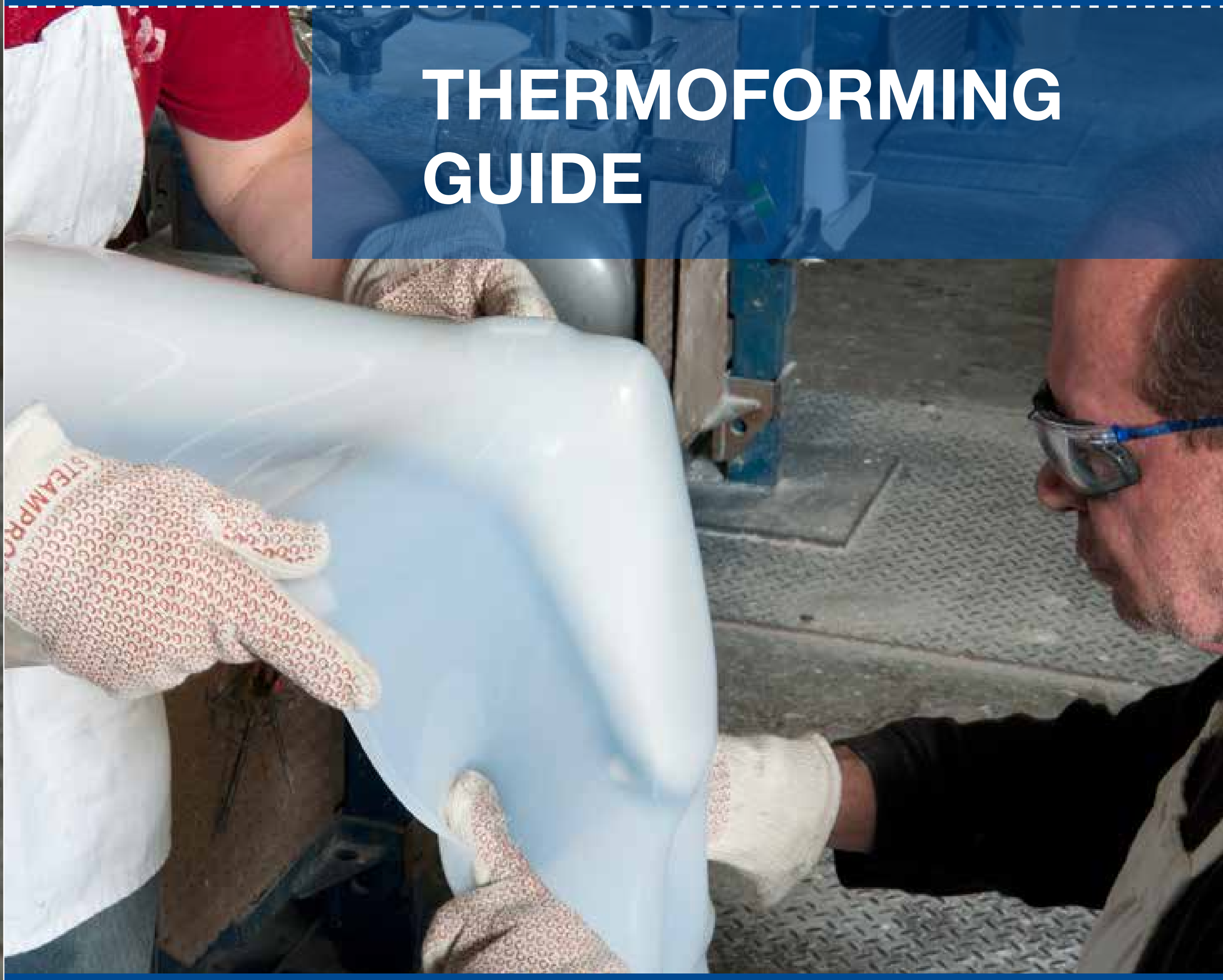
THERMOFORMING GUIDE



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THERMOFORMING
GUIDE

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THERMOFORMING GUIDE

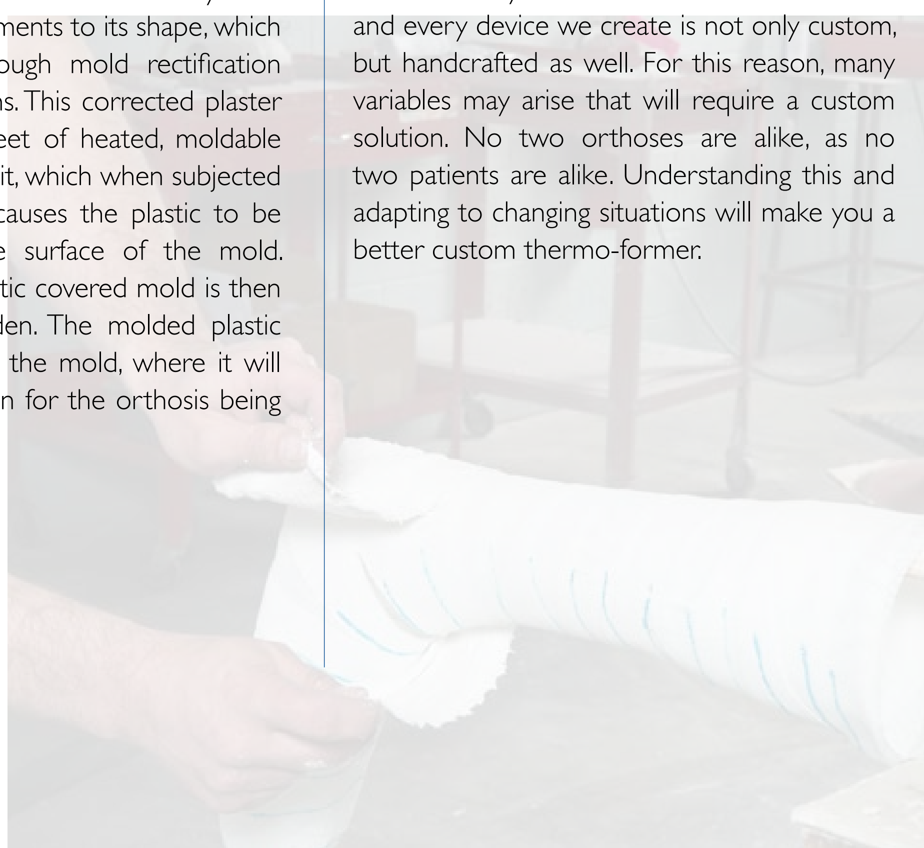
Introduction

Thermoforming is a process used in many industries to form a heated plastic sheet into various shapes. In the orthotics industry, it is a custom effort where each and every article is made to fit an individual's existing limb or other affected areas of the body (spinal, cranial, etc). Of the many orthotic devices that can be made by thermoforming, the most common are body jackets, knee-ankle-foot-orthoses (KAFO's) and ankle-foot-orthoses (AFO's).

Custom, plastic, orthotic devices are created by first making a plaster replica of a patient's extremity or body part. This mold will likely need corrections and adjustments to its shape, which can be achieved through mold rectification known as modifications. This corrected plaster model then has a sheet of heated, moldable plastic formed around it, which when subjected to vacuum pressure, causes the plastic to be impressed against the surface of the mold. Once formed, the plastic covered mold is then left to cool and harden. The molded plastic is judiciously cut from the mold, where it will become the foundation for the orthosis being created.

Once completed, the orthosis may have a variety of ankle joints, knee joints, padded liners and closures added to accomplish a wide array of corrective and supportive tasks.

This Thermoforming Guide is intended to give the reader a basic understanding of how to form an orthosis from a sheet of plastic. It is important for the reader to understand that there is no one "approved" way to accomplish this goal and many other methods may be implemented and used. For the purposes of this guide, we will endeavor to show the intended outcome and some ways to arrive at this outcome. Each and every device we create is not only custom, but handcrafted as well. For this reason, many variables may arise that will require a custom solution. No two orthoses are alike, as no two patients are alike. Understanding this and adapting to changing situations will make you a better custom thermo-former.



Step 1 – Mold Creation

Here, we will describe the steps involved in fabricating a thermoplastic AFO. The first step is to create the model from which we hope to create the orthosis. A patient's leg is wrapped in an intimately fitting and shaped plaster bandage cast. Once hardened, this cast is (cut) removed from the patient's extremity by means of a cast saw, razor knife, or scissors. This is referred to as the "negative cast" **(Figure 1)** because it represents the inverse shape we are looking to create. While corrections to the negative cast are sometimes applied, a properly molded cast won't require many changes.

Once the negative cast has been removed (cut) from the patient, it must be filled with liquid plaster to create the "positive mold." To do this, the cut line created by removing the cast from the patient can be resealed with plaster bandage to create what is essentially a sealed structure **(Figure 2)**. A steel pipe, or tube is placed in the cast's center, which will allow it to be secured to a vise later in the process for rectifications (modification). Liquid plaster is then poured into the sealed negative mold while making sure the pipe remains centered and does not touch the sides or bottom of the cast **(Figures 3 & 4)**. When the plaster has hardened, the negative cast can then be stripped from the positive mold, giving us an identical, plaster representation of the patient's body part (extremity) **(Figure 5)**.

Figure 1

Figure 2

Figure 3

Figure 4

Figure 5

Step 2 – Mold Rectification

Before the positive mold can be vacuum formed with plastic, it must first be smoothed and shaped to provide a more corrective, comfortable and a cosmetic device. It might also need certain modifications to allow for the incorporation of any number of ankle joints, motion control limiters, or other hardware. First and most important, never remove any material from a boney prominence on the mold. Doing so will likely result in pressure to the patient in that area, even if you intend to build it back up again. Once the height of that area is lost, it can't be recovered without recasting the patient, which is not a good option (and sometimes not an option at all).

Most positive models will require that the plantar aspect of the foot be flattened and shaped to replicate what happens during weight bearing. If the negative cast was taken in weight bearing using a casting plate, rectifying (flattening) it will be very easy. If the negative cast was taken in non-weight bearing position, additional considerations need to be taken into consideration. Care should be taken while carving the plantar surface to avoid removing too much material, and potentially compromising the positive mold. The heel and forefoot must also be balanced to neutral and when possible matched to one another to create a level surface **(Figure 6)**. There are exceptions to this rule but those examples of mold rectification are more advanced than the purposes of this guide.

The surfaces of the positive model will also need to be made smooth, both for comfort to the patient, and to provide a more cosmetically appealing look to the finished product **(Figure 7)**. If required, a Sureform™ tool or other carving device can be used to shape the fleshy areas smooth by carving off the high spots while filling in the low spots with plaster. This technique can counter the phenomenon called "roping" that can occur during the casting process, where, as the plaster bandage is wrapped around the soft fleshy areas of the patients body (limb), it can squeeze it into a shape that resembles rope, which is ultimately reflected in the positive mold.

Figure 6

Figure 7

Figure 8

Figure 9

To avoid pressure on the boney prominences, adjustments to the height of the surface must be made. Again, this can be accomplished many different ways, but to create a fast, accurate and repeatable modification we recommend using plaster bandage. Cut a length of bandage, fold it on itself until you arrive at the desired height of the build-up required and then cut it to the desired shape. Then wet the plaster and work it onto the mold at the location of the boney prominence until it sticks **(Figure 8)**. Once set, smooth it over with soft plaster and sand it until smooth. Flares can also be added to the proximal trim line in the same way, just be sure to form the edges accurately, as it can be very difficult to sand uneven edges smooth during the finishing process.

Once all of these rectifications have been made, the cast can then be sanded smooth **(Figure 9)**. If additional modifications or hardware needs to be added, they can be added as per the manufacturers' guidelines. Trim lines may also be added to facilitate the fabrication process later on.

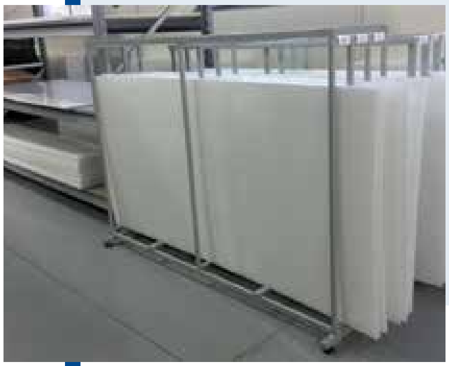
Step 3 – Plastic Selection

Several different plastics are commonly used in the fabrication of orthopedic devices. Each has its own specialized purpose, so the selection process is important. Fortunately, there are only three primary variables to consider: the type, the thickness, and the quality of the plastic.

Types of Plastic:

Copolymer – Copoly, as copolymer is commonly referred to, is a very common type of plastic used in orthotics. It is a resilient and tough material that tends to bend, or flex rather than break, or crack. While not very rigid, it's also not brittle and lends itself well to the fabrication of non-articulating AFO's and FO's. It is very forgiving while thermoforming and comes in a wide variety of colors.

Polypropylene – Often referred to as polypro, polypropylene is easy to form and provides a much more rigid structure than copoly. This makes it a good choice when control of the patient's limb is provided by the plastic structure of the orthosis, or when ankle joints are used to provide articulation. Due to its high rigidity, it also tends to be brittle, especially in cold climates, and tends to break or crack, rather than bend or flex.



Polyethylene – Also known as PE, polyethylene is a more flexible plastic and is best suited to creating anterior closure systems for lower extremity devices, body jackets or upper extremity devices. As used in the orthotic and prosthetic field, it comes in two varieties: high density (HDPE), or low density (LDPE). Polyethylene also becomes formable at a much lower temperature than copoly or polypro, so great care is required while heating.

Foam – Some orthotic devices will require the addition of a foam liner. Foam comes in two types: closed cell and open cell. The majority of foams used in the linings of AFO's and KAFO's are a closed cell, polyethylene foam. These foams are soft, easy to heat, and due to the closed cells, can be thermoformed like a sheet of plastic. Forming temperatures for foams are also low, so great care is required when heating these materials. Foams heat up very quickly, so it's important to monitor them when heating them in the oven. Most foams are typically know by brand names, such as Volara™ and Aliplast™.

Thicknesses of Plastic

Once the type of material has been selected, the appropriate thickness must be determined. For the vast majority of devices, there are only three primary choices: 1/8" (3mm), 3/16" (5mm) and 1/4" (6mm). The thinnest of these, 1/8", is usually relegated to the role of an anterior closure or liner material. Due to its thinness, it tends to stretch even thinner when over-heated. This property makes it ideal for use in DAFO's.

At the other end of the spectrum, 1/4" (6mm) plastic should only be used in situations where great strength is required. One example of when it might be appropriate to use 1/4" (6mm) plastic would be when polypro is called for use in a cold climate and copoly cannot be substituted. In the case of polypro, the extra thickness may counter the inherent brittle nature of the material. Another example for using 1/4" (6mm) plastic might be for use on a bariatric patient who is routinely breaking orthoses made of 3/16" (5mm) plastic.

This leaves us with 3/16" (5mm) plastic which is, by far, the most common thickness of plastic used to fabricate the main structure of most orthotic devices. It is thin enough that it can be worn under most clothing, yet thick enough that it can be incorporated with many of the commonly used ankle joints and motion control limiters available. In the U.S., most AFO's and KAFO's are fabricated with either polypro or copoly in a 3/16" (5mm) thickness.

Quality of Plastic

The quality of the plastic that is used is critical. While it is difficult to determine quality by simply looking at it, the proof is in the fabrication. Ask your plastic supplier for O&P grade plastic sheeting. If it is not available, ask them for plastic with the least amount of regrind possible. Once you have received the plastic from the distributor, perform a quick, informal evaluation by vacuum forming a test AFO with it. Once it has been finished and strapped, strike the calf section with a ball peen hammer. If the plastic turns white, it should prove to be a good batch of plastic. If the plastic shatters, return it to the supplier and demand a better quality plastic or seek another source. Another thing to look for when choosing plastic is any evidence of oxidation, which can give the plastic a yellowish look and typically occurs to old plastic. Old plastic won't thermoform as well as new plastic and it won't last as long either. You should refuse any plastic that isn't new in appearance.

Step 4 - Thermoforming

The process for thermoforming, or vacuum forming, is a pretty straightforward one. The idea is to carefully wrap hot plastic sheeting around a mold and put it under vacuum pressure so that it takes the shape of that mold. In order to do this properly, we will need a couple of things; an oven in which to heat an appropriately sized sheet of plastic and a source of vacuum pressure which can be used to evacuate the air from between the plastic and the mold. Other tools and materials will be used in the process, but without these two primary items, the plastic will not take the desired shape during thermoforming.

Heat - The oven that is used will have a considerable effect on the quality of the final product. Plastic can be heated with a variety of different heat sources, but if it's not heated evenly, it will not mold correctly to the positive mold. The selected oven must be large enough to accommodate the largest sheet of plastic you will be required to heat. In the U.S., infrared ovens are typically used in the thermoforming process due to their reliability and ability to heat plastic evenly **(Figure 10)**. Infrared ovens can be an expensive investment, but they will inevitably pay for themselves over time, given enough volume of work.

A less expensive option is to find an industrial convection oven **(Figure 11)**. Industrial convection ovens are sometimes difficult to find in good used condition, as they aren't always readily available. If you are able to find a used industrial convection oven, it will work well for heating plastic, but the current gold standard in the orthotics and prosthetics field is the infrared oven because of its consistency and reliability.

Regardless of which type of oven you choose, it's critical that the oven tray have a non-stick surface on which to heat the plastic. Plastic, when heated to forming temperatures, can be very sticky and will adhere to most surfaces. Also, a smooth, non-stick tray can leave the surface of the plastic free of imperfections, which may reveal themselves in the final product. Elevation can also affect the way heat is transferred to the plastic and should be considered when choosing your oven.

Figure 10

Figure 10* - fillauer.com

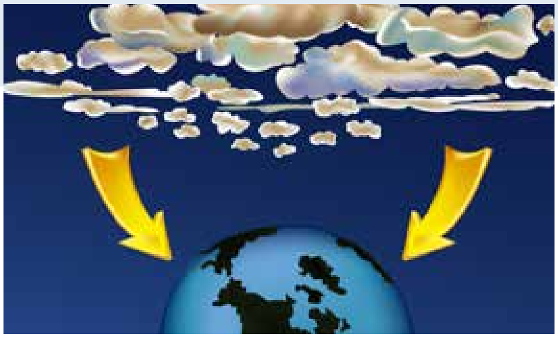
Figure 11

Figure 11**- directindustry.com

Vacuum

The air must be evacuated from between the plastic and the mold in order for it to take the shape of the mold. To do this properly, your vacuum system must be capable of pulling between 20 and 29.92 inches of mercury (Hg, a unit of measure for pressure) to properly form the types and thicknesses of sheet plastic that are commonly used in thermoforming. It is important to know that a vacuum pump will lose 0.5 PSI of performance (one inch Hg) per 1,000 feet of elevation gain. For example, a pump that provides 28 Hg at Sea Level will only provide roughly 22 Hg at 6,000 feet in elevation, so it's important to keep in mind that the higher in altitude you're trying to form plastic, the more pressure your vacuum system will require. A divisor of 2.03 should be used as the conversion factor when converting the barometric measurement of vacuum (inches of Mercury) to an industrial measurement of PSI (pounds per square inch).

Ideally, a vacuum system with a large diameter hose and a 2.5 gallon surge tank is what you need to properly form plastic to a mold. These attributes will



ensure that the air is evacuated quickly and evenly. For the purposes of this guide, we will be using the Becker Orthopedic VacStation™ **(Figure 12)**, which has all of the required features, is easy to use and provides optimal forming pressure.

Figure 12 - Becker VacStation™

Cooling

Once the hot plastic has been thermoformed, it must first cool and return to its hardened state before it can be cut and removed from the mold. If the plastic is not cooled correctly, it will not maintain the shape of the mold, but will instead deform and either spring inward or outward. To prevent this, control of the cooling process is critical. The cooling process will vary depending on the materials being used, but in general the side of the plastic that touches the mold (inside layer) should cool at the same rate as the side which is exposed to the air (outside layer). If the inside layer of plastic is in direct contact with a cold plaster mold, it will cool more rapidly than the outside layer, which must then be cooled off more quickly to match the cooling pace of the inside. Blowing compressed air across the outside of the plastic will cause the inside and outside layers to cool at roughly the same pace. Conversely, if the plastic has been formed over a foam liner, the foam will act like an insulator against the cold mold and the opposite technique will be required. In that scenario, the cooling process of the outside layer must be retarded to match the slower pace of the inside layer. This can be accomplished by applying some kind of insulation material over the plastic, such as pink home insulation material, or bubble wrap covered with Mylar™. A simple cardboard box will also suffice for this purpose, as long as the inside and outside layers of the plastic cool at roughly the same rate.

Fabricating an Articulating AFO

Model 741 - Tamarack Molding Dummies

Tamarack Molding Dummies are reusable five to ten times. They are strongly recommended to create a snug, recessed cavity for the Tamarack Flexure Joints® or Tamarack Dorsiflexion Assist Flexure Joints®.

FABRICATION TIPS

The following sequence of steps is intended as a supplement to the instructions that come with the product. Please refer to the product instructions for complete fabrication details.

Figure 1
Mark the medial and lateral ankle joint axis on the positive mold.

Figure 2
A posterior reference line across both axis should also be marked when installing a posterior stop.

Figure 3
Position one of the molding dummies on the positive mold with the included tacks.

Figure 4
The molding dummies are designed to eliminate the material gap that is caused when making the separation cut with a thin blade saw.

Modelo 741 – Tamarack Molding Dummies

Figure 5
Either mechanical (line of progression) or anatomical joint alignment can be chosen for dummy placement. One of the advantages gained by using the Tamarack Flexure Joint® is that the joints automatically co-align to a single joint axis.

Figure 6
Pull the first Vacuum Hose Nylon over the mold.

Figure 7
Pull the second Vacuum Hose Nylon over the mold.

Figure 8
Pull both nylons taught over the mold and secure them by tying them off around the manifold of the vacuum with electrical tape.

Figure 9
Wrap a piece of 3/16" (5mm) Aliplast® padding around the end of the vacuum manifold. The Aliplast® provides a place for the heated plastic to seal around.

Figure 10
Be sure to butt the Aliplast® strip against the top of the mold to prevent the heated plastic from sealing-off and cutting-off the vacuum.

Modelo 725 – Compact Double Action Ankle Joint

The Compact Double Action Ankle Joint is designed specifically for use with thermoplastic and is intended for both small adult and pediatric patients.

FABRICATION TIPS

The following sequence of steps is intended as a supplement to the instructions that come with the product. Please refer to the product instructions for complete fabrication details.

Figure 1
Mark the ankle joint axis on both the medial and lateral sides of the positive mold.

Figure 2
After contouring the ankle joint upright and stirrup and affixing them to the positive mold using the included alignment tool, use plaster to fill-in the gaps between the ankle joint and the mold.

Figure 3
A putty knife or similar tool can be used to fill-in gaps with plaster quickly and efficiently.

Figure 4
Fill-in all gaps on both ankle joints. Be sure to carefully remove any plaster that extends past the stirrup and upright so the plastic can better capture the edges of the metal surfaces.

Modelo 725 – Articulación Compacta de Doble Acción

Figure 5
Pull two Vacuum Hose Nylons over the mold and secure them to the end of the vacuum manifold with a piece of 3/16" (5mm) Aliplast® and electrical tape.

Figure 6
Apply talcum powder to the entire surface of the positive mold to prevent the Vacuum Hose Nylons from sticking to the plastic.

Figure 7
When the plastic has reached forming temperature, drape the plastic sheet over the positive mold, making sure to seal all edges.

Figure 8
Allow the plastic to cool while remaining under vacuum for at least thirty minutes.

Model 755 -Motion Control Limiter

The 755 is adjustable plantarflexion range of motion limiter that can be transformed to a solid ankle AFO. Varying degrees of plantarflexion are obtainded by grinding the bumper stop.

FABRICATION TIPS

The following sequence of steps is intended as a supplement to the instructions that come with the product. Please refer to the product instructions for complete fabrication details.

Figure 1
After preparing the mold and marking the posterior ankle axis, use a spray adhesive to hold the first layer/piece of plastic to the mold.

Figure 2
Position the first layer/piece of plastic on the mold and quickly press the 755 Molding Dummy into it according to the product instructions.

Figure 3
Using your fingers, spread the wick of the dummy horizontally over the mold and press to secure in place.

Figure 4
When the plastic has reached forming temperature, drape the plastic sheet over the mold.

Model 755 -Motion Control Limiter

Figure 5
Be sure to seal all edges of the plastic around the mold and vacuum manifold.

Figure 6
Use scissors to cut-off any excess plastic from the mold to avoid stretching due to gravity.

Figure 7
Allow the plastic to cool while remaining under vacuum for at least 30 minutes.

Figure 8
The plastic is now ready to be removed from the positive mold. Once removed, the plastic will need to be cut along the ankle axis to allow the orthosis to articulate.

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