

March 4, 2019

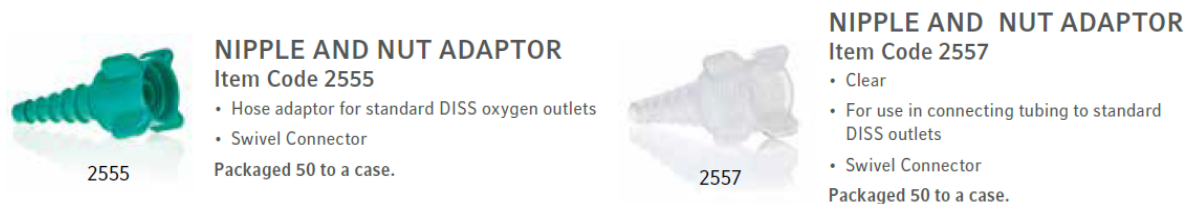
Subject: Nipple and Nut Adaptor Labeling Change to Reusable

Dear Valued Customer:

Teleflex would like to inform you that the labels for product codes 2555 and 2557 Nipple and Nut Adaptor (Christmas Tree Adaptors) have been updated from single-use only to reusable (multi-use). This change has been implemented following the completion of our cleaning validation and testing. Please see the reprocessing instructions below for details.

Please note that per Spaulding classification for best practices for cleaning, disinfection, and sterilization, these products are considered non-critical; however, Teleflex chose a conservative approach by validating a semi-critical cleaning method. Christmas Tree Adaptors are used to provide a connection between hospital wall oxygen or compressed air flowmeters to respiratory routine disposables such as nasal cannulas and oxygen or aerosol masks. Therefore, Teleflex has not performed cross-contamination studies for this product.

The reprocessing methods referenced in the Instructions For Use are outlined below.



Cleaning Guidelines

Alcohol Wash (Soak in Isopropanol (70%)) for 30 minutes. During the soak time, brush all surfaces of the adaptor until all visual debris is removed with a soft bristled brush for a minimum of 30 seconds. Let air dry or hand dry with a clean, lint-free cloth. Visually inspect components and repeat cleaning instructions if residue is present.

OR

Autoclave:

The following steam sterilization cycles may be used.

Sterilization Method	Temperature	Cycle Parameter	Exposure/Hold Time (minimum)	Drying Time (minimum)
Pre-vacuum	270°F (132°C)	Half Cycle	2 minutes	0 minutes
Pre-vacuum	270°F (132°C)	Full Cycle	4 minutes	20 minutes

For questions or additional information, please contact your local sales representative.

Sincerely,

Christina Martin
Associate Global Product Manager – Respiratory Division

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