

Seeds embedded in bio-absorbable braided suture strands & secured onto mesh

TheraMesh is a prefabricated, bio-absorbable implantable mesh embedded with TheraSeed® or AgX100® for permanent implantation.

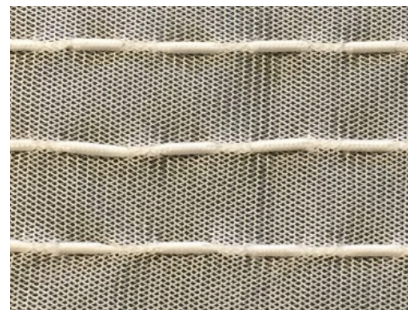
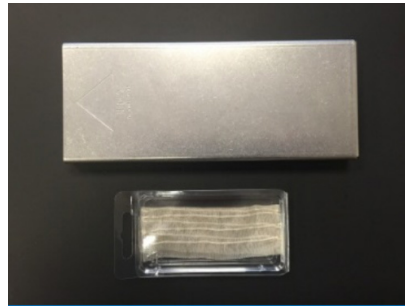
Selected Tumor Characteristics and types^{1,2}

- Localized or unresectable with low to moderate radiosensitivity
- Recurrent
- Residual following external beam radiation or excision of primary tumor
- Superficial, intrathoracic, intra-abdominal
- Lung, Pancreas, and Head & Neck
- Deep Cavity Soft Tissue Sarcoma³
 - Chest
 - Abdomen
 - Pelvis
 - Retroperitoneum
 - Deep truncal locations

Provides a flexible brachytherapy platform that may be contoured to implant surfaces

- Low energy brachytherapy seeds with rapid dose fall off to minimize dose to normal structures
 - **TheraSeed** – Pd 103:
16.9 day half life; 20-23 keV principle energy
 - **AgX100** – I 125:
59.4 day half life; 27-35 keV principle energy
- An alternative delivery system for radiotherapy to tumor beds³
 - May be suitable for anticipated close surgical margins and where other treatment options are limited³
 - May be advantageous when the target volume is irregular and complex and critical normal structures are adjacent to the tumor implant⁴
- Permanent implant allows for a higher total radiation dose to be delivered to the target volume⁴

TheraMesh is only approved for use in the U.S.A.



- Prefabricated per a physician's specification
- Bio-absorbable 90/10 (glycolide/L-lactide) mesh consists of:
 - 1 to 6 rows of flexible bio-absorbable 90/10 (glycolide/L-lactide) braided suture strands
 - Each strand row embedded with (10) TheraSeed or (10) AgX100 seeds
 - Seeds are spaced at a fixed distance of 1 cm center to center of seed
 - Strand rows are spaced at 1 cm distance
 - Bio-absorption occurs in 56-70 days
- Packaging
 - Sterile
 - Single mesh per sterile, shielded container
 - Shielded tray suitable for sterile field

TheraSeed and AgX100 are the foundation for all LDR brachytherapy product presentations. A manufacturer's Certificate of Calibration accompanies each order; an additional independent seed assay is available upon request.

References

1. Theragenics, TheraSeed Instructions for Use, Buford, GA, 2016
2. Theragenics, AgX100 Instructions for Use, Buford, GA, 2016
3. Fairweather M, Wang, J, Devlin P, et al. Safety and efficacy of radiation dose delivered via Iodine-125 brachytherapy mesh implantation for deep cavity sarcomas. *Ann Surg Oncol* (2015) 22:1455-1463
4. Devlin P, (ed), *Brachytherapy Applications and Techniques, Second Edition*, Demos Medical Publishing, LLC, New York, NY (2016)

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For specific product information, please consult your Theragenics Brachytherapy Specialist, Customer Service, or our website for the eIFU.