TAEWOONG MEDICAL
NEWSLETTER

# CONNECT

Q1
2021

TAEWOONG MEDICAL
NEWSLETTER

## CONSTANT RESEARCH FOR THE BEST SOLUTION

### HOT SPAXUS STENT

Lumen-apposing metal stent with electrocautery delivery system
for drainage of pancreatic pseudocyst or gallbladder

# TAEWOONG MEDICAL
# POST WEBINAR REVIEW Q1

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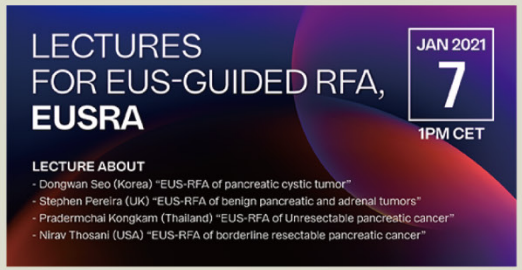
RFA




VOD

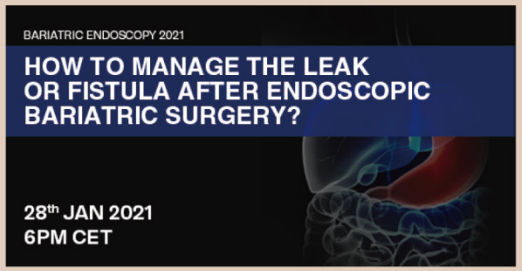
**LECTURES FOR EUS-GUIDED RFA, EUSRA**
- 7th January, 2021 / 1PM CET
- Dongwan Seo

STENT


VOD

**BILIARY INTERVENTIONS**
- 19th January, 2021 / 12PM CET
- Arthur Kaffes, Dongki Lee

STENT




VOD

**ENDOSCOPIC BARIATRIC**
- 28th January, 2021 / 6PM CET
- Devinder Bansi

STENT


VOD

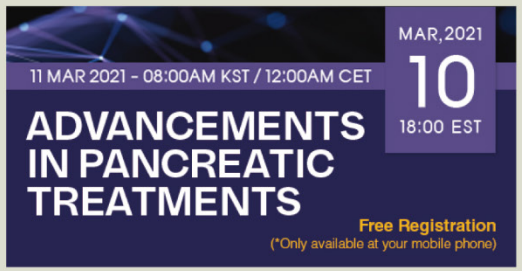
**EUS-STENT MASTER CLASS**
- 26th February, 2021 / 8:45AM CET
- Prof. Marc Giovannini

RFA


VOD

**EUS-RFA MASTER CLASS**
- 3rd March, 2021 / 5PM CET
- Marc Barthet

RFA




VOD

**EUS-RFA MASTER CLASS**
- 10th March, 2021 / 6PM EST
- Gregory B. Haber

RFA


VOD

**BILIARY RFA - ELRA**
- 18th March, 2021 / 12PM CET
- Nageshwar Reddy

TOTAL REGISTER ATTENDEES OVER **1,806**

INVITED SPEAKES **29**

APPROX. **49%** ATTENDANCE RATE

# UPCOMINGWEBINAR

APRIL
22
THURSDAY

## TAEWOONG WEBINAR

# EUS-GUIDED DRAINAGE WITH SPAXUS™&NAGI™ STENT

JOIN THE WEBINAR

KOREA 8PM / INDIAN 4:30PM / THAILAND 6PM / HK 7PM / CET 12PM

**ARTICLE THAT YOU SHOULD READ IN ADVANCE**

A novel electrocautery-enhanced delivery system for one-step endoscopic ultrasound-guided drainage of the gallbladder and bile duct using a lumen-apposing metal stent: a feasibility study

(CLICK) TO ORIGINAL ARTICLE

MODERATOR

JongHo Moon
KOREA

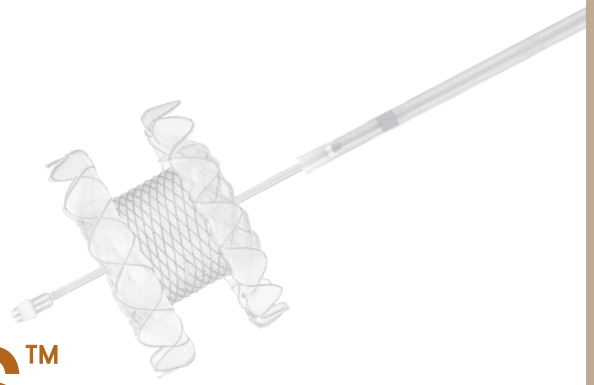
SPEAKER

Sundeep Lakhtakia
INDIA

Pradermchai Kongkam
THAILAND

Anthony Teoh
HONG KONG

# EXPERT'S INTERVIEW
# HOT SPAXUS™



We've conducted online interviews with Prof. Teoh (Hong Kong) and Prof. Kongkam (Thailand) on their HOT SPAXUS™ experience. Please visit our online training website www.taewoongotc.com for more details and for the full interview.

> **HOT SPAXUS™**
> makes the procedure a lot more enjoyable and easier to perform.

## Teoh Yuen Bun Anthony

Department of Surgery
Faculty of Medicine
The Chinese University of Hong Kong
Prince of Wales Hospital, Shatin, N.T.


## Pradermchai Kongkam

Gastrointestinal Endoscopy Excellence Center
King Chulalongkorn Memorial Hospital
Bangkok, Thailand


VOD

**Prof. Marc Barthet**

Professor of the Faculty of Medicine of Marseille,
Medical doctor of public hospital
Head of the Endoscopy unit of North Hospital in Marseille, France

# EXPERT'S INTERVIEW

# EUS-GUIDED RFA EUSRA™


World renowned leader of EUS-guided RFA, Prof. Marc Barthet was interviewed for the following questions regarding the EUSRA™ Procedure.

Please, click the link for full interview video.

Q

- What kind of patient could get clinical benefits from EUSRA™ treatment?
- What are the required characteristics for EUS-RFA needle?
- Do you think EUSRA™ is a potential product to be considered as an alternative to surgery for some patients?
- How do you evaluate EUSRA™ in terms of safety in general?

Taewoong Medical OTC

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Taewoong Medical

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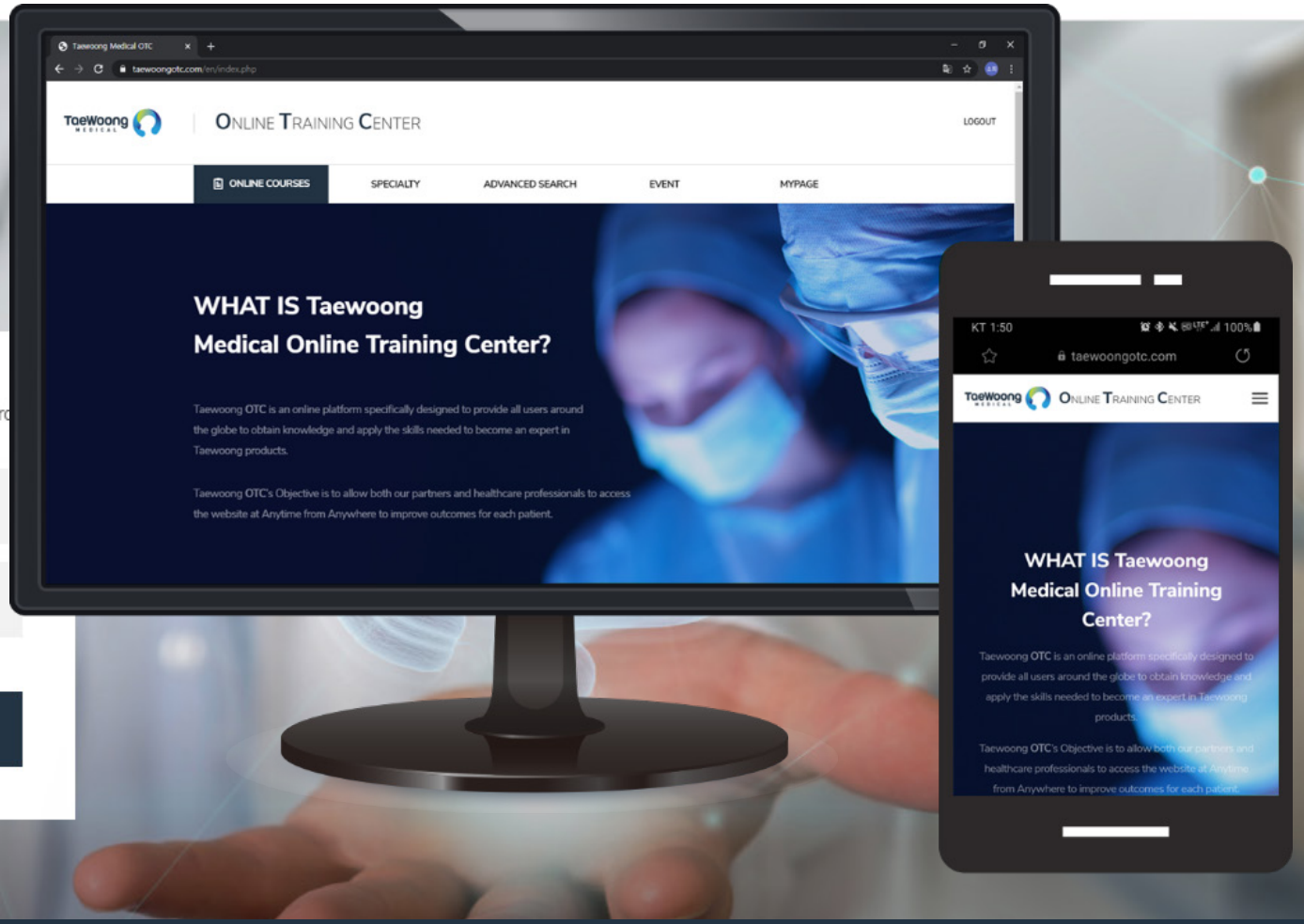
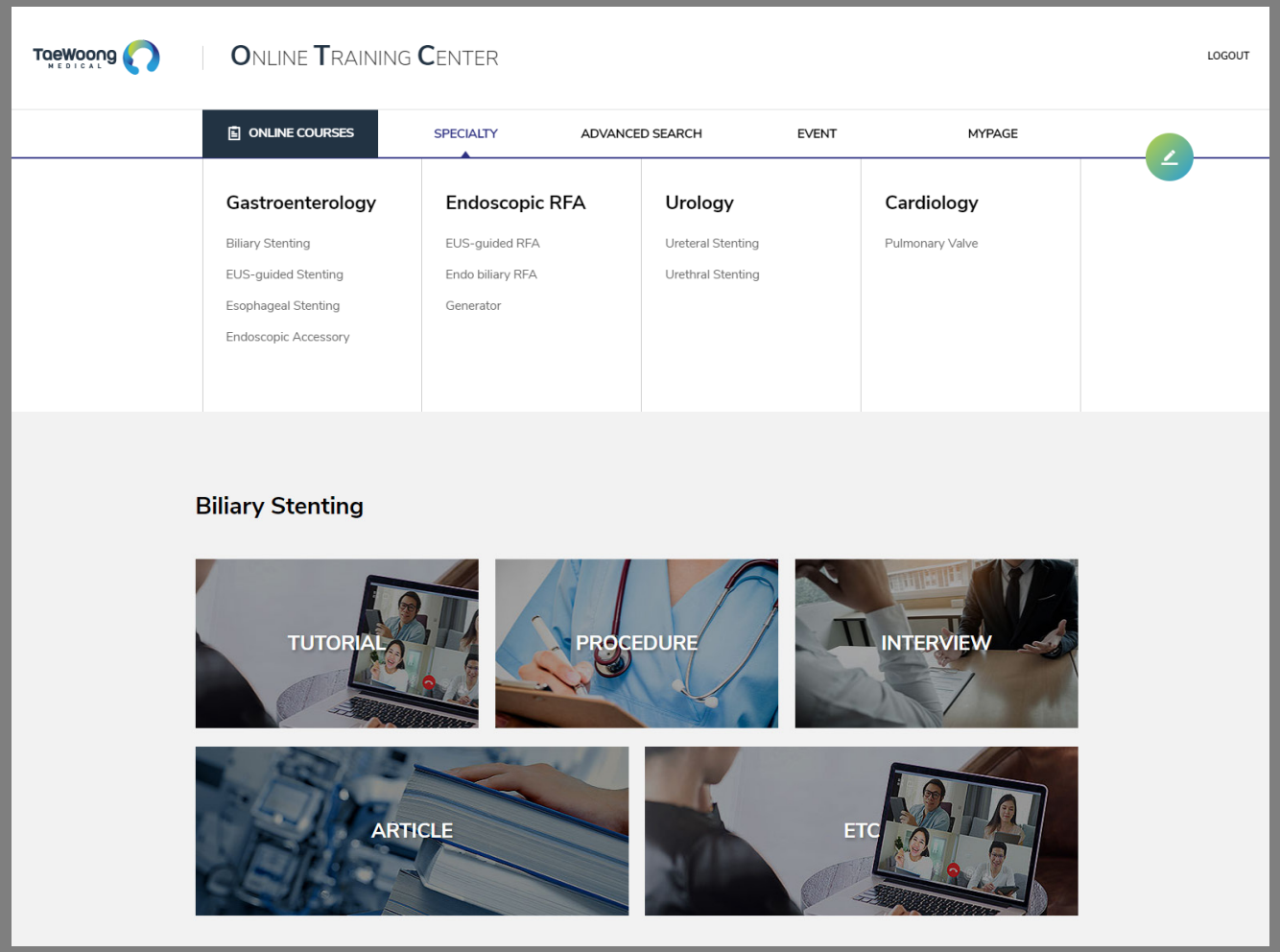


TAEWOONG MEDICAL ONLINE TRAINING CENTER

# FAQ for HOW TO USE THE OTC SITE




## Can anyone access the Taewoong OTC site?

Yes, You can!

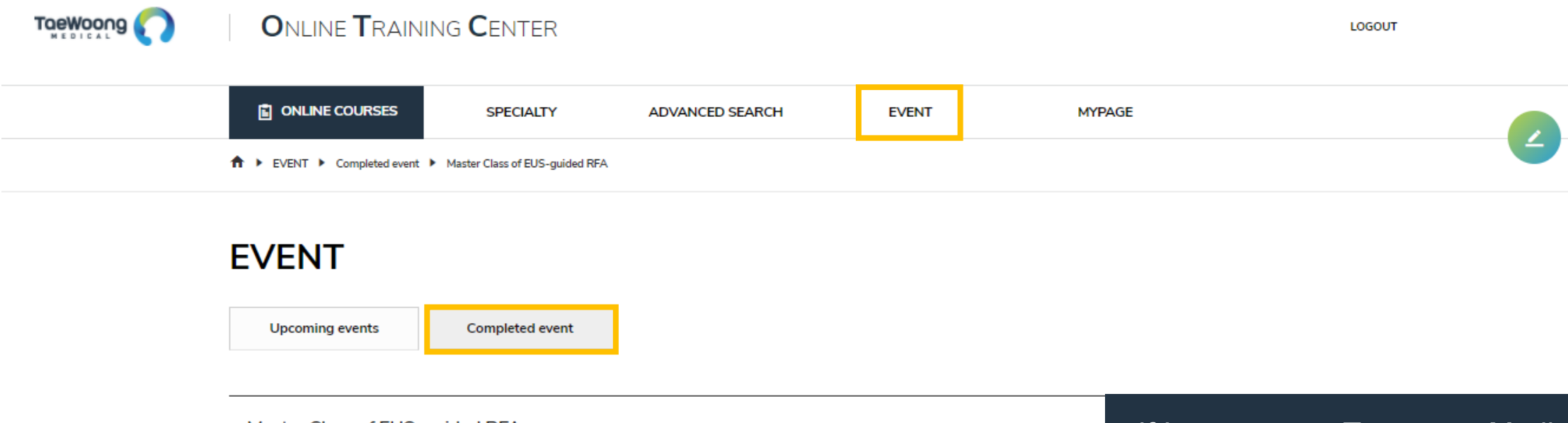
But please sign up on our website and you can log in right away.

(**Automatically approved**)

## What is the difference between **ONLINE COURSE** and **SPECIALTY**?

The **ONLINE COURSE** consists of Taewoong Medical's single products in-depth information. Currently, no related contents have been uploaded, and contents for each product will be updated sequentially in **April**.

The **SPECIALTY** is a subcategorized content divided by the type of product procedures such as tutorials, procedure videos, experts' interviews, lectures by experts, past webinar videos, and articles ETC.




## If I want to see Taewoong Medical's past webinar, where can I find it?

In general, past webinar's conducted by Taewoong Medical are uploaded to the **SPECIALTY** > (Category to which the related product belongs.)

**ETC** (Category within a week after the webinar ends.)

Alternatively, you can find the webinar replay link by referring to the webinar post in the **EVENT** page.

TaeWoong MEDICAL | ONLINE TRAINING CENTER

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ONLINE COURSES | SPECIALTY | ADVANCED SEARCH | EVENT | MYPAGE

# ADVANCED SEARCH

| | |
|---|---|
| Product Line | Gastroenterology, Endoscopic RFA, Urology, Cardiology |
| Classsification | ALL, Biliary Stenting, EUS-guided Stenting, Esophageal Stenting |
| Product Name | ALL, Giobor, Nagi, Spaxus, Hot Nagi, Hot Spaxus |
| Category | ALL, TUTORIAL, INTERVIEW, PROCEDURE, ETC, ARTICLES |

Gastroenterology ⊠ EUS-guided Stenting ⊠ Spaxus ⊠ TUTORIAL ⊠ INTERVIEW ⊠ PROCEDURE ⊠ ETC ⊠ ARTICLES ⊠

SEARCH RESULT (11)

ALL | PDF | VIDEO

PDF ARTICLE
SPAXUS™_Use of a novel lumen apposing metallic stent for drainage of the bile duct...

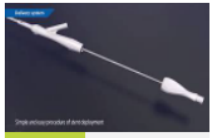
PDF ARTICLE
SPAXUS™_Comparison of Clinical Outcomes between Plastic Stent and Novel...

PDF ARTICLE
SPAXUS™_Efficacy of a novel lumen-apposing metal stent for the treatment of...

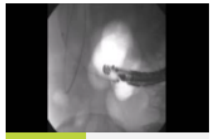
PDF ARTICLE
SPAXUS™_Feasibility and safety of endoscopic ultrasound-guided gallbladd...

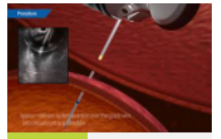

VIDEO ETC
[WEBINAR] EUS Stenting 1st Webinar_JULY 15, 2020


VIDEO ETC
[3D Animation] SPAXUS™ Stent Features & Benefit Animation


VIDEO ETC
[3D Animation] SPAXUS™ Stent - Delivery System Animation


VIDEO PROCEDURE
[PROCEDURE] SPAXUS™ Stent - Pseudocyst Drainage


VIDEO PROCEDURE
[PROCEDURE] SPAXUS™ Stent - Gallbladder Drainage

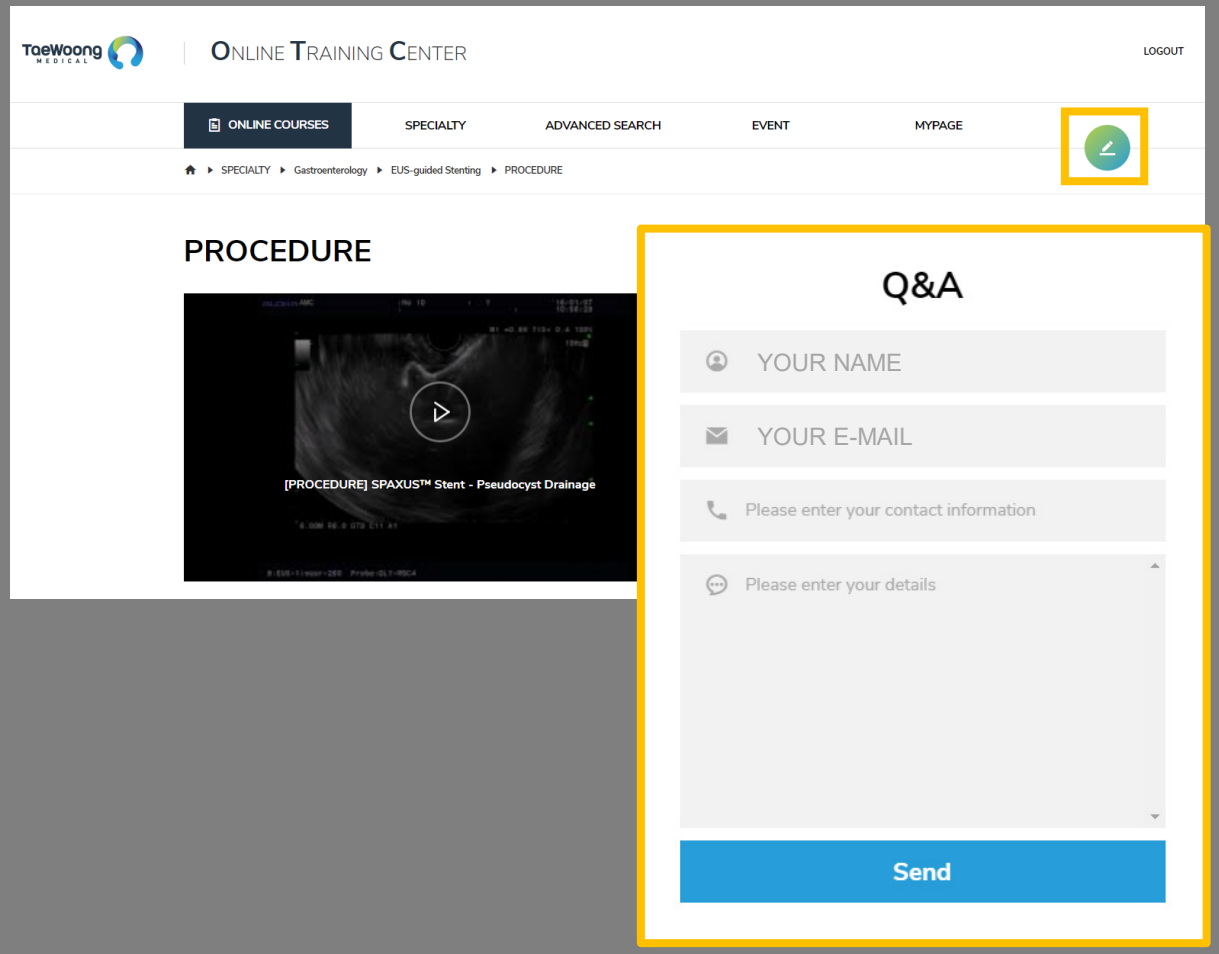

VIDEO ETC
[3D Animation] SPAXUS™ Stent - Procedure Steps


VIDEO INTERVIEW
[INTERVIEW] SPAXUS™ Stent : Symtomatic Pancreatic Pseudocyst

I would like to see all relevant content for a specific product.
How can I find it?

Using the **ADVANCED SEARCH**, you can easily find all the contents for the specific product you are looking for.

**Advanced Search** is a sequential selection method.

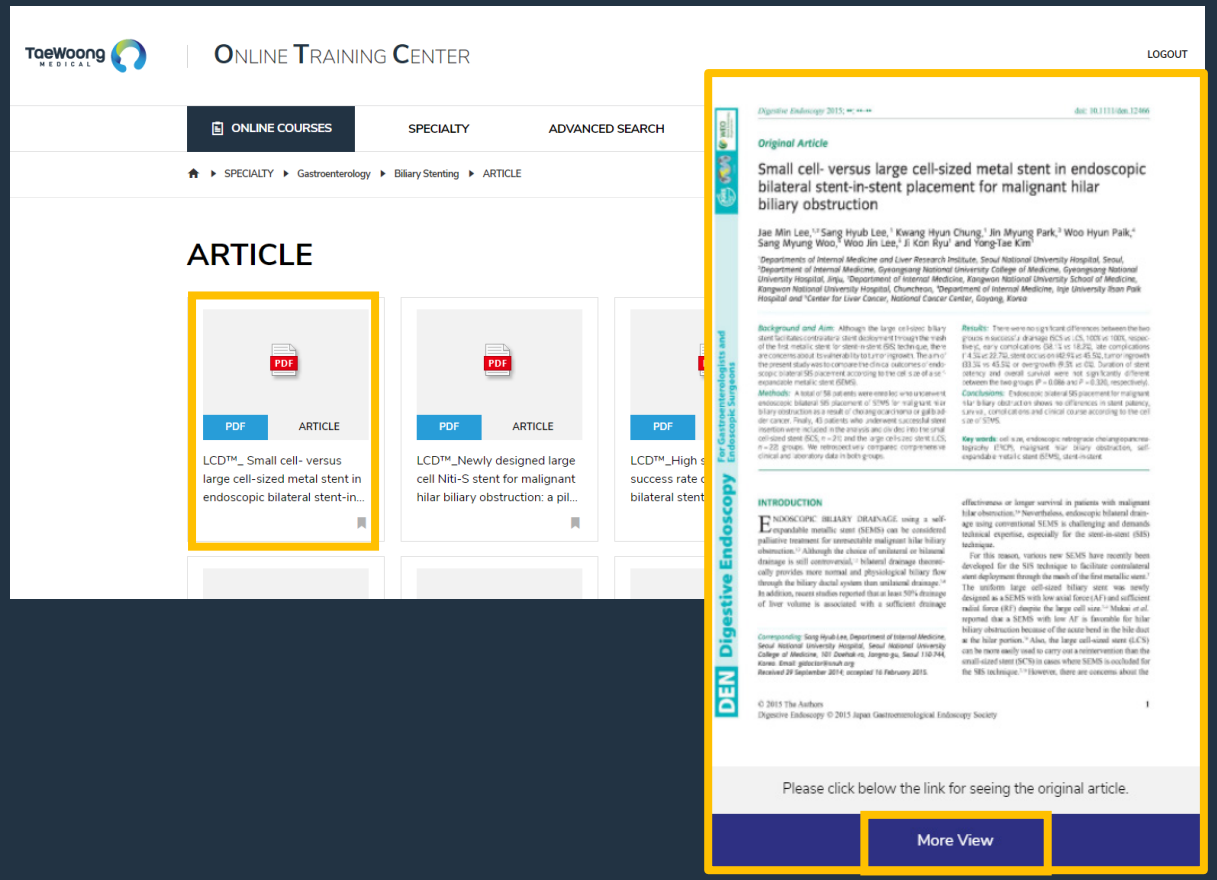


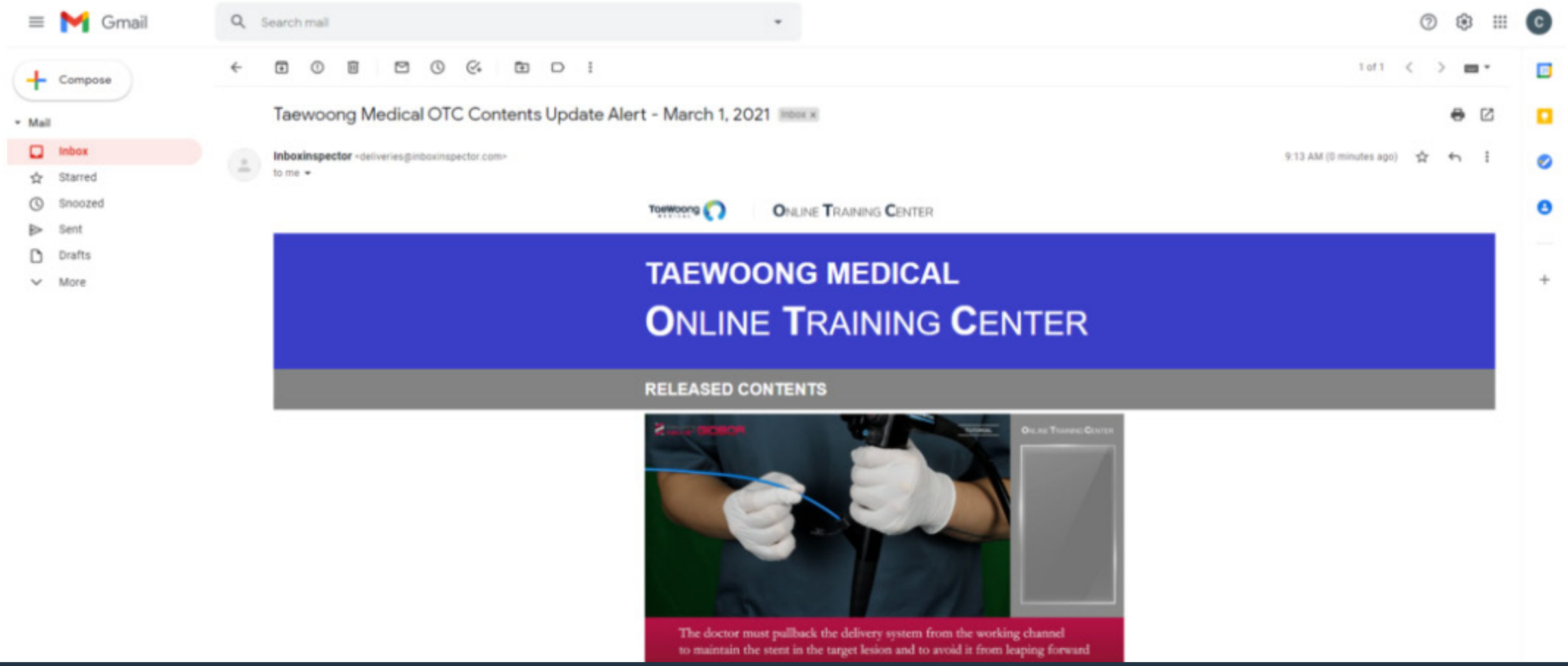

I have a question while looking at the content.
Can I ask a question right away?

Click the ask a **QUESTION ICON** in the upper right corner of the screen. If you leave a question, our staff will respond ASAP.

I would like to see an original article related to the specific product.

The OTC site provides the first page of the articles related to our products. Due to copyright issues, a link to view the original manuscript is provided. So, please click the **VIEW ICON** below.






Whenever new contents are updated on the OTC site, an **alert newsletter** is sent to the registered e-mail when you signed up. But, I have never received an OTC alert e-mail. **Where can I find them and How can I receive them?**

Currently, OTC update alert e-mails are being sent once a week or once every two weeks like above. If you haven't seen the e-mail, **check the promotion inbox or spam inbox. If the OTC alert e-mail is in the spam box, please report not spam.**

# Use of a novel lumen apposing metallic stent for drainage of the bile duct and gallbladder : Long term outcomes of a prospective international trial

by Anthony Yuen Bun Teoh et al. [Dig Endosc. 2020 Dec 7. doi: 10.1111/den.13911.]

(CLICK) TO ORIGINAL ARTICLE


## BACKGROUND

Long-term placement of lumen apposing metal stents (LAMS) with high lumen apposing force may result in adverse events. The aim of the current study was to assess the long-term efficacy and safety of a self-approximating LAMS with lower lumen apposing force for endoscopic ultrasound-guided choledochoduodenostomy (EUS-CDS) and -gallbladder drainage (EUS-GBD).

## METHODS

Five Asian institutions participated in this study. Consecutive patients suffering from obstructive jaundice with failed ERCP or acute cholecystitis that were at high risk for cholecystectomy were recruited. We evaluated the technical and clinical success rates, adverse events rates, types of interventions through the stent and the patency profile.

## RESULTS

From June 2017 to Oct 2018, a total of 53 patients received EUS-CDS (26) and EUS-GBD (27). The technical and clinical success rates were similar between the two groups (88.5% vs 88.9%, P = 1 and 88.5% vs 88.9%, P = 1 respectively). The differences in 30-day mortality rates [2 (7.7%) vs 2 (7.7%), P = 1] and adverse events [3 (11.5%) vs 3 (11.5%), P = 1] did not reach significance. Regarding long-term outcomes, two patients in each group suffered from adverse events (P = 1). One patient in the EUS-GBD group who was on direct oral anticoagulant suffered from stent induced bleeding.

## CONCLUSION

The self-approximating LAMS with lower lumen apposing force was effective and safe with a low risk of buried stent syndrome and bleeding in the longer term. The ClinicalTrials.gov Identifier was NCT03002051.

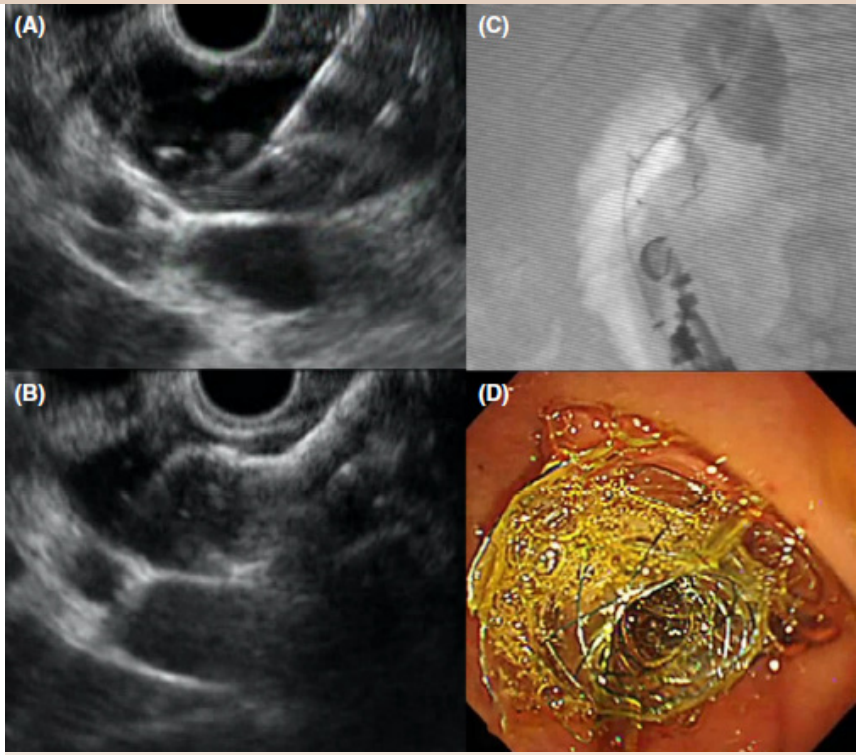




**Figure 2.** Endoscopic ultrasound (EUS) guided-choledochoduodenostomy (CDS) with self-approximating lumen apposing metallic stent (S-LAMS). (A) A 19-gauge needle was used to puncture the CBD. (B) EUS-guidance was used for monitoring the deployment of the distal flange. (C) Fluoroscopic view of after deployment of the distal flange. (D) Endoscopic view after complete deployment.

# A novel electrocautery-enhanced delivery system for one-step endoscopic ultrasound-guided drainage of the gallbladder and bile duct using a lumen-apposing metal stent : a feasibility study

by Hae Won Yoo et al. [Endoscopy. 2020 Dec 17. doi: 10.1055/a-1301-1526.]

(CLICK) TO ORIGINAL ARTICLE


## BACKGROUND

The use of a lumen-apposing metal stent (LAMS) capable of one-step endoscopic ultrasound-guided transmural drainage (EUS-TD) can increase the effectiveness of the procedure. We evaluated the newly developed electrocautery-enhanced (EC) delivery system with a LAMS for one-step EUS-guided gallbladder drainage (EUS-GBD) or choledochoduodenostomy (EUS-CDS).

## METHODS

In the animal experiment, an EC-LAMS was advanced into the gallbladder without prior tract dilation in four pigs. A conventional LAMS was inserted in another four pigs as a control group. After the animal experiment, 17 patients underwent EUS-TD using the EC-LAMS (EUS-GBD in 10 patients, EUS-CDS in 7). The primary outcome was the technical success rate.

## RESULTS

In the animal study, the mean procedure time was significantly shorter in the EC-LAMS group than in the conventional LAMS group. In the human study, the overall technical success rate was 94.1%, with one EUS-GBD failure. The clinical success rate was 100%. The overall adverse event rate was 17.6%.

## CONCLUSION

One-step EUS-GBD or EUS-CDS using the novel EC-LAMS is a feasible approach that achieves a high success rate and maintains safety.

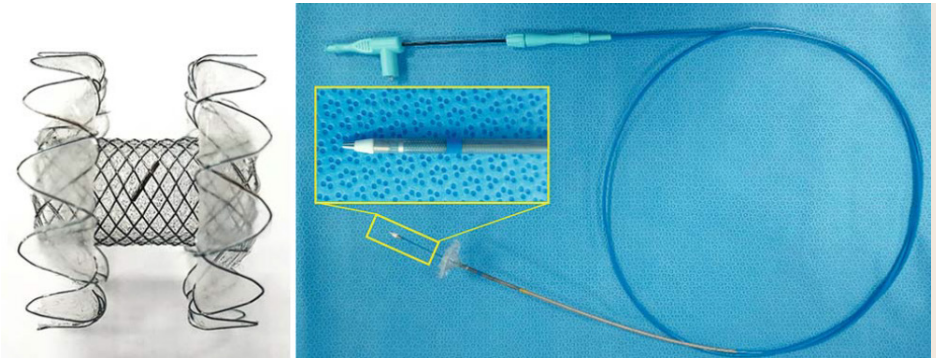



**Fig 1.** The lumen-apposing metal stent (LAMS) with the newly developed electrocautery-enhanced delivery system (Niti-S HOT SPAXUS).

▶ **Table 1** Outcomes of endoscopic ultrasound-guided biliary drainage procedures using the novel lumen-apposing metal stent with electrocautery-enhanced delivery system.

| | Type of procedure | | Total |
|---|---|---|---|
| | EUS-CDS (n = 7) | EUS-GBD (n = 10) | |
| Technical success, n (%) | 7 (100) | 9 (90.0) | 16/17 (94.1) |
| Procedure time, mean (SD), minutes | 8.6 (3.9) | 10.8 (4.9) | 9.88 (4.51) |
| Stent diameter, n (%), mm | | | |
| ▪ 8 × 20 | 6 (85.7) | 0 | 6 (37.5) |
| ▪ 10 × 20 | 1 (14.3) | 9 (90.0) | 10 (62.5) |
| Procedure site, n (%) | | | |
| ▪ Duodenum | 7 (100) | 7 (70.0) | 14 (82.3) |
| ▪ Stomach | 0 | 3 (30.0) | 3 (17.6) |
| Clinical success, n (%) | 7 (100) | 9 (90.0) | 16/17 (94.1) |

EUS-CDS, endoscopic ultrasound guided choledochoduodenostomy; EUS-GBD, EUS-guided gallbladder drainage, SD, standard deviation.

# A cholecystoduodenostomy with a new type of lumen-apposing metal stent

(CLICK) TO ORIGINAL ARTICLE

by Benedetto Mangiavillano et al. [Dig Liver Dis. 2020 Sep 1;S1590-8658(20)30402-3.]

A 67-year-old severe obese woman was admitted to our emergency room for upper right quadrant pain associated with fever (39.5°C). Biochemical evaluation showed 32 109/L WBC. Renal function was impaired. A significant increase of the cholestasis and cytolysis enzymes was also observed. An abdominal ultrasound showed an hydropic gallbladder with cholelithiasis and thickened walls. A diagnosis of multi-organ failure (MOF) was done and, after multidisciplinary discussion, we decided to drain the gallbladder by endoscopic ultrasonographic (EUS). With a linear echoendoscope (GF-UCT180, Olympus, Hamburg - Germany) we performed a cholecystoduodenostomy (CDS) with a new fully-covered bi-flange shape lumen apposing metal stent (LAMS) with an electrocautetery tip ((Hot-SpaxusR 20 × 10 mm; Taewoong Medical Co, Ltd, Goyang-si, Korea) (Figs. 1 and 2). The procedure was carried out without X-ray in intensive care unit (ICU). The release of the proximal flange of the stent was performed inside the channel of the scope and no adverse events were experienced (video). To our knowledge, this is the first report of an Hot-Spaxus® placement.

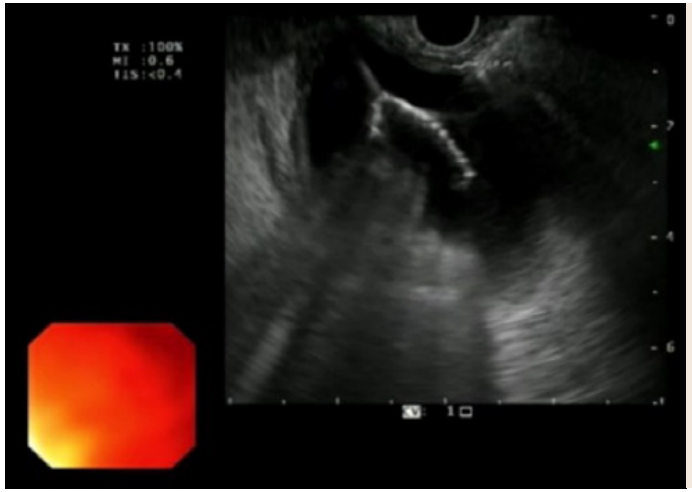


**Fig 1.** EUS appearance of the Hot-Spaxus® distal flange deployed inside the gallbladder.

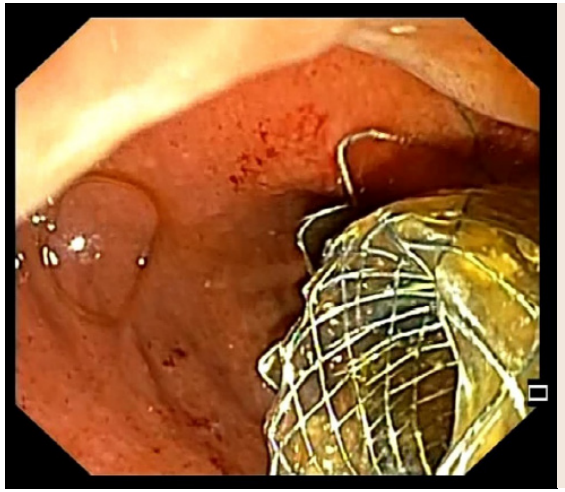


**Fig 2.** Hot-Spaxus® proxymal flange deployed inside the duodenal lumen.

# Endoscopic ultrasound-guided radiofrequency ablation of pancreatic microcystic serous cystic neoplasms: a retrospective study

by Dongwook Oh et al. [Endoscopy. 2020 Oct 15. doi: 10.1055/a-1250-7786.]

(CLICK) TO ORIGINAL ARTICLE

This study aimed to evaluate the feasibility and safety of EUS-RFA for serous cystic neoplasms (SCNs). 13 patients with microcystic SCNs with honeycomb appearance underwent EUS-RFA using a 19-gauge RFA needle. Before ablation, cystic fluid was aspirated until a thin layer of fluid remained.

Multi septated PCLs, including SCNs, are not good indications for EUS-guided ethanol lavage because of the presence of often hundreds of small cysts that do not permit uniform application or retention of the ablative liquid agent. To date, few studies have demonstrated the feasibility and safety of endoscopic ultrasound-guided radiofrequency ablation (EUS-RFA) for the management of PCLs. In our study, CR was not observed in any patients. A volume reduction was achieved in all patients, with a volume reduction of more than 66% (PR) being observed in 61.5% of patients. There are several plausible explanations for this response after EUS-RFA. Although there were no CRs, the volume of all SCNs was reduced and, after reduction of the SCN volume, symptoms were improved. Considering that the mortality of SCN is low and the morbidity and mortality of surgery are significant, follow-up after volume reduction may be a reasonable approach for symptomatic patients. In addition, the median follow-up period was less than 1 year (median 9.21 months; IQR 5.93 - 15.38), and this relatively short follow-up period may have affected the treatment response. Therefore, long-term follow-up after RFA is warranted for further treatment response evaluation. In conclusion, EUS-RFA for the treatment of microcystic SCNs is technically feasible and showed an acceptable rate of adverse events. Further large-scale long-term follow-up studies are encouraged to validate the efficacy and safety of EUS-RFA.

**Video 1.** Endoscopic ultrasound images of a microcystic serous cystic neoplasm being treated by two sessions of radiofrequency ablation.

# Efficacy of EUS-RFA in pancreatic tumors: Is it ready for prime time? A systematic review and meta-analysis

by Amaninder Dhaliwal et al. [Endosc Int Open. 2020 Oct;8(10):E1243-E1251.]

(CLICK) TO ORIGINAL ARTICLE

This article performed a systematic review and meta analysis to evaluate the efficacy of EUS-RFA in treatment of locally advanced unresectable PDAC and other pancreatic tumors. Thirteen studies reporting 165 EUS-RFA procedures on 134 patients were included. Of 134 patients, 27.94% (38) had unresectable locally advanced PDAC, 40% (53) had PNETs, 3% (4) had metastasis to the pancreas and 30% (41) had other lesions. The pooled technical success rate calculated out of the total number of procedures was 100% (95% CI [99.18 – 100], I2=0%). The pooled clinical success rate calculated out of the total number of patients was 91.58% (95% CI [82.5 – 98.08], I2 = 21.5%). The pooled overall AE rates were 14.67% (95% CI [4.77 – 27.46], I2 = 56.19 %) out of which abdominal pain was the most common with 9.82% (95% CI [3.34– 18.24], I2 = 23.76 %). Low to moderate heterogeneity was noted. In non-functional PNETs, Berthet et al noted 86% had diminished by at least 50% in size or completely by 12 months following ablation . Functional PNETs exhibited a sustained attenuation of clinical symptoms such as hypoglycemia or diarrhea, rapid normalization of secreted hormone levels, and sustained significant decrease in size of the neoplasm. PNETs had a pooled clinical success rate ranging from 83% to 100%. The secondary endpoint of this meta-analysis was to analyze AEs associated with EUS-RFA.

The overall pooled incidence of AEs was 14.67% (95% CI [4.77 – 27.46], I2=56.19%). AEs were divided into early (< 7 days) and late (> 7 days). The most common early AE was self-resolving abdominal pain (9.82% (95% CI [3.34 – 18.24], I2 = 23.76 %)). There was one report of self-resolving pancreatitis. In that instance, Choi et al. recommended a 5-mm margin from the pancreatic duct to avoid pancreatitis. Delayed AEs were reported in two studies. In all patients, no correlation was found between AEs and ablation time or energy settings. Overall, EUS-RFA has exhibited both high technical and clinical success with minimal AEs in addressing locally advanced unresectable PDAC and other pre-malignant pancreatic lesions where curative surgery is not an option. In the future, EUS-RFA may become a more widely used approach to treatment of a myriad of pancreatic lesions. Further long-term multicenter prospective studies are needed to correlate our findings.