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Launch of Single-Use Electrosurgical Knife with Fluid Injection Function to Facilitate Shorter Procedure Times for the Removal of Early Stage Tumors by ESD^{*1}

Olympus Corporation (President: Hiroyuki Sasa) today announced the launch of the DualKnifeJ^{TM*2} single-use electrosurgical knife, beginning this fall in Japan. It will become available in a global rollout to other markets as the relevant requirements are satisfied (declaration of conformity, product registration, or market clearance). The knife is designed for use in ESD^{*1}, an advanced technique of therapeutic endoscopy that allows for en bloc removal of early stage tumors that have not entered the muscle layer in the stomach, esophagus, colon, and other parts of the gastrointestinal tract. The knife has been equipped with a new fluid injection function to facilitate shorter procedure times and accurate ESD.

^{*1}: An abbreviation of endoscopic submucosal dissection. An advanced technique of therapeutic endoscopy for incision and dissection submucosal layers to treat early stage tumors.

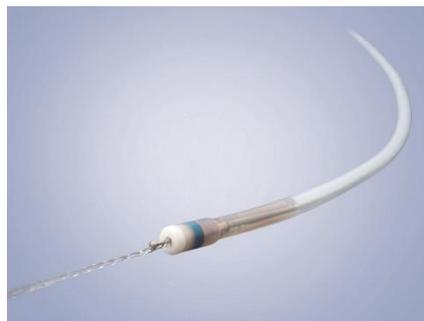
^{*2}: The marketing name for the product. See the Launch Overview section below for the full product name.

●Launch Overview

Product Name
Single Use Electrosurgical Knife KD-655 DualKnife J TM

●Main Features

In addition to maintaining the same underlying performance in existing Incision and dissection techniques, the knife also has a function that physicians can use to inject saline into exposed submucosal layers without the need to swap instruments during procedure.



DualKnifeJTM Single Use Electrosurgical Knife

Through a corporate divestiture, most functions of Olympus Medical Systems Corporation were taken over by Olympus Corporation as of April 1, 2015 as part of an organizational restructuring introduced with the aim of facilitating strategic business expansion. The medical business is made up of five business units (gastrointestinal, surgery, urology and gynecology, ENT, and medical services) and the DualKnifeJ belongs to the gastrointestinal category. The DualKnifeJ is marketed by Olympus Medical Systems Corporation.

●Launch Background

The development of various different therapy devices for use with endoscopes has led both to improved diagnostic techniques and to dramatic advances in and wider adoption of endoscopic procedures. In Japan, there has been a growing medical demand since around 2000 for ways of using endoscopes and therapy devices to deal with early stage tumors exceeding 2 cm in size that previously would have required open surgery, with ESD being used in a wider range of cases to perform en-block resection of these early stage tumors.

In response to this demand, Olympus launched the ITknife™ in 2002 as the world's first therapy device designed specifically for ESD. Subsequently, with ESD having become a common technique for the treatment of early stage stomach cancer, it was listed under Japan's insurance points system for medical procedure fee reimbursement as "submucosal dissection of early stage malignant tumors" (stomach ESD), with subsequent expansion to include the esophagus and colon. "Submucosal dissection of early stage malignant tumors" (esophagus ESD) received advanced medical designation in April 2008, followed by colon ESD in 2009, and in April 2012 "submucosal dissection of early stage malignant tumors in the colon" was listed under the insurance points system for medical procedure fees, enabling ESD to be used for most forms of lesions treated by endoscope.

DualKnife™ launched in 2008 was designed as a single device that helps physicians perform both Incision and dissection. A problem with its use, however, is the extra time and effort that results if fluid injected into submucosal layers leaks out during procedure, making it necessary to detach the knife from the endoscope and replace it with a device for injecting fluid. Olympus developed this new knife to overcome this problem.

●Details of Main Features

In addition to maintaining the same underlying performance in existing incision and dissection techniques, the knife also has a function that physicians can use to inject saline into exposed submucosal layers without the need to swap instruments during procedure.

ESD injects saline or other fluid into the submucosal layer below cancerous tissue to raise it up so that it can be incised and dissected by the knife. Sometimes, however, fluid injected at the start of the procedure can leak out over time. The new knife includes a fluid injection function that physicians can use to inject fluid into the submucosal layer as often as needed without having to swap the device each time. This helps shorten procedure times and enable more accurate ESD by making it easy to recognize the tissue to be removed and facilitating Incision and dissection. Olympus is considering this injection function for future product launches as well.

●Main Specifications

Name	DualKnifeJ™		
Model	KD-655L	KD-655Q	KD-655U
Channel Diameter	2.8 mm or more		
Working Length	1,650 mm	1,950 mm	2,300 mm
Cutting Knife Length	2.0 mm (when projected) 0.1 mm (when retracted)	1.5 mm (when projected) 0.1 mm (when retracted)	
Sterile, Single-use	yes		
Built-in Handle	Yes		

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