

# NCCN GUIDELINES<sup>®</sup> UPDATE

## SIR-Spheres<sup>®</sup> Y-90 resin microspheres for the treatment of mCRC patients with inoperable liver tumors

*Expert panel reaches uniform consensus that yttrium-90 microspheres is an appropriate option for patients with colorectal liver metastases.*

SIR-Spheres<sup>®</sup> Y-90 resin microspheres has been included as a Category 2A recommended treatment in the latest National Comprehensive Cancer Network<sup>®</sup> (NCCN<sup>®</sup>) Clinical Practice Guidelines in Oncology for colon cancer and rectal cancer. This designation denotes that there is uniform consensus among the NCCN panel that Selective Internal Radiation Therapy (SIRT) with yttrium-90 microspheres is an appropriate option in patients with liver dominant, chemotherapy resistant colorectal disease (mCRC). This recommendation places SIR-Spheres Y-90 resin microspheres at the same designation as the recommended mCRC systemic chemotherapeutic regimens in the refractory setting.

NCCN mCRC Recommended Intra-arterial Therapies	
SIRT	Category 2A*
HAI	Category 2B <sup>†</sup>
Chemoembolization	Not Recommended
Drug Eluting Beads	Not Recommended

National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology. Colon Cancer. Version 1.2017  
 \*in patients refractory to chemotherapy. <sup>†</sup>When pump installed during surgical resection procedure.

### NCCN Categories of Evidence and Consensus

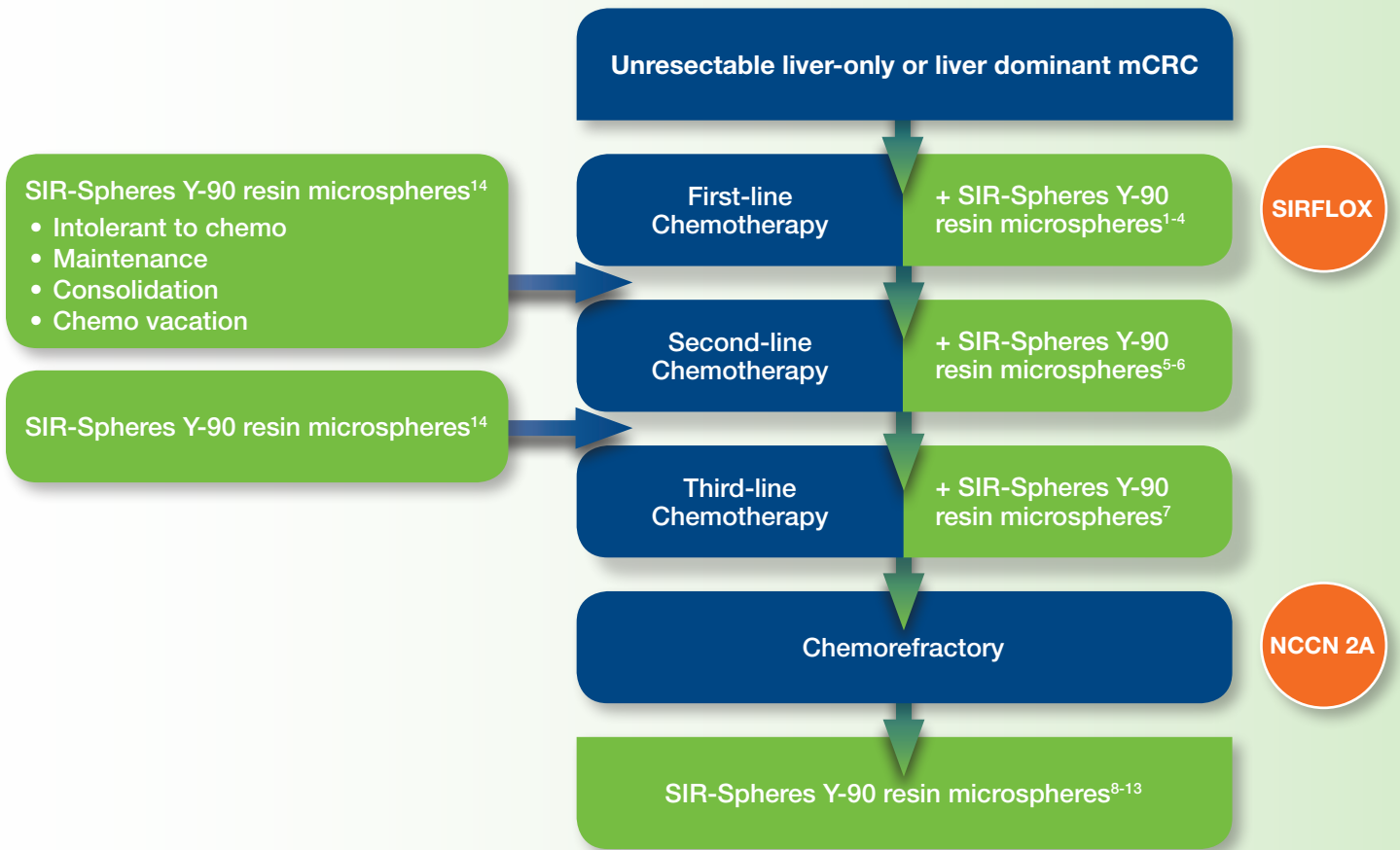
**Category 1:** Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

**Category 2A:** Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

**Category 2B:** Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.

**Category 3:** Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

# Integration of SIR-Spheres® Y-90 resin microspheres for mCRC



1. Gray et al. *Ann Oncol* 2001; 12: 1711–1720
2. van Hazel G et al. *J Surg Oncol* 2004; 88: 78–85
3. van Hazel G et al. *J Clin Oncol* 2016;34:1723–1731
4. Sharma R et al. *J Clin Oncol* 2007; 25: 1099–1106
5. van Hazel G et al. *J Clin Oncol* 2009; 27: 4089–4095
6. Lim et al. *BMC Cancer* 2005; 5: 132
7. Hendlisz A et al. *J Clin Oncol* 2010; 28: 3687–3694

8. Seidensticker R et al. *Cardiovasc Interv Radiol* 2012; 35: 1066–1073
9. Bester L et al. *J Vasc Interv Radiol* 2012; 23: 96–105
10. Cosimelli M et al. *Br J Cancer* 2010; 103: 324–331
11. Jakobs T et al. *J Vasc Interv Radiol* 2008; 19: 1187–1195
12. Kennedy A et al. *Int J Radiat Oncol Biol Phys* 2006; 65:412–425
13. Cianni R et al. *Cardiovasc Interv Radiol* 2009; 32:1179–1186
14. Fakh M et al. *Colorect Cancer* 2014; 3: 331–343

SIRTeX

SIR-Spheres®  
Y-90 resin microspheres

**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician. 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. **Intended Use / Indications For Use:** SIR-Spheres Y-90 resin microspheres are approved for use in Argentina, Australia, Brazil, Canada, the European Union (CE Mark), Switzerland, Turkey, and several countries in Asia for the treatment of unresectable liver tumors. In the US, SIR-Spheres Y-90 resin microspheres have a Pre-Market Approval (PMA) from the FDA and are indicated for the treatment of unresectable metastatic liver tumors from primary colorectal cancer with adjuvant intra-hepatic artery chemotherapy (IHAC) of FUDR (Floxxuridine). **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, 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. **Reference the Package Insert (www.sirtex.com) for a complete listing of indications, contraindications, side effects, warnings, and precautions.**