

“波士頓科技” 安博倫皮下植入式心律去顫器
“波士頓科技” 安博倫磁共振造影皮下植入式心律去顫器
安全警訊
(國內無進口受影響產品)

許可證字號：

衛部醫器輸字第 027871 號

衛部醫器輸字第 031525 號

產品英文名稱：

“Boston Scientific” EMBLEM S-ICD System

“Boston Scientific” EMBLEM MRI S-ICD System

受影響規格/型號/批號：

型號	序號(國內無進口受影響序號)
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發布對象：醫療從業人員

警訊說明：(回收/矯正原因描述)

受影響產品當電流或電壓超過可承受之負荷時，可能造成故障。

國內矯正措施：

經查，國內未進口受影響產品，故荷商波士頓科技有限公司臺灣分公司無須執行矯正行動。

廠商聯絡資訊：

公司名稱：荷商波士頓科技有限公司臺灣分公司

聯絡電話：02-26539088

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相關警訊來源(網址)：

美國 FDA：<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=184794>
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=184795>