

# *Bella Blankets*®

Protective Coverlets for Mammography

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



FAQs

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## FDA Clearance

### Is Bella Blankets approved by the FDA?

*Bella Blankets is cleared by the FDA, 510(k) Number K073262.*

### Is Bella Blankets approved for use with tomosynthesis equipment?

*The FDA clearance 510(k) Number K073262 for Bella Blankets protective coverlets applies to all mammography imaging equipment, including tomosynthesis.*

## About Bella Blankets

### Have you tested Bella Blankets on all tomosynthesis equipment?

*Bella Blankets have been tested extensively on Hologic®, GE®, and Siemens® equipment – both 2D and DBT (digital breast tomosynthesis).*



### Will Bella Blankets increase radiation dose for the patient?

*The use of Bella Blankets during a mammogram is essentially the **same average glandular dose as no coverlet.**<sup>1</sup>*

### How does Bella Blankets remove the chill?

*One of the first complaints from patients about mammograms is that the equipment is cold. By placing Bella Blankets on the receptor plate, it acts as a barrier between the equipment and the patient.*

### **How does Bella Blankets capture more breast tissue?**

*Bella Blankets has a gripping property that helps hold the breast in place as compression is applied. For instance, small dense breasts have a tendency to “squeeze out the back” during that last bit of compression; Bella Blankets holds the breast in place to give the mammographer the greatest chance to image the most tissue. The non-woven textured material also mitigates the presence of perspiration, which can improve tissue acquisition.*

### **Does Bella Blankets help to acquire more pectoral muscle?**

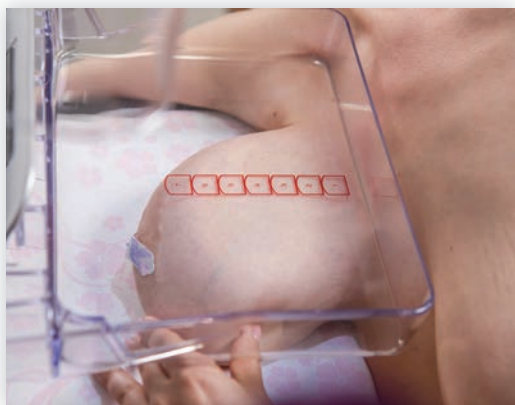
*Capturing more pectoral muscle is the result of getting as far back to the chest wall as possible. Bella Blankets are thin by design to make that happen. The gripping properties of the material help the mammographer to keep the breast in place while sliding their hand out as they apply the last bit of compression.*

### **Are there clinical studies proving that Bella Blankets help capture more breast tissue?**

*The Impact of Thin Protective Coverlets on Positioning and Tissue Acquisition in Breast Imaging Study,<sup>2</sup> shows increased tissue acquisition in 77% of the patients from previous year mammograms where no receptor plate cover had been used.*

### **How does Bella Blankets help to keep the inframammary fold open?**

*A closed IMF often relates to the breast not being “up and out”. The problem that occurs when positioning a larger breast in the MLO is that gravity will take over. As soon as the mammographer’s hand is removed to make other adjustments, the breast slides down and the IMF closes. The gripping properties of Bella Blankets keep the breast up and out and the mammographer will not lose the open IMF.*



## Application of Bella Blankets

### How do I apply Bella Blankets?

We encourage you to watch an instructional video at [beekley.com](http://beekley.com). Also, every box comes with an *Instructions For Use* document that you can refer to. Be sure to practice a few times before using with a patient. If you have further questions, contact 1.800.233.5539 or [info@beekley.com](mailto:info@beekley.com).



Vertical Channel Technology™



Easy-lift Pik-UP™ tab

### Will Bella Blankets interfere with the image?

When properly applied, Bella Blankets will not interfere with the image. Bella Blankets is thin by design to be compatible with the latest technology. Bella Blankets now features **Vertical Channel Technology** that allows air to push out and release upon application reducing air bubbles. Extensive image testing has been done to insure that the Bella Blankets design and the **Vertical Channel Technology** will not show on the image.

### What if I get an air bubble or wrinkle?

Bella Blankets **Vertical Channel Technology™** allows air to push out and be released upon application to reduce the risk of air bubbles. Practice adhering Bella Blankets a few times to become familiar with application prior to use with patients. Both air bubbles and wrinkles can show on an image and should be smoothed out before imaging.



### Will it leave a residue when we remove Bella Blankets from the receptor plate?

Bella Blankets has an easy-lift Pik-UP™ tab for easy removal and no residue will remain on the receptor plate once it is removed.

## Types of Patients That Benefit from Bella Blankets

### Do I use Bella Blankets on every patient?

We recommend that you use Bella Blankets on every patient. The main benefit to the patient is Bella Blankets ability to get more breast tissue. If you get more tissue on the image, you are going to find more cancers. [The Impact of Thin Protective Coverlets on Positioning and Tissue Acquisition in Breast Imaging<sup>2</sup>](#) study shows that using Bella Blankets also helped to improve three of the ACR's critical positioning criteria, resulting in a better mammogram for the patient. Bella Blankets can also help comfort a patient who presents with an existing inframammary lesion as well as decrease the possibility of an IMF skin tear in patients with thin fragile skin.

### We cannot get approval to use Bella Blankets on every patient just yet; whom do you suggest we use it on?

We suggest letting your mammographers use Bella Blankets at their discretion with the patients they find most difficult to position. That may include patients with large breasts, small / dense breasts, thin skin / fatty replaced breasts, breast implants, patients with physical limitations who are hard to position, or patients that are very nervous. Bella Blankets are also helpful for procedures.

### **How does Bella Blankets help the nervous patient?**

*Bella Blankets' pretty design starts the conversation when the patient enters the room. Telling the patient that it is just for her and that it will make her mammogram warmer can help relax the patient before her mammogram begins. That little conversation acts as an icebreaker and it is much easier to get a relaxed patient into proper mammographic positioning.*



### **How does Bella Blankets help with a large breasted patient?**

*The problem that occurs when positioning a larger breast in the MLO view is that gravity will take over. As soon as you remove your hand to make other adjustments, the breast slides down and the IMF closes. The gripping properties of Bella Blankets help keep the breast up and out, and the mammographer will not lose the open IMF.*

### **How does Bella Blankets help with small, dense breasts?**

*Small dense breasts have a tendency to "squeeze out the back" during that last bit of compression. Bella Blankets will hold the breast in place to give the mammographer the best chance to image the most tissue. The material also mitigates the presence of perspiration which can improve tissue acquisition on these difficult patients.*

### **How does Bella Blankets help on a thin fatty replaced breast (pancake breast) and skin folds?**

*This breast type can be challenging as the patient can be predisposed to inferior skin folds that will image as pseudo-architectural distortion. Once the mammographer reduces the skin fold with her fingers, the grip of Bella Blankets prevents the fold from recurring.*

### **How does Bella Blankets help when positioning men?**

*Men are difficult to position because they do not have a lot of breast tissue. They become even more difficult if they have chest hair and/or perspiration, making it slippery. Bella Blankets helps to keep breast tissue in place by gripping the breast and preventing slippage.*

### **How does Bella Blankets help with breast implants?**

*During implant displaced views it can be very difficult to pull the anterior breast tissue onto the receptor plate, especially with large or very new implants. The gripping properties of Bella Blankets help the mammographer to keep that anterior breast tissue on the plate as the last bit of compression is applied.*

### **How does Bella Blankets help to avoid skin tears?**

*Patients have a tendency to back up as soon as compression is released. The breast often sticks to the bare receptor plate and this can result in an inframammary tear. With Bella Blankets, once compression is released, the patient's breast will slide off the receptor reducing the chance of a skin tear.*

### **How does Bella Blankets help protect a patient who has a skin tear at the time of their mammogram?**

*Skin tears can be painful. Bella Blankets act as a protective barrier that prevents the open wound from sticking to the bare receptor, helping to avoid the skin tear from tearing more.*

## **Bella Blankets for Interventional Procedures**

### **How does Bella Blankets help during post-stereotactic clip placement views?**

*After a core biopsy, the patient may be bleeding which can worsen once compression is applied for the clip placement views. Bella Blankets will mitigate the slippery effects of blood and perspiration making positioning easier. Bella Blankets can also help protect against any blood or bodily fluids from getting on the receptor plate.*



## How does Bella Blankets help with needle localizations?

*During a needle localization, positioning can be difficult due to the presence of betadine, lidocaine, and blood. Bella Blankets helps to mitigate the slippery effects of these fluids, making positioning easier.*

## Does Bella Blankets help absorb blood or bodily fluids?

*Bella Blankets helps to absorb blood/bodily fluid. In fact, based on testing<sup>3</sup> – Bella Blankets absorbs blood quicker than other products that cover the receptor plate.*

## How Bella Blankets Help Technologists

### Does Bella Blankets align with EQUIP<sup>4</sup> initiatives?

*The new initiative is a positive movement towards better imaging and will demand a focus on better positioning. Each technologist's images will be reviewed, and if the images fail, corrective action must be set in place by the lead interpreting physician. Bella Blankets can help with positioning and tissue acquisition by helping to keep the breast in place and prevents breast from slipping out under compression.*



*In the study entitled The Impact of Thin Protective Coverlets on Positioning and Tissue Acquisition in Breast Imaging,<sup>2</sup> it was shown that using Bella Blankets increased tissue acquisition in 77% of patients as well as improve three of the ACR's critical positioning criteria. Significant improvements were seen in the acquisition of more pectoralis muscle, visualization of retroglandular fat and in seeing the inframammary fold as open compared to imaging on a bare receptor plate. By using Bella Blankets on every patient, images may also be easier to find for ACR submission.*

**This is just one more step to our day, why should we use Bella Blankets?**

*Bella Blankets may actually save time by helping to relax a nervous patient and as a result, positioning is easier. Bella Blankets should be applied on the receptor plate with the patient in the room as the technologist explains what to expect during the mammogram.*

**I understand how Bella Blankets can help the unexperienced technologist, but I have been positioning for many years – how can Bella Blankets help me?**

*Many experienced technologists use Bella Blankets because they find it easier to remove their hands out from under the breast and it acts as a “second set of hands” to hold the breast in place. It can also help to relax the patient making her body become more mobile and easier to position. All of these elements may lessen the tension on your repetitive motions as a technologist.*

**How can Bella Blankets grip the breast, yet at the same time, help the technologist slip her hands out easily?**

*As the technologist is positioning the breast and removing skin folds, her hand can move easily. Once she starts to apply compression, the non-woven material has a slight texture that helps to grip the breast in place so that the breast will not slide or move. The amount of grip is proportional to the amount of compression.*



*Positioning from lateral side for photographic purposes only.*

## Marketing / Patient Satisfaction

### **We were using another product and just switched to Bella Blankets, how do I tell my patients?**

*Most patients do not remember exactly what you used the year before, just that you used something. For patients that do remember, explain that you are using a product designed for the latest technology and that it will help get them the best clinical image by possibly getting more breast tissue.*

### **Does Bella Blankets increase patient satisfaction?**

*We have heard that patients tell their friends about Bella Blankets and some do mention Bella Blankets on their Press Ganey® surveys.*

### **How can we promote Bella Blankets at our imaging center?**

*We have many tools available to help you promote Bella Blankets as an added level of care and to differentiate your imaging center from the competition.*

## Trialing of Bella Blankets

### **How do I apply Bella Blankets to the receptor plate?**

*Before applying Bella Blankets, watch the [instructional video](#) on Beekley.com and read the [Instructions for Use](#) document. Practice adhering Bella Blankets a few times to become familiar with application prior to use with your patients. If you have further questions, contact us at 1.800.233.5539 or [info@beekley.com](mailto:info@beekley.com).*

### **How do I set up a reproducible, easy trial of Bella Blankets for my team?**

*Speak with your Beekley Medical® Account Manager at 1.800.233.5539 on how to customize a trial for your imaging center. We have different suggestions depending on the outcomes you are trying to achieve. We can help you train your staff via webinar, conference call, or possibly an in-person visit if applicable. Samples are also available to trial Bella Blankets at no cost to you.*

## **What should I monitor during a trial evaluation?**

*The most impactful trial is one that measures year-to-year images for tissue acquisition. For a simpler trial, you can survey technologists for ease of use and your patients on how Bella Blankets positively impacted their mammogram. These surveys are available upon request from Beekley Medical.*

## **How should I approach our radiologist about setting up a trial?**

*Radiologists are interested in trialing Bella Blankets for many reasons – many are looking for ways to improve image quality, help their mammographers with an aid for easier positioning to set themselves apart from the competition, and /or to impact the patient experience. We are available to call the Radiologist directly to discuss how Bella Blankets may increase tissue acquisition.*

## **Does Bella Blankets have to be approved by the Value Analysis Team (VAT) committee?**

*Depending on your organization, Bella Blankets may have to be approved by the VAT committee. Contact us and we can help prepare you with informational kits as handouts at your meeting. We are available to you and want to make this easy for you.*

## **How can Beekley Medical help me to get Bella Blankets into our imaging center?**

*Your job is hard enough... let us do the work! We are available to speak to procurement, directors, the VAT committee, and your mammography team. We can partner with you on conference calls, present a webinar, or possibly conduct an on-site visit to demonstrate Bella Blankets and to help you with tissue acquisition measurements.*

## **Ordering / Budgeting for Bella Blankets**

### **How do we purchase Bella Blankets?**

*You can place your orders by phone 1.800.233.5539 or +1.860.583.4700, fax 1.800.735.1234, or email [orders@beekley.com](mailto:orders@beekley.com). You can also order through GHX, EDI, or Beekley.com. If you do not have an account with us, set up is simple.*

### **How do we justify the investment in Bella Blankets?**

*Bella Blankets is just a few dollars and the outcome is far greater than the investment. Using Bella Blankets can help capture more breast tissue to help find potential cancers. Bella Blankets can help obtain the best image possible leading to the best clinical outcomes.*

### **Does the patient pay for Bella Blankets?**

*It is your choice, however we do not know of any customers that charge the patient directly.*

### **Can we set up automatic shipments?**

*You never have to worry about running out of Bella Blankets. We can set up automatic shipments with our Pre-Arranged Shipping Service (PASS) program. You decide how many boxes you want shipped and how often. Your automatic shipment can be changed at any time or canceled. Contact us to set up PASS for your next shipment.*

### **Can we cancel our automatic PASS shipments?**

*The automatic shipment can be stopped at any time with no penalty. You can also place your shipments on hold and start up again at any time. This service makes ordering from Beekley Medical® as easy and simple as possible.*

## **General Questions**

### **How is Bella Blankets disposed of?**

*Bella Blankets may be tossed into the wastebasket after use with a patient. However, if bodily fluid is detected, follow your hazardous waste procedure.*

### **We have limited storage; does Bella Blankets take up a lot of room?**

*There are 50 Bella Blankets per box. If you were to stack four boxes, it would be the height of a shoe box.*

### **Are Bella Blankets sanitary?**

*By placing Bella Blankets on the receptor plate, it acts like a sanitary barrier between the equipment and the patient. In fact, Bella Blankets reduce exposure to previous patient skin and disinfecting cleaner used between appointments. Each Bella Blankets is for individual use and should be disposed of after each patient.*

### **How long has Bella Blankets been available in mammography?**

*Bella Blankets have been on the market since 2008 and impacted over 6,000,000 mammograms.*

### **What are Bella Blankets made of?**

*Bella Blankets are made of a non-woven, textured fabric-like material.*

### **Is there a Bella Blankets design for men?**

*At this time we do not have a Bella Blankets design for men.*

### **Has anyone ever had an allergic reaction to Bella Blankets?**

*Bella Blankets are hypoallergenic and are not made with natural rubber latex. However, there is always the chance for an allergic reaction depending on patient's skin sensitivities.*

### **Do I still clean the equipment between patients?**

*Although Bella Blankets acts as a sanitary barrier, the equipment should still be cleaned between patients.*

### **We have tried these before, what makes the improved Bella Blankets different?**

*Bella Blankets **Vertical Channel Technology™** allows air to push out and be released upon application to reduce risks of air bubbles. A **Pik-Up™** tab helps for easy removal.*


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<sup>1</sup> Gerald J. Randall, M.S. (DABR) (Certified and Licensed Medical Physicist), "Mammo Protective Coverlets Testing", March 3 2017.

<sup>2</sup> Wagner, S. and A Merkulov, MD. 2013. "Comparison Study: Impact of Thin Protective Coverlets on Positioning and Tissue Acquisition in Breast Imaging."



<sup>3</sup> Bella Blankets Liquid Retention Performance Test. September 2016.

<sup>4</sup> "EQUIP: Enhancing Quality Using the Inspection Program", October 21, 2016, <<https://www.fda.gov/Radiation-Emitting-Products/MammographyQualityStandardsActandProgram/FacilityScorecard/ucm526238.htm>>, accessed on May 4, 2017

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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.



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