

Technical Data

Flexima®/Softima® 1-piece drainable bag for High Flow



Flexima®/Softima® 1-piece drainable bag
for High Flow

1. Administrative information about B. Braun

1.1 Name: B. BRAUN MEDICAL SAS

1.2 Status:

Manufacturer: B. BRAUN MEDICAL SAS

26 Rue Armengaud

92210 Saint-Cloud

FRANCE

www.bbraun.com

Tel: +331 41 10 53 00

1.3 Quality system certification:

B. Braun Medical SAS Quality system complies with: ISO 9001: 2015; ISO 13485: 2016

Certificating body: TÜV SÜD Product Service GmbH (0123)

2. Information on the medical device

2.1 Trademark: Flexima® /Softima®

2.2 Indication: 1-piece drainable bag for collection of body effluents for any person whose evacuation of fecal matters is characterized by a High Flow (4 to 6 liters per 24 hours).

This type of flow is met in jejunostomies derivation also called "short bowels". It can also be met for a limited period of time in ileostomy or colostomy.

2.3 Product description: 1-piece drainable bag for High Flow

Features



Security

- Barrier films which ensure barrier protection against odours and fully liquid proofness
- Comfort films which ensure smooth contact with the skin of the patient

Comfort

- High Protected filter allowing deodorization of odorous gases while degassing
- Integrated filter: no contact of charcoal with clothes, reduces risk of bag ballooning
- Soft bag shape without sharp
- Very soft non-woven on the skin side of bag
- Ergonomic shape

Discretion

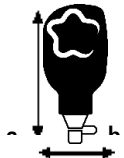
- Silent plastic film




Outlet

- Welding lines formed like a funnel for a complete evacuation of stools and to avoid the twisting effect
- 15 mm outlet to allow easy evacuation of liquid stools and food debris
- Removable cap for a very secure closing of the bag and possible connection to the distal collecting bag: the Flow Collector

2.4 Flexima References

References	Diameter in mm	a x b in mm 	Capacity according to ISO 8670-2	Colour	Packaging
42970	∅15-76	322 x 155	690 mL	Beige	Box of 30 bags Sheet of 18 filter stickers
42971				Transparent	

2.4 Softima References

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2.5 Technical specifications of the product

Latex free – PVC free

Components	Materials
Protector release	<ul style="list-style-type: none"> Silicon paper protective coating with overlapping sides
Skin protector	<ul style="list-style-type: none"> Hydrocolloids gum (main components: polyisobutylene, carboxymethylcellulose, pectin) Polyethylene white non-woven protective coating with overlapping sides Shape: flower
Collection bag	<ul style="list-style-type: none"> Flesh-coloured odour-proof multilayer film of Ethyl-vinyl acetate + polyethylene copolymer Flesh-coloured non woven made of microfibers
Leak-proof filter	<ul style="list-style-type: none"> A strip of foam impregnated with active charcoal, tightly sealed in water and gas-proof films, and which gas entry is protected by a high tech breathable and waterproof membrane
Cap	<ul style="list-style-type: none"> Polyethylene

2.6 Medical device classification

Class: I non sterile

EU Regulation: 2017/745

Notified body: NA

- ✓ No latex/ PVC
- ✓ No phthalates/ (DEHP)

3. Sterilization process if applicable

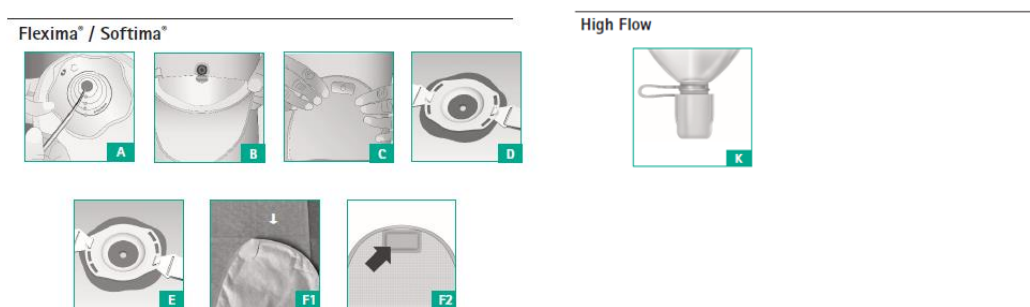
Sterilization process: **Non sterile devices**

4. Shelf life: 3 years

5. Storage conditions

Keep in a dry place
Keep away from heat

6. Instructions for use



What Flexima®-Softima® 1-piece drainable bag for High Flow is and what is used for:

Flexima®-Softima® 1-piece drainable bag for high flow are 1-piece collection bags for enterostomate with a "High Flow" cap allowing connection to a B. Braun distal bag.

Flexima® / Softima® may be used concomitantly with B.Braun stoma care accessories.

Intended purpose and indication:

The product is indicated for collection and containment of stools by patients with enterostomate. The product is not intended to be used on a skin or mucus membrane presenting a pathological change or change following disease or a wound.

Drainable "High Flow" bags are primarily intended for ileostomates and jejunostomy (in case of high flow liquid stools).

Clinical benefits & performances:

Ostomy appliances compensate for the loss of faecal continence.

Patient population:

Colostomate adults or children above four years.

Contraindications:

There are no formal contraindications for the use of Flexima® / Softima® 1-piece drainable "High Flow" bags.

Residual risks or side effects:

Peristomal skin complications can occur while using Flexima® / Softima®.

1. Preparing the skin

Wash your hands before starting the procedure.

Gently clean the peristomal area with warm water. Avoid ether, alcohol or any other topical product which could interfere with the skin protector adhesion. Carefully dab dry the skin with soft and non-shedding cloths.

2. Applying the bag

For drainable "High Flow" bags, close the closure outlet:

Drainable "High Flow" bags: Close the cap as far as maximum (K).

If you are using a Cut-To-Fit product, cut the central opening of the hydrocolloid adhesive to the size of your stoma (A) possibly with the help of the Stoma Guide. Do not cut beyond the maximum possible diameter and make sure that there is always a 2 to 3 mm margin around your stoma in order not to strangle or hurt the stomal mucosa.

Separate the bag walls by crumpling it slightly to introduce air into it.

Grasp the bag by the sides (C).

Peel off the release from the skin protector and position the bottom of the flange opening around the base of the stoma (B). Press the bottom part of the skin protector smoothly onto the skin, then place and press onto the upper part taking care not to make folds.

In order to improve the adhesion, place hands over the skin protector to warm it up (C).

3. Emptying of drainable bags

Position yourself appropriately.

Drainable "High Flow" bags:

Remove the cap by pulling it straight (K) and point it towards the toilet bowl. Once the emptying is complete, clean the cap.

After emptying of drainable bags, close the closure outlet again as indicated above.

4. Using filter protection stickers

Before bathing or showering, stick the filter protection sticker over the gas evacuation openings (F1) in order to maintain filter performances. For split cover, this must require to lift the comfort film and to stick the filter protection filter directly on the bag films. After bath or shower, remove the filter protection stickers.

5. Removing of the bag

Pull slightly on the top of the skin protector and remove the bag from the top to the bottom, while maintaining gentle pressure on the skin around the stoma with your other hand.

If you note any change on your stoma and/or peristomal skin, please contact your health care professional.

**Availability may vary from one country to another.*

National regulations for the destruction of potentially infectious materials must be observed.

Version	Date	Author	Modifications
1	2020	GMS	Initial document
2	09/2021	Anaëlle Lavarec	Update with new template Updated instructions for use paragraph to explain for product only Replacement "pouch" by "bag" Updated features