

A treatment for the temporary increase in clear nail in patients with onychomycosis



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## Nail Fungus | ClearSense™

### A treatment for the temporary increase in clear nail in patients with onychomycosis

#### What is ClearSense?

The JOULE™ ClearSense system is a laser delivery technology for cosmetic improvement of dermatologic conditions including the temporary increase in clear nail for patients with onychomycosis.

#### What causes fungal infection in the nail (Onychomycosis)?

Onychomycosis is a non-life threatening infection of the nails caused predominantly by dermatophytes (e.g., *Trichophyton Rubrum*, *Trichophyton Mentagrophytes*), and to a lesser extent by yeasts (e.g., *Candida Species*) and non-dermatophytic molds. The nail fungus usually begins growing on the skin around the nail and then enters the nail bed and nail plate. Although visual changes are often observed in the nail, a proper diagnosis using a test designed to detect the presence of nail fungus is often performed to rule out other causes for the nail's changed appearance.

#### Where does the fungal infection in the nail come from?

Fungi are everywhere—in the air, the dust, and the soil. Shower floors, locker rooms and swimming pools are suspected of being sources of the fungus, although there are no studies proving this fact.

#### What are the symptoms of fungal infection in the nail?

Infected nails often have one or more of the following undesirable changes in the nail: no luster, nail brittleness, yellow streaks, thick nails that may separate from the skin, or white spots.

#### What treatment are available for fungal infection in the nail?

Nail fungus is prevalent worldwide and up until now, has had very limited, ineffective and undesirable treatment options. These options include topical antifungal creams, oral antifungals or permanent removal of the nail.

- Topical (applied to the surface) – cannot penetrate the nail adequately to completely eradicate fungus and has to be applied daily.

- Oral (taken by the mouth) – not effective in all patients and side effects may include possible liver damage.
- Surgical removal or chemical dissolution of the nail plate – this often ineffective and traumatic procedure leaves the patient without a nail for months and at risk for reinfection.
- Permanent removal of the nail – this often results in a disfigured appearance.
- Laser treatment – short treatment times, minimal pain involved, no down time or side effects have been reported in the literature. The laser energy is delivered to the affected area (nail and surrounding skin). If all the fungal infection is killed by the laser energy, most patients experience some degree of a temporary increase in clear nail.

#### How does the ClearSense treatment work?

Sciton's ClearSense technology heats the nail and the nail bed with laser energy resulting in a decrease of nail fungus and an increase in the growth of clear nail. The treatment involves passing the laser beam over the infected nails and surrounding skin. Your physician will repeat this until enough energy has reached the nail bed. Your nail will feel warm during the treatment.

After your physician determines you have nail fungus, the ClearSense treatment may be performed with no down time.

#### What can I expect with a ClearSense treatment?

- Before Treatment – clip and debride toenails, and remove any nail polish.
- During Treatment – the doctor will wipe each nail clean with an alcohol wipe to make sure there is no dirt or debris. Baseline photos will be taken to document nail growth. At the time of treatment, you may feel a mild to moderate heat sensation.
- After Treatment – you can resume normal activity immediately after treatment, with no downtime. Nail polish can be applied 24 hours after the treatment. Use new shoes and wash socks thoroughly in hot water.

- Long Term – follow up photographs will be taken to document nail growth. Over the next several months, most patients see some degree of continuous growth of clear healthy nails.

#### How many treatments will I need?

Most infections improve after one 15-20 minute treatment, however, the number of treatments will vary depending on the severity of the nail fungus. Consult your physician for the specific number of treatments that are right for you. Immediately following treatment, no visual change in the nail will be detected, as it takes time for the clear nail to grow.

#### What are the possible side effects?

No significant side effects have been reported. You may feel slight discomfort associated with heat during treatment, but there is no pain involved post treatment. Patients may also see mild redness briefly after the treatment, but this should resolve in 24 hours.

#### What aftercare do I need?

You may resume normal activity immediately following treatment. After treatment, it is recommended to wear new shoes and socks that have been washed thoroughly in hot water to prevent reinfection and further spread of fungus.

#### Can the fungus come back?

There is a chance of re-infection as the fungus lives within the environment. Proper post-care techniques are recommended to help reduce recurrence. Consult your physician about effectiveness and outcomes.

#### Are there any clinical studies?

In a clinical study, 79% of treated toes improved in clear nail over 90 days following treatment.<sup>1</sup>

[1] Gupta et.al., *Onychomycosis Therapy: Past, Present, Future, Journal of Drugs in Dermatology, Vol.9, 9, 2010.*