



March 6, 2013

Valued Arthrex Customer

SUBJECT: Single-use/day tubing

Disposable single-use/single-day usage of pump tubing is not uncommon in orthopedic arthroscopy. Single-use/day tubing was identified in the premarket notification (510(k)) documents submitted to the FDA for both the Continuous Wave Pump and the DualWave Pump. The tubing in both pump systems was cleared for use by the FDA for single surgical day usage.

The Arthrex Extension Tubing (AR-6220) and the Arthrex ReDeuce Patient Tubing (AR-6421) have been designed with a backflow preventer which prevents contamination of the main pump tubing. Contamination control testing has been conducted to validate and support the use of these products for single-use/day usage without altering the safety or efficacy of the tubing. When used with these two extension sets, the Arthrex Main Pump Tubing (AR-6410) and ReDeuce Pump Tubing (AR-6411) may be used for single-use/day tubing.

If you have any further questions in this regard, please contact your Customer Service Representative.

Thank you for your continued business.

Best Regards

A handwritten signature in blue ink that reads "Courtney Smith". The signature is written in a cursive, flowing style.

Courtney Smith

Manager, Regulatory Affairs

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