EXHIBITOR PROSPECTUS

Maryland Orthopaedic Association's 2017 Annual Meeting February 11, 2017 Loews Annapolis Hotel

Dear Exhibitor,

On Saturday, February 11, 2017, the Maryland Orthopaedic Association will hold its Annual Winter Scientific Meeting in Annapolis. This is our most ambitious meeting of the year, and features presentations and symposia on issues of current interest to practicing orthopaedists, as well as the presentation of twelve juried scientific papers by residents and fellows. We expect over 100 orthopaedic surgeons to attend.

On behalf of the Maryland Orthopaedic Association, I invite you to participate in the upcoming Winter Scientific Meeting as an Exhibitor. The major orthopaedic hospitals in Maryland support the Annual Meeting and it draws a mix of academic and private practice doctors with whom to interact. I am sure that your company will want to reflect its commitment to orthopaedics in Maryland. Please register as soon as possible; space is limited.

Thank you for your commitment to orthopaedic education in Maryland and I look forward to seeing you at the Annual Meeting in February.

Sincerely,

Ronald Delanois, MD
President, Maryland Orthopaedic Association

IMPORTANT DATES	
January 11, 2017	Deadline for Sponsor/Exhibitor Application and Payment
January 25, 2017	Last day to Submit Copy for Final Program
February 03, 2017	Deadline for Exhibitor Representative Pre-Registration
February 11, 2017	Exhibitor Booth Set-up (6:30 - 7:00 am) Exhibit Hours 7:00 am - 4:00 pm

Contact Audrey McDonough at 877-337-1200 or amcdonough@datatrace.com for more information

APPLICATION FOR EXHIBIT SPACE

Maryland Orthopaedic Association • 2017 Annual Meeting • February 11, 2017

Company Name

Address

City State Zip

Phone

Email

Current Contact Name

Title

Signature Date

Onsite Representative(s) for the Annual Meeting

1. _____

2. _____

**Additional badges may be purchased for $200 each.*

SELECT YOUR LEVEL OF SUPPORT

☐ *Executive Booth - $15,000*
(Receives prime booth placement, badges for 10 additional representatives, workshop opportunity at Annual Meeting)

☐ *Premium Booth - $5,000*
(Receives prime booth placement and badges for 2 additional representatives)

☐ *Exhibitor Booth - $2,500*

Exhibiting fees include:
2 Representative Badges • 6 ft table • 2 chairs • 1 Pre/Post Registration Attendee list • 1 trash can

*A tabletop exhibit is recommended, however a freestanding exhibit measuring no more than 8 x 10 is permitted.**

PAYMENT

☐ *Check (Payable to Maryland Orthopaedic Association)*
☐ *Charge:* ☐ *Visa* ☐ *MasterCard* ☐ *American Express*

Card Number Expiration Date

Print Name on Card Signature

Billing Address

Billing City / State / Zip Code

PLEASE RETURN TO:

Audrey McDonough
Maryland Orthopaedic Association
110 West Road, Suite 227
Towson, MD 21204
Phone: 877-337-1200 | Fax: 410-494-0515
Email: amcdonough@datatrace.com

APPLICATION AND PAYMENT MUST BE RECEIVED BY JANUARY 11, 2017

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 arid 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 to 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.