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Radiofrequency microneedling challenged by warnings and defended by competent practice

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Radiofrequency microneedling devices suddenly came under regulatory scrutiny when a warning was issued recently by the United States Food and Drug Administration (FDA) on 15th October, 2025 against the safety of these devices, aiming to raise a concern amongst the health care professionals and public about the concerning side effects observed.[1] The point of concern was the frequency of side effects reported including disfigurement, scarring, burns, fat loss and nerve damage. In this report, FDA called for vigilance, following the right indications and emphasized adherence to proper techniques. It was also notified that radiofrequency microneedling is a medical procedure and should be done by trained healthcare professionals. Furthermore, the reporting of side effects should be ensured by both the health care professionals and the patients. This has raised a lot of concern amongst the public regarding the safe use of these devices for cosmetic indications.[2]

RF microneedling devices are cleared by FDA through 510(k) and authorized via De Novo databases. FDA authorized marketing only for specific use in certain areas of the body. As the clearance was issued for adults >22 years old, with certain indications including wrinkles and scars (acne scars on face and abdominal scars), the unauthorized marketing for indications beyond this scope was not granted by the FDA and has been mentioned in the safety communication of the agency's update.[3] This was taken up by the accrediting bodies and professional organizations including American Academy of Dermatology raising an alert regarding the class of these devices, following the indications, training of the operators and reporting of side effects.[4]

Evidence suggests that transient erythema and edema are common side effects observed with the use of RF microneedling devices, while serious adverse events are rare. Transient erythema was reported to be the most common side effect after treatment for skin rejuvenation and acne scarring according to systematic reviews, RCTs and prospective cohorts,[5] while the incidence of scarring and dyspigmentation was low with the use of these devices by trained professionals, although an underestimation of the side effects is expected.[6] The factors leading to these side effects are inappropriate selection of device parameters including depth and energy, use over high-risk anatomical sites,

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stacking passes and lack of parameter adjustment according to the skin type. The rare side effects reported till date are lipoatrophy, neuropathic symptoms and 'tram-track' scarring.[7]

Operationally, the parameters of energy and depth vary according to the anatomical sites.[8] It is recommended to do test spots in higher Fitzpatrick's skin types, avoiding stacking of pulses and initial settings can be kept low-intensity. However, these recommendations are based on the expert opinions and there is no standardized dosing protocol available yet.[9]

The Safety Communication report by FDA is comprised of a regulatory mechanism that is targeted to correct the divergence between marketing and evidence-based clinical practice, highlighting the need for reporting of side effects and strengthen the vigilance and post marketing surveillance. This should result in five tangible measures being implemented.

Using these FDA cleared devices only for indications approved by FDA while getting informed written consent for use beyond the authorized label. Patient selection and screening is crucial to rule out connective tissue diseases, keloid formation, dysesthesia, risk of pigmentation and use of isotretinoin. Adequate training sessions before the initiation of its use by health care professionals should include anatomical zoning, pass technique, use of insulated microneedles, pulse duration, energy and density. Use of carefully graded dosing in patients with darker phenotypes is recommended and high energy parameters are to be avoided in peri-orbital region and thin fat compartments. Any adverse effects observed should be promptly reported to the FDA to improve the safety.[10,11] The non-clinical use and home use are strictly prohibited.

This is an opportunity for professional societies and research journals to encourage quality assurance and quality infrastructure. The reporting standards should be maintained for skin type according to Fitzpatrick's classification and the parameters used for reporting should be aligned with CONSORT.[12] American Academy of Dermatology acknowledges the concern and suggests formation of procedural checklists and consensus syllabi. The literature gap can also be filled by launching multi-center registries and endpoints can be clearly defined along with a follow-up period of 6-12 months. Until the advisories suggest a protocol for risk stratification, aggressive treatment should be avoided in periorbital and temporal areas, darker skin phenotypes should always get a test spot done, stacking should be avoided and the subsequent session for high-risk areas should be delayed.

FDA's warning should be observed as a rectification and not a threat to this modality, thus resulting in a better inspection and improved standards. It is not justified to forgo a sustainable technology based on misconceptions and reporting of rare side effects. It will be a responsible move to ensure transparency and competence. This procedure remains a credible and beneficial tool for evidence-based aesthetics when practiced within boundaries.

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