



MammoGRI™ - Clinical Benefits and Opportunities to Validate a Potentially New Standard of Care in Mammography's

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MammoGRIP™ Company Background

Our Mission

To improve the quality of mammography through the use of MammoGRIP™, a patented medical device that will aid in earlier detection of breast cancer.



Our Position

MammoGRIP™ is the only breast positioning aide for Radiologists and Radiologic technologists that will allow them to obtain more breast tissue into the FOV (Field of View) and provide for a better mammogram and earlier detection of breast cancer.

*Mammo***GRI**TM
Saving Lives One Image At A Time

MammoGRIP™ Company Background (cont.)

MammoGRIP™ is a company dedicated to improving the efficiency, comfort and results in breast imaging procedures.

The company was founded by Nancy DeRobertis, a radiology technologist, who has 20+ years of working in breast imaging and is a registered expert with the ASRT. Her passion for excellence in women's imaging led her to develop an improved way to perform mammograms.

These improved processes and ideas have culminated in the creation of an innovative patented and trademarked method and product called MammoGRIP™ [Patent PCT/US2012/050585].



MammoGRIP Company Background (cont.)

MammoGRIP™ has been used on over 3,000 women receiving their annual mammography and has shown significant benefits compared to their previous mammograms.

In our observational studies, we achieved:

- readings of up to **30% more** breast tissue,
- with **80% of the cases showing enhanced** image quality and
- reduced radiation to the patient.

This led to identifying over a dozen **new cancers** which had previously been undetected.



MammoGRIP Company Background: Technique

MammoGRIP™ is applied onto a technologists hands before positioning a patient for each view of the mammogram. This, along with specific positioning techniques, (to maximize results) allows more breast tissue to be pulled into the image without retraction of the breast during compression.

With more breast tissue in the field of view, we are able to get better compression with no added discomfort to the patient, (since less pressure is being applied directly to the front of the breast, which is most sensitive) thus improving image quality and reducing radiation.

MammoGRIP™ also allows for less manipulation of the breast, the ability to consistently get closer to the chest wall, maximizing the amount of breast tissue to be read, improving the chances of earliest diagnosis of breast cancer and making a quicker more informative exam.

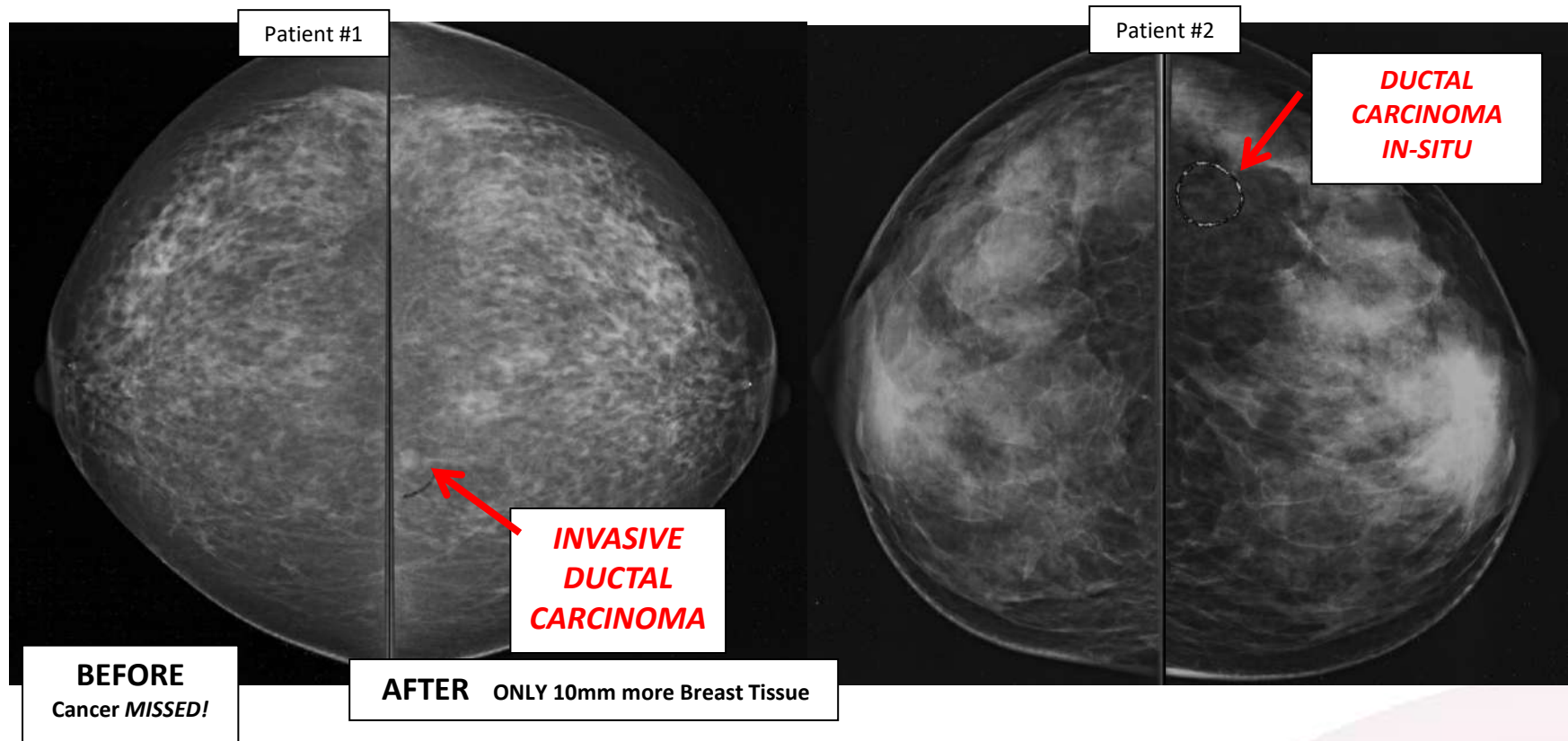


MammoGRIP Description and Benefits

- MammoGRIP is a patented method that uses a topical foam product allowing a technologists to get a better grip of the breast for a better and more productive mammography
- We have filed a pre-submission 510K and received feedback from the FDA on a filing protocol and approach (detailed later in this presentation)
- MammoGRIP increases the amount of breast tissue in FOV up to 30%
- Increases tissue closest to chest wall
- Reduces radiation
- Can be applied to all breast imaging procedures
- No modification of existing equipment necessary
- Improves image quality with the ability to increase compression with no added discomfort to patient
- Reduced length of breast compression time
- Low Cost



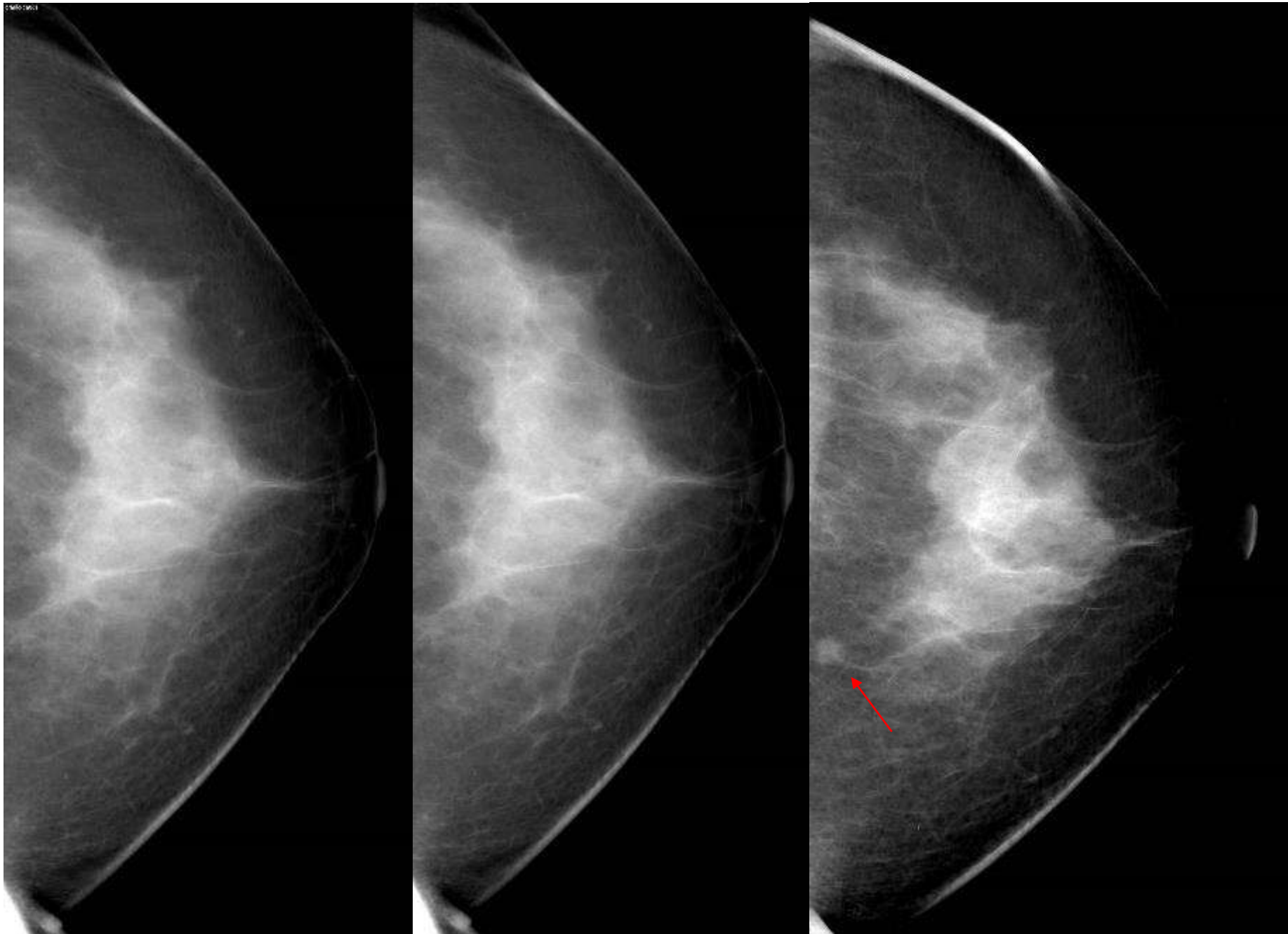
MammoGRIP- Before and After Images



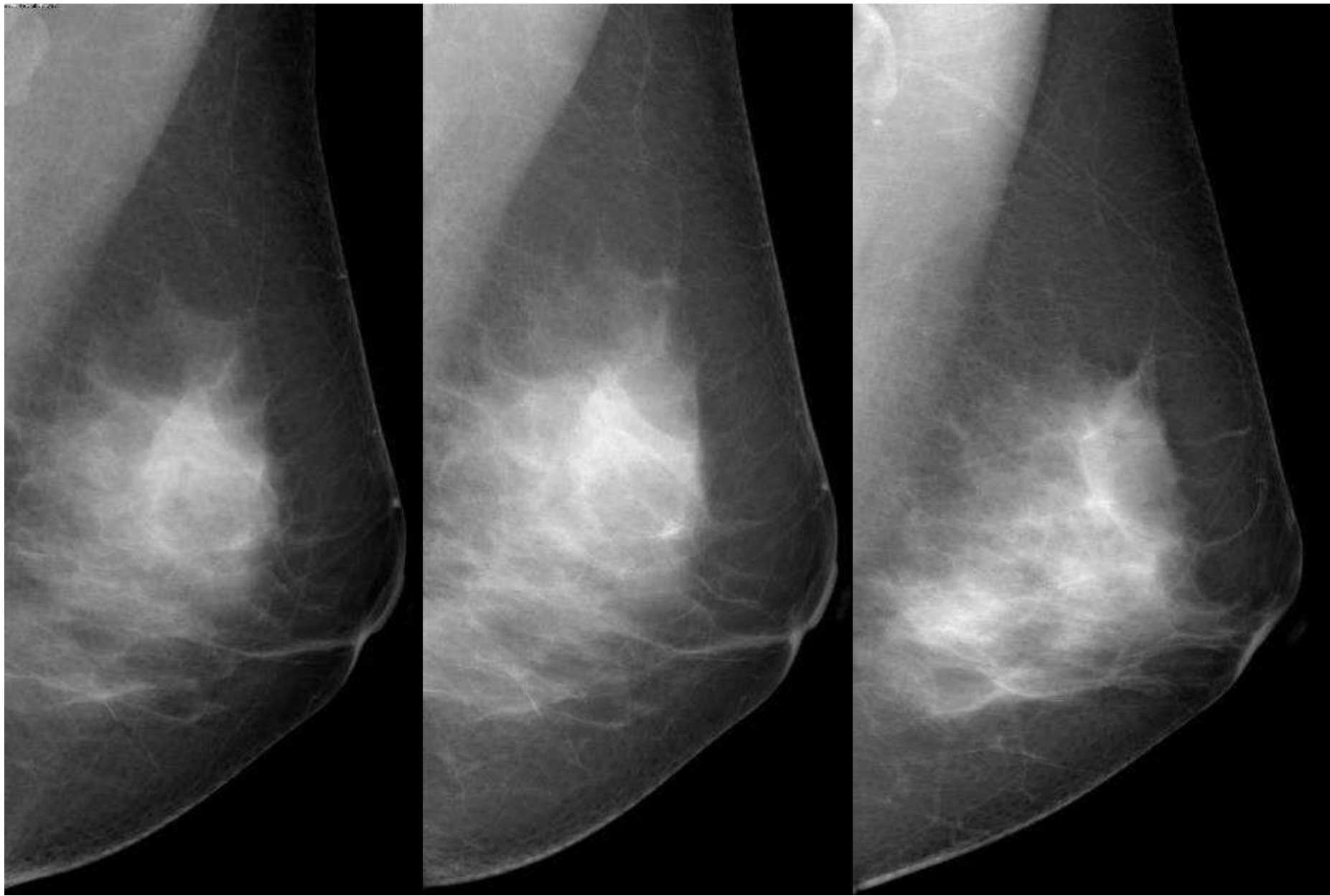
- OBTAINED UP TO 3X MORE BREAST TISSUE THAN AVERAGE SIZE OF BREAST CANCERS, 5X MORE THAN THE SMALLEST VISABLE CANCERS with LESS MANIPULATION OF THE BREAST allowing a quicker, more informative exam with less room time and a less anxious patient
- ALLOWS MORE COMPRESSION (with no added discomfort) therefore IMPROVING IMAGE QUALITY & REDUCING RADIATION EXPOSURE
- ASSISTS IN EARLIER DETECTION
- INCREASES PRODUCTIVITY DECREASES LIABILITY

These images were based on our observational studies and were submitted to FDA in the510K Pre-submission filing

MammoGRIP™
Saving Lives One Image At A Time



Same patient 3 Years in a Row by same technologist, acquiring 10 mm more breast tissue and a new mass! Never



While there's a definite improvement from priors, the mass is still not visible, proving the mass is not only posterior but more superior & medial, since this is where the MLO view is most likely missed.

<http://pubs.rsna.org/doi/full/10.1148/radiol.2481060339>

FDA Feedback- From the 510K Pre-submission Filing



FDA Feedback and Predicate Device Details

FDA Feedback: We submitted a 510K Pre-submission document that detailed 3 claims and details on a predicate device called Mammopad.

MammoGRIP™ is substantially equivalent to MammoPad®

MammoPad is a mammography accessory intended to improve comfort and positioning during mammography. While MammoPad and MammoGRIP™ differ in form – MammoPad is a foam sheet while MammoGRIP™ is a solution – the intended use of the two products are the same: to improve positioning during mammography.

The MammoPad Indications for Use are:

MammoPad is intended to provide padding for patient comfort and aid in positioning during radiologic visualization of the breast using x-ray orscintillation technology.



FDA 510K Description and Indications for Use

MammoGRIP™ Device Description

- * MammoGRIP™ is non-medicated skin adhesive solution used when conducting mammograms to enable the technologist to obtain more breast tissue onto an image.
- * MammoGRIP™ is 0.1% benzalkonium chloride foam that is applied onto the technologist's hands before positioning a patient for each view of the mammogram. This, along with the required specific positioning techniques employed during mammography, allows more breast tissue to be pulled into the image without retraction of the breast during compression. MammoGRIP™ maximizes the amount of breast tissue during imaging, while minimizing manipulation of the breast.

Indications for Use

- * MammoGRIP™ is intended to aid in positioning and increase the amount of breast tissue visualized during radiologic examination of the breast, with less manipulation of the breast.

Directions for Use

- * 1. Apply MammoGRIP™ to the palm of one hand.
- * 2. Rub hands together.
- * 3. Rub the product over all surfaces of hands and fingers until hands are nearly dry.
- * 4. Take desired view and confirm per standard institutional procedure.
- * 5. Re-apply MammoGRIP™ for each view.





Thank You

