Five Basic Steps to Proper Membrane Selection

Selecting a membrane to use with a medical device seems like a relatively simple enough process, however, without careful consideration of a number of key factors, a device can fail as a result of an improper choice. This article provides five basic steps to aid medical device designers in ensuring they are making a proper selection for their specific application.

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The design and implementation of a membrane into a device is not an art form, but fundamental knowledge of the components and their functionality can help ensure success. Whether designing a standard biomedical product or on the cusp of medical device innovation, proper use of micro or ultrafiltration membranes requires a primary understanding of the membrane technology. Some important aspects to consider when choosing the appropriate membrane are surface energy (hydrophilicity, hydrophobicity), pore size, membrane type (polymer composition), strength requirements, support requirements, flow rate, water entry pressure, and sterilizability.

Typical device applications for OEM membranes

This article will focus on the basic technology and key questions to consider when selecting membranes for use in biomedical devices and products, acting as a guide for successful product development. As with any design process, failure to properly define the requirements of the device or application from the project onset can cause significant delays in product development and market introduction.

Step One: Define the Medium Being Filtered

Is air being removed from a liquid stream or particles/contaminants from a solution? Hydrophilic membranes are best used when the fluid needs to pass through the membrane, thereby removing particles/contaminants in the process. Hydrophobic

or Oleophobic membranes are most commonly used in venting applications where high surface energy liquids such as water or protein solutions need air removed from the fluid stream. While hydrophobic membranes will repel many liquids, they will not repel oils or some alcohols. Because of this need to repel other low surface energy liquids, a secondary process is needed to render hydrophobic membranes superphobic or oleophobic. This process changes the surface chemistry of the membrane such that it will repel oils and most alcohols (with some exceptions including heptane).

Step Two: Define the Necessary Pore Size

If a ‘sterilizing’ grade filter is required, typically a 0.2 micron pore size hydrophilic membrane is used to sterilize or remove common bacteria which is 0.2 &#181m or larger in size. The pore size rating of a membrane can be determined by using the bubble point test method. The bubble point test is a simple way to evaluate the pore sizes of a membrane using either RO water or 100% IPA and air pressure. Simply stated, the bubble point test will determine the path of least resistance of an air bubble through a wet membrane. This path is usually the largest pore structure or combination of torturous paths through the membrane. Once the pore size is determined, the next step in defining the application can be addressed choosing a membrane polymer type.

Slit membrane rollstock

Step Three: Define the Membrane Polymer

Some solutions are more efficiently and effectively filtered using a certain type of membrane instead of another. For example, a PVDF (polyvinylidene fluoride) will bind less proteins than a PES (polyethersulfone) membrane. If proteins are the desired filtrate, a PVDF membrane will provide the best results when compared to a PES or MCE (mixed cellulose esters) membrane. It is also critical to select a membrane polymer that is compatible to the housing polymer so the standard heat or ultrasonic sealing methods will easily achieve the desired results. When the membrane polymer and device plastic are incompatible, bonding is often achievable only at energy levels so high that the porous structure of the membrane

is breached or collapsed.

Step Four: Define the Strength and Additional Support Needed

Will this membrane be supported by a device? If so, a substrate or non-woven backing is not needed to provide extra strength and support. If the membrane will stand alone without a rigid structure or support mechanism, most likely a membrane with a backing will be required. Based on the nature of the polymeric structure, PES and PVDF membranes can almost be considered brittle when compared side by side to an un-backed polytetrafluoroethylene (PTFE) or ultrahigh molecular weight polyethylene (UPE) membrane. PTFE and UPE are both highly flexible material and resemble plumbers tape in their look and feel. However, PES and PVDF membranes are far superior to PTFE and UPE when used in applications where protein binding and gamma sterility are crucial design criteria. Because membrane characteristics will vary between types, this reinforces the importance of defining the needs of the product, which in turn will help define the membrane used.

Step Five: Define the Flow Times or Porosity Needed

Flow times and porosity are usually dictated by the pore size chosen in Step Two, but be aware of its affects on flow times the smaller the pore size, the slower the flow for both air and liquids. Thinner membranes may provide somewhat faster flow rates, but there is a practical lower limit to membrane thickness of about 100 microns. To overcome this limitation and improve the flow rate of small pore size membranes, asymmetric and co-cast membranes have been created. Asymmetric pore structures act similar to a funnel, where one side of the membrane is more open than the other. This allows more particles to be captured without impacting the flow of the fluid stream, and the resistance to flow is limited to the portion of the membrane with the smallest pores. Co-cast membranes act in a similar fashion, but they actually have two layers of membrane that are cast in a single membrane.

Conclusion

While there are many additional factors to consider when choosing an appropriate and robust membrane for an application, the ones aforementioned are a good starting point for the novice user as well as a practical reminder for the experienced. The choices can be vast, but thorough definition of the project goals and milestones can increase success and support a timely market introduction. If still uncertain about how to select the right membrane for a project, enlist a membrane provider to guide the selection, development, and implementation process.

Online

For additional information on the technologies and products discussed in this article, see Medical Design Technology online at www.mdtmag.com [1] or Millipore Corp. at www.millipore.com [2].

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