



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
420 Stevens Ave., Suite 220
Solana Beach, CA 92075

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858-348-8050

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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
420 Stevens Ave., Suite 220
Solana Beach, CA 92075
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: MUU

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
K132815	Puregraft 50 System	01/24/2014
K092923	Puregraft 250 System	01/06/2010
K113255	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

PRODUCT ORDER INFORMATION:

Puregraft 50 Bag System

SKU# 101-012-04

Catalog # 50/PURE

Volume Output: Up to 50 mL

Box contains: 5 individually packed, sterile 50mL bags

Puregraft 250 Bag System

SKU# 101-013-04

Catalog # 250/PURE

Volume Output: Up to 250 mL

Box contains: 1 sterile 250mL bag

Puregraft 850 Bag System

SKU# 101-014-04

Catalog # 850/PURE

Volume Output: Up to 850 mL

Box contains: 1 sterile 850mL bag



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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

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 intallation, 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 pcedure 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

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		2021 APC Assignment ³	2021 HOPD Payment ⁴	2021 ASC Payment ⁴
		Office ¹	Facility ²			
Fat Transfer						
15769	Grafting of autologous soft tissue, other, harvested by direct excision (e.g. fat, dermis, fascia).	--	\$490.95	5055	\$2,977.29	\$1,504.38
15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms and/or legs; 50cc or less injectate.	\$587.95	\$487.11	5055	\$2,977.29	\$1,504.38
+15772	Each additional 50cc injectate, or part thereof (list separately in addition to code for primary procedure). Use 15772 in conjunction with 15771.	\$183.89	\$142.36	--	No Payment	No Payment
15773	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands and/or feet; 25cc or less injectate	\$592.83	\$491.99	5054	\$1,622.74	\$819.95
+15774	Each additional 25cc injectate, or part thereof (List separately in addition to code for primary procedure)(Use 15774 in conjunction with 15773)	\$178.65	\$137.13	--	No Payment	No Payment
Breast Reconstruction						
19380	Revision of reconstructed breast	--	\$826.97	5092	\$5,237.29	\$2,193.27
19366	Breast reconstruction with other technique	--	\$1,457.30	5092	\$5,237.29	\$2,193.27
19499	Unlisted procedure, breast	n/a	n/a	5091	\$3,029.55	n/a

1. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1715-F>
 2. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1715-F>
 3. <https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpaymentasc-regulations-and-notices/cms-1717-cn>
 4. <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**.



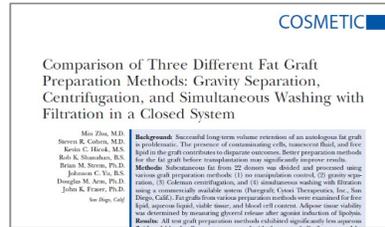
CLINICAL DATA

CLINICAL HIGHLIGHTS:

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.

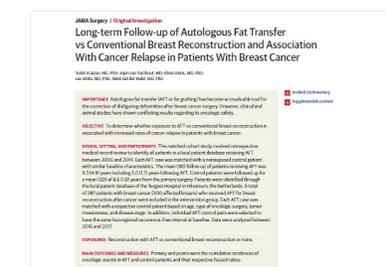
Key Takeaway: Puregraft retention is highly predicable independent of volume of injected fat when implanted in the breast.



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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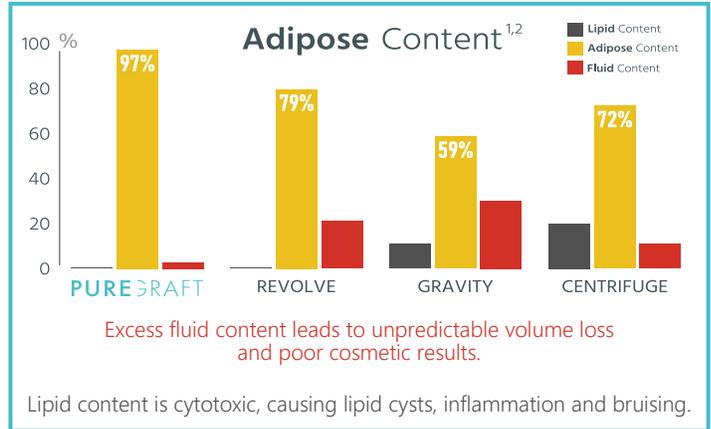
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COMPETITIVE INFORMATION

What competitive products are available?

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

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



	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

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Closed. Clean. Concentrated.

Our purification process begins and ends in the Puregraft bag.

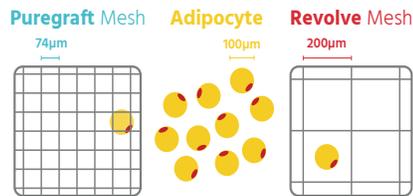
With the ability to harvest directly into Puregraft. No transfer of lipoaspirate, nor waste, until 97% purified fat is ready for injection, lowering the chance of cross-contamination, a leading cause of infection rates.



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.



1. Ansgore 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,