

# SenSura<sup>®</sup>Mio

# SenSura<sup>®</sup>Mio Convex

Click ostomy bag 2-piece closed

Ostomy baseplate

Ostomy Care



### Instructions for use

23331273 Version 1

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### 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, potentially leading to local infection.

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

### Cautions

For appropriate use, consult your healthcare professional before you start using a convex product.

### 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. 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.

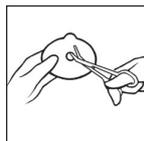
### Special storage conditions

Store baseplate horizontally.

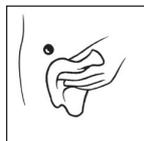
Keep away from sunlight.

## How to use

### Preparation

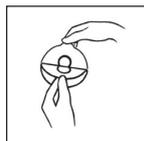


Cut a hole in the baseplate to fit the exact size and shape of the stoma using a pair of small curved scissors and the cutting guide on the baseplate. You can use the enclosed stoma measuring guide to measure the size and shape of the stoma. An exact fit between the hole and the stoma is important to reduce the risk of leakage and skin problems.



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

### Application

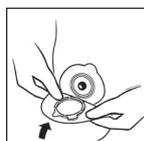


Peel off the protective film from the adhesive.



Align the baseplate around the stoma and apply pressure to the baseplate to ensure fast adhesion and a perfect fit between the adhesive and the skin around the stoma.

The adhesive must fit snugly around the stoma. To prevent leakage, it is important to ensure a tight seal around the stoma. When applying pressure to the baseplate/bag on the abdomen, begin in the area around the stoma and press the adhesive to the skin. Run a finger all the way around the stoma to ensure that the adhesive seals. Smooth the adhesive down, starting from the stoma and moving outwards to the edges, to ensure that the adhesive has made full contact with the skin.



Ensure the baseplate is dry and clean (when cleaning the baseplate only water should be used). Make sure that the lock ring is open. Align the coupling of the bag with the coupling of the baseplate.



Apply gentle pressure on the bag with your fingers until you feel the bag is correctly positioned to the baseplate.



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

### Removal



Remove the bag by opening the lock ring by pressing the small dotted tab facing your stomach with a finger tip.



Hold on to the removal ear and remove the bag by carefully pulling the bag away from the baseplate.



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.

#### Filter label



If required, to prevent wind from escaping, place one of the enclosed filter labels on the filter.

#### Belt



Adjust the belt length by pulling the straps, so it fits your body. There is no need to remove the fabric covering the buckle.

Attach each of the four belt hooks to one of the four belt ears on either side of the baseplate. Start from the front and apply a light pressure towards the stomach. Then pull the belt hooks away from the coupling, until they "click" in place.

(Only applies to products with belt ears).

#### 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.

#### Explanation of symbols



Medical device



Indicates that the product is in compliance with European legislation for medical devices



Catalogue number



Use-by date (YYYY-MM-DD)



Batch code



Date of manufacture (YYYY-MM-DD)



Manufacturer



Consult instructions for use



Do not re-use



Indicates a carrier that contains Unique Device Identifier information



Global Trade Item Number



Keep away from sunlight



This way up



Recyclable packaging



MR Safe