Written Directives for Y-90 Microspheres

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Disclosure

- Employee of Sirtex Medical, Inc.

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Written Directive

- Authorized User's (AU) written order for the administration of byproduct material or radiation from byproduct material to a specific patient
- Must be dated and signed by an AU before the administration of any therapeutic dose of radiation from byproduct material (e.g. Y-90 microspheres)

- AU may or may not be the physician *administering* Y-90 microspheres
    - "two doc model" – radiation oncologist (RO) or nuclear medicine (NM) physician is the AU
    - "one doc model" – IR is the AU

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Written Directive Evolution - 2002

- Pre and post implant Written Directive information
  - Treatment site (e.g. whole liver, left lobe, right lobe)
  - Radionuclide and form (Y-90 microspheres)
  - Prescribed dose (e.g. Gy to Tx site)
  - Maximum dose from shunting (e.g. Gy to lungs or GI tract)

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Written Directive Evolution - 2004

- Pre and post implant Written Directive information
  - Treatment site (e.g. whole liver, left lobe, right lobe)
  - Radionuclide and form (Y-90 microspheres)
  - Prescribed dose (e.g. Gy to Tx site)
  - Maximum dose from shunting (e.g. Gy to lungs or GI tract)
  - Stasis acceptable endpoint, if indicated as possibility prior to infusion

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Written Directive Evolution - 2007

- Pre and post implant Written Directive information
  - Treatment site (e.g. whole liver, left lobe, right lobe)
  - Radionuclide and form (Y-90 microspheres)
  - Prescribed dose (e.g. Gy to Tx site)
  - Maximum dose from shunting (e.g. Gy to lungs or GI tract)
  - Stasis acceptable endpoint, if indicated as possibility prior to infusion
  - Manufacturer

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Written Directive Evolution - 2008

- Pre and post implant Written Directive information
  - Treatment site (e.g. whole liver, left lobe, right lobe)
  - Radionuclide and form (Y-90 microspheres)
  - Prescribed dose (e.g. Gy to Tx site) or prescribed activity (mCi or GBq)
  - Maximum dose/activity from shunting (e.g. Gy or mCi to lungs or GI tract)
  - Stasis acceptable endpoint, if indicated as possibility prior to infusion
  - Manufacturer
  - Patient name and Date
  - Signature of AU

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Written Directive Evolution - 2011

- Pre and post implant Written Directive information
  - Treatment site (e.g. whole liver, left lobe, right lobe)
  - Radionuclide and form (Y-90 microspheres)
  - Prescribed dose (e.g. Gy to Tx site) or prescribed activity (mCi or GBq)
  - Maximum dose/activity from shunting (e.g. Gy or mCi to lungs or GI tract)
  - Stasis acceptable endpoint, if indicated as possibility prior to infusion
  - Manufacturer
  - Patient name and Date
  - Signature of AU (pre-implant only, if procedure performed as planned)

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Written Directive Evolution - 2012

- Pre and post implant Written Directive information
  - Treatment site (e.g. whole liver, left lobe, right lobe)
  - Radionuclide and form (Y-90 microspheres)
  - Prescribed dose (e.g. Gy to Tx site) or prescribed activity (mCi or GBq)
  - Maximum dose/activity from shunting (e.g. Gy or mCi to lungs or GI tract)
  - Stasis acceptable endpoint, if indicated as possibility prior to infusion
  - Manufacturer
  - Patient name and Date
  - Signature of AU (pre-implant only, if procedure performed as planned)
  - Allowance for modification of post-implant Written Directive for emergent patient conditions (e.g. artery spasm or sudden change in blood pressure)

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Written Directive Evolution - 2016

- Pre and post implant Written Directive information
  - Treatment site (e.g. whole liver, left lobe, right lobe)
  - Radionuclide and form (Y-90 microspheres)
  - Prescribed dose (e.g. Gy to Tx site) or prescribed activity (mCi or GBq)
  - ~~Maximum dose/activity from shunting (e.g. Gy or mCi to lungs or GI tract)~~
  - Stasis acceptable endpoint, if indicated as possibility prior to infusion
  - Manufacturer
  - Patient name and Date
  - Signature of AU (pre-implant only, if procedure performed as planned)
  - Allowance for modification of post-implant Written Directive for emergent patient conditions (e.g. artery spasm or sudden change in blood pressure)

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Example

Y-90 Microspheres Written Directive

Pre-Implant Documentation

Pre-implant documentation in the Written Directive is required for all Y-90 microspheres procedures.
An AU for Y-90 microspheres must sign & date prior to each administration.

Patient Name/ID _____

Treatment Site _____

Radionuclide and Physical Form Yttrium-90 microspheres

Manufacturer _____

Prescribed Activity _____ mCi / GBq or activity delivered at stasis
choose

Authorized User Signature X _____

Date _____

Post-Implant Documentation

Post-implant documentation in the Written Directive is only required if the procedure was modified.
An AU for Y-90 microspheres must sign & date within 24 hrs.

Stasis ☐ **Emergent Patient Conditions** ☐ **Delivered Activity** _____ mCi / GBq
choose

Name of Individual Making Determination of Delivered Activity _____

Provide explanation.

Authorized User Signature X _____

Date _____

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Medical Event Reporting Criteria

- Report events, except those resulting from patient intervention, involving:
  - use of the wrong radionuclide;
  - administration to the wrong individual, via the wrong route, or wrong mode of treatment;
  - total dose or activity administered differs from the prescribed dose or activity, as documented in the written directive, by 20 percent or more, except when stasis or emergent patient conditions are documented and resulted in a total dose or activity administered that was less than that prescribed; or
  - the administration of byproduct material results in dose or activity to an organ or tissue other than the treatment site, as documented in the written directive, except for shunting when shunting was evaluated prior to the treatment in accordance with the manufacturer's procedures.
- Report events from patient intervention resulting in unintended permanent functional damage.

<u>NOTIFICATIONS</u>

- NRC/State telephone notification by next calendar day; written report 15 days.
- Referring physician and patient notification within 24 hours; written report to referring 15 days.

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Medical Events

FY	% Incidence Glass	% Incidence Resin	Total % Incidence
2007	2.34%	0.21%	0.53%
2008	Unknown	Unknown	0.13%
2009	0.30%	0.17%	0.23%
2010	0.10%	0.08%	0.09%
2011	0.29%	0.13%	0.20%
2012	0.36%	0.18%	0.26%
TOTAL	**0.29%**	**0.13%**	**0.26%**

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Source: U.S. NRC Advisory Committee on the Medical Uses of Isotopes (ACMUI)
Final Yttrium-90 Microsphere Brachytherapy Medical Events Analysis, June 18, 2013
https://www.nrc.gov/docs/ML1317/ML13175A025.pdf

Medical Events

Both

- Wrong patient
- Wrong lobe
- Misread Rx

Resin

- Three-way stopcocks
- Switching between delivery & flush/arteriogram modes
- Occlusion of catheter due to microcatheter (<2.8 French)
- Slow delivery that led to settling
- Microspheres stuck to septum because vial shipped upside down

Glass

- Settling due to low flow
- Crimped line
- Low flow due to pause
- Clumping
- Leaking of priming line and reduced pressure
- Needles inserted at angle
- Possible defective catheter
- Hemostat caused deformation of tube and limited flow
- Slow flush due to small arteries
- “Dose seemed harder to push”
- Low flow rate not otherwise specified
- Piece of septum within vial impeded flow
- Clamp not fully opened

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