acumed®

Latex Statement

Healthcare Professional and Patient Information on Latex in Acumed Implants and Instruments

Acumed's implants and instruments are not manufactured with natural rubber latex. Acumed's packaging, handling, and manufacturing processes prohibit the use of, or contact with, latex materials.

The US FDA has stated that "contact with devices containing natural rubber has been associated with anaphylaxis in individuals allergic to natural rubber latex proteins."[1]

The European Commission has stated that "persons who know or suspect that they may have Type I latex allergy must avoid contact with latex products. If they are treated in healthcare they should inform the personnel about their allergy."[2]

Acumed has not tested its products for natural rubber latex allergenic proteins. Please contact us if any additional information is needed.

References

1. UCM342872, Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not Made with Natural Rubber Latex, Guidance for Industry and Food and Drug Administration Staff, December 2, 2104, www.fda.gov
2. MEDDEV 2.5/9 rev. 1 European Commission 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 Manufactures and Notified Bodies, February 2004, ec.europa.eu/growth/sectors/medical-devices/guidance_en

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