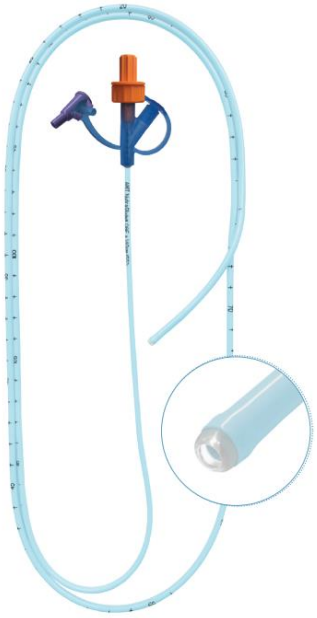
Australian Patient Information Leaflet

NutraGlide™

Nasal Feeding Tube

AMT has provided the following information as an educational resource tool. This is not intended as a substitute for professional medical care. Your FIRST source of information should be your healthcare provider.



Name/Model of the Device: NutraGlide™

Intended Purpose: The NutraGlide™ is intended to deliver enteral nutrition, medication, and fluid to neonatal, pediatric and adult patients via the naso-gastric or naso-intestinal route.

Kind or patient on whom the device is intended to be used: The NutraGlide™ Nasal Feeding Tube is indicated for the administration of nutrition, fluids, and medications in neonatal, pediatric, and adult patients.

Any special operating instructions for use of the device:
CAUTION: This feeding tube is to be placed by trained healthcare professionals only.
CAUTION: Prior to placement, please inspect all contents of the kit for damage. If the package or device is damaged, do not use the product.
CAUTION: Do not use a stylet during placement if the device was not packaged with one
WARNING: Estimation of tubing length is critical. Do not insert excess tubing as this may result in kinking of tube
Note: Stylet cannot be used with guidewire assisted placement. To remove the stylet, activate lubricious coating by injecting up to 10 mL of water into the tube. Wait 60 seconds. Carefully remove the stylet by applying gentle traction.
WARNING: Coughing or respiratory distress may indicate passage of the tube into the airway. If this is suspected, remove device immediately and reinsert.

WARNING: Caution should be taken if any type of endotracheal device is in place, as these may facilitate the passage of the feeding tube into the airway. Placement of the feeding tube into the trachea or lungs may result in serious injury.
WARNING: When guiding the feeding tube into place, discontinue insertion if any resistance is experienced and notify clinician immediately. Do not use excessive force upon insertion.
WARNING: Never reinsert stylet when tube is in patient.
Note: The OptiSol™ tip will dissolve in the gastrointestinal tract within 24-48 hours of placement
CAUTION: Tube position must be confirmed prior to use.
WARNING: This device has the potential to misconnect with small bore connectors of other healthcare applications. Only use this device to connect to compatible enteral devices. Do not use for non-enteral applications.
Note: If using a legacy-style (non-ENFit®) device, the device has the potential to misconnect to the following systems: breathing, intravenous, limb cuff, neuraxial connectors, nipples of respiratory therapy equipment, urinary, and temperature sensor connectors of respiratory humidifying equipment.
WARNING: Ensure device is connected to an enteral port only and NOT to an IV set.

Lubricous Coating Activation	
Fr Size	Recommended Volume
5F	≤ 1 mL
8F	≤ 5 mL
10F	≤ 8 mL

Store device in a dry, room temperature environment until ready to use.

Any undesirable side effect that could be caused by the use of the device:
Potential complications when using the NutraGlide™ include but are not limited to:
Patient discomfort • Nausea • Vomiting • Diarrhea • Pneumothorax • Gastrointestinal bleeding or ulceration • Gastrointestinal or esophageal perforation • Aspiration and/or aspiration pneumonia • Airway Obstruction • Tissue irritation or necrosis • Contamination

Any residual risks that could arise due to any shortcomings of the protection measures:
The NutraGlide™ is contraindicated for use in patients with anatomical abnormalities or diseases of the nose, throat, or esophagus that would prohibit safe placement of the device.

Warnings about risks that could arise from the interaction of the device with other equipment:
WARNING: This device has the potential to misconnect with small bore connectors of other healthcare applications. Only use this device to connect to compatible enteral devices. Do not use for non-enteral applications.
Note: If using a legacy-style (non-ENFit®) device, the device has the potential to misconnect to the following systems: breathing, intravenous, limb cuff, neuraxial connectors, nipples of respiratory therapy equipment, urinary, and temperature sensor connectors of respiratory humidifying equipment.
WARNING: Ensure device is connected to an enteral port only and NOT to an IV set.

Precautions and other measures that, because of those risks, should be taken by the patient or a health professional.

Placement by health professional:

This feeding tube is to be placed by trained healthcare professionals only.

Device Placement:

WARNING: Estimation of tubing length is critical. Do not insert excess tubing as this may result in kinking of tube

WARNING: Coughing or respiratory distress may indicate passage of the tube into the airway. If this is suspected, remove device immediately and reinsert.

WARNING: Caution should be taken if any type of endotracheal device is in place, as these may facilitate the passage of the feeding tube into the airway. Placement of the feeding tube into the trachea or lungs may result in serious injury.

WARNING: When guiding the feeding tube into place, discontinue insertion if any resistance is experienced and notify clinician immediately. Do not use excessive force upon insertion.

WARNING: Never reinsert stylet when tube is in patient.

WARNING: This device has the potential to misconnect with small bore connectors of other healthcare applications. Only use this device to connect to compatible enteral devices. Do not use for non-enteral applications.

WARNING: Ensure device is connected to an enteral port only and NOT to an IV set.

Removal of the **NutraGlide™**:

Note: The NutraGlide™ has satisfied biocompatibility testing as a device for long-term use per ISO 10993-1. The feeding tube should be monitored, regularly assessed, and replaced when clinically indicated based on functionality and patient condition. The feeding tube should be monitored and regularly assessed for any resistance of flow and cleanliness of the port as well as a regular patient assessment for any nasopharynx trauma such as the occurrence of pain or the development of bleeding.

Medication Administration:

Liquid medication is preferred when available. If solid medication is required, consult with your physician regarding whether it is safe to crush the medication. If safe, medication should be crushed as finely as possible (into powder form) and dissolved into water before administering medication through device. Administering solid medication through the tubing that is not properly crushed can lead to blockage in the tubing. Never crush enteric coated medication or mix medication with formula. Flush device with water after administering medication.

Unclogging a device:

CAUTION: Do not use excessive force to flush the tube. Excessive force can perforate the tube and can cause injury to the gastrointestinal tract.

The nature and frequency of regular or preventative examination, monitoring or maintenance of the device that should be undertaken:

Nasal feeding tubes are meant to be periodically replaced for optimal performance, functionality, and cleanliness. The NutraGlide™ has satisfied biocompatibility testing as a device for long-term use per ISO 10993-1. The feeding tube should be monitored, regularly assessed, and replaced when clinically indicated based on functionality and patient condition. The feeding tube should be monitored and regularly assessed for any resistance of flow and cleanliness of the port as well as a regular patient

assessment for any nasopharynx trauma such as the occurrence of pain or the development of bleeding. Device performance and functionality can degrade over time depending on many factors, including: gastric pH, medications, trauma to the device, and overall tube care. Device should be replaced if signs of failure are noted

Symptoms that could indicate that the device is malfunctioning:
Patient discomfort • Nausea • Vomiting • Diarrhea • Pneumothorax • Gastrointestinal bleeding or ulceration • Gastrointestinal or esophageal perforation • Aspiration and/or aspiration pneumonia • Airway Obstruction • Tissue irritation or necrosis • Contamination

Precautions and other measures that should be taken by the patient if the performance of the device change or the patient experiences any of the symptoms mentioned above
This feeding tube is to be placed by trained healthcare professionals only
WARNING: This device is intended for single use. Do not reuse or reprocess this medical device. Doing so may compromise biocompatibility characteristics, device performance and/or material integrity; any of which may result in potential patient injury, illness and/or death.

The expected device lifetime, anything that could shorten or lengthen the device lifetime, precautions and other measures that should be taken at, or near, the end of the expected device lifetime:
Nasal feeding tubes are meant to be periodically replaced for optimal performance, functionality, and cleanliness. The NutraGlide™ has satisfied biocompatibility testing as a device for long-term use per ISO 10993-1. The feeding tube should be monitored, regularly assessed, and replaced when clinically indicated based on functionality and patient condition. The feeding tube should be monitored and regularly assessed for any resistance of flow and cleanliness of the port as well as a regular patient assessment for any nasopharynx trauma such as the occurrence of pain or the development of bleeding. Device performance and functionality can degrade over time depending on many factors, including: gastric pH, medications, trauma to the device, and overall tube care. Device should be replaced if signs of failure are noted.

Other circumstances in which the patient should contact a health professional in relation to the operation of this device:
Patient discomfort • Nausea • Vomiting • Diarrhea • Pneumothorax • Gastrointestinal bleeding or ulceration • Gastrointestinal or esophageal perforation • Aspiration and/or aspiration pneumonia • Airway Obstruction • Tissue irritation or necrosis • Contamination

The materials and substances included in the device:
The materials of the **NutraGlide™** include the following: Medical-grade thermoplastic and Medical-grade stainless steel.

Any manufacturing residuals that could pose a risk to the patient:
There are no manufacturing residuals used that could pose a risk to the patient.

MRI Safety Information

The NutraGlide™ is MRI Safe once stylet (if used) is removed. A patient with an indwelling device can be scanned safely.

Notice that any serious incident that occurs in relation of the NutraGlide™ should be reported to Applied Medical Technology, Inc. and The Therapeutic Goods Administration (TGA):

Applied Medical Technology, Inc.
8006 Katherine Blvd | Brecksville, OH 44141
Call: +1 800 869 7382
Fax: +1 440 717 4200
Email International: ICS@AppliedMedical.Net

Therapeutic Goods Administration (TGA)
https://www.tga.gov.au

Innovating. Educating. Changing Lives.™

Made In USA

AMT Family

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www.AppliedMedical.net

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An ISO 13485 Registered Company