

SIR-Spheres® Y-90
resin microspheres
Activity Chart
(SIR-Y001 5 mL vial)



SIR-Spheres Y-90 resin microspheres (SIR-Y001 5 mL vial)

DAY THREE PRE-CALIBRATION

	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^)
12:00 AM	-90.0	2.646	7.94	0.79	214.58	21.46	180.44	5.54
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)

DAY TWO PRE-CALIBRATION

	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^)
12:00 AM	-66.0	2.042	6.12	0.61	165.53	16.55	139.19	7.18
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
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
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
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
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
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

SIR-Y001
3 DPC

SIR-Y001
2 DPC

SIR-Y001
1 DPC

SIR-Y001
Day of Calibration

SIR-Y001
Post-Calibration

Indication

^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

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SIR-Y001
1 DPC

SIR-Y001
Day of Calibration

SIR-Y001
Post-Calibration

Indication

DAY ONE PRE-CALIBRATION

	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^)
12:00 AM	-42.0	1.575	4.72	0.47	127.69	12.77	107.38	9.31
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

^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)

DAY OF CALIBRATION

	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^)
12:00 AM	-18.0	1.215	3.64	0.36	98.50	9.85	82.83	12.07
1:00 AM	-17.0	1.202	3.61	0.36	97.44	9.74	81.94	12.20
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

SIR-Y001
3 DPC

SIR-Y001
2 DPC

SIR-Y001
1 DPC

SIR-Y001
Day of Calibration

SIR-Y001
Post-Calibration

Indication

^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)

POST-CALIBRATION

	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^)
12:00 AM	6.0	0.937	2.81	0.28	75.99	7.60	63.90	15.65
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
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

SIR-Y001
3 DPC

SIR-Y001
2 DPC

SIR-Y001
1 DPC

SIR-Y001
Day of Calibration

SIR-Y001
Post-Calibration

Indication

^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-Y001
3 DPC

SIR-Y001
2 DPC

SIR-Y001
1 DPC

SIR-Y001
Day of Calibration

SIR-Y001
Post-Calibration

Indication

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 treatment of unresectable metastatic liver tumors from primary colorectal cancer with adjuvant intrahepatic artery chemotherapy (IHAC) of FUDR (Floxuridine). **Warnings / Precautions:** Inadvertent delivery of the microspheres to locations other than the intended hepatic tumor may result in local radiation damage. Due to the radioactivity and the significant consequences of misplacing the microspheres in situ, this product must be implanted by physicians who have completed the Sirtex TEC training program. A SPECT scan of the upper abdomen immediately after implantation is recommended. Patients may experience abdominal pain immediately after administration and pain relief may be required. H-2 blocking agents may be administered the day before implantation and continued as needed to reduce gastric complications. **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, radiation hepatitis, and acute cholecystitis. **Contraindications:** SIR-Spheres Y-90 resin microspheres should not be implanted in patients who have either had previous external beam radiation therapy to the liver; ascites or are in clinical liver failure. This device is contraindicated in patients with markedly abnormal synthetic and excretory liver function tests; greater than 20% lung shunting of the hepatic artery blood flow, or >30 Gy radiation absorbed dose to the lungs, as determined by the ^{99m}Tc MAA scan; disseminated extra-hepatic malignant disease, and portal vein thrombosis. This device should not be implanted in patients determined via angiogram to have an abnormal vascular anatomy that would result in significant reflux of the hepatic arterial blood flow to the stomach, pancreas, or bowel. **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) for a complete listing of indications, contraindications, side effects, warnings, and precautions.**



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