MAY 23, 2024

Covidien Japan and HOGY Medical conclude a service agreement to commence cooperation on the sale of SuReFInD®

Offering comprehensive support for precise sub-lobar resection surgeries for patients with early-stage lung cancer, and providing treatment that leads to improvements in patients' prognosis

TOKYO – May 24, 2024 – Covidien Japan, Inc., (Head Office: Minato-ku, Tokyo), one of three Medtronic subsidiaries in Japan, concluded a service agreement on May 1 with HOGY Medical Co., Ltd. (Head Office: Minato-ku, Tokyo) to cooperate on the sale of SuReFInD®, a marking medical device used on lung cancer patients. HOGY Medical is a marketing authorization holder for the product. The sale cooperation activities will commence successively from June. HOGY Medical's SuReFInD®, which is used to mark lesions, fulfills the need for precise sub-lobar resection surgeries to treat lung cancer in its early stages, when legions can only be identified with diagnostic imaging equipment. The aim is to combine this method with Endo GIA™, Medtronic Covidien's surgical stapler for lesion resection, in order to provide a comprehensive solution.



(Product name: SuReFInD/Approval number: 23000BZX00393000)

There is a growing incidence of lung cancer not only in Japan but also worldwide. Moreover, as the nature of cancer is such that its risk increases with age, the number of patients is expected to increase further over the next 20 years in Japan, where there is a rising population of elderly people.

When lung cancer is discovered at an advanced stage, the typical surgical procedure performed is to excise extensive sections where lesions have developed, by the sac (lobe) unit. However, this is accompanied by the postoperative challenge of a decline in respiratory functions caused by the significant lung loss. On the other hand, alongside advancements in CT and diagnostic imaging equipment in recent years, there has been an increase in the number of small-cell lung cancers detected, including early-stage microinvasive cancers with low malignancy. Therefore, early detection has been accompanied by a yearly increase in the number of limited resection surgeries for lung cancers without lymph node metastasis, aimed at reducing the resection area while preserving healthy lungs.

The main methods adopted for resection surgeries include resecting the lung by using a surgical stapler such as Endo GIA™. As it is possible to preserve lung functions by reducing the resection area, patients can be expected to maintain their quality of life after treatment and be rehabilitated into society more quickly.

However, unlike cancers that develop on the inner surface of the digestive tract, such as stomach cancer and colorectal cancer, which can be confirmed directly through an endoscopy, lung cancer cannot be observed directly during surgery. Furthermore, as the shape of the lung changes significantly between diagnostic imaging (when inflated after an intake of breath) and during surgery (when collapsed), it becomes challenging to identify and resect the lesion with precision during surgery. Even with limited resection surgeries that involve a small resection area, it is vital to ensure that there is an adequate resection margin (distance) from the lesion so that cancerous tissue is not left behind.

To resolve these issues, SuReFInD® is used to carry out marking procedures and embed an IC tag in or near the lung cancer lesion before surgery. By using SuReFInD®, an in-vivo medical device that employs RFID technology, it is possible to check the location of the lesion more accurately and in real-time during surgery through the RFID communications technology. Combining this with lesion resection using Endo GIA™ enables the provision of a comprehensive solution that meets the needs of precise sub-lobar resection surgeries.

With the conclusion of this service agreement between Covidien Japan and HOGY Medical, as well as the establishment of a system to supply and sell a comprehensive solution that combines SuReFInD® and Endo GIA™, the two companies aim to promote the widespread adoption of precise sub-lobar resection surgery on lungs, reduce patients' burden in receiving treatment, and contribute to improving prognosis after the surgery.

■ Comments from Dr. Toshihiko Sato, Professor, Department of Surgery (Thoracic, Endocrine, Pediatric), Fukuoka University Hospital

As thoracic surgeons, we aim to improve the treatment outcomes for lung cancer and reduce mortality from lung cancer by promoting and developing precise sub-lobar resection (PSR) surgery for the lungs. I believe that the technology built into SuReFInD® is necessary for performing such PSR, and I think that it can be one of the more effective treatment options for small-cell lung cancer.

■ Comments from Keizo Kumano, Vice President, Medical Surgical Unit, Medtronic Japan

We have set out the vision of continuing to be a leading partner in developing surgical procedures and strengthening outcomes through our innovative solutions. The number of lung cancer patients is expected to increase going forward as we approach the era of a super-aging society. In light of that, Medtronic will take a multifaceted approach that smoothly links diagnosis to appropriate treatment, with the aim of improving patients' prognosis and realizing a society where they can lead healthy lives.

■ Comments from Hideki Kawakubo, Director, President and CEO, HOGY Medical

As the aging of society picks up speed, advancements have been made in minimally invasive treatments and surgeries that reduce the burden on patients' bodies. The sales cooperation with Covidien will enable the provision of SuReFInD® to even more patients. Through that, we aim to realize medical services of an even higher quality, and to do our best to achieve health and well-being for patients.

[About SuReFInD®]

SuReFInD® is a marking medical device, developed for the purpose of supporting more accurate resection in lung resection surgeries to treat small-cell lung cancers. It was launched for sale in 2020. A microscopic IC tag that applies RFID technology is placed near the lesion via the bronchoscope channel. During the surgery, a specialized small antenna is used to accurately determine the location of the lesion for the resection.

[About marking medical devices]

These are devices used to mark the resection area on surgical sites where it is difficult to identify the location of tumors during a surgery. They are mainly used in surgeries involving lung cancer, stomach cancer, and colorectal cancer.

[About RFID technology]

Radio frequency identification (RFID) technology is an automatic recognition technology that uses radio frequencies to read and write information on IC tags without any contact.

[About Endo GIA™]

Endo GIA™ is an automatic suturing device (a type of surgical stapler) developed specially for use in endoscopic surgery, and it was the first of its kind sold in the world when it was launched in 1992. It is used primarily in resection, transection, and anastomosis (connecting the intestinal tracts and other structures in surgery). As a suturing method to replace surgical stitching alongside the popularization of minimally invasive surgeries such as endoscopic surgeries, Endo GIA™ has a history of contributing to reducing surgery time and evolving continuously. In lung surgeries, it is used for the resection and transection of lesions. By gripping the tissue and operating the handle, the mechanism enables the stapler and resecting knife to operate at the same time, thereby performing the suturing and resecting functions simultaneously. Furthermore, it comes with an extensive range of suture lengths of 30mm, 45mm, and 60mm, in addition to a diverse variety of cartridges. This supports transection in line with the surgical plan in precise sub-lobar surgeries.

Product name: Endo GIA/Approval number: 22100BZX00167000
Product name: Tri-Staple 2.0/Approval number: 22900BZX00115000
Product name: Signia Small Diameter Reload/Approval number: 30200BZX00023000
Product name: Tri-Staple 2.0 Reinforced Reload/Approval number: 30300BZX00229000
Product name: Endo GIA Ultra Universal Stapler/ Certification number: 223AABZX00019000
Product name: Signia Stapling System/Certification number: 228AABZX00088Z00
Product name: Signia Manual Adapter Tool/Notification number: 13B1X00069US023A

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com and follow Medtronic on LinkedIn.

About HOGY Medical

HOGY Medical Co., Ltd. has been engaged in the development of products that contribute to enhancing medical safety and improving profits for medical institutions since its establishment in 1961, based on the corporate philosophy of "To promote good health and prosperity through contribution to medical progress." Its history began with sterilization pouches, which it started selling in 1964 with the aim of preventing hospital-acquired infections. Since then, it has strived to ensure the stable supply of products that are safe and easy to use, including medical-use non-woven fabric products and surgical kit products. It also provides the OPERA MASTER, a system that contributes to improving management at medical institutions, as well as the Premium Surgical Kit in 2016 to support medical practitioners who are engaged in work style reform. By working with doctors on the joint development of products that contribute to improving the quality of medical services, among other efforts, it continues to evolve with future advancements in minimally invasive treatment, which aims to reduce the burden on patients' bodies.

Website: www.hogy.co.jp

SuReFInD® is a registered trademark of HOGY Medical Co., Ltd.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

Contacts:

Saori Hasegawa
Ryan Weispfenning

Public Relations
+81-3-6776-0002

Investor Relations
+1-763-505-4626

https://news.medtronic.com/Covidien-Japan-and-HOGY-Medical-conclude-a-service-agreement-to-commence-cooperation-on-the-sale-of-SuReFInD-R