

## Ultramed sterile infant feeding tube

### ✚ Ultramed sterile infant feeding tube history:

- ✓ The Infant Feeding Tube is a Short Term use device and is being used as medical device for many years under different brands. Infant Feeding Tube is made from medical grade phthalate free PVC, Master Batch medical grade phthalate free (PVC) & ROP medical grade (PVC) materials which are widely used in hospitals and clinics.
- ✓ Product on Market from 1992 with no adverse events of Recalls.
- ✓ Product is conventional Product and fully equivalence with many products in market.
- ✓ The product is approved by the Ministry of Health.
- ✓ This product is CE marked.

### ✚ Final Ultramed infant feeding tube release criteria (Features):

- ✓ Closed distal end with two later eyes.
- ✓ Tube with radio-opaque line, marked at 20 cm from the tip for accurate placement.
- ✓ Soft, frosted and kink resistant PVC tubing.
- ✓ Color coded funnel end connector for easy identification of size.
- ✓ Tube Length: 40 cm.
- ✓ Sizes: 4 FG to 10 FG.

### ✚ pile of material:

No.	Component	Base Material
1.	Tube	Medical grade phthalate free Polyvinyl chloride medical grade(P.V.C)
2.	Radiopaque line	Radiopaque Medical grade phthalate free Polyvinyl chloride grade dark blue
3.	closure	- Medical grade phthalate free Polyvinyl chloride medical grade(P.V.C) - Master batch (coloured) Medical grade.

✚ **Ultramed infant feeding tube Intended Use**

- Infant feeding tube is a medical device used to provide nutrition to babies and infants, who cannot obtain nutrition by mouth, are unable to swallow safely, or need nutritional supplementations; used to give nutrition to infants who cannot eat on their own.
- The product is sterilized using EO (Ethylene Oxide)

✚ **Ultramed infant feeding tube Principle of operation (mode of action):**

- Infant feeding tube is used to provide feeding to infants, who cannot obtain nutrition by mouth by inserting the tube into infant's mouth; by this tube nutrition can be reached.

✚ **Ultramed infant feeding tube Key performance claim:**

- Soft, frosted and kink resistant Medical grade phthalate free PVC tubing; to prevent blocking and kinking of the tube which used to provide nutrition to babies and infants who cannot eat on their own.
- Closed distal end with two lateral eyes to facilitate infusion of feeding solution.
- Tube with radio-opaque line, marked at 25 cm from the tip for accurate placement and prevent misplacement of feeding tube.
- Soft and rounded tip to prevent trauma during application
- Radio Opaque line is provided throughout the length for X-Ray visualization; to avoid over insertion of the feeding tube.

✚ **Ultramed infant feeding tube Medical condition to be used**

A feeding tube is used for infants who do not have the strength or muscle coordination to breastfeed or drink from a bottle. There are other reasons why an infant might need a feeding tube, including:

- lack of weight gain or irregular weight gain patterns
- absence or weak sucking ability or swallowing reflex
- abdominal or gastrointestinal defects
- respiratory distress
- problems with electrolyte imbalances or elimination

✚ **Are there any risks?**

- There are very few risks associated with feeding tube use. However, it can be uncomfortable for the infant, no matter how gently it is inserted. The child begins to cry or show signs of discomfort

✚ **other side effects include :**

- slight nasal bleeding
- nasal congestion
- nasal infection

When inserted incorrectly, the tip may rest in the respiratory system instead of the stomach or intestines; in this case,

The liquid food will enter the lungs, resulting in pneumonia and can, in rare cases, lead to death

- + **Intended User: The doctor in charge**
- + **Intended Patient population: babies and infants who cannot eat on their own.**

#### + **Infant feeding tube insertion procedure**

1. Swaddle your baby with a blanket; this will help prevent your child from grabbing at the tube while you are inserting it.
2. Dip the end of the tube that will be in the stomach into the water or jelly to lubricate it.
3. Gently insert the tube through the nostril or mouth and if you meet resistance, try curving the tube downward. If the tube won't move easily, if you see the tube coming out of the mouth or if there is excessive coughing, stop, remove the tube and try it again.
4. Stop inserting the tube when you reach the spot marked (as measured).
5. Tape the tube close to the nose and cheek.

#### + **Removing procedure**

1. Gently remove the tape from your child's face.
2. Pinch the feeding tube with your thumb and forefinger to prevent any liquid from flowing out while the tube is being removed. Remove the tube in one gentle motion.
3. Remember to switch nostrils with each tubing change.

##### **Call your doctor/clinic if:**

- Your child has breathing problems or a fever after choking
- Your child vomits more than one feeding
- **There are no medicinal substances used in the manufacturing of Sterile Infant Feeding Tube.**
- **There is no animal tissue used in the manufacturing of Sterile Infant Feeding Tube.**

+ **The product is available in different sizes to be more suitable for the Patient.**

#### + **Variants:**

- Infant Feeding Tube is available in different sizes (4, 5, 6, 8, 10) FG to be suitable for babies and infants who cannot eat on their own to prevent trauma and other side effect to the patient.

#### + **Cautions:**

- Do not use if package is open or damaged.
- Discard after single use.

#### + **Packaging requirements:**

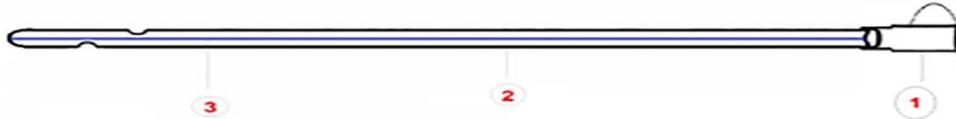
- \* **Unit Container:** Medical grade phthalate free P.V.C. with Medical paper Pouches.
- \* **Multiunit Container:** P.E. Bags & Micro single Box.
- \* **Transit Container:** 3 Piles Cartoons
- ❖ As per packaging validation report & shelf life study; the finished product conforms to the specifications and functional requirements for 5 years from the date of
- ❖ The product is free from TSE species derived materials.

### **Conditions of "handling, preservation and storage**

- For Raw Materials : Good packing condition, Out of dust, Out of direct Sun light and a room temperature
- For Finished product :
  - \* Not more than 5 cartoons on each other.
  - \* Nice Ventilated place.
  - \* Out of direct Sun light.
  - \* Room temperature.

### **Configuration: Product design**

#### **INFANT FEEDING TUBE**



- 1- Closer**
- 2 - tube**
- 3- R.OB Line Blue**