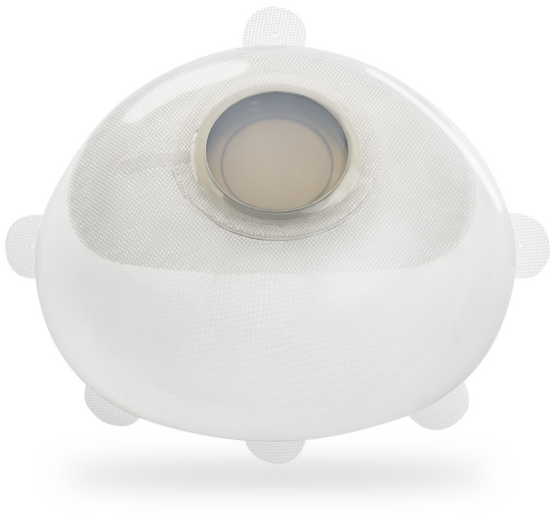
EMEA Deflation Protection Program:

MENTOR® CPX™4 Breast Tissue Expander

Mentor® is dedicated to advancing plastic and reconstruction surgery, which begins by listening to you, our customers, and responding to the ever-changing needs of healthcare providers. We believe innovation should be driven by what patients need and should be backed by science, high design and thorough testing. As of 1st June 2021 Mentor® offers the **Mentor® Deflation Protection Program** which is available for CPX™4 Breast Tissue Expander in cases of deflation with this product in a patient.



MENTOR® CPX™4 Breast Tissue Expanders can be utilized for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision and tissue defect procedures MENTOR® CPX™4 Expander is designed to preferentially expand the lower portion of the breast, allowing surgeons to continually add saline solution via an injection dome.[1]

The BufferZone ™ Self-Sealing Patch surrounds the integral injection dome to protect at least 50% more of the expander surface area (than the injection dome alone) from accidental needle puncture to minimize and/or prevent device leakage and the need for additional surgery.[2]

To take advantage of this free program, you need to report the deflation to your Mentor® sales representative or distributor, which will require the return of the expander in question for product investigation. For those situations meeting the program guidelines, Mentor® will provide a replacement expander or a credit equal to the purchase value of the expander in question.

MENTOR® EXPANDER DEFLATION PROTECTION PROGRAM CONDITIONS

- The Program is applicable to MENTOR® CPX™4 Breast Tissue Expander implanted in a patient.
- Replacement of product in question may be handled with physical product (replacement product) or by a credit to the customer's account equal to the purchase value of the product in question at the sole discretion of Mentor®.
- Only the surgeon can claim the coverage under the Program. Patients should be required to contact their surgeons in all cases.
- Mentor® reserves the right to not grant replacement product if deflation is deemed to be due to customer misuse or negligence.
- **Find more information about the EMEA Deflation Protection Program on** mentorwwllc.eu

IMPORTANT SAFTEY INFORMATION:

MENTOR® CONTOUR PROFILE™ Breast Tissue Expanders are used for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision, and tissue defect procedures. The expander is intended for temporary subcutaneous or submuscular implantation; they should be used within a time frame determined by the physician to achieve the clinically desired degree of tissue expansion. MENTOR® CONTOUR PROFILE™ Tissue Expanders include magnetic injection domes, which contain a rare earth permanent magnet, and are NOT MRI compatible. The device could be moved by the MRI causing pain or displacement, potentially resulting in a revision surgery. Do not use the MENTOR® CONTOUR PROFILE™ Tissue Expander in patients where an MRI may be needed. DO NOT use the MENTOR® CONTOUR PROFILE™ Tissue Expander in patients that have a previously implanted device such as pacemakers, drug infusion devices, artificial sensing devices, etc. that could be affected by a magnetic field. MENTOR® has not tested the in vivo effects of radiation therapy with MENTOR® CONTOUR PROFILE™ Expander devices and cannot warrant the safety of such use. The incidence of extrusion of the expander has been shown to increase when the expander has been placed in injured areas: scarred, heavily irradiated or burned tissue, crushed bone areas, where severe surgical reduction of the area has previously been performed and where steroids are used in the surgical pocket. Your patient needs to be informed and understand the risks and benefits of breast implants and tissue expanders, and she should be provided with an opportunity to consult with you prior to deciding on surgery. For detailed indications, contraindications, warnings and precautions associated with the use of all MENTOR® Implantable Devices, please refer to the Product Insert Data Sheet provided with each product or review the Important Safety Information provided at www.mentorwwllc.eu.

REFERENCES:

1. David Overaker & Stephan Rothenbuguer. 3D Imaging of comfort, CPX2/3, and Allergan style 133 Tissue Expanders for Shape and Strain Measurement , AST- 2012-0176. Page 2, 11 (par.2).
2. RATIO OF TE BLADDER & DOME TO SHELL, 2012

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