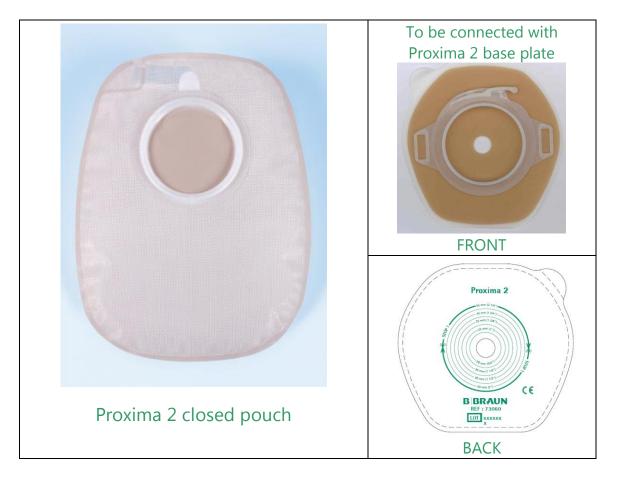


## TECHNICAL DATA SHEET

## Proxima 2 2-piece system closed pouch



1. Admin	L. 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	<b>Quality system certification :</b> B. Braun Medical Quality system complies with ISO 9001 (2000), ISO 13485						

	Certificatin						
	<b>TÜV Product</b>	Service Gmb	H (0123)				
. Informat	tion on the <b>i</b>	medical dev	rice				
2.1	<u>Trademark</u>			Pro	xima 2		
2.2	IndicationsTwo-piece system closed pouch for collection of body effluents for any person having undergonintestinal surgery of the colostomy type.Each pouch has to be connected with one Proxima 2 base plate.						
2.3	Product description       2-piece closed pouch         available in diameters 40, 50, 60 and 80 mm						
	<image/>		<ul> <li>Comfort         <ul> <li>Soft backing material on body-worn side: allowing moisture evacuation and to wipe off water from the surface</li> <li>Silent and odourproof plastic film</li> <li>Filter based on laminar technology: improved deodorisation capacity</li> <li>Integrated filter: no contact of charcoal with clothes, no risk of pouch ballooning</li> </ul> </li> <li>Security         <ul> <li>Rounded shape without angles for optimization of collecting capacity</li> </ul> </li> <li>Ease of use         <ul> <li>Integrated filter</li> </ul> </li> </ul>				
2.4	References Reference s	Diameter in mm	a x b in m a	b	Capacity according to ISO 8670-2	Colour	Packagiı g
	73140A 73150A 73160A 73180A 73240A 73250A	40 50 60 80 40 50	195 X 15	0	530 ml (for diameter – 50)	Beige Transparent	Box of 30 pouches
	73260A 73280A	60 80					

2.5	Technical specifications of the product         Latex free - PVC free				
	Components	Materials			
	Ring to lock the pouch on the base plate	Polyethylene			
	Collection pouch	<ul> <li>Beige (for the beige pouch) or transparent (for the transparent pouch) odour-proof multilayer co-extruded barrier film</li> <li>White microperforated polyethylene film on body-worn side</li> </ul>			
	Laminar filter	<ul> <li>A strip of foam impregnated with active charcoal, tightly sealed on all sides by a white Polypropylene film.</li> <li>Length: 41±1mm</li> </ul>			
2.6	Medical device classificat	tion: I non sterile			
	EU Directive:	93/42/CEE			
	Notified body:	TÜV Product Service GmbH (0123)			

## 3. Sterilization process if applicable Sterilization process: No sterilization

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4. Storag	le conditions			
	Shelf life : 5 years			
5. Instrue	ctions 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			
	Hydrocolloïd flange diameter: 40 mm / 50 mm / 60 mm / 80 mm			
	Maximum cutting size: 30 mm / 40 mm / 50 mm / 70 mm			
	Skin preparation:			
	<ul> <li>Clean the skin around your stoma with tepid water. Avoid ether, alcohol or other antiseptic which can prevent good adhesion of the protector</li> <li>Dab the skin carefully with soft tissues</li> </ul>			
	2. Application of the base plate and the pouch			
	<ul> <li>Remove the protective film from the base plate. Place the base plate over your stoma and</li> </ul>			
	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			

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**B. Braun Medical** 204, avenue du Maréchal Juin