

AssureMask®

Valiant™

ASTM
LEVEL 3



TECHNICAL DATA SHEET

FEATURES & BENEFITS

- Premium materials and over 30 years of expertise go into every Medicom AssureMask® Valiant™ mask to provide the reliable respiratory protection and optimal comfort and breathability that healthcare professionals need.
- Ample-length earloops are soft, strong, free of natural rubber latex, ultrasonically sealed and attached to the outside of the mask to prevent pulling and irritation.
- Adjustable, enclosed, plastic-covered, iron nosepiece provides customized protection and comfort.
- Made in North America to meet the highest quality and regulatory standards.

RECOMMENDED USE

- Procedure masks are intended to be worn by personnel during medical procedures to protect both the patient and the operating personnel from transfer of microorganisms, body fluids and particulate material transfer. Latex free.

PRODUCT DETAILS

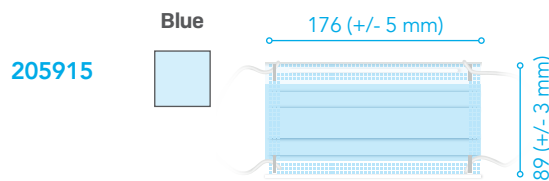
Product Name:	Medicom AssureMask® Valiant™ Procedure Earloop Face Mask
Product Type:	Single-use, non-sterile, three-layer construction
Earloop:	Polyester and spandex
Nosepiece:	Polypropylene (PP)-covered iron
Colour:	See Appendix 1
Quantity per Inner Carton:	50
Country of Origin:	USA



DETAILED MASK DIMENSIONS

Height of Earloop	63,5 mm
Pleat Depth	13 mm
Length of Nose-piece	120 mm

ITEM COLOUR DIMENSIONS



ASTM F2100 - LEVEL 3 BARRIER PROTECTION

PERFORMANCE FACTORS	TEST METHODS	RESULT
Bacterial filtration efficiency (BFE)	ASTM F2101	≥ 98%
Sub-micron particulate efficiency at 0.1µm (PFE) /	ASTM F2299	≥ 98%
Resistant to penetration by synthetic blood	ASTM F1862	@ 160 mm Hg
Differential Pressure (ΔP)	EN 14683	< 6.0 mm H ₂ O/cm ²
Flame Spread	16 CF 1610	Class 1

NON-WOVEN SPUNBOUND OUTER & INNER LAYER

Provides maximum protection against fluid penetration. Outer and inner layers made from spunbond polypropylene (SBPP).

HIGH-QUALITY MEDIA

Ensures optimal filtration and breathability. Made from melt blown polypropylene (MBPP).

SOFT, STRONG, ULTRASONICALLY SEALED EARLOOPS

Ample-length earloops are soft, strong, free of natural rubber latex, ultrasonically sealed and attached to the outside of the mask to prevent pulling and irritation.

SOFT-BOND ULTRASONICS

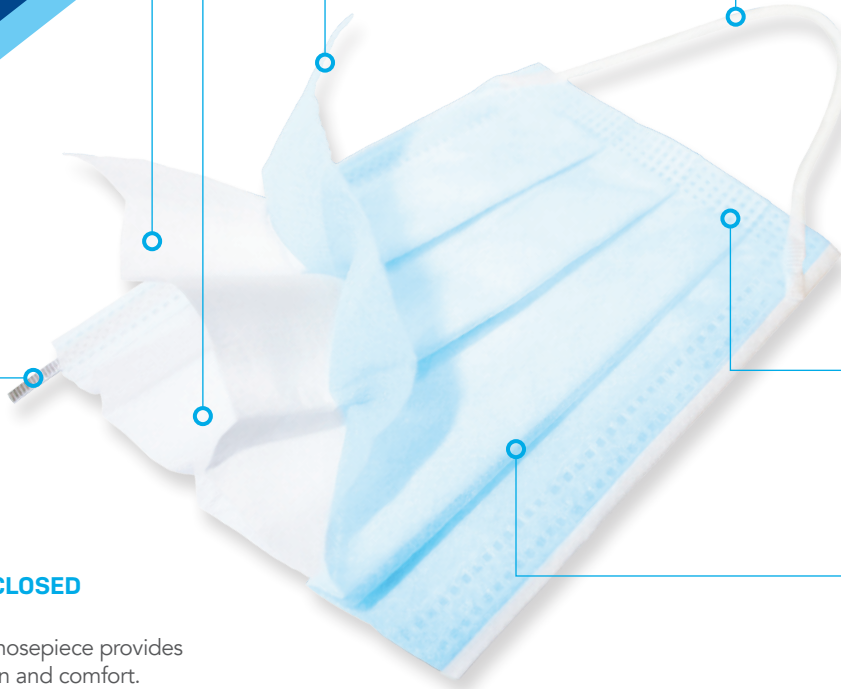
Ensure solid construction and eliminate holes and defects.

SHINGLE PLEAT DESIGN

Prevents fluid pooling and cross-contamination. Mask must be worn with pleats facing down.

ADJUSTABLE, ENCLOSED NOSEPIECE

Plastic-covered, iron nosepiece provides customized protection and comfort.



AVAILABLE COLOURS

Blue



Pink



White



Yellow



CERTIFICATION & STANDARDS

ISO 13485 certified manufacturer.
Class 1 Medical Device.
Health Canada registered medical device manufacturer.

STORAGE CONDITIONS

These masks should be disposed of after each use.
Store in a cool, dry place.
Avoid excessive heat (40 °C or 104 °F).



DONNING INSTRUCTIONS

- Fan to open pleats.
- Shape before applying to ensure a better fit.
- Pull earloops over each ear.
- With two fingers on either side of your nose, firmly shape around your nose and across your cheeks, concentrating on the bridge of your nose, to secure the seal.
- Pinch the nosepiece and make sure the base of the mask sits comfortably below your chin.

DOFFING INSTRUCTIONS

- Pull the earloops off your ears.
- Pull the mask away from your face, taking care not to touch its outer surface.
- Still holding only the earloops and taking care not to touch outer surface, dispose of mask in a clinical waste bin.
- Always wash your hands thoroughly after removing a mask.

Appendix 1 (List of items)

Item Code	Description	Packaging Information	Color	Specific Attribute	Treatment	Marketed in USA as	Marketed in Canada as
205914	Medicom AssureMask Valiant Procedure Earloop Face Masks, L3	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	White	PP-covered Iron nosepiece, Polyester & Spandex earloop, Round-knitted earloop; "Medicom" embossed at the bottom of mask	Non-Sterile	Medical Device Class 2	Medical Device Class 1
205915	Medicom AssureMask Valiant Procedure Earloop Face Masks, L3	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Blue	PP-covered Iron nosepiece, Polyester & Spandex earloop, Round-knitted earloop; "Medicom" embossed at the bottom of mask	Non-Sterile	Medical Device Class 2	Medical Device Class 1
205916	Medicom AssureMask Valiant Procedure Earloop Face Masks, L3	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Pink	PP-covered Iron nosepiece, Polyester & Spandex earloop, Round-knitted earloop; "Medicom" embossed at the bottom of mask	Non-Sterile	Medical Device Class 2	Medical Device Class 1
205917	Medicom AssureMask Valiant Procedure Earloop Face Masks, L3	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Yellow	PP-covered Iron nosepiece, Polyester & Spandex earloop, Round-knitted earloop; "Medicom" embossed at the bottom of mask	Non-Sterile	Medical Device Class 2	Medical Device Class 1

AMD Medicom Inc. | 2555 Chemin de l'Aviation, Montreal, Quebec, Canada H9P 2Z2