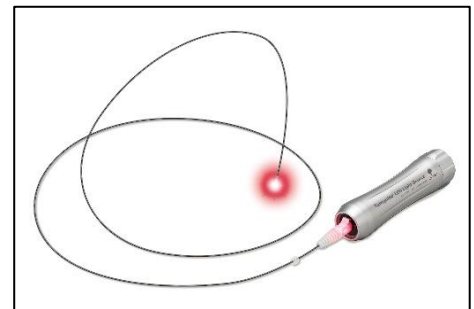


Otsuka Pharmaceutical Factory launches “Tumguide[®] Fiber” with an additional specification of outer diameters of 0.5 mm and 0.75 mm to be used with “Tumguide[®],” a device for checking the position of the nasogastric tube tip

Otsuka Pharmaceutical Factory, Inc. (Head Office: Naruto, Tokushima, Japan; President and Representative Director: Shuichi Takagi; hereinafter, “Otsuka Pharmaceutical Factory”) will launch another “Tumguide[®] Fiber,” a general medical device (gastroesophageal sterile tube and catheter for temporary use) with an additional specification of outer diameters of 0.5 mm and 0.75 mm (hereinafter, “this product”) on November 14; this device is to be connected and used with “Tumguide[®] LED Light Source,” a device for checking the position of the nasogastric tube tip.

This product is an optical fiber used in pediatric treatment that can be inserted into the nasogastric tube. The fiber is inserted into the nasogastric tube, connected with Tumguide LED Light Source (a general medical device and general-purpose light source; sold separately), and inserted into the stomach with the light at the tube tip shining; this medical device can thus facilitate a visual check of the position of the nasogastric tube tip from outside the body by using the red light (biological transparency^{*1}).



“Tumguide[®],” a device for checking the position of the nasogastric tube tip

In addition to enteral nutrition and medication, nasogastric tube procedure, wherein a feeding tube is inserted through the nose into the stomach to reduce the pressure in the stomach, is used as an administration route in many cases of nutritional management of patients who have difficulty consuming an oral diet. However, if the nasogastric tube tip is shorter than the appropriate size, or if the tube is placed in an incorrect position prior to enteral nutrition/drug administration, it may cause life-threatening complications. When a nasogastric tube is positioned, the tube tip position is checked in various ways including X-rays, aspiration of gastric juice, confirmation of the pH of aspirated liquid, and auscultation of air bubble sound. This product can be inserted into the nasogastric tube used in pediatric treatment. We hope it will contribute to reducing the physical burden on patients and to reducing the workload of healthcare professionals by reducing risks in nasogastric tube placement in pediatric treatment and by helping to avoid radiation exposure.

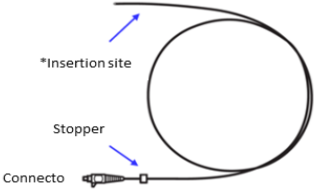
As a company with strength in clinical nutrition such as IV solution and enteral nutrition products. OPF has been providing various products and useful information for appropriate nutritional management. We will continuously provide these and develop innovative products to contribute to solving issues in medical fields, aiming to be the best partner for patients and healthcare professionals in the clinical nutrition field.

Based on the corporate philosophy of “Otsuka-people creating new products for better health worldwide,” the Otsuka Group is dedicated to contributing to the health of people around the world.

*1 A light in the wavelength range which transmits through soft tissues, but not for hard tissues such as bones and cartilages.

Product information

Tumguide® Fiber (Outer diameter 0.5mm, 0.75mm)

Medical device classification	General medical device													
Generic name	Gastroesophageal sterile tube and catheter for temporary use													
Medical device class category	Class I													
Medical device notification number	47B2X10003000002													
Shape, structure and principle	<p><Shape, structure> Raw materials (*) of the part which come in contact with blood and body fluids. Insertion site: plastics, coating agent</p> <table border="1" data-bbox="422 878 1104 1050"> <thead> <tr> <th>Displayed size</th> <th>Outer diameter of the insertion site</th> <th>Full length</th> <th>Length of the insertion site</th> </tr> </thead> <tbody> <tr> <td>Outer diameter 0.75 mm</td> <td>0.75 mm</td> <td rowspan="2">800 mm</td> <td rowspan="2">755 mm</td> </tr> <tr> <td>Outer diameter 0.5 mm</td> <td>0.5 mm</td> </tr> </tbody> </table>  <p><Principle> This product connects to the light source device and is inserted to the body while it is inserted in the nasogastric tube. The tip of the insertion site shines by the light from the light source device, which enables to check the tip position visually from outside the body.</p>				Displayed size	Outer diameter of the insertion site	Full length	Length of the insertion site	Outer diameter 0.75 mm	0.75 mm	800 mm	755 mm	Outer diameter 0.5 mm	0.5 mm
Displayed size	Outer diameter of the insertion site	Full length	Length of the insertion site											
Outer diameter 0.75 mm	0.75 mm	800 mm	755 mm											
Outer diameter 0.5 mm	0.5 mm													
Purpose of use or effect	Insert this product with the nasogastric tube into esophagus and stomach temporarily. By connecting this product to the light source device, the tip position can be visually checked from outside the body.													
Directions for use	<p>Refer to the instruction manual of the Tumguide LED Light Source for detailed directions of use.</p> <ol style="list-style-type: none"> ① Take out this product aseptically. ② Insert this product to a nasogastric tube. Fix the stopper at the position with sufficient space so that the tube tip does not stick out. ③ Turn on the Tumguide LED Light Source. After confirming that there is sufficient remaining battery charge, connect this product. ④ Insert into the stomach through the esophagus while the tip of this product is shining, and confirm the position of the tip. ⑤ After confirming that the nasogastric tube tip has been placed in the stomach, turn off the power to the Tumguide LED Light Source and remove this product from the Tumguide LED Light Source. ⑥ Remove this product promptly. 													

Storage and expiration date	<Storage> <ul style="list-style-type: none"> ▪ Store away from water. ▪ Store away from direct sunlight, high temperature, and high humidity. ▪ Storage temperature: -10°C – 45 °C ▪ Storage humidity: 0% – 95% (No condensation) <Expiration date> As stated on the product (By self-certification)
packaging	10 fibers per box
Suggested retail price (excluding tax) ^{*2}	JPY 30,000
Manufactured and distributed by	Otsuka Clinical Solutions, Inc.
Marketed by	Otsuka Pharmaceutical Factory, Inc
Comarketed by	Otsuka Pharmaceutical Co., Ltd.

^{*2} The price is shown as a reference price.

Company Profile

Otsuka Pharmaceutical Factory, Inc.

Established : October 7, 1969 (founded September 1, 1921)
 Capital : 80 million yen
 Representative : Shuichi Takagi, President, and Representative Director
 Head Office : 115 Kuguhara, Tateiwa, Muya-cho, Naruto, Tokushima 772-8601, Japan
 Employees : 2,318 (as of December 31, 2023)
 Business Description : Manufacture, sale, import and export of pharmaceuticals, medical devices, and functional foods with a focus on clinical nutritional products.
 URL : <https://www.otsukakj.jp/en/>