

Pathway Access Sheath Catheter TM INSTRUCTIONS FOR USE

1. Description

The Onset Medical Corporation's Pathway Access Sheath CatheterTM consists of a specially folded, flexible PTFE sheath mounted on a central balloon catheter. The balloon, when inflated with fluid, exerts controlled radial pressure, enlarging the folded radiopaque sheath. Once the folded sheath is expanded, it exerts controlled radial pressure on the surrounding tissue tract and wall of the target vessel. The device is designed for creating tracks to access the cardiovascular system for safe and effective introduction of other minimally invasive catheters and/or instruments.

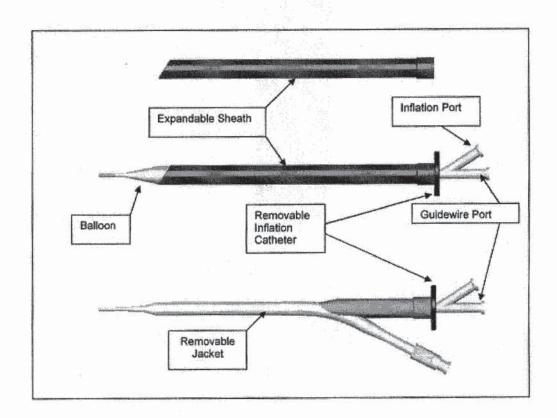


Figure 1

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