[0005] Radially expanding intravascular sheaths have been disclosed. Such sheaths tend to have complex mechanisms, such as ratcheting mechanisms that maintain the shaft or sheath in an expanded configuration once a device with a larger diameter than the sheath's original diameter is introduced.

[0006] However, delivery and/or removal of prosthetic devices and other material to or from a patient still poses a risk to the patient. Furthermore, accessing the vessel remains a challenge due to the relatively large profile of the delivery system that can cause longitudinal and radial tearing of the vessel during insertion. The delivery system can additionally dislodge calcified plaque within the vessels, posing an additional risk of clots caused by the dislodged plaque.

[0007] U.S. Patent No. 8,790,387, which is entitled EXPANDABLE SHEATH FOR INTRODUCING AN ENDOVASCULAR DELIVERY DEVICE INTO A BODY and is incorporated herein by reference, discloses a sheath with a split outer polymeric tubular layer and an inner polymeric layer, for example in FIGS. 27A and 28. A portion of the inner polymeric layer extends through a gap created by the cut and can be compressed between the portions of the outer polymeric tubular layer. Upon expansion of the sheath, portions of the outer polymeric tubular layer have separated from one another, and the inner polymeric layer is expanded to a substantially cylindrical tube. Advantageously, the sheath disclosed in the '387 patent can temporarily expand for passage of implantable devices and then return to its starting diameter.

[0008] Despite the disclosure of the '387 patent, there remains a need for further improvements in introducer sheaths for endovascular systems used for implanting valves and other prosthetic devices.

SUMMARY

[0009] The needs above and other advantages can be provided by an expandable introducer sheath for a delivery of an implant mounted on a catheter. The sheath includes an elastic outer tubular layer and an inner tubular layer having a thick wall portion integrally connected to a thin wall portion. The inner tubular layer can have a

compressed condition/folded configuration wherein the thin wall portion folds onto an outer surface of the thick wall portion under urging of the elastic outer tubular layer. When the implant passes therethrough, the outer tubular layer stretches and the inner tubular layer at least partially unfolds into an expanded lumen diameter to accommodate the diameter of the implant. Once the implant passes, the outer tubular layer again urges the inner tubular layer into the folded configuration with the sheath reassuming its smaller profile. In addition to a reduced initial profile size, the integral construction of the inner tubular layer guards against the leaks and snags of prior art split-tube and uniform thickness liner combinations. The sheath may also include selectively placed longitudinal rods that mediate friction between the inner and outer tubular layers to facilitate easy expansion and collapse, thereby reducing the push force needed to advance the oversized implant through the sheath's lumen.

[0010] Embodiments include a sheath for delivery of an implant mounted on a catheter. The sheath may include an elastic outer tubular layer and an inner tubular layer. The outer tubular layer defines an initial elastic lumen extending axially therethrough and having an initial diameter. The inner tubular layer has a thick wall portion integrally connected to a thin wall portion – such as by co-extrusion during manufacture. The thick wall portion has a C-shaped cross section with a first longitudinally extending end and a second longitudinally extending end. The thin wall portion extends between the first and second longitudinally extending ends to define an expanded lumen extending axially through the inner tubular layer. The expanded lumen has an expanded diameter larger than the initial diameter of the initial elastic lumen. The inner tubular layer, in a compressed condition, extends through the initial elastic lumen of the elastic outer tubular layer with the elastic outer tubular layer urging the first longitudinally extending end under the second longitudinally extending end of the inner tubular layer. The inner tubular layer in a locally expanded condition has the first and second longitudinally extending ends radially expanded apart, against the urging of the elastic outer tubular layer by passage of the implant, into a non-overlapping or a less overlapping condition with the thin wall portion extending therebetween to form the expanded lumen. The inner tubular layer is

13. A sheath of any one of the above claims, wherein the distal portion of the elastic outer tubular layer and inner tubular layer are reflowed onto each other into a sealed configuration.

14. A sheath of any one of the above claims, further comprising a plurality of longitudinal rods embedded within the elastic outer tubular layer.

15. A sheath of any one of the above claims, wherein a distal portion of the sheath has a flared shape.

16. A sheath of any one of the above claims, wherein the flared shape is folded into an overlapping arrangement.