



## HALYARD\* Face Mask & N95 Respirator Communication

April 12, 2023

Dear Valued Customer,

Today, the FDA issued a communication for a limited number of HALYARD\* branded face masks and two HALYARD N95 respirators. All the codes identified in the communication have been previously cleared by the FDA and on the market for many years. It is important to note that this communication indicates that the FDA is reviewing these products, and it is **not** a product recall. In fact, Owens & Minor has not received any reports of adverse events or customer complaints about HALYARD face masks or N95 respirators reporting a fluid resistance issue. Nor have there been any fluid penetration complaints about these products. In addition, there is no information or data that has emerged to date that would suggest important changes to patient management/user protection or the benefit-risk profile of HALYARD face masks.

We are disappointed that the FDA has communicated publicly despite the absence of reported complaints and the significant amount of independent accredited lab testing and performance data provided. This data demonstrates that these products continue to meet the safety and effectiveness specifications for which they were designed and labeled.

We are working closely with the FDA in its ongoing evaluation and have complied with all requests the agency has made as part of the evaluation process. As we work with FDA, we wanted to provide the product updates listed below.

- **Face masks** (fluid rated) – we believe these products continue to meet their specifications and labeling claims as cleared.
- **Face masks** (non-fluid rated) – these masks should continue to be used in accordance with their labeling. We welcome the clarity from the FDA in today's communication and we hope this clarity will be applied across the industry.
- **N95 respirators** – while we are in active discussions with the FDA, we have decided to voluntarily pause delivery on the two N95 product codes referenced in the FDA's communication.

As previously communicated, we anticipate shortages in the near-term for HALYARD\* brand earloop and surgical tie masks. We anticipate these constraints will continue into May 2023 and have acceptable alternatives and substitutions available.

Clinician safety is our highest priority, and we value the FDA's role in protecting public health. Thus, we are actively continuing the dialogue with FDA. As a leading supplier of facial protection, we know that thousands of U.S. healthcare facilities rely on Owens & Minor's



HALYARD\* brand each day for products that help ensure clinician and patient safety. We stand behind the safety of our products and regret the disruptions that this situation may cause for our U.S. healthcare customers.

Thank you for your continued partnership as we work toward a resolution. Please contact your O&M representative with additional questions or concerns.

Sincerely,

A handwritten signature in black ink that reads 'Susan Czajkowski'.

Susan Czajkowski  
Vice President, Technology, Innovation and Clinical Products



Products Impacted by FDA Import Holds or Emerging Safety Signal				Recommended Substitute Products Available for Use		
	Constrained Item	Description	EA/CS	Substitutes	Description	EA/CS
Surgical Tie Masks	47500	SOFT TOUCH* II Surgical Tie Mask, Blue, Horizontal Ties	300		<u>ASTM-Rated Tie Mask Substitutes:</u> 28806 Level 1 SO SOFT* Surgical Tie Mask, Fog-Free, Green 48207 Level 3 SO SOFT* Surgical Tie Mask, Fog-Free, Orange	
	47625	High Filtration Surgical Mask, Silver	300			
	48100	THE LITE ONE Surgical Mask, Blue	300			
	48201	Surgical Mask, Blue	300			
	48220	Duckbill Surgical Tie Mask, Blue	300			
	49214	Fog-Free Surgical Mask, Blue	300			
	49215	Anti-Fog Surgical Tie Mask, Derma-Touch Tape, Green	300			
	49216	HALYARD Duckbill Fog-Free Surgical Mask, Blue	300			
	49235	Anti-Fog Surgical Tie Mask, Green, Film Strip	300			
	48296	HYH Surgical Mask, Teddy Bears	300			
	49310	ULTI-MASK* Fog-Free Standard Surgical Tie Mask, White	300			
	48390	HYH Surgical Mask	300			
	6000	Halyard Surgical Mask	300			
	39123	FLUIDSHIELD Level 2 Expanded Chamber Surgical Mask With SO SOFT Lining, Blue and White	300			
	48247	FLUIDSHIELD* Level 3 Fog-Free Surgical Tie Mask, SO SOFT*, Orange, Anti-Glare WrapAround Visor	100			
28804	FLUIDSHIELD* Level 3 Fog-Free Surgical Tie Mask, Orange, WrapAround Anti-Glare Visor	100				
62114	FLUIDSHIELD* Level 2 Fog-Free Surgical Tie Mask, Blue with Orange Print, WrapAround Visor	100				
Earloop Masks	6001	Halyard Procedure Mask	300		<u>ASTM-Rated Earloop Substitutes:</u> 25867 Level 1 Procedure Mask, SO SOFT*, Yellow 47567 Level 1 Procedure Mask, Earloops, Yellow 47569 Level 3 Procedure Mask, Earloops, Fog-Free Foam, Aqua  <u>Comparable Tie Mask alternatives with good inventory:</u> 28806 Level 1 SO SOFT* Surgical Tie Mask, Fog-Free, Green 48207 Level 3 SO SOFT* Surgical Tie Mask, Fog-Free, Orange	
	47080	Procedure Mask, SO SOFT* Earloops, Blue	500			
	47117	Procedure Mask, SO SOFT* Earloops, Yellow	500			
	62356	THE LITE ONE* Procedure Mask, SO SOFT* Earloops, Blue	500			
	62363	Fog-Free Procedure Mask with SO SOFT* Lining and Earloops	500			
	47127	Child's Face Mask	750			
	25868	FLUIDSHIELD* Level 1 Procedure Mask, SO SOFT* Lining & Earloops, Lavender	500			
	25869	FLUIDSHIELD Level 1 Procedure Mask, Blue	500			
	48388	HALYARD Level 1 Procedure Mask, Yellow	500			
	47107	FLUIDSHIELD* Level 3 Fog-Free Procedure Mask, SO SOFT* Lining & Earloops, Orange	400			
	28797	FLUIDSHIELD* Level 3 Fog-Free Procedure Mask, SO SOFT* Earloops, Orange	400			
	47147	FLUIDSHIELD* Level 3 Fog-Free Procedure Mask, SO SOFT*, Orange, Anti-Glare WrapAround Visor	100			
28804	FLUIDSHIELD Level 3 Fog-Free Surgical Mask, Wrap Around Visor, Orange	100				
N95s	46727	Surgical N95 Respirator Mask, Orange (Regular)	210		No HALYARD* branded substitute immediately available. Please contact your O&M representative to identify alternative supplier options.	
	46827	Surgical N95 Respirator Mask, Orange (Small)	210			
	46767	Surgical N95 Respirator Mask, Orange SS (Regular)	210			
	46867	Surgical N95 Respirator Mask, Orange SS (Small)	210			
	76727	Surgical N95 Respirator Mask, Orange (Regular)	315			
	76827	Surgical N95 Respirator Mask, Orange (Small)	315			
	76767	Surgical N95 Respirator Mask, Orange SS (Regular)	315			
	76867	Surgical N95 Respirator Mask, Orange SS (Small)	315			
				SV50A	SAFEVIEW* Eyewear Assembled Glasses / Assorted Colors	50