

Lilium Otsuka Co., Ltd. Otsuka Holdings Co., Ltd.

NEWS RELEASE

September 25, 2015

"Lilium[®] α-200," a continuous urine volume sensor, will be launched in Japan

Lilium Otsuka Co., Ltd., a subsidiary of Otsuka Holdings Co., Ltd. will begin selling the "Lilium[®] α -200," a continuous, non-invasive bladder urine volume sensor on November 2nd, 2015.

This product makes it possible to continuously monitor urination schedules in patients who have lost any urge to urinate. It is anticipated that this will alleviate the need for daily lifestyle-restricting indwelling bladder ("Foley") catheters and the anxiety of incontinence.

Issues with urination independence and control are known to determine the ability of patients to return home from the hospitalⁱ, and impose a heavy burden on nursing and caregiving services.ⁱⁱ This product is expected to greatly contribute to the improvement of patient quality of life, and to reduce labor and improve the efficacy of those engaged in nursing and caregiving. Further, Lilium Otsuka expects to make a significant contribution to holistic treatments which impact the dignity of patients.

Isao Shirasaki, president and representative director of Lilium Otsuka noted,

"This product was developed in Japan based on intellectual property that was applied from a collaborative industry-government cooperative project involving the former Agency of Industrial Science and Technology (now the National Institute of Advanced Industrial Science and Technology, or AIST). We will continue to technically refine and improve this innovative medical device intended for the world as well as for Japan."

Dr. Osamu Yokoyama M.D., Ph.D., president of The Japanese Continence Society and professor on The Faculty of Medical Sciences, University of Fukui, said, "For patients with loss of urge or urinary difficulty, the beauty of this product lies in its ability to accurately monitor the size of the bladder (a measure of volume of urine retained in the bladder) and the ability to schedule bathroom trips or self-catherization. As the Japanese Continence Society initiates a certified physician system next year to begin training doctors who can professionally manage continence care, this device is thought to provide a good method to support discharge of patients to their homes."

Our corporate philosophy is "Otsuka-People creating new products for better health worldwide." Guided by this principle, we contribute to the health of people all around the world through market creation driven by innovative product development.

Product Outline in Japan

Brand name	Lilium® α-200	Power	Two AAA batteries
Medical device approval number	227ADBZX00146000	Weight	150 g (excluding batteries)
Class category	Class II	Size (mm)	120 (H) x 68 (W) x 27 (D)
Measurement accuracy	±15% , ±15mL	Medical service fee item	D 216-2 (Oct. 1, 2015-)
Device components	Main unit + ultrasonic probe	Certification date	Aug. 27, 2015
Basic function(s)	 Residual urine measurement: Measurement of bladder urine volume. Urination scheduling mode: Informs the patient when bladder urine volume is at a discretionary target level. Continuous measurement mode: Determines appropriate timing for clean- intermittent catheterization through continuous urine volume measurement. Bladder diary function: when the unit is in continuous measurement mode, patients can start the function by pressing a button at the time of urination. 		
Principle of measurement	The device estimates the volume of urine present in the bladder using indicators based on the distance between the anterior and posterior bladder walls, determined through ultrasound emitted by a detachable probe.		
Product illustration	Prob Real time search mode for measurem	e function f	een shot of bladder diary ction in continuous asurement mode MAX U D MAX U D
	Real time search mode for measurement of post-void residual		

ⁱ Survey: Effectiveness of the 2012 fiscal care fee revision and research (in Japanese)

http://www.mhlw.go.jp/file/05-Shingikai-12601000-Seisakutoukatsukan-Sanjikanshitsu_Shakaihoshoutantou/0000051896.pdf

" "Investigation of 1000 caregivers in home care." EN Otsuka Pharmaceutical Co. Ltd. press release on October 31, 2013 (in Japanese)

Corporate Profile

Lilium Otsuka Co., Ltd.

Established:	January 29, 2015		
Capital:	75 million yen		
Representative:	Isao Shirasaki, President and Representative Director		
Head Office :	4-12-6, Chiyoda, Chuo-ku, Sagamihara, Kanagawa		
Employees:	8		
Business Description:	Research and development, manufacturing, and marketing of medical devices and related products		
Shareholder:	Otsuka Medical Devices Co., Ltd. (100%)		
Website (URL)	http://www.lilium.otsuka		

(As of September 25, 2015)