ASSURANCE OF VOLUNTARY COMPLIANCE

This Assurance of Voluntary Compliance ("Assurance") is entered into between Synthes, Inc. ("Synthes" or "Company") by its undersigned counsel, and the State of New Jersey, by the Attorney General of the State of New Jersey (the "Attorney General") and the New Jersey Division of Consumer Affairs (the "Division of Consumer Affairs").

SECTION A: PREAMBLE

WHEREAS, the Attorney General and the Division of Consumer Affairs have initiated an investigation of Synthes with respect to the disclosure of financial interests of the clinical investigators involved in the clinical trials for its ProDisc products ProDisc-L (approved by the Food and Drug Administration ("FDA") under Premarket Approval Application ("PMA") P050010) and ProDisc-C (approved under P070001), pursuant to the New Jersey Consumer Fraud Act ("CFA") N.J.S.A. 56:8-1 et seq. (hereinafter, the "Investigation");

WHEREAS, the Attorney General and the Division of Consumer Affairs acknowledge that the FDA has approved premarket approval applications for ProDisc-L and ProDisc-C to be lawfully marketed in the United States;

WHEREAS, the Attorney General, the Division of Consumer Affairs and Synthes (collectively, the "Parties") seek a mutually agreeable resolution in which the interests of reliable and unbiased clinical trials and adequate disclosure of financial relationships between clinical investigators and Synthes are aligned as set forth in this Assurance;

WHEREAS, the Parties have reached an amicable agreement resolving the issues in controversy and concluding this matter without the need for further action, and Synthes having voluntarily cooperated with the Investigation and consented to the entry of this Assurance and without having admitted any violation of law or finding of fact, and without any court entering any findings of fact or conclusions of law relating to this Investigation, and for good cause shown:

IT IS on this 1st day of May, 2009 AGREED as follows:

SECTION B: EFFECTIVE DATE AND SCOPE

This Assurance covers the responsibilities and obligations of Synthes to collect, maintain, and disclose accurate data relating to the financial interests of clinical investigators involved in clinical trials of medical devices (hereafter "clinical investigators"). This Assurance applies to all ongoing and future clinical trials, except to the extent indicated to the contrary in paragraphs 1, 3, 5 and 9. Clinical trials conducted outside of the United States and not intended to be used for United States marketing authorization are not covered by this Assurance.

This Assurance shall be effective on the date that it is filed with the Division ("Effective Date").

SECTION C: ASSURANCES

(1) Contracts with Clinical Investigators: With respect to clinical trials commenced after the Effective Date, Synthes shall select clinical investigators on the basis of their qualifications, training, research and/or clinical expertise in the relevant field. Synthes' contracts with clinical investigators shall:

(a) Specify the nature of the research services to be provided and the basis for payment for those services;

(b) State, pursuant to 21 C.F.R. 812.43(c)(5), that the investigator will provide Synthes "with sufficient accurate financial information that will allow Synthes to submit complete and accurate certifications or disclosures to FDA as required under 21 C.F.R. Part 54." As defined by 21 C.F.R. 54.2(a), (b), (c), and (f), this information should include ownership interests, stock options, royalties, patent interests, trademark or copyright interests, grant payments, honoraria, and/or consulting payments (collectively "Financial Interest Information");

(c) Provide that payments or compensation of any sort are not tied to the outcome of the clinical trial with the exception of royalty payments and patent rights, or financial incentives directed solely at patient accrual or patient follow-up; and

(d) Prohibit compensation of clinical investigators and/or institutions serving as clinical sites in the form of company stock or stock options, but does not prohibit clinical investigators from otherwise owning such stocks or stock options.

(e) If Synthes acquires a company which has compensated its clinical investigators in stock or stock options in the acquired company, Synthes must exercise its due diligence to collect any relevant information from the acquired company, as well as from the clinical investigators, regarding the financial interests, must promptly input such information into Synthes' Financial Interest Information Database (in accordance with Paragraph 7), must retain such records in accordance with this Assurance (in accordance with Paragraph 8), must disclose such information on its Company Website (in accordance with Paragraph 10), and must insure that all disclosures to the FDA include such Financial Interest Information (in accordance with Paragraph 11).

(2) Due Diligence to Collect Requested Financial Interest Information: Synthes will act with due diligence to collect Financial Interest Information as set forth in Paragraph 3 detailing the Standard Operating Procedure that Synthes has adopted through this Assurance. However, in those instances where Synthes is unable to obtain the required Financial Interest Information, any required financial disclosures submitted to FDA will

include (a) a certification from Synthes that, despite its due diligence in attempting to collect this information it was unable to obtain the information, (b) an explanation of how Synthes attempted to obtain the information, and (c) an explanation of why the information was not obtainable. In addition, in those instances where Synthes is unable to obtain the required Financial Interest Information, Synthes will state "Unable to Obtain" on its Company Website pursuant to Paragraph 10.

(3) Creation of Standard Operating Procedure: Within 90 days from the Effective Date of this Assurance, Synthes shall develop a Standard Operating Procedure ("SOP") for soliciting, collecting, and disclosing the Financial Interest Information from its clinical investigators in clinical trials commencing after the Effective Date, in accordance with FDA regulations at 21 C.F.R Part 54. The SOP will include in part:

(a) A questionnaire or other tool(s) that will be provided to clinical investigators soliciting the Financial Interest Information and steps for retaining such questionnaire or other tool(s) in Synthes' files;

(b) Steps for reviewing the Financial Interest Information that is received from a clinical investigator;

(c) Steps for ensuring the Financial Interest Information and any other related financial information known to the Company is entered into the Financial Interest Information Database (see Paragraph 7 below) and is consistent with information already in that database. Information is "known to the company" if it is retained in Synthes' files, including the Financial Interest Information Database;

(d) Steps for ensuring that all financial information known to the company and required to be disclosed under 21 C.F.R. Part 54, if any, is included in each financial disclosure to FDA; and

(e) Steps for "Website Disclosure" of this information in accordance with Paragraph 10 of this Assurance.

(4) Payments to Clinical Investigators: Synthes shall pay clinical investigators a fair market value compensation for services intended to fulfill a legitimate business need. All clinical investigator agreements, in which Synthes is a party, will be in writing, will describe all services to be provided, and will state that all services are bona fide, commercially reasonable and compliant with all federal and state health care programs.

(5) Consulting Agreements with Clinical Investigators: Consulting Agreements will be written and describe all services to be provided. Selection of a consultant will be made on the basis of the consultant's qualifications and expertise to meet the defined need. Compensation paid to a clinical investigator for consulting services ("Consulting Agreements") pursuant to consulting agreements entered into after the Effective Date will be consistent with fair market value in an arm's length transaction for the services

provided and will not be based on the volume or value of the consultant's past, present or anticipated business.

(6) Financial Interest and Disclosure Training: Within 120 days from the Effective Date of this Assurance, Synthes employees involved in the development, approval, management, implementation, use or review of financial arrangements with clinical investigators and/or disclosure of financial relationships as required by federal and state laws and this Assurance shall receive training on the procedures for the collection of Financial Interest Information and the requirements of disclosure of financial interests under federal and state laws and the terms of this Assurance.

(7) Financial Interest Information Database Review: Within 90 days from the Effective Date of this Assurance, Synthes shall create a database which lists all Financial Interest Information reported to the Company and/or otherwise known to the Company related to clinical investigators ("Financial Interest Information Database"). The Financial Interest Information Database shall include all known Financial Interest Information from all of Synthes' past and present subsidiaries, affiliates, predecessors and successors. Synthes shall review the Financial Interest Information Database semi-annually to insure that the database is being maintained and that all relevant information has been entered. The financial interest information contained in the Financial Interest Information Database for each clinical investigator involved in covered clinical trial shall be maintained for 2 years following market clearance or approval of the device or for 2 years following completion of the clinical trial.

(8) Record Retention: Synthes shall maintain complete records, as required by FDA regulations, showing any Financial Interest Information and/or other information known to the Company for two years after regulatory approval.

(9) Informed Consent Disclosures: All clinical investigator agreements entered into by Synthes after the Effective Date will require that the clinical investigator disclose to the health care facility's Institutional Review Board ("IRB") and to all study subjects any Financial Interest Information that is required to be disclosed by the clinical investigator's health care facility's IRB. Synthes shall also submit all Financial Interest Information known to the Company to each IRB as part of the clinical investigator's initial IRB submission packet and/or request for protocol approval.

(10) Website Disclosures: At the time of approval of a premarket approval application or clearance of a premarket notification, Synthes will disclose: (a) the name of each clinical investigator that participated in the clinical study upon which PMA approval or 510(k) clearance was based who held a disclosable financial interest as defined under 21 C.F.R. Part 54; (b) the specific nature and value of the clinical investigator's Financial Interest Information; and (c) and any other information known to the Company on Synthes' Company Website. Such Financial Interest Information and any other information known to the Company and required to be disclosed under 21 C.F.R. Part 54 will remain on Synthes' Company Website for two calendar years from the date of initial posting. In the event that the Physicians Payment Sunshine Act or other similar federal statute is

enacted into law, Synthes will conform its Company Website disclosures to those required by the new federal law. In addition, if a federal public website is developed for such disclosures, Synthes may meet the obligation of this agreement by providing an electronic link from its Company Website to the federal public website.

(11) Disclosure and Compliance: Synthes shall comply with all federal and state regulations related to the disclosure of financial interests of all clinical investigators. Synthes will include all required financial information regarding clinical investigators that held a disclosable financial interest (as defined in 21 C.F.R. Part 54) in a covered clinical study, (as defined in 21 C.F.R. § 54.2 (e)), in any future regulatory application that requires submission of such disclosures. Based upon information known to the Company, Synthes will insure that all forms have the appropriate boxes checked and that they include all applicable attachments detailing the relevant Financial Interest Information. Synthes also agrees to conduct reasonable due diligence, to the best of its ability, to ensure that its disclosures are accurate and complete. As part of its due diligence, Synthes will review all "information known to the company" and the Financial Interest Information Database. If a disclosure includes information that was provided by an investigator that is inaccurate and that does not contradict any of the other information retained by Synthes in the Financial Interest Information Database, Synthes will not be deemed in violation of this Assurance.

(12) General Commitments: Synthes agrees to maintain its commitment to adhere to the highest principles of honesty and professionalism; the integrity of operation of health care programs; and a culture of openness, accountability and compliance with applicable federal and state laws and regulations. Synthes will continue to develop or revise current policies and procedures that are designed to ensure compliance with FDA and other applicable regulations.

(13) Mutual Understanding: The Parties have entered into this Assurance for settlement purposes only. Neither the fact of, nor any provision contained in this Assurance or any documents executed in furtherance of this Assurance shall constitute, or be construed as: (a) an admission of liability; (b) an approval, sanction or authorization by the Attorney General, Division of Consumer Affairs or any other governmental unit of the State of any act or practice of Synthes; or (c) an admission by Synthes that any of its acts or practices described in or prohibited by this Assurance are unfair or deceptive practices or otherwise violate the CFA. Neither the existence of, nor the terms of this Assurance, shall be deemed to constitute evidence or precedent of any kind in any action against Synthes, except in: (a) any action or proceeding by one of the Parties to enforce, rescind or otherwise implement or affirm any or all of the terms herein; or (b) any action or proceeding involving a Released Claim (as defined in Section 14) to support a defense of res judicata, collateral estoppel, release or other theory of claim preclusion, issue preclusion or similar defense.

(14) The Parties to this Agreement further agree that all obligations undertaken by Synthes in this Assurance shall apply prospectively. It is further agreed that nothing in this Assurance shall require Synthes to:

a. Take an action that is prohibited by the FDA or any regulation promulgated thereunder, or by FDA; or

b. Fail to take an action that is required by the FDA or any regulation promulgated thereunder, or by FDA.

(15) Rights to Assert Defenses: This Assurance shall not be construed or used as a waiver or limitation of any defense otherwise available to Synthes in any action, or of Synthes' right to defend itself from, or make any arguments in, any private individual, regulatory, governmental, or class claims or suits relating to the subject matter or terms of this Assurance. This Assurance is made without trial or adjudication of any issue of fact or law or finding of liability of any kind.

(16) Release: In consideration of the payment, undertaking, mutual promises and obligations provided for in this Assurance and conditioned on Synthes making the Settlement Payment in the manner specified in Section 15, the State of New Jersey Division of Consumer Affairs agrees to release Synthes and all of its past and present subsidiaries, affiliates, predecessors and successors (collectively, the "Released Parties") from any and all civil claims, causes of action, restitution, fines, costs, and penalties, which the State of New Jersey Division of Consumer Affairs could have brought prior to the Effective Date against Synthes arising from the Investigational Device Exemption ("IDE") submission, clinical trials, premarket approval applications, and marketing and promotion of ProDisc-L and ProDisc-C ("Released Claims"). Notwithstanding any term of this Assurance, the following do not comprise Released Claims: (a) private rights of action; or (b) actions to enforce this Assurance.

(17) Settlement Payment: The Parties have agreed to a settlement of the Investigation in the amount of $236,000.00 ("Settlement Payment"), in reimbursement of the Division of Consumer Affairs' attorneys' fees and investigative costs, pursuant to N.J.S.A. 56:8-11. Synthes will make the Settlement Payment on or before the Effective Date by certified or cashier's check made payable to "New Jersey Division of Consumer Affairs" forwarded to the undersigned:

Megan Lewis, Deputy Attorney General
Chief, Affirmative Litigation Section
State of New Jersey
Office of the Attorney General
Department of Law and Public Safety
Division of Law
124 Halsey Street - 5th Floor
P.O. Box 45029
Newark, New Jersey 07101

SECTION D: GENERAL PROVISIONS

(18) This Assurance constitutes the entire agreement between the Parties hereto and shall bind the Parties hereto and their representatives, officers, directors, agents, employees, successors, and assigns.

(19) The Parties represent that an authorized representative of each has signed this Assurance with full knowledge, understanding, and acceptance of its terms and that this person has done so with the authority to legally bind the respective Parties.

(20) The Assurance shall be governed by, and construed and enforced in accordance with, the laws of the State of New Jersey.

(21) This Assurance contains the entire agreement among the Parties. Except as otherwise provided herein, this Assurance shall be modified only by a written instrument signed by or on behalf of the Parties.

(22) Except as otherwise explicitly provided in this Assurance, nothing herein shall be construed to limit the authority of the Attorney General to protect the interests of the State of New Jersey or the people of the State of New Jersey.

(23) If any portion of this Assurance is held invalid or unenforceable by operation of law, the remaining terms of this Assurance shall not be affected.

(24) This Assurance shall be binding upon Synthes, as well as its owners, officers, directors, shareholders, founders, managers, agents, servants, employees, representatives, successors and affiliated assigns, and any entity or device through which it may now or hereafter act, as well as any persons who have authority to control or who, in fact, control and direct its business.

(25) In no event shall assignment of any right, power or authority under this Assurance avoid compliance with this Assurance.

(26) The Attorney General (or designated representative) shall have the authority to enforce the provisions of this AVC or to seek sanctions for violations hereof or both.

(27) Except as otherwise provided herein, any notices or other documents required to be sent to the Division or Synthes pursuant to this Assurance shall be sent by United States mail, Certified Mail Return Receipt Requested, or other nationally recognized courier service that provides for tracking services and identification of the person signing for the documents. The notices and/or documents shall be sent to the following addresses:

For the Division:

Megan Lewis, Deputy Attorney General
Chief, Affirmative Litigation Section
State of New Jersey
Office of the Attorney General
Department of Law and Public Safety
Division of Law
124 Halsey Street - 5th Floor
P.O. Box 45029
Newark, New Jersey 07101

For Synthes:

Lawrence A. Gross
Vice President & General Counsel
Synthes, Inc.
1302 Wrights Lane East
West Chester, Pennsylvania 19380

(28) Except as otherwise agreed to by the parties, this Assurance will expire five years from the Effective Date.

THE PARTIES CONSENT TO THE FORM, CONTENT AND ENTRY OF THIS ASSURANCE ON THE DATES OF THEIR RESPECTIVE SIGNATURES.

ANNE MILGRAM
ATTORNEY GENERAL OF NEW JERSEY

By: _____ Dated: May 1, 2009
Megan Lewis, Deputy Attorney General
Michelle Weiner, Deputy Attorney General
Attorney General of New Jersey, Division of Law

On Behalf of Synthes, Inc.

By: _____ Dated: May 1, 2009
Lawrence Gross
Vice President & General Counsel
Synthes, Inc.

By: Edward M Basile Dated: May 1, 2009
Edward M. Basile
Alan R. Dial
Counsel to Synthes, Inc.
King & Spalding LLP