

June 24, 2020

**Otsuka Pharmaceutical Factory obtains marketing approval of  
VISCOCLEAR<sup>®</sup>, gel to secure the visual field that is used for the  
endoscope for natural opening**

Otsuka Pharmaceutical Factory, Inc. (Head Office: Naruto, Tokushima, Japan; President and Representative Director: Shinichi Ogasawara; “OPF”) has obtained the marketing approval of “VISCOCLEAR<sup>®</sup>,” gel to secure the visual field used for the endoscope for natural opening<sup>1</sup> which is a medical device on June 19, 2020.

The product is a gel-shaped product with the appropriate viscosity that is used for gastrointestinal endoscopy, procedures and treatment in the digestive tract. It is injected into the digestive tract through an endoscope and improves the poor visual field caused by blood, etc., during endoscopy. It is an innovative medical device without similar products, which was developed based on the reports by Dr. Yano and his group at Jichi Medical University.<sup>2</sup>

Examinations and treatment using an endoscope that allows direct observation of the digestive tract, etc., from the inside, are commonly performed in medical practice, partly because the physical and mental burden on patients is lower than that using surgical techniques. In order to observe the digestive tract closely with an endoscope, a good visual field is required, but bleeding and food residue may result in a poor visual field. In general, air insufflation and water immersion are performed to make the observation site easier to see. However, it is difficult to secure a good visual field of the observation site when fluid containing blood or blood clots<sup>3</sup> has accumulated in the digestive tract or when a large amount of blood is bleeding.

In such a case, by injecting this product in the form of a gel with transparency and the appropriate viscosity through the tip of the endoscope, a transparent space is created on the front surface of the endoscope, thereby securing a good visual field. This will facilitate endoscopic treatment such as hemostasis even in situations where endoscopic treatment has been difficult due to poor visual fields, and it is expected that this will contribute to gastrointestinal endoscopic examinations and treatment.

OPF will continue to promote research and development in the area of surgical aid medicine and aim to contribute to medical care by creating innovative products.

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.


---

<sup>1</sup> A natural opening in the human body, such as the mouth or nose.

<sup>2</sup> Tomonori Yano et al.: *Gastrointest Endosc.* 2016 Apr;83(4):809-11. doi: 10.1016/j.gie.2015.09.048.

<sup>3</sup> A mass of blood formed when platelets, proteins, and cells in the blood adhere together.

## Product Information

Brand name	VISCOCLEAR®
Classification	Instrument & apparatus 25 speculum for medical use
General name	Gel to secure the visual field used for the endoscope for natural opening
Medical device classification	Controlled medical device
Class category	Class II
Shape, structure, and principle	<p>&lt;Shape&gt;</p> <p>Composition: xanthan gum, locust bean gum, concentrated glycerin, purified water</p> <p>Shape: gel</p> <p>&lt;Principle&gt;</p> <p>This product has viscoelastic properties that suppress the spread and flow of blood, and stool and food residues, thus allowing for securing a physical transparent space on the front surface of the endoscopic visual field and securing a good visual field.</p>
Purpose of use or effect	Securing the visual field of the esophagus, stomach, duodenum, small intestine, and large intestine in gastrointestinal endoscopic examination and treatment.
Directions for use	<p>Standard usage is shown below.</p> <p>The dosage should be appropriately determined from the standpoint of each professional.</p> <ol style="list-style-type: none"> <li>Open the package before use and transfer the product to another container such as a beaker.</li> <li>Aspirate the product into a syringe.</li> <li>The syringe is inserted into a slit of the forceps plug of the endoscope and the product is injected into the gastrointestinal tract via the forceps channel until an adequate visual field is achieved (200-600 g per procedure, depending on the site of use and the degree of bleeding).</li> <li>After performing routine procedures, the injected product is aspirated and removed as much as possible using the aspiration function of the endoscope.</li> </ol>
Packaging	<p>200 g × 10 bags</p> 
Storage and expiration date	<p>&lt;Storage&gt;</p> <p>Store at room temperature.</p> <p>Avoid freezing.</p> <p>&lt;Expiration date&gt;</p> <p>1 year</p>

## Company Profile

### Otsuka Pharmaceutical Factory, Inc.

Established	:	October 7, 1969 (founded September 1, 1921)
Capital	:	80 million yen
Representative	:	Shinichi Ogasawara, President and Representative Director
Head Office	:	115 Kuguhara, Tateiwa, Muya-cho , Naruto, Tokushima 772-8601, Japan
Employees	:	2,247 (as of December 31, 2019).
Business Description	:	Manufacture, sale, import and export of clinical nutrition products and other pharmaceutical products, medical devices, functional foods, etc.
URL	:	<a href="https://www.otsukakj.jp/en/">https://www.otsukakj.jp/en/</a>