

Obsidian® ASG

Anastomoses SafeGuard



Obsidian® ASG is an autologous, platelet rich bioactive matrix for anastomotic reinforcement and protection following resection surgery in the gastrointestinal tract. Obsidian® ASG is designed to effectively seal and heal anastomoses and is related to a low rate of anastomotic leaks.¹

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Anastomoses SafeGuard

Obsidian® ASG acts as an anastomotic reinforcement in addition to standard closing techniques following resection surgery in the gastrointestinal tract – effectively sealing and healing anastomoses.

Obsidian® ASG is an autologous, platelet rich bioactive matrix with sustained release of non-activated platelets which upon contact with tissue release growth factors improving tissue regeneration and healing of anastomoses. This completely absorbable biomatrix contains an up to 6 to 8 times multiplied concentration of non-activated platelets and continuously release growth factors over a period of 5 to 7 days. Hence the application of Obsidian® ASG accelerates tissue proliferation, and the anti-inflammatory and antimicrobial platelet properties may offer control of potential contamination. With its immediate polymerization and adhesion to tissue – even when applied on vertical, inverted or moist surfaces – Obsidian® ASG effectively seals anastomoses.

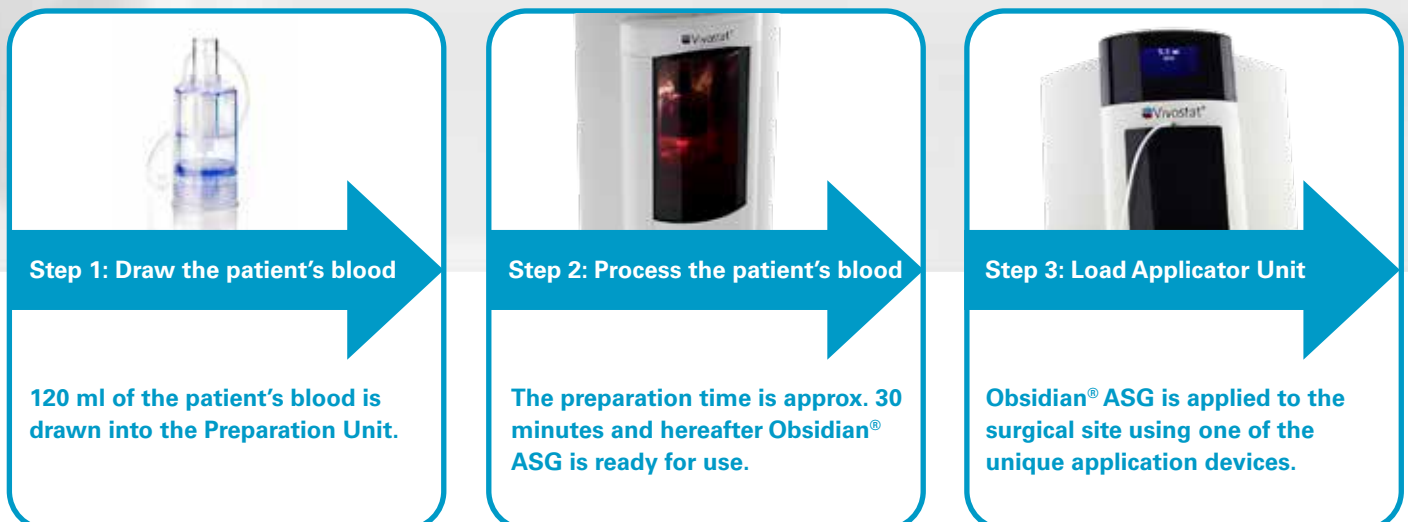
Obsidian® ASG is prepared and applied using the Vivostat® System



The Vivostat® System is the first and only system for on-site preparation and application of the fully autologous platelet rich bioactive matrix – **Obsidian® ASG**.

- **The Vivostat® Processor Unit** automatically prepares the **Obsidian® ASG** bioactive matrix from 120 ml of the patient's own blood, in a well-defined and reproducible dose.
- **Obsidian® ASG** is easily applied using the **Vivostat® Applicator Unit** with application devices suitable for various types of surgery (open surgery, endoscopy, laparoscopy, robotics). Furthermore, the **Vivostat® Co-Delivery** system makes it possible to simultaneously co-apply BMAC, stem cells, chondrocytes or medications (i.e. antibiotics) alongside **Obsidian® ASG**.

Three steps to prepare and apply



Obsidian® ASG – is easy to apply

- ✓ Obsidian® ASG is easy to apply accurately
- ✓ Compatible application devices and different spray modes offer a solution for various types of surgery (open surgery, endoscopy, laparoscopy, robotics)
- ✓ The intra- and extra-anastomotic application technique sustains the sealing and healing of anastomoses

Endoscopic Applicator Handle with inserted catheter

Obsidian® ASG application procedure

For successful application, the correct sequence of the application of Obsidian® ASG is shown in the steps below.



Step 1

After checking correct position of proximal colon, apply at least 2 ml of Obsidian® ASG over entire surface of distal colon stump.

Important: Outer edges must be completely covered.



Step 2

The stapler is closed and triggered according to the guidelines of the manufacturer and carefully transversally retracted.



Step 3

Air tightness of the anastomosis is controlled by "bubble test – water and air"; or by a contrast agent test.



Step 4

After evacuation of NaCl and adequate visualization of anastomotic area, anastomosis gets reinforced completely circumferentially applying 1.5 cm distal and 1.5 cm proximal with Obsidian® ASG.

Note: After completing application of Obsidian® ASG wait approximately 30 seconds before continuing surgical procedure until the polymerization process of the Obsidian® ASG is complete.

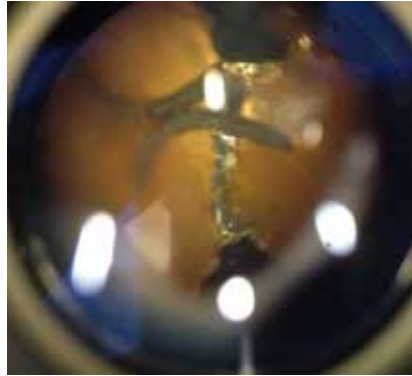
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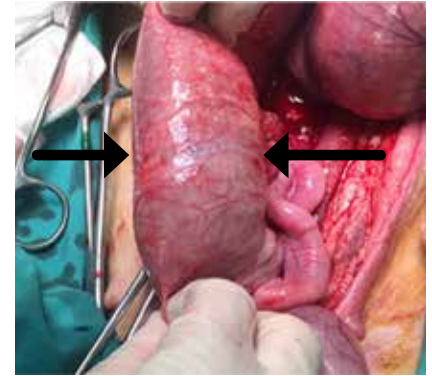
Obsidian® ASG serves as a multi-level Anastomoses SafeGuard



The photo shows the intra-anastomotically applied Obsidian® ASG providing bioactive sealing and enhancing anastomotic tissue healing.



This photo is taken through a microscope and shows how Obsidian® ASG covers the titanium clamps and acts as a staple line reinforcement.



The arrows point to the anastomotic site and show the anastomotic tissue healing on day 30 in a porcine study.²



High mechanical protection and anastomotic burst pressure^{1,2}

Intra-anastomotic bioactive sealing^{1,2}

Improves anastomotic tissue healing^{1,2}

Antimicrobial properties³⁻⁵

Can be used for staple line bleeding

Obsidian® ASG is related to a low rate of anastomotic leaks following colorectal resection¹

Obsidian® ASG is related to a low risk of anastomotic leaks¹

- Application of Obsidian® ASG following colorectal resection is related to a low rate of anastomotic leakages – 2.3% (6/261 patients)¹
- Application of Obsidian® ASG in colorectal resection is safe for patients undergoing gastrointestinal resection and related to a low rate of postoperative complications¹

Low rate of anastomotic leaks in the 261 patients study¹

Study center	Colonic resection		Rectal resection	
	1	2	1	2
No. of cases	137	40	40	44
Anastomotic leaks 100	4	0	1	1
% Anastomotic leaks	2.9	0.0	2.5	2.3
Anastomotic leaks per indication	2.3%		2.4%	

Obsidian® ASG effectively seals anastomoses^{1,2}

- Efficient air and liquid tight anastomosis sealing¹
- Immediate polymerization and adhesion to tissue – even when applied on vertical, inverted or moist surfaces⁶
- Obsidian® ASG is highly elastic and conformable to movement – high mechanical protection and anastomotic burst pressure immediately after application^{1,2}

In a porcine study Obsidian® ASG demonstrates more than double anastomotic burst pressure vs control²

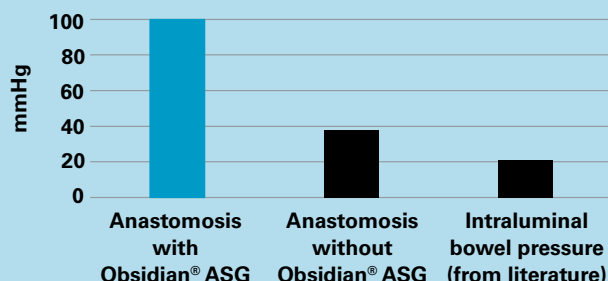
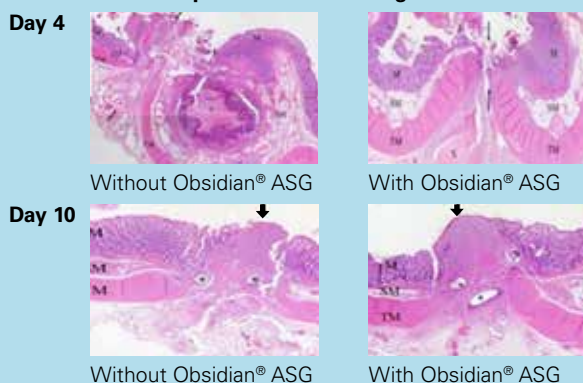


Figure modified from Dauser B. et al. 2020.²

Obsidian® ASG improves tissue healing^{1,2}

- Acts as a source of angiogenic growth factors supporting tissue proliferation and growth of new blood vessels^{1,2}
- Can be used for staple line bleeding

Obsidian® ASG improves tissue healing²



Obsidian® ASG

Anastomoses SafeGuard

Resection surgery in the gastrointestinal tract is a common treatment of colorectal cancer, inflammatory bowel diseases and esophageal cancer. The most dreaded and devastating surgical complication following resection surgery is anastomotic leak, as this leads to increased morbidity, mortality, days in hospital and costs as well as impaired patient QoL.^{1,7}



Risk of anastomotic leaks and associated effects on patient safety

Current rates of anastomotic leaks following resection vary depending on anatomic site:

- Colon: 4%⁸
- Rectum: 10%⁸
- Esophagus: 10%⁹



- Patients experiencing an anastomotic leak have increased risk of significant morbidity¹⁰
- Patients experiencing anastomotic leak have increased risk of mortality – 30-day mortality rate for patients experiencing an anastomotic leak is 10.6% versus 1.6% for patients with no an intact anastomosis¹¹



Obsidian® ASG is designed to be a cost-effective solution for anastomotic procedures¹

Anastomotic leak incurs high costs in colorectal surgery^{10,12,13}

- Anastomotic leak increases length of stay in hospital¹²
- Costs associated with a patient experiencing anastomotic leak are up to 4 times higher than those incurred by a patient with no surgical complications¹²

	 No surgical complications	 Anastomotic leak
Days in hospital ¹²	9.7 (±3.0)	29.1 (±3.0)
Cost (EUR) ¹²	approx. 18,000	approx. 72,000

Reducing the number of cases of anastomotic leak will:



Reduce healing time and morbidity



Reduce days in hospital



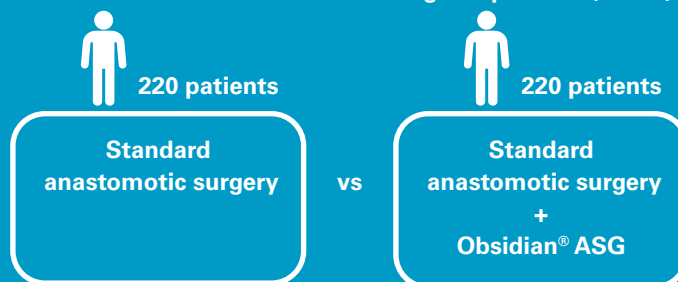
Reduce reoperations



Continued commitment to validating efficacy and cost-effectiveness of Obsidian® ASG through clinical trials

A single-blind, multicenter, randomized controlled trial initiated in December 2021 including a total of 440 patients will further validate the safety and efficacy of Obsidian® ASG in the effort to reduce frequency and severity of anastomotic insufficiency following rectal resection as well as reduce length of stay in hospital. The trial runs in 15 sites across 7 European countries under the title *Investigation of the benefit of using an autologous platelet-rich fibrin matrix (Obsidian ASG®) for treatment of anastomosis during rectal surgery (ORSY)*.¹⁴

Randomized controlled trial including 440 patients (ORSY)¹⁴



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement 968411.

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Obsidian® ASG

- ✓ improves tissue healing^{1,2}
- ✓ effectively seals anastomoses^{1,2}
- ✓ is related to a low risk of anastomotic leaks¹



Product and order information

Code	Product description
GM 720	Obsidian® ASG Set
GM 220	Obsidian® ASG Endoscopic Applicator Handle (reusable)
PRO 800	Processor Unit
APL 400	Applicator Unit
APL 404	Applicator Unit – Co-Delivery
VS 222	Foot Switch to be used with APL 400/404

References:

1. Shamiyeh A. et al. Obsidian ASG® Autologous Platelet-Rich Fibrin Matrix and Colorectal Anastomotic Healing: A Preliminary Study. *Surg Tech Int.* 2021;(39). **2.** Dauser B. et al. Histologic changes in early colonic anastomotic healing using autologous platelet-rich fibrin matrix. *Eur Surg* 2020; 52:155-164. **3.** Bayer A. et al. Platelet-released growth factors induce the antimicrobial peptide human beta-defensin-2 in primary keratinocytes. *Exp Dermatol* 2016; 25: 460-465. **4.** Knafel D. et al. In-vitro release pharmacokinetics of amikacin, teicoplanin and polyhexanide in a platelet rich fibrin—layer (PRF)—a laboratory evaluation of a modern, autologous wound treatment. *PLoS ONE* 12(7): e0181090. <https://doi.org/10.1371/journal.pone.0181090> **5.** Tohidnezhad M. et al. Thrombocytes are effectors of the innate immune system releasing human beta defensin-3. *Injury, Int. J. Care Injured* 42 (2011) 682–686. **6.** Kjaergard HK et al. Comparative kinetics of polymerization of three fibrin sealants and influence on timing of tissue adhesion. *Thrombosis Research* 2000; 98: 221-228. **7.** Sciuto A. et al. Predictive factors for anastomotic leakage after laparoscopic colorectal surgery. *World J Gastroenterol.* 2018;24(21):2247-2260. **8.** Danish Colorectal Cancer Group Annual Report 2021 (DCCG.dk) **9.** Danish EsophagoGastric Cancer Group database – Annual report 2021 RKKP'S Knowledge Center – www.rkkp.dk **10.** Turrentine FE. et al. Morbidity, mortality, cost, and survival estimates of gastrointestinal anastomotic leaks. *J Am Coll Surg.* 2015; 220(2):195-206. **11.** Frasson M, et al. Predictors for Anastomotic Leak, Postoperative Complications, and Mortality after Right Colectomy for Cancer: Results from an International Snapshot Audit. *Diseases of the Colon & Rectum, Volume 63:5* (2020). **12.** La Regina, D. et al. Financial impact of anastomotic leakage in colorectal surgery. *World J. Gastrointest. Surg.* 2019; 23:580-586. **13.** Enodien, B et al. A. The Effects of Anastomotic Leaks on the Net Revenue from Colon Surgery. *Int. J. Environ. Res. Public Health* 2022, 19, 9426. <https://doi.org/10.3390/ijerph19159426>. **14.** <https://clinicaltrials.gov/ct2/show/NCT05174910>.

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