



THV TRAINING

Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander System

23 / 26 / 29 mm Sizes

PROCEDURAL TRAINING MANUAL

See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and potential adverse events

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PROC-SOP4407EL76/G ISSUED: 07/2015



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System Overview

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Edwards

Edwards Lifesciences v. Boston Scientific Scimed

IPR2017-00060 U.S. Patent 8,992,608

Exhibit 2034 - Part 1

PROTECTIVE ORDER MATERIAL

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SAPIEN 3 Valve and Edwards Commander System

Procedural Animation



Click Above to Play Video

SAPIEN 3 Valve and Edwards Commander System

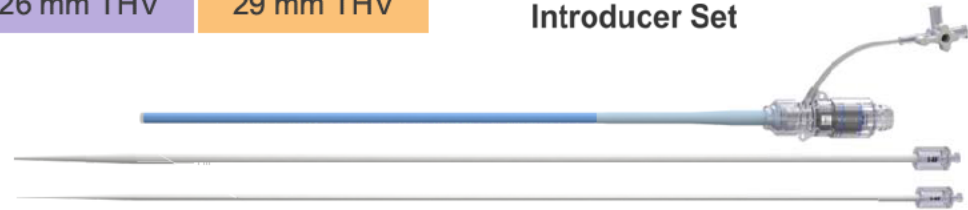
Color Coded System

Green	Purple	Orange
23 mm THV	26 mm THV	29 mm THV

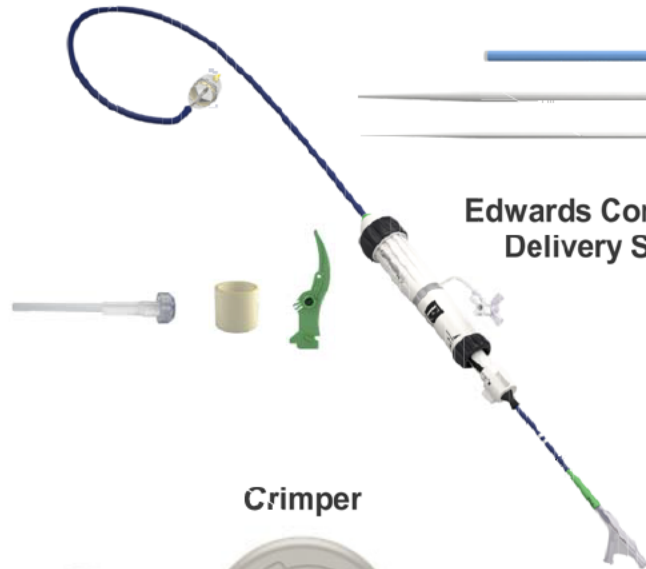
Edwards SAPIEN 3 Transcatheter Heart Valve



Edwards eSheath Introducer Set



Edwards Commander Delivery System



NOTE:
A separate dilator kit is not included with the system

Edwards Balloon Catheter



Crimper



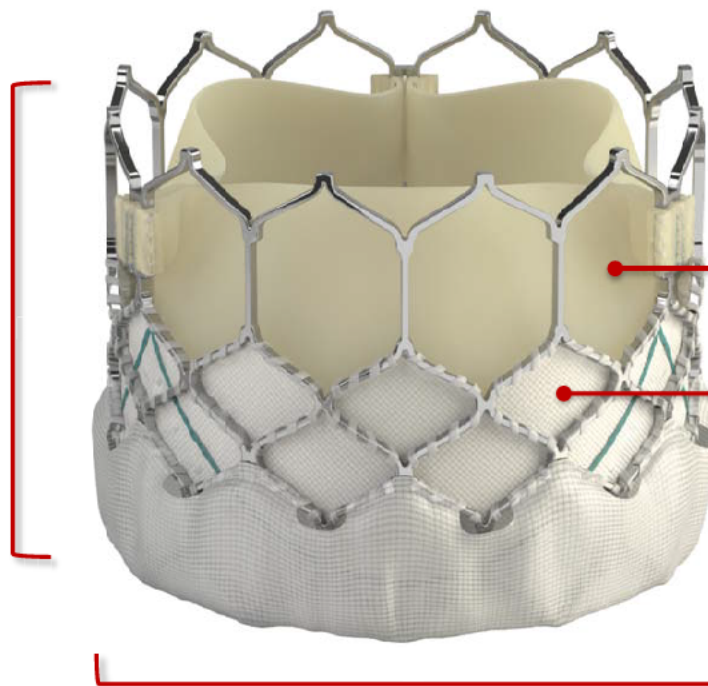
Atrion Devices (Inflation Devices)



SAPIEN 3 Transcatheter Heart Valve

Low Frame Height

- Respects the cardiac anatomy



Bovine Pericardial Tissue

- Scalloped leaflet shape
- Utilizes the same bovine pericardial tissue and processes as Edwards surgical valves

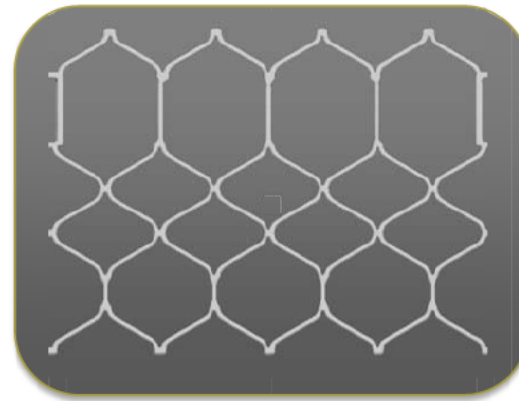
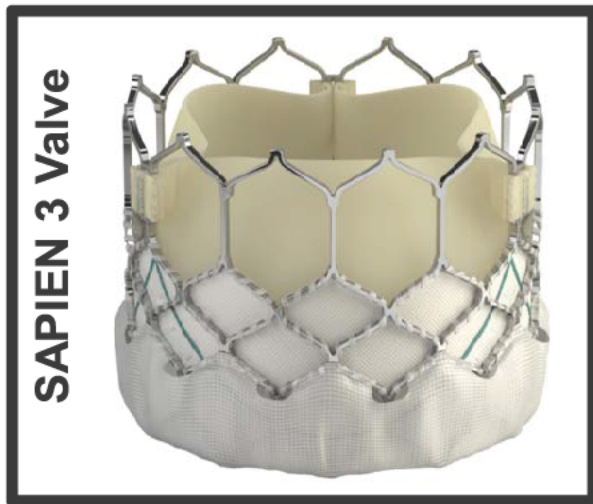
Inner Skirt

- Polyethylene terephthalate (PET)

Outer Sealing Skirt

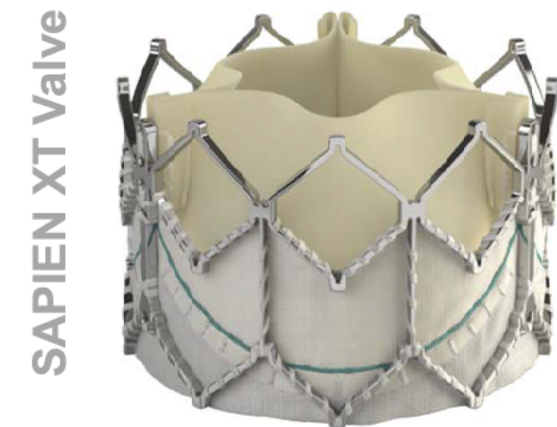
- PET outer sealing skirt designed to minimize paravalvular leak

SAPIEN 3 Transcatheter Heart Valve



Frame Design

- Wide strut angles contribute to ultra-low delivery profile
- Four rows and columns between commissures for high radial strength
- Cobalt chromium alloy frame and wide strut angles provide fatigue resistance and high radial strength for circularity



SAPIEN 3 Transcatheter Heart Valve

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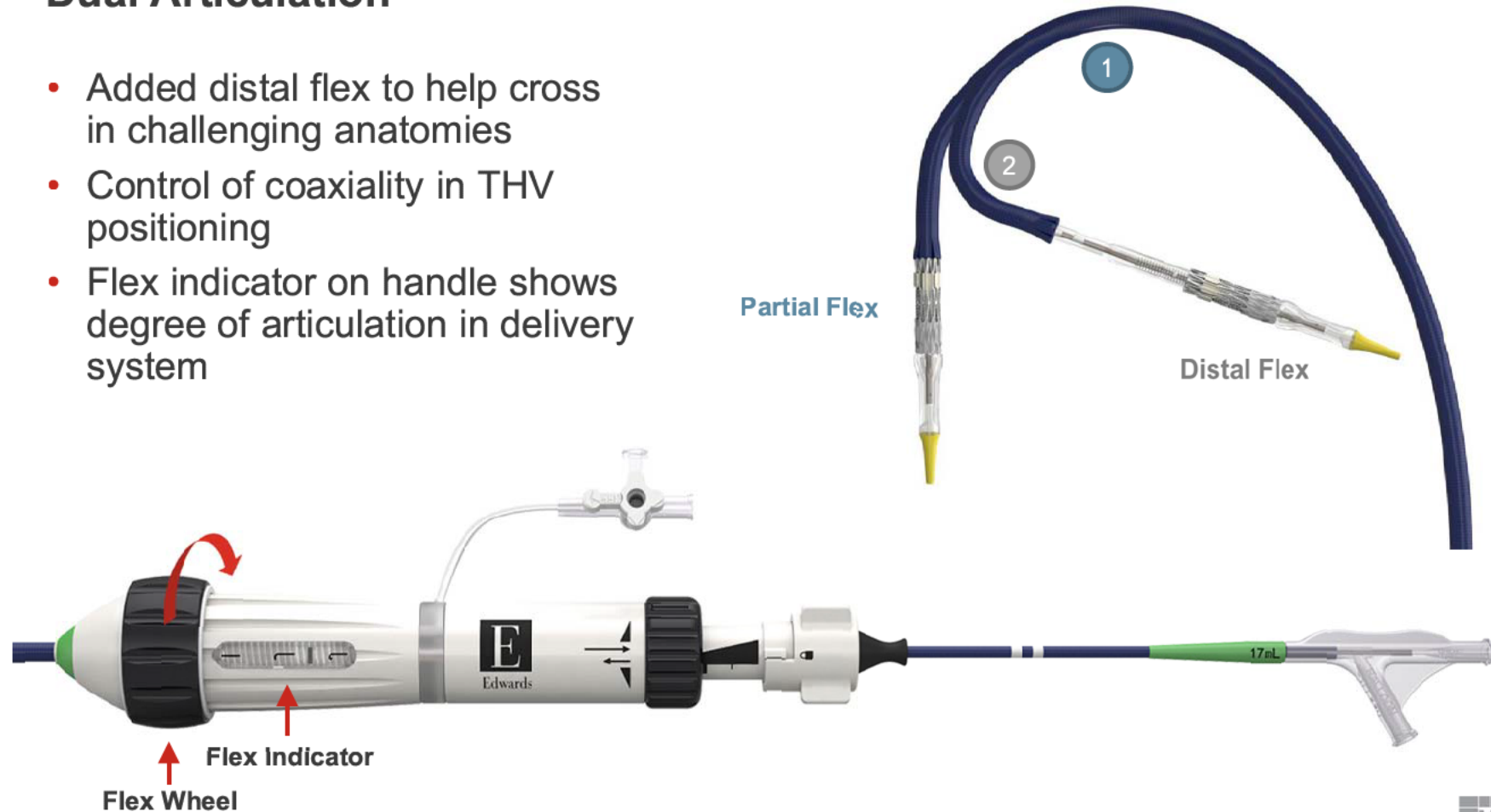
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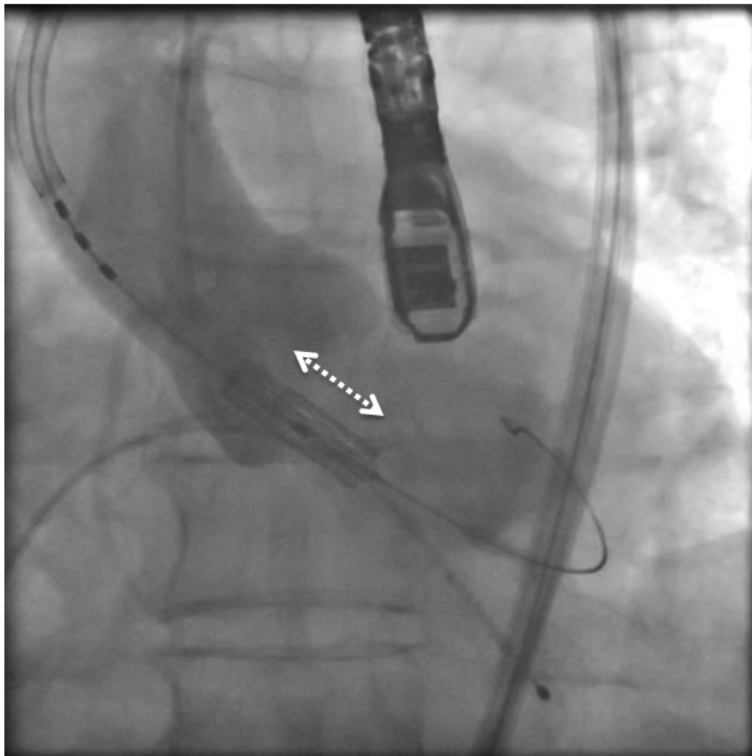
Edwards Commander Delivery System

Dual Articulation

- Added distal flex to help cross in challenging anatomies
- Control of coaxiality in THV positioning
- Flex indicator on handle shows degree of articulation in delivery system

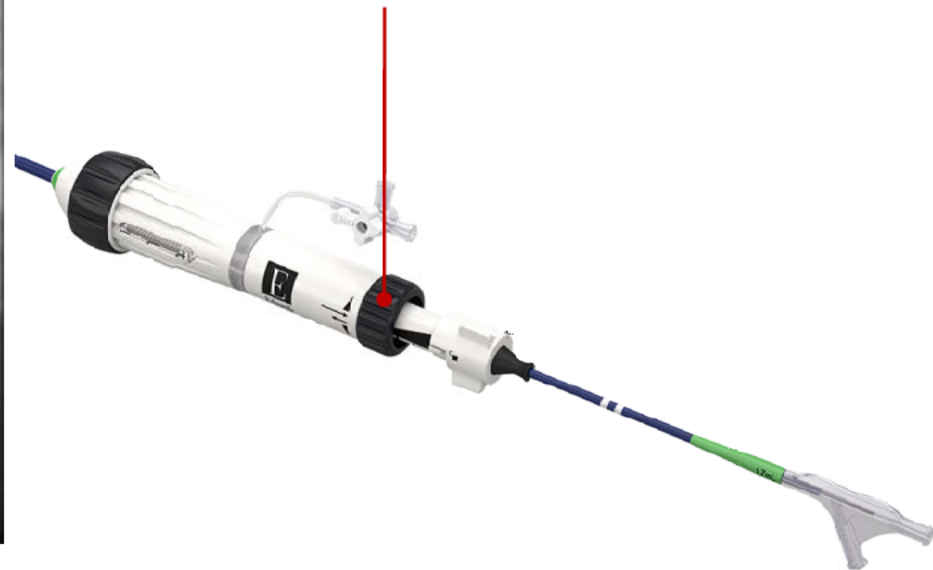


Edwards Commander Delivery System



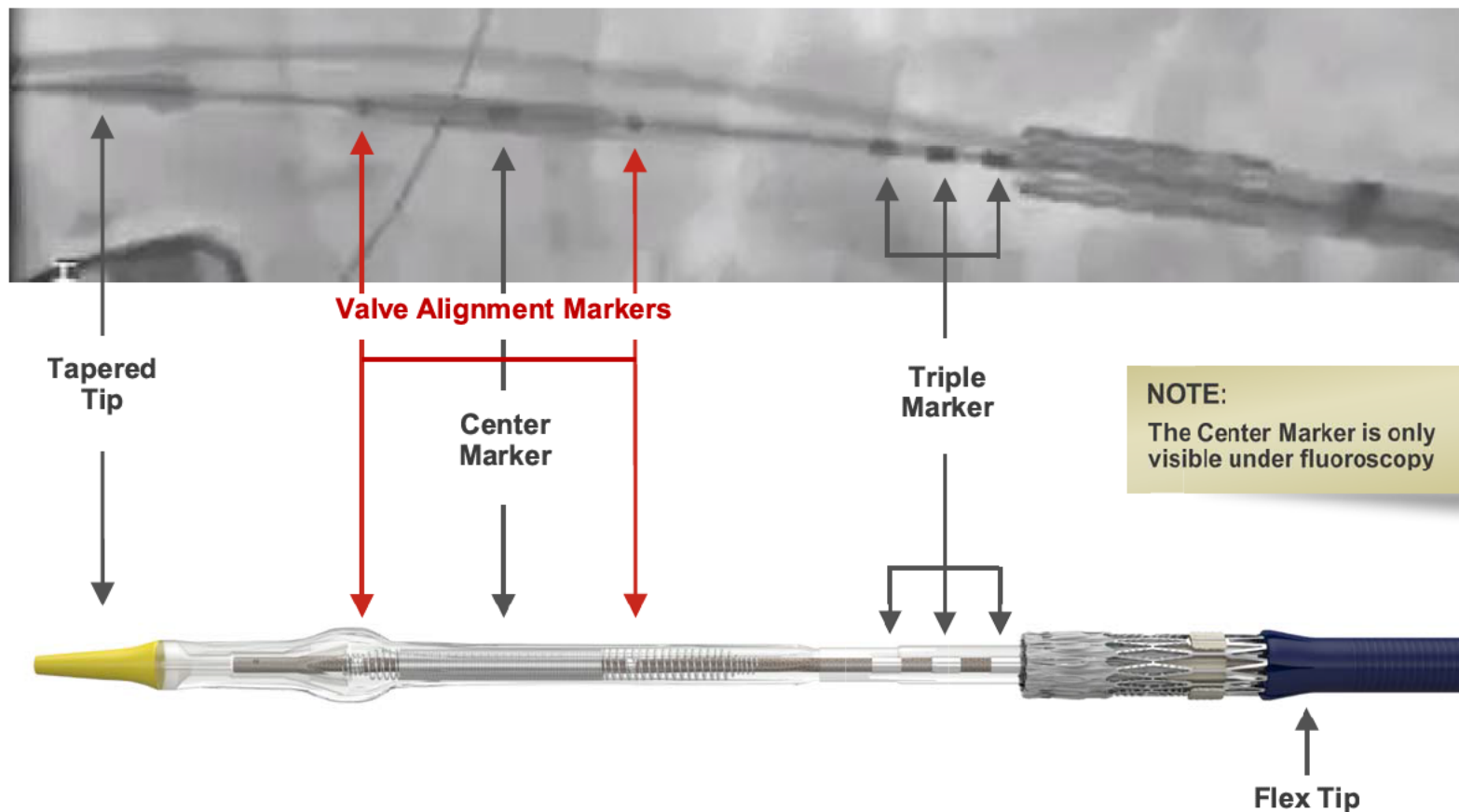
Fine Positioning

- Fine control of positioning for precise THV placement



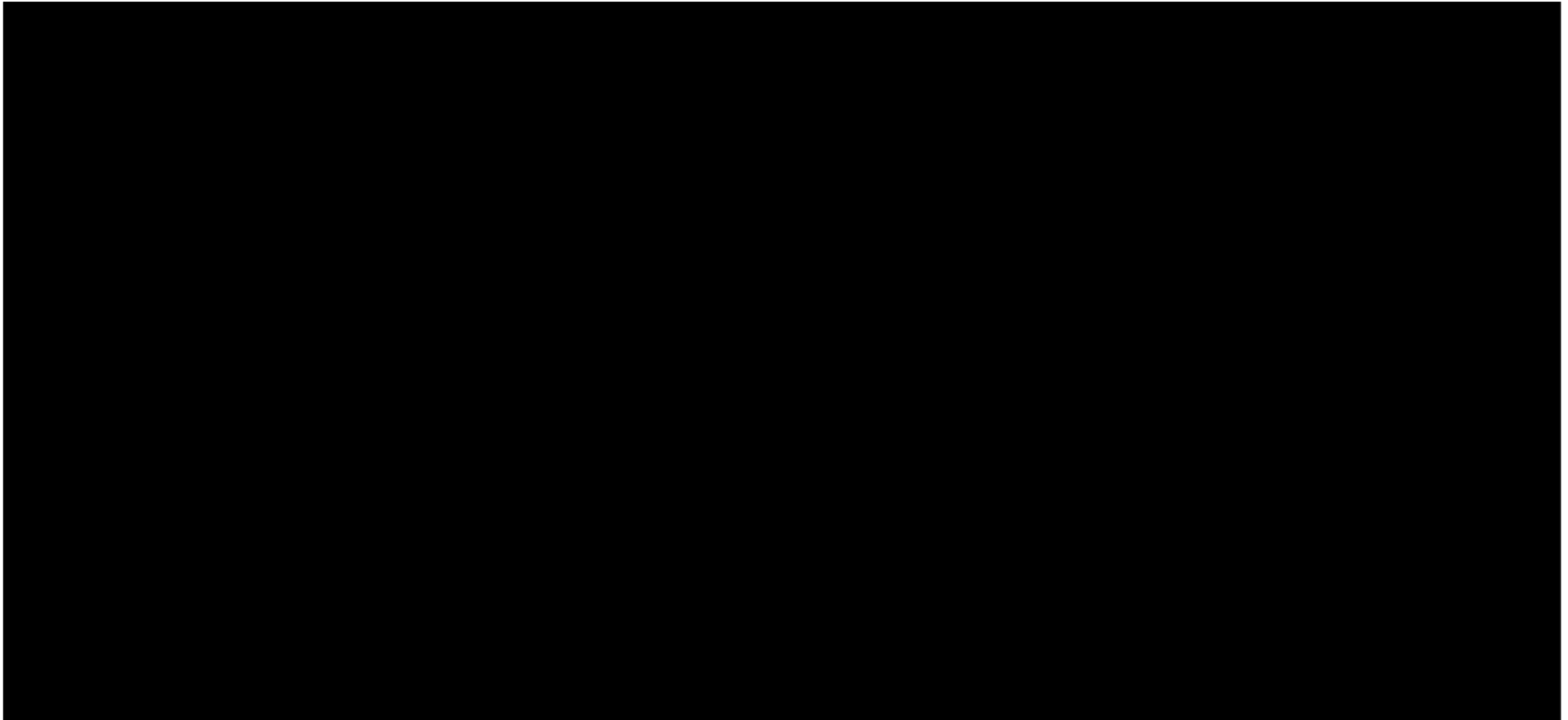
Edwards Commander Delivery System

Distal End



Edwards Commander Delivery System

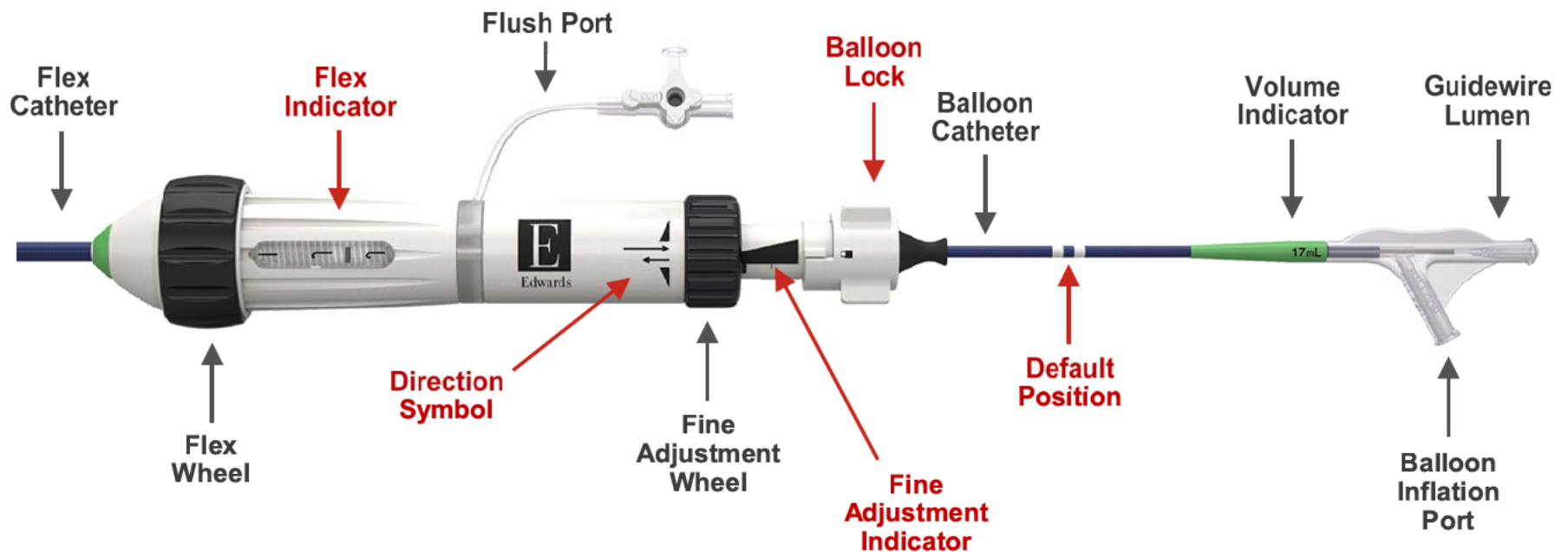
Distal End Comparison



Edwards Commander Delivery System

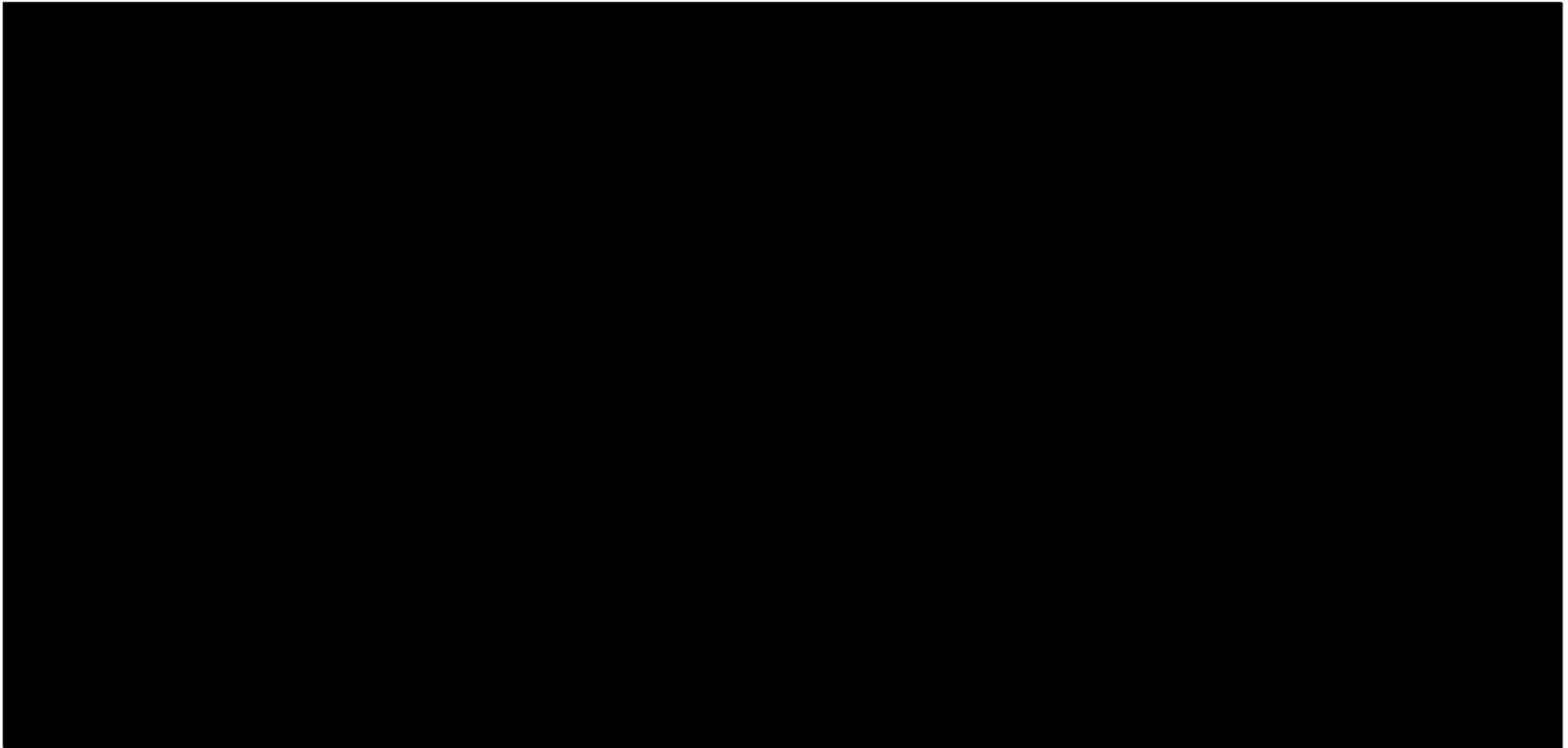
Proximal End

- New indicators and symbols
- Balloon lock allows user to **manually** lock / unlock balloon catheter



Edwards Commander Delivery System

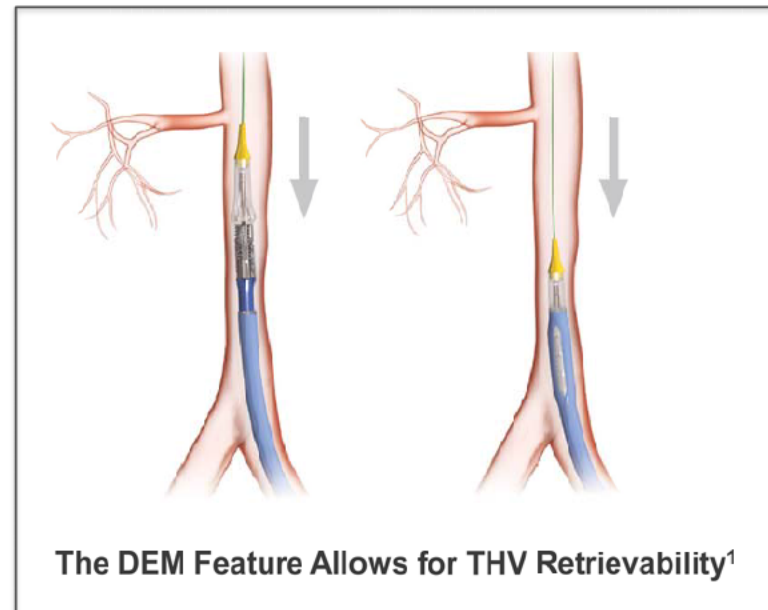
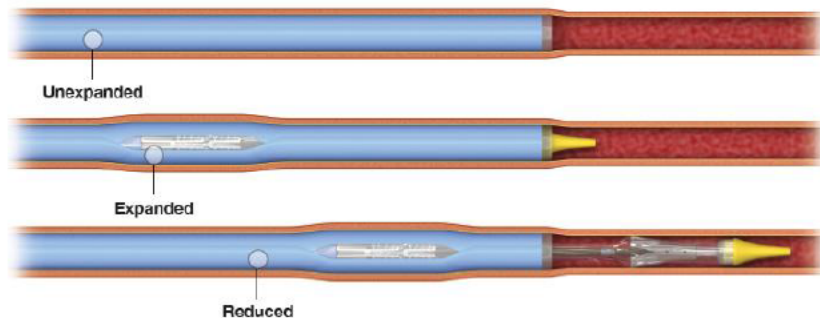
Working Length Specifications



Edwards eSheath Introducer Set

The Dynamic Expansion Mechanism (DEM) is designed to reduce vascular trauma by

- Allowing for transient sheath expansion during delivery system passage
- Reduces the time the access vessel is expanded



¹ The SAPIEN 3 valve is retrievable prior to THV deployment. THV and sheath are removed together with THV in the body of the sheath.