

Instructions for Use

Description

The DESCRIBE PFD Patch is a single-use, perfluorodecalin-infused gel-based skin barrier and optical clearing device accessory for use during laser treatment of tattoos.

Indications

The DESCRIBE PFD Patch is indicated for use as an accessory to laser tattoo removal procedures using 532, 694, 755, and 1064 nm standard Q-Switched (QS) lasers and 532, 755, 785, and 1064 nm standard picosecond lasers in Fitzpatrick Skin Type I-III patients.

Contraindications

The DESCRIBE PFD Patch is contraindicated for patients with dermatological conditions that would disrupt the integrity of the skin in the area of application. Do not use on open wounds.

Instructions for Use

1. Procure swabs.
2. Ensure treatment area is clean and dry.
3. Verify that liquid perfluorodecalin (PFD) is present within the pouch.
4. Tear open top of pouch along dotted line.
5. Immerse swab in liquid PFD within pouch.
6. Pre-wet treatment area with PFD-coated swab.
7. Remove Patch from pouch.
8. Peel Patch from its release liner.
9. Because PFD evaporates quickly, promptly apply Patch with the adhesive surface making contact with the treatment area.
10. Treat directly through the transparent Patch with selected laser.
11. Do not use more than two Patches per patient per treatment session.
12. Immediate laser retreatments may be performed in accordance with clinical signs and symptoms.
13. Discard the single-use Patch after use. Follow local governing ordinances regarding proper disposal of medical waste.

Precautions












1. For use only with laser and settings selected by trained laser operator.
2. Single-Patient-Use Only. Risk of cross-contamination. Do not reuse.
3. Do not use if product is opened, damaged, opaque or visually defective.
4. If the Patch becomes darkened or opaque with ejected pigment, replace it with a fresh DESCRIBE PFD Patch.
5. Although the product is non-flammable, keep away from open flame.
6. Wear protective gloves and safety glasses.
7. Do not perform more than four laser passes per treatment session.

Potential Adverse Events

The use of the DESCRIBE PFD Patch does not alter Potential Adverse Events from those encountered with the use of lasers alone. These potential adverse events may include redness, swelling, pigmentary changes, infection, scabbing, scarring, crusting, bruising, itching, flaking, or blistering.

Usage Note

The DESCRIBE PFD Patch does not attenuate or scatter dermatological laser treatment light. The user is not required to modify laser settings and may use maximum tolerable fluence in accordance with clinical signs and symptoms.

	For Prescription Use Only
	Consult Instructions for Use
	Single Use
	Not Made with Natural Rubber Latex
	Do Not Use if Package is Damaged
	Manufacturer
	Batch Code
	Catalog Number
	Date of Manufacture
	Authorized Representative
	Use By Date

symbols per ISO 15223



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