Edwards eSheath+ Introducer Set
Uvajalni komplet Edwards eSheath+

Directory ■ Imenik

English

Instructions For Use

The product is intended for use by physicians trained and experienced in interventional techniques. Standard techniques for placement of vascular access sheaths should be employed.

1.0 Device Description

The Edwards eSheath+ introducer set contains:

1. an expandable sheath (eSheath+) (Fig 1) that provides access into the target vessel while maintaining hemostasis and temporarily enlarges its diameter to allow for passage of a device.
2. an introducer (Fig 2) with hydrophilic coating that is used to facilitate entry and trackability of the sheath into the vessel.
3. a dilator (Fig 3) with hydrophilic coating that is used to dilate the vessel to accommodate the sheath.
4. an expansion tool (Fig 4) that is used to pre-expand the sheath during device preparation.

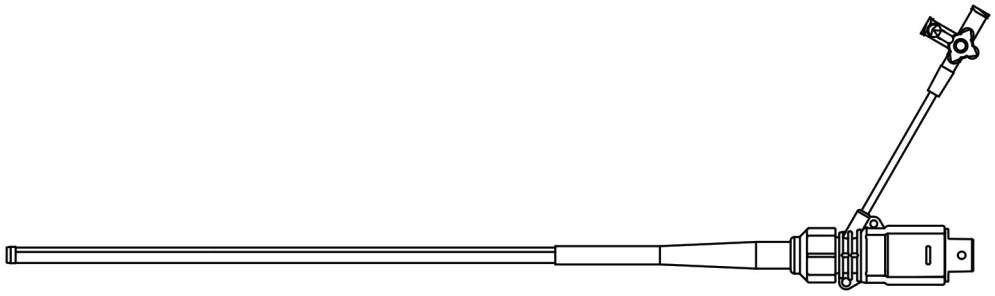


Figure 1: Sheath

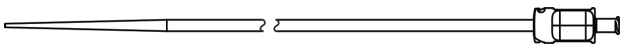


Figure 2: Introducer

Figure 3: Dilator

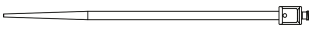


Figure 4: Expansion Tool

	914ESP	916ESP
Sheath I.D. (unexpanded)	14F (4.6 mm)	16F (5.3 mm)
Sheath O.D. (unexpanded)	6.0 mm	6.7 mm
Compatible THV	20 mm 23 mm 26 mm	29 mm
Introducer O.D.	14F	16F
Dilator O.D.	16F	18F

2.0 Intended Use

The product is intended to be used to gain access to the vasculature.

3.0 Indications

The Edwards eSheath+ introducer set is indicated for the introduction and removal of SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA transcatheter heart valve systems into the vascular system.

4.0 Contraindications

There are no known contraindications.

5.0 Warnings

The devices are designed, intended, and distributed for single use only. **Do not resterilize or reuse the devices.** There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing.

The Edwards eSheath+ introducer set must be used with a compatible 0.035 in (0.89 mm) guidewire to prevent vessel injury.

Do not mishandle the device or use it if the packaging or any components are not sterile, have been opened or are damaged (i.e., kinked or stretched, etc.), or the expiration date has elapsed.

6.0 Precautions

- Expansion tool does not contain a hydrophilic coating. Do not use as a dilator.
- The sheath temporarily enlarges to allow the passage of devices; ensure that the vasculature can accommodate the maximum diameter of the expanded sheath.
- When inserting, manipulating or withdrawing a device through the sheath, always maintain orientation of the sheath position.
- When puncturing, suturing or incising the tissue near the sheath, use caution to avoid damage to the sheath.
- Caution should be used in vessels that have diameters less than 5.5 mm or 6 mm as it may preclude safe placement of the 14F and 16F Edwards eSheath+ introducer set respectively.
- Use caution in tortuous or calcified vessels that would prevent safe entry of the introducer set.

7.0 Potential Adverse Events

Complications associated with standard catheterization and use of angiography include, but are not limited to, allergic reaction to anesthesia or to contrast media; injury including perforation or dissection of vessels; injury at the site of access that might require vessel repair; thrombosis and/or plaque dislodgment which may result in emboli formation; distal vessel obstruction; stroke; ischemia and/or death.

For a patient/user/third party in the European Economic area; if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and your national competent authority, which can be found at https://ec.europa.eu/growth/sectors/medical-devices/contacts_en.

8.0 Directions for Use

1. Visually inspect the introducer, dilator, expansion tool and sheath for surface defects and damage.
2. Flush the introducer and dilator using heparinized saline through the guidewire lumen.
3. Hydrate the length of the introducer, dilator, and sheath with heparinized saline to activate the hydrophilic coating.
4. Wet the surface of the expansion tool.
5. Flush the sheath using heparinized saline through the flush port; close the flush port.
6. Use the expansion tool to pre-expand the partially expandable portion of the sheath prior to procedural use.

   Note: After pre-expanding the sheath, inspect the length of the expandable portion for damage prior to use.
7. After removing the expansion tool, flush the sheath a second time using the heparinized saline through the flush port; close the flush port.
8. Insert the introducer completely into the sheath and turn clockwise to lock the introducer hub to the sheath hub.
9. Using standard catheterization techniques, gain access to the vessel and dilate as necessary with the dilator to accommodate the sheath.
10. Orient the sheath appropriately and maintain orientation throughout the procedure. Insert the sheath assembly using standard technique while following its progression under fluoroscopy.

    Note: The proximal tapered end of the sheath working length is larger in diameter.
11. If possible, suture the sheath into place using the suture ring(s).
12. Remove the introducer from the sheath by turning counterclockwise to unlock the introducer hub from the sheath.
13. Insert the device into the sheath.

    Note: The sheath should be intermittently flushed with heparinized saline throughout the procedure, per standard interventional technique.
14. After the completion of the procedure and removal of the device, remove the suture, and then remove the sheath entirely without torquing and do not reinsert.

9.0 How Supplied

The Edwards eSheath+ introducer set is supplied in a pouch and sterilized with ethylene oxide.

10.0 Storage

The Edwards eSheath+ introducer set should be stored in a cool, dry place.

11.0 Device Disposal

Used sheath sets may be handled and disposed of in the same manner as hospital waste and biohazardous materials. There are no special risks related to the disposal of these devices.

12.0 Hazardous Substances

This medical device does not contain hazardous substances.

13.0 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.

Refer to https://meddeviceinfo.edwards.com/ for a SSCP for this medical device.

After the launch of the European Database on Medical Devices/Eudamed, refer to https://ec.europa.eu/tools/eudamed for a SSCP for this medical device.

Slovenščina

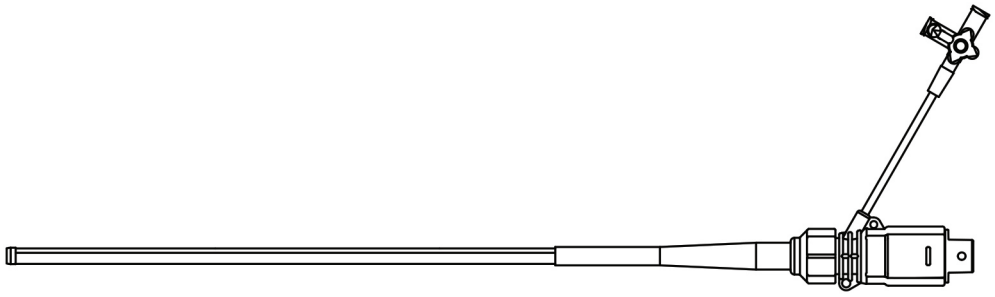
Navodila za uporabo

Izdelek je namenjen, da ga uporabljajo zdravniki, usposobljeni in izkušeni v intervencijskih tehnikah. Uporabiti je treba standardne tehnike za nameščanje vodil za vaskularni dostop.

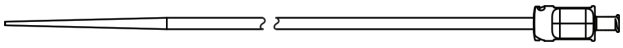
1.0 Opis pripomočka

Uvajalni komplet Edwards eSheath+ vsebuje:

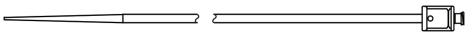
1. razširljivo vodilo (eSheath+) (slika 1) za dostop v ciljno žilo ob vzdrževanju hemostaze, hkrati pa začasno poveča premer žile, da se omogoči prehod pripomočka,
2. uvajalo (slika 2) s hidrofilno prevleko, ki se uporablja za pomoč pri uvajanju in sledenju vodila v žili;
3. dilatator (slika 3) s hidrofilno prevleko, ki se uporablja za razširitev žile, ki omogoča vstavitev vodila;
4. razširitveno orodje (slika 4), ki se uporablja za predhodno razširitev vodila med pripravo pripomočka.



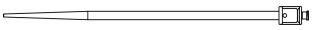
Slika 1: Vodilo



Slika 2: Uvajalo



Slika 3: Dilatator



Slika 4: Razširitveno orodje

	914ESP	916ESP
Vodilo I.D. (nerazširjeno)	14F (4,6 mm)	16F (5,3 mm)
Vodilo O.D. (nerazširjeno)	6,0 mm	6,7 mm
Združljivi THV	20 mm 23 mm 26 mm	29 mm
Uvajalo O.D.	14F	16F
Dilatator O.D.	16F	18F

2.0 Predvidena uporaba

Izdelek je namenjen za dostop do žilja.

3.0 Indikacije

Uvajalni komplet Edwards eSheath+ je indiciran za uvajanje sistemov transkatetrskih srčnih zaklopk SAPIEN 3, SAPIEN 3 Ultra in SAPIEN 3 Ultra RESILIA v žilni sistem oziroma odstranjevanje iz njega.

4.0 Kontraindikacije

Ni znanih kontraindikacij.

5.0 Opozorila

Pripomočki so zasnovani, predvideni in distribuirani samo za enkratno uporabo. **Pripomočkov ne sterilizirajte ali uporabite znova.** Podatkov za podporo sterilnosti, apirogenosti in funkcionalnosti pripomočkov po ponovni obdelavi ni.

Uvajalni komplet Edwards eSheath+ je treba uporabiti z združljivo 0,035 palci (0,89 mm) vodilno žico za preprečitev poškodb žil.

Pripomočka ne uporabljajte napačno oziroma ga ne uporabljajte, če ovojnina ali katere koli komponente niso sterilne, so odprte ali poškodovane (tj. zvite ali raztegnjene) ali jim je potekel rok uporabnosti.

6.0 Previdnostni ukrepi

- Razširitveno orodje ne vsebuje hidrofilne obloge. Ne uporabljajte ga kot dilatator.
- Vodilo se začasno poveča, da omogoči prehod pripomočkov; poskrbite, da bo žilje ustrezne velikosti za največji premer razširjenega vodila.
- Pri vstavljanju, premikanju ali odstranjevanju pripomočka skozi vodilo vedno vzdržujte usmerjenost položaja vodila.
- Pri punkciji, šivanju ali rezanju tkiva v bližini vodila bodite previdni, da preprečite poškodbe vodila.
- Pri žilah s premerom, manjšim od 5,5 mm ali 6 mm, morate biti previdni, saj lahko to prepreči varno namestitev uvajalnih kompletov Edwards eSheath+ velikosti 14 F in 16 F.
- Pri vijugastih ali kalcificiranih žilah, ki preprečujejo varen vstop uvajalnega kompleta, bodite previdni.

7.0 Možni neželeni dogodki

Zapleti, povezani s standardno kateterizacijo in uporabo angiografije, vendar niso omejeni na alergijsko reakcijo na anestezijo ali kontrastno sredstvo; poškodbe, ki vključujejo perforacijo ali disekcijo žile; poškodbe na dostopnem mestu, zaradi česar je lahko potrebna reparacija žile; tromboza in/ali premik lehe, ki lahko povzroči nastanek embolusov; zamašitev distalne žile; možgansko kap; ishemijo in/ali smrt.

Pri bolnikih/uporabnikih/tretjih osebah v Evropskem gospodarskem prostoru: če med uporabo tega pripomočka ali kot posledica njegove uporabe pride do resnega incidenta, o njem poročajte proizvajalcu in državnemu pristojnemu organu, ki ga najdete na spletnem mestu https://ec.europa.eu/growth/sectors/medical-devices/contacts_en.

8.0 Smernice za uporabo

1. Vizualno preglejte uvajalnik, dilatator, orodje za razširitev in vodilo glede okvar površine in poškodb.
2. Splaknite uvajalnik in dilatator z uporabo heparinizirane fiziološke raztopine skozi svetlino vodilne žice.
3. Hidrirajte dolžino uvajalnika, dilatatorja in vodila s heparinizirano fiziološko raztopino, da aktivirate hidrofilno prevleko.
4. Navlažite površino orodja za razširitev.
5. Splaknite vodilo s heparinizirano fiziološko raztopino skozi vhod za splakovanje; zaprite vhod za splakovanje.
6. Uporabite orodje za razširitev, da predhodno razširite delno razširljivi del vodila pred uporabo za poseg.

   Opomba: Po predhodni razširitvi vodila pred uporabo preglejte dolžino razširljivega dela glede poškodb.
7. Po odstranitvi orodja za razširitev znova splaknite vodilo s heparinizirano fiziološko raztopino skozi vhod za splakovanje; zaprite vhod za splakovanje.
8. Povsem vstavite uvajalnik v vodilo in ga zavrtite v smeri urnega kazalca, da pritrdite zvezdišče uvajalnika na zvezdišče vodila.
9. Z uporabo standardnih tehnik katetrizacije pridobite dostop do žile in po potrebi razširite z dilatatorjem, da prilagodite vodilo.
10. Ustrezno poravnajte vodilo in ohranite poravnanost med celotnim posegom. Vstavite sklop vodila s standardno tehniko, pri tem pa s fluoroskopijo sledite njegovemu napredovanju.

    Opomba: Proksimalna zašiljena konica delovne dolžine vodila ima večji premer.
11. Če je mogoče, zašijte vodilo na mestu z uporabo šivalnih obročev.
12. Odstranite uvajalnik iz vodila z vrtenjem v nasprotni smeri urnega kazalca, da odklenete zvezdišče uvajalnika z vodila.
13. Vstavite pripomoček v vodilo.

    Opomba: Vodilo je treba občasno splakovati s heparinizirano fiziološko raztopino med posegom s standardno intervencijsko tehniko.
14. Po končanem posegu in odstranitvi pripomočka odstranite šive, nato pa povsem odstranite vodilo brez navijanja in ga ne vstavljajte znova.

9.0 Kako je dobavljeno

Uvajalni komplet Edwards eSheath+ je dobavljen v vrečki in steriliziran z etilenoksidom.

10.0 Shranjevanje

Uvajalni komplet Edwards eSheath+ je treba hraniti na hladnem in suhem mestu.

11.0 Odlaganje pripomočka med odpadke

S kompleti vodil je treba ravnati in jih zavreči na enak način kot bolnišnični odpad in biološko nevarne materiale. Odlaganje teh pripomočkov ne vključuje posebnih tveganj.

12.0 Nevarne snovi

Ta medicinski pripomoček ne vsebuje nevarnih snovi.

13.0 Povzetek varnosti in klinične učinkovitosti (SSCP)

Dokument SSCP je skladen s klinično oceno priglašenega organa, na podlagi katere je bil podeljen certifikat za oznako CE. Dokument SSCP vsebuje ustrezen povzetek istih informacij.

Glejte https://meddeviceinfo.edwards.com/ za SSCP za ta medicinski pripomoček.

Po uvedbi Evropske baze podatkov o medicinskih pripomočkih/Eudamed glejte https://ec.europa.eu/tools/eudamed za SSCP za ta medicinski pripomoček.

Symbol Legend ■ Legenda simbolov

	English	Slovenščina
REF	Reorder Number	Številka za ponovno naročanje
#	Model Number	Številka modela
cm	Usable length	Uporabna dolžina
	Do not re-use	Ne uporabite znova
LOT	Lot Number	Številka serije
	Caution	Svarilo
	Consult instructions for use	Sledite navodilom za uporabo
eifu.edwards.com +1 888 570 4016	Consult instructions for use on the website	Sledite navodilom za uporabo na spletnem mestu
	Do not use if package is damaged and consult instructions for use	Ne uporabljajte, če je embalaža poškodovana, in preberite navodila za uporabo
	Exterior diameter	Zunanji premer
	Inner diameter	Notranji premer
	Store in a cool, dry place	Shranjujte na hladnem in suhem mestu.
	Keep dry	Ohranite suho
	Keep away from sunlight	Ne izpostavljajte sončnemu sevanju
UDI	Unique Device Identifier	Edinstveni identifikator pripomočka
	Temperature limit	Mejna temperatura
STERILE	Sterile	Sterilno
STERILE EO	Sterilized using ethylene oxide	Sterilizirano z etilen oksidom

	English	Slovenščina
STERILE R	Sterilized using irradiation	Sterilizirano z obsevanjem
STERILIZE	Do not resterilize	Ne sterilizirajte znova
eSheath	eSheath compatibility	Združljivost eSheath
eSheath™	eSheath compatibility	Združljivost eSheath
	Single sterile barrier system	Sistem z enojno sterilno pregrado
	Single sterile barrier system with protective packaging inside	Sistem enojne sterilne pregrade z notranjo zaščitno embalažo
QTY	Quantity	Količina
	Use-by date	Rok trajanja
SN	Serial Number	Serijska številka
	Manufacturer	Proizvajalec
	Date of manufacture	Datum proizvodnje
EC REP	Authorized representative in the European Community/ European Union	Pooblaščeni zastopnik v Evropski skupnosti/ Evropski uniji
GWC	Guidewire compatibility	Združljivost vodilne žice
NP	Nominal Pressure	Nazivni tlak
RBP	Rated burst pressure	Nazivni razpočni tlak
	Recommended guidewire length	Priporočena dolžina vodilne žice
Sheath	Minimum sheath size	Minimalna velikost vodila
Catheter	Catheter shaft size	Velikost ovojnice katetra

	English	Slovenščina
	Importer	Uvoznik
	Balloon diameter	Premer balona
	Balloon working length	Delovna dolžina balona
20 mm	For use with size 20 mm Edwards transcatheter heart valve	Za uporabo s transkatetrsko srčno zaklopko Edwards velikosti 20 mm
23 mm	For use with size 23 mm Edwards transcatheter heart valve	Za uporabo s transkatetrsko srčno zaklopko Edwards velikosti 23 mm
26 mm	For use with size 26 mm Edwards transcatheter heart valve	Za uporabo s transkatetrsko srčno zaklopko Edwards velikosti 26 mm
29 mm	For use with size 29 mm Edwards transcatheter heart valve	Za uporabo s transkatetrsko srčno zaklopko Edwards velikosti 29 mm
MR	MR Conditional	Pogojno uporabno v MR okolju
	Contents	Vsebine
	Non-pyrogenic	Apirogeno
MD	Medical device	Medicinski pripomoček
BIO	Contains biological material of animal origin	Vsebuje biološki material živalskega izvora
Rx only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Time & Temperature Sensitive	Občutljivo na čas in temperaturo
	Contains hazardous substances	Vsebuje nevarne snovi
SZ	Size	Velikost

Note: Not all symbols may be included in the labeling of this product. ■ **Opomba:** Pri označevanju tega izdelka morda niso vključeni vsi simboli.

EC REP

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