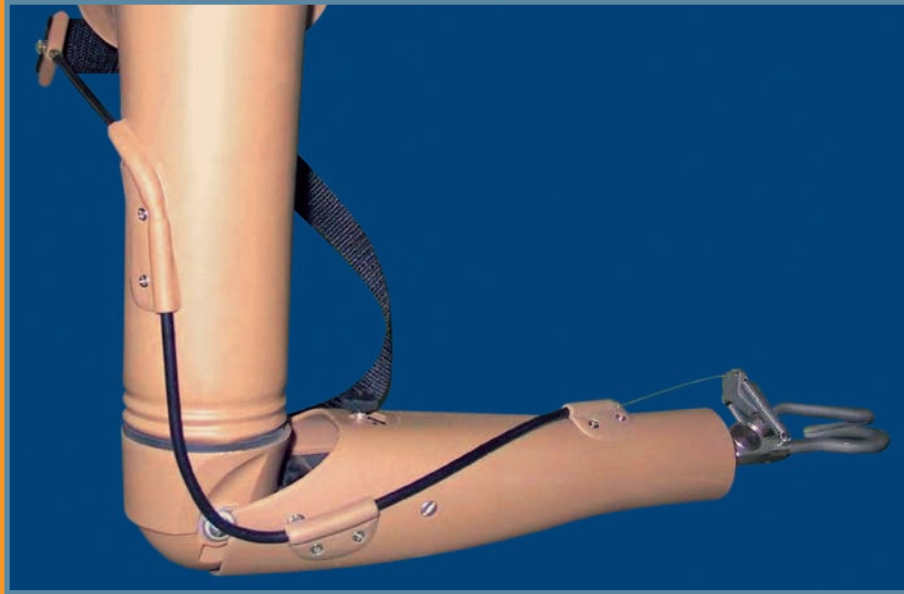


MANUFACTURING GUIDELINES



TRANS-HUMERAL PROSTHESIS

Physical Rehabilitation Programme



ICRC



ICRC

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Foreword

The ICRC polypropylene technology

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

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

The technology adopted must therefore be:

- durable, comfortable, easy for patients to use and maintain;
- easy for technicians to learn, use and repair;
- standardized but compatible with the climate in different regions of the world;
- low-cost but modern and consistent with internationally accepted standards;
- easily available.

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

For all these reasons, the ICRC preferred to develop 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 programmes back in 1979, locally available materials such as wood, leather and metal were used, and orthopaedic components were manufactured locally. In the early 1990s the ICRC started the process of standardizing the techniques used in its various projects around the world, for the sake of harmonization between the projects, but more importantly to improve the quality of services to patients.

Polypropylene (PP) was introduced into ICRC projects in 1988 for the manufacture of 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 and EthylVinylAcetate (EVA), and now of polypropylene and polyurethane, 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 patient care and training of personnel at country level.

Objective of the manuals

The ICRC's "Manufacturing Guidelines" are designed to provide the information necessary for production of high-quality assistive devices.

The main aims of these informative manuals are as follows:

- To promote and enhance 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 high-quality services.

ICRC

Assistance Division/Health Unit

Physical Rehabilitation Programme

Introduction

This document describes a method for production of **trans-humeral prostheses**, working with the ICRC polypropylene technology and orthopaedic components used at the Regional Physical Rehabilitation Centre in Battambang, Cambodia.

The casting, rectification and alignment methods used correspond to international prosthetic and orthotic (P&O) standards of practice and are therefore not described in these ICRC manufacturing guidelines.

- ▶ Patient assessment, casting and rectification of positive cast impressions are performed in accordance with P&O standards.



- ▶ Alignment lines antero-posterior and medio-lateral (A-P, M-L) are drawn on the positive mould for proper positioning of the elbow cup. In most cases, this will be along the central axis of the trans-humeral stump.

Drive nails into the distal end of the cast to ensure good adherence for the build-up of the plaster extension.



- ▶ Make a conical extension tube using EVA, plastic sheeting or some other suitable material and position it according to the alignment lines for the elbow cup. Tape the cone in place and fill it with plaster up to the level of the proximal end of the elbow cup.

For measurements see following paragraph.



- ▶ Prolong the proximal alignment lines along the plaster extension in order to facilitate positioning of the elbow cup.

The measurement from the acromion to the lateral epicondyle of the sound side, minus the distance from the elbow axis to the distal end of the elbow cup, will determine the length of the trans-humeral socket.

Drive a nail into the distal part of the build-up to ensure good adherence of the cup, and fix the cup in proper alignment with wet plaster in accordance with P&O standards (use an alignment table if available).



- ▶ Before draping the polypropylene sheet, pull a stocking over the plaster mould. Cut it at the proximal part of the elbow cup and fix it with contact glue. Dust the stocking with talcum powder.



- ▶ Measurements for polypropylene sheet:

Cup circumference + 2 cm
 Acromion circumference + 5 cm
 Length of plaster cast + 15 cm

Thickness of sheet: 4 mm

Heat the polypropylene in an oven for about 20 minutes at 180°C.



- ▶ Drape the polypropylene over the plaster model and stick the sides together along the medial side of the socket. Tighten the polypropylene around the suction cone or tube using a bicycle inner tube, rope or stocking, then open the vacuum valve.



- ▼ Remove the plaster, shape the socket trim lines and grind the medial welding seam.

Flatten the polypropylene on the distal end of the elbow cup.

Assemble the elbow unit and cut the forearm according to the measurement. The length of the forearm, including the hook, should be 1 to 2 cm shorter than the sound side. Fix the wrist unit with 4 pan head Phillips framing screws (8 x 3 mm).



- ▶ For the hook cable attachments, duplicate the outside distal part of the trans-humeral socket and the forearm with plaster bandages. Fill the two negatives with plaster and smooth them.

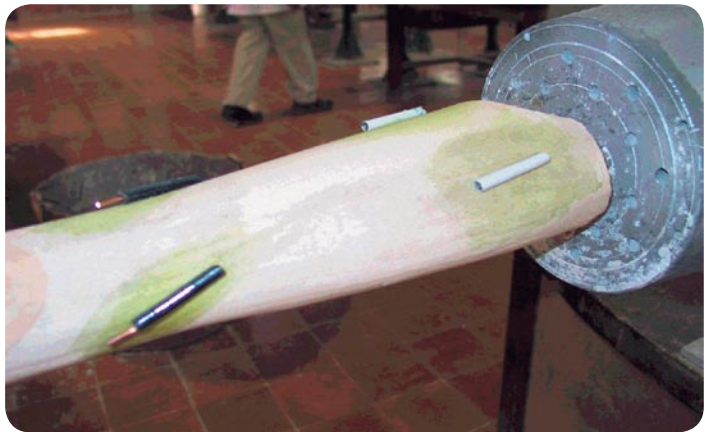


- ▶ Pull stockinet over the plaster models.



- ▶ On the arm mould, place a bicycle brake cable housing 7 cm above the distal end of the elbow cup and curve the upper part according to the position of the harness.

On the forearm, place the proximal cable housing dummy laterally, 3 cm from the elbow axis, to allow full flexion of the forearm. The distal cable housing is placed on the anterior part of the forearm, at least 5 cm from the wrist, to allow rotation of the hook.



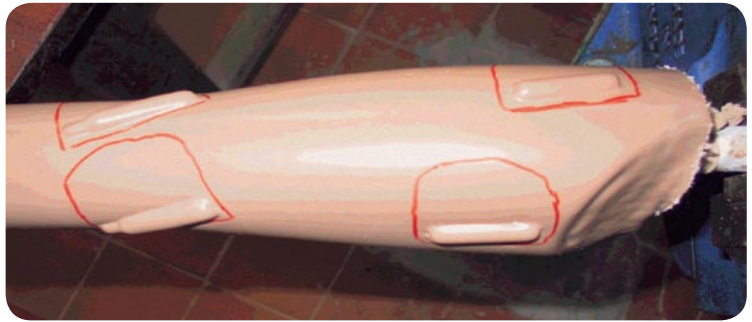
- ▶ Fix the cable housing dummies to the stockinet with contact glue.

To prevent the cable housings from being flattened when draping the polypropylene, insert an electric wire in them.

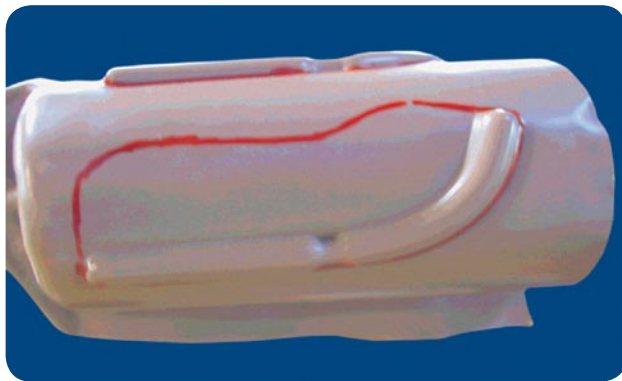
It is possible to make several hook cable attachments (e.g. left and right) on the same mould.



- ▶ Drape a 3 mm polypropylene sheet over the arm using the same measurements and draping techniques as for the trans-femoral socket.

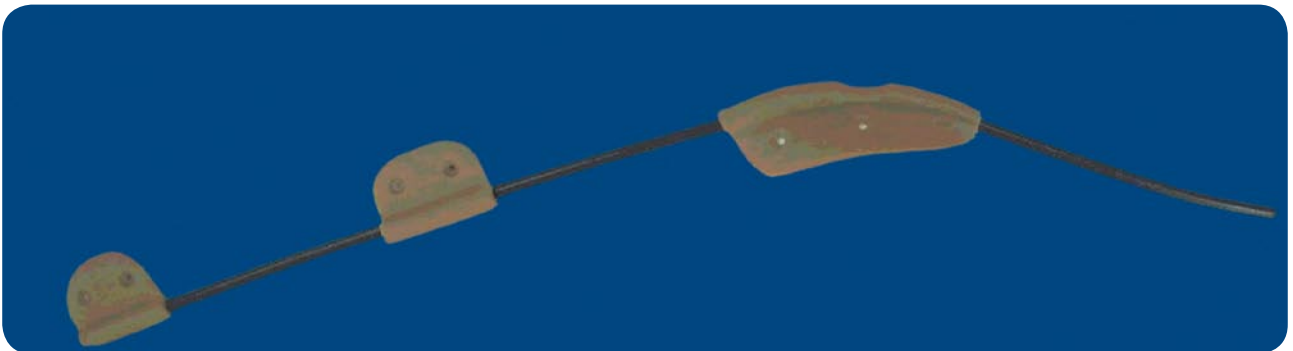
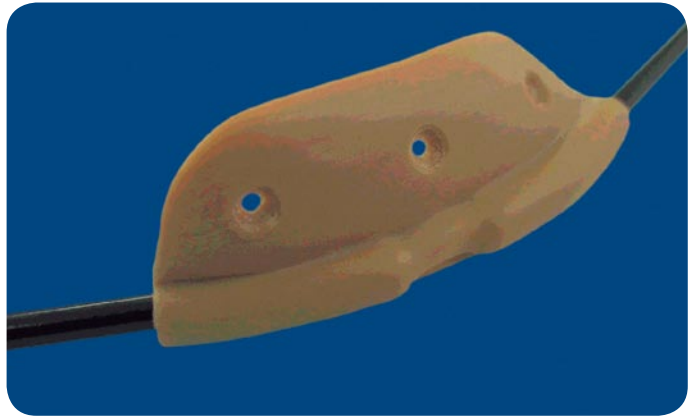


- ▶ When the polypropylene has cooled, mark the trim lines of the hook cable attachments and cut with an oscillating saw.



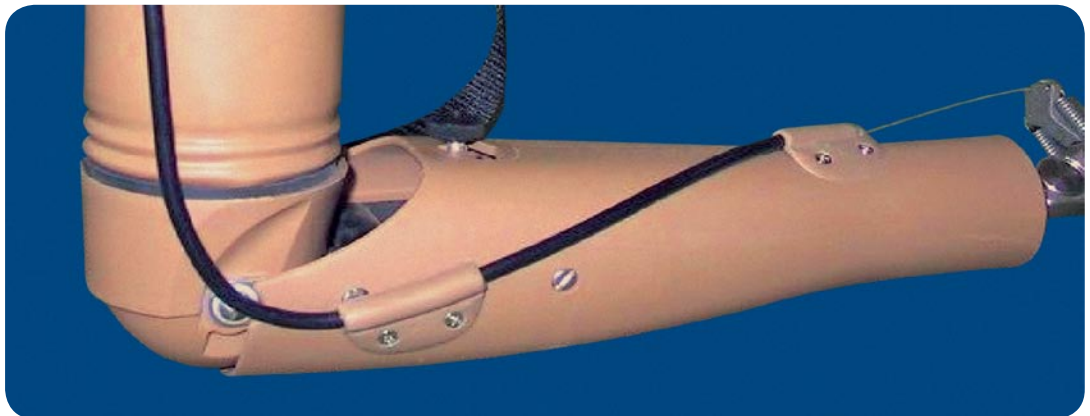
- ▼ Cut and shape the polypropylene cable fixations and insert the cable housing into the channels.

Drill holes corresponding to the diameter of the tubular rivets or screws (see next paragraph).



- ▶ The finished hook cable attachments are placed in the same position as on the plaster mould.

On the forearm they are fixed with countersunk head self-tapping screws (d1=3 mm, L=10 mm).



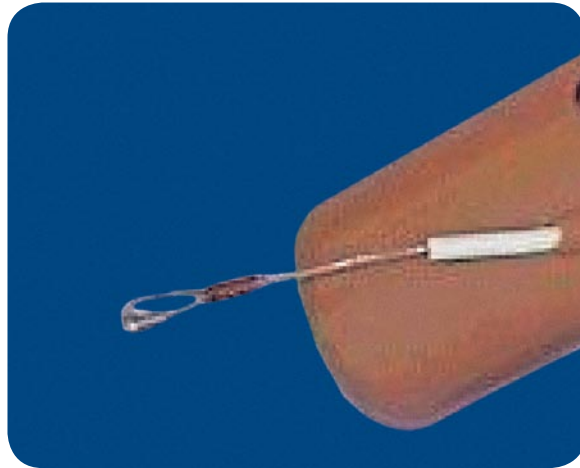
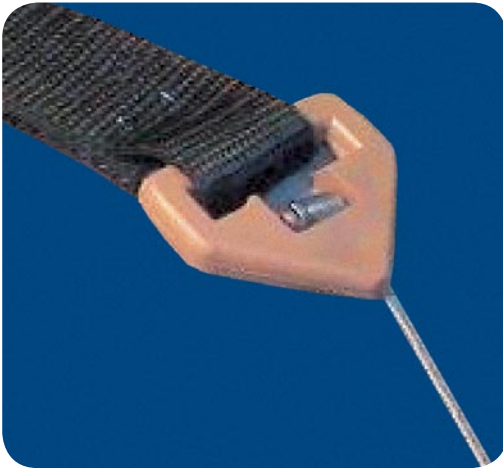
- ▶ On the trans-humeral socket, the hook cable attachment is also placed in the same position as on the plaster mould.

Fix the attachment with tubular rivets (8 x 9 mm).

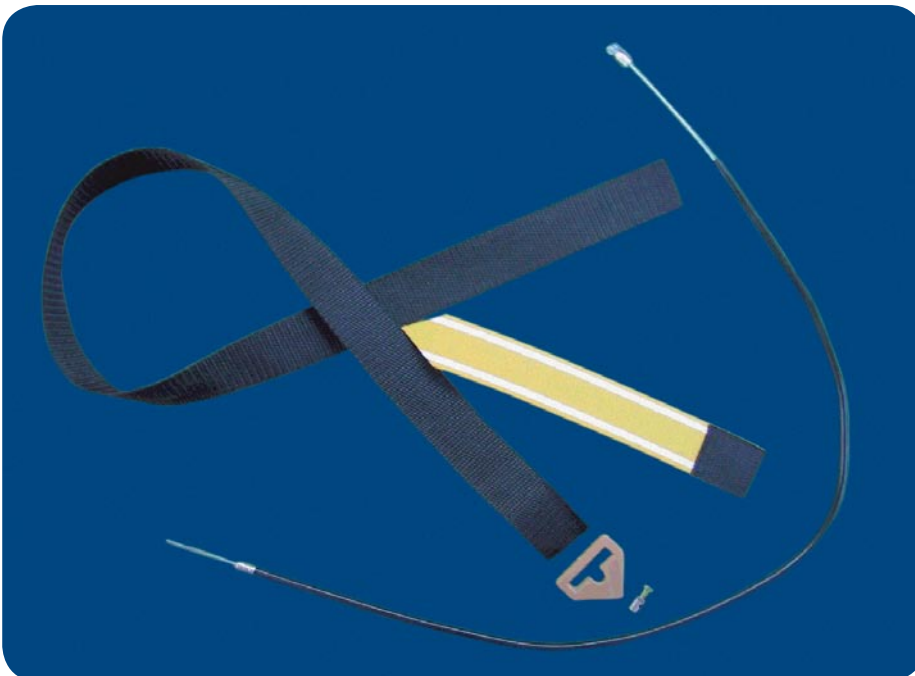
Should the position of the attachments have to be changed, warm them with a heat gun and mould them again against the arm socket or forearm.



- ▼ Insert the bicycle brake cable into the housing. On the proximal part, fix a webbing hanger with a screw clamp. On the distal part, make a loop with the cable and secure it with a small metal tube (clamp sleeve), which is flattened (pressed) around the cable.



- ▼ The simplest type of harness for operating the hook is the “figure of eight” suspension.



- ▶ Fold the nylon belt around the opposite shoulder. The connection should be adjusted in the middle of the back (spine).



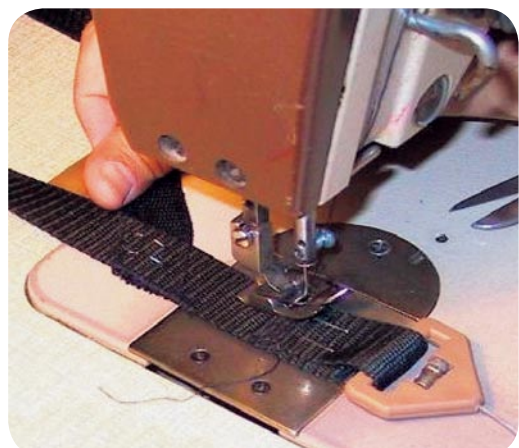
- ▶ Staple or clamp the harness together. When cutting the belt, leave it a little longer so that it can be readjusted.

Check with the amputee that the cable control system functions properly in different arm positions.

To open the hook, the patient moves his shoulder on the sound side (opposite side for double amputees) or the prosthesis forward.



- ▶ Once the harness has been adjusted so that the amputee feels comfortable with it, sew the belt connection and the fixation onto the webbing hanger.

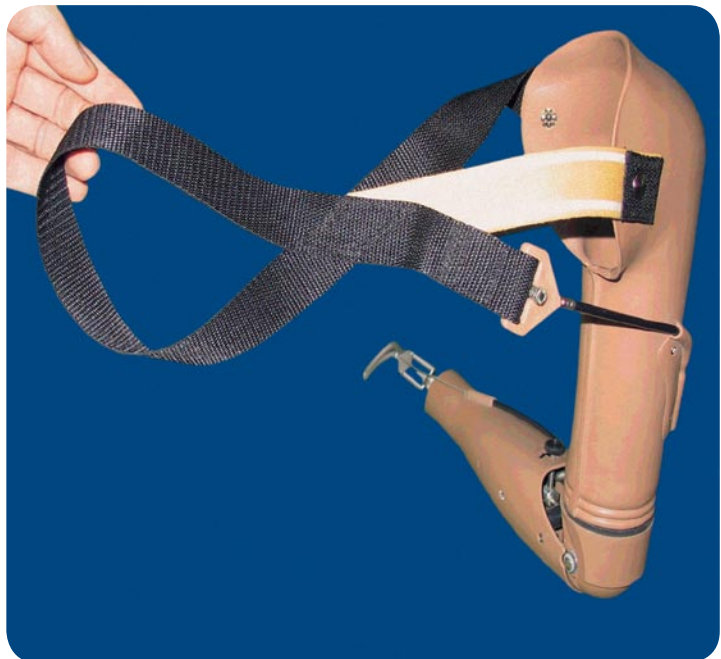


- ▶ To prevent fraying, melt the fibres at the end of the belt with a welding iron.

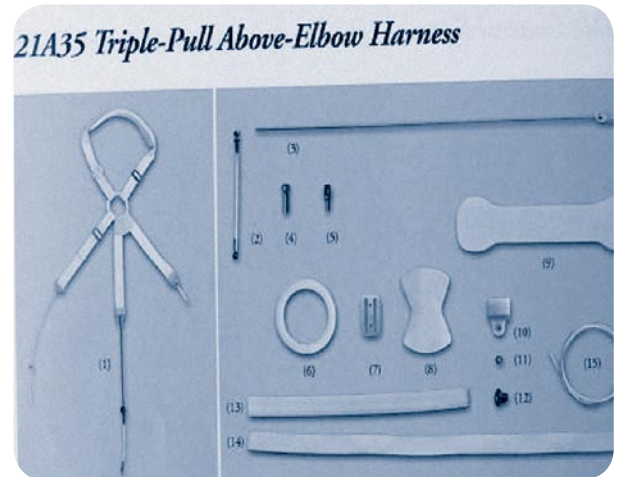
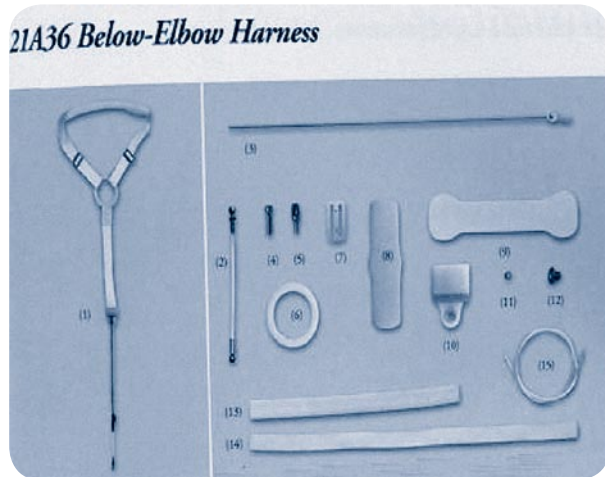


- ▶ The harness is connected to the webbing hanger on the posterior side, while the other end is fixed to the anterior wall with a tubular rivet.

The elastic strap enables the amputee to open and close the working hook.



- ▼ Other harnessing systems, such as those produced by the Otto Bock Company, may be used.





- ▶ Next to the hook or working ring, a cosmetic hand or other tool required by the patient may be attached (screwed on).



List of components, CR Equipments SA (CRE)

ICRC Code	Description	Unit of measure	Quantity
OCPOELBOKIA OCPOELBOLIA OCPOELBOERA	*Elbow, adult *Elbow kits are available in three different colours. Choose ICRC code according to colour.** ** Skin colour ** Olive colour ** Terra colour	Kit	1
	One elbow kit comprises:		
	• Elbow unit	Each	1
	• Elbow cup with M6 T-nut	Each	1
	• Rubber joint, D70 x d6 x H3 mm	Each	1
	• PP wrist unit with M10 T-nut, dia. 45 mm	Each	1
	• Pan head Phillips framing screws 8 x 3 mm for wrist unit	Each	4
OCPOHOOKAL	*Hook, adult, left, stainless steel, M10 thread <i>According to side of amputation</i>	Each	1
OCPOHOOKAR	*Hook, adult, right, stainless steel, M10 thread <i>*According to side of amputation</i>	Each	1
KORTHOOKSP	Spare parts for hook:		
	Rubber washer, D30x d10x H6 mm	Each	10
	Stainless steel spring	Each	10
OCPOHOOKKRT	*Working round ring tool, stainless steel with rubber washer <i>*On request by amputee</i>	Each	1
OCPOHANDERML OCPOHANDERMR OCPOHANDERWL OCPOHANDERWR	Terra colour:		
	Hand, man, left, terra colour	Each	1
	Hand, man, right, terra colour	Each	1
	Hand, woman/child, left, terra colour	Each	1
OCPOHANDKIML OCPOHANDKIMR OCPOHANDKIWL OCPOHANDKIWR	Beige colour:		
	Hand, man, left, beige colour	Each	1
	Hand, man, right, beige colour	Each	1
	Hand, woman/child, left, beige colour	Each	1
OCPOHANDLIML OCPOHANDLIMR OCPOHANDLIWL OCPOHANDLIWR	Olive colour:		
	Hand, man, left, olive colour	Each	1
	Hand, man, right, olive colour	Each	1
	Hand, woman/child, left, olive colour	Each	1
	Hand, woman/child, right, olive colour	Each	1

List of other manufacturing materials

ICRC Code	Description	Unit of measure	Quantity
MDREBANDP10 MDREBANDP12	Plaster bandages 10 cm or Plaster bandages 12 cm		According to stump dimension
OMIS	Plaster of Paris		According to cast dimension
OMIS	Nails	Each	4
OPLAEVAFERA03 OPLAEVAFKIN03 OPLAEVAFLIV03	EVA 3 mm, plastic sheet or other for extension tube	Each	1, dimension according to TH socket extension length
OMIS	Tubular nylon stocking, 60 or 80 mm for PP draping	Each	1, length according to TH socket
OMIS	Bicycle brake housing dummies with electric cable	Each	Length described in book cable attachments
OPLAPOLYCHOC04 OPLAPOLYCHOC05	Polypropylene 4 or 5 mm according to patient size: Polypropylene 4 mm, terra brown Polypropylene 5 mm, terra brown	Each	Dimension explained in PP draping technique
OPLAPOLYSKIN04 OPLAPOLYSKIN05	Polypropylene 4 mm, beige Polypropylene 5 mm, beige		
OPLAPOLYLIV04 OPLAPOLYLIV05	Polypropylene 4 mm, olive Polypropylene 5 mm, olive		
OPLAPOLYCHOC03 OPLAPOLYSKIN03 OPLAPOLYLIV03	Polypropylene 3 mm for cable attachment dummies: Polypropylene 3 mm, terra brown Polypropylene 3 mm, beige Polypropylene 3 mm, olive	Each	
OMIS	Definitive bicycle brake cable with housing	Each	1, cut according to patient size
OMIS	Fixation for cable attachment on forearm: Countersunk head self-tapping screws d1 = 3 mm, L = 10 mm	Each	4
OHDWRIVET081	Fixation for PP cable attachment on trans-femoral socket and harness: Tubular rivets 8 x 9 mm	Each	5
OMIS	PP webbing hanger or other fixation method	Each	1
OMIS	Harness nylon (or other) belt (width 25 mm) with elastic strap (width 25 mm) or Harness for upper limb prostheses	Each	1, length according to patient size

MISSION

The International Committee of the Red Cross (ICRC) is an impartial, neutral and independent organization whose exclusively humanitarian mission is to protect the lives and dignity of victims of war and internal violence and to provide them with assistance. It directs and coordinates the international relief activities conducted by the Movement in situations of conflict. It also endeavours to prevent suffering by promoting and strengthening humanitarian law and universal humanitarian principles. Established in 1863, the ICRC is at the origin of the International Red Cross and Red Crescent Movement.

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