

August 10, 2011

FOR IMMEDIATE RELEASE

Eisai Co., Ltd.
EIDIA Co., Ltd.

**PROTOCO2L Carbon Dioxide Insufflation System for CT Colonography
Receives Approval in Japan**

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") and its diagnostics subsidiary EIDIA Co., Ltd (Headquarters: Tokyo, President & CEO: Keisuke Watanabe, "EIDIA") announced today that EIDIA received approval on August 8, 2011 to manufacture and market PROTOCO2L, Japan's first carbon dioxide insufflation system for use as a medical device in CT Colonography, along with the carbon dioxide insufflation tube PROTOCO2L Catheter Set (collectively referred to as "the Product").

Carbon dioxide insufflation systems are widely utilized in the United States and Europe in CT Colonography, a useful screening tool for detecting and diagnosing colorectal cancer in its early stages of development. None of such systems have been approved in Japan until now, and with the aim of addressing this medical need, the Japan Radiological Society and the Japanese Society of Gastroenterology submitted a petition to Japan's Ministry of Health, Labour and Welfare calling for inclusion of the Product as a candidate for discussion by the Ministry's "Investigative Committee on Medical Devices of High Medical Need."

In order to respond to this medical needs, EIDIA (known as "Sanko Junyaku" at time of filing) submitted an application seeking manufacturing and marketing approval of the Product in June 2010. The Product will be made available as soon as possible following completion of procedures necessary for product launch.

The Product is used in CT colonography, a minimally-invasive colorectal examination performed to detect lesions such as colorectal cancer without requiring the insertion of a colonoscope into the colon. PROTOCO2L automatically regulates insufflation of medical carbon dioxide as well as the amount of insufflation gas. It inflates the large intestine with carbon dioxide supplied through the rectum via a disposable tube that is intended only for use with the Product and is provided as part of the PROTOCO2L Catheter Set. The Product uses carbon dioxide that is readily absorbed by the bowel, and is expected to enable consistent distension of the large intestine and minimize the discomfort incurred by patients during the procedure, thereby contributing to widespread use of CT colonography in colorectal examinations and the early detection of colorectal cancer.

Eisai and EIDIA have entered into an agreement with Bracco Imaging S.p.A. (Headquarters: Italy), Bracco Diagnostics Inc. (Headquarters: the United States) and E-Z-EM Canada Inc. (Headquarters: Canada) to distribute the product exclusively in Japan.

With a view to further fulfilling its corporate mission of *human health care (hhc)*, the Eisai Group established a new Eisai Japan organizational structure in June 2010 to formulate and implement comprehensive strategies across its four Japan business segments comprising prescription pharmaceuticals, consumer healthcare products, diagnostics, and generics. By providing a comprehensive range of information and products related to all aspects of integrative oncology, a defined area of therapeutic focus, Eisai and EIDIA seek to make further contributions to increasing the benefits provided to patients.

[Please refer to the following notes for a product outline, screening characteristics, a glossary of terms and product images]

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■Product Outline

1. PROTOCO2L (Controlled medical device, Controlled medical device requiring special maintenance, Installed controlled medical device)

Dimensions	266×254×140 (mm)
Weight	Approx. 4.4kg
Power-supply voltage	100V-240V
Frequency	50/60 Hz
Power consumption	25W
Manufactured and marketed by: EIDIA Co., Ltd. Co-promoted by: Eisai Co., Ltd.	

*Accessories (PROTOCO2L System Rolling Cart)

Dimensions	430×480×870 (mm)
Weight	Approx. 27.5kg

2. PROTOCO2L Catheter Set (Controlled medical device)

Units per package	24 disposable tubes per box
Manufactured and marketed by: EIDIA Co., Ltd. Co-promoted by: Eisai Co., Ltd.	

■Screening characteristics (features of CT Colonography testing)

1. This screening procedure is expected to enable testing in those people who have difficulty with the insertion of colonoscopes.
2. It is expected to be less painful than conventional colonoscopies.
3. This test reportedly lowers the risk of colorectal perforation and bleeding.

■Glossary of Terms

1. Colorectal cancer

Colorectal cancer is a malignant tumor that forms in the large intestine. In Japan, it is the third leading cause of cancer-related deaths in men, and the number one cause of cancer-related deaths in women. For women in particular, it is the most common site causing death in terms of mortality rate and number of deaths. Among all types of cancers, however, early detection through health checkups is said to be particularly effective in patients with breast cancer, endometrial cancer and colorectal cancer. Periodical health checkups are therefore an extremely important means of detecting colorectal cancer in its early stages.

2. CT Colonography (Computed Tomographic Colonography)

CT Colonography is a diagnostic procedure that uses a computer to process data captured with CT to create a three-dimensional image of the large intestine for visual evaluation of the organ from a variety of angles.

■ Product Images



(PROTOCO2L)



(PROTOCO2L Catheter Set)



(PROTOCO2L, PROTOCO2L Catheter Set, PROTOCO2L System Rolling Cart)