

ORTHOFIX INTERNATIONAL N V

FORM 8-K (Current report filing)

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **July 10, 2012**

Orthofix International N.V.

(Exact name of Registrant as specified in its charter)

Curaçao
(State or other jurisdiction of incorporation)

0-19961
(Commission File Number)

N/A
(IRS Employer Identification No.)

7 Abraham de Veerstraat
Curaçao
(Address of principal executive offices)

N/A
(Zip Code)

Registrant's telephone number, including area code: **011-59-99-465-8525**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 8.01. Other Events.

On July 10, 2012, Orthofix International N.V. (the “Company”) entered into definitive agreements memorializing the previously disclosed agreement in principle previously reached with the Department of Justice (the “DOJ”) and Securities and Exchange Commission (the “SEC”) regarding the Company’s self-initiated and self-reported internal investigation of its Mexican subsidiary, Promeca S.A. de C.V. (“Promeca”), into allegations of non-compliance by Promeca with the Foreign Corrupt Practices Act (“FCPA”). As part of the settlement of this matter, the Company has entered into (i) a consent to final judgment (the “SEC Consent”) with the SEC and (ii) a deferred prosecution agreement (the “DPA”) with the DOJ.

Under the terms of the SEC Consent, the Company will settle civil claims related to this matter by voluntarily disgorging profits to the United States government in an amount of \$5,225,701, inclusive of pre-judgment interest. The Company has also agreed to pay a fine of \$2,220,000 to the United States government pursuant to the terms of the DPA. The Company previously recorded charges of \$3.0 million during the first quarter of 2011 and \$4.5 million during the fourth quarter of 2011 to establish an accrual in anticipation of a future final resolution of these matters with both the DOJ and the SEC. The Company expects to make these settlement payments in the third fiscal quarter of 2012.

As part of the DPA, which has a term of 3 years, the DOJ has agreed not to pursue any criminal charges against the Company in connection with this matter if the Company complies with the terms of the DPA. The DPA takes note of the Company’s self-reporting of this matter to the DOJ and the SEC, and of remedial measures, including the implementation of an enhanced compliance program, previously undertaken by the Company. The DPA provides that the Company shall continue to cooperate fully with the DOJ in any future matters related to corrupt payments, false books and records or inadequate internal controls. In that regard, the Company has represented 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. The Company will periodically report to the DOJ during the term of the DPA regarding such remediation and implementation of compliance measures.

In addition, under the terms of the SEC Consent, the Company will periodically report to the SEC during a 2-year term regarding the status of such remediation and implementation of compliance measures.

The SEC Consent and the DPA do not provide for the appointment of any independent external monitor by the DOJ or the SEC.

The foregoing descriptions of the SEC Consent and the DPA do not purport to be complete and are qualified in their entirety by the text of the SEC Consent and the DPA, which are filed herewith as Exhibits 99.1 and 99.2, respectively, and which are incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits .

(d) Exhibits

99.1 Consent of Orthofix International N.V. to final judgment, to be entered on July 10, 2012, in civil action to be filed by the Securities and Exchange Commission in the United States District Court for the Eastern District of Texas, Sherman Division

99.2 Deferred Prosecution Agreement, entered into on July 10, 2012, between Orthofix International N.V. and the United States Department of Justice, Criminal Division, Fraud Section

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Orthofix International N.V.

By: /s/ Jeffrey M. Schumm
Jeffrey M. Schumm
Senior Vice President, General Counsel and Corporate Secretary

Date: July 10, 2012

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Consent of Orthofix International N.V. to final judgment, to be entered on July 10, 2012, in civil action to be filed by the Securities and Exchange Commission in the United States District Court for the Eastern District of Texas, Sherman Division
99.2	Deferred Prosecution Agreement, entered into on July 10, 2012, between Orthofix International N.V. and the United States Department of Justice, Criminal Division, Fraud Section

b. orders Defendant to pay disgorgement in the amount of \$4,983,644 plus pre-judgment interest thereon in the amount of \$242,057, for a total of \$5,225,701; and

c. orders Defendant to submit periodic reports to the U.S. Securities and Exchange Commission (the "Commission") as described in paragraph 5 of this Consent.

4. Defendant agrees to pay \$5,225,701 by certified check, bank cashier's check, wire transfer, or United States postal money order payable to the Securities and Exchange Commission within 14 days of entry of this Final Judgment. Defendant agrees that if it fails to make the payment by the date agreed and/or in the amount agreed, all outstanding payments under the Final Judgment, including post-judgment interest, minus any payments made, shall become due and payable immediately without further application to the Court.

5. Defendant undertakes to periodically, at no less than six-month intervals, during a two-year term to report to the Commission staff on the status of Defendant's remediation and implementation of compliance measures. Should Orthofix discover credible evidence, not already reported to the Commission staff, that questionable or corrupt payments or questionable or corrupt transfers of property or interests may have been offered, promised, paid, or authorized by any Orthofix entity or person, or any entity or person working directly for Orthofix, or that related false books and record have been maintained, Orthofix shall promptly report such conduct to the Commission staff. During this two-year period, Orthofix shall: (i) conduct an initial review and submit an initial report, and (ii) conduct and prepare follow-up reviews and reports, as described below:

a. Orthofix shall submit to the Commission staff a written report within 180 calendar days of the signing of this agreement 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 Kara Brockmeyer, Unit Chief, Foreign Corrupt Practices Act Unit, Enforcement Division, U.S. Securities and Exchange Commission, 100 F. Street NE, Washington DC, 20549-5030. The Commission staff may, upon written request of Orthofix and for good cause shown, approve an extension of the time period for issuance of the report.

b. Orthofix shall undertake two follow-up reviews, incorporating any comments provided by the Commission staff on Orthofix's 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 first follow-up review and report shall be completed by 180 days after the initial review. A subsequent follow-up review and report shall be completed by 180 days after the completion of the preceding follow-up review.

d. The Commission staff may, upon written request of Orthofix and for good cause shown, approve an extension of the time period for issuance of the report.

6. Orthofix shall certify, in writing, compliance with the undertakings set forth above. The certification shall identify the undertakings, provide written evidence of compliance in the form of a narrative, and be supported by exhibits sufficient to demonstrate compliance. The Commission staff may make reasonable requests for further evidence of compliance, and Orthofix agrees to provide such evidence. The certification and supporting material shall be submitted to Kara Brockmeyer, Unit Chief, Foreign Corrupt Practices Act Unit, Enforcement Division, with a copy to the Office of the Chief Counsel of the Enforcement Division, no later than sixty (60) days from the date of the completion of the undertakings.

7. Defendant waives the entry of findings of fact and conclusions of law pursuant to Rule 52 of the Federal Rules of Civil Procedure.
8. Defendant waives the right, if any, to a jury trial and to appeal from the entry of Final Judgment.
9. Defendant enters into this Consent voluntarily and represents that no threats, offers, promises, or inducements of any kind have been made by the Commission or any member, officer, employee, agent, or representative of the Commission to induce Defendant to enter into this Consent.
10. Defendant agrees that this Consent shall be incorporated into the Final Judgment with the same force and effect as if fully set forth therein.
11. Defendant will not oppose the enforcement of the Final Judgment on the ground, if any exists, that it fails to comply with Rule 65(d) of the Federal Rules of Civil Procedure, and hereby waives any objection based thereon.
12. Defendant waives service of the Final Judgment and agrees that entry of the Final Judgment by the Court and filing with the Clerk of the Court will constitute notice to Defendant of its terms and conditions. Defendant further agrees to provide counsel for the Commission, within thirty days after the Final Judgment is filed with the Clerk of the Court, with an affidavit or declaration stating that Defendant has received and read a copy of the Final Judgment.
13. Consistent with 17 C.F.R. 202.5(f), this Consent resolves only the claims asserted against Defendant in this civil proceeding. Defendant acknowledges that no promise or representation has been made by the Commission or any member, officer, employee, agent, or representative of the Commission with regard to any criminal liability that may have arisen or may arise from the facts underlying this action or immunity from any such criminal liability.

Defendant waives any claim of Double Jeopardy based upon the settlement of this proceeding, including the imposition of any remedy or civil penalty herein. Defendant further acknowledges that the Court's entry of a permanent injunction may have collateral consequences under federal or state law and the rules and regulations of self-regulatory organizations, licensing boards, and other regulatory organizations. Such collateral consequences include, but are not limited to, a statutory disqualification with respect to membership or participation in, or association with a member of a self-regulatory organization. This statutory disqualification has consequences that are separate from any sanction imposed in an administrative proceeding. In addition, in any disciplinary proceeding before the Commission based on the entry of the injunction in this action, Defendant understands that it shall not be permitted to contest the factual allegations of the complaint in this action.

14. Defendant understands and agrees to comply with the Commission's policy "not to permit a defendant or respondent to consent to a judgment or order that imposes a sanction while denying the allegations in the complaint or order for proceedings." 17 C.F.R. § 202.5. In compliance with this policy, Defendant acknowledges the deferred-prosecution agreement for related criminal conduct described in paragraph 2 above, and agrees: (i) not to take any action or to make or permit to be made any public statement denying, directly or indirectly, any allegation in the complaint or creating the impression that the complaint is without factual basis; and (ii) that upon the filing of this Consent, Defendant hereby withdraws any papers filed in this action to the extent that they deny any allegation in the complaint. If Defendant breaches this agreement, the Commission may petition the Court to vacate the Final Judgment and restore this action to its active docket. Nothing in this paragraph affects Defendant's: (i) testimonial

obligation; or (ii) right to take legal or factual positions in litigation or other legal proceedings in which the Commission is not a party.

15. Defendant hereby waives any rights under the Equal Access to Justice Act, the Small Business Regulatory Enforcement Fairness Act of 1996, or any other provision of law to seek from the United States, or any agency, or any official of the United States acting in his or her official capacity, directly or indirectly, reimbursement of attorney's fees or other fees, expenses, or costs expended by Defendant to defend against this action. For these purposes, Defendant agrees that Defendant is not the prevailing party in this action since the parties have reached a good faith settlement.

16. Defendant agrees that the Commission may present the Final Judgment to the court for signature and entry without further notice.

17. Defendant agrees that this Court shall retain jurisdiction over this matter for the purposes of enforcing the terms of the Final Judgment.

Dated: April 9, 2012

Orthofix International, N.V.

By: /s./ Jeffrey M. Schumm

On April 9, 2012, Jeffrey M. Schumm, a person known to me, personally appeared before me and acknowledged executing the foregoing Consent with full authority to do so on behalf of Orthofix International N.V. as its Corporate Secretary.

/s/ Candice McEnaney
Notary Public
Commission expires:

Approved as to form:

/s/ Peter Spivack

Peter Spivack
Hogan Lovells U.S., LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004

Outside Counsel for Orthofix International N.V.

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

UNITED STATES OF AMERICA

v.

ORTHOFIX INTERNATIONAL, N.V.,

Defendant.

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§
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§
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§
§

NO.

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:

- Base Offense. 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.
- Culpability Score. 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

- Calculation of Fine Range :

Base Fine	\$3,700,000
Multipliers	0.6 (min)/1.2 (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

13. If, during the Term of this Agreement, the Department determines, in its sole 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

17. Orthofix agrees that in the event it sells, merges, or transfers all or substantially 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

By: /s/ Robert S. Vaters
ROBERT S. VATERS
President and Chief Executive Officer

Date: July 5, 2012

By: /s/ Jeffrey M. Schumm
JEFFREY M. SCHUMM
Senior Vice President, General Counsel, and Corporate Secretary

Date: 7-5-12

By: /s/ Peter Spivack
PETER SPIVACK
Hogan Lovells US LLP

FOR THE DEPARTMENT OF JUSTICE:

DENIS J. McINERNEY
Chief, Fraud Section

Date: July 10, 2012

By: /s/ Stephen J. Spiegelhalter
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