<u>Landmark Surgery Center Completes Study of HealthySole Plus Shoe Sole</u> <u>Disinfection System Related to SSI's</u>

Landmark Surgery Center, located in St Louis Missouri, is considered one of the finest ambulatory surgical centers (ASC) in the country. Landmark surgically treats patients including high level collegiate, professional and Olympic athletes. Landmark ASC operates 3 suites 5 days a week and focuses on surgeries such as Orthopedic, GYN, ENT, Pain Management, Podiatry and Urology procedures. The #1 concern in treating the patients at Landmark has always been preventing surgical site infections (SSI's). In 2015 we began to review studies and data suggesting infections occur from the floor up. When we walk into the operating room, the pathogens on the soles of shoes, booties and dedicated theatre footwear get tracked into these sensitive areas. Once these dangerous organisms enter, they transfer to the floors, then become aerosolized and find their way onto every OR surface and ultimately to patients skin and the wound site itself, which can lead to SSI's.

In 2016 Landmark commenced a clinical study of the HealthySole Plus shoe sole disinfection system targeting the transfer of dangerous pathogens into the operating rooms to determine the efficacy of HealthySole in lowering SSI's. Landmark uses the most current safety protocols available to prevent infections. Until recently there were no protocols nor methods to decontaminate shoe bottoms. Although the use of chemicals on floors is standard protocol, it can only be done intermittently throughout the day and cannot prevent the constant spread of these pathogens into the OR setting. The available studies and data confirm the floors return to pretreatment levels of microbial load shortly after chemical disinfection.

The HealthySole decontaminates the soles of shoes, booties and dedicated theatre footwear, which are a proven vector of dangerous pathogen transmission to the floors of the OR. After researching the available data and HealthySole's claims, we agreed to test and study the HealthySole technology and established protocol requiring all OR personnel who walked in and out of a surgical suite to stand on the device for an 8 second disinfection process. The 8 second HealthySole exposure time, allows UVC light in the device to kill up to 99% of the pathogens on the soles of all footwear or booties that otherwise enter the theatre. Our study found that implementing HealthySole into our existing protocol did not interfere with workflow and was used approximately 20,000 times over the course of 10 months.

Results of the study determined HealthySole to be a significant addition to our infection control protocol. At the conclusion of the study, Landmark went from an existing low infection rate to not having a single patient contract an SSI. The only modification to our infection control protocol was the addition of HealthySole. While we cannot attribute the lack of SSI's solely to the introduction of the

HealthySole System Specifications

Model HS-PLUS

Sanitizing Device

Patents pending US and world wide

Patent No: US 9,211,352 / US 9,463,258

Patented Plastic Encapsulated UVC Germicidal Lamp

Patent No: US 6,614,039

Shoe Opening Dimensions 12 in L x 4.375 in W (305 mm L x 111

mm W)

Infra-red Foot Placement Four IR sensors located in the base (two

for toe of shoes and two for heels of shoes)

Minimum Shoe Size Women's size 6

Maximum Shoe Size Men's size 13.5

Platform Size (with Feet) 17.2 in W x 21 in D x 2.4 in H (437 mm W

x 533 mm D x 61 mm H)

System Capacity 500 lb (225 kg)

Net Weight 40 lb (18 kg)

Power Requirements 90 ~ 264VAC (47 ~ 63Hz) at 37W/115VAC

(37W/230VAC); AC power cord included

Country of Origin USA

Surface Exposure Results 97.35% exposure to UV light

HealthySole technology, we are firmly convinced that the data supports the conclusion that the HealthySole played a major role in keeping our facility safer and infection free.

Dr. Richard C. Lehman, MD U.S. Center for Sports Medicine, Chief Medical Officer, Owner.