OLYMPUS
Your Vision, Our Future

NEWS RELEASE

April 18, 2016

Launch of Single Use Aspiration Needle Designed to Provide for Shorter Procedure Times in Use with Endoscopic ultrasound-guided Fine Needle Aspiration

Olympus Corporation (President: Hiroyuki Sasa) today announced the launch this spring by its Medical Business of the Single Use Aspiration Needle EZ Shot 3 Plus, a new product in its gastrointestinal portfolio. After the initial launch in Europe and parts of the Asia-Pacific region, it will become available in a global rollout to other markets as the relevant requirements are satisfied (product registration, or market clearance). This instrument was designed to be used with an ultrasound endoscope for ultrasonically guided fine needle aspiration (EUS-FNA) of submucosal and extramural lesions within the gastrointestinal tract (i.e. pancreatic masses, mediastinal masses, perirectal masses and lymph nodes).

The aspiration needle sheath[*1] that is inserted into the ultrasonic endoscope has been made flexible to provide unparalleled access to the pancreatic head, which is difficult to reach. The needle is made from holding memory metal intended to hold its shape. Together with a sharpened tip, EZ Shot 3 Plus helps physicians avoid problems associated with difficulty in targeting due to a bent needle, and, thus, potentially shortening procedure times.

*1: The needle is encased in a coil-shaped sheath (see photograph on next page).

Endoscopic Ultrasound-Fine Needle Aspiration (EUS-FNA)

EUS-FNA, an examination technique that uses an ultrasound endoscope, enables physicians to take tissue or cell biopsies of lesions in locations such as the pancreas that cannot be accessed directly by the endoscope. One such example is by performing a needle biopsy through the wall of the gastrointestinal tract with the ultrasound scope being inserted orally and the ultrasound utilized for sub-mucosal imaging. The collected tissue can then be sent for pathology testing to check whether it is benign or malignant by examination under a microscope.

●Launch Overview

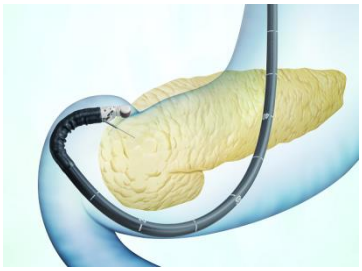
Product Name
Single Use Aspiration Needle NA-U200H EZ Shot 3 Plus

Single Use Aspiration Needle EZ Shot 3 Plus

●**Main Features**

1. **Flexibility that provides uncompromised access to difficult-to-approach locations such as in the pancreatic head, helps physicians insert the needle into the endoscope, even when the end of the scope is tightly curved. This helps shorten procedure times by reducing scope adjustments to accommodate the needle.**
2. **The needle tube is made of nitinol, a material that is flexible and has shape memory. The sharply pointed Menghini tip helps physicians to puncture the tissue and lesion at the target location.**

●**Development Background**



Endoscopic ultrasound-fine needle aspiration (EUS-FNA) was first used in the early 1990s, primarily in Europe and America. Its use has since become increasingly widespread as an exploratory technique for taking tissue or cell samples from lesions for definitive pathology diagnosis.

Uses for EUS-FNA include cases that require the needle to be inserted into difficult-to-access locations, such as in the pancreatic head that can only be reached with a high degree of curvature in the tip of the endoscope, as shown in the figure above. In such cases, the sheath inserted into the endoscope must be able to pass smoothly through the curved scope with minimal force. Furthermore, if the subsequent steps, which include adjusting the angle of the needle and its withdrawal and insertion to collect the tissue sample, can be performed without difficulty, then procedure times may be reduced. In order to achieve an accurate diagnosis it is helpful for the needle to be easy to insert into the target location. The Single Use Aspiration Needle EZ Shot 3 Plus was developed with the aim of satisfying these requirements.

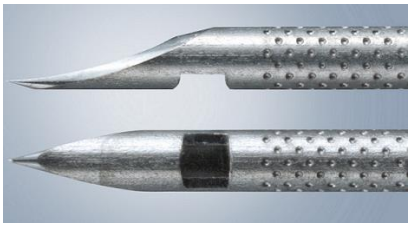
●**Details of Main Features**

1. **Flexibility that provides uncompromised access to difficult-to-approach locations such as in the pancreatic head, helps physicians insert the needle into the endoscope, even when the end of the scope is tightly curved. This helps shorten procedure times by reducing scope adjustments to accommodate the needle.**

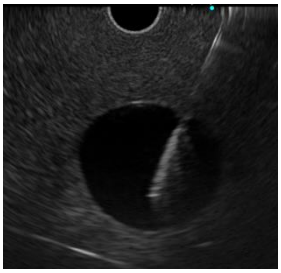
   The needle is inserted into the endoscope shrouded in a coil-shaped sheath that provides flexibility and smooth force transmission from the handle. The sheath facilitates access to difficult-to-approach locations such as in the pancreatic head by making the Single Use Aspiration Needle EZ Shot 3 Plus easy for physicians to insert and deploy the needle, even if the tip of the ultrasound endoscope is tightly curved. Furthermore, the sheath's multi-layer construction minimizes friction with the needle, which allows the needle to travel freely and smoothly.

2. The needle tube is made of nitinol, a material that is flexible and has shape memory. The sharply pointed Menghini tip helps physicians to location.

During an EUS-FNA procedure, the needle may be inserted into suspected lesions at a number of different locations or depths. The needle's shape memory helps prevent it from bending after multiple passes. A bent needle would hinder accurate puncture at the desired location and possibly reduce visibility on ultrasound. Furthermore, the sharply pointed Menghini tip is intended to help physicians to puncture tissue smoothly, even from an oblique angle. Needles are available both with and without holes along the side of the tip to satisfy physician preference.



Needle tube with a side hole



Ultrasound image – a needle tip can be seen in the middle

●Main Specifications

Model	NA-U200H-8019	NA-U200H-8022	NA-U200H-8019S	NA-U200H-8022S
Needle Tube Shape	without a side hole		with a side hole	
Maximum insertion portion diameter (mm)	ø 2.6	ø 2.2	ø 2.6	ø 2.2
Working length (mm)	1400[*2]			
Needle diameter (G)	19	22	19	22
Maximum needle length (mm)	80[*3]			

*2 Working length indicates the same length as when it is packed.

*3 Maximum needle length indicates an approximate length of the needle tube extended from the distal end of the needle sheath.

The company names and product names specified in this release are the trademarks or registered trademarks of each company.