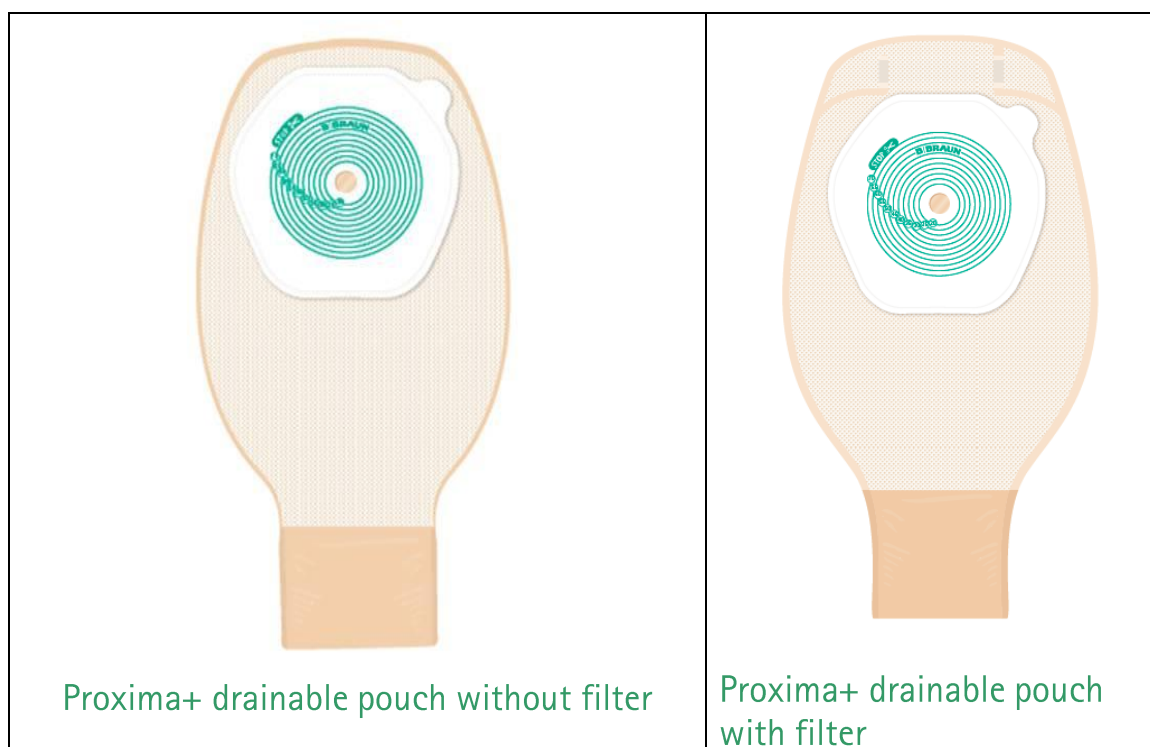


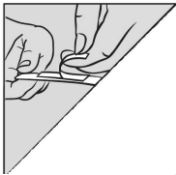
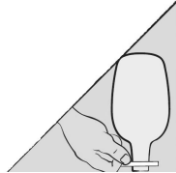
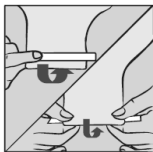
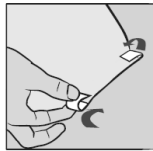


Technical Data Sheet

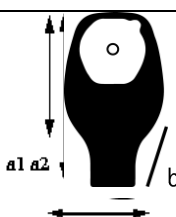
Proxima®+ 1-piece drainable pouch



1. Administrative information about B. Braun		
1.1	Name : B. Braun Medical SAS	
1.2	Status: Manufacturer : B. Braun Medical SAS France	B. Braun Medical SAS 204, avenue du Maréchal Juin 92100 – Boulogne Billancourt France www.bbraun.com Tel: +331 41 10 53 00
1.3	Quality system certification : B. Braun Medical Quality system complies with ISO 9001: 2008 / ISO 13485: 2012 / ISO 14 001: 2004 Notified body : TÜV Product Service GmbH (0123)	

2. Information on the medical device

2.1	Trademark	Proxima®
2.2	Indications	One-piece drainable pouch for collection of body effluents for any person having undergone intestinal surgery of the ileostomy or colostomy type.
2.3	Product description	1-piece drainable pouch
	Features / Patient benefits	<div> <div> Security <ul style="list-style-type: none"> Full hydrocolloid skin barrier with a well-balanced proportion of hydrocolloid nature components and adhesive nature components for: skin protection and adhesion, Shape of skin protector for a good distribution of traction force and stay in position securely Rounded shape without angles for optimization of collecting capacity </div> <div> Comfort <ul style="list-style-type: none"> Full hydrocolloid skin barrier with concentric welding lines for an increased flexibility Soft backing material on body-worn side: allowing moisture evacuation and to wipe off water from the surface Silent and odour-proof plastic film </div> <div> Ease of use <ul style="list-style-type: none"> Cut-to-fit skin protector up to 70 mm: can be cut to fit every shape of stoma & Pre-Cut flanges ready to use. Enlarged opening been to 70 mm for the evacuation of liquid or solid stools. It allows using this pouch for ileostomy and colostomy. </div> </div>
	How to use the soft clamp?	<div>  <p>1 – Remove the release paper from the adhesive strip.</p> </div> <div>  <p>2 – Center and stick the soft clamp at the bottom of the opening (on the outer side of the pouch, not on the skin side). Leave a small space between the clamp and the end of the opening. Its size should approximately be the width of the clamp.</p> </div> <div>  <p>3 – Fold the outlet backwards four times using the clamp.</p> </div> <div>  <p>4 – Squeeze the extremities of the clamp firmly to complete closure.</p> </div>
	How to use the rigid clamp?	<p>Only 3 steps:</p> <ul style="list-style-type: none"> Put the "flat" part towards the plastic film of the outlet Fold the film upwards Close with the "bigger" part <div>   </div>

2.4	References					
	References	Diameter in mm		Capacity according to ISO 8670-2	Colour	Packaging
Without filter	54210A	✂10-70 mm	a1= 235 mm a2= 295 mm b= 150 mm	650 ml	Beige	Box of 30 pouches & 30 soft-clamps + 1 rigid
	54310A	✂10-70mm			Transparent	
With filter	54410A	✂10-70mm			Beige	Box of 10 + 1 rigid clamp
	54425A	Pre-cut_25			Beige	
	54430A	Pre-cut_30			Beige	
	54435A	Pre-cut_35			Beige	
	54510A	✂10 -70 mm	Transparent			
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)Hexagon-shaped				
	Collection pouch	<u>For the transparent pouch:</u> <ul style="list-style-type: none">On the skin side: transparent film (multilayer barrier film), white non woven (polyethylene microfibers);On the external side: Transparent film (multilayer barrier film); <u>For the beige pouch:</u> <ul style="list-style-type: none">On the skin side: beige film (multilayer barrier film) + non woven (polyethylene microfibers);On the external side: Beige film (multilayer barrier film), Beige non woven (polyethylene microfibers).				
	Filter	<ul style="list-style-type: none">60mm laminar filter				
	Soft Clamp	<ul style="list-style-type: none">White adhesive foam double sides4 steel wire covered by a white polyethylene film.Dimensions : length :130 ±3mm / width :8 ±0,5mm				
	Rigid clamp	<ul style="list-style-type: none">PolypropyleneDimensions: length: 8cm (useful dimension 7cm)/ Useful Height: 1cmAudible locking system				
2.6	Medical device classification: I non sterile					
	EU Directive:			93/42/CEE		
	Notified body :			NA		

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

3. Sterilization process if applicable	
	Sterilization process: Non sterile devices
4. Shelf life	
	5 years

5. Storage conditions

Keep in a dry place
 Keep away from heat

6. Instructions for use

1. Before application

- Measure the diameter of your stoma,
- Cut the skin protector from the starter hole so it fits around your stoma. Leave a small gap around your stoma: it should not be "occluded" by the skin protector.
- Skin preparation:
 - Clean the skin around your stoma with tepid water. Avoid ether, alcohol or other antiseptic which can prevent good adhesion of the protector,
 - Dab the skin carefully with soft tissues.

2. Fitting the pouch

- Separate the inner surfaces of the pouch walls.
- Peel the protective paper from the skin protector and 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 taking care not to make folds. Smooth the entire surface of the skin protector, working from bottom to top, to ensure perfect adhesion.

3. Removing the pouch

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

4. Drainable pouches

- Take care that your pouch is closed before applying it. To that end, use the clamp provided in the box to close the bag.
- If you prefer, use a rigid clamp (to be ordered separately: ref. F00727)
- When you want to empty the pouch, remove the clamp and direct the open end of the pouch over the toilet. Wipe the end of the pouch with a tissue after it has been emptied and reapply the clamp.