

TECHNICAL DATA SHEET

Proxima 1-piece drainable pouch



Proxima drainable pouch

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	

Certificating 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

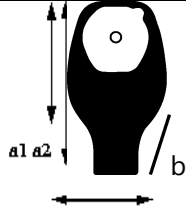


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| Security |
| <ul style="list-style-type: none"> • Full hydrocolloid skin barrier with a well-balanced proportion of hydrocolloid nature components and adhesive nature components for: skin protection and adhesion, • Shape of skin protector for a good distribution of traction force and stay in position securely • Rounded shape without angles for optimization of collecting capacity |
| 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 odourproof plastic film |
| 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 • Enlarged opening been to 70 mm for the evacuation of liquid or solid stools. It allows using this pouch for ileostomy and colostomy. |

How to use the soft clamp?

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| | 1 – Remove the release paper from the adhesive strip. | | 3 – Fold the outlet backwards four times using the clamp. |
| | 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. | | 4 - Squeeze the extremities of the clamp firmly to complete closure. |

2.4 References

	References	Diameter in mm		Capacity according to ISO 8670-2	Colour	Packaging
	55410A	10 → 70 mm	a1= 235 mm a2= 295 mm b= 150 mm	650 ml	Beige	Box of 30 pouches and 30 clamps
	55510A	10 → 70 mm			Transparent	
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: polyisobutylen, carboxymethylcellulose, pectin) Hexagon-shaped 			
	Collection pouch		<ul style="list-style-type: none"> Beige (for the beige pouch) or transparent (for the transparent pouch) odour-proof multilayer co-extruded barrier film White microperforated polyethylene film on body-worn side 			
	Clamp		<ul style="list-style-type: none"> White adhesive foam double sides 4 steel wire covered by a white polyethylene film. Dimensions : length :140±3mm / width :8 ±0,5mm 			
2.6	Medical device classification:		I non sterile			
	EU Directive:		93/42/CEE			
	Notified body:		TÜV Product Service GmbH (0123)			

3. Sterilization process if applicable	
Sterilization process:	No sterilization

4. Shelf life	
	3 years
5. Storage conditions	
	Keep in a dry place Keep away from heat

5. Instructions for use	
	<p>1. Before application</p> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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. <p>2. Fitting the pouch</p> <ul style="list-style-type: none"> 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.

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