

**EVALUATION OF SYNTHETIC BALATA FOR  
FABRICATING SOCKETS FOR BELOW-KNEE  
AMPUTATION STUMPS**

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**REPORT E-3**

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EVALUATION OF SYNTHETIC BALATA FOR FABRICATING  
SOCKETS FOR BELOW-KNEE AMPUTATION STUMPS

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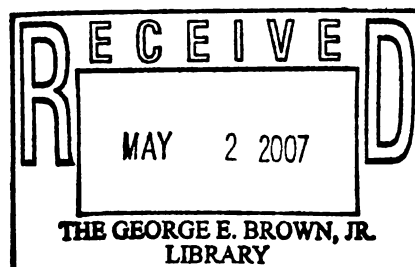
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REPORT E-3



**RD756.4 .W56 1970 c.1**  
**Evaluation of synthetic**  
**balata for fabricating**  
**sockets for ...**

## EVALUATION OF SYNTHETIC BALATA FOR FABRICATING SOCKETS FOR BELOW-KNEE AMPUTATION STUMPS

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, (b) 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<sup>1</sup> 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,<sup>2</sup> which had been softened by immersion in hot water (160 deg. F.) and then pulled over the stump (1, 2) (Fig. 2).

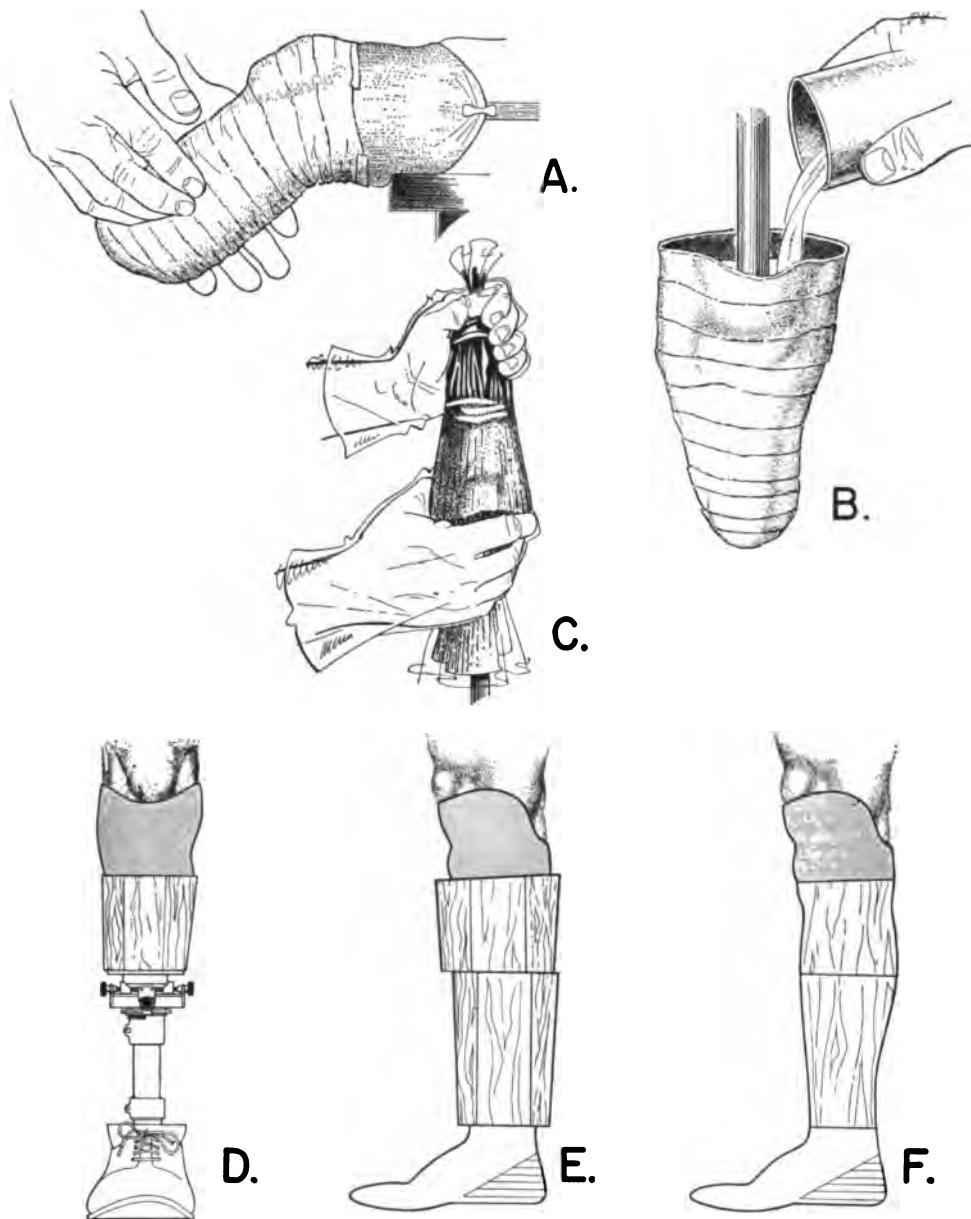
Upon the recommendations of the CPRD Subcommittee on Design and Development, the Subcommittee on Evaluation undertook responsibility for the evaluation of the new technique.

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<sup>1</sup>252 Seventh Ave., New York, N.Y. 10001.

<sup>2</sup>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.**







**Fig. 2. The air-pressure method of forming synthetic balata sockets for PTB prostheses.**



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, (b) 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.

#### PROCEDURE

A protocol (Appendix A) was developed and five clinics<sup>3</sup> 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.

#### 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-sensitive 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  $3\frac{1}{2}$  lb., and could be made in  $2\frac{1}{2}$  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

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<sup>3</sup>Rancho Los Amigos Hospital, Duke University, the University of Miami, the Veterans Administration Hospital/Los Angeles, and the Veterans Administration Hospital/Buffalo.





**Fig. 3.** The tape-wrap method of forming synthetic balata sockets.



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.

#### LITERATURE CITED

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

BK POLYSAR SOCKET EVALUATION PROJECT

Purposes of the Study:

1. To determine usefulness of Polysar as a material for socket
2. To determine 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-1 must be completed for each patient and held on file until requested by CPRD staff. (It is not necessary to complete items 3, 4, and 7 on Medical History Form.)



**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  Unsatisfactory (specify) \_\_\_\_\_  
Date Prosthesis Provided \_\_\_\_\_

Date of Second Amputation \_\_\_\_\_ Level and Side of Amputation \_\_\_\_\_

10 Cause of Amputation \_\_\_\_\_

12 Prosthetic Result:  Satisfactory  Unsatisfactory (specify) \_\_\_\_\_  
11 Date Prosthesis Provided \_\_\_\_\_

Date of Third Amputation \_\_\_\_\_ Level and Side of Amputation \_\_\_\_\_

Cause of Amputation \_\_\_\_\_

Prosthetic Result:  Satisfactory  Unsatisfactory (specify) \_\_\_\_\_  
Date Prosthesis Provided \_\_\_\_\_

**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: \_\_\_\_\_

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)
- Arteriosclerosis
- Diabetes
- Malignant Tumor
- Thrombosis
- Embolism
- Buerger's Disease
- 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.

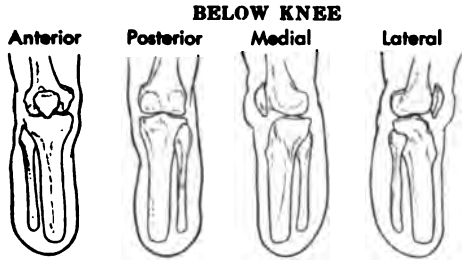
**LOWER-EXTREMITY PROSTHETIC INFORMATION**

Name of Patient \_\_\_\_\_

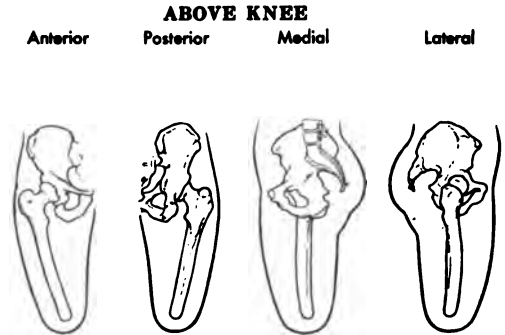
Site of Amputation \_\_\_\_\_ Right \_\_\_\_\_ Left \_\_\_\_\_

Clinic \_\_\_\_\_ Physician \_\_\_\_\_

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



- 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



Stump Length: \_\_\_\_\_ inches

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 Femoris _____			
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 \_\_\_\_\_ Concave \_\_\_\_\_

Out  Flat  In

Degree of Contracture: Hip Flexion \_\_\_\_\_°

Stump Adduction  \_\_\_\_\_° Abduction \_\_\_\_\_°

Remarks: \_\_\_\_\_

**3 Rx for Prosthesis:**

<b>4 Foot Comp. Model</b>	<b>4 Knee Comp. Model</b>	<b>Socket Materials</b>	<b>Type of Symes</b>	<b>4 Hip-Joint Model Type</b>
<b>4 Ankle Comp. Model</b>	<b>Type of Socket</b>	<b>Shank Materials</b>	<b>Hip Disartic. Type</b>	<b>Type of Suspension</b>

(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 \_\_\_\_\_

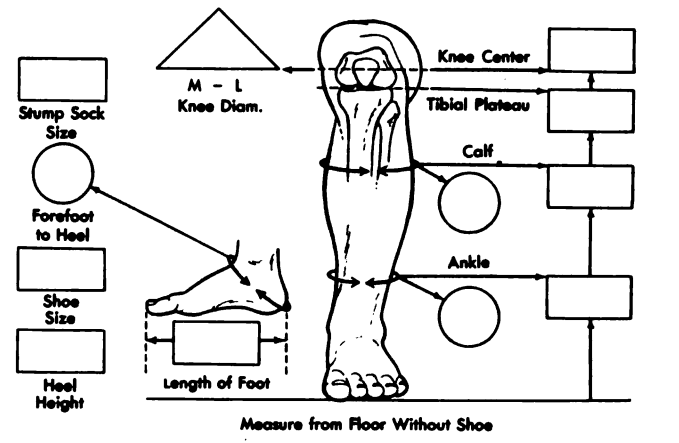
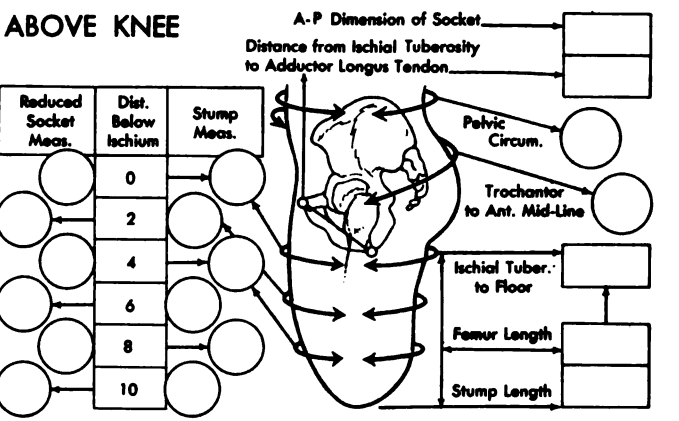
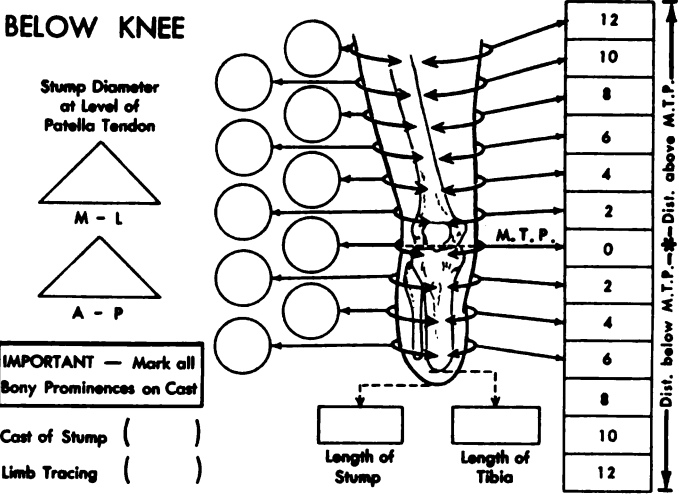
Shoe Furnished: One  Both  None   
 Shoe Lace Opening: Top \_\_\_\_\_ In. Bottom \_\_\_\_\_ In.  
 Extra Light-Weight Limb:   
 Extra Strong Limb:   
 KB or BK Knee Joints: Size \_\_\_\_\_ Style \_\_\_\_\_  
 Ankle Joint: Size \_\_\_\_\_ Style \_\_\_\_\_  
 KB or BK Thigh Lacing: Eyelets  Hooks   
 Other: \_\_\_\_\_  
 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: \_\_\_\_\_





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