Informed Consent

"Off-Label" Use of Acellular Dermal Matrices (ADMs)

INSTRUCTIONS

This document is about informed consent. It will tell you about the off-label use of acellular dermal matrices (ADMs) 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.

ADMs FOR BREAST RECONSTRUCTION OR OTHER BREAST SURGERIES

Your surgeon needs to put an implant in the right position and keep it there. Your surgeon may use biological materials called ADMs for this. Often, these materials are made from human or pig skin. These materials are processed and do not have living cells. Your own cells will grow into the ADM. The tissue will become like your own. These products may release fluid. They may need drains for a few days or weeks.

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

 _____ **Patient Initials**

CONSENT FOR SURGERY/PROCEDURE

1. I understand that using ADMs in breast reconstruction and other breast surgeries is "off-label" and not approved. ADMs have FDA approval for certain uses.
2. I understand how this treatment has been explained. I understand the benefits, risks, and disadvantages.
3. Other treatments, prescriptions, and therapies have been explained. I understand their benefits, risks, and disadvantages.
4. I agree that the risks and complications of off-label use of ADMs have been explained to me. They may include:
   - Fluid buildup under the skin (seroma). It may require drains for a long time
   - 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
   - ADM may not become part of my own tissue. It would need to be removed
5. I have told the doctor about all my allergies.
6. 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.
7. My doctor has told me whether I should stop taking any medications after getting the ADMs with breast reconstruction and other breast surgeries.
8. I am aware and accept that there are no guarantees for the results of the ADMs in my breast reconstruction and other breast surgeries.
9. The doctor has answered all my questions about ADMs 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. Steve Sample to prescribe the use of ADMs for _____, which is an "off-label" and non-approved use of ADMs.

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

 _____ **Patient Initials**

I certify that I have explained the off-label use of ADMs, 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

 _____ **Patient Initials**