



Technical Data Sheet

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PRODUCT:

Frova Intubating Introducer

PRODUCT CODE:

C-CAE-14.0-70-FI
C-CAE-14.0-70-FII
C-CAE-14.0-70-FIC

DIMENSIONS:*Without Stiffening Stylet and with Rapi-Fit® adaptors***C-CAE-14.0-70-FI**

- Catheter diameter : 14.0 Fr.
- Catheter length : 70 cm
- Interior diameter of the catheter : 3 mm

Used for the replacement of endotracheal tubes with an internal diameter of 6 mm or larger

*With Stiffening Stylet and Rapi-Fit® adaptors***C-CAE-14.0-70-FII**

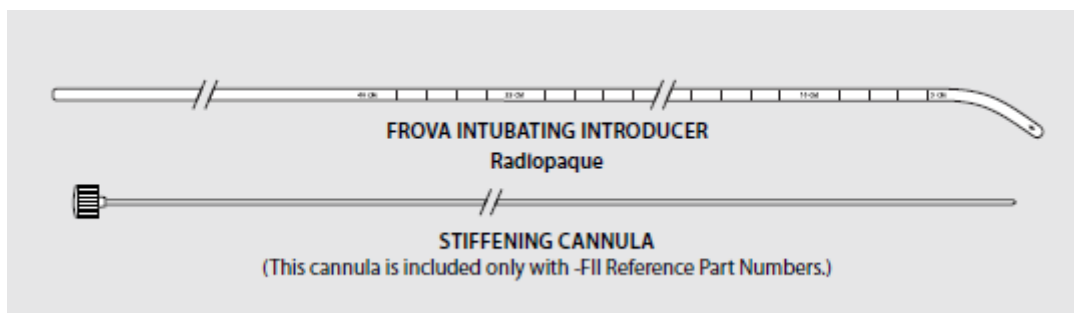
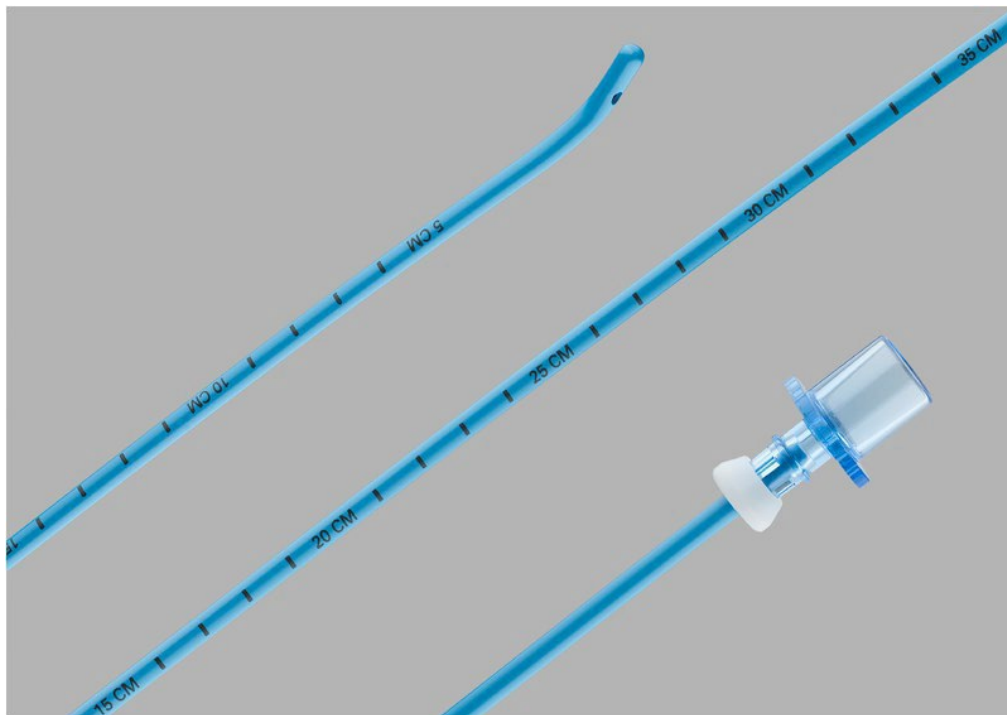
- Catheter diameter : 14.0 Fr.
- Catheter length : 70 cm
- Interior diameter of the catheter : 3 mm

Used for the replacement of endotracheal tubes with an internal diameter of 6 mm or larger

*Without Stiffening Stylet – Catheter Only***C-CAE-14.0-70-FIC**

- Catheter diameter : 14.0 Fr.
- Catheter length : 70 cm
- Interior diameter of the catheter : 3 mm

Used for the replacement of endotracheal tubes with an internal diameter of 6 mm or larger

PICTURE:

RAPI-FIT ADAPTER
15 mm connector



RAPI-FIT ADAPTER
Luer lock connector

COMPONENTS:

Catheter
Stiffening stylet
Adaptors

DESCRIPTION:

The Frova Intubating Introducer is a 14.0 French, 70 cm long radiopaque catheter introducer with centimetre markings and a blunt, curved tip that can be passed blindly into the trachea. The catheter has a through lumen with two distal sideports to ensure adequate airflow. A stiffening stylet and two Rapi-Fit®

INTENDED USE:

The Frova Intubating Introducer is intended to facilitate endotracheal intubation in patients where the visualisation of the glottis is inadequate. The 14.0 French catheter introducer has been designed for placement of a single lumen endotracheal tube whose inner diameter is 6 mm or larger.

NOTE: Do not use the Frova Intubating Introducer with double lumen endotracheal or endobronchial tubes.

NOTE: The use of removable Rapi-Fit Adapters permits the utilisation of a high and low-pressure oxygen source, if necessary, during the procedure.

CONTRAINDICATIONS:

Do not use if the epiglottis cannot be visualised when performing laryngoscopy, i.e., Grade IV Cormack & Lehane laryngoscopy classification.

PRECAUTIONS:

- The product is intended for use by physicians trained and experienced in airway management.
- Sizing of the Rapi-Fit Adapter and the Frova Intubating Introducer must match in order to provide oxygenation through the catheter introducer.
- Not for intravascular use.
- To avoid barotrauma and/or pneumothorax, examine the patient's anatomy to help determine the optimal placement for the Frova Intubating Introducer. Ensure the catheter is in the physician-preferred location relative to the carina by referencing its centimeter markings.
- Care must be taken not to provoke injury to the epiglottis and glottis, perforation of the sinus pyriformis, trachea or bronchus.
- Use of the Rapi-Fit Adapter for oxygenation may be associated with a risk of barotrauma.
- Use of an oxygen source should only be considered if the patient has sufficient egression of the insufflated gas volume.
- If a high-pressure oxygen source is used for insufflation (e.g., jet ventilator), begin at a lower pressure and work up gradually. Rising chest wall, pulse oximetry and oral air flow should be carefully monitored.
- Ensure that the Rapi-Fit Adapter is securely connected to the Frova catheter prior to oxygen delivery. Failure to properly secure the adapter to the catheter introducer may result in hypoxia, hypoxaemia and serious adverse events.
- Do not use the Frova Intubating Introducer with double lumen endotracheal or endobronchial tubes.
- Lubricate the catheter introducer and endotracheal tube before use.
- Ensure proper sizing of the endotracheal tube to be used in combination with the Frova Intubating Introducer.
- Care must be taken when introducing/removing the catheter introducer from the endotracheal tube; contact with sharp edges on the internal surface of the endotracheal tube may cause small fragments to be shaved off the catheter introducer during introduction/removal.
- Possible allergic reactions should be considered.

RECOMMENDED STORAGE INSTRUCTIONS:

Store in a clean and dry location, away from temperature extremes.

Upon removal from package, inspect the product to ensure no damage has occurred.

Direct patient contacting materials	Radiopaque polyurethane Stainless steel Polyethylene
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CE Marked	Yes
Class	IIa
Notified body number	0123
Manufacturer	William Cook Europe

Single use	Yes
Sterilized	Yes
Address of sterilization	William Cook Europe, Sandet 6, DK-4632 Bjaeverskov, Denmark
Method of sterilization	ETO
Shelf life	Up to 36 months
Biological origin	No
Latex	No
Biocompatibility	Yes
Quantity supplied	1, except for the C-CAE-14.0-70-FIC which is sold in boxes of 10