Nordson MEDICAL

PFAS-Free Materials

IN MEDICAL DEVICES

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In Medical Devices

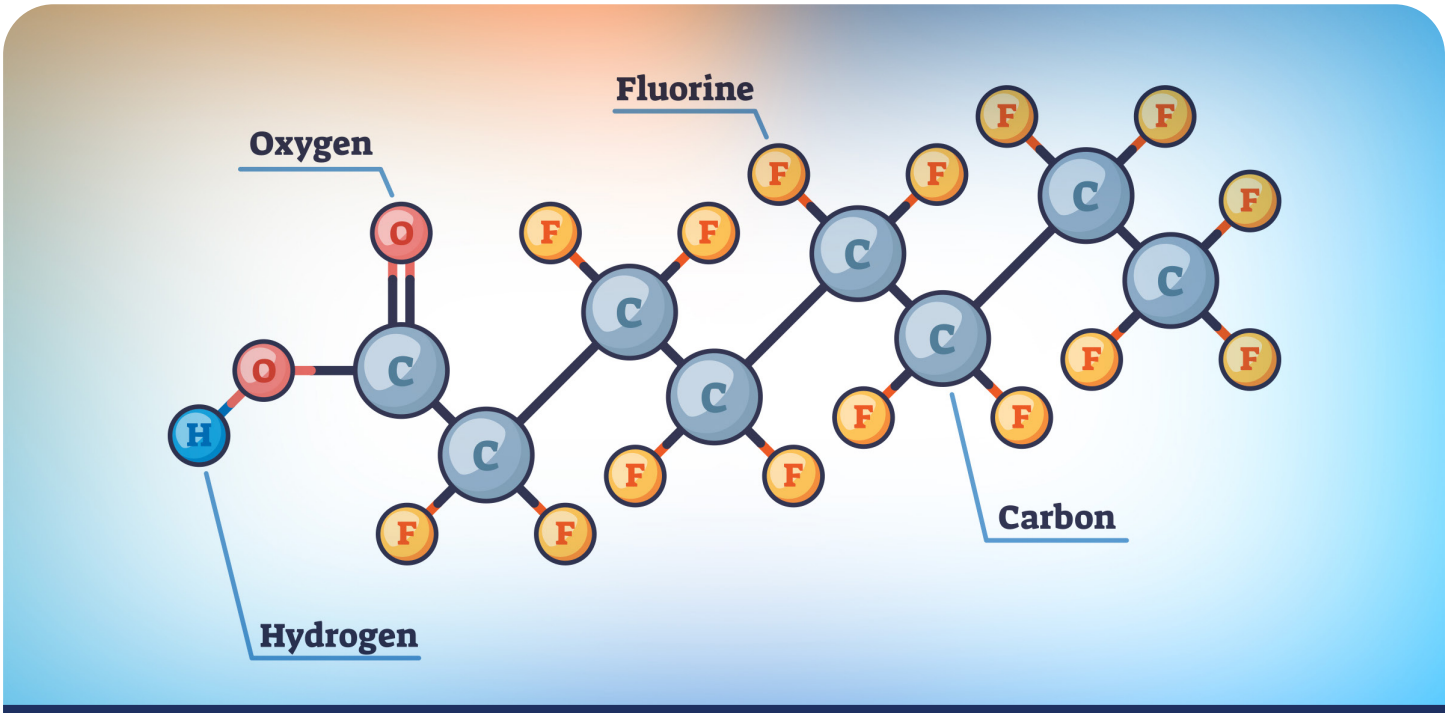
1.0 Introduction

Per and Polyfluoroalkyl substances (PFAS) are used in a broad range of applications and products throughout many industries, including the life sciences, which incorporates the medical device area. Among these, polytetrafluoroethylene (PTFE) is the most commonly used PFAS material, particularly in the majority of catheters manufactured globally.

Historically, these types of materials were selected as they possess many unique properties derived from their strong carbon-fluorine (C-F) bonds, such as excellent thermal stability, high dielectric strength and exceptional chemical inertness. Another unique property of PFAS materials is their low coefficient of friction (CoF). The fluorine atoms surround the carbon backbone, which gives the material an exceptionally stable surface coupled with low surface energy. In the medical device field, it is this low coefficient of friction (CoF) property that is utilized in medical devices such as catheters, which could comprise of a single lumen shaft, as well as more complex multi-lumen designs, introducer sheaths and balloon protectors.

While the strong carbon-fluorine (C-F) bond gives PFAS materials their unique properties, it is this bond which is the reason for Reporting Rules, possible restrictions, or possible phasing out of PFAS materials currently been investigated and implemented by various global regulatory and government bodies. The C-F bond is one of the single strongest bonds in chemistry, which means it is exceedingly difficult to break. Adding to this, the fact that these materials are synthetic means this bond is extremely resistant to natural degradation. This can lead to PFAS chemicals building up in soil and water, which can lead to a risk of contamination of living organisms through these mediums.

Because of the ongoing challenges and uncertainty in the PFAS space, organizations are starting to look for potential alternatives to PFAS materials that many of their current products are using.



Molecular structure of a typical PFAS

2.0 Scope

PFAS materials are used in many different industries and products. Because Nordson MEDICAL is a medical device components manufacturer whose customer base uses PFAS materials such as PTFE in their finished devices, it was decided to focus on PFAS-free alternatives to PTFE liners as used in products such as engineered catheter shafts. However, while this study focused on this specific area, it was felt that any findings or conclusions could also be potentially applied to other applications where PTFE type materials are currently used for their low coefficient of friction (CoF) properties in the medical device industry.

The Nordson MEDICAL Product Innovation team (PI) investigated the most suitable additives that could be compounded into standard thermoplastics to improve the coefficient of friction (CoF) properties of the materials. The desired outcome was to find a material that could compete with PTFE in this unique property. This research started with a selection process that involved collaboration with industry leaders in the supply of these additives. The resultant materials used in this study are the latest generation of these additives in the marketplace with some of the additives assessed for the first time by Nordson MEDICAL.

3.0 Materials

Table 1 below shows the materials that were selected for inclusion in this project. PTFE and Vestamid CARE ME55 were selected as the two baseline materials for the friction testing that the rest of the materials could be compared against. PTFE was selected because it is generally considered the most lubricious and commonly used liner material for engineered catheter shafts. Vestamid CARE ME55 was selected as it is a material with a similar shore hardness to PTFE, and a suitable material to load with additives while not significantly deviating from the shore hardness properties of PTFE. The PTFE tubing was produced in the Nordson MEDICAL facility in Easton. All other tubing was produced in the Nordson MEDICAL facility in Boyle.

Sample ID A1 is an EFEP material, produced in a 2-layer product. This tube has EFEP on the inner layer and Vestamid CARE ME55 on the outer layer. This EFEP material is not a PFAS-free material, however it was decided to include in this project as it is an alternative material to standard PTFE tubing generally produced via RAM extrusion. The EFEP material has an advantage in that it can be processed into tubing using conventional extrusion methods and can bond directly to certain PEBA type materials using a co-extrusion process. The EFEP grade is new to market and Nordson MEDICAL is among the first companies to perform testing with it.

TABLE 1

Sample ID	Nordson Reference	Material	Description
B1	PTFE Tube	Natural PTFE (RAM Extruded)	Baseline Data (PTFE)
B2	413170	Vestamid CARE ME55	Baseline Data (Natural PEBA)
A1	413266	EFEP/Vestamid ME55 2-Layer	Alternative Fluoropolymer to PTFE
A2	413402	Vestamid ME55 & Lubricious Additive	Lubricious Compounded Material
A3	413212	Vestamid ME55 & Lubricious Additive	Lubricious Compounded Material
A4	413335	Vestamid ME55 & Lubricious Additive	Lubricious Compounded Material
A5	413264	Vestamid ME55 & Lubricious Additive	Lubricious Compounded Material
A6	413334	Vestamid ME55 & Lubricious Additive	Lubricious Compounded Material

4.0 Extrusion Results

All materials in Table 1 were produced into tubing to the following sizes and tolerances.

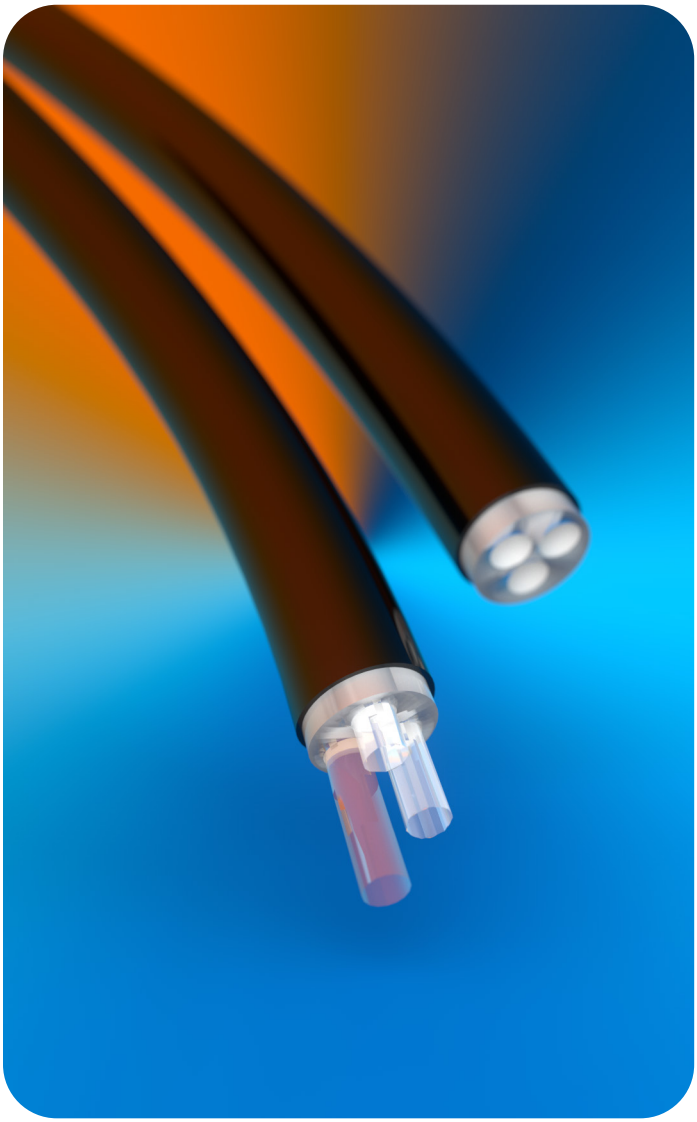
OD: 2.34 mm ± 0.03 mm

ID: 1.94 mm ± 0.03 mm

Length: 1200 mm

Extremely tight ovality was targeted also. It was essential to maintain this tight dimensional stability, as fluctuations could impact on the friction testing phase of the project.

All materials processed well, with good stability and no major observations noted outside what would be seen in the natural versions of these materials.



5.0 Friction Testing

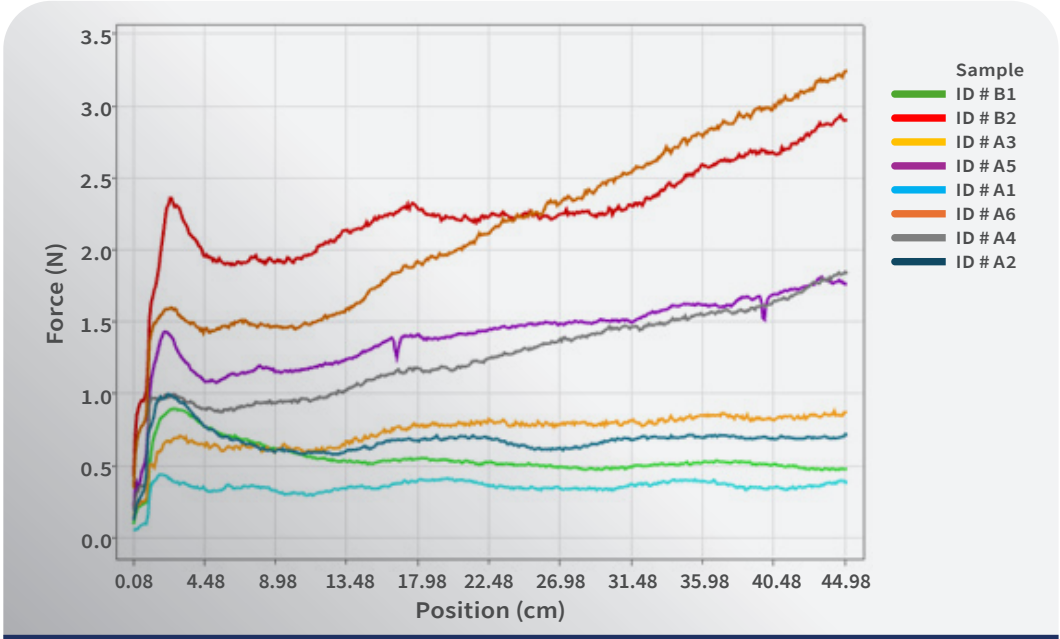
As the primary focus of this study was to assess the various lubricious additives as a PFAS-free alternative to PTFE liners, a comparative friction test to assess the lubricity of the inner lumen of the tubes was developed. There is not a specific ASTM or ISO test method for this type of friction testing on tubing, because the friction testing of these types of products is very application specific and influenced by factors such as contact materials and product traction path.

For the testing of tubing in this project, Nordson MEDICAL developed a specific test method to gather data for the ID friction. This test method is a comparison test only, as are the results. It is not meant as a test that replicates any other friction test in a medical device procedure, but rather a test that exaggerates friction for comparison purposes.

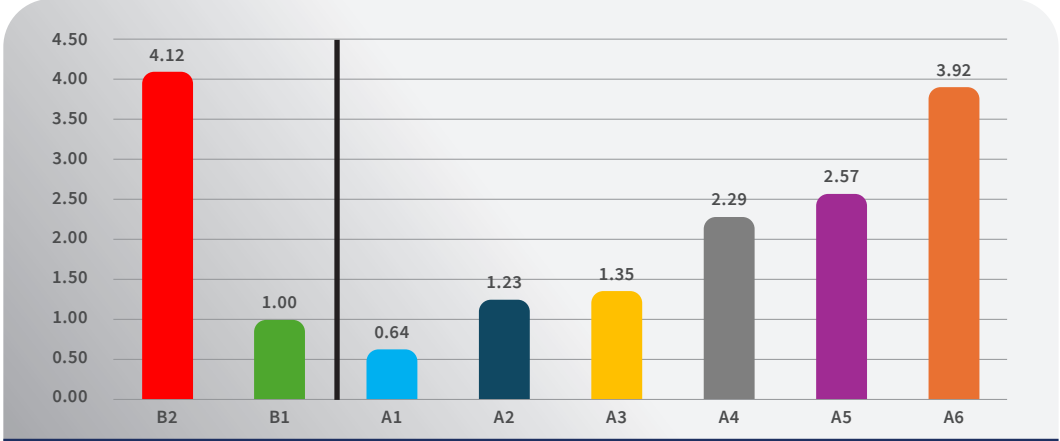
This test method consisted of a two-part fixture block which held the tubing in a specific path. A mandrel was then inserted up the ID of the tubing and the resulting insertion forces recorded. This test method was intentionally designed to create friction, meaning the mandrel OD was just 0.0005'' below the minimum tube ID. This is to ensure there is physical interference between the OD of the mandrel and the tubing ID.

- All the testing was conducted on an MSI Catheter Tester
- Testing was performed dry
- Mandrel insertion speed was 600 mm/min
- Insertion distance was 450 mm
- Two sets of testing were performed, the first with a PTFE-coated mandrel and the second with a SS mandrel (uncoated)
- 10 samples of each product were assessed in each set
- **Average** insertion force and **Maximum** insertion forces were the two values recorded
- All data was normalized to give PTFE a base line force value of 1.00. All other product results were compared against this for comparison purposes

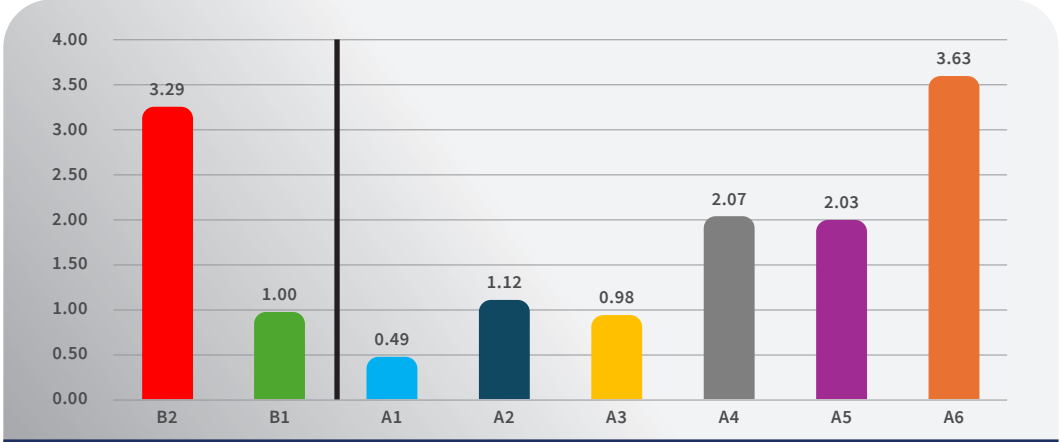
5.1 Testing with PTFE Coated Mandrel



GRAPH 1: PTFE Mandrel - Overlay Plots - Straight Fixture

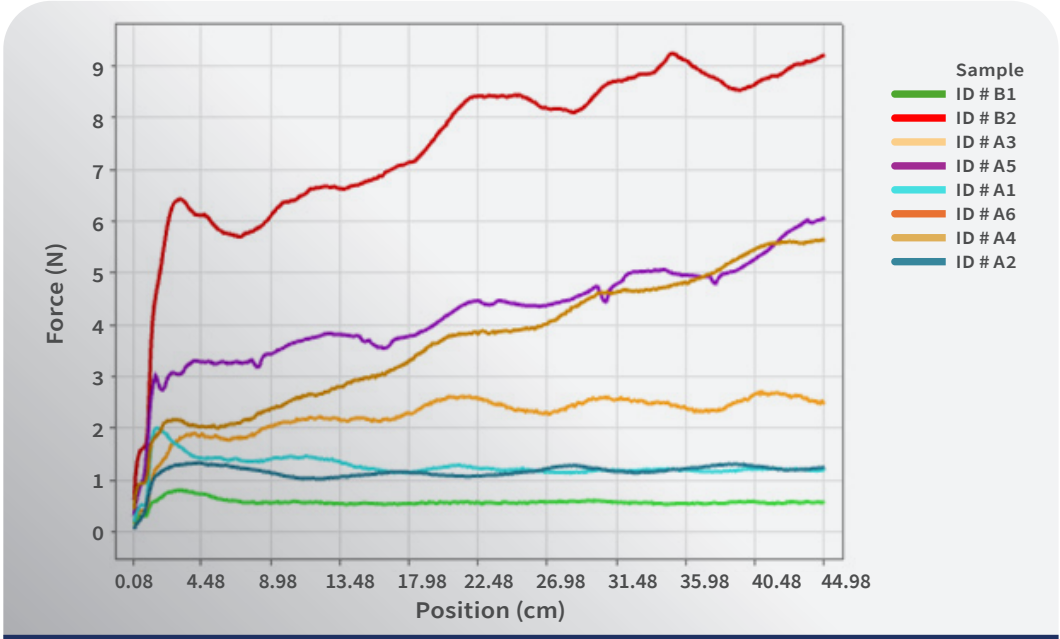


GRAPH 2: PTFE Mandrel - Normalised Average Force

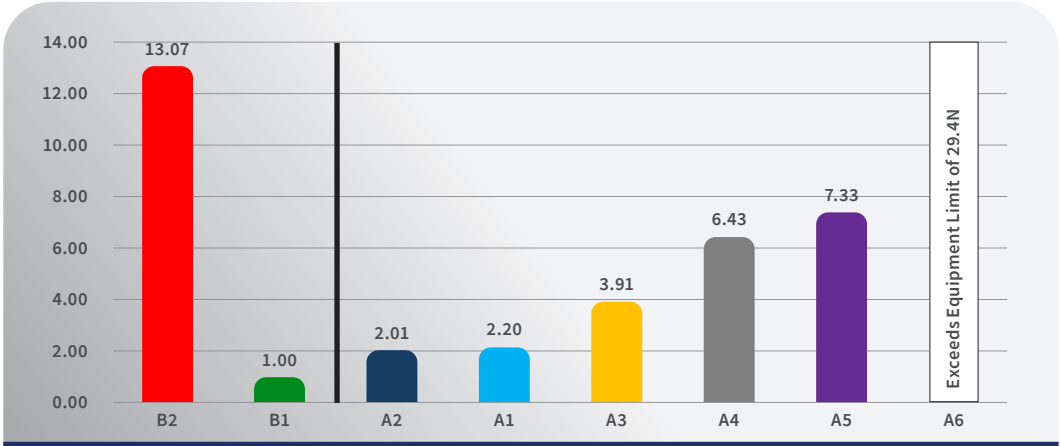


GRAPH 3: PTFE Mandrel - Normalised Max Force

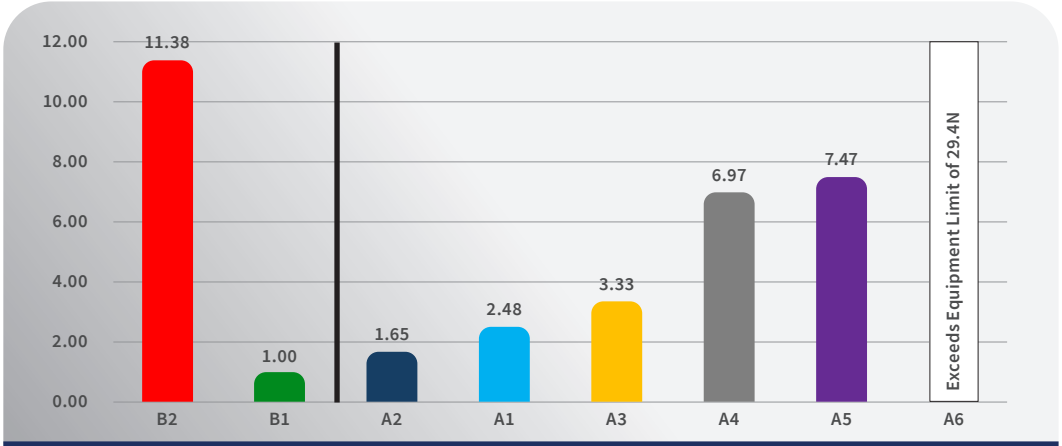
5.2 Testing with Stainless Steel Mandrel (Uncoated)



GRAPH 4: SS Mandrel - Overlay Plots - Straight Fixture



GRAPH 5: SS Mandrel - Normalised Average Force



GRAPH 6: SS Mandrel - Normalised Max Force

5.3 Friction Testing Summary & Conclusions

When using a PTFE-coated mandrel as the contact material, the best performing materials were A1, A2 and A3. A2 and A3 were close to PTFE in terms of max and average insertion force. A1 was found to have lower force results in this test than PTFE. However, this material is an EFEP polymer, so it is not a PFAS-free material. Nonetheless, based on the results seen, it could have beneficial applications outside of the PFAS-free materials area.

When using a stainless-steel mandrel as the contact material, the lubricious properties of PTFE were more pronounced than when using the PTFE-coated mandrels. However, A2 and A3 were also the closest material to PTFE in terms of friction force. A1 did not outperform PTFE in this test, however it was still one of the best performing materials.

The lubricious additives were successful in significantly reducing friction in almost all cases. With materials A2 and A3 being the standout PFAS-free options. Along with showing excellent lubricious properties these additives offer several additional advantages over PTFE including:

- Suitable for e-beam and gamma sterilization
- Ability to vary the base substrate to fine tube flexibility and other mechanical factors
- No need to etch, improving shelf life, storage and processing
- Extruded through conventional extrusion methods

It is also worth noting that almost all the Vestamid CARE ME 55 materials with the additives had significantly improved friction values over the natural Vestamid CARE ME55 material. This could prove beneficial in applications where improved lubricity is needed for these types of materials, perhaps for outer jacket tubing as an example.

As stated previously, the friction tests performed were comparison tests only. To validate these results in particular applications or products may require further testing more specifically related to the procedure where used. However, the testing does give a particularly good indication on how the selected materials compare against each other and the industry standard of PTFE.

6.0 Liners

The next step, after the friction testing of the selected materials, was to choose the two best performing candidates and prove that they could be extruded into liners as used for engineered shafts. Materials A2 and A3 were selected as the materials to move forward with into this phase.

A challenging dimensional specification was targeted for the liners, the reason being that if this liner could be produced with the selected materials with an ultra-thin wall, then a more conventional liner wall with specifications of 0.0015” or 0.002” could be produced more easily. Below is the liner dimensional specification targeted.

ID: 1.791 mm (0.07051”) ± 0.013 mm (0.00051”)

Wall (Avg.): 0.019 mm (0.00075”) ± 0.006 mm (0.00023”)

Length: 950 mm (37.40”)

Both materials were capable of been extruded to the above specifications. However, the specification did prove challenging to achieve due to the very thin-walled nature of the tubing as well as the tight tolerance. A more conventional liner wall specification of 0.0015” or 0.002” would have been more straight forward to produce. However, it was a worthwhile exercise to manufacture in the above specifications as it served the purpose of proving a worst-case scenario.

Conclusion

The proposed regulations concerning PFAS are expected to significantly impact various industries in the coming years, including the medical device sector. However, these regulations are still under development, and there is currently no finalized or universally accepted definition of PFAS across regulatory agencies. Consequently, the specific requirements and restrictions that may apply remain unclear, making it difficult to determine how the use of PFAS-containing materials in medical devices might be affected moving forward.

However, this uncertainty should not be a basis for manufacturers of these medical devices to continue designing products that may leverage existing products that contain PFAS materials. Some devices may be more difficult to design out PFAS materials, if for example, they leverage multiple properties of this material, such as low CoF, high heat resistance, dielectric strength and inertness. However, if PFAS materials are just used for their low CoF, Nordson MEDICAL has shown that there may be some viable options to replace this material. For these types of products, potential future challenges in the ability to use PFAS materials could be used as an opportunity for manufacturers to mitigate against any worst-case future regulations by exploring PFAS-free alternatives. Along with the benefits of de-risking the design, there may be potential added benefits, such as more sterilization options or cost reduction, based on reduced processing steps for non-PFAS materials.

Through Nordson MEDICAL's work on this paper, a lot of knowledge has been gained on PFAS-free materials for liner applications. If customers are starting to investigate PFAS-free alternatives for their products, whether it be for liners or some other component, we would encourage them to have a discussion with us on what they are trying to do. Through our work on these PFAS-free materials, our relationships with the material suppliers, as well as our extensive expertise in processing a broad range of thermoplastics materials and understanding their applications and properties, we would be able to suggest a tailored solution that would best suit their requirements.

About Nordson MEDICAL

Nordson MEDICAL (Nasdaq: NDSN) is a global expert in the design, development, and manufacturing of complex medical device components. As a single-source partner, we enable our customers to save costs, speed time to market, and simplify supply chain management. We work with companies at any point in the product life cycle, from concept to launch and beyond. With our flexible business model, we can provide a solution that meets the scope and scale of any project to bring innovative ideas to life.

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