

NEWS RELEASE

Lilium Otsuka Co., Ltd. Otsuka Pharmaceutical Factory, Inc. Otsuka Holdings Co., Ltd.

August 19, 2021

Lilium Otsuka launches a healthcare appliance, "Lilium-SPOT®2," as an improved version of "Lilium-SPOT®," which can easily check the amount of urine in the bladder using ultrasonic waves

Lilium Otsuka Co., Ltd. (Head Office: Sagamihara, Kanagawa, Japan; President and Representative Director: Isao Shirasaki; "Lilium Otsuka"), a subsidiary of Otsuka Pharmaceutical Factory, Inc. (Head Office: Naruto, Tokushima, Japan; President and Representative Director: Shinichi Ogasawara), launches Lilium-SPOT®2, an improved version of Lilium-SPOT®,*¹ a device for assisting urination timing prediction, as a healthcare appliance (non-medical device) that allows users to easily check the amount of urine in the bladder on August 24.

Lilium-SPOT is a healthcare appliance developed in 2018 with the aim of contributing to the nursing care settings. By applying ultrasonic waves to the position of the bladder, users can check the level of urine accumulation on a scale display. This product is useful for people who have trouble with the timing of toilet guidance, people who are not clear about their urge to urinate, or people who frequently complain about their urge to urinate, to check the level of urine accumulation and whether urine has been expelled after urination. This newly launched product has improved the following points for better performance and more convenience.

- 1. The sensitivity of ultrasonic waves has been improved by changing the shape of the probe.*2
- 2. The scale display has been subdivided into 10 levels, allowing for more accurate checks of the level of urine accumulation.
- 3. The operability has been improved, allowing for measuring urine volume immediately after startup.

In the nursing care field in Japan, which has entered a super-aged society, the importance of excretion independence is being recognized and the need for excretory care is increasing, as evidenced by the revision of the additional fee for excretion support in the 2021 revision of nursing care fees.

It is said that there are several methods for guiding people who are not clear about their urge to urinate. Among them, a method called "Prompted voiding" in which medical personnel and caregivers create a motivation for urination and encourage urination, has been included in various guidelines, and has been shown to be effective in urination management.* Several clinical studies have reported the results of ultrasound-assisted prompted voiding care for managing urinary incontinence in nursing homes. 4-6 In addition, there is one report of toilet guidance using Lilium-SPOT for day care service users who complain of frequent urination in nursing homes. 7

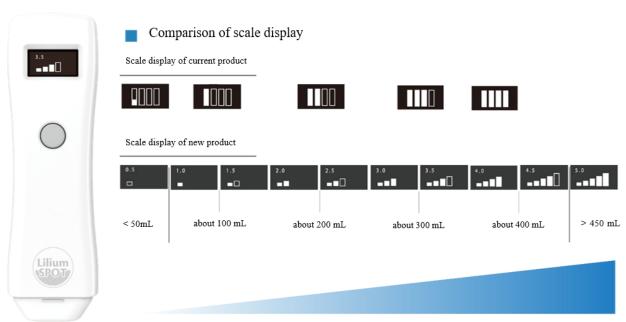
Lilium Otsuka, which has sold "Lilium α -200,"*8 a medical device that uses ultrasonic waves, since 2015, has developed Lilium-SPOT as a healthcare appliance in the nursing care field, drawing on its accumulated medical device development and manufacturing know-how. We will continue to improve our products for more convenience so that these products can help people who have trouble with urination, support their family's daily lives, and help reduce the burden on nursing care staff.

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 Lilium-SPOT will be discontinued. For users who have already purchased Lilium-SPOT, we will provide a program to switch to Lilium-SPOT2 for a fee.
- *2 This refers to the part of the device that directly contacts the body of a person to be measured.
- *3 Clinical Guidelines for Female Lower Urinary Tract Symptoms, 2nd Edition (2019, Japanese Continence Society)
- *4 Iwatsubo E, et al. International Journal of Urology. 2014; 21: 1253-1257.
- *5 Suzuki M, et al. International Journal of Urology. 2016; 23: 786-790.
- *6 Suzuki M, et al. Neurourology and Urodynamics. 2019; 38: 1-7.
- *7 Iwata K, et al. Japanese Journal of Urodynamics. 2019; 30: 339.
- *8 Bladder volume ultrasound imaging device developed and sold by Lilium Otsuka since November 2015 (Medical device approval number: 227ADBZX00146000)

Product information

Product image



The amount of urine accumulation depends on the person.



Product name (Model)	Lilium-SPOT2 (USP200)
Suggested retail price	JPY 99,000 (tax included, free shipping in Japan)
Weight/Size	160 g/45 (W) × 40 (D) × 150 (H) mm
Power source	Rechargeable battery
Included items	Charging cable, ultrasonic gel, instruction manual
Product outline	Healthcare appliance, which enables users to check the level of urine accumulation on a display scale easily at any time by applying ultrasonic waves to the position of the bladder.
Product features	 Operation assisted by voice guidance and operation by a single button Intuitive operation by sound and screen display linked to urine volume Urine accumulation is indicated on a 10-step scale* Improved operability by software improvement* *Changes from Lilium-Spot

Program to switch to Lilium-SPOT2

- For users who have purchased Lilium-SPOT in the past, we will provide a program to switch to Lilium-SPOT2 for a fee.
- With this program, users will be able to use the Lilium-SPOT as Lilium-SPOT2 by replacing some parts of the Lilium-SPOT itself and updating the software. The details will be announced to each user individually.

If you have purchased the product in the past and have completed user registration, the software update cost will be covered free of charge. This program is only valid in Japan.

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 : 2,263 (as of December 31, 2020)

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 : 21 (as of June 1, 2021)

Business Description : Research and development, manufacturing, and marketing of medical devices

and related products

URL : http://www.lilium.otsuka/en/