



Section of Nuclear Medicine
4755 Ogletown-Stanton Rd.
Newark, DE 19718
(302)733-1540 (phone)
(302)733-1518 (fax)

December 3, 2018

Dear Ms. Lanzisera:

This letter certifies that Dr. Timothy Manzone has successfully completed training in

- a. the operation of the delivery system;
- b. safety procedures, including operating and emergency procedures;
- c. clinical use applications, including procedures for written directives, the manufacturer's procedures for calculating and documenting the dose or activity to the treatment site, procedures for preparing the dose for administration, determining shunting to non-treatment sites, and performing pre- and post-vial dose measurements; and
- d. medical event reporting.

I proctored Y-90 Sir-Sphere treatment cases with Dr. Timothy Manzone on the following dates:

12/4/15 and 4/12/16

He participated in the cases from start to finish and has completed all the requirements toward becoming an authorized user of SIR-spheres.

If you should require any additional information, please feel free to reach out to me at (302)733-1540.

Sincerely,

Hung Dam, MD

Chief, Section of Nuclear Medicine, Department of Radiology

P6

07-12153-02
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RECEIVED MATERIALS

Rec'd. in LAT- 12/13/2018



SIRTEX MEDICAL INC.

300 Unicorn Park Drive

Woburn, MA 01801

Tel: +1 (781) 721 3800

Fax: +1 (781) 721 3880

November 26, 2018

Dr. Timothy Manzone
Christiana Care Health Services
4755 Ogletown-Stanton Rd
Newark, DE 19718

Dear Dr. Manzone,

Re: SIR-Spheres Yttrium-90 Resin Microspheres Authorized User (AU) Letter

This letter certifies that you completed three (3) patient cases under the supervision of and in the physical presence of a manufacturer representative in accordance with NRC's February 2016 Yttrium-90 Microsphere Brachytherapy Sources and Devices Licensing Guidance Training and Experience Section B Pathway 2 on January 27, 2015; March 6, 2015; and March 6, 2015.

Yours sincerely,

A handwritten signature in black ink that reads "William Denman, M.D.".

William Denman, M.D.
Global Chief Medical Officer

cc: Dave Mason, Regional Sales Manager

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Document ID: _____
(Revised by Sirtex)

SIR-Spheres® Microspheres Treatment: Proctoring Evaluation Form⁽¹⁾

Proctored Physicians and Institution Information

Interventional Radiologist (IR) Kevin Lie, MD
Authorized User (AU): Timothy Manzone, MD
Institution: Christiana Hospital, Newark, DE
Date Proctored: 7/16/2015
Proctor: Samuel Putnam, MD

1. Pre-Treatment Evaluation

Evaluation Item	Pass	Deficient ⁽²⁾
1. IR has received and is conversant with the "SIR-Spheres Microspheres Users Manual"	X	
2. Hospital resources		
a. Hospital has equipment to perform satisfactory visceral angiography	X	
b. Quality of hepatic angiograms		
i. Power injected	X	
ii. Anatomy identified, including variant & aberrant vessels	X	
3. Hospital has appropriate personnel assigned to the treatment team		
a. Medical physicist	X	
b. Radiation safety officer (RSO)	X	
c. Radiation oncologist/nuclear medicine or Interventional radiologist (AU)	X	
d. Nursing staff/patient coordinator	X	
4. Patient selection & pre-treatment work-up		
a. History & physical examination findings reviewed	X	
b. Relevant laboratory results reviewed (LFTs/bilirubin, blood exam., etc.)	X	
c. Triple phase contrast enhanced CT scan of chest/abdo/pelvis reviewed	X	
d. Hepatic angiograms & variant or aberrant vessels correctly identified	X	
e. MAA-Tc99 lung shunt study performed & correctly interpreted	X	
f. Patient selected for treatment is an appropriate candidate	X	
g. Pre-treatment work up is satisfactory	X	

Notes: (1) The Proctoring Evaluation Form must be completed by the Proctor following the proctoring of a SIR-Spheres microspheres treatment and forwarded to Sirtex.

(2) Please add reason and/or comments below to Section 5

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2. Dose Preparation: Sign-Off by Strtex Field personnel

Evaluation Item	Pass	Deficient	Strtex Sig
1. Nuclear medicine hot lab personnel have the policies and procedures in place to accept and prepare the SIR-Spheres microspheres dose	x		DM
2. Nuclear medicine hot lab personnel can verify and document quantity of SIR-Spheres microspheres activity delivered to the patient	x		DM
3. Nuclear medicine hot lab personnel understand radiation safety and decontamination procedures	x		DM

3. Treatment Plan

Evaluation Item	Pass	Deficient
1. SIR-Spheres microspheres dose determination is satisfactory	x	
2. Treatment plan is satisfactory (whole liver vs. lobar vs. segmental)	x	
3. Hepatic arterial implantation site(s) of SIR-Spheres microspheres is satisfactory	x	
4. Physician(s) involved understand:		
a. Disease process	x	
b. Their role in the delivery of SIR-Spheres microspheres	x	
c. Possible complications and treatment	x	
d. Treatment planning (whole liver vs. lobar vs. segmental)	x	
e. Dosimetry calculations	x	
f. Optimal catheter placement, including		
i. Need for embolization of GDA, RG, other variants and aberrants	x	
ii. Correct positioning of catheter	x	
iii. Adequate radiation shielding in place	x	
g. Satisfactory nursing care available during and after procedure	x	

4. Peri-Procedural Care & Post-Treatment Follow-up

Evaluation Item	Pass	Deficient
1. Peri-procedural care & supportive therapy/medications understood	x	
2. Post-treatment care & follow-up understood	x	
3. Post-treatment response assessment and imaging (CT/PET) schedule understood	x	

5. Comments (attach additional sheets if necessary)

Item #	Comments
	Proctoring performed to sign off the AU, Dr. Manzone; signed off.
	Dr. He previously signed off.

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6a. Approval for Proctored Cases

First Proctored Case ☐

If Pre-trained please complete section 6b

Second Proctored Case ☐

Third Proctored Case ☒ for AU only

Please complete section 6b

6b. Approval for Future Use of SIR-Spheres Microspheres

In my opinion, the hospital has the infrastructure in place to receive and to safely treat patients with SIR-Spheres microspheres: YES ☒ NO ☐

In my opinion, the Interventional Radiologist proctored is qualified to implant SIR-Spheres microspheres in cooperation with the Authorized User and does not require additional proctoring:
YES ☒ NO ☐

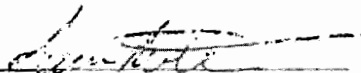
In my opinion, the Interventional Radiologist proctored requires at least one additional proctoring session:
YES ☐ NOT NECESSARY ☒

In my opinion, the Authorized User proctored is qualified to implant SIR-Spheres microspheres in cooperation with the Interventional Radiologist and does not require additional proctoring:
YES ☒ NO ☐

In my opinion, the Authorized User proctored requires at least one additional proctoring session:
YES ☐ NOT NECESSARY ☒

7. Signatures

Proctor name (print): Samuel Putnam, MD

Proctor Signature:  Date: 7/16/2015

Proctor: Please fax completed Proctoring Evaluation Form to Sirtex Regional Administrator at the following numbers:

US: +1 (978) 229 9585

EU: +49 228 1840 735

AP: +61 2 9964 8410



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Christiana Care Health Services, Inc.
ATTN: Kert F. Anzilotti, M.D., MBA, Chief
Medical Officer Acute Care
4755 Ogletown-Stanton Road
Newark, DE 19718

Date

December 31, 2018

License Number(s)

07-12153-02

Mail Control Number(s)

610919

Licensing and/or Technical Reviewer or Branch

Penny Lanzisera

☒ NotificationThis is to acknowledge receipt of your: ☒ Letter and/or ☐ Application Dated: 12/03/2018

The initial processing, which included an administrative review, has been performed.

☐ Amendment ☐ Termination ☐ New License ☐ Renewal☒ There were no administrative omissions identified during our initial review.☐ This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.☐ Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>

Follow the instructions on the form for submission.

☐ The following administrative omissions have been identified:

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region I
U. S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713
(610) 337-5260, (610) 337-5313,
(610) 337-5398, or (610) 337-5239