Reprocessing Capabilities of Newly Approved Devices for Use in Minimally-Invasive Aesthetic Procedures

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Introduction

- Single-use medical devices are commonly used in aesthetic procedures, contributing to medical waste and the potential for increased costs and environmental impact.
- Reprocessing of medical devices may reduce both cost and environmental impact.
- The landscape of new devices approved for reprocessing in aesthetic surgery is less known.

Objectives

- To comprehensively identify FDA-approved reprocessing capabilities of devices used in minimally-invasive aesthetic procedures and evaluate gaps and recommendations for potential reprocessing innovation.

Methods

- Aesthetic medical devices and their design features were identified using the publicly-available FDA Releasable 510(k) Database from January 2018 - April 2023 using the product codes GEI, GEX, and OLI.
- Only devices that posed a high risk for infection in the FDA's Reprocessing Final Guidance Appendix E were required to provide reprocessing capability information.
- Reprocessing capability was defined as inclusion of approved reprocessing procedures in device summaries.
- Single-use devices were those that included any single-use components and cannot be reprocessed.
- Costs were obtained from medical device company websites.

Table 1. Device Reusability & Cost

Device category	Device #	% reuse-able	% with cost data	Avg. cost: single-use	Avg. cost: reuse-able	Avg cost: overall
High -infection-risk						
Skin tightening	40	**2.5%**	82.5%	$34,395	$35,750	$34,436
Skin resurfacing	20	**5%**	70%	$38,211	$89,995	$41,910
Cellulite treatment	11	**81.8%**	63.6%	$86,329	-	$86,329
Full-body systems	6	33.3%	100%	$48,292	$20,000	$38,862
Non-invasive lipo.	5	**100%**	20%	-	$15,629	$15,629
Lasers						
Hair removal	54	16.7%	51.9%	-	$25,709	$19,527
Tattoo removal	20	10%	40%	-	-	$47,989
Skin resurfacing	55	12.7%	54.5%	$44,000	$56,283	$32,394
Vascular lesions	6	16.7%	66.7%	-	-	$8,775
Vein treatment	2	**0%**	50%	$36,829	-	$36,829
Combo system	83	3.6%	30.1%	$77,333	$12,210	$49,695
UV Therapy	4	25%	25%	-	$9,850	$9,850
Accessories	19	**0%**	36.8%	$1,454	-	$2,043
Non-invasive lipo.	9	11.1%	55.6%	-	-	$16,445

Results

- There were 334 applications for aesthetic devices between 2018-2023, representing 2% (334/16723) of total applications.
- High-risk devices represented 82 (24.6%) applications
- Cellulite treatment (81.8%; 9/11) and non-invasive fat lipolysis devices (100%; 5/5) represented the lowest proportion of single-use devices
- Conversely, 2.5% (1/40) of skin tightening devices, 5% (1/20) of skin resurfacing devices, and 33.3% (2/6) of full body systems had reprocessing capabilities.
- There were 252 (75.4%) laser device submissions.
- None of the laser accessories (0/11) or vein treatment devices (0/2) could be reprocessed.

Conclusion

- Reprocessing capabilities for newly approved high-infection-risk devices in aesthetic surgery is variable.
- New skin resurfacing and tightening devices have the least reprocessing potential,
- Investigation is needed into the cost of purchasing devices with reprocessing potential, coupled with the cost of reprocessing itself, versus the cost of using single-use alternatives.
- Plastic surgeons should consider the reprocessing capabilities of devices used within their practice.
- Device manufacturers should consider ongoing design initiatives to enhance reprocessing capabilities in future device design.