

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
MEDTRONIC SPINE, LLC**

I. PREAMBLE

Medtronic Spine, LLC, formerly known as Kyphon, Inc., (Kyphon) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote Kyphon's compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, Kyphon is entering into a Settlement Agreement with the United States. This CIA shall apply only to U.S. operations of Kyphon that are subject to Federal health care program requirements.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Kyphon under this CIA shall be five years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Kyphon's final annual report; or (2) any additional materials submitted by Kyphon pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "Covered Persons" includes:
 - a. all officers, directors, and employees of Kyphon;
 - b. all contractors, subcontractors, agents, and other persons who, on behalf of Kyphon, perform functions related to the sale or marketing of Reimbursable Items;
 - c. all employees of Medtronic Sofamor Danek, Inc. (MSD) (including, but not limited to, employees in Information Technology, Regulatory Affairs and Quality Assurance, Legal, Human Resources, Finance, and US Sales) who have responsibilities that directly support Kyphon in the sales or marketing of Reimbursable Items; and
 - d. all individuals who sell or market Reimbursable Items on behalf of Kyphon.

Notwithstanding the above, this term does not include part-time or per diem contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

2. "Relevant Covered Persons" includes all Covered Persons who engage in, or supervise or train Covered Persons who engage in, the marketing or sale on behalf of Kyphon of Reimbursable Items and all Covered Persons who supervise, advise, or train Covered Persons who advise or train potential or actual customers and physician-users on use and reimbursement issues related to Reimbursable Items.
3. "Arrangements Covered Persons" includes all Covered Persons involved with the development, approval, management, or review of Kyphon's Arrangements, as such term is defined in Section II.C.6.

4. “Covered Items” means those items listed in Appendix A.
5. “Reimbursable Items” means Covered Items and all other items or services marketed by or on behalf of Kyphon for which reimbursement may be made directly or indirectly by the Federal health care programs.
6. “Arrangements” shall mean every arrangement or transaction entered into by or on behalf of Kyphon that: (a) involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and (b) is between Kyphon or an entity on behalf of Kyphon and any actual or potential source of health care business or referrals to Kyphon or any actual or potential recipient of health care business or referrals from Kyphon. The term “source” shall mean any physician, contractor, vendor, or agent and the term “health care business or referrals” shall be read to include referring, recommending, arranging for, ordering, leasing, or purchasing any good, facility, item, or service for which payment may be made in whole or in part, directly or indirectly, by a Federal health care program.
 - a. “Contractual Arrangements” shall mean every Arrangement that is contractual in nature and shall include all Arrangements related to the provision of services to Kyphon, including, but not limited to, training, education, consulting, research, clinical studies, focus groups, and physician advisory boards; and intellectual property, grants, and charitable contributions.
 - b. “Non-Contractual Arrangements” shall mean all Arrangements that are not Contractual Arrangements.
7. “Kyphon” shall mean the Medtronic Spine, LLC subsidiary of MSD and Medtronic, Inc. (Medtronic) (together the Medtronic Companies) and no other component or subsidiary of the Medtronic Companies.

III. CORPORATE INTEGRITY OBLIGATIONS

Kyphon shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* MSD represented to OIG that, prior to the Effective Date, MSD appointed a Compliance Officer who is responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with Federal health care program requirements. MSD also represented that MSD's Compliance Officer has been appointed to serve as Kyphon's Compliance Officer. Kyphon shall continue to have a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of MSD or Kyphon, shall make periodic (at least quarterly) reports regarding compliance matters directly to MSD's Compliance Committee, and shall be authorized to report on such matters to the Executive Compliance Committee or the Audit Committee of Medtronic's Board of Directors at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer of MSD or any other Medtronic Company. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Kyphon as well as for any reporting obligations created under this CIA.

Kyphon shall report to OIG, in writing, any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

2. *Compliance Committee.* MSD has represented to the OIG that, prior to the Effective Date of this CIA, MSD appointed a Compliance Committee of which the Compliance Officer and MSD's President are members. The Compliance Committee shall include the Compliance Officer, MSD's President, Kyphon's General Manager, and members of MSD senior management responsible for finance, clinical, human resources, legal, sales, and operations. The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her

responsibilities (e.g., assist in the analysis of Kyphon's risk areas and oversee monitoring of internal and external audits and investigations).

Kyphon shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

B. Written Standards.

1. *Code of Conduct.* The Medtronic Companies represented to the OIG that, prior to the Effective Date of this CIA, Medtronic developed a Code of Conduct ("the Code of Conduct"), which is applicable to Kyphon. Kyphon shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all Covered Persons. The Code of Conduct shall, at a minimum, set forth:

- a. the commitment to full compliance with all Federal health care program requirements;
- b. the requirement that all Covered Persons shall be expected to comply with all applicable Federal health care program requirements and with Kyphon's own Policies and Procedures as implemented pursuant to Section III.B.2 (including the requirements of this CIA);
- c. the requirement that all Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Kyphon, suspected violations of any Federal health care program requirements or of Kyphon's own Policies and Procedures;
- d. the possible consequences to both Kyphon and Covered Persons of failure to comply with Federal health care program requirements and with Kyphon's own Policies and Procedures and the failure to report such noncompliance; and
- e. the right of all individuals to use the Disclosure Program described in Section III.F, and Kyphon's commitment to

nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

To the extent not already accomplished, within 60 days after the Effective Date, Kyphon shall distribute to each Covered Person and each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by Medtronic's Code of Conduct. Kyphon may distribute the Code of Conduct and required certification to each Covered Person either electronically or in hard-copy form. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 60 days after the Effective Date, whichever is later.

The Code of Conduct shall be periodically reviewed (at least annually) to determine if revisions are appropriate and shall be revised as necessary based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. *Policies and Procedures.* Within 120 days after the Effective Date, Kyphon shall implement written Policies and Procedures regarding the operation of Kyphon's compliance program and its compliance with applicable Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. the Federal health care programs' use of reimbursement codes in identifying Reimbursable Items;
- c. how to handle questions from Kyphon's customers or physician users regarding Federal health care program reimbursement for Reimbursable Items;
- d. how to disseminate information regarding reimbursement for Reimbursable Items;

- e. current sources of official guidance from Medicare contractors and the Centers for Medicare and Medicaid Services regarding reimbursement questions related to Reimbursable Items;
- f. approved methods of promoting, marketing, and selling Reimbursable Items in accordance with Federal health care program requirements (Sales Policies and Procedures);
- g. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute) and the regulations and other guidance documents related to this statute, and business or financial arrangements or contracts that may violate the Anti-Kickback Statute, and the applicability of the Anti-Kickback Statute to Arrangements as that term is defined in Section II.C.6; and
- h. the requirements set forth in Section III.D, including but not limited to the Arrangements Database, the internal review and approval process, and the tracking of Arrangements.

The President of Kyphon shall review and approve all Sales Policies and Procedures and any material changes to Sales Policies and Procedures prior to their adoption, and shall review all Sales Policies and Procedures annually.

Within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all Covered Persons whose job functions relate to those Policies and Procedures. Distribution may include publishing such Policies and Procedures on Kyphon's intranet or other internal web sites available to all employees. If Kyphon uses such an electronic method of distribution, it must notify the individuals receiving the Policies and Procedures that the Policies and Procedures will be distributed in such a manner, and it must adopt tracking procedures designed to track the distribution and ensure that all appropriate individuals receive the Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Kyphon shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall

be made available to all Covered Persons whose job functions relate to those Policies and Procedures.

C. Training and Education.

1. *General Training.* Within 120 days after the Effective Date, Kyphon shall provide at least one hour of General Training to each Covered Person. This training, at a minimum, shall explain:

- a. Kyphon's CIA requirements; and
- b. Kyphon's Compliance Program (including Medtronic's Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Training.*

a. Reimbursable Items Training: Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least three hours of Reimbursable Items Training. The Reimbursable Items Training shall include a discussion of:

- i. appropriate methods of promoting, marketing, and selling Reimbursable Items in accordance with all Federal health care program requirements and the Policies and Procedures required by this CIA;
- ii. the personal obligation of each Covered Person involved in the marketing and sales of Reimbursable Items to ensure that those products are marketed and sold in accordance with all applicable Federal health care program requirements;

iii. the personal obligation of each Covered Person involved in customer relations, reimbursement, sales, and marketing functions to know the applicable Federal health care program requirements and Kyphon's Policies and Procedures, and to ensure that customers are given accurate information regarding Kyphon's products, or redirected to payer resources;

iv. Medtronic's requirement that all Covered Persons shall be expected to comply with all Federal health care program requirements and with Kyphon's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);

v. applicable Federal health care program requirements; and

vi. the legal sanctions for violations of the Federal health care program requirements, and examples of such violations.

b. Anti-Kickback Training. Within 120 days after the Effective Date, each Arrangements Covered Person shall receive at least three hours of Anti-Kickback Training. The Anti-Kickback Training shall include a discussion of:

i. Arrangements that potentially implicate the Anti-Kickback Statute, as well as the regulations and other guidance documents related to this statute;

ii. Kyphon's policies, procedures, and other requirements relating to Arrangements, including but not limited to the Arrangements Database, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals required by Section III.D of the CIA;

- iii. the personal obligation of each Arrangements Covered Person to know the applicable legal requirements and Kyphon's policies and procedures;
- iv. the legal sanctions under the Anti-Kickback Statute; and
- v. examples of violations of the Anti-Kickback Statute.

New Relevant Covered Persons and Arrangements Covered Persons shall receive the relevant Specific Training within 30 days after the beginning of their employment or becoming Relevant Covered Persons or Arrangement Covered Persons, or within 120 days after the Effective Date, whichever is later. A Covered Person who has completed the appropriate Specific Training shall review a new Relevant Covered Person's or Arrangement Covered Person's work, to the extent that the work relates to customer relations, reimbursement, sales, and marketing of Reimbursable Items or the development, approval, management, use, or review of Arrangements until such time as the new Relevant Covered Person or Arrangements Covered Person completes his or her Specific Training.

After receiving the Specific Training described in this Section III.C, each Relevant Covered Person shall receive at least two hours of Reimbursable Items Training and each Arrangements Covered Person shall receive at least two hours of Anti-Kickback Training in each subsequent Reporting Period.

3. *Certification.* Each Covered Person who is required to attend training pursuant to this Section III.C shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

4. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area.

5. *Update of Training.* Kyphon shall review annually the training programs developed to satisfy the requirements of this Section III.C, and, where appropriate, update the training to reflect changes in applicable Federal health care program requirements,

any issues discovered during internal audits, the Sales and Marketing Review, the Arrangements Review, and any other relevant information.

6. *Training Methods.* Kyphon may provide the training required under this CIA through videotape, DVD, appropriate computer-based training approaches, or other comparable methods not involving in-person training. If Kyphon chooses to provide training pursuant to any such method, it shall make available at reasonable times appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

D. Compliance with the Anti-Kickback Statute.

1. *Arrangements Procedures.* Within 120 days after the Effective Date, Kyphon shall create procedures reasonably designed to ensure that each existing and new or renewed Arrangement does not violate the Anti-Kickback Statute or the regulations, directives, and guidance related to the Anti-Kickback Statute (Arrangements Procedures). These procedures shall include the following:

- a. creating and maintaining a database of all existing and new or renewed Arrangements that shall contain the information specified in Appendix B (Arrangements Database);
- b. tracking remuneration to and from all parties to Arrangements;
- c. tracking service and activity logs to ensure that parties to the Arrangement are performing the services required under the applicable Arrangement(s) (if applicable);
- d. monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Arrangement(s) (if applicable);
- e. establishing and implementing a written review and approval process for all Contractual Arrangements, including but not limited to a legal review by counsel with expertise in the Anti-Kickback Statute and appropriate documentation of all internal controls, the

purpose of which is to ensure that all new and existing or renewed Contractual Arrangements do not violate the Anti-Kickback Statute;

f. establishing and implementing a written review and approval process for all Non-Contractual Arrangements, including but not limited to an annual legal review by counsel with expertise in the Anti-Kickback Statute and appropriate documentation of all internal controls, the purpose of which is to ensure that all Non-Contractual Arrangements do not violate the Anti-Kickback Statute;

g. requiring the Compliance Officer to review the Arrangements Database, internal review and approval process, and other Arrangements Procedures on at least a quarterly basis and to provide a report on the results of such review to the Compliance Committee; and

h. implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments pursuant to Section III.I (Reporting) when appropriate.

2. *New or Renewed Arrangements.* Prior to entering into new Contractual Arrangements or renewing existing Contractual Arrangements, in addition to complying with the Arrangements Procedures set forth above, Kyphon shall comply with the following requirements (Arrangements Requirements):

a. Ensure that each Arrangement is set forth in writing and signed by Kyphon and the other parties to the Arrangement;

b. Include in the written agreement a requirement that all individuals who meet the definition of Covered Persons shall comply with Kyphon's Compliance Program, including the training related to the Anti-Kickback Statute. Additionally, Kyphon shall provide each party to the Arrangement with a copy of its Code of Conduct and Anti-Kickback Statute Policies and Procedures; and

c. Include in the written agreement a certification by the parties to the Arrangement that the parties shall not violate the Anti-Kickback Statute with respect to the performance of the Arrangement.

3. *Records Retention and Access.* Kyphon shall retain and make available to OIG, upon request, the Arrangements Database and all supporting documentation of the Arrangements subject to this Section III.D and, to the extent available, all non-privileged communications related to the Arrangements and the actual performance of the duties under the Arrangements.

E. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, Kyphon shall engage an individual or entity (or entities), such as an accounting, auditing, law, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform reviews to assist Kyphon in assessing and evaluating its sales and marketing systems, processes, policies, and procedures (the Sales and Marketing Review) and to perform a review to assist Kyphon in assessing its compliance with the obligations pursuant to Section III.D of this Agreement (Arrangements Review).

Each IRO shall assess, along with Kyphon, whether it can perform the IRO reviews in a professionally independent and objective fashion, as appropriate to the nature of the engagements, taking into account any other business relationships or other engagements that may exist. The engagement of the IRO shall not be deemed to create an attorney-client relationship between MSD or Kyphon and the IRO. The other applicable requirements relating to the IRO(s) are outlined in Appendix C to this CIA, which is incorporated by reference.

b. *Frequency of Sales and Marketing Review.* The Sales and Marketing Review shall be performed annually and shall cover each

of the Reporting Periods. The IRO(s) shall perform all components of each Review.

c. *Frequency of Arrangements Review.* The Arrangements Review shall be performed annually and shall cover each of the Reporting Periods. The IRO(s) shall perform all components of each annual Arrangements Review.

d. *Retention of Records.* The IRO(s) and Kyphon shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Kyphon) related to the engagements.

e. *Responsibilities and Liabilities.* Nothing in this Section III.E affects Kyphon's responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute.

f. *Mitigation of the Arrangements Review.* After the submission of the third Arrangements Review Report, Kyphon may request to be released from the Arrangements Review for the remaining period of the CIA. The OIG may, at its sole discretion, grant Kyphon's request.

2. *Sales and Marketing Engagement.*

a. *The Sales and Marketing Review.* The IRO shall perform a Sales and Marketing Review to assist Kyphon in assessing and evaluating its systems, processes, policies, and procedures related to the sales and marketing of Reimbursable Items. Prior to performing the Sales and Marketing Review, the IRO shall submit its workplan to the OIG for approval. If OIG does not provide comments or recommendations within 60 days, the IRO's workplan for that Reporting Period will be deemed approved. Any comments or recommendations made by the OIG in connection with a review of the submitted workplan shall not preclude the OIG from making

further comments or recommendations for future workplan(s) after reviewing the Sales and Marketing Report. The objectives of the Sales and Marketing Review shall be to examine the accuracy of information provided by Kyphon to its customers and physician users relating to Federal health care program reimbursement, if any, for its Reimbursable Items.

b. *Sales and Marketing Review Report.* The IRO shall prepare a report based upon each Sales and Marketing Review performed (Sales and Marketing Review Report). At a minimum, the Sales and Marketing Review Report shall include: (i) a clear statement of the objective intended to be achieved by the Sales and Marketing Review; (ii) a description of the specific documentation relied upon and individuals interviewed by the IRO when performing its review; (iii) a narrative description of how the Sales and Marketing Review was conducted; (iv) the results, conclusions, and recommendations developed by the IRO based upon the review performed; and (v) the names and credentials of the individuals who performed the Sales and Marketing Review.

3. *The Arrangements Engagement.*

a. *Arrangements Review.* The IRO shall perform a review to assess whether Kyphon is complying with the Arrangements Procedures and Arrangements Requirements required by Sections III.D.1 and III.D.2 of this CIA. The IRO shall randomly select a sample of 40 Arrangements that were entered into or renewed during the Reporting Period. The IRO shall assess whether Kyphon has implemented the Arrangements Procedures and, for each selected Arrangement, the IRO shall assess whether Kyphon has complied with the Arrangements Procedures and Arrangements Requirements specifically with respect to that Arrangement. The IRO's assessment shall include, but is not limited to: (i) verifying that the Arrangement is listed in the Arrangements Database; (ii) verifying that the Arrangement was subject to the internal review and approval process (including both a legal and business review) and obtained the necessary approvals and that such review and approval is

appropriately documented; (iii) verifying that the remuneration related to the Arrangement is properly tracked; (iv) verifying that the service and activity logs are properly completed and reviewed (if applicable); (v) verifying that leased space, medical supplies, medical devices, and equipment, and other patient care items are properly monitored (if applicable); (vi) verifying that the Compliance Officer is reviewing the Arrangements Database, internal review and approval process, and other Arrangements Procedures on a quarterly basis and reporting the results of such review to the Compliance Committee; (vii) verifying that effective responses are being implemented when violations of the Anti-Kickback Statute are discovered; and (viii) verifying that Kyphon has met the requirements of Section III.D.2.

b. *Arrangements Review Report.* The IRO shall prepare a report based upon the Arrangements Review performed (Arrangements Review Report). The Arrangements Review Report shall include the IRO's findings with respect to: (i) whether Kyphon has generally implemented the Arrangements Procedures described in Section III.D.1; and (ii) specific findings as to whether Kyphon has complied with the Arrangements Procedures and Arrangements Requirements with respect to each of the randomly selected Arrangements reviewed by the IRO. In addition, the Arrangements Review Report shall include any observations, findings, and recommendations on possible improvements to Kyphon's policies, procedures, and systems in place to ensure that all Arrangements do not violate the Anti-Kickback Statute.

4. *Validation Review.* In the event OIG has reason to believe that: (a) Kyphon's Sales and Marketing Review or Arrangements Review fails to conform to the requirements of this CIA; or (b) the IRO's findings, Sales and Marketing Review, or Arrangements Review are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Sales and Marketing Review or Arrangements Review complied with the requirements of the CIA and/or the findings or Sales and Marketing Review or Arrangements Review are inaccurate (Validation Review). Kyphon shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Kyphon's final Annual

Report shall be initiated no later than one year after Kyphon's final submission (as described in Section II.B) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Kyphon of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Kyphon may request a meeting with OIG for one or more of the following reasons: (a) to discuss the results of any Sales and Marketing Review, Arrangements Review, or both; (b) to present any additional information to clarify the results of the Sales and Marketing Review, the Arrangements Review, or both, or to correct the inaccuracy of the Sales and Marketing Review, the Arrangements Review, or both; or (c) to propose alternatives to the proposed Validation Review. Kyphon agrees to provide any additional information as may be requested by OIG under this Section III.E.4 in an expedited manner. OIG will attempt in good faith to resolve any Sales and Marketing Review or Arrangements Review issues with Kyphon prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

5. *Independence and Objectivity Certification.* Each IRO shall include in its report(s) to Kyphon a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the Sales and Marketing Review, the Arrangements Review, or both, and that it has concluded that it is, in fact, independent and objective.

F. Disclosure Program.

MSD has represented to the OIG that, prior to the Effective Date of this CIA, it established a Disclosure Program that includes a toll-free compliance telephone line to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Kyphon's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. To the extent not already accomplished, Kyphon shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas). Kyphon shall continue the Disclosure Program during the Term of the CIA as set forth in this Section III.F.

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good-faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably:

- (1) permits a determination of the appropriateness of the alleged improper practice; and
- (2) provides an opportunity for taking corrective action, Kyphon shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a confidential Kyphon disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be made available to OIG upon request.

G. Ineligible Persons.

1. *Definitions.* For purposes of this CIA:

- a. an “Ineligible Person” shall include an individual or entity who:
 - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
 - ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).

c. "Screened Persons" include all current owners (other than shareholders who: (i) have an ownership interest of less than 5%; and (ii) acquired the ownership interest through public trading), all current and prospective officers, directors, employees, contractors, and agents of Kyphon who perform functions related to the delivery, sale, or marketing of Reimbursable Items, and all officers, directors, and employees of MSD who perform functions related to the sale or marketing by Kyphon of Reimbursable Items.

2. *Screening Requirements.* Kyphon shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements.

a. Kyphon shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Screened Persons to disclose whether they are Ineligible Persons. Kyphon shall also screen all prospective owners prior to acquisition (other than shareholders who: (i) will have an ownership interest of less than 5%; and (ii) will acquire the ownership interest through public trading).

b. Kyphon shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

c. Kyphon shall implement a policy requiring all Screened Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section III.G affects the responsibility of (or liability for) Kyphon to refrain from billing Federal health care programs items or services furnished, ordered, or prescribed by an Ineligible Person. Kyphon understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Kyphon may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Kyphon meets the requirements of Section III.G.

3. *Removal Requirement.* If Kyphon has actual notice that a Screened Person has become an Ineligible Person, Kyphon shall remove such Screened Person from responsibility for, or involvement with, Kyphon's business operations related to the Federal health care programs and shall remove such Screened Person from any position for which the Screened Person's compensation or the items or services furnished, ordered, or prescribed by the Screened Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Screened Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Kyphon has actual notice that a Screened Person is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Screened Person's employment or contract term, Kyphon shall take all appropriate actions to ensure that the responsibilities of that Screened Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, Kyphon shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Kyphon's senior management, conducted or brought by a U.S., federal, state or local governmental entity or its agents involving an allegation that Kyphon has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Kyphon shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

Kyphon CIA

I. Reporting.

1. *Definition of Reportable Event.* For purposes of this CIA, a “Reportable Event” means anything that involves a matter brought to the attention of Kyphon’s senior management or Compliance Officer that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events.* If Kyphon determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Kyphon shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

- a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- b. a description of Kyphon’s actions taken to correct the Reportable Event; and
- c. any further steps Kyphon plans to take to address the Reportable Event and prevent it from recurring.

IV. CHANGES TO KYPHON

A. Change or Closure. In the event that, after the Effective Date, Kyphon sells, closes, purchases, or establishes a new business unit related to the delivery, sale, marketing, or furnishing of Reimbursable Items, Kyphon shall notify OIG of this fact in

writing as soon as possible, but no later than within 30 days after the date of the sale, closure, purchase, or establishment.

B. Sale of Kyphon. In the event that, after the Effective Date, Medtronic, MSD, or Kyphon proposes to sell Kyphon, Kyphon shall notify OIG of the proposed sale at least 30 days prior to the sale. This notification shall include a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. Kyphon shall also notify the prospective purchaser in writing of the CIA and its successor provision, and a copy of this notification shall be provided to the OIG. This CIA shall be binding on the purchaser, unless otherwise determined and agreed to in writing by the OIG.

C. Covered Items. In the event that, after the Effective Date, Kyphon sells, leases, or otherwise transfers the assets, intellectual property, and other rights (collectively "Rights") to any Covered Item to an unaffiliated third party, Kyphon shall notify OIG of the proposed sale at least 30 days prior to the transfer of the Rights related to such Covered Item; provided, however, that no such notification shall be required for sale of Covered Items in the ordinary course of business. This notification shall include a description of the Rights to a Covered Item to be transferred; a brief description of the terms of the transaction; and the name and contact information of the prospective purchaser, lessee, or transferee. Kyphon shall also notify the prospective purchaser, lessee, or transferee in writing of the CIA and its successor provision, and a copy of this notification shall be provided to the OIG. This CIA shall be binding on the purchaser, lessee, or transferee of the Covered Item, unless otherwise determined and agreed to in writing by the OIG.

D. Transfers to Affiliates. Medtronic, MSD, or Kyphon may transfer the capital stock, or substantially all of the assets of Kyphon, or Rights related to any Covered Item to Medtronic or a direct or indirect wholly-owned subsidiary of Medtronic, provided that Kyphon shall notify the OIG of such transfer within 30 days thereafter, and the CIA shall be binding on such transferee with respect to the Kyphon division, functions, and/or products.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, Kyphon shall submit a written report to OIG summarizing the status of its implementation of the

Kyphon CIA

requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

2. the names and positions of the members of the Compliance Committee required by Section III.A;

3. a copy of the Code of Conduct required by Section III.B.1;

4. a copy of all Policies and Procedures required by Section III.B.2;

5. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

6. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;

b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

7. a description of the Arrangements Database required by Section III.D.1.a;

8. a description of the internal review and approval process required by Section III.D.1.e;

9. a description of the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1;

10. a description of the Disclosure Program required by Section III.F;

11. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter(s); and (c) a summary and description of any and all current and prior engagements and agreements between the Medtronic Companies and the IRO;

12. a certification from each IRO regarding its professional independence and objectivity with respect to the Medtronic Companies;

13. a description of the process by which Kyphon fulfills the requirements of Section III.G regarding Ineligible Persons;

14. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken in response to the screening and removal obligations set forth in Section III.G; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;

15. a list of all of Kyphon's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; and the corresponding phone numbers and fax numbers;

16. a description of Kyphon's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

17. the certifications required by Section V.C.

B. Annual Reports. Kyphon shall submit to OIG annually a report with respect to the status of, and findings regarding, Kyphon's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in Section III.A;
2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy);
3. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
4. the following information regarding each type of training required by Section III.C:
 - a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;
 - b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

5. a description of any changes to the Arrangements Database required by Section III.D.1.a;
6. a description of any changes to the internal review and approval process required by Section III.D.1.e;
7. a description of any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1 and a complete copy of all reports prepared pursuant to Section III.E, along with a copy of each IRO's engagement letter;

Kyphon CIA

8. Kyphon's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.E;

9. a summary and description of any and all current and prior engagements and agreements between the Medtronic Companies and the IRO(s), if different from what was submitted as part of the Implementation Report;

10. a certification from the IRO(s) regarding its professional independence and objectivity with respect to the Medtronic Companies;

11. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

12. a summary of the disclosures in the confidential Kyphon disclosure log required by Section III.F that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;

13. any changes to the process by which Kyphon fulfills the requirements of Section III.G regarding Ineligible Persons;

14. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken by Kyphon in response to the screening and removal obligations set forth in Section III.G; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;

15. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

16. a description of all changes to the most recently provided list of Kyphon's locations (including addresses) as required by Section V.A.15; the corresponding name under which each location is doing business; and the corresponding phone numbers and fax numbers; and

Kyphon CIA

17. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Implementation Report and Annual Reports shall include

1. a certification by the Compliance Officer that:

a. to the best of his or her knowledge, except as otherwise described in the applicable report, Kyphon is in compliance with all of the requirements of this CIA; and

b. to the best of his or her knowledge, Kyphon has implemented procedures reasonably designed to ensure that all Arrangements do not violate the Anti-Kickback Statute, including the Arrangements Procedures required in Section III.D of the CIA;

c. to the best of his or her knowledge, Kyphon has fulfilled the requirements for New and Renewed Arrangements under Section III.D.2 of the CIA;

d. he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information in the Report is accurate and truthful; and

2. a certification by Kyphon's President that he or she has met the requirements of Section III.B.2 regarding the review and approval of Sales Policies and Procedures used by Kyphon.

D. Designation of Information. Kyphon shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Kyphon shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

Kyphon CIA

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

Kyphon:

Machelle Shields
Compliance Officer
Medtronic Sofamor Danek, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: 901.396.3133
Facsimile: 901.344.1576

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, Kyphon may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), either instead of or in addition to a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Kyphon's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Kyphon's locations for the purpose of verifying and evaluating: (a) Kyphon's compliance with the terms of this CIA; and (b) Kyphon's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Kyphon to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Kyphon's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Kyphon shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Kyphon's employees may elect to be interviewed with or without a representative of Kyphon present. Kyphon's employees shall have the right to be represented by counsel and any such employee may, at his or her option, be accompanied by counsel for Kyphon and/or his personal counsel at any interview by the OIG. Notwithstanding such arrangement, the OIG recognizes that individuals have the right to refuse to submit to interviews, and Kyphon shall not be obligated to require such individuals to submit to interviews. If any individual decides not to submit to an interview, such refusal shall not constitute a breach of this CIA. Kyphon shall not discourage employees from submitting to interviews requested by the OIG.

VIII. DOCUMENT AND RECORD RETENTION

Kyphon shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for six years (or longer if otherwise required by law) from the Effective Date.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Kyphon prior to any release by OIG of information submitted by Kyphon pursuant to their obligations under this CIA and identified upon

submission by Kyphon as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Kyphon shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Kyphon is expected to fully and timely comply with all of its CIA obligations. A breach of this CIA does not constitute a breach of the Settlement Agreement between Kyphon and the United States executed contemporaneously herewith. Any breach of the terms of that agreement does not constitute a breach of this CIA, except to the extent that such a breach independently also constitutes a breach of this CIA. A breach of this CIA does not constitute a breach of the CIA between the OIG of the HHS and MSD signed on July 17, 2006 except to the extent that such a breach independently also constitutes a breach of that CIA. Any breach of the terms of that CIA does not constitute a breach of this CIA, except to the extent that such a breach independently also constitutes a breach of this CIA. Section X of this CIA specifies all of the remedies available to the OIG if Kyphon fails to satisfy its obligations under this CIA.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Kyphon and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as “Stipulated Penalties”) in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Kyphon fails to establish and implement any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a written Code of Conduct;
- d. written Policies and Procedures;
- e. the training of Covered Persons;

f. the Arrangements Procedures and/or Arrangements Requirements described in Sections III.D.1 and III.D.2;

g. a Disclosure Program;

h. Ineligible Persons screening and removal requirements; and

i. notification of Government investigations or legal proceedings.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Kyphon fails to engage an IRO, as required in Section III.E and Appendix C.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Kyphon fails to submit the Implementation Report or any Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Kyphon fails to submit the annual Sales and Marketing Review Report or Arrangements Review Report in accordance with the requirements of Section III.E.

5. A Stipulated Penalty of \$1,500 for each day Kyphon fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Kyphon fails to grant access.)

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Kyphon as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of \$1,000 for each day Kyphon fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Kyphon stating the specific grounds for its determination that Kyphon has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Kyphon shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Kyphon

Kyphon CIA

receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.

B. Timely Written Requests for Extensions. Kyphon may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Kyphon fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Kyphon receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter*. Upon a finding that Kyphon has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Kyphon of: (a) Kyphon's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter"). Such Demand Letter shall specifically state the conduct that the OIG contends constitutes the basis for imposing the Stipulated Penalty.

2. *Response to Demand Letter*. Within 10 days after the receipt of the Demand Letter, Kyphon shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Kyphon elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Kyphon cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

Kyphon CIA

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Kyphon has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

- a. a failure by Kyphon to report a Reportable Event or take corrective action, as required in Section III.I;
- b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to engage and use an IRO in accordance with Section III.E.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Kyphon constitutes an independent basis for Kyphon's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Kyphon has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Kyphon of: (a) Kyphon's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* Kyphon shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

- a. Kyphon is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Kyphon has begun to take action to cure the material breach; (ii) Kyphon is pursuing such action with due diligence; and (iii) Kyphon has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Kyphon fails to satisfy the requirements of Section X.D.3, OIG may exclude Kyphon from participation in the Federal health care programs. OIG shall notify Kyphon in writing of its determination to exclude Kyphon (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Kyphon's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Kyphon may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Kyphon of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Kyphon shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions

in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Kyphon was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Kyphon shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Kyphon to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Kyphon requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

- a. whether Kyphon was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Kyphon had begun to take action to cure the material breach within that period; (ii) Kyphon has pursued and is pursuing such action with due diligence; and (iii) Kyphon provided to OIG within that period a reasonable timetable for curing the material breach and Kyphon has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Kyphon, only after a DAB decision in favor of OIG. Kyphon's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Kyphon upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Kyphon may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Kyphon shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Kyphon, Kyphon shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

Kyphon and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of Kyphon.

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA.

C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

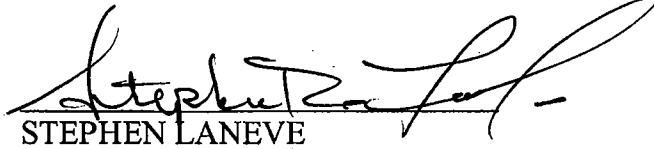
D. OIG may, at its sole discretion, agree to a suspension of Kyphon's obligations under the CIA in the event of Kyphon's cessation of participation in Federal health care programs. If Kyphon withdraws from participation in Federal health care programs and is relieved of its CIA obligations by OIG, Kyphon shall notify OIG at least 30 days in advance of Kyphon's intent to reapply as a participating provider or supplier with any

Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the CIA should be reactivated or modified.

E. The undersigned Kyphon signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

F. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF KYPHON



STEPHEN LANEVE
President
Medtronic Spine, LLC

May 12th 2008
Date



MACHELLE SHIELDS
Compliance Officer
Medtronic Spine, LLC

May 12th, 2008
Date

LAURA LAEMMLE-WEIDENFELD, ESQ.
Patton Boggs, LLP
Counsel for Kyphon

Date


ON BEHALF OF KYPHON

STEPHEN LANEVE
President
Medtronic Spine, LLC

Date

MACHELLE SHIELDS
Compliance Officer
Medtronic Spine, LLC


Date



LAURA LAEMMLE-WEIDENFELD, ESQ.
Patton Boggs, LLP
Counsel for Kyphon

5/15/08
Date

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**



GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

5/16/08

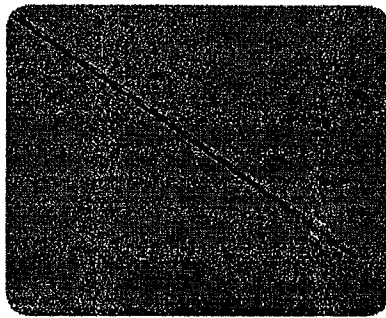
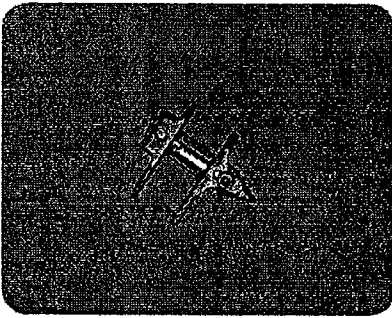
DATE



2008 PRICE LIST – US

All prices are subject to change without notice

Effective February 1, 2008



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Kyphon CIA

**Medtronic and
Kyphon Together**

Every five seconds
we help improve another life.



2008 Price List – US

Effective February 1, 2008

Balloon Kyphoplasty

A La Carte Products	Catalog No.	Unit Price
Kyphon® 11 Gauge Bone Access Needle	A02A	\$35
Kyphon® 11 Gauge Bone Access Needle, Trocar	A02B	\$35
Kyphon® 11 Gauge Bone Access Needle, Bevel	A02C	\$35
Kyphon® Mixer	A07A	\$140
KyphX Xpander® Inflation Syringe	A08A	\$130
KyphX® Advanced Osteo Introducer® Device	A10A	\$420
KyphX® Latitude II® Curette, 8.0 mm T-tip	A11B	\$220
KyphX® Latitude II® Curette, 8.0 mm T-tip (5-Pack)	A11B-05	\$950
KyphX® Latitude II® Curette, 6.5 mm Wedge tip	A11D	\$220
KyphX® Latitude II® Curette, 6.5 mm Wedge tip (5-pack)	A11D-05	\$950
KyphX® Latitude II® Curette, 8.5 mm Wedge tip	A11E	\$220
KyphX® Latitude II® Curette, 8.5 mm Wedge tip (5-pack)	A11E-05	\$950
KyphX® HV-R® Bone Cement	C01A	\$130
KyphX® HV-R® Bone Cement and Kyphon® Mixer Pack [†]	C01B	\$210
KyphX® Bone Filler Device	F04B	\$125
KyphX® Directional Bone Filler Device	F04C	\$125
KyphX® Bone Biopsy Device	F05A	\$150
KyphX® Bone Biopsy Device (10-Pack)	F05A-10	\$1,275
KyphX® Bone Biopsy Kit	F08A	\$1,415
KyphX Xpander® Inflatable Bone Tamp, 20/3	K08A	\$1,295
KyphX Xpander® Inflatable Bone Tamp, 15/3	K09A	\$1,295
KyphX Xpander® Inflatable Bone Tamp, 10/3	K13A	\$1,295
KyphX® Elevate® Inflatable Bone Tamp, 15/3	K16A	\$1,295
KyphX® Elevate® Inflatable Bone Tamp, 20/3	K16B	\$1,295
KyphX® Exact® Inflatable Bone Tamp, 10/3	K17A	\$1,295
KyphX® Exact® Inflatable Bone Tamp, 15/3	K17B	\$1,295
KyphX® Introducer Tool Kit	T01A	\$1,200
KyphX® Osteo Introducer® System	T05D	\$1,200
KyphX® Advanced Osteo Introducer® System	T05E	\$1,200
KyphX® One-Step® Osteo Introducer® System, Trocar and Diamond	T05J	\$1,200
KyphX® One-Step® Osteo Introducer® Device, Bevel	T05K	\$420

[†] Contains one of A07A and one of C01A

A La Carte Products	Catalog No.	Unit Price
KyphX® Express® Bone Filler Device	F06A	\$125
KyphX® Express® Directional Bone Filler Device	F06B	\$125
KyphX® Express® Bone Biopsy Device	F07A	\$140
KyphX® Express® Inflatable Bone Tamp, 10/2	K15A	\$1,295
KyphX® Express® Inflatable Bone Tamp, 15/2	K15B	\$1,295
KyphX® Express® Osteo Introducer® System, Bevel and Diamond	T24A	\$1,200
KyphX® Express® Osteo Introducer® Device, Trocar	T24B	\$420
KyphX® Express® Advanced Osteo Introducer® Device	T24C	\$420

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Kyphon CIA



Medtronic and Kyphon Together

2008 Price List – US

Effective February 1, 2008

Balloon Kyphoplasty

KyphoPak® Tray Products	Catalog No.	Unit Price
KyphoPak® Tray, Xpander 10/3, First Fracture with KyphX® Introducer Tool Kit	KPT1001	\$3,925
KyphoPak® Tray, Xpander 10/3, First Fracture with KyphX® Osteo Introducer® System	KPT1002	\$3,925
KyphoPak® Tray, Xpander 10/3, First Fracture with KyphX® Advanced Osteo Introducer® System	KPT1003	\$3,925
KyphoPak® Tray, Xpander 10/3, Additional Fracture	KPT1004	\$2,595
KyphoPak® Tray, Xpander 10/3, First Fracture with KyphX® One-Step™ Osteo Introducer® System	KPT1005	\$3,925
KyphoPak® Tray, Xpander 15/3, First Fracture with KyphX® Introducer Tool Kit	KPT1501	\$3,925
KyphoPak® Tray, Xpander 15/3, First Fracture with KyphX® Osteo Introducer® System	KPT1502	\$3,925
KyphoPak® Tray, Xpander 15/3, First Fracture with KyphX® Advanced Osteo Introducer® System	KPT1503	\$3,925
KyphoPak® Tray, Xpander 15/3, Additional Fracture	KPT1504	\$2,595
KyphoPak® Tray, Xpander 15/3, First Fracture with KyphX® One-Step™ Osteo Introducer® System	KPT1505	\$3,925
KyphoPak® Tray, Xpander 20/3, First Fracture with KyphX® Introducer Tool Kit	KPT2001	\$3,925
KyphoPak® Tray, Xpander 20/3, First Fracture with KyphX® Osteo Introducer® System	KPT2002	\$3,925
KyphoPak® Tray, Xpander 20/3, First Fracture with KyphX® Advanced Osteo Introducer® System	KPT2003	\$3,925
KyphoPak® Tray, Xpander 20/3, Additional Fracture	KPT2004	\$2,595
KyphoPak® Tray, Xpander 20/3, First Fracture with KyphX® One-Step™ Osteo Introducer® System	KPT2005	\$3,925

KyphoPak® Express Tray Products	Catalog No.	Unit Price
KyphoPak® Express Tray 10/2, First Fracture with KyphX® Express™ Osteo Introducer® System	KPE1001	\$3,925
KyphoPak® Express Tray 10/2, Additional Fracture	KPE1002	\$2,595
KyphoPak® Express Tray 15/2, First Fracture with KyphX® Express™ Osteo Introducer® System	KPE1003	\$3,925
KyphoPak® Express Tray 15/2, Additional Fracture	KPE1004	\$2,595

F.A.D.™— Functional Anaesthetic Discography™

Discyphor™ Products	Catalog No.	Unit Price
Discyphor™ Catheter System	DOIE	\$595
Discyphor™ Needle Kit	DOIG	\$40

2008 Price List – US

Effective February 1, 2008

IPD® — Interspinous Process Decompression

X-STOP® IPD® Implants	Catalog No.	Direct Order	RPO
6 mm X-STOP® Implant – Titanium (Sterile)	1-2206	\$3,950	\$4,625
8 mm X-STOP® Implant – Titanium (Sterile)	1-2208	\$3,950	\$4,625
10 mm X-STOP® Implant – Titanium (Sterile)	1-2210	\$3,950	\$4,625
12 mm X-STOP® Implant – Titanium (Sterile)	1-2212	\$3,950	\$4,625
14 mm X-STOP® Implant – Titanium (Sterile)	1-2214	\$3,950	\$4,625

* Request for Purchase Order (RPO) available through sales rep.

X-STOP® IPD® Instruments	Catalog No.	Unit Price
Mainbody Insertion Instrument	2-2001	\$780
Universal Wing Insertion Instrument	2-2002	\$810
Torque Limiting Hex Driver	2-2003	\$900
Small Curved Dilator	2-2004	\$305
Large Curved Dilator	2-2005	\$310
Distracting Sizing Instrument	2-2016	\$2,355
Instrument Sterilization Tray	3-3001	\$760
X-STOP® IPD® Instrument Set	4-2000	\$6,145

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APPENDIX B

ARRANGEMENTS DATABASE

Kyphon shall create and maintain an Arrangements Database to track all new and existing Arrangements, including Contractual Arrangements and Non-Contractual Arrangements, in order to ensure that each Arrangement does not violate the Anti-Kickback Statute.

A. The Arrangements Database shall contain certain information to assist Kyphon in evaluating whether each Contractual Arrangement violates the Anti-Kickback Statute, including but not limited to the following:

1. Each party involved in the Arrangement;
2. The type of Arrangement (e.g., physician-employment contract, medical directorship, lease agreement);
3. The terms of the Arrangement, including the effective and expiration dates and any automatic renewal provisions;
4. The amount of compensation to be paid pursuant to the Arrangement and the means by which compensation is paid;
5. The methodology for determining the compensation under the Arrangements, including the methodology used to determine the fair-market value of such compensation;
6. Whether the amount of compensation to be paid pursuant to the Arrangement is determined based on the volume or value of referrals between the parties;
7. Whether each party has fulfilled the requirements of Section III.D.2; and
8. Whether the Arrangement satisfies the requirements of an Anti-Kickback Statute safe harbor.

B. The Arrangements Database shall contain certain information to assist Kyphon in evaluating whether each Non-Contractual Arrangement violates the Anti-Kickback Statute, including but not limited to the following:

1. The name of the entity or individual receiving the Non-Contractual remuneration;
2. The type of Non-Contractual remuneration (listing in the aggregate multiple distributions of the same type of Non-Contractual remuneration to each entity or individual);

3. The aggregate value of each type of Non-Contractual remuneration given to each entity or individual during the Reporting Period;
4. Whether the Non-Contractual remuneration given pursuant to the Non-Contractual Arrangement is determined based on the volume or value of referrals between the parties; and
5. Whether the Non-Contractual Arrangement satisfies the requirements of an Anti-Kickback Statute safe harbor.

APPENDIX C

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.E of the CIA.

A. IRO Engagement.

Kyphon shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally-independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Kyphon if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Kyphon may continue to engage the IRO.

If Kyphon engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Kyphon shall submit the information identified in Section V.A.11 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Kyphon if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Kyphon may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. (a) if conducting the Sales and Marketing Review, assign individuals to conduct the Sales and Marketing Review engagement who are knowledgeable in the Federal health care program requirements for billing medical devices and other health care items and in sales and marketing processes and procedures compliant with those Federal health care program requirement; and

(b) if conducting the Arrangements review, assign individuals to conduct the Arrangements Review engagement who are knowledgeable in the requirements of the Anti-Kickback Statute; and

2. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each review in accordance with the specific requirements of the CIA;
2. respond to all OIG inquiries in a prompt, objective, and factual manner; and
3. prepare timely, clear, well-written reports that include all the information required by Section III.E of the CIA.

D. IRO Independence and Objectivity.

The IRO must perform the review(s) in a professionally-independent and objective fashion, taking into account any other business relationships or engagements that may exist between the IRO and Kyphon.

E. IRO Removal/Termination.

1. *Provider.* If Kyphon terminates its IRO(s) during the course of the engagement, Kyphon must submit a notice explaining its reasons to OIG no later than 30 days after termination. Kyphon must engage a new IRO in accordance with Paragraph A of this Appendix.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Kyphon to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring Kyphon to engage a new IRO, OIG shall notify Kyphon of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Kyphon may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence, or performance of its responsibilities and to present additional information regarding these matters. Kyphon shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Kyphon prior to requiring Kyphon to terminate the IRO. However, the final determination as to whether or not to require Kyphon to engage a new IRO shall be made at the sole discretion of OIG.