

18-02310-E

foiapa

From: Mark Edwards <medwards@biosciadvisors.com>
Sent: Friday, February 02, 2018 5:59 PM
To: foiapa
Subject: FOIA Request

RECEIVED

FEB 05 2018

Office of
FOI/ Services

I would like to request access to Exhibit 10.1 to the Form 8-K filed by Conceptus, Inc. on 3/1/2004. Confidential treatment was sought as to certain portions when initially filed with the Commission.

In the event that confidential treatment has not expired or has been extended, I further request that you send me the expiration date(s) from the relevant CT order(s) so I will know when I should resubmit my request.

I authorize up to \$61 in search and retrieval fees. Please send the exhibit(s) by PDF if possible.

Sincerely,

Mark

Mark G Edwards
Managing Director
Bioscience Advisors
2855 Mitchell Dr., Suite 103
Walnut Creek, CA 94598
medwards@biosciadvisors.com
925 954-1397



UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
STATION PLACE
100 F STREET, NE
WASHINGTON, DC 20549-2465

Office of FOIA Services

February 09, 2018

Mr. Mark G. Edwards
Bioscience Advisors
2855 Mitchell Dr., Suite 103
Walnut Creek, CA 94598

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-02310-E

Dear Mr. Edwards:

This letter is in response to your request, dated February 02, 2018 and received in this office on February 05, 2018, for information regarding Exhibit 10.1 to the Form 8-K filed by Conceptus, Inc. on March 01, 2004.

The search for responsive records has resulted in the retrieval of 41 pages that may be responsive to your request. They are being provided to you with this letter in their entirety at no cost.

If you have any questions, please contact me at Luetkenhausj@SEC.GOV or (202) 551-8352. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Aaron Taylor as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

A handwritten signature in black ink that reads "Jason Luetkenhaus".

Jason Luetkenhaus
Lead FOIA Research Specialist

Enclosures

Exhibit A
CONFIDENTIAL

EXCLUSIVE CO-PROMOTION AGREEMENT

THIS AGREEMENT is entered into as of October 30, 2003 (the "Effective Date") by and between **CONCEPTUS, INC.** a Delaware corporation, having an address of 1021 Howard Avenue, San Carlos, California 94070 and its permitted assigns hereunder (hereinafter referred to as "**CONCEPTUS**"), and **GYNECARE WORLDWIDE DIVISION OF ETHICON, INC.**, a New Jersey corporation, having an address of U.S. Route #22, Somerville, New Jersey 08876 and its permitted assigns hereunder (hereinafter referred to as "**GYNECARE**", together with **CONCEPTUS**, the "**Parties**" and each a "**Party**").

RECITALS

WHEREAS, **CONCEPTUS** is presently manufacturing and marketing the **CONCEPTUS Essure™** permanent birth control device (together with any Improvements thereto and next generation birth control devices, "**Essure**"); and

WHEREAS, **GYNECARE** is presently manufacturing and marketing the **GYNECARE Thermachoice®** uterine balloon therapy system (together with any Improvements thereto and next generation uterine balloon therapy systems, "**Thermachoice**" and together with **Essure**, the "**Product Lines**" and each a "**Product Line**"); and

WHEREAS, each of the Parties has a professional Sales Force (as hereinafter defined) that calls on customers in the Territory (as hereinafter defined) in order to promote their respective Product Lines; and

WHEREAS, **CONCEPTUS** desires to enhance its marketing of **Essure** in the Territory by enlisting the support and participation of the **GYNECARE** Sales Force as provided in this Agreement; and

WHEREAS, **GYNECARE** desires to enhance its marketing of **Thermachoice** in the Territory by enlisting the support and participation of the **CONCEPTUS** Sales Force as provided in this Agreement.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. DEFINITIONS

An "**Affiliate**" of a person or entity means any individual, sole proprietorship, firm, partnership, corporation, trust, joint venture or other entity, whether *de jure* or *de facto*, which, directly or indirectly, controls, is controlled by or is under common control with such person or entity. As used in this definition, "control" means the possession, directly or indirectly, of the

power to direct or cause the direction of the policies and management of a person or entity, whether by the ownership of stock, by contract or otherwise.

"Agreement" shall mean this Exclusive Co-Promotion Agreement.

"Calendar Quarter" shall mean each of the three (3) month periods commencing with January 1st, April 1st, July 1st and October 1st and ending, respectively, on the following March 31st, June 30th, September 30th and December 31st.

"Commercial Year" shall mean each twelve (12) month period starting on the Effective Date or an anniversary thereof, as applicable, during the Term of this Agreement.

"CONCEPTUS Patents" shall mean any patent or patent application in the Territory owned or controlled by CONCEPTUS during the Term of this Agreement relating to the Essure, method of manufacture or the use thereof.

"CONCEPTUS Trademarks" shall mean the trademarks set forth in Schedule A, such marks being owned and registered by CONCEPTUS or a CONCEPTUS Affiliate.

"Confidential Information" shall have the meaning provided in Section 12.1 hereof.

"Detail" (or **"Details"** and **"Detailing"**) means, with respect to either or both of the Product Lines, the activity undertaken by a sales representative during a face-to-face sales call on physicians or other health care professionals to provide information on the use, safety, effectiveness, warnings and other relevant characteristics of either or both of the Product Lines, in a fair and balanced manner consistent with the requirements of the FD&C Act, including, but not limited to, the regulations of 21 CFR Part 202, and using, as necessary or desirable, labeling or promotional materials, in an effort to increase use of the Product Lines.

"Effective Date" shall be the date shown at the top of page 1 of this Agreement.

"Essure Labeling" shall mean the labeling described in the FDA PMA submission for Essure, including but not limited to any required patient information, all labels and other written, printed or graphic matter upon any container, wrapper or any package insert or outsert utilized with or for the Essure created and developed by or for CONCEPTUS.

"FDA" shall mean the United States Department of Health and Human Services, Food and Drug Administration or any successor entity.

"FD&C Act" shall mean the United States Federal Food, Drug and Cosmetics Act, as amended from time to time.

"GYNECARE Patents" shall mean any patent or patent application in the Territory owned or controlled by GYNECARE during the Term of this Agreement relating to the Thermachoice device, method of manufacture or the use thereof.

"GYNECARE Trademarks" shall mean the trademarks set forth in Schedule B, such marks being owned and registered by GYNECARE or a GYNECARE Affiliate.

"GYNECARE Managed Strategic Customers" shall mean the list of customers attached hereto as Schedule C. Such list may be modified by the mutual written agreement of the Parties.

"Improvements" shall mean any adaptation, change, redesign, improvement, modification or development to a Product Line, the Raw Materials or the method or process of manufacture or process of manufacture or production of a Product Line.

"JMC" shall mean the Joint Management Committee formed by the parties to monitor all aspects of the Agreement, discuss issues and advise each Party prior to making certain decisions, including, developing marketing strategies, plans and budgets for co-marketing the Product Lines and coordinating marketing and sales activities and press releases relating to this Agreement, as further described in Section 2.2 hereof.

"Marketing Plan" shall have the meaning provided in Section 2.2 hereof.

"Net Sales" shall mean the revenue received by a Party, its Affiliates or sublicensees from the sale of its Product Line in the Territory to an independent third party less the following amounts: (i) discounts, including promotional, trade, volume or cash discounts, or rebates or coupon redemptions actually allowed or granted; (ii) credits or allowances actually granted upon claims or returns or pricing allowances, regardless of the party requesting the return; (iii) freight charges paid for customer delivery; (iv) sales, use, *ad valorem* or other taxes or other governmental charges levied on or measured by the invoiced amount whether absorbed by the billing or billed party and (v) allowances or credits to customers for damaged or defective goods.

"Promotion Expenses" shall mean those costs, excluding corporate and administrative overhead, marketing personnel resources, sales representative costs and incentives but including costs incurred by a Party or for its account which are specifically identifiable to the advertising, promotion and marketing of the Product Lines by the Parties in the Territory and related professional promotion and education (to the extent not performed by sales representatives), including, without limitation, television and electronic advertisements, advertorials and infomercials, print advertisements, direct mail, exhibitions at seminars and conferences, promotional samples, sales and promotional literature or other materials and market research, in each case consistent with the Marketing Plan and otherwise with the terms of this Agreement.

"Promotional Materials" shall mean all sales representative training materials and all written, printed, graphic, electronic, audio or video matter, including but not limited to journal advertisements, sales visual aids, leave items, reprints, direct mail, direct-to-consumer advertising, internet postings, broadcast advertisements, and sales reminder aids (for example, scratch pads, pens and other such items), in each case created by the Party or the Parties or on its or their behalf and used or intended for use by either or both of the Parties in connection with any promotion of either or both of the Product Lines hereunder.

"Raw Materials" shall mean the materials, components, and packaging required to manufacture and package a Product Line in accordance with the Specifications.

"Recommend" or "Recommendation" shall mean in the case of CONCEPTUS, CONCEPTUS's sales representatives providing marketing materials and recommending to potential customers the Thermachoice device exclusively over any other endometrial ablation products or procedures for use with the Essure Product Line and in the case of GYNECARE, GYNECARE's sales representatives providing marketing materials and recommending to potential customers the Essure device exclusively over any other permanent birth control products or procedures for use with the Thermachoice.

"Regulatory Approvals" shall mean any approvals (including, but not limited to, FDA approval, labeling, pricing and reimbursement approvals), product, biologic and/or establishment licenses, registrations or authorizations of any federal, state or local regulatory agency, department, bureau or other governmental entity, necessary for the commercial manufacture, use, storage, importation, export, transport or sale of a Product Line in the Territory.

"Sales Force" of a Party shall mean such Party's sales personnel calling on customers or potential customers of a Product Line or the Product Lines in the Territory.

"Specifications" shall mean the requirements with which a Product Line must conform as specified by 21 CFR §820.181 and device specifications, production process specifications, quality assurance procedures and specifications, packaging and labeling specifications, and installation, maintenance and servicing procedures and methods that are contained in the Device Master Record for the Product Line.

"Term of this Agreement" shall have the meaning provided in Section 8.1 hereof.

"Territory" shall mean the United States and its territories and possessions, including overseas United States military establishments.

"Thermachoice Labeling" shall mean the labeling described in the FDA PMA submission for Thermachoice, including but not limited to any required patient information, and all labels and other written, printed or graphic matter upon any container, wrapper or any package insert or outsert utilized with or for Thermachoice created and developed by GYNECARE.

"Third Party" shall mean any entity other than CONCEPTUS or GYNECARE.

2. MANAGEMENT

2.1 Management. The Parties shall establish a Joint Management Committee consisting of two (2) representatives of each Party which will meet at least twice a year, at mutually agreeable times and locations, to discuss and coordinate the Recommendation and/or Detailing of the Product Lines by the Parties' Sales Forces in the Territory and the strategies and programs that should be developed to maximize sales of the respective Product Lines. An alternate member designated by a Party may serve temporarily in the absence of a permanent member designated by such Party. No business shall be transacted at any meeting of the JMC unless a quorum of members is present at the time when the meeting proceeds to business. A quorum shall be at least two (2) members present in person or by their alternate, one (1) of whom must be a representative appointed by CONCEPTUS and one (1) of whom must be a

representative appointed by GYNECARE. [Subject to Section 2.2, actions by the JMC pursuant to this Agreement shall be taken through the mutual agreement of the representatives of both Parties on the JMC. Each Party shall designate one (1) of its representatives to the JMC as a Co-Chair of the JMC. Each Co-Chair of the JMC will be responsible for the agenda and the minutes of alternating meetings of the JMC and for speaking on behalf of his/her constituent for purposes of making decisions hereunder.] The JMC shall coordinate any announcement, news release, public statement, publication or presentation relating to this Agreement subject to Section 14.15. Each Party shall bear its own costs of participating in the JMC. If the JMC is unable to reach agreement on an issue, the respective Chief Executive Officers or Presidents of the Parties shall use commercially reasonable efforts to jointly resolve the deadlock

2.2 Marketing Plan. The JMC shall develop and approve a rolling two-year plan and periodic budgets for each Party for Recommendation of the Product Lines in the Territory, promotion and Detailing of the Essure Product Line in the Territory, and physician training for Essure, all as provided in this Agreement (the “Marketing Plan”). The Marketing Plan shall include a marketing, promotion and sales strategy for the co-marketing of the Product Lines by the Parties in the Territory, provided however, each Party shall have the ultimate decision making authority and have complete discretion over the deployment, marketing, promotion and sales strategy employed by its own Sales Force in connection with the Marketing Plan. The Marketing Plan shall include a budget for each Party for marketing, promotion, clinical and regulatory expenses relating to the Product Lines during the Term of this Agreement. Each Party agrees to provide for in its own internal, periodic budget, funds to meet its obligations under the mutually agreed upon JMC budget and to expend such funds as provided in the JMC budget, provided however, neither party shall be required to provide for or expend more than **[one million dollars (\$1,000,000)]** a year pursuant to the JMC budget, unless otherwise agreed to by the Parties. **[The Marketing Plan shall provide for the presence of the Essure Product Line in AAGL and ACOG conventions.]**

2.3 Meetings of the JMC.

(a) The JMC shall hold meetings at such times and places as shall be determined by the entire membership of the JMC (it being expected that meetings will alternate between the San Carlos, California offices of CONCEPTUS and the Somerville, New Jersey offices of GYNECARE), but in no event shall such meetings be held less frequently than twice a calendar year;

(b) The JMC may conduct meetings in person or by telephone or video conference or other means, provided that any decision made during a telephone conference meeting is evidenced in writing signed by one (1) of the members of the JMC from each Party;

(c) By mutual consent of the representatives of each Party, such consent not to be unreasonably withheld, either Party may invite other personnel of its organization to attend appropriate meetings of the JMC;

(d) The JMC shall keep minutes reflecting actions taken at meetings;

(e) The JMC may act without a meeting if prior to such action the JMC members agree regarding such action and a written consent thereto is signed by the Co-Chairs of the JMC; and

(f) The JMC may amend or expand upon the foregoing procedures for its internal operations by unanimous written consent.

2.4 Limitations of JMC Powers. The JMC shall not have any power to amend this Agreement or bind or incur liability on behalf of either Party hereto without such Party's express prior written authorization, and shall have only such powers as are specifically delegated to them hereunder.

2.5 Authority to Call Meetings. Notwithstanding the regular meeting schedule of the JMC, a meeting of the JMC may be called by either Party on ten (10) days written notice to the other, unless such notice is waived by the other Party. In the event of any meeting called pursuant to a notice under this Section 2.5, the Party calling the meeting shall provide with the notice an agenda for the meeting together with the information that such Party believes is relevant for the items to be discussed. Neither Party shall call more than two (2) additional meetings per Commercial Year for the JMC under this Section 2.5 without the other Party's consent. The meeting called under this Section 2.5 shall be held in Chicago, Illinois unless otherwise agreed to by the Parties.

3. SCOPE; FDA SUPPLEMENT APPROVAL AND CO-PROMOTION OF PRODUCT LINES

It is the objective of the Parties to (a) Recommend and/or Detail as provided below each other's Product Line to potential customers in the Territory after FDA approval of Supplement 1 and prior to the expiration or termination of this Agreement, and (b) provide for the training of preceptors and physicians in the Essure and Thermachoice Product Lines. To achieve this and other objectives, the Parties agree as follows:

3.1 Grant and [Exclusivity. During the Term of this Agreement and subject to the terms and conditions of this Agreement and subject to obtaining all necessary Regulatory Approvals, CONCEPTUS hereby grants to GYNECARE the exclusive right (with the exception of CONCEPTUS) to Recommend, Detail or promote Essure in the Territory for the concomitant use with an endometrial ablation device or use in a procedure preceding or following an endometrial ablation procedure and to use the CONCEPTUS Trademarks for such purpose. During the Term of this Agreement and subject to the terms and conditions of this Agreement and subject to obtaining all necessary Regulatory Approvals, GYNECARE hereby grants to CONCEPTUS the exclusive right (with the exception of GYNECARE) to Recommend or promote Thermachoice in the Territory for the concomitant use or use in a procedure preceding or following a procedure inserting a permanent birth control device and to use the GYNECARE Trademarks for such purpose. CONCEPTUS agrees that Thermachoice will be the only endometrial ablation device it will Recommend, Detail or promote in the Territory for the concomitant use or use in a procedure preceding or following an Essure procedure during the Term of this Agreement. GYNECARE agrees that Essure will be the only permanent birth control device it will Recommend, Detail or promote in the Territory for the concomitant use with

Thermachoice or use in a procedure preceding or following a Thermachoice procedure during the Term of this Agreement. For the purposes of this Agreement, the term, "permanent birth control device" shall not be deemed to include reversible or removable birth control devices such as intrauterine devices or clips or sutures. CONCEPTUS agrees that it will not collaborate, sponsor, advise or otherwise participate with a third party in any clinical trials involving any endometrial ablation device other than Thermachoice during the Term of this Agreement. Notwithstanding the foregoing, CONCEPTUS will have the right to manage and perform clinical trials or testing of other parties' endometrial ablation devices for internal use only or for addressing clinical, compatibility and/or regulatory needs, questions and/or requirements, but will not use, during the term of this Agreement, the findings, data or results for promotion, sales and marketing activities and GYNECARE will have the right to manage and perform clinical trials or testing of other parties' permanent birth control devices for internal use only or for addressing clinical, compatibility and/or regulatory needs, questions and/or requirements but will not use, during the term of this Agreement, the findings, data or results for promotion, sales and marketing activities. The foregoing grants of exclusivity shall be binding on each Party during the Term of this Agreement, but nothing in this Agreement shall be deemed to impose on a Party the duty to preclude or limit any Third Party, on its own initiative and without the assistance of such Party, from conducting clinical trials or from testing or using a Product Line or from marketing, selling or promoting a Product Line so long as a Party does not support or collaborate with such efforts. Nothing in this agreement shall be deemed to prevent or preclude either Party from entering into other agreements or other arrangements with Third Parties to promote or market their respective Product Lines provided such agreements or arrangements do not violate the exclusive rights set forth in this Section 3.1, provided however, subject to Section 12.4, CONCEPTUS shall not promote or market its Product Line or an endometrial ablation device itself or through a Third Party to the GYNECARE Managed Strategic Customers unless agreed to in writing by GYNECARE. CONCEPTUS recognizes and acknowledges that GYNECARE and its Affiliates have been, and will continue to be, actively involved in the design, development and marketing of products, devices and accessories in field of birth control. CONCEPTUS understands and agrees that GYNECARE (subject to the terms of this Agreement) and its Affiliates do or may design, develop, market, sell and distribute products which compete directly with Essure, and may continue to market, sell and distribute these and other competing products throughout the term of this Agreement.]

3.2 FDA Supplement Approval. The Parties shall cooperate in the activities and be responsible for the expenses necessary to obtain FDA approval for the use of Thermachoice with Essure by supplementing the Essure Pre-Market Approval Application ("PMA") as set forth on Schedule 3.2. The FDA approval shall be sought in two (2) separate PMA Supplements, with Supplement 1 seeking approval for the claim that Thermachoice can be safely and effectively used with Essure, but noting the absence of clinical data on expulsion and placement rates ("Supplement 1") and with Supplement 2 seeking approval for removing the note regarding expulsion and placement rates from the claim of safe and effective use based on additional clinical studies ("Supplement 2"). To the extent expenses are shared, the Parties shall jointly own, with full rights of use, the clinical and bench testing data relating to the activities necessary to obtain FDA approval for the use of Thermachoice with Essure and Supplement 1 and Supplement 2. CONCEPTUS shall prepare the submissions to the FDA and GYNECARE shall

have the right to review and comment on the submission, but CONCEPTUS shall conduct all dialogue and contact with the FDA in connection with the supplemental PMA submissions. The JMC shall first attempt to resolve any disputes between the Parties resulting from any submissions or cost over-runs or delays

3.3 Preceptors and Physician Training.

(a) [GYNECARE shall, upon execution of this Agreement, identify for training by CONCEPTUS twenty (20) preceptors (the "CONCEPTUS Preceptors") capable of teaching physicians to use Essure and willing to act as CONCEPTUS Preceptors. The CONCEPTUS Preceptors shall be proposed by GYNECARE and approved by CONCEPTUS.] CONCEPTUS shall be responsible for contracting with and training the CONCEPTUS Preceptors. CONCEPTUS, at its sole expense, shall be responsible for paying all the costs of the training of the Preceptors, including providing the personnel, equipment and samples to teach and certify the CONCEPTUS Preceptors to teach and certify other physicians in the proper use of the Essure device. CONCEPTUS, upon not less than thirty (30) days written notice, will notify GYNECARE of the times, dates and locations on the training sessions at which the CONCEPTUS Preceptors will be trained. CONCEPTUS will use all reasonable commercial efforts to contract for and appropriately train the CONCEPTUS Preceptors.

(b) [During the Term of this Agreement, GYNECARE shall be responsible for identifying physicians who meet the FDA requirements to use hysteroscopic devices and use its commercially reasonable efforts to arrange for such physicians to be trained and certified in the Essure system by the CONCEPTUS Preceptors. GYNECARE shall use commercially reasonable efforts to identify and make available for training sufficient physicians so that not less than five hundred (500) of such physicians are trained and certified (in order to be considered "certified", a physician shall have successfully completed a didactic course provided by CONCEPTUS and performed at least three (3) Essure procedures) in Essure in each of the two (2) successive twelve (12) month periods beginning on the FDA approval of Supplement 1. The Parties will cooperate in arranging and administering the physician training with respect to each of their respective Product Lines.] CONCEPTUS will contract for as independent contractors and be responsible for the payment of the costs of the CONCEPTUS Preceptors, which payment shall not exceed [three thousand dollars (\$3,000)] per full day and [one thousand five hundred dollars (\$1,500.00)] per half day of physician training and certification. [Such payments to the CONCEPTUS Preceptors will be administered by and through GYNECARE.] CONCEPTUS will provide Essure demo devices as needed for each physician to be trained by the CONCEPTUS Preceptors. [CONCEPTUS shall pay GYNECARE two thousand dollars (\$2,000.00) for each physician trained and certified by the CONCEPTUS Preceptors in a given calendar month. CONCEPTUS shall make such monthly payments to GYNECARE within thirty (30) days of the end of the calendar month in which such physician training and certification is completed. The Parties agree that the payments by CONCEPTUS to GYNECARE of two thousand dollars (\$2,000.00) per each physician trained and certified will cover all of CONCEPTUS's obligations to pay for the costs of the physician training, including the costs of the CONCEPTUS Preceptors for training and certifying the physicians in Essure. If GYNECARE or CONCEPTUS desires to train more than five hundred (500) physicians in a twelve (12) month period, it shall notify the other Party and the other Party shall

determine if it is willing to continue the training of such additional physicians at the costs set forth in this Agreement.] CONCEPTUS shall have the right to review and monitor the physician training conducted by the CONCEPTUS Preceptors and to recommend any modifications to training to promote consistency and quality or lower cost.

3.4 Promotion Efforts. After Supplement 1 has been approved by the FDA and prior to the expiration or termination of this Agreement and subject to the terms and conditions of this Agreement, GYNECARE shall deploy its Sales Force to Recommend and Detail the Essure Product Line and CONCEPTUS shall deploy its Sales Force to Recommend the Thermachoice Product Line in accordance with the Marketing Plan. Each of the Parties acknowledges that the other Party's commitments regarding JMC funds under Section 2.2 and training under Section 3.3, and the payments made to it under this Agreement under Article 4 constitute complete and adequate consideration for its entering into this Agreement and shall constitute complete satisfaction of any duty, whether express or implied, which could be imposed upon the other Party to commercially exploit its rights under this Agreement or to Recommend or Detail the other Party's Product Line and are accepted by each Party in lieu of any other minimum promotional efforts obligation on the part of the other Party, including without limitation, with respect to the promotion of the other Party's Product Line. Each Party acknowledges, understands and agrees, that it shall not challenge in any subsequent claim or action any decision or action regarding the commercial exploitation of the Products made or taken by any director, officer, employee or individual acting as agent of the other Party or its Affiliates in what such individual subjectively believes to be in its (or its Affiliate's) best interests, and that they are not required to take into account the interests of the other Party, unless such decision or action constitutes a material breach by it of any of its obligations under this Agreement. Except as otherwise expressly agreed to in the Marketing Plan, all business decisions, including, without limitation, the sale, price and promotion of a Party's Product Line under this Agreement, shall be within the sole discretion of such Party.

3.5 Mutual Obligations.

(a) Each of the Parties shall supervise, train and maintain such competent and qualified sales representatives as may be required to perform the obligations as provided in this Agreement and in the Marketing Plan. GYNECARE shall make available for CONCEPTUS to train each of GYNECARE's sales representatives who calls on potential customers in the Territory so that they are qualified to Detail Essure to physicians and CONCEPTUS shall have the right to administer a reasonable proficiency examination to each such GYNECARE sales representative. CONCEPTUS shall provide sufficient CONCEPTUS personnel, equipment, samples and training for the GYNECARE sales representatives calling on the potential customers in the Territory to be appropriately trained. This training is expected to be one (1) to two (2) days in total for all GYNECARE sales representatives. **[The number of GYNECARE sales representatives calling on potential customers in the Territory and that CONCEPTUS would be required to train is currently estimated at seventy-six (76).]** GYNECARE will use its commercially reasonable efforts to arrange for its sales representatives to be trained by CONCEPTUS at mutually convenient times, locations and numbers (but not less than **[fifteen (15)]** sales representatives per session, unless approved by CONCEPTUS). Each Party shall be responsible for the costs and expenses of its respective employees, including travel and accommodations, in performing or attending such training. Each Party shall be responsible for

the compliance of its Sales Force with all relevant terms of this Agreement and the Marketing Plan.

(b) Each of the Parties shall in all material respects conform its practices and procedures relating to its obligations under this Agreement for the Recommendation, and/or Detailing and promotion of the Product Lines in the Territory to all applicable laws, regulations and guidelines, including the FD&C Act, the Federal Health Care Programs Anti-Kickback Law, 42 U.S.C. 1320a-7b(b), the Health Industry Manufacturers Association ("HIMA") and the American Medical Association ("AMA") Guidelines on Gifts to Physicians from Industry (the "AMA Guidelines"), as the same may be amended from time to time, and shall promptly notify the other Party of and provide the other Party with a copy of any correspondence or other reports with respect to the Recommendation Detailing or promotion of the Product Lines submitted to or received from the U.S. Department of Health and Human Services or its components (including the FDA and the Office of the Inspector General), Health Canada, HIMA or the AMA relating to such laws, regulations and guidelines.

(c) At one Party's reasonable request, the other Party shall provide copies of any written communications disseminated by it generally to its Sales Force promoting the Product Lines in the Territory relating to the Marketing Plan and the joint marketing strategy for the Product Lines other than compensation, salary or benefit plans or information.

(d) In connection with the Recommendation, Detailing or promotion of the Product Lines hereunder, no Party shall make any statement, representation or warranty, oral or written, concerning the Product Lines that is inconsistent with, or contrary to, the Thermachoice Labeling, the Essure Labeling, the Promotional Materials or the Marketing Plan.

(e) Each of the Parties shall give prompt written notice to the other Party of the date on which its Sales Force commences promoting the other Party's Product Line in the Territory.

(f) Each of the Parties shall use commercially reasonable efforts to promptly refer but shall in no way be responsible for soliciting orders for the other Party's Product Lines to the other Party.

(g) During the term hereof and for a period of six (6) months after the expiration or termination of this Agreement, neither Party shall solicit for employment or employ any officer or employee of the other Party of whom it first became aware as a direct result of this Agreement; provided that this provision shall not prevent either Party from employing any such persons who contact it on their own initiative (without any actions by such Party to encourage such contact) or respond to general solicitations of employment not specifically directed towards employees of the other Party.

3.6 Proprietary Rights in the Product Lines and Promotional Materials. (a) CONCEPTUS retains and shall retain all proprietary rights and proprietary interests in Essure until the point of sale and in all Promotional Materials relating thereto. GYNECARE will neither have nor represent that it has any control or proprietary or property interests in Essure Promotional Materials solely developed or created by or on behalf of CONCEPTUS. Nothing

contained herein shall be deemed to grant GYNECARE, either expressly or by implication, a license or other right or interest in any patent, trademark, copyright or other similar property of CONCEPTUS except as may be necessary for GYNECARE to Recommend and Detail Essure as expressly provided for in this Agreement and the Marketing Plan.

(b) GYNECARE retains and shall retain all proprietary rights and proprietary interests in Thermachoice until the point of sale and in all Promotional Materials relating thereto. CONCEPTUS will neither have nor represent that it has any control or proprietary or property interests in Thermachoice Promotional Materials solely developed or created by or on behalf of GYNECARE. Nothing contained herein shall be deemed to grant CONCEPTUS, either expressly or by implication, a license or other right or interest in any patent, trademark, copyright or other similar property of GYNECARE except as may be necessary for CONCEPTUS to Recommend Thermachoice as expressly provided for in this Agreement and the Marketing Plan.

3.7 Promotional Materials.

(a) During the Term of this Agreement, CONCEPTUS shall create or co-create and develop with GYNECARE such Promotional Materials solely relating to Essure as are determined by the JMC to be necessary or appropriate under the Marketing Plan for distribution in the Territory, it being understood that the costs thereof shall be included in Promotion Expenses hereunder. CONCEPTUS shall provide GYNECARE with such Promotional Materials, in amounts which the Parties jointly determine are reasonable under the terms of the Marketing Plan. CONCEPTUS shall be responsible for complying with all regulatory requirements in the creation of such Promotional Materials and complying with any applicable government filing requirements.

(b) During the Term of this Agreement, GYNECARE shall create or co-create and develop with CONCEPTUS such Promotional Materials solely relating to Thermachoice as are determined by the JMC to be necessary or appropriate under the Marketing Plan for distribution of the Product Lines in the Territory, it being understood that the costs thereof shall be included in Promotion Expenses hereunder. GYNECARE shall provide CONCEPTUS with such Promotional Materials, in amounts which the Parties jointly determine are reasonable under the terms of the Marketing Plan. GYNECARE shall be responsible for complying with all regulatory requirements in the creation of such promotional materials and complying with any applicable government filing requirements.

(c) Other than with the advice and prior written consent of CONCEPTUS, GYNECARE shall not create or develop sales, promotional or other similar materials relating to the Essure for distribution to Third Parties.

(d) Other than with the advice and prior written consent of GYNECARE, CONCEPTUS shall not create or develop sales, promotional or other similar materials relating to Thermachoice for distribution to Third Parties.

(e) All co-promotional materials, sales materials or other similar materials and materials using a Party's trademarks, trade names and/or trade dress shall be reviewed by such Party's Copy Review/Sign-Off Committee prior to release for use by the other Party.

(f) Notwithstanding anything to the contrary herein, neither Party shall be required to distribute any Promotional Materials prepared after the Effective Date which it believes in good faith are inaccurate or misleading. The Parties shall distribute Promotional Materials of the type identified in this Section 3.7 in accordance with the terms of this Agreement and the Marketing Plan. Except as specifically permitted by this Section 3.7, neither Party shall distribute or have distributed any materials bearing the name of the other without the prior written approval of the other.

(g) CONCEPTUS shall own all right, title and interest in and to the Promotional Materials relating solely to Essure, including all copyrights appurtenant thereto but excluding any rights in or to the GYNECARE trademark. CONCEPTUS hereby grants to GYNECARE the limited, revocable right, during the Term of this Agreement, to use Promotional Materials generated pursuant to the Marketing Plan solely in connection with its promotion of Essure hereunder in accordance with the terms of this Agreement and the Marketing Plan.

(h) GYNECARE shall own all right, title and interest in and to the Promotional Materials relating solely to Thermachoice, including all copyrights appurtenant thereto but excluding any rights in or to the CONCEPTUS trademark. GYNECARE hereby grants to CONCEPTUS the limited, revocable right, during the Term of this Agreement, to use Promotional Materials generated pursuant to the Marketing Plan solely in connection with its promotion of Thermachoice hereunder in accordance with the terms of this Agreement and the Marketing Plan.

(i) The Parties shall jointly own all right, title and interest in and to the Promotional Materials relating to both Product Lines, including all copyrights appurtenant thereto but excluding any rights in or to the other Party's trademarks, trade names and/or trade dress.

3.8 Sales and Distribution; Recalls. Each Party shall have the sole right and responsibility, and shall bear all costs related thereto, to take such actions with respect to its Product Line in its sole discretion in accordance with legal requirements to maintain the authorization and/or ability to market its Product in the Territory and to establish the terms and conditions for sale of its Product Line, including, without limitation, the following: manufacturing and distributing, sales, providing customer support in a timely, comprehensive manner, including handling medical queries, all interactions that are technical or clinical in nature and which require more than a basic knowledge of its Product Line and its characteristics and performing other functions consistent with consumer practice and the Marketing Plan with respect to its Product Line, responding to product and medical complaints relating to its Product Line, quality assurance, technical support, returns, voluntary and regulatory recalls of product, Regulatory Approvals and compliance, and communications with regulatory agencies. Notwithstanding the foregoing, each Party may communicate directly with regulatory agencies regarding its own marketing activities. Each Party shall use its commercially reasonable efforts to assist and cooperate with the other Party as may be necessary or required in any recall or market withdrawal of the other Party's Product Line and any and all reasonable and documented costs and expenses incurred by the assisting Party shall be reimbursed by the other Party, except to the extent such recall or market withdrawal was the result of the failure of assisting Party to comply with its obligations under this Agreement.

3.9 Regulatory Submissions. Each Party, either directly or through a designated Third Party, shall prepare and maintain at its own expense all technical files and submissions necessary to obtain and maintain all necessary approvals or concurrences required to sell its Product Line in the Territory.

3.10 Customer Complaints. In accordance with the system of the FDA and all other applicable laws, rules and regulations, each Party shall maintain responsibility for (i) managing all customer complaints or product inquiries relating to its Product Line, (ii) reporting to government agencies and (iii) all corrective action where appropriate. Each Party agrees to provide all necessary and required support to fulfill all domestic laws and regulations with regards to customer complaints, and vigilance reporting relating to its Product Line.

4. PAYMENT TERMS.

4.1 GYNECARE Payments to CONCEPTUS. In consideration for CONCEPTUS granting GYNECARE the exclusive right to Recommend and Detail Essure in the Territory, GYNECARE shall pay CONCEPTUS [forty thousand dollars (\$40,000.00)] within thirty (30) days of the execution of this Agreement and [one hundred forty thousand dollars (\$140,000.00)]-within thirty (30) days of receipt of the FDA approval of Supplement 1.

4.2 CONCEPTUS Payments to GYNECARE. CONCEPTUS shall pay to GYNECARE [eighteen percent (18%)] of Net Sales of Essure sold to the GYNECARE Managed Strategic Customers in the Territory during the previous Calendar Quarter commencing with Net Sales occurring on or after the date of the FDA approval of Supplement 1 and continuing through the Term of the this Agreement (as amended from time to time by the

mutual written agreement of the Parties). Within sixty (60) days after the end of each full or partial Calendar Quarter during the Term of this Agreement, CONCEPTUS shall deliver to GYNECARE a true and accurate report of Net Sales sold by it, its Affiliates and distributors to the GYNECARE Managed Strategic Customers during such Calendar Quarter in the Territory, accompanied by all payments due under this Section 4.2 for the period covered by such report. Such report shall also include the information reasonably necessary for the GYNECARE to calculate Net Sales to the GYNECARE Managed Strategic Customers of the Essure product.

4.3 Method of Payment. Any payments due to a Party under this Agreement shall be made in U.S. dollars by wire transfer to a bank and account designated in writing by such Party.

5. TRADEMARKS

5.1 Essure Labeling; Ownership of CONCEPTUS Trademarks. No CONCEPTUS products distributed by CONCEPTUS in the Territory will bear the GYNECARE Trademarks without the prior written approval of GYNECARE. The Essure Product Line shall be distributed under the CONCEPTUS Trademarks and ownership and use of the CONCEPTUS Trademarks shall be governed by the following provisions:

(a) CONCEPTUS or an Affiliate of CONCEPTUS shall retain the ownership of the entire right, title and interest in and to the CONCEPTUS Trademarks.

(b) CONCEPTUS shall, at its cost and expense, maintain the CONCEPTUS Trademarks in the Territory. GYNECARE agrees that in using CONCEPTUS Trademarks in its activities under this Agreement it will not represent in any way that it has any right or title to the ownership of the CONCEPTUS Trademarks or the registration thereof, and the registration will remain in the ownership of CONCEPTUS. Such CONCEPTUS Trademarks will be used by GYNECARE on behalf of, and in the interest of CONCEPTUS, and GYNECARE will first obtain the written approval of CONCEPTUS of the form and manner in which the CONCEPTUS Trademarks will be used upon, in connection with, or in relation to materials other than Promotion Materials as may be permitted by this Agreement.

(c) GYNECARE recognizes CONCEPTUS's title in and to the CONCEPTUS Trademarks and to the registration thereof, and will not, at any time, do or authorize any act or thing that will in any way violate or impair the rights of CONCEPTUS in and to the CONCEPTUS Trademarks and the registration thereof. Wherever CONCEPTUS's trademarks or tradenames are used, e.g., on any package, label or advertisement, the first or most prominent use shall always be accompanied by a legend acceptable to CONCEPTUS indicating that Essure™ is a trademark of CONCEPTUS and the CONCEPTUS trademarks and tradenames are licensed to GYNECARE by CONCEPTUS.

(d) GYNECARE shall, upon CONCEPTUS's request, and at CONCEPTUS's expense, reasonably assist CONCEPTUS in any action reasonably necessary or desirable to protect the CONCEPTUS Trademarks used or proposed to be used hereunder. GYNECARE shall as soon as practicable notify CONCEPTUS of any apparent infringement by a Third Party of any of the CONCEPTUS Trademarks.

(e) If CONCEPTUS reasonably determines it is necessary to discontinue the use of a CONCEPTUS Trademark, GYNECARE, after discussion and upon notice and demand from CONCEPTUS, shall immediately discontinue the use of any of the CONCEPTUS Trademarks. In the event of such discontinuance, CONCEPTUS shall select a new CONCEPTUS Trademark to be used with the Essure and shall promptly notify GYNECARE in writing of such selection.

5.2 Thermachoice Labeling; Ownership of GYNECARE Trademarks No GYNECARE products distributed by GYNECARE in the Territory will bear the CONCEPTUS Trademarks without the prior written approval of CONCEPTUS. The Thermachoice Product Line shall be distributed under the GYNECARE Trademarks and ownership and use of the GYNECARE Trademarks shall be governed by the following provisions:

(a) GYNECARE or an Affiliate of GYNECARE shall retain the ownership of the entire right, title and interest in and to the GYNECARE Trademarks.

(b) GYNECARE shall, at its cost and expense, maintain the GYNECARE Trademarks in the Territory. CONCEPTUS agrees that in using GYNECARE Trademarks in its activities under this Agreement it will not represent in any way that it has any right or title to the ownership of the GYNECARE Trademarks or the registration thereof, and the registration will remain in the ownership of GYNECARE. Such GYNECARE Trademarks will be used by CONCEPTUS on behalf of and in the interest of, GYNECARE, and CONCEPTUS will first obtain the written approval of GYNECARE of the form and manner in which the GYNECARE Trademarks will be used upon, in connection with, or in relation to materials other than Promotion Materials as may be permitted by this Agreement.

(c) CONCEPTUS recognizes GYNECARE's title in and to the GYNECARE Trademarks and to the registration thereof, and will not, at any time, do or authorize any act or thing that will in any way violate or impair the rights of GYNECARE in and to the GYNECARE Trademarks and the registration thereof. Wherever GYNECARE's trademarks or tradenames are used, e.g., on any package, label or advertisement, the first or most prominent use shall always be accompanied by a legend acceptable to GYNECARE indicating that GYNECARE Thermachoice® is a registered trademark of GYNECARE and the GYNECARE trademarks and tradenames are licensed to CONCEPTUS by GYNECARE.

(d) CONCEPTUS shall, upon GYNECARE's request, and at GYNECARE's expense, reasonably assist GYNECARE in any action reasonably necessary or desirable to protect the GYNECARE Trademarks used or proposed to be used hereunder. CONCEPTUS shall as soon as practicable notify GYNECARE of any apparent infringement by a Third Party of any of the GYNECARE Trademarks.

(e) If GYNECARE reasonably determines it is necessary to discontinue the use of a GYNECARE Trademark, CONCEPTUS, after discussion and upon notice and demand from GYNECARE, shall immediately discontinue the use of any of the GYNECARE Trademarks. In event of such discontinuance, GYNECARE shall select a new GYNECARE Trademark to be used with Thermachoice and shall promptly notify CONCEPTUS in writing of such selection.

6. OPERATING PROCEDURES

6.1 Exchange of Information.

(a) Each Party shall provide the other Party with such information relating to its own Product Line and training as the other Party may reasonably require and request during the Term of this Agreement in order to support the other Party's effort for the Product Lines as provided in the Marketing Plan.

(b) During the Term of this Agreement and subject to any other provision of this Agreement, each Party will provide the other Party with all information relevant to the other Party's performance obligation for their respective Product Lines under this Agreement and the Marketing Plan within the Territory within a reasonable time after such information becomes known to the Party, provided such information is not received from an independent Third Party under a secrecy obligation. Specifically, the Sales Force of each Party shall receive the such information at substantially the same time with respect to the Product Lines.

(c) Each Party shall promptly report to the other Party all information necessary to permit such other Party to make timely reports as required by any governmental regulatory agency in the Territory regarding the Product Lines and shall promptly report within twenty-four (24) hours any customer complaints or findings associated (i) with the joint use of the Product Lines or (ii) with the use of the Product Lines that may suggest hazards, contraindications, side effects or precautions pertinent to the safety and/or performance of either of the Product Lines or require the alteration of Recommendation or Detailing activities by a Party's Sales Force. Each Party agrees to promptly notify the other Party of any FDA audit, or any audit by any other regulatory body, of its facilities used for the manufacture of its Product Line, or any request for information from the FDA, or other regulatory body, related to the manufacture of its Product Lines, as soon as practicable after the Party receives notice of such audit or request. All such communications shall be held in confidence by the Parties pursuant and subject to the terms of Article 12. Should either Party learn of any hazard that is severe, serious or unexpected, concerning the Product Lines, such hazard data shall be communicated to the other Party immediately in writing or confirmed in writing if such immediate communication is non-written. Notwithstanding anything in this Agreement to the contrary, each Party shall be responsible for complying with all applicable laws regarding the reporting of such hazards to governmental authorities with respect to its own Product Line. The aforementioned information shall be addressed as follows:

in the case of
GYNECARE to:

**[GYNECARE Worldwide division of Ethicon, Inc.
U.S. Route #22
Somerville, NJ 08876
Attention: Mr. Gregory Jones,
Director, Regulatory Affairs
Phone: 908-218-2481
Fax: 908-218-2734]**

in the case of

CONCEPTUS to: [CONCEPTUS, Inc.
1021 Howard Ave
San Carlos, CA 92706
Attention: Cindy Domecus
Phone: 650-628-4783
Fax: 650-802-2890]

or to such other address as may thereafter be provided by either Party.

(d) Each Party shall respond to medical questions or inquiries relating to their respective Product Line received by the other Party or at its sole discretion, provide to the other Party, if requested, information to enable the other Party to respond to medical questions or inquiries relating to its Product Line. All such information shall be held in confidence by the receiving Party pursuant and subject to the terms of Article 12 hereof. Each Party shall use commercially reasonable efforts to keep such information current. The Parties shall coordinate responses to anticipated inquiries and questions.

(e) CONCEPTUS shall set up appropriate sales tracking systems to separately track sales at each GYNECARE Managed Strategic Customer account in the Territory where Essure is purchased and maintain appropriate records thereof.

6.2 Product Changes. Each Party shall notify the other Party as soon as possible, but in any event prior to the changed Product Line being sold, of any change in the form, fit or function, or any component or material which would affect the form, fit or function of its respective Product Line, which the other Party needs to know to perform its obligations under this Agreement or the Marketing Plan lawfully, properly and accurately.

6.3 Product Recalls. If either Party believes that a recall or market withdrawal of either of the Product Lines is necessary, such Party shall notify the other Party immediately upon its determination and both Parties shall cooperate to allow such recall or market withdrawal to occur under the direction of the Party whose Product Line is to be recalled (as set forth in Section 3.8). The Party whose Product Line is to be recalled shall have the final authority with respect to such matters, which authority shall be exercised reasonably and in good faith.

6.4 Regulatory Obligations. Each Party shall be solely responsible for all activities in connection with the Regulatory Approvals for their respective Product Line in the Territory, including without limitation communicating and preparing and filing all reports (including without limitation medical device reports) with the FDA. Each Party agrees to cooperate with the other Party as requested, at the requesting Party's expense, in preparing and filing all such reports. Each Party shall pay all fees associated with obtaining and maintaining the Regulatory Approvals relating to its Product Line including, without limitation, any establishment license fees of such Party or Third Parties which must be paid with respect to facilities used in the manufacture of such Product Line.

6.5 Provision of Information. Each Party shall provide access to information and data that would support or undermine making the regulatory claim of the concomitant use or use in a

preceding or follow-up procedure and/or marketing of the Product Lines at no cost to the other Party upon such Party's reasonable request.

7. ACCOUNTING PROCEDURE

CONCEPTUS shall keep complete and accurate records in connection with the payments provided for under this Agreement and the information described in Article 4 hereof. CONCEPTUS shall submit to GYNECARE unaudited quarterly sales records and reports relating to Essure sales during the Term to the GYNECARE Managed Strategic Accounts (broken down by account) promptly, but in no case, more than sixty (60) days after such Calendar Quarter. GYNECARE shall have the right to nominate an independent firm of certified public or chartered accountants who shall have access no more than once each year during the Term and once after Termination of this Agreement to the books and records of CONCEPTUS relating to the Essure sales during the Term to the GYNECARE Managed Strategic Accounts during reasonable business hours for the purpose of verifying any amounts payable, or information provided relating to amounts payable, under this Agreement. The fees and expenses of the accountants performing such verification shall be borne by GYNECARE, unless, in the case of payments, CONCEPTUS's records are inadequate to perform such verification or any amount actually due exceeds five percent (5%) or more of amounts reported in which case CONCEPTUS shall bear the costs and expenses of such verification.

8. TERM OF AGREEMENT AND TERMINATION

8.1 Term. The term of this agreement ("**Term of this Agreement**") shall commence on the Effective Date and continue until the second (2nd) anniversary of the date the FDA approves Supplement 1 or until this Agreement is otherwise terminated or renewed in accordance with its terms.

8.2 Reversion of Rights Upon Termination or Expiration. Upon any termination or expiry of this Agreement pursuant to this Article 8, for whatever reason, then, in any such case, all of GYNECARE's rights hereunder regarding the Essure and the use of the CONCEPTUS Trademarks and the Promotional Materials in the Territory shall automatically terminate and automatically revert to CONCEPTUS, effective as of such time, and GYNECARE shall have no further rights thereto (except as set forth in Section 8.3 below) and all of CONCEPTUS's rights hereunder regarding Thermachoice and the use of the GYNECARE Trademarks and the Promotional Materials in the Territory shall automatically terminate and automatically revert to GYNECARE, effective as of such time, and CONCEPTUS shall have no further rights thereto (except as set forth in Section 8.3 below).

8.3 Effect of Termination. Termination of this Agreement in whole or in part shall not relieve CONCEPTUS of any amounts owed to GYNECARE, nor shall it relieve the Parties of their obligations with respect to the Product Lines distributed in the Territory during the Term of this Agreement, or with respect to limiting disclosure and use of Confidential Information. Notwithstanding anything to the contrary herein, if GYNECARE terminates this Agreement pursuant to Section 8.5, 8.6(iii) or 8.6(iv), the provisions of Section 4.2 shall survive for two (2) years after the termination of this Agreement. Upon termination or expiration hereof, GYNECARE shall promptly return to CONCEPTUS all Promotional Materials and samples of

Essure then in the possession of GYNECARE, its Affiliates and any of their respective Sales Forces and CONCEPTUS shall promptly return to GYNECARE all Promotional Materials and samples of Thermachoice then in the possession of CONCEPTUS, its Affiliates and any of their respective Sales Forces.

8.4 Termination. (a) CONCEPTUS shall have the right to terminate this Agreement if GYNECARE fails to have available for training the [twenty (20)] CONCEPTUS Preceptors within the time provided in Schedule 3.2, unless such failure is caused by CONCEPTUS, or fails to identify and make available for training at least [five hundred (500)] physicians of the total number of physicians to be certified for use in the Essure Product Line in any twelve (12) month period as required in Paragraph 3.3. GYNECARE shall have no other liability to CONCEPTUS for such failure.

(b) GYNECARE shall have the right to terminate the Agreement immediately upon notice to CONCEPTUS if a court rejects the [Settlement and License Agreement between Ovion, Inc., William S. Tremulis and Jeffrey P. Callister] and CONCEPTUS or if the settlement agreement between [Ovion Inc.] and CONCEPTUS expires or is terminated for any reason. In the event of a termination by GYNECARE under this Section 8.4(b), CONCEPTUS shall reimburse GYNECARE for any and all of the expenses it has undertaken pursuant to this Agreement, including but not limited to, the payments made by GYNECARE under Section 4.1 hereof, the training of physicians, preceptors and sales representatives in Essure and its efforts and expenses associated with seeking and obtaining Supplement 1 and Supplement 2.

(c) GYNECARE shall have the right to terminate the Agreement upon written notice if CONCEPTUS fails to obtain FDA approval for Supplement 1 on or prior to [August 30, 2004.]

(d) GYNECARE shall have the right to terminate the Agreement upon written notice if GYNECARE or CONCEPTUS is unsuccessful in gaining procedure adoption from the trained and certified physicians due to negative clinical experience or if the concomitant procedure is unfavorably reimbursed. Unsuccessful procedure adoption shall be defined as an average of one (1) or fewer procedures involving the concomitant use of Thermachoice and Essure performed per month per physicians trained and certified in Essure under this Agreement for any four (4) month period during the term of this Agreement. Unfavorable reimbursement shall be defined as device reimbursement for the concomitant use which is less than the average selling price of each of the two (2) Product Lines when used separately.

8.5 Termination for Insolvency. Either Party shall have the right to terminate this Agreement immediately effective upon written notice to the other Party in the event the non-notifying Party becomes insolvent or makes an assignment for the benefit of creditors, or in the event bankruptcy or insolvency proceedings are instituted against the non-notifying Party or on the non-notifying Party's behalf.

8.6 Other Termination. Each Party shall have the right to terminate this Agreement immediately effective upon written notice to the other Party in the event that (i) the manufacture, use or sale of the other Party's Product Line has been determined by a court of competent jurisdiction to infringe the proprietary intellectual property rights of a Third Party or (ii) its activities hereunder are determined by an appropriate regulatory agency or court to be in

violation of any applicable law, rule or regulation and such violation cannot be remedied by reasonable modifications of this Agreement or (iii) the other Party is in material breach of Section 13, or (iv) the other Party is in material breach of any other representation, warranty, covenant, agreement or obligation under this Agreement and fails to cure such breach within twenty (20) days of a written notice from the non-breaching Party, or if a cure cannot reasonably be effective in such time, fails to commence in such time or fails to diligently pursue a cure to completion or (v) the other Party's Product Line has been subject to a recall or market withdrawal.

8.7 Exercise of Right to Terminate. The use by either Party hereto of a termination right provided for under this Agreement shall not give rise to any liability or the payment of damages or any other form of compensation or relief to the other Party with respect thereto.

8.8 Damages; Relief. Subject to Section 8.7 above and 14.9 below, termination of this Agreement shall not preclude either Party from claiming any other damages, compensation or relief that it may be entitled to upon such termination. For the avoidance of doubt, any claim for damages, compensation or relief under this Section 8.8 shall be brought under Section 14.9.

8.9 Renewal Term. Subject to the Parties rights to terminate this Agreement as provided herein, the Parties may mutually agree to extend the Term of this Agreement for one (1) or more successive additional twelve (12) month renewal terms. Nothing in this Agreement shall be deemed to prevent Party from declining to extend the Term or from requiring modification the terms of the Agreement as a condition to any extension.

9. REPRESENTATIONS AND WARRANTIES.

9.1 Mutual Representations and Warranties. Each of the Parties hereby represents and warrants to the other Party as follows:

(a) such Party (i) is a corporation duly organized, validly existing and in good standing under the laws of the state in which it is incorporated, (ii) has the corporate power and authority and the legal right to own and operate its property and assets, to lease the property and assets it operates under lease, and to carry on its business as it is now being conducted, and (iii) is in compliance with all requirements of applicable law, except to the extent that any noncompliance would not have a material adverse effect on the properties, business, financial or other condition of such Party and would not materially adversely affect such Party's ability to perform its obligations under this Agreement;

(b) this Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms, and the execution, delivery and performance of the Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it. Each Party expressly represents and warrants that it has the full power and authority to enter into this Agreement and to carry out the obligations contemplated hereby;

(c) it has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement;

(d) the manufacture, use, importation, offer for sale or sale of its Product Line as contemplated hereunder does not infringe any Third Party's intellectual property right;

(e) the use of its trademarks, trade names or trade dress pursuant to the terms of this Agreement and the Marketing Plan does not and will not infringe the rights of any third party;

(f) that with respect to all regulatory filings to obtain Regulatory Approvals, the data and information in such Party's submissions are and shall be free from fraud and/or material falsity, that the Regulatory Approvals have not been and will not be obtained either through bribery or the payment of illegal gratuities, that the data and information in such Party's submissions are and shall be accurate and reliable for purposes of supporting approval of the submissions, and that the Regulatory Approvals shall be obtained without illegal or unethical behavior of any kind;

(g) it has obtained, to the extent it is required to do so, all necessary governmental approvals required in connection with the manufacture, sale and marketing of its Product Line in the Territory, including but not limited to PMA approval from the FDA; no governmental authority has threatened any action to revoke any governmental approval for its Product Line, and that the submissions which it made to the FDA were made in good faith and contained accurate and complete data and information regarding its Product Line as required by applicable laws, rules and regulations; it shall maintain for the term of this Agreement or any extension thereof all PMA approval for its Product Line; furthermore, it shall file, and maintain at its own cost for its Product Line, all appropriate registrations with the FDA and similar regulatory authorities in the Territory countries which have the authority to approve the sale of its Product Line for use in humans; and

(h) during the term of this Agreement or any extension thereof, its Product Line shall be of merchantable quality, fit for the purpose intended by this Agreement and free from defects in design, material and workmanship and manufactured and delivered in accordance with the terms of this Agreement, all applicable present and future statutes, laws, and regulations, including without limitation, good manufacturing practices ("GMP"), QSRs and ISO 9000 requirements and that during the term of this Agreement or any extension thereof its Product Line will not be adulterated or misbranded at the time of delivery to Third Parties within the meaning of the FD&C Act.

9.2 Performance by Affiliates and Third Parties. The Parties recognize that each Party may perform some or all of its obligations under this Agreement through its Affiliates provided, however, that each Party shall remain responsible for the performance by its Affiliates and shall cause such parties to comply with the provisions of this Agreement in connection with such performance. Each Party hereby expressly waives any requirement that the other Party exhaust any right, power or remedy, or proceed against an Affiliate for any obligation or performance hereunder prior to proceeding directly against such Party.

10. OWNERSHIP OF INTELLECTUAL PROPERTY AND PATENT RIGHTS.

10.1 Intellectual Property. CONCEPTUS shall have sole ownership of all right, title and interest in the Essure, CONCEPTUS Patents, CONCEPTUS Trademarks and Essure Labeling. GYNECARE shall have sole ownership of all right, title and interest in Thermachoice, GYNECARE Patents, GYNECARE Trademarks and Thermachoice Labeling.

10.2 Patent Prosecution. CONCEPTUS shall have the sole right, but not the obligation, to file applications for, prosecute and maintain the CONCEPTUS Patents. CONCEPTUS shall not be obligated to disclose to GYNECARE any prosecution information relating to the CONCEPTUS Patents. GYNECARE shall have the sole right, but not the obligation, to file applications for, prosecute and maintain the GYNECARE Patents. GYNECARE shall not be obligated to disclose to CONCEPTUS any prosecution information relating to the GYNECARE Patents.

10.3 Enforcement Rights.

(a) **Notification of Infringement.** (i) If GYNECARE learns of any misappropriation of any CONCEPTUS Patents, CONCEPTUS Trademarks or Information (the "CONCEPTUS Product Rights"), or any infringement or threatened infringement by a Third Party of the CONCEPTUS Patents in the Territory, GYNECARE shall promptly notify CONCEPTUS and shall provide CONCEPTUS with all available evidence of such misappropriation or infringement.

(ii) If CONCEPTUS learns of any misappropriation of any GYNECARE Patents, GYNECARE Trademarks or Information (the "GYNECARE Product Rights"), or any infringement or threatened infringement by a Third Party of the GYNECARE Patents in the Territory, CONCEPTUS shall promptly notify GYNECARE and shall provide GYNECARE with all available evidence of such misappropriation or infringement.

(b) **Enforcement of Patents and Product Rights in the Territory.** (i) CONCEPTUS shall have the sole right, but not the obligation, to institute, prosecute and control at its own expense any action or proceeding with respect to infringement of any CONCEPTUS Patents or any misappropriation of the CONCEPTUS Product Rights in the Territory, by counsel of its own choice. GYNECARE shall cooperate with CONCEPTUS, at CONCEPTUS's expense, in any such action or proceeding brought by CONCEPTUS against a Third Party. Any amounts recovered by CONCEPTUS pursuant to this subsection (b) shall belong exclusively to CONCEPTUS.

(ii) GYNECARE shall have the sole right, but not the obligation, to institute, prosecute and control at its own expense any action or proceeding with respect to infringement of any GYNECARE Patents or any misappropriation of the GYNECARE Product Rights in the Territory, by counsel of its own choice. CONCEPTUS shall cooperate with GYNECARE, at GYNECARE's expense, in any such action or proceeding brought by GYNECARE against a Third Party. Any amounts recovered by GYNECARE pursuant to this subsection (b) shall belong exclusively to GYNECARE.

(c) **Settlement with a Third Party.** CONCEPTUS shall have the sole right to control settlement of actions relating to the CONCEPTUS Product Rights and GYNECARE shall have the sole right to control settlement of actions relating to the GYNECARE Product Rights.

11. INDEMNIFICATION; INSURANCE

11.1 Indemnification by CONCEPTUS. Except as set forth in Section 11.2 hereof, and except to the extent caused by GYNECARE's or its Affiliates' or agent's negligent, reckless or willful acts or omissions, CONCEPTUS shall indemnify, defend and hold GYNECARE and its Affiliates and their directors, officers, employees and, agents harmless from and against any liabilities, damages, costs or expenses, including reasonable attorneys' fees (collectively, "**Liabilities**"), (a) which arise out of, relate to or result from the breach by CONCEPTUS of any of its representations, warranties, covenants or other agreements contained within this Agreement; (b) which arise from any claim, lawsuit, alleged damage, or other action by a Third Party (a "Claim"), which Claim is caused by or is alleged to have been caused by the design, manufacture, use or sale of Essure during the Term of this Agreement and/or the training provided by CONCEPTUS to the CONCEPTUS Preceptors or the training provided by the CONCEPTUS Preceptors to physicians under Section 3.3 hereof; (c) which are attributable to statements or representations by CONCEPTUS, its employees, or its agents, that are inconsistent with, or contrary to, the Essure Labeling, the Thermachoice Labeling, or Promotional Materials; (d) which, in the case of any trademark infringement claim, lawsuit or other action, result solely from GYNECARE's proper use of CONCEPTUS Trademarks in accordance with the terms of this Agreement; or (e) which arise from a claim, lawsuit or other action by a Third Party that the manufacture, use or sale of the Essure infringes the patent, copyright or other intellectual property right of a Third Party, except in each case (a) – (e) to the extent such Claim results from GYNECARE's negligence or willful misconduct.

11.2 Indemnification by GYNECARE. Except as set forth in Section 11.1 hereof, and except to the extent caused by CONCEPTUS's or its Affiliates' or agent's negligent, reckless or willful acts or omissions, GYNECARE shall indemnify, defend and hold CONCEPTUS and its Affiliates and their directors, officers, employees and, agents harmless from and against any Liabilities, (a) which arise out of, relate to or result from the breach by GYNECARE of any of its representations, warranties, covenants or other agreements contained within this Agreement; (b) which arise from any Claim, which Claim is caused by or is alleged to have been caused by the design, manufacture, use or sale of Thermachoice during the Term of this Agreement; (c) which are attributable to statements or representations by GYNECARE, its employees, or its agents, that are inconsistent with, or contrary to, the Thermachoice Labeling, the Essure Labeling, or Promotional Materials; (d) which, in the case of any trademark infringement claim, lawsuit or other action, result solely from CONCEPTUS's proper use of GYNECARE Trademarks in accordance with the terms of this Agreement; or (e) which arise from a claim, lawsuit or other action by a Third Party that the manufacture, use or sale of the Thermachoice infringes the patent, copyright or other intellectual property right of a Third Party, except in each case (a) – (e) to the extent such Claim results from CONCEPTUS's negligence or willful misconduct.

11.3 Indemnification Procedure. In the event that any Party seeks to assert a right to indemnification pursuant to Sections 11.1 or 11.2, as appropriate, such Party shall promptly provide the other Party with written notice of the claim for indemnity and full information concerning the claim. The indemnified Party shall have the right select its own counsel and control the defense. The indemnified Party shall be entitled to reimbursement of its costs and expenses, including attorneys' fees, related to the indemnified matter from the indemnifying Party on a quarterly basis, which reimbursement shall be due within thirty (30) days after receipt of an itemized invoice from the indemnified Party. No Party shall settle or compromise any claim, action or matter with respect to which indemnification has been sought without the other Party's prior written consent, which consent shall not be unreasonably withheld. The indemnified Party shall keep the indemnifying Party informed with respect to actions taken by it with regard to the matter. Failure of any Party to give prompt notice of a claim for indemnification shall not affect its right to indemnification except to the extent that the indemnifying Party shall have been prejudiced as a result of such failure, and except that the indemnifying Party shall not be liable for any expenses incurred during the period in which the indemnified Party failed to give notice.

11.4 Insurance. Each Party, at its own expense, shall maintain comprehensive general/product liability insurance with at least the minimum coverages set forth on Schedule 11.4. Each Party's insurance policy shall require at least thirty (30) days' notice to the other Party prior to cancellation or material change in the policy. Each Party shall provide that its insurance will include the other Party as an additional insured party. Such notices of cancellation or material change shall be given in accordance with Section 14.7 hereof.

12. CONFIDENTIALITY

12.1 Confidential Information. The Parties hereto recognize that non-public and/or confidential technical, scientific and other data and information relating to the Product Lines, as well as information relating to a Party's technology, know-how, processes, patent applications, trade secrets, inventions ideas, formula or test data relating to any research project, work in process, future development, engineering, manufacturing, regulatory, marketing, servicing, financing or personnel matters, present or future products, sales, suppliers, clients, customers, employees, investors or business, whether in oral, written, graphic or electronic form (hereinafter referred to collectively as "**Confidential Information**"), disclosed by one Party or its Affiliates to the other or its Affiliates hereunder, is of considerable value to the disclosing Party and is to be considered highly confidential. The Parties agree that the terms and conditions of this Agreement and the Marketing Plan shall be deemed to be the Confidential Information of each Party and disclosure of such will be limited to members of the JMC and those persons in the respective organizations that have a need to know. The Parties further agree that, subject to the rights in Section 12.4, the GYNECARE Managed Strategic Customers shall be deemed to be the Confidential Information of GYNECARE only. References to the receiving Party in this Article 12 refer to CONCEPTUS and its Affiliates, if any, on the one hand, and GYNECARE and its Affiliates, on the other hand, as the case may be.

The Parties will, through the JMC, mutually agree on the Information which is to presented to the doctors relating to the Detailing of the Product Lines. This Information is not considered to be Confidential Information. Each of the Parties will limit the dissemination of

Confidential Information of the other Party throughout its organization to those with a need to know.

The amount of Confidential Information to be disclosed shall be completely within the discretion of the disclosing Party. To the extent practical, Confidential Information shall be disclosed in tangible form and marked as "Confidential." Information disclosed in an intangible form, such as orally or by visual inspection, shall not be considered Confidential Information unless the disclosing Party confirms in writing the fact and general nature of the disclosure within one (1) month after it is made.

Notwithstanding anything in this Agreement to the contrary, neither Party shall at any time provide the other Party with any technical information or data, including but not limited to, technical information relating to their respective Product Lines, including but not limited to, information and data relating to formulation, analytical methods, unless such technical information is already in the public domain.

12.2 Obligation to Maintain Confidentiality of Information. Each Party hereby covenants not to use Confidential Information of the other Party received by it or its Affiliates, or any part thereof, outside the Territory and not to use such Confidential Information of the other Party, or any part thereof, except as expressly authorized or pursuant to the terms of this Agreement. In addition, each receiving Party shall keep all Confidential Information of the other Party received by it or its Affiliates in complete confidence and shall not disclose or make such Confidential Information of the other Party, or any part thereof, available to Third Parties except:

(a) For the purpose of obtaining and maintaining any necessary Regulatory Approvals for the sale of Product Lines under this Agreement in the Territory;

(b) To the extent that the disclosing Party may agree in writing, such agreement shall be obtained prior to such disclosure by receiving Party;

(c) To the extent that such Confidential Information can be demonstrated by written records or other credible evidence to be known to the receiving Party or its Affiliates at the time of receipt thereof from the disclosing Party or becomes known to the receiving party other than from the disclosing Party or their authorized employees or agents (provided that such source is not prohibited from disclosing such portions to the Recipient by any contractual, fiduciary or other legal obligation); and

(d) To the extent that such Confidential Information is or may become a matter of public knowledge by virtue of the action of a party other than the receiving Party or its Affiliates.

12.3 Information Disclosed Prior to Effective Date. Section 12.2 above shall also apply to the Information disclosed by a Party or its Affiliates to the other Party or its Affiliates prior to the Effective Date of this Agreement.

12.4 Survival of Obligation. Obligations under this Article 12 shall be in force during the Term of this Agreement and any extension hereof and shall survive expiration or termination (as the case may be) of this Agreement for a period of five (5) years. Notwithstanding the

foregoing, neither Party shall be prohibited or restricted in any marketing or selling of its Product Lines to any party, including any party that is one of the GYNECARE Strategic Managed Customers, after the termination of this Agreement, if such marketing and selling is part of an effort targeted at a general market of which some or all of the GYNECARE Managed Strategic Customers are a part, provided however, if GYNECARE terminates this Agreement pursuant to Section 8.5, 8.6(iii) or 8.6(iv) the provisions of Section 4.2 shall survive for two (2) years after the termination of this Agreement.

13. COMPLIANCE

13.1 Compliance with Certain Laws. Each Party agrees to comply with the applicable provisions of any Federal or state law and all executive orders, rules and regulations issued thereunder, whether now or hereafter in force, including Executive Order 11246, as amended, Chapter 60 of Title 41 of the Code of Federal Regulations, as amended, prohibiting discrimination against any employee or applicant for employment because of race, color, religion, sex or national origin; Section 60-741.1 of Chapter 60 of 41 Code of Federal Regulations, as amended, prohibiting discrimination against any employee or applicant for employment because of physical or mental handicap; Section 60.250.4 of Chapter 60 of 41 Code of Federal Regulations, as amended, providing for the employment of disabled veterans and veterans of the Vietnam era; Chapter 1 of Title 48 of the Code of Federal Regulations, as Amended, Federal Acquisition Regulations; Sections 6, 7 and 12 of the Fair Labor Standards Act, as amended, and the regulations and orders of the United States Department of Labor promulgated in connection therewith; and any provisions, representations or agreements required thereby to be included in this Agreement are hereby incorporated by reference. If either Product Line is ordered by Distributor under U.S. government contracts, each Party agrees that all applicable federal statutes and regulations applying to the other Party as a contractor are accepted and binding upon it insofar as it may be deemed a subcontractor.

13.2 Compliance with Policy on the Employment of Young Persons. Each Party and its officers have read and understand the Johnson & Johnson Policy on the Employment of Young Persons (the "Policy") attached as Schedule 13.2 hereto. In the manufacture and supply of its Product Line hereunder, each Party shall employ young persons only as permitted by the Policy. Each Party shall permit representatives of the other Party to enter its premises at any reasonable time, and each Party shall ensure that representatives of the other Party shall be permitted to enter the premises of any subcontractor involved in the manufacture or supply of its Product Line (or component thereof) at any reasonable time, in order to inspect relevant employment, health and safety records and to observe the manufacturing process. Each Party (and its subcontractors) shall maintain the records necessary to demonstrate compliance with the Policy and shall provide to the other Party a written certification of such compliance annually during the term of this Agreement. If a Party shall fail to comply with this Section, then the other Party shall have the right to terminate this Agreement forthwith, effective upon ten (10) days' prior written notice, and without payment of any penalty or termination fee, if the other Party has not cured such breach within such time.

13.3 Environment, Safety and Industrial Hygiene. Each Party hereby certifies that it is in compliance with all environmental, safety and industrial hygiene matters related to its activities under this Agreement. With respect to all environmental, safety and industrial hygiene

matters related to a Party's activities under this Agreement, each Party shall (a) comply with all applicable laws and regulations issued by national, state and local authorities, (b) inform the other Party promptly of any significant adverse event (e.g., fires, explosions, accidental discharges) and (c) inform the other promptly of any allegations or findings of violations of applicable laws or regulations. If a Party fails to meet any of these conditions, the other Party may terminate this Agreement upon ten (10) days prior written notice to the other Party if the other Party has not cured such breach within such time.

14. GENERAL PROVISIONS

14.1 Integration/Modification. This Agreement by and between the Parties hereto, is both a final expression of the Parties' agreement and a complete and exclusive statement with respect to all of its terms. The Schedules and other documents and agreements referred to or contemplated by in this Agreement, including the Marketing Plan, are incorporated herein and made a part of this Agreement by this reference. This Agreement supersedes all prior and contemporaneous agreements and communications, whether oral, written or otherwise, concerning any and all matters contained herein. No rights or licenses with respect to CONCEPTUS Patents, CONCEPTUS Trademarks, Essure Labeling, Promotional Materials relating to Essure, GYNECARE Patents, GYNECARE Trademarks, Thermachoice Labeling, Promotional Materials relating to Thermachoice are granted or deemed granted hereunder or in connection herewith, other than those rights expressly granted in this Agreement. No trade customs, courses of dealing or courses of performance by the Parties shall be relevant to modify, supplement or explain any term(s) used in this Agreement. This Agreement may only be modified or supplemented in a writing expressly stated for such purpose and signed by the Parties to this Agreement.

14.2 Relationship Between the Parties. The Parties have no ownership interest in the other and their relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship between the Parties. Neither Party is a legal representative of the other Party, and neither Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever.

14.3 Non-Waiver. The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance.

14.4 Assignment. This Agreement is binding upon and inures to the benefit of the Parties to it, and to their permitted successors and assigns. No Party may assign or delegate any or all of its rights or obligations under this Agreement without the prior written consent of the Party to this Agreement, which consent shall not be unreasonably withheld provided the proposed assignee is fully capable of performing the assignor's obligations under this Agreement. This Agreement may be transferred to any party which acquires all or substantially all of the ownership or assets of a Party, whether by acquisition or merger, and nothing in this

Agreement shall be deemed to prevent or preclude a Party from entering into and consummating such a sale or merger or from acquiring any other entity; provided, however, that in such event either Party shall have the right, at its sole discretion, to terminate this Agreement thirty (30) days after providing written notice of termination or upon the closing of the transaction, whichever date is later. Any assignment or delegation, or any other transfer or change of control by sale, acquisition, merger, or otherwise, or attempt at the same, other than as permitted hereunder, made in the absence of such prior written consent shall be void and without effect. If a Party assigns this Agreement to an Affiliate, such Party will also promptly inform the other Party and guarantee the performance by its Affiliate of all of such Party's obligations under the Agreement.

14.5 No Third Party Beneficiaries. This Agreement is neither expressly nor impliedly made for the benefit of any party other than those executing it.

14.6 Severability. If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable or illegal by a court of competent jurisdiction, such adjudication shall not affect or impair, in whole or in part, the validity, enforceability or legality of any remaining portions of this Agreement. All remaining portions shall remain in full force and effect as if the original Agreement had been executed without the invalidated, unenforceable or illegal part.

14.7 Notices. Any notice to be given under this Agreement must be in writing and delivered either in person, by any method of mail (postage prepaid) requiring return receipt, or by overnight courier or facsimile confirmed thereafter by any of the foregoing, to the Party to be notified at its address(es) given below, or at any address such Party has previously designated by prior written notice to the other. Notice shall be deemed sufficiently given for all purposes upon the earlier of: (a) the date of actual receipt; (b) if mailed, three (3) calendar days after the date of postmark; or (c) if delivered by overnight courier, the next business day the overnight courier regularly makes deliveries.

If to GYNECARE, notices must be addressed to:

**[GYNECARE Worldwide division of Ethicon, Inc.
U.S Route #22
Somerville, NJ 08876
Attention: Vice President, Marketing
Telephone: 908-218-2104
Facsimile: 908-218-3602]**

With a copy to:

**[Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Attention: Office of General Counsel
Telephone: 732-524-0400
Facsimile: 732-524-2788]**

In the case of notices given pursuant to Section 11.4:

**[GYNECARE Worldwide division of Ethicon, Inc.
U.S Route #22
Somerville, NJ 08876
Attention: Vice President, Marketing
Telephone: 908-218-2104
Facsimile: 908-218-3602]**

With a copy to:

**[Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Attention: Risk Management Department
Telephone: 732-524-0400
Facsimile: 732-524-3225]**

If to CONCEPTUS, notices must be addressed to:

**[CONCEPTUS, Inc.
1021 Howard Avenue
San Carlos, CA 94070
Attention: Mark Sieczkarek
Telephone: 650-628-4795
Facsimile: 650-628-4748]**

With a copy to:

**[CONCEPTUS, Inc.
1021 Howard Avenue
San Carlos, CA 94070
Attention: Glen Furuta
Telephone: 650-628-4781
Facsimile: 650-628-4748]**

In the case of notices given pursuant to Section 11.4:

**[CONCEPTUS, Inc.
1021 Howard Avenue
San Carlos, CA 94070
Attention: Glen Furuta
Telephone: 650-628-4795
Facsimile: 650-628-4748]**

14.8 Force Majeure. Except for the obligation to make payment when due, each Party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement by reason of any event beyond such Party's reasonable control including but not limited to Acts of God, fire, flood, explosion, earthquake, or other natural forces, war, civil unrest, accident, destruction or other casualty, any lack or failure of transportation facilities, any lack or failure of supply of raw materials, any strike or labor disturbance, or any other event similar to those enumerated above. Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the Party has not caused such event(s) to occur. Notice of a Party's failure or delay in performance due to force majeure must be given to the other Party within ten (10) calendar days after its occurrence. All delivery dates under this Agreement that have been affected by force majeure shall be tolled for the duration of such force majeure. In no event shall any Party be required to prevent or settle any labor disturbance or dispute. Notwithstanding the foregoing, should the event(s) of force majeure suffered by a Party extend beyond a three (3) month period, the other Party may then terminate this Agreement by written notice to the non-performing Party, with the consequences of such termination as set forth in Sections 8.2 and 8.3.

14.9 Arbitration. Any controversy or claim arising out of or relating to this Agreement or the validity, inducement, or breach thereof, but excluding Third Party claims ("Disputes") shall be first mediated by the Parties in an effort to reach a mutual resolution. Such mediation shall be before a mediator jointly agreed upon or, if such agreement cannot be reached, by a mediator selected from three mediators proposed by the Chicago office of the American Arbitration Association, with each party having the right to reject one of the candidates. Each Party agrees to mediate in good faith for not less than eight (8) hours. If the Dispute is not resolved by mediation, it shall be settled by arbitration before a single arbitrator in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("AAA") then pertaining, except where those rules conflict with this provision, in which case this provision controls. If the Parties cannot agree on an arbitrator, the AAA office holding the arbitration shall provide three qualified candidates and each Party shall have the right to reject one candidate. Any such arbitration decision may be enforced by any court of competent jurisdiction. The arbitrator shall be an attorney who has at least fifteen (15) years of experience with a law firm or corporate law department of over twenty-five (25) lawyers or was a judge of a court of general jurisdiction. The arbitration shall be held in [Chicago, Illinois] and in rendering the award the arbitrator must apply the substantive law of [Illinois] (except where that law conflicts with this clause), except that the interpretation and enforcement of this arbitration provision shall be governed by the Federal Arbitration Act. The arbitrator shall be neutral, independent, disinterested, impartial and shall abide by The Code of Ethics for Arbitrators in Commercial Disputes approved by the AAA. Within forty-five (45) days of initiation of arbitration, the Parties shall reach agreement upon and thereafter follow procedures assuring that the arbitration will be concluded and the award rendered within no more than eight (8) months from selection of the arbitrator. Failing such agreement, the AAA will design and the Parties will follow procedures that meet such a time schedule. Each Party has the right before or, if the arbitrator cannot hear the matter within an acceptable period, during the arbitration to seek and obtain from the appropriate court provisional remedies such as attachment, preliminary injunction, replevin, etc., to avoid irreparable harm, maintain the status quo or preserve the subject matter of the arbitration. THE ARBITRATOR SHALL NOT AWARD ANY PARTY PUNITIVE, EXEMPLARY, MULTIPLIED OR CONSEQUENTIAL DAMAGES INCLUDING

LOSS OF PROFITS, AND EACH PARTY HEREBY IRREVOCABLY WAIVES ANY RIGHT TO SEEK SUCH DAMAGES.

EACH PARTY HERETO WAIVES ITS RIGHT TO TRIAL OF ANY DISPUTE BY JURY.

EACH PARTY HERETO WAIVES ANY CLAIM TO PUNITIVE, EXEMPLARY, MULTIPLIED OR CONSEQUENTIAL DAMAGES INCLUDING LOSS OF PROFITS FROM THE OTHER.

14.10 Legal Fees. If either Party to this Agreement resorts to any legal action or arbitration in connection with this Agreement, the prevailing Party shall be entitled to recover reasonable fees of attorneys and other professionals in addition to all court costs and arbitrator's fees which that Party may incur as a result.

14.11 Governing Law. Notwithstanding its place of execution or performance, this Agreement shall be governed by and construed in accordance with the laws of the [State of Illinois], irrespective of its laws regarding choice or conflict of laws.

14.12 Interpretation

(a) **Captions & Headings.** The captions and headings of clauses contained in this Agreement preceding the text of the articles, sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction.

(b) **Singular & Plural.** All references in this Agreement to the singular shall include the plural where applicable, and all references to gender shall include both genders and the neuter.

(c) **Articles, Sections & Subsections.** Unless otherwise specified, references in this Agreement to any article shall include all sections, subsections, and paragraphs in such article; references in this Agreement to any section shall include all subsections and paragraphs in such sections; and references in this Agreement to any subsection shall include all paragraphs in such subsection.

(d) **Days.** All references to days in this Agreement shall mean calendar days, unless otherwise specified.

(e) **Ambiguities.** Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist.

14.13 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument.

14.14 Further Assurances. Each Party to this Agreement shall, at its own expense, furnish, execute, and deliver all documents and take all actions as may reasonably be required to effect the terms and purposes of this Agreement.

14.15 Public Disclosure. The Parties hereto covenant and agree that, except as provided for herein below and as expressly specified in the Marketing Plan, each will not from and after the date hereof make, issue or release any public announcement, press release, statement or acknowledgment of the existence of, or reveal publicly the terms, conditions and status of, the transactions contemplated herein, without the prior written consent of the other Party as to the content and time of release of and the media in which such statement or announcement is to be made; provided, however, that in the case of announcements, statements, acknowledgments or revelations which either party is required by law to make, issue or release, the making, issuing or releasing of any such announcement, statement, acknowledgment or revelation by the party so required to do so by law shall not constitute a breach of this Agreement if such party shall have given not less than five (5) business days prior notice to the other Party if possible, and in any case shall have obtained the other Party's prior written approval of such announcement, statement, acknowledgment or revelation. Except as permitted by this Agreement, neither Party shall not use the name of the other Party or any of its Affiliates for advertising or promotional purposes without the prior written consent of the other Party. In furtherance of the foregoing, neither Party shall originate any publicity or other announcement, written or oral, whether to the public, the press, the trade, either Party's customers or otherwise, relating to this Agreement or the existence of an arrangement between the parties, without the prior written approval of the other Party.

IN WITNESS WHEREOF, the Parties, intending to be bound hereby, have executed this Agreement as of the date first written above.

CONCEPTUS, INC.

**ETHICON, INC. BY ITS
WORLDWIDE DIVISION GYNECARE**

By: _____

By: _____

Name: Mark Sieczkarek

Name: _____

Title: President & CEO

Title: _____

SCHEDULE A
CONCEPTUS TRADEMARKS

Essure

Conceptus

SCHEDULE B
GYNECARE TRADEMARKS

GYNECARE

Thermachoice®

SCHEDULE 3.2

PRE-MARKETING APPROVAL AND EXPENSE

<u>[PMA and Marketing Activities]</u>	<u>Responsible Party</u>	<u>Projected Cost</u>	<u>Responsibility for Expenses</u>	<u>Timing</u>
<ul style="list-style-type: none"> ○ ▪ PMA Supplement #1 w/Thermachoice and Essure Filed for following Claim (or similar FDA wording): <p>"Bench and clinical studies have been performed to demonstrate that endometrial ablation of the uterus with the Thermachoice System can be safely and effectively performed with the Essure micro-inserts in place. However, there is little clinical data regarding the effect of the ablation on Essure micro-insert expulsion rates. In addition, there is little clinical data regarding Essure micro-insert placement or expulsion rates when the ablation is performed immediately prior to Essure placement."</p> 			CPTS	Dec. 1, '03
<ul style="list-style-type: none"> ▪ PMA Supplement #1 Approval 			CPTS	Mar. 15, 04
<ul style="list-style-type: none"> ▪ Commence Placement rate study in sterilization candidates (200 patients) 			Joint	Jan. 04
<ul style="list-style-type: none"> ▪ PMA Supplement 2 Filed 			CPTS	TBD
<ul style="list-style-type: none"> ▪ PMA Supplement 2 Approval with the following Claim: (or similar FDA wording): <p>"Bench and clinical studies have been performed to demonstrate that endometrial ablation of the uterus with the Thermachoice System can be safely and effectively performed with the Essure micro-inserts in place. There remains little clinical data regarding the safety or effectiveness of other technologies for thermal endometrial ablation in women with the Essure micro-inserts."</p> 			CPTS	TBD
<ul style="list-style-type: none"> • User Preference Study with Thermachoice to be tied to clinicals in PMA Supplement 2 and Essure 			(Optional)	
<ul style="list-style-type: none"> ▪ Versascope and Essure <ul style="list-style-type: none"> ○ Start Validation ○ Complete Validation 			Joint	Nov. 15, 03 Jan. 04
<ul style="list-style-type: none"> ▪ Train the Trainer (20 CONCEPTUS Preceptors) <ul style="list-style-type: none"> ○ Identify and agree on physicians ○ Train 10 CONCEPTUS Preceptors Q '04 - ○ Train 10 CONCEPTUS Preceptors Q '04] 			GYNECARE	
			Joint	4 th Q '03
			CPTS	4 th Q '04 - 1 st
			CPTS	1 st Q '04 - 2 nd

SCHEDULE C

GYNECARE MANAGED STRATEGIC CUSTOMERS

[TO BE REDACTED]

SCHEDULE 11.4

Insurance Coverages

[1.0 Definitions

Party includes each Party, its contractors, subcontractors and consultants.

2.0 Insurance Requirements

Each Party shall procure and maintain, at all times, and at its own expense, during the term of the Agreement the types of insurance(s) specified below. For product liability/completed operations, insurance coverage will remain in effect for at least five (5) years after termination of the Agreement.

Commercial General Liability

Each Party shall maintain Commercial General Liability Insurance and Product Liability Insurance with limits of not less than \$10,000,000 each occurrence and \$10,000,000 annual aggregate. Such insurance shall include worldwide coverage including coverage for USA jurisdiction claims and occurrences. Any exclusions or amendments to the policy form must be disclosed to the other Party. If any coverage is written on a claims-made basis, the retroactive date, if any, shall precede the commencement date of the performance date of this agreement. In addition, the policyholder shall purchase a five (5) year extended reporting period if the policy or policies are cancelled or not renewed and not replace by another claims-made policy with the same (or earlier) retroactive date at the time of termination of the agreement. Each Party's policy shall include the other Party, its subsidiaries, and its directors, officers and employees, as Additional Named Insureds. Each Party's policy shall waive any rights of subrogation against the other Party its subsidiaries, and its directors, officers and employees. Each Party shall supply the other Party with the above proof of insurance and forms as required upon the signing of this Agreement, but a Party's failure to demand such proof or forms shall not waive the rights to such coverage as specified herein.

Miscellaneous

All insurance policies shall provide for thirty (30) days' prior written notice to the other Party of cancellation or nonrenewal.

Certificates of insurance for all required coverages shall be provided to the other Party prior to commencement of any work on the project. Failure by a

Party to request such copies or documents shall not waive any rights to coverage under this agreement].

SCHEDULE 13.2

JOHNSON & JOHNSON POLICY

ON THE EMPLOYMENT OF YOUNG PERSONS

[This policy applies to the employment of persons under the age of 18 ("young persons") in the manufacture of any product, or any component of a product, by or for Johnson & Johnson or any of its affiliates worldwide.]

Age, Health & Safety

No person under the age of 16 shall be employed. No person between the ages of 16 and 18 shall be employed unless such employment is in compliance with the health, safety and morals provisions of the International Labour Organization Convention 138 Concerning Minimum Age ("ILO Convention 138"), a summary of which is attached hereto.

Hours

No young person shall be required to work more than 48 hours of regularly scheduled time and 12 hours of overtime per week nor more than six days per week.

Laws & Regulations

No young person shall be employed unless such employment is in compliance with all applicable laws and regulations concerning age, hours, compensation, health and safety.

External Manufacturers

No manufacturer shall be engaged to manufacture any product, or any component of a product, for Johnson & Johnson or any of its affiliates worldwide unless such manufacturer has entered into an enforceable written agreement to comply with this policy, submit to periodic compliance inspections, maintain the records necessary to demonstrate compliance and provide annual certifications of compliance. If any such manufacturer shall be found to be in breach of such agreement, the manufacturer's engagement shall be terminated.

Exceptions & Interpretations

Upon good cause shown in a specific situation, an exception to the Age and Hours (but not Health & Safety) provisions of this policy may be granted by the responsible Executive Committee Member with the concurrence of the Vice President, Administration, if such exception is consistent with ILO Convention 138 and all applicable laws and regulations. (See attached summary of ILO convention 138.) Requests for definitive interpretations of this policy should be

directed to the General Counsel.

NOTE. The Age provision of the Johnson & Johnson Policy on the Employment of Young Persons is more restrictive than ILO Convention 138. The following summary is provided only as an explanatory supplement to the Health & Safety and Exceptions provisions of the Johnson & Johnson policy. For guidance on specific situations, please contact the Johnson & Johnson Law Department.

Summary of ILO Convention No. 138

Concerning Minimum Age

- For work likely to jeopardize the health, safety or morals of the worker, the minimum age is 18; if there is adequate protection and training of the worker, then the minimum age for such work is 16.
- For work which is not likely to jeopardize the health, safety or morals of the worker, the minimum age is 14.
- For light work which is (a) not likely to be harmful to the health or development of the worker, and (b) not such as to prejudice his/her attendance at school or participation in vocational training, the minimum age is 12.]