

SUPPLEMENTAL MATERIAL

Table S1: Key Protocol Definitions

Acute success	<ul style="list-style-type: none">• Device Success: Assessed at time of procedure, successful delivery and deployment of the Abre stent in the target lesion with successful removal of the delivery system.• Lesion Success: Assessed at time of procedure, venographic evidence of <50% final residual stenosis of the stented segment of the target lesion after post-dilation, when applicable, and as assessed by core laboratory.• Procedure Success: Lesion success without procedure-related MAEs prior to hospital discharge within 30 days. <p>Note: If core laboratory is unable to assess the venographic evidence, site reported data was used.</p>
Clinically driven	Defined as the recurrence of symptoms present at baseline or the onset of new symptoms including, but not limited to venous pain, swelling, dermatitis, or ulceration related to the target limb.
Major adverse events	<ul style="list-style-type: none">• All-cause death occurring post-procedure• Clinically significant (i.e. symptomatic, confirmed by CT pulmonary angiography) pulmonary embolism• Major bleeding complication (procedural)

	<ul style="list-style-type: none"> • Stent thrombosis confirmed by imaging as assessed by core laboratory • Stent migration confirmed by imaging as assessed by core laboratory <p>Note: Migration excludes stent dislodgement at the index procedure as may occur with under-sizing of a stent.</p>
Primary assisted patency	Uninterrupted patency of the stented segment of the target lesion with a secondary intervention, also known as an adjunctive treatment (e.g. balloon venoplasty, subsequent stenting, etc.).
Secondary patency	Patency of the stented segment of the target lesion after subsequent intervention for an occlusion. Note: Confirmed by DUS, evaluated by independent core laboratory. In cases where both DUS and venography were used at the same time point, venography would be used for the primary assessment.
Target lesion	The target lesion is defined as non-malignant venous obstruction within the common iliac, external iliac and/or common femoral vein: the proximal point of the obstruction may extend to the iliac venous confluence of the inferior vena cava and the distal point may be at or above the deep femoral vein.

<p>Target lesion revascularization (TLR)</p>	<p>Any re-intervention of the stented segment of the target lesion.</p>
<p>Stent fracture</p>	<p>Fracture or breakage of any portion of the stent.</p> <p>Stent Fracture Classification: Determined by X-ray (assessed by core laboratory):</p> <ul style="list-style-type: none"> • Type 0 – No strut fractures • Type I – Single tine fracture • Type II – Multiple tine fractures • Type III – Stent fracture(s) with preserved alignment of the components • Type IV – Stent fracture(s) with mal-alignment of the components • Type V – Stent fracture(s) in a trans-axial spiral configuration
<p>Stent migration</p>	<p>Stent migration (as part of primary safety and secondary MAE endpoints): position change of a properly sized venous stent observed with an imaging modality, with displacement of the stent outside of the intended treatment segment after the conclusion of the index procedure, as determined with regard to a reference anatomic structure.</p> <p>Stent migration occurs following the proper deployment of a venous stent after the index procedure (i.e. stent movement or dislodgement during the index procedure will not be noted as stent migration).</p>

Stent thrombosis	<p>Occlusion of the stented venous segment occurring at any time following stent placement.</p> <p>Stent thrombosis may be diagnosed by Duplex Ultrasound. It needs to be confirmed by venogram or IVUS.</p>
-------------------------	--