# Informed Consent Form

## A. Background & Purpose

The ToeFX Light Therapy device is a photodisinfection therapy (PDT) technology designed for patients with onychomycosis. The complete course is approximately 1 year. There will also be an initial screening session. After 8-10 initial sessions, approximately 76% of patients experience substantial or total clearance of their fungal infection.

## B. Procedures

Prior to beginning treatment, the clinician will take a photograph of your toenail. The ToeFX Light Therapy Device consists of an LED-based light source and a blue ClearToe Serum. A clinician will file the surface of all nails on the infected foot, paint the formulation onto the nails and allow it to penetrate for 15 minutes. The clinician will then place the affected foot under a light source for another 15 minutes.

## C. Risks

There are no known risks associated with use of the ToeFX Light Therapy system. This is a non-invasive procedure. The blue colour from the ClearToe Serum will remain on the nails between treatment sessions, the extent of which is dependent on the severity of the infection. ClearToe Serum can stain clothing and furniture, and is best removed from the skin with isopropyl (70%) alcohol.

## D. Benefits

The ToeFX system has been shown to be highly effective in a laboratory and clinical setting environment. We believe that this treatment may benefit you as a sufferer of nail fungus. However, we cannot guarantee results from this treatment.

## E. Duration

After your initial screening visit, there will be initial treatments on a biweekly basis, followed by maintenance sessions every 6-8 weeks. Each visit will take approximately 40 minutes, and the duration of treatment is one year or until the nail is fully re-grown.

## F. Pregnancy

Women who think they might be pregnant, are planning to become pregnant or are nursing a child are advised to consult with their family doctor.


Corresponding e-mail: info@toefx.com

## G. If You Have Questions

If you have questions, please consult with your foot care clinician.

## L. Statement of Consent

The purpose of this treatment, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask the questions I have, and my questions have been answered to my satisfaction. I have been told whom to contact if I have additional questions. I have been given enough time to read this consent form and to consider whether or not I wish to complete this treatment.

_____

Patient's Full Name (Please Print)

_____ _____

Patient Signature
(DD/MM/YYYY)

Date Signed