

HTG MOLECULAR DIAGNOSTICS, INC.

CODE OF BUSINESS CONDUCT AND ETHICS

INTRODUCTION

HTG Molecular Diagnostics, Inc. (the “*Company*”) is committed to maintaining the highest standards of business conduct and ethics. This Code of Business Conduct and Ethics (this “*Code*”) reflects the business practices and principles of behavior that support this commitment. We expect every employee, officer and director to read and understand this Code and its application to the performance of his or her business responsibilities. References in this Code to employees are intended to cover officers and, as applicable, directors.

Officers, managers and other supervisors are expected to develop in employees a sense of commitment to the spirit, as well as the letter, of this Code. Supervisors are also expected to ensure that all agents and contractors conform to Code standards when working for or on behalf of the Company. The compliance environment within each supervisor’s assigned area of responsibility will be a significant factor in evaluating the quality of that individual’s performance. Nothing in this Code alters the at-will employment policy of the Company.

This Code cannot possibly describe every practice or principle related to honest and ethical conduct. This Code addresses conduct that is particularly important to proper dealings with the people and entities with whom we interact, but reflects only a part of our commitment. From time to time we may adopt additional policies and procedures with which our employees, officers and directors are expected to comply, if applicable to them. However, it is the responsibility of each employee to apply common sense, together with his or her own highest personal ethical standards, in making business decisions where there is no stated guideline in this Code.

Action by members of your family, significant others or other persons who live in your household (referred to in this Code as “family members”) also may potentially result in ethical issues to the extent that they involve the Company’s business. For example, acceptance of inappropriate gifts by a family member from one of our suppliers could create a conflict of interest and result in a Code violation attributable to you. Consequently, in complying with this Code, you should consider not only your own conduct, but also that of your family members, significant others and other persons who live in your household.

You should not hesitate to ask questions about whether any conduct may violate this Code, voice concerns or clarify gray areas. Section 18 below details the compliance resources available to you. In addition, you should be alert to possible violations of this Code by others and report suspected violations, without fear of any form of retaliation, as further described in Section 18. Violations of this Code will not be tolerated. Any employee who violates the standards in this Code may be subject to disciplinary action, which, depending on the nature of the violation and the history of the employee, may range from a warning or reprimand up to and including termination of employment and, in appropriate cases, civil legal action or referral for regulatory or criminal prosecution.

1. HONEST AND ETHICAL CONDUCT

It is the policy of the Company to promote high standards of integrity by conducting our affairs in an honest and ethical manner. The integrity and reputation of the Company depends on the honesty, fairness and integrity brought to the job by each person associated with us. Unyielding personal integrity is the foundation of corporate integrity.

2. LEGAL COMPLIANCE

Obeying the law, both in letter and in spirit, is the foundation of this Code. Our success depends upon each employee's operating within legal guidelines and cooperating with local, national and international authorities. We expect employees to understand the legal and regulatory requirements applicable to their business units and areas of responsibility. We hold or provide access to periodic training sessions or relevant education in order to ensure that all employees comply with the relevant laws, rules and regulations associated with their employment, including laws prohibiting insider trading (which are discussed in further detail in Section 3 below). While we do not expect you to memorize every detail of these laws, rules and regulations, we want you to be able to determine when to seek advice from others. If you do have a question in the area of legal compliance, it is important that you not hesitate to seek answers from your supervisor or the Compliance Officer (as described in Section 18).

Disregard of the law will not be tolerated. Violation of domestic or foreign laws, rules and regulations may subject an individual, as well as the Company, to civil and/or criminal penalties. You should be aware that conduct and records, including emails, are subject to internal and external audits, and to discovery by third parties in the event of a government investigation or civil litigation. It is in everyone's best interests to know and comply with our legal and ethical obligations.

3. INSIDER TRADING

Employees who have access to confidential (or "inside") information are not permitted to use or share that information for stock trading purposes or for any other purpose except to conduct our business. All non-public information about the Company or about companies with which we do business is considered confidential information. To use material non-public information in connection with buying or selling securities, including "tipping" others who might make an investment decision on the basis of this information, is not only unethical, it is illegal. Employees must exercise the utmost care when handling material inside information.

We have adopted a separate Insider Trading Policy with which you will be expected to comply as a condition of your employment with the Company. In addition, we have adopted a Window Period Policy that applies to our officers, directors and certain other employees. You should consult our Insider Trading Policy and, if applicable, our Window Period Policy, for more specific information on the definition of "inside" information and on buying and selling our securities or securities of companies with which we do business.

4. RESEARCH AND DEVELOPMENT; REGULATORY COMPLIANCE

The research and development of medical devices is subject to a number of legal and regulatory requirements, including standards related to ethical research procedures and proper scientific conduct. We expect employees to comply with all such requirements.

5. INTERNATIONAL BUSINESS LAWS

Our employees are expected to comply with the applicable laws in all countries to which they travel, in which they operate and where we otherwise do business, including laws prohibiting bribery, corruption or the conduct of business with specified individuals, companies or countries. The fact that in some countries certain laws are not enforced or that violation of those laws is not subject to public criticism will not be accepted as an excuse for noncompliance. In addition, we expect employees to comply with U.S. laws, rules and regulations governing the conduct of business by its citizens and corporations outside the U.S.

These U.S. laws, rules and regulations, which extend to all our activities outside the U.S., include:

- The Foreign Corrupt Practices Act, which prohibits directly or indirectly giving anything of value to a government official to obtain or retain business or favorable treatment, and requires the maintenance of accurate books of account, with all company transactions being properly recorded;
- U.S. Embargoes, which generally prohibit U.S. companies, their subsidiaries and their employees from doing business with, or traveling to, certain countries subject to sanctions imposed by the U.S. government, as well as specific companies and individuals identified on lists published by the U.S. Treasury Department;
- U.S. Export Controls, which restrict exports from the U.S. and re-exports from other countries of goods, software and technology to many countries, and prohibit transfers of U.S.-origin items to denied persons and entities; and
- Antiboycott Regulations, which prohibit U.S. companies from taking any action that has the effect of furthering or supporting a restrictive trade practice or boycott imposed by a foreign country against a country friendly to the U.S. or against any U.S. person.

If you have a question as to whether an activity is restricted or prohibited, seek assistance before taking any action, including giving any verbal assurances that might be regulated by international laws.

6. ANTITRUST

Antitrust laws are designed to protect the competitive process. These laws are based on the premise that the public interest is best served by vigorous competition and will suffer from illegal agreements or collusion among competitors. Antitrust laws generally prohibit:

- agreements, formal or informal, with competitors that harm competition or customers, including price fixing and allocations of customers, territories or contracts;
- agreements, formal or informal, that establish or fix the price at which a customer may resell a product; and
- the acquisition or maintenance of a monopoly or attempted monopoly through anti-competitive conduct.

Certain kinds of information, such as pricing, production and inventory, should not be exchanged with competitors, regardless of how innocent or casual the exchange may be and regardless of the setting, whether business or social.

Antitrust laws impose severe penalties for certain types of violations, including criminal penalties and potential fines and damages of millions of dollars, which may be tripled under certain circumstances. Understanding the requirements of antitrust and unfair competition laws of the various jurisdictions where we do business can be difficult, and you are urged to seek assistance from your supervisor or the Compliance Officer whenever you have a question relating to these laws.

7. ENVIRONMENTAL COMPLIANCE

Federal law imposes criminal liability on any person or company that contaminates the environment with any hazardous substance that could cause injury to the community or environment. Violation of environmental laws can involve monetary fines and imprisonment. We expect employees to comply with all applicable environmental laws.

It is our policy to conduct our business in an environmentally responsible way that minimizes environmental impacts. We are committed to minimizing and, if practicable, eliminating the use of any substance or material that may cause environmental damage, reducing waste generation and disposing of all waste through safe and responsible methods, minimizing environmental risks by employing safe technologies and operating procedures, and being prepared to respond appropriately to accidents and emergencies.

8. CONFLICTS OF INTEREST

We respect the rights of our employees to manage their personal affairs and investments and do not wish to impinge on their personal lives. At the same time, employees should avoid conflicts of interest that occur when their personal interests may interfere in any way with the performance of their duties or the best interests of the Company. A conflicting personal interest could result from an expectation of personal gain now or in the future or from a need to satisfy a prior or concurrent personal obligation. We expect our employees to be free from influences that conflict with the best interests of the Company or might deprive the Company of their undivided loyalty in business dealings. Even the appearance of a conflict of interest where none actually exists can be damaging and should be avoided. Whether or not a conflict of interest exists or will exist can be unclear. Conflicts of interest are prohibited unless specifically authorized as described below.

If you have any questions about a potential conflict or if you become aware of an actual or potential conflict, and you are not an officer or director of the Company, you must discuss the matter with your supervisor or the Compliance Officer. Supervisors may not authorize conflict of interest matters or make determinations as to whether a problematic conflict of interest exists without first seeking the approval of the Compliance Officer and providing the Compliance Officer with a written description of the activity. If the supervisor is involved in the potential or actual conflict, you should discuss the matter directly with the Compliance Officer. Officers and directors must seek any authorizations and determinations from the Audit Committee (the “*Audit Committee*”) of the Board of Directors of the Company (the “*Board*”), depending on the nature of the conflict of interest. Factors that may be considered in evaluating a potential conflict of interest are, among others:

- whether it may interfere with the employee’s job performance, responsibilities or morale;
- whether the employee has access to confidential information;
- whether it may interfere with the job performance, responsibilities or morale of others within the organization;
- any potential adverse or beneficial impact on our business;
- any potential adverse or beneficial impact on our relationships with our customers or suppliers or other service providers;
- whether it would enhance or support a competitor’s position;
- the extent to which it would result in financial or other benefit (direct or indirect) to the employee;
- the extent to which it would result in financial or other benefit (direct or indirect) to one of our customers, suppliers or other service providers; and
- the extent to which it would appear improper to an outside observer.

Although no list can include every possible situation in which a conflict of interest could arise, the following are examples of situations that may, depending on the facts and circumstances, involve problematic conflicts of interests:

- *Employment by (including consulting for) or service on the board of a competitor, customer or supplier or other service provider.* Activity that enhances or supports the position of a competitor to the detriment of the Company is prohibited, including employment by or service on the board of a competitor. Employment by or service on the board of a customer or supplier or other service provider is generally discouraged and you must seek authorization in advance if you plan to take such a position.

- *Owning, directly or indirectly, a significant financial interest in any entity that does business, seeks to do business or competes with us.* In addition to the factors described above, persons evaluating ownership in other entities for conflicts of interest will consider the size and nature of the investment; the nature of the relationship between the other entity and the Company; the employee's access to confidential information; and the employee's ability to influence the Company's decisions. If you would like to acquire a financial interest of that kind, you must seek approval in advance.
- *Soliciting or accepting gifts, favors, or any other benefit or benefits (including reputational), loans or preferential treatment from any person or entity that does business or seeks to do business with us.* See Sections 12 and 13 for further discussion of the issues involved in this type of conflict.
- *Soliciting contributions for any charity or for any political candidate from any person or entity that does business or seeks to do business with us.*
- *Taking personal advantage of corporate opportunities.* See Section 9 for further discussion of the issues involved in this type of conflict.
- *Conducting our business transactions with your family member or a business in which you have a significant financial interest.* Related-person transactions covered by our Related-Person Transactions Policy must be reviewed in accordance with such policy and will be publicly disclosed to the extent required by applicable laws and regulations.
- *Exercising supervisory or other authority on behalf of the Company over a co-worker who is also a family member.* The employee's supervisor and/or the Compliance Officer will consult with our Human Resources department to assess the advisability of reassignment.

Loans to, or guarantees of obligations of, employees or their family members by the Company could constitute an improper personal benefit to the recipients of these loans or guarantees, depending on the facts and circumstances. Some loans are expressly prohibited by law, and applicable law requires that the Board or Audit Committee approve all loans and guarantees to employees. As a result, all loans and guarantees by the Company must be approved in advance by the Board or the Audit Committee.

9. CORPORATE OPPORTUNITIES

You may not take personal advantage of opportunities for the Company that are presented to you or discovered by you as a result of your position with us or through your use of corporate property or information, unless authorized by your supervisor, the Compliance Officer or the Audit Committee, as described in Section 18. Even opportunities that are acquired privately by you may be questionable if they are related to our existing or proposed lines of business. Participation in an investment or outside business opportunity that is directly related to our lines of business must be pre-approved. You may not use your position with the Company or our corporate property or information for improper personal gain, nor should you compete with us in any way.

10. MAINTENANCE OF CORPORATE BOOKS, RECORDS, DOCUMENTS AND ACCOUNTS; FINANCIAL INTEGRITY; PUBLIC REPORTING

The integrity of our records and public disclosure depends upon the validity, accuracy and completeness of the information supporting the entries to our books of account. Therefore, our corporate and business records should be completed accurately and honestly. The making of false or misleading entries, whether they relate to financial results or test results, is strictly prohibited. Our records serve as a basis for managing our business and are important in meeting our obligations to customers, suppliers, creditors, employees and others with whom we do business. As a result, it is important that our books, records and accounts accurately and fairly reflect, in reasonable detail, our assets, liabilities, revenues, costs and expenses, as well as all transactions and changes in assets and liabilities. We require that:

- no entry be made in our books and records that intentionally hides or disguises the nature of any transaction or of any of our liabilities, or misclassifies any transactions as to accounts or accounting periods;
- transactions be supported by appropriate documentation;
- the terms of sales and other commercial transactions be reflected accurately in the documentation for those transactions and all such documentation be reflected accurately in our books and records;
- employees comply with our system of internal controls; and
- no cash or other assets be maintained for any purpose in any unrecorded or “off-the-books” fund.

Our accounting records are also relied upon to produce reports for our management, stockholders and creditors, as well as governmental agencies. In particular, we rely upon our accounting and other business and corporate records in preparing periodic and current reports that we file with the Securities and Exchange Commission (“*SEC*”). Securities laws require that these reports provide full, fair, accurate, timely and understandable disclosure and fairly present our financial condition and results of operations. Employees who collect, provide or analyze information for or otherwise contribute in any way in preparing or verifying these reports should strive to ensure that our financial disclosure is accurate and transparent and that our reports contain all of the information about the Company that would be important to enable stockholders and potential investors to assess the soundness and risks of our business and finances and the quality and integrity of our accounting and disclosures. In addition:

- no employee may take or authorize any action that would intentionally cause our financial records or financial disclosure to fail to comply with generally accepted accounting principles, the rules and regulations of the SEC or other applicable laws, rules and regulations;
- all employees must cooperate fully with our Accounting Department, as well as our independent public accountants and counsel, respond to their questions with candor

and provide them with complete and accurate information to help ensure that our books and records, as well as our reports filed with the SEC, are accurate and complete; and

- no employee should knowingly make (or cause or encourage any other person to make) any false or misleading statement in any of our reports filed with the SEC or knowingly omit (or cause or encourage any other person to omit) any information necessary to make the disclosure in any of our reports accurate in all material respects.

Any employee who becomes aware of any departure from these standards has a responsibility to report his or her knowledge promptly to a supervisor, the Compliance Officer, the Audit Committee, or one of the other compliance resources described in Section 18 or in accordance with the provisions of the Company's Open Door Policy on Reporting Complaints Regarding Accounting and Auditing Matters.

11. FAIR DEALING

We strive to outperform our competition fairly and honestly through superior performance and not through unethical or illegal business practices. Acquiring proprietary information from others through improper means, possessing trade secret information that was improperly obtained, or inducing improper disclosure of confidential information from past or present employees of other companies is prohibited, even if motivated by an intention to advance our interests. If information is obtained by mistake that may constitute a trade secret or other confidential information of another business, or if you have any questions about the legality of proposed information gathering, you must consult your supervisor or the Compliance Officer, as further described in Section 18.

You are expected to deal fairly with our suppliers, employees and anyone else with whom you have contact in the course of performing your job. Be aware that the Federal Trade Commission Act provides that "unfair methods of competition in commerce, and unfair or deceptive acts or practices in commerce, are declared unlawful." It is a violation of the Federal Trade Commission Act to engage in deceptive, unfair or unethical practices, and to make misrepresentations in connection with sales activities.

Employees involved in procurement have a special responsibility to adhere to principles of fair competition in the purchase of products and services by selecting suppliers based exclusively on normal commercial considerations, such as quality, cost, availability, service and reputation, and not on the receipt of special favors.

12. INTERACTIONS WITH HEALTHCARE PROFESSIONALS

A Health Care Professionals' first duty is to act in the best interests of patients. Companies, like ours, that manufacture, market or sell medical devices serve the interests of patients through our interactions with Health Care Professionals. To ensure that these interactions put patients first and are in compliance with applicable laws, regulations and government guidance, the Company hereby adopts the Code of Ethics on Interactions with Health Care Professionals ("*AdvaMed Code*") created by the Advanced Medical Technology Association, which is attached as **Schedule A**.

If you interact with 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 our medical devices (“*Health Care Professionals*”), you must, at a minimum, know, understand and comply with the AdvaMed Code, and all company policies covering relationships with Health Care Professionals

13. GIFTS AND ENTERTAINMENT

Without limiting the provisions of this Code that apply to interactions with Health Care Professionals as set forth above, this Section 13 addresses conduct with respect to offering or accepting business gifts and entertainment. Business gifts and entertainment are meant to create goodwill and sound working relationships and not to gain improper advantage with current or potential suppliers, vendors or partners or facilitate approvals from government officials. The exchange, as a normal business courtesy, of meals or a gift to recognize a significant life event (such as, marriage or birth of a child) is a common and acceptable practice as long as it is not extravagant. Unless express permission is received from a supervisor, the Compliance Officer or the Audit Committee, gifts and entertainment cannot be offered, provided or accepted by any employee unless consistent with customary business practices and not excessive in value. This principle applies to our transactions everywhere in the world, even where the practice is widely considered “a way of doing business.” Employees should not accept gifts or entertainment that may reasonably be deemed to affect their judgment or actions in the performance of their duties.

Under some statutes, such as the U.S. Foreign Corrupt Practices Act (further described in Section 5), giving anything of value to a government official to obtain or retain business or favorable treatment is a criminal act subject to prosecution and conviction. Discuss with your supervisor or the Compliance Officer any proposed entertainment or gifts if you are uncertain about their appropriateness.

14. PROTECTION AND PROPER USE OF COMPANY ASSETS

All employees are expected to protect our assets and ensure their efficient use. Theft, carelessness and waste have a direct impact on our financial condition and results of operations. Our property, such as office supplies, computer equipment, products, laboratory supplies, and office or laboratory space are expected to be used only for legitimate business purposes, although incidental personal use may be permitted. You may not, however, use our corporate name, any brand name or trademark owned or associated with the Company or any letterhead stationery for any personal purpose.

You may not, while acting on behalf of the Company or while using our computing or communications equipment or facilities, either:

- access the internal computer system (also known as “hacking”) or other resource of another entity without express written authorization from the entity responsible for operating that resource; or

- commit any unlawful or illegal act, including harassment, libel, fraud, sending of unsolicited commercial email (also known as “spam”) in violation of applicable law, trafficking in contraband of any kind, or espionage.

If you receive authorization to access another entity’s internal computer system or other resource, you must make a permanent record of that authorization so that it may be retrieved for future reference, and you may not exceed the scope of that authorization.

Unsolicited commercial email is regulated by law in a number of jurisdictions. If you intend to send unsolicited commercial email to persons outside of the Company, either while acting on our behalf or using our computing or communications equipment or facilities, you should contact your supervisor or the Compliance Officer for approval.

All data residing on or transmitted through our computing and communications facilities, including email and word processing documents, is the property of the Company and subject to inspection, retention and review by the Company, with or without an employee’s or third party’s knowledge, consent or approval, in accordance with applicable law. Any misuse or suspected misuse of our assets must be immediately reported to your supervisor or the Compliance Officer.

15. CONFIDENTIALITY

One of our most important assets is our confidential information. As an employee of the Company, you may learn of information about the Company that is confidential and proprietary. You also may learn of information before that information is released to the general public. Employees who have received or have access to confidential information should take care to keep this information confidential. Confidential information includes non-public information that might be of use to competitors or harmful to the Company or its suppliers, vendors or partners if disclosed, such as business, marketing and service plans, financial information, product development, scientific data, manufacturing, laboratory results, designs, databases, customer lists, pricing strategies, personnel data, personally identifiable information pertaining to our employees or other individuals (including, for example, names, addresses, telephone numbers and social security numbers), and similar types of information provided to us by our customers, suppliers and partners. This information may be protected by patent, trademark, copyright and trade secret laws.

In addition, because we interact with other companies and organizations, there may be times when you learn confidential information about other companies before that information has been made available to the public. You must treat this information in the same manner as you are required to treat our confidential and proprietary information. There may even be times when you must treat as confidential the fact that we have an interest in, or are involved with, another company.

You are expected to keep confidential information and proprietary information confidential unless and until that information is released to the public through approved channels (usually through a press release, an SEC filing or a formal communication from a member of senior management, as further described in Section 16). Every employee has a duty to refrain from disclosing to any person confidential or proprietary information about us or any other company learned in the course of employment here, until that information is disclosed to the public through

approved channels. This policy requires you to refrain from discussing confidential or proprietary information with outsiders and even with other Company employees, unless those fellow employees have a legitimate need to know the information in order to perform their job duties. Unauthorized use or distribution of this information could also be illegal and result in civil liability and/or criminal penalties.

You should also take care not to inadvertently disclose confidential information. Materials that contain confidential information, such as memos, notebooks, computer disks and laptop computers, should be stored securely. Unauthorized posting or discussion of any information concerning our business, information or prospects on the internet is prohibited. You may not discuss our business, information or prospects in any “chat room,” regardless of whether you use your own name or a pseudonym. Be cautious when discussing sensitive information in public places like elevators, airports, restaurants and “quasi-public” areas within the Company, or in and around the Company’s facilities. All Company emails, voicemails and other communications are presumed confidential and should not be forwarded or otherwise disseminated outside of the Company, except where required for legitimate business purposes.

In addition to the above responsibilities, if you are handling information protected by any privacy policy published by us, then you must handle that information in accordance with the applicable policy.

16. MEDIA/PUBLIC DISCUSSIONS

It is our policy to disclose material information concerning the Company to the public only through specific limited channels to avoid inappropriate publicity and to ensure that all those with an interest in the Company will have equal access to information. All inquiries or calls from the press and financial analysts should be referred to our Chief Executive Officer. We have designated our Chief Executive Officer as our official spokesperson for questions concerning the financial performance, strategic direction or operating performance of the Company, and operational issues such a research and development, regulatory developments, sales and marketing, etc. Unless a specific exception has been made by our Chief Executive Officer, he or she is the only person who may communicate with the press on behalf of the Company. You also may not provide any information to the media about us off the record, for background, confidentially or secretly, including, without limitation, by way of postings on internet websites, social media, chat rooms or “blogs”.

17. WAIVERS

Any waiver of this Code for executive officers (including, where required by applicable laws, our principal executive officer, principal financial officer, principal accounting officer or controller (or persons performing similar functions)) or directors may be authorized only by our Board or, to the extent permitted by the rules of The Nasdaq Stock Market, a committee of the Board, and will be disclosed as required by applicable laws, rules and regulations.

18. COMPLIANCE STANDARDS AND PROCEDURES

Compliance Resources

To facilitate compliance with this Code, we have implemented a program of Code awareness, training and review that is part of our broader compliance programs overseen by our Audit Committee. We have established the position of Compliance Officer to oversee this program. The Compliance Officer is a person to whom you can address any questions or concerns related to this Code or any other matters relating to legal or regulatory compliance. The Compliance Officer is our Chief Legal Counsel. In addition to fielding questions or concerns with respect to potential violations of this Code or any other matters relating to legal or regulatory compliance, the Compliance Officer is responsible for:

- investigating possible violations of this Code;
- training new employees in Code policies;
- conducting annual training sessions to refresh employees' familiarity with this Code;
- distributing copies of this Code annually via email to each employee with a reminder that each employee is responsible for reading, understanding and complying with this Code;
- updating this Code as needed and alerting employees to any updates, with appropriate approval of the Audit Committee, to reflect changes in the law, the Company's operations and in recognized best practices, and to reflect the Company's experience;
- overseeing the Company's compliance program and reporting to the Audit Committee material matters that may arise relating to the Company's legal and regulatory compliance efforts; and
- otherwise promoting an atmosphere of responsible and ethical conduct.

Your most immediate resource for any matter related to this Code is your supervisor. He or she may have the information you need, or may be able to refer the question to another appropriate source. There may, however, be times when you prefer not to go to your supervisor. In these instances, you should feel free to discuss your concern with the Compliance Officer. If you are uncomfortable speaking with the Compliance Officer because he or she works in your department or is one of your supervisors, please contact the Chief Executive Officer. Of course, if your concern involves potential misconduct by another person and relates to questionable accounting or auditing matters under the Company's Open Door Policy for Reporting Complaints Regarding Accounting and Auditing Matters, you may report that violation as set forth in such policy.

A compliance hotline system ("*Compliance Hotline*") is also available free of charge to those who wish to ask questions about the Company's policies, seek guidance on specific situations, submit concerns regarding questionable accounting or auditing matters or report

violations of this Code when the normal channels of communication have proven ineffective, or are impractical under the circumstances, and/or if you prefer to maintain anonymity. The toll-free telephone number, email address and URL for the Compliance Hotline are available on the Company's intranet and/or as otherwise communicated to all employees, officers and directors of the Company. The Compliance Hotline may be anonymous if you prefer, although the Compliance Officer will be unable to obtain follow-up details from you that may be necessary to investigate the matter. Whether you identify yourself or remain anonymous, your contact through the Compliance Hotline will be kept strictly confidential to the extent reasonably possible within the objectives of this Code.

Clarifying Questions and Concerns; Reporting Possible Violations

If you encounter a situation or are considering a course of action and its appropriateness is unclear, discuss the matter promptly with your supervisor or the Compliance Officer; even the appearance of impropriety can be very damaging and should be avoided.

If you are aware of a suspected or actual violation of Code standards by others, you have a responsibility to report it. You are expected to promptly provide a compliance resource with a specific description of the violation that you believe has occurred, including any information you have about the persons involved and the time of the violation. Whether you choose to speak with your supervisor or the Compliance Officer, you should do so without fear of any form of retaliation. We will take prompt disciplinary action against any employee who retaliates against you, up to and including termination of employment.

Supervisors must promptly report any complaints or observations of Code violations to the Compliance Officer. If you believe your supervisor has not taken appropriate action, you should contact the Compliance Officer directly. The Compliance Officer will investigate all reported possible Code violations promptly and with the highest degree of confidentiality that is possible under the specific circumstances. Neither you nor your supervisor may conduct any preliminary investigation, unless authorized to do so by the Compliance Officer. Your cooperation in the investigation will be expected. As needed, the Compliance Officer will consult with our outside legal counsel and/or the Audit Committee. It is our policy to employ a fair process by which to determine violations of this Code.

With respect to any complaints or observations of Code violations, including, but not limited to, matters that may involve accounting, internal accounting controls and auditing concerns under the Company's Open Door Policy for Reporting Complaints Regarding Accounting and Auditing Matters, the Compliance Officer shall promptly inform the chair of the Audit Committee, and the Audit Committee or such other persons as the Audit Committee determines to be appropriate under the circumstances shall be responsible for supervising and overseeing the inquiry and any investigation that is undertaken. In addition, any matters involving accounting, internal accounting controls and auditing concerns that are reported via the toll-free compliance hotline shall be routed to both the Compliance Officer and the Audit Committee.

If any investigation indicates that a violation of this Code has probably occurred, we will take such action as we believe to be appropriate under the circumstances. If we determine that an employee is responsible for a Code violation, he or she will be subject to disciplinary action up to,

and including, termination of employment and, in appropriate cases, civil legal action or referral for regulatory or criminal prosecution. Appropriate action may also be taken to deter any future Code violations.

Schedule A
AdvaMed Code

[see attached 12 pages]



AdvaMed

Advanced Medical Technology Association

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.

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 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.

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 on-site.

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 non-educational or non-patient-related purposes, for example, a DVD player or MP3 player/I-Pod.

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.