

MEDICAL MICRONEEDLING: INDICATIONS FOR A NEW DUAL-PURPOSE DEVICE



The Exceed™ medical microneedling system blends power, precision, and control to deliver clinically proven results for treatment of facial wrinkles and facial acne scars.

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It is no surprise, given the minimally invasive nature of the procedure and short duration of associated downtime, that microneedling is the third most frequently performed procedure at medical spas, following injections of neuromodulators and hyaluronic acid fillers.¹ While there are many types of microneedling procedures—categorized broadly as manual, mechanical, or energy-based—they have in common the use of thin needles to create tiny punctures in the skin and induce a collagen-stimulating healing process. The end result of the healing process and neocollagenesis is a reduction in the appearance of fine lines, facial wrinkles, and facial acne scars.

The recently introduced Exceed medical microneedling system (Candela), which is a mechanical device, offers a high technology option for natural repair and restoration of skin. It is the first such device to gain clearance from the FDA for use in both the treatment of facial wrinkles, as well as for treatment to improve the appearance of facial acne scars. Its designation as a Class II device is no small consideration. As a result of amendment to the FDA Code of Federal Regulations in June 2018, microneedling devices were split into two categories: Class II and Class I. Class II medical microneedling devices, which have longer needles for aesthetic use, require a higher standard of testing

and may only be purchased and used by a licensed healthcare professional. In contrast, Class I cosmetic microneedling devices have much shorter needles.

ENGINEERED FOR RESULTS

The Exceed system consists of three components—each engineered to deliver unparalleled benefits over competitor devices. The control unit is a standalone power unit designed with a bright LED screen for easy needle speed adjustments. The adjustability of needle speed yields high precision and consistent penetration. The unit offers persistent power for up to 150 needle penetrations per second, as well as onboard software that prevents overheating of the handpiece.

The ergonomically designed, lightweight handpiece provides the operator with both precision and control. It fits my hand, and, compared to other battery-operated, medical microneedling devices I've tried, it is incredibly lightweight, which helps to minimize operator fatigue. It is also simple to use: needle penetration depth (0.0-1.5mm) is easily adjusted using a dial on the handpiece, and the cartridges are affixed with an easy screw-on and off technique, which makes replacing them seamless. Something that really surprised me about the Exceed system was how it functions with minimal noise; I never realized how loud other micronee-

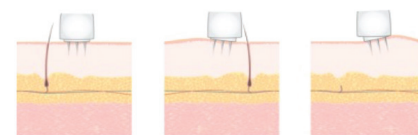


Fig. 1. The tilting plate on the cartridge adjusts to the contours of the skin's surface to ensure microneedles are always penetrating at a perpendicular orientation into the treatment area. This feature also prevents snagging on the skin.

dling devices were until I experienced the quiet operation of the Exceed system.

The single-use cartridge is perhaps the most important and innovative aspect of the system. The microneedles are constructed of sterile, stainless steel for high precision and penetrative force. The cartridge's six microneedles are clustered onto a tilting plate that adapts to the skin's surface, both facilitating access to difficult-to-reach areas and providing consistent perpendicular needle penetration (Fig. 1). This means that the treatment is performed using a circular motion, as opposed to a traditional linear or diagonal treatment pattern that might leave some skin areas under- or untreated. The tilting needle plate adjusts to every contour on the patient's skin; it maintains consistent and snag-free contact to ensure a consistent, confluent treatment pattern.

The Exceed medical microneedling system is also available with an optional footswitch for treatment versatility. I have

COMPETITIVE COMPARISON OF TREATMENT PROGRESSION

Results with the Exceed system can be seen in a patient with the device on the right side of the face and with a competitive product on the left side (Figure). In the immediate post-treatment photos, increased erythema is evident on the side of the face treated with Exceed, indicating a more profound treatment effect. There is also evidence of pinpoint bleeding on the right medial temple and upper lip, suggesting the operator achieved a desirable treatment endpoint. In the profile photos, it is easy to appreciate confluent erythema indicating a consistent treatment. Over time, and as the skin heals, a more even skin tone is achieved on the right side (Exceed) across all skin zones. By post-treatment day 4, the difference in appearance is already evident. Of note, this is after a single treatment, and



most likely the patient would experience additional healing and rejuvenation over time, especially with repeat treatment. Of note, during this patient's treatment, the competitive device ran out of power while the area of the brow was still being treated; the Exceed system was used to complete the treatment.

found the system provides truly remarkable advantages over competitive products in several domains, including power and speed, control and comfort, precision and adaptability, and quality. Most important, though, is the kind of results it delivers for patients (*see Competitive Comparison of Treatment Progression*).

EXPERIENCE AND CLINICAL EVIDENCE

One of the key reasons that many patients are looking to microneedling is that treatment is associated with fast healing and minimal downtime. The convenience of the Exceed treatment is likely a factor in the high patient satisfaction reported to date. In one survey, 86 percent of patients said that the Exceed treatment significantly improved acne scars and 88 percent would recommend the treatment to family and friends.² Similar findings were found in sampling of patients treated for signs of skin aging: 90 percent reported improvement in facial wrinkles and 78 percent saw improvement in periorbital wrinkles after 90 days.³

A study of the Exceed system for improving skin aging signs was conducted with 48 patients (median age 55.1 years) who underwent four treatment sessions at 30 days apart.⁴ For the study, a circular movement was used with varying needle depth

according to facial area: 0.7-1.5mm for glabella frown lines, 0.5-0.8mm for periorbital lines, and 0.9-1.3mm for cheek folds.

At day 150 compared to baseline, investigators recorded significant improvement in global wrinkle score. Statistically significant improvement in all three measures was also noted at day 90. The most notable side effects included mild and moderate erythema observed after treatment, but no serious adverse effects were reported.

The Exceed microneedling treatment for facial acne scars was assessed in a study of 56 patients with either ice pick, rolling, or box-car-type scars.⁵ Patients were treated in four sessions, 30 days apart. Average needle protrusion was 1.39mm, which was adjusted by the operator to achieve pinpoint bleeding. Change in facial acne scar appearance was graded by the operator using the Goodman and Baron Grading Scale of acne scarring.

By the study assessment at three months, 85 percent of subjects experienced a reduction of facial acne scarring compared to baseline, and there was a mean reduction in scarring of 0.91 ($p < .001$). Reports of mild to moderate redness of the skin on the evening of the treatment were common. The most common adverse events were bruising ($n=6$) and swollen lymph-nodes ($n=6$), but no serious adverse effects were reported.

A VERSATILE, EFFECTIVE OPTION

Used on its own, the Exceed microneedling system is a versatile, clinically-proven option for skin rejuvenation, including treatment of facial acne scars, or as an alternative to neurotoxin for facial wrinkle reduction.

I have been very pleased with the results we are able to achieve with the Exceed microneedling system as a standalone procedure. I am also comfortable using the Exceed system in conjunction with other procedures and treatments to address skin imperfections and aging skin. I have found great synergy, for example, with the Exceed system paired with bipolar fractional radio frequency for the treatment of facial acne scars. The Exceed treatment serves as an excellent gateway for a new segment of customers (such as those who are early in the aesthetic journey). From the practice's perspective, routine maintenance treatments ensure high occurrence of repeat visits. But what is truly exciting is that Exceed microneedling system provides a neurotoxin-free option for patients that require minimal downtime and maximum convenience. ■

1. AmSpa. June 2019 Medical Spa State of the Industry Report. • 2. 510(k) K182407 • 3. 510(k) K180778 • 4. Ablon G. Safety and effectiveness of an automated microneedling device in improving the signs of aging skin. J Clin Aesthet Dermatol. 2018;11(8):29-34. • 5. Data on file. FDA 510K K182407 & German Register for Clinical studies (DRKS). No. [DRKS00013187].



