18-05372-E

Sectilis

FOIA / PA Officer John Livornese
U.S. Securities & Exchange Commission
FOIA Office
100 F Street NE, Mail Stop 5100
Washington, DC 20549

July 24, 2018

Dear Mr. Livornese:

I request pursuant to the Freedom of Information Act (FOIA) 5 U.S.C. § 552. As Amended by Public Law No. 104-231,110 Stat. 3048, copies of the following agreements, based on the **File No. 0-19711 - CF#22228,** and as **FOIA Request 18-04551-E.**

Exhibit 10.1 to Form 8-K filed on 06/05/2008 by SPECTRANETICS CORP.
Exhibit Title: Manufacturing And Licensing Agreement
CIK: 789132

Exhibit 10.2 to Form 8-K filed on 06/05/2008 by SPECTRANETICS CORP.
Exhibit Title: Development And Regulatory Services Agreement
CIK: 789132

Sectilis will pay up to $122 for research, copies and review fees for all of the abovementioned agreements. Please forward all releasable material for copying. My daytime telephone number is 202-558-2356. Please call me or e-mail at research@sectilis.com to discuss the total cost or estimated cost of this research/copies should the amount exceed the price indicated in this request.

Sincerely,

Stella Vasconcellos
Research Assistant
Sectilis LLC
6931 Arlington RD. # 580
Bethesda, MD 20814

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

Office of FOIA Services

August 16, 2018

Ms. Stella Vasconcellos
Sectilis LLC
6931 Arlington Rd. # 580
Bethesda, MD 20814

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. **18-05372-E**

Dear Ms. Vasconcellos:

This letter is in response to your request, dated and received in this office on July 24, 2018, for access to Exhibit 10.1 and 10.2 to Form 8-K filed on June 5, 2008 by SPECTRANETICS CORP.

In connection with a previous request, access was granted to the subject exhibits. Therefore, we have determined to release the same exhibits (copy enclosed) to you. No fees have been assessed in this instance.

If you have any questions, please contact me at reidk@sec.gov or (202) 551-3504. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Lizzette Katilius 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,

Kay Reid

Kay Reid
FOIA Lead Research Specialist

Enclosures

10.1

Confidential Treatment Requested

EXECUTION VERSION

MANUFACTURING AND LICENSING AGREEMENT

This MANUFACTURING AND LICENSING AGREEMENT (this "Agreement") is dated as of May 30, 2008 (the "Effective Date") between Kensey Nash Corporation, a Delaware corporation having its principal place of business at 735 Pennsylvania Drive, Exton, PA 19341 (hereinafter referred to as "KNC"), and Spectranetics Corporation, a Delaware corporation having its principal place of business at 96 Talamine Court, Colorado Springs, CO 80907 (hereinafter referred to as "Spectranetics").

Whereas, pursuant to that certain Asset Purchase Agreement by and between KNC and Spectranetics, dated as of May 12, 2008 (the "Purchase Agreement"), KNC agreed to sell, effective as of the date hereof, to Spectranetics certain assets related to the KNC endovascular product line, which assets include the ThromCat, SafeCross and QuickCat products.

Whereas, Spectranetics wishes for KNC to manufacture such products and KNC is willing, for the consideration and on the terms set forth herein, to manufacture such products.

Now, therefore, in consideration of the mutual covenants and promises contained in this Agreement and other good and valuable consideration, the receipt and sufficiency of which are acknowledged, KNC and Spectranetics agree as follows:

1. DEFINITIONS

1.1 "Accounting Arbitrator" has the meaning set forth in Section 8.2 hereof.

1.2 "Additional Assets" means collectively the Additional QuickCat Assets and the Additional SC/TC Assets.

1.3 "Additional Payment" has the meaning set forth in Section 6.2 hereof.

1.4 "Additional QuickCat Assets" means collectively all (i) saleable inventory and work-in-process of the QuickCat Products, (ii) raw materials for the QuickCat Products and (iii) fixed assets used exclusively in the manufacture of the QuickCat Products, in each case that were added to KNC's books and records subsequent to the date hereof.

1.5 "Additional SC/TC Assets" means collectively all (i) saleable inventory and work-in-process of the SafeCross Products and ThromCat Products, (ii) raw materials for the SafeCross Products and ThomCat Products and (iii) fixed assets used exclusively in the manufacture of the SafeCross Products and ThomCat Products, in each case that were added to KNC's books and records subsequent to the date hereof.

1.6 "Affiliate," as applied to any Person, means any other Person, directly or indirectly, controlling, controlled by, or under common control with, that Person. The term "control" (including, with correlative meanings, the terms "controlling,"

"controlled by" and "under common control with"), as applied to any Person, includes the possession, directly or indirectly, of 10% or more of the Voting Power (or in the case of a Person that is not a corporation, 10% or more of the ownership interest, beneficial or otherwise) of such Person or the power otherwise to direct or cause the direction of the management and policies of that Person, whether through voting, by contract or otherwise.

1.7 "Agreement" has the meaning set forth in the preamble hereto.

1.8 "Blanket Purchase Order" has the meaning set forth in Section 5.2(e) hereof.

1.9 "Combined Revenue" means the sum of the SafeCross Revenue and the ThromCat Revenue for the relevant period of determination.

1.10 "Commitment" has the meaning set forth in Section 5.2(e) hereof.

1.11 "Confidential Information" shall mean all oral or written information that is disclosed by either party (the "Disclosing Party") to the other party (the "Receiving Party"), or that the Receiving Party becomes aware of as a result of its discussions and work with the Disclosing Party, and that is not generally known to the public, including but not limited to, information of a technical nature such as trade secrets; manufacturing processes or devices or know-how; techniques, data, formulas, inventions, discoveries or innovations (whether or not patentable), specifications and characteristics of current products or products under development; research projects, methods and results; matters of a business nature such as information about costs, margins, pricing policies, markets, sales, suppliers and customers; product, marketing or strategic plans; financial information; personnel records and other information of a similar nature, provided, however, that Confidential Information shall not include any information that (i) is or becomes public knowledge without breach of the Receiving Party's obligations hereunder; (ii) is rightfully acquired by the Receiving Party from a third party that is not under a confidentiality restriction on disclosure or use; (iii) was already known to the Receiving Party prior to receipt from the Disclosing Party as evidenced by written records; (iv) is independently developed by the Receiving Party; (v) is required to be disclosed by Law, provided that notice of the requirement is promptly delivered to the Disclosing Party in order to provide the Disclosing Party with an opportunity to challenge or limit the disclosure obligations; or (vi) is disclosed or used following the Receiving Party's receipt of express written consent from an authorized representative of the Disclosing Party. Notwithstanding anything to the contrary in the foregoing, all confidential or other proprietary information that is transferred by KNC to Spectranetics under the Purchase Agreement or this Agreement or that relates exclusively to the manufacture of the Products shall be deemed the Confidential Information of Spectranetics. The Receiving Party shall have the burden of proof respecting any of the aforementioned events on which the Receiving Party relies as relieving it of any confidentiality restrictions hereunder. Written disclosures for which protection is sought must be obviously

marked as "Confidential" or "Proprietary" and oral disclosures for which protection is sought must at the outset be clearly identified by the Disclosing Party as Confidential Information and submitted by the Disclosing Party in summary form to the Receiving Party, marked as above within thirty (30) days after disclosure; provided, however, that protection under Section 11 shall also be given to information that is not so marked if a reasonable person would assume that it is Confidential Information.

1.12 "Development Agreement" means that certain Development and Regulatory Services Agreement dated as of even date herewith between the parties hereto.

1.13 "Effective Date" has the meaning set forth in the preamble hereto.

1.14 "End Date" has the meaning set forth in Section 2.3 hereof.

1.15 "Equipment" has the meaning set forth in Section 4.1 hereof.

1.16 "Extended SC/TC Manufacturing Period" has the meaning set forth in Section 2.2 hereof.

1.17 "Existing Equipment" has the meaning set forth in Section 4.1 hereof.

1.18 "FDA" means the U.S. Food and Drug Administration.

1.19 "Fee Year" means, as applicable, the one year period beginning on the first day of the calendar month immediately following the month in which the SC/TC Manufacturing Period expires or is terminated for any reason, and each subsequent one year period (or portion thereof) prior to the End Date.

1.20 "Fiscal Quarter" means Spectranetics' fiscal quarter.

1.21 "Governmental Body" means any federal or state jurisdiction or government of any nature or federal governmental or quasi-governmental authority of any nature, domestic or foreign (including any governmental agency, branch or department exercising governmental or quasi-governmental powers and any governmental regulatory organization).

1.22 "Indemnified Party" has the meaning set forth in Section 16.3 hereof.

1.23 "Indemnifying Party" has the meaning set forth in Section 16.3 hereof.

1.24 "Independent Third Party" means a party who both (i) as of the date hereof owns less than fifteen percent (15%) of the outstanding capital stock of KNC and (ii) is a strategic (as opposed to a financial) investor or acquiror.

1.25 "Initial SC/TC Manufacturing Period" has the meaning set forth in Section 2.2 hereof.

1.26 "KNC" has the meaning set forth in the preamble hereof.

1.27 A "KNC Change of Control" shall be deemed to have occurred on the first to occur of any of the following events:

(a) The acquisition by any Independent Third Party or group of Independent Third Parties of fifty percent (50%) or more of the then outstanding capital stock of KNC;

(b) The consummation by KNC of a reorganization, merger or consolidation, in each case, unless, following such reorganization, merger or consolidation, more than fifty percent (50%) of the then outstanding equity of the entity resulting from such reorganization, merger or consolidation (which shall be understood to be the surviving parent in the case of a triangular merger) is then beneficially owned, directly or indirectly, by parties who were not Independent Third Parties immediately prior to such reorganization, merger or consolidation; or

(c) The consummation by KNC of the sale or other disposition of all or substantially all of the assets of KNC to an Independent Third Party.

1.28 "KNC Indemnified Party" has the meaning set forth in Section 16.2 hereof.

1.29 "Law" means any law, statute, regulation, rule or order of any Governmental Body.

1.30 "Manufacturing Period" has the meaning set forth in Section 2.2 hereof.

1.31 "Manufacturing Year" means the respective one year period beginning on the Effective Date or the applicable anniversary thereof.

1.32 "Microsoft Agreement" means that certain Microsoft OEM Customer License Agreement for Embedded Systems, effective June 18, 2007, by and between KNC and Microsoft Licensing, GP , as such agreement may from time to time be amended.

1.33 "Noncompetition Agreement" means that certain Non-Competition Agreement dated as of even date herewith between the parties hereto.

1.34 "Person" means an individual, a partnership, a corporation, a limited liability company, an association, a joint stock company, a trust, a joint venture, an unincorporated organization or a Governmental Body.

1.35 "Products" means collectively the QuickCat Product, the SafeCross Wires, the SafeCross Consoles and the ThromCat Product.

1.36 "Purchase Agreement" has the meaning set forth in the preamble hereof.

1.37 "QuickCat Manufacturing Period" has the meaning set forth in Section 2.1 hereof.

1.38 "QuickCat Products" means the QuickCat products transferred to Spectranetics pursuant to the Purchase Agreement and such products as they may be hereinafter maintained, modified, altered or further developed by or for Spectranetics, along with all successor products thereto.

1.39 "Repeated Failure" has the meaning set forth in Section 7.4 hereof.

1.40 "Revenue Share" has the meaning set forth in Section 15.1 hereof.

1.41 "Rolling Forecasts" has the meaning set forth in Section 5.2(e) hereof.

1.42 "SafeCross Consoles" means the SafeCross console product transferred to Spectranetics pursuant to the Purchase Agreement and such product as it may be hereinafter maintained, modified, altered or further developed by or for Spectranetics, along with all successor products thereto.

1.43 "SafeCross Products" means collectively the SafeCross Consoles and the SafeCross Wires.

1.44 "SafeCross Console Revenue" means the aggregate Sales Price received by Spectranetics and its Affiliates in connection with the SafeCross Console during the relevant period of determination.

1.45 "SafeCross Revenue" means the aggregate Sales Price received by Spectranetics and its Affiliates in connection with the SafeCross Products during the relevant period of determination.

1.46 "SafeCross Wires" means the SafeCross wire products transferred to Spectranetics pursuant to the Purchase Agreement and such products as they may be hereinafter maintained, modified, altered or further developed by or for Spectranetics, along with all successor products thereto.

1.47 "Sales Price" means the price per unit at which a Product is sold by Spectranetics. For the avoidance of doubt, the following items shall not be added to the price per unit in the calculation of the "Sales Price": (i) any refunds, credits or allowances actually given or credited to any party due to rejections, defects or returns of the Products, (ii) any sales, use, occupation or excise taxes, duties or other governmental charges imposed on, and paid by Spectranetics during, the importation, exportation, use or sale of Products, and (iii) any freight, postage or insurance charges actually incurred.

1.48 "SC/TC Manufacturing Period" has the meaning set forth in Section 2.2 hereof.

1.49 "SCC Price" has the meaning set forth in Section 6.1 hereof.

1.50 "SCW Commission" has the meaning set forth in Section 6.1 hereof.

1.51 "Specifications" has the meaning set forth in Section 5.1(b) hereof.

1.52 "Spectranetics" has the meaning set forth in the preamble hereof.

1.53 "Spectranetics Indemnified Party" has the meaning set forth in Section 16.1 hereof.

1.54 "Surmodics Agreement" means that certain Master License Agreement, effective May 26, 2004, by and between Surmodics, Inc. and KNC, as such agreement may from time to time be amended.

1.55 "Term" has the meaning set forth in Section 2.3 hereof.

1.56 "TC Commission" has the meaning set forth in Section 6.1 hereof.

1.57 "TC Patents" means those certain Patent Applications listed on Schedule 3.6 (a)(i) to the Purchase Agreement that have been filed with the U.S. Patent and Trademark Office or any other Governmental Body, the claims of which cover the ThromCat Product, along with the progeny thereof.

1.58 "ThromCat Products" means the ThromCat products transferred to Spectranetics pursuant to the Purchase Agreement and such products as they may be hereinafter maintained, modified, altered or further developed by or for Spectranetics, along with all successor products thereto.

1.59 "ThromCat Revenue" means the aggregate Sales Price received by Spectranetics and its Affiliates in connection with the ThromCat Products during the relevant period of determination.

1.60 "Total Console Costs" means, for the relevant period, the sum of (i) the aggregate amount paid by Spectranetics to KNC during such period for SafeCross Consoles pursuant to the terms of this Agreement and (ii) the aggregate depreciation and service costs incurred by Spectranetics during such period with respect to the Safe Cross Consoles.

1.61 "Transaction Documents" means the Purchase Agreement and all other agreements delivered pursuant thereto, including, without limitation, this Agreement.

1.62 "Transfer Price" has the meaning set forth in Section 6.1 hereof.

1.63 "USPTO" has the meaning set forth in Section 15.1(c) hereof.

1.64 "Voting Power" of any Person means the total number of votes which may be cast by the holders of the total number of outstanding shares of equity of any class or classes of such Person in any election of directors or managers of such Person without regard to the occurrence of any contingency.

2. MANUFACTURING PERIODS AND TERM

2.1 The manufacturing arrangement provided hereunder with respect to the QuickCat Products shall commence on the Effective Date and (unless earlier terminated under the provisions of Section 14.1) continue until the six (6) month anniversary hereof or such later date as may be agreed to by the parties hereto upon mutually agreeable terms, with such period as extended, if applicable, being referred to herein as the "QuickCat Manufacturing Period."

2.2 The manufacturing arrangement provided for hereunder with respect to the SafeCross Products and the ThromCat Products shall commence on the Effective Date and continue until the third (3rd) anniversary thereof (the "Initial SC/TC Manufacturing Period") unless earlier terminated under the provisions of Section 14.1. The Initial SC/TC Manufacturing Period may be extended upon mutually agreeable terms (each renewed period hereof, an "Extended SC/TC Manufacturing Period"), unless either party notifies the other party at least 12 months prior to the end of the Initial SC/TC Manufacturing Period of its intent not to renew. The Initial SC/TC Manufacturing Period, the Extended SC/TC Manufacturing Period and any extensions thereof are herein collectively referred to as the "SC/TC Manufacturing Period" and together with the QuickCat Manufacturing Period as the "Manufacturing Period".

2.3 The Term of this Agreement shall commence on the Effective Date and, unless earlier terminated in accordance with Section 14.4, continue until the later of (a) 10 years following the expiration or termination of Manufacturing Period or (b) with respect to each specific Product, the expiration date of the last to expire of (i) existing patents, (ii) patents pending as of the date hereof, (iii) patents applied for as of the date hereof and any continuation or continuation in part or re-issue thereof, in each case with respect to each specific Product (the "End Date" and the period beginning on the Effective Date and ending on the End Date, shall be the "Term"). With respect to any products jointly developed by KNC and Spectranetics after the date hereof pursuant to the Development Agreement or otherwise, the parties shall agree to the terms and conditions of transfer in connection therewith, including, without limitation, any extension of the End Date.

2.4 For the avoidance of doubt, except as set forth in Section 14.4, this Agreement shall survive the termination of the Manufacturing Period and shall remain in full force and effect after such termination, including, without limitation, with respect to Article 15.

3. LICENSE

3.1 Notwithstanding anything to the contrary in this Agreement, the Purchase Agreement or any other document executed in connection herewith or therewith, Spectranetics hereby grants to KNC a worldwide, non-transferable, fully paid and royalty-free right and license, without the right to grant sublicenses, to

manufacture the Products; provided, however that such license may be used by KNC only as may be necessary for KNC to fulfill its obligations to manufacture Products under this Agreement.

4. EQUIPMENT

4.1 The parties hereto agree and acknowledge that certain of the assets sold by KNC to Spectranetics pursuant to the Purchase Agreement include equipment that is required to manufacture the Products (the "Existing Equipment"). Spectranetics therefore agrees that the use and physical possession of the applicable Existing Equipment shall remain with KNC during the QuickCat Manufacturing Period and the SC/TC Manufacturing Period, as applicable. KNC agrees to maintain the Existing Equipment and the equipment included in the Additional Assets (collectively, the "Equipment") in good working order (including without limitation with respect to any periodic calibrations, validations and preventive maintenance) in accordance with the manufacturer's recommended maintenance and as required by any Governmental Body, and to no less standard than is consistent with its past practice, and to insure the Equipment, at its expense, against damage, destruction or theft in an amount not less than the replacement value of such Equipment. With respect to the foregoing provision in connection with the requirements of any Governmental Body, the parties agree and acknowledge that it applies to the Governmental Bodies in jurisdictions where KNC is selling the Products as of the Effective Date, and the parties agree to consult in advance regarding the requirements of any Governmental Body of any new jurisdiction where Spectranetics may in future elect to sell the Products in order to assess the cost and feasibility of any such requirements to ensure that the parties comply with all applicable requirements of Governmental Bodies for such jurisdiction.

4.2 KNC acknowledges and agrees that, at all times during and following the Manufacturing Period, Spectranetics shall remain the sole and exclusive owner of and retain title and risk of loss related to the Existing Equipment; provided that, any Equipment losses not covered by insurance that require purchase of replacement Equipment shall be treated as Additional Assets.

4.3 KNC shall provide such additional equipment as shall in the reasonable discretion of KNC be reasonably necessary to fulfill its obligations hereunder; provided, however, that if KNC fails to obtain the prior written approval of Spectranetics with respect to the purchase of any additional equipment (which approval shall not be unreasonably conditioned, withheld or delayed), then Spectranetics may, in its sole discretion, exclude such equipment from the Additional Assets. To the extent that such additional equipment shall be deemed to be Additional Assets, it shall be subject to the provisions set forth in Section 14.2.

4.4 KNC shall report to Spectranetics any material accident, as soon as reasonably possible after such accident, resulting from use of the Equipment, including without limitation accidents resulting in personal injury, property damage or

environmental release. KNC shall inform Spectranetics of any regulatory or other inspection, inquiry or audit by any Governmental Body with respect to the Products as soon as possible, but no later than five (5) days following such inspection, inquiry or audit, and shall provide Spectranetics with a copy of any report, citation or other communication issued with respect thereto.

5. MANUFACTURING AND SUPPLY

5.1 KNC agrees that during the QuickCat Manufacturing Period with respect to the QuickCat Products and during the SC/TC Manufacturing Period with respect to the SafeCross Products and the ThromCat Products, it will:

(a) manufacture and supply Spectranetics with Spectranetics' requirements for the Products in accordance with this Agreement, including manufacturing sufficient quantities of the Products in order to meet the Commitment and to use commercially reasonable efforts to have Product units available for delivery to meet unanticipated spikes in demand for Products up to fifteen percent (15%) in excess of Commitment;

(b) supply Spectranetics with Products that (i) are free from any material defect in manufacture when used under conditions of normal and proper use; (ii) conform to, and perform in all material respects in accordance with, the specifications provided on Schedule A hereto (the "Specifications"); (iii) are not adulterated or misbranded within the meaning of the U.S. Food, Drug and Cosmetic Act; (iv) comply with all applicable Laws, including the FDA Quality System Regulation, ISO 13485:2003 and any compliance updates to such Laws made during the applicable Manufacturing Period; and (v) comply with all applicable industry standards (such as by way of example only, EN, ISO, IEC, AAMI, UL, etc.) that are used to maintain a compliant quality system and obtain regulatory approvals, including without limitation standards for labeling, packaging, biocompatibility, sterilization, manufacturing environment, mechanical attributes and electrical attributes, as such applicable standards may be revised over time. KNC agrees that the foregoing applies to all industry standards of jurisdictions where KNC is selling the Products as of the Effective Date, and the parties agree to consult in advance regarding the application of Laws and Standards to any new jurisdiction where Spectranetics may in future elect to sell the Products in order to assess the cost and feasibility of any such change order to ensure that the parties comply with all applicable Laws and standards for such jurisdiction.

(c) provide packaged Product, including labeling and package inserts, in accordance with the prior written instructions or specifications of Spectranetics;

(d) not sell or otherwise transfer the Product to any Person, other than as directed by Spectranetics; and

(e) ship Product in accordance with Section 9 hereof, which shipment shall be made at Spectranetics' expense and risk of loss.

5.2 Spectranetics agrees that during the QuickCat Manufacturing Period with respect to the QuickCat Products and during the SC/TC Manufacturing Period with respect to the SafeCross Products and the ThromCat Products, it will:

(a) use its commercially reasonable efforts to sell the Products;

(b) subject to Section 14.1(b)(4), exclusively purchase all of its requirements for the Products from KNC;

(c) design and provide to KNC the appropriate instructions for use, together with all advertising, promoting and marketing aids, if any, to be packaged with Product;

(d) be solely responsible for the cost of any Product redesign it requests and approves which impacts Product or materials already manufactured, or obsoleted thereby, after the Effective Date, (e.g., specifications, artwork, labeling, configurations, packaging). Spectranetics will provide at its expense, or reimburse KNC for, any inventory requirements of materials purchased for the purpose of fulfilling the next three (3) months of the existing Annual Forecast but made obsolete as a result of such changes as well as any longer lead time components that KNC had to purchase in advance to meet its Commitment supply obligations where use of such components has been rendered obsolete by the design change. Notwithstanding the foregoing provisions, the Product prices will not change as a result of the Product changes specified as of the Effective Date in the Development Agreement;

(e) provide KNC with non-binding rolling twelve (12) month forecasts ("Annual Forecasts") and ninety (90) day forecasts ("Quarterly Forecasts") of Spectranetics's requirements of Product (collectively, "Rolling Forecasts"). Such Rolling Forecasts shall be prepared in good faith and provided initially on the Effective Date of this Agreement and each month thereafter, no less than thirty (30) days prior to the beginning of the first month covered by the Rolling Forecast. The first three (3) months of the Rolling Forecast shall be consistent with firm blanket purchase orders (the "Commitment") to purchase Products, which blanket purchase order shall be in the form attached as Schedule B hereto (each, a "Blanket Purchase Order");

(f) issue, from time to time, as shipping order (in written or electronic form) against the Commitment, which shall be in the form attached as Schedule C hereto (each, a "Shipping Order") or such other written or electronic

form as may be agreed upon by the parties from time to time, and which shall (subject to Section 9 hereof) include the ship-to location, shipping date, Product and quantity to be shipped; and

(g) except as otherwise provided in this Agreement, pay the actual documented cost of shipping Product and be responsible for all insurance, custom charges and taxes related to shipping and the distribution of the Product.

6. PRICE AND PAYMENTS

6.1 Transfer Price. The transfer price per unit (the "Transfer Price") for each Product is as follows:

Product	Transfer Price Per Unit ($US)
QuickCat Product	**$140.00**
ThromCat Product	**An amount equal to $433.68 plus the TC Commission**
SafeCross Wires	**An amount equal to $689.67 plus the SCW Commission**
SafeCross Console	**The SCC Price**

The "TC Commission" shall mean an amount equal to twelve percent (12.0%) of the average Sales Price for the ThromCat Product. The parties agree and acknowledge that the TC Commission from the Effective Date until the end of the first full Fiscal Quarter following the Effective Date shall be an amount equal to $186.44 per unit, which amount shall not be subject to adjustment except for the true-up process specified below. Fifteen (15) days prior to the beginning of each subsequent Fiscal Quarter, Spectranetics shall calculate and deliver to KNC the actual Sales Price for the prior three-month period ending on the last day of the calendar month preceding the date of calculation. Spectranetics shall adjust the TC Commission to reflect such updated Sales Price information and advise KNC of the updated amount of the TC Commission, which shall be effective on the first day and the remainder of such subsequent Fiscal Quarter.

The "SCW Commission" shall mean an amount equal to twelve percent (12.0%) of the average Sales Price for the SafeCross Wires. The parties agree and

acknowledge that the SCW Commission beginning on the Effective Date through the first full Fiscal Quarter shall be an amount equal to $229.98 per unit, which amount shall not be subject to adjustment except for the true-up process specified below. Fifteen (15) days prior to the beginning of each subsequent Fiscal Quarter, Spectranetics shall calculate and deliver to KNC the actual Sales Price for the prior three-month period ending on the last day of the calendar month preceding the date of calculation. Spectranetics shall adjust the SCW Commission to reflect such updated Sales Price information and advise KNC of the updated amount of the SCW Commission, which shall be effective on the first day and the remainder of such subsequent Fiscal Quarter.

The "SCC Price" shall mean KNC's actual purchase cost per unit (which equals the KNC variable manufacturing cost per unit) of the SafeCross Console during the applicable Manufacturing Year. The parties agree and acknowledge that the SCC Price during the Manufacturing Year ending on the first anniversary of the Effective Date shall be an amount equal to $20,975, which amount shall not be subject to adjustment. At least thirty (30) days prior to the end of each Manufacturing Year, KNC shall deliver to Spectranetics the SCC Price for the next Manufacturing Year, which price shall be effective as of the first day of such next Manufacturing Year.

Fifteen (15) days prior to the end of each Fiscal Quarter, Spectranetics will calculate the actual Sales Price for all Products sold during the prior three-month period ending on the last day of the calendar month preceding the date of calculation. For the first Fiscal Quarter, this shall include all Products sold by Spectranetics since the Effective Date. To the extent that the actual average Sales Price of any Product during the applicable calculation period differs from the Sales Price used to calculate the TC Commission or the SCW Commission for such calculation period, the parties agree that an adjustment will be calculated and paid or credited to Spectranetics, in the case of an overpayment, or to KNC, in the case of an underpayment, within thirty (30) days after the calculation of the true-up.

Along with each adjustment to the TC Commission and SCW Commission, as well as for the true-up calculations, made in accordance with this Section 6.1, Spectranetics shall deliver such documentation as may reasonably be necessary for KNC to confirm the respective calculations. For the avoidance of doubt, the parties agree and acknowledge that any disagreements of the parties with respect to the appropriate adjustments to the TC Commission, the SCW Commission and the SCC Price shall be subject to, first, audit under Section 8.1 and, if the parties cannot agree on the results of such audit, then arbitration in accordance with Section 8.2.

In addition to the foregoing adjustments, the Transfer Prices may be adjusted by mutual agreement for any changes to the Specifications as may be mutually agreed upon by the parties hereto. Notwithstanding the foregoing provisions, the

Product prices will not change as a result of the Product changes specified as of the Effective Date in the Development Agreement.

6.2 Additional SafeCross Console Payment. If the SafeCross Console Revenue attributable to any Manufacturing Year exceeds the Total Console Cost for such period, then Spectranetics shall make to KNC an additional payment equal to twelve percent (12.0%) of such SafeCross Console Revenue (the "Additional Payment"); provided, that in the event that any Additional Payment would be greater than 50% of the amount by which the SafeCross Console Revenue for such period exceeded the Total Console Cost for such period, then the amount of the Additional Payment shall be equal to 50% of the amount by which the SafeCross Console Revenue for such period exceeded the Total Console Cost for such period. Spectranetics shall deliver to KNC a written calculation of the Total Console Cost and the SafeCross Console Revenue attributable to each Manufacturing Year, along with a calculation and the payment of any Additional Payment that is owing, within forty five (45) days following the end thereof. For the avoidance of doubt, the parties agree and acknowledge that any disagreements of the parties with respect to the calculation of any Additional Payment shall be subject to, first, audit under Section 8.1 and, if the parties cannot agree on the results of such audit, then arbitration in accordance with Section 8.2.

6.3 Determination of Sales Price. In the event Products are sold together with other items at a single price, or Products are configured as a combination package containing other products, such single price shall be allocated among the Products and the other products based on the market price for such Products when sold separately, provided, that if any of such Products is not also then being sold alone, Spectranetics and KNC shall agree upon the Sales Price that could reasonably be expected for that Product or a comparable product.

6.4 Payment Terms. KNC shall invoice Spectranetics for Product shipments and Spectranetics shall pay any invoice within thirty (30) days of receipt. KNC may impose a late payment service charge of one percent (1.0%) per month on invoices not paid when due. All payments shall be in United States currency.

6.5 Subsequent Agreement on Cost Reductions. Subsequent to the date hereto, KNC and Spectranetics may, in their respective sole discretion, enter into a separate written agreement with respect to the sharing of cost reductions in cases where KNC implements a manufacturing change that results in a decrease in the cost to manufacture the Products, or the volume of purchases by Spectranetics results in a decrease of the cost to manufacture Products.

6.6 Payment of Royalties. KNC shall be responsible for royalties on sales during the SC/TC Manufacturing Period of SafeCross Product and ThromCat Product that are incurred pursuant to the Microsoft Agreement and Surmodics Agreement. Spectranetics will be responsible for payment of royalties under the Surmodics Agreement on sales of the QuickCat Product by Spectranetics during the QuickCat Manufacturing Period.

7. INSPECTION; QUALITY CONTROL

7.1 KNC shall test and inspect Products in accordance with existing procedures (or modified procedures approved in advance by Spectranetics) before shipment thereof for compliance with the applicable Specifications. KNC shall supply a Spectranetics-approved certificate of compliance to Spectranetics for Products to be shipped, stating actual testing results for compliance with the Specifications. Upon receipt of each shipment of Products, Spectranetics, or a third party designated by Spectranetics, may choose to test and inspect such Products for compliance with the applicable Specifications. Spectranetics shall make any claims regarding quantity or quality of each shipment of Products in writing to KNC within thirty (30) days of receipt thereof, specifying in reasonable detail the nature and basis for the claim and citing relevant control numbers or other information to enable specific identification of the Product in question. In the event that KNC receives a notice of rejection from Spectranetics, KNC shall, at its sole expense, replace any shipment or portion thereof of such rejected Product within thirty (30) days after receiving Spectranetics's written notice of rejection or demonstrate, to Spectranetics reasonable satisfaction why the initial rejection was unjustified.

7.2 If a shipment contains defective Product, or is deficient in quantity from the quantity stated on the applicable invoice (other than in the case of a partial shipment actually approved in writing by Spectranetics as contemplated in Section 9.1), KNC shall promptly make up the affected quantity or replace the affected Product at its expense, including cost of shipping and import. Spectranetics shall, at KNC's expense and direction, dispose of, or return to KNC, any defective Product.

7.3 Representatives of Spectranetics and Spectranetics's designated third party Product customers (to the extent agreed by KNC, such agreement not to be unreasonably conditioned, delayed or withheld) shall be permitted, upon Spectranetics's request and upon reasonable notice, to review KNC's quality system and conduct compliance audits of KNC's manufacturing facility and the Equipment. KNC shall permit representatives of Spectranetics to inspect the manufacturing facility and the Equipment to verify that the Products are being manufactured and supplied in accordance with the applicable Specifications and applicable Law. KNC shall promptly, at its sole expense, remedy or cause the remedy of any deficiencies that may be noted in any such inspection and all non-compliances and all remediation shall be subject to Spectranetics's prior written approval, such approval not to be unreasonably conditioned, delayed or withheld. KNC agrees to cooperate with Spectranetics at KNC's own expense in any recertification or requalification of any affected manufacturing facility. In addition, to the extent necessary for Spectranetics to obtain any license, permit or satisfy any other governmental requirement ("Approvals") to distribute Products in a jurisdiction, KNC agrees to provide access to its manufacturing facility and books and records to Spectranetics or its designees to conduct such audits as are necessary to obtain any necessary Approvals from any Governmental Body. In

addition, if requested by Spectranetics, KNC shall reasonably cooperate with Spectranetics in submitting any required paperwork to obtain such Approvals.

7.4 For the purposes of this Agreement, repeated failure ("Repeated Failure") will be deemed to have occurred if, at any time during any five (5) year period, a substantially similar repetitive failure or defect occurs in a particular Product (in each case, within two (2) years of delivery by KNC of the affected units thereof) indicating a common or systemic failure or root cause.

(a) In the event of a Repeated Failure, KNC and Spectranetics will cooperate to implement the following procedure:

(1) The discovering party shall promptly notify the other party upon discovery of the failure; provided, however, that, in the event of a failure that creates a risk of injury or death, the discovering party will immediately notify the other party and will also provide the other party with written notice within twelve (12) business hours of any notification made by the discovering party to any Governmental Body responsible for regulation of product safety;

(2) KNC and Spectranetics shall jointly exert commercially reasonable efforts to promptly diagnose the problem (root cause) and plan a solution or corrective and preventive action, depending on the root cause identified by the parties ("***CAPA***");

(3) Spectranetics shall prepare and consult with KNC regarding an appropriate recovery CAPA plan if the root cause is traceable to a manufacturing, design or materials issues; and

(4) KNC and Spectranetics shall mutually agree if the root cause is traceable to a manufacturing, design or materials issue on a recovery CAPA plan, customer notification, replacement scheduling and remediation, which may include a recall, field action, and return inventory replacement, and repair.

Notwithstanding the foregoing Spectranetics may undertake any and all action necessary independently of KNC.

(b) In the event of a Repeated Failure resulting from KNC's breach of this Agreement, and not from an external cause such as misuse of the Products by end users, KNC shall be responsible for, at Spectranetics's option: (i) the replacement of the defective Products if KNC is still manufacturing the Products at the time; or (ii) a credit to Spectranetics against any Transfer Prices payable by Spectranetics hereunder or against the Revenue Share payments in an amount equal to the cost to Spectranetics for qualified, non-defective replacement Products reasonably acceptable to Spectranetics. In addition, in the event of a Repeated Failure resulting from KNC's breach of this Agreement, KNC shall bear the labor costs

(and associated housing and travel costs) to replace the defective Products and the freight and transportation costs incurred in connection with the repair or replacement of the defective Products.

7.5 Any written or oral expression of dissatisfaction related to the identity, quality, durability, reliability, safety, effectiveness or performance of a Product manufactured by KNC for Spectranetics shall be considered to be a "***Complaint***." As between the parties, Spectranetics shall be the primary contact for customer Complaints. KNC shall (a) promptly and in reasonable detail notify Spectranetics within two (2) business days of receipt of notice of any Complaint or of adverse events relating to the Products of which it becomes aware, and (b) maintain a written record of all Complaints and notice of all adverse events it receives.

(a) In the event that KNC is contacted by any Governmental Body with any inquiry that would involve any disclosures about any of the Products, KNC shall notify Spectranetics within one (1) business day of such contact, providing Spectranetics with the substance of the inquiry (including any written materials which were provided) and an opportunity to respond. KNC shall allow Spectranetics to address any such inquiries relating to the Products and shall at all times do all necessary things and use its best efforts to protect the confidentiality of any of Spectranetics's Confidential Information. KNC agrees to comply with any such reasonable requests made by Spectranetics in the course of responding to any such inquiry. KNC agrees to timely provide Spectranetics with any materials generated by either KNC or the Governmental Body in responding to any inquiry relating to the Products, including, in the case of an inspection, a copy of the inspection findings and KNC's proposed response to them. In the event of any contact by any Governmental Body with Spectranetics, to the extent such inquiry may relate in whole or in part to the manufacturing of any of the Products, KNC agrees to cooperate with Spectranetics in providing any materials to the Governmental Body that may be responsive to the inquiry. All information disclosed or exchanged pursuant to this Section 7.5 shall be treated as Confidential Information of Spectranetics and shall not be disclosed to any third party without Spectranetics' prior written consent, unless such disclosure is required by applicable Law or court order (in which case KNC shall give Spectranetics prior written notice of the anticipated disclosure).

(b) As between the parties, Spectranetics shall be solely responsible for determining how a Complaint should be responded to, including any determination as to whether such Complaint should be reported to any Governmental Body, and, except as otherwise required under applicable Law, KNC shall not report any such Complaints without the prior approval of Spectranetics. At either party's request, the other party shall cooperate with such party in investigating and resolving any Complaint. KNC will communicate the outcome of the Complaint investigation by KNC to Spectranetics, and Spectranetics shall be responsible for

communicating with the affected customer. Unless approved by Spectranetics or as required by a Governmental Body, Spectranetics shall be solely responsible for contacts with any Governmental Body or the media with respect to any Complaint. Each party shall bear its own expenses regarding Complaints.

(c) KNC agrees to provide Spectranetics reasonable technical support and assistance upon request regarding questions about the Specifications, quality systems and the manufacturing processes for the Products.

8. REPORTING REQUIREMENTS; AUDIT RIGHTS

8.1 Spectranetics shall keep accurate written accounting records sufficient in detail to enable KNC to determine and verify the amounts payable by Spectranetics hereunder. Such records shall be retained for a period of not less than three calendar years after the end of the applicable measurement period. For the sole purpose of verifying the amounts payable hereunder, KNC shall have the right, at its own expense, to review such records in the location(s) where they are maintained by Spectranetics upon reasonable notice and during regular business hours and under obligations of confidentiality as provided in Section 11. If KNC proceeds with a review and such review reflects an underpayment, such underpayment by Spectranetics shall be promptly remitted by Spectranetics to KNC, and if the underpayment is equal to or greater than five percent (5%) of the amount that was otherwise due, Spectranetics shall pay, to the extent reasonable, all of the actual third party costs incurred by KNC in connection with such review.

8.2 If either party objects to the result of any audit conducted in accordance with Section 8.1 and, if the objection cannot be resolved by negotiation within thirty (30) days after the results of such audit having been communicated by the auditing party to the non-auditing party, the results of the audit, including the amount being claimed by the non-paying party, and all work papers related thereto (collectively, the "Determination Materials"), shall be submitted to a mutually acceptable auditor (the "Accounting Arbitrator"), which shall review the Determination Materials and shall determine the amount of payment owed, if any, by one party to the other, which may not be outside the range, if any, that comprised either the demand of the claiming party or any bonafide offer by the non-claiming party. The Accounting Arbitrator shall notify the parties of its determination within thirty (30) days following the receipt of the Determination Materials. The fees and expenses of the Accounting Arbitrator shall be shared equally by the parties, and all determinations pursuant to this Section 8.2 shall be in writing and shall be delivered to the parties hereto, and shall be final and binding on the parties with respect to the matters submitted.

9. PRODUCT ORDERS

9.1 With each Rolling Forecast, Spectranetics shall provide KNC with firm Blanket Purchase Orders for Products equal to not less than the Commitment. The parties agree to communicate on a regular basis to estimate the likely timing of estimated Shipping Orders, and without limiting KNC's supply obligations hereunder, Spectranetics shall use reasonable efforts to attempt to accommodate the lead times of KNC's suppliers where possible. From time to time, Spectranetics will also place Shipping Orders for full or partial shipments of the Products for such Blanket Purchase Orders during the time period covered by the Commitment. Upon its prior approval, which may be granted or withheld in its sole discretion, Spectranetics will accept partial shipments of Products should it, for any commercial reasonable reason become necessary to ship in advance of order completion. In the event that Spectranetics elects not to accept any such partial shipment, the Products that would have been delivered pursuant to such partial shipment shall (solely for purposes of Section 14.1(b)(1) hereof) be deemed to have been delivered at the time that such partial shipment would have been delivered. KNC shall use commercially reasonable efforts to comply with any reasonable revisions to Blanket Purchase Orders; provided, however, that no such revisions shall serve to reduce the Commitment. Spectranetics' Affiliates may also place Shipping Orders for delivery of Products in coordination with Spectranetics, subject to the terms and conditions of this Agreement and each such Affiliate shall be responsible for paying KNC the applicable purchase price for any Product units it purchase; provided that if such Affiliate does not pay KNC such amounts in a timely manner, KNC may charge Spectranetics for such purchases.

9.2 Each Shipping Order shall provide for the shipment of Product directly to Spectranetics, provided, however, that subsequent to the date hereof, KNC and Spectranetics may, in their sole discretion, enter into a separate written logistics agreement with respect to the shipment of Product directly to customers. So long as a Shipping Order is consistent with the Blanket Purchase Order, KNC will ship the applicable orders to Spectranetics within two (2) business days.

10. INTELLECTUAL PROPERTY RIGHTS

10.1 Except as specifically set forth herein, Spectranetics owns and shall continue to own the entire right, title and interest in and to the Products and any intellectual property relating thereto.

10.2 Each party agrees that it will not, without the other party's prior written consent, use and/or associate the other party, the other party's corporate name or any of the other party's trademarks, either orally or in writing, with any of the other party's products, except that Spectranetics shall use KNC's name and designate KNC as the manufacturer and developer or co-developer, as appropriate, of the Products, to the extent required by any applicable Law in gaining approval to market or to continue the marketing of the Products.

11. CONFIDENTIAL INFORMATION

11.1 The parties agree:

(a) To receive and hold all Confidential Information in strict confidence and to disclose such Confidential Information only to its employees and representatives who have a need to know the Confidential Information. Without affecting the generality of the foregoing, the Receiving Party will exercise no less care to safeguard the Confidential Information than it exercises in safeguarding its own Confidential Information and will be responsible for any breach of the provisions of this Section 11 by its employees and representatives (including its employees who, subsequent to the first disclosure of Confidential Information, become former employees);

(b) That the Receiving Party shall not, directly or indirectly, disclose or use the Confidential Information, in whole or in part, for any purposes other than those contemplated herein. Without affecting the generality of the foregoing, the Receiving Party shall not, directly or indirectly, disclose any such Confidential Information to any third party or use the Confidential Information for the benefit of any third party;

(c) That neither party shall, without the prior written consent of the other party, disclose to any third party the fact that the Confidential Information has been made available or any of the terms, conditions or other facts with respect to the business relationship of the parties. Any approved disclosure made shall be no more extensive than is necessary to meet the minimum requirement imposed on the party making such disclosure;

(d) That money damages would not be a sufficient remedy for a breach of this Section 11 and that the non-breaching party shall be entitled to seek equitable relief (including, but not limited to, a temporary restraining order or an injunction or specific performance), without posting bond or establishing monetary damages, in the event of any breach of the provisions of this Section 11;

(e) The furnishing of Confidential Information hereunder shall not constitute or be construed as a grant of any express or implied license or other right, or a covenant not to sue or forbearance from any other right of action by the Disclosing Party to the Receiving Party under any of the Disclosing Party's patents or other intellectual property rights;

(f) Upon the Disclosing Party's request, at any time, or upon termination or expiration of this Agreement, the Receiving Party shall immediately return all written, graphic and other tangible forms of the Confidential Information (and all copies thereof) in the Receiving Party's possession or

control except for one copy which may be retained for legal archival purposes only; and

(g) The obligations of the Receiving Party regarding disclosure and use of Confidential Information shall survive the termination of this Agreement and shall continue for ten (10) years after the End Date.

12. WARRANTIES AND REPRESENTATIONS

12.1 Spectranetics warrants that it shall comply with all applicable Laws and obtain all approvals of any Governmental Body affecting the use, possession, distribution, labeling, advertising and all forms of promotion in connection with the sale and distribution of the Products.

12.2 KNC warrants that it shall provide Spectranetics with Products which meet the Specifications and are manufactured at facilities registered with the applicable Governmental Body, to the extent required by Law, and in accordance with all applicable Laws of each Governmental Body having jurisdiction over the manufacture of Product in accordance with the provisions of this Agreement. KNC agrees that the foregoing applies to all jurisdictions where KNC is selling the Products as of the Effective Date, and the parties agree to consult in advance regarding the application of Laws and Standards to any new jurisdiction where Spectranetics may in future elect to sell the Products in order to assess the cost and feasibility of any such change order to ensure that the parties comply with all applicable Laws and standards for such jurisdiction and upon such agreement (such agreement not to be unreasonably conditioned, delayed or withheld) the foregoing warranty shall apply to any such additional jurisdiction.

12.3 KNC and Spectranetics each represent and warrant for itself that (i) it is duly incorporated and validly existing and in good standing under the Laws of the state of its incorporation, (ii) it has the full right, power, and authority to execute and perform this Agreement, (iii) this Agreement does not conflict with or otherwise result in a breach of any agreement to which such party is a party or to which it is bound, and (iv) this Agreement represents a valid, legally binding obligation of it, enforceable against it in accordance with its terms.

12.4 EXCEPT FOR THE WARRANTIES EXPRESSLY MADE IN THIS AGREEMENT, NEITHER OF THE PARTIES MAKES ANY OTHER REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR ANY WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE EVEN WHERE THE PURPOSE IS KNOWN.

13. ASSIGNMENT

13.1 Neither of the parties may assign or transfer this Agreement, in whole or in part, to a third party without the prior written consent of the other party, which consent shall not be unreasonably withheld, conditioned or delayed.

13.2 This Agreement will bind and inure to the benefit of the respective successors and permitted assigns of the parties hereto, whether so expressed or not.

14. TERMINATION; TRANSFER OF MANUFACTURING

14.1 (a) KNC shall have the right, but not the obligation, to terminate the Manufacturing Period upon sixty (60) days written notice by certified mail to Spectranetics, under the following circumstances, unless the circumstances are remedied or cured within said sixty (60) day notice period:

(1) if any amounts due KNC hereunder are unpaid within the periods provided for herein;

(2) if Spectranetics declares bankruptcy, Spectranetics makes an assignment for the benefit of its creditors, if any proceedings take place for reorganization or arrangement for the appointment of a receiver or trustee to take possession of Spectranetics's assets, or any other proceeding under Law for the relief of creditors shall be instituted; and

(3) if Spectranetics materially breaches its obligations under this Agreement.

(b) Spectranetics shall have the right, but not the obligation, to terminate the Manufacturing Period upon sixty (60) days written notice by certified mail to KNC under the following circumstances, unless the circumstances are remedied or cured within said sixty (60) day notice period:

(1) if KNC is unable for a period of three (3) successive months or four (4) months out of any six (6) months to supply Spectranetics with at least ninety percent (90%) of its Commitment, so long as such Commitment is not more than fifty percent (50%) greater on a cumulative basis than the average of the five (5) preceding months;

(2) if KNC declares bankruptcy, KNC makes an assignment for the benefit of its creditors, if any proceedings take place for reorganization or arrangement for the appointment of a receiver or trustee to take possession of KNC's assets, or any other proceeding under Law for the relief of creditors shall be instituted; and

(3) if KNC materially breaches its obligations under this Agreement.

(4) Alternatively, if KNC is unable to fulfill its supply obligations per subsection (1) above, Spectranetics may elect to continue to purchase Products from KNC on a non-exclusive basis and Section 5.2(b) shall thereafter be waived and of no further force or effect.

14.2 Upon the expiration of the QuickCat Manufacturing Period, (a) the Additional QuickCat Assets will be transferred by KNC to Spectranetics in exchange for a payment by Spectranetics equal to KNC's net aggregate book value thereof at the time of such transfer and (b) the Existing Equipment relating exclusively to the manufacture of the QuickCat Product will be transferred by KNC to Spectranetics, in each case at the expense of Spectranetics except as otherwise set forth in this paragraph. Upon the expiration of the SC/TC Manufacturing Period, (x) the Additional SC/TC Assets will be transferred by KNC to Spectranetics in exchange for a payment by Spectranetics equal to KNC's net aggregate book value thereof at the time of such transfer and (y) all Existing Equipment or other assets purchased by Spectranetics through the Purchase Agreement that remain in the possession of KNC will be transferred by KNC to Spectranetics, in each case subject to the remainder of this paragraph. In the event that either (aa) KNC elects to not extend the Initial SC/TC Manufacturing Period or applicable Extended SC/TC Manufacturing Period or (bb) Spectranetics terminates the Manufacturing Period pursuant to Section 14.1(b) or because a KNC Change of Control has occurred or KNC has requested an increase in the Transfer Prices, then the cost of removing and moving the Additional Assets and the Existing Equipment to a location designated by Spectranetics shall be borne by KNC. In all other instances, such cost will be borne by Spectranetics. Any Transfer Taxes (as defined in the Purchase Agreement) arising in connection with the transfer of ownership by KNC of the Additional Assets shall be shared equally by KNC and Spectranetics.

14.3 For the six months preceding and the six months following the expiration of each of the QuickCat Manufacturing Period and the SC/TC Manufacturing Period, KNC shall provide to Spectranetics such transition services as may be reasonably requested by Spectranetics in connection with Equipment for the respective Products, with the purpose of such services to be the validation of the equivalency of Spectranetics' packaging equipment with that of KNC. In the event that either (a) KNC elects to not extend the Initial SC/TC Manufacturing Period or applicable Extended SC/TC Manufacturing Period or (b) Spectranetics terminates the Manufacturing Period pursuant to Section 14.1(b) or because a KNC Change of Control has occurred or KNC has requested an increase in the Transfer Prices, then the cost of the transition services described in this Section 14.3 shall be borne by KNC. In all other instances, the reasonable, pre-approved cost of such services will be borne by Spectranetics.

14.4 In the event of a material failure by a party to comply with any of its obligations contained herein, the party not in default shall give to the party in default written notice specifying the nature of the default, requiring such defaulting party to make good or otherwise cure such default, and stating the non-defaulting party's intention to terminate this Agreement if such default is not cured. If such default is not cured within sixty (60) days after the date such notice was sent, then the party not in default shall be entitled, without prejudice to any other rights conferred on it by this Agreement, and in addition to any other remedies available to it by law or in equity, to terminate this Agreement by written notice of

termination to the defaulting party. Notwithstanding anything to the contrary set forth herein, any termination of this Agreement shall be subject in all respects to Section 14.6.

14.5 Termination or expiration of this Agreement for any reason will not relieve a party from accrued payment obligations or from obligations which are expressly indicated to survive termination or expiration of this Agreement.

14.6 In addition to the rights otherwise specified to survive herein, the following Articles and Sections of this Agreement shall survive its termination or expiration: Article 1, Sections 14.2, 14.3, 14.5, 14.6, Article 15 and Article 17, provided, however, if KNC materially breaches its non-competition obligations under the Non-Competition Agreement and does not cure such breach within thirty (30) days of receipt of notice, then Article 15 shall also expire.

15. REVENUE SHARE

15.1 In exchange for the services provided hereunder, Spectranetics shall pay to KNC a revenue share (the "Revenue Share") in accordance with the following:

(a) if the SC/TC Manufacturing Period ended because (i) KNC delivered written notice to Spectranetics of its intent not to extend the SC/TC Manufacturing Period beyond the Initial SC/TC Manufacturing Period or applicable Extended SC/TC Manufacturing Period, (ii) Spectranetics terminated the Manufacturing Period pursuant to Section 14.1(b), or (iii) Spectranetics elected not to extend the SC/TC Manufacturing Period beyond the Initial SC/TC Manufacturing Period or applicable Extended SC/TC Manufacturing Period due to a KNC Change of Control or a request by KNC for increased Transfer Prices, then the Revenue Share shall be an amount equal to 7.5% of the Combined Revenue attributable to each Fee Year, or

(b) if the SC/TC Manufacturing Period terminated or expired for any reason other than as set forth in clause (a) above, then the Revenue Share shall be an amount equal to 9% of the Combined Revenue attributable to each Fee Year; provided, however, that to the extent the Combined Revenue exceeds $20,000,000 for any Fee Year, then such 9% shall be reduced to 6% solely with respect to the Combined Revenue earned for such Fee Year in excess of $20,000,000 (and, for the avoidance of doubt, such 9% shall be restored with respect to each subsequent Fee Year).

(c) In the event that (i) the United States Patent and Trademark Office (the "USPTO") issues a non-appealable notice of final rejection of the TC Patents substantially in the form as written as of the Effective Date and no patent issues including a claim that covers a Product as modified pursuant to the Development Agreement and (ii) thereafter a product that competes with the ThromCat Product is introduced and such newly introduced

product would have infringed a claim of the TC Patents had such patents issued substantially in the form as written as of the Effective Date (a "Competing Product"), then the TC Commission or Revenue Share for the ThromCat Product, as applicable, shall be reduced in accordance with the following, which reduction shall be effective on the date that is the later of (x) three (3) years after the Effective Date and (y) the date the Competing Product is introduced in either the United States or outside the United States (as applicable):

(1) When the TC Commission rate equals twelve percent (12%), for every one dollar ($1) reduction in the average Sales Price of the ThromCat Product compared with the baseline average Sales Price of the ThromCat Product, as calculated by averaging the Sales Price of all ThromCat Products sold by Spectranetics during the Fiscal Quarter immediately preceding the introduction of the Competing Product, the TC Commission will be reduced by 0.02 percentage points; provided that the TC Commission rate shall not be reduced to an amount less than four and a half percent (4.5%).

(2) If the Revenue Share rate equals nine percent (9%), for every one dollar ($1) reduction in the average Sales Price of the ThromCat Product compared with the baseline average Sales Price of the ThromCat Product, as calculated by averaging the Sales Price of all ThromCat Products sold by Spectranetics during the Fiscal Quarter immediately preceding the introduction of the Competing Product, the Revenue Share rate with respect to the ThromCat Product will be reduced by 0.0125 percentage points; provided that the Revenue Share rate shall not be reduced to an amount less than four and a half percent (4.5%).

(3) If the Revenue Share rate equals seven and a half percent (7.5%), for every one dollar ($1) reduction in the average Sales Price of the ThromCat Product compared with the baseline average Sales Price of the ThromCat Product, as calculated by averaging the Sales Price of all ThromCat Products sold by Spectranetics during the Fiscal Quarter immediately preceding the introduction of the Competing Product, the Revenue Share rate with respect to the ThromCat Product will be reduced by 0.00875 percentage points; provided that the Revenue Share rate shall not be reduced to an amount less than four and a half percent (4.5%).

For purposes of illustration and not limitation, if, at the time that the conditions in the first paragraph of this Section 15.1(c) are satisfied, the Revenue Share rate equals seven and a half percent (7.5%) and the baseline average Sales Price of the ThromCat Product during the Fiscal Quarter immediately preceding the introduction of the Competing Product in the United States is $1,600, then, if the

average Sales Price in the United States during a subsequent Fiscal Quarter is $1,500, the Revenue Share rate would be reduced from 7.5% to 6.625% with respect to sales of the ThromCat Product in the United States during such subsequent Fiscal Quarter (i.e., 7.5% – (($1,600 – $1,500) x 0.00875 percentage points) = 6.625%), and the Revenue Share per ThromCat Product would be reduced from $120 (i.e., $1,600 x 7.5% = $120) to $99.38 (i.e., $1,500 x 6.625% = $99.38). Similarly, if, at the time that the conditions in the first paragraph of this Section 15.1(c) are satisfied, the TC Commission rate equals twelve percent (12.0%) and the baseline average Sales Price of the ThromCat Product during the Fiscal Quarter immediately preceding the introduction of the Competing Product in the United States is $1,600, then, if the average Sales Price in the United States during a subsequent Fiscal Quarter is $1,500, the TC Commission rate would be reduced from 12.0% to 10.0% with respect to sales of the ThromCat Product in the United States during such subsequent Fiscal Quarter (i.e., 12.0% – (($1,600 – $1,500) x 0.02 percentage points) = 10.0%), and the TC Commission per ThromCat Product would be reduced from $192 (i.e., $1,600 x 12.0% = $192) to $150 (i.e., $1,500 x 10.0% = $150).

Any TC Commission or Revenue Share rate reduction will be calculated when the true up is calculated each Fiscal Quarter.

For purposes of calculation, Product sales and average Sales Prices within the United States will be calculated separately from Product sales and average Sales Prices outside the United States, and the TC Commission or Revenue Share rate reduction will only apply to the territory (United States versus outside the United States) where the Competing Product is introduced.

Spectranetics shall deliver to KNC, within thirty (30) days after the end of each calendar quarter, reasonably detailed written accountings of the Combined Revenue for such calendar quarter (including any calculations with respect to amounts owing with respect to Product bundled with other items as set forth in Section 6.3), and units sold during such quarter, in each case on a Product-by-Product and country-by-country basis and in the form attached as Schedule D hereto. When Spectranetics delivers such accounting to KNC, it shall also deliver the TC Commission or Revenue Share due under this Section 15.1 for the calendar quarter. In addition to such quarterly reports, Spectranetics shall provide to KNC within seven (7) days of each month end (with information readily available to it in that timeframe) preliminary estimated monthly Combined Revenue calculations and units sold on a Product-by-Product and country-by-country basis in the form attached as Schedule D hereto. For the avoidance of doubt, the parties agree and acknowledge that any disagreements of the parties with respect to the calculation of the TC Commission or Revenue Share shall be subject, first, to audit in accordance with Section 8.1 and then to arbitration in accordance with Section 8.2.

16. INDEMNIFICATION

16.1 KNC agrees to indemnify, defend and hold Spectranetics and any of its officers, directors, Affiliates, employees, sales agents, successors and permitted assigns (each, a "Spectranetics Indemnified Party") harmless from and against any and all claims of third parties for any losses arising out of or resulting from: (i) any KNC breach of a representation, warranty, covenant or obligation in this Agreement; or (ii) any negligence, recklessness or wrongful intentional acts or omissions of KNC or its representatives, directors, officers, employees and agents, in connection with the activities contemplated under this Agreement, in each case, only to the extent not due to the negligence, recklessness or wrongful intentional acts or omissions of a Spectranetics Indemnified Party, or to the extent such claims are otherwise subject to indemnification under Section 16.2.

16.2 Spectranetics agrees to indemnify, defend and hold KNC and any of its officers, directors, Affiliates, employees, sales agents, successors and permitted assigns (each, a "KNC Indemnified Party") harmless from and against any and all claims of third parties for any losses arising out of or resulting from: (i) any Spectranetics breach of a representation, warranty, covenant or obligation in this Agreement; (ii) any negligence, recklessness or wrongful intentional acts or omissions of Spectranetics or its representatives, directors, officers, employees and agents, in connection with the activities contemplated under this Agreement, including without limitation any deceptive, misleading, manipulative or intentionally or recklessly inaccurate marketing or advertising practices; or (iii) Spectranetics' advertising, promoting, marketing, distributing and selling activities of Product that are not in accordance with Law, in each case, only to the extent not due to the negligence, recklessness or wrongful intentional acts or omissions of a KNC Indemnified Party, or to the extent such claims are otherwise subject to indemnification under Section 16.1.

16.3 To receive the indemnification protection provided in this Section 16, the party entitled to indemnification hereunder (the "Indemnified Party") must provide the party obligated to provide indemnification hereunder (the "Indemnifying Party") with (i) reasonably prompt notice in writing of any such claim or action, (provided that, the failure to provide such notice shall not relieve the Indemnifying Party from any of its obligations under this Article 16 except to the extent the Indemnifying Party is materially prejudiced by such failure) and (ii) information and reasonable assistance, at the Indemnifying Party's expense, as necessary or appropriate to defend or settle such claim or action. No such third party claim, except the settlement thereof which involves the payment of money only and for which the Indemnified Party is fully indemnified by the Indemnifying Party, may be settled by the Indemnifying Party without the written consent of the Indemnified Party, which shall not be unreasonably withheld or delayed. The Indemnified Party shall have the right to employ separate counsel and participate in the defense of any claim or action, at its own expense. Except as provided in the last sentence of this Section 16.3, the Indemnified Party may not settle any claim or action under this Section 16 on behalf of the Indemnifying

Party without first obtaining the Indemnifying Party's written permission, and so long as the Indemnifying Party is diligently conducting a defense as provided herein, it shall not be liable for the attorneys' fees or expenses of the Indemnified Party. If an Indemnified Party provides notice of an indemnification claim in accordance herewith and is not notified within fifteen (15) days after receipt of such notice, that the Indemnifying Party intends to defend such claim, the Indemnified Party shall (upon delivering notice to such effect to the Indemnifying Party) be entitled to defend, settle and/or compromise such claim, subject to the indemnification provided for herein.

17. MISCELLANEOUS PROVISIONS

17.1 Independent Contractor. Neither party shall have the right, power or authority to assume or create any obligations or responsibility expressed or implied, on behalf of, or in the name of, the other party, or to bind the other party in any manner or to any extent whatsoever, without the prior written approval and acceptance of the other party. Each of the parties hereto is an independent contractor for the purposes of this Agreement and nothing contained herein shall be deemed or construed to create the relationship of agency, partnership or joint venture or any other association except that of an independent contractor relationship.

17.2 Amendment and Waiver. This Agreement may be amended, and any provision of this Agreement may be waived, provided that any such amendment or waiver will be binding on each party only if such amendment or waiver is set forth in a writing executed by such parties. Waiver of a breach of the Agreement shall not constitute a waiver of any other subsequent breach of the Agreement. The waiver of any provision of this Agreement shall not constitute a continuing waiver of that provision or a waiver of any other provision of this Agreement.

17.3 Notices. All notices, demands and other communications to be given or delivered under or by reason of the provisions of this Agreement will be in writing and will be deemed to have been given when personally delivered, mailed by overnight mail, return receipt requested, or sent via confirmed facsimile. Notices, demands and communications will, unless another address is specified in writing, be sent to the addresses set forth as follows:

If to Spectranetics:

John G. Schulte
President and CEO
Spectranetics Corporation
96 Talamine Court
Colorado Springs, CO 80907
Facsimile: (719) 447-2070

With a copy to:

Roger Wertheimer
Vice President, General Counsel
Spectranetics Corporation
96 Talamine Court
Colorado Springs, CO 80907
Facsimile: (719) 447-2070

If to KNC:

Joseph W. Kaufmann
President and CEO
Kensey Nash Corporation
735 Pennsylvania Dr.
Exton, PA 19341
Facsimile: 484.713.2901

With a copy to:

David R. Shevitz
Kimberly T. Smith
Katten Muchin Rosenman LLP
525 West Monroe Street
Chicago, IL 60661
Facsimile: 312.902.1061

17.4 Severability. Whenever possible, each provision of this Agreement will be interpreted in such a manner as to be effective and valid under applicable Law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable Law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Agreement.

17.5 Complete Agreement. This document, along with the other Transaction Documents, contains the complete agreement between KNC and Spectranetics and supersedes all prior understandings, agreements and representations by or between the parties, written or oral, which may have related to the subject matter hereof in any way.

17.6 Counterparts; Electronic Delivery. This Agreement may be executed in counterparts, each of which shall be deemed to be an original, and all of which, when taken together, shall constitute one and the same instrument. Signatures sent by facsimile transmission, by email of a .pdf, .tiff or similar file or other electronic transmission shall be deemed to be original signatures.

17.7 Governing Law. The law of the State of Delaware will govern, without regard to the conflicts of law provisions thereof, all questions concerning the construction,

validity and interpretation of this Agreement and the performance of the obligations imposed by this Agreement.

17.8 Governing Law; Dispute Resolution. Except for matters arising out of Section 8.1, as provided in Section 8.2, and except where it is pursuant to the terms of this Agreement entitled to injunctive relief, prior to commencing any litigation in connection with this Agreement, each party hereto shall use commercially reasonable efforts to cause its chief executive officer to confer with the chief executive officer of the other party hereto for a period of at least 30 days, and each party hereto shall use its commercially reasonable efforts to resolve such dispute. During such 30-day period, the party seeking to commence such litigation shall attend no fewer than three (3) full business days of meetings at the other party's principal executive offices. Only after compliance with the provisions of this Section 17.8 may a party hereto commence an action in connection with this Agreement. Each party hereto hereby submits to the exclusive jurisdiction of the United States District Court for the District of Delaware and of any Delaware state court sitting in the County of New Castle, State of Delaware for purposes of all legal proceedings arising out of or relating to this agreement or the transactions contemplated hereby. Each party hereto irrevocably waives, to the fullest extent permitted by law, any objection which it may now or hereafter have to the laying of the venue of any such proceeding brought in such a court and any claim that any such proceeding brought in such a court has been brought in an inconvenient forum, and the parties hereto irrevocably agree that all such proceedings shall be heard and determined in such a Delaware state or federal court. The parties hereby consent to and grant any such court jurisdiction over the person of such parties and over the subject matter of such dispute and agree that mailing of process or other papers in connection with any such action or proceeding in the manner provided in Section 17.3 or in such other manner as may be permitted by law shall be valid and sufficient service thereof. Each party will continue to perform its obligations under this Agreement during any dispute, including without limitation paying any undisputed amounts due hereunder.

17.9 Headings. Section headings used in this Agreement are for convenience only and form no part or in any way modify or define the text of meaning or any provision of this Agreement.

17.10 Force Majeure. Neither party shall be liable or deemed in default for failure to perform any duty or obligation that such party may have under this Agreement where such failure has been directly or indirectly caused by any act of God, fire, inevitable accident, or war. The party whose performance has been so interrupted shall give the other party prompt notice of the interruption and the cause thereof, and shall use its commercially reasonable efforts to resume full performance of this Agreement as soon as possible. In addition, if a party's supplier suffers a force majeure event as defined above that shall constitute a force majeure event for the affected party hereunder, provided that the party whose supplier has

suffered the force majeure event shall have ninety (90) days to resolve the supplier issue or replace the supplier.

17.11 Damage Exclusions. EXCEPT FOR BREACHES OF CONFIDENTIALITY OBLIGATIONS OR LICENSE RESTRICTIONS, IN NO EVENT SHALL ANY PARTY HERETO BE LIABLE TO THE OTHER FOR ANY INCIDENTAL, INDIRECT, CONSEQUENTIAL OR SPECIAL DAMAGES OR LOST SALES OR PROFITS IN CONNECTION WITH ANY MATTERS RELATING TO THE BUSINESS RELATIONSHIP OF THE PARTIES, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES BY THE OTHER PARTY. THE FOREGOING SHALL NOT APPLY TO KNC'S LIABILITY IN THE EVENT THAT KNC HAS INTENTIONALLY OR WILLFULLY BREACHED THIS AGREEMENT BY FAILING TO PERFORM ITS OBLIGATIONS HEREUNDER, OR BY GROSS NEGLIGENCE HAS FAILED TO PERFORM ITS OBLIGATIONS UNDER THIS AGREEMENT.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties have executed this Agreement through their duly authorized representatives as of the date first written above.

THE SPECTRANETICS CORPORATION	**KENSEY NASH CORPORATION**
By: /s/ Guy A. Childs	By: /s/ Joseph W. Kaufmann
Name: Guy A. Childs	Name: Joseph W. Kaufmann
Title: Vice President and Chief Financial Officer	Title: Chief Executive Officer, President and Secretary

Schedule A – Specifications

Schedule B – Form of Blanket Purchase Order

Schedule C – Form of Shipping Order

Schedule D – Form of Revenue Share Reporting Schedule

10.2

Confidential Treatment Requested

EXECUTION VERSION

DEVELOPMENT AND REGULATORY SERVICES AGREEMENT

This DEVELOPMENT AND REGULATORY SERVICES AGREEMENT (this "Agreement") is dated as of May 30, 2008 (the "Effective Date") between Kensey Nash Corporation, a Delaware corporation, having its principal place of business at 735 Pennsylvania Drive, Exton, PA 19341 (hereinafter referred to as "KNC"), and The Spectranetics Corporation, a Delaware corporation, having its principal place of business at 96 Talamine Court, Colorado Springs, CO 80907 (hereinafter referred to as "Spectranetics").

WHEREAS, KNC is a company engaged in the development, marketing and sale of medical devices for a wide variety of applications;

WHEREAS, Spectranetics is a company engaged in the development, marketing and sale of medical devices for a wide variety of applications;

WHEREAS, KNC has expertise in developing and manufacturing medical devices and desires to develop products for Spectranetics under the terms of this Agreement;

WHEREAS, Spectranetics and KNC are parties to an Asset Purchase Agreement by and between KNC and Spectranetics, dated as of May 12, 2008 (the "Purchase Agreement"), and a Manufacturing and Licensing Agreement, dated as of even date herewith (the "Manufacturing Agreement");

WHEREAS, product development and regulatory services for the Products constitute an essential element of the basis for the purchase price set forth in the Purchase Agreement, Spectranetics would like KNC to conduct certain regulatory services related to the products acquired by Spectranetics under the Purchase Agreement as well as regarding any improved products developed pursuant to this Agreement, and KNC would like to conduct such regulatory services for Spectranetics, under the terms of this Agreement;

WHEREAS, Spectranetics would like KNC to develop for Spectranetics improvements of the products that Spectranetics acquired from KNC under the Purchase Agreement, and KNC would like to develop such improved products for Spectranetics, under the terms of this Agreement; and

WHEREAS, as part of the development and approval process described in this Agreement, Spectranetics will need to conduct certain clinical trials, for which the parties agree to share the expenses as described herein;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants and agreements provided herein, the parties hereto, intending to be legally bound hereby, agree as follows:

SECTION 1. DEFINITIONS

1.1 "Active Customers" shall mean the SafeCross Wire customers listed on Schedule A attached hereto.

1.2 "Agreement" has the meaning set forth in the preamble hereof.

1.3 "Approval Authority" shall mean any national (for example, the FDA), supranational (for example, the European Medicines Agency), regional, provincial, state or local regulatory agency, department bureau, commission, council, or other Government Body in any jurisdiction of the world involved in the granting of Approval or CE Marking for a Product.

1.4 "Approval" shall mean with respect to a nation or, where applicable, a multi-national jurisdiction, any approvals, clearances, licenses, registrations, waivers or authorizations necessary for the manufacture, marketing, and sale of Products in such nation or such jurisdiction. Without limiting the foregoing, "Approval" shall include, but not be limited to, pre-market approvals, and 510(k) and special 510(k) clearances from the FDA.

1.5 "CE Marking" shall mean a mandatory conformity mark on products which allows for the products to be sold in the market in the European Economic Area (EEA). The term is in the Medical Device Directive 93/42/EEC in 1993 and is obtained by the development and approval of a technical file or design dossier that is approved by an officially recognized European notified body.

1.6 "Claims" shall have the meaning set forth in Section 12.1.

1.7 "Clinical Trial Costs" means all costs directly associated with the clinical trials that are necessary in order to obtain Approvals from the FDA for the Indications described in Section 4, which costs shall include, but not be limited to, those costs set forth on Schedule 1(a) hereto; provided, however, that "Clinical Trial Costs" shall in no event include either party's overhead or indirect costs associated with its performance hereunder.

1.8 "Confidential Information" shall mean all oral or written information that is disclosed by either party (the "Disclosing Party") to the other party (the "Receiving Party"), or that the Receiving Party becomes aware of as a result of its discussions and work with the Disclosing Party, and that is not generally known to the public, including but not limited to, information of a technical nature such as trade secrets; manufacturing processes or devices or know-how; techniques, data, formulas, inventions, discoveries or innovations (whether or not patentable), specifications and characteristics of current products or products under development; research projects, methods and results; matters of a business nature such as information about costs, margins, pricing policies, markets, sales, suppliers and customers; product, marketing or strategic plans; financial information; personnel records and other information of a similar nature, provided, however, that all Information, and all correspondence with Customers and Governmental Bodies, shall be deemed the Confidential Information of Spectranetics, and provided further that Confidential Information shall not include any information that (i) is or becomes public knowledge without breach of the Receiving Party's obligations hereunder; (ii) is

rightfully acquired by the Receiving Party from a third party that is not under a confidentiality restriction on disclosure or use; (iii) was already known to the Receiving Party prior to receipt from the Disclosing Party as evidenced by written records; (iv) is independently developed by the Receiving Party; (v) is required to be disclosed by Law, provided that notice of the requirement is promptly delivered to the Disclosing Party in order to provide the Disclosing Party with an opportunity to challenge or limit the disclosure obligations; or (vi) is disclosed or used following the Receiving Party's receipt of express written consent from an authorized representative of the Disclosing Party. The Receiving Party shall have the burden of proof respecting any of the aforementioned events on which the Receiving Party relies as relieving it of any confidentiality restrictions hereunder. Written disclosures for which protection is sought must be obviously marked as "Confidential" or "Proprietary" and oral disclosures for which protection is sought must at the outset be clearly identified by the Disclosing Party as Confidential Information and submitted by the Disclosing Party in summary form to the Receiving Party, marked as above within thirty (30) days after disclosure; provided, however, that protection under Section 8 shall also be given to information that is not so marked if a reasonable person would assume that it is Confidential Information.

1.9 "Design History File" or "DHF" shall mean the manufacturer's file that contains documents or references to documents that demonstrate that the design of the device was developed in accordance with the design plan and the requirements identified as design inputs and outputs in the manufacturer's design control process and applicable regulations.

1.10 "Development and Regulatory Costs" shall mean the cost for the design, prototyping, development, testing and evaluation of the Products as set forth in the Development Plan and all other costs directly associated with obtaining Approvals from the FDA, including without limitation the costs set forth on Schedule 1(b) hereto; provided however, that "Development and Regulatory Costs" shall in no event include Clinical Trial Costs.

1.11 "Development Plan" shall mean the plan for developing and obtaining Approvals from the FDA for the Products, as set forth in Schedule B. The parties may by written agreement modify and amend Schedule B from time to time throughout the Term as required to assure successful development and commercialization of the Products.

1.12 "Development Program" has the meaning set forth in Section 3.1.

1.13 "Development Representative" shall have the meaning set forth in Section 3.2.

1.14 "Device Master Record" or "DMR" shall mean materials that may be used to provide device specifications and manufacturing procedures regarding the Products.

1.15 "Effective Date" has the meaning set forth in the preamble hereof.

1.16 "FDA" shall mean the U.S. Food and Drug Administration, or any successor thereto, having the administrative authority to regulate the marketing of human pharmaceutical products or biological therapeutic products, delivery systems, and medical devices in the United States.

1.17 "Governmental Body" shall mean any supranational, national, regional, state or local government, court, governmental agency, authority, board, bureau, instrumentality, or regulatory body.

1.18 "Indemnified Party" has the meaning set forth in Section 12.3.

1.19 "Indemnifying Party" has the meaning set forth in Section 12.3.

1.20 "Indication" shall mean the scope of an Approval, which may include, among other things, function, application or site for use.

1.21 "Information" means all ideas, inventions, discoveries, concepts, formulas, practices, procedures, processes, methods, knowledge, know-how, trade secrets, technology, designs, drawings, computer programs, skill, experience, documents, apparatus, results, clinical and regulatory strategies, results of experimentation, including without limitation samples, test data, including pharmacological, toxicological and clinical data, analytical and quality control data, manufacturing data and descriptions, patent and legal data, market data, any Device Master Records, Design History Files, financial data or descriptions, devices, assays, chemical formulations, specifications, compositions of matter, product samples and other samples, physical, chemical and biological materials and compounds, and the like, in written, electronic or other form, whether or not patentable, and all improvements thereto, in written, electronic, or any other form, and all intellectual property rights therein other than trademark rights and patent rights, in each case developed or conceived hereunder and related to the Products.

1.22 "Intellectual Property" shall mean all inventions, discoveries and innovations (whether patentable or unpatentable and whether or not reduced to practice), all improvements thereto, and all patents, patent rights, patent applications and invention disclosures, together with all reissues, continuations, continuations-in-part, revisions, extensions, and reexaminations thereof, all registered or unregistered trademarks, trade names and service marks, including all goodwill associated therewith, and copyrights, and all applications and registrations for any of the foregoing, and any trade secrets and know-how, in each case developed or conceived hereunder and relating to the Products.

1.23 "Invention" shall have the meaning set forth in Section 7.2.

1.24 "KNC" shall have the meaning set forth in the preamble hereto.

1.25 "KNC Indemnified Party" shall have the meaning set forth in Section 12.2.

1.26 "Law" means any law, statute, ordinance, directive, code, regulation, rule or order of any Governmental Body.

1.27 "Licensed Intellectual Property" shall mean the Patent Rights (as defined in the Purchase Agreement) and any other Intellectual Property owned by Spectranetics, in each case solely to the extent necessary for the development of Products or the conduct of regulatory services for Spectranetics pursuant to this Agreement.

1.28 "Manufacturing Agreement" has the meaning set forth in the recitals hereto.

1.29 "Milestone" means each of the milestones set forth in Section 6.1.

1.30 "Milestone Payments" has the meaning set forth in Section 6.1.

1.31 "New Product(s)" shall mean any follow-on, modified, or improved versions of the Original Products that are developed pursuant to the Development Plan or that the parties may mutually agree in writing to be developed under this Agreement.

1.32 "Original Products" shall mean the QuickCat Products, the ThromCat Products, the SafeCross Wires and the SafeCross Consoles.

1.33 "Product(s)" shall mean collectively the Original Products and the New Products.

1.34 "Purchase Agreement" shall have the meaning set forth in the preamble hereto.

1.35 "QuickCat Products" means the QuickCat products transferred to Spectranetics pursuant to the Purchase Agreement.

1.36 "Regulatory Representative" has the meaning set forth in Section 4.2.

1.37 "SafeCross Consoles" means the SafeCross console products transferred to Spectranetics pursuant to the Purchase Agreement.

1.38 "SafeCross Wires" means the SafeCross wire products transferred to Spectranetics pursuant to the Purchase Agreement.

1.39 "Spectranetics" shall have the meaning set forth the preamble hereto.

1.40 "Spectranetics Indemnified Party" shall have the meaning set forth in Section 12.1.

1.41 "Term" shall have the meaning set forth in Section 2.

1.42 "ThromCat Products" means the ThromCat products transferred to Spectranetics pursuant to the Purchase Agreement.

1.43 "Transaction Documents" means the Purchase Agreement and all other agreements delivered pursuant thereto, including, without limitation, this Agreement.

1.44 "Upgrade Inventory" means the specific SafeCross Consoles listed on Schedule C hereto.

SECTION 2. TERM

2.1 Term. This Agreement shall commence on the Effective Date and, unless earlier terminated as provided in Section 11.1 or 11.2, continue until the earlier of (i) the End Date (as

such term is defined in the Manufacturing Agreement) and (ii) the achievement of, and payment in full for, each Milestone (the "Term").

SECTION 3. DEVELOPMENT PROGRAM

3.1 Development Roles. Subject to the terms of this Agreement, KNC agrees to, in consultation with Spectranetics, work in good faith to develop the Products in accordance with the Development Plan (the "Development Program"). KNC and Spectranetics will jointly define the Products' specifications to meet market requirements; provided that Spectranetics shall have final approval of all design inputs, including without limitation Product needs and Specifications. The parties have agreed upon a general allocation of responsibilities for such purposes as set forth in this Section 3, and a specific allocation of responsibilities for the activities under this Agreement as set forth in the Development Plan. KNC may conduct independent development work at its own expense regarding Products other than in accordance with the Development Plan, provided that (a) KNC shall regularly update Spectranetics regarding such efforts, (b) KNC shall not incorporate any modifications or additions into the Products as a result of such efforts without the prior written consent of Spectranetics on a case-by-case basis; and (c) any modifications or Inventions resulting from such independent work shall be subject to the provisions of Section 7.2 below. Spectranetics will review and advise on product development progress, including without limitation medical input to provide assistance in the definition of the end-user product requirements and marketing specifications and phase review approval in the KNC design control process. The parties shall share equally any and all Clinical Trial Costs incurred in connection with the conduct of any pre-clinical or clinical trials performed under the Development Plan for the purpose of seeking Approvals from the FDA for Products. If Spectranetics requests a material deviation from the Development Plan for a particular Product, then KNC will provide Spectranetics an estimate of the additional development and regulatory costs that would not have otherwise been incurred by KNC in the absence of such material deviation and Spectranetics will elect either (i) to bear such additional development and regulatory costs, in which case, the parties would still share Clinical Trial Costs equally, or (ii) not to proceed with the proposed change to the Development Plan.

3.2 Development Representation. Each party shall appoint an individual to serve as its development representative (the "Development Representative") who shall be responsible for working with the other party's Development Representative in order to monitor the Development Program and the resources devoted thereto and facilitate the on-going exchange of information between the parties in connection with the Development Plan. During the course of the Development Program, the Development Representatives shall meet at times and places mutually agreed upon to discuss the progress and results of the Development Program and any modifications thereto as may be appropriate. The Spectranetics Development Representative will participate in and provide review and approval regarding Product development activities.

3.3 Efforts. Each party will devote sufficient time, attention and qualified personnel, to meet the delivery dates for any deliverables and other matters agreed to in the Development Plan in accordance with this Agreement. The parties will provide each other with such technical support relating to the development of the Products as reasonably necessary for the parties to develop the Products. The parties acknowledge that in connection with the development of the

Products, each of the parties may need access to certain Confidential Information of the other party that will be subject to the confidentiality provisions set forth in Section 8 hereof. Each party agrees to notify the other promptly of any factor, occurrence, or event coming to its attention that may affect that party's ability to meet the requirements of the Development Plan or the Development Program generally, or that is likely to cause any material delay in the delivery of deliverables.

3.4 Personnel and Resource Commitment. During the course of the Development Program, each party will commit an appropriate amount of personnel and other resources as reasonably necessary to meet the requirements of the Development Plan.

3.5 Standards. All device design activities will comply with applicable Laws, including without limitation FDA (Title 21, chapter 1, subchapter H, part 820, subpart C) and ISO 13485:2003:E design control and quality regulations. The parties agree and acknowledge that the foregoing applies to all jurisdictions where KNC is selling the Products as of the Effective Date, and the parties agree to consult in advance regarding the application of Laws to any new jurisdiction where Spectranetics may in the future elect to sell the Products to ensure that the parties comply with all applicable Laws for such jurisdiction. Spectranetics shall reserve the right to audit the DMR and DHF at reasonable times and upon reasonable notice to KNC to monitor and ensure compliance.

3.6 Sharing of Data. All data generated from the Development Program, including, but not limited to design control elements, laboratory, animal and clinical data, and also including but not limited to all regulatory submissions and correspondence to all Governmental Bodies relating to the Development Program, shall be owned by Spectranetics, copies of which KNC shall have a right to retain subject to the confidentiality obligations set forth in Section 8. To the extent that this data is generated by KNC, KNC shall promptly make such data available and share it with Spectranetics. To the extent that this data is generated by Spectranetics, Spectranetics shall promptly make such data available and share it with KNC solely for the purpose of KNC's performance of activities under this Agreement.

3.7 Additional Products. From time to time, the parties may agree to jointly develop additional Product configurations. In such event, the parties shall update the Development Plan or execute an addendum to this Agreement, such update or addendum shall describe the additional Product configurations and the modifications to the Development Program required to support the development of such additional Product configurations, and funding for such additional Product development shall be shared equally.

3.8 Development Audits.

(a) Spectranetics will have the right to conduct, either directly or through a designee, inspections, audits, and investigations of KNC's facilities, equipment, record-keeping procedures, and records related to the development of Products, including without limitation sites where KNC conducts clinical trials or analytical work, as Spectranetics reasonably deems necessary, on reasonable advance written notice, to monitor KNC's progress

and compliance with Law and the terms of this Agreement, or to address regulatory concerns relating to KNC's development efforts hereunder.

(b) Spectranetics also will have the right upon reasonable prior notice to KNC to have a representative present in KNC's facilities related to the development of Products to observe and monitor the conduct of the development of Products to confirm compliance with Law and this Agreement. If Spectranetics identifies an issue in its inspection, audit, or investigation, KNC will address such issue promptly by proposing a solution in writing to Spectranetics. KNC will not implement the solution until Spectranetics consents to the solution, such consent not to be unreasonably conditioned, delayed or withheld. Upon receipt of Spectranetics' consent, KNC shall implement the agreed upon solution.

(c) Spectranetics will have the right to inspect and audit all clinical data in KNC's control upon reasonable advance notice to KNC, during normal business hours. Additionally, KNC will provide to Spectranetics copies of all summary data generated by or on behalf of KNC in the course of performing development activities.

SECTION 4. REGULATORY SERVICES

4.1 Regulatory Roles. Subject to the terms of this Agreement, KNC shall, in consultation with Spectranetics, work in good faith to obtain the Approvals from the FDA in accordance with this Section 4 and the Development Plan. Spectranetics will advise and provide feedback to KNC on KNC's regulatory strategy. KNC and Spectranetics will jointly define the Indications and regulatory strategy for Approvals from the FDA; provided that Spectranetics shall have the final authority in its reasonable judgment with respect to any disputes between the parties with respect to the foregoing. For all Approvals from Approval Authorities outside of the United States, KNC will not be responsible for filings or communications, but KNC does agree to provide Spectranetics any applicable test data that KNC possesses regarding the applicable Product for Spectranetics' filing requirements. If Spectranetics requests that additional testing be conducted in order to satisfy the requirements of any such Approval Authority, KNC agrees to cooperate with Spectranetics and Spectranetics will bear the reasonable expense of any such additional testing.

4.2 Regulatory Representation. Each party shall appoint an individual to serve as its regulatory representative (the "Regulatory Representative") who shall be responsible for working with the other party's Regulatory Representative in order to monitor the FDA Approval progress. The Regulatory Representative will also be responsible for monitoring the resources devoted to regulatory efforts and facilitate the on-going exchange of information between the parties in connection with the FDA Approvals for the Products. During the course of the Development Program and/or the conduct of any regulatory activities under this Agreement, the Regulatory Representatives shall meet at times and places mutually agreed upon to discuss the progress and results of the regulatory services that KNC is providing and any modifications thereto as may be appropriate.

4.3 Regulatory Efforts. Spectranetics will provide KNC with such regulatory support relating to the FDA Approval of the Products as reasonably necessary. The parties acknowledge

that in connection with the FDA Approval of the Products, each of the parties may need access to certain Confidential Information of the other party that will be subject to the confidentiality provisions set forth in Section 8. Each party agrees to notify the other promptly of any factor, occurrence, or event coming to its attention that may affect that party's ability to meet the requirements of the Development Plan or the Development Program generally, or that is likely to cause any material delay in the Approvals or the CE Marking.

4.4 Personnel and Resource Commitments. During the course of the Development Program, each party will commit an appropriate amount of regulatory personnel and other resources as reasonably necessary to meet the requirements of the Development Plan.

4.5 Product Approvals. KNC shall have the responsibility for seeking the FDA Approvals (but not for CE Marking or for Approvals outside of the United States) on Spectranetics's behalf and in Spectranetics's name for the Products and funding the Development and Regulatory Costs in connection therewith. Upon obtaining any FDA Approval, KNC will transfer to Spectranetics copies of related regulatory filings and correspondence, and to the extent not already granted, title to such filings, and correspondence, including without limitation complete submission files relating to such Approvals in agreed upon formats.

4.6 Expanded Indication Approvals. KNC shall have the responsibility for the efforts to obtain Approval from the FDA for:

(a) the 7F Fixed Core ThromCat Device described in the Development Plan;

(b) the 6F Fixed Core ThromCat Device described in the Development Plan;

(c) the HDR SafeCross Console (with Improved Software Interface) described in the Development Plan;

(d) Fixed Core ThromCat (XT) Product described in the Development Plan for the peripheral vasculature Indication; and

(e) the 6F Fixed Core ThromCat (XT) Product described in the Development Plan for either a general vascular Indication or a coronary vasculature Indication.

KNC shall pay the Development and Regulatory Costs incurred in connection with the efforts to obtain such Approvals from the FDA; however the parties agree to share equally any applicable Clinical Trial Costs to obtain such Approvals from the FDA.

4.7 Interactions with Approval Authorities.

(a) Subject to this Section 4.7 and Section 4.8 below, KNC will be responsible for (i) filing applications for and obtaining FDA Approval for Products, at KNC's expense, and (ii) all substantive interactions with the FDA relating thereto. Prior to submitting any such filing or any initiating any such substantive interaction, KNC will provide to Spectranetics copies of such filing and notify Spectranetics of the content of such proposed

substantive interaction. KNC will not file any such application or initiate any substantive communication without the prior written approval of Spectranetics, which will not be unreasonably withheld or delayed.

(b) Spectranetics will cooperate, as reasonably requested by KNC, in the preparation and maintenance of such regulatory filings. In addition, at KNC's reasonable request, Spectranetics will make appropriate personnel reasonably available for meetings with the appropriate Approval Authority related to Products. Such meetings will be organized and managed by KNC. KNC will keep Spectranetics reasonably informed, on a regular basis, of material developments relating to Product regulatory filings.

(c) Each party will notify the other party of any written, electronic, or verbal communications to or from the FDA on matters related to a Product or which could reasonably be deemed to impact Product or its development, manufacture, or FDA Approval and will provide the other party, upon such other party's request, with copies of any such electronic or written communications within two (2) business days of such other party's request, or such earlier date as required by Law. Each party will have the right to comment on any proposed communication relating to a Product by the other party with the FDA pertaining to a Product, and such other party will promptly provide such party with a copy of the final such written communication. In the event that the FDA requests additional information regarding an Approval, KNC shall advise Spectranetics of the requested information and Spectranetics will work with reasonable efforts to supply the information requested by the FDA in a timely fashion to KNC. Notwithstanding anything to the contrary herein, Spectranetics shall have sole authority to determine the form and content of any communication with an Approval Authority pertaining to a Product, whether submitted by KNC or Spectranetics.

4.8 Approval and CE Marking Ownership. All applications made hereunder shall be under the Spectranetics name, and any Approvals and CE Marking received hereunder shall be owned by Spectranetics. Additionally, all supporting documentation, such as the DHF and the DMR, to the Approvals and CE Marking will be owned by Spectranetics.

4.9 Compliance with Laws. Each party will comply with all Laws with respect to activities to be performed under this Agreement.

SECTION 5. SAFECROSS SYSTEM UPGRADE

5.1 Active Customer Upgrades. Following receipt of the Approvals from the FDA contemplated in Section 4.5 for the HDR SafeCross Console (with Improved Software Interface described in the Development Plan), KNC shall perform and fund an upgrade to include new HDR and software interface for those certain SafeCross Consoles that are (i) owned by an Active Customer or (ii) included in the Upgrade Inventory; provided, however, that KNC shall not be required to perform or fund such upgrade with respect to SafeCross Consoles of any Active Customer unless Spectranetics has first used commercially reasonable efforts to sell such upgrades at their cost to each Active Customer.

5.2 New Customer Upgrades. Spectranetics shall be responsible for, and shall pay for, any upgrade of SafeCross Consoles that are not owned by an Active Customer or included in the Upgrade Inventory.

SECTION 6. ADDITIONAL PAYMENTS AND REPORTING

6.1 Milestone Payments. Spectranetics agrees to make the following payments to KNC (each a "Milestone Payment"):

(a) two million dollars ($2,000,000) within ten (10) days following the receipt of an Approval from the FDA for the 7F Fixed Core ThromCat Device described in the Development Plan;

(b) two million dollars ($2,000,000) within ten (10) days following the receipt of an Approval from the FDA for the 6F Fixed Core ThromCat Device described in the Development Plan;

(c) one million dollars ($1,000,000) within ten (10) days following the receipt of an Approval from the FDA the HDR SafeCross Console (with Improved Software Interface) described in the Development Plan;

(d) one million dollars ($1,000,000) within ten (10) days following the receipt of an Approval from the FDA for the Fixed Core ThromCat (XT) Product described in the Development Plan for the peripheral vasculature Indication; and

(e) two million dollars ($2,000,000) within ten (10) days following the receipt of an Approval from the FDA of a 6F Fixed Core ThromCat (XT) Product described in the Development Plan for either a general vascular Indication or a coronary vasculature Indication.

6.2 Currency and Method of Payments. All payments under this Agreement shall be made in United States dollars by transfer to such bank account as KNC may designate from time to time.

6.3 Clinical Trial Cost Reimbursement. Before commencing clinical trials with respect to any particular Product, Spectranetics and KNC shall negotiate with each other in good faith to agree on preliminary estimates regarding the scope, budget, allocation of expenses and methods of reimbursement in connection with such clinical trials, subject in each case to KNC's agreement as set forth in Sections 3.1 and 4.6 to share one-half of the Clinical Trial Costs. Each party agrees that actual Clinical Trial Costs may not equal the preliminary estimates and that, except for additional Clinical Trial Costs that may be incurred following a termination event pursuant to Section 11.1(b), where the KNC portion of any additional, post-termination Clinical Trial Costs would be credited against the Revenue Share as set forth in Section 11.1(b), each party's one-half share of incurred Clinical Trial Costs is non-refundable regardless of clinical trial or Approval outcome.

SECTION 7. INTELLECTUAL PROPERTY RIGHTS

7.1 Licenses.

(a) Subject to the terms and conditions of this Agreement, Spectranetics hereby grants to KNC a non-exclusive license under and to the Licensed Intellectual Property, without the right to grant sublicenses, to make, use, and import Products solely to the extent necessary to perform its obligations under the Development Plan during the Term.

(b) Subject to the terms and conditions of this Agreement, Spectranetics hereby grants to KNC a non-exclusive license under and to the Licensed Intellectual Property, without the right to grant sublicenses, to modify, reproduce, distribute, transmit, display, and produce derivative works of design documents and other copyrighted materials and documentation of Spectranetics solely to the extent necessary to perform its obligations under this Agreement.

(c) KNC shall have no right to grant sublicenses under the license rights granted to KNC pursuant to Section 7.1(a) and (b) without the express prior written consent of Spectranetics, such consent to be granted or withheld in Spectranetics' sole discretion.

7.2 Inventions. Spectranetics shall own the entire right, title and interest in and to any and all inventions relating the Products developed hereunder and any Intellectual Property relating thereto (collectively, "Inventions"). KNC hereby assigns, and shall assign, to Spectranetics all of its right, title, and interest in, to, and under any and all Inventions that are conceived, reduced to practice, or otherwise developed by KNC hereunder, either solely or jointly. KNC shall enter into binding agreements obligating all employees, consultants and contractors performing activities under or contemplated by this Agreement, including without limitation activities related to Products, to assign his or her interest in any invention conceived or reduced to practice in the course of such activities to KNC or Spectranetics. Without additional consideration, KNC shall, and shall cause its sublicensees, Affiliates, independent contractors, employees and agents to, cooperate with Spectranetics and take all reasonable additional actions and execute such agreements, instruments and documents as may be reasonably required to perfect Spectranetics' right, title and interest in and to Inventions as Spectranetics has pursuant to this Section 7.2.

7.3 Patent Prosecution and Maintenance. As between the parties, Spectranetics shall have the sole right, but not the obligation, to file applications for and to control the prosecution and maintenance of any and all patents in the Licensed Intellectual Property or claiming any Inventions, and shall be responsible for any related interference proceedings. In the event Spectranetics chooses not to take any of such protective actions with respect to any of the patents, Licensed Intellectual Property or Inventions, KNC shall have the right to take such action, at its sole expense. If such action by KNC results in any patent, Licensed Intellectual Property or Invention being registered in the name of KNC, KNC shall promptly assign all of its right, title and interest to such patent, Licensed Intellectual Property or Invention to Spectranetics in exchange for a perpetual, non-exclusive, royalty-free license, in such patent, Licensed Intellectual Property or Invention, subject to the non-competition and license restrictions set

forth in the Non-Competition Agreement and the License Agreement, respectively, between the parties dated as of even date herewith.

7.4 Infringement Actions. At any time during the Term, if either party determines that a third party is or may be infringing any patent, or may have misappropriated any other right, within the Licensed Intellectual Property or any patent filed under Section 7.3, such party shall promptly provide written notice thereof to the other party.

7.5 No Other Rights. Except for the rights expressly granted under this Agreement, no right, title, or interest of any nature whatsoever is granted b y implication, estoppel, or otherwise under this Agreement by Spectranetics to KNC.

SECTION 8. CONFIDENTIAL INFORMATION

8.1 The parties agree:

(a) To receive and hold all Confidential Information in strict confidence and to disclose such Confidential Information only to its employees and representatives who have a need to know the Confidential Information. Without affecting the generality of the foregoing, the Receiving Party will exercise no less care to safeguard the Confidential Information than it exercises in safeguarding its own Confidential Information and will be responsible for any breach of the provisions of this Section 8 by its employees and representatives (including its employees who, subsequent to the first disclosure of Confidential Information, become former employees);

(b) That the Receiving Party shall not, directly or indirectly, disclose or use the Confidential Information, in whole or in part, for any purposes other than those contemplated herein. Without affecting the generality of the foregoing, the Receiving Party shall not, directly or indirectly, disclose any such Confidential Information to any third party or use the Confidential Information for the benefit of any third party;

(c) That neither party shall, without the prior written consent of the other party, disclose to any third party the fact that the Confidential Information has been made available or any of the terms, conditions or other facts with respect to the business relationship of the parties. Any approved disclosure made shall be no more extensive than is necessary to meet the minimum requirement imposed on the party making such disclosure;

(d) That money damages would not be a sufficient remedy for a breach of this Section 8 and that the non-breaching party shall be entitled to seek equitable relief (including, but not limited to, a temporary restraining order or an injunction or specific performance), without posting bond or establishing monetary damages, in the event of any breach of the provisions of this Section 8;

(e) The furnishing of Confidential Information hereunder shall not constitute or be construed as a grant of any express or implied license or other right, or a covenant not to sue or forbearance from any other right of action by the Disclosing Party to the Receiving Party under any of the Disclosing Party's patents or other Intellectual Property rights;

(f) Upon the Disclosing Party's request at any time, or upon termination or expiration of this Agreement, the Receiving Party shall immediately return all written, graphic and other tangible forms of the Confidential Information (and all copies thereof) in the Receiving Party's possession or control except for one copy which may be retained for legal archival purposes only; and

(g) The obligations of the Receiving Party regarding disclosure and use of Confidential Information shall survive the expiration or termination of this Agreement and shall continue for ten (10) years after the date of expiration or termination, as applicable, of this Agreement.

SECTION 9. WARRANTIES AND REPRESENTATIONS

9.1 Each party represents and warrants that it is and will remain in material compliance with all applicable Laws as they may apply to this Agreement.

9.2 KNC and Spectranetics each represent and warrant for itself that (i) it is duly incorporated and validly existing and in good standing under the Laws of the state of its incorporation, (ii) it has the full right, power, and authority to execute and perform this Agreement, (iii) this Agreement does not conflict with or otherwise result in a breach of any agreement to which such party is a party or to which it is bound, and (iv) this Agreement represents a valid, legally binding obligation of it, enforceable against it in accordance with its terms.

9.3 EXCEPT FOR THE WARRANTIES EXPRESSLY MADE IN THIS SECTION 9, NEITHER PARTY MAKES ANY OTHER REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED. SPECIFICALLY, KNC MAKES NO WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE EVEN WHEN THE USE OR PURPOSE IS KNOWN TO KNC.

9.4 Additional Representations, Warranties and Covenants of KNC. KNC represents and warrants to Spectranetics that:

(a) KNC has obtained all licenses, authorizations, and permissions necessary or requisite in law for meeting and performing its obligations under this Agreement, and all such licenses, authorizations, and permissions are in full force and effect and shall be kept in full force and effect during the term of this Agreement; and

(b) in connection with the performance of its activities under this Agreement, KNC has not used, and during the Term, and in the performance of its activities under this Agreement, KNC will not use, any employee or consultant that is debarred by any Approval Authority or, to the best of its knowledge, is the subject of debarment proceedings by any Approval Authority. If KNC learns that any of its employees or consultants performing activities under this Agreement on its behalf has been debarred by any Approval Authority, or has become the subject of debarment proceedings by any Approval Authority, KNC will prohibit

such employee or consultant from continuing to perform activities under this Agreement on its behalf and will promptly notify Spectranetics thereof.

9.5 EXCEPT FOR BREACHES OF LICENSE RESTRICTIONS OR CONFIDENTIALITY OBLIGATIONS, NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY INCIDENTAL, INDIRECT, CONSEQUENTIAL OR SPECIAL DAMAGES IN CONNECTION WITH OR ARISING OUT OF THIS AGREEMENT, INCLUDING WITHOUT LIMITATION, LOSS OF PROFITS OR REVENUES, WHETHER ARISING IN CONTRACT (INCLUDING WITHOUT LIMITATION BREACH OF CONTRACT OR BREACH OF WARRANTY), IN TORT (INCLUDING WITHOUT LIMITATION NEGLIGENCE AND STRICT LIABILITY), OR ANY OTHER THEORY OF RELIEF, EVEN IF INFORMED OF THE POSSIBILITY OF SUCH DAMAGES AND EVEN IF AS A RESULT ANY REMEDY ARISING HEREUNDER OR UNDER APPLICABLE LAW FAILS FOR ITS ESSENTIAL PURPOSE. THE FOREGOING LIMITATIONS ON KNC'S LIABILITY SHALL NOT APPLY IN THE EVENT THAT KNC HAS INTENTIONALLY OR WILLFULLY BREACHED THIS AGREEMENT BY FAILING TO PERFORM ITS OBLIGATIONS HEREUNDER, OR HAS BEEN GROSSLY NEGLIGENT IN PERFORMANCE OF ITS DUTIES HEREUNDER.

SECTION 10. ASSIGNMENT

10.1 Neither of the parties may assign or transfer this Agreement, in whole or in part, to a third party without the prior written consent of the other party, which consent shall not be unreasonably withheld, conditioned or delayed; provided, however, that Spectranetics may assign this Agreement to a successor in interest without KNC's consent upon any merger, acquisition, reorganization, change of control or sale of all or substantially all of the assets of Spectranetics related to the Products.

10.2 This Agreement will bind and inure to the benefit of the respective successors and permitted assigns of the parties hereto, whether so expressed or not. Any assignment not in accordance with Section 10.1 will be null and void.

SECTION 11. TERMINATION

11.1 Termination by KNC.

(a) KNC shall have the right, but not the obligation, to terminate this Agreement upon sixty (60) days written notice by certified mail in accordance with Section 13.3 to Spectranetics, under the following circumstances, unless the circumstances are remedied or cured within said sixty (60) day notice period:

(i) if any amounts due KNC hereunder are unpaid within the periods provided for herein;

(ii) if Spectranetics declares bankruptcy, Spectranetics makes an assignment for the benefit of its creditors, if any proceedings take place for reorganization or

arrangement for the appointment of a receiver or trustee to take possession of Spectranetics' assets, or any other proceeding under Law for the relief of creditors shall be instituted; and

(iii) if Spectranetics materially breaches its obligations under this Agreement.

If the FDA finally denies Approval for an Indication, that shall not be a termination for cause event, but KNC acknowledges that no Milestone Payment will be payable for that Indication and Spectranetics acknowledges that absent material uncured breach of this Agreement by KNC leading to such denial, KNC shall have no liability to Spectranetics (other than for reimbursement of its one-half share of the accrued Clinical Trial Costs) related to such denial.

(b) KNC shall also have the right, but not the obligation, to terminate its obligations under this Agreement with respect to any particular Milestone upon sixty (60) days written notice by certified mail in accordance with Section 13.3 to Spectranetics if KNC determines in its reasonable judgment that it is not commercially reasonable to continue attempting to achieve such Milestone. In the event that KNC exercises its right to terminate the Agreement pursuant to this Section 11.1(b) and such Milestone is thereafter accomplished by or on behalf of Spectranetics, then following such accomplishment Spectranetics shall have the right to deduct from any Revenue Share (as defined in the Manufacturing Agreement) payable with respect to the particular units of ThromCat Product sold as a result of the achievement of such Milestone an amount equal to the Development and Regulatory Costs, and half of the Clinical Trial Costs, reasonably incurred and documented by Spectranetics in order for such Milestone to be achieved.

11.2 Termination by Spectranetics. Spectranetics shall have the right, but not the obligation, to terminate this Agreement upon sixty (60) days written notice by certified mail to KNC under the following circumstances, unless the circumstances are remedied or cured within said sixty (60) day notice period:

(a) if KNC declares bankruptcy, KNC makes an assignment for the benefit of its creditors, if any proceedings take place for reorganization or arrangement for the appointment of a receiver or trustee to take possession of KNC's assets, or any other proceeding under Law for the relief of creditors shall be instituted; or

(b) if KNC materially breaches its obligations under this Agreement.

11.3 Consequences of Termination. Upon expiration or any termination of this Agreement, KNC will transfer to Spectranetics any Intellectual Property and Information to which it is entitled pursuant to Section 7.2, and will, at Spectranetics reasonable expense if termination resulted from Spectranetics's material breach of this Agreement, provide reasonable assistance, including without limitation training and education, to enable it or its third party sublicensees or contractors to continue development activities for the Products, including without limitation transferring to Spectranetics all related regulatory filings, correspondence and Approvals and CE Marking for Products and title to such filings, correspondence and Approvals

and CE Marking that have not been previously transferred pursuant to Section 4. Until such transfer is completed, KNC will continue for a period of three (3) months to conduct its development responsibilities under this Agreement as requested by and at the direction of Spectranetics. In such case, Spectranetics may on its own select and negotiate with a third party collaborator to develop Products, at a time determined by Spectranetics in its sole discretion. Effective as of the effective date of such expiration or termination, to the extent that KNC has not transferred or licensed all applicable Intellectual Property to Spectranetics, then KNC will be deemed automatically to grant to Spectranetics an exclusive, sublicenseable license, under all Intellectual Property owned or controlled by KNC, to make, have made, use, sell, offer for sale, and import Products. Upon termination of this Agreement resulting from Section 11.1(a) above, Spectranetics agrees to pay to KNC the reasonable Development and Regulatory Costs incurred by KNC for development and regulatory services efforts for which Milestones Payments had not yet been earned at the effective date of termination.

11.4 Accrued Rights. Termination or expiration of this Agreement for any reason will not relieve a party from accrued payment obligations or from obligations which are expressly indicated to survive termination or expiration of this Agreement.

11.5 Survival. In addition to the rights otherwise specified to survive herein, the following Sections of this Agreement shall survive its termination or expiration: Sections 1, 3.8, 4.8, 7.2, 7.3, 7.5, 8 (for the period set forth in Section 8.1(g)), 9, 10, 11.1(b), 11.3, 11.4, 11.5, 12, and 13.

SECTION 12. INDEMNIFICATION

12.1 KNC agrees to indemnify, defend and hold Spectranetics and any of its officers, directors, affiliates, employees, sales agents, successors and permitted assigns (each, a "Spectranetics Indemnified Party") harmless from and against any and all claims, suits, actions or proceedings ("Claims") of third parties for any Losses (as defined in the Purchase Agreement) arising out of or resulting from: (i) any KNC breach of a representation, warranty, covenant or obligation in this Agreement; or (ii) any gross negligence, recklessness or wrongful intentional acts or omissions of KNC or its representatives, directors, officers, employees and agents, in connection with the activities contemplated under this Agreement, in each case, only to the extent not due to the gross negligence, recklessness or wrongful intentional acts or omissions of an Spectranetics Indemnified Party, or to the extent such Claims are otherwise subject to indemnification under Section 12.2.

12.2 Spectranetics agrees to indemnify, defend and hold KNC and any of its officers, directors, affiliates, employees, sales agents, successors and permitted assigns (each, a "KNC Indemnified Party") harmless from and against any and all Claims of third parties for any Losses arising out of or resulting from: (i) any Spectranetics breach of a representation, warranty, covenant or obligation in this Agreement; or (ii) any gross negligence, recklessness or wrongful intentional acts or omissions of Spectranetics or its representatives, directors, officers, employees and agents, in connection with the activities contemplated under this Agreement, in each case, only to the extent not due to the gross negligence, recklessness or wrongful intentional acts or

omissions of a KNC Indemnified Party, or to the extent such Claims are otherwise subject to indemnification under Section 12.1.

12.3 To receive the indemnities contained in this Section 12, the party entitled to indemnification hereunder (the "Indemnified Party") must provide the party obligated to provide indemnification hereunder (the "Indemnifying Party") with (i) reasonably prompt notice in writing of any such claim or action (provided that the failure to give a such notice promptly shall not prejudice the rights of the Indemnified Party except to the extent that the failure to give such prompt notice materially adversely affects the ability of the Indemnifying Party to defend the claim or suit), (ii) information and reasonable assistance, at the Indemnifying Party's expense, as necessary or appropriate to defend or settle such claim or action, and (iii) full authority to defend or settle the claim or suit. The Indemnified Party shall have the right to employ separate counsel and participate in the defense of any claim or action, at its own expense. Except as provided in the last sentence of this Section 12.3, the Indemnified Party may not settle any claim or action under this Section 12 on behalf of the Indemnifying Party without first obtaining the Indemnifying Party's written permission, and so long as the Indemnifying Party is diligently conducting a defense as provided herein, it shall not be liable for the attorneys' fees or expenses of the Indemnified Party. If an Indemnified Party provides notice of an indemnification claim in accordance herewith and is not notified within ten (10) days that the Indemnifying Party intends to defend such claim, the Indemnified Party shall be entitled to defend, settle and/or compromise such claim, subject to the indemnification provided for herein.

SECTION 13. MISCELLANEOUS PROVISIONS

13.1 Independent Contractor. Neither party shall have the right, power or authority to assume or create any obligations or responsibility expressed or implied, on behalf of, or in the name of, the other party, or to bind the other party in any manner or to any extent whatsoever, without the prior written approval and acceptance of the other party. Each of the parties hereto is an independent contractor for the purposes of this Agreement and nothing contained herein shall be deemed or construed to create the relationship of agency, partnership or joint venture or any other association except that of an independent contractor relationship.

13.2 Amendment and Waiver. This Agreement may be amended, and any provision of this Agreement may be waived, provided that any such amendment or waiver will be binding on each party only if such amendment or waiver is set forth in a writing executed by such parties. Waiver of a breach of this Agreement shall not constitute a waiver of any other subsequent breach of this Agreement. The waiver of any provision of this Agreement shall not constitute a continuing waiver of that provision or a waiver of any other provision of this Agreement.

13.3 Notices. All notices, demands and other communications to be given or delivered under or by reason of the provisions of this Agreement will be in writing and will be deemed to have been given when personally delivered, mailed by overnight mail, return receipt requested, or sent via confirmed facsimile. Notices, demands and communications will, unless another address is specified in writing, be sent to the addresses set forth as follows:

If to Spectranetics:

John G. Schulte
President and CEO
Spectranetics Corporation
96 Talamine Court
Colorado Springs, CO 80907
Facsimile: (719) 447-2070

With a copy to:

Roger Wertheimer
Vice President, General Counsel
Spectranetics Corporation
96 Talamine Court
Colorado Springs, CO 80907
Facsimile: (719) 447-2070

If to KNC:

Joseph W. Kaufmann
President and CEO
Jeffrey Kelly
V.P., Intellectual Property
Kensey Nash Corporation
735 Pennsylvania Dr.
Exton, PA 19341
Facsimile: 484.713.2901

With a copy to:

David R. Shevitz
Kimberly T. Smith
Katten Muchin Rosenman LLP
525 West Monroe Street
Chicago, IL 60661
Facsimile: 312.902.1061

13.4 Severability. Whenever possible, each provision of this Agreement will be interpreted in such a manner as to be effective and valid under applicable Law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable Law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Agreement.

13.5 Complete Agreement. This Agreement, along with the other Transaction Documents, contains the complete agreement between KNC and Spectranetics and supersedes all prior and contemporaneous understandings, agreements and representations by or between the parties, written or oral, which may have related to the subject matter hereof in any way.

13.6 Counterparts; Electronic Delivery. This Agreement may be executed in counterparts, each of which shall be deemed to be an original, and all of which, when taken together, shall constitute one and the same instrument. Signatures sent by facsimile transmission, by email of a .pdf, .tiff or similar file or other electronic transmission shall be deemed to be original signatures.

13.7 Governing Law. The law of the State of Delaware will govern, without regard to the conflicts of law provisions thereof, all questions concerning the construction, validity and interpretation of this Agreement and the performance of the obligations imposed by this Agreement.

13.8 Dispute Resolution. Except where pursuant to the terms of this Agreement it is entitled to injunctive relief, prior to commencing any litigation in connection with this Agreement, each party hereto shall use commercially reasonable efforts to cause its chief executive officer to confer with the chief executive officer of the other party for a period of at least thirty (30) days, and each party hereto shall use its commercially reasonable efforts to resolve such dispute. During such thirty (30) day period, the party seeking to commence such litigation shall attend no fewer than three (3) full business days of meetings at the other party's principal executive offices. Only after compliance with the provisions of this Section 13.8 may a party hereto commence an action in connection with this Agreement

13.9 Headings. Section headings used in this Agreement are for convenience only and form no part or in any way modify or define the text of meaning or any provision of this Agreement.

13.10 Force Majeure. Neither party shall be liable or deemed in default for failure to perform any duty or obligation that such party may have under this Agreement where such failure has been directly or indirectly caused by any act of God, fire, inevitable accident, or war. The party whose performance has been so interrupted shall give the other party prompt notice of the interruption and the cause thereof, and shall use its commercially reasonable efforts to resume full performance of this Agreement as soon as possible. In addition, if a party's supplier suffers a force majeure event as defined above that shall constitute a force majeure event for the affected party hereunder, provided that the party whose supplier has suffered the force majeure event shall have ninety (90) days to resolve the supplier issue or replace the supplier.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the parties have executed this Agreement through their duly authorized representatives as of the Effective Date.

THE SPECTRANETICS CORPORATION	KENSEY NASH CORPORATION
By: /s/ Guy A. Childs	By: /s/ Joseph W. Kaufmann
Name: Guy A. Childs	Name: Joseph W. Kaufmann
Title: Vice President and Chief Financial Officer	Title: Chief Executive Officer, President and Secretary

SCHEDULE 1(a) – EXAMPLES OF CLINICAL TRIAL COSTS

SCHEDULE 1(b) – EXAMPLES OF DEVELOPMENT AND REGULATORY COSTS

SCHEDULE A

ACTIVE CUSTOMERS

	Location	Serial # (if known)	Type
1	BAY MEDICAL CENTER	E0XXX	SITE OWNED
2	CAROLINAS HEALTH CARE SYSTEM	E0173	SITE OWNED
3	CHRIST HOSPITAL	E0267	SITE OWNED
4	DAYTON HEART HOSPITAL	E0273	SITE OWNED
5	DETROIT MEDICAL CENTER - HARPER U	E0217	SITE OWNED
6	EMORY CRAWFORD LONG HOSPITAL	E0262	SITE OWNED
7	EMORY UNIVERSITY HOSPITAL	E0XXX	SITE OWNED
8	HEART HOSPITAL OF AUSTIN	E0256	SITE OWNED
9	HOAG MEMORIAL HOSPITAL PRESBYTER	E0231	SITE OWNED
10	JEWISH HOSPITAL HEALTHCARE SVC	E0252	SITE OWNED
11	LEHIGH VALLEY HOSPITAL HEALTH NET	E0XXX	SITE OWNED
12	LENOX HILL HOSPITAL	E0XXX	SITE OWNED
13	MAYO CLINIC	E0221	SITE OWNED
14	MEMORIAL REGIONAL HOSPITAL	E0218	SITE OWNED
15	MOORE REGIONAL HOSPITAL	E0258	SITE OWNED
16	MOUNT SINAI MEDICAL CENTER NY	E0196	SITE OWNED
17	NEW YORK PRESBYTERIAN (Cornell)	E0219	SITE OWNED
18	NORTH CAROLINA BAPTIST MED CTR	E0XXX	SITE OWNED
19	NORTHEAST GEORGIA MEDICAL CENTER	E0XXX	SITE OWNED

	Location	Serial # (if known)	Type
20	PROVIDENCE ST VINCENT MED CTR	E0XXX	SITE OWNED
21	READING HOSPITAL	E0XXX	SITE OWNED
22	REGIONAL MEDICAL CENTER BAYONET	E0247	SITE OWNED
23	SENTARA NORFOLK GENERAL HOSPITAL	E0XXX	SITE OWNED
24	ST LUKES HEALTH SYSTEMS	E0XXX	SITE OWNED
25	ST LUKES MEDICAL CENTER	E0154	SITE OWNED
26	ST MARYS MEDICAL CENTER	E0XXX	SITE OWNED
27	THOMAS JEFFERSON UNIV HOSP	E0XXX	SITE OWNED
28	UNIV OF KANSAS HOSPITAL & MED CTR	E0255	SITE OWNED
29	WASHINGTON HOSPITAL CENTER	E0XXX	SITE OWNED

SCHEDULE B

DEVELOPMENT PLAN

1.0 Purpose:

To present the device development plans anticipated under the Regulatory and Development Agreement.

2.0 Scope:

The plans presented within describe the device criteria and project plans anticipated to commercialize the following products

2.1 7 Fr. ThromCat Fixed Core

2.2 6 Fr. ThromCat Fixed Core

2.3 Peripheral ThromCat Fixed Core

2.4 SafeCross HDR and new user interface

This document does not include the clinical study efforts that may be required to expand the indications for use from that of the current ThromCat product.

3.0 ThromCat Fixed Core Development Plan

3.1 Scope

The goal of the project is to develop an FDA cleared 7F guide catheter compatible version of the ThromCat® device. The device will include the Fixed Core transport system, no infusate delivery, a 3-zone extraction catheter, and a restyled enclosure. Design verification is underway for this program. Pending successful testing outcomes, the design will be locked and transferred to manufacturing for completion of process validations, final design review and any required design validation.

3.2 Device Criteria

- 7F guide-compatible, rapid exchange, 0.014" guidewire compatible
- Thrombus removal performance superior (at least 100% more thrombus before clogging) to 7F ThromCat (demonstrated by bench testing)
- Kink resistance/ buckling resistance improved in proximal shaft over 7Fr. ThromCat (demonstrated by bench testing)
- Deliverability (ability to reach desired vascular anatomy) similar or better than 7F ThromCat (demonstrated by bench testing)
- Helix fatique life improved over 7 Fr. ThromCat (demonstrated by bench testing).

3.3 Clinical and Regulatory Path

- Apply for FDA 510 (k) clearance for A/V graft indication using the commercial 7F ThromCat as predicate
- IDEs may be filed for studies required to obtain a US coronary, peripheral or general vascular indication - details TBD and outside the scope of this plan.

3.4 Anticipated Activities and Projected Timelines

- Final Design Review Jun 08 – Sep 08
- Submit FDA 510(k) Application A/V Jul 08 – Oct 08
- Receive 510(k) clearance A/V Oct 08 – Mar 09

3.5 Project Deliverables

- US FDA clearance to market the product under A/V indication
- Complete DHF and DMR for the product

4.0 6F ThromCat Fixed Core Development Plan

4.1 Scope

The goal of the project is to develop an FDA cleared 6F guide catheter compatible version of the ThromCat® device. The device will include the Fixed Core transport system, no infusate delivery, a redesigned tip, restyled enclosure, and full reinforced shaft design. The design is expected to be functionally comparable to the 7F ThromCat® XT. Preliminary design activities are in process.

4.2 Anticipated Device Criteria (final criteria to be determined and agreed upon by both parties in accordance with Development Agreement)

- 6F guide catheter-compatible, rapid exchange, 0.014" guidewire compatible
- Deliverability similar or better than 7F fixed core ThromCat
- Comparable or superior run-to-fail time to 7F fixed core ThromCat

4.3 US Clinical and Regulatory Path

The initial US strategy will be to apply for A/V graft clearance, if appropriate – Class II device, 510(k) with 7F ThromCat XT as predicate.

IDEs may be filed for studies required to obtain a US coronary or general vascular indication - details TBD and outside the scope of this plan.

4.4 Anticipated Activities and Projected Timelines (based on agreed upon device criteria by June 2008)

- Design Freeze Feb 09 – May 09
- Design Review Jun 09 – Sep 09
- Submit FDA 510(k) Application A/V Jul 09 – Oct 09
- Receive 510(k) clearance A/V Nov 09 – Apr 10

4.5 Project Deliverables

- US FDA 510(k) clearance to market the product under A/V indication
- Complete DHF and DMR for the product

5.0 Peripheral ThromCat Fixed Core Development Plan

5.1 Scope

The goal of the project will be to develop an FDA cleared peripheral version of the ThromCat® device for infra-inguinal arteries. The device will include the Fixed Core transport system, no infusate delivery, a restyled enclosure, and a durable full reinforced shaft design. The design is expected to be functionally comparable to the 7F ThromCat® XT, offer better cutting, with consideration for use with TurboBoost catheters as appropriate. Preliminary design activities are in process.

5.2 Anticipated Device Criteria (final criteria to be determined and agreed upon by both parties in accordance with Development Agreement)

- 6-7 Fr sheath compatible, 0.014" guidewire compatible
- Intended for Thrombectomy only, but capable of loose atheroma ingestion both fibrous and calcific as needed for successful use in peripheral arteries
- Increased thrombus removal luminal diameter

5.3 US Clinical and Regulatory Path

The initial US strategy will be to apply for A/V graft approval – Class II device, 510(k) with 7F ThromCat XT as predicate.

IDEs may be filed for clinicals studies to obtain US peripheral vascular indication- Details TBD and outside the scope of this plan.

5.4 Anticipated Activities and Projected Timelines (based on agreed upon device criteria by June 2008)

- Design Freeze Jul 08 – Jul 09
- Design Review Oct 08 – Nov 09
- Submit FDA 510(k) Application A/V Nov 08 – Dec 09
- Receive 510(k) clearance A/V Mar 09 – Jun 10
- Complete Peripheral Study Oct 09 – Feb 11
- Submit FDA 510(k) Application PV Nov 09 – Mar 11
- Receive 510(k) clearance PV Mar 10 – Sep 11

5.5 Project Deliverables

- US FDA clearance to market the product under A/V indication
- US FDA clearance to market the product with a peripheral indication
- Complete DHF and DMR for the product

6.0 SafeCross HDR with New Software interface Development Plan

6.1 Scope

The goal of the project is to improve artery wall sensing and improve the software interface. An improved (HDR) interferometer was developed and has been approved through FDA. Several OCR units have been converted to HDR and are under commercial evaluation. A new interface has been designed and has been coded into the software. Ongoing commercial evaluation will allow finalization of the software.

6.2 Device Criteria

- Improved artery wall detection (at least 10% greater resolution)
- Improved software interface (include screen images, which consist of software driven graphical displays)

6.3 US Clinical and Regulatory Path

Strategy depends upon the outcome of software validation, risk assessment and design validation activities. If no new safety or efficacy issues surface, upon completion of these activities a waiver to file

will be written to permit commercial use. If any new issues arise this may require the filing of a special 510(k) or CE change notification.

6.4 Anticipated Activities and Projected Timelines

- Final Design Review Aug 08 – Dec 08
- Receive FDA 510(k) clearance Oct 08 – Apr 09

6.5 Project Deliverables

- US FDA clearance to market the product
- Complete DHF and DMR for the product

SCHEDULE C

UPGRADE INVENTORY

	Location	Serial #	Type
1	ADVANCED CARDIAC SPECIALISTS	1008	KNC
2	ARIZONA HEART HOSPITAL	1004	KNC
3	CLEVELAND CLINIC	1000	KNC UTO
4	COMMUNITY MEDICAL CENTER	1010	KNC
5	CRIBBEN INVENTORY	1017	KNC
6	DFAS LIFPB F67100 LACKLAND AFB	E0275	KNC
7	FISHER TITUS MEDICAL CENTER	1007	KNC
8	HEART HOSPITAL OF AUSTIN	E0213	KNC - LOANED
9	HUTCHINSON HOSPITAL	E0274	KNC UTO
10	INTERNATIONAL	1019	KNC
11	INTERNATIONAL	E0172	KNC
12	JIM WITHUN INVENTORY	E0186	KNC
13	KNC	1016	KNC
14	KNC	1018	KNC
15	KNC	1022	KNC
16	KNC	1023	KNC
17	KNC	E0169	KNC
18	KNC	E0204	KNC
19	KNC	E0215	KNC
20	LASSON MAGNOLIS	E0187	KNC

	Location	Serial #	Type
21	LOANER UNIT AT VENDOR	1002	KNC
22	MARKETING	E0200	KNC
23	MEDICAL CENTER HOSPITAL	1015	KNC
24	METHODIST HOSPITAL SAN ANTONIO	1009	KNC
25	NORTH OKALOOSA MEDICAL CENTER	1012	KNC
26	OWENSBORO MEDICAL HEALTH SYSTEM	E0185	KNC
27	PINNACLE HEALTH AT HARRISBURG HOSPITAL	1001	KNC
28	SCRIPPS HEALTH GREEN HOSPITAL	E0112	KNC
29	SHAWNEE MISSION MEDICAL CTR	1011	KNC
30	SOUTH MIAMI HOSPITAL	E0190	KNC
31	SOUTHWEST GENERAL HEALTH CENTER	1003	KNC
32	ST PAUL MEDICAL CENTER	1008	KNC
33	ST VINCENT HEALTH CENTER Eerie, PA	1005	KNC
34	ST VINCENTS MEDICAL CENTER	E0176	KNC
35	UNIVERSITY OF ALABAMA BIRMINGHAM	E0271	KNC
36	VA MED CENTER SAN ANTONIO	E0162	KNC
37	VA MED CENTER SAN ANTONIO	E0177	KNC
38	VA MEDICAL CENTER SAN FRANCISCO	1006	KNC
39	VENICE REGIONAL MEDICAL CENTER	E0201	KNC
40	WELLSPAN HEALTH YORK HOSPITAL	E0228	KNC