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Sirtex Receives Expanded CE Mark Approval for SIR-Spheres® Y-90 Resin Microspheres
Broadened indication increases access to liver cancer treatment across Europe and CE-marked territories.

WOBURN, Mass. (September 8, 2025) – [Sirtex Medical \(“Sirtex”\)](#), a leading manufacturer of minimally invasive interventional oncology solutions, today announced that it has received an expanded CE Mark approval for SIR-Spheres® Y-90 resin microspheres for the treatment of patients with liver cancer. With this expansion, eligibility now covers both primary and secondary liver metastases, increasing patient access to a well-established, targeted therapy.

“This milestone is about more than regulatory approval—it’s about giving hope and options back to patients facing some of the toughest cancer diagnoses,” said Matt Schmidt, CEO of Sirtex Medical. “By expanding access to SIR-Spheres®, we’re ensuring that more people can benefit from a well-tolerated therapy when they need it most.”

Radioembolization—also known as selective internal radiation therapy (SIRT)—delivers yttrium-90 directly to tumors via the hepatic artery, allowing for high-dose, targeted radiation aiming to minimize impact to surrounding healthy tissue.

“Y-90 radioembolization has long demonstrated clinical value in managing complex liver tumors,” said Prof. Dr. med. Jens Ricke, Director of the Clinic and Polyclinic of Radiology at the University Hospital Ludwig-Maximilians in Munich, Germany. “With this expanded CE Mark, more patients will have access to a therapy that can extend life, improve quality of life, and offer hope when other treatments may no longer be effective.”

The CE Mark expansion follows an extensive review of clinical data demonstrating the safety and effectiveness of SIR-Spheres® across diverse liver metastases. Together with the FDA’s recent approval of SIR-Spheres® Y-90 resin microspheres for the treatment of unresectable HCC in the United States, this milestone underscores the growing global recognition of SIR-Spheres® as a versatile, differentiated therapy and reinforces the Sirtex commitment to advancing liver-directed interventional oncology.

For more information and details on how to incorporate SIR-Spheres® into your practice, please contact Sirtex at info-use@sirtex.com.

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About SIR-Spheres® in Europe

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 (mCRC) in patients refractory to or intolerant of chemotherapy, or
- Unresectable intrahepatic cholangiocarcinoma (iCCA), or
- Hepatic metastases by neuroendocrine tumours (mNET), or
- Other liver metastases

Caution: Consult the Instructions for Use for a complete listing of indications, contraindications, side effects, warnings and precautions.

About Sirtex

Sirtex Medical is a global healthcare company focused on advancing minimally invasive, liver-directed cancer and embolization therapies. With offices in the U.S., Australia, Europe, and Asia, Sirtex delivers innovative minimally invasive interventional oncology and embolization solutions to physicians and patients worldwide. For more information, visit www.sirtex.com.

APM-EMEA-009-07-25

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