

1.1 MammoPad Breast Cushion Application Instructions

MammoPad® breast cushions are single-use disposable medical products. They are radiolucent and latex free. Use a fresh pad for each patient. Follow this procedure to make sure the pad is properly installed.

1. Open the bag containing the MammoPad breast cushions, remove one pad, and reseal the bag.



Note

Pads must be stored in a sealed plastic bag to prevent contamination that could affect image quality. Store out of direct sunlight and seal bag when not in use.

2. Peel the paper backing from the pad and discard it.
3. Apply the adhesive side to the image platform in accordance with the instructions in the following note for your type of system. Do not apply the pad over painted decals.



Note

Selenia® and most other FFDM systems - Orient the rounded corner at the lower left side of the detector. Smooth the pad on from the back to the front of the image platform.

Dimensions® and GE systems - Orient the rounded corner at the lower right side of the detector. Smooth the pad on from the front to the back of the image platform.

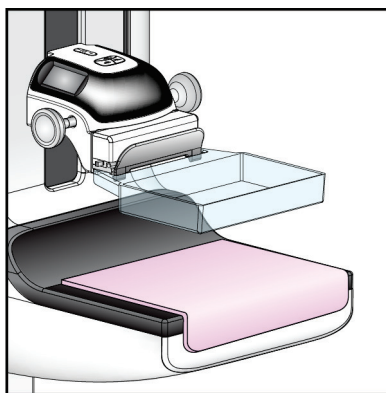


Figure 1: MammoPad Installed on an Image Platform

4. Follow your normal positioning routine for all screening views.
5. When the exam is complete, remove the pad from the image platform and discard it.



Note

If the pad was exposed to blood or body fluids, follow the biohazard materials disposal procedure for your facility.

For assistance with the MammoPad product, contact Product Support at 1-877-371-4372.

Authorized EU Representative:



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1.2 Symbols

Symbol	Description	Standard
	Prescription use only	FDA 21 CFR 801.109
	Manufacturer	ISO 15223-1:2021, Reference 5.1.1
	Authorized Representative in the European Community	ISO 15223-1:2021, Reference 5.1.2
	Use-by Date	ISO 15223-1:2021, Reference 5.1.4
	Batch code	ISO 15223-1:2021, Reference 5.1.5
	Catalog number	ISO 15223-1:2021, Reference 5.1.6
	Quantity	Hologic
	Non-sterile	ISO 15223-1:2021, Reference 5.2.7
	Do not re-use	ISO 15223-1:2021, Reference 5.4.2
 www.hologic.com/package-inserts	Access electronic Instructions for Use	ISO 15223-1:2021, Reference 5.4.3 Hologic
	CE Mark with Notified Body reference number	MDR Regulation (EU) 2017/745

Symbol	Description	Standard
	Does not contain natural rubber latex	N/A
	Recyclable symbol	Unicode, Reference U+267C

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