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TRACOE®
Gesellschaft für medizinisch
Bedarfsgegenstände mbH

TRACOE GmbH, Reichsforststraße 32, D-60528 Frankfurt/Main

S M D A

Summary

This summary of 510 (K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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Date:

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1. Products:

Trade Name: Tracheostomy Tubes TRACOE^R-FLEX

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|-----|---|-----------|
| 1. | Tracheostomy Tubes | |
| 1.1 | Low Pressure Cuffed Tracheostomy Tube TRACOE ^R -FLEX | Model 301 |
| 1.2 | Fenestrated Low Pressure Cuffed Tracheostomy Tube TRACOE ^R -FLEX | Model 302 |
| 1.3 | Cuffless Tracheostomy Tube TRACOE ^R -FLEX | Model 303 |
| 1.4 | Fenestrated Cuffless Tracheostomy Tube TRACOE ^R -FLEX | Model 304 |
| 1.5 | Laryngectomy Tube TRACOE ^R -FLEX | Model 305 |

Models 301 to 304 come in five sizes (04, 06, 08, 10, 12); model 304 comes in three sizes (06, 08, 10).

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| 2. | Accessories | |
| 2.1 | Fenestrated Inner Canulas with "Speaking Valve" for Models 302 and 304 in all five sizes | Model 401 |

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|-----|--|--|
| 3. | Replacement Parts | |
| 3.1 | Replacement parts are available for all inner cannulas of all models and sizes as well as for all plugs. | |

Classification Name: Tracheostomy Tubes
ANESTHESIOLOGY, 73JOH and 73BTO
Class II, 868.5800 and 874.4900

2. Description:

The TRACOE^R-FLEX tracheostomy tubes, the accessories as well as the replacement parts (inner cannulas and plugs) are sterile products for single patient use only. They essentially consist of a neck plate, an outer and an inner cannula. Outer and inner cannulas consists of thin walled relatively soft plastic material, which gets even softer at body temperature.

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The special feature of the TRACOE^R-FLEX tracheostomy tubes is, that the neck flange is movable in a horizontal as well as in a vertical axis, so that the cannula inside the trachea does not move, when the patient either bends or turns his head. The outer cannula can carry an inflatable low pressure high volume cuff (models 301 and 302) and/or can be perforated (models 302 and 304).

Inner cannulas with a twist-lock 15 mm adapter are non fenestrated (models 301, 302, 303 and 304); additional inner cannulas with a short blue twist-lock adapter (models 302 and 304) are fenestrated.

Fenestrated inner cannulas with an integrated "speaking valve" for models 302 and 304 are available as accessories (model 401) for all sizes.

3. Indications for use:

Model 301: device is intended for providing tracheal access for airway management including artificial ventilation.

Model 302: device is intended for providing tracheal access for airway management, in which a fenestration is needed in order to safely wean a patient from mechanical ventilation. It can also be used for phonation, if a patient with the larynx intact uses a fenestrated inner cannula with "speaking valve".

Model 303: device is intended for providing tracheal access for airway management.

Model 304: device is intended for providing tracheal access for airway management where a fenestration is needed in order to safely wean a patient from mechanical ventilation. It can also be used for phonation, if a patient with the larynx intact uses a fenestrated inner cannula with a "speaking valve".

Model 305: device is intended for providing tracheal access for airway management in patients after laryngectomy.

Model 401: device is intended for use in patients with the larynx intact in combination with TRACOE^R-FLEX model 302 and 304.

4. Predicate Devices:

TRACOE ^R -FLEX	Predicate devices	510(K) Number
Model 301	- Shiley Low Pressure Thin Cuffed Tracheostomy Tube, Non-Fenestrated	K811033
	- Modified Shiley Low Pressure Cuffed Tracheostomy Tube	K880614
	- Bivona Aire Cuff Silicone Tracheostomy Tube	K885130
	- Fome-Cuf and Aire-Cuf Tracheostomy Tubes (Shapiro-Bivona)	K862267
	- Portex Tracheostomy Tubes with Cuff	K903730

Model 302	-	Shiley Fenestrated Low Pressure Cuffed Tracheostomy Tube with Improved Cuff	K812302
	-	Shiley Disposable Cannula Fenestrated Low Pressure Cuffed Tracheostomy Tube	K865061
Model 303	-	Shiley Single Cannula Tracheostomy Tube	K810106
	-	Shiley Disposable Cannula Tracheostomy Tube	K811447
	-	Portex Tracheostomy Tubes without Cuff	K912124
	-	Tracoe Tracheostomy Tubes	K781729
Model 304	-	Shiley Cuffless Fenestrated Tracheostomy Tube	K880614
Model 305	-	Shiley Laryngectomy Tube	K821993
Model 401	-	Shiley Phonate Speaking Valve	K945406
	-	Bivona Tracheostomy Valve	K852272
	-	Tracoe Tracheostomy Tubes with Speaking Valve	K781729

5. Technological Characteristics of TRACOE^R-FLEX tubes compared to the Shiley/Mallinckrodt products

The TRACOE^R-FLEX tube models 301 to 305 correspond closely to the traditional Shiley/Mallinckrodt products LPC, FEN, CFS, CFN and LGT. For both these products series the labelling, the indications for use as well as the safety characteristics are essentially identical. The TRACOE^R-FLEX tubes show however some improvements compared to the predicate devices such as

- the TRACOE^R-FLEX tubes have a neck plate, which is connected to the outer cannula in a way, that outer and inner cannulas can move in a horizontal as well as in a vertical axis at the same time. The Shiley/Mallinckrodt tubes can only move around a horizontal axis; all other tubes on the market have fixed neck plates.
- TRACOE^R-FLEX tubes have thinner cannulas than the Shiley products.
- The material used for TRACOE^R-FLEX tubes is a much softer plastic material (polyurethane) than the material used for the Shiley products. The TRACOE^R-FLEX tubes are therefore softer and have a higher flexibility than the predicate devices.

- The thinner walls of the TRACOE^R-FLEX tubes yield at a given size of a tracheostoma a comparatively higher airflow for the patient than the predicate devices.
- The Tracoe „speaking valve“ are constructed as integral part of inner cannulas and are less bulkier than predicate devices of Shiley/Mallinckrodt and Passy-Muir.

6. Assessment of Substantial Equivalence based on non-clinical Performance Data

The performance of the TRACOE^R-FLEX tracheostomy tubes as well as of the „speaking valves“ was tested in comparison to the Shiley/Mallinckrodt tubes based on measurements of the dimensions, resistance to airflow, kink resistance and connection between cannula and neck plate. The results of all these tests showed, that all these parameters are at least as good as those of the predicate devices and in certain features like resistance to airflow of the tubes, softness of the wall and flexibility between cannula and neck plate even better.

7. Biocompatibility Assessment

All materials used are medical grade, and come with a certificate of compliance.

Elution tests of the final sterilized products according to USP23 were negative.