

12 April 2016

To whom it may concern,

In accordance with the guidance document issued by FDA *Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not Made with Natural Rubber Latex*, on December 2, 2014, the PneumoLiner labelling will include the statement "Not made with Natural rubber latex." and the following symbol;



No additional testing will be undertaken to support this statement, as a review of the material list, provided below, clearly demonstrates that natural rubber latex is not a raw material in the device or the device packaging.

The Materials used in the PneumoLiner are outlined below.

Component: Retractor	Material
Retractor Sleeve	Stevens ST625 FS 0.005" (Polyurethane film)
Sleeve Print	White Leaf SV-11521 (Print StampLeaf)
Sleeve Lubricant	Pionier 2076P (Medicinal White oil)
Distal Ring	Pellethane 2363-55D (Polyurethane)
Outer Proximal Ring	Makrolon RX-2530 1118 Tint (PC)
Removal Ribbon	70D taffeta Double Laminated (Nylon & TPU)
Inner Proximal Ring	Isoplast 2530 (Polyurethane)

Component: Retractor Introducer	Material
Introducer Shaft	Makrolon RX-2530 1118 Tint (PC)
Introducer Plunger	Purell GC7260 (HDPE) Hampton HCM5285P (Blue colourant)

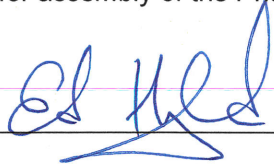
Component: Boot Assembly	Material
Boot	Colorite 6148GTX-02 (PVC)
Large Valve Upper Housing Large Valve Lower Substrate	Apec 1745 (PC)

Large Valve Lipseal	Shin-Etsu KE2090-40 (Silicone) Silcopas Yellow 90833 (Yellow colourant)
Large Crosscut Valve	Shin-Etsu KE2090-70 (Silicone)
5mm Valve Housing	Makrolon RX-2530 1118 Tint (PC)
5mm Valve Cap	Makrolon RX-2530 1118 Tint (PC) Hampton HCM 26668PC (Blue colourant for Makrolon RX-2530)
5mm Crosscut 5mm Lipseal	Wacker 3003/60 (Silicone)
Valve Lubricant	Nusil MED-420 (Silicone Lubricant)
Valve bonding adhesive	Dymax MD 1120M-UR (UV Adhesive)
Insufflation Tubing	Fre-thane Polyurethane Tubing
Barbed Elbow	Makrolon Rx2530 (Polycarbonate) 1118 Tint
Luer Stopcock- Handle Luer Stopcock- Body	Marlex 9006 (HDPE) Makrolon Rx1805 (PC)
Insufflation Valve assembly adhesive	Loctite 406 (Cyanoacrylate adhesive)

Component: PneumoLiner	Material
PneumoLiner Main Body	Stevens SS1495 SL 0.0016" (Polyurethane film)
Collar material	Stevens ST625 FS 0.005" (Polyurethane film)
PneumoLiner Tether	Brookwood Taffeta 70D Single Laminated (Nylon & TPU)
Proximal & Distal Grab Tabs	Brookwood Ripstop 30D Single Laminated (Nylon & TPU)
Opening ring	Nitinol- Super elastic Straight annealed 0.025"
Opening Ring crimp	304SS Hypo Tube (Stainless steel)
Sealing Bung	Volara 2A closed-cell foam (Polyethylene)

Component: PneumoLiner Introducer	Material
Introducer shaft	Bormed HE2581-PH (HDPE)
Introducer Plunger	Dow DMDA-8007 HEALTH+ (HDPE)

In addition, the contract manufacturer has a latex-free manufacturing controlled environment for assembly of the PneumoLiner device.



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