

Commitment to Safety and Transparency in Radiofrequency Microneedling

Dear Revival Med Spa,

As you may have heard, the FDA recently issued a Safety Communication titled “Potential Risks with Certain Uses of Radiofrequency (RF) Microneedling”. This article issues a warning to consumers, patients, and health care providers after receiving many serious complications and adverse event reports from the use of Radiofrequency (RF) Microneedling devices in dermatologic and aesthetic treatments. The FDA has indicated that it is actively evaluating reports of injuries and that the agency is working directly with manufactures to improve safety and device labeling. The article places a strong emphasis on the importance of proper training protocols and ensuring that patients understand the risks that this procedure can provide.

Rohrer Aesthetics has not received any direct communications on this matter from the FDA at this time. Our clinical and compliance teams are committed to always staying up to date with all device evaluations. Given the seriousness of the FDA safety communication, internal teams completed a full evaluation and extensive report of our PiXel8-RF and Pix:E device(s) and are happy to report that our customers are not experiencing the complications such as burns, scarring, fat loss, disfigurement and nerve damage as indicated in the safety communication when using the PiXel8-RF and Pix:E device(s). We believe this is due to our uniquely designed safety features, depth & temperature control, our extensive clinical training programs, and all treatment protocols and ongoing training opportunities made visible to all of our customers on our robust clinical training portal. Rohrer Aesthetics does not have any plans of updating our IFU or any labeling for our PiXel8-RF and Pix:E device(s) at this time and feel our device(s) are safe to use when following proper training and procedure protocols.

We remain committed to staying compliant with regulations and providing a safe and effective product to our customers. If you or your patients have any concerns that any Rohrer Aesthetics device has caused an injury, please call or email us immediately at **adverseevents@rohreraesthetics.com** and an investigation will be started. If any customers have questions directly related to this FDA safety communication regarding any of our Rohrer Aesthetic devices, please contact our customer solutions team at **customerservice@rohreraesthetics.com**.

Sincerely,
The Rohrer Aesthetics Team