



INSTRUCTION FOR USE

Infant Feeding Tube

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SPMM/RA/IND/21/INFT/IFU, Rev. No.: 01 Date: 03/06/2026

DESCRIPTION

Infant Feeding Tube is a small, soft plastic tube intended to be inserted through the nose or mouth into the stomach. The device is intended for temporary enteral administration of feedings and medicines into the stomach until the infant or baby can take food by mouth. The device is sterile, non-pyrogenic, non-toxic, and intended for single use only when the package is unopened and undamaged.

Sterilization method: ETO Sterilization

IMAGE OF THE DEVICE



Figure 1: Infant Feeding Tube

INTENDED UE

Infant Feeding Tubes are intended to provide feedings and medications into the stomach.

INTENDED PATIENT POPULATION

Infant Feeding Tube is intended to be used in neonates and infants who require feeding or medicine administration into the stomach.

INTENDED USER

Infant Feeding Tube is intended to be used by qualified doctors, trained healthcare professionals, paramedics, or nursing staff experienced in feeding tube placement and use.



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INTENDED USE ENVIRONMENT

Infant Feeding Tube is intended to be used in hospitals, clinics, neonatal care units, and other healthcare settings under medical supervision.

CLINICAL BENEFITS

- Supports administration of feeding when the infant cannot take food by mouth.
- Supports administration of medicines directly into the stomach.
- Provides temporary nutritional support under medical supervision.

PRINCIPLE OF OPERATION

Infant Feeding Tube is introduced through the nasal route or oral route into the stomach. Once correct placement is confirmed, feeding or medicine may be administered through the tube as per institutional procedure and medical advice.

PERFORMANCE CHARACTERISTICS

- Allows delivery of feed or medicine into the stomach.
- Suitable for nasogastric or orogastric route.
- Intended for temporary use only.
- Maximum retention period: Not more than 30 days.

CONTRAINDICATIONS

- Do not use if the package is opened or damaged.
- Do not use if the product is damaged, cracked, kinked, contaminated, or expired.
- Do not use if the patient has known hypersensitivity to the device material.
- Do not use where nasal or oral insertion is contraindicated as per medical judgment.
- Do not use if correct tube placement cannot be confirmed before feeding or medicine administration.

POTENTIAL COMPLICATIONS

Possible complications may include:

- Incorrect tube placement
- Airway insertion
- Aspiration
- Mucosal injury
- Bleeding
- Organ puncture or perforation
- Infection
- Irritation or discomfort

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- Vomiting or feeding intolerance
- Tube blockage, kinking, or displacement

DIRECTIONS FOR USE

General Preparation

- Step 1. Inspect the product packaging. Do not use if the unit package is opened, damaged, or not intact.
- Step 2. Check the product expiry date before use.
- Step 3. Peel open the package using aseptic technique.
- Step 4. Inspect the tube for any crack, damage, blockage, contamination, or visible defect. Do not use if any defect is observed.
- Step 5. Measure and confirm the correct insertion length according to institutional procedure.
- Step 6. Lubricate the tip of the tube with water-soluble lubricant before insertion.
- Step 7. Use maximal sterile barrier precautions during administration, as applicable.

For Nasal Route

- Step 1. Keep the neonate or infant in lying position.
- Step 2. Place a linen or protective pad across the infant's chest.
- Step 3. Lubricate the tip of the tube with water-soluble lubricant.
- Step 4. Examine the nasal route before insertion.
- Step 5. Gently insert the tip of the tube through the nasal route.
- Step 6. Advance the tube carefully towards the nasopharyngeal junction and downward to the required mark.
- Step 7. Do not apply excessive force. If resistance is felt, stop the procedure and follow institutional protocol.
- Step 8. Confirm correct placement of the tube before feeding or medicine administration.
- Step 9. Administer feeding or medicine only after correct placement is confirmed.

For Oral Route

- Step 1. Lubricate the tip of the tube with water-soluble lubricant.
- Step 2. Gently place the tip of the tube through the oral route.
- Step 3. Advance the tube carefully up to the required mark.
- Step 4. Do not apply excessive force. If resistance is felt, stop the procedure and follow institutional protocol.
- Step 5. Confirm correct placement of the tube before feeding or medicine administration.
- Step 6. Administer feeding or medicine only after correct placement is confirmed.

After Use / Removal



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- Remove the tube according to institutional procedure.
- Dispose of the device after single use.
- Do not reuse, clean, recycle, or re-sterilize the device.

WARNINGS

- Read instructions before use.
- This device shall be used only by qualified healthcare professionals.
- Confirm correct tube placement before administering feeding or medicine.
- Do not use if the package is opened, damaged, or wet.
- Do not use after expiry date.
- Do not use if the device is damaged or contaminated.
- Do not apply excessive force during insertion.
- Lubricate the tube tip before use to reduce the risk of tissue injury.
- Incorrect placement may lead to serious injury.
- Do not retain the device in the human body for more than 30 days.
- For single use only. Do not reuse, clean, recycle, or re-sterilize.
- Reuse may lead to infection, device failure, or patient injury.

PRECAUTIONS

- Check product and package integrity before use.
- Use aseptic technique during handling and insertion.
- Ensure that the correct length of tube is placed in the stomach.
- Use only water-soluble lubricant.
- Avoid kinking, crushing, or stretching the tube.
- Monitor the patient during and after insertion as per institutional procedure.
- Do not administer feeding or medicine until correct tube placement is confirmed.
- Use the device under medical supervision only.

CAUTIONS

- Carefully read all instructions prior to use.
- Do not use if package is open or damaged.
- Sterility is maintained only if the package is unopened and undamaged.
- For single use only.
- Discard after use according to hospital procedure.

STORAGE

Store the product at room temperature keeping out of direct sunlight, high humidity and exposure to water.



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EXPIRATION PERIOD

The device should not be used after the indicated expiry date.

Shelf life: 5 years

RETURN OF DAMAGED PRODUCT

Return the product in its original packaging identified by batch number, purchase information, reference details, and reason for return. Please contact the local distributor or manufacturer regarding product return or exchange.

DISPOSAL OF THE USED DEVICE

- Dispose of the used product according to hospital procedures, state regulations, national legislation, or regional legislation.
- Dispose of the device after use on a single patient.
- Dispose of opened or damaged packaging as biomedical waste, where applicable.
- Do not reuse the device.

REPORTING

In case of any adverse event or product-related complication, contact the manufacturer or authorized representative and the competent authority of the member state where the user and/or patient is established.

<u>LEGAL MANUFACTURER AND MANUFACTURING FACILITY</u>
Manufacturer: SPM Medicare Pvt, Ltd B-40, Phase-II, Noida, Gautam Buddha Nagar, UP-201305, India. Manufacturing Site 1- B-40, Phase-II, Noida, Gautam Buddha Nagar, UP-201305, India. Customer care: No.: +91-840-7070-718 Email: info@spmmedicare.com Web Site: www.spmmedicare.com

EXPLANATION OF SYMBOLS:

Symbol	Explanation	Symbol	Explanation
	Caution		Catalogue Number
	Manufacturer		Batch code
	Date & Country of manufacturer		Use-by date
	Do not re-use		Medical Device
	Consult instructions for use		Do not use if package is damaged
	Keep away from sunlight		Keep dry
	Do not re-sterilize		