

# MEDICAL BUSINESS

**Olympus Medical Business** 





# **OUR PURPOSE**

# Making people's lives healthier, safer and more fulfilling





#### Introduction

Olympus developed the world's first practical gastrocamera in 1950. This innovative device contributed greatly to establishing methods for the early diagnosis of stomach cancer, a kind of cancer that had previously been a leading cause of death in Japan. Since then, Olympus has strived to make further developments with the use of endoscopes for various forms of examination and treatment.

Advancements in minimally invasive treatments are continuously being made within the medical field. Olympus provides products/solutions to treat various diseases—not only in gastroenterology, but also urology, respiratory, etc.—which contribute to reducing the patient's pain and suffering. They also help to improve patients' quality of life (QOL) and reduce medical costs by spending shorter times in hospital and returning to normal life more quickly.

By publishing "The Olympus Medical Business" we hope to provide our investors, shareholders, and other stakeholders with a general understanding of the Medical Business of Olympus. We will also introduce recent trends in our medical devices for diagnosis and treatment.

Investor Relations, Olympus Corporation

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#### Forward-Looking Statements

"The Olympus Medical Business" contains forward-looking statements that reflect management's current views, plans, and expectations based on information available at the time of preparation. These forward-looking statements are not guarantees of future performance and involve known and unknown risks, uncertainties, future business decisions, and other internal and external factors that may cause the Company's actual results, performance, achievements, or financial position to be materially different from any future results expressed or implied by these forward-looking statements.

#### About Products

Some products in "The Olympus Medical Business" have not yet been released in some regions.



# The Olympus Medical Business

Endoscopic Solutions Division Therapeutic Solutions Division

# Early Diagnosis

- By incorporating technology aimed at improving the quality of lesion detection, diagnosis, and treatment, as well as examination efficiency, gastrointestinal endoscopes, which are one of Olympus' mainstay products, contribute to the early detection of lesions from gastrointestinal diseases such as cancer.
- If a suspicious lesion is found during the endoscopic examination, the area can be sampled for pathological examination.
- Recently, our endoscopes' magnification function is expected to enable doctors to make a definitive diagnosis immediately based on magnified images without the need to damage body tissue.



Gastrointestinal endoscopy systems

Ultrasound endoscopes

Cytology brushes



Olympus' Medical Business is divided into two divisions: Endoscopic Solutions Division (ESD), which deals with gastrointestinal endoscopes, surgical endoscopes, and medical services, etc.; and Therapeutic Solutions Division (TSD), which mainly deals with medical devices for GI-endotherapy, urology, and respiratory. With a variety of products and services developed from these two businesses, we will provide the two values of early diagnosis and minimally invasive treatment. Through this, we hope to contribute to improvements in the QOL of patients while also helping to address the worldwide trend of rising healthcare costs.

# Minimally Invasive Treatment

- Gastrointestinal endoscopes can also be used together with endotherapy devices to treat early-stage cancers, as well as various treatments such as removal of polyps and accidental foreign objects.
- In the field of urology, we are deploying devices that can be used in clinics to treat benign prostatic hyperplasia (BPH), which is expected to increase with the aging of the population, without the need for excisional surgery. It is a minimally invasive treatment that ensures no permanent foreign object remains in the patient's body.
- Unlike conventional open surgery, endoscopic surgery (laparoscopic surgery) does not require large abdominal incisions therefore patients are expected to feel less post-operative pain, spend shorter days in hospital and return to normal life more quickly.

# Endoscopic therapy





Electrosurgical knives







Surgical energy devices

# Other minimally invasive treatment



Minimally invasive treatment devices for BPH



Thulium fiber laser systems

# The Social Issues Solved by Olympus



Olympus developed the world's first practical gastrocamera to fulfill the wishes of doctors who had said they wanted some way to cure stomach cancer. Since then, we have been working together with doctors to improve endoscopic technology and enhance diagnostic and therapeutic methods. Responding to the needs of endoscopists, our advanced technologies continue to be at the forefront of the industry, and represent just one of the advantages of our products. Currently, we boast a global market share of about 70% for our mainstay gastrointestinal endoscopes.

Endoscopes play an important role in detecting and treating many types of cancer. For example, according to 2020 data, new cases of colon cancer affect about 1.9 million people annually, and it is reported that about 0.9 million of those cases are fatal, a number that is expected to increase in the years to come.

Colon cancer has a much higher probability of being cured if found in the early stages, when the cancer has not yet spread. However, early-stage colon cancer often has no subjective symptoms, and thus cancer screening is very important for early detection and treatment. About 50 million colonoscopies are performed annually for the diagnosis and therapeutic treatment of colon cancer, and Olympus products are used for many of them.



\*2 Data source: GLOBOCAN 2020





**100** Diseases or conditions treated\*4



Moreover, endoscopes are used not only for detecting and diagnosing lesions, but also for their therapeutic treatment. In addition to endotherapy devices equipped on gastrointestinal endoscopes we provide versatile medical devices for various hospital departments, such as urology and respiratory, and our devices are capable of treating about 100 diseases.

By providing treatment methods for four of the five cancers with the highest number of cases—lung, colon, prostate, and stomach\*5—and developing therapeutic devices to help treat other cancers, Olympus is contributing to the health of people around the world.

\*4 As of March 2021

\*5 As of March 2021. Data source: GLOBOCAN2020 Excluding breast cancer, which is the top cancer in terms of cases



#### Number of Cancer Cases in the World by Cancer Site







#### **Number of Cancer Patients** (2020/2040 comparison)

Estimated number of new cases from 2020 to 2040 for both sexes and all ages (All cancers, World)

2020 19.3 million 30.2 million **'n**ħħħħħ



#### Number of Deaths from Cancer (2020/2040 comparison)

Estimated number of deaths from 2020 to 2040 for both sexes and all ages (All cancers, World)



# Outline of Endoscopic Solutions Division (ESD)

In the ESD, we contribute to the medical field with a variety of products and services, including endoscope systems, scopes (flexible and rigid), and medical services.

Note: From FY2022, bronchoscopes, which were classified in the gastrointestinal endoscope segment of ESD, have been transferred into the respiratory segment of TSD. FY2021 actuals have also been restated in the same manner.



# Gastrointestinal Endoscope

A group of products for inserting endoscopes into the digestive organs through natural orifices (mouth, nose, anus) for observation and diagnosis



# Surgical Endoscope

A group of products mainly for inserting an endoscope into the abdominal cavity through a small hole on the body surface to check the condition of the cavity during surgical operations



# **Medical Service**

General repairs and service contracts for gastrointestinal endoscopes and surgical endoscopes

#### General repairs

- Repair services through repair bases worldwide
- Repair services at facilities through field services (stationary equipment such as reprocessors)

#### Service contracts

- Single-year or multi-year contracts
- Partial or complete repair cost coverage
- Priority provision of loaners during repair of defective products
- Provision of failure prevention training
- Provision of comprehensive services



Repair center

# Outline of Therapeutic Solutions Division (TSD)

Our portfolio in the TSD includes a wide range of endotherapy devices, endoscopes, and therapeutic devices for urology, respiratory, ENT, gynecology, and surgical energy devices. The various products are helping to prevent, diagnose, and treat diseases.

Note: From FY2022, bronchoscopes, which were classified in the gastrointestinal endoscope segment of ESD, have been transferred into the respiratory segment of TSD. FY2021 actuals have also been restated in the same manner.

**GI-Endotherapy** 



A group of products that are inserted into the instrument channel of flexible endoscopes and used for various endoscopic procedures. They can be used for tissue sampling, lesion removal, and hemostasis without making incisions or small holes on the patient's body surface







# ESDA

Endoscopic Solutions Division

In its Endoscopic Solutions Business, Olympus uses innovative capabilities in medical technology, therapeutic intervention and precision manufacturing to help healthcare professionals deliver diagnostic, therapeutic and minimally invasive procedures to improve clinical outcomes, reduce overall costs and enhance the quality of life for patients. Starting with the world's first gastrocamera in 1950, Olympus' Endoscopic Solutions portfolio has grown to include endoscopes, laparoscopes, and video imaging systems, as well as customer solutions and medical services.

# Features of ESD

# Competitive product development

#### > Gastrointestinal endoscope area

- From the time when Olympus developed the world's first practical gastrocamera in 1950 to today, Olympus has continued to refine its endoscope technologies in close collaboration with physicians
- Developing technologies that contribute to the improvement of the quality of endoscopy around the world, such as NBI, RDI, TXI, and EDOF

#### Surgical endoscope area

- Providing high-definition and high-quality products with 4K/3D technology
- Acquisition of advanced fluorescence imaging technology and promotion of research and development toward next-generation molecular imaging technology



Note: Market scale and growth forecast information for this page come from the Company's research. Market scale is as of March 31, 2021

Growth forecasts are projected for the fiscal year 2022 to fiscal year 2024, starting from fiscal year 2021

# Solid business foundations

## 1 Global service network

Established a global network of service locations: Europe, the Americas, Middle East, Africa, Japan, China, and Asia, which is the largest network of service sites for any global medical device manufacturer



Large endoscope repair center



Supporting training for endoscopists by opening training centers in China and other Asian countries, where demand for early diagnosis and minimally invasive treatment is expanding along with the economic growth



Olympus China Medical Training & Education Center Shanghai (C-TEC Shanghai)

# Craftsmanship for meeting physician needs

Providing more than 300 types of endoscopes through advanced manufacturing technology and high-mix, low-volume production to meet diversifying customer needs



Endoscope

# **01** Competitive product development

# Sastrointestinal endoscope area

#### Past

#### The Birth and Spread of Gastrocamera

At the department of surgery, the University of Tokyo Branch Hospital, with the support of Assistant Professor Takeo Hayashida, Dr. Uji and the Olympus technical team developed an experimental gastrocamera. This gastrocamera was launched in 1952 as the "GT-I Gastrocamera." However, as there were a number of problems with the early product and imaging techniques had not been well established, it did not catch on. Gastrocamera operations ran a deficit, and there were discussions at Olympus as to whether the business could continue on as it was. Amid this, the first place to recognize the potential of the gastrocamera and make an effort to popularize it was in the #8 Research Laboratory of the University of Tokyo Main Hospital First Department of Internal Medicine (Tasaka Internal Medicine Department: Professor Sadataka Tasaka).

The Tasaka Internal Medicine Department first assisted Olympus by offering advice regarding problems with this early instrumentation from a user's point of view. But the greater topic at the time was the need to establish a standardized technique for photographing the inside of the stomach. The gastrocamera differs from the fiberscope in that the doctor cannot directly observe the inside of the stomach during the examination. It is exceedingly difficult to get a satisfactory image while blindly maneuvering the instrument around inside the stomach.

In order to determine the location of the gastrocamera in relation to the various parts of the stomach, various daunting tasks had to be repeated, such as using X-rays and recording the gastrocamera's degree of insertion, twisting of the shaft and noting the result, and measuring the amount of air flow required to optimally insufflate the stomach. Through these experiments, a standardized imaging technique was established around 1956.

The role of the "Gastrocamera Research Group" (currently the Japan Gastroenterological Endoscopy Society), as first established and centered around the Tasaka Internal Medicine Department, cannot be forgotten. The first meeting of the Gastrocamera Research Group was held in 1955, and research reports focusing on cancer were presented. At the fifth research society meeting in 1958, there were 16 presentations and 200 attendees, and research had progressed to the clinical stage.

Along with Olympus as the manufacturer, the group established the Technology Committee (afterward the Gastrocamera Promotion Committee) in 1955. Once a month, they met to share opinions regarding failure prevention and device improvements. These efforts became the driving force behind the spread of the gastrocamera.



Dr. Uji (center), attending a clinical trial



First Gastrocamera Research Group meeting (at the podium, Professor Tasaka)

#### Present

#### Image-enhanced Endoscopy and NBI

The gastrocamera, developed by Olympus in 1950, greatly influenced early-stage stomach cancer diagnostics. Through the accumulated research that followed, it was understood that early-stage lesions could be found through slight differences in the color of mucosal surfaces within the digestive tract. A technique called "chromoendoscopy," spread rapidly starting in the 1970's. This procedure sprays various dyes on the tissue lining the GI tract in order to detect subtle lesions that are hard to detect using normal endoscopic imaging. Olympus expanded upon these principles and developed a technique called Narrow Band Imaging (NBI) that is designed to reveal subtle lesions through an optical method. NBI is one example of an imaging enhancement technique that uses a combination of optical and digital methods (opto-digital).

#### Narrow Band Imaging (NBI)

Olympus developed Narrow Band Imaging technology to enhance observation of mucosal tissue. NBI is an optical imaging technology that enhances the visibility of vessels and other tissue on the mucosal surface. NBI works by filtering the white light into specific light wavelengths that are absorbed by hemoglobin and penetrate only the surface of human tissue. As a result, with Narrow Band Imaging, capillaries on the mucosal surface are displayed in brown and veins in the submucosa are displayed in cyan on the monitor.



© Blue light : Strongly absorbed by hemoglobin in capillaries near the tissue surface, and not reflected.

- Blue light : Strongly reflected by the mucosal surface layer
   Green light : Strongly absorbed by hemoglobin in blood vessels deeper in the tissue, and not reflected.
- ④ Green light : Strongly reflected by the tissue beneath the mucosa.
  - A well-resolved image is produced by utilizing both reflected and non-reflected

Monitor screen in NBI mode



Blue : Larger blood vessel in tissue below

#### Innovative Imaging Technologies

In 2020, we launched the EVIS X1, the latest model of our endoscopy system, in Europe, Japan, and some parts of Asia. This model is equipped with the following three imaging technologies that will further improve treatment and diagnosis. It contributes to early detection, early diagnosis, and minimally invasive treatment of gastrointestinal diseases such as cancer.



EVIS X1

# TXI Texture and Color Enhancement Imaging

TXI supports better visibility of potential lesions (such as areas of inflammation, flat or depressed lesions, or even tiny precursor lesions) through enhancing texture, brightness, and color to define subtle tissue differences more clearly. With its advanced imaging technology, TXI holds the potential to reinvent white light in endoscopy. By supporting better visibility of potential and extant lesions, TXI aims to contribute to higher detection rates and improve qualitative diagnosis.



# RDI Red Dichromatic Imaging

Gastrointestinal bleeding is a serious challenge, potentially involving considerable mortality risks and management costs. RDI enhances the visibility of deep blood vessels and gastrointestinal bleeding sources, thereby helping to identify blood vessels that could require immediate treatment. It utilizes green, amber, and red wavelengths to visualize deep blood vessels. Easier identification of bleeding spots makes hemostasis quicker and easier while potentially improving the efficiency of any corresponding treatment. This minimally invasive technology could also be expected to help reduce physician stress during endoscopic therapy.



# EDOF Extended Depth of Field

EDOF combines two images at different focus distances into one perfect image to help aid diagnosis and confidant decision-making. It delivers observational excellence through continuous broad focus and seamless magnification. At the same time, the established Dual Focus function provides high magnification, which can be activated by the push of a button. This improved visibility and continuously sharp image has been developed to reduce the necessity for focal adjustments and could be expected to improve efficiency and decrease the oversight rate.



# Surgical endoscope area

#### Higher Resolution and 3D

In the area of surgical endoscopes, we established Sony Olympus Medical Solutions Inc., a joint venture with Sony Corporation, in 2013. Sony Olympus Medical Solutions is engaged in the research and development of new products that combine Sony's cutting-edge electronics technologies in areas such as digital imaging with Olympus' manufacturing and R&D expertise in the area of medical products including lenses and optical technologies.

• 4K Surgical Endoscopy System

The 4K Surgical Endoscopy System, which has about four times the number of pixels compared to full high-definition video, contributes to improved visibility during surgery with clear, high-definition images down to the finest details. In addition, the rich color reproducibility supports easy identification of the boundaries of fine tissues (blood vessels, nerves, lymph vessels, etc.). The large screen monitor and magnified view of the electronic zoom can also support detailed surgery.

Olympus launched VISERA ELITE II, a surgical endoscope system with an infra-red (IR) imaging capability in 2017. As of June 2021, the system is marketed in Japan, U.S., Europe, China (3D) and parts of Asia.

Surgical Endoscopy System with Infra-Red Imaging Capability

Surgical endoscope systems that support IR imaging, which highlights blood flow information, NBI observation using specific light spectra, and 3D stereoscopic viewing, provide the best observation images for each case.



VISERA 4K UHD



VISERA ELITE II

#### Present

#### Fluorescence Imaging

In 2021, we expanded our portfolio in the growing fluorescence imaging market in the area of surgical imaging with the acquisition of Quest Photonic Devices B.V., a Dutch medical device manufacturer.

#### • Imaging System for Fluorescence-guided Surgery

Fluorescence imaging refers to special light imaging technologies that utilize the properties of fluorescent dyes directed to specific anatomical structures. By using targeted dyes, in combination with specific light wavelengths, tissues or lesions that are nearly invisible under normal white light become visible.

We have added Spectrum® to our portfolio, a fluorescence-guided surgical imaging system for both open and laparoscopic surgery.



Future

#### **Molecular Imaging**

Research on molecular imaging technology to visualize cancer lesions using fluorescent drugs combined with antibodies that specifically bind to cancer is currently underway and is expected to be put to practical use. Quest Photonic Devices B.V., works with biotechnology companies that are developing next-generation molecular imaging dyes. These innovative dyes may enable Quest Photonic Devices B.V.'s technology to advance diagnostic opportunities in fluorescence-guided cancer surgery.

# **02** Solid business foundations

# Global service network



Map of Olympus' repair locations around the world (
 shows locations capable of major repairs\*) (As of April 2018)

Endoscopes are precision instruments used within the human body. High-quality, after-sales service is necessary to maintain safety and provide maximum functionality. In order for patients around the world to receive safe endoscopic examinations and treatment, Olympus has established the industry's leading global repair and services system. In addition, we have established a system in which each repair site can provide mutual backup in the event of an emergency such as a disaster.

#### The World's Largest Endoscope Repair Center (San José, California, U.S.)

Olympus is proud of the "San José National Repair Service Center," which is the world's largest endoscope repair center. Within the walls of the 80,000 square-meter building accented in blue, Olympus' corporate color, 450 service staff members dressed in white lab coats meticulously carry out their repair work. The San José location was established in 1979 to perform concentrated, authentic repairs (major repairs)\*, including full instrument disassembly and reassembly. Prior to this, major repairs of endoscopes had been performed at small service locations distributed throughout the U.S. However, it was decided that a centralized location where high-quality repairs coexisting with rapid repair turnaround was critical for the U.S. market. The centralization of major endoscope repair in one facility has improved both the quality and the efficiency of delivering repair services to our customers.



World's largest endoscope repair center (San José, California)

#### **High Repair Quality**

Endoscopes, which are inserted directly into the human body, must meet strict safety and performance standards. This applies both to new instruments and instruments being returned to healthcare professionals following service. Therefore, it is required that fully repaired items have the same level of quality as new products. "Safe, stable use" is one of the essential values of endoscopes. With this kind of thinking, Olympus has continued to strive to enhance its service system, ever since the start of the endoscope business in 1952.

# 2 Supporting endoscopist training

Demand for early diagnosis and minimally invasive treatment is expanding along with the rapid economic growth in China and other Asian countries. Like in Japan, the U.S., and Europe, Olympus actively supports training for endoscopists by providing training opportunities on the safe and effective use of Olympus products, which allows doctors to be familiar with new products and procedures in China and other Asian countries.

#### Efforts in China

In addition to the progress which the Chinese government is making in reforming medical care, China's population is also rapidly aging in a manner similar to U.S. and European countries. In medical facilities, therefore, the number of endoscopists are unable to keep up with the growing number of patients, making the development of new endoscopists an urgent matter. In 2008, Olympus built the China Medical Training & Education Center Shanghai in the research and industry development district outside of Shanghai in China. This site is conveniently located near Shanghai Airport, making it easy for doctors to visit from all over China. Behind the futuristic exterior of the building are located both a training center and a call center. The training center is set up to allow for the training of gastrointestinal endoscopic examinations, as well as training on the operation of endotherapy devices and surgical products. A lecture hall capable of seating close to 100 people is located on the uppermost floor and is wired for high-capacity broadband communications, making academic exchange possible for doctors both inside and outside China.

Training of sales representatives and repair and service technicians is also performed at China Medical Training & Education Center Shanghai, which contributes to improving the quality of Olympus' marketing services. The call center handles communications with medical facilities, sales representatives, repair technicians, and dealers throughout the country, with an equivalent level to that of Japan, U.S., Europe. Olympus opened similar training centers in Beijing in 2010 and in Guangzhou in 2013, further accelerating support for training new Chinese endoscopists. Based at the three in-house training centers, as well as at collaborative training centers affiliated with nationwide, Olympus is supporting training for endoscopists throughout China by providing a range of learning programs. Olympus also invites Japanese doctors to China who tutor Chinese trainers. Most recently, we have been supporting Japanese doctors who provide online lectures on the activities of Chinese trainers and evaluate as well as comment on case presentations. Through these and other efforts, Olympus has achieved remarkable growth in recent years.



#### **Chinese Sales Growth Trends in the Medical Business**



With a total population of over 1.3 billion people, India is the most promising new market second to China. From the size of its population and the speed of its economic growth, it is believed that the availability and use of medical devices in India will advance rapidly in the future. Similar to Japan and China, there are a number of gastrointestinal diseases in India amenable to endoscopic treatment, and endoscopic procedures for biliary and pancreatic diseases are very common. Olympus works with Indian academic societies and supports endoscopic training sessions. Having established a training center in Thailand in 2016 to serve healthcare professionals from Southeast Asia, Olympus is also striving to develop the medical technology infrastructure in the nations of the region and expand their use of endoscopy. Furthermore, Olympus Korea Medical Training & Education Center (K-TEC) was established in 2017. In the future, Olympus intends to continue contributing to improvements in patient quality of life (QOL) by working to help with endoscopy skill development and on the wider use of endoscopes for early diagnosis, minimally invasive treatment, and procedure.



Olympus China Medical Training & Education Center Shanghai (C-TEC Shanghai)



Various forms of training can be given within the facility

Click here for the China page of our Integrated Report 2021 (Business Growth Driven by the Chinese Market, Doctors' Perspective, A Corporate Officer's Perspective)





Olympus Korea Medical Training & Education Center (K-TEC)



## 3 Craftsmanship for meeting physician needs

The current trilateral approach of Japan/Asia, North America, and Europe is supported by the following manufacturing centers. In Japan and Asia, we have five domestic plants in Aizu, Shirakawa, Aomori, Hinode (Tokyo), and Nagano, and a plant in Vietnam. All of our mainstay gastrointestinal endoscopes are manufactured in Japan. Surgical devices are manufactured in North America based at the two manufacturing facilities. The main products are surgical devices for ear, nose and throat and surgical energy devices. In Europe, rigid endoscopes, therapeutic devices for urology/gynecology, surgical energy devices and endoscope-related equipment are manufactured at six sites in Germany, the Czech Republic and the UK.

#### Strength in Advanced Manufacturing Technology

The factories in Japan develop and manufacture gastrointestinal endoscope systems from basic components and have a unique strength in manufacturing that requires a high level of precision and one-of-a-kind assembly expertise on the part of the manufacturing staff. Flexible endoscopes are manufactured exclusively at the Aizu factory. For the main components of the endoscope, such as the imaging unit, control section, and electrical connector, there are plans to unify development and manufacturing and to isolate and develop essential key technologies, while realizing high-mix, low-volume production. For example, Olympus decided to develop the machining equipment necessary to manufacture the stainless steel distal tip of the endoscope in-house, thus keeping this knowledge within the company. Products manufactured by the Shirakawa factory include video processors and light sources for endoscopes, ultrasound endoscopes, and capsule endoscopes. The strengths here are component technologies for electrical equipment (including semiconductors and circuit boards), circuit design, and quality assurance. By employing the Kaizen (improvement) activity, quality improves daily and production lead times are dramatically shrinking. The Aomori factory features high-tech production of endotherapy devices. The factory specializes in therapeutic devices such as electrosurgical snares for gastrointestinal polypectomy, devices for use in biliary ducts, etc. The Hinode factory manufactures disposable products and prototypes. The Vietnam factory, which was established as a satellite factory of the Aomori facility, produces endotherapy devices and related products.

Characteristics of Endoscopy System Manufacturing Techniques that Realize High-Mix, Low-Volume Production

The number of different variations of endoscopes we offer grows each year, and we currently offer more than 300 different models of endoscopes. Creating endoscopes requires sophisticated manufacturing technologies as well as high-mix, low-volume production systems. On top of fulfilling these requirements, we have maintained a stance toward production that compels us to develop components and equipment ourselves should the market be unable to supply us with items that meet our expectations for craftsmanship. As the components of endoscopes have incredibly intricate structures, it is impossible to find ready-made blades for their production. Therefore, each time we need to develop new endoscope components, we start by creating custom blades and other tools capable of meeting our design specifications. The unique products Olympus offers are the result of an ongoing, comprehensive process of in-house craftsmanship, which entails resolving issues on our own. This thorough process has enabled us to earn the trust from the world that we hold today.

Detailed eye for customer needs

#### High-Mix, Low-Volume Production

In-house development of materials, capabilities, and crafted components not otherwise available

High-precision crafting technologies that create components accurate to the micron

Japanese assembly technologies that make fine adjustments based on combinations of various technologies and expertise





High-precision endoscope tips

Highly precise scope assembly process

# TSD



# **Therapeutic Solutions Division**

In its Therapeutic Solutions Business, Olympus uses innovative capabilities in medical technology, therapeutic intervention, and precision manufacturing to help healthcare professionals deliver diagnostic, therapeutic, and minimally invasive procedures to improve clinical outcomes, reduce overall costs, and enhance the quality of life for patients. Starting with its early contributions to the development of the polypectomy snare, Olympus' Therapeutic Solutions portfolio has grown to include a wide range of medical devices to help prevent, detect, and treat disease.

# Features of TSD

# Focus on three therapeutic areas (GI-Endotherapy, Urology, and Respiratory)

In TSD, we contribute to minimally invasive treatment across multiple clinical specialties. In particular, we continue to strengthen the product portfolio in the categories of GI-Endotherapy, Urology, and Respiratory.

# **02** Globally managed from the U.S.

Strengthen access to key medical clusters and customers in the U.S., the world's largest therapeutic device market.

03

Enhance capabilities and increase activity in business development in an effort to expand the product portfolio through external partnerships, licensing and M&A

Conducted multiple M&A activities, mainly in the GI-Endotherapy, Urology, and Respiratory.



Figures of "Respiratory-Capital" and "Respiratory-Consumables" exclude the impact of the Veran Medical Technologies acquisition in December, 2020

# **O1** Focus on three therapeutic areas (GI-Endotherapy, Urology, and Respiratory)

## Focus areas in the TSD

In TSD, we focus on areas where we are highly competitive. In the areas of GI-Endotherapy, Urology, and Respiratory, we are in a strong position to grow through investments in our product portfolio, educating the market on new, advanced, therapeutic techniques, and leveraging our global sales channels.



Urology 😲	Strategy Becoming cancer the differentia	y the global leader in BPH, ston rough customer-focused innova tion	e management and bladder ation and compelling clinical
Category	<ul> <li>Benign prostate</li> <li>hyperplasia</li> <li>(BPH)</li> </ul>	2 Urinary stone	3 Bladder tumor (bladder cancer)
23			
1	Minimally invasive treatment device for BPH	Thulium fiber laser system	Resectoscope
Medi-Tate	In May 2021, Olympus acquired Mexpand its urology portfolio. Representative product: iTind A minimally invasive treatment de in medical offices and clinics, no pre-treatment options.	Nedi-Tate Ltd., an Israeli medic vice for the treatment of BPH. I permanent implants for the pati	al device company, to t allows for day treatment ient, and a wide range of
	> Please refer to page	s 31-32 for main diseases, procec	dures, and products in this area.
	Delivering	market-leading solutions desig	ned to improve care and
Respiratory	Strategy prognosis and stagin	of lung cancer patients throug	h accurate, early diagnosis
Respiratory	Strategy prognosis and stagin EBUS-TBNA (Endobronchial ultrasound transbronchial needle aspiration)	of lung cancer patients throug  2 Peripheral bronchoscopy	<ul> <li>Diagnostic and therapeutic bronchoscopy</li> </ul>
Respiratory C Category Tracheobronchial tree Lymph nodes	Strategy prognosis and stagin CEBUS-TENA (Endobronchial ultrasound transbronchial needle aspiration)	of lung cancer patients throug ag  Peripheral bronchoscopy	<b>3</b> Diagnostic and therapeutic bronchoscopy
Respiratory	Strategyprognosis and staginContraction	of lung cancer patients throug ag 2 Peripheral bronchoscopy SPiN navigation system	h accurate, early diagnosis 3 Diagnostic and therapeutic bronchoscopy
Respiratory	Strategyprognosis and staginCEBUS-TENACEndobronchial ultrasound transbronchial needle aspiration)CCCEBUS-TBNA system	of lung cancer patients throug 2 Peripheral bronchoscopy SPIN navigation system	h accurate, early diagnosis 3 Diagnostic and therapeutic bronchoscopy i
Respiratory	Strategy       prognosis and stagin         Image: Construction of the stage of th	of lung cancer patients throug ag 2 Peripheral bronchoscopy SPiN navigation system uired Veran Medical Technolog ention field*4, to expand its resp	A local to improve data and h accurate, early diagnosis          3 Diagnostic and therapeutic bronchoscopy         Image: Strate of the strate
Respiratory	Strategy       prognosis and stagin and stage and stag	of lung cancer patients throug ag Peripheral bronchoscopy SPiN navigation system uired Veran Medical Technolog ention field*4, to expand its resp pracic Navigation System® a system that supports insertion ad peripheral portions of the bro	<b>3</b> Diagnostic and therapeutic bronchoscopy <b>3</b> Diagnostic and therapeutic bronchoscopy <b>3</b> Diagnostic and therapeutic bronchoscopy <b>5</b> Diagnostic and therapeutic bronchoscopy <b>1</b> Diagnostic and therapeutic bronchial valve system <b>1</b> Diagnostic and therapeutic bronchoscopes and onchus.

\*1 Endoscopic Retrograde Cholangio Pancreatography
\*2 Endoscopic Submucosal Dissection
\*3 Endoscopic Mucosal Resection
\*4 Treatment and diagnosis using a bronchoscope

# **02** Globally managed from the U.S.

Olympus' global headquarters for the TSD is located in the U.S., which is the world's largest market for therapeutic devices and the highest-selling market in our business.

We also make global decisions in the U.S. because we have access to a large number of hospitals, research institutions, competitors, and customers.



U.S.-based global headquarters for the TSD

# **03** Enhance capabilities and increase acitivity in business development in an effort to expand the product portfolio through external partnerships, licensing, and M&A

The establishment of a global headquarters in the U.S. has enabled us to efficiently and quickly expand and complement our product portfolio through collaboration with external partners, licensing, and M&A. In particular, during the recent period from 2020 to 2021, we have executed multiple M&A: in August 2020, we acquired Arc Medical Design Ltd., a UK medical device manufacturer; in December 2020, Veran Medical Technologies, Inc., a U.S. company focusing on the respiratory intervention field; and in May 2021, Medi-Tate Ltd., an Israeli medical device company. We are expanding our portfolio in GI-Endotherapy, Respiratory, and Urology, respectively. In order to contribute to minimally invasive treatments, we will continue to accelerate our growth not only through in-house development but also by considering external partnership and distribution agreement.



> Please refer to the News Release of the links for details.

#### Approach to Reusable and Single-use Endoscopy

As part of our corporate strategy unveiled in November 2019, a key strategic effort to further strengthen our leadership in endoscopy is to complement our reusable endoscopy product portfolio with singleuse endoscopes. Reusable endoscopes will continue to be the first choice for a wide range of procedures due to the strong clinical need for advanced imaging and maneuverability as well as their financial efficiency for hospitals. At the same time, as single-use endoscopy is quickly becoming a relevant option for selected procedures, the market for single-use endoscopes is expected to grow by 20-40% annually over the next couple of years.

Areas in which we plan to develop (or launched) single-use endoscopes (As of September 2021)



#### New Product Launch in the U.S.

In April 2021, Olympus announced the expansion of our respiratory portfolio with the launch of our first line of single-use bronchoscopes, the H-SteriScopes™.

Available in five models, this disposable bronchoscope includes premium features that will help clinicians target, diagnose and treat patients while enhancing workflow and productivity.



Note: The H-SteriScope portfolio is a collaboration between Veran Medical Technologies, Inc., a wholly owned Olympus subsidiary, and Hunan Vathin Medical Instrument Co., Ltd.

# Main Diseases, Procedures, and Products

#### GI: Digestive Tract (Esophagus/Stomach/Large Intestine/Small Intestine)

#### Main diseases 1 Esophageal Cancer

The walls of the esophagus are made from multiple layers of mucosa and muscle. Cancer of the esophagus typically occurs in the innermost mucosa. This is called "squamous cell carcinoma" and over 90% of Japanese people with cancer of the esophagus have this type of cancer. Habitual drinking and smoking are sources of risk. There is another type of esophageal cancer called "adenocarcinoma" which is more common in Europe and the U.S. This type of cancer is found in 60-70% of esophageal cancer cases in Europe and the U.S. The primary cause of adenocarcinoma is a condition called Barrett's esophagus, where stomach acid flows up the esophagus and causes inflammation of the esophageal mucosa.

#### Main diseases 2 Stomach Cancer

It is thought to arise in the mucosas of the stomach from gastritis and atrophy. When atrophy occurs in the mucosas of the stomach, it leads to atrophic gastritis, which can lead to "intestinal metaplasia," a condition in which the stomach-type mucosa turns into intestinal-type mucosa. Intestinal metaplasia is known to develop into cancer. Recently it has been shown that this is related to the bacterium Helicobacter pylori. H. pylori causes inflammation of the mucosa in the stomach and has been observed to lead to atrophic gastritis and intestinal metaplasia.





# Main diseases 3 Large Intestine Cancer

It is increasing in Japanese people as they are starting to eat a more Western diet. Cancer of the large intestine includes both colon cancer and rectal cancer, but colon cancer especially is increasing rapidly. Consuming animal fats causes greater secretion of biliary acid to help with digestion. There are carcinogens among the substances that develop when digesting fats. It is believed that cancer occurs in the mucosa of the large intestine.

The inside of the large intestine consists of four layers. Sometimes, benign polyps called adenomas occur in the mucosa. Many cases of colorectal cancer are believed to be related to these polyps. Furthermore, it has been recently discovered that there are also flat and depressed cancers that develop directly from the mucosa. The most common areas for colorectal cancer are the rectum and sigmoid colon, which cancers account for about 70% of all cases.

#### Main diseases 4 Colon Polyp

A tissue that protrudes from the mucous membrane of the colon is called a colon polyp. The polyp has a high probability of occurring in the rectum or the sigmoid colon, and its size is between a few millimeters and 3cm. They are largely divided into neoplastic and non-neoplastic polyps. Small polyps are generally asymptomatic, but if they become large, symptoms such as fecal occult blood and fresh blood in the stool can occur.

## Main diseases 5 Small Intestinal Ulcer

An ulcer that appears in the small intestine. Frequency of occurrence is not high, with less than a 5% chance overall of becoming a gastrointestinal tumor, however, malignancy is high since two-thirds of all small intestinal ulcers are malignant tumors. These ulcers are mainly discovered when examining such symptoms as pain, bleeding, or stricture of the abdomen. Although early diagnosis is difficult, through the improvement of endoscope technology, such as capsule endoscopes and balloon endoscopes, which enable detailed examination of the small intestine, small intestinal tumors are being discovered with greater frequency.





Small intestine and surrounding organs

#### Main diseases 1 2

#### Main scopes used in ESD

#### **Gastrointestinal Scope**

Gastrointestinal videoscopes are for viewing the stomach and duodenum through the esophagus and usually have an insertion tube length of 1,030mm. Videoscopes have a forward-facing lens on the distal tip which is ideal for observing tissue directly in front of the endoscope. Videoscopes designed to be inserted through the mouth typically have an insertion tube diameter of around 10mm; videoscopes designed for passage through the nose are about half that diameter.



Gastrointestinal videoscope

#### Main diseases 3 4

#### Main scopes used in ESD

# Colonovideoscopes are longer than gastrointestinal videoscopes in order to accommodate the long 1.5m length of the adult large intestine. Standard-length colonovideoscopes are 1,330mm long. Extended length models are 1,680mm long. The colonovideoscope has a forward-facing tip. In order to facilitate insertability into the colon a flexibility adjustment ring allows the operator to adjust the stiffness of the insertion section during the procedure. Colonovideoscopes typically have an insertion tube diameter of around 13mm.

Colonoscope



#### Main diseases 5

#### Main scopes used in ESD

# Small Intestinal Scope

This involves using an endoscope with a balloon attached on the distal end such that the inflated balloon holds the intestine open and allows the endoscope to be moved forward. Insertion can be via either the mouth or anus. As the instrument channel outlet is also provided, as on a conventional endoscope, it can be used for biopsies or to perform simple procedures. To be long enough to view the small intestine, the endoscope has a length of 2,000mm and a diameter of approximately 9mm.



Small intestinal videoscope

Single balloon enteroscope

#### Ultrasound Gastrovideoscope

In addition to regular endoscopes, Olympus manufactures "ultrasound videoscopes" that allow combined endoscopic imaging and ultrasound imaging of the organ under inspection. They have an ultrasound transducer installed on their tip. By using medical ultrasound technology, lesions that cannot be seen from the surface and are located deep in the organ can be found. In the digestive tract, this kind of endoscope is used to find tumors and cancers hidden below the surface of the GI tract and to examine varices in the esophagus. They are also used to find cancer, gallstones and pancreatic stones in the pancreas and biliary tract. Biopsy needles inserted under ultrasound guidance can diagnose hidden submucosal tumors and diagnose and treat pancreatic cysts.





Ultrasound gastrovideoscope

Ultrasound image

# ENDO-AID, an Endoscopy CAD\*1 Platform Equipped with an AI-powered Diagnostic Support Application for Colonoscopies

When used in combination with the EVIS X1 gastrointestinal endoscopy system, ENDO-AID serves as a CAD platform that can automatically detect and display possible lesions such as polyps and cancer in real time. By adding AI-powered support, ENDO-AID makes colonoscopies easier for both physician and patient and aims to improve overall clinical results regardless of the doctor's experience. Equipped with ENDO-AID CADe\*<sup>2</sup>, a detection support application for lesions in the large intestine.



### ENDOCUFF VISION™, Colonoscope Distal Attachment

This device is attached to the colonoscope's distal end to support visualization in procedures such as colonoscopy screening and polyp removal. ENDOCUFF VISION™ features a proprietary design comprised of a flexible arm with extensions placed on the device circumference. The arms open the colon's bended section and mucosal folds, providing a clearer view inside the colon and making it easier to detect polyps and adenomas. Research\*<sup>3</sup> shows that compared with standard colonoscopies, those performed using this technology increase the adenoma detection rate (ADR) by up to 11%. According to this research, each 1% improvement in the ADR lowers the risk of colon cancer by 3%.



#### PowerSpiral, Small Intestine Endoscope System

A small intestine endoscope system that reaches the target site by pulling the small intestine over the device through motorized rotation. The system incorporates the world's first foot-switch-operated motor to rotate an overtube, which is equipped with spiral-shaped fins positioned on the endoscope. The PowerSpiral may improve scope maneuverability and shorten procedure times.



\*1 Computer Aided Detection/Diagnosis: Al-powered diagnostic and detection support

\*2 Computer Aided Detection: AI-powered detection support

\*3 Williet, N., Tournier, Q., et al. Effect of Endocuff-assisted colonoscopy on adenoma detection rate: meat-analysis of randomized controlled trials. Endoscopy, 50 (9), 846-860. Doi:10.1055/a0577-3500. Available at: https://www.ncbi.nlm.nih.gov/pubmed/29698990

Diagnostic method regarding main diseases 1 2 3 4 5



A biopsy is a diagnostic procedure that removes pieces of tissue which is suspected of being a lesion, subject to pathological testing under a microscope.



**Biopsy Forceps** 

Biopsy forceps include the standard type and also a type with a needle which prevents slipping on the surface of mucosa. Various biopsy forceps are used such as a single-side opening type for the esophagus and the wide-opening type used for stiff mucosa.



Biopsy

Biopsy forceps with needle Diagnostic method

Main endotherapy devices used in TSD

regarding main diseases 4

#### regarding main diseases 1 2 3 4 5

In order to identify tumors or other lesions in the early stages, dye, such as Indigo carmine solution and Lugol iodine solution, is sprayed on the surface of the mucosa. This procedure enables easier observation of mucosal surface shape change. F

Spraying Lugol into the esophagus (image)

Spraying tube

An endotherapy device for spraying dye on an observation site.

# Method of treatment in internal medicine Polypectomy

**Dye Spraying** 

Spraying Tube

A polypectomy is a procedure that removes local elevated lesions called polyps which grow out of the mucous epithelium. A wire snare is looped around the base of the polyp, and a high-frequency electrical current is applied while the snare is tightened. The polyp is then burned off and collected using gripping forceps. There is also a method called "cold polypectomy," in which polyps of less than 10mm are squeezed and removed without applying high-frequency current.

Main endotherapy devices used in TSD

# **Electrosurgical Snare**

An electrosurgical snare is forceps made of looped metal wire. The therapeutic device applies a high-frequency current to ligate the lesion site and then burn off the lesion. Among high-frequency snares are ones that can carry out a cold polypectomy that severs the lesion without applying a high-frequency current.



Polypectomy



Electrosurgical snare

Method of treatment in internal medicine regarding main diseases 4

# **Hot Biopsy**

For small polyps and relatively flat (sessile) polyps, a procedure called a biopsy can be performed. While pinching the polyp with a biopsy forceps, high-frequency current is used to remove the tissue and cauterize the polyp base, preventing bleeding from the site.

#### Main endotherapy devices used in TSD

# Hot Biopsy Forceps

Hot biopsy forceps can collect tissue while applying a high-frequency current to a cup unit. The end section is about the same structure as a biopsy forceps. The operating section has a plug for connecting to an electrosurgical generator.



Hot biopsy

Hot biopsy forceps

Method of treatment in internal medicine regarding main diseases 1 2 3 4

# Endoscopic Mucosal Resection (EMR)

EMR enables the removal of small flat lesions such as early-stage cancers. There are several techniques for performing EMR. One of these is so-called "cap EMR" (EMRC). This procedure uses a transparent plastic cap fitted over the tip of the endoscope. The lesion is first raised by injecting normal saline into the submucosa under the lesion. The raised tissue is then sucked into the cap attached to the tip of the endoscope and is cut off using an electrosurgical snare positioned inside the cap. The lesion is then recovered using suction.

Main endotherapy devices used in TSD





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EMRC method

Clear cap

Equipped with a scope end-section, clear cap is used to remove a lesion by suction.

#### Appendix

Method of treatment in internal medicine regarding main diseases 1 2 3

# Endoscopic Submucosal Dissection (ESD)

EMR is limited to removing lesions smaller than 2cm. ESD was developed as a procedure for removing much larger (and more irregularly shaped) lesions. First, an electrosurgical electrode is used to make small burn marks to outline the area around the lesion. The lesion is then raised by injecting normal saline into the submucosa to separate the lesion from the normal tissue below. Next, the mucosa around the lesion is cut using an electrosurgical knife. The submucosa is then separated, and the lesion is recovered using forceps.



ESD

Electrosurgical knife

Main endotherapy devices used in TSD

#### **Electrosurgical Knife**

A therapeutic device for removing larger early-stage lesions. There are knives with a ceramic insulator attached to the tip of the needle knife. The insulator lowers the risk of perforation in the digestive tract and also enables large-scale mucosa removal.

Method of treatment in internal medicine regarding main diseases 1 2 3 4 5

# Hemostasis

A hemostasis procedure is sometimes required to control the bleeding that results from removing polyps and other lesions. There are several ways to stop bleeding using an endoscope.

#### Main endotherapy devices used in TSD



Clip



Clip hemostasis

High-frequency hemostatic forceps

#### Main endotherapy devices used in TSD

# High-Frequency Hemostatic Forceps

Hemostatic forceps that use high-frequency securely grip large blood vessels or hard and slippery tissue, enabling coagulation to occur.

#### Method of surgical treatment

regarding main diseases 2

# Laparoscopy-Assisted Distal Gastrectomy (LADG)

This surgery is limited in application to early-stage cancers from the lower part of the stomach (pyloric antrum) to the middle of the stomach (body of the stomach). The standard procedure is to remove at least two-thirds of the stomach and the lymph nodes around the stomach. The reason this is called a "laparoscopy-assisted" procedure is that the surgery requires a laparotomy, albeit with a smaller incision.

The two basic methods for reconstructing the stomach are the Billroth I method and the Roux-en-Y method. In the Billroth I method, the remaining stomach and the duodenum are joined. In the Roux-en-Y method, the remaining stomach and the jejunum are joined, and the remaining duodenum is connected to the bottom of the jejunum. Food flows from the stomach to the jejunum, where it mixes with digestive fluids that flow in from the duodenum.

If these surgeries are not appropriate for the patient, there is still another kind of stomach cancer surgery called Laparoscopy-Assisted Total Gastrectomy (LATG).





Billroth I method

Roux-en-Y method

Method of surgical treatment

regarding main diseases 3

# Laparoscopy-Assisted Colectomy

Colorectal cancer surgeries target the large intestine, cecum, and rectum. As with stomach cancer, the goal of these surgeries is to remove the affected area as well as the associated lymph nodes. Compared to the stomach, the structure of arteries and veins supplying the colon is simple and the removal of associated lymph nodes is easy. Therefore, it is said that there is a high chance that laparoscopy-assisted colectomy may become the standard surgery for colorectal cancer in the near future.



Laparoscopy-assisted colectomy Note: The above image of the procedure is from the case report by Dr. Arita of Kyoto Prefectural University of Medicine.

#### Surgical Systems Main therapeutic devices used in TSD

> Systems used in surgery are described on pages 36-37.

#### GI: Biliary Tract/Pancreas

#### Main diseases 1

Gallstones

A medical condition in which a stone can appear in the biliary tract (generic term for the bile duct, gallbladder, and major duodenal papilla). Gallstones that form in the gallbladder are particularly common. Biliary tract cancers, which can appear in the gallbladder and bile duct, are understood to be connected to gallstones. If gallstones injure the biliary tract, they can cause inflammation, which can turn into cancer if prolonged.

#### Main diseases 2

### **Pancreatic Cancer**

It comes from pancreatic cells. Pancreatic cancer is divided into two types: exocrine (digestive enzyme secretion system) and endocrine (hormone secretion system). About 95% of pancreatic cancer is of the exocrine type, and about 85% of these are invasive pancreatic duct cancers that occur on the epithelium of the pancreatic duct. Pancreatic cancer typically occurs in individuals who are 50-70 years old, especially in elderly males.



#### Main diseases 1 2

#### Main scopes used in ESD

#### Unlike gastrointestinal videoscopes and colonovideoscopes, duodenovideoscopes have a side-viewing tip design in which the lens and illumination optics are on the side of the scope. This enables the scope to perform procedures such as Endoscopic Retrograde Cholangio Pancreatography (ERCP) that is imaging of the pancreaticobiliary ducts via the duodenum, and for performing Endoscopic Sphincterotomy which allows removal of gallstones via the mouth. This endoscope has a prism at its tip to allow it to look perpendicular to its axis, and a forceps elevator to deflect accessory devices in the same direction. Duodenovideoscopes typically are 1,240mm long.

Note: A single-use scope is planned for future release.

#### Main diseases 1 2

#### Main scopes used in ESD

## Cholangioscope

Duodenoscope

Cholangiovideoscope is a miniature scope inserted in the instrument channel of a duodenovideoscope. It can be used for direct observation inside the narrow duct of the pancreaticobiliary system or to collect tissue.

Note: A single-use scope is planned for future release.

#### **Diagnostic method** regarding main diseases 1 2

# Endoscopic Retrograde Cholangio Pancreatography (ERCP)

ERCP is method for examining the biliary tract and pancreatic duct using a combination of endoscopic and radiographic techniques. Using an endoscope, a thin tube (cannula) is inserted through the papilla of Vater into a duct of the pancreaticobiliary system. Radiological contrast dye is then injected into the ducts, and the area is viewed using X-rays.

Main endotherapy devices used in TSD

## Cannula



FRCP



#### Cannula

A thin tube for injecting radiological contrast dye into the pancreatic or bile duct that can then be viewed by X-rays.





Side-viewing tip design (including forceps elevator system)



Cholangiovideoscope

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#### Appendix

Method of treatment in internal medicine

#### regarding main diseases 1

# Endoscopic Sphincterotomy

It is a procedure that is often used to remove gallstones. A papillotomy knife (papillotome) is inserted into the opening of the duodenal papilla, and the papillary sphincter is cut open. Following this, a stone extraction balloon or stone retrieval basket can be inserted into the biliary ducts to remove any gallstones residing in the biliary system.

#### Main endotherapy devices used in TSD

### Papillotome

An electrosurgical knife inserted into the papilla at the end of the bile duct for use in incision using high frequencies.

Main endotherapy devices used in TSD

# Stone Extraction Balloon

A balloon-shaped catheter used to scrape out small stones resembling sand and silt.

#### Main endotherapy devices used in TSD

# Stone Retrieval Basket

An endotherapy device that is used to help retrieve and remove stone fragments from the bile duct.





Endoscopic Sphincterotomy

Papillotome



Stone extraction balloon

Stone retrieval basket

Method of treatment in internal medicine

regarding main diseases 1

# Endoscopic Biliary Drainage (EBD)

If the free flow of bile to the duodenum is hindered due to gallstones or a stricture (narrowing) of the bile duct due to disease, EBD may be performed by inserting a plastic or metal stent into the duct to allow the free flow of bile.

#### Main endotherapy devices used in TSD

## **Plastic Stent**

Metal Stent

When a bile duct has a stricture or blockage, this stent is inserted into the duct and releases bile. The device is implanted for a short period of time (around several weeks).

#### Main endotherapy devices used in TSD



EBD

Plastic stent

This stent is made of metal mesh. The post-implantation lumen is larger than for a plastic stent and can be expected to have large drainage. Comparatively long-term (several months) patency and detainment is possible.

Method of surgical treatment

#### regarding main diseases 1

# Laparoscopic Cholecystectomy

This is the most common type of endoscopic surgery in Japan. The gallbladder is attached to the underside of the liver, and must be carefully removed using an electrosurgical knife and dissecting forceps. Next, the cystic artery and cystic duct are clamped with clips and cut to separate them from the liver. Finally, a trocar is inserted and the gallbladder removed from the body through the trocar using grasping forceps.

Main therapeutic devices used in TSD



> Systems used in surgery are described on pages 36-37.



Detachment of gallbladder



Removal through incision



**Benign Prostate Hyperplasia** 

#### Main diseases 1

#### (BPH)

A condition in which urination is obstructed by pressure placed on the urethra by an enlarged prostate, which is located under the bladder. Symptoms include a sensation of residual urine and more frequent trips to the toilet due to the reduced amount of urine passed at each urination.



A condition in which substances contained in urine crystalize for some reason and coalesce in the form of a stone. Typical symptoms include extreme pain, bloody urine, or the presence of the stone in urine.

Main diseases 3 B

## Bladder Tumor (Bladder Cancer)

This occurs when the urothelium becomes cancerous. While most cases (90% or more) are categorized as urothelial cancer, rare instances of squamous cell carcinoma and adenocarcinoma also occur. The main symptoms are bloody urine or pain during urination.



#### Main scopes used in TSD

# Ureteroscope/Cystoscope

They are used for viewing the urinary bladder through the urethra and the kidneys through the urinary duct. Olympus manufactures both videoscopes and fiberscopes for this application. The videoscope version supports high-definition imaging due to its high performance CCD and is also capable of NBI. Moreover, in order to facilitate the observation of the bladder neck, both the Up and Down sides bending angle of 275 degrees are realized.

Note: A single-use scope (ureteroscope) is planned for future release.



# Main scopes used in TSD Resectoscope

A resectoscope is a rigid endoscope for diagnosing and treating the urethra and bladder. It is inserted in from the external urethral orifice and used for the surgical resection of a lesion with high-frequency current.



Ureteroscope

Flexible bending function







# Transurethral Resection (TUR)

TUR is a procedure in which a surgeon inserts a resectoscope from the urethra and then, using the handle, operates a loop-shaped electrode to surgically resect tissue from an enlarged prostate or a bladder tumor with an electrosurgical knife. For a safe procedure and precise resection, the solution from Olympus is the TURis procedure, in which a resection is performed by discharging electricity from the entire area surrounding the electrode through saline.

Main therapeutic devices used in TSD

# Electrosurgical Generator

The equipment enables incision of a lesion and coagulation by connecting to an endotherapy device and generating a high-frequency current.



Resection of the enlarged prostate when a resectoscope is inserted transurethrally near the neck of the urinary bladder





Electrosurgical Generator

Resectoscope and special-use electrode

Seminal gland Prostate Testicle

Urinary system

Method of treatment regarding main diseases 1

# **Treatment through** Non-Ablative Device

Olympus is rolling out iTind, a minimally invasive treatment device that ensures urine flow by expanding the urethra over the span of five days after longitudinally implanting a three-wire nitinol device in the prostate. iTind enables a patient to be treated at a doctor's office or clinic, returning home the same day, and to achieve resolution of symptoms without a permanent implant left behind.

# Transurethral Lithotripsy (TUL)

During Lithotripsy, an urologist navigates an endoscope through the urinary tract and uses laser or ultrasonic energy to break up one or more stones in the bladder, ureter, or kidney. The resulting stone fragments may be expelled naturally or can be removed using stone retrieval baskets.

Main therapeutic devices used in TSD

# Thulium Fiber Laser System

This product uses superpulsed thulium fiber laser technology for the removal of stones in the urinary tract (the kidney, ureter, bladder, and urethra) and for resection of soft tissue. It works by breaking up the stone into tiny pieces which are then passed out of the body during urination. The device helps shorten operation time by improving performance for breaking the stones. The device is also used to treat soft tissue (such as the prostate), enabling Olympus to provide urologists with a variety of procedural solutions. The compact size of the equipment helps to save space and make movement easier between operating rooms.

#### Respiratory

# Main diseases 1 Lung Cancer

Lung cancer consists of malignant tumors of the bronchial tubes and pulmonary epithelium. Instances are on the rise due to smoking and other causes. Among cancers, it has the highest mortality rate worldwide.\*

\*WHO cancer statistics: http://www.who.int/news-room/fact-sheets/detail/cancer

#### Main diseases 2 Emphysema

A condition caused by the over-inflation of the alveoli located at the tips of the bronchi leading to the destruction of lung functions. It is defined as one of the forms of chronic obstructive pulmonary disease (COPD) in which inhalation of tobacco or other harmful substances causes inflammation of the lungs and bronchus, which in turn causes progressive breathing difficulties.

Main diseases 1 2

#### Main scopes used in TSD

## Bronchoscope

Olympus manufactures three types of bronchoscopes for viewing the lungs and bronchial tubes: videoscopes, fiberscopes, and a "hybridscope" which has both fiber-optic and video components. Bronchoscopes may be inserted either through the mouth or the nose and can travel down to examine the smallest lumens of the bronchial tree. Videoscopes have an advantage in obtaining sharp pictures of the lung through their high quality CCDs. Fiberscopes have an advantage in being smaller in diameter at the tip and therefore allow for deeper insertion into the distal portion of bronchial tubes. The hybrid type has a fiber-optic bundle in its tip and a CCD image sensor installed in its control section. This instrument incorporates advantages of both videoscope and fiberscope technology, with high insertability due to its small diameter while at the same time also producing high-quality images.

Note: In April 2021, sales started in the U.S. for Olympus' first single-use bronchoscope.



Minimally invasive treatment device for BPH



Image of removing stones with stone retrieval baskets



Thulium fiber laser system







Bronchoscope

> For details see page 23.

#### Appendix

#### **Electromagnetic Navigation System**

This system supports the insertion of bronchoscopes and therapeutic devices into narrowly diverged peripheral areas in the lung. Through the spread and expansion of low-dose CT scans, lesions on the bronchial periphery are being discovered more frequently. To address this situation, the system supports bronchial tube examinations for the purpose of collecting tissues and cells of the lesion site and conducting definitive diagnosis.



Electromagnetic navigation system

#### **Diagnostic method** regarding main diseases 1

# **EBUS-TBNA**

#### (Endobronchial ultrasound transbronchial needle aspiration)

A technique mainly for the purpose of diagnosing lymph node metastasis in lung cancer. The procedure uses ultrasonic images in real time to guide the insertion of a needle into the lymph node via the trachea and bronchus for the collection by aspiration of cell or tissue samples. The collected samples are observed and diagnosed in detail by pathological examinations before deciding on the next course of treatment.

#### Main endotherapy devices used in TSD

#### Aspiration Needle

This endotherapy device is guided by a ultrasound endoscope and is used for the collection by aspiration of cell or tissue samples from the trachea and bronchus.



EBUS-TBNA system

EBUS bronchoscope and aspiration needle



Cytology is performed by scrubbing a brush over a mucosa and observing the

A brush for collecting cells from the bronchial tubes with narrow openings. The cytology

#### Main endotherapy devices used in TSD

collected cells under a microscope.

#### Cytology Brush

Cytology





Cytology of bronchus

Cytology brush

Method of treatment regarding main diseases 2

brushes are 1-5mm in diameter and less than 10mm in length.

# **Bronchoscopic Lung** Volume Reduction

A minimally invasive procedure for emphysema. The procedure reduces lung volume by deploying a valve within the bronchial tube to close off the lung cells. Specifically, a small, umbrella-shaped valve is implanted in the lung's upper lobe bronchus via a catheter inserted into the instrument channel of a bronchoscope. The purpose is to redirect the airflow from the unhealthy part of the lung to a normal section through the effects of a one-way valve used as the implanted valve.

#### Main endotherapy devices used in TSD

## **Endobronchial Valve**

This valve is a therapeutic device for emphysema. It is used when medicines have no effect or in which neither a lung reduction procedure nor transplant surgery is not applicable. It is also used to treat postoperative prolonged air leaks arising from a pneumothorax or lung surgery.



system



Intrabronchial valve Endobronchial valve

#### Appendix

Method of treatment

#### regarding main diseases 1

**Pulmonary Resection** 

Lung cancers are now being surgically resected using endoscopes. Thoracoscopic partial lung resection surgery can be performed for removing tumors smaller than 3cm in diameter, and lung lobectomies performed for treating areas greater than 4cm in breadth.

Main therapeutic devices used in TSD

# Surgical Systems

> Systems used in surgery are described on pages 36-37



#### Main diseases 1

#### **Tympanitis**

A condition in which the infection of the middle ear by bacteria, viruses, or other germs due to a cold, etc., causing inflammation and a buildup of pus or fluid. Symptoms include headache, dizziness hearing difficulties, or the ear feeling blocked.

Main diseases 2 Sinusitis

What is commonly known as empyema is a condition resulting from inflammation of the paranasal sinus due to causes such as a common cold, hay fever, or dental decay. It results in a blocked nose with thick colored mucus. Other symptoms include headache and an impaired sense of smell.

#### Main diseases 3 Laryngeal/Pharyngeal Cancer

A throat cancer common among males. The symptoms, which include a sore throat and loss of voice, are similar to the common cold.



# Rhino-Laryngo Scope

Rhino-Laryngo videoscopes are used for looking at the ears, nose, and throat. Latest videoscopes mount ultra compact, high-performance CCD, and realize great advances in image quality compared with conventional models. They are also able to perform NBI.

Method of treatment regarding main diseases 2

# **Endoscopic Sinus** Surgery (ESS)

A minimally invasive treatment for treating sinusitis (empyema) in which chronic inflammation of the paranasal sinuses (cavities enclosed in bone located near the nasal cavity) causes them to fill with pus and contaminated mucosas. Endoscopic sinus surgery uses an endoscope to provide a view inside the nose while using a debrider to perform treatment.

Debrider

#### Main therapeutic devices used in TSD

A debrider is a surgical device for removing abnormal tissue with simultaneous use of suction and cutting.









Pulmonary Resection (image)



Nose/Throat



videoscope

Debrider

# Structure and Components of Endoscopes

#### **Outline of Gastrointestinal Endoscopy System**

Current gastrointestinal endoscopes for examining the esophagus, stomach, and large and small intestines are mostly videoscopes. Videoscopes have an electronic image sensor attached to the distal tip of the instrument. A videoscope system consists of the following equipments.

# Main body : LCD monitor

#### Video system center

The video system center converts the electrical signals from an image sensor at the tip of a videoscope into video signals and displays them on an LCD monitor.

In addition to high-definition vision, the system supports various types of image processing including color enhancement and Narrow Band Imaging (NBI). The latest units are integrated with a light source and come equipped with an LED with a long life span. To improve color reproductivity, the system has adopted five-color LEDs supporting violet, blue, green, amber, and red. It also has an automatic dimming feature (automatically adjusts the brightness) and a pump that transmits water and air.



# 2 Endoscope

1

The endoscope has three parts: the control section, the insertion section, and the connector section.

#### Control Section

The angulation knob on the control section is connected to the tip of the endoscope by a series of wires. By turning the angulation knob, the bending section at the distal end bends horizontally and vertically allowing for easier insertion into the body and the ability to view 360 degrees within body cavities.

The endoscope also contains buttons (valves) for feeding air or water and for applying suction. Covering the opening in the air/water valve will feed air into the organ being observed and will gently expand it for a better view. Depressing this valve will feed water through the endoscope to wash the viewing lens. Depressing the suction valve will allow the doctor to use the endoscope to suction any fluids which are obscuring a good view of the tissue. Endotherapy devices can be passed through the instrument channel for performing endoscopic biopsy and other treatments.

#### Insertion Section

On the tip of the insertion section, there are four main parts: 1. Objective lens and image sensor, 2. Light guides that bring light from the light source through the endoscope, 3. Instrument channel outlet where endotherapy devices can be pushed in and out (also has a suction opening), 4. Nozzle for feeding water and air.

The objective lens is typically a super-wide-angle lens in order to visualize a large area of tissue at one time. In order to view tumor tissue in a more detailed manner, some endoscopes have an optical zoom feature. They also support high-definition video displays.

Light guide fiber bundles conduct light from the external light source through the endoscope to illuminate body cavities. Endotherapy devices are pushed in and out of the instrument channel for harvesting tissue (biopsy), removing tumors, cauterizing bleeding lesions, etc. The nozzle on the distal tip is used to clean the lens with water and expand body cavities by insufflating them with air.



#### **Connector Section**



#### Connector Section

The connector section connects the endoscope with the video system center through the universal cord. Supply of air and water is also performed through this connection.

# 3 Peripheral

#### • Imaging Management Hub

Imaging management hub simplifies the process of recording, managing, and editing high-resolution endoscopic images (video and still images).



Imaging management hub

#### Appendix

#### **Outline of Surgical Endoscopy System**

The following instruments are used in endoscopic surgery. As open surgery is gradually being replaced by endoscopic surgery, the sophistication of endosurgical device has increased.

### Main body : LCD monitor Video system center

Xenon light source for IR imaging

Surgical endoscopy systems include models that are compatible with 3D endoscopes, which make it easier to grasp depth, and models equipped with 4K monitors, which provide clear, high-definition images with greater detail. The video system center with a built-in light source serves as a processor that converts the electrical signals from the videoscope into video signals to display on an LCD monitor and functions as a light source that supplies light to the scope tip via the light guide cable. Some xenon light source devices enable infra-red (IR) observation.



Imaging management hub Peripheral



#### Videoscope

In general, videoscopes have a diameter of 5-10mm and a length of 300-370mm. Their tips contain a lens, a CCD image sensor, and light guide fiber bundles for bringing illumination into the body. Some models are straight, others have deflectable tips. The CCDs in Olympus endoscopes support high-definition imaging. Focusing is unnecessary due to their broad depth of field.

#### • Rigid Endoscope (Telescope)

A wide variety of telescopes are used for various types of diagnosis and treatment. Uses in urology include transurethral prostatectomy and nephrectomy (kidney removal). Uses in ear, nose, and throat include viewing, diagnosing, and treating the eardrum, nasal cavity, and vocal cords, which is performed using a thin rigid endoscope. Rigid endoscopes are also used for myomectomy in gynecology and for viewing, diagnosing, and treating inside joint cavities in orthopedics.



Surgical videoscope

Rigid endoscope (Telescope)



#### Insufflator

The insufflator feeds carbon dioxide gas into the abdominal cavity in order to expand it and create a working space to perform surgery. A special insufflation needle (Veress needle) delivers the carbon dioxide gas to the peritoneal cavity. The insufflator monitors the pressure of the peritoneal cavity and automatically pumps in additional gas as needed to make up for gas that naturally leaks out during surgery.

#### • Imaging Management Hub

Imaging management hub simplifies the process of recording, managing, and editing high-resolution endoscopic images (video and still images).



Insufflator



Imaging management hub

#### Appendix

#### Trocar

Trocars are used to create an opening (portal) for passing endoscopic instrumentation into the body. The endoscope, forceps, electrosurgical knives, hemostatic/suturing equipment, etc., are then inserted through the trocar as needed for surgery. Olympus offers various types of trocars, such as ones that are available in diameters ranging from 5-15mm, ones that have an anti-slip balloon, and a threaded type. Currently, the most common trocars come with a sheath and are single-use.

#### • Forceps

There are various kinds of forceps—such as grasping forceps that hold tissue and needles, dissecting forceps that mechanically separates tissue, scissor forceps for cutting tissue, etc.







Tip of grasping forceps Tip of dissecting forceps



Hemostatic clip (image)



Ultrasonic energy device



High-frequency electrosurgical device (Electrode)



Bipolar & ultrasonic energy devices

#### • Hemostasis Clip

In endoscopic surgery, clips are often used to quickly close a blood vessel and stop bleeding that cannot be controlled by other means. The clips are held in a pistol-shaped clip applier. Clips are applied repeatedly like a stapler.

• Ultrasonic Energy Device

Ultrasonic devices for coagulation and cutting by converting electricity into ultrasonic vibrations. The heat is generated when the tip of the device (scissors) contacts the tissue and then cuts the tissue and causes coagulation (hemostasis).

#### • High-Frequency Electrosurgical Device (Electrode)

Olympus has commercialized electrosurgical knives that use high-frequency currents as an energy source. These devices come in two types, monopolar with one electrode and bipolar with two electrodes. Bipolar knives in particular are capable of ablation for small lesions, for example. This minimizes the risk of thermal damage to surrounding tissue.

#### • Fully-Integrated Bipolar/Ultrasonic Energy Devices

Combining the excellent hemostatic capabilities (controlling bleeding) of bipolar high-frequency energy with precise dissection of ultrasonic energy, the energy device can perform multiple tasks of vessel sealing, hemostasis, coagulation, incision, and dissection in one unit. The device meets surgeon's demands for superior medical effectiveness.

# The History of ESD: Gastrointestinal Endoscope



In 1949, with the request of Dr. Tatsuro Uji (Department of Surgery, the University of Tokvo Hospital Koishikawa Branch) that he "somehow wants to cure the stomach cancer that afflicts so many Japanese people," the Olympus technical team began development of a gastrocamera. After developing numerous essential technologies such as a miniature lamp to illuminate the inside of the stomach, a wide-angle lens to capture a large field of view, a device for winding the film, and choosing materials to construct the flexible tube used to inserted the miniature camera into the patient, they succeeded in developing a prototype in 1950 and commercialized and launched it two years later in 1952. They continued their aggressive work with doctors to improve the device, and, in turn, physicians worked on rapidly developing techniques for diagnosing ailments of the digestive organs.

However, there was a problem with the gastrocamera. Unlike the gastroscope, it could not view the inside of the stomach directly, in real time. The device blindly took photographs of the stomach's interior and the film had to be processed before the doctor could see what the gastrocamera saw. What solved this problem was the development of the fiberscope, introduced in 1957.

In 1964, with a gastrocamera already able to take sharp photographs of the stomach, Olympus released a gastrocamera with a fiberscope attached. This combined instrument allowed the doctor to both observe the stomach in real time and to take high-quality photographs for documentation. Olympus' reputation in the medical field grew. A fiberscope is made up of tens of thousands of optical fibers; each fiber with a diameter of 8 microns, a width approximately 1/10th of a human hair. As the image is transmitted optically, the endoscope itself can bend. Since doctors were now able to directly see inside the patient's body, techniques necessary for examination became easier, and the fiberscope's popularity quickly spread. The diagnostic area also expanded to the esophagus, duodenum, large intestine, bronchial tubes, and bile ducts. Furthermore, the real-time image of the fiberscope allowed medical treatment to be performed through endoscopes, which was a tremendous advantage. By inserting devices through a instrument channel and performing surgery on a tumor while looking inside the body in real time, minimally invasive procedures became possible, and reducing doctors' reliance on surgical scalpels.

#### The History of Gastrointestinal Endoscopy

#### **Roots in Ancient Greece**

"I want to view the inside of a human. I want to unravel the mysteries of life." Since ancient times, there has been a quest to find a way to observe the inside of the human body. It began with Hippocrates, the father of medicine, and ancient Greece in the 4th Century BCE. Horses were important for transportation back then and many people developed hemorrhoids from riding. By using a device, said to be the first endoscope, to observe the interior of the anus, the hemorrhoids were able to be healed through burning. Many centuries later, modern endoscopes began with the "Light Conductor," made in 1805 by the German physician Philipp Bozzini. It looked like a lantern and by inserting a metal tube into the urethra, rectum, or pharynx, the light would help with observations.

#### Named the "Endoscope" in France

In 1853, the French physician, A.J. Desormeaux, created a device for observing the urethra and bladder. This was the first time the term "endoscope" was used.

#### The First Practical Gastroscope

The first practical gastroscope appeared in 1932. It was the flexible gastroscope developed by German physician, Rudolf Schindler. It had a length of 75cm, a diameter of 11mm, and a third of the tip was curved slightly. However, since this endoscope was essentially a metal tube that was inserted into the body, the procedure was painful for the patient, and there was a possibility of accidents, such as perforation of the GI tract. Prior to WWII, their use was limited only to parts of Europe and Japan.

1985



Introduction of EVIS 1 Endoscopic Video System

In 1983, the videoscope was initially introduced in the U.S. While this first instrument was ground-breaking. Olympus' own initial offering, released in 1985, was seen as a significant improvement. A videoscope has an imaging element such as a charge coupled device (CCD) built into its distal tip. The image captured by this sensor is converted to a video signal and is then displayed on a monitor for all in the room to see. This allowed multiple doctors and healthcare professionals to observe simultaneously, and diagnostic accuracy increased rapidly. Following the introduction of videoscopes, there continued to be numerous technological advances, such as high-definition imaging, Narrow Band Imaging (NBI) and much more. Videoscopes have dramatically increased the endoscope's diagnostic and therapeutic potential.

2002



Introduction of EVIS LUCERA the World's First High-Definition Endoscopic Video System

In 2002, Olympus developed the world's first high-definition endoscopic video system. By combining advanced imaging technologies, it became possible to provide improved image accuracy capable of detecting even the smallest of lesions. The system was equipped with more advanced image processing technologies, including the index of hemoglobin (IHb) color enhancement function that highlights slight changes in mucous membrane color-the IHb pseudocolor display function that makes lesions that are normally difficult to see during observation clearly visible-and an electronic magnification function for video and still images.



Introduction of EVIS X1 Endoscopy System

In 2020, Olympus launched the EVIS X1 endoscopy system in Europe, Japan, and some parts of Asia, Our most advanced endoscopy system to date, EVIS X1 has undergone a model change from the previous models for the first time in about eight years. Aiming to improve the quality of endoscopic procedure in the detection, characterization, staging, and treatment of irregular lesions, as well as examination efficiency by endoscopy, the EVIS X1 system contributes to early detection, early diagnosis, and minimally invasive treatment of gastrointestinal diseases such as cancer by being equipped with a variety of new technologies.

#### **Examinations with Street Performers**

The first person in the world to successfully observe the stomach was the German physician, Adolph Kussmaul. In 1868, expanding on Desormeaux's endoscope, he fashioned a metal pipe with a length of 47cm and a diameter of 13mm in his medical equipment shop, and performed an examination on a sword-swallower. However, the lamp produced an insufficient amount of light, and he could not adequately illuminate the inside of the body. Therefore, there was no practical endoscope until the introduction of electric lighting. In 1879, the Germany physician, Maximilian Nitze, and the Austrian electrical engineer, Joseph Leiter, made a cystoscope using an electric light as the source. They then went on to construct an esophagoscope and a gastroscope. In 1881, the Polish physician, Jan Mikulicz-Radecki, with the help of Leiter, created a rigid gastroscope where the first third of the tip was curved.

#### The Idea of the Gastrocamera

However, the idea of a stomach camera that has an ultra-small camera attached to the tip of a flexible tube and which could take pictures inside the digestive tract emerged in Europe and the U.S. at the end of the 19th century. In 1898, the developments of two German physicians, Fritz Lange and Carl Meltzing, were presented, but as the images obtained were blurry, they proved to be impractical.

#### 1950 OLYMPUS

#### Development of the World's First Practical Gastrocamera

(See above for the rest of our Company's history.)

# The History of ESD: Surgical Endoscope



Olympus began selling laparoscopes from the German rigid scope manufacturer, Winter & Ibe GmbH (W&I, later OWI), in 1975. At that time, laparoscopes were used in gynecology for purposes such as sterilization, and in internal medicine for procedures that included observing the surface of the liver and collecting tissue for the diagnosis of liver diseases. After that, there was a growing need to attach a video camera to a rigid endoscope and for its images to be observed on a monitor. Therefore, Olympus began developing a TV system as an imaging device for surgery.

In 1986, Olympus developed and launched its first medical TV system, the OTV-S, for use with rigid endoscopes for surgical applications. Subsequently, Olympus undertook development of many products, and their imaging equipment significantly supported the advance and widespread adoption of rigid endoscope examinations using a monitor during surgery. dedicated endoscope designs were available to meet the needs of each medical specialty. In 1996, Olympus introduced the OTV-S5 video system, an Olympus Endoscopy System (OES) allowing multiple types of camera heads and videoscopes to be connected for various needs. The OTV-S5 served as a surgical imaging system, rather than just a video camera attached to a rigid scope. In 1999, Olympus also introduced the OTV-S6 video system that included a lineup of camera heads, which could withstand the autoclave (high-pressure steam) used to sterilize many instruments in operating rooms.

## The History of Endoscopic Surgery

#### Roots in Pulmonary Tuberculosis Treatment

The history of endoscopic surgery goes back to 1910, when thoracoscopes were used in the treatment of pulmonary tuberculosis. In the 1960s, endoscopes were being used in the areas of urology and gynecology in Europe. They became a common way to treat urinary stones.

#### 1975 OLYMPUS

#### Launch of Laparoscope

(See above for the rest of our Company's history.)

#### The Accomplishments of Mouret

However, the man who was instrumental in the spread of endoscopic surgery was the French surgeon, Philippe Mouret. In 1987, he performed a gallbladder removal by attaching a CCD camera to the laparoscope and projecting the resulting video image on a TV monitor. He established the current style of laparoscopic surgery where the surgery is performed cooperatively in the view of doctors, assistants, and engineers. The first endoscopic gallbladder removal in Japan was performed in 1990 by Professor Tatsuro Yamakawa of Teikyo University. Starting in 1991, endoscopes were being used to resect the stomach for the treatment of stomach cancer. Since the early 1990s there have been many technological advancements in addition to the accelerated clinical use of endoscopic surgery. As stated previously, a key development was the coupling of endoscopes to external CCD cameras. The ability to view the operation on a video monitor allowed for a high level of cooperation between doctors and their assistants. The development of devices and equipment for surgery in body cavities that cannot be reached directly by hand progressed rapidly.

# 2015



Launched VISERA 4K UHD Surgical Endoscopy System Incorporating 4K Technology

Sony Olympus Medical Solutions was established in 2013 as a joint venture with Sony. In carrying out R&D for products that contribute to medical advancement, the company was able to make full use of Sony's leadingedge electronics technology as well as Olympus' expertise in the manufacture and development of medical devices. The joint venture launched its first product in 2015, a surgical endoscope system incorporating 4K technology that provided surgeons with added value during endoscopic procedures through the use of high-resolution images, a wide color range and a wide field of view.

2017



Launched VISERA ELITE II Surgical

**Endoscope System** 

In 2017, Olympus launched systems

function. It was expected that 3D

compatible with 3D and IR observation

technology would make it easier both

to gauge depth even on a monitor and

sealing of blood vessels. Through its IR

research was advanced in the medical

field, the system allows blood vessels,

greater clarity than with the naked eye.

blood flow, etc. to be observed with

to perform procedures, such as the

excision of an affected area and the

observation capability, for which



# 2021

#### Expanding Fluorescence Imaging Market Portfolio

In 2021, Olympus made the Dutch medical equipment manufacturer, Quest Photonic Devices B.V., a wholly owned subsidiary.

Olympus thereby acquired fluorescence imaging technology that makes the blood vessels under surface tissue visible by combining near-infrared light and fluorescent dyes, so that the fluorescent agents flowing in the bloodstream shine. We look forward to expanding our portfolio in the rapidly expanding fluorescence imaging market and researching and developing next-generation molecular imaging technologies.

#### Beginning of Endoscoptic Surgery

In 1978, the German surgeon, Kurt Semm, developed an automatic insufflator. The first known endoscopic surgery was an appendectomy performed by Kurt Semm in 1981. It was the first attempt to greatly change laparoscopy, from the traditional approach through an orifice to an approach using an incision into the body. In 1985, the German surgeon, Erich Mühe, performed an endoscopic gallbladder removal.

#### Health Insurance Coverage Starts in 1992

In Japan, starting in 1992 with gallbladder removal, endoscopic surgery is rapidly becoming covered by health insurance. Hernioplasty, lung resection, and gynecological surgeries were covered by health insurance starting in 1994, stomach resection in 1995, and 18 surgeries including splenectomy and liver removal in 1996.

Activities aimed at spreading endoscopic surgery are also popular in Japan. The Society for Endoscopic Surgery was started in 1990, and the Japan Society for Endoscopic Surgery (JSES) was established in 1995. The goals of these societies include both research and education. As of July 2008, membership was over 10,000. These societies foster increased awareness of endoscopic surgery through various conferences and publications, and certify technical competence in these new procedures through their physician certification programs.

# The History of TSD: GI-Endotherapy

1966 Launched Olympus' First Biopsy

Scope and Endotherapy Devices (Biopsy Forceps/Cytology Brushes)



1970

#### Major Developments in Biliary Tract and Pancreas Fields

In 1966, Olympus introduced a biopsy fiberscope with an instrument channel to pass endotherapy devices through the endoscope's insertion tube. Along with conventional endoscopic image diagnoses, it became possible to take a sample of tissue using biopsy forceps to then be examined by a pathologist under a microscope. Endoscopic biopsy greatly streamlined early-stage stomach cancer diagnosis. Subsequently, endotherapy devices were developed separately from those for treatment and therapy. By 1968, academic conferences were presented cases of excising stomach polyps using a snare (wire loop), and using biopsy forceps through which a high-frequency electric current passed.

In 1970, Olympus launched the duodenofiberscope, and there was great progress made in diagnosis and treatment in the biliary tract and pancreas fields. By using a cannula while projecting X-rays of the biliary tract and pancreas, physicians developed techniques including endoscopic retrograde cholangio pancreatography (ERCP) to detect tumors and other lesions, and endoscopic sphincterotomy (EST) to widen the opening of the duodenal papilla with a high-frequency scalpel. AT

1975

Clip hemostasis

Contributions to New Hemostasis Techniques

In 1975, in response to the demand for less bleeding during endoscopic therapy and hemostasis with an endoscope, Olympus also launched an endotherapy device called a coagulator to cauterize and staunch sites of bleeding with a high-frequency electric current. In the same year, Olympus also launched an endoscopic clip that stops bleeding by directly grasping and pinching closed the site of bleeding. After that, improvements continued over the course of 10 years, and clipping became widely used for hemostasis and marking for resection.

# The History of TSD: Urology

1972



Nephrofiberscope and rigid cystoscope

# Launch of Nephrofiberscope and Development of Rigid Cystoscope

Diagnosis and treatment using rigid endoscopes has long been performed in the area of urology. With its origins in gastrocameras, Olympus was a newcomer to the area. In 1970, however, Olympus collaborated with the Department of Urology in the Faculty of Medicine at the University of Tokyo and developed a nephrofiberscope that allowed observation of the ureter and renal pelvis without surgical incision. The University of Tokyo was the first in the world to use this scope in clinical application.

In 1972, Olympus launched the KF nephrofiberscope designed for use in the kidneys while developing the CYS-K1 rigid cystoscope.



#### Acquisition of German Rigid Endoscope Manufacturer

1979

In 1979, Olympus made the German rigid endoscope manufacturer, Winter & Ibe GmbH (W&I), one of its subsidiaries and established the company as a manufacturing base for Olympus' rigid endoscopes. This move allowed Olympus to acquire a rigid endoscope lineup for the surgical market (including the mainstay urology market) and accelerate the expansion of its surgical business. By combining W&I's manufacturing technology with Olympus' optical technology, these new rigid endoscopes had improved optics and operability, as well as unprecedented system functionality and design.

1986



#### Improvements of Fiberscope and Contribution to Minimally Invasive Treatments

In 1986, Olympus introduced the CYF cystofiberscope and strengthened its initiatives in urology. Unlike rigid endoscopes, the CYF's flexible insertion section contributed to alleviating patient discomfort during examinations, and the bending mechanism at the tip of the fiberscope made it possible to observe a wider area inside the bladder.

Progress in improving ureterofiberscopes included the pursuit of a thinner insertion section, improved optics, and improved insertability resulting from adjustments to the diameter of the instrument channel and the distal end design. Thereafter, they became essential for the observation and treatment of the ureter.

# **1980**s



**Resects Wider Range of Lesions** 



2002

#### **Resects Mucosa in Entire Area** around Lesions

In the 1980s, endoscopic mucosal resection (EMR) became practical following joint development by physicians and Olympus. This is a surgical procedure by which saline water is injected between lesioned tissue from early-stage stomach cancer or colon cancer and regular tissue to inflate the lesion, which is then removed by means of a snare. Following the development of devices, endoscopic submucosal dissection (ESD), which allows a wider range of early-stage lesions to be endoscopically removed, was introduced in 2002.

than before.

In 2002, Olympus developed the electrosurgical knife, which reduced perforation risks by adhering a ceramic insulator to the tip of the needle-like knife. In 2008, the electrosurgical knife, which allowed adjusting the knife length based on the intended use was developed. These endotherapy devices have contributed to the development of safer procedures for resecting mucosa in the entire area around a lesion.



2020

olonoscope distal attachment

#### **Expanding Lineup of Device to Treat Gastrointestinal Disease**

In 2020, Olympus expanded its lineup of gastrointestinal disease treatment devices by acquiring the British medical device manufacturer Arc Medical Design Ltd. Having been designed to help maintain and maximize visibility during a colonoscopy or endoscopic polypectomy, the company's flagship ENDOCUFF VISION™ product is expected to contribute to the early detection and treatment of adenomatous polyps.



resection in saline) for resecting enlarged In the same year, Olympus made prostate. Olympus developed the the U.S. company Gyrus ACMI Inc. one world's first endoscopic cutting loops of its subsidiaries. Gyrus ACMI had a for TURis and a high-frequency power long history and was well respected in device to control high-frequency the endoscopy area. It was particularly currents for ablation. With TURis, the known for its expertise in urology and entire circumference of the electrode is otorhinolaryngology, as well as energy made to discharge electricity and application treatment devices centered excision takes place through an on electric scalpels. The sales force in electrolyte solution, which allows a more North America, the largest market, was stable and higher level of cutting ability strengthened and the market share was expanded.

BPH, and the SOLTIVE SuperPulsed Laser System, a thulium fiber laser device for dusting urinary stones into very fine particles for easy discharge from the body. Both are treatment devices that contribute to reducing the burden placed on patients. By introducing these products, Olympus will provide physicians and patients with new options and further enhance its portfolio in the urology area.

# The History of TSD: Respiratory



In 1968, the bronchofiberscope for the respiratory area was launched. Having received high praise for its completed products, the quality of their fiberoptics, and the comprehensive lineup of scope types, Olympus bronchofiberscopes sold well worldwide. In particular, unlike other manufacturers, Olympus gave scope users the ability to select the most appropriate insertion section specification from diameters of 3mm, 4mm, or 5mm.



giving rise to many fiberscope models, from scopes with a large 3.2mm channel to scopes with an external diameter of just 1.8mm.

Then the bronchofiberscope evolved into the bronchovideoscope. In 1993, three bronchovideoscope models were launched, and since then, the use of videoscope technology has advanced even in the respiratory area, where slim design is required.

1997



**Review of Endoscopic Ultrasonography Procedures** 

Transbronchial needle aspiration (TBNA) is a method for diagnosing lung cancer by using aspiration biopsy from a lymph node on the extra-bronchial wall. The needle for this procedure is inserted through a bronchoscope. Conventionally, the tip of the needle could not be observed. In response to requests from physicians who wished to utilize an ultrasound endoscope for this procedure so that they could see the needle, Olympus began reviewing product specifications and developing prototypes around 1997.

# 2004



EBUS-TBNA system

#### Widespread Adoption of Endoscopic Ultrasound Procedures

After many reviews and the production of prototypes, in 2004, Olympus developed and launched an ultrasound bronchoscope, which enabled confirmation of the needle tip's location during TBNA, and a specialized aspiration needle. This led to the widespread adoption of endoscopic ultrasound TBNA and EBUS-TBNA (endobronchial ultrasound transbronchial needle aspiration) and contributed to the realization of a lymph node metastasis method that is minimally invasive and possesses advanced diagnostic capabilities.

2010



Intrabronchial valve system

#### Acquisition of Emphysema and Pneumothorax Treatment Devices

In addition to diagnosing lung cancer, Olympus also made full-scale efforts to expand applications for endoscopes for non-cancerous diseases. In 2010, Olympus made Spiration, Inc. a consolidated subsidiary. This U.S. company handles minimally invasive treatment devices for lung diseases, such as emphysema and pneumothorax, and lung injuries. Olympus would go on to accelerate the company's business by providing bronchoscopic devices (valves) as a minimally invasive treatment for lung diseases, which are on the rise.

2020

Electromagnetic navigation system Acquisition of Electromagnetic Navigation System that Assists in Early Diagnosis/Staging of Lung Cancer

In 2020, Olympus acquired Veran Medical Technologies, Inc. (VMT), which specializes in the field of interventional pulmonology.

With the current widespread adoption and expansion of low-dose CT scan screenings, lesions can increasingly be found in the peripheral regions of the lungs. VMT's electromagnetic navigation system assists in the insertion of bronchoscopes and endotherapy devices into the finely branched peripheral bronchi, and by adding it to the Olympus portfolio, it will allow smoother access to lesions and further contributions to definitive diagnoses of lung cancer.

# The History of the Olympus Medical Business

Year	Main Accomplishments
1950	Development of world's first practical gastrocamera
1952	Above-mentioned gastrocamera commercialized, announced as GT-I
1955	Gastrocamera Research Group established
1964	GTF gastrocamera fiberscope released
	Established corporation in Europe
1966	GFB fiberscope for biopsy released
1968	Established corporation in U.S.
1974	Partnership with Winter & Ibe GmbH in Germany (entered into surgical endoscopy area the next year)
1979	Winter & Ibe GmbH became subsidiary
	Established U.S. location in California (currently the world's largest endoscope service center)
1982	Introduction of endoscopic ultrasound system
1985	EVIS 1 endoscopic video system announced
1987	KeyMed Ltd. (UK) became subsidiary
1989	Established Beijing residential office
	Established corporation in Singapore
1990	EVIS 100/200 series endoscopic video information system announced
1993	Established corporation in Russia
1999	Established corporation in Thailand
2000	Introduction of EVIS EXERA series endoscopic video system in Europe and North America
2001	Comprehensive partnership with Terumo Corporation for medical equipment started
2002	Introduction of VISERA series video system for endoscopic surgery
	EVIS LUCERA-the world's first high-definition endoscopic video system-released in Japan, the UK, and parts of Asia
	Established corporation in Brazil
2004	Established marketing/services company for medical equipment in China
	Celon AG (Germany) became subsidiary
2005	Small intestine capsule endoscopy system introduced in Europe (expanded afterward to North America, Japan, and other regions)
	Established center for repair of endoscopy products and management of loan units in Japanese market (Shirakawa, Fukushima Prefecture)
2006	Introduction of EVIS EXERA II and EVIS LUCERA SPECTRUM endoscopic video systems that include NBI
	Introduction of VISERA PRO surgical video endoscopy system

Year	Main Accomplishments
2006	Established service company in Vietnam (now also responsible for sales)
	Established repair center for endoscopic products in Chinese market
2008	Gyrus plc. (UK) became subsidiary
	Established new plant for the production of medical devices in Vietnam
	Established training centers in Germany and China (Shanghai)
2009	Established medical equipment marketing company in India
	Commenced operation at new factory in the Czech Republic
2010	Spiration Inc. (U.S.) became subsidiary
	Established training center in China (Beijing)
2011	Spirus Medical, Inc. (U.S.) became subsidiary
	Introduction of Surgical Imaging Platform VISERA ELITE
	Olympus' NBI Technology recognized by the Japan Institute of Invention and Innovation
2012	Introduction of EVIS EXERA III and EVIS LUCERA ELITE gastrointestinal endoscopy systems
	Introduction of THUNDERBEAT series of world-first composite electrosurgical devices that combine bipolar high-frequency current and ultrasonic energy
2013	Established Sony Olympus Medical Solutions Inc. (joint venture with Sony Corporation)
	Launched 3D surgical videoscope system (launched simultaneously with a 3D videoscope featuring a world-first tip bending function)
	Established training center in China (Guangzhou)
2015	Introduction of VISERA 4K UHD surgical endoscopy system incorporating 4K technology
2016	Established training center in Thailand
	Established corporation in Dubai
2017	Introduction of VISERA ELITE II surgical endoscope system
	Image Stream Medical, Inc. (U.S.) became subsidiary
2019	Established new global headquarters for Therapeutic Solutions Division in the U.S.
2020	Introduction of EVIS X1 gastrointestinal endoscopy system in Japan, Europe, and parts of Asia
	Acquisition of Arc Medical Design Ltd. (UK)
	Introduction of ENDO-AID AI-powered platform for the endoscopy system
	Acquisition of Veran Medical Technologies, Inc. (U.S.)
2021	Acquisition of Quest Photonic Devices B.V. (Netherlands)
	Acquisition of Medi-Tate Ltd. (Israel)

Blue items indicate the establishment of new locations and subsidiaries.

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