



**BIMINI**  
HEALTHTECH

Bimini Health Tech is dedicated to transforming the human experience, driven by passion to develop a diverse portfolio of novel technologies and therapeutics that allow people to live better, longer lives.

Our mission is to develop products that are elegant in their simplicity, proven in their reconstructive and clinical impact.

FOR QUESTIONS  
RELATED TO  
ADMINISTRATION,  
ORDERS OR  
ACCOUNTING, PLEASE  
CONTACT:

Bimini Health Tech  
8400 Belleview Drive  
Suite 125  
Plano, TX 75024

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858-348-8050

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858-217-5134

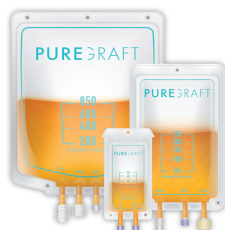
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# PURCHASING COMMITTEE PRODUCT REVIEW

# PUREGRAFT

The following material is specifically compiled to help facilitate discussions that hospital product board review committees may conduct prior to approving Puregraft™ for purchase.



The **Puregraft System** is a proven technology that utilizes an advanced lipofiltration system to streamline the graft preparation process by selectively washing lipoaspirate while draining any unwanted tumescent fluid, free lipid and debris. The system portfolio can prepare 10 – 850 mL of graft in a closed, sterile environment in less than 15 minutes, and allows for user defined hydration levels of the final graft.

## ABOUT PUREGRAFT

## GENERAL INFORMATION

### MANUFACTURER:

Bimini Health Tech  
8400 Belleview Drive, Suite 125  
Plano, TX 75024  
Telephone: 858-348-8050  
Fax: 858-217-5134

**FEDERAL TAX ID:** 46-3228559

**FDA REGISTRATION NUMBER:** 3011277972

**PRICING:** Please refer to current price list.

### Proprietary Name:

Puregraft Fat Purification System

**Product Code:** QKL

**Device Class:** II

**Regulation Number:** 21 CFR 878.5040

**Medical Specialty:** General & Plastic Surgery

**Registered Establishment Name:**

Bimini Health Tech

**FDA Status:** 510(k) Clearance:

K-Number	Product Description	Clearance Date
BK220699	Puregraft 50 System	01/24/2014
BK220689	Puregraft 250 System	01/06/2010
BK220693	Puregraft 850 System	03/07/2012

**FDA Investigational Device Exception (IDE):** None

Copies of individual 510(k) clearance letters available upon request.

### MATERIAL / ENVIRONMENT:

**Does this product contain latex?** No

**Is product sterile?** Yes

**Is product disposable?** Yes

**Is product implantable?** No

**MATERIAL SAFETY DATA SHEET (MSDS):** None

## PRODUCT DESCRIPTION

### INDICATION FOR USE:

The **Puregraft System** is indicated for use in the harvesting, filtering and transferring of autologous fat tissue for reinjecting back into the same patient for aesthetic body contouring.

### CONTRAINDICATIONS:

Intravenous applications

### NAME OF PRODUCT:

Puregraft Fat Purification System

### OFFERED IN THREE SIZES:

Puregraft 50 System

Puregraft 250 System

Puregraft 850 System

### PACKAGE INFORMATION:

11 in x 15 in x 1 in cardboard box

14 in x 7 in x 7 in cardboard box (SYNC)

### PRODUCT ORDER INFORMATION:

#### Puregraft 50 Bag System

Catalog # 50/PURE

Box contains: 5 individually packed, sterile 50mL bags

#### Puregraft 250 Bag System

Catalog # 250/PURE

Box contains: 1 sterile 250mL bag

#### Puregraft 850 Bag System

Catalog # 850/PURE

Box contains: 1 sterile 850mL bag

#### Puregraft SYNC Adipose Filtration System

Catalog # PURE/SYNC

Box contains: 1 sterile Puregraft Filtration bag, sterile SYNC unit, drain bag, slider, PAL adapter, 2 combined adapters, 2 syringes and optional Mayo stand clamp

### Product Website:

www.puregraft.com



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## PUREGRAFT PURCHASING COMMITTEE PRODUCT REVIEW

### UTILIZATION & REIMBURSEMENT

#### UTILIZATION:

**How Is Product Shipped:** Via FedEx Delivery  
**How Much Lead Time is Needed:** 5 Days  
**Method of Purchase:** Direct purchase

**Does this product require special storage considerations?** Per IFU, store in a clean, dry area between 59F - 86F

**Is this a dated product?** Yes, product contains expiration date on package label.

**What specific departments / clinical areas will use the product / procedure?**  
Plastic surgery and General surgery operating room (OR)

**What department(s) will use and/or be affected by this product?**  
Plastic Surgery, General surgery OR, Purchasing

#### REIMBURSEMENT:

The coding information listed within this guide has been included for informational purposes only.

### HOSPITAL OUTPATIENT DEPARTMENT/AMBULATORY SURGERY CENTER REIMBURSEMENT CODING AND REIMBURSEMENT RATES FOR PROCEDURES INVOLVING PUREGRAFT

CPT	Descriptor	2021 Physician Payment Office <sup>1</sup>	2021 Physician Payment Facility <sup>1</sup>	2021 APC Assignment <sup>2</sup>	2021 HOPD Payment <sup>3</sup>	2021 ASC Payment <sup>3</sup>
Fat Transfer						
<b>15769</b>	Grafting of autologous soft tissue, other, harvested by direct excision (e.g. fat, dermis, fascia).	--	\$489.68	5055	\$3596.22	\$1,823.73
<b>15771</b>	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms and/or legs; 50cc or less injectate.	\$604.57	\$504.90	5055	\$3596.22	\$1,823.73
<b>+15772</b>	Each additional 50cc injectate, or part thereof (list separately in addition to code for primary procedure). Use 15772 in conjunction with 15771.	\$193.79	\$150.19	--	No Payment	No Payment
<b>15773</b>	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands and/or feet; 25cc or less injectate	\$619.10	\$518.05	5054	\$1749.26	\$887.09
<b>+15774</b>	Each additional 25cc injectate, or part thereof (List separately in addition to code for primary procedure)(Use 15774 in conjunction with 15773)	\$189.99	\$146.04	--	No Payment	No Payment
Breast Reconstruction						
<b>19380</b>	Revision of reconstructed breast	--	\$826.05	5092	\$5,652.10	\$2,308.67
<b>19366</b>	Breast reconstruction with other technique	--	Deleted	--	Deleted	Deleted
<b>19499</b>	Unlisted procedure, breast	n/a	n/a	5091	\$3,029.55	n/a

- <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1715-F>
- <https://www.cms.gov/medicare/medicare-fee-for-service-payment/tascpaymentasc-regulations-and-notices/cms-1717-cn>
- <https://www.cms.gov/node/1291131>

For additional coding and reimbursement information, contact your local Puregraft Sales Representative or the **Reimbursement Help Desk at 858-348-8050**.

**Is there a requirement for staff training?** Puregraft recommends hospital staff review and learn equipment protocols prior to first use.

**Will there be additional implementation costs, such as installation, cost of education, impact on equipment or additional space?** No

**Does the product/procedure require a company representative to be present to operate equipment or to provide assistance to the physicians?** Per institution's plastic surgery protocol

**Will other equipment need to be leased,purchased, consigned or rented?** Yes. Accessories order form available upon request.

**What is the average length of procedure time to use this product/perform this procedure (surgery minutes)?** 15 minutes for fat purification

**Will this equipment interface with any other equipment / supplies currently utilized at this facility?** Yes, liposuction system

## PUREGRAFT PURCHASING COMMITTEE PRODUCT REVIEW

### CLINICAL DATA

#### CLINICAL HIGHLIGHTS:

### Hybrid Implant and Grafted Fat Breast Augmentation: Designing the Pathway to a Future with Breasts Free of Silicone Breast Implants

**Conclusion:** The procedure presented consistent and reproducible results. Hybrid breast augmentation can help design a pathway for a future with breasts free of silicone. This information is particularly relevant for women who have their first breast augmentation at an early age and will probably have 2 to 5 additional surgeries in their lifetime due to the nature of current silicone breast technology.

**Key Takeaway:** Patients reported a satisfaction rate of “excellent” in 83.3% of cases, and “good” in 16.7%. Physician satisfaction was rated as “excellent” in 84.5% of cases, “good” in 13.3%, and “fair” in 4.2% of cases. The mean fat volume grafted per breast was 113.63mL. The mean absorption rate was 4.53%.

### Comparison of Three Different Fat Graft Preparation Methods: Gravity Separation, Centrifugation, and Simultaneous Washing with Filtration in a Closed System.

**Conclusion:** Washing with Puregraft produces a fat graft with higher tissue viability and lower presence of contaminants compared with grafts prepared by centrifugation and gravity separation.

**Key Takeaway:** Puregraft is able to produce a 97% yield of viable adipose from lipoaspirate.

### Preliminary Assessment of the Predictability of Fat Grafting to Correct Silicone Breast Implant-Related Complications.

**Conclusion:** At 1 year, between 71.1% and 74.5% of injected fat was retained in a predictable, reproducible and effective manner.

**Key Takeaway:** Puregraft retention is highly predicable independent of volume of injected fat when implanted in the breast

### Centrifugation Versus Puregraft for Fatgrafting to the Breast After Breast Conserving Therapy.

**Conclusion:** One year postoperatively, the outcomes of the use of PureGraft bags or centrifugation to process fat for breast reconstruction after BCT did not differ. The unpredictability of the results following fatgrafting procedures is likely due to interindividual differences with yet-undisclosed causes.

**Key Takeaway:** Puregraft retention is highly predicable independent of volume of injected fat when implanted in the breast

### Long-term Follow-up of Autologous Fat Transfer vs Conventional Breast Reconstruction and Association With Cancer Relapse in Patients With Breast Cancer

**Conclusion:** No significant differences in the locoregional recurrence rates between the AFT and control groups were observed after 5 years of follow-up. These findings confirm the results of previous studies; therefore, clinical evidence suggesting that AFT is associated with increased risk for cancer relapse is still lacking.

**Key Takeaway:** Study suggests fat grafting reconstruction does not increase the risk of breast cancer recurrence when compared to more traditional techniques.



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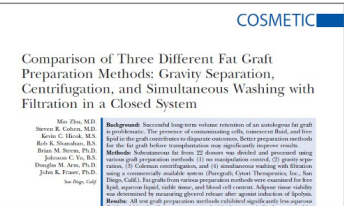
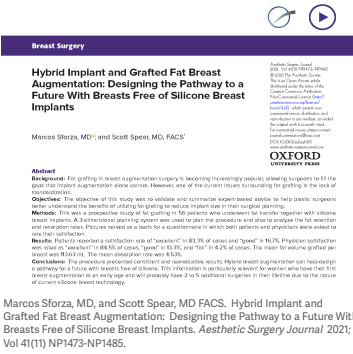
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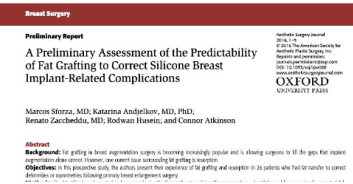
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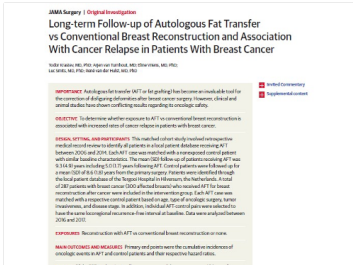
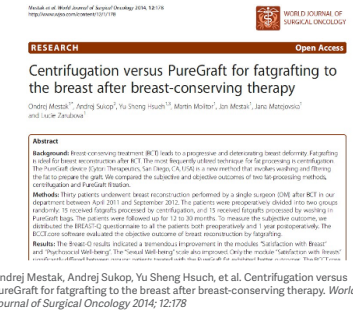
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Zhu M, Cohen SR, Hickok KC, Shanahan RK, Strem BM, Yu JC et al. Comparison of three different fat graft preparation methods: gravity separation, centrifugation, and simultaneous washing with filtration in a closed-system. *Plast Reconstr Surg* 2013; 131(4): 873-80.



Marcos Sforza, M.D., Katarina Andjelkovic, M.D., PhD; et al. A Preliminary Assessment of the Predictability of Fat Grafting To Correct Silicone Breast Implant-Related Complications. *Aesthetic Surgery Journal* 2016; 1-9



Todor Krastev, M.D., PhD; et al. Long-Term Follow-Up of Autologous Fat Transfer vs Conventional Breast Reconstruction and Association With Cancer Relapse in Patients With Breast Cancer. *JAMA Surg* doi:10.1001/2018.3744



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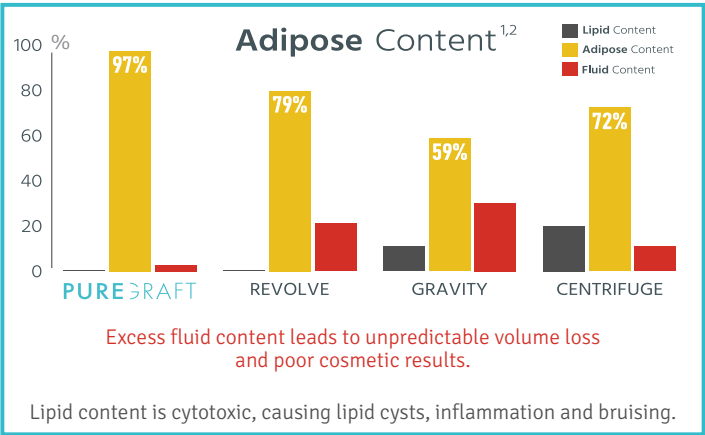
Up to **97% pure fat** for injection with Puregraft.  
Inject **18% more fat** per syringe with Puregraft than the competition.

PUREGRAFT PURCHASING COMMITTEE PRODUCT REVIEW

COMPETITIVE INFORMATION

What competitive products are available?

Revolve (Allergan), Lipografter (MTF Biologics), Tissu-Trans (Summit Medical, LLC), Centrifuge (Various), Gravity Decant (Various)



	Puregraft	Revolve	Gravity Decant	Centrifuge	Lipografter	Tissu-Trans
Purification Process	Size Based	Size Based	Density Based	Density Based	Density Based	Size Based
Processing Range	50 - 850cc	350cc	--	--	1,000cc	100 - 2,000cc
Mesh Size	74um	200um	N/A	N/A	N/A	400um
Gravitational Force Applied During Separation Process	> 1G*	1G	1G	>1G^	1G	1G
Machine Aspiration	Yes	Yes	Yes	No	No	Yes
Closed System	Yes	Yes	No	No	Yes	Yes
Container	Flexible Bag	Rigid Canister	Rigid Canister	Rigid Canister	Flexible Bag	Rigid Canister
Sterile Purification Process	Yes	Yes	Yes	No	Yes	Yes
Adipose Yield	97%	79%	59%	72%	--	--

\* Pressure separation can be increased by applying pressure bag  
^ User defined can be up to 400G

Closed. Clean.  
Concentrated.

Our purification process begins and ends in the Puregraft bag.

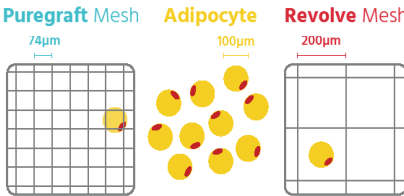
With the ability to harvest directly into Puregraft. No transfer of lipoaspirate, nor waste, until 97% purified fat is ready for injection, lowering the chance of cross-contamination, a leading cause of infection rates.



Technologies That  
Work

74µm Dialyzing Filter

Eliminate structural fat lost to waste with our optimized filter mesh that is smaller than an individual adipocyte.



Mesh vs adipocyte size for different filtration technologies

Flexible Technology

Our flexible bag technology removes fluid, lipid and other contaminants more effectively than any other separation method.



Don't Leave Good Fat  
Behind

Don't waste time and compromise sterility trying to shake, pry, and spoon fat out of a rigid canister.

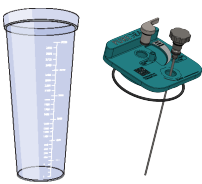
Puregraft fat is easily removed from the flexible bag, like squeezing a tube of toothpaste, with little to no waste.



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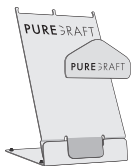
PUREGRAFT ACCESSORIES

Below are accessories available for use with the PureGraft System:



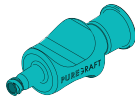
PureGraft Direct Harvest System

Reusable product that allows liposuction directly into the Puregraft 850 Filter (sold separate), includes Puregraft Instrument Set, Puregraft Direct2 Lid, Puregraft 3L Vacuum Canister and Puregraft Combined Adapter.



PureGraft Instrument Set (Easel and Slider)

Designed for use with the Puregraft 250 and 850 Systems. The Easel holds the Puregraft Bag upright and the Slider aids the user in extracting the graft from the Puregraft System.



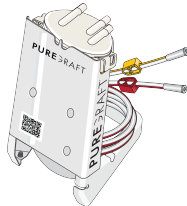
PureGraft Combined Adapter

Reusable toomey/catheter-tip to luer lock adapter, the design also enables direct connection to Puregraft 250 and 850 tissue input valve.



PureGraft Boost Adipose Micronizer

Proprietary patented single-use device designed to uniformly size harvested adipose tissue, available in 500 / 1000 / 1500µm sizes.



PureGraft SYNC™ Adipose Filtration System

Proprietary patented sterile, single-use device used for aspiration, harvesting, filtering and transferring of autologous adipose tissue for aesthetic body contouring. SYNC comes with: Filtration device with Puregraft filtration bag; drain bag; slider; 2 Puregraft Combined Adapters; 2 syringes; MicroAire® PAL adapter; Mayo stand clamp.

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500-092-01 REV A

1. Ansorge 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. Zhu M, Cohen SR, Hicok KC, Shanahan RK, Strem BM, Yu JC et al. Comparison of three different fat graft preparation methods: gravity separation, centrifugation, and simultaneous washing with filtration in a closed-system. *Plast Reconstr Surg* 2013; 131(4): 873-80.