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MEDICAL

WHITE PAPER

NEW CATHETER BASED DEVICES AND PROCEDURES DRIVING HEMOSTASIS VALVE INNOVATION

The viability of new interventions dependent on more robust componentry

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Today's hemostasis valves are a vexingly difficult engineering challenge. Beyond the minimum requirements per ISO11070 and ISO10555 for pressure and vacuum decay, emergent invasive catheter therapies are demanding much more from the introducer componentry, especially the hemostasis valve. In this article, we review some of the factors rendering older valves inadequate, and some things to consider when choosing a device development partner.

Meeting New Clinical Challenges

In the past, hemostasis valves primarily had to only maintain hemostasis during single, narrow gauge device catheter procedures. Today's valves must provide a much higher level of performance. New larger-bore, blunt tipped and multi diameter catheters require the valve to

- hold instruments precisely in place
- reduce/regulate friction as an instrument is being used
- provide visibility and low crossing forces as devices are introduced
- account for higher hydraulic pressure as larger instruments are inserted and removed
- allow devices to be introduced and removed while others are in place

...AND maintain durable hemostasis during the entire procedure.

As new catheter-based devices are being developed, engineers must consider the hemostasis valve crucial to the overall viability of their projects.

Maximizing Elastomer Science

Many of the exciting new catheter-based devices and therapies would not be possible without reimagining the hemostasis valve and its component parts. Of particular importance is the gland, the part of the valve responsible for maintaining hemostasis. New elastomeric materials must be developed for the gland to meet the increased tolerances demanded of the valves. They must maintain hemostasis around multiple devices, with a variety of distal shapes and longitudinal widths, and under a variety of procedural situations that would compromise older valve componentry.

There are many factors that are considered in the suitability of a material used in a hemostasis valve. Particularly close attention must be paid to how a given material performs at different stages of its lifecycle and the device's lifecycle. Performance, as tested at the manufacturing stage, can critically change over time and use. Engineers need to look at how component materials react to one another not only upon initial mixing of the compounds but over time as the cross-linking of molecules continues to occur, even past curing stage. Elastomers may degrade under normal usage and can be reactive to a host of environmental factors. Consideration must be given to how a material reacts to repeated sterilization, how resilient it is, and how its properties may change as it ages 'on the shelf.'

Materials must not only be evaluated in a 'standalone' environment, but also meticulously tested under the stresses of procedural use. Overall durability and the ability to withstand elongation, shedding, and damage after multiple insertions factor into a material's potential suitability. Bio-reactivity is also a factor that must be considered and carefully tested.

Choosing the Right Partner

As devices and procedures become more complex, existing component technologies are being pushed past their performance tolerances and are quickly becoming outmoded. When taking a new catheter device design past concept stage, ensure your partner is well-versed in the demands of today's complex catheter procedures. This is crucial and can provide substantial cost and time savings from development to manufacturing.

Freudenberg Medical Hemostasis Valves

Freudenberg Medical offers four different valves to address the widest possible conditions and needs for hemostasis in catheter-based procedures. Each valve has been developed for specific applications and to address increasingly larger-bore procedures, multiple device insertions, and the specific characteristics of how different catheter tips move through the valve.

The HyperSeal® and HyperSeal® XL valves have been developed to maintain hemostasis around larger and more complex catheters while maintaining a high level of performance as new procedures push technologies past the limit of previously adequate solutions. These self-sealing valves are manufactured from Freudenberg-engineered elastomeric materials that provide our development partners with the most advanced solutions for their devices, in applications up to 20 Fr, 30 Fr, and 40 Fr.

The FlexSeal® hemostasis valve was developed to provide user-actuated control over the seal while maintaining durable hemostasis around multiple devices and during repeated large-bore device insertions in 12 Fr to 26 Fr applications.

The CertuSeal® valve incorporates the slit valve technology for ≤12 Fr applications. Proprietary molding and slitting processes for these valves ensure the valve is durable and performs in a predictable way.

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