



DESCRIBE[®]
PFD PATCH

LASER TATTOO REMOVAL

with the DESCRIBE[®] PFD Patch:
An Optimal Standard of Care



SUMMARY

Nearly three in ten U.S. adults have one or more tattoos, but about one-fourth of those individuals regret their tattoos and have considered removal. While a number of tattoo removal approaches have been used over the years — including surgery, dermabrasion and chemical destruction — lasers have revolutionized the treatment. By selectively and effectively targeting tattoo ink particles, lasers can minimize damage to surrounding tissue, scarring and other side effects often seen with older techniques. However, laser tattoo removal also has a number of shortcomings, including safety issues, numerous time-consuming treatments and patient discomfort, which may include localized pain, swelling and redness. As a result, physicians often struggle to get patients to return for additional needed treatment, and many patients drop out before their tattoo is fully cleared.

Cleared by the U.S. Food and Drug Administration for use as an accessory to laser tattoo removal, the DESCRIBE® PFD Patch (PFD Patch) utilizes an optical clearing agent, perfluorodecalin (PFD), and helps address some of the laser treatment shortcomings. Recently, a group of leading experts in tattoo removal convened in a virtual roundtable discussion about the procedure and use of the PFD Patch (See page 10 for list of roundtable participants). This whitepaper captures their perspectives along with key findings from the medical literature. The participants concluded both patients and physicians should consider using the PFD Patch as part of the optimal standard of care, because it can make laser tattoo removal more effective, safer and quicker, and minimize patient discomfort compared to laser alone. As with all laser tattoo removal treatments, potential adverse events may include redness, swelling, pigmentary changes, infection, scabbing, scarring, crusting, bruising, itching, flaking or blistering.

TATTOOS ARE ON THE RISE — SO ARE REGRETS AND REMOVALS

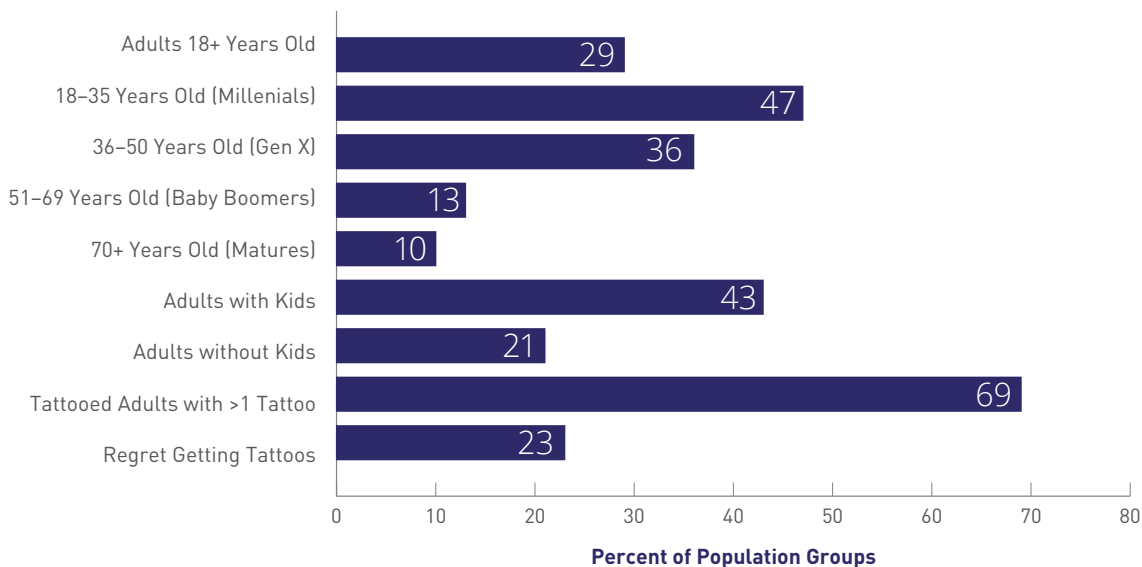
The proportion of adults with one or more tattoos has increased in recent years. A 2016 Harris Poll of 3,318 US adults found that 29% reported having at least one tattoo, up from 21% reported in 2012.^{1,2} And of those who had tattoos, nearly 7 in 10 (69%) had two or more. Tattoos are most popular among younger adults, with 47% of those age 35 years or younger reporting having at least one tattoo compared with 36% of those age 36-50 years, 13% of those age 51-69 and 10% of those age 70 years or more. (Figure 1).^{1,2}

On the other hand, the same poll found nearly one-fourth (23%) of adults regret getting a tattoo (up from 14% in 2012)^{1,2} (Figure 1), and many explore options for removal. Indeed, revenue generated from tattoo removal has jumped 440% over the last 10 years.³ In the 2016 poll, people gave a number of reasons for wanting tattoos removed (see Box).

Common reasons for tattoo removal²

- Too young when they got the tattoo
- Personality changes/does not fit present lifestyle
- Tattoo has name of someone no longer in relationship
- Poorly done/does not look professional
- Tattoo is not meaningful

Figure 1: Tattoos Among US Adults and Subgroups^{1,2}



“For me, the most important part of tattoo removal is the consultation with the patient, especially given you may have a relationship with them for a year or two, depending on how long removal will take. Patients want to get rid of the tattoo(s) in the quickest and safest way possible.”

— Matthew Avram, MD

LASER TATTOO REMOVAL: AN IMPORTANT ADVANCE

Historically, a number of different treatments — surgical excision, dermabrasion and chemical destruction — have been used to remove tattoos. However, over the past 20 years, lasers have revolutionized tattoo removal by improving clinical outcomes and decreasing side effects, and are now considered the gold standard of treatment.⁴

Laser tattoo removal is based on the concept of selective photothermolysis: the destruction of a targeted substance (e.g., tattoo ink particles). This approach minimizes damage to surrounding tissue, scarring, hypopigmentation and other side effects seen with other removal techniques.⁵

Despite the advantages of laser tattoo removal, it also has a number of limitations that make it difficult to quantify the number of treatments required to fully remove tattoos. Specifically, several tattoo- and patient-related characteristics (see list to the right) can make removal more difficult, necessitating more treatment sessions.^{6,7}



Pigment color. Black pigments are generally easier to remove, followed by red, whereas green, yellow and orange are usually more difficult to clear; however, the wavelength, peak power and pulse duration of the laser used can have a significant impact on the ease of removing different colored tattoos.



Professional vs. amateur tattoos. Professional tattoos are more difficult to remove because they tend to have greater pigment density and lie deeper in the dermis. Professionally applied, heavily inked tattoos may require up to 20 treatment sessions. Since the sessions are usually 4–8 weeks apart, complete removal can be burdensome to patients in terms of time commitment.



Location. Compared to tattoos on the head, neck and trunk, those on the extremities take longer to clear due to relatively less blood circulation.



Skin type. Melanocytes, found in the basal layer of the epidermis, also absorb laser photon energy. Therefore, patients with darker skin are usually treated with lower laser settings to reduce side effects such as hypopigmentation. This also reduces the efficacy of tattoo removal, and often requires more treatment sessions and longer times between sessions.

Figure 2: The Whitening Reaction During Laser Tattoo Removal



Another major limitation related to the laser treatment itself is the “whitening reaction” (Figure 2, left side). Each laser pass produces this response within the epidermis as a result of gas bubbles forming as cells rupture (“cavitation reaction”). Because the whitening is opaque, it delays laser retreatment until it dissipates, usually in about 20 minutes. Thus, after making a laser pass, many practitioners wait 20 minutes for the whitening to disappear before making another laser pass (the R20 method). As a result, up to 60 minutes are needed for a four-pass treatment session, which can be impractical for both patients and providers. Alternatively, a treatment session may consist of only a single laser pass (non-R20 method), but it is less effective than the R20 method at tattoo clearance.⁶

An important shortcoming of laser tattoo removal concerns exposure of the patient and provider to various potentially harmful substances. The photoacoustic effect from Q-switched (pulse duration of a nanosecond [one billionth of a second] or a picosecond [one trillionth of a second]) laser treatments can generate tissue splatter and airborne particles that may be inhaled or exposed to the skin. This so-called “laser plume” has been shown to contain bacteria, viruses (e.g., human papilloma virus and bacteriophage) and various chemicals (e.g., hydrogen cyanide, formaldehyde and benzene).^{6,8,9}

Given the limitations, shortcomings and time involved in laser tattoo removal, it is not surprising that one-third of patients drop out of treatment before it is completed.¹⁰ Clearly, methods to increase the efficiency and safety of laser tattoo removal are needed.

OPTICAL CLEARING AGENT IMPROVES LASER TREATMENT

The PFD Patch can help address this need, allowing faster, safer and more effective laser tattoo removal experiences compared to laser treatment alone.

The U.S. Food and Drug Administration (FDA) initially cleared the DESCRIBE® PFD Patch in April 2015 as a single-use accessory during tattoo removal in Fitzpatrick

Skin Type I-III patients with a 755 nm Q-Switched (QS) Alexandrite laser,¹¹ which effectively removes black- and blue-ink tattoos. In December 2017, FDA expanded the indication for use with 532, 694, 755 and 1064 nm standard QS lasers and with 532, 755, 785 and 1064 nm standard picosecond (PS) lasers, which are useful for removing a broader range of tattoo ink colors.¹²



How the PFD Patch works

The PFD Patch consists of a dual-layer medical-grade transparent silicone film. The bottom layer is tacky so it can be applied to the skin, and perforated so the optical clearing agent, perfluorodecalin (PFD), can wick into it.^{11,13,14} PFD is a stable, metabolically inert, nontoxic fluorocarbon liquid that reduces optical scattering and reflection in the skin and increases tissue transparency from the ultraviolet to the far-infrared. Although PFD rapidly evaporates if applied to the skin,¹⁵ the upper silicone layer of the PFD Patch acts as a barrier, significantly reducing the rate of evaporation.^{13,14}

Because PFD can absorb half its liquid volume of gases (including oxygen, nitrogen and steam), topical application of PFD immediately before and after a laser pass greatly reduces gas bubble formation and the whitening reaction. This allows for an additional pass within seconds (R0 method), as demonstrated in one of the first studies of PFD use in laser tattoo removal.¹⁵ Additionally, the perforations of the PFD Patch bottom silicone layer provide space to absorb the gas bubbles and whitening debris.



“We all get frustrated when patients don’t follow through with the recommended course of treatment sessions. I have found that using the PFD Patch — in addition to making treatment faster, more effective and safer — can demonstrate to patients tattoo ink ejection during the procedure, so they see the progress being made which reinforces their compliance.” — Paul M. Friedman, MD

Because the PFD Patch reduces optical scattering at the skin surface, it results in deeper penetration of energy into the skin, allowing up titration of tolerated fluence (the amount of energy delivered to a given area). For example, in the pilot study of the PFD Patch, investigators achieved 1.5x to 1.8x the fluence with use of the PFD Patch compared to laser alone. This increased energy can reach tattoo ink particles in deeper layers of the skin, which is particularly beneficial for clearing older tattoos.^{6,14}

The PFD Patch also helps protect the epidermis by conducting heat away from it, reducing the potential of epidermal injury and treatment-related adverse effects.¹⁴ The physical barrier of the PFD Patch may also help protect the physician and patient from laser-generated tissue splatter and airborne noxious substances. Because the underside of the PFD Patch is perforated, the released substances are observed to go into the silicone film rather than into the surrounding air. Table 1 summarizes the main challenges with laser tattoo removal, and how the PFD Patch addresses them.

Table 1: How the DESCRIBE® PFD Patch Addresses Challenges with Laser Tattoo Removal

Challenges With Laser Tattoo Removal	How the PFD Patch Helps Address the Challenges
Whitening reaction from single laser pass delays subsequent passes by at least 20 minutes (R20 method) or until next treatment session ⁶	PFD in the Patch absorbs the gases generated during each laser pass, reducing the whitening reaction and allowing additional passes within seconds — up to four times as many in a single treatment session ^{6,14,16}
Difficulty removing professional vs. amateur and older tattoos because tattoo ink is in deep layers of the skin ^{6,7}	PFD Patch reduces optical scattering at skin surface, typically allowing up titration of tolerated fluence and increasing energy delivery to ink particles in deeper layers of the skin ^{14,16}
Laser treatments can expose patient and provider to tissue splatter and airborne toxic substances ^{6,8,9}	PFD Patch silicone film captures tissue splatter and airborne substances, protecting physician and patient ^{6,13,14}
Patients drop out of treatment before completion due to discomfort and the time and compliance needed to undergo multiple sessions (e.g., 20 for heavily inked tattoos, 4–8 weeks apart) ^{10,14,17}	Patients are more likely to continue with treatments because the PFD Patch can reduce patient discomfort and the number of treatment sessions required since it allows up to four times as many passes in a single treatment session compared to laser alone ^{6,14,24}



“One of the major safety concerns that doesn’t get much attention is potential airborne particles, which can get into the lungs and throat, infecting the patient and the physician. Having protection against that is another reason I prefer using the PFD Patch.” — Matthew Avram, MD



Supporting evidence

One of the first studies that led to the development of the PFD Patch showed that topical application of PFD immediately after a laser pass greatly reduced the whitening reaction, allowing subsequent passes within seconds.¹⁵ This was a major advantage over the standard single-pass treatment session and the R20 method. In the randomized controlled trial, investigators used a QS ruby or Nd:YAG laser to treat half of previously untreated tattoos (n=7) with 4 passes using the R20 method, and the opposite half of the tattoo with 4 passes using PFD (R0 method). Additionally, previously treated tattoos (n=22) were treated with 3 passes using PFD and the R0 method. The tattoo halves were randomly assigned to the two treatments.¹⁵

The results showed that, with the PFD/R0 method, whitening resolved after a mean of 5 seconds compared to 20 minutes without PFD, and the total mean treatment session time was 5 minutes compared to 68 minutes. At 1-3 months follow-up, tattoos treated by the PFD/R0 method and by the R20 method (without PFD), as well as the previously untreated and treated tattoos, all showed equal fading: 51-75% (Table 2). Treatments using topical PFD were well tolerated without adverse events.¹⁵

Table 2: Tattoo Removal by R0 (Laser + PFD) and R20 (Laser Only) Methods¹⁵

Tattoo Removal Method (n)	Study Arm	Time to Whitening Reduction (75-100% Decrease)	Total Treatment Time (Mean)	Degree of Tattoo Fading at 1-3 months (Mean)
R20, 4 Passes (7)	Previously untreated symmetric tattoos, half of tattoo	20 minutes	68 minutes	51-75%
R0, 4 Passes (7)	Previously untreated symmetric tattoos, half of tattoo	5 seconds	5 minutes	51-75%
R0, 4 Passes (22)	Previously treated tattoos	5 seconds	5 minutes	51-75%



"I think the PFD Patch makes the experience safer for the patients and the physician, and increases patient satisfaction." — Jeremy Brauer, MD

The benefits of PFD were demonstrated in a subsequent pilot study¹⁴ of the PFD Patch in 17 patients with Fitzpatrick skin types I-III. Study investigators divided patients' dark blue or black tattoos into two halves, and randomly assigned one half to treatment with a nanosecond QS 755-nm Alexandrite laser plus the PFD Patch in 5-minute treatment sessions 4-6 weeks apart, and the other half to treatment with the laser alone in an equal number of separate 5-minute sessions.

Results showed:

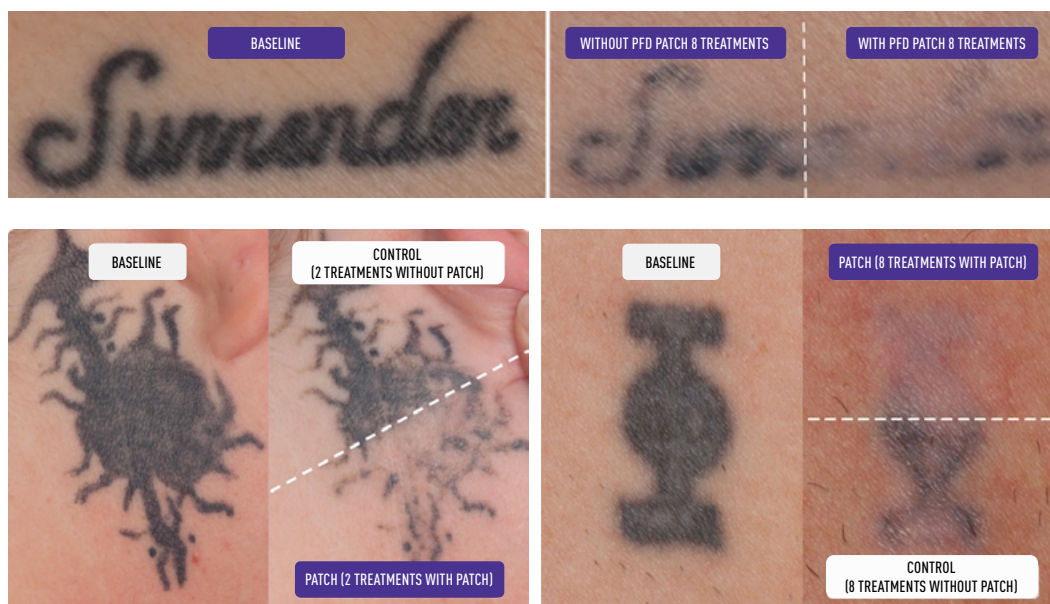
- Laser treatment with the PFD Patch allowed 3 or 4 (3.6 on average) rapid passes vs. only 1 pass with laser alone due to epidermal whitening.
- In most patients (11 of 17), tattoos treated with the laser plus PFD Patch cleared more rapidly (Figure 3) and resulted in greater patient and clinician satisfaction than with laser alone.
- The PFD Patch also allowed 1.5 to 1.8 times greater fluence than with laser alone, with no increase in adverse events (AEs).
- AEs were typical of those seen with laser tattoo removal, mild to moderate in severity, and included erythema, edema, pain, and crusting.
- The incidence of these AEs was the same for both the PFD Patch and laser-only sides of the tattoos.
- No scarring, textural changes, or unanticipated AEs events were observed.



"The value the PFD Patch provides fits well with a shift we are seeing in patients' concerns, away from lower price to wanting better quality and safety outcomes. This is especially the case in major urban areas such as Houston, because of the ethnically diverse skin types."

— Paul M. Friedman, MD

Figure 3: Tattoos Before and After Laser Treatments With vs. Without the DESCRIBE® PFD Patch¹⁴



"I've also noticed that, when the PFD Patch is used, patients seem to have an easier time with wound care where the tattoo was removed, and faster and improved wound healing."

— Cara Costner, RN



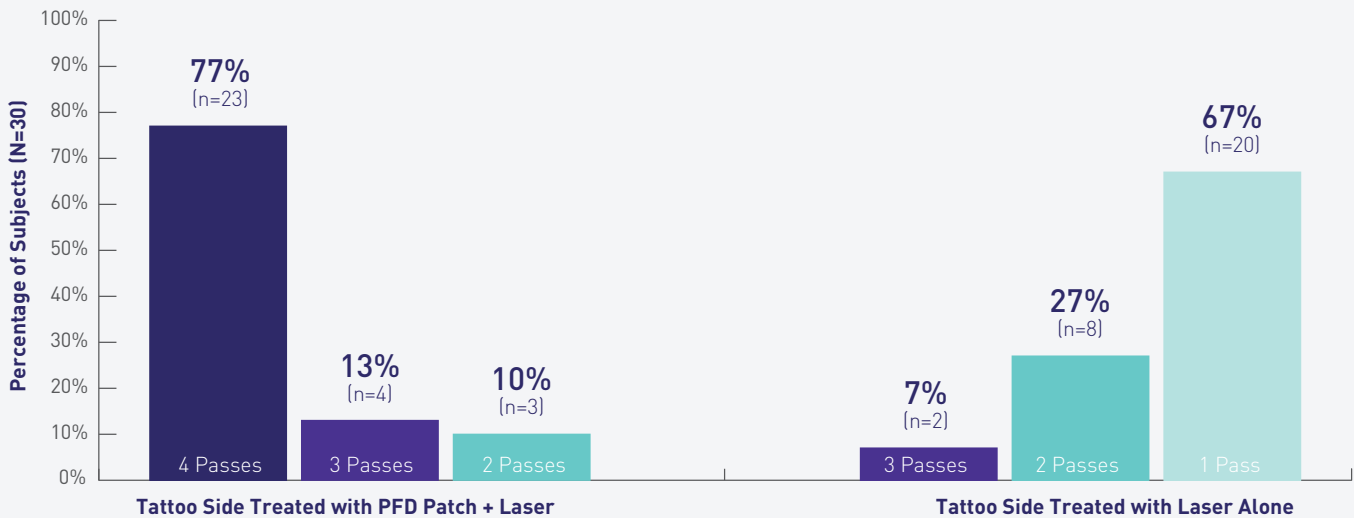
“For the patient, the most important benefit of the PFD Patch is it helps remove the tattoo more quickly. And you can tell them, ‘Oh by the way, it’s also safer, may be more comfortable, and you may have an easier time post treatment.’” Jeremy Brauer, MD

The pilot study results were confirmed in a pivotal trial⁶ with the same “split tattoo” design and which included 30 patients. The results showed that up to four times as many laser passes could be made with the laser + PFD Patch vs. laser alone (Figure 4), with an average of 3.7 passes vs. 1.4 passes, respectively, $p < 0.001$ (Figure 5).

AEs were limited to those expected during laser removal of tattoos, were transient and resolved quickly. Patient-reported pain scores on a 10-point visual analog scale were significantly lower for the tattoo side treated with PFD Patch vs. laser alone (1.5 vs. 2.4, $p = 0.029$). The proportion of patients with transient edema and erythema was lower in the PFD Patch group vs. the laser-only group (36.7% vs. 63.3% and 33.3% vs. 70.0%, respectively).

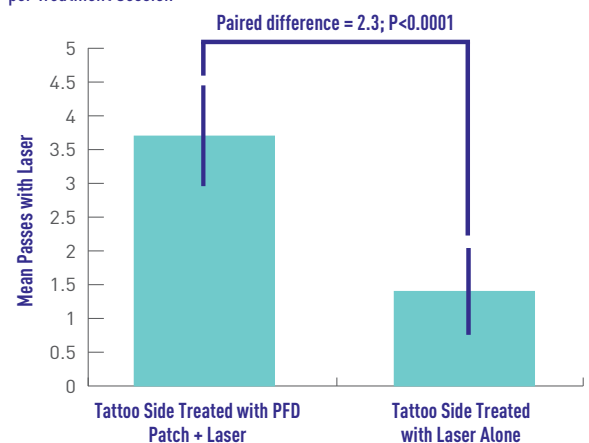
When surveyed one month after treatment, all patients preferred to continue laser-assisted tattoo removal with the PFD Patch instead of laser-only.

Figure 4: The DESCRIBE[®] PFD Patch Allows up to 4 Times as Many Laser Passes in a Treatment Session⁶



A recent analysis¹⁸ showed that optical transparency and chemical properties of the PFD Patch were unchanged with exposure to lasers of varying wavelengths, including QS (532, 694, 755 and 1064 nm) and PS (532, 755, 785 and 1064 nm) lasers. The analysis also included a retrospective chart review that supported the efficacy of the PFD Patch in patients (n=46) with diverse Fitzpatrick skin types who had tattoos with a range of colors and on various areas of the body. More recently, other retrospective chart reviews have found that removal of tattoos of various colors using the PFD Patch with Q-Switched and picosecond lasers was safe in patients of diverse Fitzpatrick skin types, and resulted in better tolerance for multiple passes compared to laser treatment alone.^{19,20}

Figure 5: The DESCRIBE[®] PFD Patch Permits More Laser Passes on Average per Treatment Session⁶



CONCLUSIONS

The demand for laser tattoo removal will continue to grow for the foreseeable future. The FDA-cleared DESCRIBE[®] PFD Patch can address a number of important shortcomings of laser tattoo removal, and should be considered an optimal standard of care when used as an accessory to the laser for the removal of tattoos. Patients who want tattoos removed and physicians who perform laser tattoo removal should consider using the PFD Patch to make the procedure safer, more effective and less time-consuming.

This work was sponsored by Merz North America, Inc. All authors were consultants and/or investigators for Merz North America, Inc. For information about how Merz handles personal data, please visit our Global General Data Protection Information [here](#).²¹

Roundtable Participants:

MODERATOR: Brian Biesman, MD, FACS, Assistant Clinical Professor, Vanderbilt University Medical Center; Department of Ophthalmology, Divisions of Dermatology and Otolaryngology; Nashville Centre for Laser and Facial Surgery, Nashville, TN

Matthew Avram, MD, Director, MGH Dermatology Laser & Cosmetic Center, Massachusetts General Hospital, Boston MA

Jeremy Brauer, MD, Clinical Associate Professor, The Ronald O. Perleman Department of Dermatology, New York University School of Medicine, New York, NY

Paul M. Friedman, MD, Director of Dermatology & Laser Surgery Center, Houston, TX and New York, NY

Cara Costner, RN, FNP, Nashville Centre for Laser and Facial Surgery, Nashville, TN

Important Safety Information:

The DESCRIBE[®] PFD Patch is a single-use, optical clearing device accessory for use in laser-assisted tattoo removal procedures. Side effects, including pain, erythema and edema were reported during laser tattoo removal. The DESCRIBE[®] PFD Patch is available only through licensed physicians. For full product and safety information, visit DescribePatch.com/IFU.

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“Some physicians aren’t using the PFD Patch because they’re not aware of it or are concerned about the cost. But once they realize they can remove tattoos more effectively, safely and quickly, and have happier patients, most will strongly consider it.”

– Matthew Avram, MD



“We have a consensus: It is highly recommended that the PFD Patch be used as part of the optimal care for patients who present for laser-assisted tattoo removal.”

– Brian Biesman, MD (Roundtable Moderator)

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