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CUSTOM DEVICE AGREEMENT

Date	Surgery Date
Physician's Name	Hospital or Clinic
Address	Address
Phone	Phone
Fax	Fax
DEA Number	Patient Identifier

Section I

Inherent in the application of this Custom Device are the risks associated with the medication, methods utilized in the surgical procedure, and the patient's degree or intolerance to the implantation of any foreign object. Spectrum Designs, Inc. warrants that reasonable care was used in the choice of materials for this Custom Device. Spectrum Designs, Inc. disclaims any additional warranties concerning the safety or efficacy of this Custom Device In any medical procedure.

Section II

I acknowledge that Spectrum Designs did not solicit the disclosure of this Custom Device idea and that I am voluntarily submitting this idea to Spectrum Designs, Inc. I assure Spectrum Designs, Inc. that I am the true owner of this Custom Device information and that I am legally free to disclose this Information.

I agree that the disclosure of this Information to Spectrum Designs, Inc does not establish any confidential relationship between Spectrum Designs, Inc. and myself regarding the subject matter of this submission. I agree that in the absence of a subsequent written contract between Spectrum Designs, Inc and myself, I hereby release Spectrum Designs, Inc. from any obligation should Spectrum Designs decide to utilize the whole or any part of the subject matter herein. No license, under any patent or patent application is granted to Spectrum Designs, Inc, by virtue of this release.

Section III

I am relying upon my own medical Judgment as to the indications, contraindications, safety, and efficacy of the Custom 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. In the event that I utilize the Custom Device in a country other than the United States of America, I will accept the sole responsibility for ensuring that this device complies with the laws and/or regulatory requirements of that country.

I further certify that I will inform any patient or their representative(s) that this device is a custom device, manufactured to my specifications. I will describe the possible complications associated with the use of this Custom Device and that Spectrum Design, Inc. disclaims any further warranties concerning the safety and efficacy of this custom device. I will obtain written consent of the parties or their representative in all but exceptional cases where this is not feasible or, in my professional judgment, is contrary to the best interest of the patient. This informed consent shall be in accordance with the policies of the Institution at which I practice.

Section IV

Description of Device (include device drawings)
Indications for Use
Device Specifications
Physician's Signature and Date