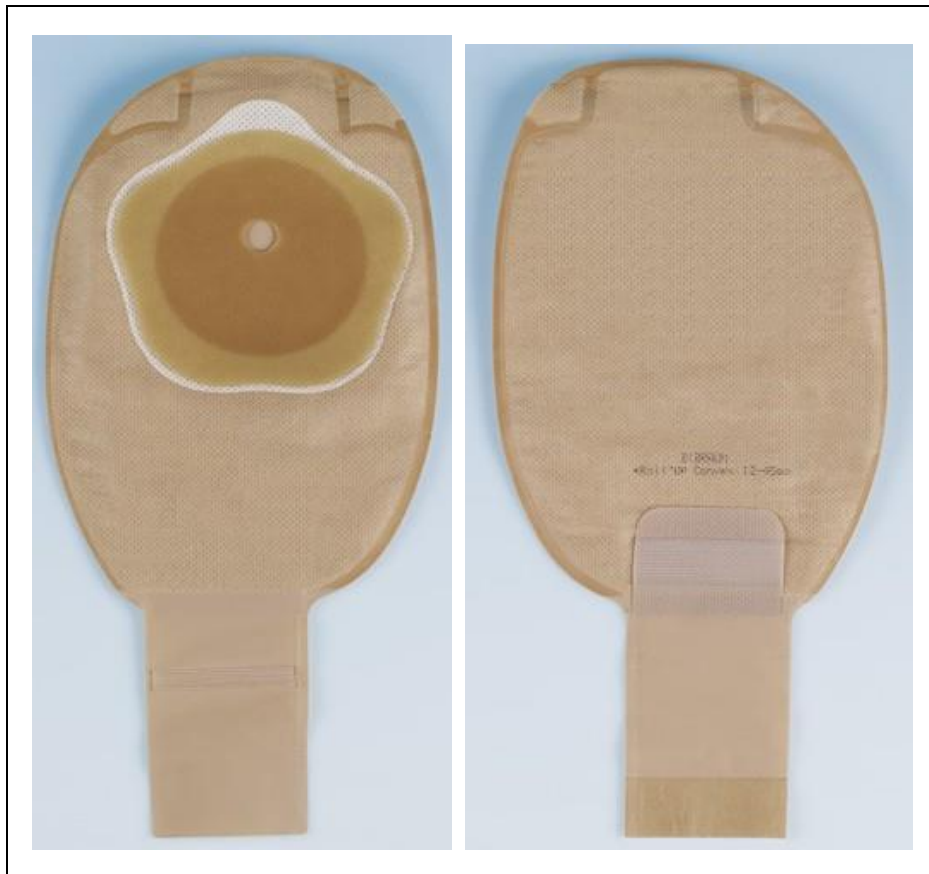

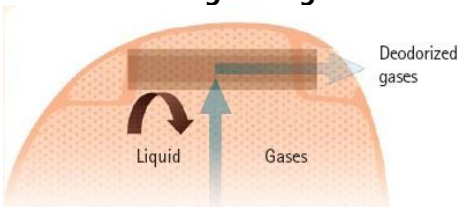



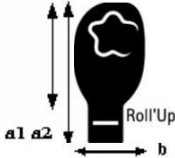
TECHNICAL DATA

Flexima® 1-piece drainable pouch with Roll'Up



1. Administrative information about B. Braun		
1.1	Name : B. Braun Medical	
1.2	Status: Manufacturer : B. Braun Medical France	B. Braun Medical 204, avenue du Maréchal Juin 92107 – BOULOGNE Cedex France
1.3	Quality system certification : B. Braun Medical Quality system complies with ISO 9001 (2000), ISO 13485 Certifying body : TÜV Product Service GmbH (0123)	

2. Information on the medical device									
2.1	Trademark Flexima®								
2.2	Indications 1-piece drainable pouch for collection of body effluents for any person having undergone an intestinal surgery of the ileostomy type.								
2.3	<p>Product description 1-piece drainable pouch with Roll'Up</p> <p>Features / Patient benefits</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;">  <p style="text-align: center;">Path length for gases</p>   </div> <div style="width: 45%;"> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td>Approved features</td> </tr> <tr> <td> <ul style="list-style-type: none"> • Skin protector type: protection of the skin, instant adhesion, adhesion reinforced with time and easy to remove </td> </tr> <tr> <td>Comfort</td> </tr> <tr> <td> <ul style="list-style-type: none"> • Very soft non-woven on skin side • Ergonomic shape of pouch which adapts to body movements • Flower shape of the skin protector for the best adaptation to skin folds </td> </tr> <tr> <td>Discretion and security</td> </tr> <tr> <td> <ul style="list-style-type: none"> • Silent and odourproof plastic film • LKP Leak-proof filter from B Braun research: gas entry in the laminar filter is protected by a high tech breathable waterproof membrane permeable to gases. </td> </tr> <tr> <td>Comfort and ease of use</td> </tr> <tr> <td> <ul style="list-style-type: none"> • 1-step system: easy-to-use outlet: patients can learn quickly how to manipulate it • Integrated soft clamp • Self-grabbing strips: easier to wash, dries quickly: more hygienic </td> </tr> </table> </div> </div>	Approved features	<ul style="list-style-type: none"> • Skin protector type: protection of the skin, instant adhesion, adhesion reinforced with time and easy to remove 	Comfort	<ul style="list-style-type: none"> • Very soft non-woven on skin side • Ergonomic shape of pouch which adapts to body movements • Flower shape of the skin protector for the best adaptation to skin folds 	Discretion and security	<ul style="list-style-type: none"> • Silent and odourproof plastic film • LKP Leak-proof filter from B Braun research: gas entry in the laminar filter is protected by a high tech breathable waterproof membrane permeable to gases. 	Comfort and ease of use	<ul style="list-style-type: none"> • 1-step system: easy-to-use outlet: patients can learn quickly how to manipulate it • Integrated soft clamp • Self-grabbing strips: easier to wash, dries quickly: more hygienic
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2.4 References							
Reference s	Colour	Diameter in mm	Maximum stoma diameter in mm	a x b in mm	Capacity according to ISO 8670-2	Packaging	
42715-	Beige	Cut-to-fit: 15-60	55		670 ml	Box of 30 pouches	
42815-	Transparent		25				
42725-	Beige	Pre-cut: 25	25	Closed (a1) 243 x 151 Open (a2) 300 x 151			
42730-		Pre-cut: 30	30				
42735-		Pre-cut: 35	35				
42740-		Pre-cut: 40	40				

2.5 Technical specifications of the product	
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 pouch:	<ul style="list-style-type: none"> Flesh-coloured silent and 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
Roll'Up	
Evacuation sleeve	<ul style="list-style-type: none"> Multilayer barrier films: vinylidene chlorine copolymer / vinyl chlorine + copolymer ethylene / vinyl acetate + chlorinated polyethylene
Self-grabbing strip	<ul style="list-style-type: none"> Extruded ribbon of self-adhesive polypropylene (adhesive of a synthetic elastomer base)
Re-glued self-grabbing strip	<ul style="list-style-type: none"> Double face adhesive of a transparent polypropylene film base and synthetic elastomer base adhesive
Slip-sheet ("Tongue") tab	<ul style="list-style-type: none"> Non woven polyethylene colaminated beige polyethylene film Self-grabbing strip Double face adhesive of a transparent polypropylene film base and synthetic elastomer base adhesive
Fold indicator	<ul style="list-style-type: none"> Low density polyethylene, 150 microns thick Double face adhesive of a transparent polypropylene film base and synthetic elastomer base adhesive

3. Sterilization process if applicable	
Sterilization process:	No sterilization

4. Storage conditions	
Shelf life :	5 years

5. Instructions for use

1/ Preparation of the skin:

- Wash your hands.
- Gently clean the area around the stoma with lukewarm water and carefully dab with soft tissues.
- Avoid using any disinfectant (ether, alcohol or other antiseptic...) as it damages the skin and prevents the proper adhesion of the pouch.

2/ Fitting your appliance:

- Cut the skin protector so it fits the size of your stoma, taking good care not to perforate the film of the pouch (**do not cut beyond the limit**).
- Close the outlet system. Separate the pouch walls by crumpling it slightly to introduce air into it.
- Peel the protective paper from the skin protector.
- Position the bottom of the flange opening around the base of the stoma.
- Press the bottom part of the skin protector smoothly onto the skin, then place and press onto the upper part.
- Smooth the entire surface of the skin protector, working from bottom to top, to ensure perfect adhesion.

3/ Removing your appliance :

- Pull slightly on the top of the pouch and remove the pouch from the top to the bottom, whilst maintaining gentle pressure on the skin around the stoma with your other hand.

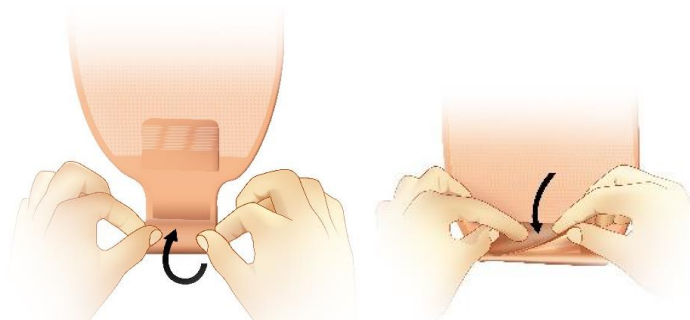
6/ Use of patch cover for filter protection:

If you wish to inactivate the filter (bath, shower...), stick an adhesive patch on both sides of the top of the pouch so that the hole for gas evacuation is blocked.

7/ With the Roll'Up system:

- Closing of the outlet:

- Fold three times the remaining sleeve onto itself using the fold indicator.
- Fold the tab back onto the plate: the two self-grabbing strips are now facing each other. Press all the length of the self-grabbing strips: a little "click" can be felt, indicating that the system is closed.



- Emptying of the pouch:

- Position yourself to empty your pouch as normal.
 - Free the evacuation sleeve by lifting the tab up.
- Caution: emptying starts at this stage.
- Unfold the sleeve.
 - Free the stool flow; when the emptying is done, expel the remaining matter in the sleeve by pressing it slightly from top to bottom. **Clean the open end of the sleeve.**

Clean carefully the open end with a non-fluffy material.

- To close the pouch, fold the sleeve as indicated above.



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