



AMERICAN SOCIETY OF
PLASTIC SURGEONS®

Informed Consent

“Off-Label” Use of Acellular Dermal Matrices (ADMs)

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**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.

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