

Evolut™ PRO+ SYSTEM COMPATIBILITY

Pilnai sukomplektuotas rinkinys -
savaimė išsiplečiantis vožtuvas su jo
įvedimo sistema, implantavimui aortos
vožtuvo pozicijoje.



Evolut PRO+
23 mm valve

EVPROPLUS-23



Evolut PRO+
26 mm valve

EVPROPLUS-26



Evolut PRO+
29 mm valve

EVPROPLUS-29



Evolut PRO+
34 mm valve

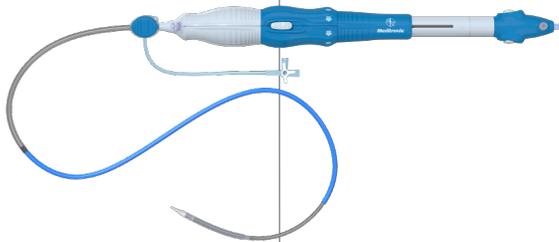
EVPROPLUS-34



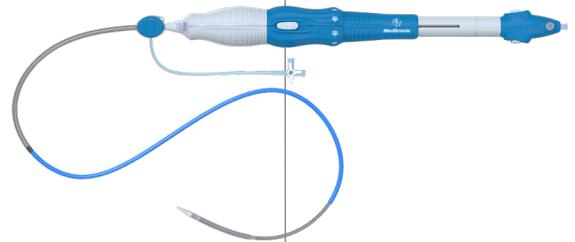
L-EVPROP23-29



L-EVPROP34



D-EVPROP23-29



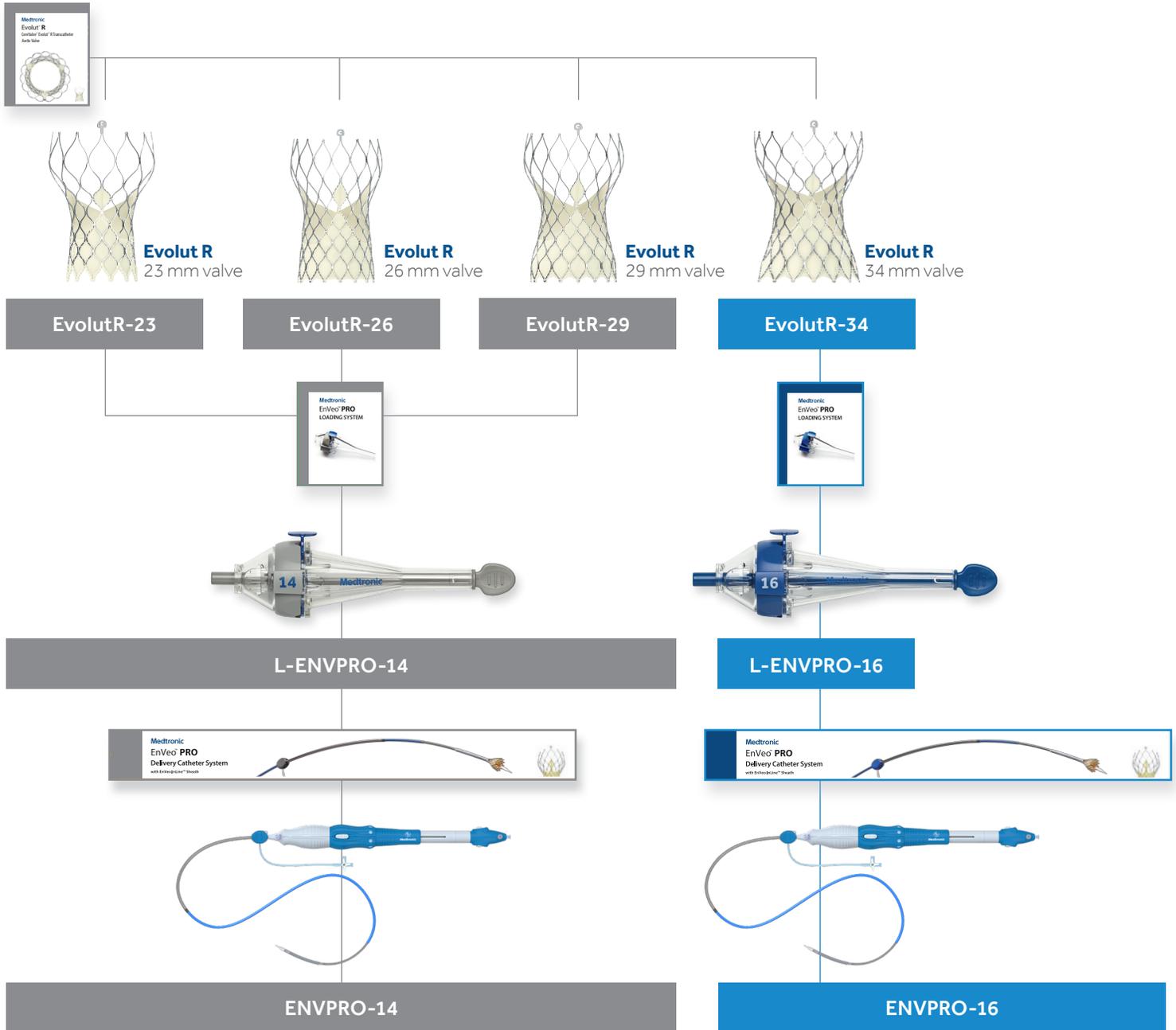
D-EVPROP34

All items shown are single-use.
Refer to Instructions for Use for a complete list of warnings, precautions, indications, and contraindications.

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Evolut™ R SYSTEM COMPATIBILITY

Pilnai sukomplektuotas rinkinys - savaime išsiplečiantis vožtuvas su jo įvedimo sistema, implantavimui aortos vožtuvo pozicijoje.



All items shown are single-use.

CAUTION: For distribution only in markets where CoreValve™ Evolut™ R and Evolut™ PRO+ Systems are approved.

See the CoreValve™ Evolut™ R, the CoreValve™ Evolut™ PRO and the the Evolut™ PRO+ device manuals for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu.

For applicable products, consult instructions for use on manuals.medtronic.com. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

The commercial name of the Evolut™ R device is Medtronic CoreValve™ Evolut™ R System, the commercial name of the Evolut™ PRO device is Medtronic CoreValve™ Evolut™ PRO System, and the commercial name of the Evolut™ PRO+ device is Medtronic Evolut™ PRO+ System.

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UC202002162 EE 04/2021

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PRODUCT SPECIFICATIONS

Evolut™ PRO+ TAVI

BIOPROSTHESIS



Evolut PRO+
23 mm Valve

Model Number:
EVPROPLUS-23

Size: 23 mm

Aortic annulus
diameter:
18-20 mm



Evolut PRO+
26 mm Valve

Model Number:
EVPROPLUS-26

Size: 26 mm

Aortic annulus
diameter:
20-23 mm



Evolut PRO+
29 mm Valve

Model Number:
EVPROPLUS-29

Size: 29 mm

Aortic annulus
diameter:
23-26 mm



Evolut PRO+
34 mm Valve

Model Number:
EVPROPLUS-34

Size: 34 mm

Aortic annulus
diameter:
26-30 mm

LOADING SYSTEM



Evolut PRO+
Loading System

Model Number:
L-EVPROP23-29

23, 26, and 29 mm TAV



Evolut PRO+
Loading System

Model Number:
L-EVPROP34

34 mm TAV

All items above are single-use. Refer to Instructions for Use for a complete list of warnings, precautions, and contraindications.

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DELIVERY CATHETER SYSTEM

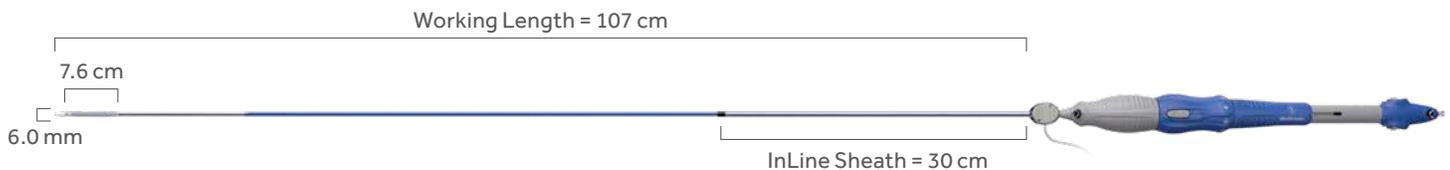
Evolut PRO+

Delivery Catheter System with InLine Sheath

14 Fr Equivalent (6.0 mm Capsule Outer Diameter)

Model Number:
D-EVPROP23-29

23, 26, and 29 mm TAV



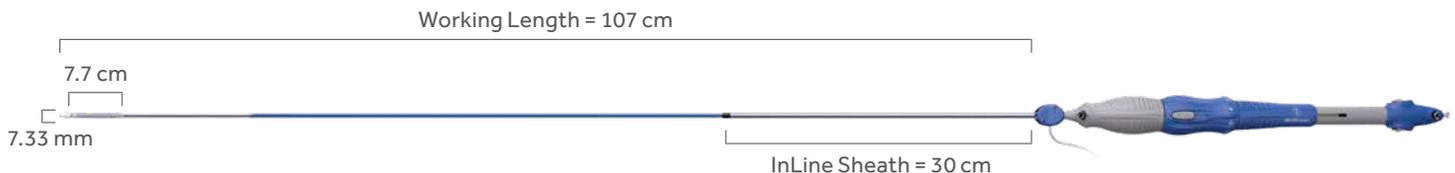
Evolut PRO+

Delivery Catheter System with InLine Sheath

18 Fr Equivalent (7.33 mm Capsule Outer Diameter)

Model Number:
D-EVPROP34

34 mm TAV



CAUTION: For distribution only in markets where Evolut™ PRO+ System is approved.

See the CoreValve™ Evolut™ R, the CoreValve™ Evolut™ PRO and the the Evolut™ PRO+ device manuals for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu. For applicable products, consult instructions for use on manuals.medtronic.com. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser. The commercial name of the Evolut™ R device is Medtronic CoreValve™ Evolut™ R System, the commercial name of the Evolut™ PRO device is Medtronic CoreValve™ Evolut™ PRO System, and the commercial name of the Evolut™ PRO+ device is Medtronic Evolut™ PRO+ System.

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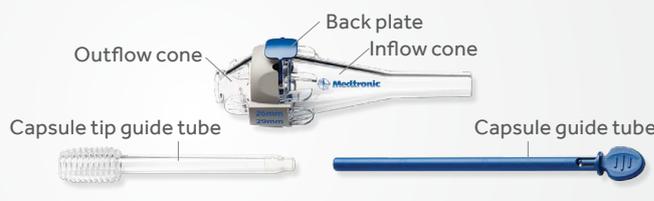


PRODUCT SPECIFICATIONS

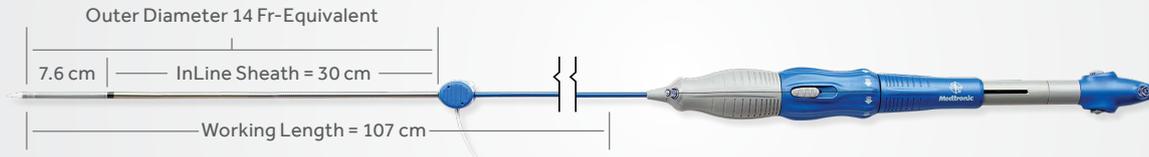
Product Specifications | CoreValve Evolut R System

CoreValve Evolut R 23, 26, 29 mm

 <p>Model Number: EvolutR-23 Size: 23 mm Aortic Annulus Diameter: 18-20 mm</p> <p>USE WITH</p>	 <p>Model Number: EvolutR-26 Size: 26 mm Aortic Annulus Diameter: 20-23 mm</p> <p>USE WITH</p>	 <p>Model Number: EvolutR-29 Size: 29 mm Aortic Annulus Diameter: 23-26 mm</p> <p>USE WITH</p>
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<h3>EnVeo™ R Loading System</h3>  <p>Model Number: LS-EnVeoR23</p> <p>USE WITH</p>	<h3>EnVeo R Loading System</h3>  <p>Model Number: LS-EnVeoR2629</p> <p>USE WITH</p>
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EnVeo R Delivery Catheter System with EnVeo R InLine™ Sheath



Outer Diameter 14 Fr-Equivalent

7.6 cm | InLine Sheath = 30 cm

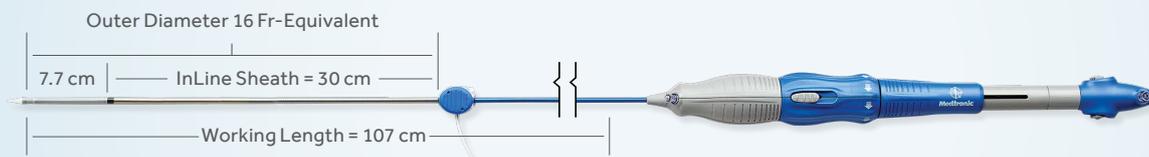
Working Length = 107 cm

Model Number: EnVeoR-L

Product Specifications | CoreValve Evolut R 34 mm System

<h3>CoreValve Evolut R 34 mm</h3>  <p>Model Number: EvolutR-34 Size: 34 mm Aortic Annulus Diameter: 26-30 mm</p> <p>USE WITH</p>	<h3>EnVeo R Loading System</h3>  <p>Model Number: LS-EnVeoR-34</p> <p>USE WITH</p>
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EnVeo R Delivery Catheter System with InLine Sheath



Outer Diameter 16 Fr-Equivalent

7.7 cm | InLine Sheath = 30 cm

Working Length = 107 cm

Model Number: EnVeoR-N

All items above are single-use. Refer to Instructions for Use for a complete list of warnings, precautions and contraindications.

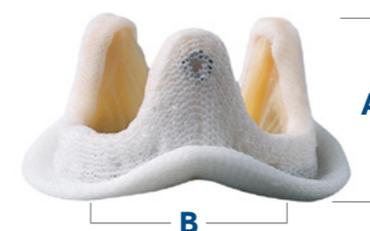
MEDTRONIC TRANSCATHETER AORTIC VALVE

**Corresponding Medtronic TAVR Valve

Anatominiai parametrai, kuriuos vožtuvas padengia:
natyvinio vožtuvo diametras - 17-30 mm;
natyvinio vožtuvo perimetras - 53,4-94,2 mm.

Vožtuvo diametrai:
23, 26, 29 ir 34 mm.

	Valve Size	Aortic Annulus Measurements		Sinus of Valsalva Diameter	Sinus of Valsalva Height
		Diameter	Perimeter		
Evolut™ PRO and Evolut™ R Valves	23 mm	17 [‡] /18 mm–20 mm	53.4 [‡] /56.5 mm–62.8 mm	≥ 25 mm	≥ 15 mm
	26 mm	20 mm–23 mm	62.8 mm–72.3 mm	≥ 27 mm	≥ 15 mm
	29 mm	23 mm–26 mm	72.3 mm–81.7 mm	≥ 29 mm	≥ 15 mm
Evolut™ R Valve	34 mm	26 mm–30 mm	81.7 mm–94.2 mm	≥ 31 mm	≥ 16 mm



A = Valve Height
B = Inner Diameter/Manufacture's Inside Diameter

Other dimensions and imagery need to be considered when determining valve size.

[‡]Measurement for TAV-in-SAV only.

**NOTE: Diameter refers to in vitro inside diameter of the respective bioprosthesis stent and excludes the xenograft tissue inside of the stent. The values noted here are reported by the respective manufacturers.¹⁻¹⁶ The dimensions of SAVs can change in vivo requiring multiple considerations for the physician to make an informed decision of what appropriate Medtronic TAVR valve size to use for TAV-in-SAV. These considerations include identification of the SAV, determination of the manufacturer's inside diameter, CT estimated measurement of the SAV's annulus dimensions and patient specifics as outlined in the Best Practices. Medtronic TAVR valve implant depth: 3–5 mm.

This information is not intended to constitute medical advice, but rather information for the physician to use in making a decision in how to best treat their patient. Sizing for use of a transcatheter aortic valve in a degenerative surgical bioprosthesis requires multiple considerations e.g., both in-vitro and in-vivo data including the failed bioprosthesis and the physician's imaging based patient measurements. The final size determination may vary based upon the unique clinical characteristics and scenario of each patient.

Home

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Stented Bioprostheses

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Stentless Bioprostheses

Edwards
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St. Jude Medical
Stented Bioprostheses

Sorin
Stented Bioprostheses

Corresponding
Medtronic TAVR
Valve Chart



PRODUCT SPECIFICATIONS

Ivedimo sistemos diametrai: 16F 23-29 mm
vožtuvams.

Bioprosthesis

Evolut™ PRO 23 mm Valve



Model Number:
EvolutPRO-23

Size: 23 mm
Aortic Annulus
Diameter:
18-20 mm

Evolut PRO 26 mm Valve



Model Number:
EvolutPRO-26

Size: 26 mm
Aortic Annulus
Diameter: 20-23 mm

Evolut PRO 29 mm Valve



Model Number:
EvolutPRO-29

Size: 29 mm
Aortic Annulus
Diameter: 23-26 mm

Evolut™ R 34 mm Valve



Model Number:
EvolutR-34

Size: 34 mm
Aortic Annulus
Diameter: 26-30 mm

Loading System

EnVeo™ PRO Loading System 23 mm TAV



Model Number: L-ENVPRO-1623

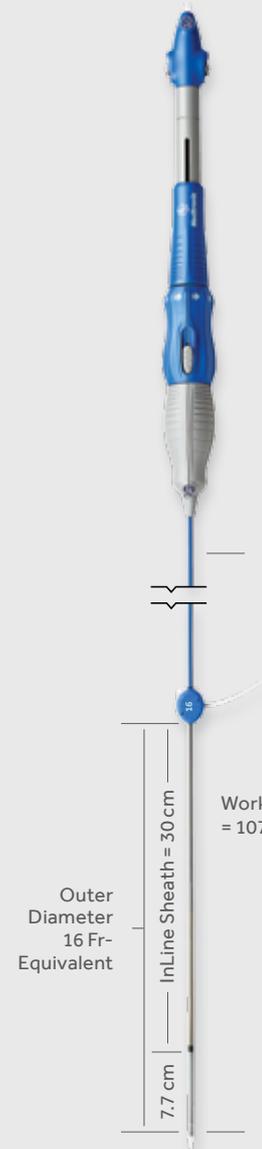
EnVeo PRO Loading System Evolut PRO 26, 29 mm TAV Evolut R 34 mm TAV



Model Number: L-ENVPRO-16

Catheter

EnVeo PRO Delivery Catheter System with InLine Sheath 16Fr Equivalent



Model Number: ENVPRO-16

Ivedimo sistemos diametrai: 16F 34 mm
vožtuvams.

Bioprosthesis

Evolut R 23 mm Valve



Model Number:
EvolutR-23

Size: 23 mm
Aortic Annulus
Diameter:
18-20 mm

Evolut R 26 mm Valve



Model Number:
EvolutR-26

Size: 26 mm
Aortic Annulus
Diameter: 20-23 mm

Evolut R 29 mm Valve



Model Number:
EvolutR-29

Size: 29 mm
Aortic Annulus
Diameter: 23-26 mm

Loading System

EnVeo PRO Loading System

23, 26, 29 mm TAV



Model Number: L-ENVPRO-14

Catheter

EnVeo PRO Delivery Catheter System with InLine Sheath

14 Fr Equivalent



Outer
Diameter
14 Fr-
Equivalent

InLine Sheath = 30 cm

Working Length
= 107 cm

7.6 cm

Model Number: ENVPRO-14

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