

**From:** Sarah Bull  
**To:** Weidner, Tara  
**Subject:** [External\_Sender] Fwd: Y-90 Dr Masino 3rd case letter from Sirtex  
**Date:** Friday, March 11, 2016 2:05:49 PM  
**Attachments:** Scan0024.pdf

---

06-06697-02  
03001265

----- Forwarded message -----

From: "Bull, Sarah" <sbull1@stamhealth.org>  
Date: Fri, 11 Mar 2016 19:04:26 +0000  
Subject: Y-90 Dr Masino 3rd case letter from Sirtex  
To: "sarbull@gmail.com" <sarbull@gmail.com>

Hi Tara-

Finally got a hold of the Sirtex representative. He has updated, and signed, his attestation letter for Dr. Masino's third Y-90 case.

Thank you so much for your help /Sarah

-----  
Sarah Bull Chief Physicist, RSO  
Bennett Cancer Center/ Stamford Hospital /30 Shelburne Rd /Stamford/ CT/ 06902  
O: (203) 276-4036 /C: (203) 417-3996  
SBULL1@StamHealth.org<mailto:SBULL1@StamHealth.org>

590405



**SIRTEX MEDICAL INC.**  
300 Unicorn Park Drive  
Woburn, MA 01801  
Tel: +1 (781) 721 3800  
Fax: +1 (781) 721 3880

Ref: 104US07

March 18, 2014

Dr. Frank Masino  
Radiation Oncologist  
Stamford Hospital  
34 Shelburne Road  
Stamford, CT 06902

Dear Dr. Masino

**Re: SIR-Spheres® Microspheres Authorized User Training and Certification**

This letter certifies that on March 18, 2014 you successfully completed training in the operation of the delivery system, safety procedures and clinical use of SIR-Spheres yttrium-90 microspheres that are to be injected via the hepatic artery to treat patients with unresectable liver tumors in accordance with the June 2012 NRC guidance. This training included three (3) supervised hands-on *in-vitro* simulated set-up and delivery procedures as well as encompassing the following:

- a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- b) Performing quality control procedures on instruments used to determine the activity of Y-90 microspheres and performing checks for proper operation of survey meters;
- c) Evaluation of each patient for the dose/activity of Y-90 microspheres to be administered to each treatment site;
- d) Calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient;
- e) Using administrative controls to prevent a medical event involving the use of byproduct material;
- f) Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures; and
- g) Follow up and review of each patient's case history for Y-90 microspheres


Dr. Masino completed his 3<sup>rd</sup> case observed by the manufacturer's representative on 1/28/16.

Sirtex would like to thank you for your support in this process.

---

® SIR-Spheres is a Registered Trademark of Sirtex SIR-Spheres Pty Ltd

Yours sincerely,

A handwritten signature in cursive script, appearing to read "Adam Paster".

Adam Paster  
Regional Sales Manager