Exhibit 10.1  
 MANUFACTURING AND SUPPLY AGREEMENT  
 This Manufacturing and Supply Agreement (the “Agreement”), effective as of January 3, 2018 (the “Effective Date”), is made by and between IsoRay Medical, Inc., a Delaware corporation with offices at 000 Xxxxx Xx., Xxxxx 000, Xxxxxxxx, XX 00000 (“IsoRay”), and GT MEDICAL TECHNOLOGIES, INC., a Delaware corporation, having its principal place of business at 000 X 0xx Xx Xxxx, XX 00000 (“GT MED TECH”). IsoRay and GT MED TECH may be referred to herein individually as a “Party”, and collectively as the “Parties”.  
 RECITALS  
 A. IsoRay is experienced in the manufacture of cesium-131 sources for use in brachytherapy.  
 B. IsoRay and GT MED TECH parties to that certain Collaborative Development Agreement, dated as of March 13, 2017 (the “Development Agreement”), under which the Parties will collaborate to develop and seek regulatory approval for a novel brachytherapy product incorporating IsoRay cesium-131 sources for the treatment of certain tumors.  
 C. IsoRay and GT MED TECH have agreed that, after such regulatory approval is obtained, IsoRay will manufacture and supply on a contract manufacturing basis, based on GT MED TECH’s purchase orders, such approved brachytherapy product incorporating IsoRay cesium-131 sources for use and/or sale for the treatment of certain tumors.  
 D. IsoRay and GT MED TECH now desire to memorialize the terms and conditions applicable to such manufacture and supply of the brachytherapy product.  
 NOW THEREFORE, in consideration for the covenants set forth below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as set forth below.  
 AGREEMENT  
 1.  
Definitions.  
 1.1 “Affiliate” means, with respect to a Party, any corporation or other business entity controlling, controlled by or under common control with such Party. The term “controlling” (with correlative meanings for the terms “controlled by” and “under common control with”) as used in this definition means either (a) possession of the direct or indirect ownership of more than fifty percent (50%) of the voting or income interest of the applicable corporation or other business entity, or (b) the ability, by contract or otherwise, to control the management of the applicable corporation or other business entity.  
 1.2 “Applicable Law” means all applicable international, national, federal, state, and local laws, ordinances, and regulations applicable to the manufacture, supply, marketing, sale and use of Products hereunder, including without limitation any applicable FDA and other Regulatory Authority requirements.  
 1.3 “Certificate of Analysis” has the meaning set forth in Section 3.2.  
 1.4 “Claim” has the meaning set forth in Section 11.1.  
 1.5 “Confidential Information” has the meaning set forth in Section 7.1.  
 1.6 “Control” means, with respect to any patent or other intellectual property, that the applicable Party owns or has a license to such patent or other intellectual property and has the ability to grant to the other Party access to and a license (or sublicense, as applicable) under same without violating the terms of any agreement with a Third Party.  
 1.7 “Defective Product” has the meaning set forth in Section 3.3(a).  
 1.8 “Disclosing Party” has the meaning set forth in Section 7.1.  
 1.9 “FDA” means the United States Food and Drug Administration or any successor thereto.  
 1.10 “Forecast” has the meaning set forth in Section 2.2.  
 1.11 “Foreground IP” has the meaning set forth in Section 5.1.  
 1.12 “GammaTiles” means the square or rectangular customizable tile carriers used to manufacture Product (as defined below).  
 1.13 “GT MED TECH Change Request” has the meaning set forth in Section 2.9.  
 1.14 “GT MED TECH Indemnitees” has the meaning set forth in Section 9.1.  
 1.15 “GT MED TECH Technology” means all patents, patent applications or other intellectual property rights (including without limitation know-how or trade secrets) that are Controlled by GT MED TECH as of the Effective Date or during the Term and that are necessary or useful to manufacture and supply the Products hereunder.  
 1.16 “Indemnified Party” has the meaning set forth in Section 9.3.  
 1.17 “Indemnifying Party” has the meaning set forth in Section 9.3.  
 1.18 “IsoRay Indemnitees” has the meaning set forth in Section 9.2.  
 1.19 “Losses” has the meaning set forth in Section 9.1.  
 1.20 “Pricing Schedule” has the meaning set forth in Section 4.1.  
 1.21 “Product” means (a) GammaTiles incorporating IsoRay’s cesium-131 source model CS-1 (“Seed”) developed by the Parties under the Development Agreement; and/or (b) general accessories, in each case for the limited purpose of aiding in the use of the Product described in subsection (a) for brachytherapy for brain cancer treatments. The specifics of the Products described in subsection (b), including price, shall be mutually agreed by the Parties from time to time.  
 1.22 “Quality Agreement” has the meaning set forth in Section 4.1.  
 1.23 “Recall” has the meaning set forth in Section 6.5(a).  
 1.24 “Receiving Party” has the meaning set forth in Section 7.1.  
 1.25 “Regulatory Approval” means any and all approvals, including supplements and amendments, licenses, registrations or authorizations of any Regulatory Authority that are necessary for the manufacture, distribution, use, marketing or sale of the Product in a regulatory jurisdiction.  
 1.26 “Regulatory Authority” means any governmental authority, including without limitation the FDA, or any other national, supra-national, regional, state or local regulatory agency, department, bureau, commission, or council, with responsibility, jurisdiction and authority to grant licenses or Regulatory Approvals or grant pricing and/or reimbursement approvals necessary for the manufacture, use, importation, packaging, labeling, marketing, or sale of medical devices in any country or group of countries.  
 1.27 “Regulatory Filings” means all applications, filings, dossiers and the like submitted to a Regulatory Authority for the purpose of obtaining Regulatory Approval from such Regulatory Authority.  
 1.28 “Specifications” means the product characteristics, processing, labeling and packaging requirements, and quality standards pertaining to the commercial manufacture of Product, which is set forth in Exhibit A. The Specification for a Product may be amended from time to time in accordance with Section 2.9 or otherwise upon mutual written agreement of the Parties.  
 1.29 “Term” has the meaning set forth in Section 10.1.  
 1.30 “Third Party” means any entity or individual other than the Parties and their respective Affiliates.  
 1.30 “Trade Secret” means information, including a formula, pattern, compilation, program, device, method, technique, or process, that derives independent economic value, actual or potential, from not being generally known to or readily ascertainable through appropriate means by other persons who might obtain economic value from its disclosure or use; and is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.  
 2. Supply of Seed. Subject to the provisions of this Agreement, IsoRay shall supply loose or braided suture Seeds for brachytherapy for brain cancer treatment to GT MED TECH on a non-exclusive basis during the term of the Agreement. The purchase price for loose or braided suture Seeds supplied under this Agreement (the “Seed Price”) shall be as set forth in the Pricing Schedule (Exhibit B) and may be adjusted by IsoRay for inflation annually based on changes to (a) the Producer Price Index for Medical Equipment and Supplies Manufacturing, All Items, published by the Bureau of Labor Statistics of the United States Department of Labor . Additionally, IsoRay may adjust the Seed Price annually, as needed to reflect material changes in isotope cost (even if such adjustment would cause the Seed Price to increase by more than the inflation adjustment provided in the preceding sentence). Changes to Seed Price based on inflation adjustments or isotope cost adjustments shall be effective upon IsoRay’s delivery of written notice to GT MED TECH specifying such change. Any other pricing adjustments to the Seeds shall be agreed upon and included in a written amendment to this Agreement, signed by both Parties. Forecasting, purchase orders, delivery, payment and other terms and conditions of this Agreement applicable to Products, shall be applicable to Seeds.  
 3.  
Manufacture & Supply of Product.  
 3.1 Manufacture and Supply; Territory. Subject to the provisions herein, and subject to receipt of the Regulatory Approval for the Product in the United States (i.e., the “510(k) Clearance,” as defined in the Development Agreement), IsoRay shall, manufacture and supply Product through drop-shipments to end users designated by GT MED TECH. For clarity, IsoRay may use Third Party subcontractors or vendors for certain aspects of the manufacturing process, such as sterilization. GT MED TECH shall purchase such Products from IsoRay, all in quantities to be set forth on purchase orders submitted from time to time by GT MED TECH in accordance with the provisions of Section 2.3. GT MED TECH shall obtain its supply of Product exclusively from IsoRay during the Term; provided, however, in the event (a) IsoRay is unwilling or unable to supply, in compliance with the terms set forth in this Agreement, quantities of Product ordered by GT MED TECH in accordance with Section 3.3 and (b) GT MED TECH is at such time in full compliance with this Agreement, then GT MED TECH shall be permitted to obtain from a Third Party manufacturer (or manufacture itself) those quantities of Product that IsoRay is unwilling or unable to supply. At all times during the Term, any and all of IsoRay’s and GT MED TECH’s obligations under this Agreement shall be subject to and in accordance with the provisions, limitations and conditions imposed by FDA in respect of the Products. On an “as needed basis" as the Product is launched in countries outside the United States, the Parties shall negotiate in good faith an amendment to this Agreement to include such additional terms as the Parties shall deem necessary to ensure compliance with applicable laws in such countries.  
 3.2 Forecasts. GT MED TECH shall submit to IsoRay, no later than the 15th day of the month preceding the start of every calendar quarter (i.e., December 15, March 15, June 15, and September 15) during the Term, a rolling forecast (“Forecast”) setting forth an estimate of the total quantity of Product GT MED TECH reasonably believes it will purchase during the four (4) calendar quarters commencing with the beginning of the subsequent calendar quarter. For the avoidance of doubt, Forecast are non-binding estimates of quantity of Product which is to be used for manufacturing planning purposes.  
 3.3 Purchase Orders. From time to time during the Term, GT MED TECH shall provide to IsoRay written purchase orders for Product(s), each of which shall specify the quantity of each Product to be delivered, the strength of the Product, the anticipated implant date, the loading configuration for the Product, the date of delivery and one or more delivery locations (each of which must be an end user facility with an appropriate license for receiving the Product). Within one (1) business day after its receipt of a purchase order that complies with the foregoing requirements, IsoRay shall acknowledge in writing its receipt and acceptance of such order, and shall confirm the date(s) for delivery of Product; provided, however, that IsoRay shall not be obligated to supply any quantities of Products hereunder to the extent (a) the amount ordered in any calendar quarter exceeds 120% of the quantity forecasted for such calendar quarter in the most recent Forecast; or (b) the delivery date is less than five (5) business days after the date of IsoRay’s receipt of the order, but in either case ((a) or (b)), IsoRay shall use good faith efforts to attempt to fill such orders to the extent it is reasonably able to do so. In addition, IsoRay shall not be obligated to accept an order if the delivery location is not appropriately licensed for receiving the Product. Any purchase orders submitted hereunder shall reference this Agreement and shall be governed exclusively by the terms contained herein. Any term or condition in any purchase order, confirmation, or other document furnished by GT MED TECH or IsoRay that is in any way inconsistent with the terms and conditions set forth in this Agreement is hereby expressly rejected.  
 3.4 Order Cancellations. GT MED TECH may cancel any purchase order prior to shipment of the Product; provided, however, that GT MED TECH shall be obligated to pay the transfer price for any such cancelled shipment, along with any shipping costs (both outbound and inbound), if applicable.  
 3.5 Storage and Handling. IsoRay shall store and handle the Products as required by the Specifications, Applicable Law, and all established safety practices for the Products and in accordance with all Quality Control Procedures.  
 3.6 Packaging and Labeling. All Products manufactured by IsoRay shall be packaged and labeled in accordance with the Specifications and Applicable Law. Any changes to the label and/or the text of any written inserts for the Product will require the prior written consent of GT MED TECH.  
 3.7 Delivery. IsoRay shall promptly report to GT MED TECH the occurrence of any event within or beyond its control which is likely to affect delivery of any ordered Products. IsoRay shall deliver the ordered Product directly to the end user at the delivery location specified by GT MED TECH in its purchase order, along with the following documentation: (a) the batch number and order number of the delivered Product(s); (b) a Certificate of Analysis, as described in Section 3.2; (c) any information and documentation set forth in the Specifications or reasonably requested by GT MED TECH; and (d) any documentation that IsoRay customarily includes in shipments of Seed-type products that it manufactures. The Parties acknowledge all shipments of Product will be routed from IsoRay to a Third Party sterilization facility as an intermediate destination prior to delivery to end user(s).  
 3.8 Shipping; Risk of Loss. All shipments of Products will be EXW (Incoterms 2010) IsoRay’s manufacturing facility with GT MED TECH’s selected shipping carrier (which carrier shall be reasonably acceptable to IsoRay). GT MED TECH agrees to separately pay expenses incurred by IsoRay in the shipment and delivery of ordered Products, including without limitation freight charges, import duties and insurance premiums, provided such expenses are listed individually in IsoRay’s invoice to GT MED TECH. Except as provided herein with respect to Defective Products, risk of loss as to Products shipped shall pass to GT MED TECH or the recipient designated by GT MED TECH (as applicable) upon delivery of such Products to GT MED TECH’s carrier at IsoRay’s manufacturing facility.  
 3.9 Changes/Engineering Change Orders. If IsoRay finds it necessary or desirable to change Specifications (including packaging, labeling and written insert) for a Product, or to change manufacturing process, raw materials, or components used by IsoRay in the manufacture of Products in a manner that affects the Specifications or the form, fit, function, or performance of a Product, IsoRay will deliver notice to GT MED TECH and will not implement any such change without GT MED TECH’s prior written consent. If GT MED TECH finds it necessary or desirable to change Specifications for any Product, GT MED TECH may deliver a request for such change to IsoRay (“GT MED TECH Change Request”), IsoRay shall promptly inform GT MED TECH of any changes to the Commercial Pricing Schedule that would result from implementing such change. Subject to pricing adjustments (under Section 5.1), IsoRay shall use commercially reasonable efforts to make any change identified in a GT MED TECH Change Request that is in response to a regulatory, sterilization methods or safety issue pertaining to the applicable Product, and will consider in good faith any other reasonable change identified in a GT MED TECH Change Request. In the event a GT MED TECH Change Request includes a major design change in the sterilization method of the Product (a “Major Sterilization Change Request”) and requires investment in IsoRay’s operation, GT MED TECH has agreed to cover the cost of such investment. IsoRay will consider making such adjustments in its operation to accommodate such Major Sterilization Change Request. In the event IsoRay does not agree to a Major Sterilization Change Request proposed by GT MED TECH reasonably and in good faith, GT MED TECH may seek a Third Party manufacturer of the Product under the Major Sterilization Change Request without further liability to IsoRay. Unless the Parties otherwise agree in writing, capital equipment purchased by IsoRay in order to implement an Major Sterilization Change Request that is paid for by GT MED TECH investment shall be GT MED TECH’s sole property and shall not be encumbered or disposed of in any way by IsoRay, except with GT MED TECH’s written consent. IsoRay shall, at its expense, maintain such capital equipment in accordance with its typical practices.  
 3.10 Obsolete Materials. As a result of a requested design change by GT MED TECH, certain materials may become obsolete, meaning that such materials are no longer used to manufacture Products and/or cannot be cost-effectively reworked to be used under the design change. At mutually-agreeable times, IsoRay shall provide GT MED TECH with an invoice for the purchase costs of such obsolete materials, and GT MED TECH shall pay such invoice within sixty (60) days after receipt thereof. At GT MED TECH’s option, IsoRay shall either return or destroy such obsolete materials at GT MED TECH expense.  
 4.  
Quality Control; Acceptance and Rejection.  
 4.1 Quality Control. IsoRay and GT MED TECH shall concurrently with this Agreement enter into a quality agreement to designate the roles and responsibilities of the Parties relative to a quality control process (the “Quality Agreement”).  
 4.2 Licensure and Standards. At its own expense, IsoRay represents and warrants it shall maintain throughout the Term of this Agreement, registered facilities, appropriate licensure and/or certifications, and applicable controls in connection with the manufacture and supply of Product hereunder, all in compliance with Applicable Laws and those quality standards as specified in the Quality Agreement. IsoRay shall notify and keep GT MED TECH informed of any government or regulatory inspections of IsoRay’s facilities that are relevant to the manufacture and supply of the Products hereunder. Other obligations relative to such inspections will be specified in the Quality Agreement.  
 4.3 Acceptance and Rejection of Product.  
 (a) GT MED TECH may reject any Product delivered under this Agreement that does not comply with the warranties set forth in Section 8.2(a) (in all cases, a “Defective Product”) by giving written notice of such Defective Product to IsoRay within seventy two (72) hours after receipt of the Product shipment, which notice shall specify in reasonable detail the grounds for such rejection.  
 (b) GT MED TECH shall return Defective Products to IsoRay at IsoRay’s expense using IsoRay’s then-standard return material authorization (“RMA”) procedures. Exhibit D describes IsoRay’s RMA procedures as of the Effective Date, and IsoRay shall provide GT MED TECH with written notice of any modifications to such RMA procedures. Subject to Section 4.3(c), IsoRay shall replace any returned Defective Products as quickly as possible, and GT MED TECH shall pay IsoRay for such replacement Product in accordance with Section 4.1, or in the event that GT MED TECH has already paid for the returned Defective Products, IsoRay shall replace such Defective Products at its own expense.  
 (c) If IsoRay disagrees with GT MED TECH’s determination that certain units of Product are Defective Product, the Parties will first use good faith efforts to settle such dispute within thirty (30) days of GT MED TECH’s notice of such alleged defects. If the Parties are unable to resolve such dispute within this thirty (30) day period, such Product shall be submitted to a mutually acceptable Third Party testing service. Such Third Party testing service shall determine whether such Product meets the Specifications, and the Parties agree that such testing service’s determination shall be final and binding on the Parties. The Party against whom the Third Party laboratory rules shall bear all costs of the Third Party testing.  
 5.  
Prices and Payment.  
 5.1 Supply Price. The transfer price for Products manufactured by IsoRay and supplied GT MED TECH shall be as set forth in Exhibit B (the “Pricing Schedule”). Such pricing shall be periodically adjusted in accordance with Sections 5.1(a)-(c) and reflected in a written amendment to the Agreement, signed by authorized representatives of both Parties.  
 (a) Open Book Pricing Formula. The price(s) for the Products shall be set using the open-book pricing formula for GammaTiles as set forth in Exhibit B. Initial pricing shall be based on: (i) best-available xxxx of material ("BOM") cost data by volume, (ii) current labor standards including assembly as developed during pilot builds of the Products, (iii) estimated scrap rates, (iv) overhead and (v) gross profit margin. Pricing may be adjusted up or down annually as a result of fluctuations in materials costs, or as a result of deviations in actual labor, scrap or warranty costs, if any, provided that any annual adjustment for costs is limited to a maximum increase of three percent (3%) (but excluding Seed Price, which can be adjusted pursuant to Section 2). Any engineering change order (“ECO”) occurring during the Manufacturing Term which impacts the BOM costs or the manufacturing process will be reviewed, and pricing shall be adjusted accordingly upon implementation of the ECO as mutually agreed upon by IsoRay and GT MED TECH.  
 (b) Quantity Dependence. The open-book pricing formula described above shall be based on a package of 6 GammaTiles, the Transfer Price shall be based on the quantity of Products manufactured and supplied under GT MED TECH’s purchase orders. IsoRay shall allocate direct and indirect labor resources and negotiate supply agreements with vendors for material quantities to meet such quantity purchase orders of GT MED TECH.  
 (c) Seed Price for the Product. Notwithstanding anything to the contrary set forth herein, the Seed Price shall not be part of the open-book process and IsoRay shall have no obligation to provide to GT MED TECH any details of its costs associated with production of Seeds. The transfer price for Product shall be equal to the sum of (i) the Seed Price and (ii) the pricing for the GammaTile, assembly of the Seed into the GammaTile and other steps in the Product manufacturing process (in the case of subsection (ii), as determined and included in accordance with the open-book process above).  
 5.2 Audit. From time to time, but with at least thirty (30) business days advanced written notice and not more than twice per calendar year, GT MED TECH may, at its sole expense, conduct an audit of IsoRay’s books and records relative to the manufacture, shipment, purchase price, and open book pricing formula for the Product as reflected in Exhibit B. (but excluding all books and records relative to the Seed Price and/or the manufacture, shipment, or purchase price of Seeds). For the avoidance of doubt, GT MED TECH has the right to audit records evidencing changes in isotope prices that led to Seed Price changes as detailed within Exhibit C.  
 5.3 Invoice and Payment. Upon shipment of Product, IsoRay shall issue to GT MED TECH a written invoice for such shipment. If applicable, costs and expenses incurred by IsoRay with such shipment, and agreed to be paid by GT MED TECH under this Agreement, shall be included as line-items on such invoice. All undisputed payments due to IsoRay shall be paid in U.S. Dollars not later than forty-five (45) days following the receipt of the invoice, which shall be no earlier than the date on which the applicable Product is delivered to GT MED TECH’s carrier by IsoRay. Unless otherwise agreed by the Parties, all payments under this Agreement shall be paid by wire transfer or electronic funds transfer of immediately available funds to a U.S.-based account designated in writing by IsoRay.  
 5.4 Taxes. Any taxes now or hereafter imposed with respect to the transactions contemplated under this Agreement (with the exception of income taxes or other similar taxes imposed upon IsoRay and measured by the gross or net income of IsoRay) shall be the responsibility of GT MED TECH, and if paid or required to be paid by IsoRay, the amount thereof shall be added to the applicable invoice and become a part of the amounts payable by GT MED TECH for such shipment.  
 6. Tooling. Tools for the manufacture of Products shall be paid for or furnished by GT MED TECH, shall be GT MED TECH’s sole property, and shall not be encumbered or disposed of in any way by IsoRay (“Tools”). The Tools shall be marked in such a way to clearly identify GT MED TECH’s ownership and shall be separated from property that does not belong to GT MED TECH. GT MED TECH shall be responsible for purchasing new Tools specifically required in connection with manufacture of the Product(s), upon request. IsoRay, at its expense, shall maintain such Tools in good working condition subject to normal wear and tear and provide GT MED TECH copies of all repair and maintenance records for such Tools. The Tools shall be used exclusively for IsoRay’s performance of its obligations under this Agreement.  
 7.  
Intellectual Property.  
 7.1 Ownership. Each Party (and its Affiliates or subcontractors) will retain all right, title and interest in any inventions, ideas, concepts, know-how, work product, and other intellectual property owned or controlled by such Party prior to or independent of the Parties’ activities under this Agreement. It is not anticipated that any new intellectual property will be created in the course of activities under this Agreement. However, in the event that a Party or its respective employees or agents develop, invent, or conceive any inventions, ideas, concepts, know-how, work product, or other intellectual property in the course of their activities under this Agreement (“Foreground IP”), such Foreground IP shall be owned by IsoRay if invented solely by employees or agents of IsoRay, and by GT MED TECH if invented solely by employees or agents of GT MED TECH or if jointly invented by employees or agents of IsoRay and GT MED TECH.  
 7.2 License to IsoRay. GT MED TECH hereby grants to IsoRay a non-exclusive, royalty-free license to use and practice the GT MED TECH Technology and if appropriate, GT MED TECH Foreground IP solely and exclusively to manufacture the Product exclusively for GT MED TECH during the Term and in accordance with the provisions of this Agreement. For the avoidance of doubt, this license (a) permits IsoRay to manufacture the Products as square or rectangular Gamma Tiles with Seeds solely for GT MED TECH. No other use of this license by IsoRay is permitted and (b) does not create any exclusivity with respect to IsoRay’s supply of Seeds under Section 2.  
 7.3 License to GT MED TECH. IsoRay hereby grants to GT MED TECH a non-exclusive, royalty-free license to use and practice any intellectual property related to the Product and Controlled by IsoRay including any IsoRay Foreground IP, solely to the extent necessary for GT MED TECH to sell and offer for sale Product manufactured by IsoRay during the Term and in accordance with the provisions of this Agreement. For the avoidance of doubt, this license permits GT MED TECH to sell the Products manufactured by IsoRay. No other use of this license by GT MED TECH is permitted.  
 7.4 Trademarks. GT MED TECH shall be responsible for the selection, registration, maintenance, and defense of all trademarks for use in connection with GT MED TECH’s sale or marketing of the Products, as well as all expenses associated therewith. As between the Parties, GT MED TECH shall exclusively own all such trademarks.  
 7.5 No Implied Licenses. Neither Party grants (or agrees to grant) to the other Party any right or license to use any of its intellectual property, know-how or other proprietary information, materials or technology, or to practice any of its patent, trademark or trade dress rights, except as expressly set forth in this Agreement.  
 8.  
Regulatory.  
 8.1 Regulatory Approvals. Ownership of the Regulatory Approval of the Product in the United States, as well as the ownership of related regulatory data and regulatory documents, is governed by terms and conditions of Article 5 of the Development Agreement. Maintenance of the Regulatory Approval for the Product in the United States shall be the responsibility of the Party that owns such Regulatory Approval, at such Party’s sole cost, unless the Parties otherwise agree.  
 8.2 Regulatory Phases and Transition. Notwithstanding Article 5 of the Development Agreement, GT MED TECH hereby notifies IsoRay of its request for the transfer of the 510(k) Clearance from IsoRay to GT MED TECH. IsoRay agrees to use commercially reasonable efforts to complete such transfer within thirty days of IsoRay’s receipt of such 510(k) Clearance. No marketing or other sale activity relative to the Product shall be undertaken until the 510(k) Clearance is received.  
 8.3 Inspections; Regulatory Action. During the term of this Agreement, GT MED TECH may periodically (but no more frequently than once per calendar year absent an inspection ‘for cause’) conduct an audit of IsoRay’s manufacturing facility for the Product and quality systems relating to the manufacture of the Product in order to verify the adherence of IsoRay to the Quality Agreement and this Agreement. Any such audit shall be during normal business hours and at GT MED TECH’s cost and expense, and GT MED TECH shall provide a minimum of thirty (30) days written notice prior to scheduling of any such audit. Additionally, IsoRay shall cooperate with any inspection by a Regulatory Authority relating to the Products and, to the extent practicable, shall give GT MED TECH advance notice of any such inspection. Each Party shall notify the other Party promptly in writing in the event such Party learns that any action has been taken or threatened by a Regulatory Authority relating to the use, sale, manufacture or storage of Products. To the extent permitted by applicable law, IsoRay shall provide GT MED TECH copies of communications with any Regulatory Authority relating to the Products; provided, however, IsoRay may redact from such copies any proprietary information relating to the Seeds. To the extent permitted by applicable law, GT MED TECH shall provide IsoRay copies of communications with any Regulatory Authority relating to the Products, solely to the extent such communications relate to Seeds or manufacturing activities undertaken by or on behalf of IsoRay; provided, however, GT MED TECH may redact from such copies any proprietary information relating to GT MED TECH products other than the Product.  
 8.4 Compliance with Laws. IsoRay shall supply Products that are manufactured in compliance with all Applicable Laws, including without limitation all Applicable Laws relating to the transportation, storage, use, handling and disposal of hazardous materials. IsoRay represents and warrants to GT MED TECH that IsoRay shall obtain and maintain all site licenses and government permits, including without limitation health, safety and environmental permits, necessary for the conduct of the actions and procedures undertaken to manufacture the Products in accordance with Applicable Laws and the Quality Control Procedures.  
 8.5 Records and Samples. IsoRay shall keep, or cause to be kept, complete, accurate and authentic accounts, notes, data and records pertaining to the manufacture, processing, testing, labeling, storage, and distribution of the Products, including without limitation master production and control records, in accordance with applicable laws and regulations. IsoRay shall retain, or cause to be retained, such records for a period of five (5) years following the date of manufacture, or longer if required by law, and upon request, shall make available to GT MED TECH copies of such records. After such time period, IsoRay shall notify GT MED TECH prior to the destruction of any records retained under this Section 8.5 and, at GT MED TECH’s request, shall transfer such records to GT MED TECH.  
 8.6 Recalls.  
 (a) In the event GT MED TECH should be required or should voluntarily decide to initiate a product recall, product withdrawal, field correction, or advisory notice with respect to any of the Products manufactured by IsoRay pursuant to this Agreement (in each case, a “Recall”), GT MED TECH shall notify IsoRay. In conjunction with such Recall, and at GT MED TECH’s request, IsoRay shall assist in the investigation of Recalls to determine the cause and extent of the problem and the Parties shall cooperate with each other concerning the necessity and nature of such action. Recalls shall be the responsibility of GT MED TECH and GT MED TECH shall bear all expenses connected therewith, except to the extent such Recall results from manufacturing defects on the part of IsoRay, and IsoRay shall bear the expenses of the Recall to the extent the Recall results from manufacturing defects on the part of IsoRay. For the purposes of this Agreement, the expenses of the Recall will include, without limitation, all expenses for notification of customers (and patients if required) and the destruction or return of the recalled Product, as well as all reasonable out-of-pocket costs and expenses incurred by GT MED TECH and IsoRay.  
 (b) In the event that IsoRay independently believes that a Recall for any of the Products may be necessary or appropriate, IsoRay shall notify GT MED TECH. The Parties shall discuss in good faith the necessity and nature of such action; however, the decision to initiate any Recall involving any of the Products shall be in GT MED TECH’s sole discretion. In the event that GT MED TECH decides to initiate under this Section 8.6(b) any Recall involving any of the Products, the coordination thereof shall be handled by GT MED TECH, whether or not such action was initially requested by IsoRay. The expenses of any such Recall shall be handled as provided in Section 8.6(a).  
 9.  
Confidentiality.  
 9.1 Confidential Information. Subject to the limitations set forth in Section 7.2, all information that is disclosed by one Party (the “Disclosing Party”) to the other Party (the “Receiving Party”) under this Agreement shall be deemed to be “Confidential Information” of the Disclosing Party. Confidential Information may include, without limitation, trade secrets, ideas, unpublished patent applications, data, processes, formulae, programs, compounds, know-how, improvements, designs, information regarding plans for research development, business plans, customer lists, marketing and sales strategies, financial records, and budgets, whether disclosed in oral, written, graphic, or electronic form.  
 9.2 Exceptions to Confidential Information. The term “Confidential Information” shall not be deemed to include information that: (a) is in the public domain or comes into the public domain through no fault of the Receiving Party; (b) is furnished to the Receiving Party on a non-confidential basis by a third party rightfully in possession of such information and not subject to a duty of confidentiality with respect thereto; (c) was already known by the Receiving Party prior to the time of receiving such Confidential Information, as evidenced by the Receiving Party’s prior written records; or (d) was independently developed by the Receiving Party without use of or access to the Confidential Information of the Disclosing Party.  
 9.3 Non-Disclosure and Non-Use of Confidential Information. During the term of this Agreement and for a period of five (5) years after the expiration or termination of this Agreement; provided, however, if the Confidential Information is a Trade Secret of the Disclosing Party, the Receiving Party shall hold such Confidential Information confidential until such Confidential Information is no longer deemed confidential under Section 9.2 above, the Receiving Party shall maintain all Confidential Information in strict trust and confidence and shall not disclose any Confidential Information to any third party or use any Confidential Information received except as may be authorized by the Disclosing Party’s prior written consent. The Receiving Party may use Confidential Information only to the extent required to perform its obligations or exercise its rights under this Agreement, and for no other purpose. In particular, neither Party shall file any patent application containing any disclosure or patent claim, the subject matter of which is derived from the other Party’s Confidential Information. Neither Party shall not use the other Party’s Confidential Information for any purpose or in any manner that would constitute a violation of any laws or regulations of the United States. Nothing in this Agreement grants either Party the right to retain, distribute, or commercialize any Confidential Information of the other Party (except that GT MED TECH has the right to distribute and commercialize Products purchased from IsoRay hereunder). Each Party, prior to disclosure of any Confidential Information of the other Party to any employee, consultant or advisor shall ensure that such person is bound by confidentiality provisions that are no less stringent than those set forth in this Article 9.  
 9.4 Third Party Confidential Information. Neither Party shall disclose to the other Party any confidential or proprietary information that belongs to any third party unless the Disclosing Party first obtains the consent of such third party. Neither Party shall represent to the other Party as being unrestricted any designs, plans, models, samples, or other writings or products that such Party knows are covered by valid patent, copyright, or other form of intellectual property protection belonging to a third party.  
 9.5 Publicity. Except for such disclosure as is deemed necessary, in the reasonable judgment of a Party, to comply with applicable laws, rules and regulations, no announcement, news release, public statement, publication or presentation relating to the existence of this Agreement, the subject matter hereof, or either Party’s performance hereunder will be made without the other Party’s prior written approval. Such obligations are in addition to the restrictions set forth above with respect to disclosures of the other Party’s Confidential Information.  
 10.  
Representations and Warranties.  
 10.1 Mutual Representations and Warranties. In addition to other warrants and representations set forth in this Agreement, each Party represents and warrants as follows:  
 (a) Existence and Power. It is duly organized, validly existing and in good standing under the laws of the state or country in which it is organized.  
 (b) Due Authorization and Enforcement of Obligations. It has the power and authority and the legal right to enter into this Agreement to perform its obligations under this Agreement, and has taken all necessary action on its part to authorize the performance of such obligations. This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms.  
 (c) No Conflict. The execution and delivery of this Agreement and the performance of such Party’s obligations under this Agreement (a) do not conflict with or violate any requirement of Applicable Laws and (b) do not conflict with, or constitute a default, or require any consent under any contractual obligation of such Party.  
 10.2 IsoRay Representations and Warranties.  
 (a) Product Warranty. IsoRay warrants that all Products delivered under this Agreement shall, at time of delivery, (i) conform to the Specifications; and (ii) be free and clear of any and all liens or other encumbrances.  
 (b) No Debarred Person. IsoRay represents and warrants that it shall not employ, contract with, or retain any person directly or indirectly to perform activities under this Agreement if such is debarred by the FDA under 21 U.S.C. § 335a(a) or disqualified as described in 21 C.F.R. § 812.119. In addition, IsoRay represents and warrants that it has not engaged in any conduct or activity which could lead to any such debarment actions. If IsoRay learns during the Term that this representation needs to be amended in light of new information, IsoRay shall promptly notify GT MED TECH of same and shall take prompt action to remedy the situation.  
 10.3 DISCLAIMER. THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS ARTICLE 10 ARE THE SOLE AND EXCLUSIVE REPRESENTATIONS AND WARRANTIES MADE BY EITHER PARTY UNDER THIS AGREEMENT, AND NEITHER PARTY MAKES ANY OTHER REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED OR ARISING BY LAW, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY ARISING FROM THE COURSE OF PERFORMANCE, COURSE OF DEALING OR USAGE OF TRADE.  
 11.  
Indemnification.  
 11.1 Indemnification by IsoRay. IsoRay shall indemnify, defend and hold GT MED TECH, its Affiliates, and their respective directors, officers, employees and agents (“GT MED TECH Indemnitees”) harmless from and against all losses, damages, costs and expenses (including reasonable legal expenses and attorneys’ fees and expenses) (collectively, the “Losses”) incurred by GT MED TECH as a result of Third Party claims, demands, suits, or actions (each, a “Claim”) brought against GT MED TECH to the extent such Losses result from (a) the gross negligence or willful misconduct of any IsoRay Indemnitee or any of IsoRay’ subcontractors; or (b) any breach of IsoRay’ obligations, warranties, representations, or covenants under this Agreement. Notwithstanding the foregoing, IsoRay shall not be obligated to indemnify GT MED TECH to the extent any Claims or Losses are based on (i) any breach of GT MED TECH’s obligations, warranties, representations, or covenants under this Agreement; or (ii) the gross negligence or willful misconduct of any GT MED TECH Indemnitee.  
 11.2 Indemnification by GT MED TECH. GT MED TECH shall indemnify, defend and hold IsoRay, its Affiliates, and their respective directors, officers, employees and agents (“IsoRay Indemnitees”) harmless from and against all Losses incurred by IsoRay as a result of Claims brought against IsoRay to the extent such Losses result from (a) the handling, possession, use, marketing, promotion, distribution or sale of any Product by GT MED TECH or any of its distributors following delivery of the Product by IsoRay under this Agreement; (b) any personal injury (including death) or property damage resulting from the use, sale, or other disposition of the Products; (c) any breach of GT MED TECH’s obligations, warranties, representations, warranties, or covenants under this Agreement; or (d) the gross negligence or willful misconduct of any GT MED TECH Indemnitee. Notwithstanding the foregoing, GT MED TECH shall not be obligated to indemnify IsoRay to the extent any Claims or Losses are based on (i) any breach of IsoRay’ obligations, warranties, representations, warranties, or covenants under this Agreement, or (ii) the gross negligence or willful misconduct of any IsoRay Indemnitee or any of IsoRay’ subcontractors hereunder.  
 11.3 Indemnification Procedures. If either Party is entitled to indemnification under this Article 11(the “Indemnified Party”), it shall give written notice to the Party providing indemnification (the “Indemnifying Party”) of any Claim that may be subject to indemnification promptly after learning of such Claim, and the Indemnifying Party shall assume the defense of such Claim. The Indemnifying Party will not be subject to any liability for any settlement of such Claim made by the Indemnified Party without the Indemnifying Party’s consent (but such consent will not be unreasonably withheld or delayed), and will not be obligated to pay the fees and expenses of any separate counsel retained by the Indemnified Party with respect to such Claim. The Indemnifying Party shall not settle a Claim covered by indemnification without the consent of the Indemnified Party (such consent not unreasonably withheld or delayed) if such settlement would impose any monetary obligation on any Indemnified Party’s Indemnitee or require the Indemnified Party or any of the related indemnitees (GT MED TECH Indemnitees if GT MED TECH is the Indemnified Party, and IsoRay Indemnitees if IsoRay is the Indemnified Party) to submit to an injunction or otherwise limit the Indemnified Party’s rights under this Agreement.  
 11.4 Insurance. During the Term and for three (3) years thereafter, each Party shall maintain in effect and good standing a comprehensive general liability insurance issued by a reputable insurance company in the amount of at least $ 2,000,000 for claims in the aggregate, and such policy shall name the other Party as an additional insured. Each Party shall promptly notify the other Party of any actual or anticipated changes in its insurance policy that would result in such Party’s non-compliance with this Section 11.4.  
 12.  
Term and Termination.  
 12.1 Term. This Agreement will become effective upon the Effective Date and will continue in effect for ten (10) years, unless earlier terminated in accordance with this Article 12 (the period during which this Agreement remains in effect, the “Term”).  
 12.2 Termination for Insolvency, Bankruptcy. Either Party may, at its option, terminate this Agreement immediately upon written notice to the other Party, in the event that such other Party (i) becomes insolvent or unable to pay its debts when due; (ii) files a petition in bankruptcy, reorganization or similar proceeding or has such a petition filed against it, which petition is not removed within ninety (90) days; (iii) discontinues it business; (iv) has a receiver appointed over all or a part of its assets; or (v) makes an assignment for the benefit of its creditors.  
 12.3 Termination Upon Breach. Either Party may, at its option, terminate this Agreement in the event of a material breach by the other Party. Such termination may be effected only through a written notice to the breaching Party, specifically identifying the breach or breaches on which such notice of termination is based. The breaching Party will have a right to cure such breach or breaches within sixty (60) days of receipt of such notice, and this Agreement will only terminate pursuant to this Section 12.3 in the event that such cure is not made within such sixty (60)-day period.  
 12.4 Survival. The provisions of Sections [8.5, 8.6, 12.4, and 12.5], and Articles [1, 7, 9, 11, and 13] will survive the expiration or termination of this Agreement.  
 12.5 Effects of Termination. Upon termination or expiration or this Agreement, (a) each Party will return and cease use of any Confidential Information of the other Party received under this Agreement; (b) each Party will promptly pay to the other, without offset or deduction, all amounts due and remaining unpaid as of the date of such termination or expiration; (c) IsoRay shall complete all work in process, fulfilling pending purchase orders as of the termination or expiration date; (d) GT MED TECH shall pay invoices for such Products shipped under such pending purchase orders; and (e) the Parties shall cooperate on the return of Tools from IsoRay’s facilities to a location designated by GT MED TECH.  
 13.  
Miscellaneous Provisions.  
 13.1 Entire Agreement. This Agreement (including the Exhibits attached, which are hereby incorporated and made part of this Agreement) sets forth the entire agreement and understanding between the Parties with respect to the subject matter of this Agreement and supersedes and merges all prior oral and written agreements, discussions and understandings between the Parties with respect to the subject matter of this Agreement, and neither of the Parties will be bound by any conditions, inducements or representations other than as expressly provided for in this Agreement.  
 13.2 Independent Contractors. In making and performing this Agreement, the Parties act and will act at all times as independent contractors, and, except as expressly set forth in this Agreement, nothing contained in this Agreement will be construed or implied to create an agency, partnership or employer and employee relationship between the Parties. Except as expressly set forth in this Agreement, at no time will either Party make commitments or incur any charges or expenses for, or in the name of, the other Party.  
 13.3 Notices. All notices and other communications provided for hereunder will be in writing and will be mailed by first-class, registered or certified mail, postage paid, or delivered personally, by overnight delivery service or by facsimile, with confirmation of receipt, addressed as follows:  
 If to IsoRay:   
IsoRay Medical, Inc.  
000 Xxxxx Xxxxxx, Xxxxx 000  
Xxxxxxxx, XX 00000  
Attention: CEO  
 Facsimile:  
 If to GT MED TECH:  
GT Medical Technologies, Inc.  
000 X 0xx Xx  
Xxxx, XX 00000  
Attn: President  
 or addressed to such other address as that Party may have given by written notice in accordance with this provision. Notices sent by facsimile will be effective upon confirmation of receipt, notices sent by mail or overnight delivery service will be effective upon receipt of delivery, and notices given personally will be effective when delivered.  
 13.4 Amendments; Modifications. This Agreement may not be amended or modified except in a writing duly executed by both Parties.  
 13.5 Waiver. Any waiver (express or implied) by either Party of any breach of this Agreement shall not constitute a waiver of any other or subsequent breach and shall in no way impair the rights of the Party granting such waiver in any other respect or at any other time. Any delay or forbearance by either Party in exercising any right hereunder will not be deemed a waiver of that right.  
 13.6 Governing Law. This Agreement will be governed by and construed in accordance with the laws of the State of Delaware, without giving effect to any choice of law principles that would require the application of the laws of a different jurisdiction.  
 13.7 Limitation of Liability. IN NO EVENT (OTHER THAN BREACH OF CONFIDENTIALITY, ARTICLE 9 WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INCIDENTAL, CONSEQUENTIAL, SPECIAL, PUNITIVE, EXEMPLARY OR INDIRECT DAMAGES, OR FOR ANY LOST PROFITS IN CONNECTION WITH THIS AGREEMENT, EVEN IF ADVISED OF THE POSSIBILITY OF THE SAME, HOWEVER CAUSED AND REGARDLESS OF THEORY OF LIABILITY, WHETHER TORT, CONTRACT, OR STRICT LIABILITY. NOTWITHSTANDING THE FOREGOING, NOTHING IN THE PRECEDING SENTENCE WILL BE CONSTRUED TO LIMIT OR MODIFY EITHER PARTY’S INDEMNITY OBLIGATIONS PURSUANT TO ARTICLE 11. ADDITIONALLY, IN NO EVENT SHALL ISORAY’S AGGREGATE LIABILITY UNDER THIS AGREEMENT EXCEED THE TOTAL OF ALL AMOUNTS ACTUALLY PAID BY GT MED TECH TO ISORAY UNDER THIS AGREEMENT DURING THE TWELVE (12) MONTHS PRECEDING THE EVENT GIVING RISE TO THE LIABILITY. The Parties agree that the foregoing liability cap shall not apply to any liabilities arising from IsoRay’s gross negligence or willful misconduct or any liabilities involving personal injury or death arising from IsoRay’s negligence in manufacturing the Product. The Parties acknowledge that the limitations of liability in this Section 13.7 and the allocation of risk herein are an essential element of the bargain between the Parties, without which IsoRay would not have entered into this Agreement.  
 13.8 Use of Name. No right, except as expressly provided for in this Agreement, is granted by this Agreement to either Party to use in any manner the name of the other or any other trade name, logo, or trademark of the other in connection with the performance of this Agreement.  
 13.9 Headings; Interpretation. The headings in this Agreement are inserted merely for the purpose of convenience and will not affect the meaning or interpretation of this Agreement. This Agreement will be construed fairly according to its terms, without regard to the identity of the drafter of any provision in this Agreement.  
 13.10 Cumulative Remedies. Termination of this Agreement, regardless of cause or nature, will be without prejudice to any other rights or remedies of the Parties as provided for in this Agreement and will be without liability for any loss or damage occasioned thereby.  
 13.11 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except a Party may make such an assignment without the other Party’s consent to a successor-in-interest to substantially all of the business assets of such Party to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other transaction. Any permitted assignment shall be binding on the successors of the assigning Party and any permitted successor or assignee of rights and/or obligations hereunder shall, in writing to the other Party, expressly assume performance of such rights and/or obligations. Any assignment or attempted assignment by either Party in violation of the terms of this Section 13.11 shall be null and void and of no legal effect. This Agreement shall be binding upon and shall inure to the benefit of each Party’s successors-in-interest and permitted assigns.  
 13.12 Severability. If any provision of this Agreement is invalid or unenforceable for any reason in any jurisdiction, such provision will be construed to have been amended to the minimum extent necessary to cure such invalidity or unenforceability. The invalidity or unenforceability of one or more of the provisions contained in this Agreement will not have the effect of rendering any such provision invalid or unenforceable in any other case, circumstance or jurisdiction, or of rendering any other provisions of this Agreement invalid or unenforceable whatsoever.  
 13.13 English Language. This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement.  
 13.14 Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed will be deemed to be an original and all of which when taken together will constitute one Agreement.  
 [Remainder of page intentionally blank. Signature page follows.]  
 IN WITNESS WHEREOF, the Parties have caused their respective authorized representatives to execute this Agreement as of the Effective Date set forth above.  
 GT MEDICAL TECHOLOGIES, Inc.] IsoRay Medical, Inc.  
 By (Signature): /s/ Xxxxxx Xxxxx By (Signature): /s/ Xxxxxx XxXxx  
 Name (Printed): Xxxxxx Xxxxx Name (Printed): Xxxxxx XxXxx  
 Title: Vice President of Operations Title: CEO  
 Attachments:  
Exhibit A: Specifications  
Exhibit B: Pricing & Open Book Pricing Formula  
Exhibit C: Isotope Material Cost Baseline  
Exchibit D: RMA Procedure  
 Signature Page for Manufacturing & Supply Agreement  
Exhibit A  
Specifications  
 1.1  
This specification addresses Model PL-6 GammaTileTM consisting of Preloaded Brachytherapy Seeds loaded into Suturable DuraGen.  
 1.2  
ProxcelanTM Brachytherapy Seeds are arranged in a precise pattern within the strand and Suturable DuraGen based on the treatment plan provided by the physician or medical physicist for an individual patient.  
 1.3  
A standard tile is 20mm x 20mm containing four seeds evenly spaced 10mm from the center of one seed to the center of the next seed as shown in figure above.  
 1.4  
The DuraGen and strands are used to orient, hold, carry and maintain spacing of the radionuclide seeds to facilitate introduction into the intracranial neoplasm.  
 1.5  
The containers are packaged in heat sealed breather bags. The packaged product is then shipped to a contract sterilizer for Electron beam sterilization.  
 1.6  
Transfer price will be based on a GammaTile package consisting of 6 standard tiles as defined in Exhibit A section 1.3.  
 Exhibit B  
Open-Book Pricing Formula & Pricing Schedule  
 Open-Book Pricing Formula for GammaTile – No Seed – Current Cost  
 Formula Item  
 Price per Seed\*  
Price per Package of 6 GammaTiles\*  
 BOM Cost – GammaTile  
 $21.44  
$514.56  
 Duragen Carrier  
 $18.75  
 $450.00  
 Stranded Material  
 $1.44  
 $34.56  
 Packaging  
 $1.25  
 $30.00  
 Total Mat’l Cost  
 $21.44  
 $514.56  
 Mat'l Scrap %  
29.2%  
 Mat'l Scrap Cost  
$6.251   
$150.00  
 Direct Assembly Labor Minutes per Gamma Tile  
[\*\*]  
[\*\*]   
 Gross Profit %  
50%   
50%  
 Mat’l Sales Price  
$42.88  
$1,029.12  
 Direct Labor  
[\*\*]  
[\*\*]  
 Overhead  
[\*\*]  
[\*\*]  
 Total GammaTile Price  
[\*\*]  
[\*\*]  
 \*Assumes 4 Seeds per GammaTile and material cost is normalized over material coverage and amount of seed.  
1 Mat’l scrap cost included in total material costs.  
 [\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
 Pricing  
 Price  
Volume (based on last twelve months of case sales.)  
 0-250  
250-500  
500-1000  
>1000  
Seed Price: High Activity (3.6U) Cesium-131 Source (per seed)\*  
$150  
$140  
$130  
$130  
Transfer Price – Product (per Seed)†  
[\*\*]  
 \*Assumes 5 days from shipment from IsoRay manufacturing facility to implant date. Additional days will include incremental pricing of $10 per day per seed.  
 † Assumes 4 Seeds per GammaTile  
 [\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
 Pass-through Costs  
 Sterilization: Sterilization costs shall be billed either directly to GT MED TECH or invoiced as a separate line-item as a pass-through costs by IsoRay. No xxxx-up to sterilization or other pass-through costs for the Product will be accessed by IsoRay  
 Exhibit C  
Isotope Material Cost Baseline  
 The cost per xxxxx from IsoRay’s two suppliers currently is as follows: Russian Supply is 86 curies at [\*\*] per xxxxx and our XXXX supply is 30 curies at approximately [\*\*] per xxxxx. IsoRay’s weighted average cost per xxxxx currently is approximately [\*\*], and the utilization of the isotope is variable based upon demand and is managed on a weekly basis. The seed price of $150 is based upon average per xxxxx cost of the noted weighted average cost above. IsoRay will submit the change in the supply cost to GT MED TECH and request an increase based upon the above analysis. E.g. If Russia changed the price to [\*\*] per xxxxx the new weighted average would be approximately [\*\*] per xxxxx and IsoRay will request an increase to the price of the isotope % of the seed price. The seed price is based upon the items noted in Exhibit B above, and the current price of a 3.6U seed with 5 days incorporated into shipping time, relative to the overall price, is 66% or $100. If the cost of the isotope increased by 27% then we would request a price increase of 27% of $100 or $27 a seed.   
 Current weighted material cost per Xxxxx - [\*\*]  
Isotope price per seed - [\*\*]  
Seed Price adjustments will be made based on % increase on the isotope cost only and IsoRay will provide evidence of such change. Changes in weighted material cost per Xxxxx driven from demand decrease at Iso Ray not related to the GammaTile product shall not impact Seed Price.  
 [\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
 Exhibit D  
RMA Procedure  
 See following page