



MERZ AESTHETICS ANNOUNCES THREE YEAR FDA CLEARANCE FOR CELLFINA™ SYSTEM

Cellfina Earns Longest FDA Cleared Duration for a Cellulite Treatment

Merz North America
Michelle Alves
Corporate Communications
6501 Six Forks Road
Raleigh, NC 27615
Office (919) 582-8101
Michelle.alves@merz.com

www.MerzUSA.com

RALEIGH, N.C. – OCTOBER 17, 2016 – BUSINESS WIRE – Merz Aesthetics, a division of Merz North America (U.S. affiliate of the global Merz Pharma Group), announced today that the U.S. Food and Drug Administration (FDA) has cleared its [Cellfina™ System](#) for the long-term improvement in the appearance of cellulite on the buttocks and thighs of adult females with no loss of benefit for up to 3 years.

“The Cellfina™ System is quickly changing the expectations that patients and physicians have had around cellulite treatments and the results they can achieve,” stated Jim Hartman, Vice President and US Head, Merz Aesthetics and OTC. “The three-year indication shows not only the scientific rigor with which the Cellfina™ System was created, but also the commitment of Merz North America toward innovation and expansion of the aesthetic market through follow-on research and clinical study.”

Cellfina™ is the only FDA-cleared minimally invasive procedure clinically proven to improve the appearance of cellulite for results that last at least three years, the longest duration of any device cleared by the FDA. The Cellfina™ System combines highly advanced, proprietary technology with a well-established procedure called subcision, to treat the structural cause of cellulite. According to market research, 78% of U.S. women have cellulite that would qualify as treatable with the Cellfina™ System.¹

“I’ve been involved with the Cellfina™ System since it was first conceived as a potential treatment for cellulite. It’s been incredibly gratifying to see the treatment perform beyond the research setting,” said Dr. Michael Kaminer, Associate Clinical Professor of Dermatology, Yale Medical School. “The Cellfina™ System has truly been the only cellulite treatment that has delivered on its initial potential, providing women with a safe and effective treatment for their cellulite.”

A board-certified dermatologist in private practice in Boston, Massachusetts, Dr. Kaminer is known as a leader, innovator and talented dermatologic surgeon and laser medicine expert. He is one of the three founding partners of SkinCare Physicians, a 15 physician, 100 employee group in Boston that is recognized as a world leader in medical and aesthetic dermatology.

¹ Survey of 1,045 women, conducted by Listen Research for Merz North America



“As a plastic surgeon, I was initially skeptical of the Cellfina™ System and the results that it could offer, having been through the launches of several other in-office cellulite treatments that claimed to have similar potential. After seeing the results first-hand, as well as the continued, proven clinical efficacy of the device, I’m a believer,” said Laurie Casas, MD, Board-Certified Plastic Surgeon and Senior Clinician Educator, University of Chicago’s Pritzker School of Medicine.

The recent clearance by the FDA was a result of a prospective, multicenter US clinical study of 55 patients that underwent a single treatment with the Cellfina™ System. The Cellfina™ System improved the appearance of cellulite in 98% of treated patients at three years, according to independent physician evaluators. Importantly, 93% of patients reported satisfaction with their treatment at the three-year mark, and noticeable improvement on the Global Aesthetic Improvement Scale (GAIS) was seen in 100% of treated patients at three years. No serious device-related adverse events were reported at any time during the pivotal trial and follow up.

About Cellfina™

The Cellfina™ System is intended for long-term improvement in the appearance of cellulite in the buttocks and thigh areas of adult females. Safety and effectiveness in other anatomical areas have not been established. The most common side effects reported were soreness, tenderness, and bruising. The Cellfina™ System is only available through a licensed physician. For full product and safety information, visit <http://www.cellfina.com/IFU>.

About Merz Aesthetics

Merz Aesthetics is a division of Merz North America, a specialty healthcare company that is dedicated to delivering a better total experience in aesthetics, dermatology and neurosciences. As part of the Merz Pharma Group, our ambition is to become the most admired, trusted and innovative aesthetics and neurotoxin company. By developing products that improve patients’ health and help them to live better, feel better and look better, we will continue to make significant contributions to the well-being of individuals around the world. In the aesthetics space, Merz provides a full portfolio of treatment options, including Device, Injectables and Skincare, that enables physicians to treat a broader range of patients and concerns with Merz technologies. To learn more about Merz Aesthetics and their full U.S. product portfolio, please visit www.merzusa.com/aesthetics-otc.

Corporate Contact:

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