

# Exhibitor Prospectus

## Society of Military Orthopaedic Surgeons

51st Annual Meeting



December 14-16, 2009  
Hilton Hawaiian Village  
Honolulu, Hawaii



[www.somos.org](http://www.somos.org)

Dear Exhibitor,

I would like to invite you to the Society of Military Orthopaedic Surgeon's 51st Annual Meeting, December 14-19, 2009, at the Hilton Hawaiian Village in Honolulu, HI. The Program Committee has developed an outstanding scientific program geared toward meeting the unique needs of the military orthopaedic surgeon, offering education and a forum for sharing information, experiences and identifying useful solutions.

The SOMOS Board of Directors is dedicated to providing both a superior scientific program and an opportunity for you to network and form relationships with the attendees. Your organization provides products and services important to the practice of military orthopaedic surgery.

We strive to provide our exhibitors with ample opportunities to meet with the doctors throughout the meeting. In addition, we have scheduled time throughout the meeting to ensure that our exhibitors are appropriately acknowledged. Your participation is critical to the success of the meeting.

I encourage you to support SOMOS in December and join us for the 51st Annual Meeting. I appreciate your interest and look forward to seeing you in Hawaii.

Sincerely,

LTC Daniel W. White, MD  
2009 President  
SOMOS

## BENEFITS OF EXHIBITING

The Society of Military Orthopaedic Surgeon's Annual Meeting is the meeting of choice for military orthopaedic surgeons. Allied Health Professionals also attend the meeting to stay ahead of the curve in the field of orthopaedics. During the Annual Meeting, SOMOS can help your company in the following ways:

- **Dedicated time with the attendees**
- **Free pre-meeting attendee mailing list**
- **Free lead retrieval**
- **Free entrance to the scientific program**
- **Signage**
- **Invitation to the Welcome Reception**
- **Acknowledgement in the Scientific Program**
- **Acknowledgement on the SOMOS web site with a link to your company web site**

## EXHIBITOR LEVELS

**Platinum Level - \$25,000**

**Gold Level - \$20,000**

**Silver Level - \$15,000**

**Bronze Level - \$10,000**

**Copper Level - \$5,000**

**Booth - \$2,500**

## SOCIETY OF MILITARY ORTHOPAEDIC SURGEONS

SOMOS was founded during the 1958 AAOS Annual Meeting and held its first organized meeting in 1963. A decade later, the Society's Board of Directors officially defined its mission as being "a forum for the interchange of medical knowledge as it relates to the practice of Orthopaedic surgery in the military."

## TRAVEL & HOTEL INFORMATION

Located on Waikiki's widest stretch of beach, the Hilton Hawaiian Village Beach Resort & Spa is nestled on 22 oceanfront acres offering the perfect mix of exceptional hotel accommodations and classic Hawaiian hospitality. Imagine lush tropical gardens, waterfalls, exotic wildlife and priceless artwork.

Hilton Hawaiian Village® Beach Resort & Spa  
2005 Kalia Road  
Honolulu, Hawaii 96815  
Tel: (808) 949-4321  
Fax: (808) 951-5458



### Registration and Badge Pick-Up

All representatives from exhibiting companies and their spouses/guests who will attend the meeting must register for the meeting. Badges for your representatives and their guests should be picked up at the Exhibitor Registration Desk. Exhibitors are allowed to register two representatives without incurring an additional charge. **REGISTRATION BADGES FOR ALL PARTICIPANTS MUST BE WORN FOR ADMITTANCE.**

#### IMPORTANT DATES

October 26, 2009	Deadline for Exhibitor Application and \$500 Deposit
November 2, 2009	Deadline to Submit Copy for Final Program
November 2, 2009	Deadline for Exhibitor Representative Pre-Registration
November 9, 2009	Final Deadline for Balance of Exhibitor fees
November 9, 2009	Deadline for Cancellation and Partial Refund
December 14, 2009	Booth Set-up by 5:00 pm
December 14 - 16, 2009	Exhibits Open
December 16, 2009	Exhibit Booth Break Down

### Payment Information

A \$500 non-refundable deposit, or the entire balance, is due with the receipt of the application by October 26, 2009. Applications submitted without a deposit will not be considered for booth assignment.

Full payment for booth space must be sent to the SOMOS office by November 9, 2009. After November 9th, the assigned booth space is open to cancellation and reassignment.

If an exhibitor wishes to cancel a reservation for space after remitting the amount invoiced, a partial refund will be granted if written notice is received prior to November 9, 2009. An exhibiting firm whose booth is not completed on the set-up day, and staffed on opening day forfeits all rights. The booth must be staffed for the entire meeting. SOMOS reserves the right to reassign space without refund.

FOR ANY ADDITIONAL INFORMATION ON EXHIBITING,  
PLEASE CONTACT:  
Cindy Eikenberg at 410-494-4994 or  
Email: ceikenberg@datatrace.com

# APPLICATION FOR EXHIBIT SPACE

Society of Military Orthopaedic Surgeons • 51st Annual Meeting • Honolulu, Hawaii • December 14 - 16, 2009

\_\_\_\_\_  
Company Name

\_\_\_\_\_  
Phone Fax

\_\_\_\_\_  
Address

\_\_\_\_\_  
City State Zip

\_\_\_\_\_  
Email

\_\_\_\_\_  
Current Contact Name

\_\_\_\_\_  
Title

\_\_\_\_\_  
Signature Date

## Onsite Representative(s) for the Annual Meeting

1. \_\_\_\_\_

2. \_\_\_\_\_

3. \_\_\_\_\_

4. \_\_\_\_\_

## Person(s) who should receive a copy of the Pre/Post Registration list

1. \_\_\_\_\_

2. \_\_\_\_\_

## SELECT YOUR EXHIBITOR LEVEL

Platinum - \$25,000     Gold - \$20,000     Silver - \$15,000

Bronze - \$10,000     Copper - \$5,000     Booth - \$2,500

## Exhibitor fees include:

8 x 10 pipe & drape booth • 6 ft table • 2 chairs • 1 trash can • 1 Pre/Post  
Registration Attendee list • Exhibitor Reception

## PAYMENT INFORMATION

Check (Payable to the Society of Military Orthopaedic Surgeons)

Charge:  Visa     MasterCard     American Express

\_\_\_\_\_  
Card Number Exp. Date

\_\_\_\_\_  
Signature

## PLEASE RETURN TO:

SOMOS  
110 West Road, Suite 227  
Towson, MD 21204  
Phone: 410-494-4994  
Fax: 410-494-0515

APPLICATION AND PAYMENT MUST BE RECEIVED BY OCTOBER 26, 2009.

## SIGNIFICANCE OF FDA CLASSIFICATIONS OF MEDICAL DEVICES

(Used with permission of the American Academy of Orthopaedic Surgeons)

In recent years, the US Food and Drug Administration (FDA) has focused increased attention on the regulatory status of certain medical devices used in orthopaedic surgery. In light of this increased scrutiny, the leadership has requested that all participants in educational courses and symposia that discuss orthopaedic devices, including the Annual Meeting, be aware of the device's FDA classification and present this information to the audience.

The FDA is the federal agency charged with protecting the public health and individual welfare. Its primary mission is to assure that the products it regulates are safe, efficacious and truthfully labeled. The agency's responsibilities also include a substantial role in the development, introduction and marketing of products.

The Food, Drug, and Cosmetic Act of 1938, as amended, establishes the basic legal framework controlling the activities of producers of food, drugs, cosmetics and medical devices. The most comprehensive set of amendments to this Act occurred in 1976. The 1976 Medical Device Amendments ("Amendments") created a complex system for regulating the development, introduction, and marketing of medical devices. These Amendments require the FDA to classify or categorize all medical devices according to their safety and effectiveness. The Amendments create three classes of devices:

**Class I** Includes those devices for which neither a standard nor a premarket approval is warranted because the general regulatory controls available to the FDA are sufficient to assure safety and effectiveness; presents little risk to the public; subject to minimal FDA regulation (e.g., registration, adherence to good manufacturing practices). Examples of Class I devices include cast materials, crutches, and wheelchairs.

**Class II** Includes those devices for which general regulatory controls are not sufficient and for which enough information exists to develop a performance standard; may present some additional risk to the public; must comply with Class I regulations and individual performance standards developed by the FDA. Examples of Class II devices include intramedullary nails, bone screws, and plates when used for long bone fractures, and cemented hip replacements.

**Class III** Includes those devices for which general regulatory controls are not sufficient to assure safety and effectiveness and there is not sufficient information to establish a performance standard. Class III devices are generally considered investigational; they have generally not been cleared for marketing for a particular purpose by the FDA. Class III devices also include all devices introduced after the enactment of the 1976 Amendments (post-enactment devices) that have not been determined to be not "substantially equivalent" to a device marketed prior to enactment (pre-enactment devices). Class III may present a substantial risk to the public. Examples of Class III devices include ligament replacements and bone substitutes and, at the time of this writing, the use of bone screws in the pedicle (although the FDA has proposed a reclassification of this particular use).

The Amendments also provide for federal control over the introduction in the market of all medical devices. This system operates independently of the FDA's classification scheme. After 1976, a medical device may lawfully be marketed in only one of three ways:

- A medical device may be the subject of a premarket notification to FDA under section 510(k) which demonstrates that it is "substantially equivalent" to a medical device available in 1976 or before (pre-enactment device);
- A medical device may be the subject of a premarket approval (PMA) application, typically involving clinical trials and follow-up, under Section 515; or
- Upon a manufacturer's petition to FDA, a medical device may be reclassified from Class III to Class II or I.

## USE OF A MARKETED DEVICE FOR NON-FDA CLEARED USES

It is legally permissible for a physician to use a commercially available and marketed medical device according to the physician's best medical knowledge and judgment, even if the medical device has not been cleared for that particular use by the FDA.

The FDA does not limit the manner in which a physician may use a medical device that has been cleared for marketing. Once the FDA has cleared a device, an orthopaedic surgeon may use it in treatment regimens or patient populations that are not included in device labeling. Such "unlabeled (or unapproved) uses" may be appropriate in certain circumstances and may reflect approaches to orthopaedic treatment that have been evaluated and reported in medical literature.

Additional requirements are imposed on physicians who use marketed devices for purposes not specified on the device label. These additional requirements include:

- The orthopaedic surgeon must be knowledgeable about the device and document that its use is based on reliable scientific evidence;
- The orthopaedic surgeon must discuss the use of the device with the patient in language the patient can understand, consistent with good medical practice; and
- The orthopaedic surgeon must specifically document the use of the device and follow-up care.

According to the FDA, use of a product in this manner is part of the "practice of medicine" and does not require the submission of an Investigational Device Exemption (IDE) or review by the physician's Institutional Review Board (IRB) unless a review is required by the institution in which the product will be used.

## USE OF AN EXPERIMENTAL OR INVESTIGATIONAL DEVICE

According to the FDA, the use of all investigational medical devices requires an approved Investigational Device Exemption (IDE) unless the investigation is exempt from the IDE regulation. Exempt investigations include investigations of medical devices which the FDA has cleared for marketing (certain Class III and Class II devices), certain diagnostic devices and custom devices.

The individual conducting research at the institution (clinical investigator) has certain responsibilities regarding the use of investigational devices. These responsibilities include:

- Using the investigational device only in accordance with the approved protocol's plan of investigation;
- Using the investigational device only with subjects under his or her personal supervision or under the supervision of other investigators who are responsible to the clinical investigator;
- Assuring that the institution's IRB reviews and approves the study; and
- Obtaining proper informed consent from subjects in the study.

Thus, the clinical investigator is prohibited from giving the device to another physician not responsible to him or her, from providing it to subjects who are not part of the investigation and from giving it to a physician in another institution for use on his/her patients.

If a situation arises that, in the judgment of the physician, calls for the emergency use of an investigation device, the sponsor of the research protocol and the institution or its IRB must approve its use. Specific FDA approval is not required under these circumstances. However, the FDA requests that the research study sponsor notify it when an investigational device has been used in an emergency situation.

The emergency use of an investigational medical device may be exempt from the FDA requirement for IRB review, provided that the emergency use is reported to the IRB within 5 working days. The FDA requires that any further use of the investigational device at the institution by subject to IRB review.

The FDA has the enforcement powers to impose sanctions on the manufacturers of investigational medical devices when they are used outside of the parameters of the clinical study. The agency may enjoin a manufacturer from shipping the medical device or seek a fine. The FDA may also question the actions of an individual physician who uses an investigational medical device in treating a patient by going to the physician's IRB and indicating that the physician is not adhering to the approved study protocols.

## THE ROLE OF THE PHYSICIAN'S MEDICAL JUDGMENT

While noting the statute and regulations stated above, the FDA is not empowered to dictate or to interfere with the care and treatment the physician believes is necessary to care for a particular patient. In a July 1993 letter to the American Academy of Orthopaedic Surgeons, the FDA made this point clear. The letter discusses the Class III FDA classification status of bone screws and concluded that currently:

"...there are no legally marketed bone plates, bone screws, spinal screws, pedicle screws, or device systems that incorporate bone screws commercially available in the United States, that have been cleared or approved (by the FDA) for spinal fixation when used for the attachment through the pedicle of a vertebra."

Nonetheless, when asked about the responsibility of the individual orthopaedic surgeons who use bone screws in the pedicle, the FDA responded:

"Throughout its history, FDA has been particularly cautious about the intersection of its legal authority to protect the public health and ability of physicians to practice medicine and surgery as they believe is most appropriate and in the best interests of their patients. At this time, FDA does not intend to involve and directly interact with orthopaedic surgeons with regard to restrictions on use of medical devices."

## CONCLUSION

It is essential that orthopaedic surgeons be aware of the FDA clearance status of the medical devices they use. Information regarding the FDA clearance status of a particular medical device may be obtained by reading the product's package labeling, by contacting the sales representative or legal counsel of the manufacturer of the device, or by contacting the FDA at 1-800-638-2041.