OFF-LABEL USE OF DEVICE

The U.S. Food and Drug Administration (FDA) requires that medical and dental devices (including electronic radiation-emitting products) used in the United States be both safe and effective. The label information on the device and in any advertising may indicate a device's use only in certain ways that are "approved" for a particular condition. The use of a device for a condition not listed on the label or in a manner different from that specified on the label is considered to be a "nonapproved" or "off-label" use of the device. Healthcare providers—based on their knowledge, education, training, experience, and available current information—may use a device for a use not indicated on the "approved" labeling if it seems reasonable or appropriate in the provider's professional judgment.

Patient's Initials

_____ I understand that this is an experimental use of this device, therefore no one can be fully aware of all possible side effects and complications.

_____ The details of this treatment, including the anticipated benefits, material risks, and disadvantages, have been explained to me in terms I understand.

_____ Alternative treatments, prescriptions, and therapies and their benefits, material risks, and disadvantages have been explained to me in terms I understand.

_____ I understand and accept that the most likely material risks and complications of using (Name of Device) for off-label use have been discussed with me and may include but are not limited to:

-
- (Include common complications/risks)
-
-

_____ I have informed the healthcare provider of all my known allergies.

_____ I have informed the healthcare provider of all medications I am currently taking, including prescriptions, over-the-counter remedies, herbal therapies and supplements, aspirin, and of any recreational drug or alcohol use.

_____ I have been advised whether I should avoid taking any or all of these medications while I am using the above device.

_____ I am aware and accept that no guarantees about the results of this device have been made.

_____ The healthcare provider has answered all of my questions regarding this device.

I certify that I have read and understand this treatment agreement and that all blanks were filled in prior to my signature.

I authorize and direct _____ to prescribe
(Name of healthcare provider)

_____,
(Name of device)

which is FDA-approved for the treatment of _____,
(Condition device is approved to treat)

for the purpose of _____.
(Condition to be treated)

Patient or Legal Representative Signature/Date/Time

Print Patient's or Legal Representative's Name

Patient's Date of Birth

Legal Representative's Relationship to Patient

Witness Signature/Date/Time

Print Witness's Name

I certify that I have explained the nature, purpose, anticipated benefits, material risks, complications, and alternatives to the proposed therapy to the patient or the patient's legal representative. I have answered all questions fully, and I believe that the patient/legal representative (circle one) fully understands what I have explained.

Healthcare Provider Signature/Date/Time