

URGENT FIELD SAFETY NOTICE

Commercial name: Kaltostat™ Cavity Dressing 2g (1x5) Sterile EEU
Kaltostat™ Dressing 5x5cm (1x10) Sterile EEU
Kaltostat™ Dressing 7.5x12cm (1x10) Sterile EEU
Kaltostat™ Dressing 10x20cm (1x10) Sterile EEU
Kaltostat™ Dressing 15x25cm (1x10) Sterile EEU

Issue Date: 19th May 2022

REF No and LOT Number(s):

Commercial Name	REF Number	LOT Number
Kaltostat™ Cavity Dressing 2g (1x5) Sterile EEU	168117	1L01100 & 1J04627
Kaltostat™ Dressing 5x5cm (1x10) Sterile EEU	168210	1J04285
Kaltostat™ Dressing 7.5x12cm (1x10) Sterile EEU	168212	1J02585
Kaltostat™ Dressing 10x20cm (1x10) Sterile EEU	168214	1M00069 & 1J04079
Kaltostat™ Dressing 15x25cm (1x10) Sterile EEU	168215	1K03599

FSCA-identifier: TW1538687

Type of action: Advice to customer: Supplemental Instructions For Use (IFU) not provided

Please note that this action only applies to the specific LOT numbers listed above and does not affect all LOTS of Kaltostat™ dressings

Description of the problem:

ConvaTec has voluntarily initiated a Field Safety Corrective Action for specific lots of Kaltostat™ dressings. During updates to Kaltostat™ IFUs additional neonatal information was added which had previously been included in a supplemental IFU. Once this update was performed the use of the supplemental IFU was removed.

During these updates the Central Eastern Europe region IFUs failed to be updated with the additional information and the supplemental neonatal IFU was removed from use. ConvaTec has executed the required actions immediately to secure this issue. Please find the supplemental IFU attached to this Field Safety Notice (see Appendix 1).

In the absence of the neonatal information from the IFU, the use of Kaltostat™ wound dressings is not recommended for infants less than 12 months of age.

Note: This batch of product is suitable for continued use in accordance with the information detailed in both the IFU supplied with the product and the supplemental IFU provided with this Field Safety Notice.

Product Identification Procedure:

The affected devices can be identified by the product reference (REF) number and the LOT number. The product code (reference number) is preceded by the word 'REF'. The lot number is preceded by the word 'LOT'.

Example of Kaltostat™ dressing



REF Number



LOT Number

Advice on action to be taken by the distributor:

Our records show that you have taken delivery of the affected products. Please follow the steps below:

1. Please immediately forward copies of the Field Safety Notice and Appendix to all customers that you have distributed the affected lot of this product to. Product can continue to be used in accordance with the instructions within the IFU supplied with the product AND the IFU supplied with this Field Safety Notice.
2. Please return a completed 'Response Form' to ConvaTec Limited via email/fax.

Advice on action to be taken by the retailer:

Our records show that you have taken delivery of the affected products. Please follow the steps below:

1. Please retain this Field Safety Notice for your records and provide a copy to your customers on request. Customers can also be advised that the Instructions for use can be obtained from the ConvaTec website. Product can continue to be used in accordance with the instructions supplied with the IFU supplied with the product AND the IFU supplied with this Field Safety Notice.
2. Please return a completed 'Response Form' to your distributor/supplier via email/fax.

Advice on action to be taken by the end user:

1. Please retain this Field Safety Notice for your information. Customers are advised that Instructions for use can also be obtained from the ConvaTec website. Product can continue to be used in accordance with the instructions supplied with the IFU supplied with the product AND the IFU supplied with this Field Safety Notice.
2. Please return a completed 'Response Form' to your distributor/supplier via email/fax.

Continue to report any adverse events involving this product to the ConvaTec Customer Care Line (see regional contact list for details) or via your local ConvaTec representative.

Regional contact person for this Field Safety Corrective Action:

CISG.CUSTOMERSERVICE@convatec.com

Transmission of this Field Safety Notice:

This notice should be sent to all distributors, retailers, and end users (where possible) who have received the affected Kaltostat™ products. If you have any questions, please contact your local ConvaTec representative. Alternatively, please write to vigilance-emea@convatec.com where the query will be registered and handled accordingly.

I hereby confirm that this notice has been notified the appropriate Regulatory Agency. We appreciate you giving your time and attention to this important notification.

Best regards,

DocuSigned by:

Agnieszka Sikorska-Brzozowska

Signer Name: Agnieszka Sikorska-Brzozowska
Signing Reason: I approve this document
Signing Time: May 19, 2022 | 4:02:13 PM BST

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Mrs Agnieszka Sikorska-Brzozowska
Senior Regulatory Affairs Manager

DocuSigned by:

Lars Bressler

Signer Name: lars bressler
Signing Reason: I approve this document
Signing Time: May 19, 2022 | 4:36:31 PM BST

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Lars Bressler
Vice President, Quality, Infusion Care
(Authorised Representative)

RESPONSE FORM
URGENT FIELD SAFETY NOTICE
PLEASE COMPLETE AND RETURN

Consignee of the device:

Consignee Account No:	
Consignee Name:	
Consignee Address:	

The following Kaltostat Cavity Dressing 2g (1x5) Sterile EEU / Kaltostat Dressing 5x5cm (1x10) Sterile EEU / Kaltostat Dressing 7.5x12cm (1x10) Sterile EEU / Kaltostat Dressing 10x20cm (1x10) Sterile EEU / Kaltostat Dressing 15x25cm (1x10) Sterile EEU (**Customer Services to edit**) have been distributed to your facility:

Invoice #	Sales Order #	REF No.	LOT No.	Quantity Delivered

I hereby confirm that the Field Safety Notice TW1538687 has been read and understood. I also confirm that I will present this information to those I have supplied. Please tick

FORM Completed and Returned From:

Name (CAPITAL LETTERS):	
Position:	
Address:	
Phone No:	
Signature:	
Date (dd/mm/yyyy):	

Appendix 1

ENGLISH

Precautions and Observations

The use of KALTOSTAT™, KALTOSTAT™ Fortex™ and CarboFLEX™ wound dressings is not recommended for infants less than 12 months of age.

ESPAÑOL-US

Precauciones y observaciones

El uso de KALTOSTAT™, KALTOSTAT™ Fortex™ y CarboFLEX™ no está recomendado para niños menores de 12 meses de edad.

FRANÇAIS CANADA

Précautions et observations

L'utilisation des pansements KALTOSTAT™, KALTOSTAT™ Fortex™ and CarboFLEX™ n'est pas recommandée chez les enfants de moins de 12 mois.

BRAZILIAN PORTUGUESA

Precauções e Observações

Não está indicado o uso dos pensos KALTOSTAT™, KALTOSTAT™ Fortex™ e CarboFLEX™ em crianças com idades inferiores a 12 meses.

中文

注意事項和觀察結果

選用KALTOSTAT™, KALTOSTAT™ Fortex™ 和 CarboFLEX™ 傷口敷料不建議用於小於12個月的嬰兒。

中文

注意事

小于12个月的不推荐使用KALTOSTAT™, KALTOSTAT™ Fortex™ and CarboFLEX™ 口料。

한국어

주의사항 및 관찰사항

KALTOSTAT™, KALTOSTAT™ Fortex™ 및 CarboFLEX™ 상처 드레싱 사용은 12개월 이하의 유아에게 권장되지 않습니다.

DEUTSCH

Zu beachtende Vorsichtsmaßnahmen

Der Gebrauch der Wundverbände KALTOSTAT™, KALTOSTAT™ Fortex™ und CarboFLEX™ wird nicht empfohlen bei Kindern unter 12 Monaten.

ITALIANO

Precauzioni e Osservazioni

L'uso di KALTOSTAT™, KALTOSTAT™ Fortex™ e CarboFLEX™ non è raccomandato nei bambini al di sotto dei 12 mesi di età.

FRANÇAIS

Précautions d'utilisation et observations

Il n'est pas recommandé d'utiliser les pansements KALTOSTAT™, KALTOSTAT™ Fortex™ and CarboFLEX™ chez les nourrissons âgés de moins de 12 mois.

ESPAÑOL-ES

Precauciones y observaciones

El uso de KALTOSTAT™, KALTOSTAT™ Fortex™ y CarboFLEX™ no está recomendado para niños menores de 12 meses de edad.

PORTUGUESA

Precauções e Observações

Não está indicado o uso dos pensos KALTOSTAT™, KALTOSTAT™ Fortex™ e CarboFLEX™ em crianças com idades inferiores a 12 meses.

NEDERLANDS

Voorzorgsmaatregelen en opmerkingen

Het gebruik van KALTOSTAT™, KALTOSTAT™ Fortex™ en CarboFLEX™ verbanden is niet aangeraden bij kinderen jonger dan 12 maanden.

SVENSKA

Försiktighet Och Observationer

KALTOSTAT™, KALTOSTAT™ Fortex™ och CarboFLEX™ förband rekommenderas inte som förband på barn under 12 månader.

SUOMI

Varotoimet Ja Huomautukset

KALTOSTAT™, KALTOSTAT™ Fortex™ ja CarboFLEX™ -sidoksia ei suositella käytettäväksi alle 12 kk:n ikäisillä lapsilla.

DANSKE

Forholdsregler Og Observationer

KALTOSTAT™, KALTOSTAT™ Fortex™ og CarboFLEX™ er ikke rekommanderet som bandage til børn under 12 måneder.

NORSK

Forsiktighetsregler Og Observasjoner

KALTOSTAT™, KALTOSTAT™ Fortex™ og CarboFLEX™ bandasje anbefales ikke til bruk på barn under 12 måneder.

ΕΛΛΗΝΙΚΑ

Προφυλάξεις και Παρατηρήσεις

Η χρήση των επιθεμάτων KALTOSTAT™, KALTOSTAT™ Fortex™ και CarboFLEX™ δεν συνιστάται για βρέφη κάτω των 12 μηνών.

MAGYAR

Figyelmeztetés

A KALTOSTAT™, KALTOSTAT™ Fortex™ és CarboFLEX™ kötszerek alkalmazása nem javasolt a 12 hónaposnál fiatalabb csecsemők esetében.

POLSKI

Środki ostrożności oraz obserwacje

Zastosowanie opatrunków KALTOSTAT™, KALTOSTAT™ Fortex™ oraz CarboFLEX™ nie jest rekomendowane wśród pacjentów poniżej 12 miesiąca życia.

ČECH

Bezpečnostní opatření

Krytí na rány KALTOSTAT™, KALTOSTAT™ Fortex™ a CarboFLEX™ se nedoporučuje používat u dětí mladších 12 měsíců.

SLOVENSKÝ

Bezpečnostné opatrenia a upozornenia

Krytia na rany KALTOSTAT™, KALTOSTAT™ Fortex™ a CarboFLEX™ sa neodporúčajú používať u detí mladších ako 12 mesiacov.

HRVATSKI

Mjere opreza i promatranja

Ne preporučuje se uporaba KALTOSTAT™, KALTOSTAT™ Fortex™ i CarboFLEX™ obloga za rane kod dojenčadi mlađe od 12 mjeseci.

SLOVENSKI

Previdnostni ukrepi in opažanja

Uporaba KALTOSTAT™, KALTOSTAT™ Fortex™ in CarboFLEX™ oblog za rane ni priporočljiva pri dojenčkih starih manj kot 12 mesecev.

РУССКИЙ

Меры предосторожности и результаты наблюдений

Использование повязок KALTOSTAT™, KALTOSTAT™ Fortex™ и CarboFLEX™ не рекомендовано у детей, не достигших возраста 12 месяцев.

ROMÂNĂ

Precautii si Observatii

Folosirea pansamentului KALTOSTAT™, KALTOSTAT™ Fortex™ si CarboFLEX™ nu este recomandata la copiii sub 12 luni.

TÜRKÇE

Önlem ve Gözlemler

12 aylıktan küçük bebeklerde KALTOSTAT™, KALTOSTAT™ Fortex™ ve CarboFLEX™ Yara Örtülerinin kullanımı önerilmemektedir.

EESTI

Ettevaatusabinõud Ja Tähelepanekud

KALTOSTAT™, KALTOSTAT™ Fortex™ ja CarboFLEX™ haavasidemete kasutamise ei ole soovitatav alla 12 kuu vanustel imikutel.

SRPSKI

Mere opreza

Primena KALTOSTAT™, KALTOSTAT™ Fortex™ i CarboFLEX™ obloga za rane se ne preporučuje kod beba starosti do 12 meseci.

LATVIEŠU

Ievērojiet piesardzību

KALTOSTAT™, KALTOSTAT™ Fortex™ un CarboFLEX™ brūču pārsēju lietošana nav ieteicama zīdaiņiem līdz divpadsmit mēnešu vecumam.

LIETUVIŲ

Atsargumo priemonės ir jspėjimai

KALTOSTAT™, KALTOSTAT™ Fortex™ ir CarboFLEX™ tvarščiai nerekomenduojami naudoti kūdikiams iki 12 mėn amžiaus.

БЪЛГАРСКИ

Предпазни мерки и тяхното съблюдаване

Употребата на превръзките KALTOSTAT™, KALTOSTAT™ Fortex™ и CarboFLEX™ не е препоръчителна при деца на възраст по-малко от 12 месеца.