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April 9, 2026

U.S. Nuclear Regulatory Commission, Region Ill
2056 Westings Avenue
Suite 400
Naperville, IL 60563-2657

Subject: Addition of Yttrium-90 Sirtex SIR-Spheres to License Number 21-32812-01MD

To Whom It May Concern:

Request:
Please add Y-90 as a line item to our allowed products as follows

6. Byproduct, Source, and/or special nuclear material	**7. Chemical and/or Physical Form**	**8. Maximum amount that licensee may possess at any one time under this license**
Yttrium-90 Permitted by 10 CFR 35.1000	Microspheres (Sirtex Wilmington LLC, Sirtex Medical Limited, or ANSTO Radiopharmaceuticals and Industrials, Model SIR-Spheres)	3 Curies Total

Authorized use:
For preparation and redistribution of microspheres in accordance with 10 CFR32.74 to persons specifically authorized by an NRC or agreement State license to receive, possess and use the microspheres for medical use as permitted by 10 CFR 35.1000

Discussion:
We are requesting an amendment to our RAM license to add Yttrium-90 SIR-Spheres as a line item (see above) which would allow receipt, possession, storage and distribution of the Yttrium-90 impregnated resin microspheres distributed by:

Sirtex Wilmington, LLC
16 Upton Drive, #2-4
Wilmington, MA 01887
Sealed Source and Device Registration Number: MA-1229-D-101-S
License Issuer: The Commonwealth of Massachusetts, Radiation Control Program

The reason for our request is that we have received interest in our pharmacy dispensing patient specific doses of Yttrium-90 SIR-Spheres provided by the manufacturer Sirtex and our requested maximum amount accounts for growth opportunities.

Based on a review of our current license, we believe that our radiation safety program contains adequate equipment for the preparation and dispensing of the Yttrium-90 SIR-Spheres as well as adequate survey protocols and training. In addition we make the following commitments to support dispensing Y-90 microspheres:

1. All Authorized Nuclear Pharmacists and additional handlers on the pharmacy staff will be provided training by the manufacturer, Sirtex, for manipulating doses prior to first use under this license. Which includes but is not limited to:
    a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys
    b. Performing quality control procedures on instruments used to determine the activity of Y-90 microspheres
    c. Performing checks for proper calculating and measuring of the activity and safely preparing the Y-90 microspheres to be delivered to the client
    d. Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, and safely using proper decontamination procedures

2. The dose calibrators used will be appropriately calibrated to ensure accurate measurements according to the manufacturer's instructions.

3. All doses will be prepared and labeled under the supervision of an Authorized Nuclear Pharmacist.

4. Only doses that have been prepared in accordance with the manufacturer's instructions will be distributed.

5. Doses will not be distributed beyond an expiration date as provided by the manufacturer.

6. Unit doses will only be shipped to medical licenses authorized to receive Yttrium-90 SIR-Spheres which will be verified on the recipient's USNRC radioactive materials license copy that is kept on file.

7. The half-life of Yttrium-90 is approximately 64 hours. The unused residual microspheres from the original manufacturer vial as well as all the preparation and potentially contaminated materials will be decayed in storage. Due to the fact that Yttrium-90 SIR-Spheres have a half-life of less than 120 days a decommissioning funding plan is not required.

8. Support will be provided by Sirtex as necessary, and specifically if any changes occur in the product or packaging.

9. According to the Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres Licensing Guidance, we would expect that the maximum per vial activity will be 189 mCi/vial. No more than one patient dose will be administered per vial.

10. All manipulation of the Yttrium-90 SIR-Spheres will be handled within a laminar flow hood that includes a dose calibrator. Quality control procedures will be performed on the dose calibrators being used to assure proper calculating and measuring of the activity. The Yttrium-90 SIR-Spheres will be transferred from the manufacturer's vial into a single patient unit dose container. All handlers will use the procedures learned from the manufacturer training to control and to contain spilled byproduct material from the Yttrium-90 SIR-Spheres and follow proper decontamination procedures.

11. The Yttrium-90 SIR-Spheres will be transferred from the manufacturers vial to a unit dose container in accordance with the manufacturer's instructions. The dose will have a label attached that includes the prescription number, medical licensee's name, radiopharmaceutical, procedure, ordered activity, calibration date/time and patient name. The dose will be shielded for transport with an appropriate dose shielding container.

12. All Yttrium-90 SIR-Spheres that remain following repackaging will be kept in the original manufacturer's vial and placed in a shielded waste area until the vial survey is background. Once the survey is background, the product labeling will be defaced and the vial will be disposed of in the daily waste barrels for final disposal with Stericycle. Any spilled byproduct material from the Yttrium-90 SIR-Spheres will also be placed in the same shielded waste area until the survey is background and then disposed of in the daily waste barrels.

Please contact me at (517) 455-9577 if you have any questions, require hard copies to be sent with original signatures, or need any other further documentation. Thank you for your continued support.

Sincerely,

Aaron Barnes, Pharm.D.
Associate Corporate Radiation Safety Officer – Pharmalogic / Hot Shots Nuclear Medicine
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Enclosures

ENGLISH

SIROS™ Dose Preparation Technical Description

The information and steps described below are recommended for the preparation of the SIR-Spheres® Y-90 resin microspheres within a Nuclear Medicine department. Read the SIR-Spheres Y-90 resin microspheres Instructions for Use and Training Manual before preparing SIR-Spheres Y-90 resin microspheres, hereinafter referred to as SIR-Spheres. **The SIROS Delivery System is intended to allow the administration of SIR-Spheres Y-90 resin microspheres.**

⚠ PRECAUTIONS

- Time, distance and shielding considerations should be used to minimize exposure to radiation.
- Ensure that the distance between any puncture holes in the septum of the D-Vial is at least 2 mm apart.

PART NUMBER	DEVICE NAME	DESCRIPTION	PHOTO
SIR-Y001	SIR-Spheres® Y-90 resin microspheres	SIR-Spheres Y-90 resin microspheres glass vial in Lead Pot	
SIR-10200	SIROS™ D-Vial Prep-Set	SIROS D-Vial Prep Set Consists of: • D-Vial transport base • D-Vial holder • D-Vial • 21 G drawing up needle • Two 25 G vent needles • Two 0.22 micron needle filters • Two blue caps	
SIR-S001	Syringe Shield	Acrylic Syringe Shield	

ADDITIONAL ACCESSORIES REQUIRED

- Forceps
- Alcohol swabs
- One 20 mL luer lock syringe
- One 5 mL luer lock syringe
- 20 mL of 5% dextrose / glucose solution (D5W/G5) or water for injection

1. UNPACKING PROCESS

A. Unpack SIR-Spheres lead pot from the plastic shipping pail and place it on the bench top.

B. Insert the D-Vial holder into the transport base and place it on the prep surface area.

C. Remove D-Vial from pouch and place in D-Vial holder.

D. Remove the aluminum seal from the center of the D-Vial with forceps and wipe the rubber septum with an alcohol swab.

2. PRIMING PROCESS

A. Connect the 0.22 micron filter to the 25 G vent needle. Insert it through the rubber septum of the D-Vial to create a vent.

B. Ensure vent needle tip is above the fill level mark.

C. Remove the blue cap from D line.

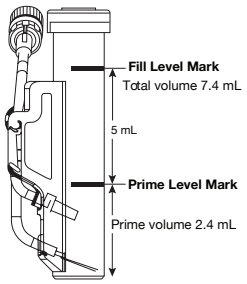
D. Attach a syringe filled with at least 10 mL of D5W or sterile water for injection to prime the D line. Fill D-Vial to fill level mark. Ensure there is no air in the D line.

E. Disconnect priming syringe from D line; attach a new blue cap to the D line connector.

F. Remove blue cap from C line.

G. Connect same priming syringe to the C line.

H. Slowly draw fluid into the syringe from the vial to prime the C line until fluid is at the prime level mark. Ensure there is no air in the C line. **Do not draw below the prime level mark.**



I. Disconnect syringe from the C line; attach a new blue cap to the C line connector.

3. DOSE DRAW PROCESS

A. Invert the lead pot and shake vigorously before opening to re-suspend the SIR-Spheres, which will have settled during shipping.

B. Quickly open the lead pot and remove the glass shipping vial using forceps.

C. Determine the total activity of SIR-Spheres in the glass shipping vial using an appropriate ion chamber (dose calibrator) and then return the glass shipping vial to the lead pot.

D. Determine the volume of SIR-Spheres suspension that needs to be withdrawn from the glass shipping vial to provide the intended patient-specific activity of SIR-Spheres.

E. Partially peel back the aluminum seal of the SIR-Spheres glass shipping vial and wipe the septum with an alcohol swab.

F. Connect the 0.22 micron filter to the 25 G vent needle. Insert it through the rubber septum of the shipping vial to create a vent. Ensure that the tip of the needle is well clear of the contents.

G. Attach the 21 G drawing upneedle to a 5 mL Luer lock syringe and place it in the acrylic syringe shield.

H. Using the shielded syringe and 21 G needle, puncture the septum of the glass shipping vial and quickly draw back and forth at least six times in order to re-suspend the SIR-Spheres thoroughly.

I. Quickly withdraw the determined volume of SIR-Spheres suspension that will provide the intended patient specific activity. Prior to removing syringe needle from Shipping Vial, draw some air through needle into syringe to draw spheres within needle up into shielded syringe.

J. Withdraw the needle from the septum and re-cap the needle using forceps. Set aside on the bench top.

K. Using forceps, swirl the glass shipping vial to re-suspend the microspheres and measure the activity remaining in the shipping vial with the dose calibrator.

L. Replace glass shipping vial into the lead pot.

M. Subtract the activity remaining in the shipping vial from the starting total activity, to determine the amount of activity that has been drawn up into the 5 mL syringe.

N. If the amount of activity that has been drawn up into the 5 mL syringe is not correct, transfer the SIR-Spheres suspension back into the glass shipping vial and repeat the steps above to obtain the prescribed level of activity.

O. Once the correct activity has been obtained, remove the vent needle from the shipping vial, and secure the lead pot cover.

P. Transfer the SIR-Spheres from the 5 mL syringe into the vented D-Vial.

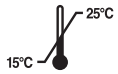
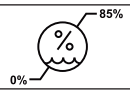
Q. If the volume of fluid in the D-Vial does not reach the fill level mark, use a 25 G needle to add D5W or sterile water for injection until the fluid reaches the fill level mark. The volume between the prime level mark and fill level mark is 5 mL.
Do not exceed the fill level mark.

R. Remove all needles from the D-Vial septum.

S. Screw on the D-Vial Holder Cap.

T. The patient-specific activity of SIR-Spheres is now ready for transport to the angiography suite in which the implantation will be performed.

SYMBOLS GLOSSARY DEFINITIONS

Symbol	Definition	Symbol	Definition
	Manufacturer		Do not re-sterilize
	Date of Manufacture		Single Use Only. Indicates a medical device that is intended for use on a single patient during a single procedure.
	Consult instructions for use		Product is not made with natural rubber latex
	Caution		Do not use if package is damaged
	Quantity		Keep dry
	Catalog number		Temperature limit
	Lot or batch code		Relative Humidity limit
	Use by date		Ionizing radiation
	Importer		Unique Device Identifier
	Sterile Barrier		Authorized representative in Switzerland
	Protective Barrier		Authorized representative in the European Community
	Non-Sterile		CE mark + Notified Body identification number
	Sterilized using irradiation		Medical Device
	Sterilized using Ethylene Oxide		Caution: Federal law (USA) restricts this device to sale by or on the order of a physician or licensed healthcare practitioner.
	Sterilized using steam		MR Safe
	Serial number		

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SIRTeX | SIR-Spheres® Y-90 resin microspheres

SIR-Spheres® Y-90 resin microspheres Activity Chart

Advancing to the next level.

The Activity You Want, The Coverage You Need

DAY THREE PRE-CALIBRATION

Calculation from Calibration (18:00 Eastern Standard Time) to Assay Time

	Hours Before Cal	Decay Factor	Total Activity	Million Spheres per GBq
8:00 AM	82	2.427	7.28	6.1
	81.5	2.414	7.24	6.1
9:00 AM	81	2.401	7.20	6.2
	80.5	2.388	7.16	6.2
10:00 AM	80	2.375	7.13	6.2
	79.5	2.362	7.09	6.3
11:00 AM	79	2.350	7.05	6.3
	78.5	2.337	7.01	6.3
NOON	78	2.324	6.97	6.4
	77.5	2.312	6.94	6.4
1:00 PM	77	2.299	6.90	6.4
	76.5	2.287	6.86	6.5
2:00 PM	76	2.275	6.82	6.5
	75.5	2.262	6.79	6.6
3:00 PM	75	2.250	6.75	6.6
	74.5	2.238	6.71	6.6
4:00 PM	74	2.226	6.68	6.7
	73.5	2.214	6.64	6.7
5:00 PM	73	2.202	6.61	6.7
	72.5	2.190	6.57	6.8
6:00 PM	72	2.178	6.54	6.8
	71.5	2.167	6.50	6.8
7:00 PM	71	2.155	6.46	6.9
	70.5	2.143	6.43	6.9
8:00 PM	70	2.132	6.40	7.0
	69.5	2.120	6.36	7.0
9:00 PM	69	2.109	6.33	7.0
	68.5	2.097	6.29	7.1
10:00 PM	68	2.086	6.26	7.1
	67.5	2.075	6.22	7.1
11:00 PM	67	2.064	6.19	7.2
	66.5	2.053	6.16	7.2
MIDNIGHT	66	2.042	6.12	7.3
	65.5	2.031	6.09	7.3

DAY TWO PRE-CALIBRATION

Calculation from Calibration (18:00 Eastern Standard Time) to Assay Time

	Hours Before Cal	Decay Factor	Total Activity	Million Spheres per GBq
1:00 AM	65	2.020	6.06	7.3
	64.5	2.009	6.03	7.4
2:00 AM	64	1.998	5.99	7.4
	63.5	1.987	5.96	7.5
3:00 AM	63	1.976	5.93	7.5
	62.5	1.966	5.90	7.5
4:00 AM	62	1.955	5.87	7.6
	61.5	1.945	5.83	7.6
5:00 AM	61	1.934	5.80	7.7
	60.5	1.924	5.77	7.7
6:00 AM	60	1.913	5.74	7.7
	59.5	1.903	5.71	7.8
7:00 AM	59	1.893	5.68	7.8
	58.5	1.882	5.65	7.9
8:00 AM	58	1.872	5.62	7.9
	57.5	1.862	5.59	8.0
9:00 AM	57	1.852	5.56	8.0
	56.5	1.842	5.53	8.0
10:00 AM	56	1.832	5.50	8.1
	55.5	1.822	5.47	8.1
11:00 AM	55	1.813	5.44	8.2
	54.5	1.803	5.41	8.2
NOON	54	1.793	5.38	8.3
	53.5	1.783	5.35	8.3
1:00 PM	53	1.774	5.32	8.4
	52.5	1.764	5.29	8.4
2:00 PM	52	1.755	5.26	8.4
	51.5	1.745	5.24	8.5
3:00 PM	51	1.736	5.21	8.5
	50.5	1.726	5.18	8.6
4:00 PM	50	1.717	5.15	8.6
	49.5	1.708	5.12	8.7
5:00 PM	49	1.699	5.10	8.7
	48.5	1.690	5.07	8.8
6:00 PM	48	1.680	5.04	8.8
	47.5	1.671	5.01	8.9
7:00 PM	47	1.662	4.99	8.9
	46.5	1.653	4.96	9.0
8:00 PM	46	1.644	4.93	9.0
	45.5	1.636	4.91	9.1
9:00 PM	45	1.627	4.88	9.1
	44.5	1.618	4.85	9.2
10:00 PM	44	1.609	4.83	9.2
	43.5	1.601	4.80	9.3
11:00 PM	43	1.592	4.78	9.3
	42.5	1.583	4.75	9.4
MIDNIGHT	42	1.575	4.72	9.4
	41.5	1.566	4.70	9.5

DAY ONE PRE-CALIBRATION

Calculation from Calibration (18:00 Eastern Standard Time) to Assay Time

	Hours Before Cal	Decay Factor	Total Activity	Million Spheres per GBq
1:00 AM	41	1.558	4.67	9.5
	40.5	1.550	4.65	9.6
2:00 AM	40	1.541	4.62	9.6
	39.5	1.533	4.60	9.7
3:00 AM	39	1.525	4.57	9.7
	38.5	1.516	4.55	9.8
4:00 AM	38	1.508	4.52	9.8
	37.5	1.500	4.50	9.9
5:00 AM	37	1.492	4.48	9.9
	36.5	1.484	4.45	10.0
6:00 AM	36	1.476	4.43	10.0
	35.5	1.468	4.40	10.1
7:00 AM	35	1.460	4.38	10.2
	34.5	1.452	4.36	10.2
8:00 AM	34	1.444	4.33	10.3
	33.5	1.437	4.31	10.3
9:00 AM	33	1.429	4.29	10.4
	32.5	1.421	4.26	10.4
10:00 AM	32	1.413	4.24	10.5
	31.5	1.406	4.22	10.5
11:00 AM	31	1.398	4.19	10.6
	30.5	1.391	4.17	10.7
NOON	30	1.383	4.15	10.7
	29.5	1.376	4.13	10.8
1:00 PM	29	1.368	4.10	10.8
	28.5	1.361	4.08	10.9
2:00 PM	28	1.354	4.06	11.0
	27.5	1.346	4.04	11.0
3:00 PM	27	1.339	4.02	11.1
	26.5	1.332	4.00	11.1
4:00 PM	26	1.325	3.97	11.2
	25.5	1.318	3.95	11.3
5:00 PM	25	1.310	3.93	11.3
	24.5	1.303	3.91	11.4
6:00 PM	24	1.296	3.89	11.4
	23.5	1.289	3.87	11.5
7:00 PM	23	1.282	3.85	11.6
	22.5	1.275	3.83	11.6
8:00 PM	22	1.269	3.81	11.7
	21.5	1.262	3.79	11.8
9:00 PM	21	1.255	3.76	11.8
	20.5	1.248	3.74	11.9
10:00 PM	20	1.241	3.72	11.9
	19.5	1.235	3.70	12.0
11:00 PM	19	1.228	3.68	12.1
	18.5	1.221	3.66	12.1
MIDNIGHT	18	1.215	3.64	12.2
	17.5	1.208	3.62	12.3

To calculate the number of spheres drawn from the vial: divide the activity drawn by the total activity in the vial, then multiply that number by 44.48 million.

DAY OF CALIBRATION

Calculation from Calibration (18:00 Eastern Standard Time) to Assay Time

	Hours Before Cal	Decay Factor	Total Activity	Million Spheres per GBq
1:00 AM	17	1.202	3.61	12.3
	16.5	1.195	3.59	12.4
2:00 AM	16	1.189	3.57	12.5
	15.5	1.182	3.55	12.5
3:00 AM	15	1.176	3.53	12.6
	14.5	1.170	3.51	12.7
4:00 AM	14	1.163	3.49	12.7
	13.5	1.157	3.47	12.8
5:00 AM	13	1.151	3.45	12.9
	12.5	1.145	3.43	13.0
6:00 AM	12	1.139	3.42	13.0
	11.5	1.132	3.40	13.1
7:00 AM	11	1.126	3.38	13.2
	10.5	1.120	3.36	13.2
8:00 AM	10	1.114	3.34	13.3
	9.5	1.108	3.32	13.4
9:00 AM	9	1.102	3.31	13.5
	8.5	1.096	3.29	13.5
10:00 AM	8	1.090	3.27	13.6
	7.5	1.084	3.25	13.7
11:00 AM	7	1.079	3.24	13.7
	6.5	1.073	3.22	13.8
NOON	6	1.067	3.20	13.9
	5.5	1.061	3.18	14.0
1:00 PM	5	1.056	3.17	14.0
	4.5	1.050	3.15	14.1
2:00 PM	4	1.044	3.13	14.2
	3.5	1.039	3.12	14.3
3:00 PM	3	1.033	3.10	14.4
	2.5	1.027	3.08	14.4
4:00 PM	2	1.022	3.07	14.5
	1.5	1.016	3.05	14.6
5:00 PM	1	1.011	3.03	14.7
	0.5	1.005	3.02	14.7
6:00 PM	0	1.000	3.00	14.8
	-0.5	0.995	2.98	14.9
7:00 PM	-1	0.989	2.97	15.0
	-1.5	0.984	2.95	15.1
8:00 PM	-2	0.979	2.94	15.2
	-2.5	0.973	2.92	15.2
9:00 PM	-3	0.968	2.90	15.3
	-3.5	0.963	2.89	15.4
10:00 PM	-4	0.958	2.87	15.5
	-4.5	0.953	2.86	15.6
11:00 PM	-5	0.947	2.84	15.7
	-5.5	0.942	2.83	15.7
MIDNIGHT	-6	0.937	2.81	15.8
	-6.5	0.932	2.80	15.9

POST-CALIBRATION

Calculation from Calibration (18:00 Eastern Standard Time) to Assay Time

	Hours Before Cal	Decay Factor	Total Activity	Million Spheres per GBq
1:00 AM	-7	0.927	2.78	16.0
	-7.5	0.922	2.77	16.1
2:00 AM	-8	0.917	2.75	16.2
	-8.5	0.912	2.74	16.3
3:00 AM	-9	0.907	2.72	16.3
	-9.5	0.902	2.71	16.4
4:00 AM	-10	0.898	2.69	16.5
	-10.5	0.893	2.68	16.6
5:00 AM	-11	0.888	2.66	16.7
	-11.5	0.883	2.65	16.8
6:00 AM	-12	0.878	2.63	16.9
	-12.5	0.874	2.62	17.0
7:00 AM	-13	0.869	2.61	17.1
	-13.5	0.864	2.59	17.2
8:00 AM	-14	0.860	2.58	17.3
	-14.5	0.855	2.56	17.3
9:00 AM	-15	0.850	2.55	17.4
	-15.5	0.846	2.54	17.5
10:00 AM	-16	0.841	2.52	17.6
	-16.5	0.837	2.51	17.7
11:00 AM	-17	0.832	2.50	17.8
	-17.5	0.828	2.48	17.9
NOON	-18	0.823	2.47	18.0
	-18.5	0.819	2.46	18.1
1:00 PM	-19	0.814	2.44	18.2
	-19.5	0.810	2.43	18.3
2:00 PM	-20	0.806	2.42	18.4
	-20.5	0.801	2.40	18.5
3:00 PM	-21	0.797	2.39	18.6
	-21.5	0.793	2.38	18.7
4:00 PM	-22	0.788	2.36	18.8
	-22.5	0.784	2.35	18.9
5:00 PM	-23	0.780	2.34	19.0
	-23.5	0.776	2.33	19.1
6:00 PM	-24	0.771	2.31	19.2

On average there are 44 million spheres in each SIR-Spheres Y-90 resin microspheres delivery vial with a standard deviation of 2.6 million. Engineering test results on file.

Manufacturer
Sirtex Medical Pty Ltd
Shop 6, 207 Pacific Highway
St Leonards, NSW 2065
Australia
Tel: +61 2 9964 8400
Fax: +61 2 9964 8410

Americas
Sirtex Medical Inc.
300 Unicorn Park Drive
Woburn, MA 01801
USA
Tel: +1 888 474 7839

www.sirtex.com

APM-US-042-07-20 V2

The activity you want.
The coverage you need.

	Hour (GMT)	GBq	Millions of spheres per GBq
4 days pre-calibration	8:00	9,963	4.5
	10:00	9,750	4.6
	12:00	9,542	4.7
	14:00	9,337	4.8
	16:00	9,138	4.9
	18:00	8,942	5.0
	20:00	8,751	5.1
3 days pre-calibration	8:00	7,686	5.8
	10:00	7,521	5.9
	12:00	7,361	6.0
	14:00	7,203	6.2
	16:00	7,049	6.3
	18:00	6,898	6.4
	20:00	6,751	6.6
2 days pre-calibration	8:00	5,929	7.5
	10:00	5,802	7.7
	12:00	5,678	7.8
	14:00	5,557	8.0
	16:00	5,438	8.2
	18:00	5,321	8.4
	20:00	5,208	8.5
1 day pre-calibration	8:00	4,574	9.7
	10:00	4,476	9.9
	12:00	4,380	10.2
	14:00	4,286	10.4
	16:00	4,195	10.6
	18:00	4,105	10.8
	20:00	4,017	11.1
day of calibration	8:00	3,528	12.6
	10:00	3,453	12.9
	12:00	3,379	13.2
	14:00	3,307	13.5
	16:00	3,236	13.7
	18:00	3,167	14.0
	20:00	3,099	14.4

To calculate the number of spheres extracted from the vial: divide the extracted activity by the total activity of the vial, then multiply this number by 44.5 million.

Optimize SIRT with
The SIR-Spheres® Advantage

ORDER-MAP-TREAT Programme

SIR-Spheres® Y-90 resin microspheres

FLEXdose Delivery Programme

FLEXdose Delivery Programme Animation

Scan me

INSIGHT Y-90
The power of knowing
with SurePlan LiverY90

Intended Use: SIR-Spheres Y-90 resin microspheres are intended for implantation into hepatic tumors via the hepatic artery.
Indications For Use: SIR-Spheres Y-90 resin microspheres are indicated for the treatment of unresectable hepatocellular carcinoma (HCC) or unresectable metastatic liver tumors from primary colorectal cancer in patients refractory to or intolerant of chemotherapy.
Consult the Instructions for Use for a complete listing of indications, contraindications, side effects, warnings, and precautions.

Manufacturer
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APM-EMEA-012-07-20 V4

SIRTeX

SIRTeX | SIR-Spheres® Y-90 resin microspheres

FLEXdose
Delivery Programme

Advancing to the next level.

Optimize activity → **Maximize** coverage

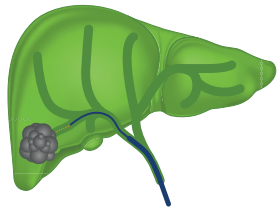
Delivery Option	4 days pre-calibration	3 days pre-calibration	2 days pre-calibration	1 day pre-calibration	Day of calibration
Activity on average 44.5 million microspheres in each delivery vial*	10.0 GBq	7.8 GBq	6.0 GBq	4.6 GBq	3.6 GBq
Dose Draw					
Example: 1.2 GBq # Microspheres (million) Activity/Microsphere	~5.3 225 Bq	~6.8 175 Bq	~8.9 135 Bq	~11.6 103 Bq	~14.8 81 Bq

*Standard deviation of 2.6 million. Engineering test results on file. Activities for the morning of the delivery day at 7:00 am GMT.

Adapt your treatment

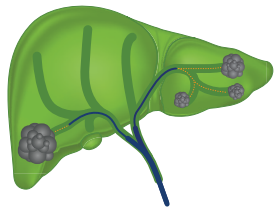
- **for targeted liver volume**
  subsegmental, segmental, lobar
- **for tumor vascularization**
  relatively hypovascular, hypervascular, impaired arteries from previous treatments
- **for treatment goal**
  enable surgery, palliative

The ACTIVITY you want for liver-sparing segmental approach



Microcatheter

The COVERAGE you need in 1 vial to treat large and/or multiple tumors



Microcatheter

The unique flexibility of SIR-Spheres Y-90 resin microspheres

Flexible treatment strategy

- Tailored activity for patient-specific needs
- Multiple injection sites
- Procedural approach can be adjusted on day of treatment
- Full control through angiographic visibility

Flexible treatment planning

- Multiple delivery options for an expedited patient path
- ORDER-MAP-TREAT programme, map and treat on the same-day or the same-stay

Flexible dose draw

- Activity ready to use when required
- Possibility to adapt the activity until the very last minute

From: Tammy Tomczak
To: Martha Pavon
Cc: Sandy Pavon
Subject: FW: Marquette Michigan (RAM License # 21-32812-01MD) Amendment Request
Date: Monday, April 13, 2026 7:03:32 AM
Attachments: Outlook-020uuh54.png
2026.4.9 Amendment Add Y-90 Marquette - FINAL.pdf

Good morning, Martha

Can you please add the attached to ADAMS?

Thank you!
Tammy

From: Aaron Barnes <abarnes@radiopharmacy.com>
Sent: Friday, April 10, 2026 8:53 AM
To: R3-DRSSMail Resource <R3-DRSSMail.Resource@nrc.gov>
Cc: Frank Plastini <fplastini@radiopharmacy.com>; Allen Doan <ADoan@radiopharmacy.com>
Subject: [External_Sender] Marquette Michigan (RAM License # 21-32812-01MD) Amendment Request

Hello Region 3 Representatives,

Please see the attached Amendment request for Marquette Michigan 21-32812-01MD. We would like to add Y-90 as an allowed product.

Please let me know if there are any questions. Thanks,

Aaron Barnes Pharm.D
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website www.pharmalogicgroup.com
Follow us on **LinkedIn**