

# Kit de Implantación Danis

SX-ELLA Prótesis Danis



# Danis



Prótesis extraíble para el tratamiento de hemorragia de las várices esofágicas

Fácil implantación sin necesidad de endoscopio / control de Rayos X

Hemostasia segura a través de la compresión directa de las várices

Ingestión oral que se mantiene desde el momento de la implantación



3D animation



## Descripción básica

### Kit de Implantación con SX-ELLA prótesis Danis

Prótesis autoexpansible de nitinol, precargada en el sistema de implantación listo-para-usar.  
Kit de implantación completo, incluye todos los elementos requeridos para la implantación.

### Indicaciones

La SX-ELLA Prótesis Danis está destinada a detener la hemorragia aguda y/o refractaria por várices esofágicas.

### Contraindicaciones

- ✓ Diagnóstico de malignidad o estenosis que afecta el esófago
- ✓ Historial clínico de radioterapia de tórax o de esófago
- ✓ Malignidad de garganta o de laringe
- ✓ Malignidad de bronquios o fístulas
- ✓ Malignidad de estómago
- ✓ Sospecha de sangrado por cuerpo extraño que lesiona el tracto gastrointestinal superior

### Características y beneficios

- ✓ La forma variable del entretejido de la prótesis se ajusta a la peristalsis esofágica - reducido grado de migración
- ✓ La compresión estandarizada de las várices da como resultado una hemostasia eficaz
- ✓ Bordes atraumáticos
- ✓ Marcadores radiopacos en ambos extremos y en el punto medio de la prótesis - para un posible control radiológico de la posición de la prótesis
- ✓ Lazadas de recuperación en aleación de calidad médica, en ambos extremos de la prótesis - alta durabilidad mecánica y resistencia a los ácidos
- ✓ Fácil extracción endoscópica después dentro de 7 días

### Beneficios del método

- ✓ Implantación fácil sin endoscopia / control de Rayos-X también en las situaciones de emergencia.
- ✓ El paciente puede seguir una dieta vía oral después de la implantación.

### Descripción adicional

Kit completo de Implantación Danis (019-08S-25-135) consta de un estuche plástico, que contiene todos los elementos requeridos para la implantación de la prótesis:

- ✓ La prótesis cargada en el sistema de implantación, el alambre guía, jeringas de plástico, boquilla, riñonera o recipiente de papel para emesis, babero o paño para secreción salival, bolsa para desechos con gancho o clip, guantes.

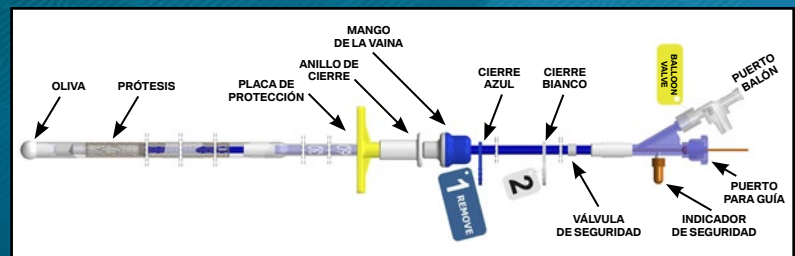
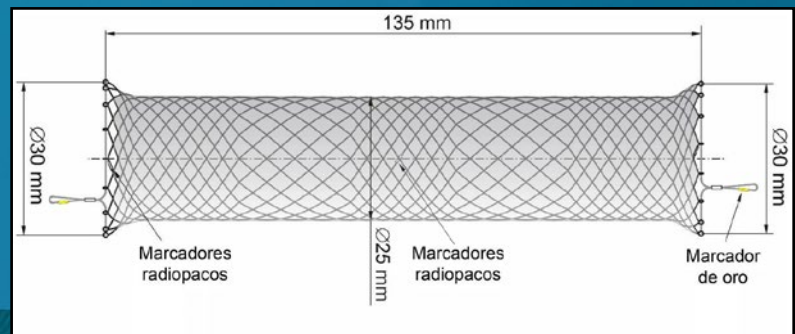
Kit Básico de Implantación Danis (019-08S-25-135-B) consta de:

- ✓ La prótesis cargada en el sistema de implantación, el alambre guía, jeringa de plástico de 50 ml.

Sistema de implantación 9.4 mm (28 F) / 6.6 mm (20 F) disponible en una longitud estándar de 60 cm.

### Medidas disponibles

REF No.	SX-ELLA Prótesis Danis			Sistema de implantación	
	Diámetro de los extremos de la prótesis [mm]	Diámetro del cuerpo de la prótesis [mm]	Longitud nominal [mm]	Longitud activa [cm]	Diámetro externo [F]
019-08S-25-135	30	25	135	60	28 / 20
019-08S-25-135-B	30	25	135	60	28 / 20



Sistema de implantación - balón gástrico desplegado



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# REFERENCES

## Danis Procedure Pack

SX-ELLA Stent Danis



### Esophageal Balloon Tamponade Versus Esophageal Stent in Controlling Acute Refractory Variceal Bleeding: A Multicenter Randomized, Controlled Trial

Escorsell, Àngels, et al.

Hepatology, 2016 Jun;63(6):1957-67. doi: 10.1002/hep.28360. Epub 2016 Jan 14.

...28 patients were finally included - Esophageal Stent (n = 13), Balloon Tamponade (n = 15)...esophageal metal stents are more effective than balloon tamponade for the temporary control of massive or refractory esophageal AVB in patients with cirrhosis... The results of our multicenter randomized, controlled trial (RCT) show that the use of self-expandable esophageal stents provides a better balance of benefits and harms than balloon tamponade...

### SX-Ella Stent Danis Effectively Controls Refractory Variceal Bleed in Patients with Acute-on-Chronic Liver Failure

Maiwall, R., Jamwal, K.D., Bhardwaj, A. et al.

Dig Dis Sci 63, 493–501 (2018). <https://doi.org/10.1007/s10620-017-4686-8>.

...Acute-on-chronic liver failure patients (n = 88, mean age 47.3 ± 10.9 years) with refractory variceal bleeds received either **Danis stent (Gr. A, n = 35)** or continued with **repeat endotherapy and vasoactive drug (Gr.B, n = 53)**. **Control of initial bleeding was significantly more in the Danis stent group** as compared to controls in both pre-match (89 vs. 37%; p < 0.001) and PRS-matched cohorts (73 vs. 32%; 0.007). Further, **bleed-related death was also significantly lower in Danis group** as compared to controls in both pre-match (14 vs. 64%; p = 0.001) and PRS-matched cohorts (6 vs. 56%; p = 0.001). In a multivariate competing risk Cox model, patients who underwent DE stenting had reduced mortality in both pre-match (p = 0.04, HR 0.36, 95% CI 0.13–0.96) and PRS-matched cohorts (p < 0.001, HR 0.21, 95% CI 0.08–0.51). **These findings highlight that Danis stent could be considered as the first-line management option for patients with ACLF with refractory variceal bleeds wherein TIPS is contraindicated.**

### A self-expanding metal stent for complicated variceal hemorrhage: experience at a single center

Wright G, Lewis H, Hogan B et al.

Gastrointest Endosc. 2010 Jan;71(1):71-8.

...10 patients with variceal hemorrhage with contraindications to TIPS insertion or BT ... Stent insertion was successful in 9 of 10 patients ... Insertion of the SX-Ella DANIS stent in patients with refractory variceal bleeding or complications of previous therapy is effective for the control of bleeding ... In selected patients, SX-Ella DANIS stent insertion offers an alternative to other methods of salvage such as BT and TIPS and could be considered a substitute for BT after a prospective trial...

### Treatment of Esophageal Variceal Hemorrhage with Self-Expanding Metal Stents as a Rescue Maneuver in a Swiss Multicentric Cohort

Fierz FC, Kistler W, Stenz V et al.

Case Rep Gastroenterol. 2013;7:97–105.

...The use of variceal stenting in 7 patients with a total of 9 bleeding episodes in three different Swiss hospitals ... insertion of the stent led to immediate bleeding control in 89% (8/9) of patients. In all of these 8 cases no re-bleeding was observed subsequently while the stent remained in situ ... thanks to their safety and easy handling, SEMS are an interesting alternative to balloon tamponade as a bridging intervention to definitive therapy including the pre-hospital setting ...



### Self-Expanding Metal Stent (SEMS): an innovative rescue therapy for refractory acute variceal bleeding

Kinesh Changela, Mel A. Ona, Sury Anand, Sushil Duddempudi

Department of Gastroenterology, The Brooklyn Hospital Center, New York, USA. 2014.

At present, **103 cases have been described in the literature**. Studies have reported **97.08% technical success** rates in deployment of SEMS. Most of the stents were intact for 4–14 days with no major complications reported. Stent extraction had a success rate of 100%. **Successful hemostasis was achieved in 96% of cases** with only 3.12% found to have rebleeding after placement of SEMS. Stent migration, which was the most common complication, was observed in 21 % of patients.

### Acute management of Refractory Variceal Bleeding in Liver Cirrhosis by Self-Expanding Metal Stents

Dechêne A, El Fouly AH, Bechmann LP et al.

Digestion. 2012;85(3):185-91.

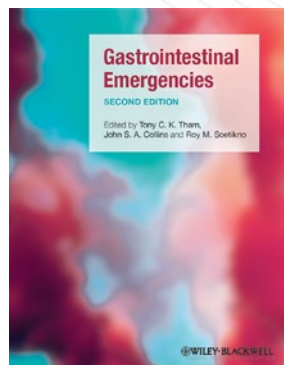
...8 patients in whom endoscopic variceal ligation failed to control variceal hemorrhage were treated ... The application of SEMS in esophageal hemorrhage showed a complete success in achieving hemostasis even after failed endoscopic variceal ligation...

### Results of a new method to stop acute bleeding from esophageal varices: implantation of a self-expanding stent

Zehetner J, Shamiyeh A, Wayand W et al.

Surg Endosc. 2008 Oct;22(10):2149-52.

...34 patients with ongoing bleeding from esophageal varices ... For all 34 patients, the implantation of the esophageal stent succeeded in stopping ongoing bleeding ... No stent-related complications occurred during or after stent implantation ... No bleeding recurrence was observed during the stent implantation ... For all the patients, the stent could be extracted by endoscopy without any complications using an extractor ... No rebleeding occurred...



### Gastrointestinal Emergencies

THAM, Tony C, John S COLLINS, Roy SOETIKNO and Tony C THAM. Gastrointestinal emergencies.

2nd ed. Hoboken, NJ: Wiley-Blackwell Pub., 2009, viii, 221 p., [4] p. ISBN 978-1-4051-4634-0.

Chapter 24 Variceal Hemorrhage. p. 141–148. ISBN 978-1-4051-4634-0.

On pages 141–148, authors describe the methods for management of acute or refractory variceal bleeding with the following description:

“...In such cases, the use of newly designed removable covered self-expandable metal stent (SX-Ella Danis stent, Ella-CS s.r.o. Czech Republic) has been recommended, as it is easier to insert and does not obstruct the esophagus...”

### Oxford Handbook of Acute Medicine

RAMRAKHA, Punit S, Kevin P MOORE and Amir H SAM. Oxford handbook of acute medicine. 3rd ed. New York: Oxford University Press, xxxvii, 869 p., [4] p. of plates. Oxford handbooks. ISBN 01-992-3092-7. Chapter 3 Gastroenterological emergencies. p. 232–233. ISBN 01-992-3092-7.

On pages 232–233, you will find a synoptic chart listing the key points of management of variceal bleeding. In the point where the techniques for temporary stabilisation of the patient with uncontrolled variceal bleeding are mentioned, there is also stated that:

“...Some centres are now using DANIS stents...”

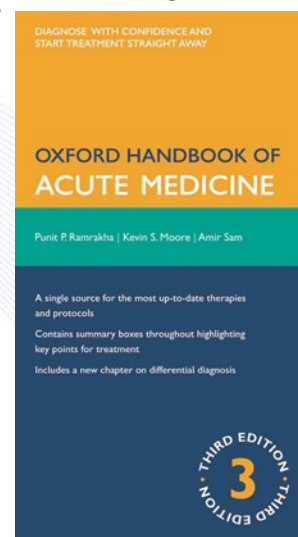
The Sengstaken-Blakemore or Linton tube can only be used in settings where experienced staff is available, whereas the use of the Danis stent is easy for the staff and significantly safer for the patient.

### Therapie-Handbuch Innere Medizin

DOMSCHKE, W et al. Therapie-Handbuch Innere Medizin. Sonderedition 2011/2012. München: Elsevier URBAN&FISCHER. ISBN 978-3-437-22107-1.

On pages 479–485, you can find the description of the management of esophageal variceal bleeding. The balloon-tamponade is also mentioned in the section describing the management of refractory bleeding. All the necessary precautions are listed along with the risks which the use of the tamponade brings. Then the authors state that:

“...Small studies show that more preferable possibility can be used. Endoscopically introduced fully covered removable stent can be used to compress the bleeding varices (DANIS-Stent)...”



### Esophageal stenting for benign and malignant disease: European Society of Gastrointestinal Endoscopy (ESGE) Clinical Guideline

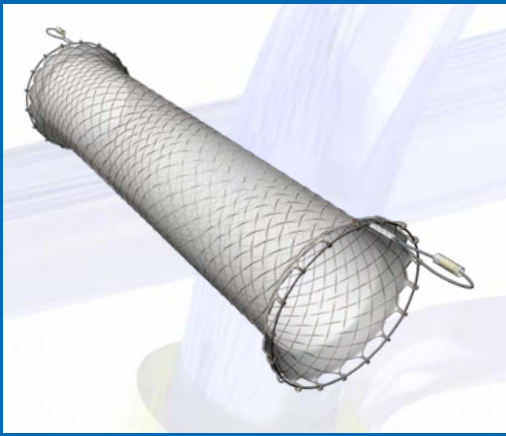
Spaander M. C. W., Baron T. H., Siersema P. D.

ESGE recommends considering placement of a SEMS for the treatment of esophageal variceal bleeding refractory to medical, endoscopic, and/or radiological therapy, or as initial therapy for patients with massive bleeding (strong recommendation, moderate quality evidence).



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# Baveno VI

## CONSENSUS

April 10-11, 2015  
Baveno, Italy

## Management of the acute bleeding episode

### Blood volume restitution

The goal of resuscitation is to preserve tissue perfusion. Volume restitution should be initiated to restore and maintain hemodynamic stability.

Packed red blood cells transfusion should be done conservatively at a target haemoglobin level between 7 and 8 g/dl, although transfusion policy in individual patients should also consider other factors such as cardiovascular disorders, age, hemodynamic status and ongoing bleeding (1b;A).

Recommendations regarding management of coagulopathy and thrombocytopenia cannot be made on the basis of currently available data (5;D).

PT/INR is not a reliable indicator of the coagulation status in patients with cirrhosis (1b;A).

### Antibiotic prophylaxis

Antibiotic prophylaxis is an integral part of therapy for patients with cirrhosis presenting with upper gastrointestinal (GI) bleeding and should be instituted from admission (1a;A).

The risk of bacterial infection and mortality are very low in patients with Child-Pugh A cirrhosis (2b;B), but more prospective studies are needed to assess whether antibiotic prophylaxis can be avoided in this subgroup of patients.

Individual patient risk characteristics and local antimicrobial susceptibility patterns must be considered when determining appropriate first line acute variceal haemorrhage antimicrobial prophylaxis at each centre (5;D).

Intravenous ceftriaxone 1 g/24 h should be considered in patients with advanced cirrhosis (1b;A), in hospital settings with high prevalence of quinolone-resistant bacterial infections and in patients on previous quinolone prophylaxis (5;D).

### Prevention of hepatic encephalopathy

Recent studies suggest that either lactulose or rifaximin may prevent hepatic encephalopathy in patients with cirrhosis and upper GI bleeding (1b;A). However, further studies are needed to evaluate the risk/benefit ratio and to identify high risk patients before a formal recommendation can be made (5;D).

Although, there are no specific studies in acute variceal bleeding, it is recommended to adopt the recent EASL/

AASLD HE guidelines which state that episodic HE should be treated with lactulose (25 ml q 12 h until 2–3 soft bowel movements are produced, followed by dose titration to maintain 2–3 soft bowel movements per day) (5;D).

### Assessment of prognosis

Child-Pugh class C, the updated MELD score, and failure to achieve primary haemostasis are the variables most consistently found to predict six week mortality (2b;B).

### Pharmacological treatment

In suspected variceal bleeding, vasoactive drugs should be started as soon as possible, before endoscopy (1b;A).

Vasoactive drugs (terlipressin, somatostatin, octreotide) should be used in combination with endoscopic therapy and continued for up to five days (1a;A).

Hyponatremia has been described in patients under terlipressin, especially in patients with preserved liver function. Therefore, sodium levels must be monitored (1b;A).

### Endoscopy

Following hemodynamic resuscitation, patients with upper GI bleeding and features suggesting cirrhosis should undergo esophagogastroduodenoscopy within 12h of presentation (5;D).

In the absence of contraindications (QT prolongation), pre-endoscopy infusion of erythromycin (250 mg IV 30–120 min before endoscopy) should be considered (1b;A).

The availability both of an on-call GI endoscopist proficient in endoscopic haemostasis and on-call support staff with technical expertise in the usage of endoscopic devices enables performance of endoscopy on a 24/7 basis and is recommended (5;D).

Patients with acute variceal haemorrhage should be considered for ICU or other well monitored units (5;D).

In patients with altered consciousness, endoscopy should be performed with protection of the airway (5;D).

Ligation is the recommended form of endoscopic therapy for acute oesophageal variceal bleeding (1b;A).

Endoscopic therapy with tissue adhesive (e.g. N-butyl-cyanoacrylate) is recommended for acute bleeding from isolated gastric varices (IGV) (1b;A) and those gastroesophageal varices type 2 (GOV2) that extend beyond the cardia (5;D).



To prevent rebleeding from gastric varices, consideration should be given to additional glue injection (after two to four weeks), beta-blocker treatment or both combined or TIPS (5;D). More data in this area are needed.

EVL or tissue adhesive can be used in bleeding from gastroesophageal varices type 1 (GOV1) (5;D).

### Early TIPS placement

An early TIPS with PTFE-covered stents within 72 h (ideally <24 h) must be considered in patients bleeding from EV, GOV1 and GOV2 at high risk of treatment failure (e.g. Child-Pugh class C <14 points or Child-Pugh class B with active bleeding) after initial pharmacological and endoscopic therapy (1b;A). Criteria for high risk patients should be refined.

### Balloon tamponade

Balloon tamponade, given the high incidence of its severe adverse events, should only be used in refractory oesophageal bleeding, as a temporary "bridge" (for a maximum of 24 h) with intensive care monitoring and considering intubation, until definitive treatment can be instituted (5;D).

### Use of self-expandable metal stents

Data suggest that self-expanding covered oesophageal metal stents may be as efficacious and a safer option than balloon tamponade in refractory oesophageal variceal bleeding (4;C).

### Management of treatment failures

Persistent bleeding despite combined pharmacological and endoscopic therapy is best managed by PTFE-covered TIPS (2b;B).

Rebleeding during the first five days may be managed by a second attempt at endoscopic therapy. If rebleeding is severe, PTFE-covered TIPS is likely the best option (2b;B).

### Research agenda

Trials of preventative strategies in acute kidney injury in variceal bleeding should be undertaken.

Treatment and prevention of HE.

Optimal use of glue obliteration in gastric variceal bleeding.

Role of endoscopic ultrasound in variceal injection therapy.

Alternative endoscopic haemostasis techniques in EVB, e.g., haemostatic powders.

Improve prognostic models: Better stratification of risk to determine applicability of updated MELD or other potential new models to improve stratification of risk to determine type of treatment.

Applicability of models to determine other issues such as timing of the initial endoscopy, duration of the drug therapy and type of treatment.

Use of early TIPS in gastric varices.

Use of balloon occluded retrograde transvenous obliteration (BRTO) in IGV.

de Franchis, R. Expanding consensus in portal hypertension: Report of the Baveno VI Consensus Workshop: Stratifying risk and individualizing care for portal hypertension. *Journal of Hepatology* **63**, 743-752 (2015).



## Danis Procedure Pack

### SX-ELLA Stent Danis

The only stent developed and designed specially for the purpose of stopping esophageal variceal bleeding

#### Features

- Easy to operate emergency device
- Instant hemostasis through direct compression of varices
- Easy implantation without the need for endoscopy or fluoroscopy
- Easy endoscopic stent removal after 7 days

#### Benefits

- Reduced migration due to special stent design
- Standardized compression of the esophageal varices with safe and effective hemostasis
- Oral intake maintained from the time of implantation
- Possibility of endoscopic examination through the implanted stent
- Special device "ELLA Extractor" for non-traumatic and easy extraction of the stent

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