



SIRTEX MEDICAL, INC.
16 Upton Drive, #2-4
Wilmington, MA 01887
Tel: 978 642 3000

May 28, 2010

Jondavid Pollock, MD
Wheeling Hospital
One Medical Park Drive
Wheeling, WV 26003

K-8
47-05322-02
03012570

Dear Dr Pollock:

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

This letter certifies that on March 10, 2010 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 September 2008 NRC guidance. This training included four (4) supervised hands-on *in-vitro* simulated set-up and delivery procedures that demonstrate possible issues encountered during the yttrium-90 microsphere administration.

As you have completed your lisenice amendments, and actively participated in three in vivo dose administrations under the observation of a designated Proctor, the criteria as set forth by the SIR-Spheres Microspheres Training, Evaluation, Certification (TEC) Program has been completed.

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

Yours sincerely,

David Liu, MD
Medical Director



SIRTEX MEDICAL, INC.
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Wilmington, MA 01887
Tel: +1 (888) 474 7839

Ref: 105US02

May 28, 2010

Vincent Caruso, MD
Wheeling Hospital
One Medical Park Drive
Wheeling, WV 26003

Dear Dr. Caruso:

Re: SIR-Spheres® Microspheres Training, Evaluation, Certification (TEC) Program

I am writing to confirm that on April 14 2010, Dr. Eric Wang presented and discussed in detail the preparation and procedures associated with the treatment of patients with SIR-Spheres yttrium-90 microspheres that are injected via the hepatic artery to treat patients with unresectable liver tumors. The patients were treated with SIR-Spheres microspheres.

Dr. Wang proctored the treatments and I am pleased to inform you that Dr. Wang considers that you and your staff are now trained in the preparation and the clinical aspects of treating patients with SIR-Spheres microspheres.

This letter also certifies that you were proctored for at least 3 cases by a Sirtex certified proctor in the use of SIR-Spheres® microspheres.

I would like to thank you and your team for your support and commitment to the Sirtex **Training, Evaluation, and Certification (TEC)** Program.

Yours sincerely,

David Liu, MD
Medical Director



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

Proctored Physicians and Institution Information

Interventional Radiologist (IR): Vincent Caruso, MD
 Authorized User (AU): Jondavid Pollock, MD
 Institution: Wheeling Hospital, Wheeling, WV
 Date Proctored: April 14, 2010
 Proctor: Eric Wang, MD

2 patients

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	X	
a. Hospital has equipment to perform satisfactory visceral angiography	X	
b. Quality of hepatic angiograms	X	
i. Power injected	X	
ii. Anatomy identified, including variant & aberrant vessels	X	
3. Hospital has appropriate personnel assigned to the treatment team	X	
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	X	
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 Sirtex Field personnel

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

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 is satisfactory	X	
4. Physician(s) involved understand:	X	
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	X	
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
Item 2	Good knowledge of anatomy + approx vessels to embolize prior to Sirtex tx
	<i>[Signature]</i>

6. 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 Signature:  Date: April 14, 2010

Proctor name (print): Eric Wang, MD

Proctor: Please email completed Proctoring Evaluation Form to Sirtex regional Medical Director at TEC@sirtex.com or fax to the following numbers:

US: +1 (978) 229 9585
EU: +49 228 1840 735
AP: +61 2 9936 1404