# IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF TEXAS SHERMAN DIVISION

UNITED STATES OF AMERICA

NO.

ORTHOFIX INTERNATIONAL, N.V.,

v.

Defendant.

**DEFERRED PROSECUTION AGREEMENT** 

Defendant Orthofix International, N.V. ("Orthofix"), by its undersigned attorneys, pursuant to authority granted by Orthofix's Board of Directors, and the United States Department of Justice, Criminal Division, Fraud Section (the "Department"), enter into this deferred prosecution agreement (the "Agreement"). The terms and conditions of this Agreement are as follows:

## Criminal Information and Acceptance of Responsibility

1. Orthofix acknowledges and agrees that the Department will file a one-count criminal Information in the United States District Court for the Eastern District of Texas charging Orthofix with one count of violating the internal controls provisions of the Foreign Corrupt Practices Act ("FCPA"), Title 15, United States Code, Section 78m(b)(2). In so doing, Orthofix: (a) knowingly waives its right to indictment on this charge, as well as all rights to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, Title 18, United States Code, Section 3161, and Federal Rule of Criminal Procedure 48(b); and (b) knowingly waives any objection with respect to venue and consents to the filing of the Information, as

provided under the terms of this Agreement, in the United States District Court for the Eastern District of Texas.

2. Orthofix admits, accepts, and acknowledges that it is responsible for the acts of its officers, directors, employees, agents, and those of Orthofix's subsidiaries as charged in the Information, and as set forth in the Statement of Facts attached hereto as Attachment A and incorporated by reference into this Agreement, and that the allegations described in the Information and the facts described in Attachment A are true and accurate. Should the Department pursue the prosecution that is deferred by this Agreement, Orthofix agrees that it will neither contest the admissibility of nor contradict the Statement of Facts in any such proceeding, including any guilty plea or sentencing proceeding.

## Term of the Agreement

3. This Agreement is effective for a period beginning on the date on which the Information is filed and ending three (3) years and seven (7) calendar days from that date (the "Term"). However, Orthofix agrees that, in the event that the Department determines, in its sole discretion, that Orthofix has knowingly violated any provision of this Agreement, an extension or extensions of the term of the Agreement may be imposed by the Department, in its sole discretion, for up to a total additional time period of one (1) year, without prejudice to the Department's right to proceed as provided in Paragraphs 13-16 below. Any extension of the Agreement extends all terms of this Agreement, including the terms of the reporting obligations under Paragraph 10 and Attachment D, for an equivalent period. Conversely, in the event the Department finds, in its sole discretion, that there exists a change in circumstances sufficient to eliminate the need for the reporting obligations described in Paragraph 10 and Attachment D,

and that the other provisions of this Agreement have been satisfied, the Term of the Agreement may be terminated early.

## **Relevant Considerations**

- 4. The Department enters into this Agreement based on the individual facts and circumstances presented by this case and Orthofix. Among the facts considered were the following: (a) following reports of bribery by employees of its wholly owned subsidiary, Promeca S.A. de C.V., Orthofix made a timely and voluntary disclosure to the Department and the United States Securities and Exchange Commission ("SEC") about potential misconduct; (b) Orthofix conducted an investigation concerning bribery and related misconduct; (c) Orthofix reported its findings to the Department and the SEC; (d) the extent of the conduct; (e) Orthofix undertook remedial measures, including the implementation of an enhanced compliance program, and agreed to undertake further remedial measures, as may be necessary under this Agreement; and (f) Orthofix agreed to continue to cooperate with the Department in any ongoing investigation of the conduct of Orthofix's current and former employees, agents, consultants, contractors, subcontractors, and subsidiaries relating to violations of the FCPA.
- 5. Orthofix shall continue to cooperate fully with the Department in any and all matters relating to corrupt payments and related false books and records and inadequate internal controls, subject to applicable law and regulations. At the Department's request, and consistent with applicable law and regulations, Orthofix shall also cooperate fully with other domestic or foreign law enforcement authorities and agencies, as well as the Multilateral Development Banks ("MDBs"), in any investigation of Orthofix, or any of its present and former officers, directors, employees, agents, consultants, contractors, subcontractors, and subsidiaries, or any other party, in any and all matters relating to corrupt payments, related false books and records, and

inadequate internal controls, and in such manner as the parties may agree. Orthofix agrees that its cooperation shall include, but is not limited to, the following:

- a. Orthofix shall truthfully disclose all factual information not protected by a valid claim of attorney-client privilege or work-product doctrine with respect to its activities and those of its present and former directors, officers, employees, agents, consultants, contractors and subcontractors, and subsidiaries concerning all matters relating to corrupt payments and related false books and records and inadequate internal controls, about which Orthofix has any knowledge or about which the Department may inquire. This obligation of truthful disclosure includes the obligation of Orthofix to provide to the Department, upon request, any document, record or other tangible evidence relating to such corrupt payments, false books and records, or inadequate internal controls about which the Department may inquire of Orthofix.
- b. Upon request of the Department, with respect to any issue relevant to the Department's investigation of corrupt payments in connection with the operations and related books and records of Orthofix and certain of its subsidiaries, Orthofix shall designate knowledgeable employees, agents or attorneys to provide to the Department on Orthofix's behalf the information and materials described in Paragraph 5(a) above. It is further understood that Orthofix must at all times provide complete, truthful, and accurate information.
- c. With respect to any issue relevant to the Department's investigation of corrupt payments, related false books and records, and inadequate internal controls in connection with Orthofix's operations, or those of any of Orthofix's present or former subsidiaries or affiliates, Orthofix shall use its best efforts to make available for interviews or testimony, as requested by the Department, present or former officers, directors, employees, agents and consultants of Orthofix as well as the officers, directors, employees, agents and consultants of contractors and subcontractors. This obligation includes, but is not limited to, sworn testimony

before a federal grand jury or in federal trials, as well as interviews with federal law enforcement and regulatory authorities. Cooperation under this paragraph shall include identification of witnesses who, to Orthofix's knowledge, may have material information regarding the matters under investigation.

d. With respect to any information, testimony, documents, records or other tangible evidence provided to the Department pursuant to this Agreement, Orthofix consents to any and all disclosures, subject to applicable law and regulations, to other governmental authorities, including United States authorities and those of a foreign government, and the MDBs, of such materials as the Department, in its sole discretion, shall deem appropriate.

# **Payment of Monetary Penalty**

- 6. The Department and Orthofix agree that application of the 2011 United States Sentencing Guidelines ("USSG" or "Sentencing Guidelines") to determine the applicable fine range yields the following analysis:
  - <u>Base Offense</u>. Based upon USSG § 2B1.1, the total offense level is 26, calculated as follows:
    - (a)(2) Base Offense Level 6

      (b)(1)(J) Benefit received more than \$2.5 million, but less than \$7 million +18

      (b)(10)(B) Sophisticated Means/Substantial Conduct Outside the U.S. +2

TOTAL 26

- Base Fine. Based upon USSG § 8C2.4(a)(1),(d), the base fine is \$3,700,000.
- <u>Culpability Score</u>. Based upon USSG § 8C2.5, the culpability score is 3, calculated as follows:
  - (a) Base Culpability Score

5

(b)(3)(B) the unit of the organization had more than 200 employees and an individual within high-level personnel condoned or was willfully ignorant of the offense

+3

(g)(1) The organization, prior to an imminent threat of disclosure or government investigation, and within a reasonably prompt time after becoming aware of the offense, reported the offense, fully cooperated, and clearly demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct

- 5

TOTAL

3

# • <u>Calculation of Fine Range</u>:

Base Fine

\$3,700,000

Multipliers

 $0.6 \, (\text{min})/1.2 \, (\text{max})$ 

Fine Range

\$2.22M / \$4.44M

Orthofix agrees to pay a monetary penalty in the amount of \$2,220,000 to the United States

Treasury within ten (10) days of the filing of the information. Orthofix and the Department agree that this fine is appropriate given the nature and extent of Orthofix's cooperation in this matter and the remediation undertaken by Orthofix. The \$2,220,000 penalty is final and shall not be refunded. Furthermore, nothing in this Agreement shall be deemed an agreement by the Department that \$2,220,000 is the maximum penalty that may be imposed in any future

prosecution, and the Department is not precluded from arguing in any future prosecution that the Court should impose a higher fine, although the Department agrees that under those circumstances, it will recommend to the Court that any amount paid under this Agreement should be offset against any fine the Court imposes as part of a future judgment. Orthofix acknowledges that no tax deduction may be sought in connection with the payment of any part of this \$2,200,000 penalty.

# **Conditional Release from Liability**

- 7. In return for Orthofix's full and truthful cooperation, and Orthofix's compliance with the other terms and conditions of this Agreement, the Department agrees, subject to Paragraph 13-16 below, not to use any information related to the conduct described in the attached Statement of Facts against Orthofix or any of its direct or indirect affiliates or subsidiaries in any criminal or civil case, except: (a) in a prosecution for perjury or obstruction of justice; (b) in a prosecution for making a false statement; (c) in a prosecution or other proceeding relating to any crime of violence; or (d) in a prosecution or other proceeding relating to a violation of any provision of Title 26 of the United States Code. In addition, the Department agrees, except as provided herein, that it will not bring any criminal case against Orthofix or any of its direct or indirect affiliates or subsidiaries related to the conduct of present and former officers, directors, employees, agents, and consultants, as described in the attached Statement of Facts, or relating to information Orthofix disclosed to the Department prior to the date on which this Agreement was signed.
- a. This Paragraph does not provide any protection against prosecution for any future corrupt payments, false books and records, or inadequate internal controls, if any, by Orthofix.

b. In addition, this Paragraph does not provide any protection against prosecution of any present or former officer, director, employee, shareholder, agent, consultant, contractor, or subcontractor of Orthofix for any violations committed by them.

## Corporate Compliance Program

- 8. Orthofix represents that it has implemented and will continue to implement a compliance and ethics program designed to prevent and detect violations of the FCPA and other applicable anti-corruption laws throughout its operations, including those of its affiliates, agents, and joint ventures, and those of its contractors and subcontractors whose responsibilities include interacting with foreign officials or other high-risk activities. Implementation of these policies and procedures shall not be construed in any future enforcement proceeding as providing immunity or amnesty for any crimes not disclosed to the Department as of the date of signing of this Agreement for which Orthofix would otherwise be responsible.
- 9. In order to address any deficiencies in its internal controls, policies, and procedures, Orthofix represents that it has undertaken, and will continue to undertake in the future, in a manner consistent with all of its obligations under this Agreement, a review of its existing internal controls, policies, and procedures regarding compliance with the FCPA and other applicable anti-corruption laws. Where necessary and appropriate, Orthofix will adopt new or modify existing internal controls, policies, and procedures in order to ensure that Orthofix maintains: (a) a system of internal accounting controls designed to ensure the making and keeping of fair and accurate books, records, and accounts; and (b) a rigorous anti-corruption compliance code, standards, and procedures designed to detect and deter violations of the FCPA and other applicable anti-corruption laws. The internal-controls system and compliance code,

standards, and procedures will include, but not be limited to, the minimum elements set forth in Attachment C, which is incorporated by reference into this Agreement.

# **Corporate Compliance Reporting**

10. Orthofix agrees that it will report to the Department annually during the term of the Agreement regarding remediation and implementation of the compliance measures described in Attachment C. These reports will be prepared by Orthofix's Chief Compliance Officer in accordance with Attachment D.

# **Deferred Prosecution**

- 11. In consideration of: (a) Orthofix's past and future cooperation, described in Paragraphs 4 and 5 above; (b) Orthofix's payment of a criminal penalty of \$2,220,000; and (c) Orthofix's implementation and maintenance of remedial measures, and independent review and audit of such measures, including Orthofix's compliance policies and periodic reporting as described in Paragraph 10 above, the Department agrees that any prosecution of Orthofix for the conduct set forth in the attached Statement of Facts, and for the conduct that Orthofix disclosed to the Department prior to the signing of this Agreement, be and hereby is deferred for the Term of this Agreement.
- 12. The Department further agrees that, if Orthofix fully complies with all of its obligations under this Agreement, the Department will not continue the criminal prosecution against Orthofix described in Paragraph 1 and, at the conclusion of the Term, this Agreement shall expire. Within thirty (30) days of the Agreement's expiration, the Department shall seek dismissal with prejudice of the criminal Information filed against Orthofix described in Paragraph 1.

## **Breach of the Agreement**

- discretion, that Orthofix has (a) committed any felony under U.S. federal law subsequent to the signing of this Agreement, (b) at any time provided deliberately false, incomplete, or misleading information, or (c) otherwise breached the Agreement, Orthofix shall thereafter be subject to prosecution for any federal criminal violation of which the Department has knowledge, including the charges in the Information described in Paragraph 1, which may be pursued by the Department in the U.S. District Court for the Eastern District of Texas, or any other appropriate venue. Any such prosecution may be premised on information provided by Orthofix. Any such prosecution that is not time-barred by the applicable statute of limitations on the date of the signing of this Agreement may be commenced against Orthofix notwithstanding the expiration of the statute of limitations between the signing of this Agreement and the expiration of the Term plus one year. Thus, by signing this Agreement, Orthofix agrees that the statute of limitations with respect to any prosecution that is not time-barred on the date of the signing of this Agreement shall be tolled for the Term plus one year.
- 14. In the event that the Department determines that Orthofix has breached this Agreement, the Department agrees to provide Orthofix with written notice of such breach before instituting any prosecution resulting from such breach. Orthofix shall, within thirty (30) days of receipt of such notice, have the opportunity to respond to the Department in writing to explain the nature and circumstances of such breach, as well as the actions Orthofix has taken to address and remediate the situation, which explanation the Department shall consider in determining whether to institute a prosecution.
- 15. In the event that the Department determines that Orthofix has breached this Agreement: (a) all statements made by or on behalf of Orthofix to the Department or to the

Court, including the attached Statement of Facts, and any testimony given by Orthofix before a grand jury, a court, or any tribunal, or at any legislative hearings, whether prior or subsequent to this Agreement, and any leads derived from such statements or testimony, shall be admissible in evidence in any and all criminal proceedings brought by the Department against Orthofix; and (b) Orthofix shall not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other federal rule, that statements made by or on behalf of Orthofix prior or subsequent to this Agreement, or any leads derived therefrom, should be suppressed. The decision whether conduct or statements of any current director or employee, or any person acting on behalf of, or at the direction of, Orthofix, will be imputed to Orthofix for the purpose of determining whether Orthofix has violated any provision of this Agreement shall be in the sole discretion of the Department. 16.

Orthofix acknowledges that the Department has made no representations, assurances, or promises concerning what sentence may be imposed by the Court if Orthofix breaches this Agreement and this matter proceeds to judgment. Orthofix further acknowledges that any such sentence is solely within the discretion of the Court and that nothing in this Agreement binds or restricts the Court in the exercise of such discretion.

# Sale or Merger of the Company

Orthofix agrees that in the event it sells, merges, or transfers all or substantially 17. all of its business operations as they exist as of the date of this Agreement, whether such sale is structured as a stock or asset sale, merger or transfer, it shall include in any contract for sale, merger, or transfer a provision binding the purchaser, or any successor in interest thereto, to the obligations described in this Agreement.

# Public Statements by the Company

- 18. Orthofix expressly agrees that it shall not, through present or future attorneys, officers, directors, employees, agents or any other person authorized to speak for Orthofix make any public statement, in litigation or otherwise, contradicting the acceptance of responsibility by Orthofix set forth above or the facts described in the attached Statement of Facts. Any such contradictory statement shall, subject to cure rights of Orthofix described below, constitute a breach of this Agreement, and Orthofix thereafter shall be subject to prosecution as set forth in Paragraphs 13-16 of this Agreement. The decision whether any public statement by any such person contradicting a fact contained in the Statement of Facts will be imputed to Orthofix for the purpose of determining whether Orthofix has breached this Agreement shall be at the sole discretion of the Department. If the Department determines that a public statement by any such person contradicts in whole or in part a statement contained in the Statement of Facts, the Department shall so notify Orthofix, and Orthofix may avoid a breach of this Agreement by publicly repudiating such statement(s) within five (5) business days after notification. Orthofix shall be permitted in other proceedings to raise defenses and to assert affirmative claims, provided that such defenses and claims do not contradict in whole or in part a statement contained in the Statement of Facts or criminal information filed in this case. This paragraph does not apply to any statement made by any present or former Orthofix employee in the course of any criminal, regulatory, or civil case initiated against such individual, unless such individual is speaking on Orthofix's behalf.
- 19. Orthofix agrees that if it or any of its direct or indirect affiliates or subsidiaries issues a press release or holds any press conference in connection with this Agreement, Orthofix shall first consult the Department to determine (a) whether the text of the release or proposed

statements at the press conference are true and accurate with respect to matters between the Department and Orthofix; and (b) whether the Department objects to the release.

20. The Department, if requested to do so, agrees to bring to the attention of governmental and other debarment authorities the facts and circumstances relating to the nature of the conduct underlying this Agreement, including the nature and quality of Orthofix's cooperation and remediation. By agreeing to provide this information to debarment authorities, the Department is not agreeing to advocate on Orthofix's behalf, but rather is agreeing to provide facts to be evaluated independently by the debarment authorities.

# Limitations on Binding Effect of Agreement

21. This Agreement is binding on Orthofix and the Department but specifically does not bind any other federal agencies, or any state, local or foreign law enforcement or regulatory agencies, or any other authorities, although the Department will bring Orthofix's cooperation and compliance with its other obligations under this Agreement to the attention of such agencies and authorities if requested to do so by Orthofix.

### Notice

22. Any notice to the Department under this Agreement shall be given by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail, addressed to the Deputy Chief – FCPA Unit, Fraud Section, Criminal Division, U.S. Department of Justice, Fourth Floor, 1400 New York Avenue, N.W., Washington, D.C. 20005. Any notice to Orthofix under this Agreement shall be given by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail, addressed to Jeffrey M. Schumm, General Counsel, Orthofix International N.V., 3451 Plano Parkway, Lewisville, TX 75056, and Peter Spivack, Hogan Lovells US LLP, Columbia Square, 555 13th Street, NW,

Washington, DC 20004, or their successors. Notice shall be effective upon actual receipt by the Department or Orthofix.

# Complete Agreement

23. This Agreement sets forth all the terms of the agreement between Orthofix and the Department. No amendments, modifications or additions to this Agreement shall be valid unless they are in writing and signed by the Department and Orthofix.

# **AGREED:**

# FOR ORTHOFIX INTERNATIONAL, N.V.:

Date: July 5, 2012  Date: July 5, 2012	By:  ROBERT S. VATERS  President and Chief Executive Officer  By:  JHFFREY M. SCHUMM  Senior Vice President, General  Counsel, and Corporate Secretary
Date:	By: PETER SPIVACK Hogan Lovells US LLP

Washington, DC 20004, or their successors. Notice shall be effective upon actual receipt by the Department or Orthofix.

# Complete Agreement

23. This Agreement sets forth all the terms of the agreement between Orthofix and the Department. No amendments, modifications or additions to this Agreement shall be valid unless they are in writing and signed by the Department and Orthofix.

# AGREED:

# FOR ORTHOFIX INTERNATIONAL, N.V.:

Date:	By:
Date.	ROBERT S. VATERS
	President and Chief Executive Officer
Date:	By:
	JEFFREY M. SCHUMM
	Senior Vice President, General
	Counsel, and Corporate Secretary
Date: 7.5.12	By: Our
Date.	PETER SPIVACK
	Hogen Lovellouk LLD

# FOR THE DEPARTMENT OF JUSTICE:

DENIS J. McINERNEY

Chief, Fraud Section

Date: 10, 2012

By:

STEPHEN J. SPIEGELHALTER

Trial Attorney, Fraud Section

United States Department of Justice

Criminal Division

1400 New York Ave., N.W.

Washington, D.C. 20005

Phone: (202) 514-2000

Fax: (202) 514-7021

Email: stephen.spiegelhalter@usdoj.gov

#### CERTIFICATE OF GENERAL COUNSEL

I have read this Agreement and carefully reviewed every part of it with outside counsel for Orthofix International, N.V. ("Orthofix"). I understand the terms of this Agreement and, based on authorization and instructions of the Board of Directors, voluntarily agree on behalf of Orthofix to each of its terms. Before signing this Agreement, I consulted outside counsel for Orthofix. Counsel fully advised me of Orthofix's rights, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this Agreement.

I have carefully reviewed the terms of this Agreement with the Board of Directors of Orthofix. I have advised and caused outside counsel for Orthofix to advise the Board of Directors fully of the rights of Orthofix, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into the Agreement.

No promises or inducements have been made other than those contained in this

Agreement. Furthermore, no one has threatened or forced me, or to my knowledge any person
authorizing this Agreement on Orthofix's behalf, in any way to enter into this Agreement. I am
also satisfied with outside counsel's representation in this matter. I certify that I am Senior Vice
President, General Counsel, and Corporate Secretary of Orthofix and that I have been duly
authorized and instructed by the Board of Directors of Orthofix to execute this Agreement on
Orthofix's behalf.

Date: <u>JULY 5</u>, 2012

ORTHOFIX INTERNATIONAL, N.V.

effey M. Schumm

Senior Wice President, General Counsel, and

drporate Secretary

#### CERTIFICATE OF COUNSEL

I am counsel for Orthofix International, N.V. ("Orthofix") in the matter covered by this Agreement. In connection with such representation, I have examined relevant Orthofix documents and have discussed the terms of this Agreement with the Orthofix Board of Directors. Based on our review of the foregoing materials and discussions, I am of the opinion that the representative of Orthofix has been duly authorized to enter into this Agreement on Orthofix's behalf and that this Agreement has been duly and validly authorized, executed, and delivered on Orthofix's behalf and validly binds and obligates Orthofix. Further, I have carefully reviewed the terms of this Agreement with Orthofix's Board of Directors and General Counsel. I have fully advised them of Orthofix's rights, of possible defenses, of the Sentencing Guidelines' provisions and of the consequences of entering into this Agreement. To my knowledge, Orthofix's decision to enter into this Agreement, based on the authorization of the Board of Directors, is an informed and voluntary one.

Date: <u>Joly 5</u>, 2012

PETER SPIVACK

Hogan Lovells US LLP for Orthofix International N.V.

#### ATTACHMENT A

## **STATEMENT OF FACTS**

The following Statement of Facts is incorporated by reference as part of the Deferred Prosecution Agreement (the "Agreement") between the United States Department of Justice, Criminal Division, Fraud Section (the "Department") and ORTHOFIX INTERNATIONAL, N.V. ("ORTHOFIX"), and ORTHOFIX hereby agrees and stipulates that the following information is true and accurate. ORTHOFIX admits, accepts, and acknowledges that it is responsible for the acts of its officers, directors, employees, agents, and those of ORTHOFIX's subsidiaries as set forth below. Should the Department pursue the prosecution that is deferred by this Agreement, ORTHOFIX agrees that it will neither contest the admissibility of, nor contradict, this Statement of Facts in any such proceeding. If this matter were to proceed to trial, the Department would prove beyond a reasonable doubt, by admissible evidence, the facts alleged below and set forth in the criminal Information attached to this Agreement. This evidence would establish the following:

### Introduction

# The Defendant and Defendant's Subsidiaries

1. Defendant **Orthofix International**, **N.V.** ("**Orthofix N.V.**"), was a multinational corporation principally involved in the design, development, manufacture, marketing and distribution of medical devices, and was incorporated in Curação. **Orthofix N.V.** sold and distributed its products around the world from facilities in the United States, the United Kingdom, Italy, Mexico, and elsewhere. **Orthofix N.V.** employed over 1,500 people and currently maintained its corporate administrative offices in Lewisville, Texas.

- 2. **Orthofix N.V.** had a class of securities registered pursuant to Section 12 of the Securities and Exchange Act of 1934 (15 U.S.C. § 78) and was required to file reports with the United States Securities and Exchange Commission under Section 15(d) of the Exchange Act, 15 U.S.C. § 780(d). **Orthofix N.V.** was publicly traded on the NASDAQ stock exchange under the ticker symbol "OFIX." **Orthofix N.V.** was an "issuer" within the meaning of the FCPA.
- 3. Orthofix Inc. was incorporated in Minnesota and was an indirectly wholly owned subsidiary of **Orthofix N.V.** Orthofix Inc. was responsible for overseeing **Orthofix N.V.**'s business operations in Latin America, including Mexico, and for fulfilling **Orthofix N.V.**'s administrative and managerial functions in connection with **Orthofix N.V.**'s operations around the world. Over 400 **Orthofix N.V.** employees were employed at Orthofix Inc.
- 4. **Orthofix N.V.**'s products included medical devices that physicians surgically implanted in patients, including fixators and bone nails that physicians used to stabilize bones in patients that had suffered serious trauma. **Orthofix N.V.**'s medical devices were sufficiently complex that personnel from **Orthofix N.V.** or one of its subsidiaries typically worked with surgeons during surgery to ensure that **Orthofix N.V.**'s products were used correctly.
- 5. Promeca S.A. de C.V. ("Promeca") was incorporated in Mexico and headquartered in Mexico City. Promeca was an indirectly wholly owned subsidiary of **Orthofix N.V.** that distributed **Orthofix N.V.**'s medical nails and fixators in Mexico. Promeca employed more than 50 employees, and its financial results were consolidated with **Orthofix N.V.**'s corporate financial statements, books, and records. **Orthofix N.V.** was responsible for ensuring Promeca's continued solvency, and **Orthofix N.V.** periodically infused Promeca with additional capital. **Orthofix N.V.** and Orthofix Inc. personnel based in the United States oversaw

hire and fire Promeca's officers.

## Defendant's Employees and Agents

- 6. "Orthofix Executive A," a citizen of Peru and legal permanent resident in the United States, was a senior manager of Orthofix Inc. who worked in the Eastern District of Texas, and elsewhere, and was responsible for **Orthofix N.V.**'s sales operations in Latin America from in or around 1991 until in or around 2008. Orthofix Executive A was a consultant to **Orthofix N.V.**, through its Italian subsidiary, Orthofix SRL, from in or around 1991 until in or around March 2004. Beginning in or around March 2004 and continuing until in or around October 2006, Orthofix Executive A served as Orthofix Inc.'s Vice President of Sales, Latin America. Orthofix Executive A then worked as a consultant to Orthofix Inc. until in or around 2008. Irrespective of Orthofix Executive A's title, Orthofix Executive A reported to other executives of **Orthofix N.V.** and Orthofix Inc. and was viewed within **Orthofix N.V.** and Orthofix Inc. as the individual responsible for developing **Orthofix N.V.**'s sales in Latin America.
- 7. "Orthofix Executive B," a citizen of the United States, was an Orthofix Inc.
  finance executive who worked in the Eastern District of Texas and elsewhere. Orthofix
  Executive B began working for **Orthofix N.V.** in or around 2001 and became a financial
  manager within **Orthofix N.V.** in or around 2003. Beginning in or around January 2008,
  Orthofix Executive B became an officer of Orthofix Inc. At various times between in or around
  2001 and in or around 2010, Orthofix Executive B's responsibilities included consolidating
  Promeca's revenues into **Orthofix N.V.**'s financial statements, reviewing Promeca's profit and
  loss figures, reviewing individual **Orthofix N.V.** journal entries, reporting financial results to **Orthofix N.V.**'s Board of Directors, and assisting in reporting **Orthofix N.V.**'s financial data to
  the United States Securities & Exchange Commission. In or around January 2007, Orthofix

Executive B also visited Promeca's offices in Mexico City to review Promeca's financial statements.

- 8. "Orthofix Executive C," a citizen of the United States, was an Orthofix Inc. finance executive who worked in the Eastern District of Texas and elsewhere. From in or around 2004 until in or around 2006 and again from in or around 2007 to present, Orthofix Executive C was the Orthofix Inc. executive responsible for overseeing Promeca's financial performance.
- 9. At various times between in or around 2001 and in or around 2010, Orthofix Executive B and Orthofix Executive C were responsible for monitoring the financial operations and results of **Orthofix N.V.**'s subsidiaries in Latin America, including Promeca.
- 10. "Promeca Executive A," a citizen of Mexico and former owner of Promeca, was Promeca's Commercial Director. Promeca Executive A reported directly to Orthofix Inc.'s President of the Americas and to Orthofix Executive A.
- 11. "Promeca Executive B," a citizen of Mexico and licensed accountant, was Promeca's Finance Manager. Promeca Executive B was responsible for Promeca's payroll, purchasing, bookkeeping, inventory controls, and taxes. Promeca Executive B reported directly to Promeca Executive A and to Orthofix Inc.'s Chief Financial Officer.

#### Defendant's Customers

12. Instituto Mexicano del Seguro Social ("IMSS") was a social-service agency of the Mexican government that provided public services to Mexican workers and their families. IMSS was created in 1943 by order of the Mexican president, who continued to select IMSS's head, and subsequent changes to IMSS programs were made by acts of Mexico's legislature. IMSS provided health care services to tens of millions of people, including workers, their families, and pensioners, at hospitals that IMSS owned and operated throughout Mexico. Mexico's

government funded IMSS through taxation and compulsory contributions.

- 13. Hospital de Traumatologia y Ortopedia Magdalena de las Salinas ("Magdelena de las Salinas") was a hospital in Mexico City, Mexico, that IMSS owned and controlled.
- 14. Hospital de Traumatologia y Ortopedia Lomas Verdes ("Lomas Verdes") was a hospital in the State of Mexico that IMSS owned and controlled.
  - 15. "Mexican Official 1" was a deputy administrator of Magdelena de las Salinas.
  - 16. "Mexican Official 2" was purchasing director of Magdelena de las Salinas.
  - 17. "Mexican Official 3" was purchasing director of Lomas Verdes.
  - 18. "Mexican Official 4" was a sub-director of IMSS.
- 19. Promeca generated approximately 65 percent of its revenues through sales to IMSS and its hospitals, including sales to Magdelena de las Salinas and Lomas Verdes.

  Orthofix N.V. and Orthofix Inc. executives were aware that Promeca's revenues relied heavily upon sales to Mexican government customers.

## **Corrupt Conduct**

- 20. From in or around 2003 through in or around March 2010, with the knowledge of Orthofix Executive A, Promeca and its employees paid approximately \$300,000 to Mexican officials, in return for agreements with IMSS and its hospitals to purchase millions of dollars in **Orthofix N.V.** products.
- 21. Promeca personnel colloquially referred to the illicit payments as "chocolates," a term commonly understood within Promeca and by Orthofix Executive A to describe a supplier's improper payments to purchasers of medical supplies and devices in exchange for an agreement to buy the supplier's goods.

- 22. In or around 2003, Promeca Executive A won the right to sell **Orthofix N.V.** products to Magdelena de las Salinas and Lomas Verdes by agreeing to pay to Mexican Official 1 and Mexican Official 2, respectively, a percentage of collected sales revenue generated through sales to the hospitals.
- 23. To implement this agreement, Promeca Executive B periodically reviewed a report of sales revenue collected from Magdelena de Las Salinas and Lomas Verdes. Promeca Executive B submitted requests for expense advancements payable to Promeca Executive B, cashed the resulting checks with the assistance of Promeca's office messenger, and delivered the cash to Promeca Executive A.
- 24. From in or around 2003 until in or around 2006, Promeca Executive A and additional Promeca employees delivered to Mexican Official 1 cash payments equal to as much as 10 percent of Promeca's collected sales to Magdelena de las Salinas.
- 25. From in or around 2006 until in or around 2007, Promeca Executive A and additional Promeca employees delivered to Mexican Official 2 cash payments equal to as much as 6 percent of Promeca's collected sales to Magdelena de las Salinas.
- 26. From in or around 2003 until in or around 2007, Promeca Executive A and additional Promeca employees delivered to Mexican Official 3 cash payments equal to as much as 5 percent of Promeca's collected sales to Lomas Verdes. Beginning in or around July 2007, Promeca stopped making cash payments to Mexican Official 3 and instead leased a vehicle for Mexican Official 3 to drive. Mexican Official 3 drove that leased car until in or around September 2010.
- 27. In or around 2008, IMSS began holding national tenders for medical-device contracts with hospitals that IMSS owned and controlled. To obtain contracts under the national

tenders in or around 2008 and 2009, Promeca Executive A agreed to pay certain IMSS officials, including Mexican Official 4, a percentage of Promeca's sales revenue collected under the contracts that IMSS awarded to Promeca. To accomplish this agreement, Promeca Executive B regularly reported to IMSS officials the amount of collected sales revenue from the national tender contracts. IMSS officials then used fictitious companies to issue to Promeca invoices for medical equipment or training in an amount equal to the payments due to the IMSS officials plus a value-added tax to make the invoices appear to be legitimate. Promeca then paid the invoiced amounts to the front companies incorporated by the IMSS officials.

- 28. Promeca recorded the bribe-related expenses on its books and records as "promotional expenses," payments for medical equipment, and training-related expenses, none of which reflected the true purpose for which the expenditures were made. Promeca consistently overspent in these categories the budget that it had communicated to **Orthofix N.V.** and Orthofix Inc.
- 29. Orthofix Executive A knew of the payments and things of value outlined above, but failed to stop the scheme or to report the scheme to **Orthofix N.V.** or Orthofix Inc.'s compliance department.

## **Defendant's Internal Controls**

- 30. **Orthofix N.V.**, which grew its direct distribution footprint in part by purchasing existing companies, often in high-risk markets, failed to engage in any serious form of corruption-related diligence before it purchased Promeca.
- 31. Although **Orthofix N.V.** promulgated its own anti-corruption policy, that policy was neither translated into Spanish nor implemented at Promeca. **Orthofix N.V.** failed to provide any FCPA-related training to many of its own personnel, including Orthofix Executive

- A. **Orthofix N.V.** also failed to train Promeca personnel for years on the FCPA, to test regularly or audit particular transactions, or to ensure that its subsidiary maintained controls sufficient to detect, deter, or prevent illicit payments to government officials.
- 32. Orthofix N.V.'s financial controls pertaining to Promeca were also inadequate. In addition to permitting unexplained variances from Promeca's budget, Orthofix N.V. discovered in 2003 that Promeca Executive A had charged in 2002 and 2003 approximately \$100,000 in cash advances against Promeca Executive A's corporate credit card. Orthofix N.V. eventually wrote off the expenses, which Promeca Executive A claimed were travel-related, because Promeca could not provide sufficient receipts. Despite Orthofix N.V.'s inability to substantiate approximately \$100,000 in cash advances, until 2010, Orthofix N.V. failed to implement any policy changes to prohibit such cash advances.
- 33. From in or around 2003 until March 2010, **Orthofix N.V.**'s finance personnel, including Orthofix Executive B and Orthofix Executive C, required Promeca to submit to **Orthofix N.V.** monthly reports concerning Promeca's financial performance. Among other things, Promeca was required to report its budget and to compare its actual expenditures to its budget. Promeca's monthly reports showed that Promeca's expenditures regularly far exceeded the budgeted amounts in several categories, including promotional expenses, travel expenses, and meetings for doctors. Those categories were all high risk, received no extra scrutiny, and were in fact budgeted funds from which Promeca made bribe payments over a multi-year period. Despite imposing the monthly reporting requirement upon Promeca, neither Orthofix Executive B nor Orthofix Executive C reviewed Promeca's monthly reports in detail. Instead, Orthofix Executive B and Orthofix Executive C viewed the reports only as a way to encourage Promeca to operate within its budget. As a result, **Orthofix N.V.** failed to identify Promeca's persistent cost

overruns or to endeavor to determine the reason for those overruns, and Promeca continued its bribery scheme for approximately seven years after being acquired by **Orthofix N.V.** 

- 34. In or around June 2006 and again in or around December 2008, **Orthofix N.V.** executives summoned Promeca's executives, including Promeca Executive A and Promeca Executive B, to meetings in Boston, during which **Orthofix N.V.** reviewed Promeca's operations, revenues, and costs. Although Promeca's books accurately reflected significant cost overruns in categories in which Promeca disguised illicit payments, **Orthofix N.V.** personnel failed to discover those illicit payments.
- Promeca's executives refer to the payment of "chocolates" as a common feature in Mexico's medical-device market. When Orthofix Executive B discussed the payment of "chocolates" with Orthofix Executive A, Orthofix Executive A stated that Promeca's competitors in Mexico were paying "chocolates," and that most companies disguised the "chocolates" on their books as training, promotional, and other sales-related expenses. When Orthofix Executive B told Orthofix Executive A that standard audits of Promeca would detect such payments, Orthofix Executive A responded only that Orthofix Inc.'s finance department and auditors would be unable to detect whether Promeca was paying "chocolates." Orthofix Executive B failed to follow up on Orthofix Executive B's conversation with Orthofix Executive A or to report the conversation to **Orthofix N.V.** or Orthofix Inc.'s compliance personnel. **Orthofix N.V.**'s audits of Promeca consisted only of standard audits mandated by Mexican statute and did not include within the scope of the audit an anti-corruption review.
- 36. From in or about 2003 through in or about March 2010, within the Eastern District of Texas and elsewhere, **Orthofix N.V.**, knowingly and willfully failed to maintain a

system of internal controls sufficient to provide reasonable assurances that: (i) transactions were executed in accordance with management's general or specific authorization; (ii) transactions were recorded as necessary to (A) permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and (B) maintain accountability for assets; (iii) access to assets was permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets was compared with the existing assets at reasonable intervals, and appropriate action was taken with respect to any differences, to wit: the defendant knowingly: (a) failed to adequately train key personnel to implement internal accounting controls meant to detect and avoid illegal payments and to identify and deter violations of those controls; (b) failed to identify and address obvious risks associated with **Orthofix N.V.**'s sales in Mexico and the operations of its subsidiary; (c) failed to monitor and control the financial transactions of its Mexican subsidiary in a manner that provided reasonable assurances that its Mexican subsidiary's transactions were executed in accordance with management's general or specific authorization; and (d) failed to monitor and control the financial transactions of its Mexican subsidiary in a manner that provided reasonable assurances that its Mexican subsidiary's transactions were recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and any other criteria applicable to such statements.

### **ATTACHMENT B**

#### CERTIFICATE OF CORPORATE RESOLUTIONS

WHEREAS, Orthofix International N.V. (the "Company") has been engaged in discussions with the United States Department of Justice, Criminal Division, Fraud Section (the "Department") regarding issues arising in relation to certain improper payments to foreign officials to facilitate the award of contracts and assist in obtaining business for the Company; and

WHEREAS, in order to resolve such discussions, it is proposed that the Company enter into a certain agreement with the Department; and

WHEREAS, the Company's Senior Vice President, General Counsel, and Corporate Secretary, Jeffrey M. Schumm, together with outside counsel for the Company, have advised the Board of Directors of the Company of its rights, possible defenses, the Sentencing Guidelines' provisions, and the consequences of entering into such agreement with the Department;

Therefore, the Board of Directors (the "Board") has RESOLVED that:

- 1. The Company (a) acknowledges the filing of the one-count Information charging the Company with violating the Foreign Corrupt Practices Act, 15 U.S.C. § 78m(b)(2)(B); (b) waives indictment on such charges and enters into a deferred prosecution agreement with the Department; and (c) agrees to accept monetary criminal penalties against Company totaling \$2,200,000, and to pay a total of \$2,200,000 to the United States Treasury with respect to the conduct described in the Information;
- 2. The President and Chief Executive Officer of Company, Robert S. Vaters, and Senior Vice President, General Counsel, and Corporate Secretary of Company, Jeffrey M. Schumm, are hereby authorized, empowered and directed, on behalf of the Company, to execute the Deferred Prosecution Agreement (and all attachments thereto) substantially in such form as

reviewed by the Board at this meeting with such changes as the President and Chief Executive Officer of Company, Robert S. Vaters, and Senior Vice President, General Counsel, and Corporate Secretary of Company, Jeffrey M. Schumm, may approve;

- 3. The President and Chief Executive Officer of Company, Robert S. Vaters, and Senior Vice President, General Counsel, and Corporate Secretary of Company, Jeffrey M. Schumm, are hereby authorized, empowered and directed to take any and all actions as may be necessary or appropriate and to approve the forms, terms or provisions of any agreement or other documents as may be necessary or appropriate, to carry out and effectuate the purpose and intent of the foregoing resolutions; and
- 4. All of the actions of the President and Chief Executive Officer of Company,
  Robert S. Vaters, and Senior Vice President, General Counsel, and Corporate Secretary of
  Company, Jeffrey M. Schumm, which actions would have been authorized by the foregoing
  resolutions except that such actions were taken prior to the adoption of such resolutions, are
  hereby severally ratified, confirmed, approved, and adopted as actions on behalf of the Company.

Date: Fucy 5, 2012	By: Jeffry M. Jeh
	Jeffrey M. Schumm Corporate Secretary Orthofix International N.V.
Date:, 2012	
•	Ву:
	James F. Gero
	Chairman of the Board of Directors
	Orthofix International N.V

form as reviewed by the Board at this meeting with such changes as the President and Chief

Executive Officer of Company, Robert S. Vators, and Senior Vice President, General Company,
and Corporate Secretary of Company, Jeffrey M. Schumm, may approve;

- 3. The President and Chief Executive Officer of Company. Robert S. Vaners, and Senior Vice President, General Coursel, and Corporate Secretary of Company. Letting M. Schumm, are hereby authorized, empowered and directed to take any and all actions as may be necessary or appropriate and to approve the forms, terms or provisions of any agreement or other documents as may be necessary or appropriate, to early out and effectuate the purpose and intent of the foregoing resolutions; and
- 4. All of the actions of the President and Chief Executive Officer of Company.

  Reshert S. Vasers, and Senior Vice President. General Counsel, and Corporate Secretary of Company, Jeffrey M. Schumm, which actions would have been unliquized by the tenegoing resolutions except that such actions were taken prior to the adoption of such resolutions, are bereby severally ratified, confirmed, approved, and adopted as actions on behalf of the Company.

Date:

. 2012

Dy

Jeffrey M. Schumm Corporate Secretors Outbolix International N.V.

Date: <u>07/04</u> .2012

By:

Jardes F. Gero Clickimson of the Board of Directors

Ortholix International N.V.

## ATTACHMENT C

## CORPORATE COMPLIANCE PROGRAM

In order to address any deficiencies in its internal controls, policies, and procedures regarding compliance with the Foreign Corrupt Practices Act ("FCPA"), 15 U.S.C. §§ 78m, 78dd-1 *et seq.*, and other applicable anti-corruption laws, Orthofix International, N.V., agrees to continue to conduct for itself and for the subsidiaries that it controls ("Orthofix" or the "company"), in a manner consistent with all of its obligations under this Agreement, appropriate reviews of its existing internal controls, policies, and procedures.

Where necessary and appropriate, Orthofix agrees to adopt new or to modify existing internal controls, policies, and procedures in order to ensure that it maintains: (a) a system of internal accounting controls designed to ensure that Orthofix makes and keeps fair and accurate books, records, and accounts; and (b) a rigorous anti-corruption compliance code, standards, and procedures designed to detect and deter violations of the FCPA and other applicable anti-corruption laws. At a minimum, this should include, but not be limited to, the following elements to the extent they are not already part of the company's existing internal controls, policies, and procedures:

- 1. Orthofix will develop and promulgate a clearly articulated and visible corporate policy against violations of the FCPA, including its anti-bribery, books and records, and internal-controls provisions, and other applicable foreign-law counterparts (collectively, the "anti-corruption laws,"), which policy shall be memorialized in a compliance code.
- 2. Orthofix will ensure that its senior management provides strong, explicit, and visible support and commitment to its corporate policy against violations of the anti-corruption laws and its compliance code.

- designed to reduce the prospect of violations of the anti-corruption laws and Orthofix's compliance code, and Orthofix will take appropriate measures to encourage and support the observance of ethics and compliance standards and procedures against foreign bribery by personnel at all levels of the company. These anti-corruption standards and procedures shall apply to all directors, officers, and employees and, where necessary and appropriate, outside parties acting on Orthofix's behalf in a foreign jurisdiction, including but not limited to, agents and intermediaries, consultants, representatives, distributors, teaming partners, contractors and suppliers, consortia, and joint venture partners (collectively, "agents and business partners"), to the extent that agents and business partners may be employed under Orthofix's corporate policy. Orthofix shall notify all employees that compliance with the standards and procedures is the duty of individuals at all levels of the company. Such standards and procedures shall include policies governing:
  - a. gifts;
  - b. hospitality, entertainment, and expenses;
  - c. customer travel;
  - d. political contributions;
  - e. charitable donations and sponsorships;
  - f. facilitation payments; and
  - g. solicitation and extortion.
- 4. Orthofix will develop these compliance standards and procedures, including internal controls, ethics, and compliance programs on the basis of a risk assessment addressing the individual circumstances of the company, in particular the foreign bribery risks facing the company, including, but not limited to, its geographical organization, interactions with various

types and levels of government officials, industrial sectors of operation, involvement in joint venture arrangements, importance of licenses and permits in the company's operations, degree of governmental oversight and inspection, and volume and importance of goods and personnel clearing through customs and immigration.

- 5. Orthofix shall review its anti-corruption compliance standards and procedures, including internal controls, ethics, and compliance programs, no less than annually, and update them as appropriate, taking into account relevant developments in the field and evolving international and industry standards, and update and adapt them as necessary to ensure their continued effectiveness.
- 6. Orthofix shall assign responsibility to Orthofix's Chief Compliance Officer for the implementation and oversight of Orthofix's anti-corruption policies, standards, and procedures. Such corporate official shall have direct reporting obligations to Orthofix's Audit Committee as an independent monitoring body and shall have an adequate level of autonomy from management as well as sufficient resources and authority to maintain such autonomy.
- 7. Orthofix will ensure that it has a system of financial and accounting procedures, including a system of internal controls, reasonably designed to ensure the maintenance of fair and accurate books, records, and accounts to ensure that they cannot be used for the purpose of foreign bribery or concealing such bribery.
- 8. Orthofix will implement mechanisms designed to ensure that its anti-corruption policies, standards, and procedures are effectively communicated to all directors, officers, employees, and, where appropriate, agents and business partners. These mechanisms shall include: (a) periodic training for all directors, officers, senior managers, and all other employees working in positions involving activities implicated by Orthofix's policies regarding anti-corruption and compliance with the FCPA, and, where necessary and appropriate, agents and

business partners; and (b) accompanying certifications by all such directors, officers, and employees, and, where necessary and appropriate, agents, and business partners, certifying compliance with the training requirements.

- 9. Orthofix will maintain, or where necessary establish, an effective system for:
- a. Providing guidance and advice to directors, officers, employees, and, where appropriate, agents and business partners, on complying with Orthofix's anti-corruption compliance policies, standards, and procedures, including when they need advice on an urgent basis or in any foreign jurisdiction in which the company operates;
- b. Internal and, where possible, confidential reporting by, and protection of, directors, officers, employees, and, where appropriate, agents and business partners, not willing to violate professional standards or ethics under instructions or pressure from hierarchical superiors, as well as for directors, officers, employee, and, where appropriate, agents and business partners, willing to report breaches of the law or professional standards or ethics concerning anti-corruption occurring within the company, suspected criminal conduct, and/or violations of the compliance policies, standards, and procedures regarding the anti-corruption laws for directors, officers, employees, and, where necessary and appropriate, agents and business partners; and
- c. Responding to such requests and undertaking appropriate action in response to such reports.
- 10. Orthofix will institute appropriate disciplinary procedures to address, among other things, violations of the anti-corruption laws and Orthofix's anti-corruption compliance code, policies, and procedures by Orthofix's directors, officers, and employees. Orthofix shall implement procedures to ensure that where misconduct is discovered, reasonable steps are taken to remedy the harm resulting from such misconduct, and to ensure that appropriate steps are

taken to prevent further similar misconduct, including assessing the internal controls, ethics, and compliance program and making modifications necessary to ensure the program is effective.

- 11. Orthofix will institute appropriate due diligence and compliance requirements pertaining to the retention and oversight of all agents and business partners, including:
- a. Properly documented risk-based due diligence pertaining to the hiring and appropriate and regular oversight of agents and business partners;
- b. Informing agents and business partners of Orthofix's commitment to abiding by laws on the prohibitions against foreign bribery, and of Orthofix's ethics and compliance standards and procedures and other measures for preventing and detecting such bribery; and
  - c. Seeking a reciprocal commitment from agents and business partners.
- 12. Where necessary and appropriate, Orthofix will include standard provisions in agreements, contracts, and renewals thereof with all agents and business partners that are reasonably calculated to prevent violations of the anti-corruption laws, which may, depending upon the circumstances, include: (a) anti-corruption representations and undertakings relating to compliance with the anti-corruption laws; (b) rights to conduct audits of the books and records of the agent or business partner to ensure compliance with the foregoing; and (c) rights to terminate an agent or business partner as a result of any breach of anti-corruption laws, and regulations or representations and undertakings related to such matters.
- 13. Orthofix will ensure that new business entities are only acquired after thorough FCPA and anti-corruption law due diligence by legal, accounting, and compliance personnel. Where such anti-corruption law due diligence is not practicable prior to acquisition of a new business for reasons beyond Orthofix's control, or due to any applicable law, rule, or regulation, Orthofix will conduct FCPA and anti-corruption law due diligence subsequent to the acquisition

and report to the Department any corrupt payments or inadequate internal controls as required in Paragraph 10 of this Agreement.

- 14. Orthofix will ensure that Orthofix's policies and procedures regarding the anticorruption laws apply as quickly as is practicable to newly acquired businesses and will promptly:
- a. Train directors, officers, and senior managers, and those employees working in positions involving activities implicated by Orthofix's policies regarding anti-corruption and compliance with the FCPA, and, where necessary and appropriate, agents and business partners, on the anti-corruption laws and Orthofix's policies and procedures regarding anti-corruption laws.
- b. Conduct an anti-corruption specific audit of all newly-acquired businesses as quickly as practicable.
- 15. Orthofix will conduct periodic review and testing of its anti-corruption compliance code, standards, and procedures designed to evaluate and improve their effectiveness in preventing and detecting violations of anti-corruption laws and Orthofix's anti-corruption code, standards and procedures, taking into account relevant developments in the field and evolving international and industry standards.

#### ATTACHMENT D

## CORPORATE COMPLIANCE REPORTING

- 1. Orthofix International, N.V. ("Orthofix"), agrees that it will report periodically, at no less than 12-month intervals, in accordance with the schedule described in Paragraph 3 below, during the three-year term of this Agreement, to the United States Department of Justice, Criminal Division, Fraud Section (the "Department") regarding remediation and implementation of the compliance program and internal controls, policies, and procedures described in Attachment C.
- 2. Should Orthofix discover credible evidence, not already reported to the Department, that questionable or corrupt payments or questionable or corrupt transfers of property or interests may have been offered, promised, paid, or authorized to or for the benefit of government officials by any Orthofix entity (including, without limitation, any Orthofix subsidiary) or person, or any entity or person working directly for Orthofix, or that related false books and records have been maintained, Orthofix shall promptly report such conduct to the Department.
- 3. During the three-year term of this Agreement, Orthofix's Chief Compliance Officer shall: (1) conduct an initial review and prepare an initial report, and (2) conduct and prepare a follow-up review and report, as described below:
- a. By no later than one year from the date on which the Information is filed, Orthofix shall issue a written report covering the prior 12-month period and setting forth a complete description of its remediation efforts to date, its proposals reasonably designed to improve the policies and procedures of Orthofix for ensuring compliance with the FCPA and other applicable anti-corruption laws, and the parameters of the subsequent reviews. The report shall be transmitted to Deputy Chief FCPA Unit, Fraud Section, Criminal Division, U.S.

Department of Justice, 1400 New York Avenue, N.W., Bond Building, Fourth Floor, Washington, D.C. 20005. Orthofix may extend the time period for issuance of the report with prior written approval of the Department.

- b. Orthofix shall undertake a follow-up review, incorporating any comments provided by the Department on its initial review and report, to further monitor and assess whether the policies and procedures of Orthofix are reasonably designed to detect and prevent violations of the FCPA and other applicable anti-corruption laws.
- c. The follow-up review and report shall be completed by no more than one-year after the initial review.
- d. Orthofix may extend the time period for submission of the follow-up report with prior written approval of the Department.