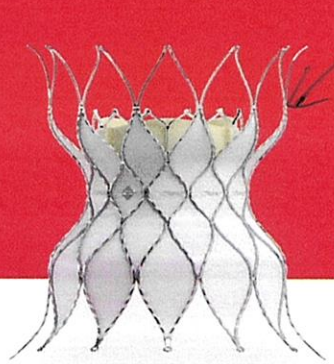
KATALOGAS Nr. 1

Edwards SAPIEN 3 valve with Alterra adaptive prestent



Technical Sheet

Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestent.

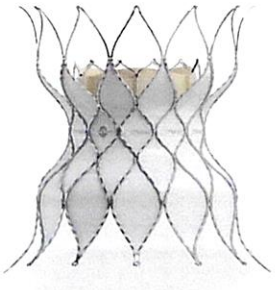
Device description

The Edwards SAPIEN 3 transcatheter pulmonary valve system with Alterra adaptive prestent consists of the Edwards 29 mm SAPIEN 3 transcatheter heart valve (THV), the Edwards SAPIEN 3 pulmonic delivery system (PDS), the Edwards Alterra adaptive prestent system and accessories.

Edwards Alterra Adaptive Prestent System consists of an Alterra adaptive prestent that is fully loaded in an Alterra delivery system and supplied together in one package.

Edwards Alterra Adaptive Prestent is used as a docking adaptor for the 29 mm Edwards SAPIEN 3 transcatheter heart valve (THV). It is comprised of a self-expanding, radiopaque, nitinol frame assembly with polyethylene terephthalate (PET) fabric covering. The prestent has designated inflow and outflow sides.
The proximal inflow section is identifiable by the presence of two triangular tabs (prestent connector) that are attached to the catheter of the delivery system. The distal outflow section is distinguished by the open cells for blood flow. The PET fabric is attached by sutures to the inside surface of the frame to create sealing at the inflow section and opening for the outflow. Sutures are also used in the center to support the middle section when an Edwards SAPIEN 3 transcatheter heart valve is implanted. Three (3) fluoroscopically visible radiopaque markers at the prestent waist help with positioning.

Outflow



Inflow

Edwards Alterra adaptive prestent
Designed to provide a landing zone for 29 mm SAPIEN 3 valve

Prestent sizing in RVOT landing zone

Perimeter	84.9 - 119.3 mm
Perimeter derived diameter*	27 - 38 mm
Prestent size	40 x 49 mm
SAPIEN 3 valve compatibility	29 mm

* Diameter range throughout cardiac cycle

Edwards Alterra adaptive prestent dimensions

Inflow sealing OD	39 mm
Outflow sealing OD	41 mm
Height	49 mm

Patient sizing range
Sizing recommendation for the prestent in the right ventricular outflow tract/pulmonary valve (RVOT/PV) landing zone are shown in the table on top.

Edwards

Intended use

The bioprosthesis with prestent is intended for use in patients requiring pulmonary heart valve replacement. The delivery systems and accessories are intended to facilitate placement of the bioprosthesis and prestent via the transfemoral access approach.

Indications

The 29 mm Edwards SAPIEN 3 transcatheter pulmonary valve system with Alterra adaptive prestent is indicated for use in the management of patients with pulmonary regurgitation who have a native or surgically-repaired right ventricular outflow tract and are clinically indicated for pulmonary valve replacement.

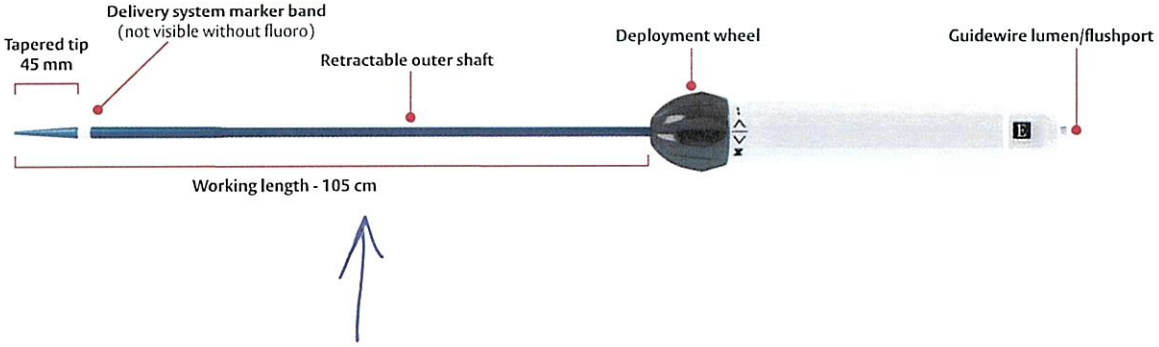
Product Description	29 mm
Edwards SAPIEN 3 Transcatheter Pulmonary Valve System	S3PAS4045CE
Edwards SAPIEN 3 Transcatheter Heart Valve	9600TFX29
Edwards SAPIEN 3 Pulmonic Delivery System	9630PL29CE
Edwards Crimper	9600CR
Edwards eSheath+ Introducer Set (16F)	916ESP
Locking Syringe	96406
Alterra Adaptive Prestent with Alterra Delivery System	29AP4045CE

Edwards Alterra Delivery System

The delivery system includes a handle which consists of a wheel that allows for deployment, two primary shafts with a flush port to flush the delivery system, and a long tapered tip at the distal end to facilitate tracking through the vasculature. A fluoroscopically visible radiopaque marker band shows the location of the tip of the outer shaft. The prestent is fully loaded in the delivery system. A stylet is included within the guidewire lumen.

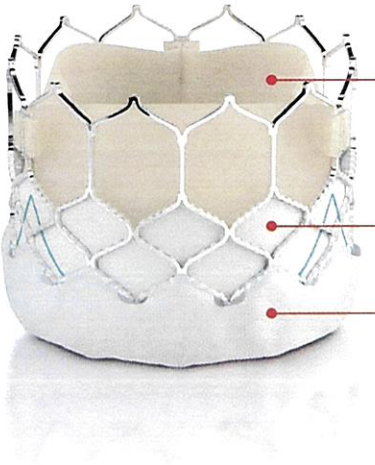
Delivery system dimensions	
Alterra capsule OD	**6.7 mm / 20 Fr**
Alterra shaft OD	**5.7 mm / 17Fr**
Wire compatibility	**0.035" / 0.89mm**

Alterra adaptive prestent is compatible with the 16Fr eSheath+ introducer set or equivalent



Edwards SAPIEN 3 Transcatheter Heart Valve

The Edwards SAPIEN 3 transcatheter heart valve is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.



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

Inner skirt
- Polyethylene terephthalate (PET)

Outer sealing skirt
- PET outer sealing skirt designed to minimize paravalvular leak

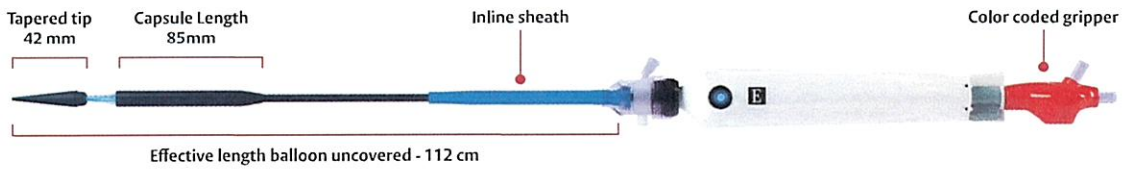
	29 mm
Tissue	Bovine pericardium, Thermafix tissue process[1]
Frame	Cobalt-chromium alloy
Crimped height[2]	31 mm
Expanded height	22.8 mm
Foreshortening	8.2 mm

[1] No clinical data are available with which to evaluate the long-term impact of the Carpentier-Edwards ThermaFix tissue process in patients

Edwards SAPIEN 3 Pulmonic Delivery System (PDS)

The Edwards SAPIEN 3 pulmonic delivery system facilitates the placement of the bioprosthesis. It consists of an inline sheath, balloon catheter for deployment of the Edwards SAPIEN 3 transcatheter heart valve, and an outer shaft and valve capsule to cover the transcatheter heart valve during insertion and tracking to the intended deployment location. The delivery system includes a tapered tip to facilitate crossing of right heart structures. The valve capsule and tapered tip are hydrophilic coated. A visual balloon shaft marker is provided to assist with balloon recapture. A stylet is included within the guidewire lumen of the delivery system. The 28 F hydrophilic coated dilator (packaged with the delivery system) is used to predilate the vessel prior to insertion of the delivery system, if necessary.

Pulmonic delivery system dimensions	
Catheter capsule outer diameter	**28.5 Fr / 9.5 mm**
In-line sheath outer diameter	**25.5 Fr / 8.5 mm**
Catheter outer shaft diameter	**17 Fr / 5.7 mm**
Guidewire compatibility	**0.035" / 0.89mm**



How Supplied

STERILE: The valve is supplied sterilized with glutaraldehyde solution. The delivery system, sheath, and crimper are supplied sterilized with ethylene oxide gas.

The Edwards Alterra adaptive prestent system is supplied pouched and sterilized by e-beam sterilization.

The THV is supplied nonpyrogenic packaged in buffered glutaraldehyde, in a plastic jar to which a tamper evident seal has been applied. Each jar is shipped in a shelf box containing a temperature indicator to detect exposure of the THV to extreme temperature. The shelf box is enclosed in Styrofoam prior to shipping.

Storage

The transcatheter heart valve must be stored at 10 °C to 25 °C (50 °F to 77 °F). Each jar is shipped in an enclosure containing a temperature indicator to detect exposure of the THV to extreme temperature. The delivery system and accessories should be stored in a cool, dry place. The prestent and delivery system must be stored in a cool, dry place.

MR Safety

MR Conditional

Non-clinical testing has demonstrated that the Non-clinical testing has demonstrated that the Edwards Alterra adaptive prestent, alone or with a deployed SAPIEN 3 transcatheter heart valve, is MR Conditional. A patient can be scanned safely immediately after placement of this implant in an MR system meeting the following conditions:

- Static magnetic fields of 1.5 Tesla and 3.0 Tesla
- Spatial magnetic gradient field of 3000 Gauss/cm (30 T/m) or less
- Maximum MR system-reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode) scanning per sequence
- Gradient system is in normal operating mode

Under the scan conditions defined above, the Edwards Alterra adaptive prestent, alone or with a deployed SAPIEN 3 transcatheter heart valve, is expected to produce a maximum temperature rise of 4.0 °C or less after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends as far as 15 mm for gradient echo images when scanned using a 3.0 T MRI system. The artifact obscures the device lumen in spin and gradient echo images. The delivery system has not been evaluated for MR compatibility and is considered MR unsafe.

Qualitative and Quantitative Information related to the valve

The Alterra adaptive prestent system and SAPIEN 3 transcatheter heart valve contain the following substance(s) defined as CMR 1B in a concentration above 0.1% weight by weight: Cobalt; CAS No. 7440-48-4; EC No. 231-158-0 Current scientific evidence supports that medical devices manufactured from cobalt alloys or stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.

For the qualitative and quantitative information on the materials and substances constituting the valve please refer to the IFU.

Summary of Safety and Clinical Performance (SSCP)

The SSCP has been adapted in accordance with the clinical evaluation assessment by the Notified Body on which CE certification has been granted. The SSCP contains a relevant summary of the same information.

The Notified Body has taken notice of and agreed with the benefit-risk rationales for the short- and long-term safety and effectiveness of the Alterra platform and the SAPIEN 3 platform.

Medical device for professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

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Proven technology that extends SAPIEN 3 valve benefits to more patients

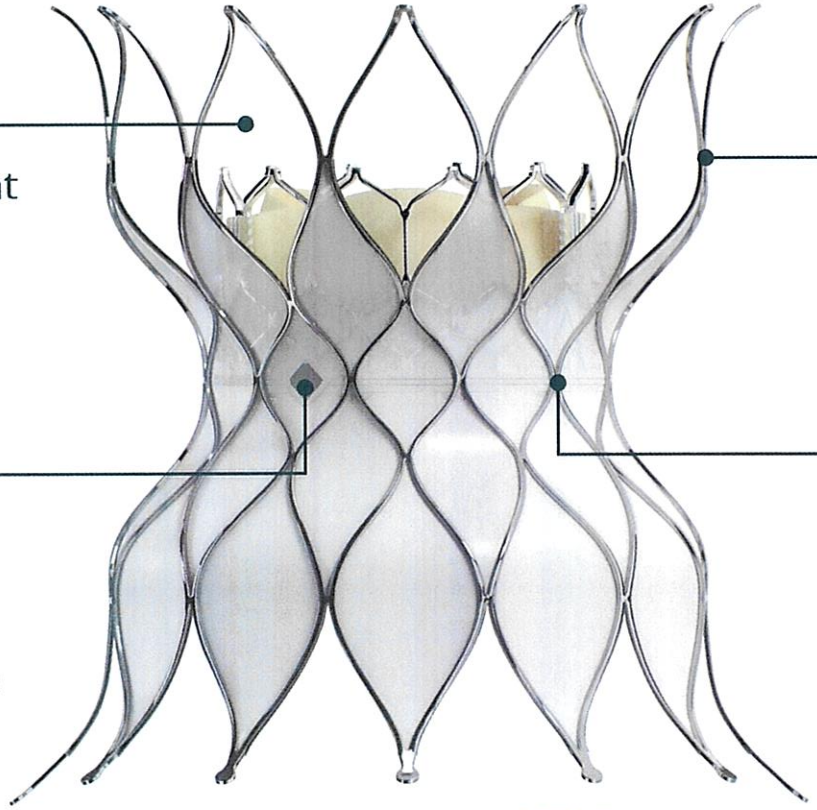
The Alterra adaptive prestent—accurate, secure placement for an expanded group of patients

Open cell geometry

Allows for distal placement without compromising flow to the branch pulmonary arteries

Sealing Zone

Provides apposition against RVOT/PA at both inflow sealing zone and outflow portion of Alterra



Fixation

Apices are designed to engage the anatomy and provide prestent stability

Landing Zone for SAPIEN 3 valve

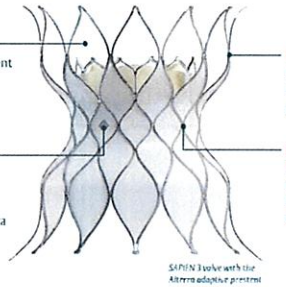
Provides valve retention by the suture band embedded in the waist

SAPIEN 3 valve with the Alterra adaptive prestent

A minimally invasive solution that helps

Proven technology that extends SAPIEN 3 valve benefits to more patients

The Alterra adaptive prestent – accurate, secure placement for an expanded group of patients



SAPIEN 3 valve with the Alterra adaptive prestent

A minimally invasive solution that helps minimize reinterventions.

Deliver excellent outcomes, delay potential reintervention, and improve quality of life[3] for more of your pulmonic patients.[7]

References:

1. Niedenbach et al. Medical care and prevention in ACHD. Cardiovasc Diagn Ther 2018;8(6):705-715
2. Hascoet S, et al. Outcomes of transcatheter pulmonary SAPIEN 3 valve implantation: an international registry. Eur Heart J. 2024;45(3):198-210
3. Dumas, V. Transcatheter Pulmonary Valve Implantation with the Alterra Adaptive Prestent, SAPIEN 3 Transcatheter Heart Valve and Pulmonary Delivery System Two-year Pooled Outcomes of the ALTERRA trial, Presented at PICS 2024, San Diego, CA
4. Aboulhosn, Jamil Five-year Results from the COMPASSION S3 Trial Treatment of Patients with a Dysfunctional RVOT Conduit or Previously Implanted Pulmonic Valve with the SAPIEN 3 Transcatheter Heart Valve; presented at PICS 2024 San Diego CA
5. Edwards Lifesciences, Alterra adaptive prestent IFU
6. Edwards Lifesciences SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestent IFU
7. FDA Summary of Safety and Effectiveness data, December 2021

Medical device for professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

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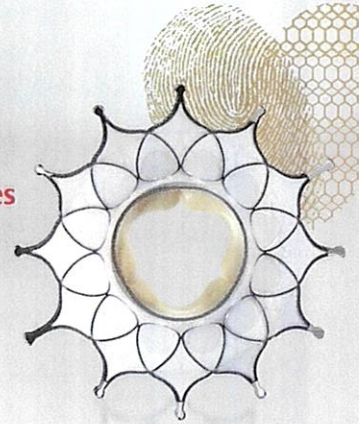
Unique patients
Excellent outcomes

The Edwards SAPIEN 3 Pulmonic Portfolio – where heart valve innovation and living life to the fullest meet



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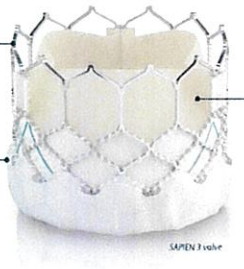
Built on a proven platform; designed for performance



Frame design
Cobalt-chromium for high radial strength.
Enhanced frame geometry for low delivery profile

Outer sealing skirt
Designed to minimize paravalvular leak

Proven valve tissue
Utilizes the same bovine pericardial tissue and process as Edwards surgical valves**

**Excludes RESILIA tissue
Image is larger than actual valve size

With pulmonic patients living longer[1] and having higher expectations for their health and quality of life, lifetime management is increasingly important.

That's why valve choice matters, and the Edwards SAPIEN 3 pulmonic portfolio delivers.[2,3]

Excellent clinical outcomes, patient after patient

	SAPIEN 3 valve at 5 years[4]* COMPASSION S3 Trial	SAPIEN 3 valve with the Alterra adaptive prestent at 2 years †† Alterra Pivotal Trial
Mortality	0% (n=42)	1.7% (n=118)
≤ Mild pulmonary regurgitation	95% (n=40)	92% (n=43)
Reintervention	2% (n=41)	2% (n=118)

Minimizing complications that impact the need for reintervention

	SAPIEN 3 valve at 5 years[4]* COMPASSION S3 Trial	SAPIEN 3 valve with the Alterra adaptive prestent at 2 years †† Alterra Pivotal Trial
Endocarditis	3.8% (n=41)	0% (n=118)
Stent Thrombosis	4.3% (valve)	4.2% (prestent) | 0.8% (valve)
Frame fracture	0%	–
Stent fracture requiring reintervention	–	0% (n=119)

*In patients with dysfunctional right ventricular outflow tract (RVOT) conduit or surgical bioprosthetic valve
†In patients with native or surgically repaired right ventricular outflow tract.
n = number of studied patients

Delivery systems that offer controlled, predictable, and precise positioning

Ready to adapt and adjust based on patient needs[5]

Alterra Delivery System
Recapture and reposition[5] with ergonomic control, smooth tracking, and a system developed specifically for the Alterra adaptive prestent.

Pulmonic Delivery System
Covered system[6] designed to track through complex anatomies and deliver the SAPIEN 3 valve into the Alterra adaptive prestent.

Edwards Commander Delivery System
Dual articulation designed for precise positioning and deployment of the Edwards SAPIEN 3 valve.

Clinical Summary

Multicenter Pivotal Study of the Alterra Adaptive Prestent for the Treatment of Pulmonary Regurgitation

Dimas VV, Babaliaros V, Kim D, et al. Multicenter Pivotal Study of the Alterra Adaptive Prestent for the Treatment of Pulmonary Regurgitation. JACC Cardiovasc Interv. 2024;17(19):2287-2297.

Study aim

The Alterra adaptive prestent was designed to expand transcatheter therapy to treat patients with dilated right ventricular outflow tract (RVOT). The study aims to report **2 years outcomes** of the ALTERRA pivotal trial in dilated native RVOTs.

Methodology

Prospective, single-arm, multicenter study design to assess the safety and effectiveness of the Alterra adaptive prestent with the 29 mm SAPIEN 3 valve in patients with dysfunctional RVOT requiring treatment of moderate or severe pulmonary regurgitation (PR).

Patients characteristics

- Median age: 23years
- Gender: 55.7% male
- NYHA class: 54.1% NYHA class I
- Diagnose: Tetralogy of Fallot (70.5%); Pulmonic valve stenosis (23%); Balloon valvuloplasty (6 patients) and Surgical valvotomy (8).

The primary end point was transcatheter heart valve (THV) dysfunction at 6 months, defined as a nonhierarchical composite of RVOT/pulmonary valve gradient 35 mm Hg or greater on transthoracic echocardiography. Patients enrolled, n=60

Results

The Alterra adaptive prestent had shown **excellent procedural outcomes** achieving **94.9% of device success**, composite of:

- Single present deployed in the desired location (100%)
- Single THV implanted in the desired location within the present (96.7%)
- RV-PA peak-to-peak gradient less than 35mm Hg post-implant (100%)
- Less than moderate PR on discharge TTE (or earliest evaluable TTE) (98.3%)
- Free of explantation at 24 h post implantation (100%)

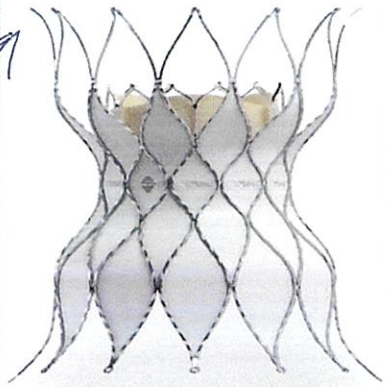
Edwards

Excellent clinical outcomes were reported at 2 years follow-up. Key outcomes reported below.

2-Year Outcomes of the ALTERRA Pivotal Trial

Prospective, single-Arm, Multicenter Study of Patients with Dysfunctional Native or Patched RVOT and ≥ Moderate PR by TTE

Trial Devices: Alterra adaptive prestent and 29 mm SAPIEN 3 THV



Screen-Fail Rate for Patient Population: 37.1% (36/97) N=60 patients implanted

Both devices implanted in a single procedure	**98.3%**
Free of explant within 24 h	**100%**
Primary Endpoint THV dysfunction at 6 months	**0% (0/59)**
RVOT reintervention	**0**
Moderate or greater PR	**0**
Mean gradient ≥35 mm Hg	**0**

2-Year Follow-Up: 96.7% (58/60)

Key Outcomes at 2 Years	
All cause mortality	**0%**
Fracture requiring intervention	**0%**
Coronary artery compression	**0%**
Endocarditis	**0%**
Sustained VT	**0%**
RVOT/PV reintervention	**1.7%**
≥ Moderate PR	**7.5%**

- At 2 years, 92.5% of patients treated in the Alterra Pivotal Trial had ≤mild PR
- No deaths, endocarditis, device embolization, or explants

Total pulmonary valve regurgitation (PR) and mean right ventricular outflow tract (RVOT) gradient were assessed by a transthoracic echocardiography (TTE) core laboratory | ALTERRA = ALTERRA Pivotal Trial Multicenter Study of Congenital Pulmonic Valve Dysfunction Studying the SAPIEN 3 THV with the Alterra adaptive prestent; PV = pulmonic valve; THV = transcatheter heart valve; VT = ventricular tachycardia.

Conclusion

It is extremely favorable to see **sustained excellent clinical outcomes out to 2 years.** The patient cohort will continue to be monitored through annual follow-up assessment up to 5 years.

As of today, we can state that dilated RVOT presents unique challenges for transcatheter management. However, what we are seeing is that not only the Alterra adaptive prestent allows to expand the transcatheter therapy for this dilated RVOT patients population but also, *"the Alterra adaptive prestent and 29 mm SAPIEN 3 THV resulted in restoration of PV competency and can be safely and effectively performed, with improvement in quality of life, as well as favorable remodeling of the right ventricle."*

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Ettevõtte Edwards eSheath sisestite komplekt
Edwards eSheath ievadītāja komplekts
„Edwards eSheath“ įvediklio rinkinys

Kaust ■ Saturs ■ Katalogas

Eesti

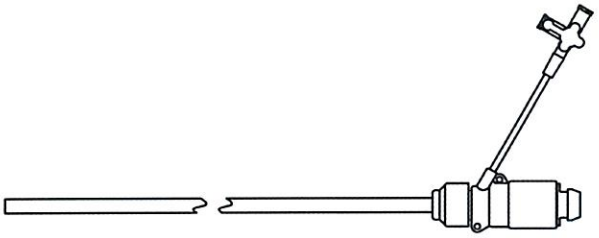
Kasutusjuhend

Toodet tohib kasutada arst, kes on läbinud vastava koolituse ja kellel on eri interventsioonitehnikate rakendamise kogemusi. Kasutada tuleb veresoonde juurdepääsu võimaldava kanüüli paigaldamise standardseid tehnikaid.

1.0 Seadme kirjeldus

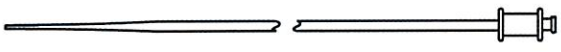
Ettevõtte Edwards eSheath sisestite komplekt sisaldab järgmisi komponente.

1. Laiendatav kanüül (eSheath) (joonis 1), mis annab juurdepääsu sihtveresoonde, säilitades hemostaasi ja suurendades ajutiselt selle läbimõõtu seadme läbipääsu võimaldamiseks.



Joonis 1

Mudel	eSheath sisediameeter (laiendamata)	eSheath välisdiameeter (laiendamata)	Ühilduv THV
9610ES14	14 F (4,6 mm)	6,0 mm	20 mm 23 mm 26 mm
9610ES16	16 F (5,3 mm)	6,7 mm	29 mm



Joonis 2

2. Kaks hüdrofiilse kattega dilataatorit (joonis 2), mida saab kasutada veresoone laiendamiseks kanüüli jaoks ja/või kanüüli sisestamise ning jälgimise hõlbustamiseks veresoones.

2.0 Kasutusotstarve

Toode on mõeldud kasutamiseks veresoontele juurdepääsu loomisel.

3.0 Näidustused

Ettevõtte Edwards eSheath sisestite komplekt on näidustatud transkateetriga südameklapisüsteemide SAPIEN 3 ja SAPIEN 3 Ultra sisestamiseks vaskulaarsüsteemi ning sealt eemaldamiseks.

4.0 Vastunäidustused

Teadaolevaid vastunäidustusi pole.

5.0 Hoiatused

Seadmed on konstrueeritud, ette nähtud ja levitatavad ainult ühekordseks kasutamiseks. **Ärge resteriliseerige seadmeid ega kasutage neid korduvalt.** Puuduvad andmed selle kohta, et seade oleks pärast taastöötlemist steriilne, mittepürogeenne ja funktsionaalne.

Ettevõtte Edwards eSheath sisestite komplekti tuleb kasutada sobiva 0,89 mm (0,035 in) juhtetraadiga, et vältida veresoone vigastamist.

Ärge kasutage seadet valesti ega kasutage seda, kui pakend või mõni komponent pole steriilne, on avatud, kahjustatud (nt niverdunud või venitatud jne) või kui aegumiskuupäev on möödunud.

6.0 Ettevaatusabinõud

- Kanüül laieneb ajutiselt, et võimaldada seadmete läbipääs. Veenduge, et veresooned mahutaksid laiendatud kanüüli maksimaalse diameetri.
- Seadet läbi kanüüli sisestades, selles käsitsedes või sealt välja tõmmates säilitage alati kanüüli asend.
- Kanüüli läheduses kude punkteerides, õmmeldes või sellesse sisselõiget tehes olge ettevaatlik ja vältige kanüüli kahjustamist.
- Ettevaatlik tuleb olla veresoontega, mille läbimõõt on väiksem kui 5,5 mm või 6 mm, sest nendesse võib olla raske paigaldada vastavalt 14 F ja 16 F ettevõtte Edwards eSheath sisestite komplekte.
- Olge ettevaatlik rebenemisohtlike või kaltsifitseerunud veresoontega, mille korral võib sisesti komplekti turvaline sisestamine olla takistatud.

7.0 Võimalikud kõrvalnähud

Standardse kateetri kasutamise ja angiograafiaga seostatud komplikatsioonid on muu hulgas allergiline reaktsioon anesteesia või kontrastaine suhtes, vigastus, k.a veresoone perforatsioon või dissektsioon, veresoone parandamist nõuda võiv vigastus juurdepääsukohas, tromboos ja/või plaagi paigaltliikumine, mis võib põhjustada emboolia moodustumist, distaalset veresoone ummistumist, insulti, isheemiat ja/või surma.

Patsiendile / kasutajale / kolmandale isikule Euroopa Majanduspiirkonnas: kui seadme kasutamise ajal või selle kasutamise tagajärjel toimus raske vahejuhtum, andke sellest teada tootjale ja riigi pädevale asutusele, kes on leitav veebisaidilt https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

8.0 Kasutusjuhend

1. Vaadake kõik komponendid üle kontrollimaks, et neis poleks vigastusi.
2. Loputage dilataatoreid juhtetraadi valendiku kaudu hepariniseeritud füsioloogilise lahusega.
3. Loputage kanüüli loputusava kaudu hepariniseeritud füsioloogilise lahusega ja sulgege loputusava.
4. Niisutage sisestit/dilataatoreid ja kanüüli kogu pikkuses hepariniseeritud füsioloogilise lahusega, et aktiveerida hüdrofiilne kate.
5. Viige üks dilataator täielikult kanüüli.

10

Lietuvių

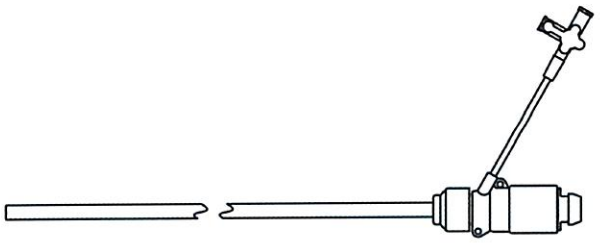
Naudojimo instrukcijos

Gaminys skirtas gydytojams, išmokytiems ir turintiems intervencinių metodų patirties. Reikia naudoti standartinius kraujagyslių prieigos movų įvedimo metodus.

1.0 Priemonės aprašymas

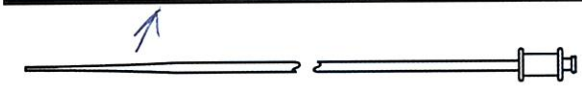
„Edwards eSheath" įvediklio rinkinys sudarytas iš toliau išvardytų dalių:

1. Išplečiama mova („eSheath") (1 pav.), suteikianti prieigą prie tikslinės kraujagyslės palaikant hemostazę ir laikinai padidinanti jos skersmenį, kad būtų galima įvesti priemonę.



1 pav.

Modelis	„eSheath" vidinis skersmuo (neišplėstos)	„eSheath" išorinis skersmuo (neišplėstos)	Suderinamas THV
9610ES14	14F (4,6 mm)	6,0 mm	20 mm 23 mm 26 mm
9610ES16	16F (5,3 mm)	6,7 mm	29 mm



2 pav.

2. Du skėtikliai (2 pav.) su hidrofiline danga, kuriuos galima naudoti kraujagyslei išplėsti, kad joje lengviau tilptų mova, ir (arba) prireikus būtų lengviau įvesti ir (arba) kraujagyslėje sekti movą.

2.0 Paskirtis

Gaminys skirtas naudoti norint patekti į kraujagysles.

3.0 Indikacijos

„Edwards eSheath" įvediklio rinkinys yra skirtas SAPIEN 3 ir „SAPIEN 3 Ultra" transkateterinių širdies vožtuvų sistemoms įvesti į kraujagyslių sistemą ir pašalinti iš jos.

4.0 Kontraindikacijos

Nėra žinomų kontraindikacijų.

5.0 Įspėjimai

Priemonės sukurtos, skirtos ir tiekiamos naudoti tik vieną kartą. **Priemonių kartotinai nesterilizuokite ir nenaudokite pakartotinai.** Nėra duomenų, patvirtinančių pakartotinai apdorotų priemonių sterilumą, nepirogeniškumą ir funkcionalumą.

„Edwards eSheath" įvediklio rinkinį reikia naudoti su suderinama 0,035 col. (0,89 mm) kreipiamąja viela, kad nepažeistumėte kraujagyslės.

Priemonę naudokite tinkamai ir jos nenaudokite, jeigu pakuotė arba bet kurios sudedamosios dalys yra nesterilios, buvo atidarytos, pažeistos (t. y. persuktos, ištemptos ir pan.) arba pasibaigė jų galiojimo laikas.

6.0 Atsargumo priemonės

- Mova laikinai padidėja, kad būtų galima įvesti priemones. Įsitikinkite, ar kraujagyslėje gali tilpti iki maksimalaus skersmens išplėsta mova.
- Įvesdami, ištraukdami priemonę arba ja manipuliuodami per movą, visada išlaikykite movos padėtį.
- Arti movos pradurdami, siūdami arba pjaudami audinį saugokite, kad nepažeistumėte movos.
- Reikia būti atsargiems naudojant mažesnėms kaip 5,5 mm ar 6 mm kraujagyslėms, nes gali nepavykti saugiai įdėti atitinkamai 14 F ir 16 F „Edwards eSheath" įvediklio rinkinio.
- Būkite atsargūs, jei kraujagyslės vingiuotos ar kalcifikuotos, nes bus sunku saugiai įvesti įvediklio rinkinį.

7.0 Galimi nepageidaujami reiškiniai

Kai kurios komplikacijos, susijusios su standartiniu kateterizavimu ir angiografijos naudojimu: alerginė reakcija į anesteziją arba kontrastinę medžiagą; sužalojimas, įskaitant kraujagyslių pradūrimą arba disekaciją; sužalojimas prieigos vietoje, dėl kurio gali prireikti tvarkyti kraujagyslę; trombozė ir (arba) plokštelių išjudinimas, dėl kurio gali susidaryti embolų; distalinė kraujagyslės obstrukcija; insultas; išemija ir (arba) mirtis.

Pacientui, naudotojui ir (arba) trečiajai šaliai Europos ekonominėje erdvėje: jeigu naudojant šį prietaisą arba dėl jo naudojimo įvyksta rimtas incidentas, praneškite gamintojui ir savo nacionalinei kompetentingai institucijai, jos kontaktinius duomenis galite rasti adresu https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

8.0 Naudojimo nurodymai

1. Apžiūrėkite priemonės komponentus, ar jie nesugadinti.
2. Praplaukite skėtiklius fiziologiniu tirpalu su heparinu pro kreipiamosios vielos spindį.
3. Per plovimo angą fiziologiniu tirpalu su heparinu praplaukite movą, tada uždarykite plovimo angą.
4. Visus įvediklius ir (arba) skėtiklius bei movą sudrėkinkite fiziologiniu tirpalu su heparinu, kad suaktyvintumėte hidrofilinę dangą.
5. Visiškai įveskite vieną skėtiklį į movą.
6. Taikydami standartinius kateterizavimo metodus, prieikite prie kraujagyslės ir kitu skėtikliu praplėskite, kiek reikia movai įvesti.
7. Nustatykite tinkamą movos padėtį ir išlaikykite šią padėtį visos procedūros metu. Taikydami standartinį metodą, įveskite movos mazgą ir stumkite į kraujagyslę, sekdami eigą fluoroskopu.

   Pastaba. Movos darbinės dalies proksimalinio kūgiško galo skersmuo yra didesnis.
8. Jei įmanoma, naudodami įsiuvimo žiedus, įsiūkite movą ir išimkite skėtiklį iš movos.
9. Įdėkite priemonę į movą.

   Pastaba. Vadovaujantis standartiniu intervenciniu metodu, per visą procedūrą movą reikia protarpiais praplauti fiziologiniu tirpalu su heparinu.
10. Užbaigę procedūrą ir išėmę priemonę, išimkite siūlus, tada nesukdami išimkite visą movą ir jos pakartotinai nedėkite.

9.0 Kaip tiekiama

„Edwards eSheath" įvediklio rinkinys tiekiamas maišelyje ir yra sterilizuotas etileno oksidu.

10.0 Sandėliavimas

„Edwards eSheath" įvediklio rinkinį reikia laikyti vėsioje, sausoje vietoje.

11.0 Priemonių išmetimas

Panaudoti movų rinkiniai turi būti tvarkomi ir šalinami taip pat, kaip ir ligoninių atliekos arba biologiškai pavojingos medžiagos. Nėra ypatingų grėsmių, kylančių šalinant šias priemones.

12.0 Pavojingos medžiagos

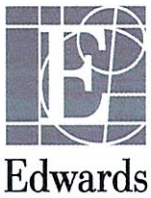
Šios medicinos priemonės sudėtyje nėra pavojingų medžiagų.

13.0 Saugos ir klinikinio veiksmingumo santrauka (SSCP)

SSCP buvo pritaikyta atsižvelgiant į notifikuotosios įstaigos atliktą klinikinį vertinimą, kuriuo remiantis suteiktas CE sertifikatas. SSCP pateikiama atitinkama tos pačios informacijos santrauka.

Šios medicinos priemonės SSCP žr. https://meddeviceinfo.edwards.com/.

Pradėjus veikti Europos medicinos prietaisų duomenų bazei („Eudamed"), šios medicinos priemonės SSCP žr. https://ec.europa.eu/tools/eudamed.



EC REP

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Web IFU

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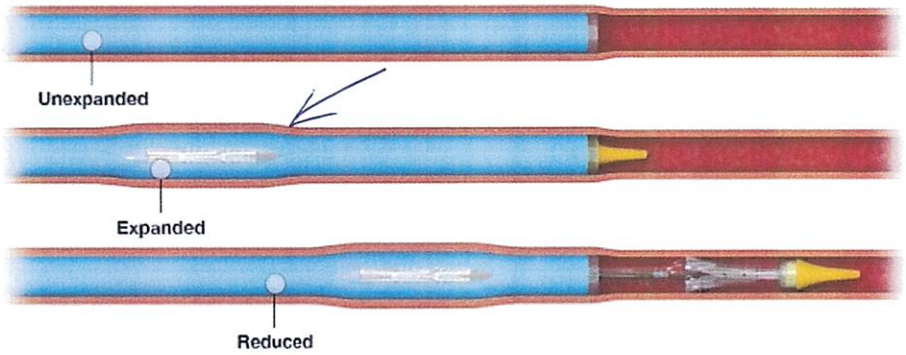
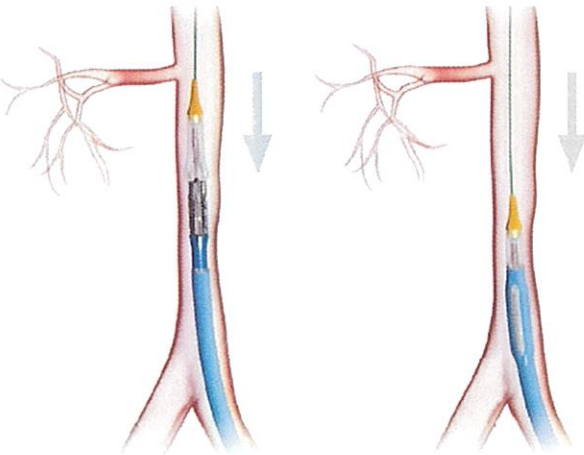
Edwards eSheath introducer set

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



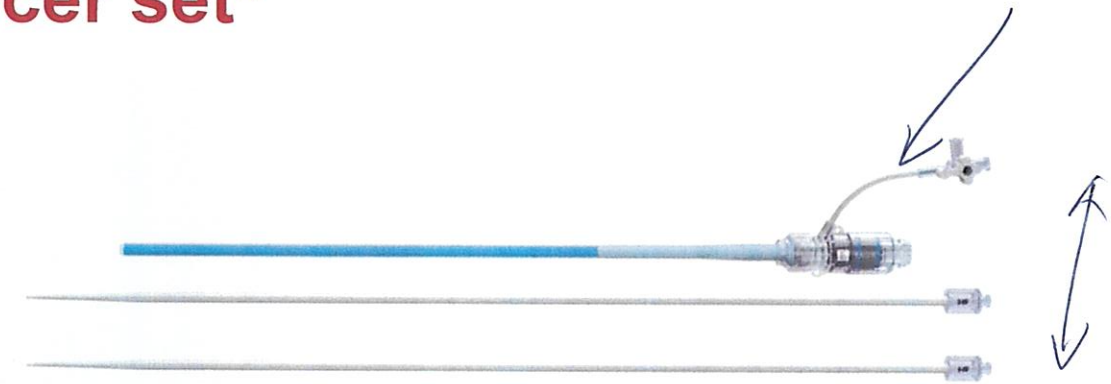


The DEM feature allows for THV retrievability[1]

[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.

Edwards eSheath introducer set*

- For 23 and 26 mm THV, no color coding for 14F sheath
- Sheath size is labeled on sheath handle
- For 29 mm THV, 16F sheath is either color coded **green** (not **orange**) or no color and sheath size is labeled on sheath handle



Note

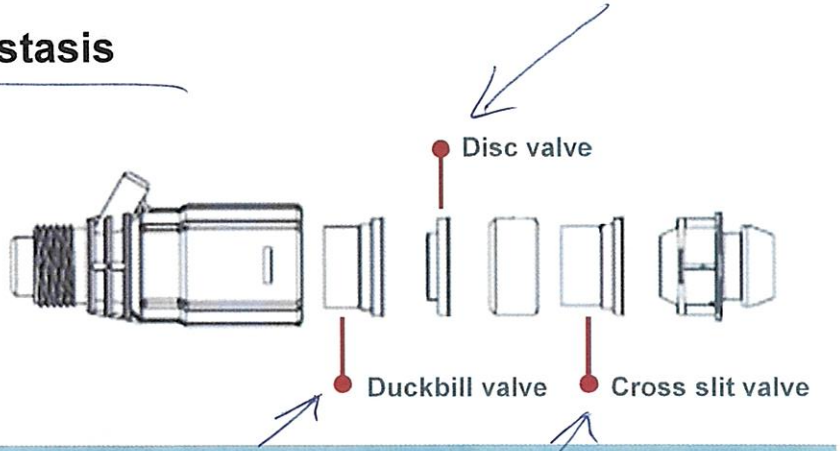
An additional dilator may or may not be included with the system for vessel dilation. If the same dilator is used for vessel dilation and sheath insertion, check to ensure dilator has not been damaged before inserting into sheath.

THV	Sheath ID (unexpanded)	Sheath OD (unexpanded)	Minimum vessel diameter
23 mm SAPIEN 3 valve	**14F (4.6 mm)**	**6.0 mm**	**5.5 mm**
26 mm SAPIEN 3 valve	**14F (4.6 mm)**	**6.0 mm**	**5.5 mm**
29 mm SAPIEN 3 valve	**16F (5.3 mm)**	**6.7 mm**	**6.0 mm**
23 mm SAPIEN XT valve	16F (5.3 mm)	6.7 mm	6.0 mm
26 mm SAPIEN XT valve	18F (5.9 mm)	7.2 mm	6.5 mm
29 mm SAPIEN XT valve	20F (6.6 mm)	8.0 mm	7.0 mm

*Refer to the IFU for any contraindications

Edwards eSheath introducer set

Tri-seal valve technology designed for hemostasis

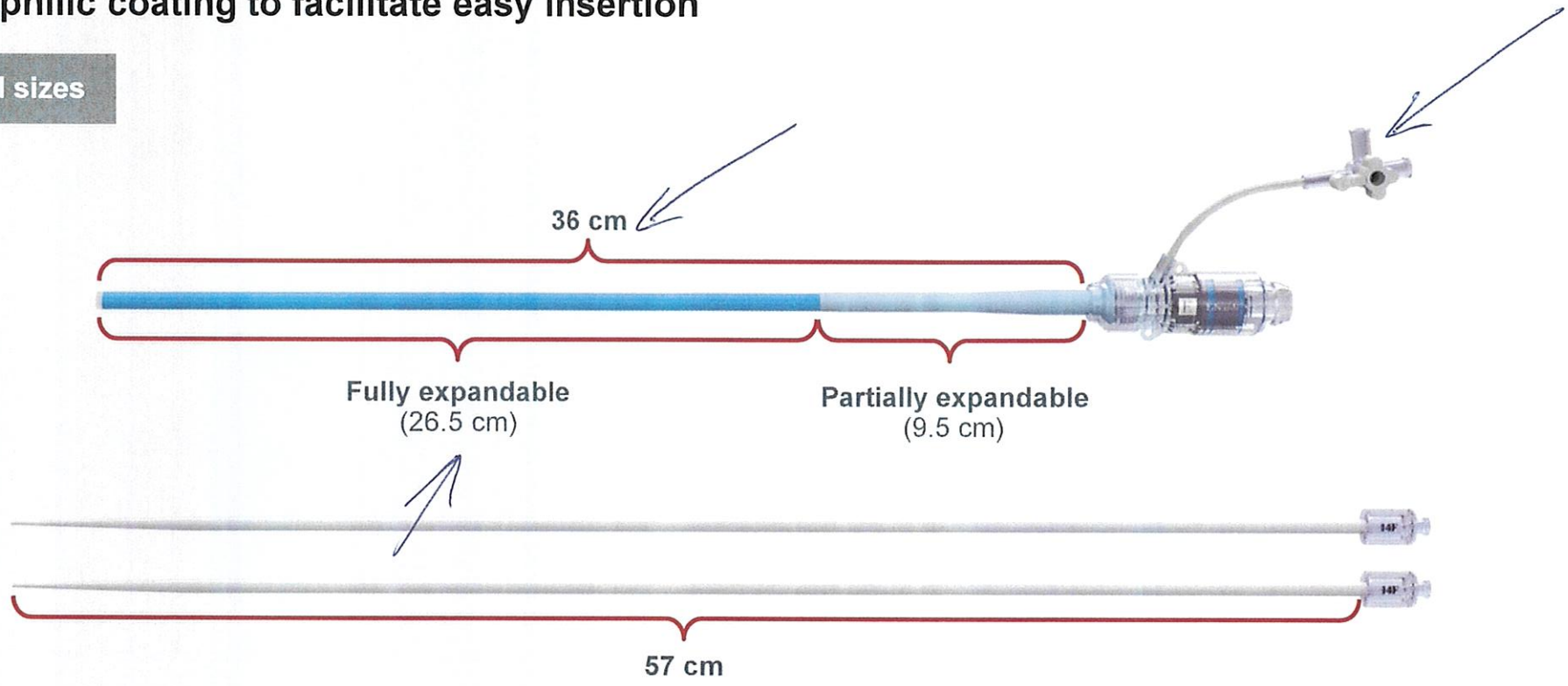


	Seal	Hemostasis
	Disc valve	Designed to provide hemostasis with a 5F or greater catheter
	Cross slit valve	Designed to provide hemostasis for guidewires ≥ 0.035"
	Duckbill valve	Designed to provide hemostasis when nothing is inside sheath

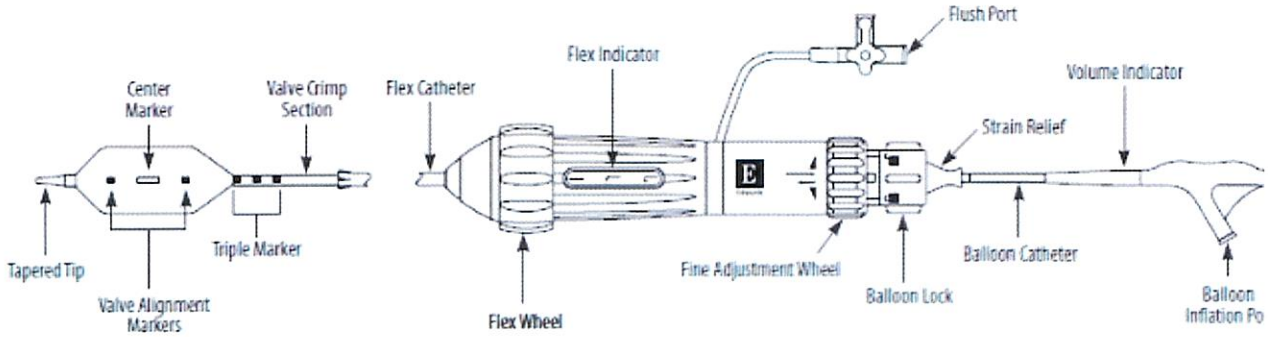
Edwards eSheath introducer set

Hydrophilic coating to facilitate easy insertion

For all sizes



Edwards

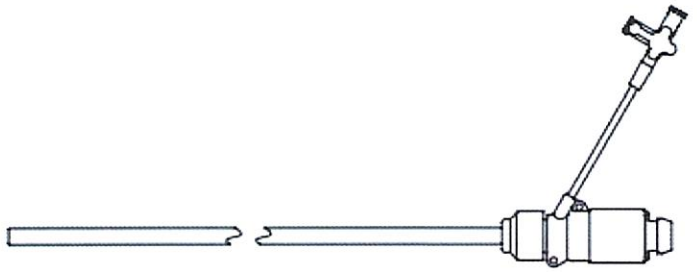


„eSheath“ įterpimo rinkinys

„Edwards eSheath“ įterpimo rinkinį sudaro:

1. Išplečiamas apvalkalas („eSheath“) leidžia patekti į tikslinę kraujagyslę, išlaikant hemostazę ir laikinai padidinti jos skersmenį, kad prietaisas galėtų lengviau praeiti.

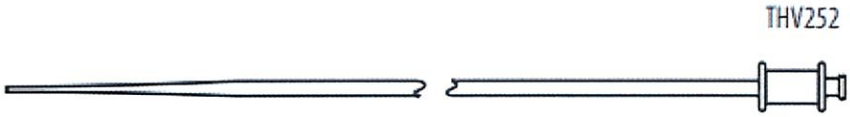
Edwards



Model	eSheath I.D. (unexpanded)	eSheath O.D. (unexpanded)
9610ES14	14F (4.6 mm)	6.0 mm
9610ES16	16F (5.3 mm)	6.7 mm

2. Du dilatatoriai su hidrofiline danga, kurie gali būti naudojami kraujagyslėms išplėsti, kad tilptų apvalkalas, ir (arba) palengvinti apvalkalo įterpimą į kraujagyslę ir jo sekimą.

„Edwards eSheath“ skirtas įtaisams, naudojamiems su „Edwards SAPIEN 3“ transkateteriniais širdies vožtuvais įdėti ir išimti.



SAPIEN 3 Valve Size	20 mm	23 mm	26 mm	29 mm
Edwards eSheath Introducer Set	14F	14F	14F	16F
Minimum Access Vessel Diameter	5.5 mm	5.5 mm	5.5 mm	6.0 mm

Kiti rinkinio komponentai

- „Qualcrimp“ žnyplių priedas (tiekiamas pakuotėje su „Edwards Commander“ tiekimo sistema) naudojamas vožtuvui užspausti/suspausti.
- Įterpimo įtaisas (tiekiamas pakuotėje su „Edwards Commander“ tiekimo sistema) naudojamas tiekimo sistemai įterpti į apvalkalą.
- „Edwards“ žnyplės sumažina vožtuvo skersmenį, kad jį būtų galima pritvirtinti prie tiekimo sistemos. Žnyples sudaro korpusas ir suspaudimo mechanizmas, kuris uždaromas ant korpuso esančia rankena. Dviejų dalių žnyplių kamštis (tiekiamas pakuotėje su „Edwards Commander“ tiekimo sistema) naudojamas vožtuvui suspausti iki numatyto skersmens.
- Išskleidimo metu naudojamas pripūtimo įtaisas su fiksavimo mechanizmu.

SAPIEN 3 Transcatheter Heart Valve

SAPIEN XT Valve

		23 mm	26 mm	29 mm
Tissue		Bovine Pericardium, ThermaFix tissue process[1]		
Frame		Cobalt-Chromium Alloy		
Native annulus size	**2D TEE diameter**	18 – 22 mm	21 – 25 mm	24 – 27 mm
	3D area	314 – 415 mm^2	415 – 530 mm^2	530 – 660 mm^2
	3D area derived diameter	20 – 23 mm	23 – 26 mm	26 – 29 mm
Crimped height		17 mm	20 mm	22 mm
Expanded height		14 mm	17 mm	19 mm
Foreshortening		3 mm	3 mm	3 mm
Inner skirt height[3]		6.7 mm	8.7 mm	11.6 mm

SAPIEN 3 Valve

		23 mm	26 mm	29 mm
Tissue		Bovine Pericardium, ThermaFix tissue process[1]		
Frame		Cobalt-Chromium Alloy		
Native annulus size	**2D TEE diameter**	18 – 22 mm	21 – 25 mm	24 – 28 mm
	3D area	338 – 430 mm^2	430 – 546 mm^2	540 – 683 mm^2
	3D area derived diameter	20.7 – 23.4 mm	23.4 – 26.4 mm	26.2 – 29.5 mm
Crimped height[(2)]		24.5 mm	27 mm	31 mm
Expanded height		18 mm	20 mm	22.5 mm
Foreshortening		6.5 mm	7 mm	8.5 mm
Inner skirt height[3]		9.3 mm	10.2 mm	11.6 mm
Outer sealing skirt height		6.6 mm	7.0 mm	8.1 mm

1 No clinical data are available with which to evaluate the long-term impact of the Carpentier-Edwards ThermaFix tissue process in patients
2 Rounded to the nearest 0.5 mm
3 Measured at bottom of zig-zag

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