

## Important Safety Considerations for REVOLVE™ System

REVOLVE™ System is a single use, sterile, disposable canister that is intended for processing, filtering, and transferring of autologous adipose tissue. The device is intended to be used by a plastic surgeon to perform autologous fat grafting in aesthetic body contouring procedures.

Autologous fat grafting should not be performed in the presence of any disease process that adversely affects wound healing, and in patients who are in poor overall health. Some common adverse effects associated with autologous fat transfer are asymmetry, over- and/or under-correction of the treatment site, tissue lumps, bleeding, and scarring.

Every patient's situation is different, so be sure to ask your surgeon if the use of REVOLVE™ System is right for you. This brochure is not intended to replace a patient's discussion with a surgeon. It does not describe all the potential risks and potential benefits associated with fat grafting procedures.

Before use, physicians should review all risk information, which can be found in the *Instructions for Use* and *User Manual* for the REVOLVE™ System.

REVOLVE™ System is available only through licensed plastic surgeons. Complete product and safety information is available at [www.lifecell.com](http://www.lifecell.com).

### References

1. <http://www.smartbeautyguide.com/procedures/injectables/fat-transfer>
2. <http://www.surgery.org/media/news-releases/fat-grafting-for-breast-augmentation>
3. <http://www.smartbeautyguide.com/procedures/injectables/fat-transfer>
4. Ansorge H, Garza JR, McMormack MC, et al. Autologous fat processing via the revolve system: quality and quantity of fat retention evaluated in an animal model. *Aesthet Surg J*. 2014 Mar 1;34(3):438-47.

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# REVOLVE™

NATURAL BEAUTY BY DESIGN™

## For Natural Body Enhancement



Model

## What Is Fat Grafting?

Fat grafting involves taking fat from one area of your body and transferring it to another. During the procedure, a surgeon will perform liposuction to remove fat from an area where there is an excess, such as the inner thighs, stomach, or lower back. The fat is then processed and injected into the area of your body where enhancement or volume is desired. The technique is known as “autologous” fat grafting because the fat comes from your own body.

## When Would You Consider Fat Grafting?

- If you wish to improve your body contour, fill bodily depressions, and rejuvenate your breasts or face
- For use in breast reconstruction, to fill in contour irregularities, or hide obvious signs of breast implants
- If you have areas that appear wrinkled or sunken
- If you desire more permanent correction than what is provided by temporary fillers

## What Are the Benefits of Fat Grafting?<sup>1</sup>

- Your body is unlikely to reject your own fat cells reducing the chance of foreign body reaction
- Offers a more "natural way" to create volume enhancement using your own fat cells
- Fat grafting is a minimally invasive surgery

## What Are the Risks of Fat Grafting?<sup>2</sup>

Fat cells that are removed from one body site and injected into another do not always survive. Multiple fat grafting sessions may be required to achieve your desired volume enhancement.

You will need to have an adequate supply of excess fat for the procedure. While results may be immediately visible, swelling may take several months to resolve.

Fat injected into the breast may be absorbed by the body, may become liquid and form a cyst, may calcify, or may produce scarring.

Fat grafting may also produce changes in the breast that may be deemed suspicious during examination by a physician or on mammography, and may lead to further testing to determine if the findings are related to breast cancer.

Some common adverse effects associated with autologous fat transfer are asymmetry, over and/or under-correction of the treatment site, tissue lumps, bleeding, and scarring.

Autologous fat grafting should not be performed in the presence of any disease process that adversely affects wound healing, and in patients who are in poor overall health.

# Where Can Fat Grafting Be Used?<sup>3</sup>

## Breast Procedures

Fat grafting in the breast offers a more “natural” way to enhance shape and volume in the breasts by using the patient’s own tissue.

### • Breast Reconstruction

If you undergo a mastectomy to treat breast cancer, you may want to consider reconstructive surgery to repair your lost or damaged breast tissue. As part of the reconstructive procedure, your surgeon may use fat grafting as an adjunct to implant breast reconstruction. Fat grafting can help to improve overall aesthetic results in reconstructive surgery.

### • Breast Revision

If you have irregularities following a breast implant procedure, the irregularities can be filled in with fat to produce a smoother contour.

### • Breast Augmentation

Fat grafting may also be performed at the same time as placement of implants to enhance breast shape and add cleavage. If you desire a modest increase in breast size, (one half cup to a full cup size), you may be a good candidate for fat grafting in the breast. If you have sagging breasts or want a significant increase in breast size, breast augmentation with fat transfer alone may not be appropriate.

## Facial Reconstruction

- If you have facial creases, such as laugh lines, smile lines, and crow’s-feet, your surgeon may inject fat removed from another part of your body to add volume, increase fullness, or fill in the wrinkles.

## Buttock Augmentation

- If you desire fuller, more curvy buttocks, you may consider a “Brazilian butt lift,” which uses fat grafting to provide a more rounded buttocks. Liposuction is commonly used to both sculpt the surrounding area and collect the fat to be injected.



Model

# How Does REVOLVE™ System Work?

## Step 1: Fat Harvesting



Artist rendering

Your surgeon will perform liposuction to remove fat from an area of the body where you have excess fat, such as the inner thighs, stomach, buttocks, lower back. Your surgeon will make small incisions and insert a thin tube or cannula through these incisions. The fat is then suctioned out of your body using a surgical vacuum or syringe and collected directly into REVOLVE™ System canister. Liposuction is normally performed under general anesthesia or with intravenous sedation.

## Step 2: Wash/Process the Fat with REVOLVE™ System



Your surgeon will clean the fatty tissue in REVOLVE™ System. It will be washed and processed to separate the tissue from fluid waste and contaminants. The entire process is done in a single closed device.

## Step 3: Fat Transfer



Artist rendering

After the fat is processed, your surgeon will transfer the cleaned fat to a syringe and then inject it where volume enhancement is needed. Your surgeon will graft the fat to your breast or desired area in order to enhance volume, shape, or correct deformities.

# Ask Your Surgeon About REVOLVE™ System

Designed by a consortium of the world's leading plastic surgeons and scientists, REVOLVE™ System from LifeCell optimizes adipose tissue for reimplantation in patients. This sterile, disposable device is intended for processing, filtering and transferring the patient's own fat tissue. The device controls critical variables in fat processing and is capable of large volume processing, which may minimize operating time required to complete fat grafting. REVOLVE™ System can be refilled and emptied multiple times on the same patient in the same surgery.

A pre-clinical study showed that REVOLVE™ System removes more free oil and red blood cells from the fat graft than either the decantation or centrifugation methods. These are two techniques commonly used by surgeons to wash and filter fatty tissue in fat grafting procedures. It is important to know that correlation of these pre-clinical results to results in human has not been established.<sup>4</sup>

## Questions to Consider Asking Your Surgeon

1. Do I have enough fat for a fat grafting procedure?
2. Where will the fat be extracted from?
3. When can I consider that my results will be permanent?
4. Will I need to be fat grafted several times?
5. What are the potential complications?
6. What happens if my weight changes after fat grafting?
7. Does fat grafting for breast augmentation make it harder to detect cancer in mammograms?
8. Are you a board-certified or board eligible plastic surgeon?
9. Is the surgeon facility accredited?

Additional product and safety information is available at [www.lifecell.com](http://www.lifecell.com)