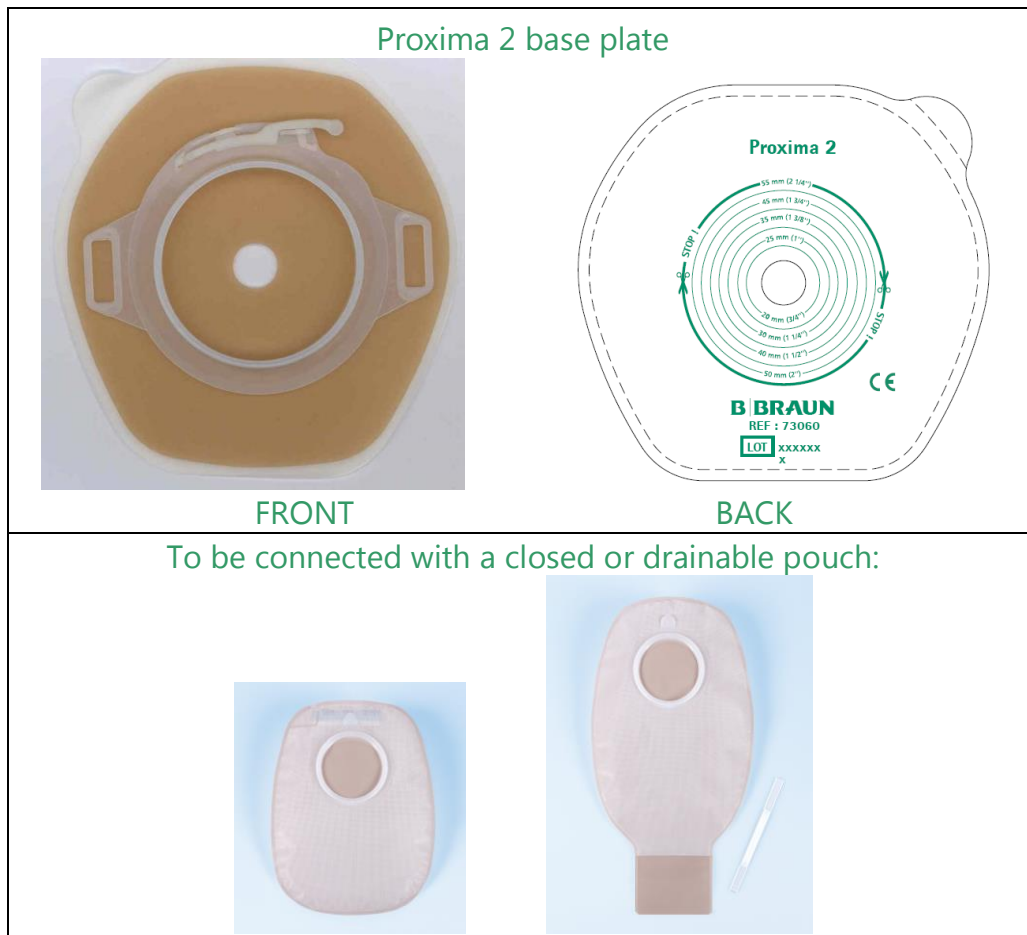


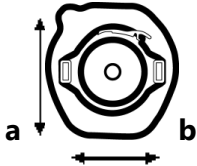


# TECHNICAL DATA SHEET

## Proxima 2 2-piece system base plate



<b>1. Administrative information about B. Braun</b>		
<b>1.1</b>	<b>Name : B. Braun Medical</b>	
<b>1.2</b>	<b>Status:</b> <b>Manufacturer : B. Braun Medical</b> <b>France</b>	B. Braun Medical 204, avenue du Maréchal Juin 92107 – BOULOGNE Cedex France
<b>1.3</b>	<b>Quality system certification :</b> B. Braun Medical Quality system complies with ISO 9001 (2000), ISO 13485	

	<b>Certificating body :</b> TÜV Product Service GmbH (0123)								
<b>2. Information on the medical device</b>									
<b>2.1</b>	<b>Trademark</b>		Proxima 2						
<b>2.2</b>	<b>Indications</b> 2-piece system base plate with full hydrocolloid skin protector. Each base plate is to be connected with one Proxima 2 pouch which is available as closed or drainable.								
<b>2.3</b>	<b>Product description</b>		Base plate Available in diameter 40, 50, 60 and 80 mm corresponding respectively to maximum stoma diameters of 30, 40, 50 and 70 mm						
	<b>Features / Patient benefits</b>								
	 <p>Individual cardboard</p>  <p>FRONT BACK</p>		<table border="1"> <tr> <td><b>Security</b></td> </tr> <tr> <td> <ul style="list-style-type: none"> <li>Full hydrocolloid skin barrier: protection of the skin, adhesion reinforced with time and easy to remove</li> </ul> </td> </tr> <tr> <td><b>Ease of use</b></td> </tr> <tr> <td> <ul style="list-style-type: none"> <li>Easy-to-use locking system: <ul style="list-style-type: none"> <li>Audible click will make you sure that the pouch is attached to the ring</li> <li>For pouch removal, lift the locking lever and gently peel pouch away from the flange, starting from the top</li> </ul> </li> <li>Release paper with a printed cutting target, the product name, the reference, the batch number and CE mark.</li> <li>Easy-to-clean base plate</li> </ul> </td> </tr> <tr> <td><b>Comfort</b></td> </tr> <tr> <td> <ul style="list-style-type: none"> <li>Low profile base plate, incorporating belt loops</li> <li>Primary packaging: environment friendly individual cardboard</li> <li>One single release paper to remove makes it easy to use.</li> </ul> </td> </tr> </table>	<b>Security</b>	<ul style="list-style-type: none"> <li>Full hydrocolloid skin barrier: protection of the skin, adhesion reinforced with time and easy to remove</li> </ul>	<b>Ease of use</b>	<ul style="list-style-type: none"> <li>Easy-to-use locking system: <ul style="list-style-type: none"> <li>Audible click will make you sure that the pouch is attached to the ring</li> <li>For pouch removal, lift the locking lever and gently peel pouch away from the flange, starting from the top</li> </ul> </li> <li>Release paper with a printed cutting target, the product name, the reference, the batch number and CE mark.</li> <li>Easy-to-clean base plate</li> </ul>	<b>Comfort</b>	<ul style="list-style-type: none"> <li>Low profile base plate, incorporating belt loops</li> <li>Primary packaging: environment friendly individual cardboard</li> <li>One single release paper to remove makes it easy to use.</li> </ul>
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<b>2.4</b>	<b>References</b>								
	<b>Reference s</b>	<b>Diameter in mm</b>	<b>Maximum stoma diameter in mm</b>						
			<b>a x b in mm</b>						
									
			<b>Packaging</b>						
	73040A 73050A 73060A 73080A	40 50 60 80	30 40 50 70						
			108 x 106 108 x 106 108 x 112 135 x 133						
			Box of 10 base plates						

<b>2.5</b>	<b><u>Technical specifications of the product</u></b>	
	Latex free - PVC free	
	<b>Component</b>	<b>Material</b>
	Protector release	<ul style="list-style-type: none"> <li>• Silicon coated protective paper that extends beyond the gum.</li> </ul>
Skin protector	<ul style="list-style-type: none"> <li>• One layer of hydrocolloid gum (main components: polyisobutylen, carboxymethylcellulose, pectin).</li> <li>• Transparent film protective coating that extends beyond the gum.</li> <li>• Hexagon-shaped</li> </ul>	
Coupling system	<ul style="list-style-type: none"> <li>• Support ring: polyethylene</li> <li>• Lock: polyamide</li> </ul>	
<b>2.6</b>	<b><u>Medical device classification:</u></b>	I non sterile
	<b><u>EU Directive:</u></b>	93/42/CEE
	<b><u>Notified body:</u></b>	TÜV Product Service GmbH (0123)

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

<b>4. Storage conditions</b>	
<b><u>Shelf life :</u></b>	3 years

<b>5. Instructions for use</b>	
	<p>Proxima 2 is a 2-piece collecting device for ostomates with:</p> <ul style="list-style-type: none"> <li>- A base plate with a skin protector and a pouch carrying ring with security locking</li> <li>- A collecting pouch either: <ul style="list-style-type: none"> <li>o Closed, with an integrated filter for deodorization and evacuation of gasses,</li> <li>o Drainable, with a large evacuation sleeve (70 mm) allowing the evacuation of even thick effluents and a soft clamp</li> </ul> </li> </ul> <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>

### **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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