



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

CUSTOM DEVICE PATIENT RELEASE

Date	Surgery Date
Physician's Name	Patient's Name
Physician's DEA Number	Patient's Social Security Number or ID Number
Physician's Phone Number	Custom Device Required

The purpose of this Custom Device Patient Release is to inform you of the conditions for release and receipt of your custom device. Any specific questions or concerns regarding this release, the custom device and/or the medical use of the custom device should be directed to your physician.

Patient: your signature below indicates your complete agreement to the following:

I understand that Spectrum Designs Medical, Inc. (Spectrum) will manufacture a custom device as prescribed by my physician. I understand that this custom device will be forwarded to my physician, or his/her designated hospital, clinic or medical facility, for the medical use, which will include implanting the device. I further understand that if the treatment is canceled, this device will be returned to Spectrum for disposal or will be disposed of by my physician.

Prior to my signature of this release, I have had the opportunity to discuss with my physician the general known and unknown risks associated with the use of this device. I am aware that my physician has determined that I am a suitable candidate for medical treatment. I have decided that I am willing to accept the risks along with the benefits of implant surgery. I am aware that the risks and benefits may vary depending on the patient and the prescribed treatment.

I am aware that further information regarding my custom device may be provided to me, with the custom device, in the form of a package insert. I am also aware that I may be requested to sign a Patient Informed Consent prior to my treatment, indicating that I have been informed of the custom device benefits as well as known and unknown risks. I may also be required to sign other consents as seen fit by my physician.

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

On behalf of myself and my heirs, I fully assume all risks for the medical use of the custom device and do hereby irrevocably and unconditionally release and forever discharge Spectrum, its successor and predecessor corporations, its parent and subsidiary corporations, and all of their principals, agents, employees, and attorneys, from any and all legal liability and/or damages relating to the medical use of the custom device including, but not limited to any negligence in the manufacture and distribution of the custom device, but excluding gross negligence or willful misconduct of Spectrum.

I agree that any dispute involving the custom device or this Release will be subject to binding arbitration before one arbitrator in Santa Barbara, California, USA, in accordance with the rules of the American Arbitration Association. The laws of the State of California shall apply to this release and any associated arbitration.

No representations have been made to me to induce me to sign this Custom Device Patient Release, and I do so of my own free will. I hereby sign the appropriate signature areas below and agree to the terms of this release without reservation.

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