



August 9, 2023

Dear Valued Customer,

Since our last update, Owens & Minor has continued to engage with the U.S. Food and Drug Administration (FDA) to understand and address the agency's concerns about [certain HALYARD\\* facial protection products](#).

We are reaching out to share a progress update to keep you informed of these activities and to help assure your clinicians and patients of the continued safety of our products. Additionally, we are also providing you with our new fall product formulary list to meet your needs for the upcoming respiratory season, per our usual annual protocol. The formulary can be viewed by clicking [here](#), or starting on page three of this document.

#### ***HALYARD product quality***

- The FDA completed an evaluation of all facilities involved in the manufacture and distribution of HALYARD facial protection and found no concerns with our quality management systems.
- We have conducted significant internal testing as well as external, independent third-party laboratory testing verifying the continued safety and performance of HALYARD facial protection products.
- Per standard regulatory protocol for all FDA-cleared products sold in the U.S. market, we continue to evaluate for any post-market data that could indicate an emerging concern about product quality. Notably, we have not received any complaints or reports of adverse events that would indicate a real-world concern with the safety or effectiveness of HALYARD facial protection products when used in accordance with their design and labeling.

#### ***HALYARD face masks***

- Provided FDA with significant testing and performance data demonstrating that fluid-rated HALYARD face masks continue to provide the rated level of fluid resistance.
- Aligned with the FDA on a go-forward strategy to secure the release of certain products that were previously on import hold. **Product codes 28797, 28800, 28804 and 62116 are now available** to order from our fall formulary.

#### ***HALYARD N95 surgical respirators***

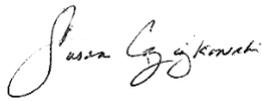
- *Product code 46827 (FLUIDSHIELD Surgical N95 Respirator Mask, Orange, Level 3, Size Small)*: identified a process variance affecting filtration efficiency for a single shipped lot (**lot # AM2164811**) of N95 surgical respirators. Although we have not received any real-world complaints or reports related to filtration, **we have voluntarily issued a field action to remove this lot from the market**. Our internal testing indicates that other shipped lots of this product code provide the expected level of filtration

protection, with the additional use of a face shield for fluid protection as previously noted in our [Product Communication](#).

- *Product code 46727 (FLUIDSHIELD Surgical N95 Respirator Masks, Orange, Level 3, Size Regular):* Per our previously posted [Product Communication](#), existing customer inventory of this product can be used with a face shield on top when fluid barrier protection against splashes, sprays, or splatter is needed.

We value your continued partnership and patience as we work through this matter. The FDA's review process is ongoing, and we will share additional updates as we are able. Please do not hesitate to reach out to your Owens & Minor account manager if we can provide any assistance in the meantime.

Sincerely,

A handwritten signature in black ink that reads "Susan Czajkowski". The signature is written in a cursive style with a large initial 'S'.

Susan Czajkowski  
Vice President, Clinical Products  
Owens & Minor

**HALYARD\* FACIAL PROTECTION FORMULARY – FALL 2023**

Category	Product Code	Description	Eaches Per Case
<b>SURGICAL &amp; PROCEDURE MASKS</b>			
Mask - Procedure	00152	Procedure Mask, Cone, Headband, Blue	300
Mask - Procedure	62363	Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, White	500
Mask - Procedure	32856	Procedure Mask, SO SOFT* Lining, Child, Disney® Characters, Ages 4-12	750
Mask - Surgical	37525	Surgical Mask, Expanded Chamber, Green	300
Mask - Surgical	48100	Surgical Mask, Lite One, Blue	300
Mask - Surgical	48390	Surgical Mask, SO SOFT* Lining, White	300

<b>ASTM LEVEL 1 FACE MASKS</b>			
Earloop	25867	Level 1 FLUIDSHIELD* Procedure Mask, SO SOFT* Lining and Earloops, Yellow	500
Earloop	47567	Level 1 Procedure Mask, Earloops, Yellow	500
Earloop	41802	Level 1 FLUIDSHIELD* Procedure Mask, Fog-Free Foam Strip, SO SOFT* Lining, White	500
Earloop	47568	Level 1 Procedure Mask, Blue	500
Earloop	57578	Level 1 Procedure Mask, Earloops, Pink	500
Earloop	48388	Level 1 Procedure Mask, SO SOFT* Earloops, Yellow	500
Earloop	25869	Level 1 FLUIDSHIELD* Procedure Mask, SO SOFT* Lining and Earloops, Blue	500
Earloop with Visor	41803	Level 1 FLUIDSHIELD* Procedure Mask, WrapAround Visor, Fog-Free Foam Strip, SO SOFT* Lining, White	100
Tie Mask	28806	Level 1 FLUIDSHIELD* Surgical Mask, Fog-Free Foam Strip, SO SOFT*Lining, Green	300
Tie Mask	28802	Level 1 FLUIDSHIELD* Surgical Mask, SO SOFT* Lining, Blue	300
Tie Mask	41805	Level 1 FLUIDSHIELD* Surgical Mask, SO SOFT* Lining, White	300
Ties with Visor	39118	Level 1 Surgical Mask, High Clarity WrapAround Visor, Horizontal Ties, SO SOFT* Lining, Blue	100

<b>ASTM LEVEL 2 FACE MASKS</b>			
Earloop	62115	Level 2 FLUIDSHIELD* Procedure Mask, Blue	500
Earloop with Visor	62116	Level 2 FLUIDSHIELD* Procedure Mask, WrapAround Visor, Fog-Free Foam Strip, Blue	100
Tie Mask	39123	Level 2 FLUIDSHIELD* Surgical Mask, Expanded Chamber, SO SOFT* Lining, Blue & White	300
Ties with Visor	39124	Level 2 FLUIDSHIELD* Surgical Mask, Expanded Chamber, High Clarity WrapAround Visor, SO SOFT* Lining, Blue & White	100
Ties with Visor	62114	Level 2 FLUIDSHIELD* Surgical Mask, WrapAround Visor Fog-Free Foam Strip, Blue with Orange Print	100

<b>ASTM LEVEL 3 FACE MASKS</b>			
Earloop	00148	Level 3 FLUIDSHIELD* Procedure Mask, Fog-Free Foam Strip, SO SOFT* Lining, Blue	400

Earloop	47569	Level 3 Procedure Mask, Fog-Free Foam Strip, Aqua	500
Earloop	28797	Level 3 FLUIDSHIELD* Procedure Mask, Fog-Free Foam Strip, Orange	400
Earloop with Visor	28800	Level 3 FLUIDSHIELD* Procedure Mask, WrapAround Visor, Fog-Free Foam Strip, Orange	100
Earloop with Visor	47137	Level 3 FLUIDSHIELD* Procedure Mask, Visor, Fog-Free Foam Strip, SO SOFT* Lining, Orange	100
Earloop with Visor	00146	Level 3 FLUIDSHIELD* Procedure Mask, WrapAround Visor, Fog-Free Foam Strip, SO SOFT* Lining, Blue	100
Tie Mask	48207	Level 3 FLUIDSHIELD* Surgical Mask, Fog-Free, SO SOFT* Lining, Orange	300
Ties with Visor	48237	Level 3 FLUIDSHIELD* Surgical Mask, Visor, Fog-Free Foam Strip, SO SOFT* Lining, Orange	100
Ties with Visor	28804	Level 3 FLUIDSHIELD* Surgical Mask, Fog-Free Foam Strip, Anti-Glare WrapAround Visor, Orange	100

#### EYEWEAR

Eyewear	SV50A	Eyewear Assembled Glasses, SAFEVIEW*, Assorted colors	50
Eyewear	SV250L	Eyewear Replacement Lenses, SAFEVIEW*,	250
Eyewear	SV100F	Eyewear Frames, SAFEVIEW*, Assorted Colors	100
Eyewear	50005	SAFEVIEW* CURVE* Comfort Eyewear	100

#### FACE SHIELDS

Face Shield	41205	Face Shield, Anti-Fog Film with Foam Band, Headband	40
Face Shield	41204	Face Shield, Anti-Fog Film with Foam Band, Headband, Long	40

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