

Amalgatome® SD Wound Excision & Skin Grafting and Mesh|EX® Skin Graft Meshing Devices

Overview for Hospital Procurement



prepared by



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About Exsurco Medical: We advance the healing power of skin by providing innovative wound debridement/excision, skin grafting and skin graft meshing devices. We are committed to improving patient lives and outcomes by advancing innovation, product development, and the marketing of medical devices for healthcare professionals.

- FDA Registered Medical Device Manufacturer (Reg #: 3011981870)
- Compliant to 21 CFR 820-FDA GMP
- ISO 13485:2016 Registration (Reg #: FM 609546)



Our Mission: To enable our customers to advance the healing power of skin with pride, passion, and performance.

Our Values:



Value Added Services:

- **Meetings with Management:**
 - Return on investment analysis
 - Annual business reviews
- **Surgical Applications Team:**
 - Start-up; multi-shift or on-call support
 - Sterile Processing and Sterilization Training
 - Additional training and support visits throughout the year
- **Follow up visits as needed for:**
 - Equipment Inspection
 - Equipment Performance Review
- **OEM Repair/Service Department:**
 - Certified Technical Specialists are trained in the operation of our equipment and consumables. Our Service and Repair Order (SRO) provides customers with detailed estimates on repairs to ensure that the down time of our devices are minimized.
- **Warranty Packages:**
 - Manufacturer's warranty for one year
- **Additional Services:**
 - Clinical Support 24/7 with representatives
 - Web-based instructional videos

The Amalgatome® SD is a Wound Excision and Skin Grafting Device.
One Device. Multiple Capabilities.



There is a way to get **Real Results** for Excision and Grafting:




- ✓ Reducing [OR time](#) and patient [LOS](#)
- ✓ Recovering [consistently uniform skin grafts](#)
- ✓ Removal of damaged tissue [without over excising](#)
- ✓ Reliable device for autograft recovery even for [inexperienced hands](#)




*****Click the links for more source material and information.*****

2023 List Pricing:



Product Description	Part #	Additional Info	Unit	2023 Price
Amalgatome SD Skin Grafting and Wound Debridement Device (2" and 4")	SDSYSTEM024	Reusable Device	each	\$20,000.00
Amalgatome SD Excision Ring Blade 2"	X101789	Sterile, Disposable	5/box	\$1,526.00
Amalgatome SD Excision Ring Blade 4"	X101788	Sterile, Disposable	5/box	\$1,555.00

Top Brand Features Comparison for Dermatomes:

	<u>Exsurco Medical</u>	<u>Biomet Zimmer</u>	<u>Padgett (Integra)</u>
Company			
Name of Device	Amalgatome SD	Electric or Air Dermatome	Electric Dermatome
Intended Use	Designed to excise soft tissue in varying widths and thicknesses for skin grafting and wound debridement. It is indicated for open wounds, including wound site preparation (debridement and sharp debridement), removal of necrotic tissue and eschar (soft tissue excision), and autograft recovery.	Designed as a skin grafting instrument that is intended to provide variable graft thickness and width capabilities for use in plastic surgery and/or burn treatment.	Designed as a skin grafting instrument that is intended to provide variable graft thickness and width capabilities for use in plastic surgery and/or burn treatment.
Mechanism of action	System uses pneumatic powered device to power the handpiece and turn the gears that power the excision surface. The 360-degree cutting surface is a blade with geared teeth and ball bearings that allow device to spin at high RPM to power the cutting action.	The blade moved side to side (oscillates) at a high speed. The desired thickness of the graft is predetermined by the operator and set by using the pointer on the thickness guide scale. The actual thickness of the harvested tissue is highly dependent upon the operator technique and the condition of the tissue being harvested.	The blade moved side to side (oscillates) at a high speed. The desired thickness of the graft is predetermined by the operator and set by using the pointer on the thickness guide scale. The actual thickness of the harvested tissue is highly dependent upon the operator technique and the condition of the tissue being harvested.
	Pull toward body-Circular excision blade powers device as graft is recovered	Push away from body, blade oscillates in back/forth motion	Push away from body, blade oscillates in back/forth motion
Year Invented	2017	~1950s (image shown is current model, ~1990s)	~1950s (image shown is current model, ~1990s)
Skin Grafting and Wound Debridement	Yes, indicated for both procedures	No, grafting only	No, grafting only
Grafting Blade Type	Circular	Rectangular	Rectangular

	<u>Exsurco Medical</u>	<u>Biomet Zimmer</u>	<u>Padgett (Integra)</u>
Company			
Name of Device	Amalgatome SD	Electric or Air Dermatome	Electric Dermatome
Blades Required	Up to 2	Up to 6	Up to 6
Skin Graft Widths	2 inch and 4 inch (provided with 2 separate cutting heads)	1 in., 1.5 in., 2 in., 3 in. and 4 in. (determined by blade guard opening)	2 in., 3 in., 4 in., 5 in and 6 in (determined by blade guard opening)
Autograft Site Options	Anterior/Posterior Upper and Lower Legs, Anterior/Posterior Abdomen, Anterior/Posterior Upper and Lower Arms, Scalp	Anterior/Posterior Upper Legs, Posterior Abdomen	Anterior/Posterior Upper Legs, Posterior Abdomen
Graft Width Features	Handpiece comes with a 2" and 4" cutting head for varying width needs.	5 individual graft plates provided for surgeon to load onto dermatome over the blade to determine the needed width	5 individual graft plates provided for surgeon to load onto dermatome over the blade to determine the needed width
Depth Control Knob	Depth Control Knob located on top of the cutting head to adjust thickness	Depth control knob on side to adjust thickness	Depth control knob on side to adjust thickness
Depth Control Increments (Thickness)	0.000"-0.045", at 0.001" increments	0.000 to 0.030", in 0.002" increments	0.0025" to 0.040", in 0.002" increments
Split and Full Thickness	Both	Split Only	Split Only
Adults and Pediatrics	2" head allows for pediatric use	Blade guard determines cutting width, device is still 4" wide which can obstruct surgeon view.	Blade guard determines cutting width, device is still 4" wide which can obstruct surgeon view.
Weight (lbs.) & Length (in)	3-3.6 lbs. / ~8 in	2.6 lbs. / ~8 in	2.2-2.6 lbs. / ~8 in
Reusable Device	Reusable Handpiece/Cutting Head system with disposable 360 Deg geared excision surface	Reusable handpiece and blade guard attachments	Reusable handpiece and blade guard attachments
Sterile Disposables	Sterile ring blades, single use	Sterile blades, single use	Sterile blades, single use
Power delivery mode	Medical grade air or nitrogen	Electric Power Box/ Medical grade air or nitrogen	Electric Power Box/ Medical grade air or nitrogen
On/Off Switch	Yes, safety lever located on handpiece for On/Off	Yes, safety lever located on handpiece for On/Off	Yes, On/Off thumb switch

Standard Dermatome vs Amalgatome SD - Preventative Maintenance & Repair Costs Comparison

	Amalgatome® SD	Standard Dermatome
		
Customer Price	\$20,000	\$8,000
Indications for Use	Skin Grafting <u>and</u> Wound Debridement	Skin Grafting
Manufacturers Warranty (Year 1)	Yes	Yes
Manufacturers Warranty (Year 1) Serviced By	Exsurco	OEM or Third Party
After Year 1 Serviced By	Exsurco	Third Party
Calibration Required	No	Yes
Preventative Maintenance (PM) Required	Yes, annually	Yes, quarterly
PM Costs*	\$2,700	\$2,000
Minor (Minimum) Repair*	\$225	\$1,000
Major Repair*	\$900	\$3,000
Average Repair*	\$600	\$2,000
Average Repair Events Annually**	2	6
Average Repair Events Annual Costs	\$1,200	\$12,000
Shipping Costs for Repairs	\$200	\$600
PM Costs Annually	\$2,700	\$8,000
Pneumatic Hose Replacements	\$3,900	n/a
Shipping Costs for PMs	\$100	\$400
TOTAL COSTS FOR PMs and Repairs	\$8,100	\$21,000
	Amalgatome® SD	Standard Dermatome
Service Costs of Ownership		
Year 1 - Initial Purchase	\$20,000	\$8,000
Year 2	\$8,100	\$21,000
Year 3	\$8,100	\$21,000
Year 4	\$8,100	\$21,000
Year 5	\$8,100	\$21,000
Total Cost of Ownership Over 5 Years	\$52,400	\$92,000

Cost savings with the Amalgatome SD:

Over 5 years **\$39,600**
 Annually Years 2 to 5 **\$12,900**
 Annual % Savings **-61%**

*Data pulled from Third Party posted pricing.

**Expert customer interviews.

Amalgatome SD Cost Benefit Analysis:

1. **Supply Cost Model** – displays cost savings by switching to Exsurco related to changes in products and supplies.

- *Assumptions: 15 patients per month, discontinue use of standard dermatome and other disposable such as Versajet, and decrease in the use of scalpels and weck blades.*

Supply Cost Model		
Surgical Supplies used for Grafting/Debridement:	Current	Exsurco
Disposable Dermatome blades/procedure	6	2
Price per Dermatome blade	\$60.00	\$308.00
Additional Disposable 1/procedure: Ex: Misonix	0	0
Price per Disposable 1	\$450.00	\$0.00
Additional Disposable 2/procedure: Ex: VersaJet	1	0
Price per Disposable 2	\$850.00	\$0.00
Additional Disposable 3/Procedure: Scalpel (Weck)	30	4
Price per Disposable 3	\$2.70	\$2.70
Additional supply cost (if needed, otherwise N/A)	\$0.00	\$0.00
Total supply cost per procedure:	\$1,291.00	\$618.70
Supply cost savings per procedure with Exsurco:		\$672.30
Total Number Grafting & Debridement Procedures/Year		180
Annual supply cost savings		\$121,014

2. **Procedure Time Reduction Model** – displays cost savings by switching to Exsurco related to a reduction in procedure times in the operating room.

- *Assumptions: same as above model and 30% reduction in grafting time and 40% reduction in excision time.*

Procedure Time Reduction Model		
Surgical Time During Procedure:	Current	Exsurco
Total Avg. Time Spent Grafting (min)	30	21
Total Avg. Time Spent Excising (min)	75	45
Grafting procedures/yr	108	108
Excision procedures/yr	72	72
Total Grafting/Excision time (min/yr):	8640	5508
Cost per surgical min (\$/min):	\$150	\$150
Annual surgical cost for debridement & grafting procedures:	\$1,296,000	\$826,200
Annual surgical time cost savings:		\$469,800

Amalgatome SD Cost Benefit Analysis (continued):

3. Additional Revenue Potential Model – displays revenue potential by switching to Exsurco over standard dermatomes. The time saved by switching to Exsurco can then be filled with other surgical cases that result in potential revenue.

- *Assumptions: same as both above models and 50 more cases per year at \$2,500 earnings per surgical case.*

Additional Revenue Potential Model		
Surgical Time:	Current	Exsurco
Total Grafting time (min)	30	21
Total Excision time (min)	75	45
Grafting procedures/yr	108	108
Debridement procedures/yr	72	72
Total Grafting/ Excision time (min/yr)	8640	5508
Total surgical time reduction:	3132	
Average surgical case (min) (not including Turn over Time):		
		120
Number of potential surgical cases that can be added per year in the time saved by using Exsurco:		
		50
Hospital contribution margin per surgical case (\$/case)		
		\$2,500
Potential additional revenue:		
		\$125,000

4. ICU Length of Stay Reduction Model – displays savings potential by switching to Exsurco over standard dermatomes. The potential of one less trip to the OR could result in end stage grafting sooner, thus less ICU days.

- *Assumptions: same as all the above models and used data from *Foster K, MD, MBA, FACS; January 2019; The Health Economic Impact of Introducing a Novel Technology into the Burn Center: A Case Study of Autologous Cell Harvesting Device; 37th Annual North American Burn Society; Park City, UT*

ICU Length of Stay Reduction Model		
ICU Length of Stay	Current	Exsurco
Number of Procedures	3	2
Ave. Anesthesia Costs (\$4,706 x # Procedures) ³	\$14,118	\$9,412
Ave. Cost OR Trip (\$150/min x # Procedures) ³	\$47,250	\$19,800
Surgical Costs:	\$61,368	\$29,212
Surgical Cost Savings:		
		\$672
Potential length of stay shortening given less OR procedures - Average Cost Per Day (\$8,362³ x 3 Less ICU Days)		
		\$32,156
Total Potential Savings for ONE Patient		
		\$32,828
Potential at 15 patients:		
		\$492,425

The Mesh|EX[®] Skin Graft Meshing Devices.
Because the perfect graft deserves the perfect mesh.






A reusable device that processes the skin from a whole piece of tissue with no fenestrations (holes) into a piece of tissue with apertures into the graft, allowing it to expand up to four times its size. This allows for greater surface area able to be covered with the graft. System may allow for changing meshing ratio or size of aperture in the graft, and max width of 4.25" graft.

The Mesh|EX Sterilization Tray will consist of an internal instrument basket with component placement bracketry, handles, and a lid. The brackets to hold the individual components are configured within the sterilization tray specifically for securing the Exsurco Mesher Components.

2023 List Pricing:

Product Description	Part #	Additional Info	Unit	2023 Price
Mesh EX Kit Includes:				
<ul style="list-style-type: none"> Sterilization Tray with lid 3 cutting rollers for graft expansions of 1:1, 2:1 and 3:1 	X101892	Reusable Device	each	\$20,000.00
Mesh EX Graft Carrier, 14" long	X101886	Sterile, Disposable	20/box	\$700.00

Top Brand Features Comparison for Meshers:

Company	Exsurco Mesh EX 	Biomet Zimmer 	Brennen (previously Molnycke, now Stellen Medical) 
Year Launched	2023	1969	~1990
General Features			
Gear Ratio(s)	One Mesher, 3 interchangeable expansion ratios included: 1:1, 2:1, 3:1	One Mesher, 4 interchangeable expansion ratios included: 1.5:1, 2:1, 3:1, 4:1	All sold separately, expansion ratios available, 1:1, 2:1, 3:1, 4:1, 5:1, 6:1
Mesh Pattern Action	Cutting Knives	Cutting Knives	Punched slits, not cutting
Skin Graft Thickness	0.005"-0.020"	No limits listed	0.010"-0.015"
Device Lubrication Required?	No	Yes	Yes
Meshed Graft Widths Max	4.25"	4"	4.5"
Handle/Crank design	Dual direction continuous crank	One direction ratchet	One direction ratchet
Cutting Roller Protection	Larger diameter bearings	None	Cannot be removed, secured within the device
Disposable Carrier Required?	Yes, carriers are one/patient	Yes, carriers may be one/graft	No
Disassembly Required for Sterilization?	No	No	Yes
Sterilization Container Type	Casket	Blue Wrap Tray	Casket or Blue Wrap Tray
Sterilization Container Included	Yes	Yes	No

Mesh|EX Cost of Ownership Analysis:**Meshers (Initial Capital Investment)**

Skin Graft Mesher
 Skin Graft Mesher Ratio 1:1 Only
 Skin Graft Mesher Ratio 2:1 Only
 Skin Graft Mesher Ratio 3:1 Only
 Skin Graft Mesher Ratio 4:1 Only*
 Sterilization Container

*Exsurco's 3:1 very close to Brennen 4:1.

Mesher Carriers (Disposable Investment)

Assuming 15 meshing cases per month
 Standard Carrier 20/box at \$35.00 each
 Standard Carrier 10/box at \$50.00 each¹

Service Needs

Service Events @ \$1,800.00 each x 3 Mesher/Rollers
 Service Events @ \$1,800.00 each x 3 Mesher/Rollers
 Service Events @ \$2,600.00 each x 3 Meshers

Total Investment Year 1²**Total Investment Each Subsequent Year³****Total Cost of Ownership over 7 years⁴**

	Mesh EX	Brennen	Zimmer
			
	\$20,000 included	\$0	\$10,500
		\$9,000	\$4,000
		\$9,000	\$4,000
		\$9,000	\$4,000
		\$9,000	\$4,000
		\$7,500	included
	\$20,000	\$43,500	\$26,500
	Mesh EX¹	Brennen	Zimmer
	Annual Price	Annual Price	Annual Price
	\$6,300	\$0	\$0
	\$0	\$0	\$27,000
	\$6,300	\$0	\$27,000
	Mesh EX	Brennen	Zimmer
	2 Events/Yr	2 Events/Yr	2 Events/Yr
	\$10,800	\$0	\$0
	\$0	\$0	\$10,800
	\$0	\$15,600	\$0
	\$10,800	\$15,600	\$10,800
	\$26,300	\$59,100	\$64,300
	\$17,100	\$15,600	\$37,800
	\$128,900	\$152,700	\$291,100

Calculations, References and Assumptions:

Prices subject to change. This is for example purposes only. There are other replacement parts and services based on wear & tear.

(1) Note: Mesh|EX carriers are one/patient, Zimmer may be one/graft. Assumed 2 carriers per case.

(2) Assumes no damage causing a void to the warranty for Mesh|EX. Also assumes that neither Brennen or Zimmer offer a product warranty.

(3) Subsequent year costs are carriers and service needs.

(4) Assumes product life of 7 years. (NOTE: Product end of life has not been defined for the Mesh|EX device.)

Supporting Documents Included as Attachments:

- Amalgatome SD Value Analysis Team Slide Deck 2023
- Mesh|EX Product Intro Slides 2023
- Amalgatome SD, Reimbursement Coding Guide
- Amalgatome Sole Source Provider Statement