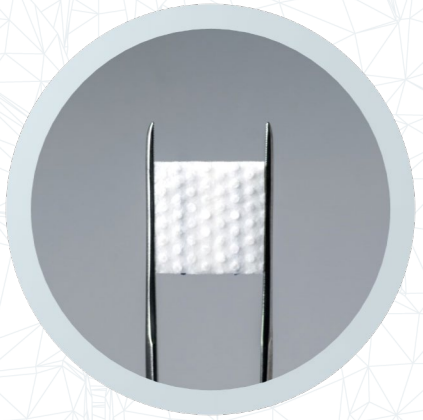
Insertion of Palladium-103 Radioactive Collagen Tile Implant

ICD-10 Coordination and Maintenance Committee Meeting
September 12, 2023

GammaTile®

GammaTile® Overview

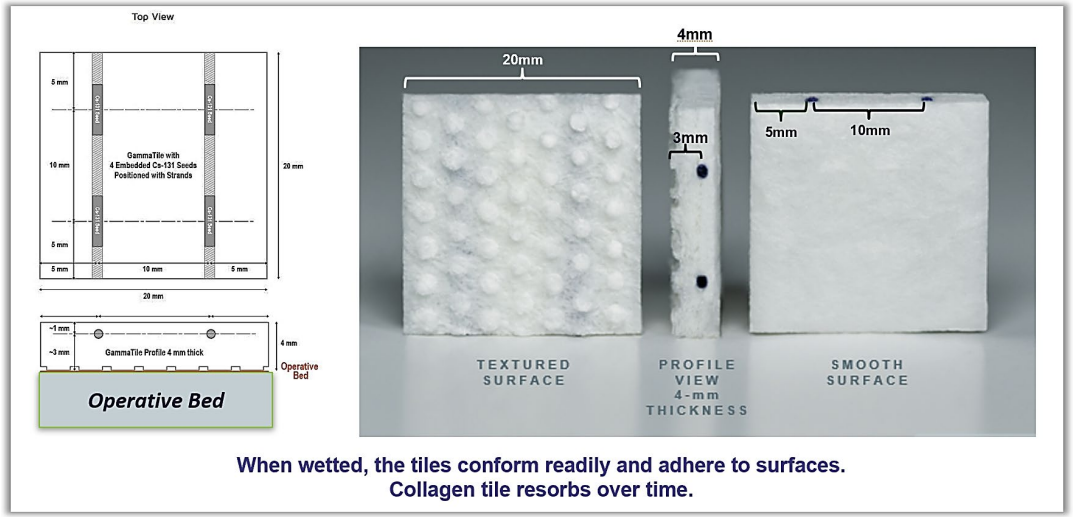
- GammaTile® is an FDA-cleared radiation option for patients with newly diagnosed malignant and recurrent brain tumor histologies, including gliomas, brain metastases, and meningiomas
- GammaTile® gives patients:
  - A “one and done” radiation treatment
  - Improved access to care and reduced treatment burden (time, travel, and cost)



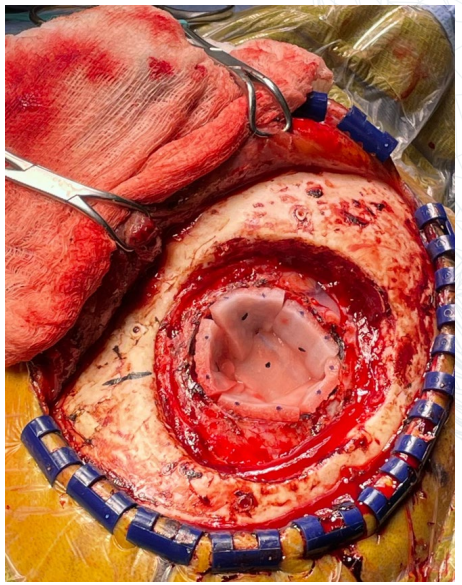
GammaTile® Therapy Overview

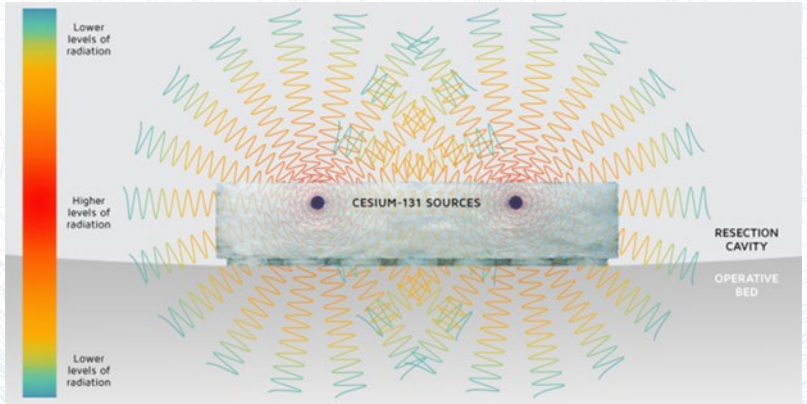
- The current FDA cleared GammaTile® is a permanently implanted, bioresorbable, flexible collagen tile embedded with radioactive Cesium-131 (Cs-131) radiation sources

- The tiles are placed within the resection cavity immediately after the tumor is removed to deliver radiation to any remnant tumor cells



When wetted, the tiles conform readily and adhere to surfaces.
Collagen tile resorbs over time.





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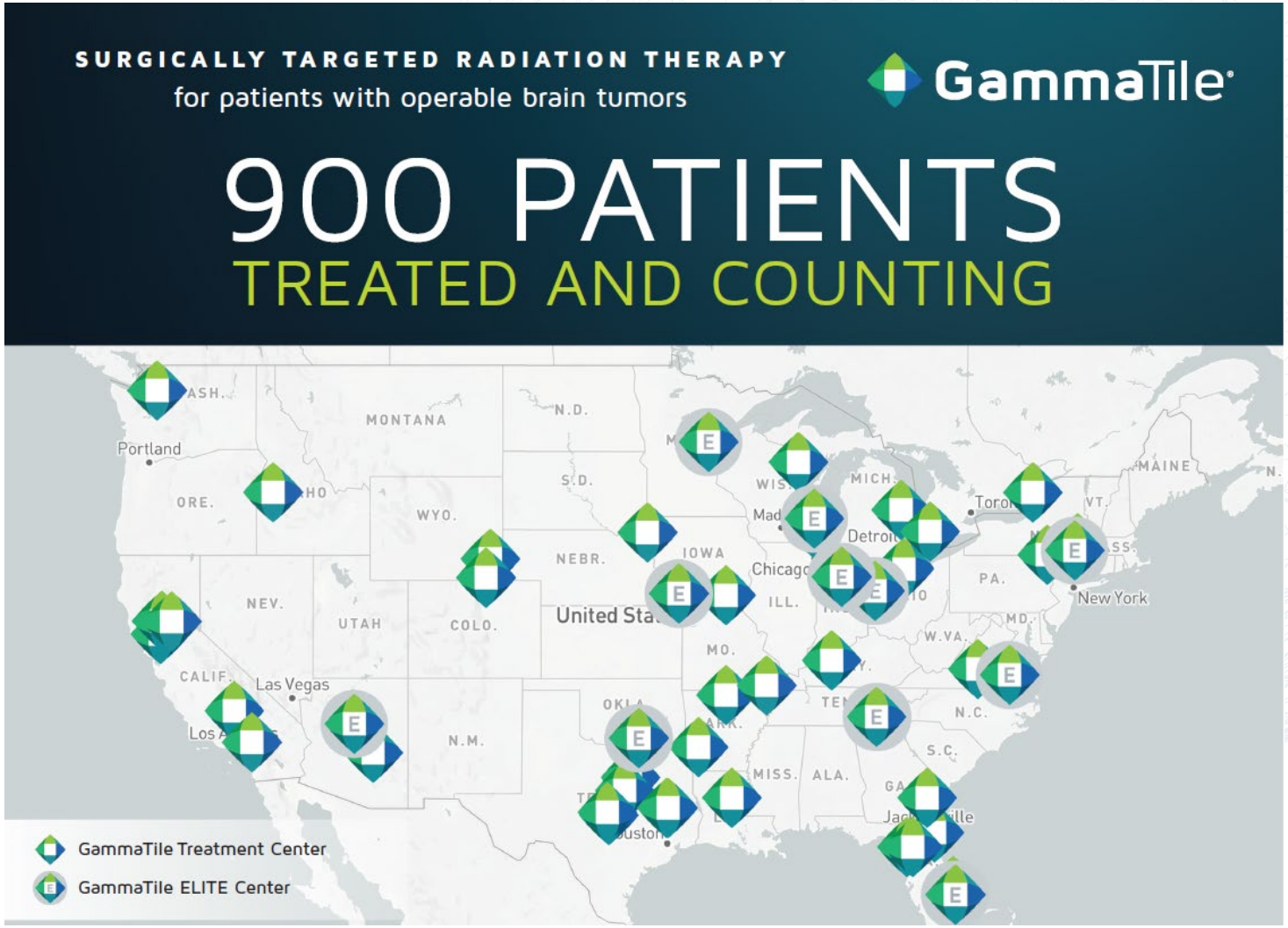
GammaTile® Expands Access to Care & Improves Quality of Life

- GammaTile® is currently available at 95 acute care hospitals throughout the United States.
- More than 900 patients with brain tumors have benefitted from the “one and done” radiation treatment since 2019 launch
- Patients do not have to return to a care facility for follow up radiation treatments
  - Expands access to care by eliminating follow up visits
  - Improves quality of life for patient and care givers by reducing travel burden



The Need for a New Configuration of GammaTile®

- Supply Constraint: Only current supply of medical grade Cesium-131 is located outside of U.S.
- A supply chain disruption occurred in 8/2022, stopping patient treatments for ~4 weeks
- Supply Constraint Solution: A new configuration of GammaTile® using Palladium-103
  - Palladium-103 has several domestic sources and a similar dose profile
- This new configuration will not replace the existing device but will be offered alongside the current Cs-131 GammaTile® configuration
- A Pd-103 GammaTile® will give clinicians more flexibility to modulate the radiation, due to the reduced depth of radiation penetration
- Palladium-103 sources of the type planned for GammaTile® are FDA-cleared to treat a variety of tumors (free seeds and seeds on a string (510(k) K993552 and K082159, respectively)(next slide)

FDA clearance language for the Pd-103 seed formulation is as follows:

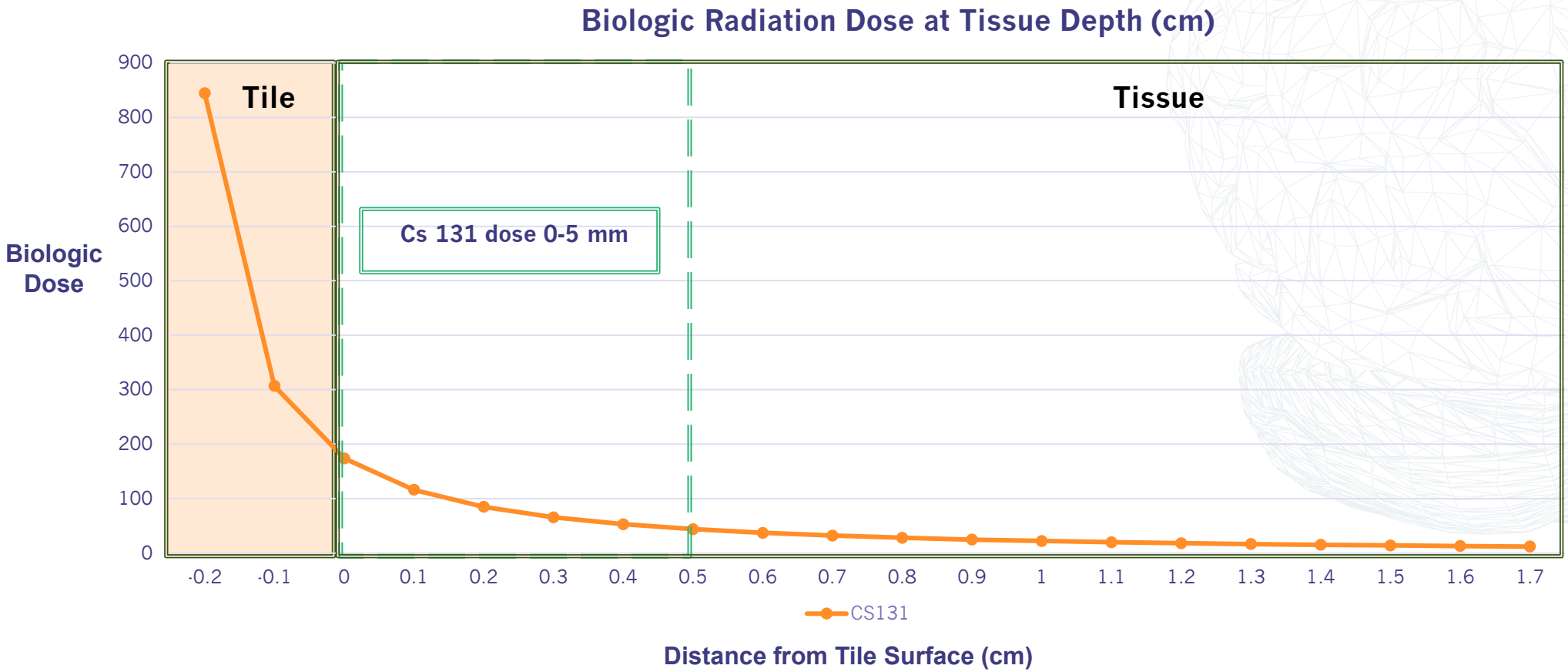
"The TheraSeed® Pd-103 device is indicated for tumors with any of the following characteristics:

- Localized
- Unresectable
- Low to Moderate Radiosensitivity

The tumors may be of the following type:

- Superficial
- Intrathoracic
- Intra-abdominal
- Lung, Pancreas, Prostate, Head and Neck
- Residual Following External Beam Radiation or Excision of Primary Tumor
- Recurrent"

Graph of Biologic Radiation Doses with current Cs-131 GammaTile®



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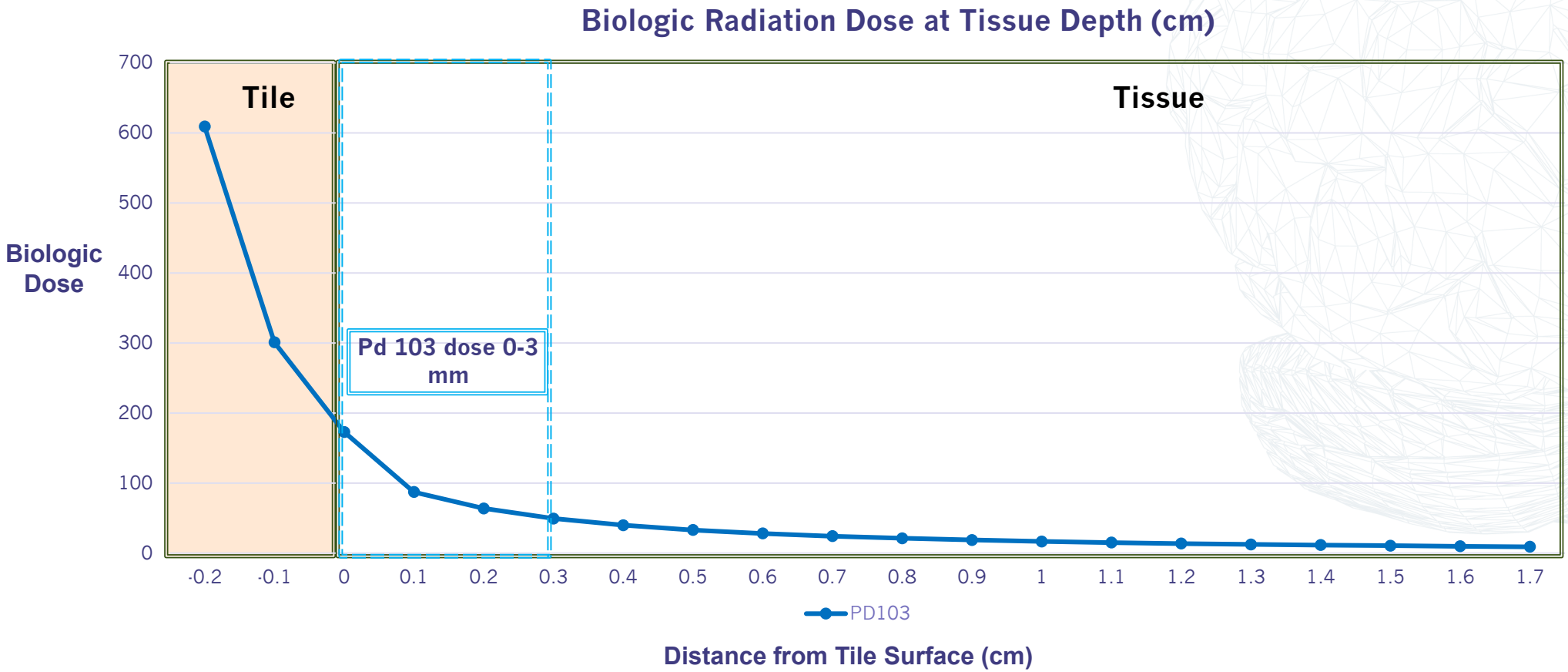
Graph of Biologic Radiation Doses with Pd-103 GammaTile®



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Graph of Biologic Radiation Doses with Cs-131 vs Pd-103 GammaTile®

A Pd-103 GammaTile® will give clinicians more flexibility to modulate the radiation, due to the reduced depth of radiation penetration

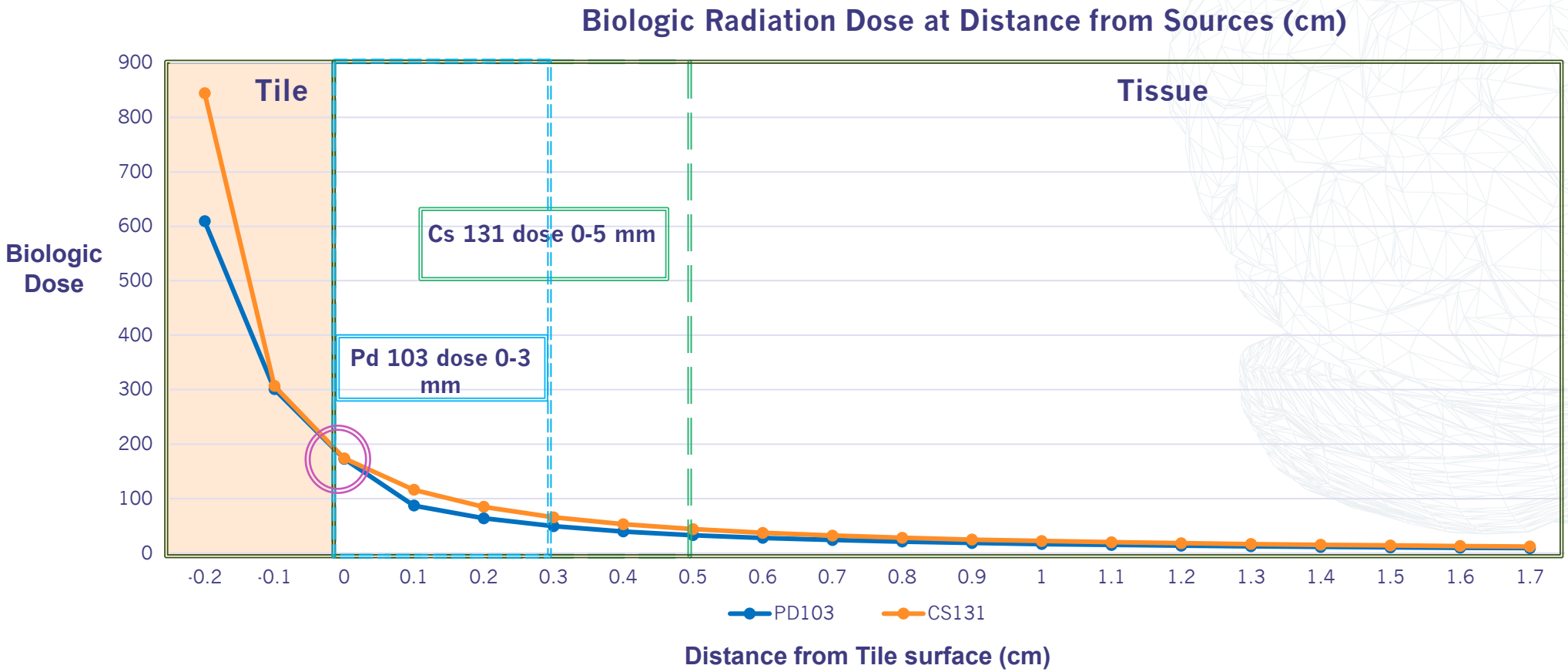

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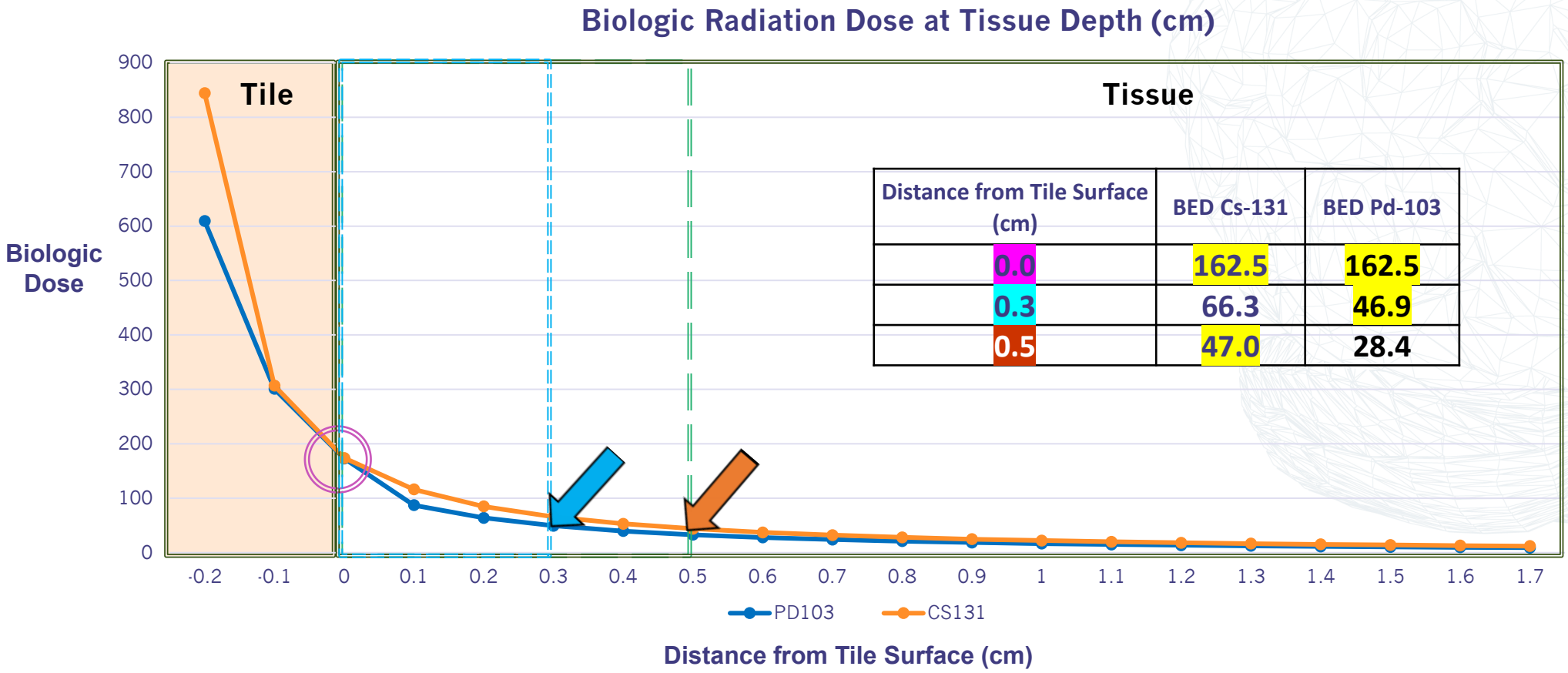
Table of Biologic Radiation Doses with Cs-131 vs Pd-103 GammaTile®

A Pd-103 GammaTile will give clinicians more flexibility to modulate the radiation, due to the reduced depth of radiation penetration



Distance from Tile Surface (cm)	BED Cs-131	BED Pd-103
0.0	162.5	162.5
0.3	66.3	46.9
0.5	47.0	28.4

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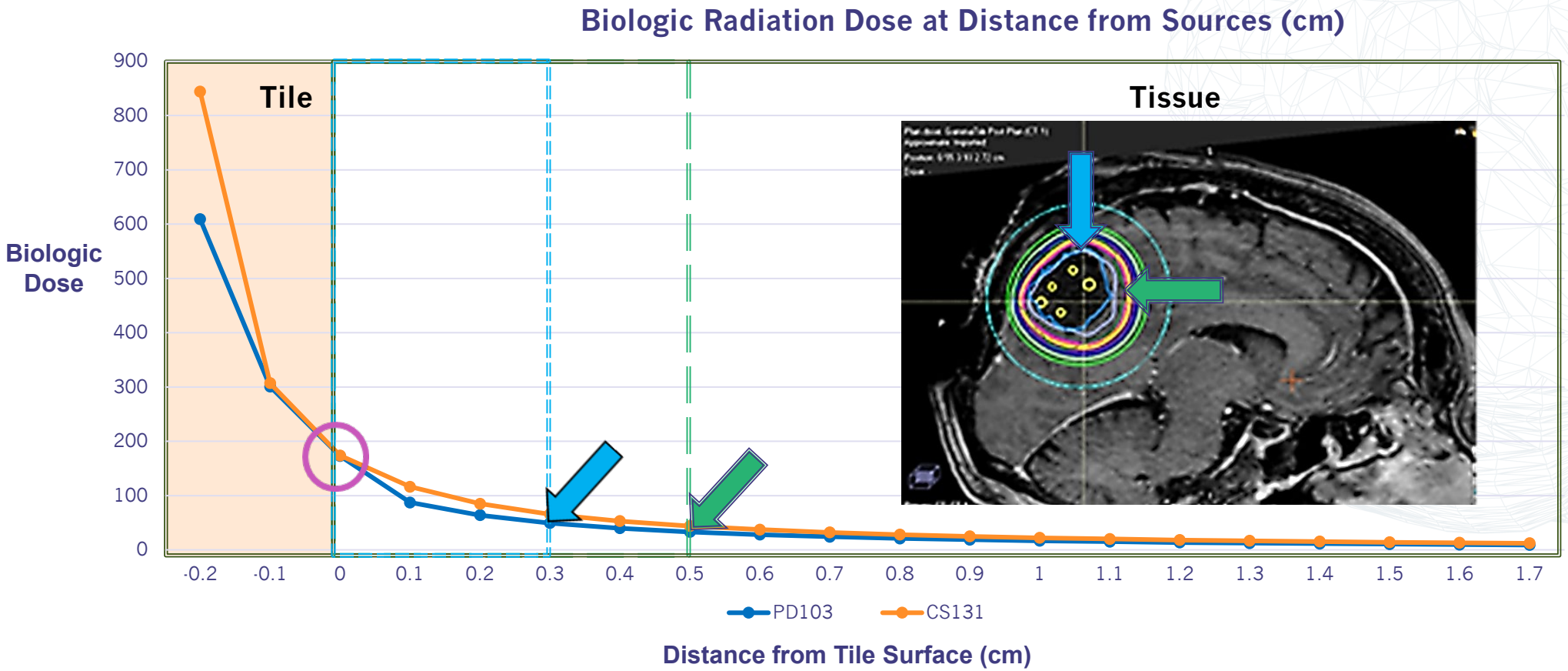
Clinical Example of Biologic Radiation Doses with Cs-131 vs Pd-103 GammaTile®

A Pd-103 GammaTile will give clinicians more flexibility to modulate the radiation, due to the reduced depth of radiation penetration



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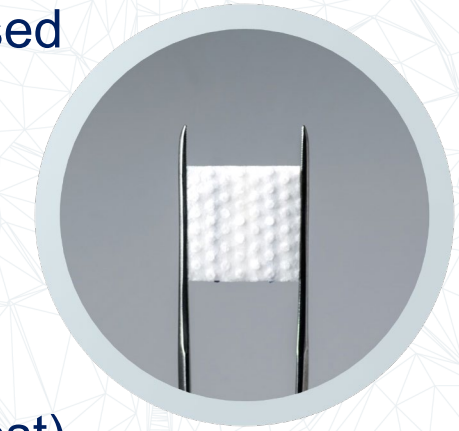
Documentation

- Documentation of the number of tiles implanted is included in the operative record, typically in surgeon's procedure note, the radiation oncology procedure note, or both. Stating the brain location and number of tiles utilized is typical.

- Operative dictation language to refer to the device could be Palladium-103 GammaTile® (or Pd-103 GammaTile®), Palladium-103 Collagen Tile Brachytherapy (or Pd-103 Collagen Tile Brachytherapy), or Palladium-103 Tile Brachytherapy (or Pd-103 Tile Brachytherapy).

Summary

- GammaTile® is an FDA-cleared radiation option for patients with newly diagnosed malignant and recurrent brain tumor histologies, including gliomas, brain metastases, and meningiomas
- GammaTile® in either isotope configuration gives patients:
  - A “one and done” radiation treatment
  - Improved access to care and reduced treatment burden (time, travel, and cost)
- GT Medical Technologies is creating a new GammaTile® configuration with Palladium-103 to resolve supply constraints and better serve patients



Thank you

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