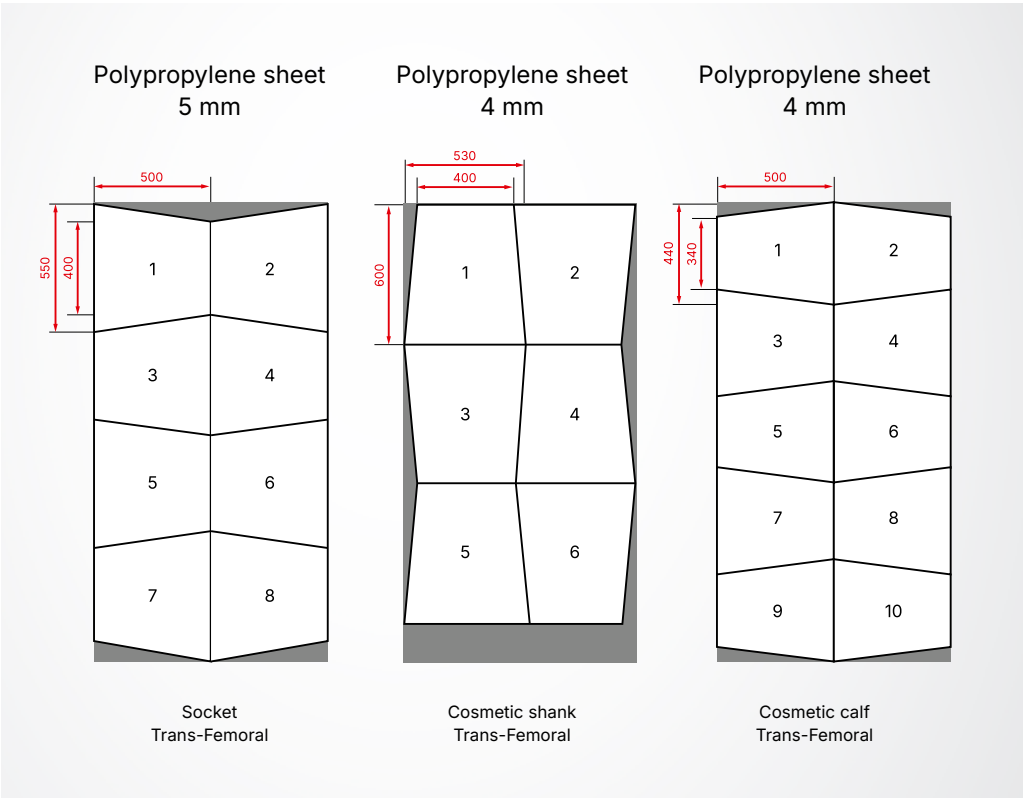

Fig 21

1.5 PP thickness

Suppliers make PP of different standard thicknesses: 3 mm, 4 mm and 5 mm (Fig 22).
The thickness should be selected according to the desired rigidity (or flexibility) of the socket (or of the entire device in the case of an orthosis). Some recommendations are given below.

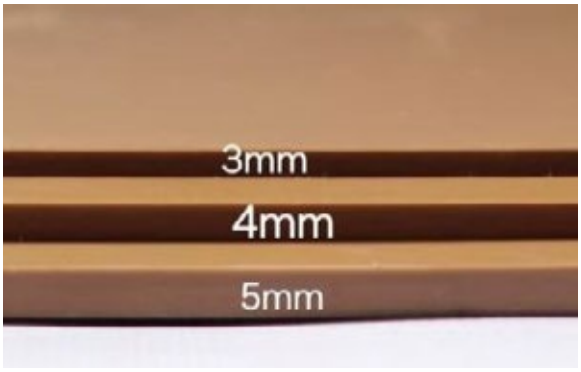

Fig 22

For prostheses:
- 3 mm – for upper-limb sockets and cosmetic covers.
- 4 mm – for sockets for lightweight service users (under 60 kg) and cosmetic covers.
- 5 mm – for sockets for medium and heavyweight service users (over 60 kg).

For orthoses:
- 3 mm – foot orthoses (FO) and ankle-foot orthoses (AFO) for children and lightweight service users (20-30 kg and under) as well as upper-limb orthoses.
- 4 mm – FO, AFO and knee-ankle-foot orthoses (KAFO) for mediumweight service users (60-65 kg).
- 5 mm – AFO and KAFO for heavyweight service users (over 65 kg).

1.6 Preparing the positive plaster model

The rectified positive plaster model should be smoothed using wire mesh or sandpaper, cleaned thoroughly and then fixed on a cone of the right size (see above). To facilitate the suction action, the positive plaster model should be covered by a layer of nylon lady's stocking, perlon or cotton tubular stockinette, and lightly dusted with talcum powder to prevent it sticking to the hot PP.

In addition to the explanations of the previous paragraph above, for large and long positive plaster models (such as adult-sized KAFOs, for example), it is recommended to staple a cotton tubular stockinette cord along the entire length of the positive, on the part of the PP that will not be used, in order to create an airflow that will allow suction to be more effective from top to bottom (Fig 23).

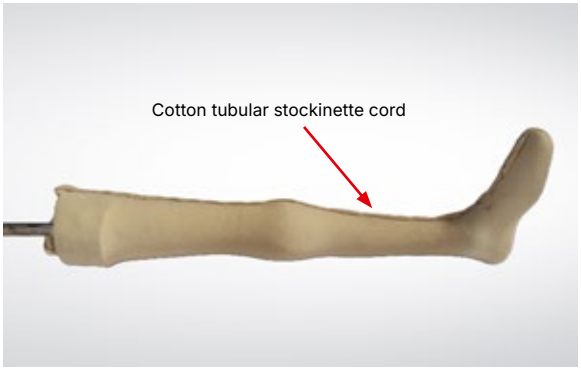

Fig 23

Some technicians use too much talcum powder, especially over the cotton tubular stockinette, so that it does not mark and stick to the surface of the PP. However, bad results are due to bad practices (excessive heating time, temperature too high, etc.) and talcum powder will not mask the consequences of this. Stockinette/stockings leave a light pattern on the internal surface of the socket. This is normal.

Be very careful with the use of talcum powder over the positive plaster model if you want to obtain a solid seam when manufacturing prosthetic sockets.

Use talcum powder when you don't want two PP sheets to stick to each other or when you want to be able to open a cosmetic cover without having to cut it. In such cases, lightly coat the PP sheet with talcum powder before putting it in the oven. The talcum powder prevents the two PP surfaces from sticking together so it is easier to separate them along the contact line once they are completely cool.

Use dry or sealed positive plaster casts. This prevents water vapour being produced between the cast and the hot polypropylene, which leaves a blister effect to the plastic (Fig 24).
Moulding over a damp positive plaster cast also causes the polypropylene to cool quicker on the inside than the outside, thus introducing stress and "springing" (plastic not fitting intimately with the cast). In such cases, the best course of action is to immediately remove the PP (taking care not to break the positive plaster model) and repeat the thermoforming process.



Fig 24

2. Thermoforming operation

If all the precautions described above are followed, the thermoforming operation should be straightforward.

When the PP is taken out of the oven (Fig 25 and 26) it starts to cool very quickly. This leaves very little time for the draping operation. We, therefore, recommend that two people carry out the draping phase, especially for large and long positive plaster models. One person should focus on air tightness along the seam, while the other focuses on the cone.



Fig 25



Fig 26

2.1 Draping PP sheets

Prepare the following tools beforehand: gloves, scissors, rubber/elastic strap for tightening around the cone, and stamps to imprint a number on the device (if applicable).

Step 1
Fix the positive plaster model on the right size cone (Fig 27) and cover with cotton tubular stockinette. To prevent the cotton tubular stockinette sticking to the hot surface of the PP, talcum powder may be used in moderation.

Tip: Stuff any gaps between cast and cone with scrap cotton tubular stockinette to prevent a blowhole being sucked into the PP.



Fig 27

Step 2
Properly heat and drape the PP sheet over the positive plaster model and vacuum cone, making sure you keep the symmetry (have the same amount of sheet on either side) and avoid any folds or wrinkles (Fig 28).



Fig 28

Step 3
Press together the flaps hanging below the positive plaster model to turn the PP sheet into an airproof bag and squeeze along the entire length of the seam up to the vacuum cone (Fig 29).

Make sure you keep the seam line straight. This is important for the look and the durability of the device.



Fig 29

Step 4
Once you are satisfied with the air tightness all along the seam and around the cone, the vacuum valve can be opened to enable thermoforming (Fig 30 and Fig 31). Make sure there is air tightness and proper vacuum flow throughout the thermoforming (see the technical tips below).



Fig 30

Step 5
After checking the initial suction and vacuum flow, you can ensure air tightness around the cone using a rubber strap, and then cut off the excess PP (Fig 30); this action also helps to create a good seal. However, take care not to make the seam too narrow or puncture the PP with the point of the scissors.

Tip: For heavier TF or KAFO service users, push a piece of the excess PP into the “ischial seat” area for extra seat strength (Fig 32).

Stamp the device with its registration number if applicable (Fig 33). Then leave the plastic to cool.

Keep the vacuum machine running for at least 8 to 10 minutes to ensure proper thermoforming.



Fig 31

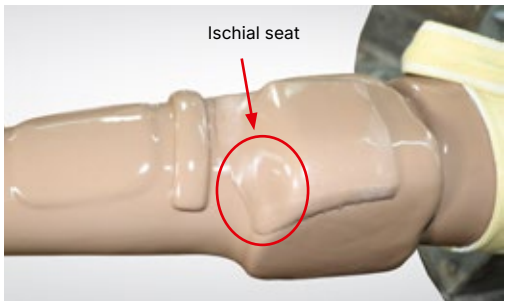

Fig 32



Fig 33

Step 6
For TT and TF sockets, as soon as the PP cools down to 60-70°C (OK to handle), make a circular incision to cut the top off the moulding to allow the PP to retract and thereby prevent deformities of the concave areas of the socket (Fig 34): see section 1.1 "Polypropylene characteristics and use" above.

As previously mentioned, there is not much time for the thermoforming operation (from taking the PP out of the oven to cutting the PP waste and stamping the registration number). Technicians should therefore have streamlined procedures in place and perform them without hesitation.



Fig 34

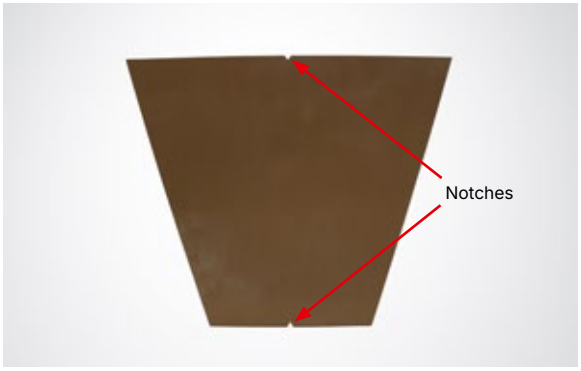

Fig 35



Fig 36

Technical tips

Here are some details to bear in mind:

- Keep the PP sheet symmetrical (same amount of sheet on either side of the positive plaster model) to ensure seam quality.
  The easiest way to achieve this is to make two small notches halfway along the top and bottom edges of the PP sheet, as shown (Fig 35).

- When draping, make sure the notch of the long side of the PP sheet lines up with the centre of the vacuum cone and the notch on the shorter side lines up with the centre of the distal end of the positive plaster model. This will make sure it is symmetrical.

- The proximal edge of the PP sheet should be perpendicular to the vacuum cone and the sheet should never extend beyond the proximal edge of the cone (Fig 36).
  By keeping to this correct positioning, there will be no need to cut the PP on the cone, which leads to unavoidable damage of both the cone and the blade of the oscillating saw. And after cooling, it will be easy to remove the POP positive model with the PP socket/shell from the cone without using any tools.

- Ensure windows are closed and there is no draught, which aids moulding. This prevents uneven cooling and introducing stress into the polypropylene.

2.2 Setting (consolidation) time

After thermoforming, the PP must be left for at least 6 hours before removing from the positive cast – this is the minimum setting (or consolidation) time recommended in the technical literature[3]. If you fail to abide by this, there is a strong chance that the PP thermoforming will lose its proper shape and volume.

[3] Original research article "The effects of cooling time on the dimensional stability of thermoforming polypropylene" - Journal of Prosthetics and Orthotics - Volume 35 . Number 3 . 2023

3. Quality control

The main quality criteria of good thermoforming are as follows:

1. The seam line is perfectly shaped from inside and almost invisible. The cotton tubular stockinette leaves a uniform but not rough pattern on the inside surface of the socket or shell if it is an orthosis (Fig 37).

2. Both sides of the seam line are perfectly bonded along the entire length. The seam has homogeneous structure without any holes, cavities, etc (Fig 38).

3. The PP is perfectly shaped in all the concave shapes of the positive plaster model, as well as in all the grooves of the cup. The grooves are clearly visible from outside. The socket/shell surface is free of bubbles, bumps and any other defects (Fig 39).



Fig 37



Fig 38

Remember that PP is a recyclable material and scraps should therefore be collected in order to be recycled either by your centre (if you have the right machinery) or by a specialized institution if available. Scrap PP requires special disposal, as the process of its chemical disintegration is very long and damaging for the environment.

For detailed information about thermoforming specific devices (e.g. lower-limb or upper-limb prosthetics and orthotics), please refer to the relevant Rehab'Impulse Manufacturing Guidelines.



Fig 39

List of equipment and accessories

Rehab'Impulse Code	Item Description	Used for
74-02508	Water-based vacuum pump with connection kit	Thermoforming
74-00346	Vacuum Pump VA25 Litre - Hr	Thermoforming
74-01570 S	Tube, enveloping suction (small size)	Thermoforming
74-01575 M	Tube, enveloping suction (medium size)	Thermoforming
74-02511 L	Tube, enveloping suction (big size)	Thermoforming
74-01940	Oven Infrared 380V, with 2 Teflon sheet	Thermoforming
74-00903	Roll of Teflon, 1m wide, 10m meter long	Thermoforming
74-02061	Oven Infrared Teflon coating sheet	Thermoforming
74-00744	Glove, heat protection, isothermal, pair, size 10	Thermoforming
74-02530	Oven infrared lamp 460 W / 230 V with reflector 385 mm	Thermoforming
74-02531	Oven infrared lamp 460 W / 230 V with reflector 485 mm	Thermoforming
74-01585	Flexible Hose for vacuum, Ext Dia. 21,7 mm - Int Dia. 16mm - 25m	Connection between vacuum pump & tube
74-01587	Hose Clamp, Dia. 15-24mm	Hose fixation
74-02509	Filter for vacuum pump VA25 Litre - Hr	Vacuum pump maintenance
74-02510	Oil for vacuum pump VA25 Litre - Hr	Vacuum pump maintenance
74-01579	Thermometer	Oven temperature control
74-00911	Scissors, trimming scissor, "tailor", 235mm	Polypropylene cutting
74-00787	Punch numbers, 9 numbers, Size 6mm, in PP box	Device's registration number
74-00778	Punch letters, 26 letters, Size 4 mm, plus dot, in PP box	Device's registration number

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