



AMERICAN SOCIETY OF  
PLASTIC SURGEONS®

# Informed Consent

## “Off-Label” Use of Galatea Surgical Mesh

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## **INSTRUCTIONS**

This document is about informed consent. It will tell you about the off-label use of **Galatea Surgical Mesh** for breast reconstruction and other breast surgeries.

It is important that you read this whole document carefully. Signing the consent agreement means that you agree to the surgery that you have talked about with your plastic surgeon.

## **GENERAL INFORMATION**

The Food and Drug Administration (FDA) requires medical devices in the United States to be safe and work well. Each device’s label and advertising say that the device may be used in ways that are “approved” by the FDA.

An “off-label” use of a device means that it is not listed as an “approved” use on the label. The FDA does not approve of this. However, doctors may use a device in a way that is not listed on the “approved” label. They can do so based on everything they know and have worked with. They can also do so if the use is reasonable and helpful.

## **GALATEA SURGICAL MESH FOR BREAST RECONSTRUCTION OR OTHER BREAST SURGERIES**

Your surgeon may recommend use of Galatea Surgical Mesh, namely Galaflex, during your breast surgery with or without breast implants. Galatea scaffolds are bioabsorbable, monofilament and constructed of poly-4-hydroxybutyate (P4HB™) - an advanced, biologically derived polymer. This scaffold adds support to the healing tissues. P4HB is FDA approved for soft reinforcement in plastic and reconstructive surgery procedures.

The FDA has not approved **Galatea Surgical Mesh** for breast reconstruction or other breast surgeries. That said, **Galatea Surgical Mesh** have FDA approval for certain uses, like soft tissue coverage. That allows surgeons to use **Galatea Surgical Mesh** in an “off-label” way. For instance, in breast reconstruction or another breast surgery.



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**CONSENT FOR SURGERY/PROCEDURE**

1. I understand that using **Galatea Surgical Mesh** in breast surgeries is “off-label” and not approved. **Galatea Surgical Mesh** have FDA approval for certain uses. These surgical mesh products are cleared for the repair and reinforcement of soft tissue where weakness exists.
2. The FDA is aware of increased use of surgical mesh products in breast surgery. However, **the safety and effectiveness of surgical mesh in breast surgery, including in augmentation or reconstruction, has not been determined by the FDA.**
3. Becton, Dickinson and Company (BD), Galatea’s manufacturer has updated their labeling for these products, including updated warnings and precautions. The FDA is issuing a letter to ensure that health care providers are aware that surgical mesh products, including BD’s mesh products, have not been determined by the FDA to be safe and effective for use in breast surgery.
4. I understand how this treatment has been explained. I understand the benefits, risks, and disadvantages.
5. Other treatments, prescriptions, and therapies have been explained. I understand their benefits, risks, and disadvantages.
6. I agree that the risks and complications of off-label use of **Galatea Surgical Mesh** have been explained to me. They may include:
  - Fluid buildup under the skin (seroma).
  - Breast infection
  - Slow healing or opening of the cut (wound dehiscence)
  - Bleeding (hematoma)
  - A breast implant or tissue expander may become exposed. It would need to be removed
  - The skin on the breast could die (skin necrosis)
  - Capsular contraction could happen again
  - The implant could move around in the breast
  - **Galatea Surgical Mesh** may not become part of my own tissue. It would need to be removed
7. I have told the doctor about all my allergies.
8. I have told the doctor about all the medications I am currently taking, like my prescriptions, over-the-counter drugs, herbal supplements, aspirin, and any non-prescription drug or alcohol use.
9. My doctor has told me whether I should stop taking any medications after getting the ADMs with breast reconstruction and other breast surgeries.
10. I am aware and accept that there are no guarantees for the results of the **Galatea Surgical Mesh** in my breast reconstruction and other breast surgeries.
11. The doctor has answered all my questions about **Galatea Surgical Mesh** in breast reconstruction and other breast surgeries.

With my signature, I certify that I have read and understood this document and that I agree to it.

I permit Dr. Siamak Agha to prescribe the use of **Galatea Surgical Mesh** for breast surgery with or without breast implants, which is an “off-label” and non-approved use of **Galatea Surgical Mesh**.

I CONSENT TO THE PROCEDURE OR TREATMENT AND THE ITEMS LISTED ABOVE (1-9).  
I UNDERSTAND THE EXPLANATION AND HAVE NO MORE QUESTIONS.

\_\_\_\_\_  
Patient or Person Authorized to Sign for Patient

\_\_\_\_\_  
Date/Time

\_\_\_\_\_  
Witness

\_\_\_\_\_  
Date/Time

I certify that I have explained the off-label use of Galatea Surgical Mesh, the benefits, risks, and complications, and other options to the patient or the patient’s legal representative. I have encouraged the patient/legal representative (circle one) to ask questions and have answered all their questions.

\_\_\_\_\_  
Physician Signature/Date/Time