

INTRAVASCULAR INTRODUCER DEVICES

FIELD

[0001] This application is related to devices for introducing a catheter or other device into a patient's vasculature, such as for delivering a medical device into the body.

BACKGROUND

[0002] A conventional method of introducing a transcatheter prosthetic heart valve into a patient's vasculature and toward the heart includes using a conventional introducer device to create an access port through the skin to a vein, and using a separate loader device to load a delivery catheter, with a crimped prosthetic heart valve mounted thereon, into and through the introducer device into the vasculature. The loader device typically covers the crimped heart valve with a sheath to protect it while the delivery catheter is passed through hemostatic seals in the introducer device. Covering the crimped prosthetic heart valve can reduce the risk of the crimped prosthetic heart valve migrating relative to the delivery catheter and can reduce the risk of the crimped prosthetic heart valve being damaged when it passes through the seals of the introducer device.

SUMMARY

[0003] Disclosed herein are embodiments of introducer devices that provide hemostatic sealing and allow a delivery catheter to be inserted into and retrieved from a patient's vasculature. A delivery catheter can be passed through the device's seals without the use of a separate loader device that covers a medical device, such as a crimped prosthetic heart valve, that is mounted on the delivery catheter.

[0004] ~~Some disclosed introducer devices~~ An aspect of the present invention provides a device for introducing a catheter into a patient's vasculature, the device comprising a housing, a distal sheath extending distally from the housing and adapted to be inserted into a patient's vasculature with the housing positioned outside of the patient's vasculature, a distal hemostatic seal mounted within the housing, ~~and a proximal hemostatic seal mounted within the housing at a location proximal to the distal hemostatic seal,~~ and a shuttle or tube positioned within the housing that is movable longitudinally relative to the distal hemostatic seal and the housing between a proximal position and a distal position, wherein in the proximal position a distal end of the tube is positioned proximal to

the distal hemostatic seal with the distal hemostatic seal closed, and wherein in the distal position the distal end of the tube extends through the distal hemostatic seal, and wherein a proximal end of the tube, or an end of another tube of the device, is movable longitudinally relative to the proximal hemostatic seal between a first position within the proximal hemostatic seal and a second position not within the proximal hemostatic seal.

[0005] In some embodiments, when the tube is in the distal position, a proximal end of the tube is positioned distal to the proximal hemostatic seal and the proximal hemostatic seal is closed, and when the tube is in the proximal position, the proximal end of the tube extends through the proximal hemostatic seal.

[0006] In other embodiments, the introducer includes a second tube, such as a fixed part of the housing, and the proximal hemostatic seal is movable longitudinally relative to a proximal end of the second tube between a distal position wherein the second tube extends through the proximal hemostatic seal and a proximal position wherein the proximal hemostatic seal is closed and positioned proximal to the second tube. In such embodiments, the housing can comprise a main housing and a proximal end portion that are movable longitudinally relative to each other, and the proximal hemostatic seal is mounted within the proximal end portion while the second tube is part of the main housing.

[0007] The tube that opens the distal seal can be part of a shuttle that is slidable relative to the housing and the distal seal. The shuttle can also include an actuator that extends radially through the housing and forms a handle or grip on the outside for a user to manipulate. In some embodiments, the shuttle actuator can slide along a slot in the housing, and the slot can be configured to allow the shuttle to be locking in the distal or proximal position by twisting the shuttle actuator relative to the housing.

[0008] When the proximal seal is opened, a delivery catheter can be inserted through a proximal port in the device and into the tube between the seals without the delivery catheter contacting the proximal seal. Then, the tube can be moved to the distal position to allow the delivery catheter to be advanced distally from the tube into the distal sheath without contacting the distal hemostatic seal. After the medical device carried on the delivery catheter is advanced through the introducer, the seals can hemostatically seal around the proximal portions of the catheter while a procedure occurs.

[0009] In some embodiments, the process can be generally reversed to allow the delivery catheter with a medical device still mounted thereon to be retrieved back