#rethinking critical care

hygh-tec® drainage

Stool drainage system

hygh-tec® bag

Stool collection bag

Instructions for use

hyghtec.com

hygh-tec®

balloon technology for critical care

Contents

Dear patient, dear user,

For enquiries relating to product training, supply of products or additional products please contact

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Note:
As a device user facility, importer and or distributor you must report deaths and serious injuries that a device has or may have caused or contributed to our USA based authorized representative who will forward onto the Manufacturer of this device. You should also report any malfunction of the device that may have contributed to patient injury or potential injury. This ensures the manufacturer can establish complaint records and adverse event files for reporting to the FDA and other competent authorities.

hygh-tec® drainage | Product description and clinical benefit

Unlike silicone-based stool drainage systems, hygh-tec® drainage has a drainage head made of polyurethane that positions the drainage system past the sphincter muscle and seals it. The balloon on the drainage head is dumbbell-shaped and has already been moulded to its full working dimensions during production.

The transanal balloon segment [B] is positioned inside the anal canal. An elastically deformable, transanal shaft element [C] runs through the inside of the drainage head. This shaft element takes up the stool in the rectum and drains it through the anus. The stool-draining transanal shaft element [C] has a wave-shaped profile, which supports its elastic straightening. When the sphincter muscle tone is normal, the shaft element folds into the anal canal in a radial direction. If the sphincter muscle tightens, the shaft element in the anal canal straightens in an elastic manner, releasing the drainage pathways for the stool to be drained.

Unlike silicone-based stool drainage systems, the drainage balloon is inflated with air, not water. The quantity of air to be used is specified and makes the balloon [A + B + D] tension-free and flaccid. The loosely filled balloon envelope clings in a sealing manner to the respective anatomy of the rectum and anus. The anterior, intra-rectal segment of the balloon [A] absorbs the respective force in the rectum and at the same time translates it into a sealing of the anal canal in the central, transanal segment of the balloon [B]. The transanal segment of the balloon [B] therefore adapts to the respective tone and the respective level of opening of the sphincter muscle. This enables continuous sealing of the anus even in patients who are conscious and mobilised.

The drainage head is inflated with an inflating syringe included with the product [N]. In order to do this, the syringe is connected to the inflation port [J] labelled “Air”. The volume to be used for the inflation (85 ml of air) is marked on the cylinder of the inflation syringe.

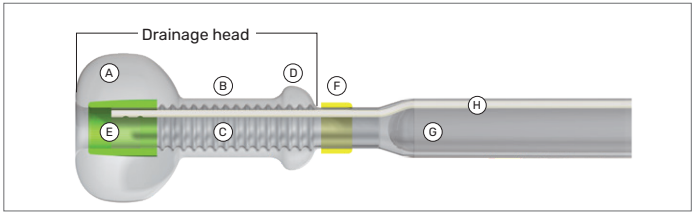
Another port [K] marked “Irrig.” is used to supply liquid to irrigate the system to clean it or for the rectal irrigation of the patient.

The drainage tube [G] connects to the drainage head [A – E] positioned transanally and connects the head unit [A– E] to the stool collection bag [M]. The connection to the bag is by means of a bayonet fastening. The sampling port for stool sampling [I] is found in the lower third of the drainage tube. The drainage tube [G] can be connected or blocked at any height using a freely adjustable closure strap [L].

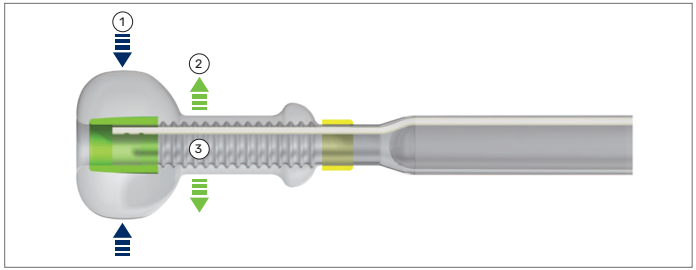
The stool collection bag [M] is equipped with a carbon filter to release intestinal gas. The contents of the bag is hidden from the user by means of a large-scale print on the bag. The stool collected in the bag can be viewed and inspected by the user on the transparent reverse of the bag.

hygh-tec® drainage | Component identification

A – intra-rectal balloon segment | B – transanal balloon segment |
C – transanal shaft element | D – pre-anal balloon segment |
E – gel-olive | F – yellow ring for position control | G – drainage tube |
H – irrigation channel | I – sampling port | J – inflation port with cap |
K – irrigation port | L – closure strap | M – stool collection bag with connector |
N – inflation syringe



hygh-tec® drainage | Function



hygh-tec® drainage dynamically adapts to the respective position of the anal sphincter muscle. The loosely inflated drainage head takes up the pressure in the rectum in the intra-rectal balloon segment (1) and uses it to seal the sphincter muscle in the transanal balloon segment (2) at the same time.

The transanal shaft element (3) by hygh-tec® drainage folds up elastically in the anal canal when the sphincter muscle tone is normal and straightens in the respective opening of the anus in an elastic manner if the tone decreases. hygh-tec® drainage therefore helps with the free and unhindered flow of stool.

hygh-tec® drainage | Indications for use and contraindications

The hygh-tec® drainage is a fecal management system that is intended for continuous, trans-anal drainage and collection of liquid or semi-liquid stools and to provide access for the administration of medications. The device is not intended for use on pediatric patients.

The product is intended to be used in professional healthcare facilities, such as intensive care settings. The product is used by qualified intensive care staff or professional, trained nursing staff.

The product is only used to adult patients who are critically ill and in intensive care, for immobile or immobilised patients and/or in some cases mobile patients with persistent diarrhoea.

hygh-tec® drainage is intended for single patient use only.

The following applies when using the product hygh-tec® drainage:

- continuous, transanal drainage of stools that will flow and liquid stools over a maximum duration of use for 29 days.

The indication for the use of the product is to be made under the sole decision by the doctor treating the patient. The type and severity of the underlying diseases and the risks associated with the use of the product are to be weighed against the expected benefit of continuous stool drainage by the doctor.

The following are contraindications for the use of the product hygh-tec® drainage:

- Unclear, not diagnostically clarified, traumatic, ischaemic or inflammatory damage to the rectum or the anus.
- Unclear, not diagnostically clarified mass in the region of the rectum or the anus.
- Unclear, not diagnostically clarified bleeding in the region of the rectum or the anus and accumulations of blood in the patient's stool.
- Diagnostically clarified, malignant mass in the region of the rectum or the anus.
- Previous surgery in the patient's colon, rectum or anus in the last six months.
- Phase of spinal shock.
- Known allergic hypersensitivity to the materials used in the product (polyurethane, PVC, polycarbonate, silicone).
- Use for pediatric patients
- Use in pregnant patients.
- Formed stools or stools that will not flow.
- Use of the product over a period of more than 29 days.

Warning

There is a potential risk of misconnections with connectors from other health-care applications, such as intravenous equipment, breathing and driving gas systems, urethral/urinary, limb cuff inflation neuraxial devices and other enteral and gastric applications.

Warnings

The following warnings shall be taken into consideration when deciding to use the product and over the course of the entire use of the product:

- Known, diagnostically clarified, chronically degenerative, inflammatory or ischaemic changes to the rectum and the anus must be assessed by the doctor providing treatment and ruled out as a potential contraindication for the use of the product.
- Previous surgery in the patient's colon, rectum or anus in the last six months must be clarified by the doctor providing treatment in terms of the postoperative conditions and postoperative perfusion situation before the product is used.
- Strictures or stenoses in the region of the rectum or the anus that present a potential obstacle when inserting and positioning the drainage must be medically assessed before the product is used.
- Advanced haemorrhoids that tend towards bleeding must be medically assessed before the product is used.
- In the case of patients with a known tendency to bleed and those on anticoagulant therapy, it is necessary to watch for potential accumulation of blood in the drained stools over the course of use of the product.
- The respective risk of lesions of the perianal skin and the skin on the buttocks and the upper thigh caused by pressure must be assessed in patients with disorders of rectal, anal or pre-anal sensitivity. This applies in particular in the case of patients with injuries to the spinal cord.
- Treatment with catecholamines to support the circulatory system: catecholamines are regularly used to stabilise the circulation in patients who are critically ill. Catecholamines can reduce circulation (perfusion) in the peripheral tissues of the body to a critical extent and therefore result in the development of tissue damage caused by perfusion. Damage of this type can occur in the rectum in particular during continuous stool drainage, with the intra-rectal segment of the balloon lying on the mucous membrane in the rectum over extended periods of time. It is necessary to check for potential ulcerations of the rectal mucous membrane over the course of stool drainage, particularly in the case of the administration of high doses of catecholamines with a vascular narrowing, vasoconstrictive effect. Higher grade damage to the rectum can be identified by the user by potential accumulation of blood in the stool.
- The balloon on the drainage head shall only be inflated with air.
- Mixing up the inflation port on the drainage head with the irrigation port: Both ports have a Luer connector. The correct connection to the irrigation port of the drainage must therefore be ensured, particularly when irrigating the system to clean it using a syringe filled with water. The port for the supply of liquids is marked with the letters "Irrig". The port for inflating the drainage head with air is marked "Air". Accidental injection of liquids into the drainage head leads to an increase in pressure in the drainage balloon. This can result in the tube element of the drainage head which drains the stool collapsing, permanently closing the drainage and resulting in subsequent abdominal congestion of stools and intestinal gas.
- If stools are discharged from or leak out of the patient's anus over the course of the use of the product, the balloon in the drainage head should be deflated completely and then re-inflated with 85 ml of air. Inflating above 85 ml will not improve the seal. Overinflating the balloon can lead to a partial or complete closure of the tube components draining the stools inside the drainage head. Permanently closing the lumen draining the stool can lead to the abdominal congestion of stools and intestinal gas.
- If the balloon of the drainage head is deflated and re-inflated with 85 ml of air, it is necessary to ensure that the balloon is fully deflated before re-inflating. This means overinflation of the balloon caused by the residual volume remaining will be avoided. Overinflating the balloon can lead to a partial or full closure of the lumen of the drainage which drains the stools.
- When infusing or injecting liquids via the irrigation port on the drainage, no substances that are harmful to the mucous membrane may be applied. The indication for the rectal application of substances may only be made by the doctor providing treatment. Any toxic interactions between the substance administered and the drainage materials (polyurethane, PVC, polycarbonate, silicone) must be clarified before application.
- No media with too high a temperature that harm the mucous membrane may be supplied when irrigating the system to clean it and during rectal irrigation.
- Formed, partially formed or thick, viscous stools cannot be effectively drained. A continuous flow of stools must therefore be ensured during use and the patient checked for the abdominal congestion of stools and intestinal gas. If the stools are unable to flow, use of the product shall be discontinued.

hygh-tec® drainage | Precautions

- The patient's anal canal and rectum must be probed or digitally inspected before insertion of the drainage. Any masses or signs of rectal or anal bleeding must be diagnosed prior to use to ensure safe use. Formed, partially formed or thick, highly viscous stool residue in the rectum should be removed where possible by means of the rectal insertion of a conventional irrigation system before the product is inserted.
- When digitally probing the rectum, the tone of the anal sphincter muscle must be assessed. If there is no or insufficient tone or the anus is gaping open, the efficacy of the seal and the anchoring of the drainage could be impaired. If the tone of the sphincter muscle is pathologically high DRESS score five, this must be assessed by the doctor providing treatment about the likelihood of the development of damage to the anus caused by pressure.
- If the drainage is expelled from the rectum, the drainage head can be reinserted by the user. In order to do this, the drainage head is completely removed and once again inflated with 85 ml of air following further transanal positioning.
- To prevent damage to the rectum caused by pressure, the drainage tube draining the stool may not be used under persistent tensile stress.
- Inform the doctor providing treatment immediately of the patient indicates any pain or irritation in their abdomen, rectum or anus.
- The stools drained must be checked for potential accumulation of blood over the course of the use of the stool drainage. If this is observed, potential causes related to a lack of perfusion must be clarified by the doctor providing treatment immediately.
- After prolonged periods of use it is common for the sphincter muscle to take up to two days for normal function to be restored.
- In the case of the infusion or injection of liquids into the patient's rectum, media that are at body temperature should be avoided to avoid unwanted rectal stool emptying reflexes.
- When using the product, particularly when irrigating the system to clean it, it is necessary to ensure a sufficient gradient between the patient's rectum and the collection bag to assist with irrigation flow in the system.
- Possible changes in the patient's fluid balance must be taken into account when supplying liquids rectally in patients with heart failure and kidney failure.
- The drainage system must not be used in conjunction with other catheters or devices positioned in the anal canal.

- Avoid situations where the patient's body lays on or applies pressure laid on the drainage tube. This will prevent damage to tissue caused by pressure and any blockages of stool flowing.
- Persistent discharge or leakage of stool in the region of the patient's peri-anal and sacral skin can cause irritation and inflammatory reactions of the epidermis there.
- The product may only be used if the packaging is not damaged.
- The product is designed for single use and only intended to be used on a single patient. The products and the components attached to it may not be processed and used in another patient.
- In the case of obese patients, it is necessary to check for damage to the skin in the buttock and upper thigh regions caused by pressure. This can be caused by the pre-anal part of the drainage head that is positioned there.
- The continuous drainage of stools with a particularly high fat content can lead to the partial stiffening of the drainage tube that provides drainage. In these cases, the drainage system should be removed and replaced with a new drainage system.

hygh-tec® drainage | Use of the product

A – Preparing the patient

1. Position the patient lying down on their left side, if possible, to insert the drainage system.
2. Palpate the rectal ampulla. Use a lubricant.
   Check for potential masses or narrowing within the rectum and the anus prior to any insertion.
3. If there are stools in the rectal ampulla, the patient should be prepared by administering a rectal enema. Use a conventional rectal irrigation set for this purpose.
4. Ensure that there is sufficient tone in the anal sphincter muscle.

B – Preparing the system

1. Remove the system from its packaging and visually check there is no damage to the components.
2. Connect the drainage system to the stool collection bag provided.
   Twist the locking ring until it snaps into place.

3. Completely deflate the drainage system balloon using the inflation syringe provided.
4. Coat the front third of the drainage head system with lubricant gel.

C – Inserting the system

1. Insert the drainage head carefully around two-thirds of the way into the anus.
2. Open the yellow cap of the inflation port. Inflate the drainage head with 85 ml of air. Use the inflating syringe provided. Ensure the inflation speed is moderate to avoid triggering an anal opening reflex or an elimination reflex. The balloon will be a bit underinflated and soft in the rectum. Do not exceed the specified inflation level of 85 ml of air. Close the yellow cap of the inflation port.
3. Check the degree of inflation of the pre-anal balloon segment (D) protruding from the anus. The balloon part must look and feel inflated and tension-free.

   Warning
   There is a potential risk of overinflation of the balloon. Under no circumstances the balloon should be overfilled with over 85 ml of air. The indication for overfilling is when the pre-anal balloon segment (D) does not feel tension-free but hardened. Overinflating the balloon can lead to a partial or complete closure of the tube components draining the stools inside the drainage head. Permanently closing the lumen draining the stool can lead to the abdominal congestion of stools and intestinal gas.
4. Check the transanal position of the drainage head. The yellow position control ring must be visible outside of the anus. With normal anatomy, the lower section of the balloon part of the drainage head will protrude from the anus.
5. Check the degree of inflation of the section of the balloon protruding from the anus. The balloon should look and feel inflated.
6. Uncoil the drainage tube. Ensure that the drainage system outlet is clear and unobstructed. Attach the collection bag low enough below the patient.

We also recommend:

7. Carry out the first irrigation of the system approximately 30 minutes after inserting the drainage system. Preferably use 500 ml of a crystalloid infusion solution that is at body temperature. Use a conventional infusion set. It is important to connect the irrigation solution to the irrigation port marked “Irrig” and to ensure a moderate flow of the solution. If the flow is too quick it can trigger an anal opening reflex or an elimination reflex.

D – Drainage system maintenance – once per shift

1. Check the correct transanal position of the drainage head. The yellow ring must be visible outside of the anus.
2. Check the inflation of the drainage head. The balloon part of the drainage head protruding from the anus must be look and feel inflated. If the inflation level of the balloon is not clear or the inflation level cannot be assessed by the user, the drainage head should be fully deflated and then re-inflated with 85 ml of air. Use the inflating syringe provided.
3. Irrigate the system to clean it once per shift with 150 ml irrigation solution. Preferably use a crystalloid infusion solution and a conventional infusion set. Ensure a moderate flow of the solution. If the flow is too quick it can trigger an anal opening reflex or an elimination reflex.
   It is important to connect the irrigation solution to the irrigation port labelled “Irrig”.
4. Ensure that the consistency of the stools is sufficiently able to flow.
5. Check the free, unimpeded flow of stool from the patient to the collection bag. The tube should be lying freely and not twisted. Monitor for signs of stool congestion. Check the patient’s bowel activity on a regular basis by auscultation.

Every three days:

Completely deflate the drainage head and re-inflate the balloon with 85 ml of air. Use the inflation syringe included.

E – Additional information and instructions:

If stools are discharged from the anus:

If stools still leak from the anus even though the drainage system is correctly transanally positioned, the following causes are possible:

- rectal congestion of stool caused by a shift in the drainage lumen, in particular as a result of stools that do not flow sufficiently or cannot drain;
- overinflation of the drainage head with a full closure or collapse of the drainage lumen and subsequent rectal congestion;
- insufficient tone in the anal sphincter muscle;
- an agitated and especially vigilant patient;
- insufficient inflation of the drainage head;

If the leakage of stools is identified, the drainage head should be fully deflated and then re-inflated with 85 ml of air. Inflating above 85 ml will not improve the seal on the drainage system. Overinflating the drainage head can lead to a collapse of the tube components draining the stools inside the drainage head that closes the lumen. A closure of this type can lead to rectal congestion of stool and therefore to the system overflowing.

If the inflation level of the balloon is not clear or not able to be assessed:
The balloon on the head unit should then be fully deflated and then re-inflated with 85 ml of air. Use the inflating syringe provided.

If the balloon cannot be deflated using the inflating syringe, damage to the inflation port of the drainage head [J] may have occurred during the course of use. If this is the case, cut the inflation port off. The air will release automatically. The stool drainage system can then no longer be used. A new drainage system must be inserted to continue use.

If the drainage system slides out of the rectum:
There could be various causes of this, such as:
- rectal congestion of stool caused by a shift in the drainage lumen, in particular as a result of stools that do not flow sufficiently or cannot drain;
- insufficient tone in the anal sphincter muscle;
- an agitated and especially vigilant patient;
- insufficient inflation of the drainage head;

The drainage system can continue to be used. Wipe the drainage head with a dry cloth and reinsert it into the rectum according to section C “Inserting the system”.

If the drainage head slides into the rectum:
The sliding of the drainage head positioned transanally in the rectum has been observed particularly in patients in a sitting position. The correct positioning of the drainage system must therefore be carefully checked in patients who are sitting and those with their upper body elevated. The correct position can be ensured by the yellow ring, which must be visible outside of the anus.

F – Rectal irrigation

1. Position the patient lying down on their left side, if possible.
2. Position the red closure strap approx. 10 cm / 4 inches from the patient’s anus and tighten the strap.
3. Preferably use a crystalloid infusion solution at normal body temperature and a conventional infusion set for the rectal irrigation.
   WARNING: Connect the irrigation solution to the irrigation port labelled “Irrig”.
4. To end the irrigation process, loosen the strap and slide it to the collection bag.

G – Oral stool modification

The successful use of the stool drainage system depends on the consistency of the stool to be drained being sufficiently able to flow. Stools that will flow may be controlled by means of oral stool modification prescribed for the patient. Any shifts in the patient’s fluid balance should be monitored as to the stools ability to flow and remining liquid. Oral stool modification requires a medical prescription by a qualified Doctor.

H – Sampling

Position the red closure strap approximately 5 cm / 2 inches below the sampling port and tighten the strap there. Insert the hub of the sampling syringe as far as possible into sampling port and collect the stool sample. Loosen the strap and slide it to the collection bag.

I – Changing and disposing of the collection bag

1. The collection bag should not remain connected to the draining catheter for more than 48 hours.
2. Avoid contamination with stools when changing the collection bag. Position the closure strap immediately adjacent to the connector and tighten it in such a way that it seals.
3. Seal the used bag using the associated closure cap. Dispose of the bag properly in accordance with local hospital / facility regulations. Comply with the specifications on the disposal of contaminated products / waste and for stools containing pathogens from patients with infectious diseases.

4. Connect the drainage system connector to the fresh stool collection bag. Twist the locking ring until it snaps into place.

5. Loosen the strap and slide it to the collection bag.

J – Removal and disposal of the drainage system

1. Completely deflate the drainage head and remove the drainage system carefully from the rectum.

2. Dispose of the used drainage system in accordance with local hospital / facility regulations. Comply with the specifications on the disposal of contaminated products / waste and for stools containing pathogens from patients with infectious diseases.

K – Storage conditions

Ambient temperature 15 °C to 30 °C / 59°F to 86°F

There are no further storage-related restrictions for hygh-tec® drainage and hygh-tec® bag.

hygh-tec® drainage | MRI Safety Information

MR Conditional

Non-clinical testing has demonstrated that the hygh-tec® drainage is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla, with
- Maximum spatial field gradient of 12,900 G/cm (129 T/m)
- Maximum force product of 229,000,000 G^2/cm (229 T^2/m)
- The valve with the spring shall be placed outside the Field of View (FoV) during the MR imaging. Therefore, MR image artifacts are not expected.

Physical testing of RF-induced heating has not been performed, since electrically conductive components are smaller than 2 cm and no other devices are used within a radius of 3 cm.

hygh-tec® drainage | Product content

stool drainage with closure strap, stool collection bag, inflation syringe, instructions for use

The hygh-tec® bag is only to be used in conjunction with the hygh-tec® drainage products.

Overview of products

Product	REF	Description
hygh-tec® drainage | 1 bag	V01-10024	Stool drainage system | 1 bags
hygh-tec® drainage | 3 bags	V01-10025	Stool drainage system | 3 bags
hygh-tec® bag	V01-10026-05	Stool collection bags (5 pcs)
hygh-tec® bag	V01-10026-10	Stool collection bags (10 pcs)

Explanation of symbols

Rx only	Caution: Federal law restricts this device to sale by or on the order of a physician.
	Manufacturer
	Use-by date
	Batch code
	Catalogue number
	Non-sterile
	Do not use if package is damaged and consult instructions for use
	Temperature limit
	Do not re-use
	Consult instructions for use
	Caution
	MR Conditional
	Importer

Manufacturer

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Rx only

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