DIVESTITURE AGREEMENT

1. This Divestiture Agreement is entered into by and between the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS), Synthes, Inc. (Synthes), and its subsidiary Norian Corporation (Norian). Synthes and Norian are hereafter collectively referred to as “the Companies.” Synthes, Norian, and the OIG are hereafter collectively referred to as “the Parties.” This Divestiture Agreement addresses the arrangement between the Parties regarding the divestiture of the assets and operations of Norian to an unrelated third party, as further described below.

2. The United States Attorney's Office for the Eastern District of Pennsylvania has been investigating certain conduct of Synthes and Norian, and the Companies have agreed to enter a global resolution of the matter. As part of the global resolution, the Companies will plead guilty to criminal charges and enter into a civil Settlement Agreement with the United States (Settlement Agreement), and Synthes will enter a Corporate Integrity Agreement (CIA) with the OIG. Synthes has agreed to plead guilty to a Superseding Information to be filed in United States of America v. Synthes, Inc., Criminal Action No. 09-403-02 (E.D. Pa.) (“Synthes Criminal Action”) to one misdemeanor count of violating 21 U.S.C. §§ 331(a) and 333(a)(1) for introducing into interstate commerce two medical devices (known as Norian XR and Norian SRS) that were adulterated and misbranded. Norian has agreed to plead guilty to a Superseding Information to be filed in United States of America v. Norian Corporation, Criminal Action No. 09-403-01 (E.D. Pa.) (“Norian Criminal Action”) to one felony count of violating 18 U.S.C. § 371 and 110 misdemeanor counts of violating 21 U.S.C. §§ 331(a) and 333(a)(1) for introducing into interstate commerce Norian XR and Norian SRS that were adulterated and misbranded.

3. The guilty plea by Norian in the Norian Criminal Action constitutes a basis for the OIG to mandatorily exclude Norian from participation in Federal health care programs under section 1128(a)(3) of the Social Security Act (the “Act”), 42 U.S.C. § 1320a-7(a)(3).

4. The guilty plea by Synthes in the Synthes Criminal Action constitutes a basis for the OIG to permissively exclude Synthes from participation in Federal health care programs under section 1128(b)(1) of the Act, 42 U.S.C. § 1320a-7(b)(1). The OIG contends that the Covered Conduct (as alleged in the Settlement Agreement) also constitutes a basis for the OIG to permissively exclude Synthes from participation in Federal health care programs under section 1128(b)(7) of the Act, 42 U.S.C. § 1320a-7(b)(7). As set forth in the Settlement Agreement, the OIG will agree to waive permissive exclusion against Synthes in consideration of Synthes' obligations in the Settlement Agreement and the CIA, and conditioned on Synthes’
full payment of the Settlement Amount set forth in Paragraph III.1 of the Settlement Agreement and Synthes’ compliance with the terms of this Divestiture Agreement.

5. Synthes has represented to the OIG that it intends to sell all the assets and operations of Norian (collectively “Norian Assets”) to an entity (or entities) that prior to the sale is (are) not related to or affiliated with Synthes. The purchasing entity(ies) shall hereafter be referred to as the “Buyer.” Synthes represents that the Buyer shall not be directly or indirectly owned or controlled by Synthes.

6. In order to implement the exclusion of Norian in a way that minimizes disruption to beneficiaries of Federal health care programs and other individuals or entities who may purchase or use Norian products, and consistent with the terms of this Divestiture Agreement: (1) the Companies agree to cause the divestiture of the Norian Assets to Buyer; and (2) the OIG agrees to withhold issuance of a notice of intent to exclude Norian under section 1128(a)(3) of the Act, 42 U.S.C. § 1320a-7(a)(3) until May 25, 2011, subject to the terms of this Divestiture Agreement. Such divestiture (Divestiture) shall include either: (1) the sale of the Norian Assets to an unrelated Buyer; or (2) the dissolution of Norian.

7. The Companies agree that they shall take all prudent and reasonable steps to ensure the Divestiture is completed on or before May 24, 2011, subject to the terms of this Divestiture Agreement.

8. The OIG will not implement any exclusion of Norian before May 25, 2011 if: (1) the OIG, in its sole discretion, determines that the Companies undertake all prudent and reasonable steps to ensure that Divestiture is completed on or before May 24, 2011; and (2) Synthes approves a corporate resolution to dissolve Norian under California General Corporation Law (GCL) on or before May 24, 2011.

9. Beginning in October 2010, Synthes agrees to provide the OIG with reports due on the first business day of each month in order to update the OIG on the status of, and steps taken to effectuate, the Divestiture. Information in such status reports shall include, but is not limited to, identification of prospective Buyers, the status of the negotiation of the sale of the Norian Assets, the status of any regulatory approvals, the status of due diligence reviews, and any other material information that may affect the Divestiture. Synthes shall provide to the OIG any and all documents and records relating to the Divestiture upon the OIG’s request.

10. The OIG agrees to meet with any bona fide prospective Buyer of the Norian Assets.

11. In the event that the Companies have taken all prudent and reasonable steps to complete the Divestiture by May 24, 2011, but will not be able to complete the
Divestiture by that date, the Companies may, on or before May 24, 2011, request an extension of time to complete the Divestiture, which extension, including the length of any such extension, may be granted or denied at the OIG’s sole discretion. The OIG agrees to consider any reports submitted by Synthes in accordance with Paragraph 9, above, when determining whether to grant or deny the request and the length of any extension.

12. If the Companies fail to fully and adequately complete the Divestiture by May 24, 2011, and notwithstanding any extension of time that may be granted by OIG in accordance with Paragraph 11, the OIG in its sole discretion may impose a stipulated penalty of up to $10,000 per day for each day after May 24, 2011 that the Companies have failed to complete the Divestiture. Such stipulated penalties shall accrue until: (i) the Companies complete the Divestiture; or (ii) OIG issues a notice of exclusion in accordance with Paragraph 13 below. Payment of the stipulated penalties shall be made by electronic funds transfer to an account to be specified by the OIG.

Upon OIG’s delivery to the Companies of its demand for stipulated penalties, and as an agreed-upon contractual remedy for the resolution of any dispute arising under this Divestiture Agreement regarding stipulated penalties, the Companies shall be afforded certain review rights comparable to those provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the stipulated penalties sought pursuant to this Divestiture Agreement. Specifically, OIG’s determination to demand payment of stipulated penalties shall be subject to review by an HHS Administrative Law Judge and, in the event of an appeal, the HHS Departmental Appeals Board, in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving stipulated penalties shall be made within 10 days after receipt of the OIG’s demand for stipulated penalties under this Divestiture Agreement.

Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for stipulated penalties under this Divestiture Agreement shall be whether the Companies completed the Divestiture by May 24, 2011, and the number of days after May 24, 2011, during which the Companies had not completed the Divestiture. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to stipulated penalties. If the ALJ agrees with OIG regarding a failure by the Companies to complete the Divestiture in accordance with Paragraph 6 and orders the Companies to pay stipulated penalties, such stipulated penalties shall become due and payable 20 days after the ALJ issues such a decision unless the Companies request review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the stipulated penalties shall become due and payable 20 days after the DAB issues its decision.
The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this Divestiture Agreement agree that the DAB’s decision (or the ALJ’s decision if not appealed) shall be considered final for all purposes under this Divestiture Agreement.

13. The Companies and the OIG agree that if the Companies fail to complete the Divestiture by May 24, 2011, the OIG in its sole discretion may issue a notice of exclusion to Norian under section 1128(a)(3) of the Act, 42 U.S.C. § 1320a-7(a)(3), based on Norian’s agreement to plead guilty to the above-referenced charges in the Norian Criminal Action.

The Companies and the OIG also agree that if the Companies fail to complete the Divestiture by May 24, 2011, the OIG in its sole discretion may rescind the releases granted to Synthes in the Settlement Agreement and issue a notice of exclusion to Synthes under section 1128(b)(1) of the Act, 42 U.S.C. § 1320a-7(b)(1), based on Synthes’ agreement to plead guilty to the above-referenced charges in the Synthes Criminal Action.

If the OIG issues any notice of exclusion pursuant to this Divestiture Agreement based upon the Companies’ failure to complete the Divestiture, the Companies agree not to contest the exclusion of Norian or Synthes or the period of exclusion of Norian or Synthes, in any administrative forum, or state or federal court. With respect to any notice of exclusion issued by the OIG, the Companies agree to waive any and all notice and/or appeal rights provided under 42 C.F.R. Parts 1001 and 1005. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the relevant period of exclusion, Norian or Synthes may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3005. The exclusion shall go into effect 30 days after the date of the Companies’ receipt of the notice of exclusion.

14. Until the Companies have completed the Divestiture, the Companies shall operate Norian in a manner consistent with this Divestiture Agreement. The Companies shall not transfer any of the Norian Assets to any related entity, or to any subsidiary or affiliate of the Companies.
15. All notices, reports, and payments of stipulated penalties required by this Divestiture Agreement shall be submitted to the following:

OIG: Administrative and Civil Remedies Branch
      Office of Counsel to the Inspector General
      Office of Inspector General
      U.S. Department of Health and Human Services
      Cohen Building, Room 5527
      330 Independence Avenue, SW
      Washington, DC 20201
      Attention: Mary E. Riordan, Senior Counsel

Synthes and Norian:

Jeffrey B. Miller
Chief Compliance Officer
Synthes, Inc.
1302 Wrights Lane East
West Chester, PA 19380
Telephone: 610.719.5241
Facsimile: 610.719.5141

Unless otherwise specified, all notices, reports, and payments required by this Divestiture Agreement may be made by certified mail, overnight mail, hand delivery or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

16. This Divestiture Agreement shall be binding on the successors, assigns, and transferees of Synthes and Norian.

17. This Divestiture Agreement shall become final and binding on the date by which Synthes is obligated to pay the Settlement Amount as set forth in the Settlement Agreement. This Divestiture Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement.

18. This Divestiture Agreement shall terminate on the date on which the Companies complete the Divestiture. Notwithstanding such termination, all stipulated penalties imposed by the OIG prior to the termination of this Divestiture Agreement shall continue to be owed by the Companies unless and until fully paid. This Divestiture Agreement may be modified only with the prior written consent of the Parties to this Divestiture Agreement.
19. The undersigned Synthes and Norian signatories represent and warrant that they are authorized to execute this Divestiture Agreement on behalf of the Companies. The undersigned OIG signatory represents that he is signing his Divestiture Agreement in his official capacity and that he is authorized to execute this Divestiture Agreement.
On Behalf of Synthes, Inc. and Norian Corporation

Michel Orsinger  
President and Chief Executive Officer  
Synthes, Inc.

Date  
9/15/2010

Michel Orsinger  
President  
Norian Corporation

Date  
9/15/2010

Jonathan L. Diesenhaus  
Peter S. Spivack  
Hogan Lovells US LLP  
Counsel for Synthes and Norian

Date  
9/22/10
On Behalf of the Office of Inspector General
of the Department of Health and Human Services

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

Date 9/23/10