



February 1, 2013

To Whom It May Concern:

The CareFusion Infant Flow<sup>®</sup> LP System consists of a variable flow generator, nasal prongs, nasal masks, cotton bonnets and headgear fixation. The system is designed to work with various electromechanical drivers that produce the drive pressures to the generator mechanism. This non-sterile, single use noninvasive system is intended to provide the patient with Continuous Positive Airway Pressure (CPAP) and Bilevel (SiPAP) therapies. It is to be used in hospitals, hospital type facilities and intra-hospital transport environments by skilled clinicians.

The CareFusion Infant Flow<sup>®</sup> LP System is indicated for the treatment of spontaneously breathing infants up to 5 Kg. The Infant Flow<sup>®</sup> LP System components, including the respiratory abdominal sensor used in apnea detection and triggering, do not contain Latex and Bisphenol A.\* The components are manufactured without the use of Phthalates, such as, DEHP.

*Vertimas žemiau*

See Table-1 for a breakdown of materials used in the Infant Flow LP System.

Best Regards,

Lorelee Goehle  
Senior Global Product Manager  
Respiratory Technologies-Ventilation

\*FDA 21 CFR 801.437 User Labeling for Devices that Contain Natural Rubber

*Vertimas:*

*Infant Flow LP sistemos komponentai, tame tarpe ir kvėpavimo sensorius apnėjos nustatymui, savo sudėtyje neturi lateksu ir Bisphenolio A. Komponentų gamyloje nenaudojami ftalatai (kaip pvz. DEHP.)*



*Vertimas Lietuvos Respublikos Sveikatos apsaugos ministro padėjėjas*

## Infant Flow® LP Assembly Material Description

Table 1: Infant Flow® LP Components

<b>Generator Assembly</b>		<b>Material</b>
Cap, jet body, exhaust elbow & receiver		Acrylic
Adhesive		Non-latex
<b>Relief Valve Assembly</b>		
Body & cap		Acrylic
Umbrella valve		Silicone Class VI Elastomer
Foam disk		Medical Grade Polyurethane Foam
<b>Tube Assembly, Exhaust</b>		
Tubing, popple 14"		Polypropylene Copolymer & Polyolefin Elastomer
Tubing, sound reducing 10"		Polyolefin Elastomer
10 mm/10 mm tubing connector		Polypropylene
Drive & pressure lines		Non-phthalate PVC
<b>Support Block Assembly</b>		
Support tee base		Thermoplastic Elastomer
Tube retainer, support tee		Hook & Loop Nylon
Velcro, support tee		Nylon Hook Natural
<b>Other Kit Components</b>		
Sizing guide		Clear Cellulose Acetate
Tray, lid & prong clamshell		PET, Medical Grade
<b>Prongs &amp; Mask</b>	<i>Kanulės ir kaukės (visų dydžių)</i>	
Prongs & masks, all sizes		Silicone & Medical Grade Colorants
Small clamshell		PET, Medical Grade
<b>Bonnets</b>		
Bonnets		Cotton Jersey Knit
Support pad		Nylon Loop Fabric & Foam
<b>Headgear</b>		
Headgear		Nylon Loop Fabric and Foam
Support pad		Nylon Loop Fabric & Foam

*Silikonas ir medicininiai daiktai.*

Pagamintos iš silikono

*Vertimas šiuos  
2013.11.06*

*Direktorius  
Gediminas Čiurėnas*

