

Intended purpose

The ostomy bag is intended to passively collect output from a stoma. The adhesive baseplate is attached to the ostomy bag and is intended to adhere to intact skin around the stoma.

Indications

The device is indicated for people with a stoma.

Warnings

Re-use of the single use product is not recommended as cross contamination may occur.

Reprocessing, washing, disinfection and/or (re)sterilisation may compromise product characteristics, causing additional risk of physical harm or infection to the user.

Information

Single use ostomy bag.

The products are intended to be stored in the box until removed for use, as the box protects the products and the label on the box contains important information like batch code, use-by date and a unique barcode.

The device does not have to be removed before an MR scan as it is MR safe.

Coloplast accepts no liability for any injury or loss that may arise if this product is used in a manner contrary to Coloplast's current recommendations.

Special storage conditions

Store product horizontally.

Keep away from sunlight.

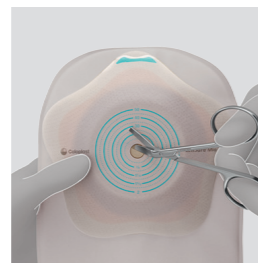
Reporting of incidents

If, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority.

How to use

Preparation

1



Cut a hole in the adhesive to fit the exact size and shape of the stoma using a pair of small curved scissors and the cutting guide on the adhesive.

You can use the enclosed stoma measuring guide to measure the size and shape of the stoma.

Your stoma shape can change so it is recommended that you measure it when it is biggest. This is often when you sit down.

An exact fit between the hole and the stoma is important to reduce the risk of leakage and skin problems.

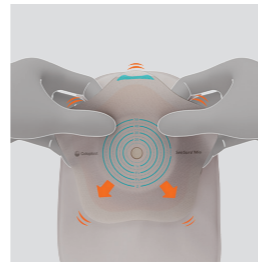
2



Thoroughly clean the stoma and the surrounding skin area. The skin must be completely dry before application of the adhesive.

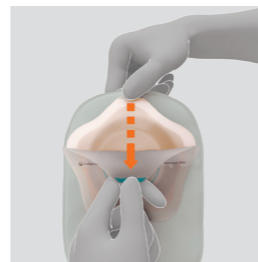
Application

3



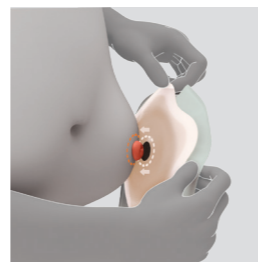
Flip all 5 petals to prepare the adhesive for application.

4



Peel off the protective film from the adhesive.

5



Hold the adhesive with the petals folded back. Align the center part of the adhesive around the stoma.

Press the center part carefully onto the skin.

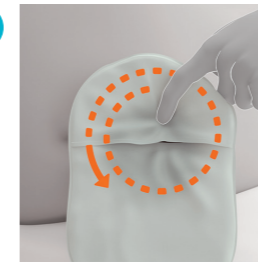
Then flip the petals down over the outward area.

6



Press the adhesive firmly onto the skin from the center and out.

7



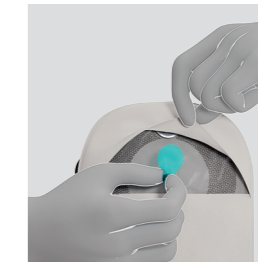
Use your index finger to find the soft stability ring that surrounds your stoma. Carefully apply pressure on the adhesive between the ring and your stoma (or directly on the stability ring) to ensure the centre part of the adhesive forms a tight seal to the skin.

8



Apply pressure from the centre of the adhesive and outwards in multiple directions to ensure secure adhesion between the adhesive and the skin around the stoma.

Filter label



If you wish to temporarily prevent gas escaping from the bag, place one of the enclosed filter stickers over the filter to close it. Closing the filter for prolonged periods will cause the bag to inflate so it should only be done for a short period of time.

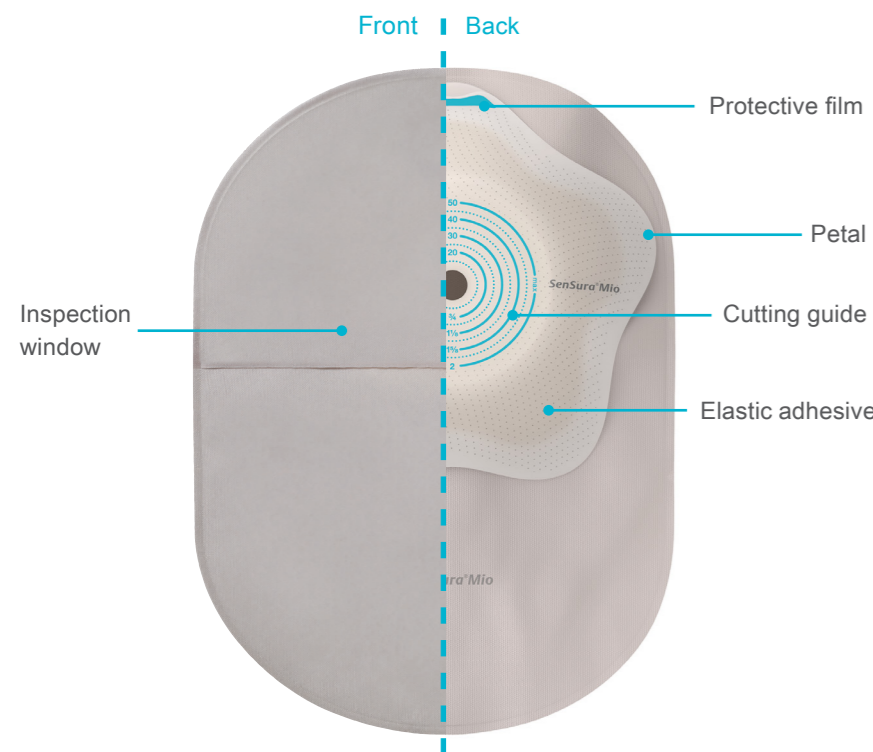


Instruction for use also available on video

To see the instruction video you can either scan the QR code or go to

<https://www.coloplast.co.uk/use1piececlosed>

Product features



Removal



Gently remove the bag by pulling the removal ear on the adhesive away from the stomach and roll the adhesive slowly downwards.

Apply light pressure on your skin with your free hand to help removal.

Disposal

The product is intended for single use only and should be disposed of in accordance with local guidelines, e.g. with normal household waste.

Do not flush the product down the toilet.

Dealing with recurring issues

? The adhesive is not sticking properly to the skin

Make sure to follow the application instructions in this leaflet and ensure the skin is completely clean and dry before applying. It's important that there is full contact between the adhesive and every furrow of the skin. Put pressure on the adhesive when applying to ensure sufficient adhesion.

? The skin is red and/or irritated under the baseplate

Irritated skin can have many causes. It can be caused by leakage from not using the right appliance or the correctly-sized cutting template. But it can also be a result of insufficient cleaning or rapid removal of the adhesive which can stress the skin. If the skin is red, an adhesive remover might be helpful. Discuss the issue with your stoma care nurse as soon as possible.

? Leakage under the adhesive

Leakage can have many causes. It can be a result of the body or stoma changing shape or height, or an incorrect application of the adhesive. Consider taking the online BodyCheck self-assessment at www.bodycheck.coloplast.com to see if your body profile has changed. If so, you might need a different appliance, or you could benefit from a supporting product. It is important to discuss the issue with your stoma care nurse as soon as possible.

Explanation of symbols

MD Medical device	Do not re-use
CE Indicates that the product is in compliance with European legislation for medical devices	UDI Indicates a barcode as containing Unique Device Identification
REF Catalogue number	GTIN Global Trade Item Number
Use-by date (YYYY-MM-DD)	Keep away from sunlight
LOT Batch code	This way up
Date of manufacture (YYYY-MM-DD)	Recyclable packaging
Manufacturer	MR MR Safe
Consult instructions for use	



Instructions for use

23325243 Version 1

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SenSura[®] Mio Concave

Concave ostomy bag

1-piece closed bag



Instructions for use