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Microfield Guard White Paper

INTRODUCTION:

As a foot and rearfoot and reconstructive rear foot and ankle podiatric surgeon for one of the largest Native American tribal health care systems and hospitals in Oklahoma, one of my primary tasks is foot and ankle preservation surgery on severely contaminated, infected, and ischemic necrotic lower extremity wounds. Surgical procedures of this nature are performed by the surgeons in conjunction with seasoned surgical team members consisting of anesthesiologists or nurse anesthetist, scrub techs, and circulating nurses; however often there will be new personnel in the operating room consisting of nursing students observing from the sidelines and osteopathic medical students scrubbed in who are just recently introduced into the operating theater. It ultimately is the responsibility of the surgeon to ensure not only the health and safety of the patient, but also the health and safety of medical personnel involved in providing medical surgical care or are learning from the surgical procedure being performed only a few feet away.

Lower extremity contaminated foot and ankle wounds have historically been treated with surgical debridement and irrigation to remove the nidus of infection and contamination from the surrounding viable bone and soft tissue envelope to allow the remaining portion of the lower extremity to be as clean as possible prior to primary wound closure, delayed wound closure, negative pressure therapy device application, graft application, or alternative long-term wound healing modalities, and allow for antibiotics to be more effective against a lower bioburden load. Initially wound irrigation systems consisted simply of bulb syringe with normal saline solution, or sterile water to gently flush out the wound site and the resulting fluid was collected with a bowl and/ or towel. As medical irrigation debridement equipment advanced, irrigation fluids were propelled with much greater force to increase the effectiveness of the irrigation fluid removing contaminated body fluids including blood, purulence, and micronized foreign material, soft tissue, and bone from the surgical site. A slurry of contaminated fluid is created from the mixture of the irrigation solution, body fluids, and micronized biological particulate upon impact of the irrigation fluid with the surgical site. Generally infected surgical sites are irrigated with high volumes of fluid, with most lower extremity foot and ankle contaminated wounds irrigated with 3 L of normal saline. All this contaminated fluid must be disposed of appropriately, while limiting exposure of this contaminated fluid to the surgical team members and observers.

One of the primary concerns with pulse lavage systems is splash back of the ejected irrigation fluid hitting the wound of the patient with such force as to ricochet contaminated fluid back into the face of the surgeon and surgical staff. Splash back poses significant risk of contaminated fluid coming in direct contact with surgeon and surgical staff's eyes and mucosal membranes. Such, contact of blood borne pathogens to these portals of entry requires patient and staff blood testing, initial medical evaluation and subsequent follow-ups, incident report, and sometimes Workmen's Compensation; identical to that blood borne pathogens that occurred from needle sticks. Face shields and mask are worn to help reduce risk associated with splash back, however, this protective equipment does not provide absolute protection, due to risk of fluid entering at the junction of the face shields and mask. Additionally impervious gowns and gloves are worn, that are fluid resistant, but not fluid proof to leakage.

Keeping a sterile surgical field is critical in all surgeries. Difficulties and frustrations arise when there is already infection and contamination originating at the surgical site. When infection and contamination is already present at the surgical site, it is imperative to divide the surgery into the initial contaminated portion, and then the subsequent de-contaminated portion. Pulse lavage allows for the creation of a contaminated surgical wound to a cleaner surgical wound; however, this is often accomplished at the expense of contaminating the adjacent surgical field, which can subsequently re-contaminate the surgical wound if appropriate precautions are not taken. Utilizing a waterproof barrier and appropriately and rapidly removing contaminated fluid greatly reduces contaminated fluid impregnating the surgical drapes and field with debris that can subsequently be reintroduced into the surgical wound status post wound debridement and irrigation.

Slips and falls are one of the leading injuries leading to work-related injuries in healthcare environments. Pulse lavage irrigation and blood that is not appropriately managed generally drips down surgical drapes and pools beneath the feet of the surgeon and scrub techs. This can readily lead to the surgeon slipping and falling while operating on the patient with sharp instruments, resulting in injury either the patient, surgeon, or both individuals.

Due to this multitude of health and safety issues created by pulse lavage irrigation systems utilized in lower extremity surgery, an effective simple cost-efficient way of managing contaminated pulse lavage fluid was ultimately needed. Block Island Technologies met this challenge by providing the foot and ankle surgeon with the patented Microfield Surgical Irrigation Bag. The Microfield Surgical Irrigation Bag was developed by a highly respected senior podiatric foot and ankle surgeon to address the issues of contaminated pulse lavage fluid management. Block Island Technologies sought the voluntary honest opinion and insight of several foot and ankle surgeons by providing them multiple Microfield Surgical Irrigation Bags to utilize in their surgical cases requiring contaminated pulse lavage fluid management.

LENGTH OF STUDY:

12 months. Study began on June 1, 2021 and concluded on May 31, 2022.

LOCATION OF STUDY: Choctaw Nation Health Service Authority medical campus. Talihina, Oklahoma

STUDY PARTICIPANTS:

Jason L. Seiter, D.P.M., Diplomat of American Board of Foot and Ankle Surgery, Fellow of American College of Foot and Ankle Surgeons. Podiatric surgeon at Choctaw Nation Health Service Authority medical campus, Talihina, Oklahoma.

Surgical scrub technicians and surgical scrub registered nurses at Choctaw Nation Health Service Authority medical campus, Talihina, Oklahoma.

Oklahoma State University College of Osteopathic Medicine Tulsa Oklahoma, third year osteopathic medical students on surgical rotations at Choctaw Nation Health Service Authority medical campus, Talihina, Oklahoma.

Arkansas College of Osteopathic Medicine Fort Smith Arkansas, third year osteopathic medical students on surgical rotations at Choctaw Nation Health Service Authority medical campus, Talihina, Oklahoma.

PURPOSE: To determine if the Microfield Surgical Irrigation Bag:

Protected the surgeon, nurses, and assistance from biohazardous toxic materials?

Prevented hazardous debris from contaminating the operating room?

Resulted in faster operating room turnover?

Prevented debris in the surgical field from hitting the surgeon, falling back into the sterile field and further contaminating the surgical site?

Prevented a possible user slip and fall incident because of fluid on the operating room floor?

Did the instructions for use on the package allow for ease of application of the lavage bag?

Would you recommend this device to other surgical colleagues?

MATERIALS:

Materials tested:

Block Island Technologies Microfield Surgical Irrigation Bag.

Adjunctive Materials utilized in conjunction with the tested material:

Battery-powered pulse lavage gun.

Minimum of 1 L normal saline up to a standard of 3 L normal saline. 3 L normal saline utilized for majority of cases.

Powered vacuum suction.

Elevating leg bump to elevate the foot and ankle approximately 8 inches off the operating table to facilitate clearance of the Microfield Surgical Irrigation Bag off the operating table to facilitate pulse lavage irrigation and drainage.

Sterile surgical drapes.

Standard podiatric instruments for surgery.

SURGICAL CASES UTILIZING THE BLOCK ISLAND TECHNOLOGIES MICROFIELD SURGICAL IRRIGATION BAG:

Single toe amputation.

Multiple toe amputation.

Single partial ray amputation.

Multiple partial ray amputation.

Transmetatarsal amputation.

Incision and drainage.

Wound debridement and irrigation.

BENEFITS:

Minimum storage space utilized to store product.

Simple 5 step instructions on package with single sentence statement with accompanying picture to facilitate easy first-time use without training of all surgical personnel.

Clear bag to allow direct visualization of surgical wound irrigation site.

Thickness of lavage bag prevents suction from collapsing bag, while still maintaining good suction and collection of fluid at bottom of bag at site of drain.

Thickness of lavage bag prevents unintentional punctures through the lavage bag caused from pulse lavage gun tip and sharp edges of bone.

Flexible lavage bag to allow easy manipulation and maneuvering of lavage bag around the surgical site.

Easy to tie and untie draw strings at top of bag to allow for secure connection to patient, extremity.

Prevents splatter of contaminated irrigation fluid onto surgical field outside of the bag.

Prevents splatter of contaminated irrigation fluid into the eyes and mucosal membranes of surgical personnel.

Prevents pooling of fluid on the surgical floor.

Simplicity allowed for correct use by seasoned surgeons and knob's medical students.

COMPLICATIONS:

No complications were experienced with the use of this product.

No splatter of contaminated irrigation fluid occurred into the eyes or mucosal membranes of surgical personnel or individuals observing surgical procedures.

No accidental punctures or leakage of the lavage bag occurred.

No pooling of irrigation fluid occurred on the surgical field, nor floor.

CONCLUSION:

Block Island Technologies Microfield Surgical Irrigation Bag has met all desired goals in managing and disposing of contaminated surgical irrigation fluid away from the surgical site of the foot and ankle while maintaining the safety of the patient and surgical personnel.

IMPRESSION:

Block Island Technologies Microfield Surgical Irrigation Bag has become part of the standard required piece of safety equipment utilized for contaminated foot and ankle surgeries requiring irrigation with pulse lavage for Jason Seiter DPM and his surgical team.

Jason Seiter, DPM, highly recommends the Block Island Technologies Microfield Surgical Irrigation Bag to all foot and ankle surgeons utilizing pulse lavage systems to provide appropriate protection to there are patient's, surgical staff, and to the foot and ankle surgeon.