

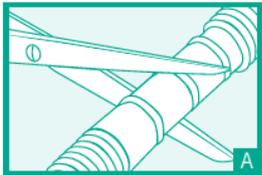
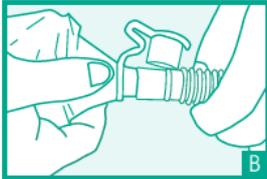
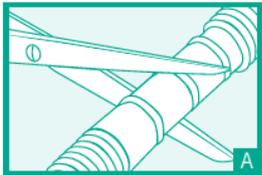
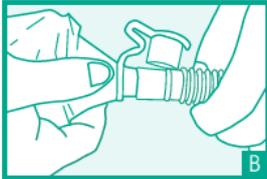
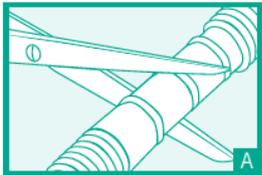
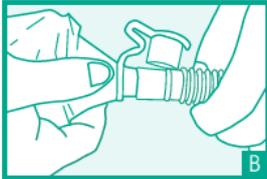
Technical data sheet

Flow Collector



1. Administrative information about B. Braun		
1.1	Name : B. Braun MEDICAL SAS	
1.2	Status: Manufacturer : B. Braun MEDICAL SAS France	B. BRAUN MEDICAL SAS 26 Rue Armengaud 92210 Saint-Cloud FRANCE www.bbraun.com Tel: +331 41 10 53 00
1.3	Quality system certification : B. Braun Medical SAS Quality system complies with ISO 9001: 2008 ; ISO 13485: 2016 ; ISO 14 001: 2004 Certificating body : TÜV Product Service GmbH (0123)	

2. Information on the medical device	
2.1	Trademark Flow Collector
2.2	<p>Indications</p> <p>Drainable distal 2L, collecting bag with long evacuation tubing for high flow liquid stools (4 to 6 litres in 24 hours). This type of flow is found in case of derivation jejunostomies also called "short bowels". It can also be done for a limited period of time in ileostomy or colostomy after surgery or chemotherapy.</p> <p>This product can be connected with Flexima®/Softima® 1 piece High Flow/ Almarys® Twin+ sterile/ Flexima®/ Softima® Key Maxi and Flexima®/ Softima® 3S High Flow pouches. The collector can be placed on the floor or higher than the floor. It must always be lower than the pouch.</p>

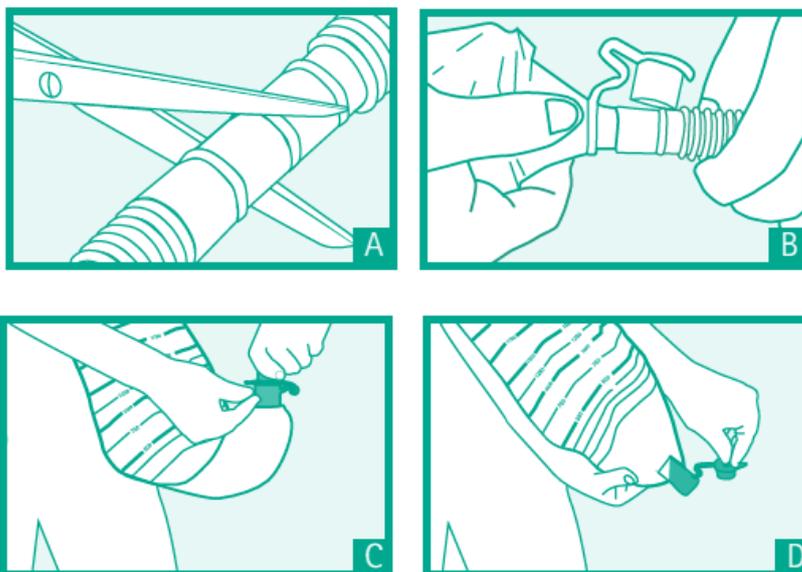
2.3	<p>Product description Distal non sterile collecting bag</p> <p>Closer look on characteristics of the system</p> <table border="1" style="width: 100%;"> <tr> <td style="width: 40%; vertical-align: top;"> <p>Ambulatory patient wearing the High Flow System: Almarys® Twin+ base plate and pouch for high flow connected with the Flow Collector</p> </td> <td style="width: 20%; text-align: center;">  </td> <td style="width: 40%; vertical-align: top;"> <p>The full length of the transfer tubing (1,5 m) can be used when the patient is bedridden, for instance. For a use of the Flow Collector in ambulatory conditions, adjustment of length is possible by cutting the tubing every 30 cm.</p> </td> </tr> <tr> <td></td> <td style="text-align: center;">  </td> <td style="vertical-align: top;"> <p>The connection between the pouch and the Flow Collector is easy and highly resistant.</p> </td> </tr> <tr> <td></td> <td style="text-align: center;">  </td> <td style="vertical-align: top;"> <p>Emptying of the Flow Collector is easy, with no risk of splashing.</p> </td> </tr> </table>	<p>Ambulatory patient wearing the High Flow System: Almarys® Twin+ base plate and pouch for high flow connected with the Flow Collector</p>		<p>The full length of the transfer tubing (1,5 m) can be used when the patient is bedridden, for instance. For a use of the Flow Collector in ambulatory conditions, adjustment of length is possible by cutting the tubing every 30 cm.</p>			<p>The connection between the pouch and the Flow Collector is easy and highly resistant.</p>			<p>Emptying of the Flow Collector is easy, with no risk of splashing.</p>
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<p>Features / Patient benefits</p> <ul style="list-style-type: none"> • Increased security and comfort • Transfer tubing permanently connected to the distal bag for an easy and highly resisting connection to the pouch • White opaque tube for more discretion • Transfer tubing with 15 mm diameter and anti-bending system for an easy drainage of stoma pouch • Punched holes at the top of the bag to hang it • Clear approximate graduation (Approx. 2L) on the side of the transparent bag for an easier examination and quantification of the effluents (necessary to adapt the food intake of the patients in case of jejunostomy for instance) • A cap at the bottom end for an easy emptying 										

			<ul style="list-style-type: none"> of the collector and no risk of splashing • 2 ways of opening, with grip for easier emptying • A resistant white opaque backing material for more discretion 							
2.4	References									
	References	Dimensions (Nominal size): width, length, capacity	Colour							
	039900-	<u>Bag</u> : useful length (closed bag) : 325 mm, width: 272 mm Capacity : 2l	Transparent/ White opaque							
039901-	<u>Transfer tubing</u> : diameter: 15 mm Length: 1,5 m; possible cut every 30 cm	Box of 15 bags <i>Products are individually wrapped</i>								
2.5	Technical specifications of the product									
	Latex free <table border="1"> <thead> <tr> <th>Components</th> <th>Materials</th> </tr> </thead> <tbody> <tr> <td>Collecting bag</td> <td>• PolyVinylChloride with DINP</td> </tr> <tr> <td>Transfer tubing</td> <td>• Polyethylene + Ethylene-vinyl acetate (EVA)</td> </tr> <tr> <td>Emptying cap</td> <td>• Polyvinylchloride with DEHT</td> </tr> </tbody> </table>			Components	Materials	Collecting bag	• PolyVinylChloride with DINP	Transfer tubing	• Polyethylene + Ethylene-vinyl acetate (EVA)	Emptying cap
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Transfer tubing	• Polyethylene + Ethylene-vinyl acetate (EVA)									
Emptying cap	• Polyvinylchloride with DEHT									
2.6	Medical device classification: EU Directive: Notified body :	I non sterile 93/42/CEE NA								

3. Sterilization process if applicable	
Sterilization process	No sterilization

4. Shelf life	
	Shelf life : 2 years
5. Storage conditions	<ul style="list-style-type: none"> ✓ Keep away from heat ✓ Keep in a dry place

6. Instructions for use



Drainable collecting system for high flow liquid stools. This product ensures the collection of high flow liquid stools being connected to the stoma bag of the patient. It is to be used with the Almarys® Twin+ pouches for High Flow, Flexima®/Softima® pouches for High Flow, Flexima®/Softima® Key Maxi and Flexima®/Softima® 3S for High Flow. The collector can be placed on the floor or higher than the floor. It must always be lower than the stoma bag.

1. Fitting your appliance

Adapt the length of the tubing to the desired size with scissors by cutting it in the middle – against the edge – of the smooth areas (cutting is possible every 30 cm) (A).

Close the green drainage cap by pressing it before the connection.

Connect the tubing to the drainage system of the stoma bag by placing the outlet of the pouch inside the Flow Collector's tube (B).

Disconnection after use: pull on the tubing while pressing it slightly and close the drainage system of the stoma pouch. One Flow Collector can be used for a duration of about 72 hours.

Caution: do not use any gelifying product in the stoma bag in order to avoid blockage in the tubing.

N.B.:

1. It is possible to get a rough measurement of the effluent volume thanks to the measuring scales in the front of the collecting pouch. For a more precise evaluation, use a measuring collector.

2. It is possible to use B. Braun Ileo Gel+ by introducing 2 to 4 sachets in the Flow Collector (through the green cap at the lower end of the pouch). It solidifies stools: the pouch is then more silent and the emptying is easier.

2. Use of the drainage system

For an easier emptying, lay it on the toilets seat (C). Open the cap using the grip and taking good care to maintain it higher than the pouch.

Maintain the cap between the thumb and the index finger during the emptying (D).

Once the collecting pouch is empty, clean the cap with tap water or with a wipe (caution: do not use fluffy material) to maintain leakproofness.