PHILIPS

Duo Venous Stent System

Duo Hybrid and Duo Extend

Distinctly different Duo

Duo Hybrid features a distinct integrated design that uniquely combines crush resistance and flexibility into one stent.

Introducing Philips Duo Venous Stent System – Duo Hybrid and Duo Extend

Engineered for greater crush resistance and flexibility, Duo Venous Stent System is built to address the multiple anatomical challenges of the deep venous system and includes two stents – Duo Hybrid and Duo Extend.[1]

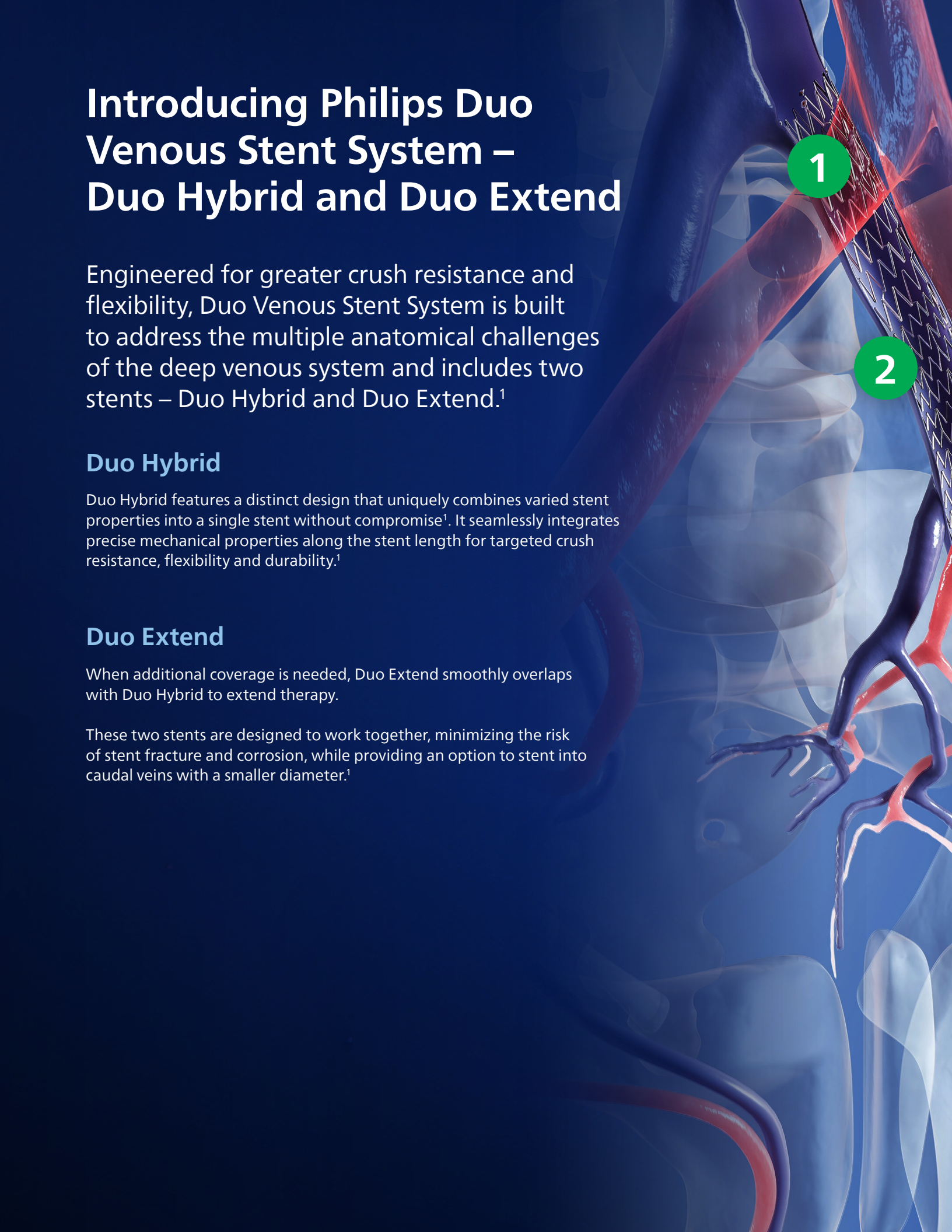
Duo Hybrid

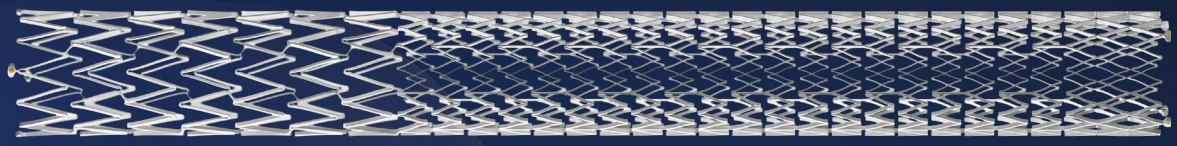
Duo Hybrid features a distinct design that uniquely combines varied stent properties into a single stent without compromise[1]. It seamlessly integrates precise mechanical properties along the stent length for targeted crush resistance, flexibility and durability.[1]

Duo Extend

When additional coverage is needed, Duo Extend smoothly overlaps with Duo Hybrid to extend therapy.

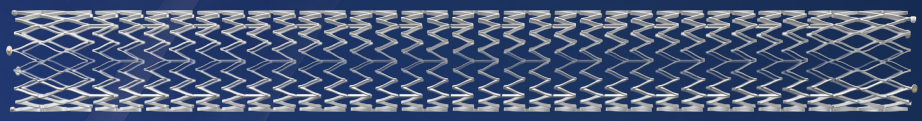
These two stents are designed to work together, minimizing the risk of stent fracture and corrosion, while providing an option to stent into caudal veins with a smaller diameter.[1]





Duo Hybrid key features

1. High crush resistant segment is designed to resist compression from overlapping arteries
2. Gradual transition segment leads to a highly flexible segment
3. Highly flexible segment provides both strength and flexibility



Duo Extend key features

4. Overlap segment is configured to overlap with Duo Hybrid
5. Highly flexible segment is designed to mitigate kinks during deep knee and hip flexion
6. Inflow reinforcement designed to maintain the cross-sectional area to optimize blood flow

VIVID study clinical evidence[2]

Venous stent for the Iliofemoral Vein Investigational clinical trial using the Duo Venous Stent System

Duo Venous Stent System offers the ability to treat a broad range of patients with Chronic venous insufficiency (CVI) — from simple to complex lesions.

Study design and purpose

- Global, prospective, multi-center, single-arm, non-blinded study
- Evaluate the safety and effectiveness of the Philips Duo Venous Stent System, intended for the treatment of symptomatic iliofemoral venous outflow obstruction

Patients and enrollment

- 162 patients with 219 lesions
- Prospectively enrolled for nonthrombotic iliac vein lesion (NIVL), postthrombotic syndrome (PTS) and acute deep vein thrombosis (aDVT) disease states

1 Primary endpoints

Primary effectiveness endpoint

90.2%

primary patency at 12 months

Primary patency performance goal was met

Primary safety endpoint

98.7%

30-day freedom from MAE

Primary safety endpoint goal was met

Primary patency by patient population at 12 months

87% aDVT

95% NIVL

79% PTS

2 Secondary endpoints at 12 months

0 stent fractures

0 stent migration

100% procedural success

Sustained improvements in functional and quality of life metrics

Reduced

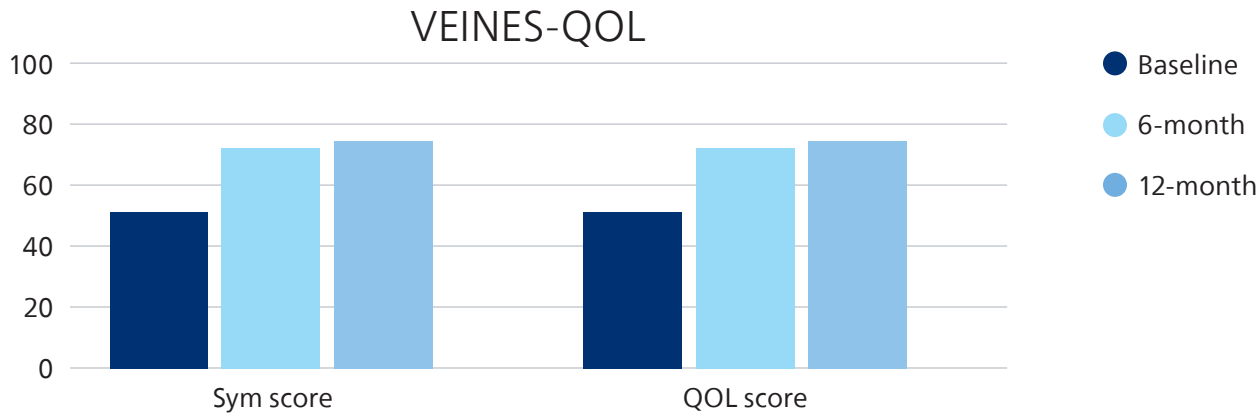
Substantial reduction in pain and PTS symptoms at 6 months and sustained to 12 months

- Mean Villalta score from 10 (mild/moderate symptoms) to 3 (no symptoms)
- VCSS Pain score from 2 to 0.5

Improved

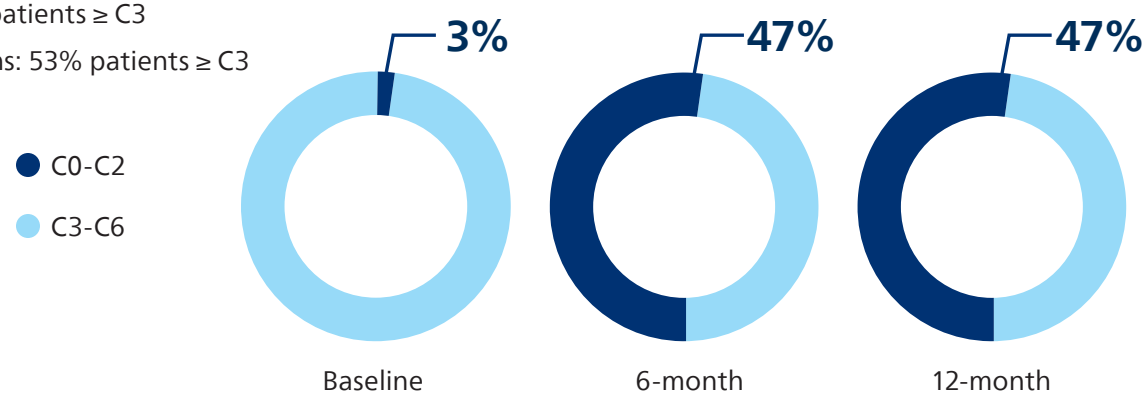
Improved quality of life compared to baseline

- EQ-5D-3L improvements across all indexes
- VEINES improvement across both indices by 6 months



Improved CEAP classification by 6 months

- Baseline: 97% patients ≥ C3
- 6 and 12 months: 53% patients ≥ C3

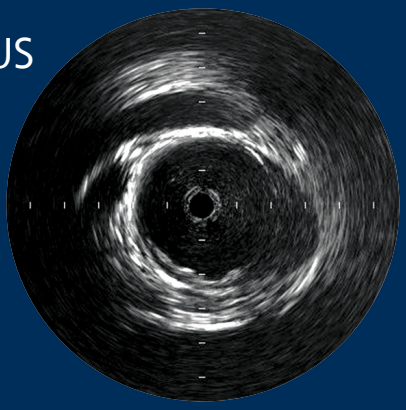


See clearly. Stent confidently with IVUS.

Only Philips offers the powerful combination of IVUS expertise and a distinct venous stent portfolio designed for the multiple anatomical challenges of deep venous anatomy.

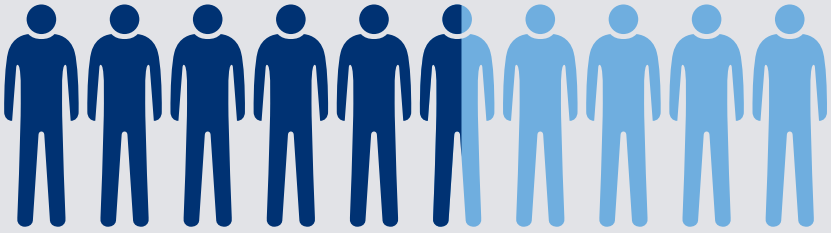
IVUS is critical in accurately assessing the vessel to determine optimal patient care. IVUS can help identify if there is a need for a stent, the size and location for the stent, as well as evaluate lumen gain post stenting.

IVUS correlated to a **28%**



reduction in repeat venous interventions, hospitalization or death in a study over 20,000 deep venous interventions[3]

IVUS changed **57%**



of venous treatment plans[4]

Distribution of treatment plan changes in 57 of 100 patients

35 patients
changed plan from no treatments to stent placement

13 patients
changed number of stents planned

6 patients
changed plan from no treatment to other intervention

3 patients
changed plan from treatment to no treatment

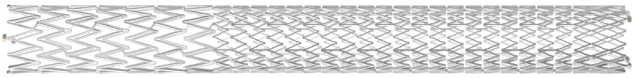
IVUS gives you the visualization you need to see clearly and stent confidently.

Your versatile solution for deep venous disease

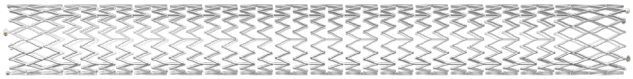
Duo Hybrid and Duo Extend are mounted on a familiar triaxial delivery platform. The combination of precise deployment, minimal foreshortening, and radiopaque markers that aid visualization under fluoroscopy, make delivery of the stents easy to plan and execute.[1]

Product specifications

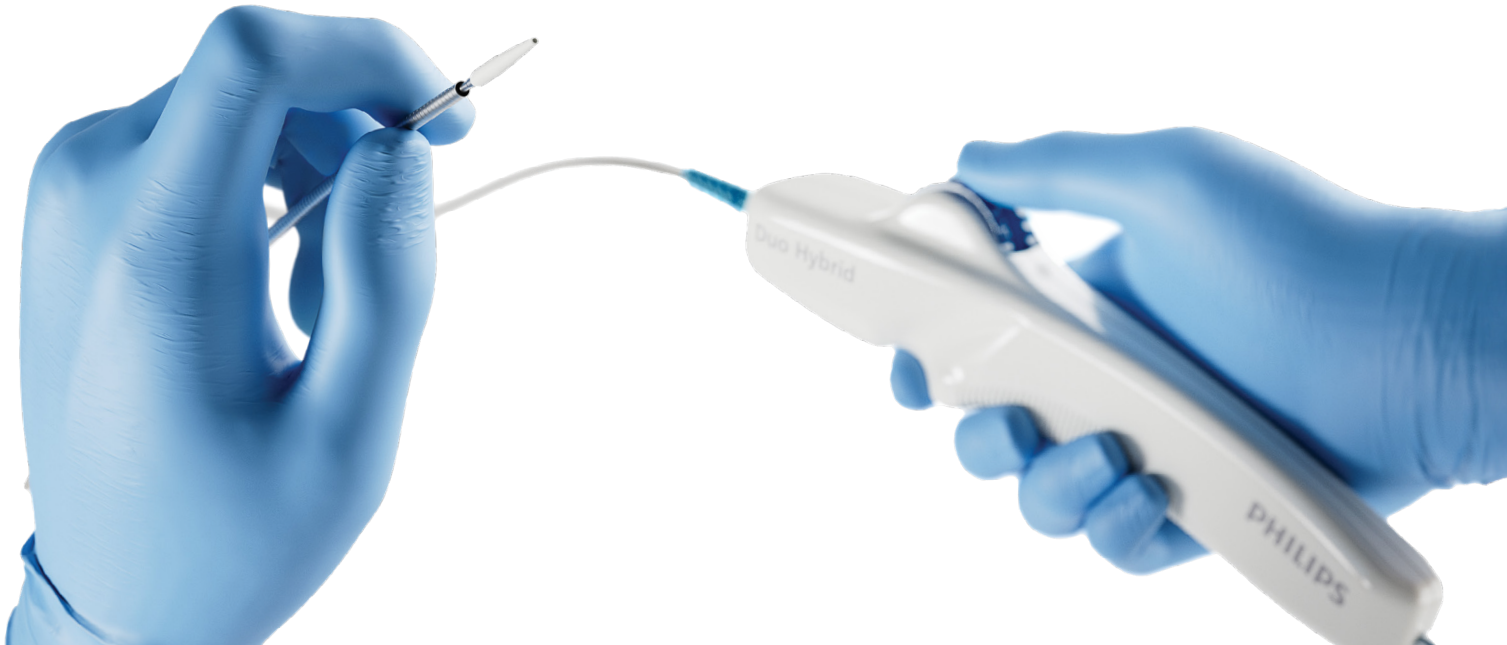
The triaxial, over-the-wire delivery system is 0.035" guidewire compatible and is available in 120 cm catheter length



Duo Hybrid	Lengths (mm)					
Diam (mm)	**60**	**80**	**100**	**120**	**140**	**160**
12	9 Fr	9 Fr	9 Fr	9 Fr	9 Fr	9 Fr
14	9 Fr	9 Fr	9 Fr	9 Fr	9 Fr	9 Fr
16	10 Fr	10 Fr	10 Fr	10 Fr	10 Fr	10 Fr
18	10 Fr	10 Fr	10 Fr	10 Fr	10 Fr	10 Fr



Duo Extend	Lengths (mm)					
Diam (mm)	**40**	**60**	**80**	**100**	**120**	**140**
12	9 Fr	9 Fr	9 Fr	9 Fr	9 Fr	9 Fr
14	9 Fr	9 Fr	9 Fr	9 Fr	9 Fr	9 Fr
16	10 Fr	10 Fr	10 Fr	10 Fr	10 Fr	10 Fr



1. Data on file: D062749
2. P230021 Summary of Safety and Effectiveness Document
3. Divakaran S, Meissner MH, Kohi MP, et al. Utilization of and Outcomes Associated with Intravascular Ultrasound during Deep Venous Stent Placement among Medicare Beneficiaries. J Vasc Interv Radiol. 022;33(12):1476-1484.e2. doi:10.1016/j.jvir.2022.08.018
4. Gagne PG, Tahara RW, Fastabend CP,et al. Venography versus intravascular ultrasound for diagnosing and treating iliofemoral vein obstruction. J Vasc Surg:Venous and Lym Dis 2017;5:678-87.

Brief statement

Philips Duo Venous Stent System

Intended use:
The Duo Venous Stent System is intended for use in the iliofemoral veins for the treatment of symptomatic venous outflow obstruction. The Duo Hybrid Stent is intended to be used in the iliac vein at the confluence of the inferior vena cava only. The Duo Extend Stent is intended for use in the common iliac and common femoral vein.

Contraindications for use:
The Duo Venous Stent System is contraindicated for the following: 1. Patients with a known hypersensitivity to nickel-titanium alloy (Nitinol). 2. Patients unable to receive standard medication used for interventional procedures including anticoagulants, contrast agents and antiplatelet therapy. 3. Patients who are judged to have a lesion that prevents complete inflation of a balloon dilation catheter or proper placement of the stent or the stent delivery system. 4. Tortuous vascular anatomy significant enough to prevent safe introduction and passage of the device to its intended location. 5. Duo Hybrid jugular or contralateral vascular access.

Prior to implanting the Duo Venous Stent System, please review the instructions for use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Caution:
Federal law restricts this device to sale by or on the order of a physician.

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