



# 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 powered by Nano-Pulse Stimulation™ (NPS™) technology is used for clearing difficult-to-treat spots and bumps comprised of cells.

## What is the CellFX procedure?

The CellFX procedure is an innovative procedure to clear common skin conditions, such as benign spots, bumps or growths known as lesions. Most common skin lesions are made up of abnormal cells. The CellFX procedure clears the cells of a lesion while sparing the surrounding non-cellular dermis (layers of skin tissue) – helping to prevent unnecessary damage and to minimize the risk of scarring.<sup>1-4</sup>

## What is a skin lesion?

A lesion is the medical term for a part of the skin that has an irregular appearance compared to the healthy skin around it. A lesion is typically made up of cells, caused by malformations of the structure of the skin.

On the surface of your skin, a lesion can look like a spot, bump, or growth, can be flat or raised, can have pigment or be clear and can appear anywhere on the face and body. While the lesion appears at the surface of your skin, most cells of a lesion extend underneath the surface into the deeper layers of your skin (the dermis) and can reside at unknown depths.

Many factors, including the natural aging process, can cause different types of lesions. Common benign (non-cancerous) lesions include: sebaceous hyperplasia (SH), seborrheic keratosis (SK), common non-genital warts, acne and certain moles.

## How does the CellFX procedure work?

The CellFX procedure uses an innovative technology that uniquely works deep at the cellular level where the skin problem resides. The technology uses ultrafast electrical energy pulses to alter the cells that cause lesions.

This procedure is cell-specific, which means it affects cells and only cells. There is almost no effect on the surrounding non-cellular dermis (skin). The CellFX procedure uses non-thermal energy (no heat or cold) which reduces the risk of damage or scarring, and supports a more gentle healing process.

## 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 common warts.\* Its effect on other common lesions is currently being studied by leading skin experts.

*\*does not include genital warts*

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

The difference with the CellFX procedure is that it affects cells and only cells. This means it can clear the lesion – which is primarily comprised of cells – without affecting the surrounding non-cellular skin tissue.

The science behind the CellFX procedure is called Nano-Pulse Stimulation™ (NPS™) technology. NPS technology is based on a non-thermal energy, which means it does not generate heat or cold. Other methods such as burning, freezing or cutting involve unnecessary destruction of surrounding skin tissue in removing a lesion, which can lead to slower recovery times and risk of scarring or other permanent undesired effects.

The ability to affect only cells using a non-thermal energy provides your doctor unique control in clearing the lesion. All these beneficial differences can help minimize the risk of scarring, lessen the chance of lesion recurrence and support a better healing process.

## How long does the CellFX procedure take?

Your doctor will schedule the total appointment time required for your visit. The actual time for the CellFX procedure session is typically 15 minutes or less depending on the number of lesions to clear. Preparation of your skin typically takes a few minutes 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. Your doctor will design a treatment plan that works for you.

## How soon can I return to normal activity?

Generally, most patients can immediately return to normal activity. Your doctor may recommend wearing a small bandage and/or ointment to protect the area during the initial healing process.

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Your doctor can explain that individuals experience energy-based procedures differently. This experience can range from no sensation to tingling or twitching and can vary depending on the location of your lesion, individual sensitivity, anesthesia used, and response to anesthesia.

After your doctor numbs the lesion area, the treatment tip will be placed on top of the lesion. You may feel pressure from the microneedles of the treatment tip. Your doctor will then begin a series of rapid energy pulses (a “cycle”) that will be delivered to the lesion area. This delivery lasts about 10-15 seconds for each lesion area.

During the procedure, you may feel a mild sensation while the energy pulses are being delivered.\* You 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 you feel discomfort, let your doctor know and your doctor may choose to administer additional anesthesia.

*\*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.”)*

## Is there any special preparation?

Prior to the procedure, there is typically no special preparation needed, unless specified by your doctor. For instance, for facial lesions, your doctor may recommend to remove makeup prior to your appointment.

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

Your doctor will instruct you on proper post-procedure care, as the healing process and period of time can vary by individual depending on the size, location and type of lesion, your skin type, and natural variations in healing rates.

Immediately after the procedure, the majority of patients may experience temporary reactions that include mild redness and/or swelling at the treatment site. Some patients may experience minor bleeding due to microneedle insertion.

Within a week of the procedure, you may experience signs of the normal and expected healing process at the treatment site. A crust will form on the surface of the lesion area. After the cells of the lesion clear, new cells will regenerate, and the crust will shed as the new skin layer emerges. You may experience mild to moderate reddening, mild crusting, and mild scabbing as part of the normal healing period.

During the remaining healing period, you may experience temporary skin effects. The most common potential effect is mild pigmentary changes (temporary darkening of the treatment area). Like many common aesthetic procedures, pigmentary changes are more often seen in patients with darker skin tones.

Less common temporary skin effects include slight facial contour changes caused from clearance of the lesion, which resolves as normal skin tissue regenerates and fills in the area.

## 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?”)*

## When will I see results?

Lesions typically clear within 30-60 days. As the lesion clears and new cells regenerate to form a new skin layer, the gradual return to normal skin appearance can take between 60-90 days.

Your doctor will advise what the normal healing time would be for the particular lesion type and your skin type. Larger or deeper lesions may require longer periods of time to complete the clearance and healing process.

## How many visits are needed?

Most lesions can successfully clear with a single procedure session. Your doctor may provide guidance on the number of procedure sessions you may likely need for optimal results. For instance, for more difficult-to-treat lesions, your physician may recommend a second procedure session.

As the healing period progresses, if you believe that the lesion(s) or portion of the lesion(s) remain(s), contact your physician for follow-up.

## 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.

*\*Certain contraindications apply. Please consult with your doctor.*

## How much does a CellFX procedure cost?

The CellFX procedure is a cash-pay procedure and the cost will vary, based on the number of lesions. Consult with your doctor for more detailed information.

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 sebaceous 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>.



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