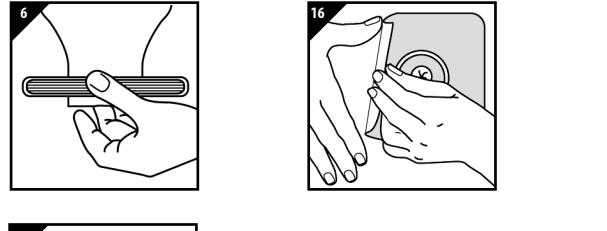
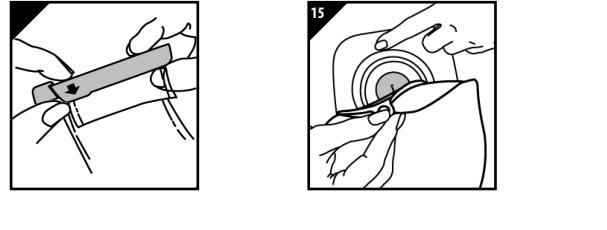
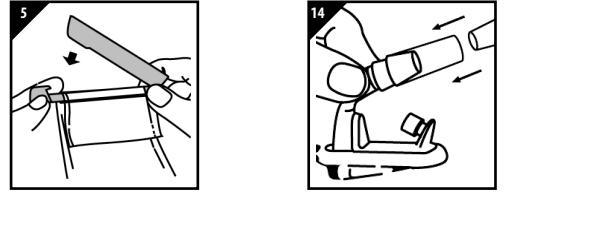
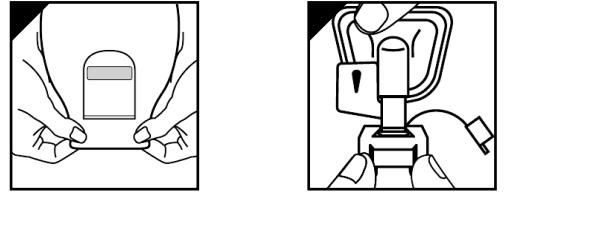
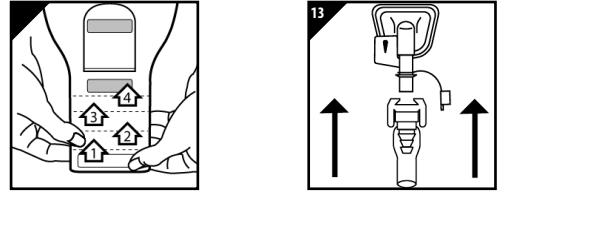
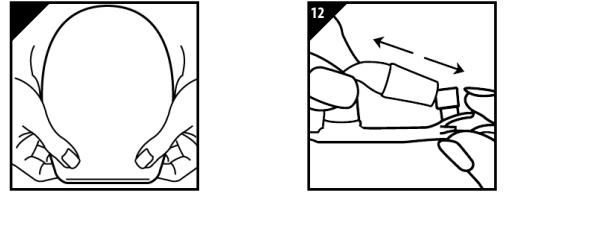
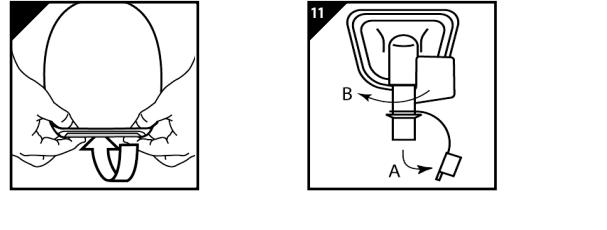
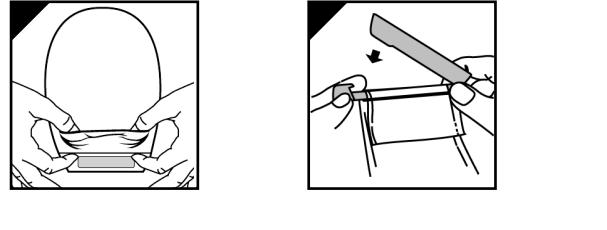
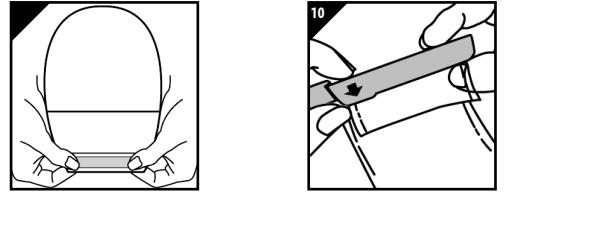
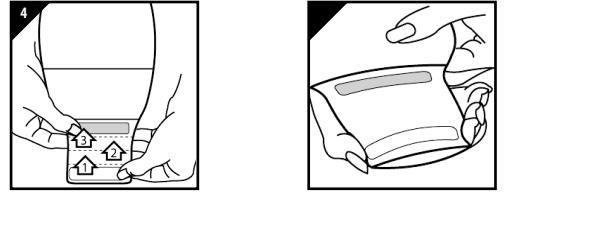
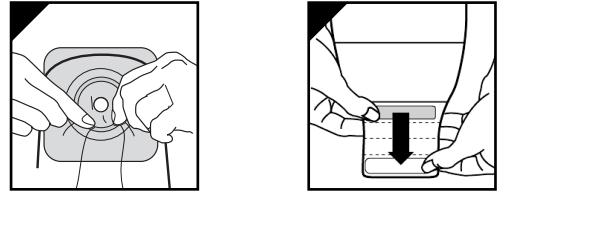
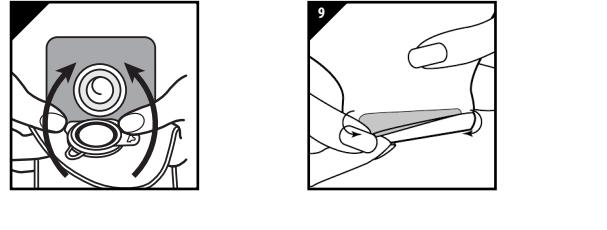
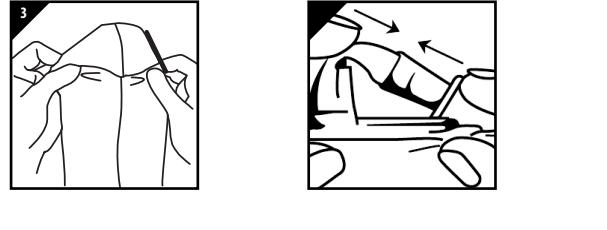
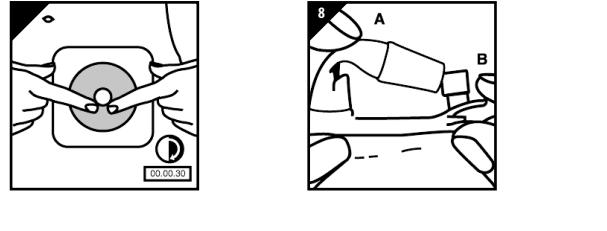
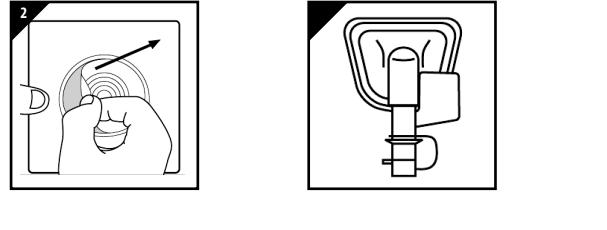
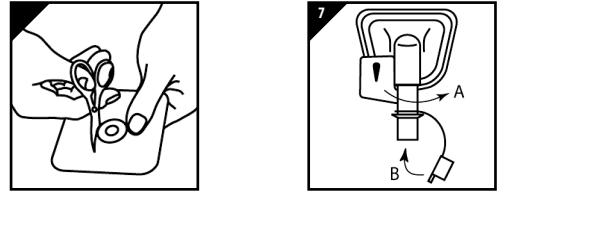
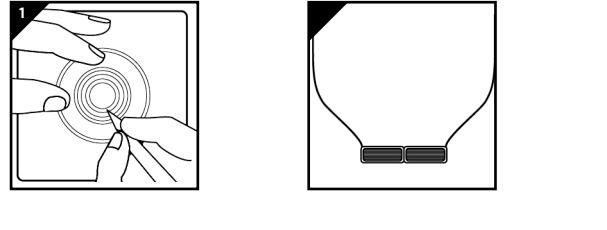


NATURA®



en ENGLISH

Two-Piece Cut-to-Fit or Pre-Cut Ostomy System

INSTRUCTIONS FOR USE

(Must be used with the same size NATURA® pouch)

INTENDED USE:

Management of stomal output.

INDICATION FOR USE

For use with a colostomy, ileostomy or urostomy.

PRECAUTIONS AND OBSERVATIONS:

Caution: Patients with a flush ostomy, when associated with meatuses and the absence of a urinary reservoir should be informed that they have reported cases of sores found in the area of the ostomy. Moderate appropriate clinical management and evaluate the ostomy if the adhesive product is determined to be defective.

Important:

A medical professional should assess the need for skin barriers with consistency prior to use.

Directions for use:

1. Skin Preparation

Your hands and the skin surrounding the stoma must be clean, dry and free from substances before applying any ostomy system.

2. Skin Barrier Preparation

A) Cut-To-Fit Skin Barriers

(Figure 1) Trace the shape of the stoma onto the skin barrier. Cut the skin barrier just outside the tracing leaving a 1cm (4") (0.6 cm) of skin barrier between the cut edge and the flange. Smooth out cutting with your finger.

B) Pre-cut Skin Barriers

Select a skin barrier with pre-cut stoma opening slightly larger than your stoma.

Notes: 1) The tape collar may cause irritation for users wearing diapers or incontinence products. If irritation occurs, cut the collar away from the adhesive product.

2) Protect the stoma from trauma.

3. Applying the Skin Barrier

(Figure 2) Trace the shape of the stoma onto the skin barrier. Center the opening of the skin barrier onto the stoma. Apply a barrier to the skin around the stoma. Use a retractor if needed to provide a better view of the stoma. Use a retractor if needed to provide a better view of the stoma.

4. Application of the Skin Barrier

(Figure 3) Separate an adhesive baria for the skin barrier to fit around the stoma. Press firmly and smooth out the adhesive product. Handle gently and desensitize the skin barrier to prevent irritation.

5. Application of the Skin Barrier

A) Cut-To-Fit Skin Barriers

(Figure 4) Trace the shape of the stoma onto the skin barrier. Center the opening of the skin barrier onto the stoma. Apply a barrier to the skin around the stoma. Use a retractor if needed to provide a better view of the stoma.

6. Application of the Skin Barrier

(Figure 5) Separate an adhesive baria for the skin barrier to fit around the stoma. Press firmly and smooth out the adhesive product. Handle gently and desensitize the skin barrier to prevent irritation.

7. Application of the Skin Barrier

(Figure 6) Remove the release liner from adhesive strip. Press the closure to the skin barrier to allow for a better seal. Wear as long as comfortable and secure. Wear time may vary.

8. Applying The Pouch

(Figure 7) Insert the closure pouch to allow to enter. Line up the skin barrier and pouch flange and press on the bottom of the flange. Then move to the top of the flange, pressing as you go around. Tug on pouch to ensure secure connection.

9. Applying The Pouch

(Figure 8) Insert the closure pouch to allow to enter. Line up the skin barrier and pouch flange and press on the bottom of the flange. Then move to the top of the flange, pressing as you go around. Tug on pouch to ensure secure connection.

10. Closing The Pouch

(Figure 9) Close the closure pouch.

11. Disposal

This device is for single-use only and should not be re-used. Re-use may lead to increased risk of infection or cross contamination. Physical properties of the device may no longer be optimal for intended use.

After use, this product may be a potential biohazard. Handle and dispose in accordance with accepted medical practice and applicable local laws and regulations.

If during the use of this device or as a result of an incident, do not use again. Please report to the manufacturer and to your national authority.

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**Indicates a trademark of ConvaTec Inc.

12. Removal Of The Skin Barrier

(Figure 16)

13. Disposal

This device is for single-use only and should not be re-used. Re-use may lead to increased risk of infection or cross contamination. Physical properties of the device may no longer be optimal for intended use.

After use, this product may be a potential biohazard.

Handle and dispose in accordance with accepted medical practice and applicable local laws and regulations.

If during the use of this device or as a result of an incident, do not use again. Please report to the manufacturer and to your national authority.

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**Indicates a trademark of ConvaTec Inc.

16. Instructions for use

Two pieces of NATURA® ostomy closure system

使用說明

(與同尺寸的 NATURA® 造口袋裝配使用)

1. 使用目的

設計用途

設計用於

設計說明

兩件式自剪型或預剪型造口系統

使用說明

(與同尺寸的 NATURA® 造口袋裝配使用)

2. 使用目的

設計用途

設計用於

設計說明

NATURA® 造口袋

使用說明

(與同尺寸的 NATURA® 造口袋裝配使用)

3. 使用目的

設計用途

設計用於

設計說明

NATURA® 造口袋

使用說明

(與同尺寸的 NATURA® 造口袋裝配使用)

4. 使用目的

設計用途

設計用於

設計說明

NATURA® 造口袋

使用說明

(與同尺寸的 NATURA® 造口袋裝配使用)

5. 使用目的

設計用途

設計用於

設計說明

NATURA® 造口袋

使用說明

(與同尺寸的 NATURA® 造口袋裝配使用)

6. 使用目的

設計用途

設計用於

設計說明

NATURA® 造口袋

使用說明

(與同尺寸的 NATURA® 造口袋裝配使用)

7. 使用目的

設計用途

設計用於

設計說明

NATURA® 造口袋

使用說明

(與同尺寸的 NATURA® 造口袋裝配使用)

8. 使用目的

設計用途

設計用於

設計說明

NATURA® 造口袋

使用說明

(與同尺寸的 NATURA® 造口袋裝配使用)

9. 使用目的

設計用途

設計用於

設計說明

NATURA® 造口袋

使用說明

(與同尺寸的 NATURA® 造口袋裝配使用)

10. 使用目的

設計用途

設計用於

設計說明

NATURA® 造口袋

使用說明

(與同尺寸的 NATURA® 造口袋裝配使用)

11. 使用目的

設計用途

設計用於

設計說明

NATURA® 造口袋

使用說明

(與同尺寸的 NATURA® 造口袋裝配使用)

12. 使用目的

設計用途

設計用於

設計說明

NATURA® 造口袋

使用說明

(與同尺寸的 NATURA® 造口袋裝配使用)

13. 使用目的

設計用途

設計用於

設計說明

NATURA® 造口袋

使用說明

(與同尺寸的 NATURA® 造口袋裝配使用)

14. 使用目的

設計用途

設計用於

設計說明

NATURA® 造口袋

使用說明

(與同尺寸的 NATURA® 造口袋裝配使用)

15. 使用目的

設計用途

設計用於

設計說明

NATURA® 造口袋

使用說明

(與同尺寸的 NATURA® 造口袋裝配使用)

16. 使用目的

設計用途

設計用於

設計說明

NATURA® 造口袋

使用說明



Effective

ARTWORK SPECIFICATION

Artcode	1262903V4
Artwork Description	INS NATURA FOR USE 40# INT
ICC*	421228, 421229, 421230, 421231, 421269, 421270, 421271, 421272, 421273, 421274, 402200, 402201, 402202, 402203, 402204, 402205, 402206, 402207, 402208, 402209, 402210, 402211, 401900, 401901, 401902, 401903, 401925, 401926, 125278, 125279, 125280, 125281, 125282, 125283, 125284, 125285, 125286, 125287, 125288, 125289, 401577, 401984, 413157, 125263, 125264, 125265, 125266, 125900, 125901, 125902, 125903, 125904, 401574, 401575, 401576, 401906, 401948, 401949, 401950, 401951, 401980, 401981, 401982, 401983, 410293, 410294, 410295, 410296, 410297, 413100, 413101, 413102, 413103, 413104, 413153, 413154, 413155, 413156, 413177, 413178, 413179, 413180, 413181, 413182, 413183, 413184, 413185, 413186, 413187, 413188, 420219, 402220, 402221, 402222, 421224, 421225, 421226, 421227, 421235, 421236, 421237, 421238, 421239, 421240, 421241, 421259, 421260, 421261, 421262, 421263, 421264, 421265, 421266, 421267, 421268, 421275, 421276, 421277, 421278, 421279, 421280, 421281, 421282, 421284, 423554, 423297, 423296, 402219, 402218
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KOM/REF*	N/A
IS Code*	N/A
Component Type	Insert
LR#	LR-005065
Existing Art Code being Revised	1262903V4
REQUIREMENT	SPECIFICATION
Bucket	GBL
Local Code(s)	N/A
Size Code / Dieline	10012
Dimensions	Flat: 711.2mm X 609.6mm (28" X 24") Folded: 101.6mm x 101.6mm (4" x 4")
Color(s) / Colour(s)	Black
Specification Reference(s)	MT56-005
Bar Code: UPC (A) or GTIN**	N/A
Bar Code: PZN – Code 39**	N/A
Bar Code: JAN-13**	N/A

* NOTE: Bar Code: See artwork for positioning, magnification and truncation. Scanability verified to ANSI grade "C" or better.

HISTORY

Effective

12-AUG-2009 / 1262903: 1. New artwork created to launch Worldwide

8-MAY-2012 / 1262903A1: The ConvaTec Ltd, Deeside address was revised to the full street address as identified on the BSI certificates, as required for compliance with EU regulations. Artcode and revision date updated.

22-JAN-2013 / 1262903A1: Update size code from 9989 to 10012 (per K.Washam) on art spec. Art code stays the same.

09-JUN-2015 / 1262903G1: Address change From: Skillman, NJ 08558 To: Greensboro, NC 27409, SAP art code version changed to the G1, Copyright date to be updated , Revision date updated (Issue date changed to Revision date if applicable), Artwork Specification updated.

30-NOV-2016 / 1262903G1: Changing the source of manufacturing from ConvaTec Greensboro North Carolina, USA; to ConvaTec, Haina, Dominican Republic. Carton Art Code will show Multiple ICC Codes and SAP codes, as broken down in spec documentation.

No change to art content or art code revision, documentation update only.

28-Apr-2021 / 1262903V1: All symbols were updated in accordance with ISO 15223-1:2016 and MDR compliance. Update caution symbol explanation. Added MD symbol and the corresponding definition and symbol added to the IFU in all languages required. Art version change to V1. Copyright and revision date updated. Convatec logo updated. Added language codes. Added EC rep and importers symbol and address. Added importer symbol with explanation. Updated Chinese telephone information. Removed Japanese address. Updated Australian and New Zealand contact information. Added Croatian, Icelandic and Macedonian languages. Removed/replaced existing Hrvatski language. Added IFU statements, Intended use and indication for use. Removed lot and expiry symbol and their corresponding explanations. Added ® symbol after the trademarks and updated TM symbol with ® symbol all throughout the IFU as NATURA, INVISICLOSE, and ACCUSEAL trademarks. Removed from TM statement "NATURA, INVISICLOSE, and ACCUSEAL are registered trademarks of Convatec Inc. in the United States" or any similar or equivalent statement in every languages to read as " indicates trademarks of Convatec Inc." in their corresponding languages.

13-Sep-2021 / 1262903V1: No artwork change, new ICC and SAP codes added to the artwork specification.

07-Dec-2021 / 1262903V2: Updated Turkey address. Added CH REP and importer symbol and address. Added symbols "contains biological material of animal origin", "non-steril", "do not use if package is damaged", "Single sterile barrier system", "Single sterile barrier system inside protective packaging" and "sterilized using irradiation" with explanation and translation acc. SM-079379. Updated CE mark to CE2797. Added sentence: Do not use if the sterile package is torn or damaged (in all language). Updated revision date and version. Updated language title to ICELANDIC. Added "Directions for use" in all languages.

18-Mar-2022 / 1262903V2: Updated ICC and SAP codes. Removed CE NB. Added UKCA mark. Removed sentence "Do not use if the sterile package is torn or damaged". Removed symbols with explanation and translation :Sterilized using irradiation, Single sterile barrier system inside protective packaging, Single sterile barrier system and Do not use if package is damaged.

22-Sep-2022 / 1262903V3: Indiquindications therapeutiques changed on Indications. Added "la" between enlevez and bande: "enlevez la bande". Added 'or wrap flap down around pouch tail' in French at the end of this paragraph "ou enroulez le rabat autour de la queue de la pochette. Translated "All rights reserved" to "Tous droits réservés". Corrected numbers of Figures.

14-Mar-2024 / 1262903V4: Removed the Canadian tel. number. Updated ICC and SAP codes in ARTWORK SPECIFICATION. Legal manufacturer Canada address added. Added Triman logo with explanations.

24-July-2024 / 1262903V4: Added new SAP codes. No artwork change.

WI-0010, Ver. 7.0