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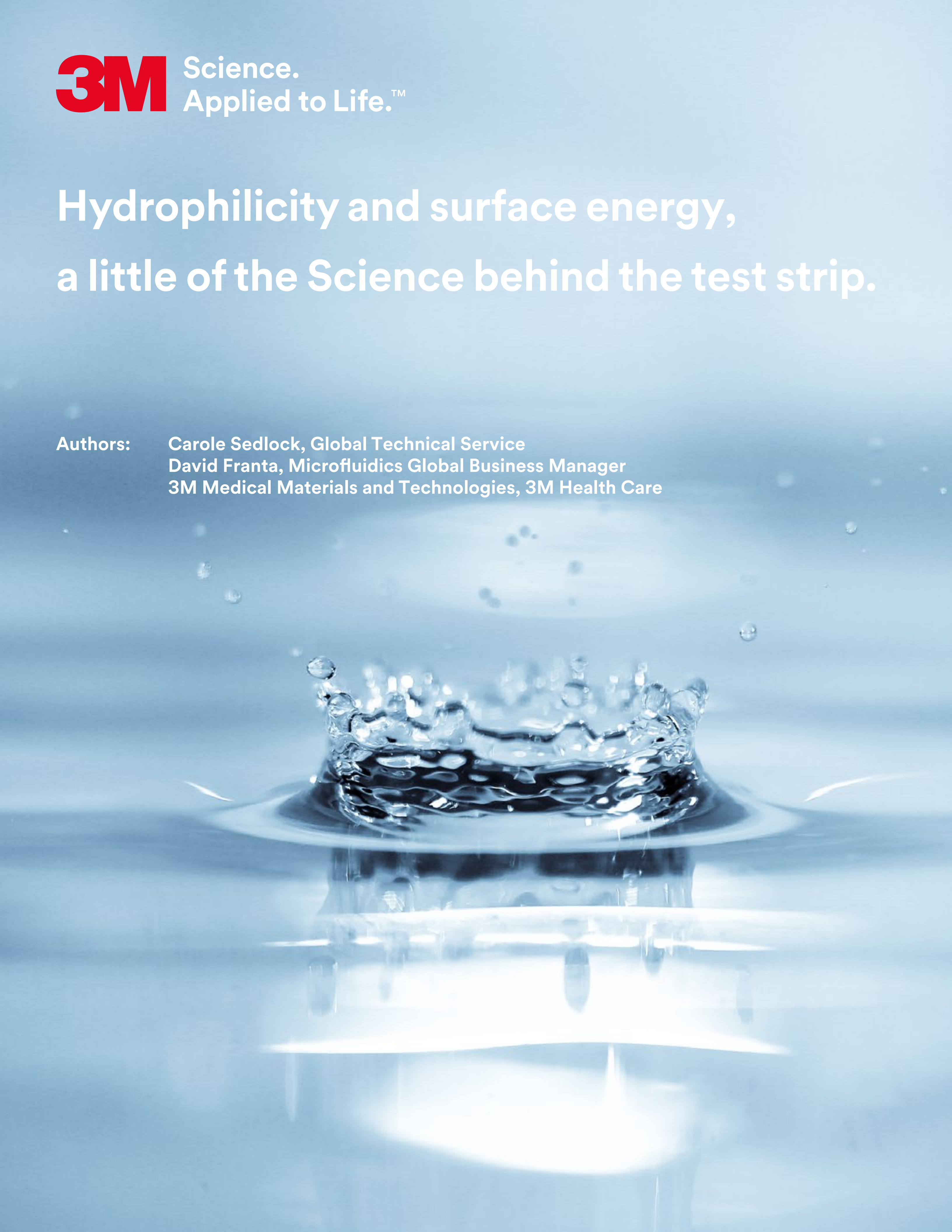
Hydrophilicity and surface energy, a little of the Science behind the test strip.

Authors: Carole Sedlock, Global Technical Service
David Franta, Microfluidics Global Business Manager
3M Medical Materials and Technologies, 3M Health Care



Design engineer considerations when selecting materials and designing microfluidic devices.

Microfluidics is the science of moving microscopic volumes of fluids through tiny channels in a device. Microfluidics technology is used in the construction of blood glucose strips, lab-on-a-disc / lab-on-a-chip applications, and other diagnostic consumables and devices. The applications for devices using microfluidics are varied with examples such as pathogen detection, chronic disease monitoring, cancer screening, genetic biomarker detection, food and environmental monitoring.

Patients and their caregivers rely on the accuracy and ease of use with point-of-care and other lab-on-a-chip devices. With the evolution of diagnostic science, microfluidic devices are now able to measure and analyze a small biologic sample in minutes, instead of the historical days or weeks. A shift from centralized laboratory locations to small portable devices for point of care testing and results enable people to make decisions in managing their chronic disease from home instead of the physician's office.

It turns out the measurement process with a microfluidic device is quite complex. For example, when measuring blood glucose levels, an enzyme in a test chamber reacts with the glucose in the blood sample and changes oxidation state. The enzyme then reacts with a molecule of glucose to transfer the charge, allowing for electro-chemical detection. The electrodes in the test strip and the meter then work together to measure an electro-chemical current and report the glucose concentration – letting the patient know if their glucose level is high, low or right on target.

Today, medical device design engineers work to develop new devices, with the resulting innovations in improving our ability to manage chronic disease and ultimately the quality of life for millions of people. There are many complexities when integrating multiple technologies to form microfluidic devices that may be fabricated into high volume diagnostic consumables. That's why it's critical that the materials used in their construction deliver consistently reliable performance, time after time.

The ability to consider material and precision fabrication properties, while additionally leveraging sensing and chemical know how are just the beginning to moving microscopic amounts of fluid through tiny channels. A typical strip design is the use of a transparent hydrophilic top film designed to wick or promote movement of the sample blood drop into a capillary test chamber. The test strip chamber is likely formed via lamination of one or more "spacer" layers that have been processed via a notch cutting operation to form a channel. The bottom layer is usually a reagent pad deposited onto a conductive layer that contains circuitry to allow electrochemical measurements.

Depending on the end-use application, a variety of materials can be used. Materials such as the silicon and glass materials were used in early devices to today's polymer-based thermoplastics, elastomers, and paper-based membranes.

- Thermoplastic and paper-based materials are good for large-scale production and integrated into high speed automated systems.
- The paper-based materials are more cost-effective and sustainable
- Plastic materials are potentially more expensive, yet offer durability, uniformity, chemical resistance, and optical transparency.

Advances in robotics, artificial intelligence, 3D printing and laser cutting make the use of polymer-based materials well suited for the low-cost manufacture of complex systems on a microscale[1].

Moving Fluid

Common to all microfluidic devices is the need to move fluids such as liquid sample or assay materials from place to place for subsequent processing or measurement. In some complex devices, microfluidic structures are also designed for additional functions such as mixing, separation, and accumulation are common features. Interestingly many of the fluidic designs have analogs to electric circuits with simple fluid pathways acting like wires in an electric circuit. The design of microfluidic networks to accomplish all the functions required for the final assay can be quite complex.

Along with design complexity, each channel should be manufactured to exacting specifications and tolerances. If not, the accuracy of the finished device may be compromised. For example, some blood glucose test strips may rely on the timing of the blood flow to the enzyme. If the speed of reaction is not consistent, it could affect the accuracy of the reading or cause an error in the system. In a more complex lab-on-a-chip device with multiple fluid paths and other microfluidic features, the rate of flow and timing of the fluidic circuit likely must be controlled for a dependable reaction.

The modern point of care diagnostic devices often relies on miniaturization, allowing rapid and precise tests in small-sized devices, where channels and features may be measured in the tens of microns. Reliability of performance means that some not so visible properties, such as surface energy or hydrophilicity of the construction materials used in the fabrication of the device become critical.

Hydrophilicity

Hydrophilicity is a critical feature in fluid flow mechanisms used for microfluidic devices. The resistance to fluid flow is especially important in a passive flow device where capillary action is used to move fluid such as test strips. Hydrophilic surfaces are "water-loving", in that they allow fluids to wet out or flow across a surface and promote fluid flow through a channel into a test chamber. The surface energy or degree of hydrophilicity varies widely in device construction materials from water-repelling or hydrophobic (low surface energy) to hydrophilic (high surface energy) where water easily wets a surface. The requirements of your device such as fluid sample type, channel design, reaction volumes required, and other reaction specific conditions such as time and temperature all interact to produce unique challenges for device engineers.

The choice of quality materials is often a critical decision in device design that can affect overall system performance.

Contact Angle

Surface hydrophilicity is generally measured by a test of the water contact angle using an instrument called a goniometer. A measured drop of liquid (usually de-ionized pure water) is dispensed onto a given surface and the angle at which the fluid contacts the surface is then measured. The lower the contact angle, the more the drop spreads on the surface and the more hydrophilic the surface. In general, for a surface to be considered hydrophilic the contact angle should be less than 90 degrees[2]. In practice for microfluidic device applications, a contact angle of 45 degrees or less is commonly used to mean the surface is hydrophilic.

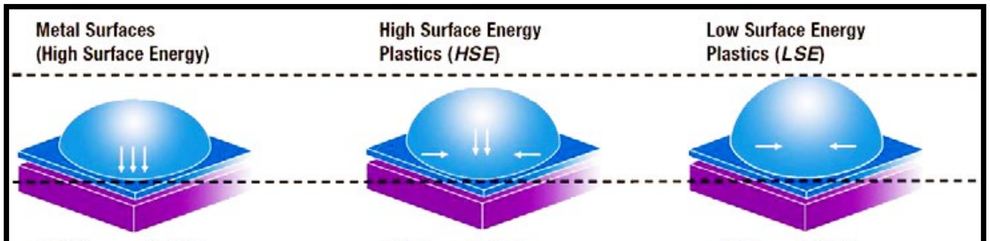
Figure 1 demonstrates the difference in the hydrophilicity of a contact angle from 117° to 72°, however, to achieve adequate fluid flow, most microfluidic devices require a hydrophilic surface with a contact angle 45° or less.

Figure 1

A material such as bare polyester in practical use does not have enough hydrophilicity to promote flow, but it can be functionalized by various surface treatments such as plasma or chemical top coatings to create a hydrophilic surface. Since surface treatments vary from one manufacturer to the next it is important to determine the compatibility of any hydrophilic treatment with your specific device. Compatibility is measured in terms of the functionality of flow mechanics, and fabrication methods, and potential interactions with the sample fluids and reagents.

Surface Energy

As mentioned previously, the surface energy is an important factor in the determination of wettability for a liquid, but the surface energy of materials also plays a critical role in bonding materials together with adhesives or when applying a coating to a surface. High energy, highly wetting surfaces are generally easier to attach reagents, enzymes, inks, and conductive materials compared to low energy surfaces[3]. When creating a fluid channel with adhesives, using methods such as by bonding multiple structured layers, a high energy surface usually helps to adhere quicker, stay put longer and form a tighter seal.



mJ/m²	Surfaces
1103	Copper
840	Aluminum
753	Zinc
526	Tin
458	Lead
700-1100	Stainless Steel
250-500	Glass

mJ/m²	Surfaces
50	Kapton® Industrial Film
47	Phenolic
46	Nylon
45	Alkyd Enamel
43	Polyester
43	Epoxy Paint
43	Polyurethane Paint
42	ABS
42	Polycarbonate
39	PVC Rigid
38	Noryl® Resin
38	Acrylic

mJ/m²	Surfaces
37	PVA
36	Polystyrene
36	Acetal
33	EVA
31	Polyethylene
29	Polypropylene
28	Polyvinyl Fluoride Film
18	PTFE Fluoropolymer

Figure 2

Figure 2 illustrates the surface energy differences in several surfaces.

Fluid Channel

Creating fluid channels can be achieved using a variety of methods. A few examples include etching, machining, casting, laser cutting, die cutting and molding. The dimensions of a channel, the shape, and surface properties of the channel all affect the amount of fluid volume allowed to enter the device and the fluid speed.

Bonding two materials together to build a channel can be accomplished by various methods such as adhesives, sonic welding, and heat bonding. Compatibility of the bonding materials and methods used to construct the channel play a critical role in the fidelity, reproducibility, and stability of the fabricated channel.

Compatibility when bonding the materials together is essential when fabricating large numbers of devices is desired. Along with the bonding and construction materials for a device also consider that the test fluids, coatings, enzymes, reagents, and electrical components may interact and should be evaluated once the device is assembled.

Example Bonding Types

Heat Bonding

Heat bonding materials are associated with melting of materials or coatings and can be utilized to create a channel structure. The process requires pressure and uniform heat that is dependent on the materials which are chosen to properly bond to the surface. Care must be taken to ensure that the amount of heat and pressure required will not deform the microfluidic geometries, degrade reagent chemistries, or effect device hydrophilicity.

Adhesives

Liquid adhesives and pressure sensitive adhesives tapes are also used to create microfluidic devices. Liquid adhesives may have some advantages as they can be dispensed to specific areas without the need to die cut and remove unneeded materials. The disadvantages are exacting dispensing is required, and uniform curing is necessary to avoid inconsistencies in the channel performance, bonding, and dimensions. Dispense errors such as overflow onto channel fluid paths could alter flow dynamics.

Pressure Sensitive Adhesives (PSAs) have some advantages as they can be manufactured with precision thickness and could likely combine with various backings to create and maintain stable channel dimensions. In addition, since PSAs can be supplied as roll stock material the handling and registration during fabricated by die cutting and/or laser cutting is simplified. In addition, many PSAs can be precision coated to various thicknesses and produced as a transfer adhesive (no backing), single coated film (adhesive one-sided coating) or finally double coated spacer tape (two-sided coating) to accommodate the wall dimension needed for specific channel dimensions. To properly bond a PSA, it is important to match the adhesive chemistry with the other device materials surface energy and understand the correct bonding (lamination) conditions.

Figure 3 demonstrates the effect of a materials surface energy and typically how easy or difficult it will be to form a bond on bare uncoated materials.

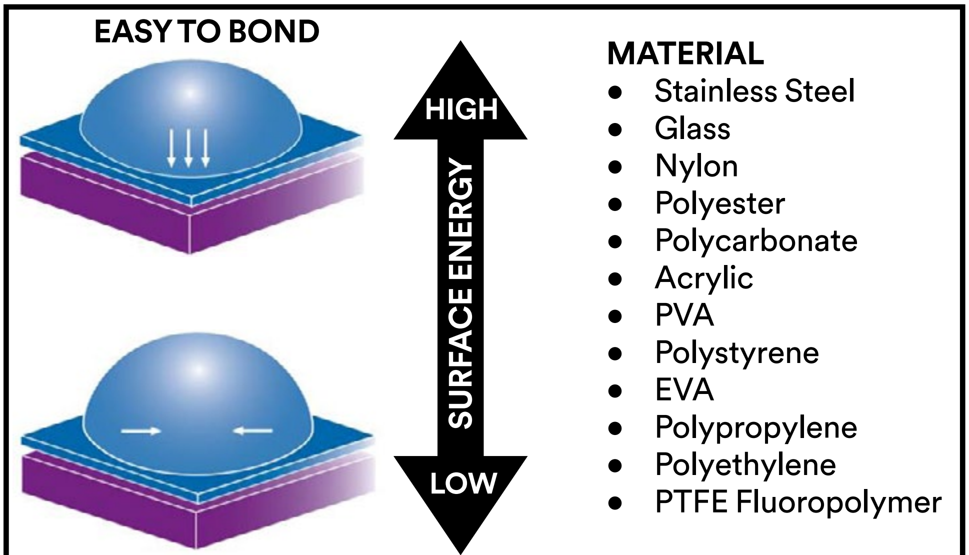


Figure 3

In all bonding applications, it is important to assess strength and stability of the bond produced by considering the materials to be bonded with the methods and potential bonding chemistries deployed. The materials used for bonding should be assessed for compatibility with the channel materials and test chemistries both during fabrication and during the device use over the life of the product.

Other Considerations

Interfering substances: Take time to understand if there are there extractable or chemical products that could bloom to the surface or outgas and interact with either the test fluids or other components of the device. In some cases, mobile species contained in the device construction materials may present problems under certain conditions such as elevated temperatures or when exposed to particular solvents.

Processing: What processing conditions will each component be exposed to during fabrication and how will they interact? Consider exposure to lubricants, substances on equipment rollers, lamination variations, contaminants from handling, storage conditions and exposure to heat and/or humidity, along with selecting proper packaging materials to protect at-risk materials. Materials used during prototyping or development may behave differently when used in production environments at scale.

Shelf Life: What is the expected shelf life of the finished product? Will the chosen materials maintain their properties and function throughout the expected shelf life of the finished product? Do any of the construction materials have shelf-life considerations and can properties change during storage.

Conclusion

Discovery, innovation, and development of new materials and technologies such as 3D printing are rapidly enabling the healthcare of the future[1,3]. Each application offers a unique set of challenges but understanding material properties and how device materials interact will help avoid potential pitfalls. Enabling patients to take ownership in managing their chronic disease is possible only if the medical device delivers a consistent, accurate result, time after time. Selecting a design partner and material supplier you can trust to deliver consistent materials, evolve as the market changes, and that you can rely upon to solve a variety of challenges is crucial to success.

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Medical Materials & Technologies
3M Center, Building 275-5W-05
St. Paul, MN 55144-1000 USA

Phone 800-584-2787
Web www.3M.com/MedTech

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