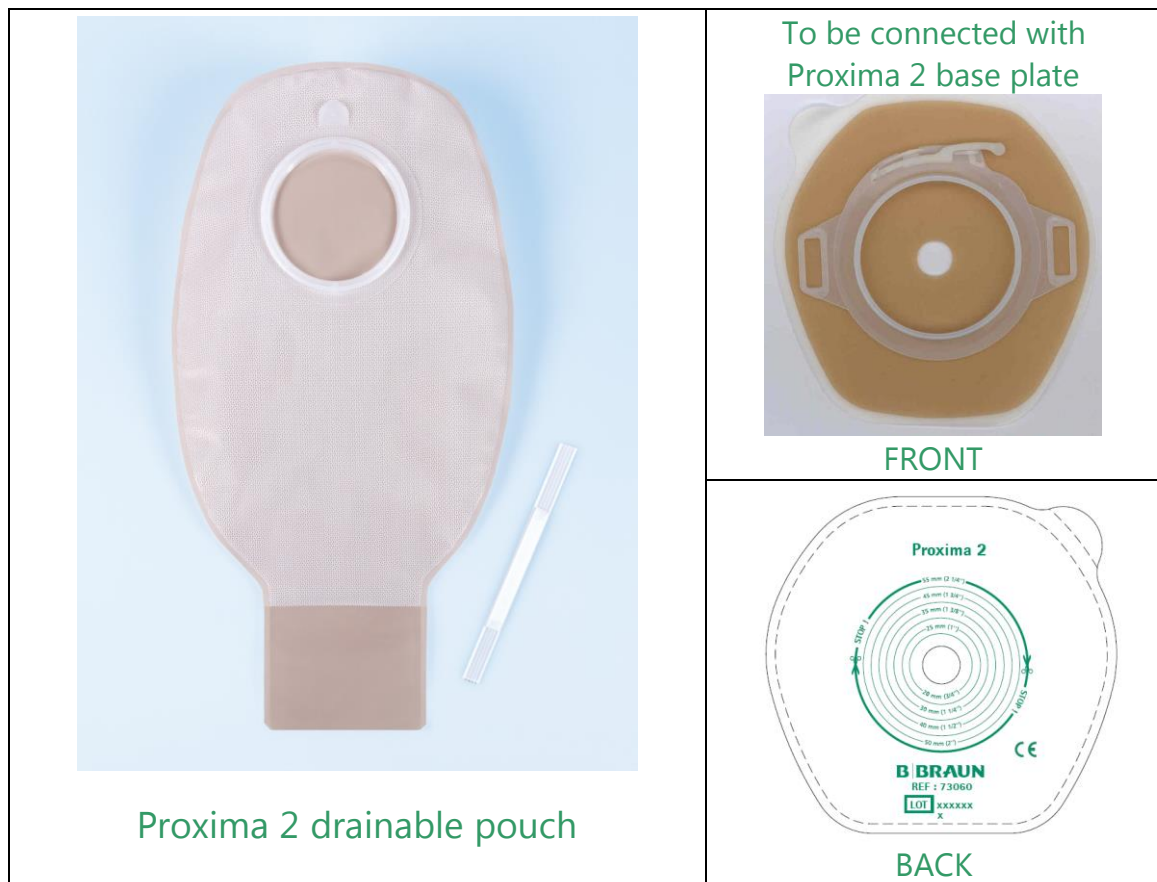



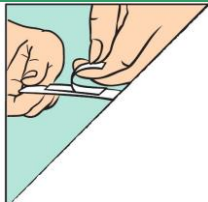
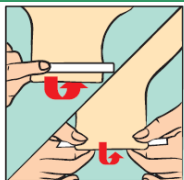
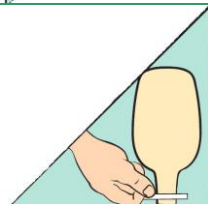
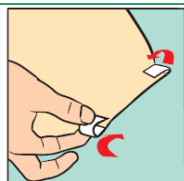
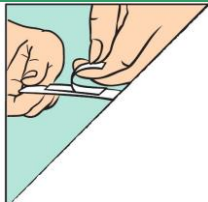
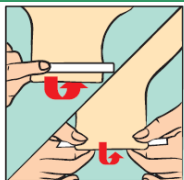
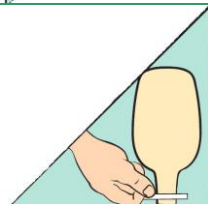
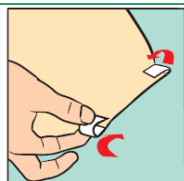
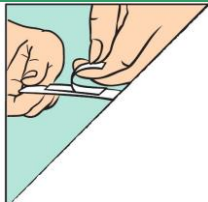
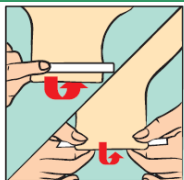
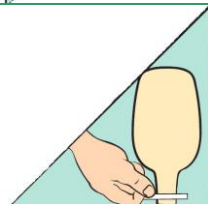
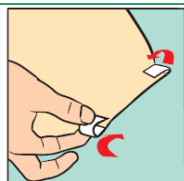
TECHNICAL DATA SHEET

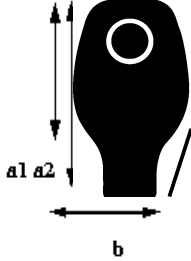
Proxima 2 2-piece system drainable pouch



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	

	Certifying body : TÜV Product Service GmbH (0123)
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2. Information on the medical device									
2.1	Trademark Proxima 2								
2.2	Indications Two-piece drainable pouch for collection of body effluents for any person having undergone intestinal surgery of the ileostomy or colostomy type. Each pouch has to be connected with one Proxima 2 base plate.								
2.3	<p>Product description 2-piece drainable pouch available in diameters 40, 50, 60 and 80 mm</p> <p>Features / Patient benefits</p> <div style="display: flex; align-items: flex-start;"> <div style="flex: 1;">  <p style="text-align: center;">OPENED CLOSED</p> </div> <div style="flex: 1; border: 1px solid black; padding: 5px; margin-left: 10px;"> <p>Ease of use</p> <ul style="list-style-type: none"> • Enlarged opening been to 70 mm for the evacuation of liquid or solid stools. It allows using this pouch for ileostomy and colostomy. • Soft adhesive clamp <p>Security</p> <ul style="list-style-type: none"> • Rounded shape without angles for optimization of collecting capacity <p>Comfort</p> <ul style="list-style-type: none"> • Soft backing material on body-worn side: allowing moisture evacuation and to wipe off water from the surface • Silent and odourproof plastic film </div> </div> <p>How to use the soft clamp?</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%; text-align: center;"></td> <td style="width: 50%;">1 – Remove the release paper from the adhesive strip.</td> <td style="width: 25%; text-align: center;"></td> <td style="width: 25%;">3 – Fold the outlet backwards four times using the clamp.</td> </tr> <tr> <td style="text-align: center;"></td> <td>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.</td> <td style="text-align: center;"></td> <td>4 - Squeeze the extremities of the clamp firmly to complete closure.</td> </tr> </table>		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.
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2.4	References								

	References	Diameter in mm		Capacity according to ISO 8670-2	Colour	Packaging
	73340A 73350A 73360A 73380A	40 50 60 80	a1= 235 mm a2= 295 mm b= 150 mm	740 ml (for diameter 50)	Beige	Box of 30 pouches
	73340A 73350A 73360A 73380A	40 50 60 80			Transparent	
2.5	Technical specifications of the product					
	Latex free - PVC free					
	Components	Materials				
	Ring to lock the pouch on the base plate	<ul style="list-style-type: none"> Polyethylene 				
	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. Storage conditions	
Shelf life :	5 years

5. Instructions for use	
1. Before application	<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 Hydrocolloid flange diameter: 40 mm / 50 mm / 60 mm / 80 mm Maximum cutting size: 30 mm / 40 mm / 50 mm / 70 mm 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
2. Application of the base plate and the pouch	<ul style="list-style-type: none"> Remove the protective film from the base plate. Place the base plate over your stoma and gently press the skin protector onto your skin taking care not to make folds

- Ensure locking system is open by moving the lever gently upwards without forcing. Press pouch and base plate together starting at the bottom. Run your fingers around the coupling on the outside of the pouch from the bottom to the top: when a slight click is heard, the pouch is securely positioned on the base plate.
- Push the lever down to lock the system. Check that the pouch is securely locked onto the base plate by gently tugging on the pouch

3. Removal of the pouch

- Make sure the tab on the bag is aligned with the lever on the base plate
- Open the locking mechanism by moving the locking lever gently upwards
- Hold the tab on the plastic ring of the pouch then gently pull the pouch out of the base plate, starting at the top and working downwards

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

Please note:

The Proxima 2 base plate is also compatible with the pouches of the range Almarys® Twin+

B | BRAUN

B. Braun Medical

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