

# Apocrine™ Prosthetic Liner Coating

## Evaluating a New Product to Minimize Prosthetic Liner Contamination & Odor

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**ABSTRACT:** Contamination of the gel lining interface of lower limb prosthetic devices by bacterial waste is nearly universal. In most cases, contamination leads to strong odors and an increased risk of skin irritation or infection. Contamination is highly distressing yet currently not preventable. It potentially threatens the health and quality of life of amputees. No product currently on the market addresses these common issues for more than a few hours. The Apocrine Prosthetic Liner Coating, a liquid application developed and tested by an inter-disciplinary team of surgeons, scientists and prosthetists, is designed to provide long-lasting odor reduction, enhanced hygiene, decontamination, deep cleaning and increased user comfort for over two weeks. Apocrine has potential to become the standard of care for lower limb prosthetic hygiene. Test data and field testing suggest Apocrine will fundamentally improve the personal and professional lives of millions of vulnerable amputees.

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### BACKGROUND

#### THE LOWER LIMB AMPUTEE POPULATION

Lower limb amputations are projected to rise from the current United States prevalence of 1.8 million to over 4.2 million by 2025<sup>1,2,3</sup>. The European Union reports similar projections<sup>4</sup>.

Fifty-four percent of amputations are a result of chronic limb ischemia (CLI) due to peripheral arterial disease (PAD) and to vascular disease incident to diabetes mellitus (DM)<sup>5</sup>. Risk factors for PAD include diabetes and atherosclerosis. Prevalence of these risk factors is rising concomitant to the aging global population and lifestyle-related risk factors. The American Diabetes Association (ADA) reports that one out of three Americans has pre-diabetes (90% of whom are unaware of their diagnosis), and one in eleven Americans has diabetes<sup>6</sup>.

Trauma (auto and other accidents, and military trauma), accounts for 45% of lower limb amputations<sup>7</sup>. Individuals with gangrene, congenital deformities, chronic osteomyelitis and malignant tumors represent 1% of this population<sup>8</sup>. Major lower limb amputation sites include below the knee amputation (BKA), above the knee amputation (AKA), knee disarticulation and hip disarticulation. The average age at amputation is 63 years, and average post-amputation lifespan currently ranges from 11-17 years.

As the prevalence of individuals living with lower extremity prosthetics rises, younger and more athletic

individuals will be among them. Younger amputees involved in sports, older individuals maintaining health and fitness, and military members dedicated to fitness expect prosthetics to support their active lifestyles. Athletes sweat and challenge the lower limb prosthetic environment with higher physical activity. Moist environments are ideal for microbial growth and contamination.

#### HOW DOES CONTAMINATION OCCUR?

Synthetic gel liners serve two main functions, 1) connect the prosthesis to the residual limb and 2) to cover this interface. Mechanical and shear forces between the residual limb and prosthetic socket shave off skin and skin cells for the 6-14 hours a limb is typically worn daily. Lifestyle factors such as smoking, pets, physical activity and other household factors exacerbate the challenge to the interface environment hygiene. The prosthetic liner traps heat, leading to excessive sweating along with compressive micro-movement. Moist environments with dead skin create an ideal environment for bacterial breeding. Bacterial by-products generate strong odor and toxicity regardless of the actions of the amputee in accord with existing standards of care.

#### QUALITY OF LIFE

Orthopedic surgeons, prosthetists and other orthopedic professionals are familiar with the emotional strain experienced by new amputees. Anxiety due to loss of limb, and fear of the unknown are natural responses to this traumatic life event. Once a prosthetic

liner becomes contaminated, the odor can be shocking and embarrassing to the amputee. Prosthetists report that new amputees, already in a vulnerable state, often feel responsible for hygiene issues they are, in fact, unable to control. Questions of cleanliness, and embarrassment upon removal of a prosthetic limb are common. The emotional toll can have a severe effect on personal and professional quality of life.

**WHAT ARE THE AVAILABLE TREATMENT OPTIONS?**

Current standards of care for lower limb prosthetic liner care include alcohol cleaners, detergents, sprays and socks. No current option provides long term relief from the issues related to prosthetic liner contamination. The cost of products can also be an issue for some patients.

Table 1: Current Prosthetic Liner Hygiene Treatment Options.

TREATMENT	COMMENT
Alcohol cleaners, wipes	Effectiveness limited to evaporation times
Silver impregnated liner socks	Effective on skin but does not address prosthetic liner odor
Silver impregnated liners	Embedded silver not uniform. Does not address cleaning, odor, or skin protection.
Various sprays	Last a few hours only – 2x days use
Apocrine™	Effective decontamination and odor reduction/ elimination for up to two weeks. Simple to use, applied just 2x/month. Affordable price

**APOCRINE PROSTHETIC LINER COATING**

Christopher Born, MD, a leader in clinical orthopedic practice and research for over thirty-five years, had been concerned for many years about the unacceptable state of liner hygiene and the deleterious effects that this had on the quality of life of his patients. He collaborated with prominent materials scientist John Jarrell PhD, PE, to create Apocrine, a solution de-

signed to be both an effective and affordable treatment for this pervasive problem.

Apocrine is a patented product containing titanium dioxide and silver with proprietary polymer additives. This chemistry is designed to enable a controlled silver release from the titanium dioxide matrix to minimize prosthetic liner contamination and odor over an approximately two-week period. This would provide the patient with a sustainable improvement in quality of care. Other silver/titanium dioxide products have been unable to match this performance.

Apocrine is designed to be compatible with all brands of prosthetic liners with bi-monthly treatments. Designed for ease of application by the prosthetist or even by the amputee themselves, Apocrine provides liquid delivery in single-use dispensers with no mixing or measuring necessary. It is designed to provide complete coverage of the liner gel interface.

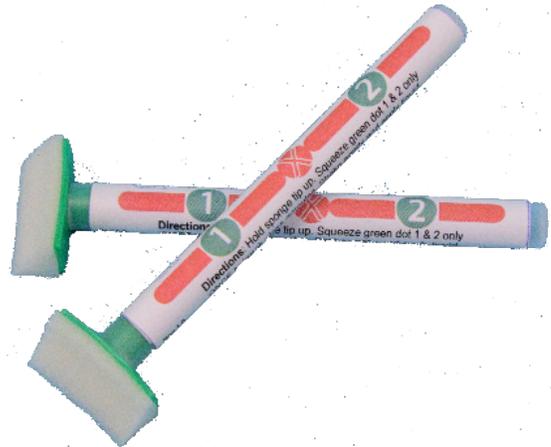


Figure 1: Single use Apocrine applicator provides easy, effective liner coverage.

**FIELD TESTING**

In initial observational user-experience field testing, twelve challenging patients with complaints of odor and other signs of contamination at four test sites participated in trial applications of Apocrine for liner hygiene.

Nunnery Orthotic & Prosthetic Technologies (NOPT) in Kingstown, RI found rapid and appreciable symptomatic improvement with Apocrine use in 75-80% of

participating patients. Patients consistently reported compelling positive changes in symptomology (odor and hygiene) and comfort. In some cases, patients were able to self-apply the liquid, while in others the clinician assisted application. Once treated, most participants asked for ongoing applications. No skin reactions or adverse events were observed nor reported during NOPT testing. No negative patient feedback was received throughout field testing, which is ongoing.

Across three additional test sites, including Atlantic Prosthetics and Orthotics (APO) of Westport, MA; Rogerson Orthotics & Prosthetics (ROP) of Boston; and Medical Center Orthotics & Prosthetics (MCOP) of Boston, patient experience was overall favorable, with positive attributes of Apocrine use identified. Of seven patients, four described the product as effective or highly effective. One patient was lost to follow-up and two dropped out of testing after the first application, one of whom experienced a blister not attributed to product testing.

#### **CLINICIAN COMMENTARY**

Prosthetist Michael Nunnery, CPO, found the application simple and observed that Apocrine performed well, even on worn liners, which are often hygienically challenging. Nunnery reported consistent positive results with no adverse events. He continues to encounter challenging candidates with odor and discomfort as these are common in a prosthetic practice. Participants continue to respond well in NOPT ongoing field tests.

One Massachusetts prosthetist reported that one patient he tested realized greatly reduced and marked difference in odor. Prosthetists from ROP found Apocrine highly effective in a very active patient and effective in another. Prosthetists from MCOP noted overall reductions in odor with use. All prosthetists undertaking early user-experience trials suggested potential dramatic improvements with Apocrine use, and the need for comprehensive trials to further determine product efficacy and generate broad user experience feedback.

#### **CASE STUDIES**

##### **Case Study 1.**

VV is a 51 year old woman with BKA secondary to DM. VV reports wearing prosthetics most of every day. Apocrine was applied to two roll-on locking liners with five successive treatments to date. Patient reported good results, lack of odor and good skin integrity. No adverse events. “The application to my gel liners has reduced the odors since the first application”, VV reports. “I look forward to seeing if the application will permanently reduce odors in my gel liner over time and look forward to continued use of the application”.

##### **Case Study 2.**

JT is a 54 year old man with DM and BKA secondary to trauma. Prior to treatment with Apocrine, JT reported a high degree of sweating and skin rashes with accompanying discomfort. An orthopedic patient of Christopher Born, MD, he was referred to prosthetist Michael Nunnery CPO for exploration of options to address complaints. The prosthetist placed an alternative gel lining for a cooler environment with some relief. The rash, however, persisted over a year of treatment. When Apocrine became available, Nunnery instructed JT to the application process. Patient has reported a dramatic improvement in odor when he removes his prosthesis, and significant improvement in skin rash and discomfort. JT makes multiple regular requests for Apocrine, and self-administers at home.

##### **Case Study 3.**

CO is a 73 year old male with BKA secondary to DM, who received treatment on an existing odiferous nine-month old liner. After Apocrine application, CO’s wife reported resolution, with very little odor of the original well-worn liner. CO continues to use the treated liner.

##### **Case Study 4.**

LW is a 58 year old male with AKA secondary to motor vehicle accident (MVA). He complained of odor prior to original treatment with Apocrine, and experienced significant reduction in odor to his well-worn liner upon treatment. A subsequent new liner was also

treated with excellent results and reported patient satisfaction.

#### Case Study 5.

RP is a 94 year old woman with BKA secondary to PVD. After treatment, RP reports no odor to liner; skin integrity is observationally good. No adverse skin reactions were reported. RP seeks continued treatment.

Initial field testing suggests Apocrine provides superior performance to existing care, and fits amputees' needs for a long lasting, easy to use and cost-effective solution to prosthetic liner contamination.

## CONCLUSION

Apocrine may represent a compelling and life-changing improvement over current standards of care for lower limb amputation liner care by enhancing comfort, hygiene and quality of life. Lab data and field testing suggest dramatic improvements over current care alternatives, excellent patient acceptance and enthusiastic response to trial applications without adverse events. Field test participants and prosthetic professionals report overwhelmingly positive results with evidence for rapid adoption of Apocrine as the option of choice for liner care and maintenance.

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## AUTHOR INFORMATION

**Michael Nunnery CPO**, of Nunnery Orthotics & Prosthetics is past President of the American Academy of Orthotists and Prosthetists, member of American Orthotic & Prosthetic Association, and the Amputee Coalition of America. He is a charter board member of the Rhode Island Society of Orthotists & Prosthetists, and a member of the University of Rhode Island Biomedical Engineering Professional Advisory Board.

**Christopher Born MD, FACS, FAAOS** is the Intrepid Heroes Professor of Orthopaedic Surgery at the Brown University Alpert Medical School and Emeritus Director of the Orthopaedic Trauma Service of Rhode Island Hospital. He is a member of The Orthopedic Trauma Association, founder of the Foundation for Orthopedic Trauma, and Founding Director of the Weiss Center for Orthopaedic Trauma Research

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