

**Transradial PCI, Anti-thrombotic
Safety & Potency**

**What do we know and what do we
need to know?**

CDRH View

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Transradial Approach to PCI

- Devices (needles, guidewires, sheaths, guide catheters, etc.) used during a transradial access procedure reach market through the 510(k) clearance process.
- Devices used during a transradial procedure have a general vascular access indication in the Instructions for Use (IFU).



Transradial Approach to PCI

- In most cases, the collection of clinical data is not a requirement for 510(k) clearance of general vascular access devices.
- The additions to device labeling and/or specific claims regarding the use of devices for transradial procedures would need to be supported by clinical data.

TREAT REGISTRY

- CDRH welcomes the initiation of well-designed clinical trials that will allow for the evaluation of device safety and effectiveness of transradial PCI as well as the potential application of higher doses of antithrombotics during a PCI which could impact drug labeling.

Unresolved Issues with Transradial PCI

- The true incidence of radial artery occlusion and its clinical sequelae.
- The durability of previously accessed radial arteries as CABG conduits.
- The true learning curve for transradial PCI (including the crossover rate to transfemoral)

Unresolved Issues with Transradial PCI (cont.)

- The safety of same-day discharge after transradial PCI.
- The safety and effectiveness of higher doses of antithrombotics during the PCI procedure.

Use of TREAT data

- Imbedded studies within the TREAT Registry could be used to inform device labeling.
- Subset data gathered on a particular device under a prospectively defined protocol could support an indication and/or labeling claims specific to radial access.



Device Manufacturers

For questions about a specific device and/or proposed changes to device labeling:

- We can provide input regarding the plan for collecting and evaluating study data.
- For specific questions, a “preIDE” submission with a subsequent meeting or teleconference may be appropriate.



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