



**SIRTEX MEDICAL INC.**  
300 Unicorn Park Drive  
Woburn, MA 01801  
Tel: +1 (781) 721 3800  
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Ref: 105US03

January 13, 2014

Dr Ken Zinn  
Bridgeport Hospital  
267 Grant Street  
Bridgeport CT 06110

06-01060-01  
030-01247

Dear Dr Zinn

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

I am writing to confirm that on June 28<sup>th</sup>, 2011, Dr Randall Smith 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 Smith proctored the treatments and I am pleased to inform you that Dr Smith 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, Certification (TEC) Program**.

Yours sincerely,

Eric First, M.D.  
Medical Director – Americas

cc: <Account Manager>  
TEC@sirtex.com



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Ref: 105US03

January 15, 2014

Dr Hughes  
Bridgeport Hospital  
267 Grant Street  
Bridgeport CT 06610

Dear Dr Hughes

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

I am writing to confirm that on June 28<sup>th</sup>, 2011, Dr Randall Smith 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.

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

Yours sincerely,

Eric First, M.D.  
Medical Director – Americas

cc: <Account Manager>  
TEC@sirtex.com



**Preceptor Statement**

U.S. Nuclear Regulatory Commission  
Region I  
2100 Renaissance Blvd, Suite 100  
King of Prussia, PA 19406-2713

Re: Preceptor Statement for Dr. Scott Williams

Gentlemen & women of the NRC,

I am writing to confirm that between the dates of April 26, 2011 and June 28, 2011, Dr. Scott Williams directly participated in five (5) Y-90 Sirtex SIR-spheres procedures during the initial start up of the Selective Internal Radiation Therapy (SIRT) program at Bridgeport Hospital. These cases were supervised by the local Sirtex representative and various certified proctors provided by the Sirtex company.

I attest that Dr. Scott Williams, who is already an authorized user for 35.100, 35.200 and 35.300 uses, under Bridgeport Hospital's NRC License No. 06-01060-01, has satisfactorily achieved a level of competency to function independently as an authorized user for 35.1000 use of Y-90 Sirtex microspheres for the treatment of patients with unresectable liver tumors.

Sincerely,

Dr. Kenneth Zinn

Telephone Number

2-7-14

Date