Title: DEVICE FOR FACILITATING THE INSERTION OF A GUIDEWIRE INTO THE TIP OF AN INTERVASCULAR GUIDEWIRE GUIDED DEVICE

Abstract: The invention provides a device for threading an end of a guidewire into a catheter, the catheter having a tip connected to an inner lumen of the catheter, the inner lumen dimensioned to receive the guidewire therethrough. The device comprises: a guidewire receiving port; a catheter tip receiving port; a channel connecting the guidewire receiving port to the catheter tip receiving port. The channel is dimensioned to pass the outer thickness of the guidewire therethrough and the channel is dimensioned to block passage of the outer thickness of the catheter therethrough. A contiguous section of the guidewire receiving port, the catheter tip receiving port and the channel form an open passageway from which the guidewire and catheter, once the guidewire is threaded into the catheter, are disengaged from the device. The open passageway may be covered by a flap mounted to the device which releasably covers the contiguous open section of the guidewire receiving port, the catheter tip receiving port and the channel.

Published:
— with international search report

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DEVICE FOR FACILITATING THE INSERTION OF A GUIDEWIRE INTO THE TIP OF AN INTERVASCULAR GUIDEWIRE GUIDED DEVICE

FIELD OF THE INVENTION

This invention relates to a device facilitating the insertion of a guidewire into the lumen of a catheter through the tip of the catheter. Catheters that are threaded in this manner are commonly called over the wire catheters or monorail catheters and are presently used in cardiology, radiology, and neurology. They are used in cardiology in procedures such as percutaneous transluminal coronary angioplasty (PTCA).

BACKGROUND

PTCA is a technique used to dilate an area of arterial blockage with the help of a catheter that has an inflatable balloon at its tip.

In classical PTCA procedures, a guiding catheter is percutaneously introduced into the cardiovascular system of a patient and advanced therein until the distal tip of the guiding catheter is disposed within the aorta adjacent the ostium of the desired coronary artery. A guidewire is an extremely thin wire with a flexible tip. Typically the physician or operator inserts a guidewire through the guiding catheter into the coronary arteries of the heart. The tip of the guidewire is then guided across the blockage and advanced beyond it. The physician controls the movement and direction of the guidewire by gently manipulating the end that sits outside of the patient.

This guidewire can now serve as a "guide" over which a catheter may be threaded. The catheter will have a hollow lumen extending from the end that first enters the patient through all or a portion of the length of the catheter. To insert the catheter into a patient, the proximal tip of the guidewire (the end outside the patent) is fed into the lumen of the catheter through the distal tip of the catheter. The distal tip of the catheter is then fed along the guidewire, into the patient’s body and through the cardiovascular system until the tip of the catheter is positioned at a target site in the coronary arteries. The end of the catheter may be variously modified to include a balloon to expand arterial narrowings, to deploy a cylindrical device
known as a stent to prevent arterial wall recoil after balloon expansion, or to do other intraarterial manipulations.

As will be appreciated by those skilled in the art, threading the one end of the guidewire into the lumen of the catheter through the catheter tip can be physically challenging because of the miniscule dimensions of the parts involved. Typically the guidewire has a diameter of .014” and the catheter tip has an inner diameter of approximately .016”-.017”. The current approach relies on the technical ability of the physician to insert or thread the guidewire into the catheter at its tip.

Threading the guidewire into the lumen of the catheter through a small opening at the tip of the catheter can be difficult and time consuming, creating a potentially dangerous delay when quick action is required to safeguard the patient.

Additional damage can be encountered during manual insertion of the guidewire into the catheter tip, including kinking, crimping, or otherwise injuring the catheter tip, balloon or stent.

Some of the latest generations of stents have a drug coating on their surface. Since the stent is close to the tip of the catheter, typically, the physician must grip the catheter tip to assist in guiding the guidewire into the tip, thereby touching the stent. However, touching the stent may alter the effectiveness of the drug because some of the drug may be displaced.

Accordingly, what is needed is a hands-off approach, permitting the operator to rapidly and safely thread the guidewire into the catheter lumen without touching the stent located at the tip of the catheter. The present invention provides a device that (i) relieves the technical skill factor required to effectively thread the guidewire into the catheter lumen and (ii) provides a barrier to minimize hand contact with the stent when the catheter is being threaded onto the guidewire.
SUMMARY OF THE INVENTION

In accordance with one aspect of the present invention, there is provided a device for threading an end of a guidewire into a catheter, the catheter having a tip connected to an inner lumen of the catheter, the inner lumen dimensioned to receive the guidewire therethrough, wherein each of the guidewire and the catheter has an outer thickness, the device comprising: a guidewire receiving port; a catheter tip receiving port; and a channel connecting the guidewire receiving port to the catheter tip receiving port; wherein the channel is dimensioned to pass the outer thickness of the guidewire therethrough and the channel is dimensioned to block passage of the outer thickness of the catheter therethrough, and wherein a contiguous section of the guidewire receiving port, the catheter tip receiving port and the channel form an open passageway from which the guidewire and catheter, once the guidewire is threaded into the catheter, are disengaged from the device.

In accordance with another aspect of the present invention, there is provided, a device as described herein, further comprising a flap mounted to the device which releasably covers the contiguous open section of the guidewire receiving port, the catheter tip receiving port and the channel.

In accordance with another aspect of the present invention, there is provided a device as described herein wherein the flap is hingedly affixed to the device.

In accordance with yet a further aspect of the present invention, there is provided a device as described herein wherein the flap is deformable and releasably covers the contiguous open section of the guidewire receiving port, the catheter receiving port and the channel, through pressure applied externally to the flap.

In accordance with yet another aspect of the present invention, there is provided a device as described herein wherein the flap is fully releasable from the device.

In accordance with still another aspect of the present invention, there is provided a device as described herein wherein the fully releasable flap is mounted to the device by a heat seal or by adhesive.
In accordance with another aspect of the present invention, there is provided a device as described herein wherein the flap is tearable.

In accordance with yet a further aspect of the present invention, there is provided the device as described herein wherein the guidewire receiving port and the catheter tip receiving port are each funnel shaped with each funnel narrowing towards the channel.

In accordance with another of the present invention, there is provided the device as described herein wherein the channel is dimensioned where the channel meets the catheter tip receiving port to hold the outer thickness of the catheter at the tip of the catheter in a snug fit.

Additional aspects of the invention will become apparent to those skilled in the art upon reference to the detailed description taken in conjunction with the provided figures.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing summary, as well as the following detailed description of preferred embodiments of the invention, will be better understood when read in conjunction with the appended drawings. For the purpose of illustrating the invention, there are shown in the drawings embodiments which are presently preferred. It should be understood, however, that the invention is not limited to the precise arrangements shown. In the drawings, the same reference numerals are employed for designating the same elements throughout the several figures. In the drawings:

FIGURE 1 is a top plan view of one embodiment of the invention without a flap or from which the releasable flap has been removed;

FIGURE 2A is a top plan view of the embodiment of FIGURE 1 with one embodiment of the releasable flap shown in place;

FIGURE 2B is a top plan view of a variation of the embodiment shown in FIGURES 1 and 2A, wherein the releasable flap is not fully releasable;

FIGURE 3 is a perspective view of the embodiment shown in FIGURE 1;

FIGURE 4 is bottom plan view of the embodiment shown in FIGURE 1;
FIGURE 5 is a front elevational view of the embodiment shown in FIGURE 1; FIGURE 6 is a rear elevational view of the embodiment shown in FIGURE 1; and FIGURE 7 is a top plan view of the embodiment shown in FIGURE 1 illustrating a guidewire being thread into a catheter.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIGURE 1 shows an embodiment of a device 10, as viewed from the top. In this embodiment, the device 10 has the basic form of a rectangular block with a guidewire receiving port 20 at one end thereof 12 and a catheter tip receiving port 30 at an opposite end thereof 14 with a channel 40 joining the guidewire receiving port 20 to the catheter tip receiving port 30. As can best be seen in the perspective view of FIGURE 3, each of the guidewire receiving port 20, the catheter tip receiving port 30 and the channel 40 is a recessed void space at a top surface 16 of the device 10, opposite from a bottom surface 18 of the device 10. The three of the guidewire receiving port 20, the catheter tip receiving port 30, and the channel 40 together form a passageway 50 from the one end 12 of the device 10 to the opposite end 14.

The device 10 may take any shape that allows for a passageway to be placed therein joining the one end 12 to the opposite end 14. In the embodiment of FIGURE 1, the device 10 is more narrow at the one end 12 than at the opposite end 14. The shape could be described as "bottle-shaped" or "violin-shaped". This shape merely allows a person using the device 10 to more easily tell the one end 12 from the opposite end 14. In the embodiment of FIGURE 1, the guidewire receiving port 20 is found at the one end 12, which is the more narrow end of the device 10. As a person using the device will know that a guidewire is more narrow than a catheter, it will help him or her remember that the guidewire receiving port 20 is found at the one end 12, which is more narrow.

The passageway 50 may be covered by means of a flap 60 (not shown in FIGURE 1). The flap 60 can take any form so long as it releasably covers the passageway 50. The flap 60 can be fully detachable from the device 10 or partially detachable from the device 10. In an embodiment where the flap 60 is fully detachable, the flap 60 can take the form of a film or
tape that is attached to the top surface 16 of the device 10 that can be peeled off of the top surface 16 of the device 10. In such an embodiment, the flap 60 can be attached to the top surface 16 of the device 10 by means of a heat seal or an adhesive. FIGURE 2A shows a top plan view of such an embodiment wherein the flap 60 is in the form of a clear film 62, mounted on the top surface 16 of the device 10. The clear film 62 may be removed by pulling on a tab 64. In the embodiment shown in FIGURE 2A, the tab 64 is shown at the one end 12 of the device 10, towards the guidewire receiving port 20. However, the tab 64 may be located anywhere on the film 62 to allow access for the person using the device 10 to grip the tab 64 to remove the film 62. In this embodiment, the film 62 is fully removable from the top surface 16 of the device 10, but it need not be fully removable in a broader aspect of the invention. All that is required for this broader embodiment is that the film 62 release from the top surface 16 to such a degree to allow the passageway 50 to be fully open along the top surface 16. The importance of the flap 60, in this embodiment in the form of the film 62, covering the open surface of the passageway 50 comprising the guidewire receiving port 20, the catheter tip receiving port 30, and the channel 40, being releasable to an extent to allow the passageway 50 to be open along the top surface 16 will be seen below when use of the device 10 to thread a guidewire into the lumen of a catheter is explained in detail. In the embodiment shown in FIGURE 2B, the film 62 is only partially removable from the top surface 16 of the device 10. The film 62 may be fixedly attached to the top surface 16 at a seam 66 on the opposite side of the top surface 16 of the device 10 from the tab 64. By being fixedly attached at the seam 66, one can release the film 62 by lifting the tab 64 to separate the film 62 from the top surface 16 of the device 10. Once lifted to expose the passageway 50, the film 62 stays attached to the top surface 16 along the seam 66. Because the film 62 does not fully disengage from the device 10, the film 62 does not have to be disposed of as a separate piece of material, which is helpful in an operating room setting, where tidiness can be important. The seam 66 may be provided on either side on the passageway 50.

Use of the device 10 to thread an end 102 of a guidewire 100 into a lumen 202 of a catheter 200 through a tip 204 of the catheter 200 will be described with the aid of FIGURES 5, 6 and 7. The tip 204 of the catheter 200 is placed in the catheter tip receiving port 30. In the embodiment shown in FIGURES 5, 6 and 7, the catheter tip receiving port 30 is funnel-shaped, with the base of the triangular funnel being at the end 14 of the device 10, and the funnel narrowing and decreasing in depth as the catheter tip receiving port 30 approaches the
channel 40. At a point 42, either at a point 49 where the catheter tip receiving port 30 meets the channel 40, or within a first portion 43 of the channel 40, the channel 40 is preferably dimensioned to hold an outer thickness of the tip 204 of the catheter 200 in a snug fit. In the embodiment shown in FIGURE 7, the first portion 43 of the channel 40 is dimensioned to snugly fit a length of a particular design of the catheter 200 including the tip 204. However, other dimensions of the first portion 43 of the channel 40 are contemplated such that the tip 204 may be held snugly anywhere along the first portion 43 of the channel 40. A second portion 45 of the channel 40 is dimensioned to allow the guidewire 100 to pass but is too small to allow the catheter 200, and in particular the tip 204, to pass. The second portion 45 of the channel 40 is shown in FIGURE 7 as having a uniform cross-section but may have other dimensions. The tip 204 is thus snugly held somewhere between the point 49 and a meeting point 47 between the first portion 43 and the second portion 45 of the channel 40.

The snug fit will allow the catheter 200 to be held in place in the catheter tip receiving port 30 while the end 102 of the guidewire 100 is threaded into the lumen 202 of the catheter 200. However, the snug fit will still allow easy disengagement of the catheter tip 204 from the point 42 of the channel 40 when the catheter 200 is detached from the device 10 once the guidewire 100 is threaded into the lumen 202 of the catheter. Once the catheter tip 204 has been placed into the catheter tip receiving port 30 and snugly positioned within the channel 40 at the point 42, the guidewire 100 may be threaded into the catheter 200. The end 102 of the guidewire 100 is fed into the guidewire receiving port 20. In the embodiment shown in FIGURE 7, the guidewire receiving port 20 is funnel-shaped, with the base of the triangular funnel being at the end 12 of the device 10, and the funnel narrowing and decreasing in depth as the guidewire receiving port 20 approaches the channel 40. The guidewire receiving port 20 narrows to a point 44, where it meets the channel 40. The channel 40 is dimensioned so that it has a diameter that is wider than that of a outer thickness of the guidewire 100, so as to allow the guidewire 100 to freely slide through the channel 40. The guidewire end 102 is fed into the guidewire receiving port 20, into the channel 40, past the point 44, towards the point 42, where the catheter tip 204 is being held. As the guidewire end 102 is fed past the point 42, it will be fed through the catheter tip 204, into the lumen 202 of the catheter 200. When referring to the tip 204 as being snugly fit or positioned, it will be understood to mean that the tip 204 is positioned such that the end 102 of the guidewire 100 can not avoid entering the tip 204 when inserted past the point 42.
In this embodiment the guidewire receiving port 20 and the catheter tip receiving port 30 are described as being in the shape of triangular funnels. However, any other shape that allows the end 102 of the guidewire 100 to be placed in the guidewire receiving port 20 and the tip 204 of the catheter 200 to be placed in the catheter tip receiving port 30, and the end 102 and the tip 204 to be fed towards the channel 40, may be suitable.

Once the guidewire end 102 is threaded into the lumen 202 of the catheter 200, the device 10 may be disengaged from the threaded guidewire 100 and the catheter 200 combination by releasing the flap 60. The flap 60 is not shown in FIGURES 1 and 7, but one can easily understand that if the flap 60 took the form of the film 62 illustrated in either of the embodiments of FIGURES 2A and 2B, all that one would have to do to release the flap 60 would be to pull back the film 62 via the tab 64. In the embodiment shown in FIGURE 2A, the film 62 is peeled back from the top surface 16 of the device 10, thereby exposing the passageway 50. The device 10 can then be removed from the threaded guidewire 100 and the catheter 200 combination, thereby exposing the catheter tip 204 which can be fed into an artery of a patent, for example, by further threading the catheter 200 along the guidewire 100. In the embodiment shown in FIGURE 2B, the film 62 is peeled back in a similar manner, exposing the passageway 50. In this embodiment, however, the film 62 does not fully disengage from the device 10. The passageway 50 is still exposed, but the film 62 still remains attached to the device 10 along the seam 66. Then the device 10 can be disengaged as a unitary item with the film 62, allowing for more easy disposal of the device 10.

A person skilled in the art will realize that the flap 60 can take other forms than the embodiments discussed above. All that is necessary is that the flap be able to releasably cover a contiguous surface of the passageway 50 that may be disengaged from the passageway, allowing for disengagement of the guidewire 100 and the catheter 200 combination once the guidewire 100 has been threaded into the lumen 202 of the catheter 200. The flap 60 could take the form of a hinged cover that is hinged on one side of the device 10 and is releasably attached to another side of the device 10 on an opposite side of the passageway 50. The releasable means of attachment could be by way of a snap fit of a groove on the flap 60 and a tab on the "another" side of the device 10, or other similar arrangement. In this embodiment, the flap 60 can be of unitary construction with the
remainder of the device 10 such that all of the device 10 is made of one material, and the hinge between the flap 60 and the remainder of the device 10 is a seam. This embodiment is possible when the device 10 is made of a plastic material.

The device 10 does not have to be fully disengageable from the guidewire 100 and the catheter 200 combination. In this embodiment, the flap 60 is deformable. Once the guidewire 100 is threaded into the lumen 202 of the catheter 200, the flap 60 may be deformed by bending or stretching to release the contiguous surface of the flap 60 covering the passageway 50. Alternatively, the flap 60 may be arched, or otherwise loosely cover the passageway 50 so that the operator may press down, for example with his or her thumb to cover the passageway 50. In this embodiment, release of thumb pressure will cause the flap 60 to separate from the passageway 50. Any of these embodiments of the flap 60 will allow the guidewire 100 and the catheter 200 combination to be released from the tight fit of the passageway 50. The tip 204 of the catheter 200 can be slid out from under the flap 60 of the device 10, thereby exposing the tip 204 for insertion into the patient through the femoral artery, for example. The deformed, arched or lose embodiment of the flap 60 has the effect of widening the passageway 50, allowing the device 10 to be disengaged from the tip 204 of the catheter 200, allowing device to be slid over the catheter 200 to a site removed from the tip 204, and the patient, as the tip 204 is fed further into the patient.

In an alternative embodiment, the flap 60 can take the form of a tearable film. Once the guidewire 100 is fed into the lumen 202 of the catheter 200, the guidewire 100 and the catheter 200 combination may be simply pulled away from the device 10, thereby ripping the tearable film and disengaging the device 10.

When the flap 60 takes the form of a film, the person skilled in the art would understand that the film may be attached to the device 10 by means of adhesive, a heat seal or other suitable means. When the flap 60 takes the form of a hinged cover, the person skilled in the art would understand that the non-hinged side of the cover may be attached to the device 10 by means of adhesive, a releasable snap lock or other suitable means. When the flap 60 takes the form of a deformable, arched or loose cover, the person skilled in the art would understand that such a cover may be attached to the device 10 by any suitable means on both sides of the passageway 50 so long as the portion of the cover between the attachment means on both
sides of the passageway 50 is sufficiently deformable, arched or loose to permit the guidewire 100 and the catheter 200 combination to disengage from the tight fit in the passageway 50.

In a preferred embodiment, the flap 60 will leave portions of one or both of the guidewire receiving port 20 and the catheter tip receiving port 30 uncovered, a portion thereof close by the ends 12 and 14 of the device 10, respectively. These uncovered portions can assist an operator in placing the catheter tip 204 in catheter tip receiving port 30 and the guidewire 100 into the guidewire receiving port 20, by effectively forming a guiding lip to assist in insertion.

In another embodiment, the flap does not have to be present as part of the device 10. In this embodiment, a flap that is external to the device may be placed over the open passageway 50. This external flap can be any surface which can removably cover the passageway 50. The external flap may even be the operator’s thumb. However, when the operator uses his or her thumb, the thumb may come in contact with a stent which may be close to the catheter tip 204. However, even when used with the operator’s thumb as a flap, hand contact with the stent will be reduced from the alternative of not using the device 10, since then the operator could likely handle the stent with both the thumb and the index finger when gripping the catheter tip 204.

In the embodiment shown in the bottom plan view of FIGURE 4, the device 10 is fitted with a series of ridges 70. Having the ridges 70 on the bottom surface 18 of the device 10 allows one to pick up the device 10 more easily once it has been placed on a surface, such as a table.

The device 10 is preferably made of sterilizable material. The device 10 may comprise sterilizable plastic, stainless steel, nitinol, latex, wood, or a combination thereof.

From the foregoing, it will be observed that numerous variations and modifications may be effected without departing from the true spirit and scope of the novel concept of this invention.
CLAIMS:

1. A device for threading an end of a guidewire into a catheter, the catheter having a tip connected to an inner lumen of the catheter, the inner lumen dimensioned to receive the guidewire therethrough, wherein each of the guidewire and the catheter has an outer thickness, the device comprising:
   a guidewire receiving port;
   a catheter tip receiving port; and
   a channel connecting the guidewire receiving port to the catheter tip receiving port;
wherein the channel is dimensioned to pass the outer thickness of the guidewire therethrough and the channel is dimensioned to block passage of the outer thickness of the catheter therethrough, and wherein a contiguous section of the guidewire receiving port, the catheter tip receiving port and the channel form an open passageway from which the guidewire and catheter, once the guidewire is threaded into the catheter, are disengaged from the device.

2. The device of claim 1, further comprising a flap mounted to the device which releasably covers the contiguous open section of the guidewire receiving port, the catheter tip receiving port and the channel.

3. The device of claim 2, wherein the flap is hingedly affixed to the device.

4. The device of claim 2, wherein the flap is deformable and releasably covers the contiguous open section of the guidewire receiving port, the catheter receiving port and the channel through pressure applied externally to the flap.

5. The device of claim 2, wherein the flap is fully releasable from the device.

6. The device of claim 5, wherein the fully releasable flap is mounted to the device by a heat seal.

7. The device of claim 5, wherein the fully releasable flap is mounted to the device by adhesive.
8. The device of claim 2, wherein the flap is tearable.

9. The device of claim 1, wherein the guidewire receiving port and the catheter tip receiving port are each funnel shaped, with each funnel narrowing towards the channel.

10. The device of claim 1, wherein said channel is dimensioned where the channel meets the catheter tip receiving port to hold the outer thickness of the catheter at the tip of the catheter in a snug fit.
FIG. 7
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
   IPC: A61M 25/01 (2006.01)
   According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
   Minimum documentation searched (classification system followed by classification symbols)
   IPC: A61M 25/01
   ECLA: A61M 25/06H, H1; A61M 25/09C; FI: A61M 25/00&320B, 320F; FT: 4C167/AA31

   Documentation searched other than minimum documentation to the extent that such documents are included in the fields

   Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)
   EPDOC, Canadian Patent database, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
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[X] See patent family annex.

[ ] Further documents are listed in the continuation of Box C.

Date of mailing of the international search report: 22 March 2006 (22-03-2006)

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