

December 12, 2022

**Otsuka Pharmaceutical Factory launches Lilium one[®],
a medical device that measures urine volume in the bladder
specialized for single measurement**

Otsuka Pharmaceutical Factory, Inc. (Head Office: Naruto, Tokushima, Japan; President and Representative Director: Shinichi Ogasawara; “OPF”) will launch a portable ultrasonic diagnostic device for the bladder “Lilium one[®]” on March 1, 2023.

This product is a medical device that measures urine volume in the bladder using ultrasound. While “Lilium α -200” and its successor “Lilium IP200” are mainly designed for continuous measurement of urine volume, this product was developed to meet the needs of medical professionals who want to measure urinary bladder volume more conveniently and whenever necessary, and is specialized for single measurement. The product was named “Lilium one” because the part in contact with the patient (the probe) and the main unit are integrated into one unit, and measurement can be performed with a single push of a button with one hand.



Liliumone[®]


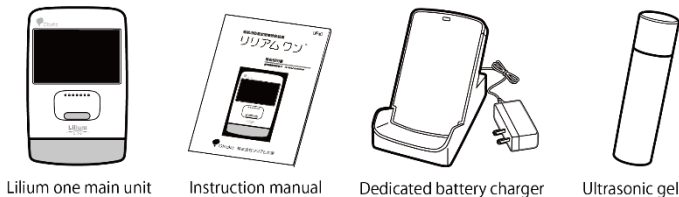
There is a growing need for bladder function checks (checking and understanding patterns of residual urine volume, urine storage, and voiding volume) and urinary care for patients with frequent urination, urine leakage, and difficulty passing urine due to various diseases. In the medical and nursing care fields in Japan, which has entered a super-aging society, the importance of urinary independence has been recognized, as evidenced by the expansion of the urinary independence guidance fee, which was newly established in the 2008 revision of medical service fees and renamed the additional fee for urinary independence support in the 2020 revision of medical service fees. In addition, residual urine volume is used as an indicator for diagnosis and treatment of dysuria, and residual urine measurement has become an essential test in medical guidelines related to dysuria.

The product will be marketed by OPF under an exclusive sales agreement with the manufacturer and distributor, Lilium Otsuka Co., Ltd. (Head Office: Sagamihara, Kanagawa, Japan; President and Representative Director: Isao Shirasaki; “Lilium Otsuka”). Lilium Otsuka, which has sold medical devices that use ultrasound since 2015, has developed this product by leveraging its expertise in medical device development and manufacturing.

The management vision of OPF is to be “The Best Partner in Clinical Nutrition.” In addition, we are expanding our business areas to cover the entire healthcare process, such as prevention, diagnosis, treatment, and monitoring. Among these, we have been enhancing our products in the fields of urology and urination, including the marketing of Lilium α -200 since 2016, and launching its successor product, Lilium IP200, this year, as well as intermittent urinary catheters, Actreen and OT-Balloon Catheter. We will continue to develop products that can contribute to excretion care for patients.

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.

Product Information

Generic name	Portable Ultrasonic Diagnostic Device for the Bladder
Product name	Lilium one
Medical device certification number	303ADBZX00050000
Accuracy	±(15% + 20 mL)
Measurement result display range	0 to 600 mL If the measurement result is larger than 600 mL, “> 600 mL” will be displayed.
Power source	Rechargeable battery (built-in lithium-ion battery)
Class category	Controlled medical device (Class II), Specified controlled medical device
Weight	Approx. 200 g
Size (mm)	77.9 (W) × 24.4 (D) × 124.0 (H)
Medical fee item	D216-2 Residual urine measurement test
Certification date	May 28, 2021
Basic function	Measurement of urine volume in the bladder
Principle of measurement	Ultrasonic waves are directed to the bladder, the amount of urine in the bladder is estimated, and displayed numerically.
Configuration	1) “Lilium one” main unit Probe: Elastomer, flame-retardant ABS 2) Dedicated battery charger for “Lilium one”
Suggested retail price	JPY 410,000 (excluding tax) as the Lilium one kit (including the main unit, dedicated battery charger, and ultrasonic gel)
Device photo	
Contents of Lilium one kit	 <p style="text-align: center;">Lilium one main unit Instruction manual Dedicated battery charger Ultrasonic gel</p> <p style="text-align: center; font-size: small;">The items included in the package and product specifications are subject to change without notice.</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	:	2,266 (as of December 31, 2021)
Business Description	:	Manufacture, sale, import and export of clinical nutrition products and other pharmaceutical products, medical devices, functional foods, etc.
URL	:	https://www.otsukakj.jp/en/

Lilium Otsuka Co., Ltd.

Established	:	January 29, 2015
Capital	:	75 million yen
Representative	:	Isao Shirasaki, President and Representative Director
Head Office	:	1-1-1, Chuo, Chuo-ku, Sagamihara, Kanagawa 252-0239, Japan
Employees	:	18 (as of December 31, 2021)
Business Description	:	Research and development, manufacturing, and marketing of medical devices and related products
URL	:	https://www.lilium.otsuka/en/