

SIR-Spheres® Y-90 resin microspheres Activity Chart

(SIR-Y001 5 mL vial)



SIR-Spheres Y-90 resin microspheres (SIR-Y001 5 mL vial)									SIR-Y001 3 DPC
									SIR-Y001 2 DPC
DAY THREE PRE-CALIBRATION									SIR-Y001 1 DPC
	Elapse Time (In hours)	Decay Correction Factor	SIR-Y001 Activity in GBq	SIR-Y001 Activity in GBq per .5mL	SIR-Y001 Activity in mCi	SIR-Y001 Activity in mCi per .5mL	SIR-Y001 Specific Activity Bq Per Sphere^	SIR-Y001 SIR-Spheres per GBq (reported in millions^)	SIR-Y001 Day of Calibration
12:00 AM	-90.0	2.646	7.94	0.79	214.58	21.46	180.44	5.54	Indication
1:00 AM	-89.0	2.618	7.85	0.79	212.27	21.23	178.50	5.60	
2:00 AM	-88.0	2.590	7.77	0.78	209.99	21.00	176.58	5.66	
3:00 AM	-87.0	2.562	7.69	0.77	207.73	20.77	174.68	5.72	
4:00 AM	-86.0	2.534	7.60	0.76	205.49	20.55	172.80	5.79	
5:00 AM	-85.0	2.507	7.52	0.75	203.28	20.33	170.94	5.85	
6:00 AM	-84.0	2.480	7.44	0.74	201.10	20.11	169.10	5.91	
7:00 AM	-83.0	2.454	7.36	0.74	198.93	19.89	167.29	5.98	
8:00 AM	-82.0	2.427	7.28	0.73	196.79	19.68	165.49	6.04	
9:00 AM	-81.0	2.401	7.20	0.72	194.68	19.47	163.71	6.11	
10:00 AM	-80.0	2.375	7.13	0.71	192.58	19.26	161.95	6.17	
11:00 AM	-79.0	2.350	7.05	0.70	190.51	19.05	160.20	6.24	
12:00 PM	-78.0	2.324	6.97	0.70	188.46	18.85	158.48	6.31	
1:00 PM	-77.0	2.299	6.90	0.69	186.44	18.64	156.78	6.38	
2:00 PM	-76.0	2.275	6.82	0.68	184.43	18.44	155.09	6.45	
3:00 PM	-75.0	2.250	6.75	0.68	182.45	18.24	153.42	6.52	
4:00 PM	-74.0	2.226	6.68	0.67	180.49	18.05	151.77	6.59	
5:00 PM	-73.0	2.202	6.61	0.66	178.54	17.85	150.14	6.66	
6:00 PM	-72.0	2.178	6.54	0.65	176.62	17.66	148.52	6.73	
7:00 PM	-71.0	2.155	6.46	0.65	174.72	17.47	146.93	6.81	
8:00 PM	-70.0	2.132	6.40	0.64	172.85	17.28	145.35	6.88	
9:00 PM	-69.0	2.109	6.33	0.63	170.99	17.10	143.78	6.95	
10:00 PM	-68.0	2.086	6.26	0.63	169.15	16.91	142.24	7.03	
11:00 PM	-67.0	2.064	6.19	0.62	167.33	16.73	140.71	7.11	

^On average there are 44 million spheres in each SIR-Y001 delivery vial with a standard deviation of 2.6 million microspheres (FR-006).

SIR-Spheres Y-90 resin microspheres (SIR-Y001 5 mL vial)									SIR-Y001 3 DPC
									SIR-Y001 2 DPC
DAY TWO PRE-CALIBRATION									SIR-Y001 1 DPC
	Elapse Time (In hours)	Decay Correction Factor	SIR-Y001 Activity in GBq	SIR-Y001 Activity in GBq per .5mL	SIR-Y001 Activity in mCi	SIR-Y001 Activity in mCi per .5mL	SIR-Y001 Specific Activity Bq Per Sphere^	SIR-Y001 SIR-Spheres per GBq (reported in millions^)	SIR-Y001 Day of Calibration
12:00 AM	-66.0	2.042	6.12	0.61	165.53	16.55	139.19	7.18	Indication
1:00 AM	-65.0	2.020	6.06	0.61	163.75	16.37	137.70	7.26	
2:00 AM	-64.0	1.998	5.99	0.60	161.99	16.20	136.22	7.34	
3:00 AM	-63.0	1.976	5.93	0.59	160.24	16.02	134.75	7.42	
4:00 AM	-62.0	1.955	5.87	0.59	158.52	15.85	133.30	7.50	Indication
5:00 AM	-61.0	1.934	5.80	0.58	156.82	15.68	131.87	7.58	
6:00 AM	-60.0	1.913	5.74	0.57	155.13	15.51	130.45	7.67	
7:00 AM	-59.0	1.893	5.68	0.57	153.46	15.35	129.05	7.75	
8:00 AM	-58.0	1.872	5.62	0.56	151.81	15.18	127.66	7.83	Indication
9:00 AM	-57.0	1.852	5.56	0.56	150.18	15.02	126.29	7.92	
10:00 AM	-56.0	1.832	5.50	0.55	148.56	14.86	124.93	8.00	
11:00 AM	-55.0	1.813	5.44	0.54	146.96	14.70	123.58	8.09	
12:00 PM	-54.0	1.793	5.38	0.54	145.38	14.54	122.25	8.18	Indication
1:00 PM	-53.0	1.774	5.32	0.53	143.82	14.38	120.94	8.27	
2:00 PM	-52.0	1.755	5.26	0.53	142.27	14.23	119.64	8.36	
3:00 PM	-51.0	1.736	5.21	0.52	140.74	14.07	118.35	8.45	
4:00 PM	-50.0	1.717	5.15	0.52	139.23	13.92	117.08	8.54	Indication
5:00 PM	-49.0	1.699	5.10	0.51	137.73	13.77	115.82	8.63	
6:00 PM	-48.0	1.680	5.04	0.50	136.25	13.63	114.57	8.73	
7:00 PM	-47.0	1.662	4.99	0.50	134.79	13.48	113.34	8.82	
8:00 PM	-46.0	1.644	4.93	0.49	133.34	13.33	112.12	8.92	Indication
9:00 PM	-45.0	1.627	4.88	0.49	131.90	13.19	110.92	9.02	
10:00 PM	-44.0	1.609	4.83	0.48	130.48	13.05	109.72	9.11	
11:00 PM	-43.0	1.592	4.78	0.48	129.08	12.91	108.54	9.21	

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SIR-Spheres Y-90 resin microspheres (SIR-Y001 5 mL vial)									SIR-Y001 3 DPC
									SIR-Y001 2 DPC
DAY ONE PRE-CALIBRATION									SIR-Y001 1 DPC
	Elapse Time (In hours)	Decay Correction Factor	SIR-Y001 Activity in GBq	SIR-Y001 Activity in GBq per .5mL	SIR-Y001 Activity in mCi	SIR-Y001 Activity in mCi per .5mL	SIR-Y001 Specific Activity Bq Per Sphere^	SIR-Y001 SIR-Spheres per GBq (reported in millions^)	SIR-Y001 Day of Calibration
									SIR-Y001 Post-Calibration
12:00 AM	-42.0	1.575	4.72	0.47	127.69	12.77	107.38	9.31	Indication
1:00 AM	-41.0	1.558	4.67	0.47	126.32	12.63	106.22	9.41	
2:00 AM	-40.0	1.541	4.62	0.46	124.96	12.50	105.08	9.52	
3:00 AM	-39.0	1.525	4.57	0.46	123.62	12.36	103.95	9.62	
4:00 AM	-38.0	1.508	4.52	0.45	122.29	12.23	102.83	9.72	
5:00 AM	-37.0	1.492	4.48	0.45	120.97	12.10	101.73	9.83	
6:00 AM	-36.0	1.476	4.43	0.44	119.67	11.97	100.63	9.94	
7:00 AM	-35.0	1.460	4.38	0.44	118.38	11.84	99.55	10.05	
8:00 AM	-34.0	1.444	4.33	0.43	117.11	11.71	98.48	10.15	
9:00 AM	-33.0	1.429	4.29	0.43	115.85	11.58	97.42	10.26	
10:00 AM	-32.0	1.413	4.24	0.42	114.60	11.46	96.37	10.38	
11:00 AM	-31.0	1.398	4.19	0.42	113.37	11.34	95.34	10.49	
12:00 PM	-30.0	1.383	4.15	0.41	112.15	11.22	94.31	10.60	
1:00 PM	-29.0	1.368	4.10	0.41	110.95	11.09	93.30	10.72	
2:00 PM	-28.0	1.354	4.06	0.41	109.75	10.98	92.29	10.84	
3:00 PM	-27.0	1.339	4.02	0.40	108.57	10.86	91.30	10.95	
4:00 PM	-26.0	1.325	3.97	0.40	107.40	10.74	90.32	11.07	
5:00 PM	-25.0	1.310	3.93	0.39	106.25	10.62	89.35	11.19	
6:00 PM	-24.0	1.296	3.89	0.39	105.11	10.51	88.39	11.31	
7:00 PM	-23.0	1.282	3.85	0.38	103.98	10.40	87.43	11.44	
8:00 PM	-22.0	1.269	3.81	0.38	102.86	10.29	86.49	11.56	
9:00 PM	-21.0	1.255	3.76	0.38	101.75	10.18	85.56	11.69	
10:00 PM	-20.0	1.241	3.72	0.37	100.66	10.07	84.64	11.81	
11:00 PM	-19.0	1.228	3.68	0.37	99.57	9.96	83.73	11.94	

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SIR-Spheres Y-90 resin microspheres (SIR-Y001 5 mL vial)									SIR-Y001 3 DPC
									SIR-Y001 2 DPC
DAY OF CALIBRATION									SIR-Y001 1 DPC
	Elapse Time (In hours)	Decay Correction Factor	SIR-Y001 Activity in GBq	SIR-Y001 Activity in GBq per .5mL	SIR-Y001 Activity in mCi	SIR-Y001 Activity in mCi per .5mL	SIR-Y001 Specific Activity Bq Per Sphere^	SIR-Y001 SIR-Spheres per GBq (reported in millions^)	SIR-Y001 Day of Calibration
12:00 AM	-18.0	1.215	3.64	0.36	98.50	9.85	82.83	12.07	SIR-Y001 Post-Calibration
1:00 AM	-17.0	1.202	3.61	0.36	97.44	9.74	81.94	12.20	Indication
2:00 AM	-16.0	1.189	3.57	0.36	96.40	9.64	81.06	12.34	
3:00 AM	-15.0	1.176	3.53	0.35	95.36	9.54	80.19	12.47	
4:00 AM	-14.0	1.163	3.49	0.35	94.33	9.43	79.33	12.61	
5:00 AM	-13.0	1.151	3.45	0.35	93.32	9.33	78.47	12.74	
6:00 AM	-12.0	1.139	3.42	0.34	92.32	9.23	77.63	12.88	
7:00 AM	-11.0	1.126	3.38	0.34	91.32	9.13	76.79	13.02	
8:00 AM	-10.0	1.114	3.34	0.33	90.34	9.03	75.97	13.16	
9:00 AM	-9.0	1.102	3.31	0.33	89.37	8.94	75.15	13.31	
10:00 AM	-8.0	1.090	3.27	0.33	88.41	8.84	74.34	13.45	
11:00 AM	-7.0	1.079	3.24	0.32	87.46	8.75	73.54	13.60	
12:00 PM	-6.0	1.067	3.20	0.32	86.52	8.65	72.75	13.75	
1:00 PM	-5.0	1.056	3.17	0.32	85.59	8.56	71.97	13.89	
2:00 PM	-4.0	1.044	3.13	0.31	84.67	8.47	71.20	14.05	
3:00 PM	-3.0	1.033	3.10	0.31	83.75	8.38	70.43	14.20	
4:00 PM	-2.0	1.022	3.07	0.31	82.85	8.29	69.67	14.35	
5:00 PM	-1.0	1.011	3.03	0.30	81.96	8.20	68.92	14.51	
6:00 PM	0.0	1.000	3.00	0.30	81.08	8.11	68.18	14.67	
7:00 PM	1.0	0.989	2.97	0.30	80.21	8.02	67.45	14.83	
8:00 PM	2.0	0.979	2.94	0.29	79.35	7.93	66.72	14.99	
9:00 PM	3.0	0.968	2.90	0.29	78.49	7.85	66.01	15.15	
10:00 PM	4.0	0.958	2.87	0.29	77.65	7.76	65.30	15.31	
11:00 PM	5.0	0.947	2.84	0.28	76.81	7.68	64.59	15.48	

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SIR-Spheres Y-90 resin microspheres (SIR-Y001 5 mL vial)									SIR-Y001 3 DPC
									SIR-Y001 2 DPC
POST-CALIBRATION									SIR-Y001 1 DPC
	Elapse Time (In hours)	Decay Correction Factor	SIR-Y001 Activity in GBq	SIR-Y001 Activity in GBq per .5mL	SIR-Y001 Activity in mCi	SIR-Y001 Activity in mCi per .5mL	SIR-Y001 Specific Activity Bq Per Sphere^	SIR-Y001 SIR-Spheres per GBq (reported in millions^)	SIR-Y001 Day of Calibration
12:00 AM	6.0	0.937	2.81	0.28	75.99	7.60	63.90	15.65	SIR-Y001 Post-Calibration
1:00 AM	7.0	0.927	2.78	0.28	75.17	7.52	63.21	15.82	
2:00 AM	8.0	0.917	2.75	0.28	74.36	7.44	62.53	15.99	Indication
3:00 AM	9.0	0.907	2.72	0.27	73.56	7.36	61.86	16.17	
4:00 AM	10.0	0.898	2.69	0.27	72.77	7.28	61.19	16.34	
5:00 AM	11.0	0.888	2.66	0.27	71.99	7.20	60.54	16.52	
6:00 AM	12.0	0.878	2.63	0.26	71.21	7.12	59.88	16.70	
7:00 AM	13.0	0.869	2.61	0.26	70.45	7.04	59.24	16.88	
8:00 AM	14.0	0.860	2.58	0.26	69.69	6.97	58.60	17.06	
9:00 AM	15.0	0.850	2.55	0.26	68.94	6.89	57.97	17.25	
10:00 AM	16.0	0.841	2.52	0.25	68.20	6.82	57.35	17.44	
11:00 AM	17.0	0.832	2.50	0.25	67.47	6.75	56.73	17.63	
12:00 PM	18.0	0.823	2.47	0.25	66.74	6.67	56.12	17.82	
1:00 PM	19.0	0.814	2.44	0.24	66.02	6.60	55.52	18.01	
2:00 PM	20.0	0.806	2.42	0.24	65.31	6.53	54.92	18.21	
3:00 PM	21.0	0.797	2.39	0.24	64.61	6.46	54.33	18.41	
4:00 PM	22.0	0.788	2.36	0.24	63.91	6.39	53.75	18.61	
5:00 PM	23.0	0.780	2.34	0.23	63.23	6.32	53.17	18.81	
6:00 PM	24.0	0.771	2.31	0.23	62.55	6.25	52.60	19.01	

^On average there are 44 million spheres in each SIR-Y001 delivery vial with a standard deviation of 2.6 million microspheres (FR-006).

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. **Indications for Use:** SIR-Spheres® Y-90 resin microspheres are indicated for the local tumor control of unresectable hepatocellular carcinoma (HCC) in patients with no macrovascular invasion, Child Pugh-A cirrhosis, well-compensated liver function, and good performance status. They are also indicated for the treatment of unresectable metastatic liver tumors from primary colorectal cancer with adjuvant intra-hepatic artery chemotherapy (IHAC) of FUDR (Floxuridine). **Warnings / Precautions: Non-Target Delivery of SIR-Spheres Microspheres:** Inadvertent delivery of SIR-Spheres microspheres to extra-hepatic structures such as the esophagus, stomach, duodenum, gallbladder or pancreas may result in radiation injury to these structures. Meticulous angiographic technique must be employed to prevent the non-target delivery of SIR-Spheres microspheres to any extra-hepatic structures. **Radioembolization Induced Liver Disease (REILD):** Delivery of excessive radiation to the normal liver parenchyma may result in REILD. The risk of REILD may also be increased in patients with pre-existing liver disease. Consideration should be given to reducing the prescribed activity of SIR-Spheres microspheres in the following clinical settings: Reduced liver functional reserve due to steatosis, steatohepatitis, hepatitis or cirrhosis, Elevated baseline bilirubin level, Non-selective treatment of small tumor burden (< 5% liver involvement), Small liver volume (< 1.5 L), Prior hepatic resection, Prior liver directed therapy. **Radiation Pneumonitis:** High levels of implanted radiation and/or excessive shunting to the lung may lead to radiation pneumonitis. Limit radiation dose to ≤ 30 Gy per treatment and ≤ 50 Gy cumulatively. **Limited Radiation Dosimetry Planning Precision:** The amount of radiation delivered to HCC targets has been found to differ compared to the amount planned. Similar levels of precision should not be assumed when planning for Y-90 microsphere radiation therapy compared to when planning for external beam radiation therapy. **Side Effects:** Common side effects are fever, transient decrease of hemoglobin, mild to moderate abnormality of liver function tests, abdominal pain, nausea, vomiting, and diarrhea. Potential serious effects due to exposure to high radiation include acute pancreatitis, radiation pneumonitis, acute gastritis, acute cholecystitis and radioembolization induced liver disease (REILD). **Contraindications:** SIR-Spheres microspheres are contraindicated in any patient who has: portal vein thrombosis, ascites or clinical liver failure, markedly abnormal synthetic and excretory liver function tests (LFTs), such as total bilirubin > 2.0 mg/dL or albumin < 3.0 g/dL, > 20% lung shunting of the hepatic artery blood flow, or > 30 Gy radiation absorbed dose to the lungs for a single treatment, or > 50 Gy cumulative radiation absorbed dose to the lungs if the patient is re-treated, as estimated by the 99mTc MAA scan, pre assessment angiogram that demonstrates abnormal vascular anatomy that would result in significant reflux of microspheres to the stomach, pancreas or bowel and had previous external beam radiation therapy to the liver. **Contraindications for Patients with mCRC:** Disseminated extra-hepatic malignant disease, been treated with capecitabine within the two previous months, or who will be treated with capecitabine at any time following treatment with SIR-Spheres microspheres. **Contraindications for Patients with HCC:** Comorbidities or poor overall health (e.g., ECOG performance status rating> 2) which may make the patient a poor candidate for locoregional radiation treatment, disseminated extra-hepatic malignant disease. **General Information:** SIR-Spheres Y-90 resin microspheres may only be distributed to a duly licensed or accredited facility capable of handling therapeutic medical isotopes. This product is radioactive and should thus be handled in accordance with all applicable standards and regulations. **Consult the Instructions for Use (www.sirtex.com/sir-spheres/risks_adverse-events) for a complete listing of indications, contraindications, side effects, warnings, and precautions.**

SIR-Y001 3 DPC
SIR-Y001 2 DPC
SIR-Y001 1 DPC
SIR-Y001 Day of Calibration
SIR-Y001 Post-Calibration

Indication



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

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