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Instructions for use

VacStent GI™

Colon

VAC Stent GI™

IMPORTANT

READ CAREFULLY BEFORE USE

KEEP THESE INSTRUCTIONS FOR FUTURE CONSULTATION

Contents

1. General safety information

For general guidelines, functional inspections and disassembly of multi-component devices, please contact your local sales representative or the manufacturer directly.

The product may not be modified and may be used only according to its intended purpose.

Read the instructions for use

The instructions for use are part of the product. Failure to follow them can result in serious injury or even death.

- Read and follow the instructions for use

Damaged packaging

If the sterile packaging is damaged, the product may no longer be used.

- Dispose of product

Use before the expiry date

Material fatigue may occur after the expiry date has been exceeded. The product, as well as the packaging, may become brittle and permeable and consequently unstable and unsterile. Safe use of the product is no longer guaranteed.

- Use the product only before the expiry date
- Dispose of the product when the expiry date has passed

1.1 Explanation of the safety symbols used

Important information is indicated visually in these instructions for use. This information is essential for avoiding risks to the patient and operating personnel and for preventing damage and malfunctioning of the VacStent GI™.

1.1.1 Symbols in the instructions for use


Caution


Information

1.1.2 Symbols on the packaging

Batch number


Follow instructions for use

Article number


Sales partner

Medical device


Manufacturer

Unique product identification


Date of manufacture YYYY-MM-DD

Sterilised with ethylene oxide


Use by YYYY-MM-DD


Do not reuse


Packaging unit

Do not resterilise


Do not use if packaging is damaged


Single sterile barrier system


Store in a dry place


Single sterile barrier system with protective outer packaging


Keep away from sunlight

Caution: Under US federal law, this device may be sold only to a physician or on order of a physician.

Further information about the symbols used can be found on our website: www.moeller-medical.com/glossary-symbols

1.2 Single use

The VacStent GI™ is approved for single use only.

Do not reuse disposable items

There is a risk of infection for the patient, user or third parties when reusing disposables.

- VacStent GI™ should be disposed of properly after one use *(Section 1.5)*

No reprocessing of disposable articles

Cleaning, disinfection and sterilisation may compromise essential material properties and product parameters, leading to device failure.

- Do not clean, disinfect or sterilise

1.3 Transport and storage information

- Store in a dark, dry and clean place, in the closed original carton.
- The VacStent GI™ must not be exposed to organic solvents.

1.4 Precautionary measures

- Patients with allergies to nickel-titanium alloys (nitinol) may have an allergic reaction to the stent.
- No product cross-reactions are known at this time.
- The patient's consent must be obtained.

1.5 Proper disposal

The packaging must be disposed of in accordance with local guidelines and laws.

Proper disposal of the VacStent GI™

The used VacStent GI™ must be disposed of properly. There is a risk of infection if there is contact with it.

- Dispose of the item according to your facility's biohazardous medical waste guidelines

1.6 Manufacturer's responsibility

Möller Medical GmbH guarantees that the VacStent GI™ has been developed and manufactured with the necessary care and caution.

2. Description

The VacStent GI™ is a sterile-packaged, disposable product and should be used only in conjunction with appropriate accessories.

2.1 Intended use

The VacStent GI™ combines a vacuum sponge with a covered stent. The intraluminal sponge is positioned in the oesophagus/stomach or the intestine, and conditions the wound. The stent seals the sponge against the lumen, thus ensuring passage. This achieves both objectives of leakage treatment: draining the inflammatory wound secretion via negative pressure wound therapy (NPWT), and sealing the leakage via the stent with its liquid-tight coating. Treatment with the VacStent GI™ continues until the leak is healed through secondary wound healing.

2.2 User

This description alone does not provide sufficient background knowledge for the direct use of the VacStent GI™. The use of the VacStent GI™ is permitted only by trained professionals. Instruction from a gastroenterologist experienced in handling these products is strongly recommended.

2.3 Indication

The VacStent GI™ is indicated for the treatment of leaks in the colorectal region of the colon that can be reached endoscopically. Using the VacStent GI™ enables drainage of inflammatory wound secretion by means of negative pressure wound therapy (NPWT), and sealing of the leak through the liquid-tight, coated stent, taking preservation of the intestinal passage into account. The VacStent GI™ can also be used preventively to avoid insufficiency.

2.4 Contraindications

Contraindications include:

- Severe coagulopathy
- Treatment-resistant sepsis with immediate indication for surgery
- Significant tissue ischaemia in the area of the insufficiency or wound cavity, larger than the longitudinal diameter of the VacStent GI™
- No or difficult access to the colorectal region of the colon

3. Complications

3.1 Possible complications during the procedure

- Stent malpositioning resulting in an uncovered or incompletely covered leak
- Perforation of the colon outside the existing leakage by the guide wire or introducer
- Perforation when removing a VacStent GI™ after a longer period of use due to the growth of granulation tissue or mucosa into the sponge cylinder
- Loss of the sponge cylinder (slippage from the stent) when removing the VacStent GI™ after a long period of use
- Bleeding caused by manipulation at the leakage or in the wound cavity during debridement or also when extracting a VacStent GI™ after a long period of use
- Displacement of the lumen
- Infection
- Stent occlusion due to incorrect insertion

3.2 Possible complications after the procedure

- Occlusion of the sponge so that suction is no longer possible
- Stent occlusion due to ingrowth of granulomatous tissue into the stent
- Stent occlusion due to fecal impaction with occlusion of the free lumen
- Collapse of the colon lumen can lead to bowel obstruction
- Later scar stenosis of the colon due to excessive formation of granulation tissue in the area of the leakage or at the ends of the stent
- Stent migration
- Breakage of the nitinol filaments of the stent
- Inadequate sealing of the leakage by the VacStent GI™ and thus progression of sepsis
- Death

3.3 Restrictions

The VacStent GI™ may be used in any individual regardless of their gender, age, weight, height or ethnic origin, at the doctor's discretion. Children, and particularly large or particularly small people are the exception to this rule as no data are available for them.

3.4 Reporting

All incidents or serious adverse events that occur in connection with the device are to be reported to the manufacturer and the competent authorities of the member state in which the user and/or patient is based.

4. Product description

Scope of delivery of the VacStent GI™:

- Covered stent
- Introducer
- Y-piece

The covered stent is composed of nitinol wire, a drainage catheter and a sponge cylinder. The nitinol wire has a tubular mesh structure. This design makes the stent more flexible and facilitates automatic deployment.

Function of the catheters:

- The external catheter holds the stent together until the stent is extended
- The inner catheter enables correct placement of the stent
- The drainage catheter drains the wound secretion

There are 6 X-ray markers incorporated into the stent to aid imaging during and after stent application. There are 2 opposite X-ray markers at the two ends and in the middle of the stent.

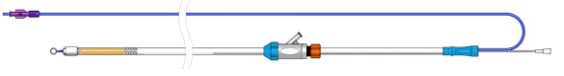

Figure1:
General overview VacStent GI™

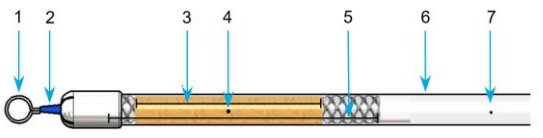

Figure 2:
Proximal end of the VacStent GI™

1	Stabilising wire	5	Covered stent
2	Olive tip	6	External catheter
3	Sponge cylinder	7	Borehole
4	Central X-ray marker		

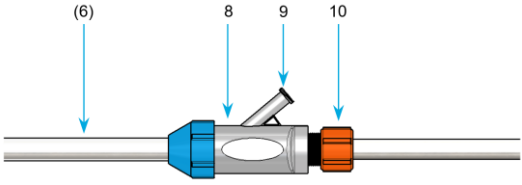

Figure 3:
Middle section of the VacStent GI™

8	Front handle	10	Fixation
9	White Luer connector		

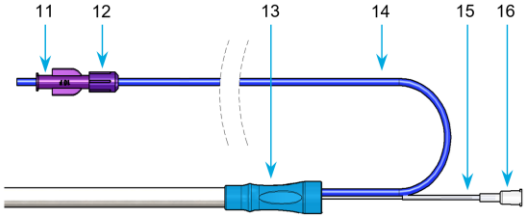

Figure 4:
Distal end of the VacStent GI™

11	Purple Luer connector	14	Drainage catheter
12	Union nut	15	Internal catheter
13	Rear handle	16	Transparent Luer connector

5. Preparation

5.1 Additional equipment required

- Imaging:
  - X-ray fluoroscopy unit
  - Endoscopy unit with flexible endoscopes
- Guide wire, with flexible tip
  - 0.035 inch (=0.89 mm) thick
- Syringe, flushing system where applicable
  - Recommendation: at least 50 ml
- Endoscopic grasping forceps
- Variable medical low-vacuum pump with secretion cylinder

Observe the pump manufacturer's specification

Setting range from 40 to 125 mmHg Pump must ensure constant suction.

- Follow the instructions for use of the manufacturer of the low vacuum pump

5.2 Visual inspection

Open the outer packaging and check for any damage to the primary packaging. Then open the primary packaging and remove the VacStent GI™. Make sure that the stent system is not damaged. If you suspect that the sterility or functionality of the VacStent GI™ has been compromised, do not use the VacStent GI™.

5.3 Flush catheters

- The catheters of the VacStent GI™ must be flushed with a syringe before insertion (recommendation: 50 ml syringe)
- The NaCl solution must not be warmer than body temperature, otherwise the stability of the external catheter will be impaired
- The stent must remain completely inside the outer catheter during flushing

Stent cannot be inserted

A partially released stent, due to altered shape, cannot be inserted.

- Discard the VacStent GI™ with a partially released stent and take a new one

PREPARATION

5.3.1 Flush drainage catheter

Facilitates removal of the stent from the outer catheter.
Supports positioning the sponge cylinder.

1 Repositioning the purple Luer connector (hereinafter PLC)
   a) Loosen the union nut on the PLC
   b) Detach the PLC from the drainage catheter
   c) Screw the PLC onto the syringe
   d) Push the drainage catheter into the opening of the PLC until resistance is felt
   e) Tighten the union nut of the PLC
2 Flush the sponge cylinder with at least 20 ml NaCl solution until it is dark grey

5.3.2 Flush external catheter

Facilitates removal of the stent from the outer catheter.

There is a small hole on the outer catheter, about 20 cm from the distal end. Liquids can leak out at this point. The hole can be held shut during flushing. Fluids leaking from the hole do not affect the function of the stent.

1 Hold the small hole shut
2 Flush via the white Luer connector with at least 20 ml NaCl solution

5.3.3 Flush internal catheter

Facilitates the insertion of the guide wire.

1 Remove the stabilising wire
2 Flush via the transparent Luer connector with at least 5 ml NaCl solution

6. Application

6.1 Precautionary measures

Sedation

The patient should be sedated for the procedure at the discretion of the doctor performing the procedure.

6.2 Place stent

Wire cannot be inserted

If the guide wire is too thick, the VacStent GI™ cannot be inserted and placed.

- Only use specified guide wire thicknesses (Section 5.1)

The visual inspection can be carried out with:

- radiological fluoroscopy (X-ray marker)
- endoscopic visual tracking (monitor)

Preparing for stent placement

1 Insert the endoscope into the rectum
2 Advance endoscope up to the expected leak
3 Inspect, debride and measure the leak
4 Advance endoscope at least another 20 cm proximally
5 Insert the guide wire and place it at least 20 cm above the leak
6 Withdraw the endoscope when the guide wire is in place

Stent positioning

7 We recommend applying a suitable lubricant for better insertion into the rectum
8 Insert the guide wire through the hole of the olive tip into the inner catheter
9 Push the previously flushed stent *(section 5.3)* forward over the guide wire under visual control
10 The proximal end of the stent must be 1 to 2 cm above the upper edge of the leak
11 The distal end of the stent should be at least 1 to 2 cm below the lower edge of the leak
12 Visually check the position of the stent before it is released
13 Remove the guide wire when the stent is in place

Release stent

14 Release the safety lock by unscrewing the orange fastener
15 Hold the rear handle with one hand
16 With the other hand, slowly and carefully pull the front handle towards the back handle
17 At the beginning, increased resistance is noticeable
18 Recommendation: Secure the rear handle at the hip
19 Release the stent completely under visual control
20 Flush the sponge cylinder via the purple Luer connector with at least 40 ml NaCl solution to straighten it
21 Wait at least three minutes until the stent deployment is nearly complete
22 Visually check deployment

Retract introducer

23 Unscrew the purple luer connector, pull it off the drainage catheter and set aside for later. It is needed for stent removal
24 The stent must not slip out of place when the introducer is withdrawn
25 Withdraw the introducer carefully, under visual control
26 The stent must be observed when removing the introducer to ensure it does not slip during withdrawal
27 Advance the drainage catheter while pulling the introducer
28 Hold the drainage catheter close to the body as soon as it is visible at the rectum
29 Visually check the correct positioning of the stent
30 There may be a jerk when the introducer is removed. To prevent the stent from slipping, it is essential to work very carefully here
31 Check that the drainage catheter is free of kinks, otherwise the wound fluid cannot be suctioned out
32 Reattach the purple luer connector approximately 10 cm from the end of the drainage catheter

Incorrect pump setting

If the suction is too low, it is possible that the stent will slip and can no longer be drained.
Collapse of the intestinal lumen possible due to excessive suction.

- Use pumps only in the specified setting range (Section 5.1)

Connect stent to pump

33 Cut the Y-piece so that it fits onto the drainage catheter
34 Connect the drainage catheter to a suitable low vacuum pump via the Y-piece
35 Switch on the low vacuum pump
36 Set the low vacuum pump between 40 and 125 mmHg
37 Initially we recommend 125 mmHg. In the course of treatment, the Negative pressure can be reduced at the physician's discretion
38 Check suction

6.3 Controls during the period of application

After placement, the position of the stent must be checked radiologically. Endoscopic inspection must not be performed until the stent has fully deployed.

The frequency of the check-ups is at the discretion of the attending doctor.

Controls on the patient:

- Follow-up examinations to detect signs of complications
- Position of the stent (optical control)
- Soft stools
- Meteorism, increase in abdominal girth, nausea

Controls on the pump:

- Draining wound fluid
- Pressure and pressure loss of the low vacuum pump
- Continuous suction
- Leakage
- Kinking of the drainage catheter

6.4 Diet during the period of use

The attending doctor evaluates whether an osmotic laxative is to be administered for soft bowel movements.

6.5 Withdrawing the VacStent GI™

Risk of injury when withdrawing

In the sponge cylinder of the VacStent GI™ granulation tissue can develop. If the wound is not flushed with NaCl before removal, the wound margin may tear again. There is a risk of injury.

- Flush with NaCl before extraction

1. Switch off the low vacuum pump, at least 2 hours before removal to stop suction
2. Detach the drainage catheter from the Y-piece
3. Reposition the purple Luer connector *(Section 0-1)*
4. Flush the drainage catheter with at least 40 ml NaCl solution
5. Insert endoscope and grasping forceps
6. Perform a visual check of the stent position
7. Grasp the extraction thread at the distal stent end with endoscopic grasping forceps.
8. Loosen the extraction thread by pulling it gently
9. Gently pull on the drainage catheter to aid removal
10. Remove stent
11. Remove potentially attached residues of the sponge cylinder
12. Endoscopic control of the leak

6.6 Replacing the VacStent GI™

Risk of injury when withdrawing

If the sponge cylinder remains in place for too long, it will granulate into the tissue. When removing it, the wound margin may tear open.

- Replace the VacStent GI™ with a new one after 72 hours at the latest

The attending doctor is responsible for determining how often the system should be changed. The cumulative duration of use of the inserted stents must not exceed 30 days! Factors influencing this period include the quality of the wound secretion and the degree of clogging of the sponge cylinder.

1. Removing the stent *(Section 6.5)*
2. Visual inspection of the wound cavity
3. Inserting a new VacStent GI™ *(Section 6.2)*

7. Annex

7.1 Delivery form

The VacStent GI™ is supplied sterile and is intended for single use only.

7.2 Technical data

Name	VacStent GI™
Components	Titanium, nickel, medical silicone
Design	Braided silicone-coated stent, with sponge cylinder
Packaging	Length x width x height 1385 mm x 100 mm x 35 mm
Date of manufacture	See packaging
Sterilisation	Sterilised with EO gas (ethylene oxide)

7.3 Order numbers

VacStent GI™ Ø36x80	REF 00004230
VacStent GI™ Ø30x120	REF 00004231

7.4 Contact details

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