

FOR IMMEDIATE RELEASE

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U.S. FDA Approves New MENTOR® MemoryGel BOOST™ Breast Implant

Implant provides the natural feel patients desire with increased form stability to shape the breast

Recent study shows patients and surgeons both preferred the MENTOR® MemoryGel BOOST™ Breast Implant as feeling more like a natural breast versus another leading brand

Irvine, Calif., (January 13, 2021) – Mentor Worldwide LLC, the number one global brand in breast aesthetics, and part of the Johnson & Johnson Medical Devices Companies** today announced that the U.S. Food and Drug Administration (FDA) approved the MENTOR® MemoryGel BOOST™ Breast Implant for breast augmentation in women at least 22 years old, and for women of all ages undergoing breast reconstruction. This product will be commercially available for surgeons in the United States in early 2022.

Nearly 400,000 women undergo breast implant surgeries every year in the U.S.*, and selecting an implant is a very personal decision and critical part of the journey. Each patient's preferences and goals are unique, and that means providing surgeons with a wide range of sizes and profiles to enhance their ability to individualize a patient's results. While there are many options currently available, surgeons cite the need for an implant with increased form stability to help shape the breast, without sacrificing the soft, natural feel that patients desire.

“Our commitment to innovation is driven, first and foremost, by the needs of our customers and patients, and providing them with the highest quality products to achieve their desired outcome,” said Lori Tierney, Worldwide President, Mentor Worldwide LLC. “With this pivotal addition to our MemoryGel® portfolio, we are thrilled to provide a meaningful range of options to meet surgeon objectives and patient preferences, beyond what is currently available in the breast aesthetics market.”

According to a recent survey, patients and surgeons both preferred the MENTOR® MemoryGel BOOST™ Breast Implant as feeling more like a natural breast versus another leading brand.†

* ASPS 2016 Plastic Surgery Statistics: <https://www.plasticsurgery.org/news/plastic-surgery-statistics>

† Head-to-head in- person tabletop product comparison (MENTOR® MemoryGel BOOST™ Breast Implants vs. Allergan Inspira Cohesive) with 297 respondents.

MemoryGel BOOST™ brings together Mentor’s proprietary highly cohesive gel, an innovative implant shell design and precision fill ratio, the combination of which provides an implant with increased form stability to shape the breast.

“Through science-based design and innovation, we are able to offer both increased form stability and a natural feel in the same product,” said Krasimira Hristov, Director of R&D, Mentor Worldwide LLC. “The MemoryGel BOOST™ Breast Implant is truly a unique innovation that satisfies an unmet need and expands the MemoryGel® product line.”

For more than 30 years, Mentor has been trusted and respected by surgeons and their patients, with over seven million women worldwide choosing Mentor® Breast Implants for their breast augmentation and breast reconstruction journeys. Mentor also offers the industry’s best and most comprehensive enhanced warranty, and all MENTOR® Breast Implants are backed by the Mentor Promise Protection Plan, which provides free and automatic coverage for patients who qualify.†

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.

About Mentor Worldwide LLC

Mentor Worldwide LLC, part of Johnson & Johnson Medical Devices Companies, is a leading supplier of breast implants in the global aesthetic market. The company develops, manufactures, and markets innovative, science-based products for surgical and non-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 is the only manufacturer whose silicone breast implants are made in the U.S.A.

For more information about Mentor, visit: www.mentorwwllc.com

About Johnson & Johnson Medical Devices Companies

At Johnson & Johnson Medical Devices Companies, we are helping people live their best lives. Building on more than a century of expertise, we tackle pressing healthcare challenges, and take bold steps that lead to new standards of care while improving people’s healthcare

† Mentor Promise Protection Plan provides the most financial assistance for the broadest range of complications.

experiences. In surgery, orthopaedics, vision and interventional solutions, we are helping to save lives and paving the way to a healthier future for everyone, everywhere. For more information, visit www.jnjmedicaldevices.com.

**The Johnson & Johnson Medical Devices Companies comprise the surgery, orthopaedics, vision and interventional solutions businesses within Johnson & Johnson's Medical Devices segment.

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 BOOST™ Breast Implant. 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, any of the other Johnson & Johnson Medical Devices Companies 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 January 3, 2021, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent 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. Neither Mentor Worldwide LLC / the Johnson & Johnson Medical Devices Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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

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 Safety Information:

The MENTOR® Collection of Breast Implants are indicated for breast augmentation - in women who are at least 22 years old for MENTOR® MemoryGel® Breast Implants or MENTOR® MemoryShape® Breast Implants, and at least 18 years old for MENTOR® Saline Breast Implants, and 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 breast 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. There are risks associated with breast implant surgery. You should be aware that breast implants are not lifetime devices and breast implantation may not be a one-time surgery. 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. Breast implants are not lifetime devices and breast implantation may not be a one-time surgery. The most common complications for breast augmentation with MemoryGel® Implants include any reoperation, capsular contracture, nipple sensation changes, and implant removal with or without replacement. The most common complications with MemoryShape® Implants for breast augmentation include reoperation for any reason, implant removal with or without replacement, and ptosis. A lower risk of complication is rupture. 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 Augmentation Patients about MENTOR® MemoryGel® Breast Implants. For MemoryShape® Implants: Patient Educational Brochure – Breast Augmentation with MENTOR® MemoryShape® Breast Implants and Quick Facts about Breast Augmentation & Reconstruction with MENTOR® MemoryShape® Breast Implants. For MENTOR® Saline-filled Implants: Saline-Filled Breast Implants: Making an Informed Decision. 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. 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.

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