



Teleflex was valued at over \$3 billion, a 5.9% increase over the previous year. An important product category within VADs is represented by peripherally-inserted central catheters. PICCs first gained popularity in the US in the 1980s, becoming increasingly popular because of their reduction in cost and potential complications. Today they are used progressively more to deliver chemotherapy and other intravenous fluids and medications [5]. Moreover, clinicians are beginning to utilize power-injectable PICCs for patients who could possibly require imaging in the future. The leading PICC vendors include, in addition to listed above, companies such as Cook, AngioDynamics, Arrow (acquired by Teleflex in 2007), and Vygon. Growth in the market for power-injectable PICCs has simultaneously increased the market for polyurethane PICCs, as power-injectable PICCs are predominantly constructed from polyurethane.

PICCs have several advantages over centrally inserted central catheters, such as options for bedside insertion by nursing staff and local anesthesia, and low risks of pneumothorax and major hemorrhage [6, 7]. The major PICC parameters indicated by the vendors in the FDA submissions and operation manuals are maximum injection pressure and flow rate, as well as kink resistance. Injection rate has been the limiting factor for power injection with a constant maximum pressure rate. Usually injection pressure of 300 psi (2,068 kPa) is specified as the limit, and the flow rate of 2 mL/sec is often quoted as a safe value in tests, though rates of 5 mL/sec and higher are possible [8-11].

Exceeding the maximum flow rate or the maximum pressure of power injection may result in catheter failure and/or catheter tip displacement. Designs optimized computationally or through solving inventive problems can reduce the probability of failure. These solutions are discussed in this article.

## 1.2. Blood Clot Filters

Inferior vena cava (IVC) filters are implanted into the vena cava to trap blood clots, preventing or reducing the likelihood of a life-threatening pulmonary embolism (PE). IVC filters can be made of stainless steel, titanium, or nickel-titanium (nitinol).

The IVC filters can be permanent or retrievable. Permanent filters, which are designed to remain in the patient without the ability to be removed, should ensure secure fixation to the vena cava wall to prevent migration of the filter. Retrievable filters are designed so that they can be removed from the vein with catheter-based retrieval devices when the risk of PE has subsided or when the patient no longer has a contraindication to anticoagulation therapy.

Most designs of IVC filters are collapsible cone-shaped arrays which comprise axisymmetrically arranged struts with hooks (barbs) on the wire ends to secure the filter to the vena cava wall, and locators, which position the filter in the vein (Fig. 1b). These filters have been designed for compression into a small size to facilitate introduction into a vascular passageway and subsequently expandable into contact with the walls of the passageway [12]. Permanent filters include a structure to anchor the filter in place within the vein, for instance, by elongate diverging anchor members with hooked anchors that penetrate the vessel wall. The hooks on the fil-

ters of this type are relatively stiff and do not bend, and within two to six weeks after a filter has been implanted, the endothelium layer grows over the hooks and locks the filter in place. After that, any attempt to remove the filter results in a risk of rupture of the vena cava [12].

To those patients who have only a short term risk of pulmonary embolism, and therefore are averse to receiving a permanent implant, retrievable blood clot filters present a more attractive alternative. If such a filter is withdrawn before the endothelium layer grows over the anchor members, damage to the vena cava wall is minimized. However, after growth of the endothelium layer the combined inward and longitudinal movement of the filter sections as they are drawn apart can tear this layer.

Retrievable filters need to satisfy stringent requirements and still can lead to multiple complications. As of 2010, there were three retrievable filters approved by the Food and Drug Administration (FDA): 1) Gunther Tulip (Cook, Inc., Bloomington, Indiana), 2) Recovery Filter (Bard Peripheral Vascular, Inc., Tempe, Arizona), and 3) OptEase (Cordis Endovascular, Warren, New Jersey) [13]. In 2007, 167,000 filters were implanted, with a projection of approximately 259,000 filters being implanted in patients in 2012. This growth may be linked to the introduction of retrievable filters [14]. A significant complication, prevention of which is discussed below, is difficulty of filter removal, arising due to in-growth (endothelialization) of the filter.

## 2. METHODOLOGY: RESOLVING CONTRADICTIONS. THE CASE OF THE PERIPHERALLY INSERTED CENTRAL CATHETERS

### 2.1. Single Lumen Catheter. Separating Contradictory Requirements in Space

In many cases, the catheter must be able to operate in multiple modes, which presents strict requirements to its design and material. For instance, to simplify insertion and reduce discomfort, PICCs and other semi-permanent catheters are generally made thin and flexible, which limits their structural strength, and, in turn, the maximum pressure and flow rate a catheter can handle. This leads to *contradictory requirements* to the design and material of the device. For instance, in terms of the wall thickness, the catheter needs to be highly flexible in order to facilitate/enhance its penetration, and therefore the thickness of the walls and the moment of resistance of its cross-section should be low; however, the wall thickness needs to be high to increase the maximum pressure and flow rate during power injection. (The external diameter of the catheter is limited by the vein diameter and cannot be varied).

Another requirement to the catheter design is visibility under X-ray fluoroscopy, by which the location of the tip of the catheter is ascertained. To that end, a radio-opaque agent, such as BaSO<sub>4</sub>, is often introduced in the catheter material. However, presence of radio-opaque agents is known to weaken the catheter materials [15].

Likewise, exposure to alcohol or other solvents leads to degradation of such catheter materials as polyurethane [15]. A combination of these two factors (BaSO<sub>4</sub> and alcohol) can lead to a failure in the proximal part of the catheter, which is















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