Date: September XX, 2020

Olympus reference: QIL 153-010

FIELD SAFETY NOTICE

INFORMATION ON ADVERSE EVENTS OBSERVED DURING POWERSPIRAL (PSF-1) PROCEDURES

Attention: Operating Room Manager, Risk Management Department

	Model name	Serial / Lot number
(1)	INTESTINAL VIDEOSCOPE OLYMPUS PSF-1	All
(2)	SINGLE USE POWERSPIRAL TUBE DPST-1	All

Dear Health Care Practitioner,

During the first 9 months from the launch of the PSF-1 Intestinal Videoscope in March 2019 to December 2019, 5 cases of GI- mucosal laceration or its perforation have been reported with no malfunction of the device. Olympus believes that the clinical condition of each patient prior to the procedure possibly contributed to a certain extent to each adverse event.
In addition, Olympus has become aware about additional cases of laceration or perforation until July 2020 which are currently still under investigation/evaluation by the manufacturer. The appropriate actions will be defined by the manufacturer depending on the outcome of the investigations.

Olympus as the manufacturer of the mentioned devices confirms that the occurrence of these adverse events do not show an increased risk for patients, users or others and are within the expected range. The only purpose of this letter is to remind you to read the *Instructions for Use* carefully and to re check the "*Contraindications*" and "*Precautions*" mentioned in the *Operation Manual* in order to minimize risks for your patients and ensure a safe procedure with the product.
Parts of the contraindications and precautions are shown on page 3 and 4.

Additionally we would like to inform you that Olympus also added a new section to the "PowerSpiral Educational Web Contents" named "Patients with altered GI anatomy" showing some recommendations of the PowerSpiral Experts Group (PSEG). Please find an extract of the mentioned website section on page 5 of this letter.

Further, Olympus updated the "PowerSpiral Educational Web Contents" (Web address: https://www.olympusprofed.com/gi/powerspiral/met/)" for user training to share detailed information on 5 adverse events that occurred within the first 9 months after the launch to point out again the importance of reading the IFU carefully. Please confirm that you took notice of the Web Contents by returning the Reply Form.
Please note part of "PowerSpiral Educational Web Contents" related to the 5 cases are excerpted and shown on page 6.

Actions to be taken by the user:

Our records indicate that your facility has purchased one or more of the above-referenced PSF-1 Intestinal Videoscopes. Therefore, Olympus requires you to take the following actions:

1. Carefully read the ***Instructions for Use*** including the "***Contraindications***" and "***Precautions***" immediately and review the "***PowerSpiral Educational Web Contents***".
2. Indicate on the enclosed Reply Form that you have received and understood this Field Safety Notice and the importance of following the Instructions for Use accompanied by the devices carefully by returning the completed Reply Form back to your Olympus representative (xxx) latest by XXXX.
3. If you have further distributed this product, identify your customers, forward them this Field Safety Notice including the attachments and appropriately document your notification process and let us know accordingly.

Olympus regrets any inconvenience caused and fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact Olympus directly at (XXX) XXX-XXXX from Monday till Friday or by e-mail at XXX.

Yours Sincerely,

Part of "Contraindications" and "Precautions" from the "Important Information - Please Read Before Use" section of the PSF-1 Operation Manual

As for the pre-existing patient condition, the instruction manual of the subject device describes following contraindications and precautions;

Excerpt from P.2 and P.3 of PSF-1 Operation Manual (English Rev.06).

Contraindications

Patients not suitable for a prolonged endoscopic procedure under deep anesthesia or general endotracheal intubation including:

- Medical instability preventing anesthesia
- Inability to gain consent
- Known perforation
- Uncontrolled coagulopathy
- Recently placed feeding jejunostomy (e.g. less than two weeks)
- Pediatric patients, especially infants and toddlers
- Patients having a stent or other instruments implanted in the intestinal tract that may obstruct the passage of the single use PowerSpiral tube.

For antegrade approach

- Perforated ulcer
- Esophageal or gastric varices
- Foregut stenosis
- Deep mucosal laceration
- Suspected or diagnosed eosinophilic esophagitis
- Unable to accept biteblock

For retrograde approach

- Severe active inflammation of colon
- Anal stenosis
- Colonic stricture

Excerpt from P.8 of PSF-1 Operation Manual (Rev.06).

Precautions

Follow the warnings and cautions given below when handling this endoscope. This information is to be supplemented by the warnings and cautions given in each chapter.

WARNING

- Before performing endoscopy or treatment, thoroughly evaluate conditions of the patient. Passage of the single use PowerSpiral tube may result in patient injury, bleeding, and/or perforation depending on a patient's condition.
- When inserting the endoscope, thoroughly observe the inside of the body cavity to evaluate whether it is appropriate to continue the endoscopy. Passage of the single use PowerSpiral tube may result in patient injury, bleeding, and/or perforation.

Excerpt from P.9 of PSF-1 Operation Manual (Rev.06).

Precautions

Follow the warnings and cautions given below when handling this endoscope. This information is to be supplemented by the warnings and cautions given in each chapter.

WARNING

- When performing endoscopy in a patient with adhesions and it cannot be confirmed the endoscopy will be performed safely, the procedure must be stopped. However, when its potential benefits are greater than its risk, carefully insert or withdraw by rotating the endoscope through a part of adhesion. Patient and/or adhesion injury, bleeding, and/or perforation may result.
- The safety of this endoscopy has not been established in patients with the following conditions. Perform endoscopy and endoscopic treatment in these patients only when its potential benefits are greater than its risks.
  - Known stricturing diseases such as Crohn's disease
  - Any prior abdominal or pelvic surgery including altered anatomy
  - Pregnancy
  - Radiation enteritis
  - History of dysphagia or known esophageal swallowing disorders
  - Mild to moderate inflammation of colon
- If it is assumed that the single use PowerSpiral tube may not be extracted from the patient's body cavity when the rotation mechanism does not function, then do not use the endoscope for the procedure. Passage of the single use PowerSpiral tube may result in patient injury, bleeding, and/or perforation.
- Carefully determine the applicability of a patient with a history of surgery in the gastrointestinal tract. Passage of the single use PowerSpiral tube may result in patient injury, bleeding, and/or perforation.
- During endoscopic treatment, keep the insertion section and the bending section as straight as possible. If there is a loop or a bend on the insertion section or the bending section, the operation cannot be performed as intended, and patient injury, bleeding, and/or perforation can result.
- Some adverse events due to endoscopic examinations and treatments such as mucosal damage, perforation, mucosal inflammation, bleeding, infection, fever, pain (such as abdominal pain and sore throat), abdominal distention, discomfort (such as abdominal discomfort and swallowing discomfort), digestive dysfunction (such as indigestion, vomiting and nausea), dysphagia (such as odynophagia), respiratory system disorder (such as mediastinal emphysema, respiratory instability, hypoxemia, aspiration pneumonia and cough), hiccup, cardiovascular problem (such as bradycardia, tachycardia, hypotension and hypertension), pancreatitis, hyperamylasemia, hyperlipasemia, intestinal obstruction, intestinal necrosis, intussusception, and parotitis have been reported.
  Not only during but also after an endoscopic examination with this product, observe the patient and check these adverse events to prevent danger. Take appropriate measures if necessary.

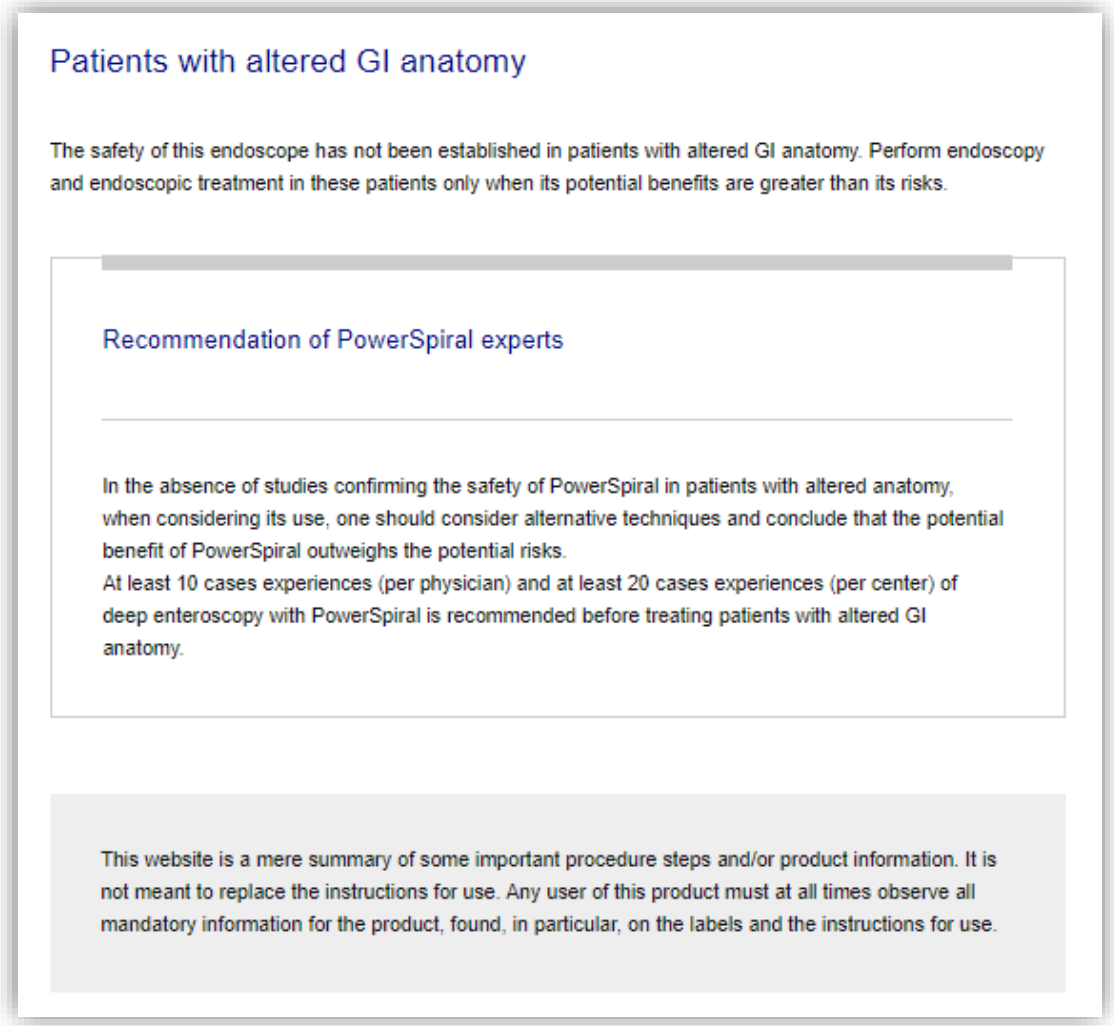
Part of "Patients with altered GI anatomy" section of PowerSpiral Educational Web Contents

Excerpt from PowerSpiral Educational Web Contents.

Web address: https://www.olympusprofed.com/gi/powerspiral/met/

- Page information: Gastroenterology > PowerSpiral Enteroscopy > Procedure information > Antegrade Approach

1-1. Patients with altered GI anatomy



Patients with altered GI anatomy

The safety of this endoscope has not been established in patients with altered GI anatomy. Perform endoscopy and endoscopic treatment in these patients only when its potential benefits are greater than its risks.

Recommendation of PowerSpiral experts

In the absence of studies confirming the safety of PowerSpiral in patients with altered anatomy, when considering its use, one should consider alternative techniques and conclude that the potential benefit of PowerSpiral outweighs the potential risks.
At least 10 cases experiences (per physician) and at least 20 cases experiences (per center) of deep enteroscopy with PowerSpiral is recommended before treating patients with altered GI anatomy.

This website is a mere summary of some important procedure steps and/or product information. It is not meant to replace the instructions for use. Any user of this product must at all times observe all mandatory information for the product, found, in particular, on the labels and the instructions for use.

Part of "Reported Adverse Events" section of PowerSpiral Educational Web Contents

Excerpt from PowerSpiral Educational Web Contents.

Web address: https://www.olympusprofed.com/gi/powerspiral/met/

- Page information: Gastroenterology > PowerSpiral Enteroscopy > Procedure information > Reported Adverse Events

2-2. Reported Adverse Events

	Adverse Event	Location	Age, gender, and body measurements	Patient's condition	Insertion direction	Anesthesia	Experts' comments	Relevant information link
1	Bowel perforation	NA	NA	Crohn's disease (Diagnosed via exam)	Retrograde	NA	· Safety unknown for known stricturing diseases such as Crohn's disease: Perform exam only when benefits outweigh risks.	2-4 Precautions
2	· Esophageal tear · Esophageal perforation	NA	NA	Dysphagia	Antegrade	NA	· Safety unknown for history of dysphagia and esophageal stricture: Perform exam only when benefits outweigh risks. · All patients with a history of dysphagia should undergo a formal evaluation which includes an EGD before performing PowerSpiral.	2-4 Precautions
3	Ileal perforation	Terminal ileum	81-year-old, Female, 158cm, 58kg, BMI:23.2	· Small intestine bleeding · Diverticulosis	Retrograde	Deep sedation	· Continuous rotation in the same location may result in bowel injury with mucosal disruption, bleeding, and deeper injury with perforation, especially within the terminal ileum. · Repositioning the patient and the scope or adding manual abdominal compression if no advancement is achieved. If the rotating power segment is in the same position, this should be a warning to assess continuing efforts or terminating the procedure.	4-1 General Techniques 4-2 Insertion Tips
4	· Superficial esophageal tear · Small esophageal perforation	Upper esophagus	50-year old, Female, 173cm, 51kg, BMI:17.0	· Tight upper esophageal sphincter · No past medical history of dysphagia	Antegrade	GA	· Patient's thin body habitus (BMI 17.0) may be problematic for scope intubation. · Confirmation of PowerSpiral insertion accommodation using a bougie (54-60Fr) is highly recommended, especially in early experience (first 10 cases). · If passage into the esophagus remains difficult, repositioning of the patient's position and use of head and neck repositioning by the anesthesiologist or anesthetist may be useful.	4-2 Insertion Tips 4-3 Withdrawal Tips 4-4 Antegrade Approach Note 5-1 Emergency Withdrawal
5	Severe mucosal injury in proximal esophagus	Proximal esophagus	78-year-old, Female, 160cm, 71kg, BMI:27.7	· The proximal esophagus may have been less relaxed · No past medical history of dysphagia	Antegrade	Deep sedation	· Pre-intubation bougie dilation useful if there is any resistance to intubation · General anesthesia may provide more complete muscle relaxation · Neck positioning is important	4-2 Insertion Tips 4-3 Withdrawal Tips 4-4 Antegrade Approach Note

REPLY FORM – QIL 153-010

FIELD SAFETY NOTICE **INFORMATION ON ADVERSE EVENTS OBSERVED DURING POWERSPIRAL (PSF-1) PROCEDURES**
[Name & Address of Hospital/Medical Facility]
[Dept/Attn]
[**Date]**

I herewith acknowledge the receipt of your Field Safety Notice (FSN) related to the PSF-1 Intestinal Videoscope.
I understand the necessity to carefully follow the Instructions for Use and confirm that I have transferred the content of the attached FSN to all affected departments on which this action has an impact.

Name (Signature) _____

Name (Print) _____

Position _____

Please fax this completed reply form to Olympus at [contact number] latest by XXXX