PHILIPS

Duo Venous Stent System

Duo Hybrid and Duo Extend

VIVID study clinical evidence[1]

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

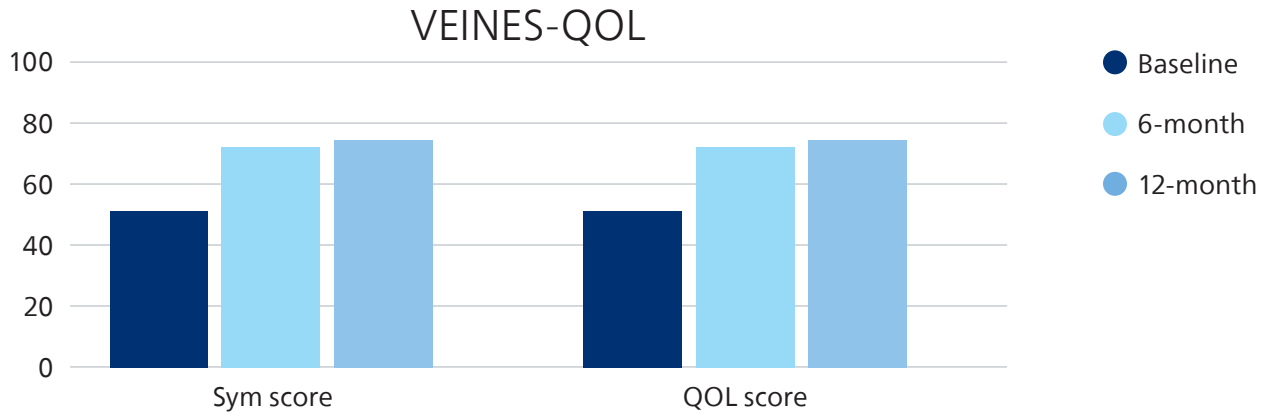
Substantial reduction in pain and PTS symptoms at 6 months and sustained to 12 months

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

Improved

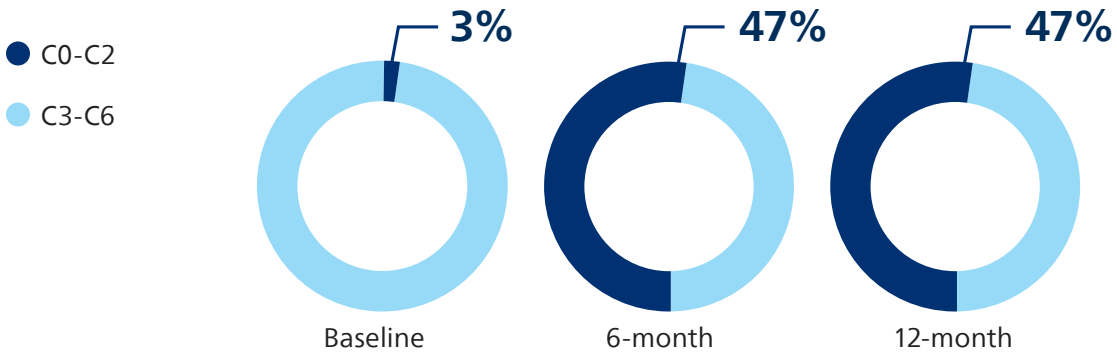
Improved quality of life compared to baseline

- 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



1. P230021 Summary of Safety and Effectiveness Document

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.

D062900-00 022024

Philips
3721 Valley Centre Drive, Suite 500
San Diego, CA 92130 USA
www.philips.com/IGTdevices