

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

How does the CellFX procedure work?

The delivery of NPS energy causes the cells to begin a process of Regulated Cell Death (RCD). The cells in the area treated with NPS energy are gradually 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 cellular-based benign lesions.

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.

Contraindications apply. See the CellFX System User's Guide for details.

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

The CellFX System uses an entirely new energy modality called Nano-Pulse Stimulation (NPS) technology that uses ultrafast, high-amplitude electrical energy pulses to clear cellular structures while sparing surrounding non-cellular dermal foundation.

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. Because each lesion can be treated in a matter of seconds, it's practical to treat multiple lesions in a single procedure.

How soon can patients return to normal activity?

Most patients can immediately return to normal activity after the CellFX procedure. The healing process and period of time can vary by individual depending on the size, location and type of lesion, skin type, and natural variations in healing rates.

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 the appointment.

Each lesion area will need to be anesthetized. Please refer to the recommended dual-stage anesthesia technique with 1) a deep lidocaine administration; and 2) a superficial lidocaine administration (bleb). This is similar to the technique used when preparing for a punch biopsy.

What should patients expect during a CellFX procedure?

After numbing the lesion area, the treatment tip will be placed on top of the lesion and microneedles will surround 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. A cycle lasts about 10-15 seconds for each lesion.

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 twitching and muscle stimulation, and can vary depending on location of the lesion(s), individual sensitivity, anesthesia technique used, and response to anesthesia.

During the procedure, the patient will hear a clicking sound as the cycle of energy pulses is being delivered. Along with the pressure of the microneedles, the patient may feel certain sensations, such as tapping, and may also experience twitching or muscle stimulation.* Because the nervous system communicates and functions via electrical energy signals, twitching and muscle spasms are normal reactions. These potential reactions are temporary and should subside after the cycle is complete.

**With local anesthesia, most patients reported feeling no to mild pain during the procedure depending on individual sensitivity of the patient*

Frequently Asked Questions

Addressing pain versus sensations

Patients may relate the sensations during the energy pulses as pain. It is important to set expectations with your patients on the distinct sensations they may experience with the CellFX procedure:

1. Discomfort or pain with anesthesia injection
2. Sensations while energy pulses are being delivered

Individual sensitivity may also depend on the lesion area. Be sure to set proper expectations about the difference between pain and the potential sensations. For example, patients with lesions near a sensory nerve, especially on the face, will be more sensitive to the energy pulses and may be more prone to experiencing twitching or muscle stimulation while pulses are being delivered to those areas.

To optimize patient comfort, a recommended anesthesia technique by physicians currently performing the CellFX procedure is a dual-stage anesthesia technique with: 1) a deep lidocaine administration; and 2) a superficial lidocaine administration (bleb). This is similar to the technique used when preparing for a punch biopsy.

If patient asks about level of energy used:

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 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.

If patients ask about results:

To set proper expectations and context of when results can be seen, it may be helpful for your patients to understand that the overall skin recovery process happens in the following stages:

- Gradual clearance of cellular lesions
- Early regeneration by cells (skin healing)
- Natural replacement of normal tissue
- Return of normal skin appearance over time

Timing of each of these stages will vary by lesion size, anatomical location, skin type and treatment level used.

How many visits are needed?

The CellFX System provides a wide range of treatment levels for you to choose from based on location, lesion type and patient skin type.

The use of higher treatment levels (higher energy settings) and deeper treatment tip depth is typically needed for the larger, deeper lesions. This typically results in a longer healing process for cells to completely clear followed by the process of regenerating new skin cells. Larger, deeper lesions may require a second procedure session, whereas smaller lesions may be able to clear with a single procedure session.

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 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.

CONTACT US

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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. 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>.