

TECHNICAL BULLETIN

LATEX SENSITIVITY

The FDA has issued a Latex Labeling requirement, 21 CFR 801.437, that states: "A labeling statement is required for devices that contain natural rubber when the rubber contacts humans". The European Union has a similar requirement.

The ON-Q* Pump is manufactured with multiple layers. The outer layer of the pumping chamber is composed of natural rubber latex. This natural rubber layer is prevented from contacting humans by two other layers.

The inner layer of the pumping chamber is a synthetic thermoplastic elastomer.

- The inner layer contacts the fluid pathway and prevents contact with the natural rubber layer.
- The outer cover of the pump is made of PVC. This outer cover surrounds the pumping chamber which eliminates direct human skin contact with the natural rubber layer.

Independent laboratory testing has been conducted on the ON-Q* Pump fluid pathway and the actual natural rubber latex component itself to measure the potential amount of natural rubber proteins extracted. Two methods were used:

- The Modified Lowery Assay to measure the total extractable proteins associated with the natural rubber; and
- The ELISA Inhibition Assay to measure the amount of antigenic protein in the natural rubber.

Based on current tests methods available today, no natural rubber proteins were detected for either test method for both the fluid pathway of the ON-Q* Pump and the latex component itself.

All remaining system components are not made from natural rubber latex; however, manufacturing facility may contain natural rubber latex.

Conclusion: The natural rubber layer of the pump does not come into human contact.

In addition, laboratory testing could not detect any extractable proteins from either the pump fluid pathway or the natural rubber component itself.

There are inherent risks in all medical devices. Please refer to the product labeling for **Indications, Cautions, Warnings and Contraindications**. Failure to follow the product labeling could directly impact patient safety. Physician is responsible for prescribing and administering medications per instructions provided by the drug manufacturer. Refer to www.halyardhealth.com for additional product safety **Technical Bulletins**.

Please contact the Clinical Services Department at 800-444-2728 or 949-923-2400
if you have any questions regarding this information.
