OFF-LABEL USE OF DEVICE

Since the early 1960s, the U.S. Food and Drug Administration (FDA) has required that medical 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 dose different from that specified on the label is considered to be a “nonapproved” or “off-label” use of the device. Physicians—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 physician’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 doctor of all my known allergies.

_____ I have informed the doctor 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 doctor 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)
This form is for reference purposes only. It is a general guideline and not a statement of standard of care and should be edited and amended to reflect policy requirements of your practice site(s), CMS, and accreditation requirements, if any, and legal requirements of your individual state(s).

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.

Physician Signature/Date/Time