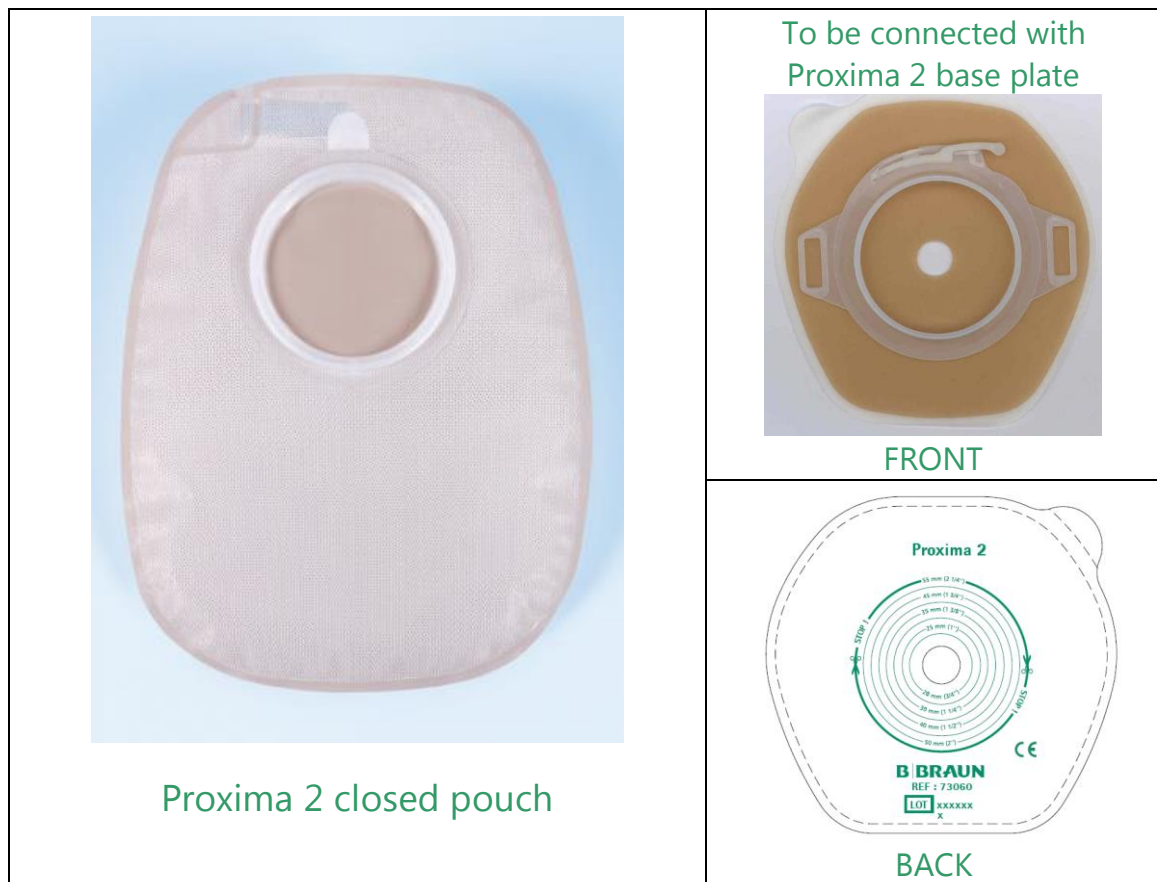


# TECHNICAL DATA SHEET

## Proxima 2 2-piece system closed pouch



Proxima 2 closed pouch

To be connected with  
Proxima 2 base plate

FRONT

BACK

1. Administrative information about B. Braun		
1.1	<b>Name : B. Braun Medical</b>	
1.2	<b>Status:</b> <b>Manufacturer : B. Braun Medical France</b>	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	



<b>2.5</b>	<b>Technical specifications of the product</b>	
	Latex free - PVC free	
	<b>Components</b>	<b>Materials</b>
	Ring to lock the pouch on the base plate	<ul style="list-style-type: none"> <li>• Polyethylene</li> </ul>
Collection pouch	<ul style="list-style-type: none"> <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 style="list-style-type: none"> <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>	
<b>2.6</b>	<b>Medical device classification:</b>	I non sterile
	<b>EU Directive:</b>	93/42/CEE
	<b>Notified body:</b>	TÜV Product Service GmbH (0123)

<b>3. Sterilization process if applicable</b>	
<b>Sterilization process:</b>	No sterilization

<b>4. Storage conditions</b>	
Shelf life :	5 years

<b>5. Instructions for use</b>	
	<p><b>1. Before application</b></p> <ul style="list-style-type: none"> <li>• Measure the diameter of your stoma</li> <li>• 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</li> <li>• Skin preparation: <ul style="list-style-type: none"> <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> </li> </ul> <p><b>2. Application of the base plate and the pouch</b></p> <ul style="list-style-type: none"> <li>• 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</li> <li>• 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</li> <li>• 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</li> </ul> <p><b>3. Removal of the pouch</b></p> <ul style="list-style-type: none"> <li>• Make sure the tab on the bag is aligned with the lever on the base plate</li> <li>• Open the locking mechanism by moving the locking lever gently upwards</li> <li>• 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</li> </ul>