

# Silicones in Prosthetics

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This article includes the report distributed by Dow Corning Corporation, entitled "Silastic Pads for Limb Prostheses," and information on a variety of other uses of Silicones as employed by Northwestern University Prosthetic Research Center in the fabrication of prostheses.

## Silastic Pads for Limb Prostheses

### Introduction

Clinical work at Northwestern University Prosthetic Research Center and Prosthetic-Orthotic Education, supplemented by field experience, has shown Silastic RTV to be a versatile and useful material in the field of prosthetics.

Silastic RTV is a non-toxic material which has a very low exotherm and gels at room temperature. The set time can be controlled by the amount of catalyst added. The injection of the RTV fluid enables pressures to be evenly distributed over the entire distal end of the stump and makes it possible:

- a) To form an intimately contoured distal pad
- b) To accommodate any change in stump volume distally
- c) To control the amount of pressure at the end of the stump under weight bearing
- d) To convert a conventional open end socket to a closed end socket with distal contact

It is obtainable in various densities, thereby affording a broad selection for the different applications as required in A/K and B/K sockets, upper extremity sockets, etc.

### Materials

The Dow Corning silicones used for making the limb pads are:

1. Silastic 385 Elastomer for Above-Knee Distal Pads (formerly Silastic RTV 502 or Medical Silastic 382)
2. Silastic 386 Foam Elastomer for Below-Knee Distal Pads (formerly Silastic RTV S-5370 foam)
3. Medical Silastic S-5391 Elastomer. A low viscosity room temperature curing silicone rubber for coating the Foam Silastic to prevent perspiration absorption and provide a tougher surface. Excellent for laminating.
4. Medical Fluid 360, 20 centistokes viscosity for lowering the consistency of the solid elastomer to facilitate injection.

Other silicones recommended by the group at Northwestern include Dow Corning 555 Fluid to assist in releasing the formed pad from the stump (this may or may not be necessary); Silastic RTV 1200 Primer and Silastic 140 Adhesive to bond the formed pad permanently to the prosthesis.

### **Preparation of Materials**

All of the Silastic elastomer formulations are two-component systems comprising a base and catalyst. Directions for combining the ingredients are on the labels. These silicone elastomers must, of course, be catalyzed just prior to use. For best results the catalyst should be added rapidly and be dispersed uniformly throughout the base by vigorous stirring for approximately 30 seconds. Working time can be increased by cooling the ingredients or by reducing the amount of catalyst. It is recommended that the prosthetist prepare two or three small batches before using the materials clinically to get a "feel" for the systems and their reactivity.

The Medical Fluid 360, 20 centistokes viscosity, can be used as a thinner. It can be added to either of the solid RTV systems to lower viscosity and thereby increase flow. Do not use Medical Fluid 360, 20 centistokes viscosity, with the Foam. Addition of up to 10% of the Fluid will not affect the properties of the final product. The Fluid must be added before catalyzing the mixture. Addition of Fluid somewhat extends the working time of the system.

Dow Corning 555 Fluid or a 5 to 10% solution of a household synthetic detergent are recommended as release agents where trouble is anticipated in removing the formed pad from the stump. In most cases no release agent will be needed.

Silastic elastomer systems bond reasonably well to most prosthetic parts if allowed to set up in contact with the part. The use of Silastic RTV 1200 Primer and Silastic 140 Adhesive is recommended where it is desirable to bond the cured pad to the prosthesis. As with any bonding operation, the surface must be thoroughly cleansed for best results. Light sanding followed by a solvent wipe is recommended.

### **Note**

The catalyst used with the RTV systems is somewhat toxic in its pure state. Rinse the area thoroughly with running water if catalyst is dropped on skin.

Although shelf life of the RTV systems is indicated to be six months, normally they will be perfectly OK for much longer times. Material that has not set up or thickened appreciably in the container is satisfactory to use. The catalysts will decrease in reactivity rather rapidly on prolonged exposure to air. Keep containers tightly closed and transfer catalyst to a smaller container when the air space exceeds approximately  $\frac{1}{4}$  of the total volume of the vessel.

The solid and foam Silastic elastomers are compatible with each other and may be combined in various proportions to obtain semi-solid pads of intermediate densities. Foaming under pressure (confined) also results in a pad of higher density.

### **Equipment**

Almost any hand caulking gun of approximately 12-ounce capacity is satisfactory for injecting the solid or foam elastomers. The gun must be of a type that can be assembled quickly because of the short set-up time of the RTV systems. Use a gun with tapered nozzle. An adaptor cut from neoprene is inserted into the valve for the A/K pad when solid RTV is used. The same gun is used for B/K injection.

### **Stump Preparation**

1. Shave all hair from the distal portion of the stump for total contact A/K suction sockets.
2. If foam is to be used, apply household detergent solution to the stump as a separator and allow to dry. Vaseline may also be used.

### **Socket Preparation**

1. Ensure that there is a space of  $\frac{1}{2}$ " between the end of the stump and the socket. If there is too big a cavity, use  $\frac{1}{2}$ " rubber foam cut and glued to the socket to reduce the amount of Silastic needed.
2. In the case of a B/K, drill a  $\frac{3}{8}$ " hole just proximal to the distal pad.
3. In a PTB, remove the distal portion of the soft insert if there is insufficient room for foam, otherwise cut a hole in the insert opposite the  $\frac{3}{8}$ " hole in the socket.
4. If an unfinished wood socket is being used, lightly coat the distal part with Vaseline to facilitate removal of the pad.
5. Insert an air bleed tube into the posterior lateral or posterior medial corner of the socket, and ensure that the bottom end is at the same level as the end of the stump. The tube should be small and flexible, with an ID of about  $1/16$ ". It can be a short piece of the plastic insulation from #12 copper electric wire. By blowing into the tube, ensure that it is not blocked by the stump.

### **Fitting Preparation**

Where a suction socket is worn, pull the amputee into the socket in the normal manner.

If the amputee wears a stump sock, pull a separator over the stump sock. A tailored sleeve of PVA, capped at the distal end, is satisfactory for B/K stumps or long A/K stumps. Where the A/K stump is short, pre-form a flat sheet of PVA over a cast and pull this on to the distal end of the socket. Any reliefs needed can be formed with  $\frac{1}{2}$ " felt, held to the stump sock with friction tape and the PVA separator pulled over all.

### **Procedure**

1. Mix the Silastic 385 elastomer in large containers and thoroughly spatulate, then pour the contents into the cylinder. Mix the Silastic 386 Foam elastomer in the cylinder of the caulking gun.
2. Push the nozzle of the gun into the neoprene valve adaptor opening and inject the Silastic into the socket. Continue the injection until the amputee feels slight pressure from the fluid. If the pressure is excessive and tends to force him out of the socket, release the plunger and allow excess Silastic to run back into the cylinder. The amputee should stand erect with most of his weight on the prosthesis.
3. Allow the Silastic to set—the time required can be estimated by checking the remains in the cup.
4. Remove the gun and cut the connecting piece of cured Silastic with a knife.
5. When using foam, remove the gun immediately after injection and hold a finger over the hole. If excess pressure is felt, allow some of the foam to escape out of the hole. If pressure is maintained in the socket it will produce a firmer foam.
6. Remove the pad from the A/K socket.
7. At the valve hole, cut a hole in the Silastic pad to allow the amputee to pull his stump into the socket. (Figure 1)
8. Re-insert the plug and cut the protruding piece flush with the outside wall of the pad. The plug may be glued to the valve cap using Silastic Adhesive 140. In this case a small air hole must be made in the plug.
9. If the valve is pre-set to touch the stump under weight bearing, a plug will not be necessary.

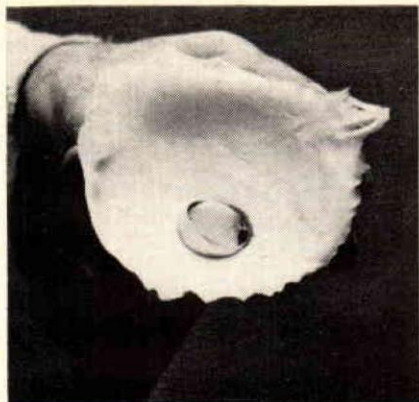


Figure 1

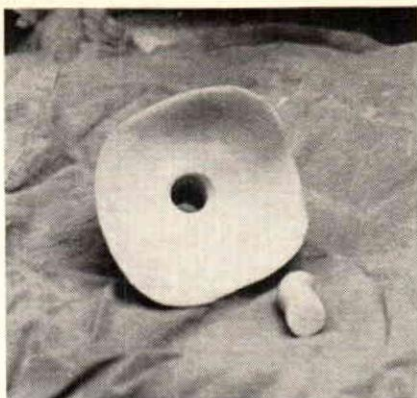


Figure 2

### Finishing Process

1. Fill any voids in the pad with the same material.
2. Trim any feather edges that are apt to fold over when pulling the stump into the socket.
3. Remove any prominent ridges formed by the stump with a sanding cone or a burr. (Figure 2)
4. If foam is used, a skin should be formed over the surface to help to prevent absorption of sweat into the pad. A small mixture of S-5391 is prepared and applied thinly to the surface. Smooth the skin before it gels by wiping sparingly with Silastic Medical Fluid 360.
5. Dust with talc to eliminate any tackiness.
6. Test for pressure as the amputee takes a few steps. If pressure is excessive, relieve by removal of rubber from the distal end of the pad or by minor sanding of the proximal surface.
7. RTV may be glued permanently in the prosthesis with Silastic 140 Adhesive and Silastic RTV 1200 Primer.

### Laminating Silastic

It is sometimes desirable to fabricate a socket having flexible areas of laminated Silastic as an integral part of the socket. The viscosity of Silastic is much higher than that of polyester and makes complete saturation of the lay-up more difficult. The use of a vacuum system is imperative and greatly helps in overcoming this difficulty. The elastomer generally used is S-5391, diluted if necessary by Medical Fluid 360. Addition of up to 10% of the Fluid will not affect the properties of the final product. Addition of more than 10% will extend the working time and the resultant rubber will be softer. In no case should more than 30% by weight of thinners be added. The thinners should be added to the base resin and thoroughly mixed before the catalyst is added. The set or working time of the Silastic is affected by temperature and humidity. The working time can also be changed by varying the amount of catalyst used.

This application has been used to advantage in fabricating a body socket for a bilateral hip disarticulation amputee. The amputee was a paraplegic with a sensory level of T9 who underwent a right urethrostomy. In addition, he was subject to deep decubiti of the buttock and sacral areas. The upper part of the socket was made of a combination of rigid and flexible polyester to obtain comfortable support from the rib cage. The distal part of the socket was made of an inner Silastic S-5391 laminate with a chamber

between the laminate and the polyester shell. While the socket was still on the cast, Silastic 386 was injected into the chamber under the Silastic laminate, which resulted in a contoured foam seat area. (Figure 3)

The same technique was employed to form a soft distal end in B/K sockets, and also to form flexible anterior and posterior panels in A/K sockets. (Figure 4) While the areas laminated with the Silastic varied as to location, shape and size, the basic technique was as follows:

Determine the thickness required for the flexible laminate (usually two or three layers of nylon stockinette are sufficient). Pull the stockinette over the cast and mark the areas to be flexible, then pull a PVA bag over the lay-up and tape off the areas to contain the Silastic. Pour a mix of Silastic S-5391 into the bag, turn the vacuum on, and work the Silastic into the designated areas. After the Silastic has set, strip off the PVA bag. Apply any further lay-up directly over the Silastic and unsaturated areas of the previous lay-up. Pull another PVA bag over the finished lay-up and proceed with the polyester laminate. The polyester will not adhere or bond to the cured Silastic.

An open weave of stockinette is preferred for laminating. Nylon, cotton and dacron stockinette have been used successfully. An initial layer of banlon and a final layer of banlon improves the finish of the laminate. The thickness of the insert can be controlled by the number of layers in the lay-up. The thicker the insert the slower set time is necessary to allow complete penetration of the Silastic. The resin should also be worked into the lay-up by hand, and a draw of approximately 20 in. Hg. should be maintained until the Silastic has set. String excess resin from undercuts. If coloring of the resin is desired, the polyester color seems to be compatible to the silicones.

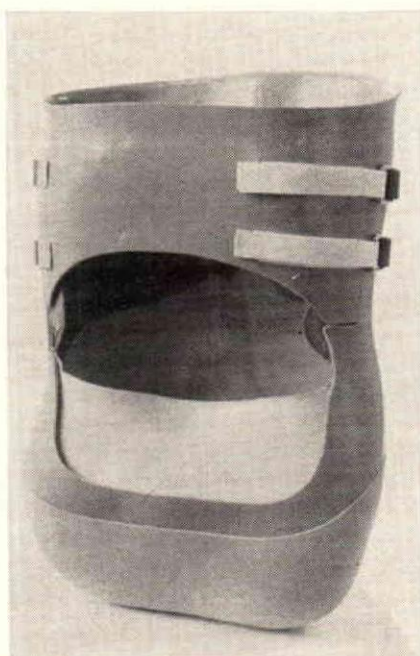


Figure 3

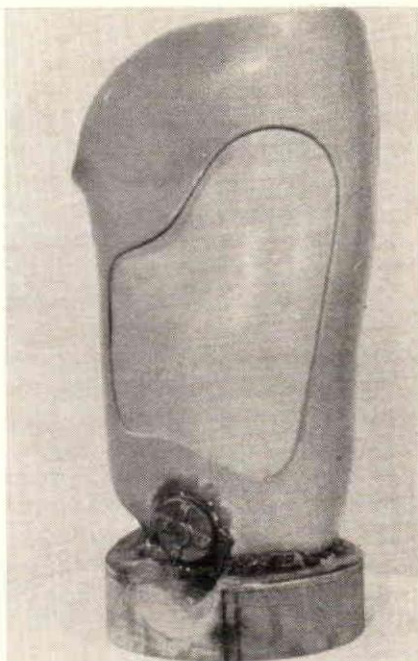


Figure 4

### Hip Disarticulation

Silastic 385 has been used to form a pad in the seat area of the hip disarticulation socket. The cast was modified in the normal manner and smoothed. Two coats of Ambroid varnish were applied to the cast and allowed to dry. A thin coat of Vaseline was applied to the seat area. A mix of Silastic 385 (no thinners) was prepared and spatulated on to the cast in the area selected, allowed to set up and the edges trimmed where necessary. The set of the 385 was accelerated by increasing the amount of catalyst to the mix. No thinners were added to the mix in order to maintain the viscosity of the material. As a result, there was little difficulty due to "running" of the 385 on the cast. The surface of the Silastic was smoothed and controlled by hand. The fingers were kept wet by dipping in Silastic Thinners to prevent pulling of the Silastic during the smoothing operation.

Where the attachment area for the hip joint was formed during lamination of the socket, the cavity formed was filled with 385.

The urethane build-up which located the hip joint placement was removed from the cast and the area was then smoothed and a smear of Vaseline applied as a separator. The socket was prepared by drilling the attachment holes and bolting the inner plate to the socket with two bolts. The center hole was drilled with a  $\frac{3}{8}$ " drill. The socket was replaced on the cast and secured by a web belt or pressure sensitive friction tape.

The 385 was injected through the center hole and allowed to set. Because the cavity was large, a 50-50 mixture of 385 and 386 was used to reduce the weight. The 385 and 386 resins were mixed together and poured in the caulking gun. 4% of the 386 catalyst was added and mixed for 25 seconds. (The resultant foam increases approximately twice its original volume). Set time was approximately three minutes. The pad was glued in place using Silastic 1200 Primer and Silastic 140 Adhesive.

### Hemipelvectomy

The build-up of the lateral wall of the cast for joint placement and cosmesis for a hemipelvectomy results in a large cavity to be filled. To avoid adding excessive weight to the socket, Silastic 386 is a good material to use as a filler, provided the surface is reinforced with stockinette. The procedure is as follows:

Remove the urethane build-up from the cast, smooth the area and apply a separator—Vaseline or detergent solution, etc. Stretch a piece of stockinette across the cast covering the area to be foamed and hold with staples. Prepare the socket for injection by installing the hip joint and drilling the center hole with a  $\frac{3}{8}$ " drill, then replace and secure the socket to the cast. Inject the Silastic 386 into the cavity. (Figure 5) Remove the socket from the cast and the pad from the socket. Trim off excess stockinette, coat the surface of the pad with Silastic S-5391, and glue the pad to the socket. Rough the area of the socket to be glued with sandpaper. Coat the roughed area of the socket with 1200 Primer and allow to dry. Shorten the drying time by careful use of a heat gun. Glue with 140 Adhesive. (Figure 6)

### Below-Knee

The principal application of Silastic in B/K prostheses has been to obtain distal contact to the stump to prevent or alleviate an edematous condition. This is done by injecting the Silastic into the distal end of the B/K socket with the amputee standing and bearing equal weight on both legs. Silastic 386 is the material of choice; Silastic 385 has had limited

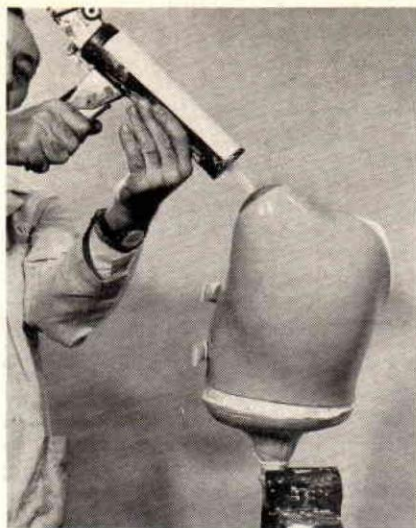


Figure 5



Figure 6

use with satisfactory results. J. Caldwell, C.P. of J. E. Hanger, Orlando, Florida, has recommended the addition of stockinette (preferably banlon) to the contacting surface of the pad, thus enhancing the strength and durability of the foam pad.

The procedure requires a thin stump sock pulled on to the stump, a PVA bag capped at the distal end as a separator over the stump sock, and a sock of banlon tailored at the distal end pulled over the separator. Vent tubes are inserted in the socket and the patient dons the prosthesis. Silastic 386 is injected in the routine manner and allowed to set. The pad is removed from the socket and the banlon is trimmed at the junction of the foam. A skin of S-5391 should be applied to the surface to prevent absorption of sweat into the open structure of the foam. The pad is then replaced and glued if desired into the prosthesis.

### Symes

Prior to forming a distal pad, the cast was prepared at the distal end by filling in any deep scar areas and building up any relief areas necessary. The cast was smoothed to eliminate any roughness or pits in the plaster, and coated with Ambroid. The Ambroid was lightly greased with Vaseline.

A cardboard was formed around the distal end of the cast to hold the Silastic. The cardboard form included the whole weight bearing area of the distal stump and any areas anteriorly that required relief. An appropriate amount of Silastic 385 was mixed and poured into the cardboard container. After the Silastic had set, the cardboard and the pad were removed from the cast. The distal edges of the pad were removed with scissors or a sharp knife and these corners radiused on a sanding disc or cone. The pad was approximately  $\frac{1}{4}$ " thick at its thinnest part. The pad was replaced on the cast and a separator of PVA was pulled over all.

A laminated Silastic insert for proximal weight bearing Symes may be fabricated using the technique as described by A. Finnieston, C.P. in *AOPA Journal* of June, 1963, entitled "The Patella Tendon-Bearing Below-Knee Prosthesis: Fabrication of a Silicone Rubber Soft Insert."

## Partial Feet

A satisfactory gait may be achieved with a good Chopart or Lisfranc amputation without the aid of a prosthesis. It is not unusual, however, for support to be required to help to stabilize the foot in the shoe, to increase the anterior support during ambulation and to assist in preventing buckling of the toe of the shoe. This is sometimes attempted by stuffing the toe of the shoe with rags or old stockings.

Silastic is an excellent material to use as a shoe filler, permitting an intimate fit between the filler and the stump with a minimum expenditure of time or effort. Silastic 385 as a filler adds excessive weight to the shoe; Silastic 386 is a good material to use; a mixture of 385 and 386 in varying proportions will allow any density of foam desired; S-5391 is used as a barrier to prevent absorption of sweat into the foam.

The techniques used at NU are offered as a guide. An insole of cloth (stockinette) is cut and inserted into the shoe. A sock of banlon is tailored and pulled on the stump, the seam line being kept under the foot. A light coat of Vaseline or a silicone spray is applied to the inside of the shoe. 50 grams of Silastic 386 are prepared with 4% catalyst and poured into the toe of the shoe. The amputee immediately inserts his stump in the shoe and stands with equal weight bearing. The operator should lace the shoe. The amputee stands until the foam has set, usually three minutes. The foam and insert are then removed from the shoe. The banlon sock is trimmed at the junction of the foam, a thin skin of S-5391 is applied to the surface of the foam, and the filler is again inserted into the shoe. The banlon imbedded in the foam adds strength to the surface of the foam and prevents cracking and breakdown. Nylon and cotton are effective, but the ribs of the weave produce a coarse finish. Banlon is preferred because of the finish obtained by the fine weave. (Figure 7)

Another technique consists of using the Silastic 386 as a filler for the toe of the shoe. The contacting surface of the foam filler is cut away to a depth of approximately  $\frac{1}{4}$ ". The cavity produced between the stump and the remaining foam is then filled with Silastic 385 and allowed to set. The resultant surface is helpful in preventing absorption of sweat into the foam and produces a durable surface without adding a lot of weight to the shoe. (Figure 8)

One case presented to NUPRC required a weight bearing filler to accommodate a heel deficiency. (At the time a cork filler was used, but was not satisfactory). A plug of wood was used to maintain the correct height and attitude of the foot in the shoe. The patient was seated and shown

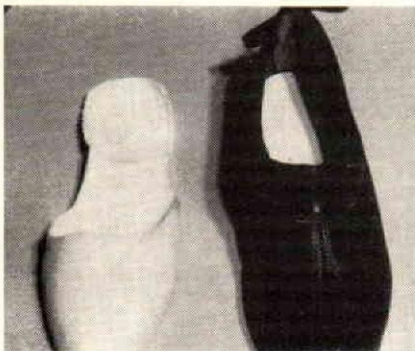


Figure 7

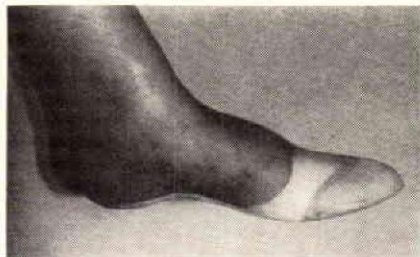


Figure 8



how to maintain the foot in an angle of dorsiflexion. This was necessary to contain the Silastic 385 in the desired area. A mix of 385 was made and poured into the heel of the shoe. The patient put the shoe on and remained seated until the Silastic had set. The pad produced was comfortable and durable and has been in use for approximately ten months.

V. Meadows, of Meadows & Wesela, Grand Rapids, Michigan, has made over 100 pairs of arch supports of Silastic 385 by the following procedure:

An impression is taken of the foot by means of a block of casting foam obtained from Hersco Arch Products Corporation, 137 E. 25th St., New York. A slurry of plaster is poured in the impression and the resultant male mold is modified as required. A container made of cardboard is formed around the cast. Silastic 385 is mixed and poured into the container. Care is taken to allow the Silastic to form up and around the back of the heel. After the Silastic has set it is removed from the mold, then trimmed and ground as necessary. The Silastic formed around the heel holds the support in the proper position and eliminates the necessity for gluing the insole or arch supports to the shoe.

### Upper Extremity Sockets

Silastic 386 has proved to be a valuable material in helping to obtain or maintain an intimate fit in the upper extremity sockets. It has also been useful as a means to provide padding for relief of bony prominences such as the distal end of the radius or ulna in a wrist disarticulation prosthesis. A contact fit distally in an A/E socket obtained by the use of Silastic 386 can relieve pressure from the socket under the axilla, and may also, in the case of a short A/E, allow the reaction point of the harness to be lowered on the socket with undue discomfort to the end of the stump. The technique used at NU is as follows:

Pull the stump sock on the stump and a PVA bag over the stump as a separator. To reinforce the foam, pull a light stump sock of either banlon, stockinette, etc. over the PVA bag. Insert a bleeder tube into the socket to allow air to escape during the foaming process. Weigh an appropriate amount of Silastic 386 and 6% catalyst in separate containers. Where possible, the harness should be worn, leaving the socket free. Mix the Silastic in the socket for 25 seconds, then insert the stump into the socket and support the socket during the foaming process. Remove the formed pad from the socket and trim off excess stockinette. Apply a thin coat of S-5391 to the surface of the foam as a vapor barrier. Clean the socket and rough the area to be bonded with sandpaper, then apply a coat of 1200 Primer and dry. Apply Silastic 140 Adhesive to the socket around the proximal edge of the pad and insert the pad.

In the case of a short A/E, it is not always feasible to pull a PVA bag over the stump as a separator, in which case it is necessary to remove any hair from the stump and under the axilla. A 5% solution of household detergent, such as Vel or Tide, in water makes an excellent separator when applied to the stump and allowed to dry.

In a partial hand prosthesis, a comfortable fit was achieved by forming a pad of Silastic 386 between the distal end of the socket and the bony prominences of the stump.

The intimate fit and the insulating qualities of the foam do create a problem concerning sweat. The skin of Silastic S-5391 is helpful in preventing absorption of sweat into the foam. The amputee should wear a clean stump sock and clean the socket with a solution of baking soda and water, or soap and water, household detergent, etc.

### Experimental

Other applications of Silastic have been tried experimentally. These innovations are mentioned, not as completed techniques, but as items of interest.

1. S-5391 as coating for cotton webbing in harness applications.
2. S-5391 as coating for the inner surface of plaster splints.
3. S-5391 as a laminated cover for the shank of a prosthesis.
4. S-5391 or 385 to make molds to reproduce parts.
5. 386 as build-ups for body contours (shoulder build-up for fore-quarter).
6. The viscosity of the 385 may be increased to a paste consistency by the addition of an inert filler to the elastomer. The filler used was sulca flox.
7. To separate Silastic from itself, paraffin dissolved in Xylene is recommended.

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## Dr. Lawrence W. Friedmann Appointed To Top Medical Post at Institute for Crippled and Disabled

Lawrence W. Friedmann, M.D., a specialist in physical medicine and rehabilitation and an authority on low back injuries, has been named Director of Medical Services at the Institute for the Crippled and Disabled by James N. Burrows, the Director of the rehabilitation center. The Institute is located at 23rd Street and First Avenue in New York City.

Dr. Friedmann is Instructor in Physical Medicine and Rehabilitation at the College of Medicine, New York University, with which the Institute for the Crippled and Disabled is professionally affiliated. He holds appointments as Assistant Attending Physician at New York University Hospital; Assistant Visiting Physician in the Department of Physical Medicine and Rehabilitation at City Hospital, Elmhurst, Queens, New York; and as Clinician for the Corona Stroke Project, New York City Department of Health.

Since joining the Institute's staff in 1962, Dr. Friedmann has held a series of increasingly responsible positions, the most recent being that of Associate Medical Director. In his new post, he is in charge of providing handicapped persons of all ages and with many types of disability with a broad range of medical services including orthopedics, neurology, internal medicine, physical and occupational therapy, and special programs for amputees.

He is a graduate of Syracuse University and received his medical degree at the Howard University College of Medicine, Washington, D.C. While a resident in physical medicine at the New York University Institute of Physical Medicine and Rehabilitation, Dr. Friedmann served on the Institute for the Crippled and Disabled's staff. For two years, he was a medical officer with the United States Air Force, and before that he was a resident at the Bronx Municipal Hospital Center of the Albert Einstein Medical College.