

Press Release

Nobelpharma Co., Ltd.

Announcing Sales Launch of TITANBRIDGE®
First Medical Device to Receive SAKIGAKE Designation
Medical Device for the Treatment of Adductor Spasmodic Dysphonia

Nobelpharma Co., Ltd. (Head Office: Chuo-ku, Tokyo; President and CEO: Jin Shiomura) is announcing that sales of TITANBRIDGE®, a medical device to be used for type II thyroplasty for the treatment of adductor spasmodic dysphonia (device generic name: device for thyroid cartilage fixation) were launched on July 2.

This device was the first medical device to be awarded the SAKIGAKE designation in February 2016, was then designated as an orphan device in September 2016, and obtained marketing approval on December 12, 2017.

The type II thyroplasty using TITANBRIDGE® is a unique medical technique that was developed in Japan ahead of the rest of the world in 2001 by Dr. Nobuhiko Isshiki, Professor Emeritus, Kyoto University, to achieve continuing symptomatic relief in patients with adductor spasmodic dysphonia by preventing excessively tight closure of the glottis and maintaining the glottic opening. Kumamoto University and the Translational Research Informatics Center of the Foundation for Biomedical Research and Innovation (now the Translational Research Center for Medical Innovation of the Foundation for Biomedical Research and Innovation at Kobe) cooperated to launch an investigator initiated trial after being selected to conduct research on rare and intractable diseases under the Health and Labor Sciences Research Grants in 2014 (continued until 2016 under the Japan Agency for Medical Research and Development).

Adductor spasmodic dysphonia is a type of focal dystonia, an intractable neurological disease of unknown cause common among young women. There has been no definitive treatment for this disease that would maintain a degree of improvement in the vocal disorder previously established anywhere in the world, so the prompt practical use of this therapeutic technique using the TITANBRIDGE® is expected to be a major ray of hope for patients who suffer from adductor spasmodic dysphonia. Nobelpharma will continue to contribute to society by providing drugs and medical devices for unmet needs in the future.

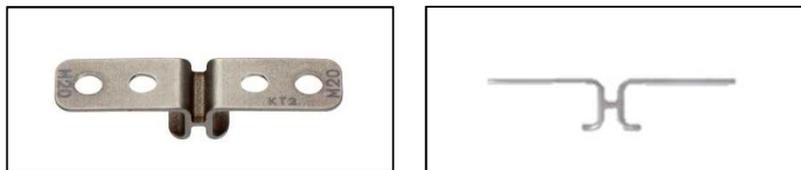
【Contact for more information】

Nobelpharma Co., Ltd.

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There are 3 types of TITANBRIDGE®, a standard specification (M), one for patients with short thyroid cartilage (S), and one for patients with thick thyroid cartilage (L), and there are 7 specifications of opening widths for each of them.



Product name	Opening widths (mm)
TITANBRIDGE® S20~S60	2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0
TITANBRIDGE® M20~M60	
TITANBRIDGE® L20~L60	



High management medical device TITANBRIDGE®

Medical device approval number: 22900BZX00409000



About Nobelpharma

Nobelpharma has been contributing to the provision of necessary treatments for overlooked diseases through development of medicines since 2003. Our development priority is on medicines and medical devices for unmet needs that are strongly desired by patients associations and medical associations. Currently, we have obtained marketing approval for 14 products, mostly focused on medicines and medical devices for unmet needs, and of those 10 products have received the orphan drug or device designation.