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Notification date: 12/19/2019
Notification reference number: CN-RPII-BHFHRZ

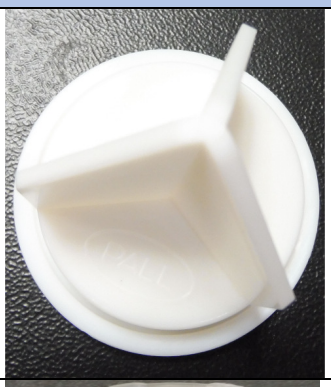
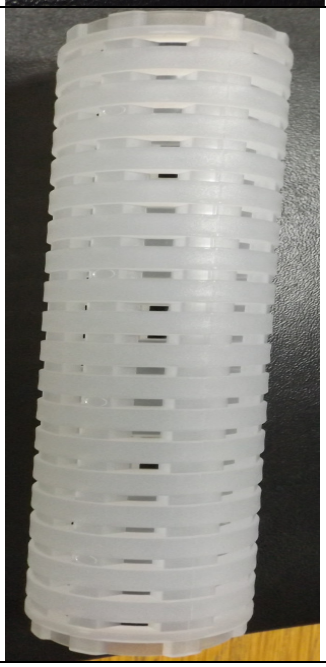
Important Customer Notification

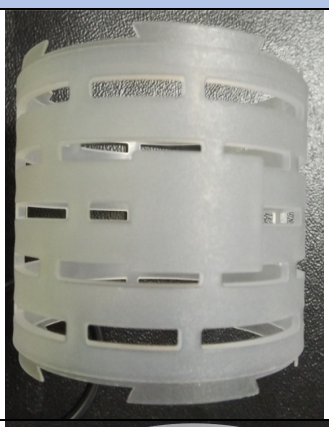
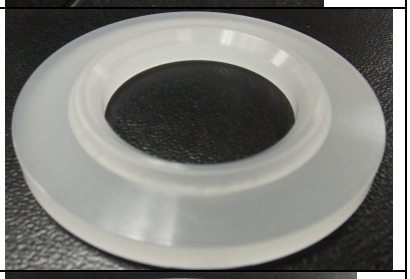
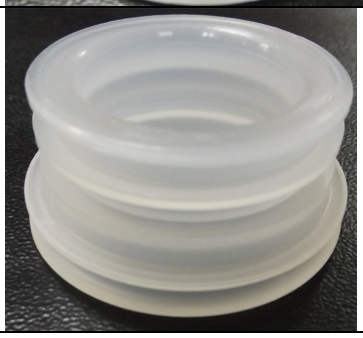
Purpose	Relocation of mold tools used to make injection molded components in Pall direct flow filtration (DFF) products
Affected products	Direct flow filters made by Pall Corporation See Appendix 1: Prefixes of filter cartridge and capsule part numbers in scope
Change to fluid or air contact component(s)?	Yes
Change process stages	Formal notification: this document Effective date: 3/19/2020
Pall manufacturing plants impacted	Pall plants manufacturing DFF products or incorporating these products into finished goods located in: Belgium: Hoegaarden; China: Beijing; Germany: Dreieich; Japan: Nihon; The Netherlands Medemblik; Puerto Rico: Fajardo; United Kingdom: Ilfracombe, Newquay and Portsmouth; USA: Cortland, Deland and Timonium.
Customer action required	Please accept this information for your records
Pall point of contact	Please email your inquiries about this change to: customernotification@pall.com
Authorized by	 Mark Baree Quality Director Biotech Consumables

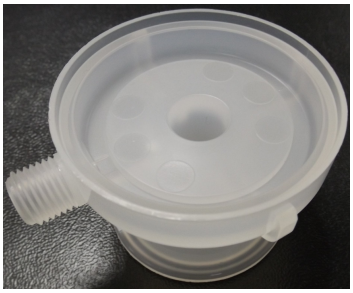
Description of change

You are receiving this change notification because our records show that you have been purchasing Pall Biotech DFF products incorporating molded components shown in Table 1.

Table 1: Components affected by this change

Finished Good Format Impacted	Molded Components	Example Image
Filter assembly or filter element including those used in capsule configurations	Filter fin	
	Core	

Finished Good Format Impacted	Molded Components	Example Image
Filter assembly or filter element including those used in capsule configurations	Cage	
	Endcap	
	Adaptor	

Finished Good Format Impacted	Molded Components	Example Image
Filter capsule	Capsule bowl	
	Capsule head	

We are currently relocating the mold tools producing the components listed above from our current supplier to another qualified Pall supplier.

There is no change to raw materials or specifications of the molded parts. There is no impact on the form, fit or function of the products in scope.

We will maintain existing component part numbers and finished good part numbers. Traceability will be ensured by component and finished good lot numbers.

A validation plan summary is shown in Appendix 2.

Reason for the change

To reduce component lead time, improve quality, and assure continuity of supply.

Impact on customer operations and/or recommended action(s)

As there is no expected impact on form, fit, function or quality of the affected finished goods, this notification is for information only.

Please see Appendix 2 validation plan summary

Supply chain information

We expect to have completed the transfer of all mold tools by July 2020.

Additional information

If anyone else within your organization should be made aware of this notification, please forward them a copy of this letter or advise us accordingly.

Please email your inquiries about this change to: customernotification@pall.com

This notification has been cleared for release by Pall Quality Assurance.

We appreciate your continued use of Pall products.

Appendix 1 - Prefixes of filter cartridge and capsule part numbers in scope

Filter Cartridges (Leading Characters in Product Part Number)	Filter Cartridge Style Name	Examples of Complete Part Number
AB	AB style	AB05HTPFR7PVH4, AB1EKV7PH4, AB2NF7PH4, AB3DFL7PH4
MCY	MCY style,	MCY1001J012PH4, MCY1002NAPH4, MCY1003FMPH2ENG
MCY	MCY junior style	MCY1110J060PH4, MCY2220NFPH4, MCY2230V002PVJ, MCY3330PFRPVH4, MCY4440DJLPH4, MCY4463J012PH4
SLK	Sealkleen™	SKL7002NFP, SLK7001DFL, SLK7001PFR
SBF	SBF junior	SBF1PFRPJ, SBF1DV50PH4, SBF1NFPH4
AVF	AVF style	AVF021V002PVH4

Filter Capsules (Leading Characters in Product Part Number)	Filter Capsule Style Name	Examples of Complete Part Number
KA02	Mini Kleenpak™	KA02EKVP2G, KA02PFRP2, KA02V002P2G, KA02DFLP2S
KA	Kleenpak	KA1EKVP1G, KA2NFP1, KA3PFRP1
NP & NT	Kleenpak Nova	NP1LUPRMP1G, NP5LDFLP1G, NP6EBVP1G, NP7UBP1G, NP8MSTGQP1, NT6Y005P1G, NT7Y030P1G, NT8J100P1G
C	Novasip™	C3DFLP1, C3NFP1, C3PFRP1, C3PFRP1A
DFA	DFA	DFA3001UBP, DFA3001UUAP, DFA4001J060P
BY	Mini Profile®	BYA015P6

Appendix 2 - Validation plan summary

Test Type	Test Details and Acceptance Criteria	Status

Installation and performance qualification for all implicated mold tools for all components and all finished goods affected by this change.	Installation, Operational and Performance Qualification (IQ, OQ, PQ) of the existing mold tools transferred to the new supplier to demonstrate that manufactured parts meet Pall's requirements and can be used to produce finished goods of correct quality.
	
	IQ by the new supplier will include:
	• Gate type & position
	• Runner type
	• Cavity identification
	• Molding material
	• Press size
	• Critical to quality dimension check
	
	OQ by the new supplier will include:
	• T1 mold run:
	  ○ Process window mold runs to determine single point process settings
	  ○ Fully completed process setting sheet
	• Appearance evaluation
	• Shrinkage study
	• Initial sample inspection report
	• Process capability study
	• Equivalence report
	• Conclusion
	
	PQ by the new supplier will include:
	• Cold starts
	• Appearance evaluation
	• Process capability study
	• Conclusion
		Complete for already transitioned components.
		To be completed for any not transferred components before transfer

Test Type	Test Details and Acceptance Criteria	Status
Component checks for all implicated components for all finished goods	Each component type manufactured at the new supplier will be checked for • Dimensional equivalency to existing components: Each component must display the same dimensions as the component manufactured at the current supplier. • Shot weight equivalency to existing components: Each component must be packed out to the same degree as the component manufactured at the current supplier • Imaging investigation for voids: Each component must display equivalent or less void volume compared to components manufactured at the current supplier to ensure equivalent strength	Complete for already transitioned components. To be completed for any not transferred components before transfer
Test Type	**Test Details and Acceptance Criteria**	**Status**
Manufacturability testing for pharmaceutical grade finished goods	Per component the production of a filter validation batch to demonstrate that the manufacturing of parts at a different molder has not had a detrimental impact on Pall's ability to successfully use these components in routine production manufacture. Batches must pass associated testing and display typical product yields. During manufacturing of validation batches, the product must pass specified (routine) i-process testing as applicable to the product and component type such as: • Leak testing • Break testing • Burst testing (capsules) • Gap gauging of welds Validation batches must meet all applicable lot release tests and thus the criteria for Pall's Certificate of Test for Pharmaceutical-Grade filters. These tests may include, depending on the filter part number: • Fabrication integrity • Autoclave challenge testing • Microbial retention • Effluent quality ○ Cleanliness (particulates) ○ Oxidizable substances / Total Organic Carbon (TOC) and water conductivity ○ pH ○ Endotoxins/pyrogens	Complete for already transitioned components. To be completed for any not transferred components before transfer

Test Type	Test Details and Acceptance Criteria	Status

Manufacturing of all finished goods	All batches of finished goods manufactured with components made at the new supplier must pass specified (routine) in-process testing as applicable to the product and component type, such as:
	• Leak testing
	• Break testing
	• Burst testing (capsules)
	• Gap gauging of welds
	
	All batches of P-Grade finished goods manufactured with components made at the new supplier must meet all applicable lot release tests and thus the criteria for Pall's Certificate of Test for Pharmaceutical-Grade filters. These tests may include, depending on the filter part number:
	• Fabrication integrity
	• Autoclave challenge testing
	• Microbial retention
	• Effluent quality
	  ○ Cleanliness (particulates)
	  ○ Oxidizable substances / Total Organic Carbon (TOC) and water conductivity
	  ○ pH
	  ○ Endotoxins/pyrogens
		Complete for already transitioned components.
		To be completed for any not transferred components before transfer