



**LABORATORIES, INC.**

4 SPERRY ROAD, FAIRFIELD, NJ 07004 U.S.A.

**Subject:** Changes to Tristel ULT User Guide and Labeling

**Date:** April 1, 2026

Dear Valued Customer,

At Parker, we are committed to continuously improving our products and supporting materials to ensure they remain clear, accurate, and aligned with your needs. We greatly value the feedback we and our partner Tristel Solutions Ltd. receive from users, partners, and clinical teams, and several updates have been made directly in response to your input.

The following changes have been made to the Tristel ULT User Guide and Label. You will see these updated materials in Tristel ULT product lots manufactured from February 2026 onwards, beginning with lot C0226007.

If you hold copies of Tristel ULT User Guide and labeling in electronic files and folders, please be sure to update your records with the updated versions.

**Key Updates:**

<i>Current Version – TRI/FDA/007 - 1 - PM-125- 0000A</i>	<i>New Version – TRI/COM/112 - VI - PM-125- 0000B</i>	<i>Reason for change</i>
<b>PRECAUTIONS</b> 1.Wear gloves and safety glasses when reprocessing devices.	<b>PRECAUTIONS</b> 1.Wear appropriate personal protective equipment (PPE) when reprocessing medical devices.	Based on biocompatibility of Tristel ULT we recommend use of gloves and glasses to protect from accidental exposure to Tristel ULT foam. Some healthcare facilities have additional/other PPE requirements for device reprocessing. To avoid any conflict with facilities’ own protocols we have update wording so that facilities



		can use their internal risk assessment and consider overall practices when prescribing PPE.
<b>PRECAUTIONS</b> 8. Do not perform more than 20 disinfection procedures per day (8 hours). The limitation to 20 procedures per day for an operator is based on the 8-hour OSHA permissible occupational exposure limit for chlorine dioxide.	<b>PRECAUTIONS</b> 8. Do not perform more than 40 disinfection procedures per day (8 hours). The limitation to 40 procedures per day for an operator is based on the 8-hour OSHA permissible occupational exposure limit for chlorine dioxide.	An updated inhalation exposure study confirmed that 40 Tristel ULT disinfection cycles performed in 8-hour period, when used in clinical environment in accordance with user instructions, did not exceed permissible exposure limits.
<b>TOXICOLOGICAL INFORMATION</b> Tristel ULT was evaluated for inhalation exposure during use. In a study simulating 20 disinfection procedures, the average 8-hour TWA reading did not exceed the U.S. OSHA permissible exposure limit of 0.1ppm for chlorine dioxide, and the results of the average 15-minute STEL readings did not exceed the California Division of Occupational Safety and Health PEL of 0.3ppm.	<b>TOXICOLOGICAL INFORMATION</b> Tristel ULT was evaluated for inhalation exposure during use. In a study simulating 40 disinfection procedures, the average 8-hour TWA reading did not exceed the U.S. OSHA permissible exposure limit of 0.1ppm for chlorine dioxide, and the results of the average 15-minute STEL readings did not exceed the California Division of Occupational Safety and Health PEL of 0.3ppm.	
<b>WARNINGS</b> Based on biocompatibility testing, Tristel ULT Foam is	<b>WARNINGS</b> <i>Sentence removed</i>	This text has been removed from the 'Warnings' section as it was repeated content



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<p>irritating to the eye and is classified as a slight irritant to skin.</p>		<p>from the Toxicological Information section. There has been no change in the safety or performance of Tristel ULT.</p>
<p><b>HOW SUPPLIED DESCRIPTION</b> 45-13 Tristel Test Strips starter pack: A vial/bottle of 50 test strips. Stopwatch. Polyethylene container. 10ml measure syringe. User Guide.</p>	<p><b>HOW SUPPLIED DESCRIPTION</b> 45-13 Tristel Test Strips starter pack: A vial/bottle of 50 test strips. Stopwatch. Polyethylene container. 10ml measure syringe. User Guide. 50 MRC check complete stickers.</p>	<p>Updated description of the product content to reflect addition of the 'MRC check complete stickers' to the Tristel Test Strips.</p>
<p><b>HOW SUPPLIED DESCRIPTION</b> 45-10 Tristel Test Strips: A vial/bottle of 50 test strips. User Guide.</p>	<p><b>HOW SUPPLIED DESCRIPTION</b> 45-10 Tristel Test Strips: A vial/bottle of 50 test strips. User Guide. 50 MRC check complete stickers.</p>	<p>Updated description of the product content to reflect addition of the 'MRC check complete stickers' to the Tristel Test Strips.</p>

- ✓ Improved layout and content flow
  - Several sections, including User Training and General Information on Medical Device Reprocessing, have been repositioned for a more intuitive flow.
  - Label content has been condensed to a clearer, three-page format.
  
- ✓ Updated training and device compatibility sections with addition of QR codes for quicker access to training materials and device compatibility information.



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✓ Updated MATERIAL AND DEVICE COMPATIBILITY section with additional ultrasound probe brands that have been confirmed compatible with Tristel ULT.

These updates reflect our continued commitment to product quality, user safety, and making your experience with Tristel ULT as straightforward as possible.

If you have any questions about these changes or require further information, please do not hesitate to contact your Parker representative or contact Customer Service at [customerservice@parkerlabs.com](mailto:customerservice@parkerlabs.com).

Sincerely,

A handwritten signature in blue ink that reads "Candy Beck".

Candy Beck  
Senior Regulatory Specialist  
Parker Laboratories, Inc.