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For Immediate Release

MENTOR™ MemoryGel™ Enhance Breast Implant Receives FDA Approval for Largest Size Breast Implants for Reconstruction

MemoryGel™ Enhance Breast Implant is the first and only implant line created specifically for women with larger breast cup sizes undergoing breast reconstruction and reconstruction revision

ATHENA Study findings demonstrate the safety and efficacy of larger-volume silicone breast implants for patients with larger breasts who request postmastectomy, implant-based breast reconstruction

Irvine, Calif. (December 2, 2024) – Mentor Worldwide LLC, the number one global brand in breast aesthetics, and part of Johnson & Johnson MedTech, today announced the U.S. Food and Drug Administration (FDA) approved MENTOR™ MemoryGel™ Enhance Breast Implants for primary and revision reconstruction breast surgery in post-mastectomy women. This first-of-its-kind silicone gel-filled implant line features an expanded range of base widths, projections, and volumes in an entirely new range of sizes extending from 930 cc to 1445 cc, the largest on the market. Mentor plans to commercially launch MemoryGel™ Enhance Breast Implants in the U.S. beginning in mid-2025.

More than 150,000 women in the U.S. undergo breast reconstruction annually[1], and this growing patient population is becoming more diverse.[2,3]An increasing number of these patients require larger breast implants due to factors such as body frame, breast size, or extensive tissue removal during mastectomy. Previously, women with larger cup sizes faced limitations to their breast reconstruction options as the largest implant available was 800 cc[4]. In many cases, this led to compromises in achieving optimal aesthetic outcomes, as insufficiently sized implants could not adequately meet reconstruction tissue volume requirements for some women.[5]

"We are proud to introduce MemoryGel™ Enhance Implants, a truly meaningful innovation that reflects our commitment to inclusivity and addressing the long-standing patient need for larger breast implant options," said Alenka Brzulja, Worldwide President, Mentor Worldwide LLC. "By expanding the choices available for breast reconstruction, we are breaking down barriers and ensuring that every woman has equal access to options tailored to her unique anatomy and preferences. Our goal is to support the overall well-being, confidence, and sense of wholeness for every woman undergoing breast reconstruction, ultimately enhancing her journey through comprehensive breast cancer care."

With the launch of MemoryGel™ Enhance Breast Implants, breast reconstruction patients in need of larger implants are afforded the same clinical benefits as those patients for whom proportionately sized implants are already available. This new implant line will enable surgeons to deliver desired results for women who were previously underserved, having limited options to regain their original breast size or achieve projection and symmetry with the unaffected breast.[6,7]

"The size of implants currently on the market is not reflective of the diverse body types of women, especially women with larger cup sizes who undergo reconstructive surgery following a breast cancer diagnosis," says Alanna Rebecca, M.D., plastic and reconstructive surgeon at the Mayo Clinic in Phoenix, Arizona, and co-author of the anticipated ATHENA study publication. "A woman's body type should never limit her options in reconstruction, which is why this latest approval is an

[1] Reconstructive procedures by type U.S. 2022. Statista. Accessed July 9, 2024. https://www.statista.com/statistics/1451909/number-of-reconstructive-procedures-in-the-us-by-type/#:~:text=Number%20of%20reconstructive%20procedures%20performed
[2] Ward ZJ, Bleich SN, Cradock AL, et al. Projected U.S. State-Level Prevalence of Adult Obesity and Severe Obesity. N Engl J Med. 2019;381(25):2440-2450. doi:10.1056/NEJMsa1909301
[3] Centers for Disease Control and Prevention United States Cancer Statistics: Data Visualizations. Female breast. Accessed 19 February 2024, https://gis.cdc.gov/Cancer/USCS/#/Trends/
[4] Centers for Disease Control and Prevention Nutrition, Physical Activity, and Obesity: Data, Trends and Maps. Adults who have obesity. Accessed 19 February 2024, https://nccd.cdc.gov/dnpao_dtm/rdPage.aspx?rdReport=DNPAO_DTM.ExploreByTopic&islClass=OWS&islTopic=&go=GO & Centers for Disease Control and Prevention United States Cancer Statistics: Data Visualizations. Female breast. Accessed 19 February 2024, https://gis.cdc.gov/Cancer/USCS/#/Trends/
[5] Larger-volume Silicone Breast Implants Are Safe in Breast Reconstruction: Data From the ATHENA Multicenter, Prospective Study of 400 Patients Patrick B. Garvey, MD; Alan Larsen, MD; Roman Skoracki, MD; Risal Djohan, MD; Mark R. Migliori, MD; Marissa M. Tenenbaum, MD; Jeffrey D. Friedman, MD; Joseph M. Serletti, MD; Alanna M. Rebecca, MD; William Kane, MD
[6] Panchal H, Matros E. Current Trends in Postmastectomy Breast Reconstruction. Plast Reconstr Surg. 2017;140(5S Advances in Breast Reconstruction):7S-13S
[7] Malekpour M, Malekpour F, Wang HT. Breast reconstruction: Review of current autologous and implant-based techniques and long-term oncologic outcome. World J Clin Cases. 2023 Apr 6;11(10):2201-2212. doi: 10.12998/wjcc.v11.i10.2201. PMID: 37122510; PMCID: PMC10131028.

exciting step for the breast cancer community as we pave the way for inclusivity along the full continuum of breast cancer care."

This approval is supported by 3-year findings from the prospective, multicenter, ongoing 10-year ATHENA study, which demonstrated the safety and effectiveness of MemoryGel™ Enhance larger-volume silicone breast implants after three years, in women who underwent post mastectomy and implant-based breast reconstruction.

Mentor's FDA approval of MemoryGel™ Enhance Breast Implants marks a significant advancement in breast reconstruction, exemplifying the company's commitment to stand behind all women with a more comprehensive and inclusive portfolio enabling surgeons to offer more personalized options for their patients and expand the population they serve by addressing a broader and more diverse range of women's needs.

WARNING:

- Breast implants are not considered lifetime devices. The longer people have them, the greater the chances are that they will develop complications, some of which will require more surgery.
- Breast implants have been associated with the development of a cancer of the immune system called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). This cancer occurs more commonly in patients with textured breast implants than smooth implants, although rates are not well defined. Some patients have died from BIA-ALCL.
- Patients receiving breast implants have reported a variety of systemic symptoms such as joint pain, muscle aches, confusion, chronic fatigue, autoimmune diseases and others. Individual patient risk for developing these symptoms has not been well established. Some patients report complete resolution of symptoms when the implants are removed without replacement.

The sale and distribution of Mentor Breast Implant Devices are restricted to users and/or user facilities that provide information to patients about the risks and benefits of the device prior to its use in the form and manner specified in approved labeling to be provided by Mentor Worldwide LLC.

Important information: Prior to use, refer to the instructions for use supplied with this device for indications, contraindications, side effects, warnings and precautions.

Caution: US law restricts this device to sale by or on the order of a physician.

Important Safety Information:

The MENTOR™ Collection of Breast Implants are indicated for breast reconstruction. Breast implant surgery should not be performed in women:
· With active infection anywhere in their body
· With existing cancer or pre-cancer of their breasts who have not received adequate treatment for those conditions
· Who are currently pregnant or nursing
Safety and effectiveness have not been established in patients with autoimmune diseases (for example lupus and scleroderma), a weakened immune system, conditions that interfere with wound healing and blood clotting, or reduced blood supply to breast tissue. Patients with a diagnosis of depression, or other mental health disorders, should wait until resolution or stabilization of these conditions prior to undergoing breast implantation surgery.

Breast implants are not lifetime devices and breast implantation may not be a one-time surgery. There are risks associated with breast implant surgery. The chance of developing complications increases over time. You may need additional unplanned surgeries on your breasts because of complications or unacceptable cosmetic outcomes. Many of the changes to your breast following implantation are irreversible (cannot be undone) and breast implants may affect your ability to breastfeed, either by reducing or eliminating milk production. The most common complications for breast reconstruction with MENTOR™ MemoryGel™ Breast Implants include any reoperation, implant removal with or without replacement, and capsular contracture. The health consequences of a ruptured silicone gel breast implant have not been fully established. MRI screenings are recommended three years after initial implant surgery and then every two years after to detect silent rupture. Breast implants are also associated with the risk of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), an uncommon type of lymphoma. An individual's risk of developing BIA-ALCL with MENTOR™ Breast Implants is low based on the incidence of worldwide cases.

Detailed information regarding the risks and benefits associated with MENTOR™ Breast Implants is provided in several educational brochures. For MemoryGel™ Implants: Important Information for Reconstruction Patients about MENTOR™ MemoryGel™ Breast Implants

These brochures are available from your surgeon or visit www.mentorwwllc.com. It is important that you read and understand these brochures when considering MENTOR™ Breast Implants.

About Mentor Worldwide LLC
Mentor Worldwide LLC, part of Johnson & Johnson MedTech, is a leading supplier of breast implants in the global aesthetic market. For more than 40 years, Mentor has developed, manufactured, and marketed innovative, science-based products for surgical medical procedures that allow breast surgery patients to improve their quality of life. The company is focused on two strategic areas: breast reconstruction and breast augmentation. Mentor products are available in 118 countries, and more than 9 million women worldwide have MENTOR™ Breast Implants. For more information about Mentor, visit www.mentorwwllc.com.

About Johnson & Johnson
At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity. Learn more about our MedTech sector's global scale and deep expertise in cardiovascular, orthopaedics, surgery and vision solutions at https://thenext.jnjmedtech.com. Follow us at @JNJMedTech and on LinkedIn. Mentor Worldwide LLC is part of Johnson & Johnson MedTech.

Cautions Concerning Forward-Looking Statements
This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding MENTOR™ MemoryGel™ Enhance Breast Implants. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Mentor Worldwide LLC, Medical Device Business Services, Inc., and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: uncertainty of commercial success; challenges to patents; competition, including technological advances, new products and patents attained by competitors; manufacturing difficulties and delays; product efficacy or safety concerns resulting in product recalls or regulatory action; changes to applicable laws and regulations, including global health care reforms; changes in behavior and spending patterns of purchasers of health care products and services; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of Mentor Worldwide LLC, Medical Device Business Services, Inc., nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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