

CODE OF ETHICS
ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS IN CHINA

ADOPTED BY THE CHINA BOARD OF THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION
Effective January 1, 2016

I. Preamble: Goal and Scope of AdvaMed China Code

1. 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"¹) 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.
2. The AdvaMed China Board is a China-based governance group of AdvaMed that consists of AdvaMed member companies' most senior company executives in China.
3. The China Board recognizes the obligation to facilitate ethical interactions between Companies and institutions 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 People's Republic of China ("institutional Health Care Professionals") as well as the individuals employed by these institutions (and who are not full-time employees of a Company) who are also involved in the provision of health care services and/or items to patients and who also purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies' Medical Technologies ("individual Health Care Professionals"). Unless otherwise specified, the term "Health Care Professionals" refers to individuals and institutions.

4. 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

¹ Medical Technologies (also referred to as Medical Devices and/or In Vitro Diagnostics) are further defined in the Global Harmonization Task Force (GHTF) document *Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'*
<http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n071-2012-definition-of-terms-120516.docx>



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.

5. *Interactions with Health Care Professionals*

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

- A. *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 and training. Regulators often require this type of training as a condition of product approval.
- B. *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 that better serve patients.
- C. *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.
- D. *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.
- E. *Support Appropriate and Efficient Use.* Providing service, technical or other support intended to aid in the appropriate and efficient use or installation of the Company's Medical Technologies.

6. *Interactions with Third Party Sales and Marketing Intermediaries*

To ensure and improve ongoing patient and clinician access to innovative, reliable and effective Medical Technologies, it is often necessary for Companies to engage third party intermediaries to assist in the marketing, sale and/or distribution of the Companies' products or services. The form of, and terminology used by Companies to describe relationships with these third party sales and marketing intermediaries varies, but may include distributors, wholesalers, distribution or sales agents, marketing agents, brokers, commissionary commercial agents and independent sales representatives with which the Company has a direct contractual relationship ("Third Party SMIs").

It is essential that Companies' interactions with Third Party SMIs, as well as Third Party SMIs' behavior on a Company's behalf (including Third Party SMI interactions with Health Care Professionals and governmental officials) are conducted pursuant to all applicable legal and ethical principles.

7. *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.

8. *Local Laws, Regulations and Government Guidance Shall Prevail*

All Companies have an independent obligation to ensure that their interactions with Health Care Professionals comply with all applicable laws, regulations and government guidance within the jurisdictions that they operate. Applicable laws, regulations or government guidance may provide more specificity than this Code, and Companies should seek counsel to address any additional questions. 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.

II. Code of Ethics Compliance

All Companies doing business in China are strongly encouraged to adopt and certify to 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 in China.

1. A Company that wishes to certify to the Code is required to submit to AdvaMed an annual certification that the Company has adopted the Code and has implemented a compliance program designed to uphold the principles of this Code. This certification must be signed by the most senior executive responsible for the Company's Medical Technology operation in China. For Companies headquartered in China, this would be the Chief Executive Officer or individual with equivalent responsibility within the certifying company. For Companies headquartered outside of China, this would be the most senior representative of the certifying Company's Medical Technology operation in China. This certification must additionally be signed by the Company's Chief Compliance Officer for China or individual with equivalent responsibilities within the certifying Company. AdvaMed will publish on its website a list of those Companies that have submitted this annual certification.
2. 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.

3. Companies are strongly encouraged to follow the following 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.
4. Companies are strongly encouraged to ensure that interactions with individual Health Care Professionals (or to individual units within an Institutional Health Care Professional) are appropriately disclosed to the institution or employer. If applicable laws, regulations or institutional rules specifically require disclosure to a different body, then disclosure should be made in accordance with the applicable laws, regulations or rules.

III. Company-Conducted Product Training and Education

1. Companies have a responsibility to make training and education on their products and Medical Technologies available 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.
2. Training and Education programs include, but are not limited to, "hands on" training sessions, cadaver workshops, lectures and presentations. In fact, many medical device regulatory agencies encourage – or even mandate – companies to conduct training and education to facilitate the safe and effective use of certain Medical Technologies.
3. Companies should adhere to the following principles when conducting training and education programs concerning Medical Technologies for Health Care Professionals:
 - A. 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 and/or to deliver training in cooperation with an institutional Health Care Professional.
 - B. 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.
 - C. 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.
 - D. 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

1. Third-party educational conferences are *bona fide* independent, educational, scientific, and policymaking conferences promoting scientific knowledge, medical advancement and the delivery of effective health care. These typically include conferences organized by national, regional, or specialty medical associations and conferences sponsored by continuing medical education providers. These may also include conferences organized by hospitals and other Institutional Health Care Professionals.
2. Companies should ensure that support for third-party conferences preserves the independence of medical education and should not be used as a means of inappropriate inducement. Companies may support these conferences in various ways:
 - A. *Conference Grants*. Companies may provide a grant to the conference organizer to reduce conference costs. They may also provide grants to a training institution or the conference organizer 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 organizer selects the attending Health Care Professionals who are in training. Such grants should be paid only for a genuine, independent educational function and may only be used to reimburse the legitimate expenses for bona fide educational activities. All grant arrangements and sponsorships should be appropriately documented and should not be provided as an unlawful inducement. The conference organizer should independently control and be responsible for the selection of program content, faculty, educational methods, and materials.
 - B. *Support for Conference Attendance by HCPs*. Under the following conditions, Companies may sponsor individual HCPs to attend third-party educational conferences:
 - i. Companies cannot reimburse HCPs' travel expenses directly to the HCP;
 - ii. Companies may recommend the list of HCPs to attend educational meetings, from an educational and scientific perspective, and should develop internal procedures to ensure that company-sponsored attendees are properly qualified;
 - iii. Companies should establish internal controls to evaluate and qualify 3rd party service providers (e.g. logistics/travel agencies), if they want to reimburse 3rd party service providers (e.g. logistics/travel agencies) for meeting related expenses.
 - C. *Conference Meals and Refreshments*. Companies may provide funding to the conference organizer to support the provision of meals and refreshments to conference attendees. Companies may also 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 organizer 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.

- D. *Faculty Expenses.* Companies may make grants to conference organizer for reasonable honoraria, travel, lodging, and modest meals for Health Care Professionals who are bona fide conference faculty members.
- E. *Advertisements and Demonstration.* Companies may purchase advertisements and lease booth space for Company displays

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 but they may occur in other cities within China or in overseas locations. 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 any expenses (including 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

1. 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, 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:
 - A. 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.
 - B. Consulting arrangements should be entered into only where a legitimate need for the services is identified in advance and documented.
 - C. Selection of a consultant should be made on the basis of the consultant's qualifications and expertise to meet the defined need.
 - D. 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.

- E. Compensation paid to a consultant should not be paid in cash.
 - F. 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 reasonable costs for travel, lodging, local transportation and modest meals.
 - G. 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.
 - H. 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.
 - I. 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.
2. **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. 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.
 - B. 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 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 Health Care Professional. Such activities include, for example, theater, sporting events, skiing, golf, lavish meals and leisure or vacation trips. These activities also include recreational activities such as city tours organized in conjunction with bona fide travel. Such entertainment or recreational events or activities 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

1. 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.
 - A. **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.
 - B. **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.
 - C. **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. 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.
2. **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:
 - A. Section III: Company-Conducted Product Training and Education.
 - B. Section IV: Supporting Third-Party Educational Conferences.
 - C. Section V: Sales, Promotional, and Other Business Meetings.
 - D. Section VI: Consulting Arrangements with Health Care Professionals.

IX. Travel Associated with Health Care Professional Business Interactions

A Company's interactions with Health Care Professionals as outlined in Sections III, IV, V and VI of this Code may require Individual Health Care Professionals to travel within China or internationally. Accordingly, Companies may provide reasonable travel expenses for Individual Health Care Professional travel consistent with the limitations in this section. Additional principles apply when Companies provide travel expenses for Individual Health Care Professional travel to Third Party Educational Conferences. These additional principles are described in Section IV of this Code of Ethics.

- A. *Purpose.* There must be a bona fide scientific, educational, or business purpose to provide travel to an Individual Health Care Professional and the length of the trip must be commensurate with this purpose. Companies must not provide recreational activities, side trips, city tours, or any other activities that do not support the bona fide professional interest of the travel.
- B. *Location.* Companies should adopt objective criteria to select locations and venues. Local alternatives should be considered before sponsoring travel for Individual Health Care Professionals. Further, Companies are encouraged to consider China-based alternatives before sponsoring international travel for Individual Health Care Professionals.
- C. *Reasonable Expenses.* Companies may provide for reasonable flights, hotels, meal and incidental expenses for Individual Health Care Professional travel.
- D. *Participants.* A Company may not provide travel or other expenses for guests of Individual Health Care Professionals, or for any other person who does not have a bona fide professional interest in the activity requiring travel.
- E. *Reimbursement.* Companies are encouraged to pay for flights/hotels directly where practical. Reimbursement of travel-related expenses over RMB 500 should not be made in cash.

X. Educational Items and Branded Promotional Items

1. As permitted by applicable laws and regulations, 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 modest fair market value. A Company may not provide items that are capable of use for non-educational or non-patient-related purposes, for example, a smartphone, tablet computer, laptop, etc.
2. Companies may provide branded promotional items of minimal value to Health Care Professionals related to the Health Care Professional's practice. Such items could include stationery items, USB drives, mouse pads, and other items bearing a company's logo. Such items should have a value of RMB 200 or less.
3. This section is not intended to address the legitimate practice of providing products for evaluation and demonstration purposes, which is addressed in Section XII.
4. Under no circumstances should companies provide the following items to Health Care Professionals: alcohol, tobacco, cash, gift cards, or other cash equivalents.

XI. Research, Academic and Public Education Grants; Charitable Donations

1. Companies may provide research and educational grants and charitable donations to Health Care Professionals, in accordance with applicable laws and regulations. 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.
2. A Company should ensure, when providing such grants or donations, that the donation or grant is (a) handled by the financial department of the Institutional Health Care Professional and is used according to the donor or grant agreement for bona fide non-profit activities; (b) accepted by the legal entity of the Institutional Health Care Professional, not internal departments or individual Health Care Professionals; and (c) not conditioned on buying products or services or otherwise linked to other conditions that might affect fair competition.
3. 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 medical or healthcare 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. *Academic and Public Education Grants.* Academic and public information grants may be provided for legitimate purposes, including, but not limited to, the examples below. A Company may not make academic or public information grants to Individual Health Care Professionals, or to Individual Health Care Professionals in training.
 - i. *Academic Grants.* 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.
 - ii. *Public Education Grants.* 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 other organizations with a bona fide charitable purpose. Companies should exercise diligence to ensure the *bona fide* nature of the charitable organization or charitable mission.

XII. Evaluation and Demonstration Products

1. 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 Professionals regarding the use of products. Under certain circumstances described below, a Company may provide reasonable quantities of products to Institutional Health Care Professionals at no charge for evaluation and demonstration purposes.
2. Companies should ensure that the provision of evaluation and demonstration products is neither conditioned on buying products or services, nor linked to other conditions that might affect fair competition.
3. This section is limited to providing evaluation and demonstration products only and is not intended to address any other arrangement.
4. 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.
 - A. *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. The terms of an evaluation of single-use devices should be disclosed in writing to the Health Care Professional. If applicable laws, regulations or institutional rules specifically require disclosure to a different body, then disclosure should be made in accordance with the applicable laws, regulations or rules.
 - B. *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 and in writing with the Institutional Health Care Professional, not internal departments or individual Health Care Professionals. 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.
 - C. *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.

5. Companies should provide Health Care Professionals with documentation and disclosure regarding the no-charge status of evaluation and demonstration products unless applicable laws, regulations or institutional rules specifically require disclosure to a different body, in which case disclosure should be made in accordance with the applicable laws, regulations or rules.

XIII. Third Party SMI Relationships

Companies are encouraged to adopt a Third Party SMI Management Compliance Program in addition to an overall compliance program, applicable to all relevant personnel, including a Company's senior leadership. Taking into account a variety of risk-based factors, as well as local applicable laws; such programs may include the following elements:

- A. Written Policy/Procedure.
- B. Risk Assessment.
- C. Due Diligence Program.
- D. Written Contract.
- E. Training and Education.
- F. Monitor/Audit.
- G. Appropriate Corrective Action.