

PEEL-AWAY INTRODUCER SHEATH HAVING PROXIMAL FITTING

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to medical devices and more particularly to introducer sheaths which are used for the transcatheter introduction of catheters and other apparatus to a patient.

Introducer sheaths are commonly used in various medical procedures where a catheter is transcatheterously introduced to an interior body lumen or cavity, such as a blood vessel or a hollow body organ. Typically, the introducer sheath comprises a thin-walled sheath tube which is introduced through a previously formed needle penetration together with an internal stylet or obturator, where the stylet or obturator has a tapered distal end which extends from the sheath and dilates the previously formed hole as the sheath is advanced. After the combination of the sheath and stylet/obturator has been introduced, the stylet/obturator is removed, leaving a relatively large diameter working channel defined by the axial lumen of the sheath.

Various improvements in the design of such introducer sheaths have been proposed. Of particular interest to the present invention, peel-away introducer sheaths have been designed where the sheath is weakened along opposed axial lines to facilitate splitting when the proximal end of the sheath is pulled apart. Such peel-away sheaths are useful when it is desired to remove the sheath from around a catheter or other device which remains in place in the transcatheterous penetration. In particular, the sheath may be withdrawn and split or pulled apart to facilitate such removal. Without the ability to peel away the sheath, it would be impossible to remove the sheath over an enlarged proximal hub or housing on the catheter or other device which remains in place.

Another improvement comprises the attachment of a gas or liquid sealing valve on the proximal end of the sheath. The inclusion of the sealing valve permits the exchange of working catheters while the introducer sheath remains in place, with the valve minimizing gas or liquid loss during an interventional procedure.

The inventors herein have recognized a need to combine the benefits of a peel-away sheath with the placement of a sealing valve or other fitting at the proximal end of such sheath. In the case of sealing valves in particular, it has been recognized it would be desirable to permit catheter exchange through the sheath and, after placement of a final catheter, withdrawal and removal of the sheath while the final catheter remains in place. Additionally, in certain interventional and diagnostic procedures, it would be desirable to remove the valve to allow passage of a biopsy sample, stone, or other specimen too large to pass through the valve.

The mounting of valves and other fittings on the proximal end of a peel-away sheath, however, presents a number of difficulties. It will be very difficult to design valves and other complex fittings which are able to break away as the sheath is broken apart. Moreover, the attachment between the valve or other fitting and the sheath should not result in any reduction in the available diameter of the working channel, e.g. the valve and/or valve attachment should not provide a reduction of the inside diameter and constriction in the working channel. Additionally, the attachment of the valve or other

fitting to the sheath should not compromise the structural integrity of the handle on the sheath in any way. That is, the presence of the fitting should not make it more difficult to break apart the handle or compromise the strength of the handle so that it becomes more fragile (i.e. it is more likely to be accidentally broken).

For these reasons, it would be desirable to provide peel-away introducer sheaths having fittings attached at their proximal ends, where the fittings and their manner of attachment do not reduce or constrict the working channel provided by the sheath. The attachment of the fittings should also not compromise the structural integrity of the sheath and/or associated sheath handle so that the sheath can be broken apart in a normal manner and will not be subject to failure. Additionally, it would be desirable to provide peel-away introducer sheaths which may be broken away, leaving in place a proximal fitting, so that the sheath may be withdrawn and removed without the requirement of breaking apart the fitting. Furthermore, it would be desirable to provide the physician with easy valve removal when it is necessary to pass a relatively large object, such as a biopsy sample or stone, through the sheath during a procedure.

2. Description of the Background Art

Peel-away introducer sheaths are described in U.S. Pat. Nos. 5,098,392; 4,983,168; 4,596,559; 4,412,832; and Re. 31,855. A splittable trocar which receives a tubular member in its proximal end is described in U.S. Pat. No. 3,653,388. Other splittable medical devices are described in U.S. Pat. Nos. 4,411,654; 3,550,591; and 3,382,872.

Non-splittable introducer sheaths having valves and other fittings permanently mounted on their proximal ends are available commercially from suppliers, such as Angeion Corp., Minneapolis, Minn. (e.g., the Angestat™ hemostasis valve introducer), and Arrow International, Inc. Reading, Pa.

SUMMARY OF THE INVENTION

According to the present invention, a peel-away introducer sheath incorporates a transition element at its proximal end. The transition element may be a hemostatic valve, gas or liquid sealing septum, multiport adapter, or any other fitting which can perform a useful function when attached to the proximal end of the sheath. The transition element is attached by a union to a splittable handle secured to the proximal end of the shaft, usually being detachably secured by a conventional detachable union, such as a threaded connection, bayonet connection, taper lock, or the like. In this way, the transition element may be removed and replaced, and more importantly may be released from the remainder of the sheath prior to splitting the sheath handle and pulling the sheath apart. In this way, the introducer sheath may be utilized in a conventional manner with the transition element in place, e.g. with a gas or liquid sealing valve to facilitate catheter exchange. The sheath may then be split apart after a final catheter has been introduced therethrough and the transition element disconnected, leaving only the transition element in place on the catheter.

In a first particular aspect of the present invention, the transition element includes an axial passage aligned with both the sheath lumen and handle aperture, where the diameter of the axial passage is at least as large as the diameters of the lumen and the aperture. In this way, the introducer sheath including the transition element is