

STRUCTURAL HEART PROCEDURAL SR TEMPLATE

WG-01/12

Public Comment

11 March 2024



CHANGES SINCE LAST REVIEW (THIS PAGE TO BE DELETED PRIOR TO PC)

- Update names of TID 5301 Pre-coordinated Echo Measurement and TID 5302 Post-coordinated Echo Measurement so they can be incorporated in structural heart root template.
- Parameterize AnatomicSite in TID 5302 to accommodate different anatomic sites for Simplified Echo and Structural Heart.
- Review / rework terminology:
 - Added definitions for all new terms
- Updated pen/Closed items

CHECKLIST (THIS PAGE TO BE DELETED PRIOR TO PC)

- 1.) PowerPoint overview - clear/complete for all stages ([this](#))
- 2.) Open/closed issues - Clear/complete for PC, All closed for LB, All gone for FT ([reviewed in January, updated in March](#))
- 3.) Add new attributes to Part 15 Annex E (de-identification) as appropriate ([N/A](#))
- 4.) Add attributes for Creator RSA Digital Signature Profile (Part 15) ([complete](#))
- 5.) Verify content item constraints (Part 16) ([reviewed in January](#))
- 6.) Confirm PS3.2 has obvious place to record any “shall describe in Conformance Statement” ([N/A](#))
- 7.) Part 18 Annex H ([N/A](#))
- 8.) Update Part 3 Annex F with directory record entries for new IODs ([N/A](#))

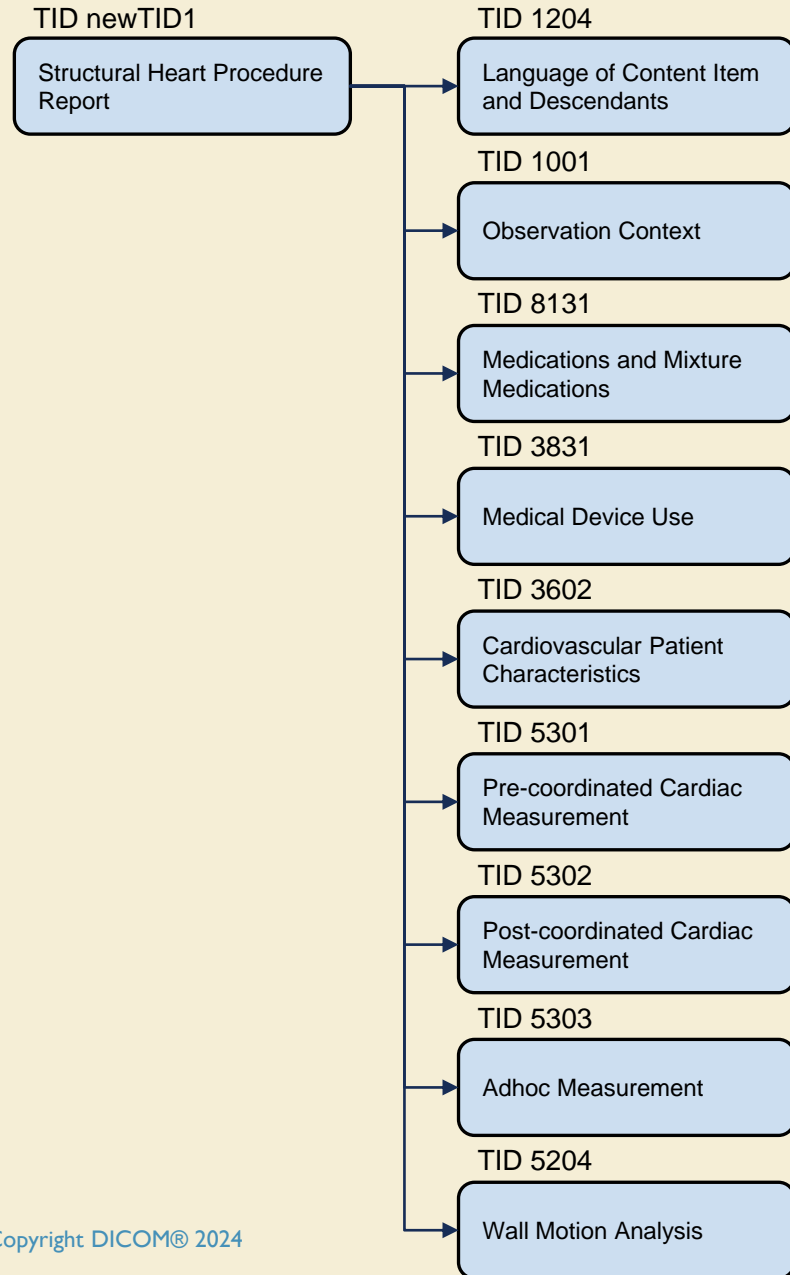
OVERVIEW

Scope:

- Periprocedural imaging for Structural Heart procedures.
 - Structural Heart procedures are trans-catheter techniques to repair or replace a valve and treat structural abnormalities of the heart.
 - Periprocedural imaging includes pre-operative assessment, intraprocedural assessment, and follow-up for Structural Heart Procedures.
- Multimodality CT (or MRI), and echocardiogram.
- Procedures:
 - TAVI: Transcatheter Aortic Valve implantation
 - TAVR: Transcatheter Aortic Valve Replacement
 - TTVP: Transcatheter Tricuspid Valve Procedure
 - TTVR: Transcatheter Tricuspid Valve Repair
 - TEER: Transcatheter Edge-to-Edge Repair
 - TMVr: Transcatheter Mitral Leaflet Clip Procedure
 - TMVR: Transcatheter Mitral Valve Replacement
 - LAAC: Left Atrial Appendage Closure

BACKGROUND

- Pre-operative assessment: CT and/or echocardiography are commonly used for detailed anatomical assessment of the heart, aiding in the planning of transcatheter approaches and proper sizing of implants.
- Intraprocedural assessment: Echocardiography and fluoroscopy are utilized for continuous monitoring during the procedure, ensuring accurate device deployment, positioning, and function.
- Follow-up evaluation: CT and/or echocardiography are commonly employed for assessing device placement, function, and identifying potential complications such as perivalvular leaks or device migration during post-procedural follow-up.
- Standardized measurements have been established by implant manufacturers, the Society of Thoracic Surgeons (STS) and the American College of Cardiology (ACC) for all three periprocedural phases.



Design Choices

- Use Existing SR SOP classes
- Use Simplified Echo Procedure sub templates, TUDs 5301, 5302 and 5303 (modified to support multimodality image acquisition).
- Pre-coordinated terms

TERMINOLOGY

Context Identifier	Context Group Name
newCID1	Structural Heart Procedures
newCID2	Structural Heart Devices
newCID3	Structural Heart Measurement
newCID4	Structural Heart Aortic Valve Measurement
newCID5	Structural Heart Mitral Valve Measurement
newCID6	Structural Heart Tricuspid Valve Measurement
newCID7	Structural Heart Echo Measurements
newCID8	Left Atrial Appendage Closure Measurement
newCID9	Structural Heart Procedure Anatomic Site
newCID10	Peripheral Access Anatomic Site
newCID11	Indication for Structural Heart Procedure
newCID12	Bradycardiac Agents
newCID12	Transesophageal Echocardiography Scan Planes

Sources:

- Peer review publications
- STS/ACC registry data elements
- ASE guidelines
- Device Inserts (Watchman, Amulet, MitraClip)
- IHE CPN (Cardiac Procedure Note)
- Clinical Applications