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Corporation

Confidentiai Treatment Request Highlighted Copy

DISTRIBUTION AGREEMENT

Article I.

This Distribution Agreement ("Agreement") is made as of October 6, 2006 ("Effective Date") by and between Boston Scientific Corporation, One Boston Scientific Place, Natick, MA 01760 ("Buyer"), and Bovie Medical Corporation, 7100 30th Avenue-North, St. Petersburg, FL 33710 ("Seller") for the purpose of purchase, sale and delivery of Products (as defined in Section 1.1) in accordance with this Agreement. Buyer and Seller are herein referred to collectively as "Parties" and individually as a "Party."

MAILING ADDRESSES AND FAX NUMBERS FOR NOTICES, ETC. UNDER AGREEMENT

Seller:	with copy to:
Bovie Medical Corporation	Bovie Medical Corporation
7100 30 th Avenue North	7100 30 th Avenue North
St. Petersburg, FL 33710	St. Petersburg, FL 33710
Attn: Moshe Citronowicz, COO	Attn: General Counsel
Fax: (727) 344-3876	Fax: (727) 344-3876
Buyer:	with copy to:
Boston Scientific Corporation	Boston Scientific Corporation
One Boston Scientific Way	One Boston Scientific Place
Marlborough, Massachusetts 01752-1242	Natick, Massachusetts 01760-1537
Attn: President, Oncology	Attn: General Counsel

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto hereby agree as follows:

Fax: (508) 650-8956

1. Purchase and Sale.

Fax: (508) 683-5693

1.1 <u>Products</u>. For purposes of this Agreement, "**Product**" shall mean the medical resection device having a sintered tip, manufactured by Seller, as more particularly described in the Specifications (defined below) attached hereto as Exhibit A. Additional products, together with specifications and pricing therefor, may be added to this Agreement by mutual agreement of the Parties in accordance herewith.

1.2 Exclusivity. Seller will manufacture, offer and sell on an exclusive, worldwide basis Products to and for Buyer during the term of this Agreement. Seller shall not offer or sell to any third party or for itself or its Affiliates or have made, offered or sold on its behalf the Products. Buyer shall purchase the minimum quantity of Products, as described in Sections 1.3(b) and 1.3(f), below. For purposes of this Agreement, "Affiliate" means, as to either Party, any other person or entity that, directly or indirectly, controls, is under common control with, or is controlled by, that Party. For purposes of this definition, "control" (including, with its correlative meanings, the terms "controlled by" and "under common control with"), as used with respect to any person or entity, shall mean direct or indirect ownership of more than 50% of the stock or (partnership) shares of such person or entity.

1.3 Ordering.

(a) Buyer shall place all orders with Seller for Products under this Agreement on Buyer's form of purchase order. A copy of Buyer's current purchase order form is attached hereto as Exhibit B and is made a part hereof. All Buyer purchase orders shall set forth the Specifications (including relevant revision level), quantities, and delivery schedule, and shall state such additional terms and conditions as Buyer may deem appropriate. If a Buyer purchase order conflicts with this Agreement as to Specifications, terms or conditions, the Specifications, terms and conditions of this Agreement shall control. No other terms or conditions (including those on Buyer's purchase order) and no modification,

alteration or amendment of this Agreement shall be binding on the Seller unless accepted in writing, in advance, by an authorized officer of Seller.

Buyer will deliver to Seller an initial binding purchase order for two hundred (200) units (b) for the first three (3) calendar months of Product (the "Initial Purchase Order"). Buyer shall deliver such Initial Purchase Order to Seller with a mutually agreed lead-time prior to the first Product delivery date set forth on that Initial Purchase Order. The first calendar month of the Initial Purchase Order will be deemed to be the month in which the Initial Purchase Order is placed. From time to time, Buyer may also place additional purchase orders for Product. "Contract Year" means the one-year period beginning on the Product Launch Date and ending on the 12-month anniversary thereof, and each successive one-year period thereafter, during the term of this Agreement. Notwithstanding anything herein to the contrary, Buyer shall purchase a minimum of Three Thousand Five Hundred (3,500) units of Product during the first two (2) Contract Years of the term of this Agreement as follows: during the first Contract Year, a minimum of Fourteen Hundred (1,400) units in order quantities of at least 200 (as the Initial Purchase Order), 400, 400, and 400, respectively; and during the second Contract Year, a minimum of the difference between Thirty-Five Hundred (3,500) and the actual number of units purchased by Buyer during Contract Year One, with no single order quantity being less than two hundred and fifty (250) units. The quantity of Product ordered by Buyer prior to the Product Launch Date (if any), subject to the minimum per-order quantities set forth above, shall accrue to the 3,500 unit minimum purchase requirement for the first two (2) Contract Years. "Product Launch Date" means the date the Seller ships to Buyer Product for commercial resale (subject to all required regulatory approvals), but no later than ninety (90) days after mutual execution of the design transfer document required under applicable law; provided, however, that Seller timely ships Product to Buyer in accordance with the Initial Purchase Order.

(c) Within five (5) Business Days after receipt of a purchase order from Buyer, Seller shall acknowledge receipt and confirm whether the order can be supplied within the delivery dates set forth therein. Unless Seller advises Buyer to the contrary, in writing and within five (5) Business Days of the date Seller receives Buyer's sent purchase order, Seller shall be conclusively presumed to have accepted the Specifications, quantities, due dates, and other terms of such purchase order. For purposes of this Agreement a "**Business Day**" means any day, other than Saturday, Sunday, or a legal holiday in Massachusetts or Florida.

(d) Due dates on the purchase orders are the dates that the Products must be received at Buyer's facility indicated on that purchase order. Orders arriving up to three (3) Business Days early or three (3) Business Days late will be considered on time. As soon as it becomes apparent to Seller that it cannot meet a due date on a purchase order, Seller shall notify Buyer in writing of the expected delivery delay.

(e) Seller shall invoice Buyer and Buyer shall pay all shipping, insurance and related charges. Seller shall pay premium freight charges in excess of normal shipping charges to ensure timely deliver of Products ordered pursuant to a purchase order if Seller is responsible for a delay in shipment unexcused by Force Majeure (as set forth in Section 7.3).

(f) In the first two (2) Contract Years, Buyer shall purchase at least the minimum quantity of Product as set forth in Section 1.3(b), above, at the unit transfer price set forth in Exhibit E (Transfer Pricing) for that period. Thereafter, during each of the next three (3) Contract Years during the term of this Agreement, if Buyer orders any Product, Buyer shall issue a binding purchase order for a minimum of One Thousand (1,000) units of Product, with a minimum per-shipment quantity of not less than Two Hundred and Fifty (250) units, for delivery during the subsequent 12-month period.

"Pricing Period" means the six (6) month period beginning on the commencement date of the first Contract Year, and each successive six (6) month period thereafter during the term of this Agreement.

As set forth in Exhibit E, for Products purchased during Contract Years one (1) and two (2), the price per unit of Product purchased during such twenty-four (24) month period shall be (a) \$225.00 for the first 3,500 units purchased, and (b) \$107.25 for all Product above the first 3,500 purchased (whether purchased in Contract Year 1 or 2).

The initial pricing set forth in Exhibit E is based on the Specifications Revision "A-1," as set forth in Exhibit A. Seller reserves the right to amend the pricing in Exhibit E for the Product in accordance with changes to the Specifications requested by Buyer; provided, that (i) Seller will provide Buyer advance notice of any such price change, (ii) Seller will implement such changes to the Specifications and amend such pricing, only upon Seller's receipt of the Buyer's Oncology division's president's written approval thereof.

During each of Contract Years three (3) through five (5), for each Pricing Period, Buyer will initially pay the Product transfer price (set forth in Exhibit E) that corresponds to the forecasted quantity of Products to be ordered for that Pricing Period as set forth in the twelve (12)-month rolling forecast delivered by Buyer in accordance with Section 1.6 of the Agreement on the last day of the second month immediately preceding the commencement of such Pricing Period. Within thirty (30) days following the end of each of Pricing Period during Contract Years three (3) through five (5), the Parties will compare the total amount actually paid for Products by Buyer during that Pricing Period with the total amount which should have been paid based upon the actual purchases of Products in such Pricing Period using the applicable Product prices set forth in Exhibit E, as amended. Any difference will be paid to the appropriate Party within forty-five (45) days following the end of the applicable Pricing Period.

(g) Buyer shall timely place and Seller shall timely fulfill binding purchase orders as required under this Agreement. However, if (i) Seller is unable to fulfill such binding purchase orders, (ii) Product is recalled as permitted under Section 3.11 (Product Recalls), or (iii) Buyer rejects or returns all or any part of a shipment of Product as permitted under Section 3.4 (Product Acceptance) or 3.12 (Product Returns), as applicable, Seller shall suspend Buyer's minimum purchase obligations set forth in this Section 1.3 until fifteen (15) business days after either (x) Seller is able to fulfill such binding purchase orders, or (y) Seller satisfies its applicable obligations under Section 3.4, 3.11, or 3.12.

1.4 <u>Shipping; Freight Terms</u>. Subject to the terms set forth in Section 1.3, above, Seller shall deliver Products that meet the Specifications in accordance with the quantities, timing and shipping destination specified in Buyer's purchase orders utilizing Buyer's appointed carriers and Buyer's contracted rates. Seller shall deliver all Products to Buyer free and clear of all liens and encumbrances or other defects in title. All Products shall be shipped F.O.B. St. Petersburg, FL.

1.5 Inventory; Scheduling.

(a) Except as expressly set forth herein, during the term of this Agreement, Buyer shall purchase its Product requirements exclusively from Seller (including Products required for engineering, testing, and clinical trials, if any) and from no other manufacturer, person or entity, including, without limitation, any division or Affiliate of Buyer.

(b) Buyer shall provide Seller with firm purchase orders for Products in accordance with the procedures and requirements set forth in Section 1.3; provided, however, that Buyer shall have the right, exercisable only one (1) time per any three (3) month period, up to five (5) Business Days prior to the date of shipment, and with the prior written consent of Seller, which shall not be unreasonably withheld, to issue binding, written change orders to delay up to twenty-five percent (25%) of the quantity of Products on such purchase orders by no more than sixty (60) calendar days from their originally scheduled shipment date. Buyer agrees to accept partial shipments of Products from Seller should it, for any commercially reasonable reason, become necessary to ship in advance of Seller's ability to complete

each order. Seller shall make all commercially reasonable efforts to comply with any revisions to a purchase order consistent with the provisions of this Agreement.

(c) Seller shall maintain its production capacity with respect to finished products and raw materials at One-Hundred and Thirty Percent (130%) of all undelivered Product quantities on open purchase orders for the then-current month. Seller will immediately notify Buyer in the event of any material obsolescence, supply shortage, or other interruption or potential interruption, in supply of any Products, or component or sub-assembly thereof, as soon as Seller becomes aware of such.

(d) Within the mutually agreed lead-time for the Initial Purchase Order set forth in Section 1.3(b), above, Seller shall accumulate a finished goods inventory of Products to be held in reserve equal to the average monthly quantity, based on the Initial Purchase Order. Thereafter, for each subsequent month, Seller will hold in inventory an amount of finished Products equal to the average monthly quantity of the then-current Binding Forecast (defined below). All Products held in inventory pursuant to this Section shall be referred to herein as "Shelf Inventory." Seller may only deplete Shelf Inventory when Buyer's orders exceed the applicable Binding Forecast. Seller will at all times throughout the term of this Agreement maintain the agreed upon Shelf Inventory level, except that Seller will replace any units taken from Shelf Inventory in accordance with previous sentence within thirty (30) days of the date Seller takes such units from Shelf Inventory.

1.6 Estimates of Requirements.

(a) At the same time Buyer issues its Initial Purchase Order, and by the last day of each calendar month thereafter, Buyer shall deliver to Seller a written, twelve-month rolling forecast of Buyer's requirements for Products. The first three (3) months of each such twelve-month rolling forecast shall be binding upon Buyer (the "**Binding Forecast**") and the remaining nine (9) months of each such forecast will be non-binding and subject to adjustment. Seller shall, no later than twenty-five (25) days after receipt of each twelve-month rolling forecast delivered pursuant to this Section, notify Buyer of any prospective problems of which Seller is aware that might prevent Seller from meeting Buyer's forecasted requirements or estimated delivery dates. In the event Seller so notifies Buyer of any issues in meeting quantities, Seller shall state in writing the quantity of Products it estimates it can deliver and Buyer shall only be required to purchase such revised quantity.

(b) In addition to the forecasts delivered pursuant to Section 1.6(a), above, Buyer will create a non-binding twelve-month forecast for Products, the first month of which will be the month this Agreement is signed and delivered and which will be attached hereto as Exhibit C. For the avoidance of doubt, Exhibit C is being delivered for planning purposes only and no portion of Exhibit C will be binding on either Party hereto.

(c) Seller and Buyer agree to cooperate with each other and work jointly to establish and maintain a smooth and efficient timetable for the manufacture and supply of Products to Buyer hereunder. Seller shall use commercially reasonable efforts to supply Buyer with all of its Product requirements, including, but not limited to, the use of commercially reasonable efforts to accommodate "Rush" orders from Buyer; <u>provided</u>, <u>however</u>, Seller shall not be in breach of this Agreement for any failure or delay to supply quantities of Products which exceed the Binding Forecast for the then-current month by more than twenty five percent (25%).

1.7 <u>Materials Requirements Process.</u>

(a) Seller will deliver to Buyer a list of all components with lead times greater than twelve (12) weeks ("Long Lead Time Components") upon the Parties' mutual finalizations of and approvals for, the Product requirements, Specifications, design, and bill of materials, which list shall be set forth as Exhibit D and attached hereto. Seller shall use its best efforts to reduce and minimize the number of Long Lead Time Components. Seller shall use reasonable efforts to update the list of Long Lead Time Components every quarter and to present an updated list of Long Lead Time Components to Buyer. Each revised list of Long Lead Time Components shall be deemed an amendment to Exhibit D. In the event that Seller fails to present an updated list of Long Lead Time Components, (i) the Parties shall continue to rely on the preceding list (as updated in writing by the Parties) and (ii) Buyer will accept responsibility for Long Lead Time Components ordered outside the lead times set forth in the list provided that Seller can demonstrate to Buyer's reasonable satisfaction that such components were ordered in accordance with the then-current vendor lead times. (Buyer acknowledges that lead times constantly change and the Seller might not always be able to present Buyer with a current list of Long Lead Time Components.)

(b) Buyer shall be financially liable for all Long Lead Time Components when ordered in accordance with this Section 1.7 if Buyer terminates this Agreement without cause or Seller terminates this Agreement pursuant to Section 7.1(a) or (d). Seller shall otherwise be financially liable for all Long Lead Time Components. Specifically, Buyer's component liability for Long Lead Time Components shall be equal to Seller's delivered cost (delivered cost is the cost paid by Seller for the components, net of all credits and discounts, plus a materials margin equal to Fifteen Percent (15%)) of all components ordered in support of any Binding Forecast. At Buyer's request, Seller shall use commercially reasonable efforts to minimize Buyer's component liability by attempting to return components to the vendor; provided, however, that Seller shall not be obligated to attempt to return to a vendor components that are, in the aggregate, worth less than One Thousand Dollars (\$1,000).

2. Pricing; Payment; Continuous Improvement.

2.1 Pricing; Escalation. Prices for the Products are set forth in Exhibit E attached hereto, and include packaging (as set forth in the then-applicable Specifications) and taxes. Subject to the provisions of Section 1.3(f), such prices shall be fixed for the initial two (2) Contract Year period of this Agreement. Thereafter, Seller may adjust prices for each successive Contract Year period of this Agreement, according to the annual Producer Price Index for Finished Goods ("PPIFG") or its replacement if so identified by the publisher, published by the United States Department of Labor, Bureau of Labor Statistics ("BLS"); provided, that such increases or decreases will be capped at Five Percent (5%) of the previous Contract Year's Product transfer price. Such PPIFG shall not be seasonally adjusted. The frequency for periodic adjustments hereunder shall be annual, using the first publication of the annual value in the month following the anniversary month of each successive Contract Year period of this Agreement. The adjustments shall be calculated using the "simple percentage method" as set forth by the BLS. Such PPIFG-based price changes shall be in addition to price changes (if any) permitted under Section 1.3(f).

2.2 <u>Payment</u>. Payment will be due forty five (45) days from Buyer's receipt of Seller's invoice, except to the extent Buyer in good faith disputes each invoice. Seller shall invoice Buyer at the time of shipment of the applicable Product and as otherwise provided for hereunder.

2.3 Continuous Improvement; Seller Performance Business Reviews. During the term of this Agreement, Seller shall use commercially reasonable efforts (including reasonable engineering support) to improve and enhance Product design, quality, performance and manufacturing processes (collectively, "Improvements") so as to maintain or increase the competitive advantage of the Products as compared to similar products in the marketplace. Improvements may result from Seller's own initiative ("Boyie Improvements") or the request or suggestion of Buyer ("BSC Improvements") but, if a proposed BSC Improvement or Bovie Improvement changes the Specifications or requirements of a purchase order the proposed Improvement must be approved in writing by Buyer prior to implementation as described in Section 3.1 hereof. Buyer shall pay Seller for waste or remanufacturing of raw materials, work-inprogress, intermediate sub-assemblies and finished goods inventory, which are rendered unusable by said BSC Improvements or any other changes approved by Buyer (collectively, "Waste Reimbursement"); provided, however, Buyer shall not be responsible for Waste Reimbursements for Bovie Improvements. BSC Improvements approved in accordance with this Section 2.3 and Section 3.1 hereof shall be promptly incorporated into the Specifications and Products in accordance herewith. In order to establish an effective system to identify and achieve productivity and quality objectives, BSC Improvements and

Bovie Improvements, Seller shall submit a productivity report to key administrators designated by Buyer on a mutually agreeable basis. Seller's and Buyer's representatives will meet as reasonably requested by Buyer for the specific purpose of driving mutual productivity and quality objectives.

2.4 <u>Tooling and Capital Equipment</u>. In addition to the price for each Product set forth on Exhibit E, Buyer shall reimburse Seller the actual cost, net of all third party credits and discounts, plus a fifteen percent (15%) management fee ("Management Fee"), of tooling, machining, molding, and other capital expenditures necessary or appropriate for the manufacturing of Product and that are purchased solely for use in connection with manufacturing Product (collectively, "**Manufacturing Equipment**"). Buyer will not be responsible for paying for any Manufacturing Equipment unless Buyer approves the purchase of such Manufacturing Equipment in writing in advance of purchase. Payment for Manufacturing Equipment will be due in accordance with Section 2.2. Seller will use Manufacturing Equipment solely in connection with the manufacturing of Products for Buyer. Buyer will at all times have title to and own all Manufacturing Equipment. Seller shall not take any action that would cause a lien or other encumbrance to be placed on any Manufacturing Equipment. At all times while the Manufacturing Equipment is in Seller's custody and control, Seller will maintain adequate levels of loss insurance to cover loss or damage to the Manufacturing Equipment.

2.5 <u>Payment of Start-up Fee</u>. Upon the execution of this Agreement, Buyer shall pay Seller a non-refundable start-up fee of One Hundred and Fifty Thousand Dollars (\$150,000.00) ("Start-up Fee"), which is in addition to any other payments from Buyer due hereunder.

3. Quality Assurance; Recordkeeping; Notification. The following obligations of Seller set forth in Sections 3.1 through 3.10 shall be collectively referred to throughout this Agreement as the "QA Standards".

3.1 Changes. Seller shall not make any changes to its documentation, shipping, manufacturing process (including vendors) or manufacturing location, pertaining to any Product, to any Product (including materials, packaging, labeling and Directions for Use) or to the Specifications unless approved by Buyer in writing in advance. All such changes shall be submitted to Buyer no later than sixty (60) days prior to Seller's proposed date of implementation for such change. If a proposed change is approved by Buyer in writing in its sole discretion, Seller shall be responsible for properly communicating and implementing such change, including with respect to any of Seller's vendors. Seller shall notify Buyer in writing and must receive approval by Buyer prior to any (a) use of any nonconforming material in the manufacture of any Product, (b) implementation of any Seller-authorized temporary deviation that could affect the production, interconnectivity, sterility, or handling of any Product, or (c) implementation of any Seller-initiated corrective action that could affect the safety or efficacy of any Product. Without limiting any other of Seller's obligations hereunder, Seller will assume full responsibility and costs for any product development activities necessary to remedy any nonconformance in Products (with respect to quantity, Specifications, requirements and delivery dates), including costs to implement such changes on all units in the field and in inventory. Notwithstanding anything in this Agreement to the contrary, Buyer shall pay Seller for Waste Reimbursements, as set forth in Section 2.3 above.

3.2 <u>Seller's Vendors</u>. At Buyer's request, Buyer will perform a quality system assessment of the vendors who provide Seller with raw components/materials, sub-assemblies or contract services for Products. All such vendors who provide Seller with such materials and services as of the Effective Date are set forth on Exhibit F attached hereto, which Exhibit F will be amended from time to time as Seller's vendors change. Buyer shall confirm in writing to Seller no later than thirty (30) days after the Effective Date (and no later than thirty (30) days after the date of any amendment to Exhibit F) the vendors listed on Exhibit F with which Buyer's Oncology Business (defined below) has a pre-existing relationship (collectively, "**Buyer's Vendors**"). Seller agrees to assist Buyer in arranging visits and inspection of the plants at which Seller's vendors manufacture any component/material, sub-assembly or service for any Product. Seller shall not change the outsourcing of any sub-component of any Product unless approved in writing in advance by Buyer in accordance with Section 3.1 hereof. In addition, Seller shall obtain Buyer's prior written approval, which Buyer shall not unreasonably withhold, with respect to each supplier, including a new supplier or a change to an existing supplier, of any material, component, sub-

assembly or service relating to any Product as described in Section 3.1 hereof. For avoidance of doubt, Seller shall not incorporate into any Product any material, component or sub-assembly purchased from a third-party supplier, or permit any third party to perform services relating to a Product, unless approved in writing in advance by Buyer in accordance with Section 3.1 hereof. Buyer agrees, on behalf of its Oncology Business, not to contract directly with any vendors listed on Exhibit F, as amended, who supply Seller with Product components, for components of the Product for sale by Buyer's Oncology Business during, and for a period of two (2) years after any termination or expiration of, this Agreement for any reason except as set forth in the next sentence; provided that this restriction in no way applies to or otherwise limits Buyer's right to contract directly with (a) Mott Corporation ("Mott"), (b) Buyer's Vendors, or (c) any vendor that Buyer introduces to Seller, and further, except as permitted in subclauses (a), (b) and (c) of this sentence, Buyer's Oncology Business will not accept via intra-company transfer or otherwise such Product components purchased by Buyer or its Affiliates from Seller's vendors listed on Exhibit F, as amended. Notwithstanding the foregoing, such restriction on Buyer's Oncology Business' contracting with Seller's vendors as set forth in the preceding sentence shall not apply in the event Seller breaches this Agreement and Buyer terminates therefor pursuant to Sections 7.1(a), 7.1(b)(i), or 7.4, hereof. Seller agrees that, at such time as the Parties mutually execute the design transfer document referenced in Section 1.3(b), Seller will enter into, and during the balance of the term of this Agreement, will maintain, a written supplier agreement with Mott for the supply of the sintered tip incorporated into the Product, and a written understanding with Mott whereby Buyer would be able to visit and inspect Mott upon reasonable notice; provided, that Seller agrees that it will not at any time during and for a period of five (5) years after any termination or expiration of this Agreement for any reason enter into an exclusive supply arrangement or any other agreement or arrangement with Mott that would limit Mott's ability to sell or otherwise provide any components or products to Buyer or its Affiliates. As used herein, "Buyer's Oncology Business" means that part of Buyer's business primarily responsible for Buyer's oncological business.

3.3 Product Conformity. Seller will manufacture Products in accordance with the thencurrent (a) Specifications, (b) applicable regulations relating to the current Good Manufacturing Practices (as defined by the Food, Drug and Cosmetic Act, as amended) and similar protocols ("cGMP"), (c) the United States Food and Drug Administration ("FDA") quality system regulations ("QSR"), including master device and lot history records, ISO 13485 requirements, ISO14971 requirements, MDD requirements and CMDCAS requirements, and (d) other pertinent rules and regulations of FDA and similar regulatory bodies in other applicable jurisdictions set forth in the Specifications, as amended. In the event that Seller is required or deems it desirable to obtain ISO Quality System Certification, Seller shall promptly notify Buyer in writing of Seller's selection (or change in registrar) for obtaining ISO Quality System Certification. Seller shall maintain a current Declaration of Conformity status with EU Notified Bodies per MDD requirements when Buyer is distributing in European markets. During the term of this Agreement, Seller will maintain or cause to be maintained the Product manufacturing facility's registration as a certified medical device manufacturing facility and will maintain such facility registration with all applicable regulatory bodies or cause such facility to be maintained such that the facility would pass an audit for compliance with cGMP and QSR. Seller shall maintain ongoing quality assurance and testing policies sufficient to satisfy its obligations under this Agreement, and Seller's standard quality assurance policies. Any non-conformance in Product, material or process which Seller wishes to use "as is" or rework will require prior written approval from Buyer. Seller will assume full responsibility and its costs for any product development activities necessary to remedy any nonconformance in Products arising exclusively from defects in Product design, manufacture or materials, or from deviation from quality standards (but not in any way from Product claims, which are the sole responsibility of Buyer), which non-conformance is not approved by Buyer in accordance with the requirements of the preceding sentence. Seller shall be responsible for obtaining and maintaining any required regulatory filings and registrations set forth in the Specifications, as amended, including ISO registration ("CE Mark") and 510(k) filings with the FDA (collectively, the "Regulatory Filings") for the Products under Seller's notified body or through other applicable Regulatory Authorities (defined below and set forth in the Specifications, as amended); provided, that Buyer will have the right to review any Regulatory Filings and provide comments on such filings (which Seller will consider in good faith) before they are submitted by Seller; and further, provided, that Buyer will at all times upon notice to

Seller have the right to make any Regulatory Filings with Regulatory Authorities outside of the United States in Buyer's name and Seller will provide Buyer with access to all documents necessary or appropriate for Buyer to make such Regulatory Filings and with authorization to use such documents and the information contained therein to make Regulatory Filings as the distributor of Products. Upon termination or expiration of this Agreement, Buyer may purchase from Seller physical and legal ownership of all Regulatory Filings for the Product, including all documents and communications to and from the pertinent Regulatory Authorities. Products will bear Seller's regulatory registration mark(s), including Seller's CE Mark. As used in this Agreement, "**Regulatory Authority**" means any national supra-national, foreign, regional, state or local regulatory agency, department, bureau, notified body, commission, council or other governmental entity, including FDA, as set forth in the Specifications, as amended.

3.4 Product Acceptance. Each shipment of Product from Seller to Buyer shall be inspected by Seller prior to shipment and shall contain such quality control certificates reasonably requested by Buyer certifying, among other things, that the Products are in conformity with Specifications. All Products are subject to final inspection and acceptance at Buyer within thirty (30) Business Days of delivery. Buyer shall notify Seller within thirty (30) Business Days of delivery of any apparent defective material or workmanship or non-conformity of any Product to the Specifications or applicable purchase order. If Buyer fails to notify Seller within thirty (30) Business Days of delivery of an apparent defect, Buyer will be deemed to have accepted the Product; provided, that the warranty contained in Section 8 hereof shall survive such acceptance. Without prejudice to any other right or remedy of Buyer, in case any Product is defective in material or workmanship or otherwise not in conformity with the Specifications or the requirements of Buyer's purchase order, Buyer will have the right to reject it; provided, however, that Buyer shall notify Seller of any rejection hereunder, and the basis for it, in writing, within the thirty (30) Business Day timeframe set forth above. Any Product that has been rejected must be replaced by and at the expense of Seller promptly after notice. Buyer will return all rejected Products to Seller at Seller's expense. Seller shall investigate the cause for the rejection and provide to Buyer in writing all proposed corrective actions associated with the cause for rejection. From time to time during the term of this Agreement, Buyer may also request final inspection testing results from Seller, in addition to the quality control certificates, as evidence that the supplied Product meets Specifications. Seller will timely and fully respond to all such requests.

- 3.5 <u>Complaints and Corrective Action</u>.
- (a) As used in this Section:

(1) "**Complaint**" means any written, electronic or oral communication, that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a Product after it is released for distribution (marketed).

(2) "**Complaint Investigation**" means a documented process for determining the root cause (or the most probable cause) of a Complaint.

(3) "Medical Device Report" or "MDR" means a report filed with FDA to communicate an event when Seller or Buyer becomes aware (as such phrase is defined in 21 CFR 803.3(c)) of information that reasonably suggests that one of its marketed Products:

- (i) May have caused or contributed to a death, Serious Injury or serious deterioration in the state of health of a user or patient; or
- (ii) Has malfunctioned (see definition of Reportable Malfunction in 21 CFR 803.3 (n)) and that the Product or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or Serious Injury of a user or patient if the malfunction were to recur.

(4) "Medical Device Vigilance Report" or "MDV" means the official notification provided to regulatory authorities outside of the United States of adverse events deemed reportable pursuant to the local laws and/or regulations.

- (5) "Serious Injury" means an injury or illness that:
 - (i) Is life threatening (i.e. when continued use of the device is likely to have resulted in the death of a patient or when a patient was at substantial risk of dying at the time of the adverse event); or
 - (ii) Results in permanent impairment or damage to a body structure or body function, or necessitates medical or surgical intervention to preclude permanent impairment or permanent damage to a body structure or body function.

Buyer will be the initial contact for all Complaints from its customers. Buyer may (b) require Seller to perform Complaint Investigations related to the manufacturing, Seller's design, or packaging of Products in order to investigate the cause of any such Complaints and to determine any required corrective actions. In connection with every Complaint Investigation, Seller will perform a lot history or device history review of the affected Product. If the Complaint is accompanied by or followed by return of the subject Product to Buyer, Buyer will return to Seller the Product that is the subject of the Complaint; provided, Buyer may at its option perform an initial evaluation of the returned Product to determine the root cause of failure. Seller will maintain records of all such Complaint Investigations as required by cGMP and other applicable rules and regulations of any Regulatory Authority. No later than fifteen (15) business days after Seller's receipt of a written request from Buyer to perform a Complaint Investigation including receipt of the allegedly defective Product (unless such Product is unavailable), Seller will provide Buyer with an initial report of such Complaint Investigation, and no later than thirty (30) days after Seller's receipt of a written request from Buyer to perform a Complaint Investigation including receipt of the allegedly defective Product (unless such Product is unavailable), Seller shall perform and provide to Buyer a written report of such Complaint Investigation, including a complete investigation that contains a root cause analysis and corrective action recommendations. In the event of an MDR or MDV, Buyer may require Seller to expedite the Complaint Investigation in order to comply with any applicable regulatory filing requirements of any Regulatory Authority.

(c) Seller will be responsible for filing all required Complaint reports (including MDRs and/or MDVs) with the appropriate Regulatory Authorities. In any event, Buyer retains the right to file all required Complaint reports, including MDR and MDV reports; <u>provided</u>, <u>however</u>, that Buyer shall immediate notify Seller, in writing, of its intention to file such reports.

(d) Seller will maintain a cross-reference from Seller's Complaint response to Buyer's associated Complaint file numbers. Seller will complete all corrective actions, including any corrective actions identified in a response to Buyer pursuant to this Section 3.5 or any corrective actions reasonably requested by Buyer, within a mutually agreed upon timeframe, and upon request of Buyer, provide written evidence of such completion.

Buyer shall have the right to have employees and other 3.6 Inspection; Access. representatives of Buyer (including external auditors and representatives of Buyer's notified body) present at any plant or production facility relating to or used in connection with the manufacturing of Product during normal business hours to conduct an initial and periodic inspections of such facilities and manufacturing procedures for compliance with ISO, cGMP and QSR, and the Specifications and to inspect Seller's inventory of Products, work-in-process, raw materials to be used for Products, production records, design history file, quality manuals, regulatory dossiers and such other matters as may be pertinent to proper quality assurance of Products to be delivered hereunder. Buyer agrees to give Seller a minimum of two (2) Business Days' prior notice of any such inspection "for cause" and ten (10) Business Days' prior notice for any other inspection. Seller shall immediately use its best efforts to take such action as is required to correct any deficiencies identified by Buyer or its representatives relating to the production of any Product. Seller is not currently a party to, and shall not enter into, any third-party manufacturing agreement relating to any Product that does not grant to Buyer and its representatives, as third-party beneficiaries, rights to inspect the plant or plants at which Product components or materials are manufactured on the terms set forth in this Section. Seller further agrees to use its best efforts to provide such documentation or conduct such analyses as Buyer or its representatives may reasonably request in

connection with any regulatory submission or audit hereunder. In accordance with applicable laws and regulations governing regulatory inspections, Seller shall permit authorized representatives of relevant regulatory authorities, including FDA, to inspect any plant and production facilities relating to or used in connection with the manufacture of any Product.

3.7 <u>Records</u>. For the longer of seven (7) years after delivery to Buyer of each Product, or such longer period as may be required by cGMP and other applicable rules and regulations of any Regulatory Authority or by law, Seller shall: (a) maintain traceability records for each Product, including the manufacture date and lot number of each unit of Product and each component and material comprising the Product; (b) maintain records subject to 21 CFR 820 Subpart M (such as the Device Master Record, quality system record and Complaint files); and (c) provide Buyer a copy of such records without charge upon Buyer's request. Upon termination or expiration of this Agreement, such records shall be placed in escrow on terms mutually agreed to by the Parties.

3.8 <u>Required Notification</u>. Each Party hereto shall immediately notify the other Party by fax, with confirming notice by Overnight Delivery, as soon as a Party becomes aware of any: (a) defect or condition which renders or may render any Product ineffective or dangerous; (b) Product that is not in compliance with the Specifications (including manufacturing process, labeling or packaging) or other QA Standards; (c) breach by either Party of the terms of this Agreement; (d) regulatory, FDA or ISO inspections or other communications with regulatory, FDA or ISO authorities related to a Product or that would in any way impact the Product or either Party's performance hereunder; or (e) infringement by any party of intellectual property rights applicable to the Product. Without limiting the generality of the foregoing, each Party will notify the other Party immediately if it becomes aware of any death or bodily injury caused by a Product (or suspected to be caused by a Product) or any malfunction of a Product.

3.9 <u>EEO Laws</u>. Seller acknowledges that Buyer is an equal employment opportunity/affirmative action employer subject to Executive Order 11246, the Vietnam Era Veterans Readjustment Assistance Act, Section 503 of the Vocational Rehabilitation Act, and their implementing regulations (collectively, "**EEO Laws**"). Seller may be governed by these laws and implementing regulations which are incorporated into this Agreement by reference. By acceptance of this Agreement, Seller certifies that it complies and will continue to comply with all applicable EEO Laws, and it shall not discriminate on the basis of race, age, color, religion, gender, sexual orientation, disability, veteran status, national origin or any other characteristic protected by federal, state or local law.

3.10 <u>Quality Plan</u>. Seller and Buyer shall establish a quality plan which will define the quality practices, the resources and the activities relevant to Products that are designed and/or manufactured for Buyer. This plan will define how the quality requirements will be met and will be approved in writing by both Parties.

3.11 Product Recalls.

(a) If, in the judgment of Seller or Buyer, any Product defect or any government action requires a recall of, or the issuance of an advisory letter regarding, any Product, either Party shall undertake such recall or issue such advisory letter only after notification to and consultation with the other Party. Each Party shall notify the other Party within two (2) Business Days of becoming aware (as such phrase is defined in 21 CFR 803) of any issue that could lead to a field action related to the Products. The Parties shall endeavor to reach an agreement prior to making any recall or issuing any advisory letter regarding the manner, text and timing of any publicity to be given in such matters in time to comply with any applicable legal or regulatory requirements, but such agreement will not be a precondition to any action that either Party deems necessary to protect users of Products or to comply with any applicable governmental orders or mandates. The Parties agree to provide reasonable assistance to one another in the event of any recall or issuance of any advisory letter. Notwithstanding anything in this Agreement to the contrary, Buyer shall have the right to manage any Product recall.

(b) In the event of a recall of Product, Seller shall correct any deficiency relating to its manufacturing, packaging, testing, labeling, storing or handling of Product, if applicable, or cause the vendor of any material, component, or sub-assembly incorporated into Product to do likewise with respect to such material, component, or sub-assembly, and shall, at Seller's option, either (i) at its cost replace each unit of Product recalled (including units held in inventory by Buyer or its customers) with a corrected Product within a reasonable period of time, or (ii) refund the Buyer's purchase price thereof. Seller shall promptly pay or reimburse Buyer for its costs and expenses (i.e., shipping, quality control testing, and notification) incurred by Buyer as a result of any recall or advisory letter; provided, however, that if the recall is related to requirements or Specifications (i.e., materials, design or process changes, and Product claims) originating with Buyer, then Buyer will pay the costs and expenses incurred for such recall.

3.12 <u>Product Returns</u>. Seller shall accept returns of Product shipped by Seller if: (a) the request to return such Product is received within thirty (30) Business Days of invoice date (or, if later, the date that shipment is received); (b) the Product is returned in new condition, salable and in its original packaging, and (c) the reason for the return is directly related to defective product quality. Nothing express or implied in this Section 3.12 shall be deemed to modify or diminish the right of Buyer to reject Products in accordance with the provisions of Section 3.4 or limit the warranty for Products set forth in Section 8.

3.13 <u>Compliance with Laws</u>. Seller will comply with all applicable laws and regulations of the Regulatory Authorities set forth in the Specification, as amended, pertaining to the testing, manufacture, labeling or packaging of Products or pertaining to performance by Seller of its obligations under this Agreement, including the maintenance of ongoing quality assurance and testing procedures to comply with applicable regulatory requirements. Without limiting the generality of the foregoing, Seller will (a) report to every applicable Regulatory Authority within any relevant time periods all events that are required to be reported (including any death or serious bodily injury caused by a Product); and (b) deliver, within the permitted time periods, all annual or other periodic reports required to be delivered to every applicable Regulatory Authority. Seller represents and warrants that it is the legal manufacturer of the Product.

Product Specifications; Packaging and Labeling. All Products delivered by Seller 3.14 hereunder shall be in full compliance with the Specifications therefor and shall be ready for end-user sale, including all packaging, labeling, instructions-for-use and sterilization set forth therein, as amended. All Products shall be labeled (including bar coding/UPN numbers) in accordance with the work instructions, procedures and label text/graphics specified in writing from time to time by Buyer and mutually approved by Buyer and Seller. Buyer shall give Seller at least thirty (30) days advance written notice of any change to its labeling procedures prior to the date when such changes are to take affect. Notwithstanding anything in this Agreement to the contrary, Buyer shall pay Seller for Waste Reimbursements, as set forth in Section 2.3 above. All Products will be marked to make it clear that they have been manufactured by Seller and are being distributed by Buyer. Buyer may include Product as a component in any kit or collection of products. Buyer maintains the right to over-label Products as it deems necessary or appropriate in accordance with work instructions, procedures, and label text/graphics, which are mutually approved by both Parties hereto. Seller is not responsible for any over-labeling or any consequences As used in this Agreement, "Specifications" for the Product means the specifications set forth thereof. on Exhibit A, as revised from time to time pursuant to the next sentence, and as provided by Seller and approved by Buyer, including the part number, revision level, controlled drawing, and packaging and sterilization instructions for the Product and all requirements of any applicable laws and regulations of the Regulatory Authorities, specified therein. The Parties understand that the Specifications may need to be revised from time to time up to the Product Launch Date. Each version (each, a "Revision Level") of the Specifications will be labeled with a Revision Level number ("Revision Level Number"), starting with "A-1," and continuing sequentially with "A-2," "A-3," etc., and each revision of the Specifications will be so labeled and attached to this Agreement. Each subsequent Revision Level will replace and supersede all former Revision Levels for all purposes hereunder, except with respect to Article 4 of this Agreement. Attached to this Agreement as Exhibit A as of the Effective Date is Revision Level "A-1."

4. Confidential Information; Intellectual Property.

4.1 <u>Confidential Information</u>.

"Confidential Information" means all information disclosed by or on behalf of either (a) Party hereto (a "Disclosing Party") to the other Party hereto (a "Receiving Party"), or any of the Receiving Party's employees, officers, directors, Affiliates, subcontractors, agents, successors or assigns (collectively "Representatives" and together with the Disclosing Party, the "Disclosing Group"), including information (i) relating to the matters that are the subject of this Agreement, including the terms, existence and nature of this Agreement, (ii) all other information regarding the Disclosing Party's past, present or future research, technology, know-how, ideas, concepts, designs, products, markets, customer information, computer programs, prototypes, processes, machines, articles of manufacture, compositions of matter, business plans and operations, technical information, drawings, specifications (including Specifications), (iii) BSC Improvements or Bovie Improvements (as applicable), and (iv) any knowledge or information developed by the Disclosing Party as a result of work in connection with this Agreement that directly relates to the Product, except information which is: (i) at the time of disclosure, or thereafter becomes lawfully part of the public domain through no act or omission by the Receiving Party; (ii) lawfully in the possession of Receiving Party prior to disclosure by or on behalf of Disclosing Party, as shown by written records; (iii) lawfully disclosed to the Receiving Party by a third party which did not acquire the same under an obligation of confidentiality from or through the Disclosing Group; or (iv) independently developed by the Receiving Party without use of Confidential Information, as shown by written records. If a Receiving Party believes in good faith that it is required by law to disclose any Confidential Information, it shall provide notice to the Disclosing Party, prior to making such disclosure so as to allow Disclosing Party time to undertake legal or other action, to prevent such disclosure or otherwise obtain confidential treatment of such disclosure.

(b) A Receiving Party shall not, without the prior consent of the Disclosing Party, disclose any Confidential Information to anyone for any reason at any time or use any Confidential Information for any purpose except as requested by the Disclosing Party. The Receiving Party shall limit dissemination of Confidential Information to only those Receiving Party Representatives having a "need to know." A Receiving Party shall not, except as permitted under this Agreement: (i) appropriate or use a Disclosing Party's Confidential Information in Receiving Party's own manufacture of Products for itself or for any third party or for any other purpose; or (ii) by virtue of either this Agreement or its supply or purchase of Products, as applicable, obtain any title to, or any interest or license in, any Confidential Information of a Disclosing Party.

(c) Neither Party shall issue a press release or other public announcement concerning this Agreement (or any term sheet, bids, negotiations or other related information), the transactions contemplated herein, or the relationship between the Parties without the prior written approval of an authorized representative of the other Party, which approval shall not be unreasonably withheld or delayed.

(d) Neither Party shall: (i) disclose to the other Party any confidential or proprietary information belonging to any third party without the consent of such party; or (ii) represent as being unrestricted any designs, plans, models, samples, or other writings or products that the Disclosing Party knows or has reason to know are covered by valid patent, copyright, trade secret, or other form of intellectual property protection.

4.2 <u>Buyer's Property</u>. All tangible property provided to Seller in connection with this Agreement, including: Product requirements, drawings, standard operating protocols, quality testing and other documentation, all samples, Buyer's Confidential Information, all reports, brochures, manuals, sales literature, all equipment and tooling, provided by Buyer to test, manufacture or assemble the Products, and all Manufacturing Equipment (collectively, "**Buyer's Property**") shall be and remain the exclusive property of Buyer unless otherwise agreed in writing. Seller shall: (a) keep and maintain in its custody

and subject to its control any Buyer's Property that it receives or develops during the term of this Agreement, for the sole benefit of Buyer; (b) use Buyer's Property solely in furtherance of fulfilling its obligations to Buyer under this Agreement; and (c) return or surrender to Buyer all Buyer's Property within fifteen (15) days after termination or expiration of this Agreement or otherwise upon written request by Buyer provided; however, such return of Buyer's Property does not interfere with Seller's performance hereunder.

4.3 Intellectual Property.

(a) Buyer and Seller acknowledge and agree that (i) the performance of engineering services; and (ii) the development of designs, concepts, inventions, prototypes and the like, and intellectual property relating thereto, by Seller prior to the Effective Date, either solely or in cooperation with others including Buyer, which relate solely to any medical device having a sintered, conductive metal tip, are within the scope of this Agreement and the results of such services and development are the exclusive property of Buyer and included within the definition of BSC Intellectual Property provided in Section 4.3(b). Consideration for such services and development has been accounted for in the price of the Products herein.

Except for Seller's intellectual property related solely to electrosurgical generators (e.g., (b) RF energy generation, monitoring and control), (i) all intellectual property, both domestic and foreign, including any and all tangible and intangible trade secret rights, patents rights (including registrations, applications, renewals, extensions, continuations, divisions, reexaminations and reissues), processes, know-how, prototypes, Specifications, drawings, designs, tools, industrial property rights, inventions, Improvements (excluding manufacturing processes), developments or discoveries, conceived or made by Buyer or Seller, whether patentable or not, related solely to any medical device having a sintered, conductive metal tip, (ii) Buyer's Confidential Information, and (iii) Buyer's Property (except Manufacturing Equipment) (collectively, "BSC Intellectual Property"), shall be the exclusive property of Buyer, and Seller shall cooperate in assigning, and hereby does assign, all right, title, and interest in and to such BSC Intellectual Property to Buyer. All copyrightable works developed by Seller, either alone or with others, related to BSC Intellectual Property, are "works made for hire" and are hereby assigned to and shall belong exclusively to Buyer, and any and all copyright rights to such works, including the right to copy or reproduce the works, create further derivative works, file for copyright registration, and renew such rights, are hereby assigned to, and shall be the exclusive property of, Buyer.

(c) Seller agrees to cooperate with Buyer in the preparation, prosecution, filing and maintenance of the BSC Intellectual Property during the term of this Agreement and thereafter, and Buyer agrees to pay Seller reasonable compensation for such cooperation.

(d) To the extent there is jointly invented and jointly owned intellectual property, each Party hereto agrees to cooperate with the other Party with the preparation, prosecution, filing and maintenance of the intellectual property during the term of this Agreement and thereafter beyond that provided by the Agreement. Each Party agrees to pay the other Party reasonable compensation for such cooperation beyond the term of this Agreement.

(e) During the term of this Agreement, and any extension thereof, Buyer hereby grants to Seller a worldwide, royalty-free, non-exclusive license to use the BSC Intellectual Property solely for the purpose of fulfilling its obligations hereunder. No other license is granted by Buyer therein or in any other of Buyer's intellectual property. Buyer reserves to itself exclusive ownership and rights in the BSC Intellectual Property, except to the extent of the limited license granted in this section.

(f) Seller agrees that there shall be no consideration provided by Buyer to Seller not expressly contemplated in this Agreement for Seller's manufacturing know-how and other intellectual property used by Seller in the manufacture and delivery of Product to Buyer.

4.4 <u>Co-Branding</u>

(a) All labeling, packaging, materials for advertising and marketing, websites, and user and technical documentation for Products (collectively, "Materials") will be co-branded with both the Boston Scientific and Bovie names (the "Co-Brand"). Unless otherwise mutually agreed to by the Parties in writing, the Co-Brand shall be present on all Materials in a size and format to be mutually agreed upon by the Parties, but in all cases so that each name is prominent and reasonably legible to the naked eye. The Parties will work in good faith to agree to one or more standard Co-Brand templates for use on the Materials, which Templates shall specify the acceptable visual characteristics of the Co-Brand for use on Materials, and as long as one of these templates is used, Buyer may use the Co-Brand without the further prior approval of Seller. Any deviation from the template will require the prior written approval of Seller, which approval shall not be unreasonably withheld.

(b) Buyer will use Seller's trademarks as adjectives and not as nouns or verbs, and not in the plural or possessive form. In advertising and marketing materials, Buyer shall distinguish Seller's trademark from surrounding text by using bold, italics or the appropriate visual tools, or by capitalization or the use of quotation marks, and will use the proper trademark symbol in connection with Seller's trademarks.

(c) Seller hereby grants to Buyer a fully paid-up, royalty free license to use Seller's trademarks solely in connection with the marketing, distribution, import, export, use, offer to sell and sale of the Products.

(d) Seller will take such actions as are reasonably necessary to prosecute and maintain its trademarks and shall inform Buyer of any changes in or additions to any trademark used in the Co-Brand materials.

(e) Except as required under this Agreement, and as set forth in this Section 4.4 (Co-Branding), in no event will Seller be permitted to use Buyer's trademarks without the prior written consent of Buyer.

(f) Combining the Parties' trademarks is permitted only as mutually agreed to by the Parties for purposes of the Co-Brand.

5. Insurance and Indemnification.

5.1 <u>Insurance</u>. Seller shall: (a) during the term of this Agreement, maintain commercial general liability insurance, naming Buyer as additional insured and loss-payee; and (b) immediately notify Buyer in writing of any change or cancellation relating to such policy. Prior to execution of this Agreement, Seller shall provide Buyer with a certificate of insurance evidencing such insurance.

5.2 Indemnification.

(a) Seller shall indemnify, defend and hold harmless Buyer and its Affiliates and their respective directors, officers, employees and agents from and against any claim, action, suit, demand, damage, expense or losses (including reasonable attorneys' fees) (collectively, "Claims") resulting from or in any way relating to: (i) the gross negligence, intentional misconduct, or violation of law by Seller or Seller Representatives in the performance of, or its failure to perform, any of Seller's obligations under this Agreement; (ii) any material breach of Seller's representations, warranties, covenants or obligations under this Agreement, including Seller's obligation to deliver Product under this Agreement; or (iii) infringement or alleged infringement of any third party intellectual property rights with respect to any Product provided by Seller to Buyer hereunder to the extent that infringement is found by a court of competent jurisdiction to result from the use or sale of a Bovie Improvement or the incorporation of Bovie Intellectual Property into a Product.

(b) Buyer shall indemnify, defend and hold harmless Seller and its Affiliates and their respective directors, officers, employees and agents from and against any Claims resulting from or in any way relating to: (i) the gross negligence, intentional misconduct, or violation of law by Buyer in the

performance of, or its failure to perform, any of Buyer's obligations under this Agreement; (ii) any material breach of Buyer's representations, warranties, covenants or obligations under this Agreement, or (iii) infringement or alleged infringement of any third party intellectual property rights with respect to any BSC Intellectual Property (including Specifications or requirements provided by Buyer to Seller hereunder), except to the extent that infringement is found by a court of competent jurisdiction to result from Buyer's use, manufacture, offer to sell, or sale of Bovie's Intellectual Property or Bovie's Improvements incorporated into a Product.

(c) Each Party's obligations to the other Party under this Section 5.2 are conditioned upon the Party seeking indemnification: (i) providing notice to the indemnifying Party of any Claims promptly, but not later than thirty (30) days after the Party knows of such Claim; (ii) permitting the indemnifying Party to assume full responsibility for the defense of such Claim; (iii) assisting the indemnifying Party in defense of such Claim; and (iv) not compromising or settling any such Claim without the indemnifying Party's prior consent. Notwithstanding the foregoing, a Party's failure to give the notice specified in Section 5(c)(i), or delay in giving such notice, shall not affect such Party's right to indemnification under this Section 5.2 except to the extent that the indemnifying Party has been prejudiced by such failure or delay. In addition, the indemnifying Party may not settle a claim without the indemnified Party's consent unless such settlement includes a full release or license for both past and future sales of Product at no additional cost to the indemnified Party.

6. <u>Remedies</u>. Termination of this Agreement, or the exercise of any other remedy, shall not be deemed to be an exclusive remedy hereunder, and shall be in addition to any other remedies available at law or in equity (including a Party's right to obtain specific performance and other equitable relief for other Party's material breach).

7. <u>Term</u>.

7.1 <u>Term; Termination</u>. The initial term of this Agreement shall commence on the Effective Date and expire on the fifth (5th) 12-month anniversary of the Product Launch Date of the Product. This Agreement will automatically renew for additional one-year periods, unless notice of cancellation is delivered by either Party at least one hundred and eighty (180) days prior to the end of the then current term. Notwithstanding the above, this Agreement shall terminate:

(a) subject to Section 7.1(b), sixty (60) days after notice of a material breach from one Party to the other, but only if such breach remains uncured at the end of such 60-day period; <u>provided</u>, <u>however</u>, that this Agreement shall terminate immediately upon notice of breach to a Party if the same or similar material breach was the subject of a previous notice of breach pursuant to which a 60-day cure period was previously provided to such Party;

(b) subject to the Force Majeure provisions of Section 7.3, immediately upon notice from Buyer if: (i) Seller does not satisfy Buyer's binding purchase order requirements for any two (2) consecutive months; (ii) Buyer determines in good faith that Five Percent (5%) or more of any particular Product manufactured and delivered to Buyer during a calendar month is defective, or does not meet the Specifications for such Product, anytime after the first ninety (90) days of the term of this Agreement; (iii) Buyer believes in good faith that Seller's quality assurance policies do not comply with Section 3; or (iv) Buyer reasonably determines that any material breach hereunder does or may negatively impact the performance of any of Buyer's Products, Buyer's reputation, patient safety or the safety of any other persons or the environment;

(c) in accordance with Section 7.3 or 7.4 hereof;

(d) immediately upon notice from a Party if the other Party has become the subject of voluntary or involuntary bankruptcy, receivership, or insolvency proceedings;

(e) following one hundred and twenty (120) days written notice from Buyer of its intent to terminate for convenience;

(f) immediately upon notice from Seller if Buyer fails to make payments to Seller in accordance with the provisions of Section 2.2, above.

7.2 <u>Fulfillment Upon Termination</u>. (a) Upon termination (except pursuant to Section 7.1(e), above) or expiration of this Agreement, Seller shall be obligated to fulfill any then open binding purchase orders, and Buyer shall be obligated to purchase (a) all Products on open binding purchase orders not yet purchased, and (b) all then-existing Shelf Inventory; <u>provided</u>, <u>however</u>, that in no event shall Buyer be required to purchase any Product (including work-in-process or raw materials or Shelf Inventory) after any termination of this Agreement by Buyer pursuant to Section 7.1(a), (b), (c) or (d).

(b) Upon termination pursuant to Section 7.1(e), above, in Contract Years One or Two, if Buyer has not purchased the minimum quantity of Product units for Contract Years One and Two, as set forth in Section 1.3, above, Buyer shall immediately purchase or, at its election, pay for in cash the transfer price of the number of Product units equal to the difference between Thirty-Five Hundred (3,500) and the actual number of Product units purchased to that point in time by Buyer. Upon termination pursuant to Section 7.1(e), above, after Contract Year Two, Buyer shall be obligated to purchase (a) all Products on then open binding purchase orders not yet purchased, and (b) all then-existing Shelf Inventory.

7.3 <u>Force Majeure</u>. If a Party's performance is delayed because of war or similar unrest, terrorism, fire, act of God or other similar cause that is beyond its control and which such Party could not have reasonably prevented, such delay in performance shall not be considered a breach of this Agreement; <u>provided</u>, <u>however</u> that if such delay continues for sixty (60) days or more, then: (a) the other Party may upon notice cancel all or any portion of unfilled orders; and (b) that other Party may immediately terminate this Agreement.

7.4 <u>Failure to Supply</u>. If Seller fails to meet its binding supply obligations under any binding purchase orders provided by Buyer pursuant to Section 1.3, and such failure:

(a) remains uncured for more than sixty (60) days, then such shortfall shall be sold to Buyer at a price discount of ten percent (10%), and this discount will remain in effect for three (3) consecutive months after the failure to supply has been cured; and

(b) results in less than the specified number of Product units being delivered to Buyer for any five (5) months, whether consecutive or not, at any time during the term of this Agreement, then Buyer may terminate this Agreement immediately upon written notice and initiate a manufacturing transfer pursuant to Section 7.5 hereof to be completed by Seller at Seller's expense.

7.5 <u>Manufacturing Transfer</u>. In the event of any termination of this Agreement, Seller shall physically transfer to Buyer, at Buyers expense, all of Buyer's Property held by Seller. Buyer may purchase from Seller, all tooling developed by Seller and not previously charged to Seller.

8. <u>Warranty</u>.

In addition to any other representations and warranties of Seller herein, Seller represents and warrants to Buyer that all Products supplied to Buyer hereunder shall: (a) conform to the Product Specifications, (b) be manufactured, labeled, packaged and tested in accordance with the applicable regulatory approvals therefor and the applicable laws and regulations relating to the manufacture, labeling, packaging and testing of Products, and (c) be free from defects in design, materials and workmanship. Seller shall provide all end-users of all Products a limited warranty that reasonable care has been used in the design and manufacture of the Products. If a Product does not conform to the warranties set forth above, Seller will replace the Product, issue Buyer a refund, or issue Buyer a credit toward future purchases, solely at Seller's discretion.

9. <u>Miscellaneous</u>.

9.1 Seller is an independent contractor of Buyer, and neither Party has the power to bind the other. Subject to the limitations of Force Majeure set forth in Section 7.3, above, time is of the essence in performance hereunder.

9.2 Neither Party shall assign this Agreement or its obligations hereunder, whether voluntarily or involuntarily, without the express prior written consent of the other Party, except that either Party hereto may assign all of its rights and obligations under this Agreement to any purchaser, directly or

indirectly, of (a) in the case of Seller, all or substantially all of Seller's assets (or stock), and (b) in the case of Buyer, all or substantially all of Buyer's Oncology Business assets (or stock), without the other Party's consent. Any permitted assignee hereunder is deemed to have assumed the assignor's performance obligations in favor of the non-assigning Party.

9.3 This Agreement is fully binding upon either Party's successors and permitted assigns.

9.4 All requests, approvals, consents and notices must be in writing and will be effective as of the date actually received and, unless otherwise specified in this Agreement, shall be sent as follows: (i) certified mail - return receipt requested; (ii) a nationally recognized overnight delivery service that guarantees overnight delivery and requires the signature of recipient; or (iii) facsimile, transmission confirmed; to the addresses and fax numbers indicated on the first page of this Agreement; provided, however, that a copy is also sent one of the foregoing methods of subsection (i) or (ii), above

9.5 This Agreement: (i) is governed by the laws of The State of New York, without reference to its internal principles of conflicts of laws; (ii) together with all Exhibits thereto (which are hereby incorporated into this Agreement) is the entire and exclusive set of terms and conditions for transactions made with respect to the Products; (iii) supersedes conflicting terms of purchase orders, invoices or other documents issued under it; and (iv) may only be modified by a writing signed by both Parties.

9.6 Headings of the articles, sections and subsections of this Agreement, and the name of this Agreement, are for reference purposes only and shall not limit or affect the meaning or construction of the terms and conditions hereof. Whenever the words "include", "includes" or "including" are used in this Agreement, they shall be deemed in each instance to be followed by the words "without limitation."

9.7 No failure of either Party to enforce any right under this Agreement shall be deemed a waiver thereof.

9.8 For purposes of clarity, nothing in this Agreement shall restrict: as to Buyer, the right to pursue alternative resection device technology or Dissimilar Devices (defined below) from third parties or, as to Buyer or Seller, from developing alternative resection device technology or Dissimilar Devices internally or from selling any such Dissimilar Devices. As used herein, a "Dissimilar Device" is a medical device whose manufacture, use, importation, offer for sale, or sale, would not, if performed by a party other than Buyer (or its licensee) infringe BSC Intellectual Property.

9.9 All obligations and rights which are by their nature continuing, including the obligations contained in Sections 3.7 and 7.2 and Sections 4 through 6, and 8, shall survive the expiration or termination of this Agreement.

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Additional Representations and Warranties. Each Party hereby represents and warrants 10. to the other that: (a) the execution and delivery of and performance under this Agreement by such Party does not, and will not, conflict with or violate any other agreement or obligations with third parties or any restrictions of any kind or any law to which it is bound or subject; and (b) it has the unrestricted right to disclose any information it submits to the other Party, free of all claims of third parties, and that such disclosures do not breach or conflict with any confidentiality provisions of any agreement to which it is a party. Each Party hereto further hereby represents and warrants that (x) it owns or has sufficient license and right to intellectual property used in connection with or incorporated into the Product; and (y) the manufacture, use, importation, offer for sale, and sale of the Product does not and will not infringe the intellectual property rights of any third party.

ACCEPTANCE OF AGREEMENT

By signing below the undersigned acknowledge and accept all terms and conditions of this Agreement.

SELLER: BOVIE MEDICAL CORPORATION BUYER: BOSTON SCIENTIFIC CORPORATION

By:	/S/ Moshe Citronowicz	By:	
	(Signature)		(Signature)
Print Name:	Moshe Citronowicz	Print Name:	Dave McClellan
Title:	Vice President/COO	Title:	President, Oncology Division
Date Signed:	10/06/06	Date Signed:	

By:

(Signature)

Print Name: Ghislain Gackiere

Title: **Finance Director**

Date Signed:

EXHIBIT A: PRODUCT AND PRODUCT SPECIFICATIONS

PLEASE SEE ATTACHED

Author	Document Number	Rev	Page
Thomas Feldhaus		Level A-1	1-12

EXHIBIT A Version A-1 to Exhibit 10.12 – Highlighted



BOVIE – **Resection Device**

Product Specifications

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Author	Document Number	Rev	Page
Thomas Feldhaus		Level A-1	2-12

Table of Contents

1	INT	TRODUCTION	4
1	1.1	Purpose	
	1.2	Scope	
2	AP	PLICABLE DOCUMENTS	4
1	2.1	Standards	
3.0) GEN	NERAL DESCRIPTION	
	3.1 Co	oncept Drawing	
		pplication	
		1 Intended Use	
	3.2.2	2 Intended Users	6
	3.3 Qu	uality System Requirements	
		1 US Requirements	
		2 Canadian Requirements	
	3.3.3	3 European Classifications	7
	3.3.4	4 Quality System Requirements	7
4	PR	ODUCT DOCUMENT STRUCTURE	
4	4.1	Project Documentation	7
4	1.2	Model Number Format	
5	PR	ODUCT REQUIREMENTS	
4	5.1	Electrical and Mechanical	
	5.1.1		
	5.1.2		
	5.1.3	3 Shipping and Handling	10
	5.1.4		
6	Pro	tection Against Hazards	10
7	Pac	ckaging	
-	7.1	Labeling	
,	7.2	Packaging Configuration	
	• And	Tackaging Configuration	UL sessesses
	7.3	Manufacturing	

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	<u>Author</u> Thomas Feldhaus	Document Number	<u>Rev</u> Level A-1	<u>Page</u> 3-12
Title: Product Spec	cification: Resection Device			

List of Tables	
Table One – Standards	Page 4
Table Two – Device Classifications	Page 6
Table Three – Model Number Format	Page 7

List of Figures

Figure One – Concept Drawing

Page 5

Author	Document Number	Rev	Page
Thomas Feldhaus		Level A-1	4-12

1 INTRODUCTION

1.1 PURPOSE

This Product Specification defines preliminary product requirements and constitutes a part of the Design Inputs for the Resection Device Project for Boston Scientific Corporation ("BSC").

1.2 SCOPE

This Product Specification sets forth the requirements, provided by BSC, for the Resection Device, (the "Device").

2 APPLICABLE DOCUMENTS

The following is a list of all documents and other sources of information referenced in this Product Specification.

2.1 STANDARDS

Standard	Version/Date	Description	
21 CFR Part 820		Medical Devices, Current Good Manufacturing Practices, Final Rule, Quality System Regulation.	
HF-18	2001	AAMI/ANSI Electrosurgical Devices	
10993-1	3; Date 8-1-03	AAMI/ANSI/ISO Biological evaluation of medical devices – Par Evaluation and Testing	
EN 980	2003 04/16/2003	Graphical symbols for use in the labeling of medical devices	
EN ISO 14971	2000 AMD 1 2003 03/01/2003	Medical devices – Application of risk management to risk management to medical devices (ISO 14971:2000)	
ISTA 2A 2006	2006	Performance Test for Packaged-Products Weighing 150 lbs (68 kg) or Less	

 Table 1 - Applicable Standards for Medical Devices (US)

3.0 GENERAL DESCRIPTION

The Device is a sterile, single use electrosurgical device intended to be used in conjunction with an electrosurgical generator for the delivery of radiofrequency ("RF") current and sterile saline for hemostatic sealing and coagulation of soft tissue in accordance with instructions and user procedures provided by BSC. The device is not intended for any other unspecified uses.

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	<u>Author</u> Thomas Feldhaus	Document Number	<u>Rev</u> Level A-1	<u>Page</u> 5-12
Title: Product Speci	fication: Resection Device			

3.1 CONCEPT DRAWING

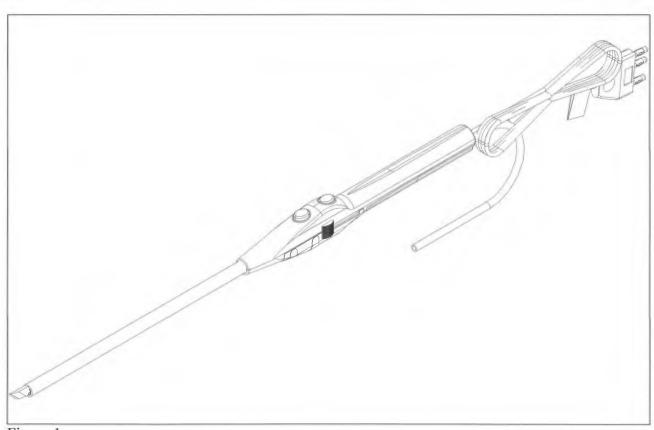


Figure 1

3.2 APPLICATION

3.2.1 INTENDED USE

The Device is a sterile, single use electrosurgical device intended to be used in conjunction with an electrosurgical generator for the delivery of radiofrequency current and sterile saline for hemostatic sealing and coagulation of the soft tissue in accordance with instructions and user procedures provided by BSC. The device is not intended for any other unspecified uses.

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Author	Document Number	Rev	Page
Thomas Feldhaus		Level A-1	6-12

3.2.2 INTENDED USERS

Users of this Device will be healthcare professionals such as medical doctors and nurses, who are qualified and trained in electrosurgical procedures.

3.3 QUALITY SYSTEM REQUIREMENTS

The Device has the following classifications for FDA, CMDR, and MDD classification.

Device	US Classification	Canada Classification	MDD Classification
Resection Device	п	III	IIb

Table 2 - Device Classifications

3.3.1 US REQUIREMENTS

To market medical products, the Food and Drug Administration (FDA) must determine that a medical device is substantially equivalent to similar marketed medical devices. The Bovie Regulatory department intends to use the dissecting sealer device manufactured by TissueLink as a predicate device.

3.3.1.1 CLASSIFICATION

The Device's classification is Class II.

3.3.1.2 SAFETY AND EFFECTIVENESS REQUIREMENTS

The Device will meet electrical safety requirements (ANSI/AAMI HF-18:2001).

3.3.1.3 QUALITY SYSTEM REQUIREMENTS

Quality system requirements are specified as part of 21 CFR Part 820, Quality System Regulation.

3.3.2 CANADIAN REQUIREMENTS

To market medical products in Canada, a license application must be presented to Health Canada. Once the license application is approved, the medical product can be labeled and made available for sale in the Canadian provinces.

3.3.2.1 CLASSIFICATION

Class III

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	<u>Author</u> Thomas Feldhaus	Document Number	<u>Rev</u> Level A-1	<u>Page</u> 7-12
Title: Product Specifica	tion: Resection Device			

3.3.2.2 SAFETY AND EFFECTIVENESS REQUIREMENTS

Safety and effectiveness requirements closely correspond to the essential requirements of the Medical Device Directive. A list of Health Canada recognized standards has been issued as of April 11, 2002 in Policy on Recognition and Use of Standards under Medical Device Regulations.

3.3.2.3 QUALITY SYSTEM REQUIREMENTS

Health Canada requires manufacturers of Class II, III and IV device to demonstrate that their devices are manufactured in accordance with internationally recognized standards. Demonstration of compliance with the quality system requirements will be required at the time an application is made for a medical device license.

3.3.3 EUROPEAN CLASSIFICATIONS

3.3.3.1 CLASSIFICATION

The Device is classified IIb (Rule 9) in accordance with the Medical Devices Directive Annex IX.

(Reference: Guidelines for the Classification of Medical Devices – MEDDEV 2.4/1 Rev. 8, July 2001)

3.3.3.2 CONFORMANCE ASSESSMENT ROUTE

The Device assessment route will be via Annex II (full quality assurance system).

3.3.4 QUALITY SYSTEM REQUIREMENTS

Bovie Medical Corporation ("Bovie") has been certified to ISO13485

4 PRODUCT DOCUMENT STRUCTURE

4.1 **PROJECT DOCUMENTATION**

Documents will be in standard Bovie document format.

4.2 MODEL NUMBER FORMAT

The following table lists the Device's model number and corresponding product / catalog code.

Catalog #	Comments
TBD	Laparoscopic Monopolar Device
	Open Abdominal Monopolar
TBD	Device

Table Three

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Author Thomas Feldhaus ification: Resection Device	Document Number	Rev	Page	
Thomas Feldhaus		Level A-1	8-12	

5 PRODUCT REQUIREMENTS

The following section will describe requirements for the insulated handle and shaft with electrode tip.

5.1 ELECTRICAL AND MECHANICAL

The Device hardware is comprised of two (2) major components: (i) an Insulated Handle and (ii) a Shaft with Electrode Tip. RF energy is passed through the Insulated Handle through the Shaft to the Electrode Tip by a powered lead from an electrosurgical generator.

5.1.1 INSULATED HANDLE

The Insulated Handle encases the controlling mechanism for the flow of saline, and activation and selection of the RF current for the Device.

5.1.1.1 Insulated Handle and Power Cord Insulation Resistance

The insulation of the Insulated Handle and Power Cord shall meet Requirements of Section 4.2.5.4 Dielectric withstands of accessories ANSI/AAMI HF-18:2001

5.1.1.2 Insulated Handle Ergonomics

The Insulated Handle shall be designed for comfortable and efficient hand operation. It will incorporate an over-mold to give the body an elegant feel and soft touch.

5.1.1.3 Insulated Handle Electrical Cord

The Insulated Handle Electrical Cord shall be approximately ten (10) feet in length and incorporate a 3-prong electrical plug.

5.1.1.4 Insulated Handle Flow Control Mechanism

The Device will have a flow control mechanism, either on the tubing or in the handle itself so the flow can be regulated by the user within the sterile field.

5.1.1.5 Insulated Handle Tubing Length

The tubing length should be approximately seven (7) feet in length and incorporate an I.V. spike on the end to attach directly to a hanging IV bag.

5.1.1.6 Insulated Handle Tubing Material

The tubing material should be a material that will resist kinking but should not have so strong a memory as to pull the probe off of the sterile field.

5.1.1.7 Insulated Handle Activation Buttons

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	<u>Author</u> Thomas Feldhaus	Document Number	<u>Rev</u> Level A-1	<u>Page</u> 9-12	
Title: Product Specificat	ion: Resection Device				

The Device should have a Cut and Coagulation Mode. "Cut"/"Coag" buttons must be easy to operate.

5.1.1.8 Insulated Handle Compatibility

- The Insulated Handle should have compatibility with standard RF generators used for electrocautery and standard grounding pad.
- The Insulated Handle should have compatibility with standard 0.9% saline I.V. bag.

5.1.2 SHAFT AND ELECTRODE TIP

The Shaft and Electrode Tip provide the actual working portion of this system.

5.1.2.1 Saline Flow Rate of Device

The Saline flow rate prior to use will be 1 - 7cc/minute.

5.1.2.2 Device (Shaft) Length

The Device should be straight and have two (2) lengths: one for laparoscopic monopolar procedures (approximately thirty-two (32) cm) and one for open monopolar procedures (approximately fourteen (14) cm).

5.1.2.3 Shaft Configuration

The Shaft will be hollow to allow for fluid to flow to the sintered stainless steel tip. The inside diameter of the Shaft should be equal to the inside diameter of the tubing that feeds fluid to the Shaft to minimize any flow restriction in the fluid circuit.

5.1.2.4 Tip Material

The Tip shall be made of porous sintered 316ss stainless steel material.

5.1.2.5 Tip Strength

The porous blade tip to shaft tensile bond strength (axial mode) must be greater than 30 lbs. after being subjected to a full-power simulated use duty cycle.

The porous blade tip to shaft bond strength in an flexural mode must be greater than 16.5 lbs. after being subjected to a full-power simulated use duty cycle.

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Author	Document Number	Rev	Page
Thomas Feldhaus		Level A-1	10-12

5.1.2.6 Tip performance

• Bovie will exert its best efforts to meet the design goal that tip cutting performance be superior to competitive devices with respect to cutting speed. Tip will have the ability to coagulate soft tissue when performed in a suitable simulated use environment.

5.1.3 SHIPPING AND HANDLING

4.1.3.1 Shipping Temperatures

Tropical (Wet and Dry) Conditions and Winter (Frozen) Conditions per ISTA 2A.

4.1.3.2 Transportation Testing

The Final Product Packaging Configuration for the Device shall meet the finished device requirements after being subjected to Simulated Transportation Conditioning per ISTA 2A.

5.1.4 STERILIZATION

5.1.4.1 Withstand 2x ETO Sterilization.

5.1.4.2 EN 550: 1994 – Sterilization of Medical Devices – Validation and routine control of ethylene oxide sterilization.

5.1.4.3 AAMI/ANSI/ISO 11135 -1994 Medical Devices – Validation and routine control of ethylene oxide sterilization.

6 PROTECTION AGAINST HAZARDS

A Hazard/Risk Analysis will be performed throughout the design process. The Hazard/Risk Analysis will be documented and filed as part of the design history file.

7 PACKAGING

7.1 LABELING

7.1.1 Package must be labeled in accordance with both BSC and Bovie Labeling Standards.

7.1.2 BSC and Bovie branding, including mutually approved trademarks, will be on the Handle and/or the shaft.

7.1.3 The Device is to have a three (3) year shelf life under normal storage conditions.

7.2 PACKAGING CONFIGURATION

• The Tip and Shaft protector shall be included into the Design.

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	<u>Author</u> Thomas Feldhaus	Document Number	<u>Rev</u> Level A-1	<u>Page</u> 11-12	
Title: Product Specific	ation: Resection Device				

- The Scratch Pad shall be packaged with the Device.
- The Device will be packaged in a Sterile Pouch.

7.3 MANUFACTURING

Final assembly and packaging will be performed by Bovie.

Author	Document Number	Rev	Page
Thomas Feldhaus		Level A-1	12-12

APPROVALS

Thomas Feldhaus	Date
Rick Pfahl	Date
Rick Kozloff	Date
John Woody	Date
Lillian Eshem	Date
Fred Baron	Date
	Rick Pfahl Rick Kozloff John Woody Lillian Eshem

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EXHIBIT B: BUYER'S FORM OF PURCHASE ORDER

PURCHASE ORDER

Boston Scientific Corporate Headqu	arters		Page 1
One Boston Scient Natick, MA 01760 USA	tific Place		Purchase Order No. 6056307
			This number must appear on all invoices, packages and correspondence
		Ship to Address:	correspondence
		Boston Scientific Corporate Headquarters One Boston Scientific Place Natick, MA 01760 USA Bill to Address: Boston Scientific Corporate Headquarters One Boston Scientific Place Natick, MA 01760	
		USA	Tax Exemption No.
Telephone: FAX:	5086478600 5086479416		04-2695240
Date Ordered: 9-28-2006	FOB VNCR: FOB: Ship Point - Collect		Mode of Transportation
Buyer No. 06B NAT		Confirm To: John Q. Public	

Terms of Payment Within 45 days Due net

Item	Port Number Quantity	UOM	Description Due Date	Unit Price	Taxable	Revision Total
00010			(Test Purchase Order)			
	1.00 EA			150.00/100	Y	0.00
Balance Due	: 0.03					
Item Text:						
*** Item Car						
*** Item Car	nceled ***				2.1	
				TOTAL ORDE	ER:	0.00
				CURRENCY:		USD
				Authorized Sig JOHN SMITH		
				BUYER		

No changes or substitutions can be made to DSC specified components or he processing of those components without prior notification and approval of the purchasing department.

EXHIBIT C: NON-BINDING 12-MONTH FORECAST

Surgical	Resection
----------	-----------

Year 1

	Month	Month 2	Month 3	Month	Month 5	Month <u>6</u>	Month 7	Month 8	Month 9	Month 10	<u>Month</u> <u>11</u>	<u>Month</u> <u>12</u>	Totals
Units	200	100	75	75	100	100	100	125	125	125	125	150	1400

EXHIBIT D: LONG LEAD TIME COMPONENTS

(To be provided as set forth in Section 1.7(a))

EXHIBIT E: TRANSFER PRICES

Units Purchased in Contract Years 1-2 (in aggregate)	Price per Unit*
1-3500 3501 or more	\$225.00 \$107.25
Units Purchased in Contract Years 3-5 (annually)	Price per Unit*
1000-1750	\$225.00
1751-3500	\$165.00
<mark>3501-5000</mark>	\$107.25
<mark>5001-7000</mark>	\$103.00
7001 or more	<mark>\$95.00</mark>

*Note: use of this Exhibit, including the determination of applicable pricing, is subject to the provisions of Section 1.3 of the Agreement.

EXHIBIT F: SELLER'S VENDORS

The following list is tentative as of the Effective Date, and Seller reserves the right to amend this list upon finalization and approval of the Specifications and Bill-of-Materials for the Product.

- 1. Modern Medical Equipment Mfg., Ltd., 5F Gold King Building, 35 Tai Lin Pai Road, Kwai Chung, N.T., Hong Kong.
- **2.** Mott Corporation, 84 Spring Lane, Farmington, CT 06032, 860-747-6333.
- **3.** International Sterilization Laboratories, 217 Sampey Road, Groveland, FL 34736, 352-429-3200.