

**Contact:**

Loree Bowen/Applied Medical

lbowen@appliedmedical.com/949-713-7920

**Clinical Study Demonstrates Significantly Decreased Incidence of P. Acnes Contamination**

**Through the Use of a Wound Protector Drape in Shoulder Arthroplasty**

**Applied Medical's Alexis® Orthopaedic Protector Shown to Act as a Physical Barrier**

**Against P. Acnes Bacteria**

**RANCHO SANTA MARGARITA, Calif. (March 21, 2019)** – New clinical evidence demonstrates increased value of the use of a wound protector drape in shoulder arthroplasty procedures to decrease incidence of Propionibacterium acnes (P. acnes) contamination. A recent [study](#) published in the November 2018 edition of the *ANZ Journal of Surgery* demonstrates that use of the Alexis Orthopaedic protector, a medical device designed to isolate the superficial tissue layer from the surgeons' gloves, instruments and retractors, significantly decreases the incidence of P. acnes infection in the surgical field by acting as a physical barrier.<sup>1</sup>

P. acnes is a bacterium that may be transmitted from the subdermal tissues to deeper tissues during shoulder arthroplasty surgery, resulting in a deep, incisional surgical site infection (SSI). The aim of this study was to demonstrate a decreased prevalence of P. acnes bacteria in the surgical field by isolating subdermal tissue layers using a wound protector drape.

The study found that the incidence of P. acnes in the surgical field decreased fivefold due to the physical barrier provided by the Alexis Orthopaedic protector.<sup>1</sup> The study hypothesizes that a decreased presence of P. acnes in the surgical field decreased the rate of transmission to deeper tissues, resulting in fewer deep P. acnes infections following shoulder arthroplasty procedures.

Infections stemming from P. acnes can be costly and do not present with obvious signs of infection such as swelling, drainage and tenderness; instead, patients report unexplained pain, stiffness or component loosening later than the diagnosable time period for a postoperative infection.<sup>2</sup>

“The Alexis Orthopaedic protector provides a wide range of benefits to the surgeon, from improved exposure and visualization to the protection of soft tissue,” said Amy Garces, Vice President of Clinical Development at Applied Medical. “This study demonstrates even greater benefits to both the surgeon and the patient in the form of decreased infection, which is an important clinical initiative for all of us at Applied Medical.”

### Study Design

This prospective clinical study was conducted to determine whether a wound protector drape can act as a physical barrier against migrating *P. acnes* bacteria. Microbiological swabs were taken at three different times during the procedures.

The first swab was taken on the shoulder's subdermal tissue layer upon dissection. The second swab was taken on the surface of the protector's sheath after the prosthesis was attached, the surgical area was washed, and the subcapularis was reattached. The protector was removed and the third swab was taken on the same location of subdermal tissue layer as the first swab. This process was conducted over a consecutive series of 47 patients.

### About SSI

SSI accounts for 20 percent of healthcare-associated infections,<sup>3</sup> resulting in approximately \$3.5 billion to \$10 billion annual healthcare expenditures in the United States.<sup>4</sup> Additionally, incisional SSI may lead to increased postoperative pain, poor wound healing and incisional hernias.<sup>5-9</sup>

### About the Alexis Orthopaedic Protector

Developed and manufactured by Applied Medical, the [Alexis Orthopaedic protector](#) shields soft tissue, including skin, fat, muscles and nerves from sharp instrumentation and debris while providing 360-degrees of atraumatic retraction of the incision. The sheath also maintains moisture at the wound margins and minimizes the presence of bacteria in the wound space. The Alexis Orthopaedic protector is available in a wide range of sizes and flexibility levels to suit a variety of surgical needs.

### About Applied Medical

[Applied Medical](#) is dedicated to providing innovative solutions that enhance patient outcomes and enable the advancement of minimally invasive surgery. As a new generation medical device company, Applied Medical is proud to have a significant and sustainable impact on healthcare by delivering breakthrough technologies that enhance clinical care and satisfy the pressing economic needs of our customers.

Applied Medical is committed to being a part of the overall solution to reduce SSI through research, education and awareness. The company has developed [stopsurgicalsiteinfection.com](http://stopsurgicalsiteinfection.com) as a comprehensive resource for healthcare professionals to learn more about the prevention of SSI.

Founded in 1987 and headquartered in Southern California, Applied Medical is a rapidly growing, global organization that is proud to provide our products and unique business model to more than 75 countries.

1. Smith ML, Gotmaker R, Hoy GA, et al. Minimizing Propionibacterium acnes contamination in shoulder arthroplasty: Use of a wound protector. *ANZ J Surg.* 2018; 88(11):1178-1181. (Level of Evidence 4)
2. Hsu JE, Bumgarner RE, Matsen FA III. Propionibacterium in shoulder arthroplasty: What we think we know today. *J Bone Joint Surg Am.* 2016;98(7):597-606.
3. Klevens RM, Edwards JR, Richards CL Jr, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. *Public Health Rep.* 2007;122(2):160-166. (Level of Evidence 4)
4. Scott RD. The direct medical costs of healthcare-associated infections in U.S. hospitals and the benefits of prevention. [https://www.cdc.gov/hai/pdfs/hai/scott\\_costpaper.pdf](https://www.cdc.gov/hai/pdfs/hai/scott_costpaper.pdf). Published March 2009. Accessed May 21, 2018. (Level of Evidence 4)
5. Horan TC, Culver DH, Gaynes RP, et al. Nosocomial infections in surgical patients in the United States. January 1986-June 1992. National Nosocomial Infections Surveillance (NNIS) System. *Infect Control Hosp Epidemiol.* 1993;14:73–80. (Level of Evidence 4)
6. Le Huu Nho R, Mege D, Quaissi M, et al. Incidence and prevention of incisional hernia. *J Visc Surg.* 2012;149:e3–e14. (Level of Evidence 4)
7. Alfonso JL, Pereperez SB, Canoves JM, et al. Are we really seeing the total costs of surgical site infections? A Spanish study. *Wound Repair Regen.* 2007;15:474–481. (Level of Evidence 4)
8. Perencevich EN, Sands KE, Cosgrove SE, et al. Health and economic impact of surgical site infections diagnosed after hospital discharge. *Emerg Infect Dis.* 2003;9:196–203. (Level of Evidence 4)
9. Cruse PJE, Foord R. A five-year prospective study of 23,649 surgical wounds. *Arch Surg.* 1973;107:206–210. (Level of Evidence 2)