

# Prótesis BD

## SX-ELLA Prótesis Esofágica Degradable BD



# Prótesis BD



Biodegradable

Sistema de implantación único

Excelente flexibilidad

Marcadores radiopacos



3D animation



## Descripción básica

### Prótesis SX-ELLA Esofágica Degradable BD

La Prótesis BD está destinada a pacientes mayores de 18 años y está indicada para el tratamiento de estenosis esofágicas benignas refractarias: estenosis esofágicas refractarias (pépticas, cáusticas o anastomóticas) en las que falló la terapia estándar con dilatación repetida.

#### Características y beneficios

- ✓ Material biodegradable – Polidioxanona - la prótesis degrada generalmente en 3 a 4 meses después de la implantación; no hay necesidad de extracción.
- ✓ La integridad y la fuerza radial de la prótesis se mantienen durante 6–8 semanas después de la implantación - período extendido de dilatación, en comparación con los métodos convencionales.
- ✓ Diseño antimigración - extremos acampanados - reducido grado de migración.
- ✓ Marcadores radiopacos - inserción precisa de la prótesis.
- ✓ Procedimiento de compresión simple - tubo de compresión incluido.
- ✓ Sistema de implantación PULL - punta de oliva divisible - división automática durante la liberación de la prótesis; prevención del atrapamiento de oliva; segura extracción del sistema de implantación.

#### Descripción adicional

La prótesis debe ser comprimida por el tubo de compresión en el sistema de implantación, justo antes de la implantación.

Sistema de implantación de 6.0 mm / 9.4 mm (18 F / 28 F), disponible en una longitud estándar de 75 cm.

Alambre guía recomendado de 0.035" (0.89 mm) - ultra rígido - longitud mínima de 220 cm.



Punta de oliva / Vaina



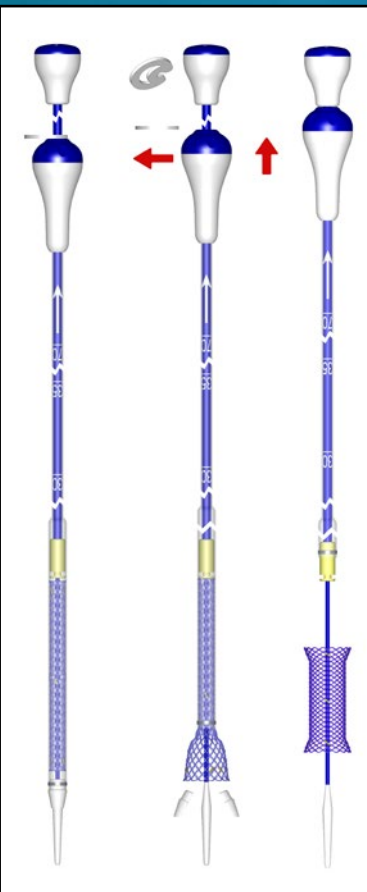
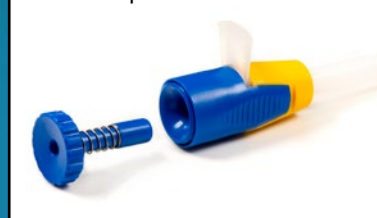
Punta de oliva divisible



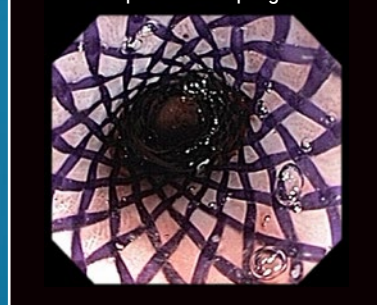
Mango de vaina



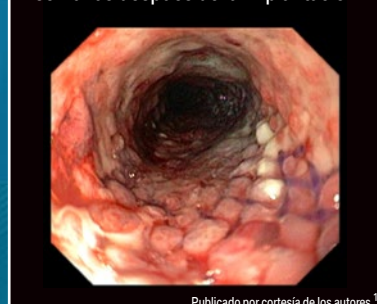
Tubo de compresión



Prótesis después del despliegue



4 semanas después de la implantación



Publicado por cortesía de los autores <sup>1</sup>

<sup>1</sup>. van Boeckel PG, Vleggaar FP, Siersema PD. A comparison of temporary self-expanding plastic and biodegradable stents for refractory benign esophageal strictures. Clin Gastroenterol Hepatol. 2011;9(8):653-9



#### Medidas disponibles

REF No.	Diámetro del cuerpo de la prótesis [mm]	Diámetro de los extremos de la prótesis [mm]	Longitud de la prótesis [mm]
019-10A-23/18/23-060	18	23	60
019-10A-23/18/23-080			80
019-10A-23/18/23-100			100
019-10A-25/20/25-060	20	25	60
019-10A-25/20/25-080			80
019-10A-25/20/25-100			100
019-10A-28/23/28-060	23	28	60
019-10A-28/23/28-080			80
019-10A-28/23/28-100			100
019-10A-31/25/31-060	25	31	60
019-10A-31/25/31-080			80
019-10A-31/25/31-100			100
019-10A-31/25/31-135			135

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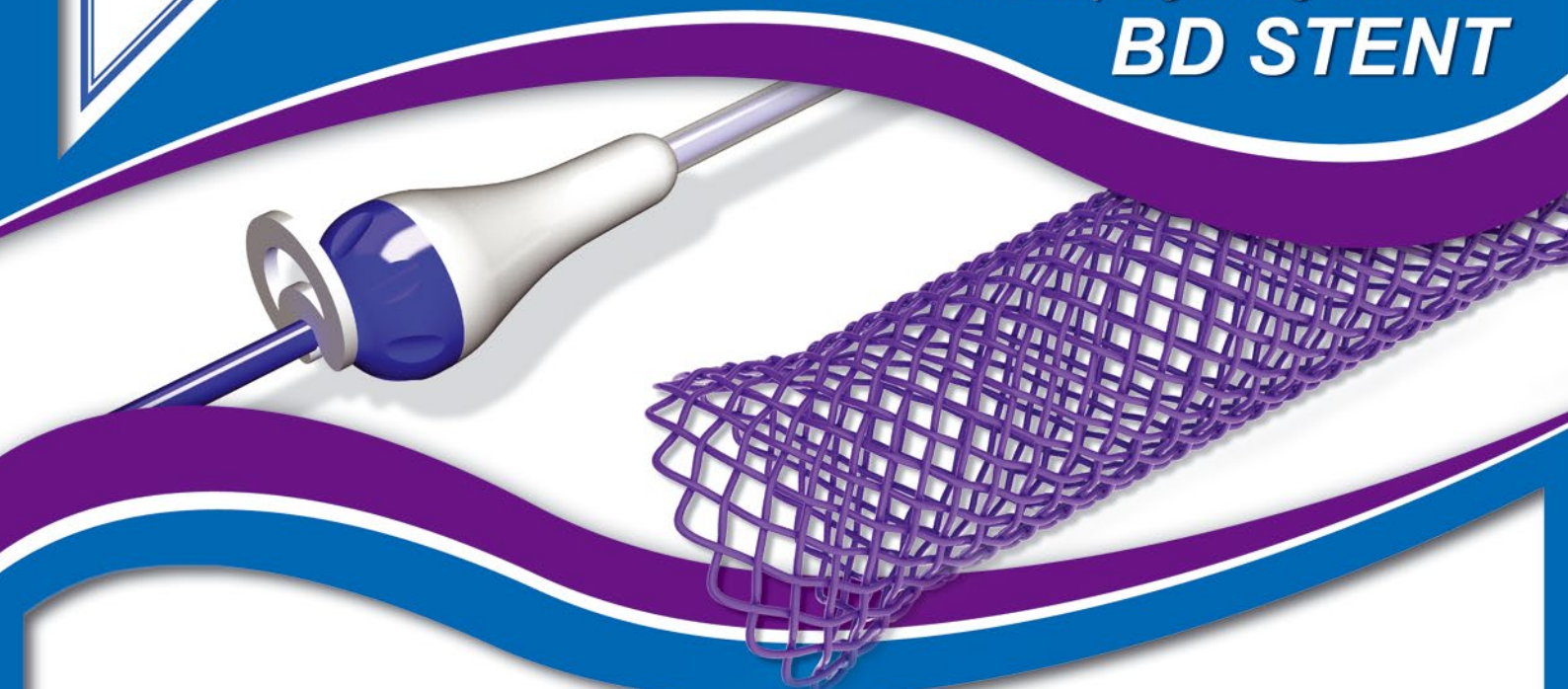
URL: www.ellacs.eu





# REFERENCES

## SX-ELLA Stent Esophageal Degradable BD BD STENT



### 1) Dilation or biodegradable stent placement for recurrent benign esophageal strictures: a randomized controlled trial

Daisy Walter, Maarten W. Van Den Berg, Meike M. Hirdes, Frank P. Vleggaar, Alessandro Repici, Pierre H. Deprez, Laurence Lovat, Bartolomé L. Viedma, Bas L. Weusten, Raf Bisschops, Renan Haidry, Elisa Ferrara, Keith J. Sanborn, Erin E. O'Leary, Jeanin E. Van Hooft, Peter D. Siersema

Endoscopy. 2018 Mar. Georg Thieme Verlag KG Stuttgart. New York, ISSN 0013-726X

**At 3 months, the biodegradable stent group (n = 32) underwent significantly fewer endoscopic dilations for recurrent stricture compared with the dilation group (n = 34;  $P < 0.001$ ). By 6 months, the groups were similar. The number of patients experiencing adverse events was similar between the groups.**

**Through 12 months, the groups were similar for the EQ-5D composite score ( $P = 0.57$ ). However, patients in the biodegradable stent group reported a significantly better quality of life through 12 months than patients in the dilation group based on the EQ-5D VAS ( $P = 0.01$ ). Within the biodegradable stent group, the WHO performance score significantly improved compared with baseline; however, no difference was seen in the dilation group. Through 12 months, the biodegradable stent group showed a significantly higher level of activity as measured by the WHO performance score compared with the dilation group.**

### 2) The use of reabsorbable ELLA stent in the treatment of benign stenosis

D. Esposito, F. Calabrese, L. Fanti, E. Viale, P.A. Testoni

Abstracts of the 24th National Congress of Digestive Diseases / Digestive and Liver Disease 50/S2 (2018) e63–e238

**A total of 20 reabsorbable stents were inserted to 9 patients, one was lost on follow-up, 6 patients had a clinical and endoscopic resolution at the end of follow-up (75%), 1 had a neoplastic relapse and 1 underwent the positioning of a SEMS. The most common adverse event encountered was the formation of granulation tissue creating a substenosis in 2 (10%) patients (successfully treated with another ELLA stent insertion). Self limiting bleeding was seen in 1 (5%) patient and 1 (5%) patient complained with pain controlled by mean of analgesics.**

**The insertion of a reabsorbable stent is a safe procedure, with a success rate of 75% but with a multiple number of devices/patient needed since the use of a single stent is seldom sufficient. Such a procedure should be considered as a therapy to be used in repeated sessions similarly to dilation therapy.**

### 3) Endoscopically placed stents: a useful alternative for the management of refractory benign cervical esophageal stenosis

Nogales Óscar, Clemente Ana, Caballero-Marcos Aránzazu, García-Lledó Javier, Pérez-Carazo Leticia, Merino Beatriz, López-Ibáñez María, Pérez Valderas María Dolores, Bañares Rafael, González-Asanza Cecilia.

Rev Esp Enferm Dig 2017. doi: 10.17235/reed.2017.4795/2016.

**A total of 23 stents (13 FCSEMS and 10 BDS) were placed in 12 patients (median 1.92, range 1-4, 6 patients received at least one BD Stent). The technical success rate was 96% (22/23 stents). Eight patients (66.6%) maintained adequate oral intake at the end of follow-up (median 33.3 months, range 3-84 months). All patients complained of minor cervical pain after placement**



*that was well controlled with mild analgesia. Migration was recorded in 7/23 stents (30.4%) and epithelial hyperplasia in 4/23 stents (17.4%). Interestingly, migration was observed in 7/13 FCSEMS (53.8%) but not in BDS (0%;  $p = 0.005$ ) cases. All the migrated FCSEMS were successfully repositioned using endoscopy. In addition, significant epithelial hyperplasia was recorded in four of 23 stent cases (17.4%), all of which involved BDS. No severe adverse events were noted.*

#### **4) Efficacy and tolerability of biodegradable stents for recurrent benign oesophageal strictures: The Leeds experience**

N. Rabb, H. Procter, N. Burr, V. Appleby, S. Everett

25th UEG Week 2017; Oct. 28-Nov.1- Barcelona; Spain

*20 patients with 37stents were included. 30 day adverse events included 4 (11%) stent migrations and 12 (32%) with significant pain, 3 patients requiring in-patient pain control (<3 days). There were no significant bleeds or perforations.*

*12 months following first EBS insertion 18(90%) required further endoscopic intervention due to recurrent symptoms. **There was a significant reduction in median number of interventions in the 12m following EBS insertion compared to the preceding 12m (2 vs. 7 respectively,  $p=0.0003$ ).** Repeated EBS insertion appears a reasonable strategy for the most resistant strictures.*

#### **5) Single and sequential biodegradable stent placement for refractory benign esophageal strictures: a prospective follow-up study**

M. M. C. Hirdes, P. D. Siersema, P. G. A. van Boeckel, F. P. Vleggaar

Endoscopy. 2012 Jul;44(7):649-54.

*In total, 59 stents were placed in 28 patients. **All patients had previously been treated with at least 10 dilations within 6 months;** eight patients (29 %) had also been treated previously with placement of one or more SEPS or SEMS. After initial stent placement, the median dysphagia-free period was 90 days (range 14–618 days). Clinical success (absence of dysphagia  $\geq 6$  months after stent placement) was achieved in seven patients (25 %) and major complications occurred in eight patients (29 %). **Three patients are currently dysphagia-free.** After placement of a second biodegradable stent, the median dysphagia-free period was 55 days (range 25–700 days) and clinical success was achieved in 15% of patients. **Three patients are currently dysphagia-free.** After placement of a third stent, the median dysphagia-free period was 106 days (range 90–150 days), but none of the patients was clinically dysphagia-free. **A possible explanation for the high complication rate may lie in the large diameter of the biodegradable stent.** In seven of eight patients with major complications a 25-mm-diameter stent with 31-mm flares was placed.*

*Conclusion: Placement of a single biodegradable stent is only temporarily effective in the vast majority of patients with RBES treated in a tertiary referral center. Sequential stenting may however be an option to avoid serial dilations.*

#### **6) The role of biodegradable stents in the management of benign and malignant oesophageal strictures: A cohort study**

Stephen McCain, Scott McCain, Barry Quinn, Ronan Gray, Joan Morton, Paul Rice

The Surgeon (2015), <http://dx.doi.org/10.1016/j.surge.2015.01.002>

*17 stents were inserted to 9 patients for benign disease. Of the 9 patients who underwent a total 18 attempts at BD stenting for benign strictures, 5 were symptom free at follow-up. 4 patients with benign disease required re-intervention with a BD stent. 1 patient had 5 BD stents inserted at different time points, 1 patient had 3 BD stents inserted and 2 patients had 2 stents inserted. Median re-intervention time was 260 days (range 91-525).*

*This study has shown BD stenting to be a very efficacious method of symptomatic relief of oesophageal stricture induced dysphagia, resulting in a significant improvement in dysphagia score post-stenting. **BD stenting has an excellent safety profile, with no major complications and no stent related mortality. It would appear to offer patients with benign disease greater than 50% possibility of long-term symptom resolution.** For those who require re-intervention, the duration of absence of symptoms and re-intervention time is significantly longer than would be expected with either dilatation or SEMS or SEPS.*

#### **7) A comparison of the temporary placement of 3 different self-expanding stents for the treatment of refractory benign esophageal strictures: a prospective multicentre study**

Jorge Manuel Tavares Canena, Manuel José Antunes Liberato, Ricardo António Natário Rio-Tinto, Pedro Miguel Pinto-Marques, Carlos Manuel Menezes Romão, António Vasco Mello Pereira Coutinho, Beatriz Alda Henriques Costa Neves and Maria Filipa Costa Neves Santos-Silva

BMC Gastroenterol. 2012 Jun 12;12:70

*This study prospectively evaluated 3 groups of 30 consecutive patients with RBESs who underwent temporary placement of either SEPSs (12 weeks,  $n = 10$ ), biodegradable stents ( $n = 10$ ) or FCSEMSs (12 weeks,  $n = 10$ ). Migration occurred in 11 patients: 6 (60%) in the SEPS group, 2 (20%) in the biodegradable group and 3 (30%) in the FCSEMS group ( $P = 0.16$ ). A total of 8/30 patients (26.6%) were dysphagia-free after the end of follow-up: 1 (10%) in the SEPS group, 3 (30%) in the biodegradable group and 4 (40%) in the FCSEMS group ( $P = 0.27$ ). **More reinterventions were required in the SEPS group ( $n = 24$ ) than in the biodegradable group ( $n = 13$ ) or the FCSEMS group ( $n = 13$ ) ( $P = 0.24$ ).***

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