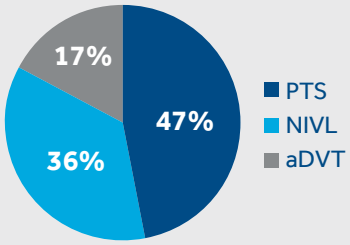
ABRE CLINICAL STUDY 12-MONTH DATA

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*

98.6%	87.1%	79.8%
NIVL	aDVT	PTS

Primary patency by patient population

The primary effectiveness performance goal was exceeded.†

PRIMARY SAFETY ENDPOINT

98%

Freedom from MAEs at 30 days**

The MAE rate of 2% 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.

†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, clinically significant pulmonary embolism, procedural major bleeding complication, 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 verified by core lab via X-ray.

***Position change of a venous stent > 1 cm from its original location at the conclusion of the index procedure, as determined with regard to a reference anatomic structure, as verified by core labs.

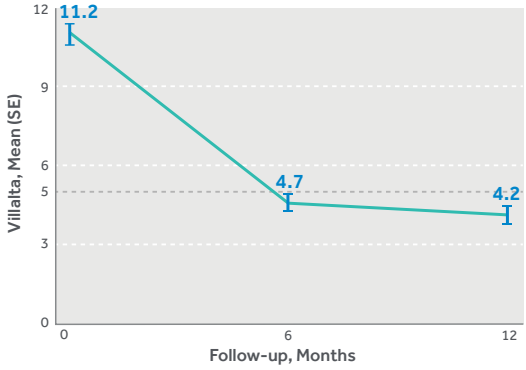
†††Device success: Successful delivery and deployment of the Abre stent in the target lesion with successful removal of the delivery system.

Source: ABRE CSR v1.2 30/JUL/2020.

Medtronic

Sustained and clinically meaningful improvements in quality of life (QoL) measures and venous functional assessment scores (Villalta and Venous Clinical Severity Scores) at 12 months compared to baseline ($p < 0.001$).[1]

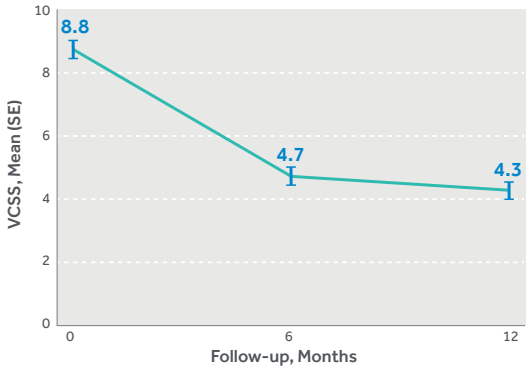
Villalta Results



Villalta Score:	Mean ± SE (n)
Day 0:	11.2 ± 0.4 (199)
6 Months:	4.7 ± 0.3 (191)
12 Months:	4.2 ± 0.4 (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.

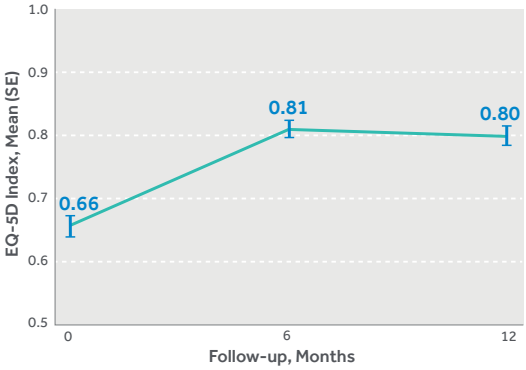
VCSS Results



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 disease, to 30, indicating severe disease.

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 questionnaire that assesses the subjects' health status on that day on a range of 0–1 (worst health to best health).

Source: ABRE CSR v1.2 30/JUL/2020.

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
Age (< 50 years)	41.5% (83/200)
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)
Smoking (active)	12.0% (24/200)
Thrombophilia	11.5% (23/200)
Cancer (ongoing or remission)	11.0% (22/200)
IVC filter present	5.0% (10/200)

*Primary effectiveness endpoint was primary patency at 12 months post-procedure, defined as meeting all of the following: freedom from occlusion and ≥ 50% restenosis of the stented segment of the target lesion and freedom from clinically driven target lesion revascularization.
†Primary safety endpoint was MAEs within 30 days post-procedure, including all-cause death, clinically significant pulmonary embolism, major procedural bleeding complication, 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.

Source: ABRE CSR v1.2 30/JUL/2020.

PROCEDURAL DATA*

Assessment	Included Subjects
Target limb — left	92% (184/200)
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)

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

Source: ABRE CSR v1.2 30/JUL/2020.

Brief Statement

Intended Use/Indications: The Abre™ venous self-expanding stent system (Abre™ stent system) is indicated for use in the iliofemoral veins for the treatment of symptomatic venous outflow obstruction.

Contraindications: Do not use the Abre™ stent system with patients with known hypersensitivity to nickel titanium (nitinol), with patients who are judged to have a lesion that prevents complete inflation of a balloon dilatation catheter or proper placement of the stent or the stent delivery system, and with patients in whom anticoagulant or antiplatelet therapy is contraindicated.

Potential Adverse Effects of the Device on Health: The potential adverse effects (e.g., complications) associated with the use of the Abre™ stent system include, but are not limited to, access failure, access site infection, allergic reaction to contrast medium or procedure medications; aneurysm; AV fistula; bleeding; bruising; death; device breakage; device maldeployment; edema; embolization; fever; hematoma; hypertension; hypotension, nausea, or other vasovagal response; infection; myocardial infarction, arrhythmia, or other cardiovascular insufficiency; open surgical repair; pain; pseudoaneurysm; renal insufficiency or renal failure (new or worsening); respiratory distress or pulmonary embolism; sepsis; stent fracture; stent malapposition; stent malposition; stent migration; stroke, paradoxical embolism, transient ischemic attack, or intracerebral hemorrhage; tissue necrosis; venous occlusion, restenosis, or thrombosis, within or outside of stented segment; and vessel damage, including intimal injury, dissection, perforation, or rupture.

Warnings, precautions, and instructions for use can be found in the product labeling at http://manuals.medtronic.com.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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