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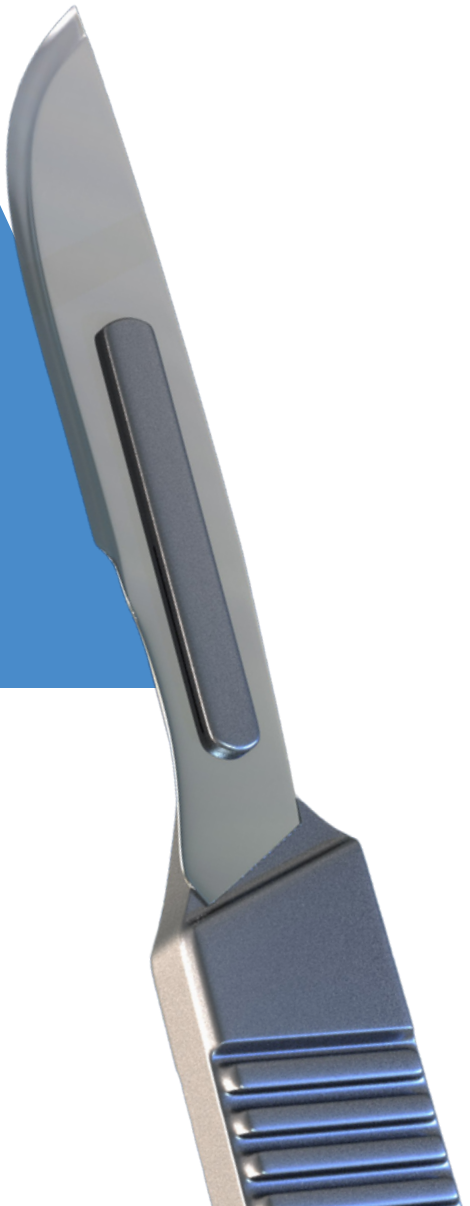
WHITEPAPER

Superior Surgical Efficiency and Outcomes: The Economic Advantages of Planatome® Nano-Polished Surgical Blades



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Executive Summary

This whitepaper provides an economic analysis and justification for hospital executives, administrators, and clinicians to support the adoption of Planatome® Nano-Polished Surgical Blades. We focus on the benefits of clinical superiority and enhanced operational efficiency through improved performance, durability, procedural efficiency, safety, and adherence to ESG principles.

The economics are further supported by surgeon testimonials throughout this document. The advent of the Planatome Nano-Polished Surgical Blade marks a significant leap in surgical instrument technology. Registered in 2018 as a 510(k) exempt Class I surgical instrument, it stands as the first true advancement in scalpel technology, which has seen minimal innovation since 1915.

Clinical Superiority: Impact on Healing

Nano-polished blades produce clinically superior outcomes over conventional blades. Planatome blades are designed to minimize tissue trauma, evidenced by a 90% wound closure rate within 72 hours compared to only 10% for conventional blades. The reduced inflammatory response associated with these blades correlates with less postoperative pain and accelerated healing, substantially improving patient outcomes.[i]

For details of the clinical benefits provided by the Planatome blade, reference our clinical whitepaper: "Superiority of Nano-Polished Surgical Blades: An Analysis of Their Impact on Healing and Implications for Postoperative Outcomes"

(https://planatome.com/nano-polished-surgical-blades-white-paper/)

[i]Douglas M, Jeffcoat KL. Whitepaper: Superiority of Nano-Polished Surgical Blades: An Analysis of Their Impact on Healing and Implications for Postoperative Outcomes. Planatome Internal Company Document. 2023.

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Surgical Performance

Control and Precision

In the surgical environment, control of the cut during use is paramount to positive outcomes. When surgeons cut, the blade must respond with precision, allowing for a user to determine and maintain magnitude and direction of cut, without undue force required by the user. As a blade dulls, the increase in force needed to maintain the depth of the cut can impede control and precision. The blade feeling "dull" relates directly to this reduced performance over the use of the blade.

In a controlled benchtop environment, applying an identical force on Planatome and conventional blades, in all instances, resulted in Planatome blades exhibiting improved performance or "sharpness", by producing deeper and more consistent cuts throughout the use-life of the blade.[ii] In comparison to the conventional blades Planatome excels, providing 23-85% improved depth of cut through 24.5" of cut length. (Figure 1)

Depth of Cut (in) at Cut Distance

Planatome provides 23-85% improved depth of cut throughout a 24" cut distance.

	@ 1.75" Cut Distance	**@ 12.25" Cut Distance**	**@ 24.5" Cut Distance**
Planatome Cut Depth	0.0351"	0.0112"	0.0053"
Conventional Cut Depth	0.0271"	0.0024"	0.0008"
Average Delta	0.0079" **23% Improvement**	0.0088" **78% Improvement**	0.0045" **85% Improvement**
p-value (.05 significance)	*5.51E-06*	*5.36E-10*	*1.18E-06*

Figure 1

Daria Hamrah, DMD, FAACS, FADSA

"Love the blades! Definitely better than the standard blades that I've been using! They feel sturdier and don't bend as easily. Cut and carve with less effort and greater precision, as you can cut with more gentle pressure."

[ii] Dale N, Jeffcoat KL. Benchtop Performance and Durability Testing of Planatome blades versus Conventional blades. Planatome Internal Company Document. 2024.

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Economic Benefits

Durability & Cost Savings

As cost pressures continue to increase within the healthcare industry, hospital administrators and economists are continually focused on the value of the products and services they recommend to their clinics. The drive to increase use and efficiency and lower healthcare costs while improving the lives of those they serve is critical to running a clinically focused, economically successful business.

Recent durability testing has revealed that Planatome blades exhibit superior durability, maintaining an optimal cutting edge longer than conventional blades and reducing blade exchange frequency. This efficiency translates to overall cost savings by reducing procedural interruptions, which increases surgical staff focus, reduces operating room time and excess inventory requirements.

Steven Fagien
MD, FACS

"I have opened up multiple #15 conventional scalpel blades and they're just completely dull from the start. It is something other surgeons as well as I have experienced, so you need to replace it with a new one. I think in my practice, the incremental increase in cost of whatever those tools might be is worth it to my patients and for me because if ultimately, they're happy, then I'm happy."

Anthony A Admire,
MD, FACS

"All the Planatome blades, of every size perform consistently well with repeated use, therefore less blades need to be switched out per case, thus reducing costs."

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Durability & Edge Consistency

During extended cutting, conventional blade damage is multiplied and cutting efficiency or durability is lost as blades wear. Manufacturing-based defects in the blade edge can dull and flake off, resulting in inconsistent edge geometry, flat spaces, and micro-cavities throughout the blade edge. In a clinical setting, these defects in geometry result in the tearing, ripping, and adherence of cells within these micro-cavities, which further reduce the performance of the blade feel or “sharpness”.

Planatome blades are nano-polished utilizing Chemical Mechanical Polishing (CMP), a process from semiconductor manufacturing, which results in a significantly improved and near molecularly perfect surface finish during the manufacturing process. By definition, an overall smoother finish means less imperfections and variation along the edge of the blade. Unlike a conventional blade, the smooth and consistent finish along nano-polished blades means a significant improvement in durability. Planatome blades wear in a more controlled fashion, without the large defects and effects of the conventional blade edge design. (Figure 2)

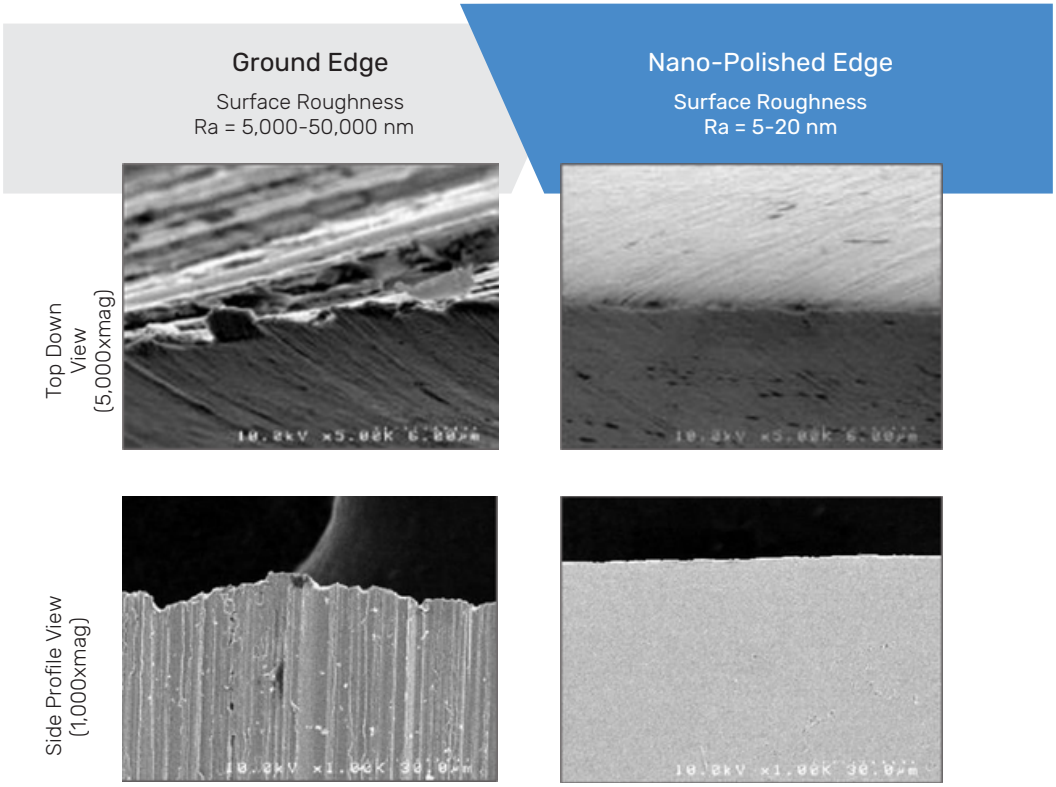

Figure 2

Blade Durability Planatome vs. Conventional

Planatome blades tested against conventional blades exhibit a 4.7x higher durability within a controlled benchtop testing environment. (Figure 3) The patented finish allows Planatome blades to cut an average of 76.7" versus 16.4" by the conventional blades before failure. (Figure 4)

Improvements in blade durability provide a two-fold value improvement to a hospital/clinic supply chain by (1) reducing the total number of blades required for the surgical procedure, and (2) reducing inventory, both in the hospital storage as well as in the surgical suite, thereby reducing total purchasing quantities and minimizing inventory holding cost.

Average Cut Length to Failure (in)

Planatome provides a 4.7x improvement in durability over conventional blades.

Planatome	76.7"
Conventional	16.4"
Average Delta	60.3" **4.7x Improvement**
p-value (.05 significance)	*1.49E-08*

Figure 3

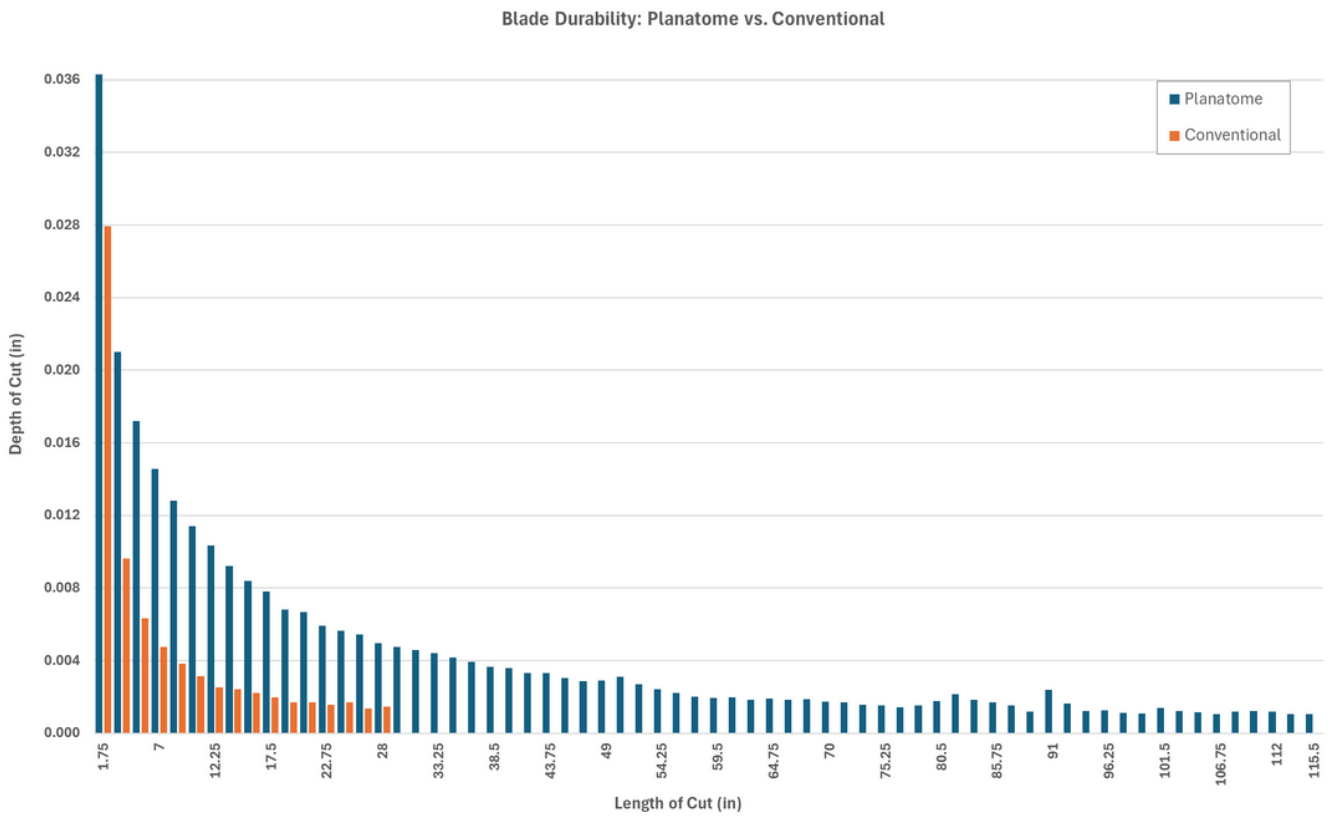

Figure 4

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Surgeon Testimonials: Validation through Real-World Insights

To further examine the value of the nano-polished finish on the surgical blade, the following surgeon testimonials provide real world context and validity to the benchtop durability testing results noted above. They have been acquired from experienced surgeons, in multiple human cases, and within multiple tissue types. We continue to see universally positive testimonials regarding improved durability, performance, and control.

Sachin Shridharani, MD, FACS

"Better ergonomics – ease of use to create incision; good feel, clean incision. Clean incision is a better cut. More durable means using fewer blades. As an example, I performed a bilateral thigh lift with one Planatome vs 3-4 standard scalpels. It's a paradigm shift on how you use a blade."

Dr. Atanu Biswas, MD

"There is a clear difference. I used only one #10 and one #15 Planatome blade for a breast reduction, which usually requires 5-10 regular blades per case. I feel that use of one Planatome blade is the equivalent to 7-10 conventional blades. The handling characteristics are much better. It's weird since most of us just take it for granted that a blade is a blade, but there is a clear difference."

James Kondrup, MD, FACOG

"When I'm doing a myomectomy and having to be more precise with the scalpel, I go through many blades, sometimes 15, 20, up to 25 blades. This requires removal and changing each blade because they dull within a few minutes. When I did my last myomectomy where I used the Planatome blades the Planatome blades were lasting longer. If you can have a blade that continues on, you don't have to use as many blades, make as many changes, and you're golden in that situation!"

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Operating Room Efficiencies

Cost Savings

Operating rooms are costly to run, with inflation-adjusted variable costs averaging $26.58 per minute depending upon the procedure and geographic location.[iii] As previously discussed, healthcare costs are increasing year over year, and it is imperative for hospital and clinical administrators to evaluate new products with an eye for improved cost efficiency and sustainability while maintaining and improving clinical outcomes.

Table 5 provides a breakdown of the downtime and efficiency loss in USD for various scalpel and blade exchange scenarios commonly seen in the surgical theater. The average number of conventional blades used varies per surgical procedure type and complexity, however in product validation studies when specialties requiring heavy blade use are prevalent (i.e. plastics), surgeons may require up to 15 blade exchanges per procedure.[iv]

Due to the high cost of operating room time, blade exchanges can add up to significant and often overlooked inefficiencies, increasing cost to the hospital or clinic. For example, with a 4-blade exchange, costs can increase by $8.86 to well over $212.64 per procedure due to the increased blade handling and exchanges. (Figure 5)

As durability for the Planatome blade is 4.7x that of the conventional blade, 4 exchanges, would be required with conventional blades to achieve the combined cutting distance of a single Planatome blade. Planatome blades offer significantly improved durability, leading to cost savings by reducing the number of blades used and exchanged during surgeries. Setting aside the primary clinical benefits, this durability difference alone puts the Planatome blades on economic parity with conventional blades. This coupled with superior patient healing and reduced postoperative complications is all upside to patients, surgeons, medical staff, and healthcare facilities.

Total Downtime w/Conventional Blade vs Planatome

	Time per Occurance (sec)	Total Downtime w/Conventional Blade (sec)	Surgical Room Efficiency Loss ($USD)*
Acquire full scalpel (blade and handle) from w/in sterile field & exchange	5.0	20	$ 8.86
Replace blade on handle from w/in sterile field & exchange	15.0	60	$ 26.58
Acquire blade from inside surgical room, transfer to sterile filed, replace blade on handle & exchange	25.0	100	$ 44.30
Acquire blade from outside surgical room, replace blade on handle & exchange	120.0 +	480 +	$ 212.64 +

*2014 inflation-adjusted to 2024

Figure 5

[iii] Childers CP, Maggard-Gibbons M. Understanding Costs of Care in the Operating Room. JAMA Surg. 2018;153(4):e176233.

[iv] Jeffcoat KL. Validation of Planatome Surgical Blades in Human Cases. Planatome Internal Company Document. 2023.

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Safety in the Operating Room: Blade Exchanges

As healthcare workers, we all strive to improve upon the clinical outcome and lives of our patients. When occupational dangers and harms interfere with the surgical process, impacting downtime or worse yet, impact to the healthcare workers safety, it can not only be operationally impactful, but physically and/or psychologically impactful to those providing care. Fear of occupational harm due to sharps is always a concern in the operating room.[v] 30.3% of all sharps injuries occurred in the OR, with reusable and disposable scalpels together causing 7.3% of injuries across all environments, placing this type of device third among all injury-causing sharps. Further, "...nearly two thirds (64.4%) of injuries from scalpel blades occurred after use or during passing, disassembling, or disposal." [vi]

Figure 6 highlights the range of costs associated with management of occupational exposures to blood and bodily fluids from scalpel cuts.

Operating room safety can be enhanced with fewer blade exchanges, less movement in the surgical field, and by reducing surgical procedure interruptions. Planatome's 4.7x improved durability over conventional blades, results in less operating room exchanges and leads to improved focus on the operating field with reduced opportunities for occupational exposures due to unintended and unnessecary healthcare worker impacts.

Cost of the Management of Occupational Exposures to Blood and Body Fluids from Scalpels [vii]

	Cost ($USD 2024)*	
	Mean	Range
Overall costs to manage reported exposures	-	$ 119 - 8,109
Exposures to patients infected with human immunodeficiency virus (HIV)-infected source patients including those coinfected with hepatitis B or C virus	$ 4,117	$ 1,520 - 8,109
Exposure to patients infected with unknown or negative infection status	$ 630	$ 119 - 1,442
Exposure to patients infected with hepatitis C virus	$ 1,090	$ 312-1,435

*Adjusted for inflation 2003 to 2024

Figure 6

[v] Vose, J. G., & McAdara-Berkowitz, J. (2009). Reducing scalpel injuries in the operating room. AORN journal, 90(6), 867-872.

[vi] Jagger, J., Bentley, M., & Tereskerz, P. (1998). A study of patterns and prevention of blood exposures in OR personnel. AORN journal, 67(5), 979-996.

[vii] O'Malley EM, Scott RD, Gayle J, et al. Costs of Management of Occupational Exposures to Blood and Body Fluids. Infection Control & Hospital Epidemiology. 2007;28(7):774-782.

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Sustainability for the Future

Reducing Operating Room Waste

Every year, the amount of medical waste generated from healthcare facilities increases at an astounding rate.[viii,ix,x] Since 1992, a 15% annual increase in the waste produced by US hospitals, will result in an estimated 110.4B lbs of waste by the end of 2024.[xi,xii] Of the total amount, 70% of the volume of waste in the hospital will originate from the OR.[xiii,xiv] It is imperative that device manufacturers support administrative staff in upholding Environmental and Safety Guideline (ESG) objectives.

With an estimated 5 billion blades sold worldwide per year, waste from these blades quickly add up, resulting in ~10.56MM lbs of medical sharps and packaging waste per year. As the Planatome blade has the potential to increase durability by 4.7x or more, OR efficiencies not only increase, but the total handling and waste generated are significantly reduced. A conservative 1:4 ratio of Planatome blade to conventional blade usage provides an opportunity to reduce sharps and general packaging waste by over 75% in ORs. Worldwide this equates to a staggering 7.92MM lbs a year that can be reduced, resulting in less environmental impact and hospital waste disposal cost.

[viii] Denny NA, Guyer JM, Schroeder DR, Marienau MS. Operating Room Waste Reduction. AANA Journal. 2019. 87(6), 477-482.

[ix] Eckelman MJ, Sherman J. Environmental impacts of the U.S. health care system and effects on public health. PLoS One. 2016;11(6):e0157014.

[x] Mosquera M, Andrés-Prado MJ, Rodríguez-Caravaca G, La tasa P, Mosquera ME. Evaluation of an education and training intervention to reduce health care waste in a tertiary hospital in Spain. Am J Infect Control. 2014;42(8):894-897.

[xi] Campion N, Thiel CL, Woods NC, Swanzy L, Landis AE, Bilec MM. Sustainable healthcare and environmental life-cycle impacts of disposable supplies: a focus on disposable custom packs. J Clean Prod. 2015;94:46-55.

[xii] Demark RE Jr, Smith VJ, Fiegen A. Lean and green hand surgery. J Hand Surg Am. 2018;43(2):179-181.

[xiii] Martin DM, Yanez ND, Treggiari MM. An initiative to optimize waste streams in the operating room: RECycling in the Operating Room (RECOR) Project. AANA J. 2017;85(2):108-112.

[xiv] Rigante L, Moudrous W, de Vries J, Grotenhuis AJ, Boogaarts HD. Operating room waste: disposable supply utilization in neurointerventional procedures. Acta Neurochir (Wien). 2017;159(12):23372340.

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Economically Viable Future of Advanced Surgical Care

Incorporating Planatome Nano-Polished Surgical Blades improves patient care while advancing and achieving economic and operational goals. This technology promises substantial clinical benefits, operational efficiencies, safety enhancements, and ESG compliance, making it a prudent choice for healthcare facilities aiming to lead in surgical innovation and economic performance.

Seldom does a product come along that not only improves upon the clinical impacts to patients but can also lead to a safer environment and more cost-efficient operation. Planatome technology stands to positively impact patients and healthcare facilities worldwide.

Planatome Technology provides improved performance, durability, economical efficiencies, and safety to clearly benefit hospitals and clinics worldwide.