December 15, 2017

Press Release

Nobelpharma Co., Ltd.

Marketing Approval Granted for TITANBRIDGE™
First SAKIGAKE Designated Medical Device
to Treat Adductor Spasmodic Dysphonia

Nobelpharma Co., Ltd. (Head Office: Chuo-ku, Tokyo; President and CEO: Jin Shiomura) received marketing approval today for 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; Code: NPC-17).

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 (See Figures.). The efficacy of this technique was subsequently demonstrated by further rounds of clinical research conducted by Dr. Isshiki and other physicians that included approximately 400 cases by 2014.

Kumamoto University and the Translational Research Informatics Center of the Foundation for Biomedical Research and Innovation 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. Nobelpharma submitted the marketing approval application on June 30, 2017.

Adductor spasmodic dysphonia is a type of focal dystonia that is an intractable neurological disease of unknown cause, often seen in young women, for which no treatment has been established to maintain the improvement in the degree of vocal disorder. Under such circumstances, this medical technique using TITANBRIDGE™ is expected to bring great hope for those patients suffering from adductor spasmodic dysphonia as it becomes available for practical application.

TITANBRIDGE™, also designated as an orphan device in September 2016, was the first medical device to receive the SAKIGAKE designation for fast track review in February 2016, upon fulfilling the criteria for innovativeness, severity of and extremely high efficacy for the target disease, and for the intent for early development and approval application filing in Japan ahead of the rest of the world.

Among all the SAKIGAKE designated medical devices, pharmaceutical products, in-vitro diagnostic products and regenerative medicines, TITANBRIDGE™ has become the first product to receive marketing approval.

【Contact】
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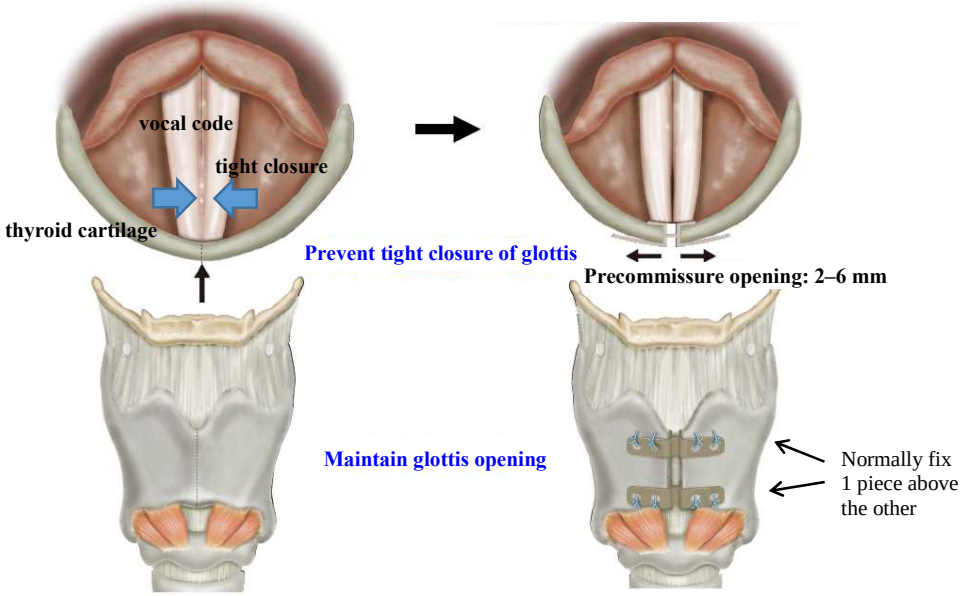
(Reference)



Figures provided by Kumamoto University with some modifications

Figure 1　Usage of TITANBRIDGE™

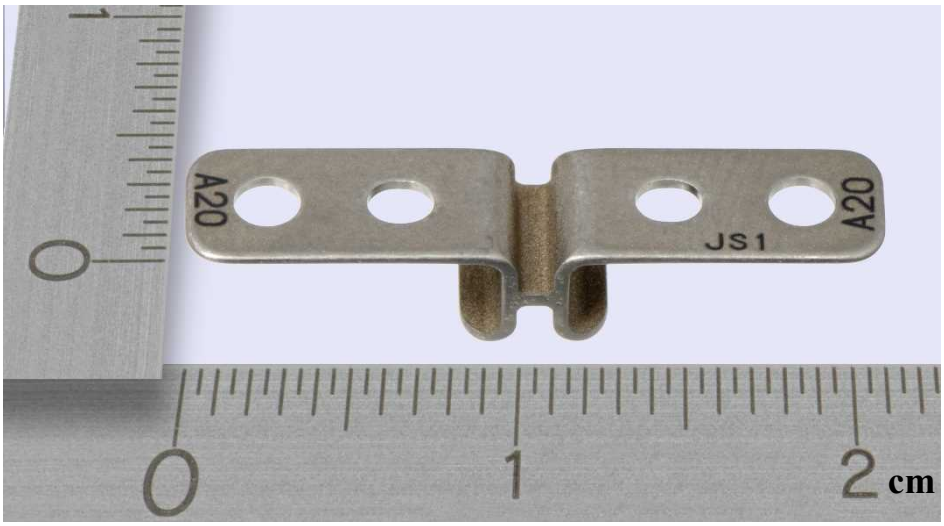


Figure 2 TITANBRIDGE™