

FORM 2

THE PATENTS ACT, 1970
(39 of 1970)
AND
THE PATENTS RULES, 2003

**COMPLETE
SPECIFICATION**

(See Section 10; rule 13)

TITLE OF THE INVENTION

**“SYSTEMS AND METHODS FOR PERCUTANEOUS INTRAVASCULAR
ACCESS AND GUIDEWIRE PLACEMENT”**

APPLICANT

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The following specification particularly describes
the invention and the manner in which
it is to be performed

What is claimed is:

1. A device for creating intravascular access and guidewire placement, comprising:
 - a main body having a first lumen;
 - a piercing member disposed in said lumen, and configured to be moved
 - 5 distally out of said lumen and to pierce through tissue while being distally moved;
 - a handle attached to said main body and having an actuator for moving said piercing member;
 - a second lumen within the piercing member; and
 - a guidewire disposed in said second lumen for delivery into a desired site
 - 10 from a distal end of said second lumen.
2. The device as recited in Claim 1, wherein the piercing member has a sharp point on one end thereof.
3. The device as recited in Claim 1, and further comprising a third lumen within said main body, outwardly of the first lumen.
4. The device as recited in Claim 2, wherein the piercing member is retractable into the first lumen.
5. The device as recited in Claim 4, wherein the third lumen is defined by a needle guide having shape memory properties, the needle guide being actuatable to a curved orientation by adjustment of a position of the main body to create an incrementally adjustable radius of curvature on the needle guide.

6. The device as recited in Claim 5, wherein the piercing member has shape memory properties, and is actuatable to create an incrementally adjustable radius of curvature.
7. The device as recited in Claim 4, wherein said actuator comprises a slide.
8. The device as recited in Claim 5, and further comprising an actuator on said handle for actuating the needle guide to a curved orientation.
9. The device as recited in Claim 8, wherein said actuator comprises a rotatable knob.
10. The device as recited in Claim 1, wherein said first lumen is defined by a needle guide having an atraumatic distal tip.
11. The device as recited in Claim 10, wherein said atraumatic distal tip is comprised of a polymer material.
12. The device as recited in Claim 10, wherein said atraumatic distal tip comprises radiopaque materials.
13. The device as recited in Claim 12, wherein the radiopaque materials comprise a plurality of coils constructed of a radiopaque material.
14. The device as recited in Claim 2, wherein said sharp point comprises a lancet point and primary bevels.

15. A method of creating intravascular access and guidewire delivery, comprising:
- positioning the main body of a device within a primary vessel;
- manipulating a distal end of the device to engage an inner wall of the primary vessel and to push the primary vessel into close engagement with an adjacent secondary vessel; and
- extending the piercing member distally from the main body, through the wall of the primary vessel, and through an adjacent wall of the secondary vessel, so that the end of the piercing member is disposed within the secondary vessel for creating a communicating aperture on the opposing walls of the primary and secondary vessel.
16. The method as recited in Claim 15, and further comprising a step of incrementally adjusting a radius of curvature of the piercing member.
17. The method as recited in Claim 15, wherein the positioning step is performed percutaneously.
18. The method as recited in Claim 15, and further comprising a step of advancing a guidewire distally through a lumen in the piercing member from the primary vessel into the secondary vessel.
19. The method as recited in Claim 18, and further comprising a step of withdrawing the device from the vessel, thus leaving the guidewire in place and crossing from the primary vessel to the secondary vessel through said communicating aperture.

Dated this 02 day of June 2014