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[Insert Company Name] Policy and Procedure

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Purpose

This policy states the requirements for interactions with Healthcare Professionals (HCPs) including physicians and nurses, and Government Officials. As a medical device distributor, we must ensure we do not interfere with medical decision-making through improper incentives. We also must take all necessary steps to be familiar with and keep to the laws and regulations governing any contact we may have with HCPs and Government Officials.

Scope

This document applies to all company employees, sub-distributors, independent agents and other representatives. It covers the following topics:

- A. Governing Rules
- B. Our Position Against Bribery and Corruption
- C. Hospitality (Meals) for Healthcare Professionals or Government Officials
- D. Gifts to Healthcare Professionals or Government Officials
- E. Sponsorships of HCPs to Third-party Educational Conferences or Product Training Meetings (“events”)
- F. Grants and Donations
- G. Consulting Services with Healthcare Professionals or Government Officials
- H. Funding for Advertising and Exhibit or Booths Fees
- I. Control of Promotional Materials
- J. Expense Reports for Interactions with HCPs or Government Officials
- K. Tenders
- L. Conflicts of Interest
- M. Customer Complaint Handling
- N. Accepting Payment for Product from Patients
- O. Reporting Concerns

Policies and Procedures

A. Governing Rules

1. We must follow all international bribery laws, including the U.S. Foreign Corrupt Practices Act, the UK Bribery Act and the OECD Convention on Combating Bribery.
 - [Click [here](#) to see if applicable. If not, delete statement.] Our country, along with thirty-eight other countries (to date), have adopted, the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions.

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2. We must follow all applicable laws for [country name].
3. We must follow the industry code for our country: [insert name and link to code].
4. We must follow our company's Code of Conduct [if in existence – if not, delete requirement].
5. We must follow the codes of our medical device business partners:
 - List codes, as applicable
6. We must follow our internal policies and procedures, including the requirements listed in this document.

B. Our Position Against Bribery and Corruption

1. You must not offer or make an improper payment to any HCP, Government Official or any other person.
 - An improper payment means a bribe, kickback or any financial payment or benefit improperly offered or made to obtain or retain business. Improper payments may include anything of value, in cash or in kind. This can include travel, meals, entertainment, gifts, donations or grants if done inappropriately. These items could be considered bribes if given to the HCP or Government Official directly, or to the spouse, child, friend or another person with a relationship to the HCP or Government Official. Improper payments can also include giving items or resources free of charge that the HCP or Government Official would normally have to pay for. This can include the salary for office staff, excessive samples or equipment loans that are not made in accordance with this policy. Commissions or sales arrangements, discounts, and rebates may also be an improper payment if made for an inappropriate purpose.
 - An improper payment can be made directly or indirectly, in cash or "in-kind."
2. You must not encourage or allow others to offer or make improper payments.
3. You must not ask for or receive any improper payment from any person, or encourage or allow others to do so.
4. These restrictions apply even if a country or culture considers improper payments are considered an acceptable business practice in.
5. These restrictions apply even to payments of small amounts to ensure or speed up the proper performance of a Government Official's routine duties. (These may be called "facilitation payments.")
6. The following are some examples of bribery. All of these activities are prohibited:

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- Pay cash to reward or thank a healthcare professional or government official for placing an order or using our products (pay per procedure)
- Sponsor a healthcare professional or government official to a product training meeting or medical conference as a reward for current or future product orders
- Pay expenses for the spouse of a healthcare professional or government official who is attending a product training meeting or a medical conference
- Support illegal payments with fake consulting contracts or other false transactions
- Hire the friend, relative or employee of a healthcare professional or government official to encourage or reward the purchase of products
- Provide any other form of personal benefit to a healthcare professional or government official to encourage or reward the purchase of products

C. Hospitality (Meals) for Healthcare Professionals or Government Officials

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| Principle | We do not offer anything of value—including hospitality, meals or entertainment—to improperly influence an HCP to use or consider using our products. |
| Allowed activities | <ol style="list-style-type: none">1. You may provide meals to HCPs or Government Officials.2. Meals must be modest in value and part of a proper business interaction.3. You must hold a meal in an appropriate venue that supports business purpose of the meeting.4. You must hold to these per person meal limits:<ul style="list-style-type: none">• Breakfast - [amount in local currency]• Lunch - [amount in local currency]• Dinner - [amount in local currency] |
| Prohibited activities | <ol style="list-style-type: none">5. You may not split the cost of a meal, including before or after dinner drinks, to avoid these limits.6. You may not use your own money to purchase a meal, if the meal is offered on behalf of company business. This refers to expenses that are not submitted for reimbursement by the company. |

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| | <ol style="list-style-type: none">7. You may not invite or pay for the meal of an HCP's or Government official's guest, such as a spouse.8. You may not provide entertainment as part of the meal or at any other time. Entertainment includes social, sporting, recreational and cultural activities. |
| Approval requirements | 9. [Enter your approval requirements for these types of expenses] |
| Documentation requirements | 10. See Section K Expense Reports for Interactions with HCPs or Government Officials below. |

D. Gifts to Healthcare Professionals or Government Officials

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| Principle | We do not offer anything of value—including educational or promotional items—to improperly influence an HCP to use or consider using our products. |
| Allowed activities | <ol style="list-style-type: none">1. You may provide educational or promotional items to HCPs or Government Officials.2. Educational and promotional items must be modest in value and infrequent.3. Educational and promotional items must be related to the medical profession, benefit patients or serve a genuine educational function.<ul style="list-style-type: none">• You must have written approval from the [enter role of appropriate party] if you wish to provide an item that does not meet these requirements.4. A single item may not exceed [amount in local currency]. This includes any applicable taxes.<ul style="list-style-type: none">• An item's value is decided on the item's retail cost, not the cost to our company to purchase the item. |
| Prohibited activities | <ol style="list-style-type: none">5. You may never give cash or cash equivalents, such as gift cards, as a gift. |

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| | 6. You may not use your own money to purchase a gift, if the gift is offered on behalf of company business. This refers to expenses that are not submitted for reimbursement by the company. |
| Approval requirements | 7. [Enter your approval requirements for these types of expenses, including items that are not related to the medical profession, benefit patients or serve a genuine educational function] |
| Documentation requirements | 8. You [must/should] keep track of the items you give to HCPs or Government Officials, including recipient name, item description, item value and date of giving. [Outline local process for tracking items.] |

E. Sponsorships of HCPs to Third-party Educational Conferences or Product Training Meetings (“events”)

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| Principle | We do not offer anything of value—including trips to conferences or product training meetings—to improperly influence an HCP to use or consider using our products. |
| Allowed activities | <ol style="list-style-type: none">1. You may support the attendance of individual HCPs at Third-party Educational Conferences or a Product Training and Medical Education meeting (“sponsorship”).2. Our company will pay for the following expenses as part of the sponsorship. These expenses must be reasonable and necessary:<ul style="list-style-type: none">• Registration fees to the event (as applicable)• Transportation<ul style="list-style-type: none">• Air travel: The class of travel must comply with the laws and industry codes of the HCP’s country of residence. If no industry code exists, business class travel is allowed only when the flight is five-hours or longer (one-way, inclusive of all legs of travel).• Train travel: First or second-class is allowed, regardless of the duration of the trip.• Accommodations |

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| | <ul style="list-style-type: none">• The hotel must be modest (three or four stars) and provide easy access to the event. We will only pay for the number of nights reasonably required for a participant to attend the event.• Meals must be modest and meet the requirements listed in the meals section above. <p>3. Whenever possible, our company or a company-selected vendor should arrange the HCP's travel details. HCPs should not make any travel plans themselves if other arrangements can be made.</p> <ul style="list-style-type: none">• Our company should directly organise and pay for the registration, transportation, accommodation and meal costs with the respective vendors, agencies or conference organizers.• For costs that could not be paid for directly and in advance, such as taxi fares and mileage costs, we permit reimbursement if the HCP provides original receipts and if the costs are allowed under applicable laws, industry codes and these rules. <p>4. You must select HCPs who are actively engaged in the practice of medicine that is the focus of the event or that have medical interest in the topic of the event.</p> <ul style="list-style-type: none">• Select HCPs when the event's content will be new and useful to them. Do not sponsor an HCP to multiple events that generally include similar information. <p>5. You must consider the following criteria when considering a third party conference for a sponsorship.</p> <ul style="list-style-type: none">• The agenda should be available in advance, and the meeting content should be related to the specialty and/or medical practice of the HCP.• The meeting should have a significant amount of the time dedicated to relevant scientific content.• The conference organiser should be well known, respected and have previous experience organising appropriate and robust scientific conferences.• Social activities, if any, should be modest, incidental and not have the effect of independently attracting participants. |
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| | <p>6. You must contact the HCP's employer prior to providing the sponsorship. For [insert TPS's country name], employer [select one - notification/approval] is required.</p> <ul style="list-style-type: none">• See the [list local location – templates available from TPS Toolkit] for a template letter. |
| Prohibited activities | <p>7. You may not pay a fee to an HCP for the time spent attending an event.</p> <p>8. You may not invite or pay for the travel, accommodation or meal costs of an HCP's guest, such as a spouse.</p> <ul style="list-style-type: none">• If a guest attends, you cannot facilitate his or her travel, hotel arrangements or any other activities. <p>9. You may not pay for entertainment or recreation activities for HCPs attending an event. You may not pay for mini-bar, spa fees or other similar expenses.</p> |
| Approval requirements | <p>10. You must submit HCP sponsorships for approval to [enter role of appropriate party]. You must provide the following information [add more requirements as your business requires]:</p> <ul style="list-style-type: none">• Event name, location and dates• Name of sponsored HCP(s) and description of their interest in the content of the event• Name of any sales representative(s) who will attend the event and the educational / business justification for their attendance• Travel class and details of accommodations including flight and hotel dates• Anticipated costs, including registration fees, travel costs, etc.• Disclosure if the institution or individual that will benefit from the sponsorship is involved in a tender or other purchasing decision. |
| Documentation requirements | <p>11. You must keep a copy of the employer [select one - notification/approval] letter and submit relevant expense through the expense reporting process.</p> |

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F. Grants and Donations

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| Principle | We do not offer anything of value—including grants or donations—to improperly influence an HCP to use or consider using our products. |
| Allowed activities | <ol style="list-style-type: none">1. Our company may provide grants or donations to a non-profit and/or charitable organisation, medical institution, accredited educational programme vendor, medical foundation or professional society that is entitled to receive grants or donations under local laws.<ul style="list-style-type: none">• Grants include Education Grants, Fellowships, and Product Donations.• Donations include financial or in-kind support provided to a non-profit or charitable organisation to further the objectives of the organisation, and/or to support genuine fund-raising drives for projects undertaken by the organisation.• Grants and donations do not include goods or services. Any goods or service must be purchased at fair market value.2. Our company may give grants for the following purposes:<ul style="list-style-type: none">• Reduce conference costs• Fund reasonable honoraria, travel, lodging and meals for HCPs that are conference faculty• Provide modest meals and receptions for conference attendees• Support fellowships programs for HCPs if our company has no influence on the selection of the fellow• Provide support to fund the purchase of medical textbooks, subscriptions to medical publications, anatomical models or similar3. If a request for a grant or donation is given to sales personnel, they must forward it to the [enter role of appropriate party]. |
| Prohibited activities | <ol style="list-style-type: none">4. We do not provide grants or donations under any of the following circumstances:<ul style="list-style-type: none">• To an individual HCP• To offer a price concession |

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| | <ul style="list-style-type: none">• To recognize past, present or future use of medical device products or services• To fund parties, entertainment or similar events (e.g. sporting or cultural events, city tours, musical performances) <p>5. Sales personnel may not do any of the following:</p> <ul style="list-style-type: none">• Control or unduly influence any decision relating to grants or donations• Make any commitments on behalf of our company regarding grants and donations in advance of approval• Communicate to the recipient organisation that funding will be provided |
| Approval requirements | <p>6. The following information must be submitted in writing before a grant or donation will be considered:</p> <ul style="list-style-type: none">• The request from the organisation with its name, address and, if applicable, its not-for-profit status. This request should include:<ul style="list-style-type: none">• A description of the proposed grant or donation (e.g., funds, equipment, etc.)• A description of the specific purpose of the proposed grant or donation• The amount requested with an explanation or budget of how the funds or donated items will be used• Any other information required to describe the specific request <p>7. The [enter role of appropriate party] must approve all grants or donations before any commitment, payment or provision of equipment or services is made.</p> |
| Documentation requirements | <p>8. We must maintain documentation of each grant or donation given including letter of request from the institution and proof of approval.</p> |

G. Consulting Services with Healthcare Professionals or Government Officials

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| Principle | We do not offer anything of value—including consulting agreements—to improperly influence an HCP to use or consider using our products. |
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| Allowed activities | <ol style="list-style-type: none">1. We may hire healthcare professionals or government officials as consultants to help us achieve a necessary and documented business need.2. We only hire consultants based on their qualifications and experience.3. We gain advance approval of the consultant's employer where required by local law or industry code. We notify consultant's employer when the consultant is employed partially or fully by the government.4. We pay fair market value or less for the services provided. We also may reimburse a consultant for reasonable and modest expenses that are incurred as a necessary part of performing a consulting service. We only reimburse expenses when allowed by our policies, local country laws and the applicable industry code.5. We only pay consultants upon receipt of acceptable documentation from the healthcare professional. |
| Prohibited activities | <ol style="list-style-type: none">6. We do not select consultants for a consulting service based on their past or potential purchases or endorsement of our products or services.7. We do not allow sales personnel to control or unduly influence any decision to select a consultant for a consulting service. |
| Approval requirements | <ol style="list-style-type: none">8. The [enter role of appropriate party] must approve all consulting services before any commitment, payment or provision of services is made. |
| Documentation requirements | <ol style="list-style-type: none">9. We document all consulting services must be documented in a contractual agreement that includes, at a minimum, a detailed description of the services to be provided and fee arrangements based on fair market value.<ul style="list-style-type: none">• We fully execute the contract before the healthcare professional provides any services.• We retain a copy of the healthcare professional curriculum vitae (CV) or other record of his qualifications to perform the service.• We retain records of any payments made for the service.• We retain written evidence of services performed (such as a work plan, completed by the consultant). |

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H. Funding for Advertising and Exhibit or Booths Fees

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| Principle | We believe HCP education promotes the safe and effective use of medical device products. |
| Allowed activities | <ol style="list-style-type: none">1. Our company may fund advertising, exhibits or booths at third-party events.2. We will consider the following factors before funding advertising, exhibits or booths:<ul style="list-style-type: none">• The number of HCPs expected to attend based on prior year attendance figures for the same or similar events• The agenda of the meeting• The location of the meeting3. Exhibit / booth fees should be reasonable for the size of the booth, the number of attendees, the exhibit floor hours and the costs for a booth at an equivalent event. |
| Prohibited activities | <ol style="list-style-type: none">4. Our company will never pay advertising or exhibit / booth fees in exchange for past or potential purchases of our products or services. |
| Approval requirements | <ol style="list-style-type: none">5. The [enter role of appropriate party] must approve advertising or exhibit/ booth fees of [enter amount in local currency] or more in writing in advance. |
| Documentation requirements | <ol style="list-style-type: none">6. You must complete the Payment for Booth Space approval form [or local equivalent]. |

I. Control of Promotional Materials

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| Principle | We only promote our products for approved uses. |
| Allowed activities | <ol style="list-style-type: none">1. You must only use approved promotional material from a medical device business partner. This is to ensure that promotion it is consistent with product approvals and applicable legal and regulatory requirements.<ul style="list-style-type: none">• “Promotional materials” means all materials concerning a medical device business partner’s products intended for those who use, pay for or receive the products (HCPs, patients, hospitals, etc.). These |

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| | include, but are not limited to, labelling, advertising, reprints of journal articles or reference texts, sales and marketing aids, and exhibition displays, each in any printed, digital, electronic, or other media format. |
| Prohibited activities | <ol style="list-style-type: none">2. You must not mislead or deceive the customer, misrepresent the product, include any false statements or unsubstantiated claims of performance, or imply or suggest that a product is safe or effective for an unapproved or “off label” use.3. You may not create your own promotional materials, including printed materials, websites, etc. |
| Approval requirements | <ol style="list-style-type: none">4. All COMPANY NAME promotional material must be approved and provided by COMPANY NAME for use in our country. [Insert requirements for other medical device business partners.] |
| Documentation requirements | <ol style="list-style-type: none">5. Not applicable |

J. Expense Reports for Interactions with HCPs or Government Officials

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| Principle | We provide accurate information—in our books and records and to all our stakeholders. |
| Allowed activities | <ol style="list-style-type: none">1. You must submit for reimbursement all expenses incurred on behalf of HCPs, Government Officials and other customers.2. You must submit for reimbursement all payments made to HCPs, Government Officials and other customers. Payments may include consulting fees, grants, donations, etc. |
| Prohibited activities | <ol style="list-style-type: none">3. You may not pay for any expenses related to HCP or Government Official interactions from your own pocket and not seek reimbursement. |
| Approval requirements | <ol style="list-style-type: none">4. [Enter local requirements]. |
| Documentation requirements | <ol style="list-style-type: none">5. Your expense report must include the following information:<ul style="list-style-type: none">• The participant names, including yourself and any other company representatives |

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| | <ul style="list-style-type: none">• A description of the expense (business meal, air fare, etc.)• The business reason for the expense, including the names of any products discussed• The total amount of the expense• The date of the expense• [Enter any other local requirements] |
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K. Tenders

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| Principle | We believe that tenders are designed to promote transparency, objectivity and fair and open competition. |
| Allowed activities | <ol style="list-style-type: none">1. "Tender" can mean an offer from a supplier to sell products or services or an invitation (such as a Request For Proposal, or RFP) from a purchaser to make such offers.2. We may respond to a tender.3. Public or private tender offers may include "extra" requirements. To be acceptable, these "extra" requirements must be transparent, specific and requested equally from all bidders in the tender. Also they must meet any local legal requirements. The following type of "extra" requirements are usually acceptable: [this list may be edited based on local law]<ul style="list-style-type: none">• Requirements directly related to products involved in the tender, e.g. essential product training at appropriate locations• Approved discounts and rebates paid to the purchaser which are properly documented on the invoice and any other relevant records of the transaction (as opposed to those paid to a third party) |
| Prohibited activities | <ol style="list-style-type: none">4. We do not allow behaviour that distorts fair competition. This may include the following:<ul style="list-style-type: none">• Telling competitors about intended price increases.• Agreeing with competitors to pricing terms, or other fundamental aspects of the tender. |

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- Agreeing with competitors to submit a high bid in a tender in order to allow a competitor to win the tender contract.
 - Agreeing with competitors to withhold submission to a tender in which we would have otherwise participated.
 - Agreeing with competitors to limit tender submissions to certain regions or countries.
 - Engaging in improper side negotiations with tender authorities, or others that can influence the decision of tender awards. This does not prevent discussions that are specifically authorized under applicable rules or are only for the purpose of clarifying the content of tenders.
 - Improperly influencing tender specifications to exclude competitor products that would otherwise meet the purchaser’s needs.
5. If a company we represent has another distributor or agent in our markets, this distributor is considered a competitor. We cannot do any of the activities stated above with this competitor.
6. We may not attempt to improperly influence tendering authorities to award a contract to us. Examples of prohibited actions include the following:
- Offering, promising or providing anything of value to individuals who are involved in, or can influence, tender awards. This includes gifts, meals, consulting arrangements, sponsorship, grants, donations, travel, or the like.
 - Offering, promising or providing anything of value to third parties at the request or direction of individuals who are involved in, or can influence, tender awards.
 - Linking the timing of grants, donations or other items of value to the submission of a tender or tender award.
 - Offering, promising or providing prohibited “value adds” as part of the tender submission.
7. We cannot offer the following types of “extra” requirements in a tender: [this list may be edited based on local law]
- Requirements negotiated after the tender is issued

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| | <ul style="list-style-type: none">• Rebates paid to one party (such as a hospital) in situations where the contract is with another party (such as a public agency, or a wholesaler or distributor)• Inappropriate benefits to individual healthcare professionals, for example, a holiday party for the nurses or golf days for surgeons• Training that is at inappropriate locations• “Extra” requirements that may be or look like a bribe to the tendering entity |
| Approval requirements | 8. [Enter local requirements]. |
| Documentation requirements | 9. [Enter local requirements]. |

L. Conflicts of Interest

1. We do not hire any immediate family member of an HCP or Government Official to encourage the HCP or Government Official to use or buy products or services or to obtain or retain business.
2. We do not allow any individual whom we know to have an immediate family relationship with any HCP or Government Official to act as the sales or account representative for that HCP or Government Official without written approval from the [enter applicable role].

M. Customer Complaint Handling

1. All written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a product after it has been released for distribution must be reported to the appropriate medical device business partner.

N. Accepting Payment for Product from Patients

[Delete this section if it does not apply to your market.]

In some markets, sales representatives may accept payments directly from patients. Collecting cash should be discouraged. However, in exceptional circumstances, if there are no other reasonable options, appropriate controls should be implemented.

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1. [List department/individual] issues an invoice for direct payment by patients. The invoice is based on the [sales order / sale price].
2. A sales representative must gain the patient's signature on the invoice to confirm the amount the patient paid for the product.
3. A sales representative must return the signed invoice with the payment to [list department/individual].
4. [List department/individual] will mail the patient a receipt to acknowledge the payment.

O. Reporting Concerns

1. You must report any actual or suspected misconduct to the appropriate medical device business partner's reporting line.
 - a. Company hotline.
 - b. [list others, as applicable]

Approvals

| | | | |
|---------------------|--|--------------|--------------|
| Author: | [enter name of document owner/author - may delete if same as approver] | Date: | [enter date] |
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Revision History

| Current Revision | Major Changes | Reason for Change |
|------------------|---------------|-------------------|
| 1.0 | New Policy | NA |