MANUFACTURING GUIDELINES

PROSTHETICS-ORTHOTICS THERMOFORMING POLYPROPYLENE (DRAPING TECHNIQUE)

Physical Rehabilitation Programme

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Foreword

The ICRC polypropylene technology

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

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

Therefore, it must be: durable, comfortable, and easy for patients to use and maintain; easy for technicians to learn to use and repair; standardized, but compatible with the climate in different regions of the world; affordable, but modern and consistent with internationally accepted standards; readily available.

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

For all these reasons, the ICRC developed 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 Programme in 1979, locally available materials such as wood, leather and metal were used, and orthopaedic components manufactured locally.
In the early 1990s the ICRC began to standardize the techniques used in its various projects around the world; this was done for the sake of uniformity, but an even more important consideration was improving the quality of services for people with physical disabilities.

Polypropylene was introduced into ICRC projects in 1988, for manufacturing 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 (PP) and ethylene vinyl acetate (EVA), and now of polypropylene and polyurethane, has 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 care for service users and training for personnel at country level.

Objectives of the manuals

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

The main aims of these informative manuals are as follows:
to promote and enhance the 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 good-quality services.

Physical Rehabilitation Programme
Health Unit
Assistance Division
ICRC

1 INTRODUCTION

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

The thermoforming (or thermodraping) operation applies to the manufacturing out but nevertheless requires the 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 socket – not only solidity but also those linked with the initial shape of a positive – depend entirely on the proper thermoforming technique being used.

An external cosmetic cover determines the look of a prosthesis. In some cases (e.g. trans-tibial (TT) prostheses and the thigh part of trans-femoral (TF) prostheses), this cover can also take some load (exoskeleton weight-bearing). If this is the case, there are some specific points to consider.

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

Before getting into the details of the thermoforming operation itself in section 3, section 2 of this document clarifies a few issues, including:

- who carries out the thermoforming operation
- characteristics of the polypropylene raw material
- heating: temperature and duration
- installing a vacuum device
- preparing the positive mould.

2 GENERAL POINTS

2.1. Who carries out the thermoforming operation?
The set-up of physical rehabilitation centres varies and depends on many factors, such as the number of employees dedicated to prosthetic and orthotic device production.

Big centres with a significant production volume generally have some employees specialized in the manufacturing phases of the thermoforming operation. In medium and small centres, the technicians themselves usually carry out thermoforming. But whatever the centre's size and set-up, the prosthetist-orthotist who took the cast is responsible for the device's quality at the end of the day.

This means that even if specially trained bench workers carry out the thermoforming operation, the result (and consequently the final quality of the device) remains the responsibility of the prosthetist-orthotist who delegates this task to them. Prosthetist-orthotists must make sure they give all the necessary instructions for the staff member in charge to perform the thermoforming process properly. Regular supervision and mentoring by senior prosthetist-orthotists is therefore essential to ensure production quality.

2.2. 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. The dilation coefficient is the length increase (dilation) that the material experiences when its temperature is raised. All materials increase their length when heated – this is the result of an increase in the distance between the molecules in their lattice – but the increase is much more significant in plastics than in woods or metals, 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 real length retraction of the socket, as we see in Fig. 2, is about 5 mm.


Fig.1

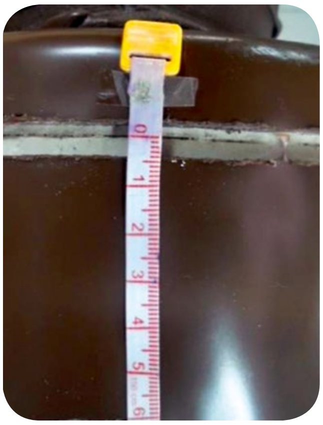


Fig.2

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 socket. This is not noticeable during the PP heating or moulding, but can be observed during or after cooling.

Consequences for the dimensions of sockets or cosmetic covers
Once the plaster of Paris (POP) mould is removed, the socket or the cosmetic cover will be slightly smaller than the original shape. You have to anticipate this.

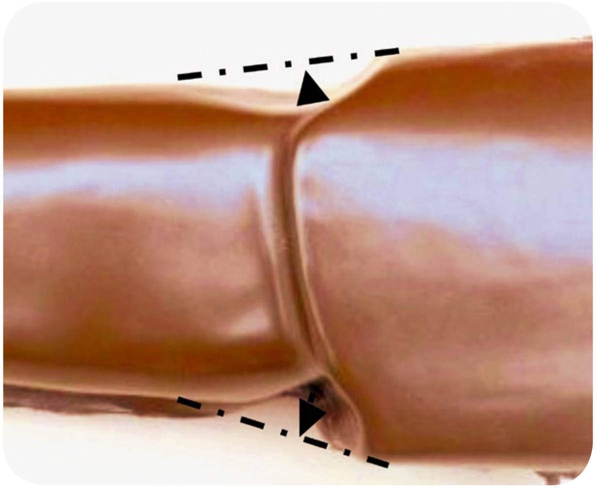


Fig. 3

Consequences for the shape of sockets or cosmetic covers

1. Convex forms: 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 mould is removed, and final dimensions will be slightly smaller.
2. Concave forms: As cooling shrinkage exerts heavy forces on the PP in all directions, concave forms will tend to disappear. Internal PP tensions mean that the PP will try to span the shortest distance (represented in Fig. 3 below by the dotted line) between the nearest convex points of the positive. This force will tend to delaminate the PP socket from the positive and decrease the positive's concave forms in the direction indicated by the arrows.

All concave areas of the shape are concerned; these are actually the most crucial areas for a well-fitting socket:
For TF quadrilateral sockets:

- ischial support
- inguinal area (Scarpa's triangle)

For TT sockets:

- patella tendon support
- popliteal area
- supracondylar suspension areas.

In order to avoid drastic changes and minimize the impact of retracting forces during cooling, we recommend shaping the positive's proximal part so that it is slightly conical from the proximal side outwards to the distal side (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.

In Fig. 4 the positive's proximal shape is slightly conical from the proximal side outwards to the distal side (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.

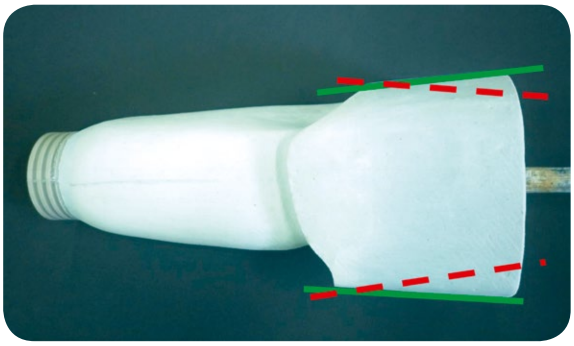


Fig. 4

2.3. Heating PP

The essential factors for successful thermoforming are:

- heating temperature
- heating duration
- temperature homogeneity in the oven
- Teflon lining condition.

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
- Copolymer: A polymer whose chain consists of macro-molecules (monomers) with different composition and structure.

The heating temperature for these two materials is different. Remember to set your oven to the right temperature:

175-180°C for homopolymer
165-170°C for copolymer.

Two points to bear in mind concerning heating:

- **Internal oven temperature should not exceed the proper level.**
  Operators sometimes increase the temperature to 200-210°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 set 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 from time to time and then adjust the controller if necessary.

Heating duration

This depends on the thickness of the PP sheet. Here is an easy method for estimating heating time: 5 minutes for each millimetre of thickness + 10 minutes.

Hence:
For 3 mm: heating duration is (5 x 3) + 10 = 25 min
For 4 mm: heating duration is (5 x 4) + 10 = 30 min
For 5 mm: heating duration is (5 x 5) + 10 = 35 min

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 brown) during thermoforming and welding. You may have to adjust the time in the oven for thermoforming or the heat gun temperature for welding.

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 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) – elimination of defects usually requires intervention by a specialist;
- 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.

Teflon liner condition

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.

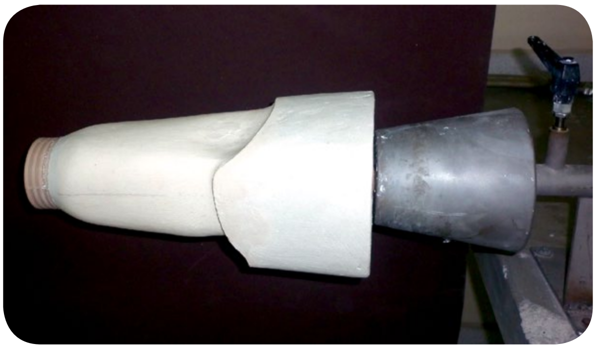
2.4. Installing cones and a vacuum device

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 below). For more information, refer to the *Physical rehabilitation centres: Architectural programming handbook*.

Special cones to fix positives can be ordered from the ICRC Standard List (or CRE products catalogue). They make it easy to fix the positive in place and ensure efficient suction during the thermoforming operation.

There are three sizes of cones:

- large for large positives (e.g. TF)
- medium for average positives (e.g. TT)
- small for small positives (e.g. trans-radial (TR) or orthoses for children).

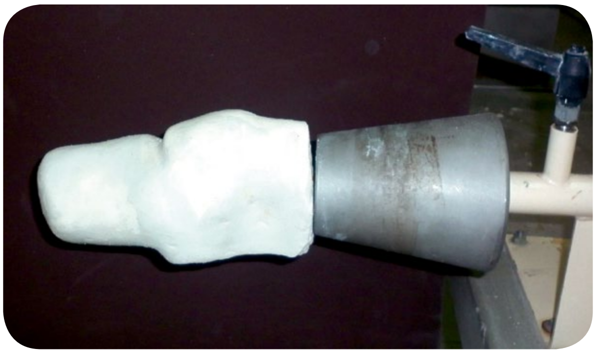


To protect vacuum cones and maintain suction quality, it is absolutely forbidden to use any cutting device over the cones that could damage them (e.g. oscillating saw, knife).

For an ergonomic working position, the height of the cone's axis should be between 1.05 and 1.15 m from the ground.

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

- smaller positives on the smaller cones
- medium positives on the medium cones
- large positives on the large cones.



Vacuum devices (the example below is a CRE device used by the ICRC; other devices available on the market could be used) contain three elements:

1. Water pump

2. Water tank:
Maintain the right water level (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.

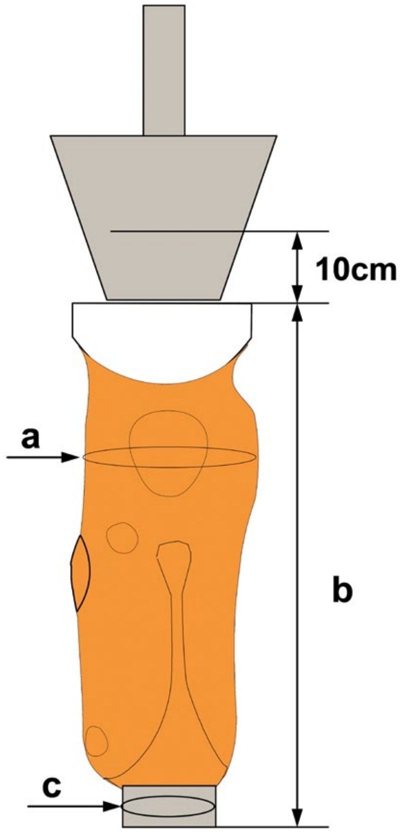
3. Manometer:
Measures and controls the vacuum level.

2.5. PP sheet dimensions

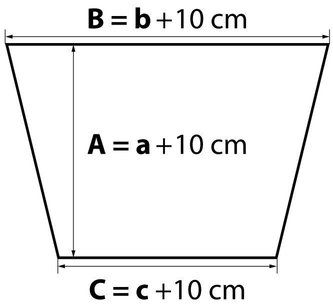
For a successful thermoforming operation, follow the guidelines below for cutting PP sheets.

The diagram opposite shows an example of the dimensions that should be taken from the positive. Here, the dimensions are:

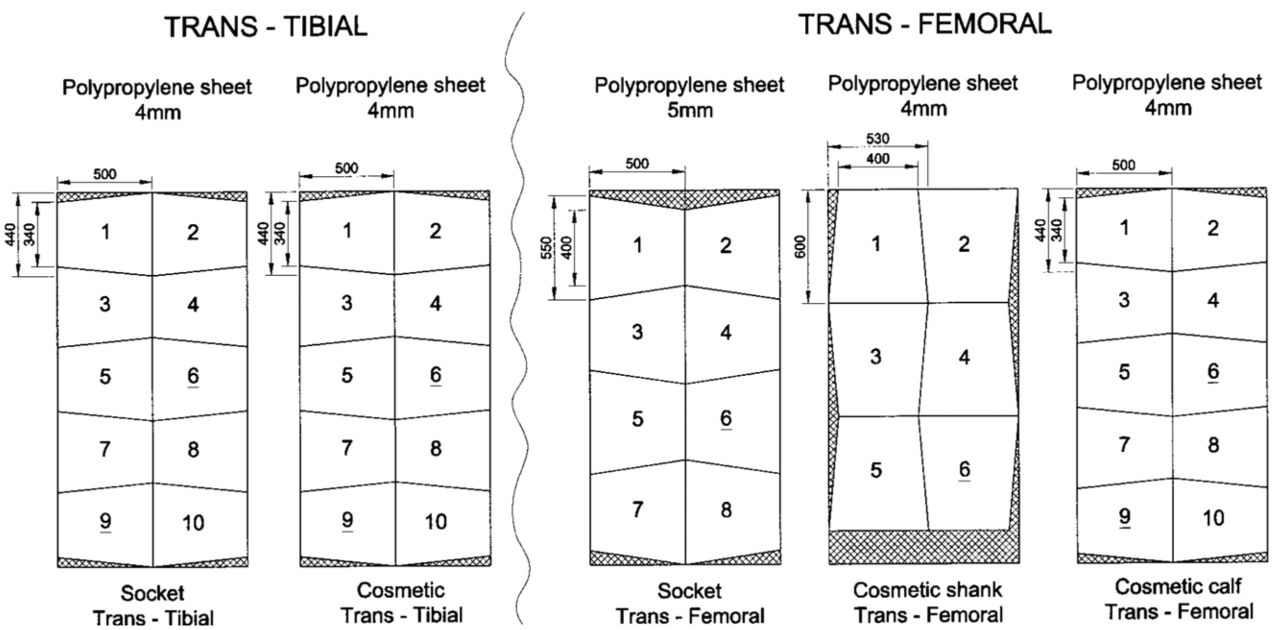
- **a** circumference at femoral condyles (biggest dimension)
- **b** length of positive
- **c** circumference at cup (smallest dimension).



The dimensions of the corresponding PP sheet should be as follows:



Practice has shown that pieces with the same dimensions (i.e. patterns) may frequently be used for the same operations. That means it is possible to cut the entire sheet into standard pieces. This helps organize work and minimize waste. However, pre-cut pieces can be used only if their dimensions follow the guidelines given above. If not, a PP blank with the correct dimensions must be cut specially (see relevant *Manufacturing Guidelines*).
Some possibilities for pre-cutting standard 200 cm x 100 cm polypropylene sheets are shown below:



2.6. PP thickness

Suppliers make PP of different standard thicknesses: 3 mm, 4 mm and 5 mm. 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.

For prostheses:

3 mm – for upper-limb sockets and cosmetic covers 4 mm – for sockets for lightweight patients (60-65 kg and under) and cosmetic covers 5 mm – for sockets for medium and heavy-weight patients (over 65 kg)

For orthoses:

3 mm – foot orthoses (FO) and ankle-foot orthoses (AFO) for children and light-weight patients (60-65 kg and under) as well as upper-limb orthoses
4 mm – FO, AFO and knee-ankle-foot orthoses (KAFO) for medium-weight patients (65-80 kg)
5 mm – AFO and KAFO for heavy-weight patients (over 80 kg)

2.7. Preparing the positive

The positive mould 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 mould should be covered by a layer of nylon, perlon or cotton stockinet, lightly powdered with talcum powder to prevent it sticking to the hot PP.

Some technicians use too much talcum powder, especially over the cotton stockinet, 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. Stockinet/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 mould if you want to obtain a solid seam when manufacturing prosthetic sockets.

You can also use talcum powder on the PP sheet, but only in the following cases:

- when the hot moulded object will be removed from the positive without being cut (e.g. cosmetic cover)
- when you want to save the positive for reuse after the thermoforming operation.
- In such cases, lightly coat the PP sheet with talcum powder before putting it in the oven. The talcum powder prevents two PP surfaces from sticking together too much so it is easier to separate them along the seam line once they are completely cool.

There is a widely held belief that the POP positive mould must be completely dry or the thermoforming will go wrong, the shape will be lost and the internal surface of the socket will become bumpy. Our experience shows that a dry or damp positive is not the determining factor in good thermoforming.

The problem of a bumpy internal surface along with loss of socket shape is related to insufficient vacuum during thermoforming. This problem is more obvious when the plastic sheet is put directly on the cold cast and then over an ethylene vinyl acetate (EVA) liner/pad. Immediately after the initial contact with the cold surface of the POP, the internal surface of the PP sheet begins cooling down and hardening (due to the effect of rapid temperature exchange between hot and cold objects). If during this process the vacuum is lost (completely or partially), the permanent contact between the PP sheet and the positive mould is lost too. In such cases, the best course of action is to immediately remove the PP (taking care not to break the positive) and repeat the thermoforming process.

3 THERMOFORMING OPERATION

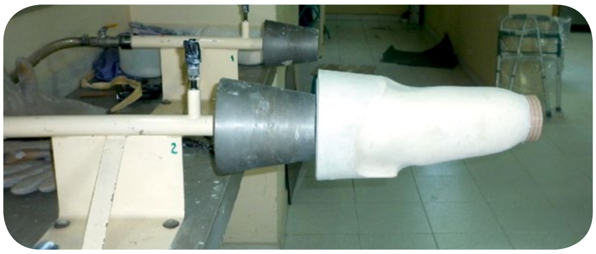
If all the precautions described above are followed, the thermoforming operation should be straightforward.

But when the PP is taken out of the oven 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 moulds. One person should focus on air tightness along the seam, while the other focuses on the cone.

3.1. Draping PP sheets

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

Step 1



Fix the positive on the right size cone and cover with stockinet.
To prevent the stockinet 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 stockinet to prevent a blowhole being sucked into the PP.

Step 2

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

For best results, two people should perform this operation.

Step 3

Press together the flaps hanging below the positive to turn the PP sheet into an airproof bag and squeeze along the entire length of the seam up to the vacuum cone.

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

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.
Make sure there is air tightness and proper vacuum flow throughout the thermoforming. (See the technical tips below.)

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.
Tip: For heavier TF patients, push a piece of the excess PP into the "seat" area for extra seat strength.

Stamp the prosthesis with its registration number if applicable. Then leave the plastic to cool.

Keep the vacuum machine running for at least 8 to 10 minutes to ensure proper thermoforming.
If you are making TT or TF sockets, here are some details to bear in mind:

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 (see section 2.2 "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 waist and stamping the number). Technicians should therefore have streamlined procedures in place and perform them without hesitation.

Technical tips

- Keep the PP sheet symmetrical (same amount of sheet on either side of the positive) 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.
- 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. This will make sure it is symmetrical.
- The proximal edge of the PP sheet should always be lined up with the distal edge of the vacuum cone. The sheet should never extend beyond the proximal edge of the cone.

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 with the PP socket from the cone without using any tools.

3.2. Setting (consolidation) time

After thermoforming, the PP must be left for 24 hours – this is the correct setting (or consolidation) time recommended in the technical literature.
If you fail to abide by this, there is a strong chance that the socket will lose its proper shape and volume.
Artificial cooling (such as with a blow gun or water) is not recommended because it will create abnormal tension in the PP.

4 QUALITY CONTROL

It is the responsibility of senior prosthetist-orthotist staff to monitor thermoforming performance and quality. They should point out any manufacturing defects while praising good-quality work in order to motivate technicians to perform and improve their skills.
It is easy to check whether the thermoforming operations are achieving good results.

We suggest using the following criteria:

1. The seam line is perfectly shaped from inside and almost invisible.
   The stockinet leaves a uniform but not rough pattern on the inside surface of the socket.

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

3. The PP is perfectly shaped in all the concave shapes of the positive mould, as well as in all the grooves of the cup. The grooves are clearly visible from outside. The socket surface is free of bubbles, bumps and any other defects.

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 *Manufacturing Guidelines*.

MISSION

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