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INTRODUCTION

No other tool best personifies the surgeon's commitment to the profession as the scalpel. A surgeon may be an excellent diagnostician with the warmest bedside manner, but the ability to wield the scalpel and other tools in the armamentarium to deliver the outcomes a patient needs sets a practitioner apart in a medical specialty. Likewise, the sharpness of a scalpel is the most important aspect of the instrument itself, and it can have a major impact on the overall experience of a surgery, whether it is removing a suspicious skin growth in the office or doing facial reconstruction in the hospital operating

room. While the degree to which a scalpel is used in each and the importance of a surgeon's scalpel performance varies considerably by procedure, all surgeons can agree that they want the best tools available to deliver the best results for their patients while minimizing their own frustration.

Southmedic

Three main stakeholders have an interest in the sharpness of a scalpel during a surgery: the patient on whom it is used, the surgeon who uses it, and the

healthcare facility that purchases and stocks the product. The goal of this paper is to show how the relatively small but critical item of a surgical scalpel can have a major impact on overall satisfaction with the case for all concerned parties. The cost of a scalpel blade is nearly inconsequential compared to the overall cost of performing surgery, but more importantly, the choice of blade can have unforeseen consequences that healthcare facilities should take into consideration.

As a global market research and consulting company with a major focus on healthcare technology, Frost & Sullivan has been tracking medical device trends for decades. This paper will describe the decades-long experience that surgeons have had with Southmedic's scalpel blades, which they claim are able to deliver the most consistently sharp incisions of any blades they have tried in their careers. To better understand why physicians who have adopted these blades are so loyal to them, Frost & Sullivan interviewed five surgeons specializing in plastic, orthopedic, vascular, and ear, nose and throat (ENT) surgery who have been using Southmedic blades almost exclusively in recent years. According to Southmedic, sales in the United States for scalpel blades could be as high as \$150 million in 2020 with tens of millions of blades sold every year. Choosing the right blades is important not only to surgeons themselves but also the healthcare system as a whole.



Southmedic: A Commitment to Quality and Innovation

With almost 40 years of experience in developing innovative healthcare products, Southmedic was established in 1983 in Barrie, Ontario, to manufacture the Anaeslock, a vaporizer interlock system developed by Lee McDonald, the founder and current CEO of the company. Today, Southmedic is a privately held company with a portfolio of proprietary respiratory, surgical, PPE, and wound management products. The company manufactures and distributes medical devices to 80 countries, including the United States. Southmedic has a demonstrated commitment to developing innovative products, while continuing to drive the adoption of technologies and processes to improve its current portfolio.

The company takes pride in the fact that it places a significant focus on in-house research and development. Ken Noseworthy, chief technology officer and senior vice president of sales at Southmedic, states, "We understand how important it is to ensure every aspect of our business is performed at the highest level. We take our role in the healthcare system very seriously because we know what is at stake."

In 2008, Southmedic acquired the medical device assets of American Safety Razor's blade and scalpel division. The company integrated operations into its own facilities, while at the same time perfecting the blade sharpening and polymer coating process that make them the sharpest on the market. The stainless steel for the blades is stamped and heat treated in the United States, while all remaining steps are completed by Southmedic in its own clean room facilities in Canada. The blades are sharpened and the proprietary polymer coating is applied. Southmedic attributes the sharpness of its blades to the unique formulation and application of the anti-drag coating and not to the stainless steel metal from which its blades are manufactured.



Once the blades are manufactured, the company runs them through a fully automated cleaning process and a batch quality control check before final packaging. The molding of the disposable handles and sterilization of the blades is performed at Southmedic, whereas the scalpels are coordinated by Southmedic to be sterilized by an accredited laboratory. The scalpels are sold by themselves for use with a reusable handle as well as part of an integrated design with single-use handles.

David Squires, the director of engineering at Southmedic, explains, "We developed a one-of-a-kind rotary blade grinding CNC [computer numerical control] piece of machinery. All we have to do is load the stamped blades and it grinds the blade down, hones it, resharpens it, and produces a finished blade. The nice thing about being CNC controlled is that it can make minute changes up to .0001 mm on any component of the grind. It gives us infinite changeability to anything on that blade." The company has a fully automatic cleaning process for the blades as well.

Looking under a microscope, a blade should not have nicks or a serrated edge. A sharp blade with a smooth edge will result in an incision with less tissue drag and trauma. Southmedic's precision grinding technology and advanced polymer coating provides an improved cutting





view under 700x magnification

edge to its stainless steel scalpels and blades. Squires states that the company's primary focus is on perfecting the factors that contribute to a sharp blade since there is no international standard to accurately test the sharpness of a blade. Among the factors that Squires says the computer controls are the CNC machinery grind rate, the cleanliness and type of the grinding wheels, and the precision in the coating application, and the regular maintenance of the machinery.

Dr. Jerry Wong, a plastic surgeon in private practice focusing on hair restoration, explains, "The less friction the blade has as you push it through the skin means there is no resistance or sticking to the sides of the scalpel, which means you can achieve a clean release. That puts less distortion on the skin as the blade slides through the skin as you cut it." In contrast, non-coated blades cause an irregular or serrated cut that may require redundant cuts to rectify.



Non-coated blades cause an irregular or serrated cut that may require redundant cuts to rectify.

— Dr. Wong, plastic surgeon in private practice

Beyond just good design and manufacturing, Southmedic's blades have lived up to their reputation because of the quality control processes the company supports. Every batch of blades is scrutinized under a microscope for angle and sharpness and recorded in batch records. These records are traceable down to the original certification of the steel. The blades are stored in an environmentally controlled room to prevent atmospheric damage to the steel since Southmedic has found that even minor changes to temperature and humidity can affect a blade's sharpness.

Benefits to Patients

While the scalpel blade is a surgeon's tool, the patient is the end beneficiary of the better incisions that it can deliver. A sharper scalpel can offer better accuracy and more precise incisions to achieve the primary surgical objectives. Of course, patients are not generally consulted on which surgical blades are to be used on them, so it is up to the surgical team and the facility providing the care to operate in their best interest by sourcing superior products.

"Patients judge the quality of their surgery on the appearance of their skin incision. The beauty of the Southmedic blade is that it does not produce chatter with curved incisions, such as around the umbilicus. With other blades you get scalloping around an incision like that. With the Southmedic blade you get better appearance and healing because you cause less tissue harm as you go," according to Dr. Sandy McDonald, vascular surgeon at the Royal Victoria Regional Health Centre in Barrie.

McDonald continues, "What matters the most for the patient is the quality of your work. The only part the patient sees is the skin incision, so having a clean cut that is able to be closed neatly is important. The sharper the blade, the less pressure you have to apply so you are able to have more precision."

Surgeons interviewed by Frost & Sullivan were confident that using sharper scalpel blades allowed them to stay more focused as surgeons, thereby ensuring that they delivered the best results for their patients. Most noted that a sharper blade ensured that they could deliver the best cosmetic appearance for an incision scar. It was clear that the importance of a sharp scalpel blade varies depending on the type of surgery. Surgeons remarked that procedures involving small, complex incisions of the skin, especially around the face, were where sharp scalpels were the most important. Some surgeries require a physician to use a blade throughout the entire case, whereas in other procedures there might only be a single initial incision whereupon the surgeon continues with radiofrequency ablation, scissors, or other tools. Naturally, those



procedures where a surgeon uses a scalpel more frequently will demand a superior product.

Noseworthy states, "Southmedic blades impact the entire patient and clinical experience. By providing premium blades and scalpels to hospitals, the physician using our blades and scalpels have confidence they are using the best available products to help give patients the best possible outcomes. Improving the patient experience can have long-term implications for cost reduction, lessening strain on the entire healthcare system."

A surprising finding was how regularly surgeons reported encountering new scalpel blades that were duller than normal when pulled directly from their packaging. While some surgeons opted to still use those blades but to do so carefully, others threw the blades away in favor of a replacement. In addition to wasted blades and time, this uncertainty related to the consistency of the blade's sharpness contributed to the stress that surgeons felt when initiating their procedures. The physicians interviewed emphasized that a happy and focused surgeon was in the best position to deliver superior results to the patient.

Surgeons interviewed by F&S reported that before using Southmedic blades, approximately 10% of new blades pulled from their box did not feel as sharp as the other 90%.

10%

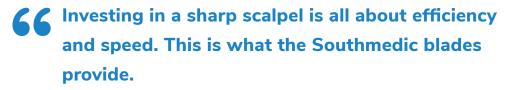
Benefits to the Surgeon

The use of a scalpel and the relative importance of the skills associated with it may vary by surgical specialty, but every surgeon places great interest in making the best possible cut. Surgeons expect the best from themselves, their team, and the tools they use to care for their patients. No other instrument can better demonstrate a surgeon's skill than the scalpel. If a surgeon lacks confidence in the ability to make precise incisions, it can have a ripple effect across the entire case.

Surgeons are trained to pay attention to details, because they know that sometimes a seemingly small variation that only they can detect can mean the difference between life and death. Noseworthy mentions, "While in some industries you might have to see it to believe it, when you are working with surgeons, it is important that you allow them to feel the difference too. We show the physician a microscopic zoomed photo of tissue after a cut with a Southmedic blade versus a cut with a competitive product (see image on page 5). Then we have them perform a cut test on a piece of felt. Not only can the surgeon feel the reduced drag when using our blades, they might be able to hear it too."

A high-quality scalpel blade delivers a number of benefits for the surgeon and the team. Foremost, superior patient outcomes can be expected due to more precise cuts. Specialties such as otolaryngology, dermatology, and vascular and plastic surgery are especially reliant on making precise incisions to provide the best outcomes. Dr. Murray Allen, a plastic surgeon and assistant professor at the University of Ottawa, believes that "a sharp blade has more value in smaller procedures that you might often do in the office or surgery center because you want to have maximum control compared to large incisions in 'hospital surgeries' where the incisions are larger, but in many ways simpler. This is true especially when it comes to sensitive areas like the skin on the eyelid or other similar places."

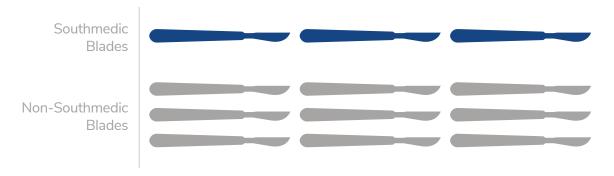
Dr. Wong expands on this point regarding the hair transplant surgeries he performs: "If a scalpel is dull it will depress the skin and that bends the follicle into the skin. When that happens, you end up with a transection that risks cutting the follicle. With hair transplantation, you don't want to cut the follicle adjacent to the strip of skin because it causes the scars to look wider because you don't have adjacent hair growing next to each other." He goes on to explain that a sharp blade is critical in his work because in his cases the angle of the blade cannot be more than five degrees off in order to get the exact transection into the skin on the patient's scalp.



— Dr. Allen, plastic surgeon and assistant professor at the University of Ottawa

Sharper blades also allow for faster cases and usually fewer blades consumed. For example, Dr. Wong mentioned that he uses three Southmedic blades per surgery and is able to cut up to 20 cm with each blade. Using a duller blade, he reports he would have to use 9 or 10 and would only be able to cut 5 to 7 cm with each blade. This could add up to 40 minutes to each of the 8 to 10 surgeries he does in a week.

Number of Blades Required to Complete One Hair Restoration Surgery



Similarly, Dr. McDonald explains, "Precision matters with skin incisions. As a vascular surgeon, I often have to do really long neck incisions. To minimize the incision, I have to carefully place the incision keeping in mind how to deliver less damage to the skin since it is so readily visible. Once in the artery, the incision is even more important. I have done a lot of vascular surgeries and the quality of knife and instruments makes a big difference. If an artery is heavily diseased and calcified, the Southmedic 15 blade works best because it can go through any part of the artery I need to go through so that outcomes are best."

Some interviewed surgeons explained that when they use Southmedic blades, the pathologists and laboratory technicians to whom they send their tissue samples often remark on how the clean lines along the edges of the sample give pathologists more confidence in their own assessments. By using a sharper scalpel, surgeons can effectively deliver samples to the lab that may ultimately reduce the

size of the tissue margins they need to take on the first pass. The result is not only tissue sparing and cosmetically beneficial for the patient, but also more operational efficiency since a surgeon is likely to get the answers they need with fewer tissue samples.

Dr. Robert Hekkenberg, ENT surgeon at Royal Victoria Regional Health Centre in Barrie, explains, "I do a lot of skin cancer work so it's important that pathologists get a clean edge of the lesion for histology. Southmedic blades give a true cut. With the competitor, I've gotten a whole dummy box and that can be very frustrating."

Finally, the reproducibility and consistent quality of Southmedic blades builds trust with the physician. Squires mentions, "At Southmedic, we have monthly and quarterly meetings where we review every customer complaint and tradeshow feedback. It's how we ensure blade-edge quality satisfaction from the end user." The high level of quality control that Southmedic places on its products means that a surgeon never reaches for a dull blade straight out of the box. Equipped with high-quality blades, surgeons can have the confidence that they are delivering the best care to their patients and that the hospital in which they are performing the case is equally committed to quality.

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The beneficial design features of Southmedic blades are not limited to the sharp cutting edges, but also other safety and ergonomic characteristics. Southmedic also offers a fully integrated disposable safety scalpel that features a clear plastic sheath that protects surgical personnel against accidental injury. The simple locking and unlocking mechanism maintains ease of access and safe passes, while a single



push allows the sheath to permanently lock out, eliminating the potential for accidental sharps injuries during hand-offs, disposal, or recycling. In addition to its fully disposable safety scalpels, Southmedic's portfolio includes safety blade cartridges for use with reusable handles. The company's products include different sized blades as well, including dermaplaning designs for use in dermatology and beauty clinics. Southmedic also produces larger blade sizes available for use by histotechnologists, pathologists, tissue recovery technicians at organ banks, and morticians. These have a strong and stiff

custom plastic handle that is meant for heavier use, making it ideal for organ retrieval and autopsies.

Benefits to Providers

Healthcare facilities and physicians have the same goal: to provide their patients the best care available. To ensure that they are delivering optimal outcomes to patients as well as keeping their clinical team satisfied, provider facilities must be confident that they are making sound business decisions. Sourcing a high-quality surgical blade can deliver financial and operational benefits in addition to the clinical benefits described earlier. There is a positive financial correlation in paying a slightly higher price for better-quality surgical blades. It not only produces better patient outcomes that, in turn, result in improved patient satisfaction, but it also ensures more satisfied surgeons. Southmedic blades are priced competitively in the market, and offer substantially better value than low-cost alternatives. Surgeons pay attention to details: when a hospital is responsive to the fundamental need of helping a surgeon deliver better incisions, they invest in the relationship with that clinician. While OR managers and administration should rightfully evaluate the benefits of a medical device compared to its costs, scalpel blades are exactly the types of products where physician preference should remain paramount. The benefit to the patient and surgeon is high, and the cost delta to a facility is negligible, if it exists at all.

Attracting and retaining accomplished clinicians is paramount to running a successful surgical department. Surgeons that are well-known in their fields and sought after can be a deciding factor for patients contemplating going under the knife. Facilities that understand the needs of physicians by demonstrating a commitment to their tools are likely to better retain their surgeons. A facility that wants to be a technology leader need not always look at the next multimillion-dollar robotic surgery system or proton beam accelerator. These providers understand that upgrading to superior products like a sharper scalpel blade also can improve the results of their surgical procedures.

OR time is valuable, and one of the most critical benefits a sharper blade can deliver for an OR manager is time savings. A blunt blade results in imperfect incisions that take additional time to correct. Dr. McDonald states, "If a blade is not sharp then the possibility of it functionally slipping off the margins is high and it can go into the surrounding tissue. The blade takes the path of least resistance. This increases chances of unnecessary trauma." In addition to the added time taken to prevent or manage unnecessary trauma or rework, there is a greater likelihood of time wasted swapping out "dummy" blades that are dull straight from the box. Dull blades may produce pathology samples that are inconclusive because of their damaged margins, requiring additional sampling time. Making that small investment in superior blades like Southmedic's can result in significant time savings when calculated over the many cases a busy healthcare facility performs.

100% of surgeons interviewed by Frost & Sullivan believed a sharper scalpel blade like Southmedic's would save them time in their procedures thanks to less rework and time spent replacing dull blades.

Assume a scenario where a surgeon using a sharper scalpel blade conservatively saves 5 minutes of OR time thanks to less repeat work due to dull blade edges, fewer blade swap outs and avoiding dummy blades entirely. Even with a conservative estimate of US\$10 per minute of OR time, this would result in \$50 of savings for an average surgery, far exceeding the cost of a blade with premium cutting capabilities.¹

^{1.} Source: Childers CP, Maggard-Gibbons M. Understanding costs of care in the operating room. [published online February 28, 2018] AMA Surg. doi:10.1001/jamasurg.2017.6233

KEY TAKEAWAYS



CONCLUSION

Scalpel blades are a critical tool in nearly all surgical procedures. Despite their ubiquitous nature, some administrators, OR managers, and even clinicians are under the false impression that all blades are of equal quality. Yet, the experiences that surgeons described during Frost & Sullivan interviews suggest otherwise. Surgeons' years of training and experience in their craft give them a sensitivity to the quality of the tools they use. When lives are at stake, they deserve the best products that a facility can offer. For years, Southmedic has invested in its blade and scalpel design, manufacturing, and quality assurance processes in order to consistently deliver the sharpest blade possible for every single surgery. Dr. Allen notes, "To me, investing in a sharp scalpel is about efficiency and speed. This is what the Southmedic blades provide." While the financial investment for sourcing the best blade possible is small, the impact on patient outcomes and surgeon satisfaction can be significant.



NEXT STEPS

- Schedule a meeting with our global team to experience our thought leadership and to integrate your ideas, opportunities and challenges into the discussion.
- Interested in learning more about the topics covered in this white paper? Call us at 877.GoFrost and reference the paper you're interested in. We'll have an analyst get in touch with you.
- Visit our <u>Digital Transformation</u> web page.
- Attend one of our <u>Growth Innovation & Leadership (GIL)</u> events to unearth hidden growth opportunities.

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