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Device & Method for Releasing Catheters from Cardiac Structures

Background of the Invention
Functional mitral valve regurgitation (FMR) and heart failure (HF or CHF) are responsible for significant morbidity, mortality and cost to the healthcare system. Methods and devices have been developed to accomplish ventriculoplasty on the left ventricle of the human heart for patients suffering from FMR and/or CHF, during which anchors are placed within the left ventricular myocardium in the sub-annular region between the mitral annulus and the papillary muscles. A tether is slidably coupled to the anchors and subsequently cinched in order to reduce the mitral annulus, creating mitral valve competence. In addition, the LV wall dimension is reduced, relieving wall stress and facilitating LV reverse remodeling.

In order to accomplish ventriculoplasty via a trans-femoral transcatheter approach, it is advantageous to place a template in the subannular region through which anchors can be delivered into the LV myocardium. This template, or guide tunnel (GT), can be indexed to landmarks and held in place by a number of methods, including mechanical interference with the LV wall, direct attachment to the LV wall, or other means. One advantageous method of direct attachment involves threading the tether around latches in the GT itself, such that the process of delivering anchors into the wall also attaches the GT to the wall.

In order to remove the GT after the anchors have been placed, the latches would have a means to release the tether. The latches could be opened, for example, by releasing a pull wire that secures one end of the latches, allowing the tether to escape through the open ends of latches as the GT is removed.

A more advantageous embodiment would cause the latches themselves to withdraw into the wall of the GT such that they are completely removed from the region of the LV wall and the tether. With this embodiment there would be no ability for the latches to snag on the tether, anchors or other structures.

Brief Description of the Drawings
Figure 1 depicts the short axis view of the left ventricle (LV), showing the aortic outflow tract and the LV chamber.
Figure 2 shows the same short axis view of the LV, with a guide (G) across the aortic valve (AV) and tangent to the LV wall.
Figure 3 depicts a guide tunnel (GT) catheter deployed from the G and extending around and alongside the LV wall. Radiopaque markers and windows are disposed along the outer radius of the GT wall, through which catheters can be deployed.
Figure 4 depicts a delivery catheter (DC) deployed from the GT through a window, and in contact with the LV wall.
Figure 5 depicts a short axis view of the LV with the G and GT in place, and in which DCs were used to deploy anchors into the myocardium to a predetermined depth from the first two windows. A DC is shown exiting the third window in order to deploy the next anchor. The anchors are slidably connected to a tether, which is laced behind latches in the GT.
Figures 6a, 6b, 6c depict one embodiment of a GT catheter and detail views of its distal and proximal ends.
Figures 7a, 7b, 7c illustrate a detail view of the GT with a latch in the closed configuration, with the latchwire removed, and with the latch open, respectively.
Description of the Invention
The current invention is directed toward removing a catheter from a body organ generally, after it has been located and fixed into position during an interventional procedure, for instance in a cath lab procedure. Specifically, the current invention is especially well suited to removing a template catheter, or Guide Tunnel (GT) from the subannular region of the left ventricle (LV) of the heart.

An illustrative procedure will be described in the following figures, though it should be appreciated that the current invention can be employed in many other procedures as well. Referring to Figure 1, a cath lab procedure involving a patient’s LV typically employs fluoroscopy and, among other views, a short axis view of the LV. Figure 1 shows the short axis of the left side of the heart (10) with the surrounding myocardium (11), endocardium (12), LV chamber (13) and aortic outflow tract and aortic valve (14).

In Figure 2 a Guide catheter (20), with a distal opening (21) is inserted across the aortic valve (14) and placed tangent to the endocardium (12). Subsequently a GT catheter (30) is placed (Figure 3) against or near the endocardium (12). The GT can be used as a template device, using windows (31) and radiopaque markers (32) to direct the placement of devices, such as anchors, into the myocardium of the LV. Finally, (Figure 4) a Delivery Catheter (DC) (40) is tracked up GT (30) such that the distal tip (41) exits a preferred window (31) and contacts endocardium (12). Advancing Delivery Catheter (40) further causes it to penetrate endocardium (12) to a desired depth.

After a first anchor (50), secured to a tether (70), is delivered (Figure 5) into endocardium (12), subsequent Delivery Catheters (40) are indexed to adjacent windows (31) to deliver subsequent device components such as links (60, 61) and additional anchors (51). As the delivery catheters deploy anchors into the myocardium, the tether (70) becomes laced around latches (33), fixing GT (30) to the LV wall (11, 12) and maintaining its location with respect to anatomical features. After the last device components have been delivered, GT (30) must be detached from the LV (11) wall and removed through Guide (20).

Figure 6a shows a preferred embodiment of GT (30) configured to facilitate its removal, with a distal end (34) (Figure 6b) containing windows (32) and latches (33), and a proximal end (Figure 6c) containing port (35) and port (36) to control the release of latches (33). The latches themselves (Figure 7a) are comprised of polymer tabs (37), a lumen (38a) through which is routed a fiber latch cable (38b) that is looped over tabs (37) and around a latchwire (39b) residing in a lumen (39a). Latch cable (38b) is then tensioned and secured by cap to maintain the tabs (37) in a closed position.

The latches are opened by first removing latchwire (39) (Figure 7b) by retracting the cap of port (35) (Figure 6c) to which the proximal end of latchwire (39) is attached, then retracting the cap of port (36) that secures the proximal end of latch cable (38b), such that the loops of latch cable (38b) over tabs (37) are withdrawn (Figure 7c) into lumen (38a). GT (30) is then free of tether (70) (not shown), and GT (30) may be removed.
# PROVISIONAL APPLICATION FOR PATENT COVER SHEET – Page 1 of 2

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

## INVENTOR(S)

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<th>Given Name (first and middle if any)</th>
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Additional inventors are being named on the separately numbered sheets attached hereto.

## TITLE OF THE INVENTION (500 characters max):

Device and Method for Releasing Catheters from Cardiac Structures

## Direct all correspondence to:

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## ENCLOSED APPLICATION PARTS (check all that apply)

- [ ] Application Data Sheet. See 37 CFR 1.76.
- [ ] CO(s), Number of COs
- [ ] Drawing(s) Number of Sheets 2
- [ ] Other (specifically described in the invention) Number of Pages 2

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- [ ] Applicant certifies micro entity status. See 37 CFR 1.29.
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Short axis view of LV

Figure 1