



**SIRTEX MEDICAL INC.**  
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Ref: 105US03

March 30, 2016

Frank A. Masino, M.D.  
Stamford Hospital  
30 Shelburne Rd  
Stamford, CT 06902

Dear Dr. Masino,

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

This letter certifies that you completed three patient (3) cases under the supervision of and in the physical presence of a manufacturer representative in accordance with NRC's February 2016 Yttirum-90 Microsphere Brachytherapy Sources and Devices Licensing Guidance Training and Experience Section B Pathway 2 on the following dates: May 29, 2015; January 19, 2016; and January 25, 2016. Completed Form 102s documenting each patient case are enclosed.

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

Yours sincerely,

A handwritten signature in black ink, appearing to read "Eric First", is written over a faint rectangular stamp.

Eric First, M.D.

Chief Medical Officer – Americas

## SIR-Spheres® Microspheres Treatment: Proctoring Evaluation Form<sup>(1)</sup>

### Proctored Physicians and Institution Information

Interventional Radiologist (IR): \_\_\_\_\_  
 Authorized User (AU): Frank Masino, MD  
 Institution: Stamford Hospital  
 Date Proctored: May 29, 2015  
 Proctor: Adam Paster

### 1. Pre-Treatment Evaluation

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

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

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

**2. Dose Preparation: Sign-Off by Sirtex Field personnel**

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

**3. Treatment Plan**

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

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

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

**5. Comments** (attach additional sheets if necessary)

Item #	Comments



**6a. Approval for Proctored Cases**

First Proctored Case ☒

If Pre-trained please complete section 6b

Second Proctored Case ☐

Third Proctored Case ☐

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): Adam Butler

Proctor Signature: Adam Butler

Date: 5/29/15

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

## SIR-Spheres® Microspheres Treatment: Proctoring Evaluation Form<sup>(1)</sup>

### Proctored Physicians and Institution Information

Interventional Radiologist (IR): \_\_\_\_\_  
 Authorized User (AU): Frank Masino, MD  
 Institution: Stamford Hospital  
 Date Proctored: January 19 2016  
 Proctor: Adam Paster

### 1. Pre-Treatment Evaluation

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

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

**3. Treatment Plan**

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

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

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

**5. Comments (attach additional sheets if necessary)**

Item #	Comments



**6a. Approval for Proctored Cases**

First Proctored Case ☐

If Pre-trained please complete section 6b

Second Proctored Case ☒

Third Proctored Case ☐

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): Adam Parker

Proctor Signature: Adam Parker

Date: 3/25/16

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



Document ID: \_\_\_\_\_  
(Allocated by Sirtex)

## SIR-Spheres® Microspheres Treatment: Proctoring Evaluation Form<sup>(1)</sup>

### Proctored Physicians and Institution Information

Interventional Radiologist (IR): \_\_\_\_\_  
Authorized User (AU): Frank Masino, MD  
Institution: Stamford Hospital  
Date Proctored: January 25 2016  
Proctor: Adam Paster

### 1. Pre-Treatment Evaluation

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

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

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**2. Dose Preparation: Sign-Off by Sirtex Field personnel**

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

**3. Treatment Plan**

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

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

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

**5. Comments (attach additional sheets if necessary)**

Item #	Comments





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(Allocated by Sirtex)

**6a. Approval for Proctored Cases**

First Proctored Case ☐

If Pre-trained please complete section 6b

Second Proctored Case ☐

Third Proctored Case ☒

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): 994m 0916

Proctor Signature: Ali Omer

Date: 3/25/16

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

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