Evaluation of Synthetic Balata for Fabricating Sockets for Below-Knee Amputation Stumps

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At the present time, most sockets for artificial limbs are made of a plastic laminate (usually polyester resin and Dacron) which has been molded over a modified replica of the stump. A replica of the stump is required because human tissues cannot withstand the temperatures generated by the exothermic reaction of the plastic as it cures. The replica is modified, using general rules established by research groups, in order to achieve a relationship between the stump and socket that is physiologically satisfactory, yet permits weight-bearing and provides stability. In addition, reliefs must be provided to accommodate bony prominences and any tender spots. A simple plaster-of-paris wrap will usually be too loose for normal use. Therefore, fabrication of plastic-laminate sockets with presently available materials involves at least the following steps (Fig. 1): (a) development of a female mold of the stump by wrapping the stump with plaster-of-paris bandages, (ft) casting a male model of the stump by filling the female mold with plaster of paris, (c) modification of the male model by trimming away plaster in selected areas and building it up in other areas when necessary, and *(d)* lay-up and cure of the plastic laminate. The average time required to make a hard socket below-knee plastic prosthesis is eight man-hours.

It has been the goal of a number of research workers to find a simpler and less time-consuming method for fabricating satisfactory sockets for all levels of amputation. After many experiments involving a number of casting methods and a variety of materials, the Veterans Administration Prosthetics Center[2] by 1961 had developed a technique for molding a socket of synthetic balata directly over a below-knee stump. The first successful results were achieved by using an air-pressure sleeve over a tube of synthetic balata,[3] which had been softened by immersion in hot water (160 deg F) and then pulled over the stump *(1,2)* (Fig. 2).

Upon the recommendations of the CPRD Subcommittee on Design and Development, the Subcommittee on Evaluation undertook responsibility for the evaluation of the new technique.

The claims of the development laboratory were: (a) a substantial decrease in elapsed time between measurement of the stump and production of a wearable limb, thereby speeding the rehabilitation process, (ft) a substantial reduction in man-hours involved, (c) a capability for easy adjustment of the prosthesis at any time, and *(d)* a decrease in the amount of skill and training required to produce an adequate socket.

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[2] 252 Seventh Ave., New York, N.Y. 10001.

[3] From Polysar X-414 resin produced by the Polymer Corporation Limited, Sarnia, Ontario, Canada.

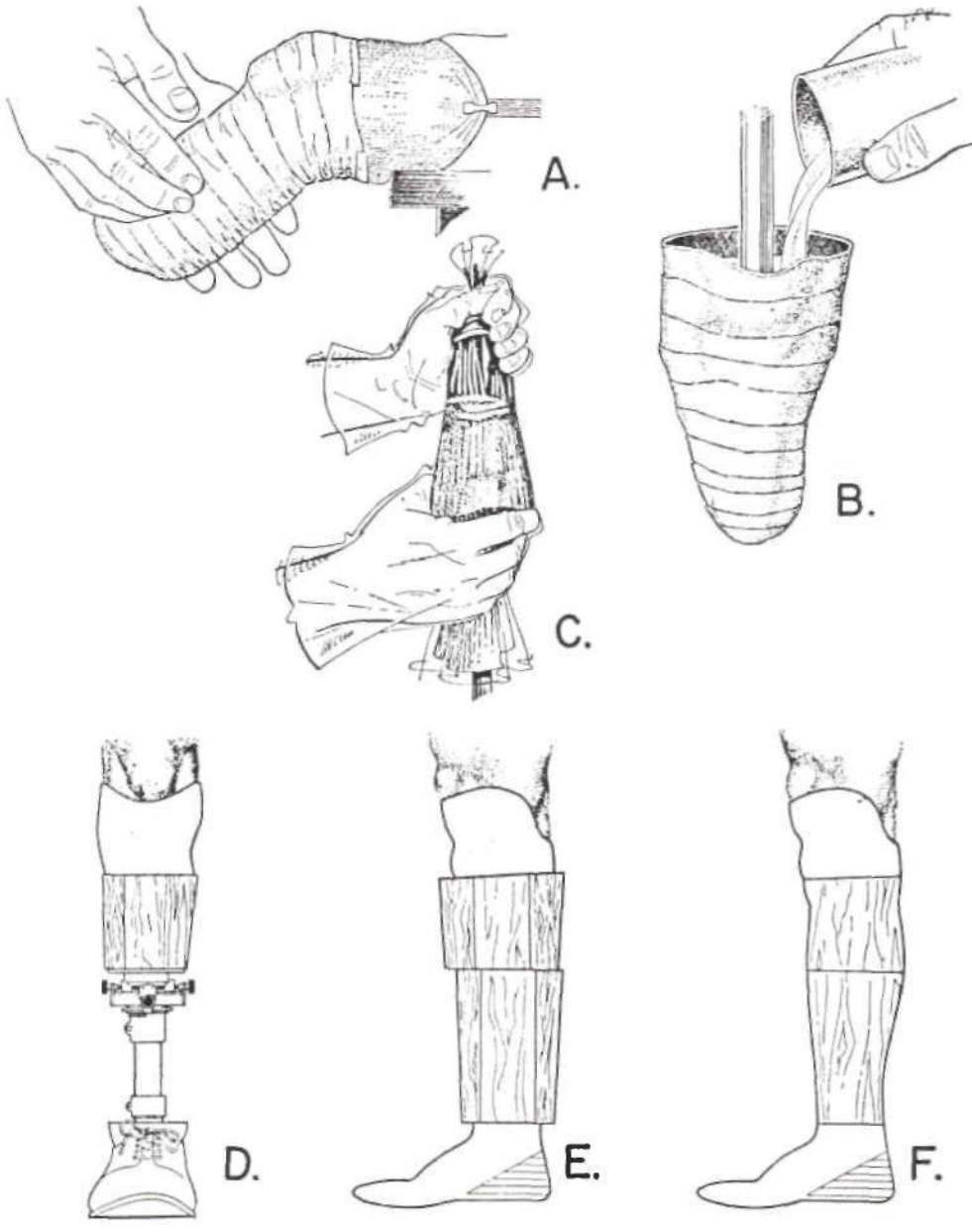


Fig. 1. Steps in the fabrication of a plastic prosthesis for a below-knee amputation. *A,* taking the plaster cast of the stump; *B,* pouring plaster in the cast to obtain model of the stump; *C,* introducing plastic resin into fabric pulled over the model to form the plastic-laminate socket; *D,* the plastic-laminate socket mounted on an adjustable shank for walking trials; *E,* a wooden shank block inserted in place of the adjustable shank after proper alignment has been obtained; *F,* the prosthesis after the shank has been shaped. To reduce weight to a minimum, the shank is hollowed out and the exterior covered with a plastic laminate.

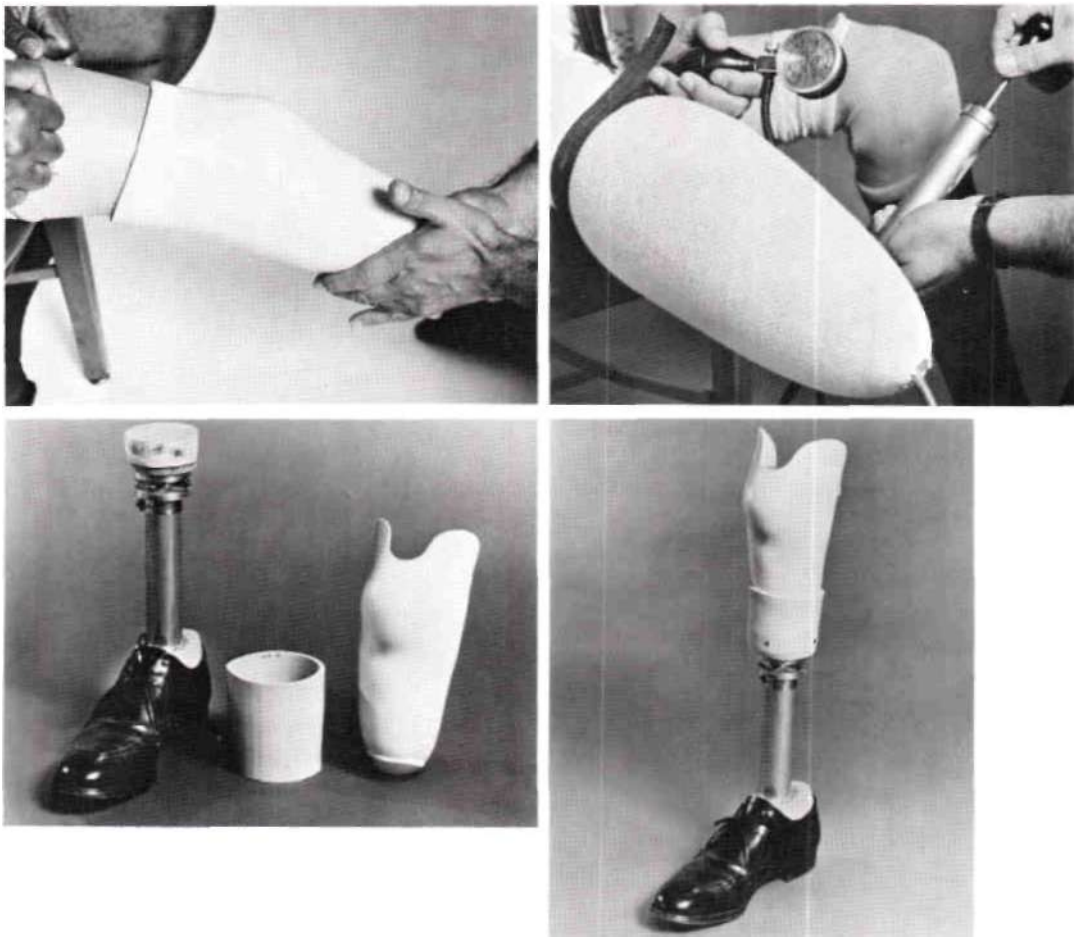


Fig. 2. The air-pressure method of forming synthetic balata sockets for PTB prostheses: application of the tube to the lubricated sleeve of the stump; application of pressure to the sock-covered pressure sleeve; and the socket and bonded tubing attached with screws to the pylon.

PROCEDURE

A protocol (given at the end of this article) was developed and five clinics[4] were asked to participate in the evaluation. The prosthetists from the clinics were trained as a group at the Veterans Administration Prosthetics Center on November 6-8, 1968. Each clinic was requested to fit five new amputees and five amputees who had worn PTB prostheses before, and provided with sufficient material and equipment to carry out the fittings.

[4] Rancho Los Amigos Hospital, Duke University, the University of Miami, the Veterans Administration Hospital/Los Angeles, and the Veterans Administration Hospital/Buffalo.

RESULTS

Follow-up in the spring of 1969 revealed that all the prosthetists were encountering difficulty in obtaining adequate fits in nearly all cases except those with long tapered stumps, most of the sockets being too loose proximally. To overcome this problem, the VAPC devised a method whereby the air bag was eliminated, and molding pressure was

brought about by wrapping the softened balata tube with one-inch-wide elastic webbing and controlling the shape of the socket with the hands and fingers as it cooled.

All of the participating prosthetists were instructed in the revised method, and other prosthetists were instructed in the new procedure at the same time. Shortly afterwards, plastic pressure-sen-

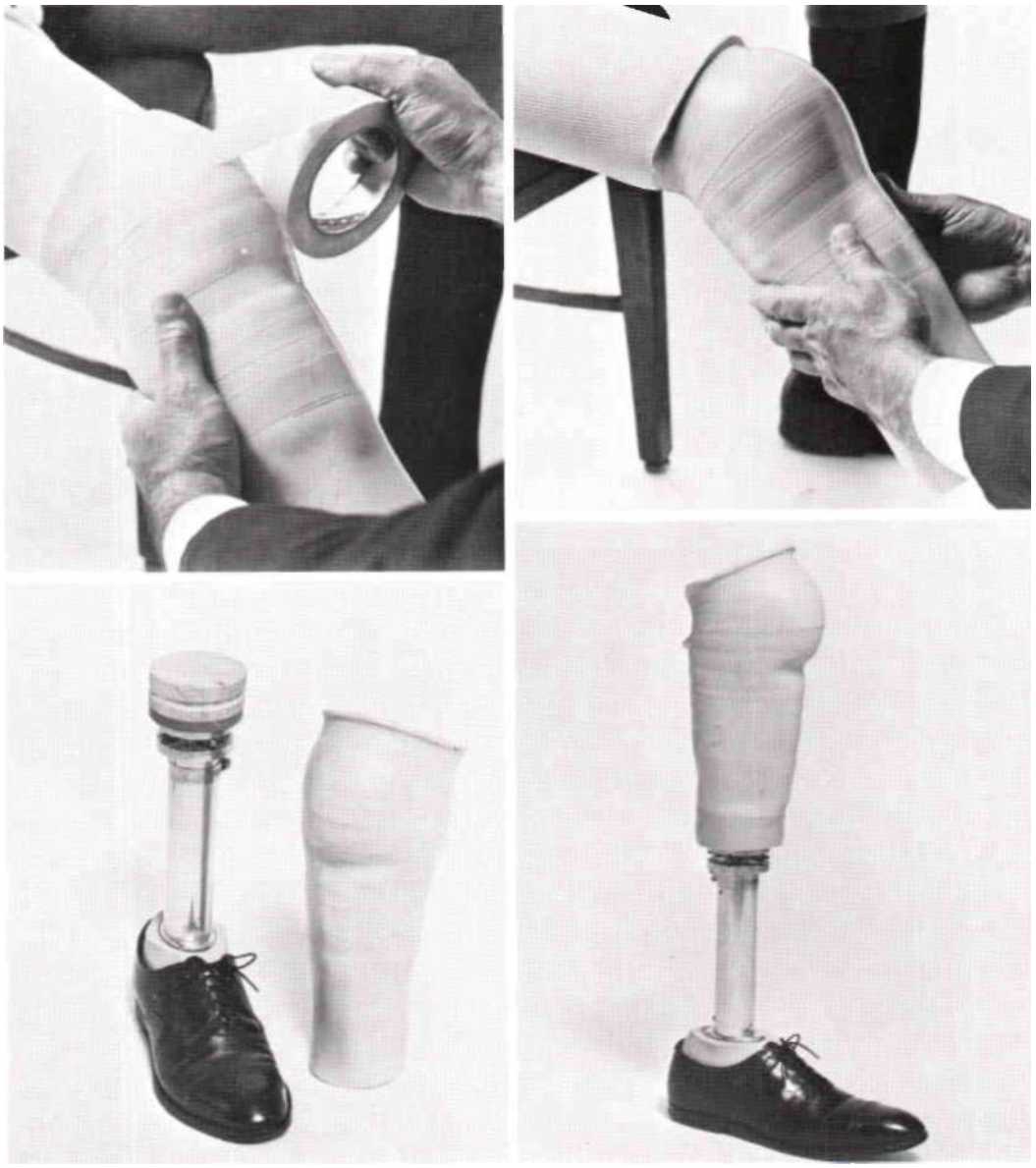


Fig. 3 The tape-wrap method of forming synthetic balata sockets: application of pressure with elastic, pressure-sensitive tape; molding by hand to define the medial tibial flare and tibial crest; and the heated socket bottom joined to the pylon by an elastic tape wrap. *(Courtesy Veterans Administration Prosthetics Center. New York, N Y)*

sitive tape was substituted for the elastic webbing (Fig. 3) (3).

The results with the revised procedure were considerably better. The average synthetic balata prosthesis, with pylon but without cosmetic treatment, weighed 3 1/2 lb, and could be made in 2 1/2 hr. All of the claims of the developer were substantiated with the exception of the relative amount of skill required, a factor that would be very difficult to measure at this stage of development. At any rate, it is safe to say that no more skill is required for the new technique than for older methods.

All prosthetists who used the technique, with one exception, felt that synthetic balata is quite useful for temporary prostheses. Some have adopted the method as standard procedures where procurement practices permit use of temporary prostheses of this type.

CONCLUSIONS

When this technique is used, a considerable saving in time can be effected, and the patient can be provided with a prosthesis within a few hours. Furthermore, the use of synthetic balata permits easier adjustment of the socket later, and the adjustable pylon permits adjustment in alignment at any time.

It is therefore recommended that use by federal and state agencies of the VAPC technique for fabricating below-knee temporary prostheses be encouraged, and that the technique be included in the curricula of all below-knee prosthetics courses.

REFERENCES

1. Fleer, Bryson, and A. Bennett Wilson, Jr., Construction of the patellar-tendon-bearing below-knee prosthesis, *Artif. Limbs,* 6:2:25-73, June 1962.
2. The Staff, Veterans Administration Prosthetics Center, Direct forming of below-knee patellar-tendon-bearing sockets with a thermoplastic material, *Orth. and Pros.,* 23:1:36-61, March 1969.
3. Staros, Anthony, and Henry F. Gardner, Direct forming of below-knee PTB sockets with a thermoplastic material, *Bull. Pros. Res.,* 10-12:34-47, Fall 1969.

PROTOCOL FOR BK POLYSAR SOCKET EVALUATION PROJECT

The purposes of the study are:

1. To determine the usefulness of Polysar as a material for sockets;

2. To determine the usefulness of the Gardner technique of socket fabrication using the pneumatic bag;

3. To gather information on the use of pylon prostheses, including cosmetic treatment, for use by designers and manufacturers.

Each prosthetist is requested to fit five new patients and five patients who have worn PTB prostheses before. Instructions given in the VAPC manual should be followed as closely as possible.

A data-collection sheet including the Medical History Form A- and Lower-Extremity Prosthetic Information Form B-l must be completed for each patient and held on file until requested by the CPRD staff. (It is not necessary to complete items 3, 4, and 7 on the Medical History Form.)

INSTRUCTIONS: FORM A

1. *Site of Amputation*
Indicate side and level of amputation(s) being fitted. Use appropriate standard abbreviations—R for right—L for left. (E.g., right below-knee = RBK)

FQ = Forequarter
SD = Shoulder Disarticulation
AE = Above Elbow
ED = Elbow Disarticulation
BE = Below Elbow
WD = Wrist Disarticulation
PH = Partial Hand
HP = Hemipelvectomy
HD = Hip Disarticulation
AK = Above Knee
KB = Knee Bearing (all cases using outside joints)
BK = Below Knee
SY = Syme
PF = Partial Foot

2. *Type of Case*
New = Stump never previously fitted.
Old = Replacement prosthesis. (Fill out item 14 regarding cause of replacement.)

3. *Source of Patient*
a. List official name of amputee clinic and physician clinic chief for all clinic cases.
b. List name of physician who refers a non-clinic case.
c. Check "Case Not Referred" in all instances where prosthetist writes the limb prescription.

4. *Source of Payment*
The more common sources of payment for a limb are:
State Bureau of Vocational Rehab.
Veterans Administration
State Crippled Children's Comm.
Workmen's Compensation
Insurance Company
Public Welfare Agency
Amputee or Family

5. *Medical Complications*
Consult clinic physician or doctor who referred case for proper item(s) to be checked.

6. *Condition of Other Extremities*
Include loss of toes, fingers or partial foot or partial hand amputations, if present.

7. *Post-Prosthetic Training*
If answer is "No," specify. The remark, "Previous prosthetic wearer," will apply in most cases where training is not prescribed.

8. *Amputation History*
Many diabetic and arteriosclerotic cases have had one or more previous amputations involving one or both of their lower extremities. This form provides space for three such amputations. *Do not record a "partial foot"* as a separate amputation on this form. Record as a separate amputation a reamputation at a higher level. A high percentage of such reamputations occur within six weeks of the original amputation and are due to a failure of the wound to heal properly. Record the cause of such reamputations as "Failure of amputation of _____ (date) _____ to heal." These stumps are never fitted, so the items "Date Prosthesis Provided" and "Prosthetic Result" would be left blank. Multiple amputations that occasionally occur in injury cases should be recorded as a single amputation, listing the two or more levels (left above elbow and right below elbow as LAE-RBE). In old amputations, if exact dates are unknown, record an estimate.

9. *Level and Side of Amputation*
Use standard abbreviations as listed above.

10. *Cause of Amputation*
For a correct diagnosis, consult with the clinic chief or physician who refers the case. One of the following listed causes will apply in nearly all cases:

Injury (specify type)	Thrombosis
Arteriosclerosis	Embolism
Diabetes	Buerger's Disease
Malignant Tumor	Infection

11. *Date Prosthesis Provided*
Record the date of the initial check-out of the completed prosthesis. Leave this item and the following item "Prosthetic Result" blank in all new cases since the tear-off Form A will have been forwarded to the National Academy of Sciences before this information is known. At periodic intervals, you will receive a list of the new cases you have sent and, at that time, by referring to your facility copy of Form A, you will be able to furnish this information.

12. *Prosthetic Result*
Consider the age and physical condition of the amputee as well as the purpose for which the device was provided in recording this item. In an elderly person, limited ambulation about his home might be considered as "Satisfactory."

13. *Protective Surgery*
An increasing number of vascular cases are today receiving protective surgery to prevent or delay amputation. Consult the clinic chief or referring physician for type of procedure used. These include: sympathectomy, thrombendarterectomy, arterial graft, and venous graft.

14. *Old Cases*
Indicate reason for replacing present prosthesis.

15. *Remarks*
This space can be used to note any item of importance not covered previously or to add additional information on any of the above data items.

MEDICAL HISTORY

(Name of Facility)

Name of Patient _____ Date _____

Male ☐ Female ☐ Date of Birth _____ Height _____ Weight _____

1 Site of Amputation _____ 2 Type of Case: New _____ Old _____

3 Source of Patient (prosthetic prescription)

☐ Amputee Clinic _____ Clinic Chief _____

☐ Name of Physician _____ ☐ Case Not Referred

4 Source of Payment _____ Occupation _____

5 Medical Complications (check conditions that can affect type of prescription or use of prosthesis)

☐ Heart Disease ☐ Arthritis ☐ Serious Visual Impairment

☐ Mental Disease ☐ Obesity ☐ Other (specify) _____

6 Condition of Other Extremities ☐ Amputated Level _____

☐ Normal ☐ Vascular Disease ☐ Paralysis

☐ Other (specify) _____

Amputee Received Pre-Prosthetic Training: Yes ☐ No ☐ (specify) _____

7 Post Prosthetic Training Prescribed: Yes ☐ No ☐ (specify) _____

8 Amputation History

Date of First Amputation _____ 9 Level and Side of Amputation _____

Cause of Amputation (if congenital, describe) _____

Prosthetic Result: ☐ Satisfactory Date Prosthesis Provided _____

☐ Unsatisfactory (specify) _____

Date of Second Amputation _____ Level and Side of Amputation _____

10 Cause of Amputation _____

12 Prosthetic Result: ☐ Satisfactory 11 Date Prothesis Provided _____

☐ Unsatisfactory (specify) _____

Date of Third Amputation _____ Level and Side of Amputation _____

Cause of Amputation _____

Prosthetic Result: ☐ Satisfactory Date Prosthesis Provided _____

☐ Unsatisfactory (specify) _____

13 Protective Surgery

Date	Procedure	Extremity

14 Old Cases

Replacement of Present Prosthesis: (Type and Age) _____

☐ Worn Out ☐ Outgrown ☐ Weight Gain ☐ Weight Loss

☐ Present Prosthesis Unsatisfactory (Cause)

15 Remarks: _____

Form A-

INSTRUCTIONS: FORMS B-1 AND B-2

1. Forms B-1 and B-2 provide certain information that has already been entered on Form A. These items are repeated for the convenience of the shop worker.
2. Draw in approximate length and shape of stump to show a Syme, knee disarticulation, or hip disarticulation amputation level. Indicate location of stump abnormalities with an "X" and identify each "X" with appropriate code letters (e.g., Bs for bone spur, etc.). Use space under "Remarks" for additional information on any item.
3. Rx for Prosthesis: Record physician's prescription. For example, "One PTB below-knee prosthesis."
4. Give model name and/or number as provided by supplier of item.
5. In measurement diagrams:


= circumference
= distance between two points
= diameter

LOWER-EXTREMITY PROSTHETIC INFORMATION

Name of Patient _____

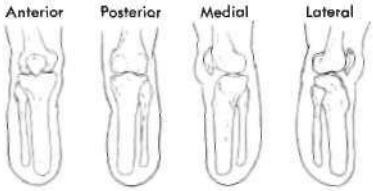
Site of Amputation _____ Right _____ Left _____

Clinic _____ Physician _____

(Show Location of Stump Details, Identify with Code Letters)

BELOW KNEE

Anterior Posterior Medial Lateral

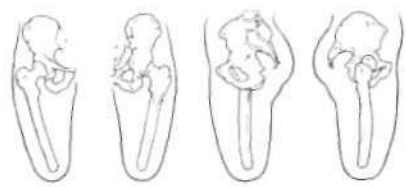


Stump Length: _____ inches

A = abrasion
B = boil or skin infection
Bu = bursa
Bs = bone spur
D = discoloration
E = edema
I = irritation
M = muscle bunching
P = pressure point
R = redundant tissue
S = scar
T = trigger point

ABOVE KNEE

Anterior Posterior Medial Lateral



Stump Length: _____ inches

BELOW-KNEE STUMP CHARACTERISTICS

Stump Shape: _____ Distal Padding: _____

Subcutaneous Tissue: Heavy ☐ Light ☐

Distal Pressure Tolerance: None ☐ Slight ☐ Good ☐

Condition of Thigh Musculature: Atrophy ☐ Normal ☐

Condition of Stump Musculature: Atrophy ☐ Normal ☐

Knee Stability: _____

Range of Knee Motion: _____

Degrees of Knee Contracture: _____ °

Condition of Cut Bones: Tibia _____ Fibula _____

Remarks: _____

ABOVE-KNEE STUMP CHARACTERISTICS

Stump Musculature	Soft	Average	Hard
General			
Hamstring Group			
Gluteal Group			
Rectus Femorus			
Adductor Longus			

Subcutaneous Tissue: Heavy ☐ Light ☐

Ischium: Toughened ☐ Pressure Sensitive ☐
Muscle Padding Prominent

Position of Trochanter: Anterior ☐ Midline ☐ Posterior ☐

Previous Ischial Bearing: Yes ☐ No ☐

Stump Lateral Contour: Convex Out ☐ Flat ☐ Concave In ☐

Degree of Contracture: Hip Flexion °
Stump Adduction ☐ ° Abduction °

Remarks:

3 Rx for Prosthesis:

4 Foot Comp. Model	**4** Knee Comp. Model	Socket Materials	Type of Symes	**4** Hip-Joint Model Type
4 Ankle Comp. Model	Type of Socket	Shank Materials	Hip Disartic. Type	Type of Suspension

B-1

(Consult instructions on back for all items marked with numbers)

LOWER-EXTREMITY PROSTHETIC MEASUREMENTS

Name of Patient _____ Phone _____ Date _____

Address _____ City _____ State _____

Male ☐ Female ☐ Date of Birth _____ Height _____ Weight _____

Type Prosthesis _____ Right ___ ___ Left _____

Shoe Furnished: One ☐ Both ☐ None ☐

Shoe Lace Opening: Top ___ In. Bottom ___ In.

Extra Light-Weight Limb: ☐

Extra Strong Limb: ☐

KB or BK Knee Joints: Size _____ Style _____

Ankle Joint: Size _____ Style _____

KB or BK Thigh Lacing: Eyelets ☐ Hooks ☐

Other: _____

Thigh Lacer Height: _____

Shoulder Loop Size: _____

Waist Belt Size: _____

Finish of Limb: Plastic Laminate ☐

Rawhide Enamel ☐

Color: Caucasian ☐ Negroid ☐

Light Brown ☐ Medium ☐ Dark Brown ☐

Check Strap: Lace ☐ Leather Strap ☐

Measured by: _____

Shop Alterations

Lengthen Thigh ___ In. Shorten Thigh ___ In.

Lengthen Shin ___ In. Shorten Shin ___ In.

KB or BK Lace Opening: Top ___ In. Bottom ___ In.

Set BK Lacer on Joints:

Higher ___ In. Lower: ___ In.

Lateral BK Joint Head:

Set In ___ In. Set Out ___ In.

Medial BK Joint Head:

Set In ___ In. Set Out ___ In.

Fit Foot In Shoe: Tight ☐ Loose ☐ Medium ☐

Make Heel Cushion: Soft ☐ Medium ☐ Firm ☐

Special Changes: _____

Fitted By: _____

Finished BK Limb, Knee Center to Floor: ___ In.

Finished AK Limb, Ischium to Floor: ___ In.

Weight of Finished Limb: ___ lbs. ___ oz.

Special Features: _____

Date Completed: _____

B-2