

Attachment A: Instructions for Use (IFU) Updates

Change From	Change To	Location												
<p>Appropriate stent size selection is crucial. Stent undersizing can lead to stent migration and suboptimal luminal diameter. Use Table 1 for guidance in selecting the appropriate stent size.</p>	<ul style="list-style-type: none"> • Avoid landing in the cranial or caudal end of the stent within the common iliac vein at the transition curve to the external iliac vein and internal iliac vein confluence, as it may result in tenting or kinking of the vessel. Extending stent length beyond the curve should be considered to minimize risk of migration. Stent migration can potentially lead to vessel occlusion, thrombus formation, vessel damage, embolism, and/or need for surgical intervention, including potential for open surgical removal from the heart. • Selection of the appropriate stent diameter and length is crucial. An undersized stent can result in stent migration and suboptimal luminal diameter. Stents with a diameter of $\leq 14\text{mm}$ and/or lengths of $\leq 80\text{mm}$ should be assessed for applicability as a stand-alone stent because of migration risk, particularly in non-thrombotic iliac vein lesions and in patients that have had a previous DVT, but otherwise have normal veins with an iliac vein compression. <p>Ensure that there is appropriate stent apposition to the vessel wall to secure sustained fixation through changing vessel size and shape during the procedure and post-procedural patient movement. Options to ensure appropriate stent apposition include visualization with IVUS during the procedure, confirming that the stent is extended around a curve, that the stent diameter is constrained by the vessel below the stent's nominal diameter, or that the stent is anchored by a second stent</p>	<p>Section 4 Precautions</p>												
<p>Considering the estimated anatomic vessel diameter, use <i>Table 1</i> to select the Abre stent diameter size. Choose a stent length that extends beyond both ends of the target lesion, with at least 1 cm on each side of the lesion to reduce the risk of restenosis.</p> <p>Table 1. Sizing Guide</p> <table border="1" data-bbox="126 1633 581 1978"> <thead> <tr> <th>Stent diameter (mm)</th> <th>Estimated anatomic vessel diameter (mm)</th> <th>Stent length (mm)</th> </tr> </thead> <tbody> <tr> <td>10</td> <td>7.5-9.5</td> <td>40, 60, 80, 100, 120, 150</td> </tr> <tr> <td>12</td> <td>9.5-11.5</td> <td>60, 80, 100, 120, 150</td> </tr> <tr> <td>14</td> <td>11.5-13.5</td> <td>60, 80, 100, 120, 150</td> </tr> </tbody> </table>	Stent diameter (mm)	Estimated anatomic vessel diameter (mm)	Stent length (mm)	10	7.5-9.5	40, 60, 80, 100, 120, 150	12	9.5-11.5	60, 80, 100, 120, 150	14	11.5-13.5	60, 80, 100, 120, 150	<p>Considering the estimated anatomic vessel diameter, use <i>Table 1</i> to select the Abre stent diameter size. A recommended way to calculate the equivalent diameter of an elliptical lumen is to determine the circle with the same perimeter. The root-mean-square of the major and minor axes of the ellipse provides a very good approximation. To achieve good wall apposition, it is recommended that a stent is chosen with a diameter of 2mm greater than the reference vessel diameter.</p> <p>Intraprocedural IVUS is encouraged (as a complementary imaging modality to venography) to more accurately determine the reference vessel diameter, the extent of disease, and the degree of stenosis. Considerations should be made for dynamic changes of the veins. Ensure the patient is suitably hydrated because hydration may impact vessel shape and size.</p> <p>Determine the cranial and caudal placement zones for the stent, with a goal of stenting from "healthy" vessel tissue to "healthy" vessel tissue. Extending the stent length caudally to support fixation in an unaffected vessel is encouraged to prevent stent migration. It is particularly important to extend the stent length</p>	<p>Section 7 Stent Size Selection</p>
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16	13.5-15.5	60, 80, 100, 120, 150	<p>caudally in non-thrombotic iliac vein lesions and in patients that have had a previous DVT, but have otherwise normal veins with an iliac vein compression.</p> <p>Caution: Avoid placing the cranial end or caudal end of the stent within the common iliac vein at the transition curve to the external iliac vein and internal iliac confluence. Improper placement of the stent may result in tenting or kinking of the vessel. Extending stent length beyond the transition curve is recommended to minimize risk of migration. Stent migration can potentially lead to vessel occlusion, thrombus formation, vessel damage, embolism, and/or the need for surgical intervention, including open surgical removal from the heart.</p>																						
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<p>Caution: Appropriate stent size selection is crucial and ensures appropriate stent apposition to the vessel wall. Stent undersizing can lead to stent migration and suboptimal luminal diameter. Use Table 11 for guidance in selecting the appropriate stent size.</p>			<p>Table 1. Sizing Guide</p> <table border="1" data-bbox="610 506 1166 852"> <thead> <tr> <th data-bbox="610 506 760 646">Stent diameter (mm)</th> <th data-bbox="760 506 909 646">Estimated anatomic vessel diameter (mm)</th> <th data-bbox="909 506 1166 646">Stent length (mm)</th> </tr> </thead> <tbody> <tr> <td data-bbox="610 646 760 709">10</td> <td data-bbox="760 646 909 709">7.5-9.5</td> <td data-bbox="909 646 1166 709">40, 60, 80, 100, 120, 150</td> </tr> <tr> <td data-bbox="610 709 760 741">12</td> <td data-bbox="760 709 909 741">9.5-11.5</td> <td data-bbox="909 709 1166 741">60, 80, 100, 120, 150</td> </tr> <tr> <td data-bbox="610 741 760 772">14</td> <td data-bbox="760 741 909 772">11.5-13.5</td> <td data-bbox="909 741 1166 772">60, 80, 100, 120, 150</td> </tr> <tr> <td data-bbox="610 772 760 804">16</td> <td data-bbox="760 772 909 804">13.5-15.5</td> <td data-bbox="909 772 1166 804">60, 80, 100, 120, 150</td> </tr> <tr> <td data-bbox="610 804 760 835">18</td> <td data-bbox="760 804 909 835">15.5-17.5</td> <td data-bbox="909 804 1166 835">60, 80, 100, 120, 150</td> </tr> <tr> <td data-bbox="610 835 760 852">20</td> <td data-bbox="760 835 909 852">17.5-19.0</td> <td data-bbox="909 835 1166 852">60, 80, 100, 120, 150</td> </tr> </tbody> </table> <p>Caution: Selection of the appropriate stent diameter and length is crucial. An undersized stent can lead to stent migration and suboptimal luminal diameter. Stents with a diameter of ≤ 14mm and/or lengths of ≤ 80mm should be assessed for applicability as a stand-alone stent because of migration risk, particularly in non-thrombotic iliac vein lesions and in patients that have had a previous DVT, but otherwise have normal veins with an iliac vein compression.</p> <p>Caution: Ensure that there is appropriate stent apposition to the vessel wall to secure sustained fixation through changing vessel size and shape during the procedure and post-procedural patient movement. Options to ensure appropriate stent apposition include visualization with IVUS during the procedure, confirming that the stent is extended around a curve, that the stent diameter is constrained by the vessel below the stent's nominal diameter, or that the stent is anchored by a second stent.</p>	Stent diameter (mm)	Estimated anatomic vessel diameter (mm)	Stent length (mm)	10	7.5-9.5	40, 60, 80, 100, 120, 150	12	9.5-11.5	60, 80, 100, 120, 150	14	11.5-13.5	60, 80, 100, 120, 150	16	13.5-15.5	60, 80, 100, 120, 150	18	15.5-17.5	60, 80, 100, 120, 150	20	17.5-19.0	60, 80, 100, 120, 150	
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<p>Perform post-deployment balloon dilation as needed, using an appropriately sized balloon catheter with conventional dilation techniques.</p>	<p>Perform post-deployment balloon dilation, using an appropriately sized balloon catheter with conventional dilation techniques.</p>	<p>Section 10.4 Post Stent Deployment</p>																							