



Spectrum Designs, Inc
6387-B Rose Lane
Carpinteria, CA 93013
(800) 239-6399
(805) 684-7678
(805) 684-0497 Fax

MOULAGE KIT FOR CUSTOM IMPLANTS

DESCRIPTION

This kit provides the surgeon with the necessary materials to create a moulage pattern. The completed pattern is then shipped to Spectrum Designs Medical, Inc. and utilized in the fabrication of a Custom Implant Device.

Three documents must be completed when placing an order for a Custom Implant Device (see below).

The ordering physician must complete and sign the following forms:

- **Custom Device Agreement**
- **Custom Device Design** (reverse of this page)

In addition to the above form, the patient receiving the Custom Device must complete and sign a release of liability form, indicating he/she is aware of the surgical risks involved with Custom Device surgery.

- **Custom Device Patient Release**

MOULAGE INSTRUCTIONS

Warning: The model compound in this kit is for external use only. Do not attempt to apply the compound to open wounds or an area distorted by swelling.

Step 1

Cover each body area where moulage will be made with petroleum jelly, plastic wrap or other suitable covering.

Step 2

Prepare to make model compound. Ratio is one part water to two parts compound.

Step 3

Mix model compound in plastic bag provided. Thoroughly knead the compound. Allow five minutes for compound to set inside the bag.

Step 4

Apply model compound where implant will be placed. Do not apply to an open wound or areas distorted by swelling. Sculpt surface to correct dimensions. Smooth surface using sandpaper (supplied) or moistened hands. A larger moulage may be reinforced by using gauze bandages. Allow moulage to set up for approximately five to 10 minutes before removing.

Step 5

Trim and fit moulage. Be sure of dimensions, edges and desired thickness.

Step 6

Dry moulage completely, preferably by using a heat lamp, hair dryer or dry oven at a moderate temperature not to exceed 300 degrees Fahrenheit.

PACKAGING AND SHIPPING INSTRUCTIONS

Required documentation, completed and signed by physician and patient, must accompany the shipment.

- **Custom Device Agreement**
- **Custom Device Design**
- **Custom Device Patient Release**

Carefully wrap the moulage in paper towels or newspaper. Do not wrap moulage in plastic, as it will mildew during shipment. Place the carefully wrapped moulage with copies of the required documentation in an appropriate size shipping carton. Bubble-packaging or other suitable material should be used to protect the moulage during shipment. Send your shipment to: Spectrum Designs Medical, Inc., 6387-B Rose Lane, Carpinteria, CA 93013.

RETURN POLICY

Custom devices are not returnable for refund or credit.

INFORMATION DISCLOSURE

Spectrum Designs, Inc (Spectrum) has exercised reasonable care in the choice of materials and manufacture of all custom devices. Spectrum excludes all warranties, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness of use. Spectrum shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from the use of this device or service. Spectrum neither assumes nor authorizes any other additional liability or responsibility in connection with a service or product.

PRODUCT ORDERING INFORMATION

Please direct inquires to:

Spectrum Designs Medical, Inc.
6387-B Rose Lane
Carpinteria, CA 93013

(800) 239-6399 USA/Canada
(805) 684-7678 World Wide
(805) 684-0497 Fax

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.