

# Comfort Cushion™

## Radiolucent Cushion for use in Mammography Exams

### Instructions for Use (IFU)



#### Description

Comfort Cushion™ is a single-use, disposable, and radiolucent cushion that is placed between the patient's breast and the breast support surface during mammography. The purpose of this product is to allow the patient to feel more comfortable and less cold during the mammographic examination. Comfort Cushion will not interfere with image quality; and allows for artifact-free images in both Full Field Digital Mammography (FFDM) and Digital Breast Tomosynthesis (DPT). Patient radiation dose and image quality are equivalent to that when using no Comfort Cushion. <sup>1</sup>

#### Models / Specifications

Model	Cushion Size	Fits Receptor Plate Size	Mammography Systems
MCC001	Large, 29cm x 30cm	24cm x 30cm	FFDM, DPT
MCC002	Medium, 25cm x 29cm	18cm x 24cm	FFDM, DPT

#### Indication for Use

Comfort Cushion is a mammography breast cushion that the technician will adhere to the top surface of the receptor plate prior to a patient's mammography exam.

#### Intended Use

Comfort is intended to be used for the comfort of the patient during a mammography exam.

- The use of the product is limited to the indications and instructions for use provided in this IFU.
- The product is not intended to support, supplement, and/or augment the performance of the mammography equipment.
- Any off-label use of the product is not recommended.

#### Adverse Effects / Contraindications

None known.

#### Precautions / Warnings

- Single use only. DO NOT reuse.
- Non-sterile device.
- For direct contact with intact skin only.
- Discard cushion after use per your facility's bio-hazardous material disposal policy and protocols.
- DO NOT use if cushion appears damaged or has been contaminated with dust or other particles.

#### Hypo-Allergenic

Comfort Cushion materials are considered hypoallergenic and is not expected to cause skin irritation. However, due to differences in allergen sensitivities or even heightened skin sensitivities in various persons, skin irritation may occur.

- Biocompatibility tested per ISO 10993 for Skin Irritation and Skin Sensitization.
- Not made with Natural Rubber Latex

#### Material Specification

- Medical Grade Foam with Acrylic Adhesive and Paper Liner with Silicone Release for easy removal from product.
- Low-Tack Adhesive for easy removal of cushion without leaving adhesive residue on surfaces.

#### Shelf Life

Best when used within 2-years from the manufacturing date on the product label.

#### Storage Conditions

Recommended storage conditions to maintain device quality:

- Storage Temperature 16°C-55°C
- Relative Humidity 15%-60%

#### Medical Device Label Symbols Glossary

For information on the medical device symbols used on the product labeling, reference web address:

[https://www.pdchealthcare.com/symbols\\_glossary](https://www.pdchealthcare.com/symbols_glossary)

<sup>1</sup> Technical analysis of Comfort Cushion for radiolucency, artifact-free qualities, and radiation dose when used with analog and digital mammography systems was performed by a Breast Imaging Consultant.

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#### Set Up Guidance

- Top surface of the mammography receptor plate should be cleaned prior to application.
- Practice adhering Comfort Cushion to the receptor plate to become familiar with application prior to use with patients.

#### Instructions for use:

1. Remove paper liner to expose the adhesive side of the Comfort Cushion.
2. Place Comfort Cushion adhesive side down starting at the far edge of the white line on the breast support surface.
3. Smooth cushion against the breast support surface with the palm of hand; removing all air bubbles or wrinkles as these may show on the mammography image.
4. Press Comfort Cushion firmly at all corners to secure the cushion to the breast support surface.
5. To remove Comfort Cushion from the breast support surface, pull up from one corner of the cushion.
6. Discard cushion after each patient use according to your facility's bio-hazardous material disposal policy and protocol.
7. DO NOT reuse cushion with other patients. Cushion is disposable and only intended for a single-use with one patient.