

## PinPointe™ FootLaser™ Consent Form

PinPointe™ FootLaser™ is cleared by the FDA for the temporary increase in clear nails in patients with onychomycosis (nail fungus). The Nd: YAG FootLaser energy penetrates the nail and destroys the fungus and other organisms in and under the nail plate. The laser has no effect on skin or soft tissue. As with any procedure there is some risk of unsatisfactory outcomes and side effects, including the following:

**Please initial before each statement, indicating you have read and understand the statement.**

\_\_\_\_ I understand that the clinical results may vary in different patients. There is no guarantee this treatment will work, as it depends on the severity of your condition and your chance of reinfection due to uncontrollable environmental conditions. In some patients, a touch-up or repeat session with the laser may be necessary. The cost for touch ups/retreatments will be \_\_\_\_\_.

\_\_\_\_ I understand that the fungus may not be completely destroyed and that the nail may become re-infected or that there may be other types of infections present for which the PinPointe FootLaser may not be an effective treatment. The nail may continue to be discolored or not attached to the nail bed. This treatment will not change the shape, width or other deformity of the nail plate.

\_\_\_\_ I understand that my nail may be debrided (thick nail reduced) prior to the laser procedure to allow the laser energy to better penetrate the nail.

\_\_\_\_ I understand some of the potential side effects may include: feeling of warmth and/or slight or mild pain (*only during treatment*), redness of the treated skin around the nail (*lasting 24 to 72 hours*), discoloration or burn marks may occur on the nail, slight swelling of the treated skin around the nail (*lasting 24 to 72 hours*), in rare cases the laser creates 'sparks' on the surface of the nail – this does not cause any problems; in rare cases, blistering of the treated skin around the nail and scarring of the treated skin around the nail has occurred.

\_\_\_\_ I understand that photographs may be taken before and/or after my procedure and at follow-up visits. I further understand that these photographs and patient data may be used for medical documentation, research, or publication. Private health information, such as patient's name and date of birth will be removed to protect patient privacy.

\_\_\_\_ I understand that post-treatment care is an important part of the treatment and I agree to follow all post-treatment recommendations to ensure best results.

\_\_\_\_ I certify that I have read or have had read to me the contents of this form. I have had the opportunity to ask questions and all of my questions have been answered. I voluntarily agree to the terms of this agreement/consent.

Patient Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_