SenSura®Mio SenSura®Mio Convex

Ostomy bag 1-piece closed

Ostomy Care



Instructions for use 23324360 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.

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

Cautions

For appropriate use, consult your health care 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 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.

Coloplast How to use

Preparation



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.

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 adhesive.

Application



Peel off the protective film from the adhesive.



Align the adhesive around the stoma and press it firmly onto the skin. 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.



Apply pressure on the bag to ensure fast adhesion and a perfect fit between the adhesive and the skin around the stoma.

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.

Filter label



If required, to prevent gas 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

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П	Ν/Ι	
П	IVI	וט

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 barcode as containing Unique Device Identification



Global Trade Item Number



Keep away from sunlight



This way up



Recyclable packaging



MR Safe