EndoShape	STANDARD OPERATING PROCEDURE	Document No.: ESI 900001 Rev.: B
Title:	**ENDOSHAPE Code of Conduct and Policy Regarding Reporting of Potential Violations Effective as of October 2015**	

EndoShape, Inc. is committed to good corporate citizenship. Our policy is to conduct our business affairs honestly and ethically. This Code of Conduct ("Code") provides a general statement of ENDOSHAPE's expectations regarding the ethical standards to which each director, officer and employee should adhere while acting on our behalf. The Code sets out basic principles to guide our employees, officers and directors, as well as contractors and others who conduct business on behalf of ENDOSHAPE. All of our employees, officers and directors must conduct themselves accordingly and seek to avoid even the appearance of improper behavior. This Code governs how we act and think about the conduct of our business. Conduct in violation of this policy is unacceptable in the workplace and in any work-related setting outside the workplace. Any employee or contract worker who violates this Code will be subject to disciplinary action, up to and including termination of employment or engagement.

In addition to complying with this Code, ENDOSHAPE employees must comply with our other policies as reflected in our Employee Handbook, our Comprehensive Compliance Program and other policies and procedures.

Compliance with Laws

We must comply with all national, state and local laws applicable to Company activities and should perform our duties and discharge our responsibilities in an honest and ethical manner.

Patient Well Being

Our primary goal is to improve the lives of patients and we strive to place patient well-being first when balancing risks and benefits.

Conflicts of Interest

Directors

Members of our Board of Directors owe fiduciary duties to ENDOSHAPE and its stockholders/investors, and are expected to act in the best interests of ENDOSHAPE and its stockholders/investors. Each director is responsible for ensuring that other commitments do not conflict, or materially interfere with, his/her responsibilities to ENDOSHAPE. Directors should avoid activities that may interfere with the ability to perform his/her fiduciary duties objectively and effectively. If a director has any concerns about whether serving as a director, officer, employee or consultant of another company might conflict with his or her duties to ENDOSHAPE, such concerns should be raised at an executive session of the Board in advance of accepting an invitation to serve on the other company's board, or as an officer or employee of that company. The independent directors shall consult, as appropriate, with management and counsel in assessing the potential conflict. Directors also are required to disclose any potential conflict of interest, or personal interest in a transaction that the Board is considering in an executive session of the Board. If a potential conflict of interest arises between Board meetings, then directors should disclose such potential conflict to the Chair of the Nominating and Governance Committee. Additionally, a director shall recuse him/herself from participation in any deliberation or decision regarding a matter or transaction in which there is a conflict of interest between his/her personal interests and ENDOSHAPE's interests. Related party transactions must be disclosed to the Audit/Compliance Committee.

Employees and Contractors

We should avoid situations in which our personal, family or financial interests conflict or even appear to conflict with those of ENDOSHAPE or compromise its interests. We should handle all actual or apparent conflicts of interest between our personal and professional relationships in an honest and ethical manner. Conflicts are not always clear-cut. A "conflict of interest" exists when our own private interest interferes in any way with the interests of the Company. A conflict situation can arise when we take action or have interests that may make it difficult to perform our Company work objectively and effectively. Conflicts of interest may also arise when we, or a member of our family, receive improper personal benefits as a result of our position in the Company, such as when a family member or we receive substantial gifts from companies that we do business with.

It is almost always a conflict of interest when we work simultaneously for a competitor, customer or supplier. We are not allowed to work for a competitor as a consultant or board member without prior written consent. The best policy is for us to avoid any direct or indirect business connection with our customers, suppliers or competitors, except on the Company's behalf. We owe a duty to the Company to advance its legitimate interests when the opportunity to do so arises. If a conflict or potential conflict of interest exists, contact the Compliance Officer for further guidance.

Full, Fair and Accurate Disclosure

It is of paramount importance to all of us that ENDOSHAPE's disclosure in documents filed with the Securities and Exchange Commission, in other ENDOSHAPE public communications or with the investors is full, fair, accurate, timely and understandable. We must take all steps necessary to assist ENDOSHAPE in fulfilling these responsibilities, consistent with our role in the Company. We should give prompt, accurate and complete answers to all inquiries in connection with ENDOSHAPE's preparation of public disclosures and reports and disclosures to our investors.

Code of Ethics for Senior Management

Any person holding the title of Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, Controller, Principal Accounting Officer, or Vice President, Finance ("Senior Management") bears a special responsibility for promoting integrity throughout the Company. Furthermore, the Senior Officers have a responsibility to foster a culture throughout the Company that ensures the fair and timely reporting of the Company's results of operation and financial condition and other financial information.

Because of this special role, each member of Senior Management will:

- Perform his/her duties in an honest and ethical manner;
- Handle all actual or apparent conflicts of interest between his/her personal and professional relationships in an ethical manner;
- Take all necessary actions to ensure full, fair, accurate, timely and understandable disclosure in reports and documents that the Company files with, or submits to,

government agencies and in other public communications as well as those to our investors;

- Comply with all applicable laws, rules and regulations of federal, state and local governments; and
- Proactively promote and be an example of ethical behavior in the work environment.

Scientific Integrity

Research integrity is fundamental to the scientific process and to ENDOSHAPE's ability to bring novel products to market.

All ENDOSHAPE research and development must be conducted according to all applicable laws and regulations, authorship rules and to the generally accepted ethical standards of the scientific community. Scientific misconduct, such as fabrication, falsification or plagiarism in proposing, conducting or reporting research, disregards the intellectual contributions and property of others, impedes the progress of research and corrupts the scientific record. It is prohibited.

Respect in the Workplace

Discrimination based on race, color, religion, national origin, sexual orientation, sex, age or disability, as well as certain forms of harassment, is illegal in the United States and many other countries. ENDOSHAPE does not permit harassment or discrimination prohibited by law.

Fellow employees, colleagues, customers, vendors, competitors and government officials are all to be treated with respect. Disruptive, abusive or otherwise inappropriate behavior at work or while representing ENDOSHAPE is not tolerated.

Alcohol and Drugs in the Workplace

ENDOSHAPE is committed to providing a drug-free, healthful and safe environment. ENDOSHAPE does not permit the possession, manufacture, distribution, sale or use of alcohol or illegal drugs on Company premises, except moderate use of alcohol by adults at Company-sponsored or Company-sanctioned events.

Environmental, Health and Safety

Each of us is responsible for observing the safety and health rules and practices that apply to our work, and for compliance with environmental, health, and safety laws and regulations. While at work, you must:

- Observe posted warnings and regulations;
- Take precautions necessary to protect yourself and your co-workers, including wearing appropriate clothing and protective equipment;
- Immediately report to appropriate management any potentially unsafe condition or any environmental or safety concern;
- Immediately report any accident or injury sustained on the job; and

- Follow proper practices related to waste disposal, emissions and use of toxic materials.

Gifts, Bribes and Improper Payments

We forbid payments of any kind to any person either to obtain an improper advantage in selling goods and services or to advance our interests with governmental authorities. Among the prohibited activities are:

- Payments, gifts or services intended to influence or even appearing to influence a government official's actions; and
- Furnishing something of value to an intermediary (e.g. an employee of a customer) with the intent of having the intermediary do something that would violate this policy.

Reasonable expenditures for gifts and entertainment for non-governmental business contacts may be made if such expenditures are related to a business relationship, have been appropriately authorized, are correctly recorded on the books of the Company and do not conflict with laws and our specific policies related to interactions with healthcare professionals, as discussed below. Entertainment or gifts, however, should not be of substantial monetary value or exceed the value customarily provided in the industry.

The pharmaceutical and healthcare industries are subject to specific laws, regulations and practices relating to payments to physicians and customers. Information about the Company's policies in this area is provided below under "Healthcare Laws—Product Information and Marketing."

Corporate Communications

In voluntary compliance with federal securities laws (we are not governed by these laws since we are not a publically traded company), you may not disclose material non-public information (internal information about the Company) to anyone outside the Company except as required in the performance of your regular duties. In order to preclude any inadvertent disclosure of confidential information, the following procedure must be adhered to:

- If a statement or other information is sought from anyone outside the Company, including the press or financial community, the requestor should be directed to the CEO and/or COO. This procedure applies to anyone from outside the Company who is seeking information about our Company or our fields of technology.

Trading Compliance

You cannot legally trade in the securities of other companies with which we do business if you know of material information, which is not yet known to the public (such non-public information is commonly known as "insider information"). Material information is any type of information, positive or negative, that could reasonably be expected to affect the market price of these company's securities.

If you are aware of any material inside information concerning these other companies, or about others with which ENDOSHAPE either has plans for a possible transaction or from whom

ENDOSHAPE has received information under an obligation of confidentiality, generally, you cannot legally:

- Buy or sell these other company securities in the situation described above or advise anyone else to do so;
- Communicate such information to other persons (this activity is referred to as "tipping");
- Engage in any other action to take personal advantage of that information.

Healthcare Laws

Product Information and Marketing

We are committed to providing information to physicians and patients that is accurate, supported by scientific evidence, and in every context, presented honestly and fairly. In your marketing efforts or as part of medical information activities, you must not:

- Use false or misleading information or make any other form of misrepresentation;
- Overstate the efficacy of our products;
- Downplay or misrepresent the risks associated with our products or safety information; or
- Use materials or messages that have not been approved under relevant Company procedures.

Our labeling, advertising, promotion and sales activities must meet these standards.

We are also committed to abiding by the laws and regulations that apply to advertising and promotion of our products, including rules of regulatory authorities such as the FDA. All employees engaged in marketing and sales activities must understand the basic rules and policies that ENDOSHAPE follows. If you are engaged in such activities, you must be familiar with and comply with the regulations and our internal policies, including our Comprehensive Compliance Program. If you have any questions about the laws that apply to your activities in the country in which you operate, you should consult with your supervisor or the Compliance Officer.

Product Experience Disclosure

You are required to inform us of any adverse reactions to our products when you become aware of them. For more information about your obligation in this area you should consult the Complaint Handling Process SOP 001024.

Interactions With Healthcare Professionals

In many countries, anti-kickback laws prohibit the offering of anything of value that is intended to influence a person to recommend, prescribe, or purchase a healthcare product that may be reimbursed by the government (e.g., Medicare or Medicaid in the United States). Several states in the United States have similar laws that also apply to products reimbursed by private payers. The Company is committed to complying with these laws. Many elements of

your interactions with physicians or other customers and the programs the Company offers need to be reviewed to ensure compliance with these complex laws. If you are involved in the marketing or sale of Company products in the United States, you should become familiar with Company rules and policies in this area. For other countries, please check with the Compliance Officer.

In response to anti-kickback laws, ENDOSHAPE has adopted the ADVAMED code, a voluntary code of conduct for interactions with healthcare professionals (see appendix 1). The Company requires compliance with the ADVAMED Code as Company policy in the United States. The ADVAMED Code limits gifts, entertainment and certain other activities between Company employees and healthcare professionals. The Code also addresses topics such as continuing education and consulting and speaker arrangements. If you are involved in marketing and selling activities at ENDOSHAPE in the United States, you must read, understand and comply with the ADVAMED Code in your interactions with healthcare professionals, including medical students, formulary committee members, and all individuals licensed to prescribe drugs or medical devices.

Patient Privacy

During the course of our business activities we may have the opportunity to have access to a person's medical records or medical or other personal information. This information is entrusted to us with the understanding that it will be kept confidential. You must guard the confidentiality of all personal information, including medical information, to which you have access. Disclosure and use of such information must be consistent with the Company's privacy policies. Privacy laws and policies vary from country to country. For more information please contact the member of the Legal department that supports your group.

Business Intelligence

You must never use or ask any third party to use unlawful or unethical means, such as misrepresentation, deception, theft, spying, or bribery, to gather competitive intelligence.

You are free to gather intelligence about companies from public sources such as their web site and published articles and through other lawful means.

Intellectual Property

Protection of our intellectual property — including scientific and technical knowledge, know-how and experience, trade secrets, patents, trademarks, and copyrights — is essential to maintaining our competitive advantage.

Much of the information developed in research, development, manufacturing, marketing, sales and other activities is original or sensitive in nature and important for our success. Such information must be safeguarded. This confidential or proprietary information includes any information maintained in secrecy that gives us an opportunity to obtain an advantage over competitors who do not know about it or use it. Examples of confidential or proprietary information include marketing plans, sales data, results of clinical trials, research and technical data, manufacturing techniques, information regarding potential business development opportunities, and pricing information and strategies. All confidential or proprietary information must be protected by employees and not disclosed to outsiders. Its loss through inadvertent or

improper disclosure could be harmful to the Company. Never provide confidential information to outsiders without having a written form of confidentiality agreement signed in a form approved by the CEO and/or COO. Do not discuss confidential information in public places where others may overhear. Be careful when using the fax machine, e-mail and other forms of electronic communication to make sure information is not inadvertently sent to the wrong party.

Employees and agents of the Company are required to sign agreements reminding them of their obligation not to disclose the Company's confidential or proprietary information while employed and after they leave the Company. The loyalty, integrity and sound judgment of employees both on and off the job are essential for protection of our information.

In addition to protecting our intellectual property rights you must respect the intellectual property rights of others. Unauthorized use of the intellectual property rights of others is unethical and may expose the Company to civil lawsuits and damages. Theft or misappropriation of intellectual property may result in significant fines and criminal penalties for the Company and you.

Antitrust and Competition Laws

Our policy is to compete fairly and legitimately and to comply with antitrust laws (sometimes called competition laws). These laws are complex and not easy to summarize. At a minimum, these laws prohibit agreements between the Company and our competitors that affect prices, terms or conditions of sale or fair competition. These laws prohibit agreements or understandings (written or unwritten):

- between the company and any of its competitors regarding prices, terms, or conditions of sale
- restraining full and fair competition

To avoid violations of the law or even the appearance of impropriety, you should not engage in discussions with competitors that relate to prices, terms and conditions of sales, costs, profits, product capacity, volume, market share, sales territories or allocation of customers.

Antitrust laws apply to many aspects of business behavior. Many countries have competition laws that are sometimes more stringent than United States antitrust laws and regulate, among other things, distribution agreements, patent copyright and trademark licenses, territorial restrictions on resellers, rebates and discounts to customers and pricing policies generally. Those employees with responsibilities in business areas that may be impacted by antitrust and competition laws, particularly those engaged in marketing and sales activities, must be fully aware of the laws and their implications. These laws are vigorously enforced. Violations may result in severe penalties, including criminal sanctions against individual employees. You should seek advice from the CEO or COO if you are unsure as to whether certain activities may be problematic.

Business and Scientific Records

We have records management policies and procedures to ensure records are maintained, stored, and when appropriate, destroyed in accordance with our needs and in

compliance with applicable laws and regulations. You are expected to be familiar with the specific requirements of your business and location as well as applicable Company procedures.

All data must be recorded according to ENDOSHAPE's scientific, manufacturing and Quality Assurance/Quality Control standard operating procedures and in accordance with all applicable laws and regulations.

Company records include paper documents, handwritten notes, voicemail, e-mail, audio or video media, computer files on disk, servers or tape and any other medium that contains information about the Company or our business activities.

Our Records Retention Procedure 001011 is available through the Regulatory Affairs and Quality Assurance (RAQA) department.

ENDOSHAPE Property and Resources

You are responsible for appropriate use of ENDOSHAPE facilities, equipment and services. All ENDOSHAPE facilities and equipment are ENDOSHAPE property. ENDOSHAPE reserves the right to access all of its property as permitted by applicable local law.

Personal use of company time, equipment or other resources must be reasonable and not interfere with business operations or job responsibilities. You should use good judgment and obtain approval from your supervisor in uncertain circumstances.

Any use of ENDOSHAPE facilities, equipment or services not specifically described here must be in accordance with applicable ENDOSHAPE policies.

International Issues

Employees involved in international business must be aware that many additional laws and regulations apply to your activities in all of the areas mentioned above and, in particular, in the field of healthcare. For more information or if you have any questions, please contact the CEO and/or COO.

The United States and other countries where we do business have laws that restrict or prohibit doing business with certain countries and parties. The United States also has laws that regulate how companies must respond to boycotts enforced by one set of countries against another.

Employees responsible for international business must be aware of these laws and how they apply. Anyone not familiar should consult with the CEO or COO prior to negotiating any international transaction.

Further Information

Please contact the Compliance Officer if you have any questions about this Code or require further information.

The most current version of this Code will be posted on the Company's website and filed as an exhibit at the Company. Any substantive amendment or waiver of this Code may be made only by the Board of Directors upon a recommendation of the Audit and Compliance Committees, and will be disclosed, including the reasons for such action, on the Company's

website and by a filing with the Board of Directors. ENDOSHAPE will maintain the disclosure about such amendment or waiver on the website for at least twelve months and shall retain the disclosure concerning the action for at least five years.

Reporting and Compliance Procedure

If you become aware of conduct by an officer, director, employee or contract worker that you believe in good faith is a potential violation of this Code, you are obligated to notify the Compliance Officer as soon as possible. This obligation includes any complaint or concern regarding ENDOSHAPE's accounting, internal accounting controls, or auditing matters, or any concerns regarding questionable accounting or auditing matters.

If you wish to report such matters ***anonymously***, you may describe the concern or complaint to the Compliance Officer by one of the following methods:

By Mail:

EndoShape, Inc.
Compliance Officer
5425 Airport Blvd., Suite 101
Boulder, CO 80301

By Toll-Free Telephone:

844-870-5069 (direct line to the Compliance Officer)

You should provide reasonable detail of the complaint, including as much detail regarding the matter, date of occurrence and individuals involved as possible in order to allow the Compliance Officer to properly consider and investigate your concern or complaint.

Persons outside ENDOSHAPE may also report complaints or concerns to the Compliance Officer by the Mail or Toll Free Telephone methods.

Allegations of violations of the Code should be made only in good faith and not with the intent to embarrass or to put someone in a false light. If you become aware of a suspected or potential violation, don't try to investigate or resolve it on your own. Prompt disclosure under this Code is vital to ensuring a timely and thorough investigation and resolution. You are expected to cooperate in internal or external investigations of alleged violations of the Code.

In response to every good faith report of conduct potentially in violation of the Code of Conduct, ENDOSHAPE will undertake an effective and thorough investigation, and if improper conduct is found, ENDOSHAPE will take appropriate disciplinary and remedial action. ENDOSHAPE will attempt to keep its discussions with any person reporting a violation confidential to the extent reasonably possible without compromising the effectiveness of the investigation.

Employees and contract workers **are protected by law from retaliation for reporting possible violations** of this Code of Conduct or for participating in procedures connected with an investigation, proceeding or hearing conducted by ENDOSHAPE or a government agency with respect to such complaints. ENDOSHAPE will take disciplinary action up to and including

the immediate termination of any employee or contract worker who retaliates against another employee or contract worker for reporting any of these alleged activities.

Approved by:

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William Aldrich
Chief Executive Officer, EndoShape, Inc.

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Jeff Castleberry
Chief Operating Officer, EndoShape, Inc.

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Peter H. Calcott
Chief Compliance Officer, EndoShape, Inc.

CODE OF ETHICS
ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS
ADOPTED BY THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION

I. Preamble: Goal and Scope of AdvaMed Code

The Advanced Medical Technology Association ("AdvaMed") represents companies that develop, produce, manufacture, and market medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities ("Medical Technologies") in order to enable patients to live longer and healthier lives (collectively "Companies," and individually "Company"). AdvaMed is dedicated to the advancement of medical science, the improvement of patient care, and, in particular, the contributions that high quality, innovative Medical Technologies make toward achieving these goals. AdvaMed recognizes the obligation to facilitate ethical interactions between Companies and 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 Companies' Medical Technologies in the United States ("Health Care Professionals").

Medical Technologies

Medical Technologies are often highly dependent upon "hands on" Health Care Professional interaction from beginning to end—unlike drugs and biologics, which act on the human body by pharmacological, immunological or metabolic means. For example, implantable Medical Technologies are often placed in the human body to replace or strengthen a body part. Surgical Medical Technologies often serve as extensions of a physician's hands. In other circumstances, Medical Technologies are noninvasive reagents, instrumentation and/or software to aid in the diagnosis, monitoring and treatment decisions made by Health Care Professionals. Some Medical Technologies work synergistically with other technologies, or are paired with other products that deploy devices in the safest and most effective manner. Many Medical Technologies require technical support during and after deployment.

Interactions with Health Care Professionals

The scope of beneficial interactions between Health Care Professionals and Companies is broad and includes interactions intended to:

• *Promote the Advancement of Medical Technologies.* Developing and improving cutting edge Medical Technologies are collaborative processes between Companies and Health Care 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 electronic, *in vitro* diagnostic, surgical, or other Medical Technologies often requires Companies to provide Health Care 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.* Companies' support of *bona fide* medical research, education, and enhancement of professional skills improves patient safety and increases access to Medical Technologies.

• *Foster Charitable Donations and Giving.* Companies make monetary and Medical Technology donations for charitable purposes, such as supporting indigent care, as well as patient and public education. This increases access to—as well as the quality of—care and treatment in patient populations that may not otherwise be reached.

The Purpose of the Code of Ethics

AdvaMed recognizes that Health Care Professionals' first duty is to act in the best interests of patients. Companies can serve the interests of patients through beneficial collaborations with Health Care 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. AdvaMed recognizes the obligation to facilitate ethical interactions between Companies and Health Care 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.[1] To that end, AdvaMed restates and amends its Code of Ethics and Frequently Asked Questions (collectively "Code of Ethics" or "Code"), effective July 1, 2009.

II. Code of Ethics Compliance

All Companies are strongly encouraged to adopt this Code and to implement an effective compliance program – one which includes policies and procedures that foster compliance with the Code with respect to their interactions with Health Care Professionals related to Medical Technologies. A Company that adopts the Code is strongly encouraged to submit to AdvaMed an annual certification that the Company has adopted the Code and has implemented an effective compliance program. This certification must be signed by the Company's Chief Executive Officer and Chief Compliance Officer or individuals with equivalent responsibilities within the certifying Company. AdvaMed will publish on its website a list of those Companies that have submitted the annual certification.

Companies that are AdvaMed members shall, and Companies that are non-members may, supply contact information for the Company's Compliance Department or an anonymous hotline to facilitate reporting of possible violations of the Code. AdvaMed will publish on its website the contact information supplied by each such Company.

[1] The principles of the Code are derived from a variety of authorities, including the federal Anti-kickback Statute. Throughout the Code, we refer to the concept of an "unlawful inducement" to reflect Anti-kickback Statute prohibitions.

Companies are strongly encouraged to follow the seven elements of an effective compliance program, appropriately tailored for each Company, namely: (1) implementing written policies and procedures; (2) designating a compliance officer and compliance committee; (3) conducting effective training and education; (4) developing effective lines of communication (including an anonymous reporting function); (5) conducting internal monitoring and auditing; (6) enforcing standards through well-publicized disciplinary guidelines; and (7) responding promptly to detected problems and undertaking corrective action.

Note: This Amended and Restated Code supersedes and replaces all previous AdvaMed Codes of Ethics. Companies adopting this Code shall communicate the principles of this Code to their employees, agents, dealers and distributors with the expectation that they will adhere to this Code. All Companies have an independent obligation to ensure that their interactions with Health Care Professionals comply with all applicable laws and regulations. The information provided by the Department of Health and Human Services, Office of Inspector General ("OIG"), as well as applicable laws or regulations, may provide more specificity than this Code, and Companies should address any additional questions to their own attorneys. This Code of Ethics is intended to facilitate ethical behavior, and is not intended to be, nor should it be, construed as legal advice. The Code is not intended to define or create legal rights, standards or obligations. Any interpretation of the provisions of this Code, as well as Companies' interactions with Health Care Professionals not specifically addressed in this Code, should be made in light of the following principle: Companies shall encourage ethical business practices and socially responsible industry conduct and shall not engage in any unlawful inducement.

III. Company-Conducted Product Training and Education

Companies have a responsibility to make training and education on their products and Medical Technologies available to Health Care Professionals. Companies may also provide education to Health Care 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 Companies' Medical Technologies, *e.g.*, information about disease states and the benefits of Medical Technologies to certain patient populations. Training and Education programs include, but are not limited to, "hands on" training sessions, cadaver workshops, lectures and presentations, and grand rounds. In fact, the U.S. Food and Drug Administration mandates training and education to facilitate the safe and effective use of certain Medical Technologies. Companies should adhere to the following principles when conducting training and education programs concerning Medical Technologies for Health Care 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 Health Care Professional's location.

• 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 who have the technical expertise necessary to perform the training.

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

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 accredited continuing medical education providers. Companies may support these conferences in various ways:

• *Conference Grants.* Companies 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 Health Care Professionals in training. Companies 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 Health Care 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 any body 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.* Companies may provide funding to the conference sponsor to support the provision of meals and refreshments to conference attendees. Also, Companies themselves may provide meals and refreshments for Health Care Professional attendees if such meals and refreshments are provided: (1) to all Health Care 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 Health Care Professional attendees if the Company providing such meals and refreshments 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 Health Care 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

Companies may conduct sales, promotional, and other business meetings with Health Care Professionals to discuss, for example, Medical Technology features, sales terms, or contracts. Often, these meetings occur close to the Health Care Professional's 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 Health Care 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 Health Care Professional business interactions.

VI. Consulting Arrangements with Health Care Professionals

Companies engage Health Care 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 Company-sponsored training and other services. Companies 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. Companies should comply with the following standards in connection with consulting arrangements with Health Care 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 should not be based on the volume or value of the consultant's past, present or anticipated business.

• A Company 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 Company 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.

• Company-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. Companies should not provide recreation or entertainment in conjunction with these meetings.

• A Company'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 Health Care Professional as a consultant. Companies should consider implementing appropriate procedures to monitor compliance with this section.

Provisions on Payment of Royalties. Arrangements involving the payment of royalties to a Health Care Professional should meet the contractual standards set forth above. Health Care 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. A Company should enter into a royalty arrangement with a Health Care Professional only where the Health Care 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 Health Care 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 Health Care Professional 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. (Companies

may, however, elect to enter into separate consulting agreements with Health Care Professionals for marketing services if such services meet the requirements set forth in this Section VI above.)

Companies are strongly encouraged to consider whether it is appropriate and practicable to exclude from the calculation of royalties the number of units purchased, used, or ordered by the Health Care Professional and/or members of the Health Care Professional's practice.

VII. Prohibition on Entertainment and Recreation

Company interactions with Health Care 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, a Company should not provide or pay for any entertainment or recreational event or activity for any non-employee Health Care Professional. 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 the Company engages the Health Care Professional as a speaker or consultant; or (3) whether the entertainment or recreation is secondary to an educational purpose.

VIII. Modest Meals Associated with Health Care Professional Business Interactions

A Company's business interactions with Health Care 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 Health Care Professional's 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 Health Care Professional's place of business, for example, (1) where the Medical Technology cannot easily be transported to the Health Care Professional's 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. A Company may provide a meal only to Health Care Professionals who actually attend the meeting. A Company may not provide a meal for an entire office staff where everyone does not attend the meeting. A Company also may not provide a meal where its representative is

not present (such as a "dine & dash" program). A Company may not pay for meals for guests of Health Care Professionals or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

Other principles. Depending on the type of business interaction or meeting, additional principles may apply, as described in other sections of this Code of Ethics. Specifically:

• Section III: Company-Conducted Product Training and Education.

• Section IV: Supporting Third-Party Educational Conferences.

• Section V: Sales, Promotional, and Other Business Meetings.

• Section VI: Consulting Arrangements with Health Care Professionals.

IX. Educational Items; Prohibition on Gifts

A Company occasionally may provide items to Health Care Professionals that benefit patients or serve a genuine educational function for Health Care Professionals. Other than medical textbooks or anatomical models used for educational purposes, any such item should have a fair market value of less than $100. A Company may not provide items that are capable of use by the Health Care Professional (or his or her family members, office staff or friends) for noneducational or non-patient-related purposes, for example, a DVD player or MP3 player/iPod.

A Company may not give Health Care Professionals any type of non-educational branded promotional items, even if the item is of minimal value and related to the Health Care Professional's work or for the benefit of patients. Examples of non-educational branded promotional items include pens, notepads, mugs, and other items that have a Company's name, logo, or the name or logo of one of its Medical Technologies. Companies also may not provide Health Care 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 Health Care Professionals and/or patients having timely and complete coverage, reimbursement, and health economic information. Consequently, a Company may provide such information regarding its Medical Technologies if it is accurate and objective. A Company also may collaborate with Health Care 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 the Company's Medical Technologies and the services and procedures in which they are used when providing coverage, reimbursement and health economics information and materials to Health Care Professionals, professional organizations, patient organizations, and payors.

• Collaborating with Health Care Professionals, their professional organizations, and patient groups to conduct joint advocacy on coverage, reimbursement and health economics issues; supporting Health Care 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 Health Care Professionals regarding the Company'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 the Company's Medical Technologies, including where and how they can be used within the continuum of care.

• Providing information related to the Company's Medical Technologies regarding available reimbursement revenues and associated costs.

• Providing information relating to changes in coverage or reimbursement amounts, methodologies and policies and the effects of such changes in order to facilitate a Health Care Professional's decision to buy or use the Company's Medical Technologies.

• 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 Company's Medical Technologies.

• Facilitating patient access to the Company's Medical Technologies by providing Health Care 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 Health Care Professional to facilitate patient access to the Company's Medical Technology, and subject to appropriate privacy safeguards, the Company 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 a Company's own Medical Technology; however such assistance should not be provided as an unlawful inducement.

A Company may not interfere with a Health Care Professional's independent clinical decision-making or provide coverage, reimbursement and health economics support as an unlawful inducement. For example, a Company should not provide free services that eliminate an

overhead or other expense that a Health Care 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, a Company 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

A Company may provide research and educational grants and charitable donations. However, a Company may not provide such grants or donations as an unlawful inducement. Therefore, a Company should: (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. A Company'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 Health Care Professional or institution will receive a grant or donation or the amount of such grant or donation. Companies should consider implementing 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, a Company 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.

Company-initiated or directed research involving a Company'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, a Company may make educational grants to conference sponsors or training institutions. A Company may not make educational grants to individual Health Care Professionals.

• *Advancement of Medical Education.* A Company 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.* A Company may make grants for the purpose of supporting education of patients or the public about important health care topics.

c. Charitable Donations

A Company 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. Companies should exercise diligence to ensure the *bona fide* nature of the charitable organization or charitable mission.

XII. Evaluation and Demonstration Products

Providing products to Health Care 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 Health Care Professional regarding the use of products. Under certain circumstances described below, a Company may provide reasonable quantities of products to Health Care 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.

Company products that may be provided to Health Care 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 Health Care 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. Company products provided for evaluation are typically expected to be used in patient care.

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. Companies should 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 Health Care Professional's location at the conclusion of the evaluation period unless the Health Care Professional purchases or leases the products.

Demonstration. Company demonstration products are typically unsterilized single use products or mock-ups of such products that are used for Health Care Professional and patient awareness, education, and training. For example, a Health Care 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. Demonstration products also are

typically identified as not intended for patient use by use of such designations as “Sample,” “Not for Human Use,” or other suitable designation on the product, the product packaging, and/or documentation that accompanies the product.

A Company should provide Health Care Professionals with documentation and disclosure regarding the no-charge status of evaluation and demonstration products.