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Development of Introducer Sheath Assembly for Heart Valve Insertion

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Abstract: ***The present article concerns an introducer sheath for inserting an artificial heart valve into the human body circulatory system. When a sheath is inserted into the wall of a blood vessel, an opening is created through which blood can exit the vessel. Percutaneously placed introducer sheaths allow catheters to be passed into blood vessels. Even after several usage, the introducer sheath is super low-profile, incredibly flexible, kink resistant, and lubricious. The gadget is introduced into the introducer sheath via a temporary ingressive tube. A radiopaque marker is attached to the distal end of the introducer sheath for better visibility during fluoro-imaging. A dilator is included in the introducer sheath to allow access to the introducer sheath via percutaneous vascular access. After a bigger diameter intravascular device is implanted, the sheath features a slit for temporary expansion to return to its previous shape.***

Keywords: Introducer sheath, Ingressive tube and Heart valve

1. Introduction

It is well known that introducer sheath plays an important role for placing an implant using specific catheters at proper place during surgical procedure and its appropriate design makes it simple to use the implant. Sheaths for various applications for stents, peripherals, endoscopic surgeries etc. are widely used and known. However, present article discloses a about an introducer sheath having its application for Aortic Heart Valve using intravascular catheters. Intravascular catheters, such as an angioplasty catheter, are introduced percutaneously using the flexible sheath. We have come up with a range of ingenious ideas to improve the safety and effectiveness of this treatment for a variety of vascular disorders. Intravascular catheters create an entryway for additional or other intravascular devices to be inserted later. For example, the introducer sheath distal end is placed into the patient femoral artery in the groin and pushed distally into the artery until the sheath is firmly seated within the artery. Prior to the development of the percutaneous insertion method, entry into the vessel was accomplished by first cutting the skin with a scalpel to expose the vessel of interest, and then inserting a needle or other puncture apparatus through the vessel wall. The introducer sheath is usually introduced into the vascular percutaneously through the skin. Introducer with a lower profile that locally extends within the patient vasculature is desired to broaden the availability of large-profile trans-catheter devices to patients with smaller vessel diameters. After that, the needle is advanced into the skin tissue until it reaches the vessel of interest. Because the wider profile introducer sheath necessitates a larger puncture hole, the healing process takes longer.

2. Material and Methods

The main shaft of the sheath has straight slits throughout the length of it allowing temporary shaft expansion. Polyurethane, PTFE, nylon, silicon, and other materials can be used for the outer tube shaft. The outer sheath can be 12 to 16 Fr in diameter. The dilator has a tapered distal tip that allows its insertion into the human vasculature over the guide wire or needle. The dilator outside diameter is 3 to 8 mm and distal tapering tip should be 15 to 35 mm ling. The outer layer is constructed of a softer, more elastic material. The dilator, temporary ingressive tube, and haemostatic valve are all joined at the proximal end of the main shaft in the introducer sheath. Polyurethane, PTFE, nylon, silicon, and other materials can be used for the sheath shafts outer tube.

A tubular sheath is formed by coaxially extruding a relatively soft (lower durometer), more elastic outer material and a rigid inner material that can expand radially. A sheath as described here can be utilized with a device that is tiny enough to fit through the sheath without expanding it, but has a larger diameter (at least in certain areas) when it needs to be retrieved. The multilayer sheath facilitates the introduction of an introducer sheath into a calcified femoral artery. Heat shrinks the PTFE inner layer, which wraps around the outer layer through the slit. An additional temporary ingressive tube is provided for the loading of any balloon expandable device during insertion.

A balloon-loaded stent is placed in an ingressive tube, which is then introduced through a haemostatic valve into the introducer sheath. PTFE, silicone, PET, or any other Polyimide material can be used for ingressive tubes (short tubes). The aggressive tube diameter can range from 5 to 15 mm. Introducer sheath diameter can range from 10 to 20 Fr. Sheath maximal expansion is entirely dependent on the outer tubing elasticity. A radiopaque tip is located at the distal end of the sheath shaft.

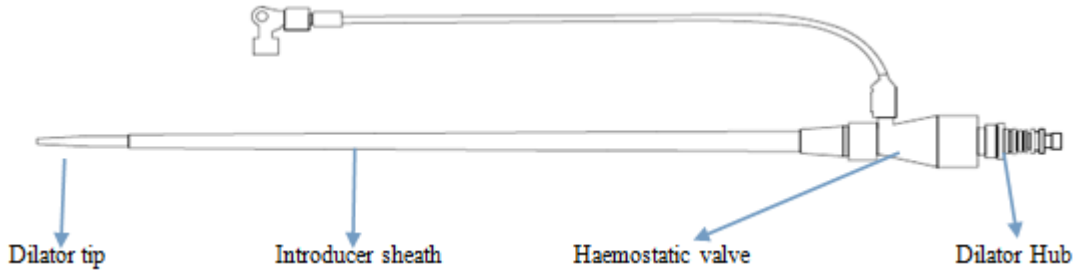

Figure 1

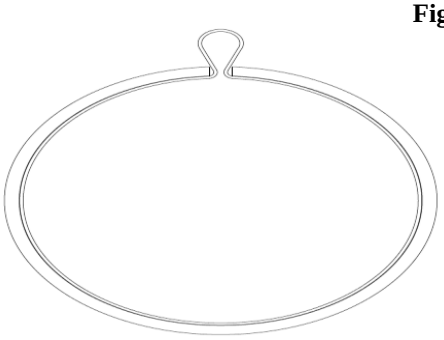

Figure 2

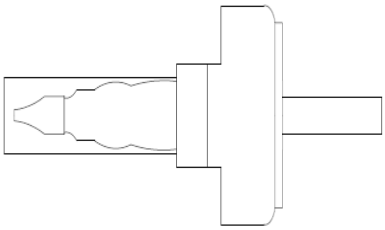

Figure 3

Sr. No	Parameters	Ranges
1	Outer sheath diameter (Fr)	12 to 16
2	Distal tapered tip (mm)	15 to 35
3	Dilator outer diameter (mm)	3 to 8
4	Dilator inner diameter (mm)	0.5 to 2.0
5	PTFE outer diameter (mm)	2 to 12
6	Aggressive tube diameter (mm)	5 to 15
7	Length of Ingressivge tube (mm)	40 to 80
8	Unexpanded dimeter of introducer sheath (Fr)	10 to 20
9	Expanded diameter of introducer sheath (Fr)	12 to 22
10	Barium sulphate composition (%)	10 to 60

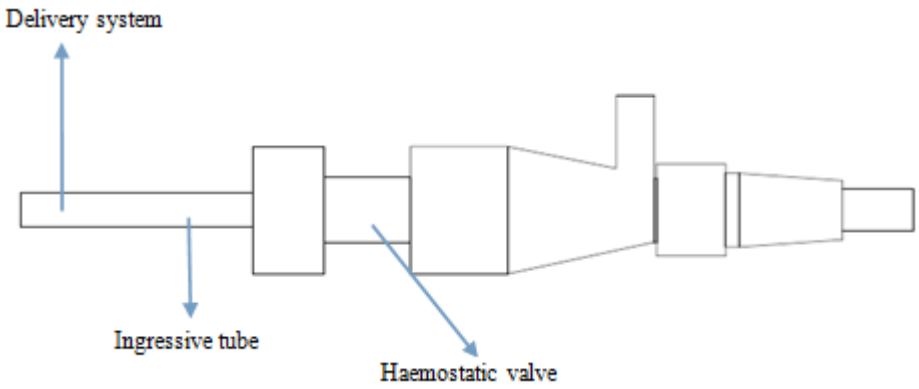

Figure 4

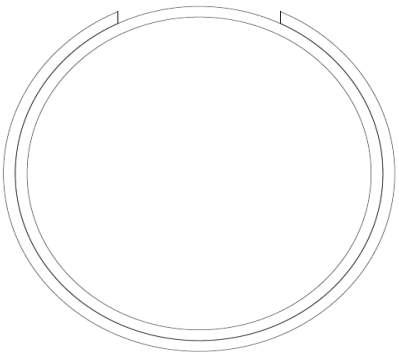

Figure 5:

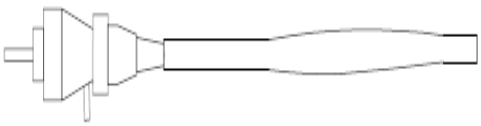

Figure 6:

Figure 7

A brief description of the drawings

Figure 1 depicts the introducer sheath with all of its components;
Figure 2 depicts the introducer sheath in its normal position;
Figure 3 depicts the balloon with the crimped heart valve loaded in the temporary ingressive tube;
Figure 4 depicts the insertion of the ingressive tube into the introducer sheath;
Figure 5 depicts the expanded region of the introducer sheath due to the insertion of the heart valve;
Figure 6 depicts the side view of the introducer sheath in expanded position;
Figure 7 depicts how to retrieve and re-sheath the heart valve in the introducer sheath.

3. Result and Discussion

The introducer sheath is a great revolutionary medical tool. They help facilitate even insertion into the vessels. The hemostatic valve helps to reduce blood leakage during the surgery. It helps to facilitate, set and undo the devices. Introducer sheaths are used when a larger catheter is needed, such as for rapid volume delivery or pulmonary artery catheterization. The outer layer of an introducer sheath usually contains some geometric shape, such as a slit, overlapping part, and changing thickness, which makes it stiffer, while the inner layer is less elastic and has a greater potential to extend radially. Because the outer layer is softer and more elastic, it does not require as many geometric shapes to aid in expansion. The outer layer could have a different shape than the inner layer, and it does not have to be cylindrical. The sheath described here is particularly beneficial for providing a sheath for various devices to be placed into a human or non-human animal body, such as heart valves, stents, occluders, or guide wires. Although some vessel expansion is required, it is preferable that it be radial and short-term in order for the vessel to return to its former shape without enlarging the incision.

A sheath with a smaller diameter can be used to deliver a device with a larger diameter, or it can be used to withdraw a retrievable device more readily if the device is in its retrieved form, which has a bigger diameter than in its delivered condition, all while reducing vessel blockage. It is preferable that the vessel not be enlarged, or that if it must be enlarged, that it be done for a short period of time to allow the vessel to recover. The multilayer sheath facilitates the introduction of an introducer sheath into a calcified femoral artery. If the artery calcification is stubborn, the single layer sheath will kink or develop an uneven inner surface, making any cardio-vascular device difficult to manoeuvre. Only the outer tube of the sheath protects the device from damage in a multi-layered sheath, but the interior layer of the sheath is unflustered, allowing for quick and easy travel of the cardio-vascular device via the introducer sheath.
The haemostatic valve is used to restrict the outflow of bodily fluids through the sheath, as well as to introduce the dilator and control the insertion of the dilator. The device may be introduced into the vascular quickly and easily without inflicting harm to the human vasculature because of the sheath expansion. The sheath reverts to its original shape after expansion. In fluoroscopic imaging, the radiopaque distal tip of the sheath aids in sheath placement for transcaval approach for heart valve implantation. For cardiac valve insertion, the tip guides the puncturing spot from vein to artery.

4. Conclusion

The inflatable introducer sheath allows for easy percutaneous insertion and removal of multi-sized intravascular devices. The percutaneous procedure used here plays a significant part in the insertion of the introducer sheath shaft into the body, which results in a superior outcome for the implantation of an artificial heart valve into the human body vasculature. The split shaft has many tubes for shaft expansion, allowing passage for the introducer sheath to be inserted. During an interventional procedure, the haemostatic valve and silicon profile block blood flow from the groin area.

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