



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2021-3487**

13 DEC 2021

TO: ALL HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS

SUBJECT: Voluntary Recall of Rüsç Endotracheal Tube

The Food and Drug Administration (FDA) warns all healthcare professionals and establishments on the voluntary recall of affected lots/batch of Rüsç Endotracheal Tube imported and distributed by East Lane Corporation:

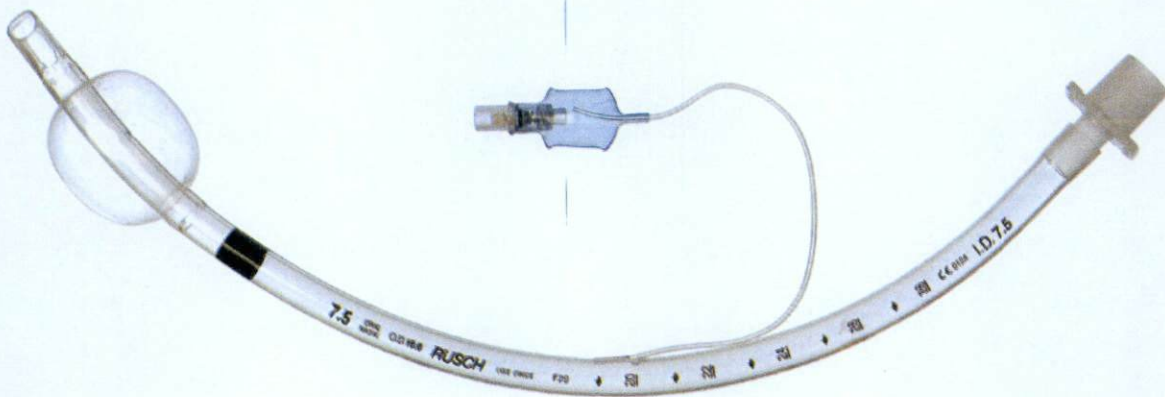


Figure 1. Photo of Rüsç Endotracheal Tube

Teleflex is initiating a Field Safety Corrective Action due to reports that the endotracheal tube cuff could be inflated while the pilot balloon remained flat. In the event of the pilot balloon remaining flat, there is the potential risk of injury to the patient as the pilot balloon no longer reflects the condition of the cuff. The risk persists in situ, therefore clinicians should evaluate the risk benefit to individual patients of extubation and reintubation.


In light of the foregoing, all concerned healthcare professionals, establishments, and the general public are warned to discontinue further use, sale, and distribution of the Rüsç Endotracheal Tube.



All FDA Regional Field Offices and Regulatory Enforcement Units, in coordination with law enforcement agencies and Local Government Units, are requested to ensure that product is not sold or made available in the market or areas of jurisdiction.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health, and Research through e-mail at cdrhr@fda.gov.ph, or call (02) 8857-1900 loc. 8301.

Dissemination of this advisory to all concerned is hereby requested.


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Director General

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