

Urgent Customer Communication

Reminder of Magnet in the MENTOR® Breast Tissue Expanders (CPX4) (All Product Codes and Lots)

Date

Dear Valued Customers,

The Mentor team has learned that some surgeons are not aware of the presence of a magnet in the dome of MENTOR® Breast Tissue Expanders (CPX4). Mentor includes contraindications in the Instructions for Use related to other medical devices that could be affected by the magnetic field of these tissue expanders.

It's important for surgeons to be aware of the magnets when considering these devices for use in patients who have or may receive implanted devices that could be affected by a magnetic field. There can be a range of consequences that may result from the off-label concomitant use of the expander with a magnetically sensitive implantable device. If implanted, the interaction with the expander magnet could result in failure or malfunctions of the concomitant device and potentially result in a serious harm depending on the function and patient condition effected by the other implantable medical device.

There is no product deficiency in MENTOR® Breast Tissue Expanders and there are no new risks identified. Surgeons should continue to use the CPX4 Tissue Expanders as directed.

Mentor takes your patients' safety seriously. Mentor's ongoing updates to its labeling, include implementing changes to patient implant cards and updating the patient information data sheets, which will further highlight information about the presence of magnets in the device.

Next Steps:

1. Please maintain awareness of this letter and pass it on to anyone in your facility that needs to be informed.
2. Please complete, sign, and **return the Business Reply Form.**

If you have additional questions about this information, please contact Johnson & Johnson Medical Information Request. (www.jjmedir.com).

Again, we thank you for your continued support of MENTOR® Breast Tissue Expander products. We value you as a customer and appreciate the opportunity to assist you. If you have any questions, please contact your local representative.

Sincerely,



Gabriela Cabral
Director, Quality and Compliance

Urgent Customer Communication

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Date

Dear Distributor,

The Mentor team has learned that some surgeons are not aware of the presence of a magnet in the dome of MENTOR® Breast Tissue Expanders (CPX4). Mentor includes contraindications in the Instructions for Use related to other medical devices that could be affected by the magnetic field of these tissue expanders.

It's important for surgeons to be aware of the magnets when considering these devices for use in patients who have or may receive implanted devices that could be affected by a magnetic field. There can be a range of consequences that may result from the off-label concomitant use of the expander with a magnetically sensitive implantable device. If implanted, the interaction with the expander magnet could result in failure or malfunctions of the concomitant device and potentially result in a serious harm depending on the function and patient condition effected by the other implantable medical device.

Our records indicate that you may have ordered or received product subject to this customer notification. **PLEASE DISTRIBUTE THIS INFORMATION TO ALL COUNTRIES THAT SELL CPX4 BREAST TISSUE EXPANDERS.**

There is no product deficiency in MENTOR® Breast Tissue Expanders and there are no new risks identified. Surgeons should continue to use the CPX4 Expanders as directed.

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Gabriela Cabral
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