

REVOLVE™

Advanced Adipose System



EXPERIENCE HIGH-QUALITY, PREDICTABLE FAT GRAFTING PERFORMANCE^{1,*}

*Correlation between these results and results in humans has not been established.

REVOLVE™ Advanced Adipose System

Indications and Important Safety Information

INDICATIONS

The REVOLVE™ Advanced Adipose System (REVOLVE™ System) is used for aspiration, harvesting, filtering, and transferring of autologous adipose tissue for aesthetic body contouring. This system should be used with a legally marketed vacuum or aspirator apparatus as a source of suction. If harvested fat is to be re-implanted, the harvested fat is only to be used without any additional manipulation. REVOLVE™ System is intended for use in the following surgical specialties when the aspiration of soft tissue is desired: plastic and reconstructive surgery, gastrointestinal and affiliated organ surgery, urological surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, and laparoscopic surgery.

Please see Important Safety Information throughout this brochure.

LEADING THE WAY IN FAT PROCESSING^{2,3}

REVOLVE™ System is an integrated system for high-quality fat processing designed by adipose transplantation pioneers and founders of the International Federation for Adipose Therapeutics and Science (IFATS).¹

#1

COMMERCIAL DEVICE
FOR FAT PROCESSING

in the U.S. for aesthetic
and reconstructive procedures^{2,3,*}

>75,000
PATIENTS TREATED⁴

Used by more than
1200
HOSPITALS AND
SURGICAL CENTERS⁴

*Market share data through February 2018.

Important Safety Information (Continued)

CONTRAINDICATIONS

Contraindications to autologous fat transfer include the presence of any disease processes that adversely affect wound healing, and poor overall health status of the individual.

Dessiree

Actual fat transfer patient.
REVOLVE™ System used for fat processing.

Individual results may vary.





ONE CLOSED, DISPOSABLE SYSTEM

The only all-in-one fat processing device that harvests, filters, actively washes, and removes strands^{1,5}

A. MESH FILTER¹

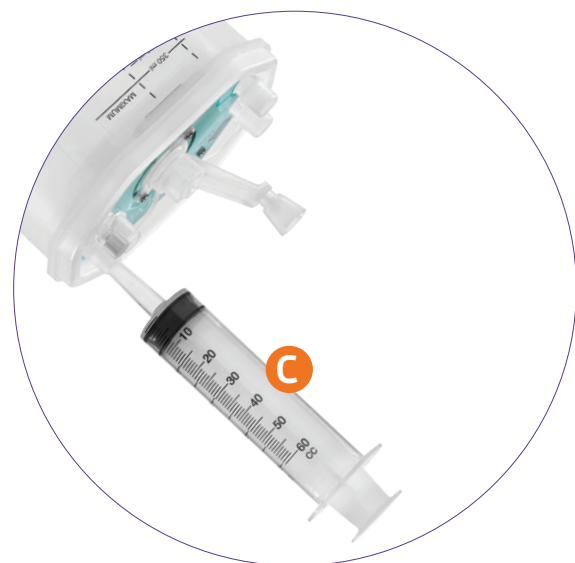
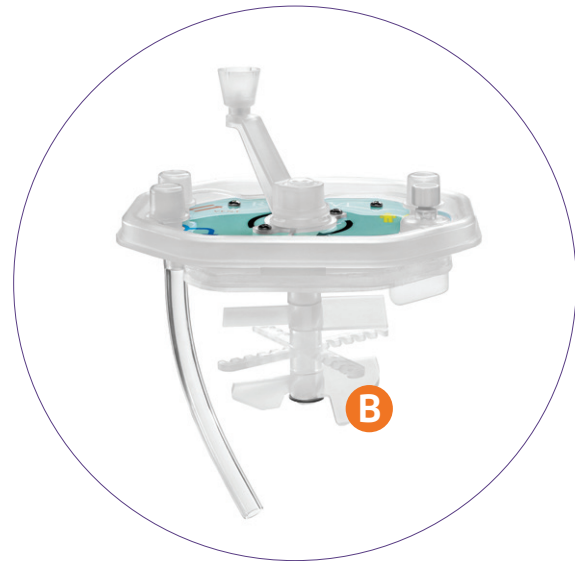
- Designed to filter and strain lipoaspirate during the harvesting phase and active mechanical washing process
- Rapidly concentrates adipose tissue, eliminates free oil, and removes tumescent fluid and cell debris

B. PROPELLER FOR ACTIVE WASHING¹

- Removes collagen strands to minimize injection syringe clogging
- Ensures fat is thoroughly washed via rotating paddles
- Enhances washing process for high-quality fat

C. SYRINGE EXTRACTION

- Allows loading of syringes for injection directly from canister to minimize steps¹
- Flexible extraction port can utilize catheter tip as well as Luer-Lok syringe⁶



Important Safety Information (Continued)

WARNINGS

REVOLVE™ System must be used within the same surgical procedure. Reuse of this device in the same patient in a subsequent surgical procedure, or for more than one patient, may result in infection and/or transmission of communicable diseases. Do not use the product if sterile packaging is damaged.

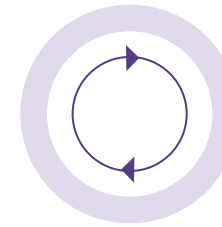
This device will not, in and of itself, produce significant weight reduction. This device should be used with extreme caution in patients with chronic medical conditions such as diabetes, heart, lung, or circulatory system disease or obesity. The volume of blood loss and endogenous body fluid loss may adversely affect intra and/or postoperative hemodynamic stability and patient safety. The capability of providing adequate, timely replacement is essential for patient safety.

DESIGNED FOR EASE AND PREDICTABILITY^{1,7}



TIME EFFICIENT⁷

- Processes up to 350 mL of adipose tissue (~ 700 mL of lipoaspirate) in less than 10 minutes^{1,6}
- Proven to save time and potential costs compared to centrifugation⁸
- All-in-one integrated device that harvests, processes, and extracts lipoaspirate within one canister¹



INTEGRATED, CLOSED SYSTEM

- Minimizes tissue handling and exposure to outside air
- Controls critical fat grafting variables, such as pH, osmolarity, and contaminants
- Sterile, single-patient, disposable device



EASY TO USE

- User-friendly system minimizes training, preparation, and clean-up time, requiring only one operator
- Can be placed in the sterile field, in line with aspiration and waste devices
- Integrated system allows loading of syringes for injection directly from canister¹

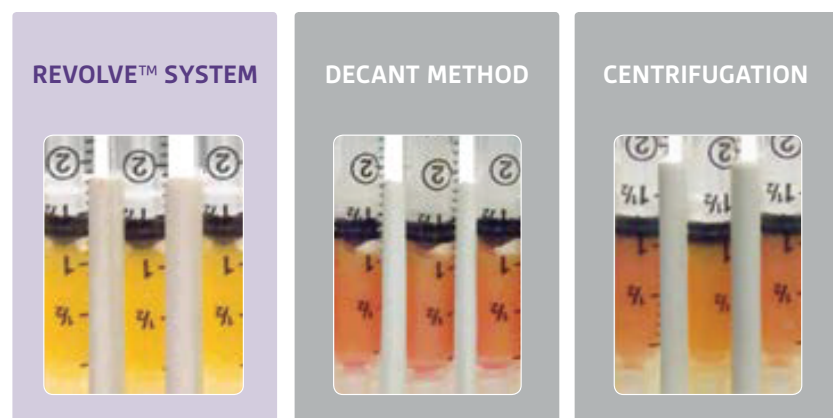


REVOLVE™
Advanced Adipose System

Results based on laboratory and animal model data

PROVIDES HIGHER CONCENTRATION OF ADIPOSE GRAFT TISSUE¹

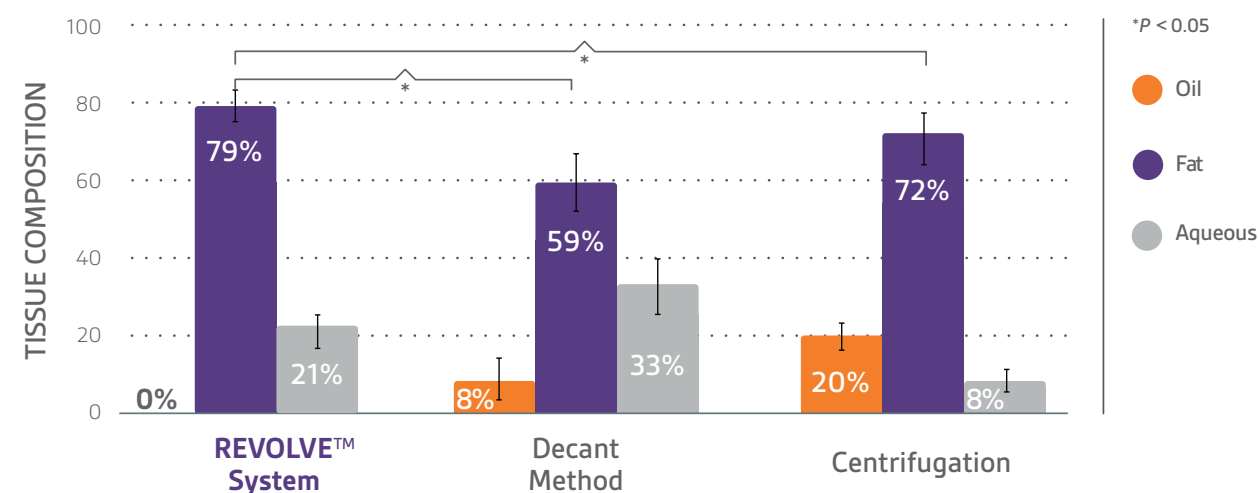
Consistently improves graft quality and provides predictable results



In a laboratory study, fat processed using three different methods was evaluated for adipose tissue concentration, pH, osmolality, hematocrit assays, and percent of oil and aqueous content.

REVOLVE™ System yielded a higher concentration of adipose tissue, eliminating free oil and significantly reducing aqueous fluid and red blood cell debris.

COMPOSITION OF PROCESSED TISSUE^{1,*}

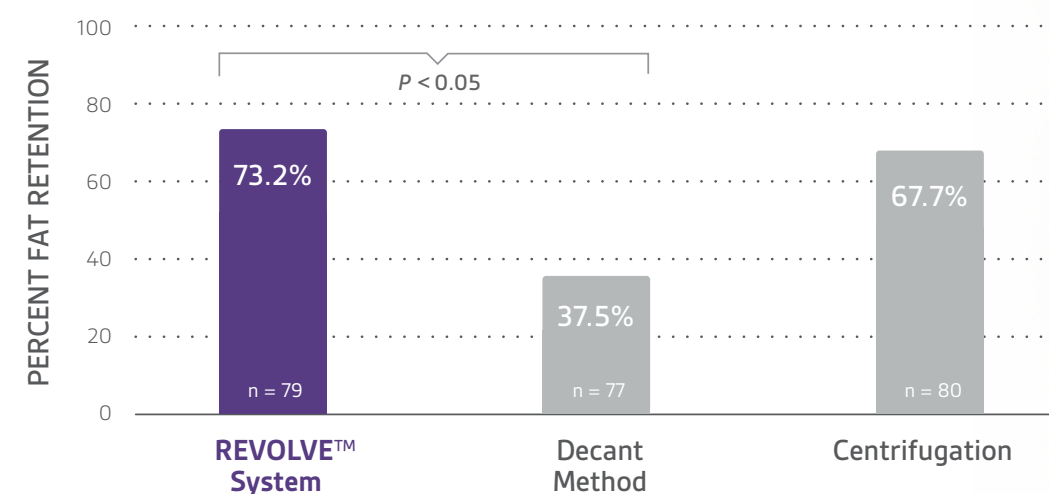


*Correlation of these results to results in humans has not been established.

PRODUCES MORE RELIABLE FAT GRAFT RETENTION¹

In an animal model, REVOLVE™ System yielded significantly higher fat graft retention than decantation and similar results to centrifugation.^{1,*}

PERCENT OF IMPLANTED FAT RETAINED



In a preclinical study, human fat was processed using three different methods: REVOLVE™ System, decantation, and centrifugation (processed at 1200 g for 3 minutes). Fat samples from each group were implanted into mice and explanted after 28 days and evaluated for a head-to-head comparison of volume retention.

*Correlation of these results to results in humans has not been established.

Important Safety Information (Continued)

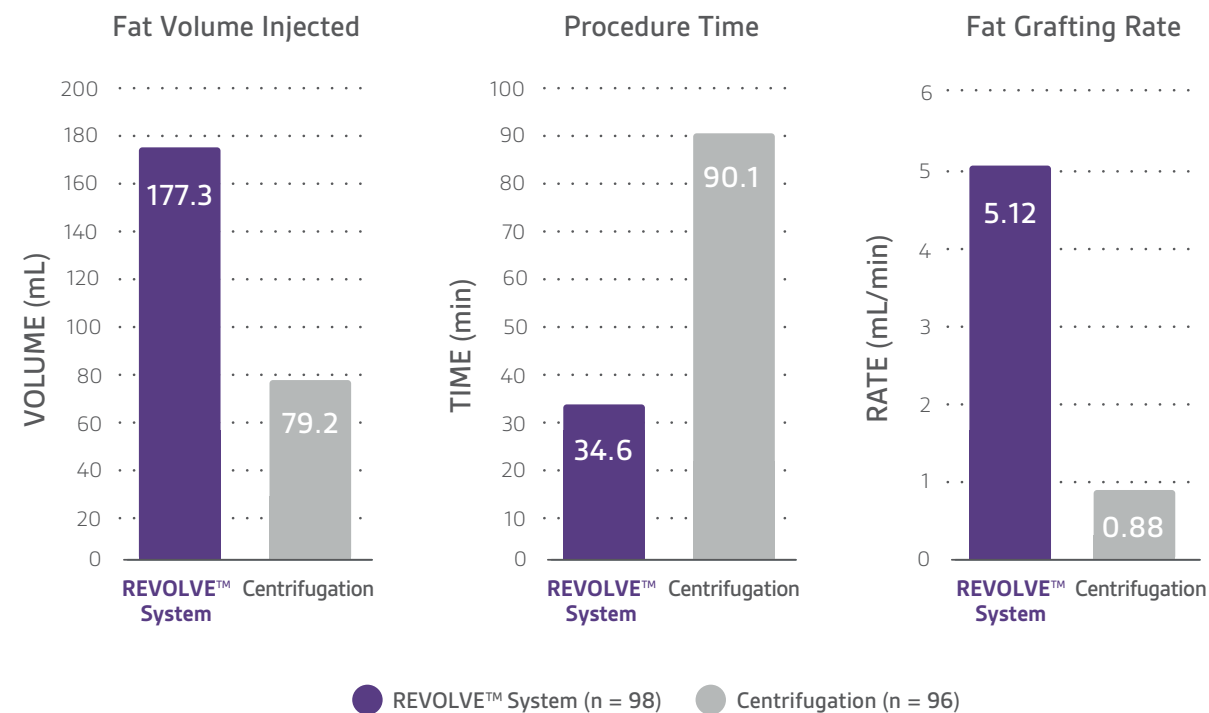
PRECAUTIONS

REVOLVE™ System is designed to remove localized deposits of excess fat through small incision and subsequently transfer the tissue back to the patient. Use of this device is limited to those physicians who, by means of formal professional training or sanctioned continuing medical education (including supervised operative experience), have attained proficiency in suction lipoplasty and tissue transfer. Results of this procedure will vary depending upon patient age, surgical site, and experience of the physician. Results of this procedure may or may not be permanent. The amount of fat removed should be limited to that necessary to achieve a desired cosmetic effect. Filling the device with adipose tissue over the maximum fill volume line can lead to occlusion of the mesh resulting in mesh tear.

HIGHER VOLUMES OF FAT INJECTED IN LESS TIME⁸

REVOLVE™ System processed higher volume of fat in less time, significantly reducing operating room (OR) time compared to centrifugation⁸

IMPROVED OPERATIVE OUTCOMES WITH USE OF REVOLVE™ SYSTEM VS CENTRIFUGATION⁸



A retrospective study reviewed 96 patients with fat grafts processed by centrifugation and 98 patients with fat grafts processed by REVOLVE™ System. The endpoints measured included volume injected after processing and time to complete (from lipoaspiration to fat injection); grafting rate reflects volume of fat injected over the time taken to complete procedure. In this study, REVOLVE™ System processed more fat per minute than centrifugation, decreasing operating time and potential OR costs.⁸

REDUCED COMPLICATIONS⁸

Lower nodule and cyst formation, fewer reoperations

Compared to centrifugation, REVOLVE™ System resulted in significantly lower nodule and cyst formation, and significantly fewer reoperations to add more soft tissue.^{8,*}

FEWER COMPLICATIONS WITH REVOLVE™ SYSTEM VS CENTRIFUGATION⁸

| | REVOLVE™ SYSTEM (n = 98) | CENTRIFUGATION (n = 96) | RELATIVE RISK (95% CI) | P VALUE |
|----------------------------|-----------------------------|----------------------------|---------------------------|---------|
| Nodule Formation | 10 (10.2%) | 27 (28.1%) | 2.8 (1.4, 5.4) | 0.004 |
| Cyst Formation | 7 (7.1%) | 18 (18.8%) | 2.6 (1.1, 6.0) | 0.023 |
| Fat Necrosis | 3 (3.1%) | 9 (9.4%) | 3.1 (0.9, 11.0) | 0.131 |
| Proportion of Reoperations | 37 (37.8%) | 56 (58.3%) | 1.5 (1.1, 2.1) | 0.007 |

*Controlled for age, body mass index, and prior chemotherapy exposure.

The study was a retrospective cohort of consecutive patients who underwent autologous fat grafting during reconstructive breast surgery with REVOLVE™ System or centrifugation. The endpoints measured included proportion of patients undergoing reoperation and complication rates for each group during 6 months following the fat grafting procedure.⁸

Important Safety Information (Continued)

ADVERSE EFFECTS

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. Potential adverse effects associated with REVOLVE™ System include fat necrosis, cyst formation, infection, chronic foreign body response, allergic reaction, and inflammation.

INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS

The REVOLVE™ Advanced Adipose System (REVOLVE™ System) is used for aspiration, harvesting, filtering, and transferring of autologous adipose tissue for aesthetic body contouring. This system should be used with a legally marketed vacuum or aspirator apparatus as a source of suction. If harvested fat is to be re-implanted, the harvested fat is only to be used without any additional manipulation. REVOLVE™ System is intended for use in the following surgical specialties when the aspiration of soft tissue is desired: plastic and reconstructive surgery, gastrointestinal and affiliated organ surgery, urological surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, and laparoscopic surgery.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Contraindications to autologous fat transfer include the presence of any disease processes that adversely affect wound healing, and poor overall health status of the individual.

WARNINGS

REVOLVE™ System must be used within the same surgical procedure. Reuse of this device in the same patient in a subsequent surgical procedure, or for more than one patient, may result in infection and/or transmission of communicable diseases. Do not use the product if sterile packaging is damaged.

This device will not, in and of itself, produce significant weight reduction. This device should be used with extreme caution in patients with chronic medical conditions such as diabetes, heart, lung, or circulatory system disease or obesity. The volume of blood loss and endogenous body fluid loss may adversely affect intra and/or postoperative hemodynamic stability and patient safety. The capability of providing adequate, timely replacement is essential for patient safety.

PRECAUTIONS

REVOLVE™ System is designed to remove localized deposits of excess fat through small incision and subsequently transfer the tissue back to the patient. Use of this device is limited to those physicians who, by means of formal professional training or sanctioned continuing medical education (including supervised operative experience), have attained proficiency in suction lipoplasty and tissue transfer. Results of this procedure will vary depending upon patient age, surgical site, and experience of the physician. Results of this procedure may or may not be permanent. The amount of fat removed should be limited to that necessary to achieve a desired cosmetic effect. Filling the device with adipose tissue over the maximum fill volume line can lead to occlusion of the mesh resulting in mesh tear.

ADVERSE EFFECTS

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. Potential adverse effects associated with REVOLVE™ System include fat necrosis, cyst formation, infection, chronic foreign body response, allergic reaction, and inflammation.

REVOLVE™ System is available by prescription only.

For more information, please see the Instructions for Use (IFU) and User Manual for REVOLVE™ System available at www.allergan.com/RevolveIFU or call 1.800.678.1605.

To report an adverse reaction, please call Allergan at 1.800.367.5737.



Dessiree

Actual aesthetic surgery patient with fat transfer.
REVOLVE™ System used for fat processing.

Individual results may vary.

REVOLVE™
Advanced Adipose System

EXPERIENCE HIGH-QUALITY, PREDICTABLE FAT GRAFTING PERFORMANCE^{1,*}

Contact your Allergan representative to learn more

*Correlation between these results and results in humans has not been established.

REVOLVE™
Advanced Adipose System



REVOLVE™ System is available by prescription only.

CALL 1.800.367.5737 TO ORDER REVOLVE™ SYSTEM TODAY

| PACKAGING | | SYRINGES | |
|--------------|-------------|--------------|--|
| Product Code | Quantity | Product Code | Description |
| RV0001 | 1 Unit Pack | 122P0444 | 60 mL Catheter Tip Syringes 40-Pack/Case |

For more information, please call

ALLERGAN CUSTOMER SOLUTIONS AT 1.800.367.5737,

or visit **WWW.REVOLVEFATGRAFTING.COM/HCP**

REVOLVE™ System is available by prescription only.

For more information, please see the Instructions for Use (IFU) and User Manual for REVOLVE™ System available at www.allergan.com/RevolveIFU or call 1.800.678.1605.

To report an adverse reaction, please call Allergan at 1.800.367.5737.

References: 1. Ansong H, Garza JR, McCormack 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;34(3):438-447. 2. Data on file, Allergan, January 2020. Aesthetic Monthly Tracker. 3. Data on file, Allergan, January 2020. Plastic Surgery Monthly Tracker. 4. Data on file, Allergan, 2020. REVOLVE System Sales Data. 5. Data on file, Allergan, 2017. Competitive Information. 6. REVOLVE System Instructions for Use, 2017. 7. Data on file, Allergan, July 2008. Research and Development Report. 8. Gabriel A, Maxwell GP, Griffin L, Champaneria MC, Parekh M, Macarios D. A comparison of two fat grafting methods on operating room efficiency and costs. *Aesthet Surg J.* 2017;37(2):161-168.



Allergan® and its design are trademarks of Allergan, Inc.
REVOLVE™ System and its design are trademarks of LifeCell Corporation, an Allergan affiliate.
© 2020 Allergan. All rights reserved. RVL114538-v2 03/20