

Exhibitor Prospectus

Southern Orthopaedic Association 27th Annual Meeting

June 16 - 19, 2010
El Conquistador Resort
Fajardo, Puerto Rico



Dear Exhibitors,

I would like to invite you to the Southern Orthopaedic Association's 27th Annual Meeting, June 16-19, 2010, at El Conquistador Resort in Fajardo, Puerto Rico. The Program Committee has developed an outstanding scientific program that should be educational, informative, and entertaining.

The leadership of SOA is dedicated to developing a superior scientific program of relevant and leading edge issues facing orthopaedists, while providing an opportunity for YOU to network and form relationships with the attendees. Your organization provides the products and services that our members depend on in their practices every day.

That is why we strive to provide our exhibitors with ample opportunities to meet with the doctors throughout the meeting, including invitations to the social and recreational events. In addition, we have scheduled time throughout the meeting to ensure that our exhibitors are appropriately acknowledged. Your involvement is critical to the success of the meeting!

I encourage you to support the SOA in June and join us for the 27th Annual Meeting. I appreciate your interest, and look forward to seeing you in Puerto Rico.

Sincerely,

C. Lowry Barnes, MD
2010 President
Southern Orthopaedic Association



Fajardo, Puerto Rico

Fajardo is known as "*La Metrópolis del Sol Naciente*" (the city that guards the sun of the Caribbean). Fajardo was founded in 1772. It was originally named Santiago de Fajardo.

Fajardo is one of the most originally beautiful spots on the island's shores. Located in the east region of the island, bordering the Atlantic Ocean, north of Ceiba and east of Luquillo.

Fajardo is a major boating center, with a wide range of rentals and charters available, with daily and sport-diving excursions as well as scheduled ferries and air service carrying passengers and cargo to Culebra and Vieques.

Fajardo's perfect beaches are bounded by calm, clear water ideal for snorkeling, Seven Seas Beach, offers plentiful water sports facilities, offshore points for sailing, snorkeling and plenty of scuba diving.

SOUTHERN ORTHOPAEDIC ASSOCIATION

The Southern Orthopaedic was founded by a small group of dedicated orthopaedists with a desire to establish a regional orthopaedic association for physicians living in the southern states of the United States. The Southern Orthopaedic Association was founded in 1983 to serve its members and fulfill its mission of developing and fostering the art and science of medicine in the specialty of orthopaedic surgery.

Active members reside in the states of Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, Missouri, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, West Virginia and the District of Columbia.

BENEFITS OF EXHIBITING

The Southern Orthopaedic Association's Annual Meeting is the meeting of choice for orthopaedic surgeons practicing in the southern states. DOs and Allied Health Professionals also attend the meeting to stay ahead of the curve in the field of orthopaedics. The SOA provides continuing medical education to those individuals who are on the forefront of both scientific and socio-economic orthopaedic causes. During the Annual Meeting, SOA can help your company in the following ways:



DEDICATED TIME WITH THE ATTENDEES

Your company representatives will have the opportunity to interact with the SOA meeting attendees during the continental breakfasts, and coffee breaks held in the exhibit hall. Also, the Scientific Program will include opportunities to "Visit the Exhibitors." A special Exhibitor Reception will be held on Friday evening. During the reception, registered physicians and their families will visit you at your booth while enjoying a refreshing drink and a bite to eat.



FREE PRE-CONFERENCE ATTENDEE MAILING LIST

Exhibitors will receive a complimentary pre-registered attendee mailing list approximately four weeks before the meeting. You can use the list to promote your products/services in advance and potentially boost traffic at your booth.

FREE LEAD RETRIEVAL

To assist you in your post-meeting marketing efforts, the SOA will supply, upon request, a FINAL list of registrants which will allow you to easily conduct follow-up correspondence with interested registrants via mail.

ATTENDANCE AT THE SCIENTIFIC PORTION OF THE MEETING

To better prepare and equip your sales force, SOA welcomes and encourages your registered representatives to attend the scientific program portion of the meeting. This will enable your company to gather the most current and relevant information in the orthopaedic field, further build rapport with the attendees, and gain a competitive advantage in the industry.

ACKNOWLEDGEMENT IN THE SCIENTIFIC PROGRAM

Your company will be listed in the Scientific Program along with contact information, website address, and a brief company description.

ATTENDEES REGISTER WITH EXHIBITORS FOR DRAWINGS

Attendees will be encouraged to visit and register daily with each exhibitor for special daily drawings.



EXHIBITOR INFORMATION

As a premium exhibitor, you will enjoy all of the exhibitor benefits, plus these additional benefits:

Premium Benefits

- Plaque in recognition of your participation awarded at the Exhibitor/Poster Reception
- Invitation to the President's Private Party
- Invitation to the Welcome Reception
- Invitation to the Gala Dinner
- Entrance in the Golf Tournament
- Signage
- Complimentary exhibit booth
- Acknowledgement on the SOA web site with a link to your company web site



Premium Levels

Platinum Level - \$35,000

Platinum Exhibitors receive 10 invitations to the Welcome Reception and Gala Dinner, invitation to the President's Private Party, 5 Golf Tournament tickets (non-transferable), and a complimentary exhibit booth.

Gold Level - \$25,000

Gold Exhibitors receive 8 invitations to the Welcome Reception and Gala Dinner, invitation to the President's Private Party, 4 Golf Tournament tickets (non-transferable), and a complimentary exhibit booth.

Silver Level - \$15,000

Silver Exhibitors receive 6 invitations to the Welcome Reception and Gala Dinner, invitation to the President's Private Party, 3 Golf Tournament tickets (non-transferable), and a complimentary exhibit booth.

Bronze Level - \$10,000

Bronze Exhibitors receive 4 invitations to the Welcome Reception and Gala Dinner, invitation to the President's Private Party, 2 Golf Tournament tickets (non-transferable), and a complimentary exhibit booth.

Copper Level - \$5,000

Copper Exhibitors receive 2 invitations to the Welcome Reception and Gala Dinner, invitation to the President's Private Party, 1 Golf Tournament ticket (non-transferable), and a complimentary exhibit booth.



TRAVEL & HOTEL INFORMATION



Escape to a cliff-top oasis, where the azure colored Caribbean Sea seamlessly merges with the rolling surf of the wide Atlantic.

To reserve a room, call El Conquistador at 888-543-1282 and mention you're attending the SOA Meeting to ensure you receive the discounted rate of \$189 per night.

Luis Muñoz Marin International (SJU) in San Juan is the most convenient airport.

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. Premium exhibitors are allowed to register up to four representatives without incurring an additional charge. Exhibitors are allowed to register two representatives without incurring an additional charge. **REGISTRATION BADGES FOR ALL PARTICIPANTS MUST BE WORN FOR ADMITTANCE.**

IMPORTANT DATES

| | |
|--------------------|--|
| April 9, 2010 | Deadline for Cancellation and Partial Refund |
| May 13, 2010 | Deadline for Exhibitor Application and \$500 Deposit |
| May 18, 2010 | Final Deadline for Balance of Exhibitor fees |
| May 18, 2010 | Deadline to Submit Copy for Final Program |
| May 23, 2010 | Deadline for Exhibitor Representative Pre-Registration |
| June 16, 2010 | Exhibitor Booth Set-up |
| June 17 - 19, 2010 | Exhibits Open (6:30am – 12:30pm) |
| June 19, 2010 | Exhibit Booth Break Down |

Payment Information

A \$500 non-refundable deposit, or the entire balance, is due with the receipt of the application no later than May 13, 2010. Applications submitted without a deposit will not be considered for booth assignment.

Full payment for booth space must be sent to the SOA office by May 18, 2010. After May 18, 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 April 9, 2010. 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. The SOA reserves the right to reassign space without refund.

FOR ANY ADDITIONAL INFORMATION ON EXHIBITING,
PLEASE CONTACT:

Chuck Freitag at 866-762-0730 or 410-494-4994 or
Email: cfreitag@datatrace.com

APPLICATION FOR EXHIBIT SPACE

Southern Orthopaedic Association • 27th Annual Meeting • Fajardo, Puerto Rico • June 16-19, 2010

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 LEVEL OF PARTICIPATION

- Platinum - \$35,000 Gold - \$25,000 Silver - \$15,000
 Bronze - \$10,000 Copper - \$5,000 Other _____

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 Southern Orthopaedic Association)
 Charge: Visa MasterCard American Express

Card Number _____ Exp. Date _____

Signature _____

PLEASE RETURN TO:

Southern Orthopaedic Association
110 West Road, Suite 227
Towson, MD 21204
Phone: 866-762-0730
Fax: 410-494-0515

APPLICATION AND PAYMENT MUST BE RECEIVED BY MAY 13, 2010.

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.