

Are you or a loved one considering Breast Reconstruction?

stryker

Thanks to advancements in technology, there are now devices that can help surgeons make better decisions during surgery. The ability to make better decisions intraoperatively may result in improved surgical outcomes.^{1,2}

The information provided in this document should not be construed as medical advice or as a substitute of speaking to your surgeon. Speak to your surgeon in order to determine if the use of SPY Imaging is appropriate for your situation.

All surgery presents risk and breast reconstruction is a major surgery. Risks specific to breast reconstruction include bleeding, blood clots, infection, healing problems, tissue death (necrosis), loss of breast sensation, problems with implants, tissue expanders or other devices used, uneven breasts or the need for revisionary surgery.



Immediate/Direct-to-Implant Breast Reconstruction

Permanent breast implants are placed at the same time of mastectomy. Expansion process is avoided.

Advantages:

- Eliminates the need for a second operation since reconstruction is performed at the same time as the mastectomy.
- Research has shown that patients who have immediate breast reconstruction after mastectomy experience less anxiety, depression and have improved psychosocial well-being compared to those who undergo delayed reconstruction.³

Disadvantages:

- Immediate reconstruction requires a longer and more complex surgery.⁴
- Not all patients are candidates for direct to implant reconstruction.⁵
- More difficult procedure that many surgeons may not be comfortable performing.⁵
- Surgical complications can arise during or after surgery such as infection, tissue death (necrosis), healing problems, bleeding or blood clots.



Staged Implant based Breast Reconstruction

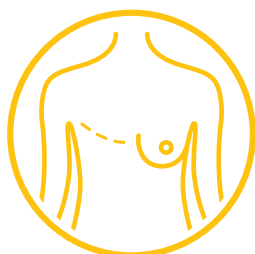
This option rebuilds the breast in several stages and often requires tissue expansion through the use of devices known as tissue expanders. Tissue expanders are devices that are temporarily implanted to expand the breast skin and are eventually replaced by permanent breast implants.

Advantages:

- Provides time to treat patient with radiation or other cancer treatments.
- After a mastectomy, a tissue expander can be used during a staged breast reconstruction to slowly stretch breast skin and/or chest wall muscles to make room for a permanent implant.

Disadvantages:

- This type of reconstruction requires multiple surgeries and tissue expanders may temporarily cause pain.
- Tissue expansion may require a few months of frequent doctors' appointments to complete the inflation.
- Surgical complications can arise during or after surgery such as infection, tissue death (necrosis), healing problems, bleeding or blood clots. There may be a period of time when you have no breasts at all and this may leave you feeling uncomfortable.
- Tissue expanders are not available for use on every patient and complications may result from use of tissue expanders.



Delayed Breast Reconstruction

Breast reconstruction is performed weeks, months or years after the mastectomy. Unlike staged reconstruction, delayed reconstruction may not specifically be planned out at the time of a mastectomy or lumpectomy.

Advantages:

- Delaying reconstruction gives you time to focus on treatments, and discuss and research the type of reconstruction that best suits your needs. For example, some women don't want to have to make decisions about reconstruction while being treated for breast cancer.

Disadvantages:

- For some, being without breasts for a period of time can be emotionally difficult.
- Surgical complications can arise during or soon after surgery such as infection, tissue death (necrosis), healing problems, bleeding or blood clots.



Autologous Breast Reconstruction

Autologous Breast Reconstruction, can be performed at time of mastectomy or delayed until after treatment.

- **DIEP Flap:** A patient's own skin and tissue (no muscle) is taken from the abdomen to reconstruct the breast after mastectomy
- **TRAM Flap:** A patient's lower abdominal skin, fat and one of the rectus muscles are transferred to the mastectomy site to recreate the breast.
- **Fat Grafting:** Primarily used as an adjunct to a breast reconstruction procedure, fat tissue is removed from one part of the body – often the belly or buttocks – via liposuction and injected into the breast area.

1. Sood, M. "Potential of the SPY Intraoperative Perfusion Assessment System to Reduce Ischemic Complications in Immediate Postmastectomy Breast Reconstruction." Annals of Surgical Innovation and Research, 2013.

2. Duggal, C. "An Outcome Analysis of Intraoperative Angiography for Postmastectomy Breast Reconstruction." Aesthetic Surgery Journal, Jan. 2014.

3. Al-Ghazal SK et al. The psychological impact of immediate rather than delayed breast reconstruction (European Journal of Surgical Oncology) Feb. 2000

4. Dave R, O'Connell R, Rattay T, et al. The iBRA-2 (immediate breast reconstruction and adjuvant therapy audit) study: protocol for a prospective national multicentre cohort study to evaluate the impact of immediate breast reconstruction on the delivery of adjuvant therapy. BMJ Open 2016

5. Weenk, M. "Factors Influencing the Decision to Pursue Immediate Breast Reconstruction after Mastectomy for Breast Cancer." Gland Surg, Feb. 2017.

What is SPY Fluorescence Imaging Technology?

SPY Elite and **SPY-PHI Fluorescence Imaging technology** have high definition video cameras to make it possible for surgeons to visualize blood flow in real-time.



Blood flow. It's critical to healing.

Adequate blood supply ensures delivery of oxygen and nutrients to tissue, which is critical to healing. Today clinical judgement is the most common method of assessing blood flow. However, the human eye is limited in what it can see and SPY imaging is a tool available to surgeons that can increase the ability to determine quality of blood flow. SPY fluorescence technology allows physicians to see beyond the limits of the human eye to visually assess blood flow in skin flaps and tissue in real-time.

Real-time visualization

The ability to visualize blood flow in real time, when it matters most during the course of surgery, has been shown in clinical research to be important for improving surgical outcomes.^{1,2}

Why is this **important**?

Even a few hours of impaired blood flow can cause irreversible damage that can often lead to post-operative complications. Complications following mastectomy and breast reconstruction may be physically disfiguring and emotionally devastating. Most importantly, complications may delay the start of further treatments, such as chemotherapy and radiation.³

By seeing whether or not tissue is adequately perfused during a reconstructive surgery, surgeons may make critical decisions that could potentially reduce the risk of devastating complications related to poorly perfused tissue.⁴



Over 5 years, the proportion of U.S. breast cancer patients opting for breast reconstruction after mastectomy grew by about two-thirds.⁵

1. Sood, M. "Potential of the SPY Intraoperative Perfusion Assessment System to Reduce Ischemic Complications in Immediate Postmastectomy Breast Reconstruction." *Annals of Surgical Innovation and Research*, 2013.
 2. Duggal, C. "An Outcome Analysis of Intraoperative Angiography for Postmastectomy Breast Reconstruction." *Aesthetic Surgery Journal*, Jan. 2014.
 3. Venturi: Venturi, M et al. SPY Elite's Ability to Predict Nipple Necrosis in Nipple-Sparing Mastectomy and Immediate Tissue Expander Reconstruction (PRS Global Open) May 2017.4. TBD
 4. Al Ghazal: Al-Ghazal SK et al. The psychological impact of immediate rather than delayed breast reconstruction (*European Journal of Surgical Oncology*) Feb. 2000
 5. U.S. Agency for Healthcare Research and Quality, 2009

Frequently asked questions and answers

How does SPY fluorescence imaging work?

SPY Technology relies on a near-infrared light source and as such, emits no ionizing radiation. Indocyanine green (ICG) is intravenously injected into the patient's body and the SPY technology is used to visualize blood flow in your body. The fluorescent agent (ICG) has been used for over 50 years. SPY imaging technology is cleared by the United States Food and Drug Administration for use in capturing and viewing fluorescence images for the visual assessment of blood flow in plastic, micro and reconstructive surgical procedures.

Does the imaging agent used cause any after effects?

In general, indocyanine green (ICG) is very well tolerated and has no discernable after effects for the patient. It is non-toxic and metabolized by the liver. **However, ICG is not advised for patients who are allergic to iodine.**¹

Is there information or evidence in the medical literature supporting the use of SPY technology?

Yes. In fact, many clinical studies have shown that the use of SPY fluorescence imaging in reconstructive surgery may allow surgeons to make decisions that result in improved patient outcomes. In the multiple clinical papers, a minimum of 50 specifically support the use of SPY in breast reconstruction.^{2,3}



1. Indocyanine Green IFU

2. Sood, M. "Potential of the SPY Intraoperative Perfusion Assessment System to Reduce Ischemic Complications in Immediate Postmastectomy Breast Reconstruction." Annals of Surgical Innovation and Research, 2013.

3. Duggal, C. "An Outcome Analysis of Intraoperative Angiography for Postmastectomy Breast Reconstruction." Aesthetic Surgery Journal, Jan. 2014.