

Bella Blankets®

Protective Coverlets for Mammography

Better Positioning... Better Imaging... Bella Blankets.



Now get more breast tissue with Bella Blankets. Every millimeter counts™.

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We are able to acquire more breast tissue and get further back on the cc views and get the IMF much easier now with Bella Blankets.

~ Manager of Imaging Services, Vandalia, IL



Challenges in Breast Imaging

A Mammographer's Reality

A mammographer's goal is to capture the best clinical images while providing the patient with a positive experience. It is considered one of the most challenging professions within medical imaging.

Technologists have many factors to think through when positioning the patient – breast type, anatomy, physical limitations or ailments, as well as the patient's emotional state.

They also are required to comply with quality control and regulatory guidelines, earn continuing education credits, and be knowledgeable about new technology updates to the imaging equipment.

In addition, technologists' movements can take a toll on the body due to poor posture when positioning or repetitive motion that may cause injury.

Mammographers are dedicated to their craft and take pride in their role to help detect early stages of breast cancer.

However, no matter how dedicated the mammographer, many imaging centers struggle with inconsistencies of positioning techniques and suboptimal images.

Bella Blankets is the radiologists' preference and they will notice the difference in tissue acquisition if we do not use Bella Blankets.

~ Radiology Manager, Sterling, CO



The Facts – Positioning is the #1 Failure of ACR Requirements

In 2015, the American College of Radiology (ACR) found that of all the clinical images which were deficient on the first attempt at accreditation, 92% were deficient in positioning. In facilities that were already ACR-accredited, 79% of all unit accreditation failures were also due to positioning.¹

Although approximately 15% of patients are difficult to position and have limitations that would make the perfect image almost impossible to achieve;² proper positioning improvements are a focus on all patient images.

Proper positioning is inclusive of proper visualization of nipple, position of pectoralis major, pectoral–nipple distance, inframammary fold, and adequate coverage of all breast quadrants.³

In a study focused on positioning, it was found that skin and fat folds were present on approximately 15% of MLO images.⁴

The pectoralis muscle is visualized on only 30-40% of patients in the CC view.⁵



MQSA EQUIP Initiative

MQSA's Enhancing Quality Using the Inspection Program⁶ (EQUIP) initiative prepares facilities to address image quality on a continual basis and include the lead interpreting physician and/or interpreting physician as the person ultimately responsible for the image quality. The goal is to ensure the interpreting physician is continually inspecting image quality and putting corrective actions in place for poor image quality. As a result, many facilities are looking for solutions to help make improvements.

We have found it easier to locate images to submit for ACR using Bella Blankets. You have to have the perfect set of images for ACR, but you should work to have perfect images on all patients possible.

~ Mammography Supervisor, Orangeburg, SC

The Solution

Bella Blankets® protective coverlets for mammography can help capture more breast tissue. Cancers that occur at the chest wall may not be visualized if breast tissue is missing from the image. Every millimeter counts™ when looking for clusters of micro-calcifications.

In a clinical study,⁷ 58 patient images using Bella Blankets were compared to prior year images (where no protective coverlet had been used) to determine if more breast tissue was acquired with Bella Blankets. The results presented significant improvements that fall under the ACR critical positioning criteria:

- 77% of patients had increased tissue acquisition
- When measuring the PNL in both views, the average increase was 0.41 cm
- 48% of patients showed improved visualization of pectoralis muscle
- Visualization of retroglandular tissue went from 86% PY (prior year) to 96%
 CY (current year)
- Visualization of IMF as "open" went from 67% PY to 87% CY

We trialed Bella Blankets on ten of our patients and every one liked them. That's when the radiologist and I realized their value. Patients like them and we were getting more breast tissue on every study.

~ Mammmography Technologist, Saint Louis, MO



Bella Blankets aligns with proper positioning initiatives to support EQUIP guidelines.

Bella Blankets protective coverlets have been used on over 6 million mammograms. Based on the study results above, 4.2 million mammograms may have seen increased tissue acquisition when using Bella Blankets.

80% of Bella Blankets protective coverlets customers surveyed say they get more breast tissue on their images compared to prior images where another product or nothing was used on the receptor plate.⁸

Bella Blankets helps position the breast and capture more breast tissue.

Don't leave the cancer in the room.

 Susan Sprinkle-Vincent, Mammography Educator

Bella Blankets' texture keeps breast tissue from sliding back, and is easy for the technologist to get her hand out from under the breast without losing breast tissue. We documented more tissue Year to Year in both CC and MLO views during trial period.

~ Medical Imaging Manager, Nashville, TN

Bella Blankets® Protective Coverlets Advancement in Technology

- **Vertical Channel Technology™** only from Beekley Medical® allows air to push out and release upon application, reducing air bubbles.
- **Easy-lift Pik-UP™ tab** supports ergonomic initiatives with easy removal. Bella Blankets will not leave any residue on the receptor plate.
- The use of Bella Blankets protective coverlets during a mammogram is essentially the **same average glandular dose as no coverlet.** This is important since the breast is one of the more sensitive areas on the body, and therefore more sensitive to radiation and cancer risk. 10
- Bella Blankets are one time use. Reduces exposure to previous patient's skin and to disinfecting cleaner used between appointments.
- Bella Blankets' FDA 510(k) clearance applies to all mammography imaging equipment.

Our patients are aware that we are using Bella Blankets and other facilities don't and this helps our patients from going elsewhere. The cost is easily justified when you consider the clinical and financial benefits to our organization.

~ Mammography Supervisor, Torrington, CT



Vertical Channel Technology™



Easy-lift Pik-UP™ tab

Patient Types and Positioning

What Patient Types do Bella Blankets® Help the Most?

Every patient deserves the most breast tissue possible on their image. Bella Blankets protective coverlets may help the technologist with factors such as challenging breast types, anatomy, emotional state, and procedures.

Breast Type:

- Secures perspiring/oily skin
- Prevents folds on a thin, fatty-replaced (pancake) breast
- · Holds small/dense breasts in place
- Grasps anterior breast tissue during implant displacement views
- · Keeps large breasts "up and out" in the MLO view ensuring an open IMF
- Grips breast tissue on male patients

Anatomy:

- Pectus excavatum
- Kyphotic
- Prior breast surgeries

Emotional State:

- Nervous
- Scared

Procedures:

- Needle localizations
- · Post stereotactic clip placement views
- Galactograms
- Blood absorption on procedures



Positioning from lateral side for photographic purposes only.

I've used Bella Blankets on a patient that had a lumpectomy and I was able to stabilize her breast a little better and get more breast tissue as a result.

~ Mammography Technologist, Cass Lake, MN

A very small breasted patient was imaged, and without the Bella Blankets I am certain we would have not gotten as much tissue. Having Bella Blankets helps grab and hold the breast.

~ Radiology Director, Windsor, VT

In the summertime, larger breasted patients are often sweaty. Before using Bella Blankets, as the compression spreads out the breast, it would ooze out at the chest wall. Bella Blankets does not allow the patient to slide out of compression, yet allows the technologist to lift and reposition the patient.

~ Lead Mammography Technologist, Oshkosh, WI

Getting Started

We're here to help

Call us! Beekley Medical® can be available for an in-service visit to help you implement Bella Blankets® protective coverlets.

Before using Bella Blankets protective coverlets, it is recommended to watch the instructional video at beekley.com.

Once you get started, the most impactful difference you may see is increased tissue acquisition when compared to prior year images. With the new EQUIP guidelines, radiologists are embracing initiatives to improve image quality.

Even the Most Experienced Technologist Can Utilize Bella Blankets To Help:

- Immobilize breast
- Slide hands out easily before compression
- · Keep breast in place
- Reduce motion
- Reduce skin folds
- Open IMF
- Prevent skin tears
- Protect open infections
- · Protect sensitive skin



MLO view

How to introduce Bella Blankets to your patients:

Patients appreciate when they receive an extra level of care, whether it is listening to their concerns, getting to know them personally, a touch on the shoulder, or offering Bella Blankets protective coverlets for their mammogram. To help you get started, here is what we suggest to open the dialogue with your patient:

"Mrs. Jones, I am going to use Bella Blankets on your mammogram today and it is only used for you. Although we clean the equipment between patients, this gives you an extra level of protection. It also removes the chill from your mammogram, making it warmer" (encourage her to touch Bella Blankets, most patients comment on the pretty design).

"And that is not all this pretty coverlet does. It helps keep your breast in place after I position you, helping to get more breast tissue on your image for the doctor to see."

MBella Blankets helps get more breast tissue because of its ability to hold the breast in place, prevents it from sliding out, or breast dropping due to the smooth surface of the detector.

~ Women's Imaging Manager, Tucson, AZ

A patient came in for her first mammogram and was very scared. I explained the procedure to her, pointed out Bella Blankets, and told her that it is not going to be cold. After that she seemed to soften her stance and was relaxed enough that I was able to get the images I needed.

 Mammography Supervisor, Corpus Christi, TX

We have a lot of patients who are heavier and have sores in the crease of their breasts. Bella Blankets really help those patients from tearing even more.

~ Mammography Technologist, Crookston, MN

Marketing Support

Beekley Medical® also provides support materials to aid in successful implementation:

- Welcome Kit various tools using the Bella Blankets design to help decorate the reception area when you start using Bella Blankets
- Patient Posters educate patients on the importance of Bella Blankets
- Patient Satisfaction Surveys receive feedback from your patients on Bella Blankets
- Website Templates advertise that you use Bella Blankets protective coverlets
- Newspaper Ad Templates announce that your center is now using Bella Blankets or promote breast cancer awareness initiatives

Use Bella Blankets® to help promote your breast center:

- Bring Bella Blankets protective coverlets to outreach educational programs
- Host a breast health "ladies night" at your imaging center and include Bella Blankets as a discussion point when you share what is unique to your breast center
- Use the Bella Blankets support materials

Take advantage of Beekley Medical's inventory management tools:

 Our team can work with procurement to set up ordering information in your system. Automatic shipment options, no backorders, same or next day shipping, no restocking fees, and open communication are all part of our commitment to you.

Sella Slankets

Productive Counties for Mannrography

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Hella Blankets allow the patient to relax so the technologist is able to obtain more chest wall tissue.

~ Lead Mammographer, Spring Hill, TN

When a patient is comfortable and you don't have to do a lot of repeats, they continue to come to you because they trust you to take care of them.

~ Mammography Technologist, Edna, TX

Instructions for Use



1. Remove Bella Blankets® from liner.



2a. Place adhesive side down and smooth by starting at the front of receptor plate while holding the top.



2b. Or apply by starting at the back of receptor plate then pull taut to the front.



Use the palm of your hand to smooth and adhere center to top of the receptor plate.



From the center, smooth outward to adhere. Remove air bubbles or wrinkles for best image quality.



 After exam, remove by pulling the Pik-UP™ tab from the corner and discard.

Visit beekley.com for a video demonstration

Practice adhering Bella Blankets a few times to become familiar with application prior to use with patients.

¹ "Poor Positioning Responsible For Most Clinical Image Deficiencies, Failures", April 11, 2016, http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityScorecard/ucm495378.htm, accessed on May 4, 2017.

Louise C. Miller, RT RM. "What Every Mammography Technologist Would Like Their Radiologist To Know About: Image Quality" (Part 2 of a 3 part series), The Member Newsletter of the Society of Breast Imaging, September 2014, https://www.mammographyeducation.com/wp-content/uploads/2014/09/SBI-ARTICLE_MILLER-.pdf

³ Manju BP, Teotia R, Narang M, and Krishna H. "Breast Positioning during Mammography: Mistakes to be Avoided", *Breast Cancer: Basic and Clinical Research*, 2014:8, pp. 119-124 https://journals.sagepub.com/doi/10.4137/BCBCR.517617

Bassett LW, Hirbawi IA, DeBruhl, N, Hayes MK. "Mammographic positioning: evaluation from the view box." Radiology. 1993;188(3): pp 803-806. http://pubs.rsna.org/doi/10.1148/radiology.188.3.8351351

⁵ Advanced Health Education Center. "All in a Days Work" presentation, February 9, 2015, http://www.aheconline.com/mktg/course_materials/Mammo_All_In_A_Days_Work/3-MM_All_in_a_Days_Work.pdf, accessed on May 4, 2017.

^{6 &}quot;EQUIP: Enhancing Quality Using the Inspection Program", October 21, 2016, https://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityScorecard/ucm526238.htm, accessed on May 4, 2017

⁷ Wagner, S. and A. Merkulov, MD. 2013. "Comparison Study: Impact of Thin Protective Coverlets on Positioning and Tissue Acquisition in Breast Imaging."

⁸ Bella Blankets Clinical Advantages Survey 2017, Beekley Medical®

⁹ Gerald J. Randall, M.S. (DABR) (Certified and Licensed Medical Physicist), "Mammo Protective Coverlets Testing", March 3 2017.

¹⁰ New York State Department of Health, Radiation and Health, 10/2007. https://www.health.ny.gov/publications/4402.pdf. Accessed on May 10, 2017.

Available in two sizes:



REF 310

50 / Box

Size: 22.9cm x 27.9cm Intended for use on 18cm x 24cm receptor plate

REF **311**

QTY **50 / Box**

Size: 29.2cm x 33.0cm

Intended for use on 24cm x 30cm receptor plate

Every millimeter counts™

Place your order today to start acquiring more breast tissue and better patient experience.

> Call 1.800.233.5539 | Fax 1.800.735.1234 Visit beekley.com | Email info@beekley.com

Customers outside the U.S. - Contact your local distributor for pricing and product availability. To locate a distributor call +1.860.583.4700 or email international@beekley.com

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WARNINGS AND PRECAUTIONS:

- Non-Sterile
- Single Patient Use Only; Do Not Reuse
- Smooth out any air bubbles or wrinkles that may occur as they may show on the image

Bella Blankets are hypoallergenic and are not made with natural rubber latex.









If any serious incident occurs in relation to this device, report it to Beekley Medical and to the competent authority of the Member State in which the user and/or patient is established.



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