CUSTOM IMPLANT ORDER FORM

Physician's Name: _____ Telephone: _____

Address: _____ City _____ State _____ Zip _____

Patient Name: _____

Quantity: _____ Surgery Date: _____

All Custom Implant Orders must be pre-paid. Please allow at least four weeks for fabrication.

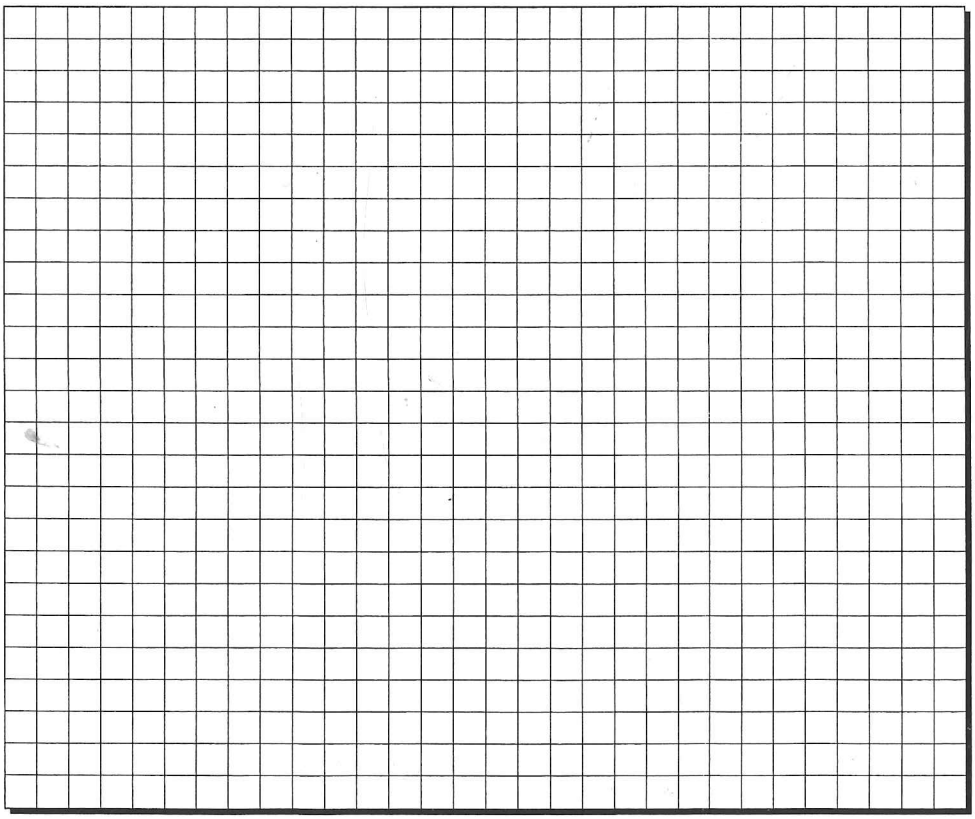
Surgeon's Certification and Signature:

I am relying on my own medical judgement as to the indications, contra-indications, safety and efficacy of this custom device and certify that it will be used exclusively by myself and it is intended to meet my special needs in the course of my professional practice. I further agree to idemnify and defend Hanson Medical, Inc. if any adverse event or lawsuit results from my use of this device other than for gross negligence on the part of Hanson Medical, Inc.

Surgeon's Signature: _____ Date: _____

PLEASE PHOTOCOPY THIS FORM TO PLACE YOUR ORDER

Sculpting clay moulage kits available. Call 800 • 771 • 2215



Durometer

- ☐ Firm
- ☐ Medium
- ☐ Soft
- ☐ Extra Soft

If your implant requires suture tabs, please indicate size and location.

Please sketch front, top and side views. Indicate dimensions.

1 block = _____ centimeter(s).

Caution: United States Federal Law restricts this device to sale by or on the order of a licensed physician.

HANSON MEDICAL, INC.

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Distributör Sverige:
Promeduc Surgical AB
Rubanksgatan 8
SE-741 71 Knivsta
Tel: 018-54 54 00
E-post: promeduc@promeduc.se
www.promeduc.se

Physician Custom Device Agreement

Date _____ Surgery Date _____

Physician Name _____ Hospital/Clinic _____

Address _____ Address _____

_____ _____

_____ _____

Tel _____ Tel _____

Fax _____ Fax _____

Patient Name _____

Inherent in the use of this Custom Implant are risks associated with the medication, methods utilized and the patient's degree of tolerance of the implantation of any foreign object. Hanson Medical warrants that reasonable care was used in the manufacture of this device. Hanson Medical disclaims any additional warranties concerning the safety or efficacy of this device.

I acknowledge that Hanson Medical did not solicit the disclosure of this custom device idea and that I am voluntarily submitting this idea to Hanson Medical. I assure Hanson Medical that I am the true owner of this custom device information and that I am legally free to disclose this information.

I am relying on my own medical judgment as to the indications, contraindications, safety and efficacy of this device. I certify that this custom device will be used under my personal supervision and that it will not be supplied to another physician or institution.

I further agree to indemnify and defend Hanson Medical, Inc. if any adverse event or lawsuit results form the use of this device.

I certify that I will inform any patient or their guardian(s) that this is a custom device, manufactured to my specifications. I will explain the possible complications associated with the use of this custom device and that Hanson Medical disclaims any warranties concerning the safety and efficacy of this custom device. I will obtain written consent of the patient or their guardian(s) before implanting this device.

Device Description _____

Device Specifications _____

Physicians Signature & Date _____

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Patient Custom Device Release

I understand that Hanson Medical, Inc. will manufacture a custom device as prescribed by my physician. Prior to my signature of this release, I have discussed with my physician the general known and unknown risks associated with the use of this device. I am aware that the risks may vary depending on the patient and the prescribed treatment. I am aware that this device is unique and one of a kind, manufactured for me only, and that no studies have been conducted on the safety and efficacy of the device. I have decided that I am willing to accept the risks associated with the implantation of this custom device.

I understand that if this custom device does not function satisfactorily after treatment, I could undergo revision surgery (re-operation), during which I may subject myself to further surgical risks.

On behalf of myself and my heirs I herby irrevocably and unconditionally release and forever discharge Hanson Medical, Inc., its successor and predecessor corporations and parent or subsidiary corporations, and all of their agents, principles and employees from any and all legal liability and/ or damages relating to the medical use of this custom device.

I fully understand and agree to the terms of this release and sign it of my own free will.

Patient Signature	Date	Patient Name Typed/ Printed
Parent/ Guardian Signature	Date	Parent/ Guardian Name Typed/ Printed
Witness Signature	Date	Witness Name Typed/ Printed

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MOULAGE KIT INSTRUCTIONS

Moulage Clay consists of a two part system - Part A and Part B. They catalyze each other when mixed thoroughly for 5 minutes and set up hard in another 8 -12 minutes. A marking pen can be used to out-line the desired area. Shaving of the hair is optional but there may be some patient discomfort with removal of the cured moulage.

DO NOT USE LATEX GLOVES as it will inhibit the cure of the material. Mix the desired amount of material at a 1:1 ratio (equal amount of A and B) until it is a uniform color. Shape material into a ball and press onto desired area. Once the moulage clay is on patient, shape material to desired model shape. Repeat this process if more material is needed. Smooth the moulage and contour the surface. Allow moulage to dry for 8 -12 minutes.

If you are not satisfied with the shape of the moulage, it can be carved with a scalpel or a knife. Do not be concerned if the moulage is not perfectly smooth. We will smooth the surface for you, if necessary.

Let the patient view the moulage in place in order to get his her input. Mark the moulage with superior and inferior orientation. If you desire sutures (reinforced silicone tabs), mark the moulage in the applicable locations with squares (□). If you desire fenestrations (small holes), mark the moulage in the applicable locations with circles (o).

If you have any questions or need assistance with your moulage or filling out the custom order form, please call us at (800)771-2215 and we will be happy to help you in any way possible. You may also call our Custom Technicians at (805)238-6295.