

Frequently Asked Questions

What is the CellFX System?

The CellFX® System is a multi-application platform designed to address a broad range of dermatologic conditions, notably the clearance of general benign lesions. The CellFX System harnesses patented Nano-Pulse Stimulation™ (NPS™) technology, which delivers nano-second pulses of electrical energy to non-thermally clear cells while sparing adjacent non-cellular tissue.¹⁻⁴

What is the CellFX procedure?

The initial use of CellFX procedures will be the clearance of common benign skin lesions, including sebaceous hyperplasia (SH), seborrheic keratosis (SK) and cutaneous non-genital warts – and will offer unrivaled value across an expanding spectrum of future clinical applications.

How does the CellFX procedure work?

The delivery of NPS energy causes the cells to begin a natural process of Regulated Cell Death (RCD). The cells in the treated area with NPS energy are gently cleared through the body's normal metabolic processes, similar to how other non-viable cells are cleared.

What kind of skin problems can be addressed with the CellFX procedure?

The CellFX procedure is currently used to clear common benign lesions, such as sebaceous hyperplasia (SH), seborrheic keratosis (SK) and cutaneous non-genital warts. Additional clinical studies to evaluate its effect on other common lesions are currently underway.

Who is a candidate for CellFX?

The CellFX System is intended to be used for dermatological procedures in adult patients (22 years old and older) for the reduction, removal, and/or clearance of cellular-based benign lesions.

The CellFX System shall not be used:

- on patients having local or systemic infection
- for lesions in the vicinity of implanted electronic devices or implanted devices with metal parts; do not use in the thoracic area if a pacemaker is implanted
- for lesions of the eyes, including the eyelids
- on patients with a history of epilepsy or cardiac arrhythmia
- on patients having recent history of myocardial infarction or structural heart disease

How is the CellFX procedure different from other ways to clear lesions?

The CellFX System is powered by Nano-Pulse Stimulation™ (NPS™) technology, which delivers nano-second pulses of electrical energy. Unlike conventional thermal technologies, NPS technology non-thermally clears cells, while sparing adjacent non-cellular dermis.

The CellFX System:

- Fulfills the unmet need for clearing common yet difficult-to-clear skin lesions
- Offers the potential for reduced risk of scarring with a gentler healing process
- Promotes re-epithelialization with reduced risk of scarring
- Provides overall better patient experience and return to desired skin appearance

FREQUENTLY ASKED BY PATIENTS

How long does the CellFX procedure take?

The actual time for the CellFX procedure session is typically 15 minutes or less depending on the number of lesions. Preparation includes numbing the lesion area and each lesion usually requires only 10-15 seconds of pulsing.

Can multiple lesions be treated in one procedure?

Yes, multiple lesions and lesion types may be treated in one procedure session. Each lesion can be treated in a matter of seconds, so it's practical to treat multiple lesions in a single 15-minute procedure.

How soon can patients return to normal activity?

Generally, most patients can immediately return to normal activity. Simple wound care should be recommended, such as wearing a small bandage or ointment for at least 7 days.

Is there any special preparation?

In general, cleansing the lesion area with an alcohol wipe is commonly enough for most patients. For facial lesions, consider requesting the patient to remove makeup prior to their appointment.

As with any procedure involving broken skin, appropriate wound care steps should be taken to optimize wound protection and skin healing. In clinical studies, common ointment and/or a small bandage were used, typically for the first 7 days post-procedure. Physicians are encouraged to use their own method for wound management for procedures of this type.

What should patients expect during a CellFX procedure?

After numbing the lesion area, the treatment tip will be placed on top of the lesion. The patient may feel pressure from the microneedles of the treatment tip. A series of rapid energy pulses (a "cycle") will be delivered to the lesion area. This delivery lasts about 10-15 seconds for each lesion area.

If patient asks about what the procedure feels like:

As with other energy-based devices, individual experiences will vary. This experience can range from no sensation to tingling or twitching and can vary depending on location of the lesion, individual sensitivity, anesthesia used, and response to anesthesia.

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During the procedure, the patient may feel a mild sensation while the energy pulses are being delivered.* The patient may also experience minor twitching. Because the nervous system communicates and functions via electrical energy signals, twitching is not an unusual reaction. These potential reactions are temporary and should subside after the cycle is complete. If the patient feels discomfort, you may opt to administer additional anesthesia.

Patients may relate the sensation caused by the energy pulses as pain. Individual sensitivity may also depend on the lesion area. Any areas near a nerve, especially on the face, will be more sensitive to the energy pulses. Be sure to set proper expectations between the difference between pain and the potential sensation and mild twitching.

**With the use of local anesthesia, patients reported feeling no to mild pain during the procedure (average pain score of 2 based on a scale of 0-10, with 0 being "no pain" and 2 being "mild pain".)*

If patient asks about high amplitude/high voltage:

You can compare the energy of the CellFX procedure with that of a common static electric discharge – for example, when a person walks on a carpeted floor and then touches a metal doorknob. That type of electric discharge is about 30 kilovolts (30,000 volts). The pulses delivered by the CellFX System are typically much less than this.

What should patients expect after a CellFX procedure? What is the healing process like?

(Refer to patient FAQs and Post-Procedure Care Guide)

Are there any side effects with the CellFX procedure?

In clinical studies, no serious side effects have been reported. *(Also see "What should I expect after a CellFX procedure?" in patient FAQs)*

If patients ask about results:

At your discretion, you can provide general guidance on expected results, based on clinical studies:

- SH efficacy: 80% of treated lesions (clear or mostly clear) by 60 days post-procedure – based on energy level ranges of 30 mJ/mm³ to 60 mJ/mm³
- SK efficacy: 82% of treated lesions (clear or mostly clear) by 106 days post-procedure
- Warts efficacy: 81% of treated lesions completely clear by 60 days post-procedure

This general guidance should be adjusted based on lesion type, skin condition, anatomical location, and treatment level used.

How many visits are needed?

Most lesions can be successfully cleared with a single procedure session. Depending on the lesion type and treatment level used, a second procedure session may be required.

Is it safe?

Clinical studies have shown the CellFX procedure to be safe and effective. No serious side effects or adverse events have been reported. It is currently approved for the reduction, removal and/or clearance of cellular-based benign lesions.

CELLFX SYSTEM BASICS (CYCLES, CYCLE UNITS, TREATMENT TIPS, TREATMENT LEVELS)

What is a cycle?

A cycle is the series of nano pulses delivered to the skin intended to clear a particular lesion. A single cycle is used to treat a single lesion. Each cycle has associated cycle units, which is determined by the tip type and treatment level selected.

What is a cycle unit?

A cycle unit is the CellFX System designation of stored capacity that allows you to perform procedures. Each treated lesion will have a number of cycle units associated with it. Cycle units are loaded onto a CellFX console and decremented by a specified amount each time a cycle is delivered. Cycle units can be replenished by purchase through the CellFX Marketplace™ – the secure, online portal for CellFX System business services.

How do I know what treatment settings to use?

The treatment levels available on the CellFX System have been evaluated in clinical studies for safety and efficacy. Please refer to the CellFX System User's Guide for suggested treatment level (TL) ranges.

How do I order more cycle units and treatment tips?

CellFX Marketplace is your go-to online portal for CellFX System business services. Once an account is established, orders can be placed. Login at CellFXMarketplace.com to access your account.

1. Kaufman D, et al. A dose-response study of a novel method of selective tissue modification of cellular structures in the skin with nanosecond pulsed electric fields. *Lasers in Surgery and Medicine* 2019; 52:315-322. 2. Munavalli G, et al. Safety and efficacy of nanosecond pulsed electrical field treatment of sebaceous gland hyperplasia. *Dermatologic Surgery* 2020; 46:803-809. 3. Hruza G, et al. Safety and efficacy of nanosecond pulsed electrical field treatment of seborrheic keratoses. *Dermatologic Surgery* 2019; 00:1-8. 4. Newman J, et al. A dose-response study of nanosecond energy pulses on facial skin. *J of Cosmetic and Laser Therapy* 2020. Accessed online at: <https://doi.org/10.1080/14764172.2020.1827151>.



Emergo Europe B.V.
Prinsessegracht 20
2514 AP The Hague
The Netherlands



CONTACT US

+1 833-257-3393

Monday-Friday

6:00 a.m. to 5:00 p.m. PST

support@cellfx.com