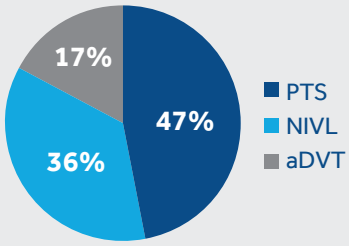
ABRE CLINICAL STUDY 12-MONTH DATA

Abre™ Venous Self-expanding Stent System

THE ABRE STUDY DIFFERENCE

DIVERSE SET OF PATIENTS



CHALLENGING PATIENT POPULATION

44%

of subjects (88/200) had stents that extended below the inguinal ligament into the common femoral vein (CFV).

PRIMARY EFFECTIVENESS ENDPOINT

88%

Primary patency at 12 months*

92.4%

Freedom from clinically driven target lesion revascularization through 12 months†

The primary effectiveness performance goal was exceeded.**

PRIMARY SAFETY ENDPOINT

98%

Freedom from MAEs at 30 days††

The MAE rate was significantly lower than the performance goal.**

SECONDARY ENDPOINTS

0%

Stent fracture at 12 months***

0%

Stent migration at 12 months†††

100%

Device success****

*Primary Patency was defined as meeting all of the following criteria at 12 months post-procedure: Freedom from occlusion or restenosis ≥ 50% of the stented segment of the target lesion and freedom from clinically-driven target lesion revascularization.

†390-day clinically driven TLR rate as component of primary patency. Freedom from CD-TLR was measured through 12 months.

**The effectiveness and safety performance goals (PG) were met with statistical significance ($p < 0.0001$). The primary effectiveness PG was 75% and the primary safety PG for MAE rate was 12.5% based on the literature. The 30-day MAE rate was 2.0%.

††MAEs included all-cause death occurring post-procedure, clinically significant pulmonary embolism, procedural major bleeding, stent thrombosis, and stent migration. MAEs were adjudicated by a Clinical Events Committee, except stent thrombosis and stent migration, which were assessed by an imaging core laboratory.

***Fracture or breakage of any portion of the stent determined by X-ray.

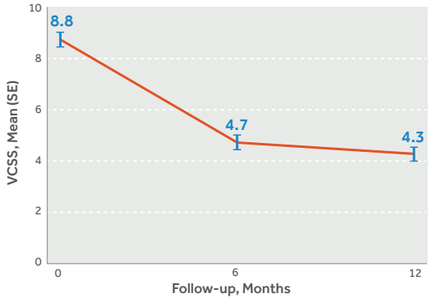
†††Position change of a venous stent observed with an imaging modality > 1 cm from its original location at the conclusion of the index procedure, as determined with regard to a reference anatomic structure.

****Device success: Successful delivery and deployment of the Abre stent in the target lesion with successful removal of the delivery system.

Medtronic

Sustained and statistically significant improvements in quality of life (QoL) measures and venous functional assessment scores (Villalta and Venous Clinical Severity Scores) at 12 months compared to baseline ($p < 0.001$).

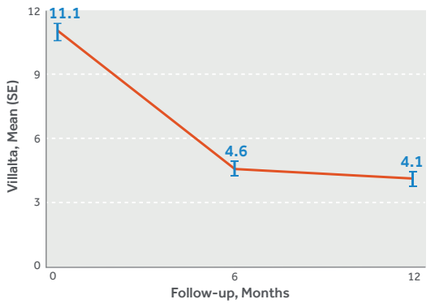
VCSS Results



VCSS Score:	Mean ± SE (n)
Day 0:	8.8 ± 0.3 (199)
6 Months:	4.7 ± 0.3 (191)
12 Months:	4.3 ± 0.3 (192)
$p < 0.001$	

Venous Clinical Severity Score (VCSS) measures venous disease severity over time and in response to treatment. VCSS scores range from 0, indicating no desease, to 30, indicating severe disease.

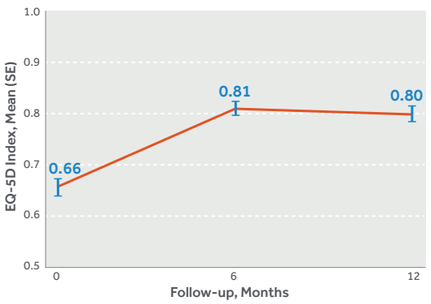
Villalta Results



Villalta Score:	Mean ± SE (n)
Day 0:	11.1 ± 0.4 (199)
6 Months:	4.6 ± 0.3 (191)
12 Months:	4.1 ± 0.3 (192)
$p < 0.001$	

Villalta score categorizes the severity of PTS (score > 5 diagnoses PTS; score > 14 categorizes severe PTS). Symptoms of PTS assessed by Villalta include pain, heaviness, clinical signs such as skin induration and redness, and presence of venous ulcers.

EQ-5D Quality of Life Results



EQ-5D Index:	Mean ± SE (n)
Day 0:	0.66 ± 0.02 (200)
6 Months:	0.81 ± 0.01 (192)
12 Months:	0.80 ± 0.02 (192)
$p < 0.001$	

EQ-5D is a generic QoL that assesses the subjects' health status on that day on a range of 0–1 (worst health to best health).

ABRE CLINICAL STUDY DESIGN

Purpose and Indication	Evaluate the safety and effectiveness of the Abre venous self-expanding stent system, intended for the treatment of symptomatic iliofemoral venous outflow obstruction
Sample Size	200 subjects
Initial Clinical Presentation	Acute DVT, post-thrombotic syndrome (PTS), and nonthrombotic iliac vein lesion (NIVL)
Follow-up	1, 6, 12, 24, and 36 months
Study Design	▪ Prospective, multicenter, single-arm ▪ Designed to meet literature-based performance goals: – 12-month primary effectiveness endpoint* – 30-day primary safety endpoint†

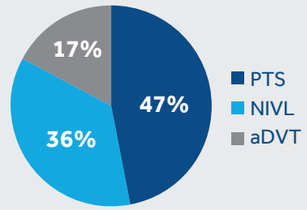
BASELINE DEMOGRAPHICS

Demographics	Included Subjects
Age (years) (mean ± SD)	51.5 ± 15.9
Female	66.5% (133/200)
BMI (kg/m²) (mean ± SD)	29.5 ± 7.1

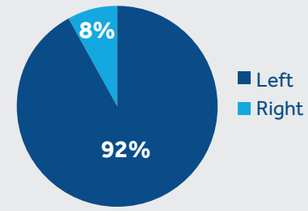
BASELINE MEDICAL HISTORY

Medical History	Included Subjects
Previous history of venous thromboembolism	52.0% (104/200)
Hypertension	31.0% (62/200)
Venous claudication	30.0% (60/200)
Known family history of DVT	22.0% (44/200)
Pulmonary embolism	17.0% (34/200)
Thrombophilia	11.5% (23/200)
IVC filter present	5.0% (10/200)
Cancer (ongoing or remission)	11.0% (22/200)
Smoking (active)	12.0% (24/200)

Primary Indication



Target Limb



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PROCEDURAL DATA*

Assessment	Included Subjects
Reference vessel diameter (mm) (mean ± SD)	15.0 ± 2.7
% Area stenosis (mean ± SD)†	74.9 ± 16.8
% Diameter stenosis (mean ± SD)†	62.8 ± 28.7
Subjects with occluded lesions	25.6% (50/195)
Lesion length (mm) (mean ± SD)	112.4 ± 66.1
Total stented length (mm) (mean ± SD)	134.3 ± 58.0
Number of Abre stents implanted per subject	1.5 ± 0.6
Stented vein location*	
Common iliac vein	96.0% (192/200)
External iliac vein	80.5% (161/200)
Common femoral vein	44.0% (88/200)

*Data from IVUS.
†Site data was used when core laboratory data was not available, stent extended across the locations.

See the device manual for detailed information regarding the instructions for use, 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.

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