

### 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 baseplate.

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.

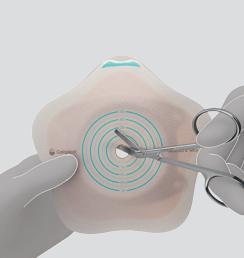
### Reporting of incidents

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 baseplate to fit the exact size and shape of the stoma using a pair of small curved scissors and the cutting guide on the baseplate.

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.

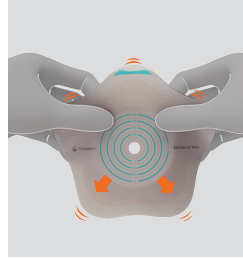
2



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

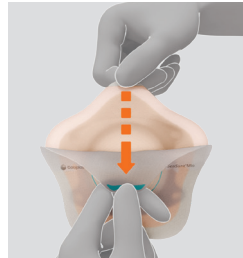
### Application

3



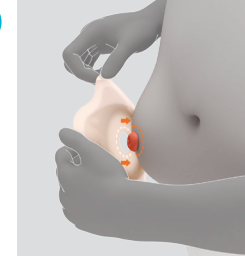
Flip all 5 petals to prepare the baseplate for application.

4



Remove the protective film from the baseplate.

5



Hold the baseplate with the petals folded back. Align the centre part of the baseplate around the stoma.

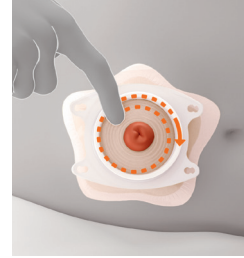
6



Press the centre part carefully onto the skin. Then flip the petals down over the outward area.

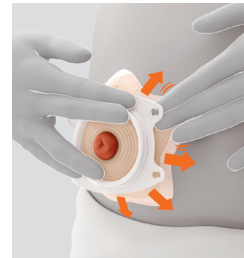
Press the baseplate firmly onto the skin from the centre and out.

7



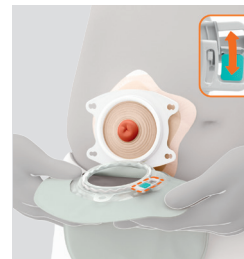
Place your index finger inside the coupling ring that surrounds your stoma. Carefully apply pressure on the baseplate between coupling ring and your stoma to ensure the centre part of the baseplate forms a tight seal to the skin.

8



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

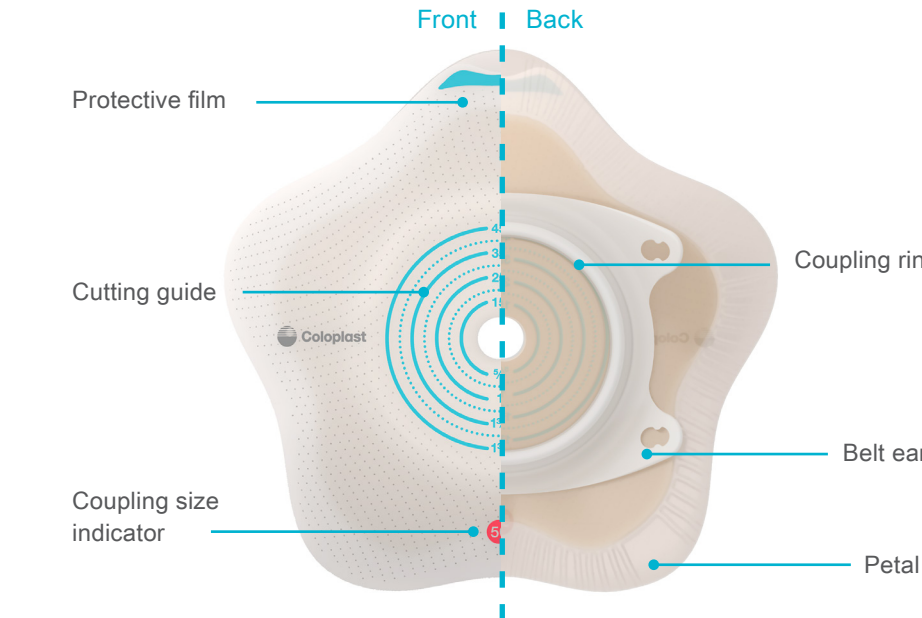
9



Before applying the bag, make sure the baseplate is clean. Check that the lock ring is open.

Line up the bottom of the bag coupling with the bottom of the baseplate coupling.

### Product features

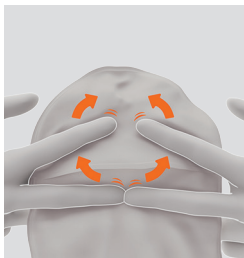


10



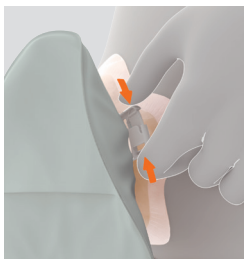
Connect the bag and the baseplate together from the bottom with your middle fingers.

11



Scroll your index fingers upwards and apply gentle pressure to the top of the coupling **until you feel the bag is securely fastened** to the baseplate.

12

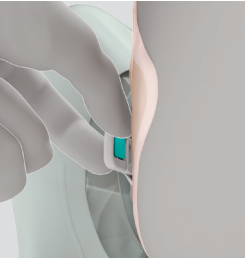


Close the lock ring by pressing the lock together. The bag is securely attached to the baseplate when you hear a 'click'.

Gently pull the bag to check that it is correctly attached.

## Removal

1



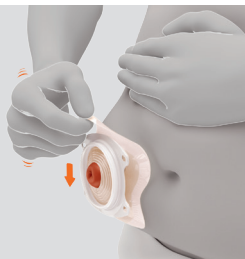
Press the small turquoise tab facing your stomach with a finger tip to open the lock ring.

2



Hold onto the bag's removal ear and remove the bag by **carefully pulling** the bag away from the baseplate.

3



Gently remove the baseplate by pulling the removal ear on the baseplate away from the stomach and roll the baseplate 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.

**More information on the bag**  
For more information on how to use the bag, please refer to the instruction for use that accompany the retail box for the bags.



Instruction for use also available on video  
To see the instruction video you can either scan the QR code or go to <http://www.coloplast.com/concave/howtouse/2piecebaseplate>

## Dealing with recurring issues

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**The baseplate 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 baseplate and every furrow of the skin. Put pressure on the baseplate when applying to ensure sufficient adhesion.

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**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.

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**Leakage under the baseplate**  
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 baseplate. Consider taking the online BodyCheck self-assessment at [www.bodycheck.coloplast.com](http://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. Discuss the issue with your stoma care nurse as soon as possible.

## Explanation of symbols

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

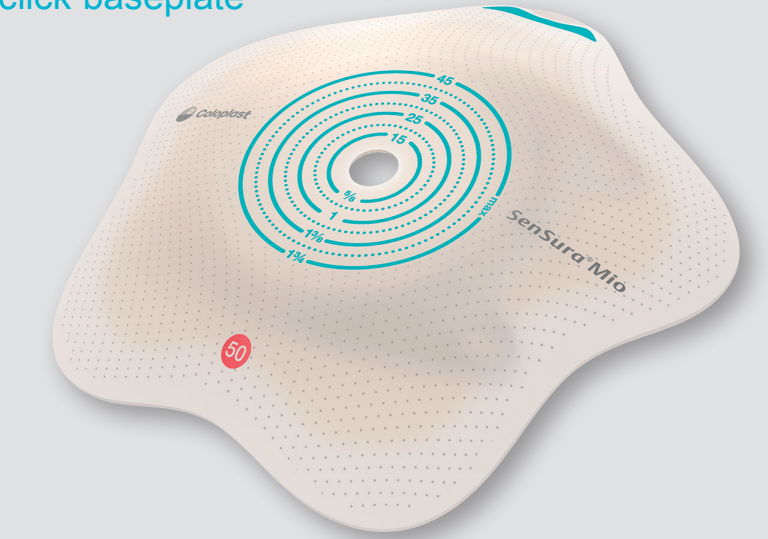
**CE** Coloplast A/S  
Høtveddam 1  
3050 Humlebaek  
Denmark  
**Instructions for use**  
23325250 Version 1  
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# SenSura<sup>®</sup> Mio Concave

## Concave ostomy baseplate

### 2-piece click baseplate



## Instructions for use