ETHICON

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

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Natural Rubber Latex Components in Ethicon Products, Manufacturing Processes and Packaging

Dear valued customer:

Thank you for your inquiry regarding the use of natural rubber latex in Ethicon products.

Because of increased awareness of natural rubber latex sensitivity, we have reviewed our products to identify those that may contain natural rubber latex which come in contact with either the patient or the user.

As of the date of this letter, to the best of our knowledge:

The following Ethicon Products contain latex and are labeled as "Containing Natural Latex Rubber."

- J-VAC™ Reservoirs (Code No. 2160[+], 2161, 2162, 2163) contain latex as part of the anti-reflux valve.
- BLAKE® Silicone Drain Kits (Code No. 2205[+], 2207[+], 2236[+], 2238[+], 2259, 2261, 2262, 2263, 2264, 2265, & 2268[+]) contain latex as part of the anti-reflux valve on the J-VAC Reservoir.
- RETENTION SUTURE BOLSTER (Code No. 450G, 470G) is made of latex tubing.

+ Note: As of Q1 2013, Ethicon began manufacturing these products without natural rubber latex. Products previously manufactured with latex may remain in the market. Since both versions of product may be on the market simultaneously, please refer to the product labeling which will declare latex content as applicable.

The following Ethicon product [++] has been identified as having been manufactured in facilities using latex gloves during the manufacturing process:

- ETHICON INTERCOAT Absorbable Adhesion Barrier Gel (Code No. IC100, GKIC100)

++ Note: As of the end of 2013, the Ethicon manufacturing facilities where these products are manufactured have switched to using non-latex gloves. However, products that were manufactured with latex gloves may still be in the supply chain and present in the market.

Ethicon products are in compliance with current regulations and standards that include:

- MEDDEV 2.5/9 rev. 1, Feb 2004, "Guidelines on Medical Devices: Implications of the Medical Devices Directives (93/42/EEC) in Relation to Medical Devices Containing Natural Rubber Latex: A Guide for Manufacturers and Notified Bodies"
- 21 CFR 801.437: "User Labeling for Devices that Contain Natural Rubber"
- BS EN ISO 15223-1:2016, "Medical Devices. Symbols To Be Used With Medical Device Labels, Labelling And Information To Be Supplied. General Requirements"

If you have any questions or concerns, please feel free to contact our USA Customer Support Center or contact your local representative:

- USA: I-877-Ethicon (1-877-384-4266), option 6
- Worldwide: 1-513-337-8901
- E-mail: customersupport@eesus.jnj.com