

CUSTOMER NOTICE - URGENT - MEDICAL DEVICE FIELD SAFETY NOTICE

DUODERM CGF DRS 10X10CM (1X5PK) NAI
DUODERM XTHIN DRS 10X10CM (1X10PK) NAI
DUODERM XTHIN DRS 15X15CM (1X10PK) NAI

Dear Product User,

We are writing to inform you of a potential product packaging issue affecting batches of the above listed products. An increasing trend of in complaints related to open seals, tears and rips in the primary packaging was reported in 2020 for DuoDERM Extra Thin and DuoDERM CGF products families. As the potential hazard is the dressing being open or the product being sealed within the seam of the primary package, there is potential for a breach in the sterile barrier resulting in a possible risk of infection, delayed wound healing and increased scarring. For this reason, ConvaTec are initiating a voluntary recall of product potentially affected by this issue. The following batches of products are being recalled:

ICC #	Lot#
187957	9J02859
187955	9L01731
187955	9H01234
187955	9M01779
187660	9B02984Y
187660	9K05775
187660	0A03460
187660	9A04124Y

NOTE: Only the product codes and lot numbers identified within this notice are affected.

We are providing you with this communication to make you aware of the issue and outline the steps that you can take if you have product affected by this issue.

- 1) Check all DuoDERM products in your possession against the Product Codes and Lot Numbers listed above.
- 2) Please return all affected stock to your original supplier for reimbursement.

ConvaTec strives to provide the highest quality products and services to every customer. We want to reassure you that we have addressed the issue on the manufacturing line and corrected product has been distributed into the market.

Contact details of local representative (name, e-mail, telephone, address etc.)*

ConvaTec Hong Kong Customer Service

Tel: (852) 2516 9182

Email: CSHK@CONVATEC.COM

顧客通知 - 緊急 - 醫療器材安全警訊通知

DUODERM CGF DRS 10X10CM (1X5PK) NAI
DUODERM XTHIN DRS 10X10CM (1X10PK) NAI
DUODERM XTHIN DRS 15X15CM (1X10PK) NAI

產品使用者您好，

我們特此寫信向您告知，潛在的產品包裝問題影響了以上列出的產品批次。在 2020 年對於 DuoDERM 超薄型和 DuoDERM CGF 產品系列的呈報中，關於封口有開口、主要包裝中有破裂或撕裂的投訴有增加的趨勢。潛在危險是開封的敷料或在主要包裝封口內密封的產品，可能會失去滅菌阻隔效果，這可能造成感染、延遲傷口癒合和增加疤痕的風險。基於此原因，ConvaTec 發起自行召回活動，召回可能受到此問題影響的產品。目前召回下列產品批次：

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187957	9J02859
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備註：僅本通知內識別的產品代碼和批號受到影響。

我們向您提供此份通訊內容，讓您注意到問題，並大致說明持有此問題影響的產品時可以採取的步驟。

- 1) 檢查您持有的所有 DuoDERM 產品，比對以上列出的產品代碼和批號。
- 2) 請將所有受影響的庫存退還到原始供應商以獲得補償。

ConvaTec 努力向每個客戶提供最高品質的產品和服務。我們向您保證，我們已解決製造產線上的問題，校正後的產品已經配銷到市場上。

當地代表的詳細聯絡資料 (姓名、電子郵件、電話、地址等) *

ConvaTec Hong Kong Customer Service

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