



A Comparison of Lubricious Materials & Additives

FOR EXTRUDED MEDICAL TUBING

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1.0 Introduction:

1.1 BACKGROUND:

For medical device designers looking for a lubricious surface for catheter-based devices, PTFE, FEP, and HDPE have traditionally been the go-to materials for extrusions.

As a contact layer for interfacing devices, these lubricious materials can ease insertion into the body or into another device, increase sensitivity of movement, and boost pushability.

However, these materials may not always be the optimal choice for a particular application, due to cost, performance, or process considerations.

To provide medical device designers with additional options, leading material manufacturers have developed low-friction additives that can be blended with medical polymers to significantly decrease surface friction and give extruded tubing a more lubricious surface.

Additives can be used with most existing medical polymers without significantly affecting the original properties of the primary material.

These lubricious materials can be used:

- As a tubing liner
- As an alternative to hydrophilic coatings
- As a way to improve bonding to other components

1.2 PURPOSE:

The next question for medical device designers is which lubricious material or additive is right for their project. This can be a challenge due to a lack of data in the marketplace. Data from manufacturers of lubricious additives is generally limited to how their products affect the lubricity and mechanical properties of the medical tubing they are blended with. However, test results cannot be accurately compared across manufacturers.

Nordson MEDICAL's technical staff conducted independent testing to understand the performance of several market-leading lubricious additives to common extruded medical polymers. Table 1 and Table 2 show the selected additives and materials, respectively. We tested these extrusions for:

- Extrusion capability
- Dimensional stability
- Lubricity
- Elongation
- Tensile strength
- Adhesive bond strength

We also tested the lubricious additives to determine the effects of aging, sterilization, and pad printing processes. The results are summarized in this technical paper.

2.0 Materials:

2.1 SELECTED ADDITIVES:

As shown in Table 1, we tested 4 market-leading additives from 4 manufacturers.

TABLE 1. SELECTED ADDITIVES:

Lubricious Product	Percent Additive	Manufacturer	Additive Material Composition
EverGlide®	8%	Polymer Dynamix	Modified polysiloxane
Mobilize	3%–7%	Compounding Solutions	Proprietary
PEBASlide	6.7%	IPC	Nanotechnology based
ProPell S™	3%	Foster	Proprietary

2.2 SELECTED MATERIALS:

All of the lubricious additives in Table 1 can be combined with a wide range of commonly used engineering thermoplastics, including nylon, Pebax®, TPU, polyethylene, polypropylene, PET, ABS, and polycarbonate.

We compared these lubricious additives with 2 fluoropolymers, which are inherently lubricious. Both are manufactured by Daikin:

- NEOFロン™ EFEP RP-5000
- NEOFロン™ PFA AP-210

These fluoropolymers share some characteristics with PTFE but offer several advantages: they are easier to extrude, easier to bond to, and can be gamma sterilized.

As shown in Table 2, our control samples were Pebax 4033 SA 01 MED Natural, Tecoflex™ EG-80A Natural, and PTFE.

All materials were extruded to the same dimensions:

- Outer diameter: 1.95 mm
- Inner diameter: 1.35 mm
- Length: 450 mm

TABLE 2. SELECTED MATERIALS:

Base Material	Additive Material	Type
Pebax 4033 SA 01 MED, Natural	None	Nonlubricious control
Tecoflex EG-80A, Natural	None	Nonlubricious control
PTFE	None	Lubricious control
Pebax 4033 SA 01 MED	EverGlide	Lubricious additive
Pebax 4033 SA 01 MED	Mobilize	Lubricious additive
Pebax 4033 SA 01 MED	PEBASlide	Lubricious additive
Pebax 4033 SA 01 MED	ProPell S	Lubricious additive
Tecoflex EG-80A	ProPell S	Lubricious additive
Tecoflex EG-80A	Mobilize	Lubricious additive
NEOFロン EFEP RP-5000	None	Fluoropolymer (inherently lubricious)
NEOFロン PFA AP-210	None	Fluoropolymer (inherently lubricious)

METHODOLOGY:

Nordson MEDICAL staff extruded the materials in Table 2 using a conventional 3/4" extruder (PTFE was ram extruded by an external source). First, we extruded the natural materials and recorded all extrusion settings and parameters as a baseline.

Second, we extruded the materials with additives using parameters as close as possible to the natural versions to minimize process variation that could have an impact on testing results.

We used the manufacturers' recommended processing conditions in the set-up when available. Our results are based on limited trials, conducted to provide initial guidance for materials selection (For specific applications, we would work with the customer to analyze and optimize the process for their needs).

RESULTS:

We observed little to no difference between extrusions of the materials with additives and extrusions of the natural versions of the materials. The Tecoflex showed slight instability during the extrusion process, but that was to be expected because of the material's natural tackiness.

3.0 Dimensional Stability:

METHODOLOGY:

We tested each of the materials in Table 2 for dimensional stability with a sample size of 20, based on an acceptable quality limit (AQL) of 2.5%. Outer diameter (OD) dimensional capabilities were measured using an offline laser scan micrometer (Scantron XLS 35XY). The results are given as OD Tolerance, which is the Range divided by 2 or (maximum - minimum)/2 for the 20 samples tested.

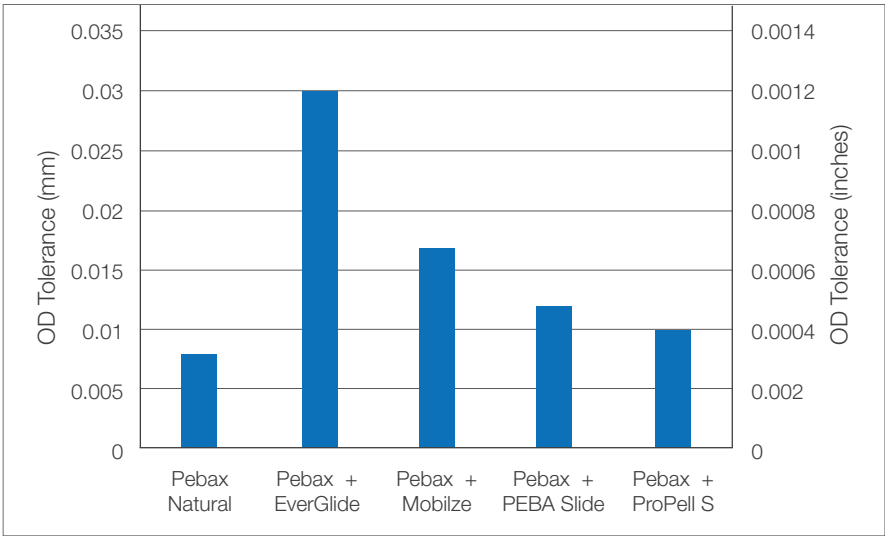
RESULTS:

The following graphs show the dimensional stability based on final inspection data from the extrusion runs.

Pebax:

The Pebax natural material showed the greatest OD stability. Adding additives to the Pebax slightly decreased stability, but the results were still well within acceptable levels given an outer diameter spec of 1.95 mm.

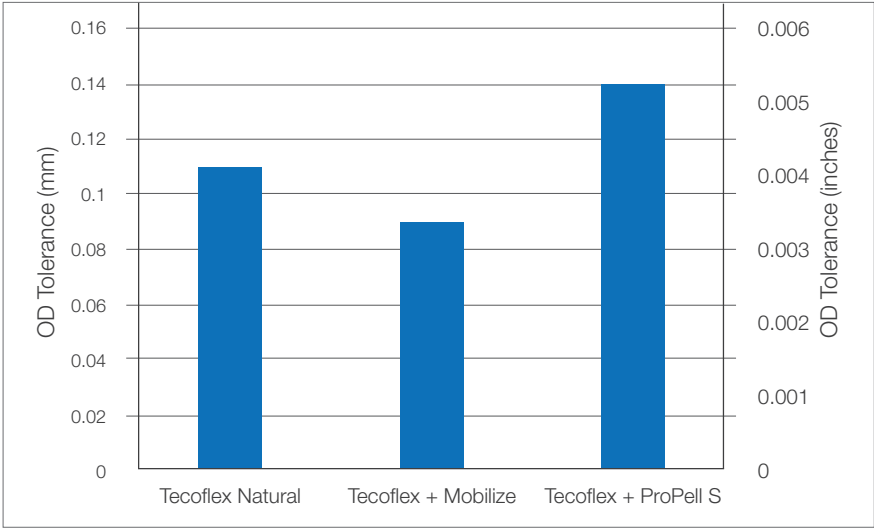
FIGURE 1. OD STABILITY: PEBAX:



Tecoflex:

The OD stability was very similar for the Tecoflex materials with additives compared to the Tecoflex natural material.

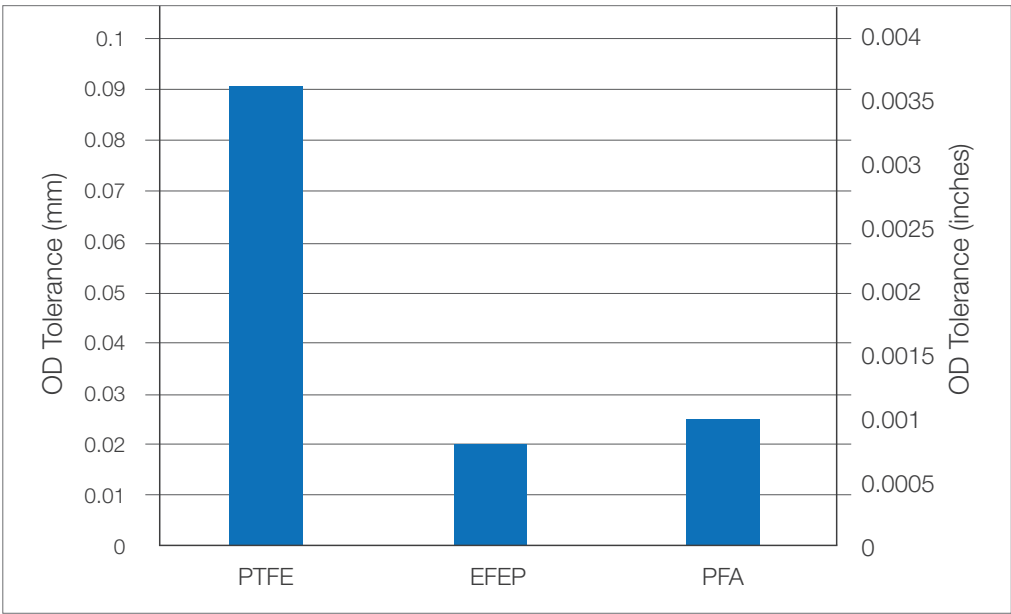
FIGURE 2. OD STABILITY: TECOFLEX:



Fluoropolymers:

The OD range on the EFEP and PFA samples that Nordson MEDICAL extruded was much tighter than the tolerance of the ram-extruded PTFE. The conventionally extruded test samples used vacuum forming, which typically yields tighter tolerances.

FIGURE 3. OD STABILITY: FLUOROPOLYMERS:



CONCLUSIONS:

Dimensional testing showed that OD stability was within acceptable limits for OD ranges and tolerances for medical tubing. Medical device designers considering lubricious additives should not be overly concerned about their effect on dimensional stability.

4.0 Mechanical Testing:

4.1 LUBRICITY:

METHODOLOGY:

A specialized external test laboratory carried out the lubricity testing for Nordson MEDICAL. The sample size was 20, based on an AQL of 2.5%.

A test fixture was fitted to the base of a tensile tester. This was a wet test using deionized water at 37°C. The samples were clamped in the test fixture. The tensile tester pulled the sample horizontally through the grips at a rate of 3 inches/minute. The force required to pull the sample a distance of 75 mm was graphed against the distance travelled. The test was performed with both silicone (GP 60W) grips and PTFE grips. Figures 4–9 show the mean results of the required forces.

RESULTS:

Pebax:

All samples with additives proved to have reduced friction compared to the Pebax natural material. When tested with PTFE grips, the Pebax + EverGlide samples had the best results. When PTFE is pulled against PTFE, the surface interaction can increase friction, which is why some materials had better results when tested with PTFE grips. Of the samples tested with silicone grips, the PTFE samples showed the best results.

FIGURE 4. LUBRICITY: PEBAX - PTFE GRIPS:

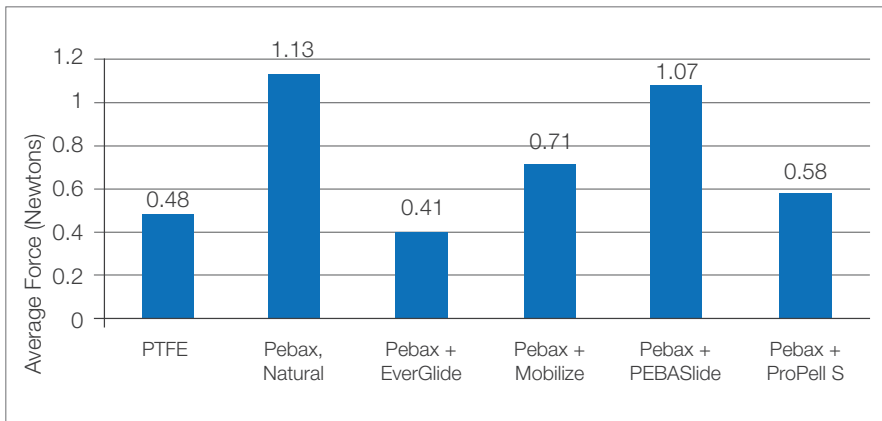
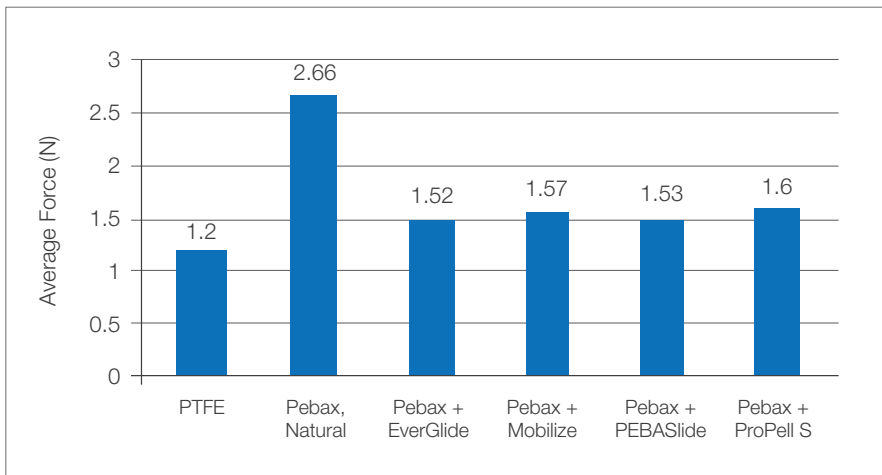


FIGURE 5: LUBRICITY: PEBAX - SILICONE GRIPS:



Tecoflex:

All samples with additives showed reduced friction compared to the Tecoflex natural material, when tested with both PTFE and silicone grips. The results were not close to the PTFE material, which was to be expected due to the inherent tackiness of the Tecoflex material.

FIGURE 6. LUBRICITY: TECOFLEX - PTFE GRIPS:

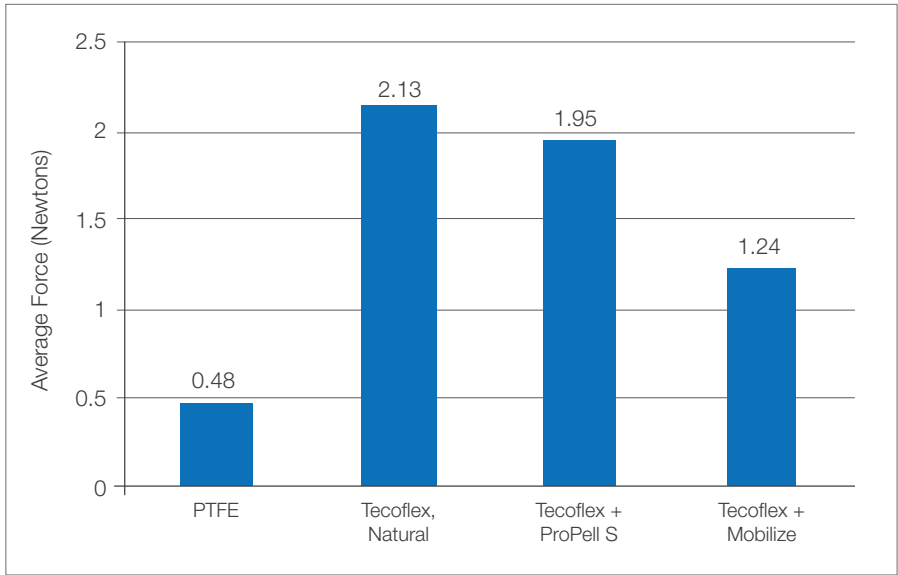
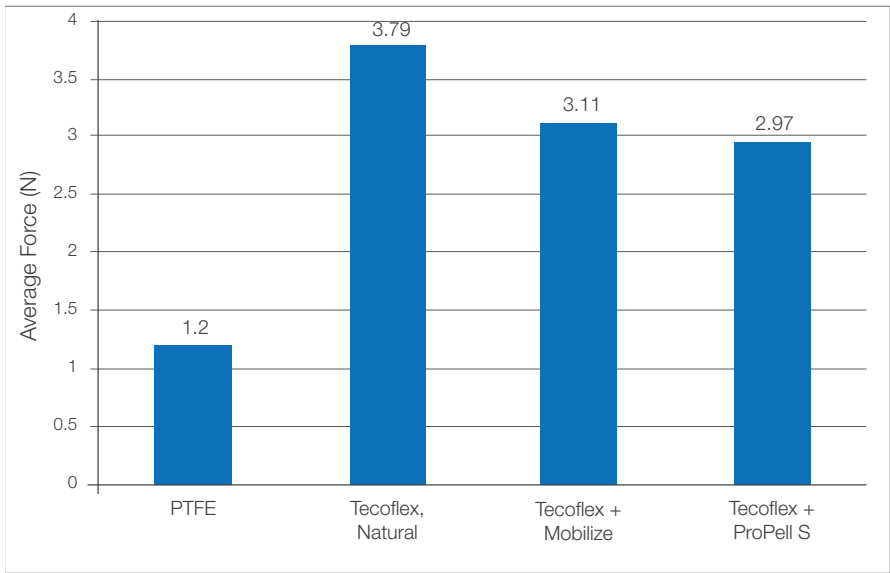


FIGURE 7: LUBRICITY: TECOFLEX - SILICONE GRIPS:



Fluoropolymers:

When tested using PTFE grips, the PFA and PTFE samples had similar results, with PFA showing a 4% greater friction force than the PTFE. Again, the PTFE results were expected due to PTFE/PTFE surface contact. However, the EFEP samples had a 31% reduction in friction compared to the PTFE. When tested with silicone grips, the PTFE samples gave the best results of the fluoropolymers.

FIGURE 8. LUBRICITY: FLUOROPOLYMERS - PTFE GRIPS:

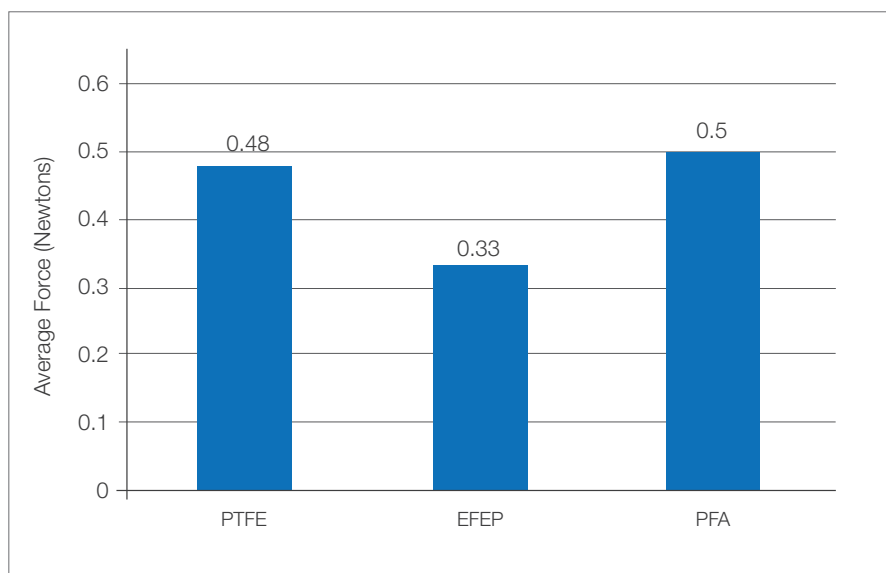
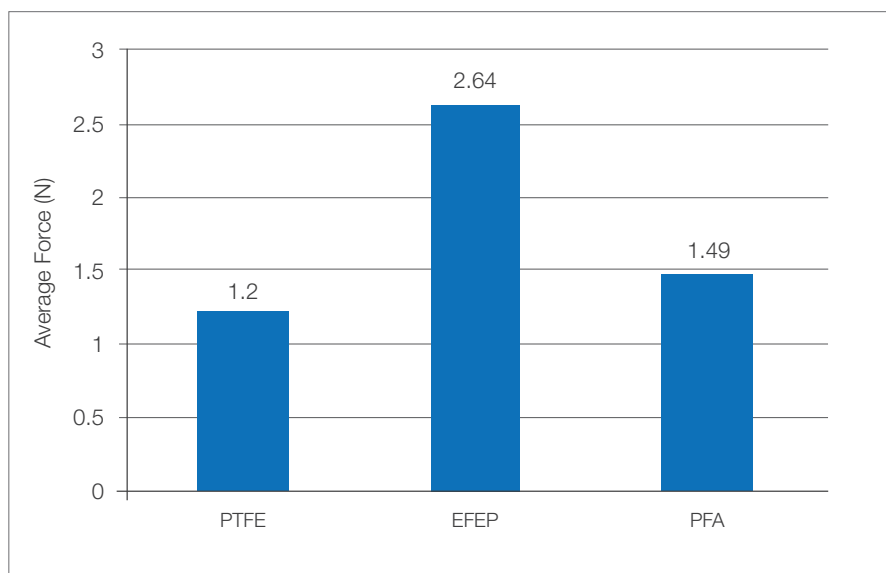


FIGURE 9: LUBRICITY: FLUOROPOLYMERS - SILICONE GRIPS:



CONCLUSIONS:

The EFEP samples tested with PTFE grips showed the greatest reduction in friction compared to PTFE (31%), suggesting that EFEP could perform well as an alternative to PTFE if it were in contact with, for example, a PTFE-coated mandrel. The Pebax + EverGlide sample also performed very well. An advantage of this combination is that it can be extruded on conventional equipment, whereas EFEP requires modified extrusion equipment.

4.2 ELONGATION:

METHODOLOGY:

Each of the materials in Table 2 was tested for elongation at break with a sample size of 20, based on an AQL of 2.5%. We measured elongation using a vertical tensile tester (Tinius Olsen model H10KT).

- Gauge length: 25 mm
- Speed: 250 mm/min
- Clamp pressure: 50 psi
- Temperature: 23°C

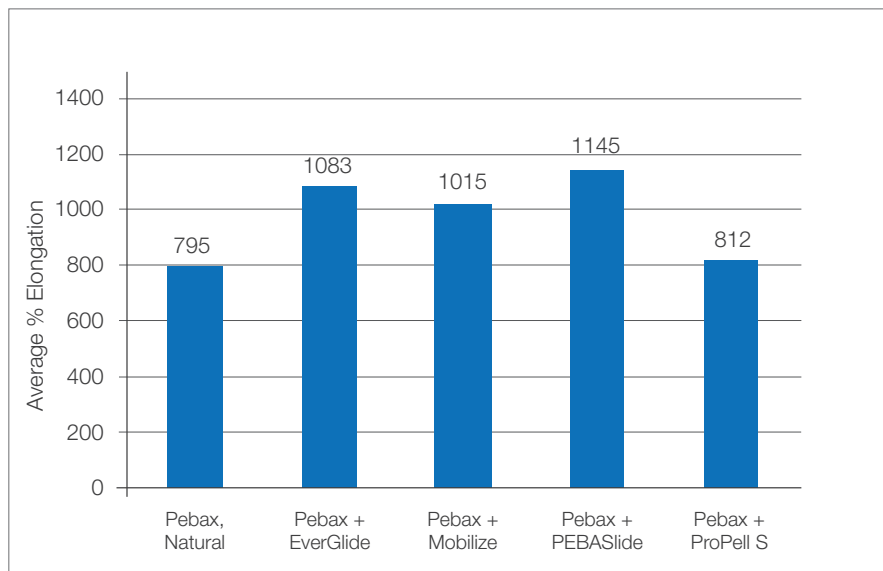
RESULTS:

The following graphs show the elongation results based on final inspection data from the extrusion runs.

Pebax:

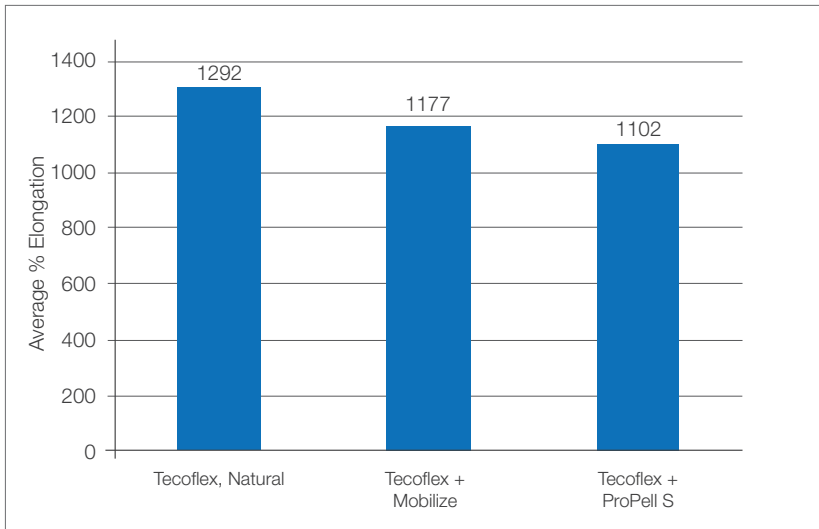
We found an increase in elongation on all tubing with lubricious additives compared to the Pebax natural material. The Pebax + ProPell S samples showed elongation very similar to the natural material.

FIGURE 10. ELONGATION: PEBAX:

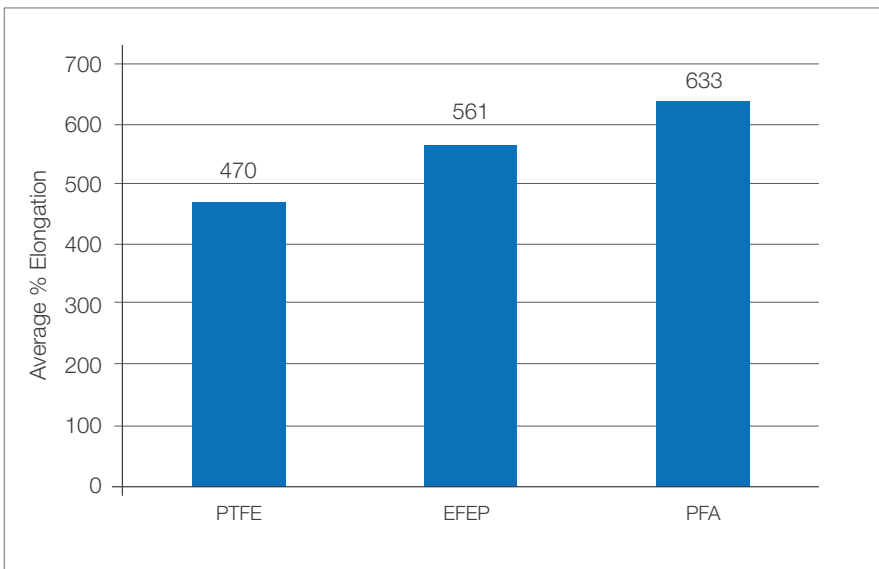


Tecoflex:

We found a slight decrease in the elongation results (10%–15%) for the Tecoflex materials with additives over the natural version of the material.

FIGURE 11. ELONGATION: TECOFLEX:**Fluoropolymers:**

Elongation results for samples of the 3 fluoropolymers were relatively similar to one another.

FIGURE 12. ELONGATION: FLUOROPOLYMERS:**CONCLUSIONS:**

The data showed no major changes in elongation with lubricious additives or fluoropolymers compared to the base materials. This suggests that medical device designers should not be overly concerned about the effects of additives on elongation. If a customer needs a tube to have a certain elongation, we can optimize the mechanical properties by adjusting the extrusion process.

4.3 TENSILE STRENGTH:

METHODOLOGY:

Each of the materials was tested for tensile strength at break with a sample size of 20, based on an AQL of 2.5%. We measured tensile strength using a vertical tensile tester (Tinius Olsen model H10KT):

- Gauge length: 25 mm
- Speed: 250 mm/min
- Clamp pressure: 50 psi
- Temperature: 23°C

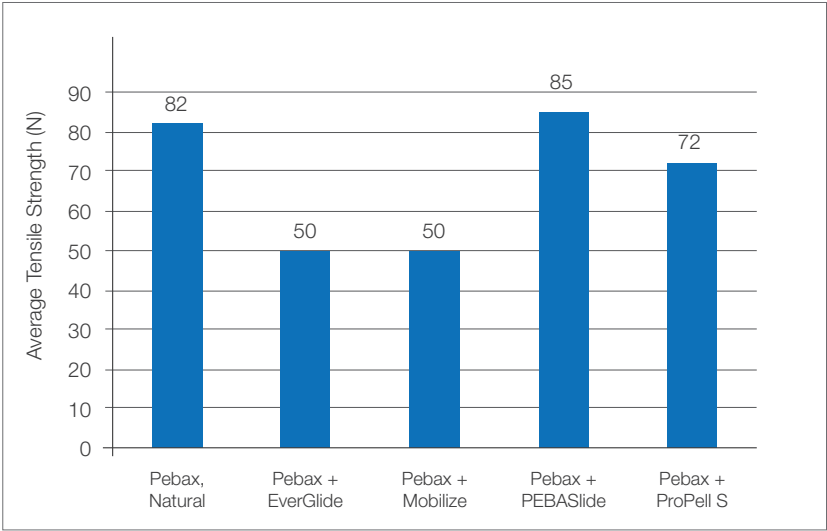
RESULTS:

The following graphs show the tensile strength results based on final inspection data from the extrusion runs.

Pebax:

We found a decrease in tensile strength on Pebax tubing with EverGlide and Mobilize when compared to the Pebax natural material. The Pebax + PEBASlide samples showed a slight increase in tensile strength, and the Pebax + Propell S samples had results similar to the natural material.

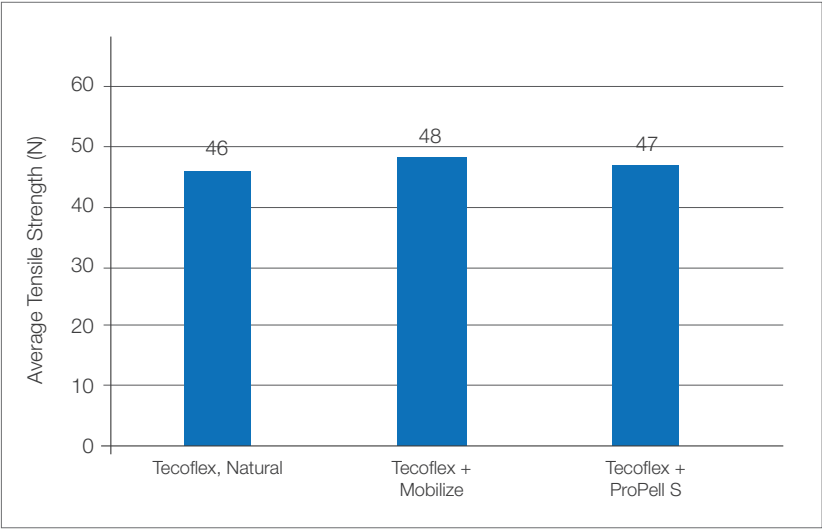
FIGURE 13. TENSILE STRENGTH: PEBAX:



Tecoflex:

The Tecoflex material with additives had tensile strength results very similar to the Tecoflex natural material.

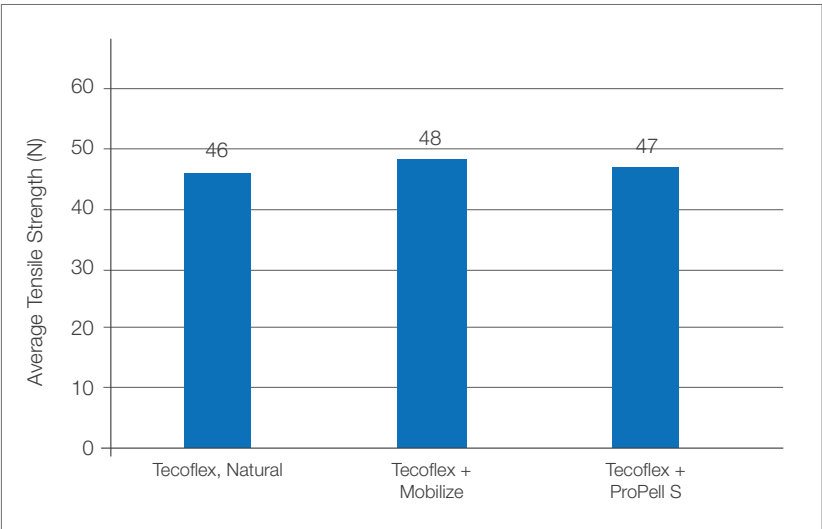
FIGURE 14. TENSILE STRENGTH: TECOFLEX:



Fluoropolymers:

The EFEP samples gave the highest tensile strength reading. The PFA and PTFE samples had similar tensile strength results.

FIGURE 15. TENSILE STRENGTH: FLUOROPOLYMERS:



CONCLUSIONS:

According to the data, some additives with Pebax show a significant decrease in tensile strength compared to natural Pebax. If strength is a critical design feature in a Pebax device, designers should consider materials that behave the most like natural materials; for example, Pebax + ProPell S or Pebax + PEBASlide, as opposed to Pebax + EverGlide or Pebax + Mobilize.

However, the tensile strength of the Tecoflex with additives was almost identical to the natural version, and the tensile strength of the fluoropolymers (PFA and EFEP) increased compared to the PTFE. Therefore, designers considering these materials can be confident that the tensile strength would be the same if not better than the natural materials.

4.4 ADHESIVE BOND STRENGTH:

METHODOLOGY:

To determine if the materials with the lubricious additives were capable of bonding in the same way as the natural materials, we bonded standard Luer lock fittings to each extrusion using Loctite® 4310 Flashcure Light Cure Adhesive. As the goal was to compare the lubricious additives, we only tested Pebax, which is the only material that was combined with all additives. Three types of Luer materials were used in this test: ABS, PC, and PVC.

The sample size was 10. We tested the samples using a tensile strength tester (Instron):

- Test speed: 200 mm/min
- Gauge length: 10 mm
- Clamp pressure: 30 psi
- Temperature: 23°C

RESULTS:

All failures were adhesive failures. The Pebax + ProPell S samples had results very similar to the Pebax natural material, when tested with all 3 Luer materials. The Pebax + PEBASlide samples had the next best results, with bond strength actually increasing slightly for the PC Luer and decreasing 20% on average across the 2 other Luer materials. The results for the Pebax + EverGlide and Pebax + Mobilize samples were lower than the Pebax natural material, with an average reduction in bond strength of 45% for the Mobilize and 30% for the EverGlide.

FIGURE 16. ADHESIVE BOND STRENGTH: ABS LUER:

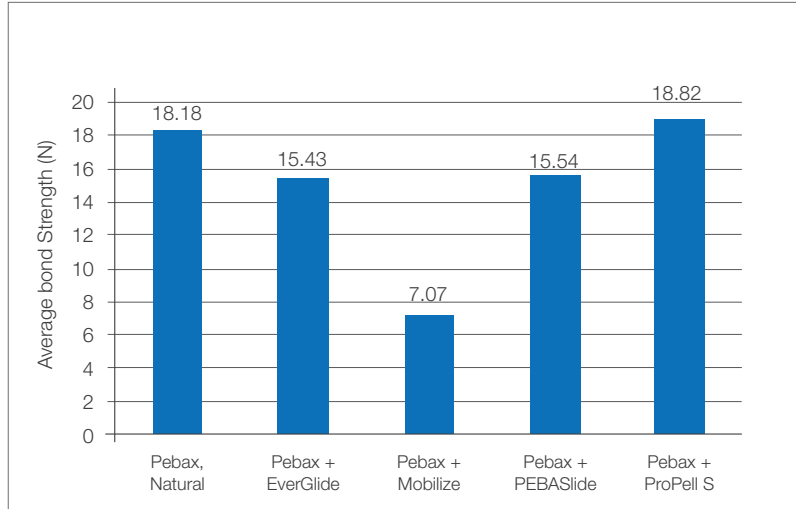
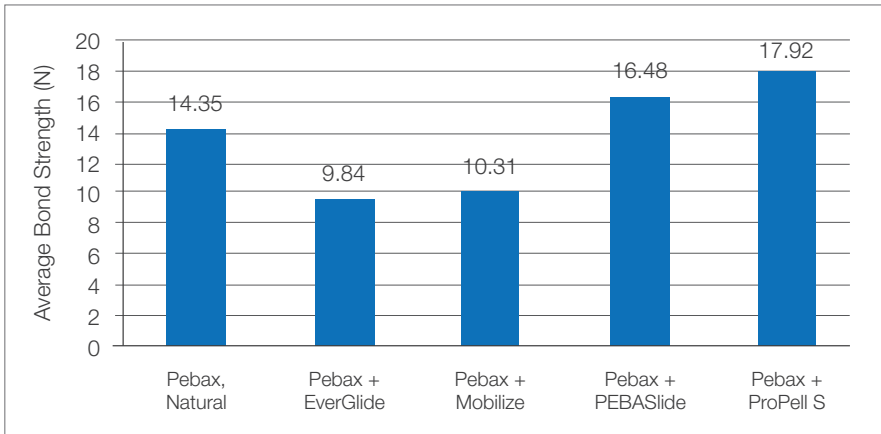
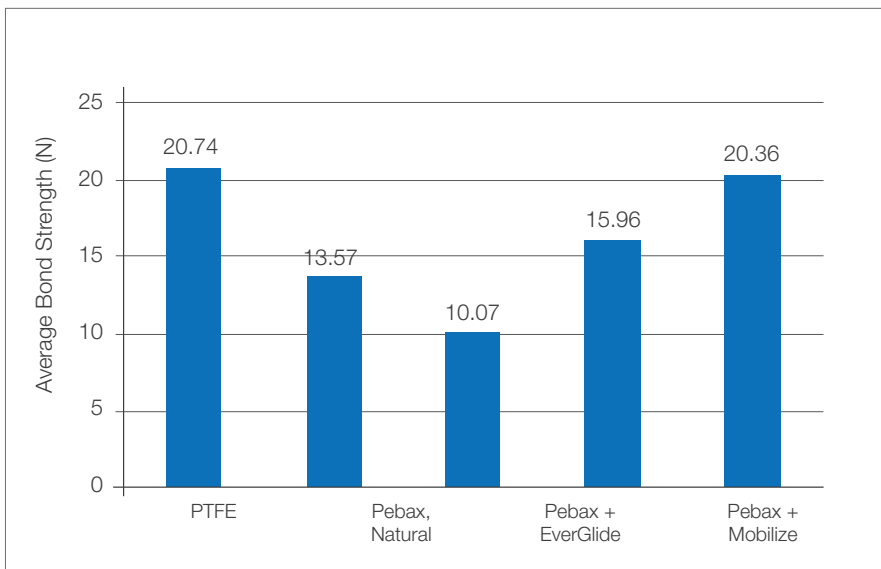


FIGURE 17. ADHESIVE BOND STRENGTH: PC LUER:**FIGURE 18: ADHESIVE BOND STRENGTH: PVC LUER:****CONCLUSIONS:**

Before selecting a lubricious additive, designers should consider whether the tubing would be bonded to other components. If so, they should be aware that some additives, such as EverGlide and Mobilize, show much lower bond strength than the Pebax natural material, Pebax + PEBASlide, or Pebax + Propell S.

Table 5 in the Appendix shows the full results of testing for dimensional stability, elongation, lubricity, tensile strength, and bonding for all materials.

4.5 PAD PRINT TESTING:

METHODOLOGY:

We wanted to determine whether the materials with lubricious additives were capable of being pad printed upon in the same manner as the natural materials. We printed the materials using a pad printer (TAMPOFLEX model # TF 150 E) and Tampa® Star TPR ink (Black 980). The temperature was 23°C. Sample size was 5.

All tubing was wiped down with 100% alcohol before printing to achieve better print quality. We performed a standard adhesive tape test 48 hours after printing. A section of tape was pressed onto the print and removed quickly. If the print were well adhered, the tape would not remove any part of the print.

RESULTS:

All tubing samples showed good print quality right after printing. We found that the tape test had little or no effect on the print quality 48 hours after printing. The exceptions were one Pebax + ProPell S tube and one Pebax + EverGlide tube, for which the tape removed a small amount of the print.

We observed that the tubing with the lubricious additives had printing properties very similar to the natural materials. However, all printing was done on untreated tubing. If the tubing had been subjected to corona or plasma treatments before printing, it might have shown even better print quality and adherence.

CONCLUSIONS:

The results showed that the materials with the lubricious additives were as capable of being pad printed with depth markers or logos as the natural materials. Decreasing surface friction with these lubricious additives does not significantly affect print quality.

5.0 Aging Testing:

METHODOLOGY:

We replicated 6 months of aging to determine whether the materials with lubricious additives were as capable of withstanding the aging process as the natural version of the material. We placed samples of all tubing with the additives, including the fluoropolymer materials, in Nordson MEDICAL's environmental test chamber (ECO HTCL CL 400) at 55°C with a relative humidity of 6% for 20 days. The sample size was 10 based on an AQL of 10.0%.

RESULTS:

Table 3 shows the results of tests for dimensional stability, elongation, and tensile strength after simulated aging. We observed very little variation in the dimensional stability after aging. The difference between the tensile strength and elongation after extrusion and after aging for the materials with the additives is also roughly in line with the Pebax natural material. Tensile strength and elongation are given as averages of the 10 samples tested.

TABLE 3. AGING: DIMENSIONAL AND MECHANICAL RESULTS:

Material	Baseline OD Stability	OD Stability Post Aging	Baseline Elongation	Elongation Post Aging	Baseline Tensile Strength	Tensile Strength Post Aging
Pebax 4033 SA 01 MED, Natural	±0.008 mm	±0.009 mm	795%	704%	82 N	82 N
Pebax 4033 SA 01 MED + EverGlide	±0.03 mm	±0.026 mm	1083%	1141%	50 N	50 N
Pebax 4033 SA 01 MED + Mobilize	0.017 mm	±0.017 mm	1015%	1037%	50 N	50 N
Pebax 4033 SA 01 MED + PEBASlide	±0.012 mm	±0.011 mm	1145%	1137%	85 N	85 N
Pebax 4033 SA 01 MED + ProPell S	±0.010 mm	±0.010 mm	812%	728%	72 N	72 N
NEOFLON EFEP RP-5000	±0.019 mm	±0.017 mm	561%	557%	82 N	82 N
NEOFLON PFA AP-210	±0.025 mm	±0.026 mm	633%	804%	65 N	65 N

CONCLUSIONS:

We can conclude that adding lubricious additives to the natural materials has no major adverse effects on the dimensional properties of the tubing after a simulated aging process. While there was a slight difference in the mechanical properties, the difference was relatively small, so designers can have confidence in the stability of these extrusions.

6.0 Sterilization Testing:

METHODOLOGY:

We conducted tests to determine whether the materials with lubricious additives were as capable of withstanding sterilization as the natural version of the materials. We confirmed with the manufacturers that all additives and materials could be EtO sterilized. However, no manufacturer provided test results for gamma sterilization. For this reason—and because PTFE cannot be sterilized by gamma radiation—we passed the lubricious additives and the fluoropolymer materials through gamma sterilization.

We used the same samples that had previously been age tested, with a sample size of 10 based on an AQL of 10.0%. The samples were treated with a standard dose of 25–40 kGy. Table 4 shows the results of tests for dimensional stability, elongation, and tensile strength after gamma sterilization.

RESULTS:

According to the certificate of irradiation from the sterilization company, the calculated minimum dose was 34.8 kGy and the calculated maximum dose was 35.9 kGy. We observed little difference in the dimensional stability compared to the natural materials when the tubing was inspected after sterilization. However, the gamma sterilization process did affect the mechanical properties of the tubing, increasing the elongation in almost all samples and decreasing the tensile strength in all samples. We also observed these changes in the natural materials.

TABLE 4. STERILIZATION: DIMENSIONAL AND MECHANICAL RESULTS:

Material	OD Stability Post Aging	OD Stability Post Sterilization	Elongation Post Aging	Elongation Post Sterilization	Tensile Strength Post Aging	Tensile Strength Post Sterilization
Pebax 4033 SA 01 MED, Natural	±0.009 mm	±0.011 mm	704%	925%	82 N	82 N
Pebax 4033 SA 01 MED + EverGlide	±0.026 mm	±0.025 mm	1141%	1289%	50 N	50 N
Pebax 4033 SA 01 MED + Mobilize	±0.017 mm	±0.017 mm	1037%	1244%	50 N	50 N
Pebax 4033 SA 01 MED + PEBASlide	±0.011 mm	±0.011 mm	1137%	1293%	85 N	85 N
Pebax 4033 SA 01 MED + ProPell S	±0.010 mm	±0.012 mm	728%	817%	72 N	72 N
NEOFLON EFEP RP-5000	±0.017 mm	±0.019 mm	557%	574%	82 N	82 N
NEOFLON PFA AP-210	±0.026 mm	±0.026 mm	804%	662%	65 N	65 N

CONCLUSIONS:

The data showed that, while gamma sterilization did not significantly impact the dimensional properties of the tubing, it did affect the mechanical properties. It increased elongation in almost all samples and decreased tensile strength in all samples. We also observed these changes in the natural materials, indicating that the changes were due to the sterilization process rather than the lubricious additives.

We also noted that mechanical properties of the EFEP showed very little change after the sterilization process. This suggests that EFEP could be a good lubricious option for a device that cannot be EtO sterilized but still needs to maintain most of its original mechanical properties.

7.0 Conclusion:

The findings from this report indicate that lubricious additives and materials are capable of being extruded on conventional extrusion equipment with no significant stability or processing issues over the natural versions of the materials.

The data shows that the lubricious additives and materials have comparable—and in some cases, better—dimensional stability than the natural materials. However, the mechanical properties of the materials with the additives are affected in some cases. We recommend that designers consider the critical mechanical requirements of the end device before selecting a material, so as not to compromise important design characteristics.

The results of testing also show that all the additives show reduced friction compared to the natural materials. This is more pronounced in some additives. When tested with the PTFE grips, the PFA material performed almost as well as PTFE, and the EFEP material performed even better. These materials could prove to be good options for designers for applications that require increased lubricity when PTFE is not an option.

We also found that all materials were capable of being bonded, printed, aged, and gamma sterilized. Some of the additives and materials performed better than others in each of these tests. So again, we recommend that designers carefully consider the processes to which the final device will be subjected when selecting materials.

From the findings of this report, we feel that these lubricious additives and materials give medical device designers additional options and flexibility in developing new and improved medical devices.

8.0 Appendix:

8.1 DIMENSIONAL AND MECHANICAL TESTING RESULTS TABLE:

As noted in section 4.4.3, Table 5 shows the full results of testing for dimensional stability, elongation, lubricity, tensile strength, and adhesive bond strength for all materials.

TABLE 5. DIMENSIONAL AND MECHANICAL TESTING: FULL RESULTS:

Extruded Material	Dimentional Stability (±mm)	Elongation (%)	Frictional Force (Lubricity) PTFE Grips (N)	Frictional Force (Lubricity) Silicone Grips (N)	Tensile Strength (N)	Adhesive Bond Strength (N)	Bonding (N)	Bonding (N)
						ABS Luer	PC Luer	PVC Luer
Pebax 4033 SA 01 MED, Natural	0.008	795	1.13	2.66	82	18.18	14.35	20.74
Tecoflex EG 80A, Natural	0.11	1292	2.13	3.79	46	N/A	N/A	N/A
PTFE	0.09	470	0.48	1.20	54	N/A	N/A	N/A
Pebax 4033 SA 01 MED + ProPell S	0.010	812	0.58	1.60	72	18.82	17.92	20.36
Pebax 4033 SA 01 MED + PEBASlide	0.012	1145	1.07	1.53	85	15.54	16.48	15.96
Pebax 4033 SA 01 MED + Mobilize	0.017	1015	0.71	1.57	50	7.07	10.31	10.07
Pebax 4033 SA 01 MED + EverGlide	0.03	1083	0.41	1.52	50	15.43	9.84	13.57
Tecoflex EG-80A + ProPell S	0.14	1102	1.95	2.97	47	N/A	N/A	N/A
Tecoflex EG-80A + Mobilize	0.09	1177	1.24	3.11	48	N/A	N/A	N/A
PTFE	0.09	470	0.48	1.20	54	N/A	N/A	N/A
NEOFLON EFEP RP-5000	0.019	561	0.33	2.64	82	N/A	N/A	N/A
NEOFLON™ PFA AP-210	0.025	633	0.50	1.49	65	N/A	N/A	N/A

About Nordson MEDICAL

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