

Owen Mumford – Recall of Unifine® Pentips®

On November 7, 2017, <u>Owen Mumford announced</u> a voluntary, user-level recall of one lot of <u>Unifine</u>
 <u>Pentips</u> 5 mm pen needles due to a potential sterility issue.

Product Description	NDC #	Lot #
Unifine Pentips 5 mm pen needles, 100 count	08470-3550-01	1705722
Unifine Pentips 5 mm pen needles, 30 count	08470-1150-01	1705722

- Unifine Pentips pen needles work with all major brand injection pens for subcutaneous insulin administration.
- A device was identified to have been potentially compromised by water in the end user level
 packaging. Exposure to liquid may compromise sterility. This may appear as discoloring or yellowing
 of the device's protective seal. The product was discovered on-site, within Owen Mumford's control.
 The remaining lot has been placed on hold. Following third-party laboratory evaluation, Owen
 Mumford has determined this affected product has come in contact with water.
- This voluntary recall has been issued as a precautionary measure. There have been no complaints, adverse events or end user reports as of November 3, 2017.
- Anyone with an existing inventory of the recalled Unifine Pentips should stop use and distribution, and contact Owen Mumford Customer Service Department at **1-800-421-6936** for return information.



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