

July 7, 2017

Marketing Approval Application Submitted to MHLW for NPC-17 (titanium bridge), the First Medical Device to Receive the SAKIGAKE Designation

Nobelpharma Co., Ltd. (Chuo-ku, Tokyo) has submitted its application for marketing approval for NPC-17 (titanium bridge) to the Ministry of Health, Labour and Welfare on June 30.

NPC-17 (hereafter "this product") is used for type II thyroplasty for the treatment of adductor spasmodic dysphonia. Type II thyroplasty using this product is a medical technique unique to Japan that was developed in 2001 ahead of the rest of the world by Dr. Nobuhiko Isshiki, Professor Emeritus, Kyoto University, as a definitive treatment for the symptoms of adductor spasmodic dysphonia.

Dr. Isshiki received the "Isshiki Award" in 2011 from the Royal College of Surgeons of England (RCS) in recognition of his long-standing contribution both domestically and internationally, including this type II thyroplasty.

Adductor spasmodic dysphonia is a type of focal dystonia that is an intractable neurological disease of unknown cause often seen in young women. There is no definitive treatment for this disease, and the early commercialization of this therapeutic technique is expected to be a great ray of hope for those patients suffering from adductor spasmodic dysphonia.

This product was the first medical device to receive the SAKIGAKE designation from the Ministry of Health, Labour and Welfare in February of last year, upon fulfilling the criteria for innovativeness, the importance of the target disease, extremely high efficacy for the target disease, and the intent for early development and application in Japan ahead of the rest of the world.