# ICD-10-PCS Coding Change Request for Intra-Operative Application of Brachytherapy

Submitted by CivaTech Oncology

*ICD-10 Coordination and Maintenance Committee*
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# Presenter

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# Additional codes needed for intraoperative application of brachytherapy

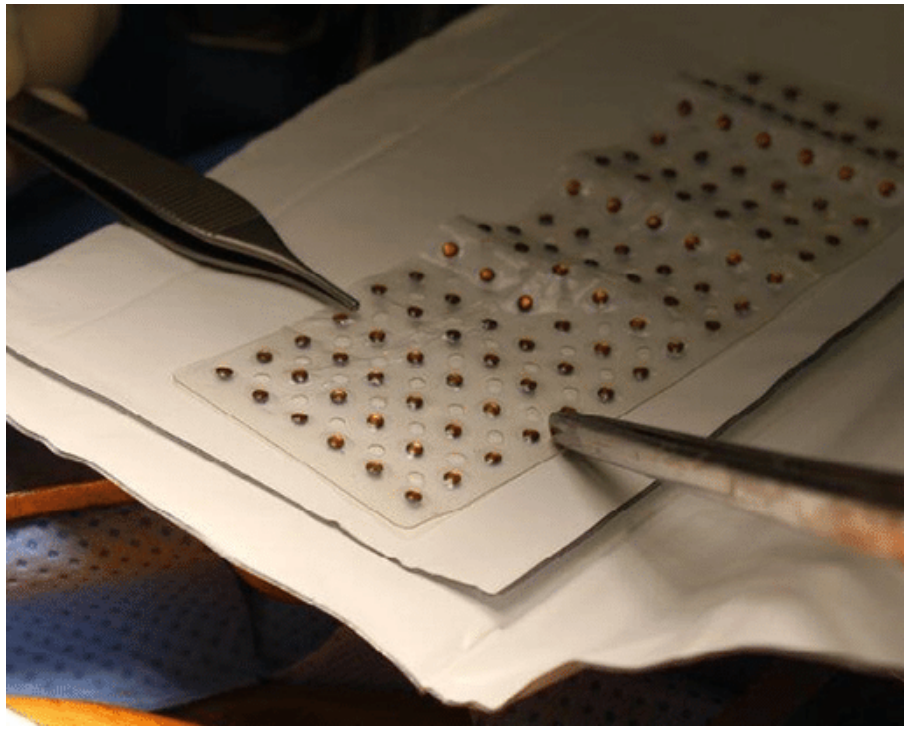
- New treatment sites
  - To code for brachytherapy in new treatment sites where brachytherapy has not been applicable
- New technology
  - To ensure unique identification of intraoperative application of brachytherapy using the CivaSheet device during cancer surgeries

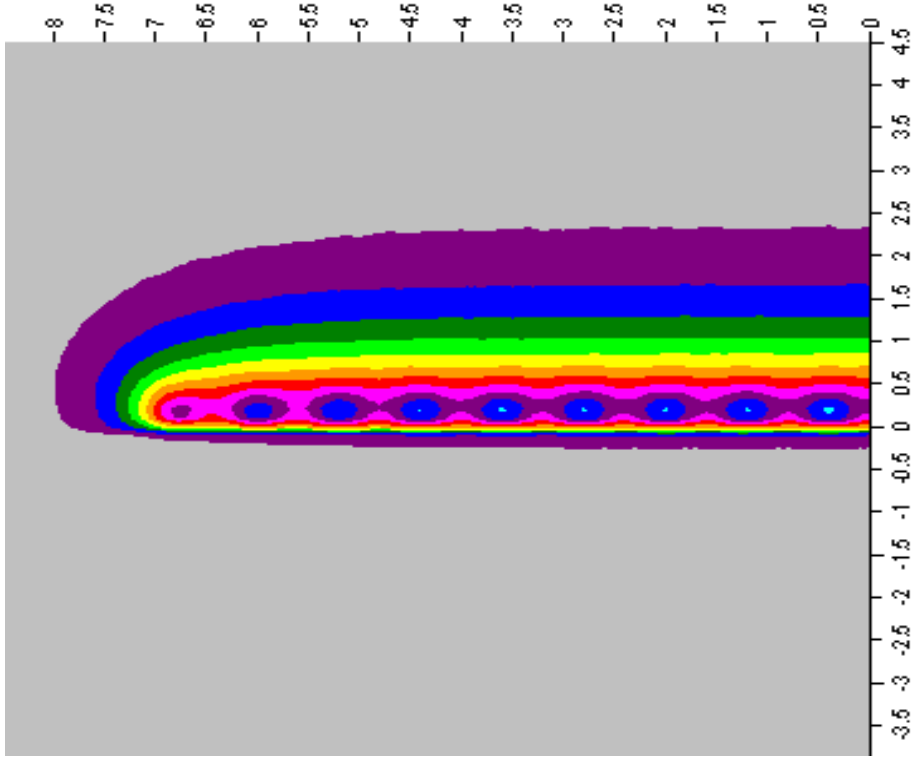
# What is the CivaSheet®?

- **CivaSheet** is an implantable, low-dose rate (LDR) brachytherapy device, containing an array of radioactive palladium-103 sources.
- **Configuration** -- Sources are encapsulated in an organic polymer and embedded in a flexible, membrane-like bioabsorbable substrate. Two sizes are now available.
- **Unidirectional** -- Each source is gold shielded on one side, so the therapeutic dose is delivered only on one side.

# The CivaSheet

- Sources with integrated gold shielding are embedded in a thin, bioabsorbable sheet designed for intra-operative application.
- The first unidirectional brachytherapy source available – with over 90% reduction of radiation dose on back side due to shielding.





# CivaSheet design enables intraoperative radiation

- **Ordinary brachytherapy seeds**:
  - Radiate in all directions and expose neighboring tissues to radiation
  - Tend to move around after placement, when the surgical site is closed and healing
- **CivaSheet, in contrast**:
  - Unidirectional configuration and shielding enables administration of aggressive radiation dose to surgical margins in close proximity to radio-sensitive tissues, which may have already received substantial doses of radiation
  - Sources are embedded in a new, bio-absorbable membrane that prevents source movement and is designed specifically for intraoperative application of radiation (therapy continues after surgery)

# Advantages seen by clinicians

- **One-Way Delivery of Radiation** -- Prevents damage to adjacent, healthy tissues.
- **Customizable** -- The sheet can be cut to size in the OR and is conformable to the patient's tumor cavity. Radiation dose can be specified as appropriate for the patient.
- **Keeps Sources In Place** – The sheet holds the sources in position following surgery. (Individual seeds not in a matrix are in danger of moving as the surgical site is closed and heals.)
- **FDA Cleared** -- “For use as a permanent interstitial brachytherapy source for treatment of selected localized tumors.” (The particular types of tumors that might be treated is not specified.)
- **Dosimetric Studies Completed and Reviewed** -- Listed on the American Association of Physicists in Medicine registry.
- **Can Avoid Additional Procedures** -- Can eliminate need for post-surgery external beam radiation.
- **No removal needed**

# Clinicians moving toward **new** applications

- Advantages of CivaSheet open up new clinical applications for intraoperative brachytherapy incident to cancer surgery.
- New body systems requested to be added for brachytherapy are:
  - Upper and Lower Arteries and Veins (any vessels, specifically including hepatic and femoral arteries)
  - Musculoskeletal System (including sites: Skull, maxilla, mandible, sternum, rib(s), humerus, radius/ulna, pelvic bones, femur, tibia/fibula, other bone)
- New treatment sites requested within coded body systems are:
  - Central/cranial nerve (In Central and Peripheral Nervous System)
  - Vagina, vulva (In Female Reproductive System)
  - Upper extremities and lower extremities (In Anatomical Regions)

# Current status of CivaSheet

- Cleared by FDA and Nuclear Regulatory Commission in 2014.
- Dosimetric studies needed to support clinical use have been completed.
  - The American Association of Physicists in Medicine (AAPM) added CivaSheet to the “Joint AAPM/IROC Houston Registry of Brachytherapy Sources Complying with AAPM Dosimetry Prerequisites” in May 2018.
  - Registry placement should facilitate use by broader range of clinicians.
- The CivaSheet is in limited use. 71 cases have been treated to date, mostly in investigational contexts.
  - Clinical trials for treatment of pancreatic cancer are ongoing at 6 leading centers with NIH/NCI funding. Expected enrollment is 92 participants. Additional ongoing trials, still recruiting, will address lung cancer, prostate cancer, and abdomino-pelvic solid tumors.

# Use of CivaSheet to date

- Administered during surgery for cancers: bladder, colorectal, gynecological, head and neck, sarcoma, pancreas, lung, breast, and prostate.
- Results show no adverse events, radiation injuries or local recurrences within the field of CivaSheet radiation. (Seven patients omitted from table because of limited follow-up.)

| Indication | Number of Patients | Radiation Injury | Adverse Events | Local Recurrence in Field |
|---|---|---|---|---|
| Bladder | 2 | 0 | 0 | 0 |
| Colorectal | 18 | 0 | 0 | 0 |
| Gynecological | 6 | 0 | 0 | 0 |
| Sarcoma | 20 | 0 | 0 | 0 |
| Pancreas | 17 | 0 | 0 | 0 |
| Lung | 5 | 0 | 0 | 0 |
| Breast | 1 | 0 | 0 | 0 |
| Prostate | 2 | 0 | 0 | 0 |
| Total | 71 | 0 | 0 | 0 |

# Descriptor of technology

- Existing coding specifically identifies Pd-103 (Isotope, Character 6)
- A modality qualifier is available for a LDR source.
- The ability to deliver radiation in one direction, sparing neighboring, healthy tissue from radiation toxicity is key to the effective clinical use of this technology.

# Summary

- CivaTech Oncology recommends creation of new codes to accommodate intraoperative application of brachytherapy,
- Note that addition of coding for novel body systems and treatment sites will be needed regardless of outcome of CivaSheet's NTAP application.


Application submitted by CivaTech Oncology, Inc.

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