Method and apparatus for constant access to catheter lumen for automatic injection of contrast medium, saline flush allowing free catheter manipulation and device delivery
(Contrast Injection)

Project Design Specifications

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Function:

Angiography is a technique to produce x-rays of the inside of blood vessels, and over 1.6 million procedures are conducted yearly on humans alone. A small amount of contrast medium is injected through a syringe at the point of interest, which allows the image to show up clearly. Manifolds are prevalent in most delivery systems, because they allow multiple access points to the catheter. Contrast agent, saline flush delivery, stent insertion access, and other injection agents can simultaneously be injected because of this device. It is our group's goal to redesign this manifold to be much more user-friendly, and ultimately be compatible with a power injector. Other important ergonomic factors will also be addressed in the manifold's design, as well as other aspects in the angiographic process including various connection issues and air/blood detection methods.

Client Requirements:

- Design should streamline angiographic process
- Design should monitor saline level while in use
- Manifold should be modified to work with a power injector if possible
- Syringe must meet all medical device standards
- A 'Virtual Syringe' should be developed for use with the power injector, if possible
- Connection point between catheter and manifold should be adapted to a more user-friendly system
- Free-access to the catheter should be maintained at all times

1. **Physical and Operational Characteristics**
    a. **Performance Requirements:** The main component of the device will be a manifold which will allow for easy fluid management for injections. It must be

compatible with current power injectors, which will be used for contrast agent delivery. It must be able to deliver both contrast and saline flush to a catheter. However, the manifold must also have extra ports to allow for injections of other fluids. The device must allow for constant access to the catheter during use.

b. **Safety:** The device must make detection of air and blood in the fluid easy. This can be done via sensors such as ultrasound or by making the presence of air and blood easy to see visually. Prevention of air bubble development and blood influx must also be included in the design. The device must be able to be easily rinsed with a saline flush at any time. A waste removal system must also be implemented in the design.
c. **Accuracy and Reliability:** The device must be able to accurately and consistently deliver the desired volumes of saline and contrast agent at the desired flow rates. The device must be robust enough that it will not break and that components will not become disconnected during operation.
d. **Life in Service:** The device is intended for one time use, so sterilization via autoclaving or chemical sterilization is not an issue. The device must be disposable.
e. **Shelf Life:** The device should be able to remain in operating condition for long periods of time. Since the device is to be made mainly of plastics, this should not be an issue.
f. **Operating Environment:** The device will be used in a surgical setting for x-ray procedures. It must be inert to x-ray radiation and any substance it is used to inject, which is primarily saline and contrast agent but could include other fluids.
g. **Ergonomics:** The stopcocks must be easily manageable. Detection of air and blood must be easy to perform quickly. The device should be space efficient and not cumbersome to the operator. Input ports should be easily accessible. Connection to fluid reservoirs should be quick and efficient to perform.
h. **Size:** The manifold portion of the device should be about 6 inches long and 2 inches wide. In essence, the device should not become cumbersome to the operator during use. The entire device, including manifold, tubing, y-connectors, etc., must be as space efficient as possible.
i. **Weight:** The manifold, tubing, and y-connectors should be lightweight.
j. **Materials:** Plastic commonly used in medical tubing and manifolds, must be chemically inert, nonreactive to x-ray radiation, and robust.
k. **Aesthetics, Appearance, and Finish:** Must look professional. Pieces must be clear for the most part, but stopcock handles should be color coded.

2. **Product Characteristics**
    a. **Quantity:** Our client requests one unit be built.

b. **Target Product Cost:** The device should be competitive with current manifolds on the market, in the range of

3. **Miscellaneous**
    a. **Standards and Specifications:** The final product must meet medical device standards.
    b. **Customer:** The intended user of this device will be used by doctors and researchers who are performing diagnostic and interventional angiographers.
    c. **Patient Related Concerns:** The design must allow for controlled injections to patients, prevent air bubbles from being injected, prevent blood from flowing back up into the manifold and contaminating fluid, and must be ergonomic so that inexperienced operators may be able to correctly use the device.
    d. **Competition:** The Avanta Fluid Management Injection System made by Medrad performs many of the functions intended for this device, but is expensive and not widely used. There are very few other devices that combine the use of the manifold fluid management system and the ease of use of the power injector in the manner this device is intended for.