

Safety Notice

Medical Devices

Convex Two-Piece Skin Barriers (Natura /Surfit /Combihesive Wafers)

Priority 2 – Warning



HPRA Safety Notice: SN2019(30)

Issue Date: 12th November 2019

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
ConvaTec	V41499

ISSUE

ConvaTec has issued a Field Safety Notice (FSN) after receiving complaints that the starter hole (stoma hole) is off-centre on Convex Two-Piece Skin Barriers manufactured between February 2017 and September 2018. In a number of associated incidents this led to a stomal cut.

Users are advised to follow the instructions in the accompanying FSN to determine if they have any devices affected by this issue. Users who identify affected devices are advised to return the devices to ConvaTec.

Please refer to the accompanying FSN for further details and for a list of the affected product codes and lot numbers (Attachment 3 of FSN)

ACTION OR RECOMMENDATIONS

The HPRA advises that **End Users/Patients:**

- 1 Read this Safety Notice and the accompanying ConvaTec FSN carefully.
- 2 Determine if you have affected products in your possession by referring to *Attachments 1, 2 & 3 of ConvaTec's FSN*.
- 3 If you identify any off-centre product, please contact ConvaTec to organise device return.
- 4 If you have any health concerns, please contact a healthcare professional.
- 5 Contact the ConvaTec FSCA Help Desk, using the contact information provided at the bottom of this Safety Notice if you are uncertain of the action required.
- 6 Report any concerns regarding these devices or any adverse incidents involving these devices to ConvaTec and to the HPRA.

The HPRA advises that **Retailers/Pharmacies:**

- 1 Read this Safety Notice and the accompanying manufacturer's FSN carefully.
- 2 Determine if you have affected products in your inventory and where possible identify which of your customers have received affected product.
- 3 Display the "Ostomy Product User Letter" (*Attachment 2 of FSN*) in a visible location in your store and on your website if possible.
- 4 If you have contact details for customers who? have received products within the scope of the FSN, provide the "Ostomy Product User Letter" (*Attachments 1, 2 & 3 of FSN*) to these customers.
- 5 If you identify any off-centre product in your inventory, or if you receive affected products from your customers, please contact ConvaTec to organise device return.
- 6 Forward a copy of this Safety Notice and the FSN to all relevant personnel within your organisation or to any other organisations/persons to which/whom these devices have been transferred.
- 7 Report any concerns regarding these devices or any adverse incidents involving these devices to ConvaTec and to the HPRA.

TARGET GROUPS

Ostomy Users
Pharmacies
Online retailers
Nursing Homes
Ostomy Support Groups

General Practitioners
Emergency Departments
Public and Private Hospitals
Public Health Nurses
Stoma Care Nurses

BACKGROUND

ConvaTec has issued an FSN advising users of their Convex Two-Piece Skin Barriers, specifically Natura /Surfit /Combihesive Wafer products, to be aware of an issue associated with an off-centre Starter Hole (stoma hole). ConvaTec has indicated that this issue is visually detectable to users and is advising users to check product in their possession to determine whether it was manufactured within the associated time period (February 2017 to September 2018) and whether the starter hole is visually off-centre.

ConvaTec has determined that the risk of injury associated with this issue is low. However, it has been indicated there is a potential for mild pain, skin irritation, bleeding and tissue damage. Based on this, ConvaTec has advised users to review products in their possession to determine if they are impacted by this issue. Further information on affected units and actions to be taken by the users can be found in the accompanying ConvaTec FSN.

Appendix A of this FSN provides a list of products confirmed to be supplied to the Irish market. However, ConvaTec has been unable to confirm that units outside this listing have not been provided to the Irish market by distributors located outside of Ireland. Therefore, users and retailers should refer to the full product list in ATTACHMENT 3 of the FSN when reviewing their units.

The HPRA is issuing this Safety Notice to raise awareness of this issue. Please refer to the accompanying FSN for further details.

MANUFACTURER CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

ConvaTec Limited,
First Avenue,
Deeside Industrial Park
Deeside,
Flintshire,
CH5 2NU,
United Kingdom

Telephone: +44 (0) 744 2188 256
E-mail: tracey.fairclough@amcaregroup.co.uk
Website: <https://www.convatec.ie/>

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie