

Edwards SAPIEN 3 Transcatheter Pulmonary valve system with the ALTEIRA ADAPTIVE PRESTENT device preparation

NOTE: Only certain steps shown. Refer to DOC-0168306 for full instructions, prescribing information, including indications, contraindications, warnings, precautions and potential adverse events.

Alterra delivery system preparation

- 1 Remove lid**
- 2 Ensure gap between outer shaft and tip**
- 3 Flush inner lumen with heparinized saline**
- 4 Re-advance outer shaft**
- 5 Remove stylet**
- 6 Flush wire lumen with heparinized saline**

Pulmonic delivery system preparation

De-air the delivery system

- 1 Remove lid**
- 2 Attach inflation device and de-airing syringe**
- 3 Pull negative 3-5 times until delivery system is de-aired**
- 4 Push for positive prep**
- 5 Return to neutral**
Note: Do not remove the balloon cover during de-airing.
- 6 Ensure the inflation device volume is set to 33 mL**

Nominal inflation volume	33 mL
Rated burst pressure	7 atm

Crimp the THV delivery system

- 1 Remove balloon cover**
- 2 Center THV in open crimper aperture and partially crimp until valve fits securely into Qualcrimp accessory**
Cut suture directly across from knot and pull at knot to remove
- 3 Insert THV into crimping accessory and place in crimper, ensuring THV is centered within aperture**
- 4 Perform partial crimp**

Crimp the THV delivery system (continued)

- 5 Verify valve orientation with implanting physician**
Warning: The physician must verify correct orientation of the valve prior to its implantation.
- 6 Perform four full crimps, hold for 5 seconds each and remove from crimper**

Outflow ← **Inflow (outer sealing skirt)**
Coaxial

Between internal shoulders

Final stop

Coaxial

Note: Make sure the valve is between the shoulders of the delivery system

Caution: The THV should not remain fully crimped and/or in the valve capsule for over 15 minutes as leaflet damage may result and impact valve functionality. Keep the THV hydrated until ready for implantation to prevent damage to the leaflets which may impact valve functionality.

Flush the THV delivery system

- 1 Attach syringe to delivery system**
- 2 Fill capsule and pull delivery system valve back into it while flushing**
- 3 Lock delivery system**
Lock
Balloon shaft marker
- 4 Flush inline sheath and advance to capsule**
- 5 Remove stylet**
- 6 Flush wire lumen**
- 7 Hydrate tapered tip and valve capsule**
- 8 Perform final check before transferring to operating physician**

Pulmonic delivery system preparation

For professional use. CAUTION: Federal (United States) law restricts these devices to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions, and adverse events.
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