



## CODE OF ETHICS OPERATIV'S INTERACTIONS WITH HEALTHCARE PROFESSIONALS

(Based on ADVAMED Code of Ethics, effective July 1st, 2009)

Operativ is dedicated to the advancement of medical science, the improvement of patient care, and to the contributions that improve quality and reduce costs associated with joint replacement surgery. Operativ recognizes the obligation to facilitate ethical interactions between those individuals or entities involved in the provision of health care services and/or items to patients, which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Operativ's devices or services in the United States ("Healthcare Professionals").

Operativ's products and services are often highly dependent upon "hands on" Healthcare Professionals interaction from beginning to end. These products and services often serve as extensions of a physician's hands and require technical support during and after deployment.

### ***Interactions with Healthcare Professionals***

The scope of beneficial interactions between Healthcare Professionals and Operativ is broad and includes interactions intended to:

- *Promote the Advancement of Medical Technologies by Developing and improving techniques and collaborative processes between Operativ and Healthcare Professionals.* Innovation and creativity are essential to the development and evolution of Medical Technologies, which often occur outside a Company's laboratory.
- *Enhance the Safe and Effective Use of Medical Technologies.* The safe and effective use of sophisticated Navigation, surgical, or other Medical Technologies often requires Operativ to provide Healthcare Professionals appropriate instruction, education, training, service and technical support. Regulators often require this type of training as a condition of product approval.
- *Encourage Research and Education.* Operativ's support of *bona fide* medical research, education, and enhancement of professional skills improves patient safety and increases access to Medical Technologies.
- *Encourage vetted Patient Education.* Operativ recognizes the superiority of computer navigation, minimally invasive surgical techniques, and other advanced surgical methods related to joint replacement. To promote the dissemination of these methods, Operativ will develop strategic partnerships with independent entities to provide *bona fide*, vetted information to patients.

### ***The Purpose of the Code of Ethics***

Operativ recognizes that Healthcare Professionals first duty is to act in the best interest of patients. Operativ can serve the interests of patients through beneficial collaborations with Healthcare Professionals. To ensure that these collaborative relationships meet high ethical standards, they must be conducted with appropriate transparency and in compliance with applicable laws, regulations and government guidance. Operativ recognizes the obligation to facilitate ethical interactions with Healthcare Professionals in order to ensure that medical decisions are based on the best interests of the patient. The ethical principles that govern these interactions are the subject of this Code of Ethics.

### **II. Code of Ethics Compliance**

Operativ is fully committed to this Code and has implemented an effective compliance program – one which includes policies and procedures that foster compliance with The Code with respect to their interactions with Healthcare Professionals.

### **III. Company-Conducted Product Training and Education**

Operativ has a responsibility to make training and education on their products and Medical Technologies available to Healthcare Professionals. Operativ may also provide education to Healthcare Professionals. “Training” means training on the safe and effective use of Medical Technologies. “Education” means communicating information directly concerning or associated with the use of the Companies’ Medical Technologies. Training and Education programs include, but are not limited to, “hands on” training sessions, cadaver workshops, lectures and presentations, grand rounds, town hall lectures, multi-media and social media, and remote presentations. Companies should adhere to the following principles when conducting training and education programs concerning Medical Technologies for Healthcare Professionals:

- Programs and events should be conducted in settings that are conducive to the effective transmission of information. These may include clinical, educational, conference, or other settings, such as hotels or other commercially available meeting facilities. In some cases, it may be appropriate for a Company representative to provide training and education at the Healthcare Professional’s location. It may also include multi-media and remote meetings that foster education and save on associated costs.
- Programs providing “hands on” training on Medical Technologies should be held at training facilities, medical institutions, laboratories, or other appropriate facilities. The training staff used by the Company should have the proper qualifications and expertise to conduct such training. Training staff may include qualified field sales employees, surgical assistants, surgeons, and others who have the technical expertise necessary to perform the training.
- Operativ may provide Healthcare Professional attendees with modest meals and refreshments in connection with these programs. Any such meals and refreshments should be modest in value and subordinate in time and focus to the training and/or educational purpose of the meeting.
- Where there are objective reasons to support the need for out-of-town travel to efficiently deliver Training and Education on Medical Technologies, Operativ may pay for

reasonable travel and modest lodging costs of the attending Healthcare Professionals. It is not appropriate for Companies to pay for the meals, refreshments, travel, or other expenses for guests of Healthcare Professionals or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

- Operativ cannot provide anything of value to Healthcare Professionals that is not directly related to education on its products and/or technologies. However, Operativ is obligated to ensure that only *bona fide*, evidence-based, and vetted information is related to consumers and patients regarding advanced techniques in joint replacement. To this end, Operativ may refer Healthcare Professionals to independent, strategic partners to enable and ensure effective and *bona fide* patient education.

#### **IV. Supporting Third-Party Educational Conferences**

*Bona fide* independent, educational, scientific, and policymaking conferences promote scientific knowledge, medical advancement and the delivery of effective health care. These typically include conferences sponsored by national, regional, or specialty medical associations and conferences sponsored by hospitals and accredited continuing medical education providers. Operativ may support these conferences in various ways:

- *Conference Grants.* Operativ may provide a grant to the conference sponsor to reduce conference costs. They may also provide grants to a training institution or the conference sponsor to allow attendance by medical students, residents, fellows, and others who are Healthcare Professionals in training. Operativ may provide grants when: (1) the gathering is primarily dedicated to promoting objective scientific and educational activities and discourse; and (2) the training institution or the conference sponsor selects the attending Healthcare Professionals who are in training. Such grants should be paid only to organizations with a genuine educational function and may be used to reimburse only the legitimate expenses for *bona fide* educational activities. Such grants also should be consistent with applicable standards established by the conference sponsor and anybody accrediting the educational activity. The conference sponsor should independently control and be responsible for the selection of program content, faculty, educational methods, and materials.
- *Conference Meals and Refreshments.* Operativ may provide funding to the conference sponsor to support the provision of meals and refreshments to conference attendees. Also, Operativ may provide meals and refreshments for Healthcare Professional attendees if such meals and refreshments are provided: (1) to all Healthcare Professional attendees (with the limited exception noted below), and (2) in a manner that is consistent with applicable standards established by the conference sponsor and the body accrediting the educational activity. Meals and refreshments may be provided to fewer than all Healthcare Professional attendees if Operativ satisfies all other principles related to meals set forth in Section VIII. Any meals and refreshments should be modest in value, subordinate in time and focus to the purpose of the conference, and clearly separate from the continuing medical education portion of the conference.
- *Faculty Expenses.* Companies may make grants to conference sponsors for reasonable honoraria, travel, lodging, and modest meals for Healthcare Professionals who are *bona fide* conference faculty members.

- *Advertisements and Demonstration.* Companies may purchase advertisements and lease booth space for Company displays at conferences.

## V. Sales, Promotional, and Other Business Meetings

Operativ may conduct sales, promotional, and other business meetings with Healthcare Professionals to discuss, for example, Medical Technology features, sales terms, or contracts. Often, these meetings occur close to the Healthcare Professionals place of business. It is appropriate to pay for reasonable travel costs of attendees when necessary (*e.g.*, for plant tours or demonstrations of non-portable equipment) and/or to provide occasional modest meals and refreshments in connection with such meetings. However, it is not appropriate to pay for meals, refreshments, travel, or lodging of guests of Healthcare Professionals or any other person who does not have a *bona fide* professional interest in the information being shared at the meeting. See Section VIII for additional principles related to the provision of meals associated with Healthcare Professionals business interactions.

## VI. Consulting Arrangements with Healthcare Professionals

Operativ may engage Healthcare Professionals to provide a wide-range of valuable, *bona fide* consulting services through various types of arrangements, such as contracts for research, product development, development and/or transfer of intellectual property, marketing, participation on advisory boards, presentations at Operativ-sponsored training and other services. Operativ may pay consultants fair market value compensation for performing these types of services, ***provided that they are intended to fulfill a legitimate business need and do not constitute an unlawful inducement.*** Operativ should comply with the following standards in connection with consulting arrangements with Healthcare Professionals:

- Consulting agreements should be written and describe all services to be provided. When a Company contracts with a consultant to conduct clinical research services, there should also be a written research protocol.
- Consulting arrangements should be entered into only where a legitimate need for the services is identified in advance and documented.
- Selection of a consultant should be made on the basis of the consultant's qualifications and expertise to meet the defined need.
- Compensation paid to a consultant should be consistent with fair market value in an arm's length transaction for the services provided and ***must not be based on the volume or value of the consultant's past, present or anticipated business.***
- Operativ may pay for documented, reasonable and actual expenses incurred by a consultant that are necessary to carry out the consulting arrangement, such as costs for travel, modest meals, and lodging.
- The venue and circumstances for Operativ's meetings with consultants should be appropriate to the subject matter of the consultation. These meetings should be conducted in clinical, educational, conference, or other settings, including hotel or other commercially available meeting facilities, conducive to the effective exchange of information.

- Operativ-sponsored meals and refreshments provided in conjunction with a consultant meeting should be modest in value and should be subordinate in time and focus to the primary purpose of the meeting. ***Operativ will not provide recreation or entertainment in conjunction with these meetings.***
- Operativ’s sales personnel may provide input about the suitability of a proposed consultant, but sales personnel should not control or unduly influence the decision to engage a particular Healthcare Professionals as a consultant.

***Provisions on Payment of Royalties.*** Arrangements involving the payment of royalties to a Healthcare Professional should meet the contractual standards set forth above. Healthcare Professionals, acting individually or as part of a group in which they are an active participant, often make valuable contributions that improve products or Medical Technologies. They may develop intellectual property, for example, patents, trade secrets, or know-how, under a product or technology development or intellectual property licensing agreement. Operativ should enter into a royalty arrangement with a Healthcare Professional only where the Healthcare Professional is expected to make or has made a novel, significant, or innovative contribution to, for example, the development of a product, technology, process, or method.

A significant contribution by an individual or group, if it is the basis for compensation, should be appropriately documented. The calculation of royalties payable to a Healthcare Professional in exchange for Intellectual Property should be based on factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence. For example, royalties paid in exchange for Intellectual Property should not be conditioned on: (1) a requirement that the Healthcare Professionals purchase, order or recommend any product or medical technology of the Company or any product or technology produced as a result of the development project; or (2) a requirement to market the product or medical technology upon commercialization.

Operativ may, however, elect to enter into separate consulting agreements with Healthcare Professionals for marketing services if such services meet the requirements set forth in this Section VI above.) Operativ will exclude from the calculation of royalties the number of units purchased, used, or ordered by the Healthcare Professionals and/or members of the Healthcare Professionals practice.

## **VII. Prohibition on Entertainment and Recreation**

Operativ interactions with Healthcare Professionals should be professional in nature and should facilitate the exchange of medical or scientific information that will benefit patient care. To ensure the appropriate focus on an educational and/or informational exchange and to avoid the appearance of impropriety, Operativ will not provide or pay for any entertainment or recreational event or activity for any non-employee Healthcare Professionals. Such activities include, for example, theater, sporting events, golf, skiing, hunting, sporting equipment, and leisure or vacation trips. Such entertainment or recreational events, activities, or items should not be provided, regardless of: (1) their value; (2) whether Operativ engages the Healthcare Professionals as a speaker or consultant; or (3) whether the entertainment or recreation is secondary to education.

## **VIII. Modest Meals Associated with Healthcare Professionals Business Interactions**

Operativ’s business interactions with Healthcare Professionals may involve the presentation of

scientific, educational, or business information and include, but are not limited to, the different types of interactions described in Sections III through VI of this Code of Ethics. Such exchanges may be productive and efficient when conducted in conjunction with meals. Accordingly, modest meals may be provided as an occasional business courtesy consistent with the limitations in this section.

**Purpose.** The meal should be incidental to the *bona fide* presentation of scientific, educational, or business information and provided in a manner conducive to the presentation of such information. The meal should not be part of an entertainment or recreational event.

**Setting and Location.** Meals should be in a setting that is conducive to *bona fide* scientific, educational, or business discussions. Meals may occur at the Healthcare Professionals place of business. However, in some cases the place of business may be a patient care setting that is not available for, or conducive to, such scientific, educational, or business discussions. In other cases, it may be impractical or inappropriate to provide meals at the Healthcare Professionals place of business, for example, (1) where the Medical Technology cannot easily be transported to the Healthcare Professionals location, (2) when it is necessary to discuss confidential product development or improvement information, or (3) where a private space cannot be obtained onsite.

**Participants.** Operativ will provide a meal only to Healthcare Professionals who actually attend the meeting. Operativ will not provide a meal for an entire office staff where everyone does not attend the meeting. Operativ will not pay for meals for guests of Healthcare Professionals or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

#### **IX. Educational Items; Prohibition on Gifts**

Operativ occasionally may provide items to Healthcare Professionals that benefit patients or serve a genuine educational function for Healthcare Professionals. Other than medical textbooks or anatomical models used for educational purposes, any such item should have a fair market value of less than \$25.00. Operativ may not provide items that are capable of use by the Healthcare Professionals (or his or her family members, office staff or friends) for non-educational or non-patient-related purposes, for example, a DVD player or MP3 player/I-Pod. Operativ will not give Healthcare Professionals any type of non-educational branded promotional items, even if the item is of minimal value and related to the Healthcare Professionals work or for the benefit of patients. Examples of non-educational branded promotional items include pens, notepads, mugs, and other items that have Operativ's name, logo, or the name or logo of one of its Medical Technologies. Operativ will not provide Healthcare Professionals with gifts such as cookies, wine, flowers, chocolates, gift baskets, holiday gifts or cash or cash equivalents.

This section is not intended to address the legitimate practice of providing products for evaluation and demonstration purposes, which is addressed in Section XII.

#### **X. Provision of Coverage, Reimbursement and Health Economics Information**

As Medical Technologies have become increasingly complex, so have payor coverage and reimbursement policies. Patient access to necessary Medical Technology may be dependent on

Healthcare Professionals and/or patients having timely and complete coverage, reimbursement, and health economic information. Consequently, Operativ may provide such information regarding its Medical Technologies if it is accurate and objective. Operativ may also collaborate with Healthcare Professionals, patients and organizations representing their interests, to achieve government and commercial payor coverage decisions, guidelines, policies, and adequate reimbursement levels that allow patients to access its Medical Technologies.

Permissible activities involving the provision of coverage, reimbursement and health economic information may include, but are not limited to:

- Identifying the clinical value of Operativ's Medical Technologies and the services and procedures in which they are used when providing coverage, reimbursement and health economics information and materials to Healthcare Professionals, professional organizations, patient organizations, strategic partners, and payors.
- Collaborating with Healthcare Professionals, their professional organizations, and patient groups to conduct joint advocacy on coverage, reimbursement and health economics issues; supporting Healthcare Professionals and their professional organizations in developing materials and otherwise providing direct or indirect input into payor coverage and reimbursement policies.
- Promoting accurate Medicare and other payor claims by providing accurate and objective information and materials to Healthcare Professionals regarding Operativ's Medical Technologies, including identifying coverage, codes and billing options that may apply to those Medical Technologies or the services and procedures in which they are used.
- Providing accurate and objective information about the economically efficient use of Operativ's Medical Technologies, including where and how they can be used within the continuum of care.
- Providing information related to Operativ's Medical Technologies regarding available reimbursement revenues and associated costs.
- Providing accurate and objective information designed to offer technical or other support intended to aid in the appropriate and efficient use or installation of the Operativ's Medical Technologies.
- Facilitating patient access to Operativ's Medical Technologies by providing Healthcare Professionals with assistance in obtaining patient coverage decisions from payors. This assistance may include providing information and/or training on payor policies and procedures for obtaining prior authorization, and providing sample letters and information on medical necessity and appeals of denied claims. In addition, at the request of a Healthcare Professional to facilitate patient access to Operativ's Medical Technology, and subject to appropriate privacy safeguards, Operativ may assist the patient by facilitating the preparation and submission of requests for coverage determinations, prior authorizations, pre-certifications and appeals of denied claims, relating to Operativ's own Medical Technology; however such assistance should not be provided as an unlawful inducement.

Operativ may not interfere with a Healthcare Professionals independent clinical decision-making

or provide coverage, reimbursement and health economics support as an unlawful inducement. For example, Operativ will not provide free services that eliminate an overhead or other expense that a Healthcare Professional would otherwise of business prudence or necessity have incurred as part of its business operations if doing so would amount to an unlawful inducement. Further, Operativ should not suggest mechanisms for billing for services that are not medically necessary, or for engaging in fraudulent practices to achieve inappropriate payment.

## **XI. Research and Educational Grants and Charitable Donations**

Operativ may provide research and educational grants and charitable donations. However, Operativ ***will not provide such grants or donations as an unlawful inducement***. Therefore, Operativ will: (a) adopt objective criteria for providing such grants and donations that do not take into account the volume or value of purchases made by, or anticipated from, the recipient; (b) implement appropriate procedures to ensure that such grants and donations are not used as an unlawful inducement; and (c) ensure that all such grants and donations are appropriately documented. Operativ’s sales personnel may provide input about the suitability of a proposed grant or charitable donation recipient or program, but sales personnel should not control or unduly influence the decision of whether a particular Healthcare Professional or institution will receive a grant or donation or the amount of such grant or donation. Operativ will implement procedures to monitor compliance with this section.

### **a. Research Grants**

Research provides valuable scientific and clinical information, improves clinical care, leads to promising new treatments, promotes improved delivery of health care, and otherwise benefits patients. In furtherance of these objectives, Operativ may provide research grants to support independent medical research with scientific merit. Such activities should have well-defined objectives and milestones and may not be linked directly or indirectly to the purchase of Medical Technologies.

Operativ-initiated or directed research involving Operativ’s Medical Technologies (such as clinical study agreements) is addressed separately in Section VI.

### **b. Educational Grants**

Educational grants may be provided for legitimate purposes, including, but not limited to, the examples below. As noted in Section IV, Operativ may make educational grants to conference sponsors or training institutions. Operativ will not make educational grants to individual Healthcare Professionals.

- *Advancement of Medical Education.* Operativ may make grants to support the genuine medical education of medical students, residents, and fellows participating in fellowship programs that are charitable or have an academic affiliation, or other medical personnel. (For additional considerations regarding educational grants, see Section IV.)
- *Public Education.* Operativ may make grants and provide content for the purpose of supporting education of patients or the public about important health care topics. However, Operativ ***will not provide such grants or content as an unlawful inducement***.

### **c. Charitable Donations**

Operativ may make monetary or Medical Technology donations for charitable purposes, such as

supporting indigent care, patient education, public education, or the sponsorship of events where the proceeds are intended for charitable purposes. Donations should be motivated by *bona fide* charitable purposes and should be made only to *bona fide* charitable organizations or, in rare instances, to individuals engaged in genuine charitable activities for the support of a *bona fide* charitable mission. Operativ will exercise diligence to ensure the *bona fide* nature of the charitable organization or charitable mission.

## **XII. Evaluation and Demonstration Products**

Providing products to Healthcare Professionals at no charge for evaluation or demonstration purposes can benefit patients in many ways. These benefits include improving patient care, facilitating the safe and effective use of products, improving patient awareness, and educating Healthcare Professionals regarding the use of products. Under certain circumstances described below, Operativ may provide reasonable quantities of products to Healthcare Professionals at no charge for evaluation and demonstration purposes. This section is limited to providing evaluation and demonstration products only and is not intended to address any other arrangement.

Operativ products that may be provided to Healthcare Professionals for evaluation include single use (*e.g.*, consumable or disposable products) and multiple use products (sometimes referred to as “capital equipment”). These products may be provided at no charge to allow Healthcare Professionals to assess the appropriate use and functionality of the product and determine whether and when to use, order, purchase, or recommend the product in the future.

***Single Use/Consumables/Disposables.*** The number of single use products provided at no charge should not exceed the amount reasonably necessary for the adequate evaluation of the products under the circumstances.

***Multiple Use/Capital.*** Multiple use products provided without transfer of title for evaluation purposes should be furnished only for a period of time that is reasonable under the circumstances to allow an adequate evaluation. The terms of an evaluation of such multiple use products should be set in advance in writing. Operativ will retain title to such multiple use products during the evaluation period and should have a process in place for promptly removing such multiple use products from the Healthcare Professionals location at the conclusion of the evaluation period unless the Healthcare Professionals purchases or leases the products.

***Demonstration.*** Operativ demonstration products are typically unsterilized single use products or mock-ups of such products that are used for Healthcare Professionals and patient awareness, education, and training. For example, a Healthcare Professional may use a demonstration product to show a patient the type of device that will be implanted in the patient. Demonstration products typically are not intended to be used in patient care. Operativ will provide Healthcare Professionals with documentation and disclosure regarding the no-charge status of evaluation and demonstration products.