

Sample Informed Consent: Suggested Verbiage

I request and authorize Dr. _____ or designated person to perform the following procedure utilizing temperature-controlled radiofrequency technology.

Procedure: _____

Area(s) to be treated: _____

Please read each of the items carefully and initial each section.

_____ The areas for treatment have been reviewed with me today and I am in agreement. I have been thoroughly and completely advised regarding the objectives of the procedure. I understand that the practice of medicine and surgery is not an exact science and results may differ for each patient. No results have been guaranteed.

_____ I understand that according to the Warnings in the Instructions for Use for radiofrequency devices, patients with previously implanted electronic devices (such as cardiac pacemakers, AICD, defibrillators, mechanical valves, etc. or electrical stimulation implants or devices) that could be impacted by radiofrequency should consult their specialist physician prior to treatment.

_____ I understand that radiofrequency may interact with implantable devices (such as neuro stimulators, metal IUDs, Cochlear implants and metal implants.) I have discussed this with my physician and they have consulted the instructions for use for all prior to treatment.

_____ I understand that treatments should not be performed on patients who are pregnant, have a urinary tract or skin infection or wound in or around the area of treatments.

_____ I am aware the risks associated with this procedure may include but are not limited to:

- Discomfort/pain during and/or after the treatment.
- Swelling/edema following the procedure.
- Redness (erythema) of the treated area.
- Headache, nausea
- Other possible side effects of radiofrequency treatment modalities include: blistering, burn, scarring, bruising, nerve damage, and induration.

Note: ask your physician to refer to User Manual and Instructions for Use for full list of potential side effects and warnings/cautions.

_____ I understand the importance of the pre and post treatment instructions and that failure to comply with these instructions may increase the possibility of complications.

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_____ I consent to having clinical photographs taken before, during and after my procedure. I understand that these photographs are an important part of my medical record.

_____ The nature and effects of the procedure, the risks, the ramifications, complications, as well as alternative treatments have been fully explained to me by the physician or designated clinician and I understand them. The benefits of the proposed procedure, along with the probability of success have also been discussed with me. I have been given the opportunity to ask questions and have received satisfactory answers.

I certify that I have read the above authorization and that I fully understand it.

Signature of Patient/Date

Signature of Provider / Date

Signature of Witness/Date