

## **MENTOR INTRODUCES NEW TISSUE EXPANDER WITH SMOOTH SURFACE FOR PATIENTS UNDERGOING BREAST RECONSTRUCTION**

*The Company Receives 510(k) Clearance for CPX4 Smooth Breast Tissue Expander*

CHICAGO, IL – Sept. 26, 2018 -- Johnson & Johnson Medical Devices Companies\* today announced that MENTOR Worldwide LLC, a global leader in breast aesthetics, has introduced a tissue expander with a smooth surface to its line of CPX4 Breast Tissue Expanders in the United States. The product will be on show at the 2018 American Society of Plastic Surgeons (ASPS) annual meeting taking place in Chicago from Friday, September 28, 2018 onwards.

Tissue expanders are used for breast reconstruction after mastectomy to expand the breast pocket to accommodate a breast implant. The new CPX4 device has a smooth surface designed to help ease insertion and removal[1], and now includes additional suture tabs[2] to enhance fixation while reducing the risk of rotation for subcutaneous and submuscular breast reconstruction.

“I am looking forward to using the CPX4 Smooth expander in prepectoral and submuscular breast reconstruction,” said Mark Migliori, MD,\*\* a board certified plastic surgeon in Edina, Minnesota. “I believe it will offer ease of use during placement and removal with the added protection of the proprietary BufferZone, along with providing a natural breast shape and a soft comfortable expander for the patient.”

About 1 in 8 women in the United States will develop invasive breast cancer over the course of their lifetime. In 2018, this means an estimated 266,120 new cases of invasive breast cancer are expected to be diagnosed.[3]

### *ATHENA Clinical Trial Update*

MENTOR also has plans to expand its portfolio of breast implants to broaden access for women who currently have few sizing options. In 2015, the company received U.S. Food and Drug Administration (FDA) Investigational Device Exemption (IDE) approval for its ATHENA[4] clinical trial, which is evaluating the safety and effectiveness of larger sizes of MENTOR MemoryGel® Breast

Implants for breast reconstruction patients with larger chest widths, larger breast sizes, higher BMI or greater amounts of removed mastectomy tissue.

The ATHENA study is the largest pre-approval, manufacturer-sponsored breast implant clinical trial registered with the FDA to date, in terms of number of reconstruction patients enrolled. As of September 2018, more than 330 women across 32 investigational sites have been enrolled. MENTOR anticipates completing enrollment of the full 400 patients by the end of 2018.

### **About MENTOR Worldwide LLC**

MENTOR Worldwide LLC 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](http://www.mentorwwllc.com)

### **About the Johnson & Johnson Medical Devices Companies**

The Johnson & Johnson Medical Devices Companies' purpose is to reach more patients and restore more lives. Having advanced patient care for more than a century, these companies represent an unparalleled breadth of products, services, programs and research and development capabilities in surgical technology, orthopedics, interventional and specialty solutions with an offering directed at delivering clinical and economic value to health care systems worldwide.

### **Cautions Concerning Forward-Looking Statements**

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding the CPX4 Smooth Breast Tissue Expander. 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 December 31, 2017, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," in the company's most recently filed Quarterly Report on Form 10-Q and in the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at [www.sec.gov](http://www.sec.gov), [www.jnj.com](http://www.jnj.com) or on request from Johnson & Johnson. Neither the Janssen Pharmaceutical Companies 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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\*The Johnson & Johnson Medical Devices Companies comprise the surgery, orthopaedics, and interventional solutions businesses within Johnson & Johnson's Medical Devices segment.

\*\* Mark Migliori, MD, is a paid consultant to MENTOR Worldwide LLC.

[1] Internal R&D document #100617163

[2] CPX4 Smooth has additional tabs compared to CPX4 Siltex

[3] [https://www.breastcancer.org/symptoms/understand\\_bc/statistics](https://www.breastcancer.org/symptoms/understand_bc/statistics) (Accessed September 4th 2018)

[4] <https://clinicaltrials.gov/ct2/show/NCT02724371> (Accessed September 4th 2018)