

# SIR-Spheres® Y-90 resin microspheres Terms and Conditions of Sale (North America)

(Applicable to orders originating and shipping from North America)

# 1. Intent and Application

These are the terms and conditions ("Terms") are applicable to the sale of SIR-Spheres® Y-90 resin microspheres products and related materials, as well as drawn patient-specific doses (the patient-specific doses referred to as "Dosed Products", and collectively, the "Products") and as sold by Sirtex Medical, Inc. or its corporate affiliates (collectively, "Seller") to the Buyer entity purchasing such Products ("Buyer").

These Terms set forth the only terms and conditions under which Seller will sell Products to Buyer notwithstanding any conflicting term or condition contained in any purchase order (PO), request for proposal, purchase agreement, or any other form submitted by Buyer (collectively, "Order"). If, however, a written contract executed by Seller and Buyer is already in existence covering the purchase of Products, the terms of such contract shall prevail to the extent that it is inconsistent with these terms.

Seller hereby objects to and rejects any and all additional or contrary terms and conditions in Buyer's purchase order and in any other document issued by Buyer, none of which shall be part of any contract between Seller and Buyer or otherwise binding on Seller.

## 2. Orders and Cancellations

Buyer shall purchase from Seller, and Seller shall supply to Buyer, such quantities of Products as may be from time to time ordered by Buyer in accordance with the Terms at the pricing defined and communicated by Seller. Pricing is subject to change. For Dosed Product orders, Buyer must submit to Seller's radiopharmacy provider all case-specific dosing and prescription information required at time of purchase. Buyer is solely responsible for the accuracy and correctness of such submitted information. Any and all information submitted must be properly de-identified in accordance with Section 164.514(a) of the HIPAA Privacy Rule. Under no circumstances shall Buyer submit any identifiable patient information to Seller.

Orders and cancellation requests are to be submitted and will be governed in accordance with the Sirtex Ordering and Cancellation Policy ("Policy") a copy of which will be provided to Buyer upon request.

#### 3. Discounts

Buyer and Seller each acknowledge that it is their intent to establish a business relationship in which any rebates, discounts, payments, and credits provided to Buyer by Seller ("Discounts") comply with the exceptions to the U.S. Anti-Kickback Statute set forth at 42 U.S.C. 1320a-7b(b)(3) and the "Safe Harbor" regulations regarding discounts set forth in 42 C.F.R. 1001.952(b); and the parties believe that the relationship contemplated by this agreement is in compliance with those requirements. Neither Buyer nor Seller are, by virtue of this agreement or otherwise, willfully offering, paying, soliciting, or receiving remuneration in return for referring an individual to or from each other for the furnishing of any item or service reimbursed under the Medicare or other federal or state health care programs. Pricing hereunder does not take into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a state health care program.

Seller will provide Buyer with invoices that fully and accurately disclose the discounted price of all Products purchased hereunder to allow Seller to comply with the Discount Safe Harbor regulations, including sufficient information to enable it to accurately report its actual cost for all Product purchases. Buyer is responsible for any applicable reporting requirements related to pricing and/or discounts, and specifically agrees to report all discounts to its payors as may be applicable in accordance with the requirements of the Anti-Kickback Statute and any other applicable laws or regulations.

#### 4. Delivery

Products ordered by Buyer will be delivered, subject to availability, to a Buyer-designated destination ("Designated Location") that is appropriately licensed as may be applicable and capable of receiving and processing the Products. Seller may require Buyer to submit, and Seller shall provide upon request, explicit authorization and supporting documentation for Buyer to deliver Products to the Designated Location. Either Buyer has furnished to Seller or Seller has validated documentation evidencing that the Designated Location possesses the necessary capabilities, licenses, permits and authorizations to accept delivery of the Products on behalf of Buyer. Seller will not deliver Products to the Designated Location until Seller has received, reviewed, and accepted such documentation.

Buyer may designate a new Designated Location for delivery of the Products only upon prior written notice to Seller via Seller's applicable authorization of designated location process, and subject to Seller's review and acceptance, which shall not be unreasonably withheld.

#### 5. Acceptance

Except as noted below, successful delivery of Products to the Designated Location will perfect Seller's claim for payment for such Products in full. Buyer is solely responsible for payment for all successfully delivered Products and Seller shall not be required to seek payment from any Buyer Representative or other third party. In the event of a patient death or sudden decline in health that eliminates Buyer's need for the Product, Buyer should notify Seller immediately and may cancel any unshipped portion of the order in accordance with the terms set forth in the Policy. In the event that Products provided to Buyer are the subject of a voluntary or mandatory recall by Seller ("Recalled Products") or are otherwise confirmed by Seller to have been defective when delivered to the Designated Location ("Defective Products"), then Seller shall promptly replace such Recalled Product or Defective Product without additional cost to Buyer, provided that, if replacement is not possible, Seller shall refund to Buyer any amounts actually paid by Buyer with respect to such Recalled Products or Defective Products. Buyer recognizes that the Products require special care in handling, storage, processing, use and transport. Buyer is solely responsible for any and all costs associated with Designated Location's improper handling, storage, transport and/or processing of Products. Improper handling, storage, transport, processing or use of any Products by Buyer or any of its employees, the Designated Location, or any third party pharmacy, storage or shipping company or any other third party engaged by Buyer (each a "Buver Representative"), including, without limitation, any handling, storage, transport or preparation of Product for dosing in a manner that is not in accordance with the Seller's specifications, training, training materials and/or instructions, not in compliance with applicable federal, state or local regulations, or any other negligence or intentional misconduct on the part of Buyer or any Buyer Representative (collectively, "Buyer Actions"), shall void Buyer's rights to reject such Products or cancel orders under this Section and shall release Seller from all obligations to cancel orders, pay costs or replace Products under this Section. THE REMEDIES SET FORTH IN THIS SECTION WILL BE BUYER'S SOLE REMEDY FOR REJECTED. RECALLED OR DEFECTIVE PRODUCTS.

## 6. Payment

Buyer shall make payment to Seller with respect to all Products within thirty (30) days following delivery in accordance with Section 3. Buyer shall make such payments in US Dollars by electronic transfer to the bank account designated by Seller. All amounts which are not paid by Buyer as required by these Terms shall be subject to a late charge equal to twelve percent (12 %) per annum or the highest rate permitted

by law, whichever is lower. If any payment due hereunder is overdue by more than thirty (30) days, Seller reserves the right to require payment prior to delivery for additional Products until such delinquency is corrected.

## 7. Shipping Terms

Unless otherwise agreed in writing, all Products shipped by Seller are delivered FOB Destination (Incoterms 2020) to Buyer's Designated Location, with title and risk of loss passing to Buyer upon receipt at such.

For each order that Seller accepts, Seller shall acknowledge and confirm each order's delivery dates. Buyer agrees that Seller shall not be responsible for any delays, cancellations, or shortages arising, directly or indirectly, from acts of God or the public enemy, governmental restrictions, decrees or orders, floods, fire, collapse, delay or defaults of common carriers, failure or curtailment of Seller's usual source of supply, earthquakes, explosion, epidemic, war, invasions, terrorist acts, civil unrest, riots, strike, labor difficulties, embargoes, or, without limiting the foregoing, any other delay beyond Seller's reasonable control; provided, however, that Seller shall use reasonable efforts to notify Buyer of anticipated delays and to fill such orders as soon as reasonably practicable. If any order for stock Products is not shipped within thirty (30) calendar days from the date Seller received such order, or Seller notifies Buyer that any order will not be shipped within thirty (30) calendar days from the date Seller received such order, or delay such order, then upon written notice to Seller prior to shipment of any delayed order, Buyer may cancel such order in whole or in part.

## 8. Limited Non-Transferable Warranty

Seller warrants only that, at the time of manufacture, Products (i) are manufactured in accordance with good manufacturing practices, as required by the United States Food and Drug Administration; (ii) conform to manufacturer's specifications; (iii) are free from defects in materials and workmanship; and (iv) are not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act as amended. Seller also warrants that it has clear title to Products and that Products shall be delivered free of liens and encumbrances. THE FOREGOING WARRANTIES ARE EXCLUSIVE AND IN LIEU OF AND SHALL SUPERSEDE ALL OTHER WARRANTIES OF ANY KIND, WHETHER WRITTEN, ORAL. EXPRESS, OR IMPLIED. THERE ARE NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. PRODUCTS ARE NOT INTENDED FOR RESALE AND ANY RESALE OF PRODUCTS BY BUYER VOIDS ALL PRODUCT WARRANTIES, BOTH EXPRESS AND IMPLIED. No representative of Seller may change any of the foregoing and Buyer accepts Products subject to all terms hereof. Buyer acknowledges that the Products are medical devices that have risks, including those described in the Instruction for Use for the Products. Accordingly, Seller expressly makes no warranties that the Products will be safe and effective when used, including in each application, in each patient or under any and all circumstances.

## 9. Indemnification.

Buyer agrees to indemnify, defend and hold harmless Seller and its affiliates, and the officers, directors, employees, contractors and agents of any of the foregoing, from and against any and all claims, demands, or causes of action for injury or death to persons or damage to property (including all costs and reasonable attorney's fees incurred in defending any claim, demand, or cause of action) (collectively, "Losses") that Seller may incur or suffer in connection with any third-party claim arising from (i) a Buyer Action, and/or (ii) Buyer's submission of inaccurate or incorrect patient or prescription information with a Dosed Product order.

#### 10. Limitation of Remedies and Damages

Buyer's sole and exclusive remedy for any claim arising by reason of or in connection with the sale, purchase, delivery, or use of Products, regardless of whether such claim is based on tort law, breach of contract, breach of warranty, or any other legal theory ("Claim") shall be the repair or replacement of any

nonconforming Products at Seller's sole option. UNDER NO CIRCUMSTANCES SHALL SELLER BE LIABLE FOR LOSS OF USE, LOST PROFITS, OR ANY OTHER COLLATERAL, SPECIAL, CONSEQUENTIAL, OR OTHER DAMAGES, LOSSES, OR EXPENSES IN CONNECTION WITH OR BY REASON OF ANY CLAIM OR BREACH, WHETHER SUCH CLAIM OR BREACH IS FOUNDED IN TORT OR CONTRACT. The foregoing constitutes the sole and exclusive remedies of Buyer and the exclusive liability of Seller.

No right, duty, or obligation of Seller arising hereunder or relating to the Products, including, but not limited to, actions for breach of warranty, breach of contract, or negligence, is assignable by the Buyer or by operation of law.

#### 11. Compliance with Regulations and Policies

Buyer shall comply with, and shall require Buyer's representatives to comply with, all applicable laws and regulations in the handling, storage, processing, dosing and use of Product, and in performance of the other activities applicable to Buyer under this agreement. Buyer specifically acknowledges that the FDA approved labeling for the Product provides for single patient use only and therefore agrees that no residual Product remaining in a vial following administration to a patient shall be used for further treatment or research purposes.

Buyer shall notify Seller within one business day of receipt of notification that any Designated Location no longer has the permits, approvals or licenses required to handle, store, process, use, or distribute Product, and within one business day of receipt by any Buyer representative of any correspondence from any regulatory authority related to Product.

Buyer shall ensure that its agreements with its third-party contractors, including but not limited to the Designated Location if using a radiopharmacy not contracted with the Seller, contain provisions consistent with Buyer's obligations under this agreement.

#### 12. Miscellaneous Terms

- a) **Waiver.** No waiver by any party of any breach on the part of the other party will be a waiver of any subsequent breach.
- b) **Independent Contractor.** Each party is an independent contractor and not the agent, partner, or employee of the other party.
- c) **No Third-Party Rights.** Nothing in these terms shall be construed as creating or giving rise to any rights in third parties or persons other than the named parties herein.
- d) Governing Law and Venue. These Terms and the agreement arising therefrom are being delivered and executed in the Commonwealth of Massachusetts. Any action brought regarding the validity, construction, performance, breach, termination, or enforcement of this agreement or these Terms shall be governed in all respects by the internal laws of the Commonwealth of Massachusetts, without regard to the principles of conflicts of laws and shall in no way be subject to the United Nations Convention on Contracts for the International Sale of Goods. Jurisdiction and Venue for any action or proceeding brought regarding the validity, construction, performance, breach, termination, or enforcement of this agreement or these Terms shall be exclusively the courts of the Commonwealth of Massachusetts, and the parties expressly agree and consent to the personal jurisdiction of the courts of the Commonwealth of Massachusetts, and further consent to service of process issued by such Court.