PHILIPS

Important safety information
Philips Duo Venous Stent System – Duo Hybrid & Duo Extend

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 veins.

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.

Warnings/precautions

1. Read all instructions carefully. Failure to properly follow the instructions, warnings and precautions may lead to serious consequences or injury to the patient.
2. It is not recommended that Stent implants be used in patients that are allergic/intolerant to contrast media and are not amenable to pretreatment with steroids and/or antihistamines.
3. The Stent implant may cause a thrombus or thrombo-embolization or may migrate from the site.
4. Before insertion of the primary dilatation catheter, it is recommended that the appropriate antiplatelet and/or anticoagulant therapy be administered.
5. Perform all device deployment under fluoroscopic guidance.
6. Use caution when moving the Duo Venous Stent System catheter through already deployed stent implants.
7. This device should only be used by physicians who have received appropriate training.

8. Post stent implant balloon dilatation is recommended. Failure to adequately size the stent implant may result in inadequate tissue apposition and risk of stent migration or occlusion.
9. Use caution (advance slowly) during advancement of post-dilatation balloon catheter through deployed Stent implants.
10. Fully deflate post-dilatation balloon prior to withdrawing balloon catheter.
11. Do not use excessive force when using this device as this could result in damage to the device, including component fracture, or venous injury.
12. Do not use the system without the guidewire extending beyond the tip of the delivery catheter.
13. Failure to position and fix the delivery system during Stent implant deployment may result in improper placement of the Stent implant.
14. Care should be taken not to kink the delivery system. If kinking occurs this could result in the inability to reach the target treatment site and to properly deploy the Stent implant.
15. Rotation of the Delivery System Thumbwheel prior to repositioning the delivery system could result in inadvertent deployment of Stent implant.
16. If the Stent implant cannot deploy, remove the delivery catheter, and use a new device.
17. It is recommended that the Delivery System be used with a 0.035" guidewire.
18. Is recommended that the 9F and 10F Delivery Systems be used with 9F and 10F introducer sheaths, respectively.
19. Duo Venous Stent System Storage and Preparation
    a. The Duo Venous Stent System is designed and intended for single use only. DO NOT re-sterilize and/or reuse the device.
    b. Reuse of this product, including reprocessing and/or re-sterilization, may lead to a failure of the device to perform as intended and/or a loss of critical labeling/use information, all of c. which present a risk to patient safety.
    c. Store in a dark, dry place.
    d. Do not use if the pouch is open or damaged. If it is suspected that the sterility or performance of the device has been compromised, the device should not be used.
    e. Use prior to the "Use-by" date specified on the package.
    f. If the system cannot be flushed, do not use the system.
20. Duo Venous Stent System handling

    a. Avoid contamination of the Stent implant(s). As with any type of vascular implant, contamination may lead to infection, thrombosis, or pseudoaneurysm.

    b. Do not use with Ethiodol or Lipiodol contrast media to avoid possible damage to the delivery system components.

    c. Do not expose the delivery system to organic solvents (e.g., alcohol).

21. Stent implant placement

    a. The Duo Hybrid Stent (high crush resistance segment) is intended to be used in the common iliac vein at the confluence of the IVC only.

    b. The Duo Extend Stent is intended for use in the common femoral vein and the external iliac vein.

    c. Do not use with power injection systems.

    d. If resistance is encountered at any time during the insertion procedure, do not force advancement of the delivery system. Forcing the delivery system through resistance may cause damage to Stent implant or vessel. Carefully withdraw the Duo Venous Stent System without deploying a Stent implant.

e. If resistance is felt when beginning deployment, do not force deployment. Carefully withdraw the Duo Venous Stent System without deploying the Stent implant.
f. The Duo Hybrid and Duo Extend Stent(s) are not designed for repositioning or recapturing.
g. Once the stent is partially or fully deployed, do not attempt to drag or reposition the Stent implant with the delivery system, as this may result in Stent or vessel damage.
h. Stenting across a major branch vessel could cause catheterization difficulties during future diagnostic or therapeutic procedures.
i. If a long lesion needs to be stented, consider using the longest available single stent rather than overlapping stents. If multiple stents are placed in an overlapping fashion, they should be of similar composition (i.e., Nitinol).
j. The Duo Extend Stent has not been clinically evaluated as a stand-alone device and should only be used in conjunction with the Duo Hybrid Stent.
k. The long-term outcomes following repeat dilatation of previously implanted stents are unknown.
l. The safety and effectiveness of this device for use in the arterial system have not been established.
m. In the event of symptomatic thrombosis within the Stent implant, thrombolysis/thrombectomy and balloon venoplasty should be attempted, per standard of care.

22. Stent implant removal
    a. In the event of a complication such as infection, surgical removal of a Stent implant may be required. Standard surgical procedure is appropriate.
23. Post implant
    a. Re-crossing a Stent implant with adjunct devices should be performed with caution to avoid damage or displacement of the implanted stent.
    b. Do not attempt to re-sheath the device within the deployed Stent implant treatment area as this could result in displacement.
    c. Used products are considered biohazardous material and should be disposed of properly as per hospital or lab protocol.
    d. In patients requiring the use of antacids and/or H2-antagonists before or immediately after Stent implant placement, oral absorption of antiplatelet agents (e.g., aspirin) may be adversely affected.

MRI safety information

Non-clinical testing has demonstrated that the Duo Venous Stent is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T or 3 T, only
- Maximum spatial field gradient of 4,000-gauss/cm (40-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg (Normal Operating Mode)
- Circularly polarized (quadrature-driven) coil only

Under the scan conditions defined, an implant from the Vesper Duo Venous Stent is expected to produce a maximum temperature rise of less than 2.0°C after 15-minutes of continuous scanning (i.e. per pulse sequence).

In non-clinical testing, the image artifact caused by an implant from the Vesper Duo Venous Stent extends approximately 5-mm from this device when imaged with a gradient echo pulse sequence and a 3-T MR system. The lumen of this stent could be visualized on the T1-weighted, spin echo and gradient echo MR images.

Additional information

The heating effect in the MRI environment for fractured stents is unknown. The presence of other implants or the health state of the patient may require reduction of the MRI limits listed above.

Vesper Medical recommends that patients register the conditions under which this Stent implant can be MRI scanned safely with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.

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

The Duo Venous Stent System IFU can be found online at: www.vespermedical.com/eIFU

Philips Duo Venous Stent System – Duo Hybrid and Duo Extend is manufactured by Vesper Medical, Inc. a wholly owned subsidiary of Royal Philips.