

TheraSphere

Minimally embolic, intra-arterial ⁹⁰Y radiotherapy for primary liver cancer

- **Low toxicity**
- **Successful reimbursement**
- **Outpatient treatment**
- **Potential for downstaging**
- **Treatment for partial or branch PVT patients**

Checklist to Setting Up Your Site

- Presentation and receipt of TheraSphere Reference Manual
- Forward copy of your IRB Approval Letter and Radioactive Materials License to MDS Nordion
- Complete the TheraSphere Customer Information Form and forward to MDS Nordion
- TheraSphere Delivery System received by your on-site contact person
- Nalgene waste jars and Merit syringes ordered for first treatments (required for each infusion)
- TheraSphere Training reservation made for team members
- Patient selection and preparation for first patient treatments
- MDS Nordion Product Specialist contacted to coordinate first patient treatment
- Complete TheraSphere dose order form and forward to MDS Nordion

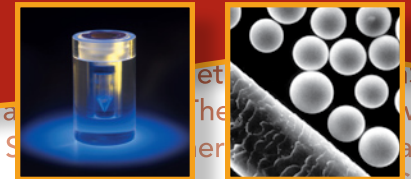
Contacts

Our team of clinical specialists is available to answer any questions and can show you how the TheraSphere Program can benefit your hospital and your patients. To learn more, please contact us at therasphereprogram@mdsinc.com and one of our local specialists will assist you.

TheraSphere[®]

An Innovative Treatment for Liver Cancer

Powerful • Targeted • Safe



Please visit our website www.therasphere.com

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Manufactured by



Physician Information Pamphlet

TheraSphere is a **powerful** Yttrium-90 microsphere therapy that delivers uniform, **targeted** internal radiation therapy and a **safe** treatment option for primary liver cancer.

www.therasphere.com

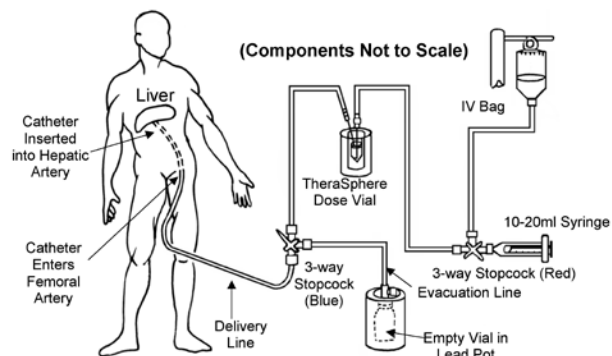
U.S. Market

MDS Nordion's TheraSphere[®], Yttrium-90 (⁹⁰Y) glass microspheres, is a technologically advanced form of brachytherapy. It has been approved as a Humanitarian Use Device authorized by federal (USA) law for use in radiation treatment or as a neoadjuvant to surgery or transplantation in patients with unresectable hepatocellular carcinoma (HCC) who can have placement of appropriately positioned hepatic arterial catheters.

The device is also indicated for HCC patients with partial or branch portal vein thrombosis/occlusion, when clinical evaluation warrants the treatment. TheraSphere is the only medical device approved in the U.S. to treat primary liver cancer patients with portal vein thrombosis (PVT).

TheraSphere represents the next generation of radioactive microspheres. ⁹⁰Y is an integral constituent of the glass matrix, and is not bound to the microsphere surface.

TheraSphere is delivered to the liver via a catheter placed into the femoral artery and guided by fluoroscopy to the hepatic artery. Once the catheter is properly positioned, the physician infuses TheraSphere, which localizes preferentially in the tumor. Precise lobar administration, identifying and mitigating vascular abnormalities minimizes the potential for inadvertent flow of TheraSphere into non target tissue, including the gastrointestinal tract.

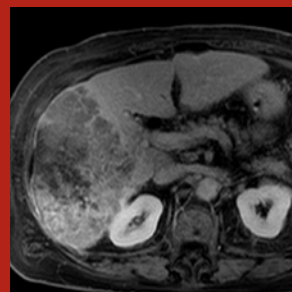


TheraSphere is administered under the supervision of a US NRC authorized user, who is part of a team that may include a medical oncologist, radiation oncologist, nuclear medicine specialist and interventional radiologist.

Product Facts	
Glass microsphere size	20 – 30 micron diameter
⁹⁰ Y radioactive emissions	pure beta emitter (avg. energy 0.9367 MeV)
⁹⁰ Y Half-life	64.1 hours
Average penetration range in tissue	2.5 mm
Dose sizes	3, 5, 7, 10, 15, 20 GBq (at calibration)

Successful Outcomes Using TheraSphere

Patient MRI/CT Scan



HCC tumor



8 months post-TheraSphere*



HCC tumor in PVT patient



1 year post-TheraSphere*

*Single dose treatment

TheraSphere Coverage and Payment

TheraSphere has a history of favorable coverage and reimbursement by Medicare and commercial health insurers. The following questions are most frequently asked by hospitals that are considering developing a TheraSphere program.

Q) Will my hospital be reimbursed for the use of TheraSphere?

A) TheraSphere is covered and reimbursed by Medicare, and a large number of national and regional commercial or private health plans. For Medicare patients, TheraSphere has been assigned a separate HCPCS code, C 2616 "Brachytherapy Seed, Yttrium-90," for billing purposes, and has a separate Ambulatory Payment Classification, APC 2616 for payment. Currently, TheraSphere is being reimbursed on the basis of "charges reduced to cost" which should enable the hospital to be reimbursed for their acquisition cost.

Commercial health plans that cover TheraSphere frequently require pre-certification or prior authorization. For plans that do not have coverage policies for TheraSphere, appeals based upon medical necessity may be important for securing coverage. Hospitals that are successful in being reimbursed for TheraSphere tend to implement best practices such as:

- Coordinate physician and hospital pre-certification processes.
- Initiate pre-certification or prior authorization early in the patient evaluation, prior to determining patient eligibility for TheraSphere treatment.
- Involve the patient, should an appeal of coverage denial be necessary.
- Recognize that "Doctor to Doctor" contact with the health plan's Medical Director is the most effective way to communicate the medical necessity of TheraSphere treatment.
- Involve and partner with the TheraSphere Reimbursement Services team.

Q) How do I code and bill for the administration of the product?

A) Coding for the actual administration of TheraSphere is typically based upon hospital policy and the medical specialty that is designated as the "authorized user". Hospitals typically use either CPT 77778 (complex interstitial radiation source application) or CPT 79445 (radiopharmaceutical therapy by interarterial particulate administration). Hospitals also have used CPT 37204 (Transcatheter occlusion or embolization) in conjunction with one of the administration codes. Coding guidance for all stages of TheraSphere treatment including patient evaluation, diagnostic work-up, product administration and treatment follow-up is available from MDS Nordion.

For more information, or if you require assistance with any reimbursement issues, please contact us at theraspherereimbursement@mdsinc.com and one of our reimbursement specialists will assist you.