



URGENT FIELD SAFETY NOTICE

Event-2025-07350

October 21st, 2025

Dear Valued Customer,

Cardinal Health is issuing a Field Safety Notice on our Kendall SCD™ 700 Sequential Compression System due to potential safety risks when used with non-Original Equipment Manufacturer (non-OEM) power cords.

Product Code	Description	UDI
29525	Kendall SCD™ 700 Sequential Compression System (with U.S. power cord)	10192253023008
29525B	Kendall SCD™ 700 Sequential Compression System (with U.S. power cord / TAA Compliant)	10884521129627
295250	Kendall SCD™ 700 Sequential Compression System (with E.U. power cord)	10192253023015
295251	Kendall SCD™ 700 Sequential Compression System (with U.K. power cord)	10192253023022
295254	Kendall SCD™ 700 Sequential Compression System (with Chinese power cord)	10192253023039
295255	Kendall SCD™ 700 Sequential Compression System (with Australian power cord)	10192253023046
295257	Kendall SCD™ 700 Sequential Compression System (with Japanese power cord)	10192253023053
295258	Kendall SCD™ 700 Sequential Compression System (with Brazilian power cord)	10192253023060
295259	Kendall SCD™ 700 Sequential Compression System (with India power cord)	10192253023077
H29525	Kendall SCD™ 700 Sequential Compression System (home configuration with U.S. power cord)	10884521151277
U29525	Kendall SCD™ 700 Sequential Compression System (refurbished with U.S. power cord)	10192253057010
UH29525	Kendall SCD™ 700 Sequential Compression System (refurbished home configuration with U.S. power cord)	10884521155688

Purpose of this letter:	<p>The purpose of this letter is to warn users of potential safety risks when the Kendall SCD™ 700 Sequential Compression System is used with non-original (non-OEM) power cords. To ensure safe operation, please ensure you are using only original (OEM) power cord manufactured by I-Sheng as shown in figure 1 below.</p> <p>Please discontinue use of any non-original (non-OEM) power cords. If you are using a power cord other than an OEM power cord manufactured by I-Sheng.</p> <p>To verify that you are using the correct power cord, please refer to Figure 1 at the end of this letter.</p> <p>Approved I-Sheng OEM power cord part numbers are listed at the end of this letter, shown in figure 2.</p>
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Risk to Health:	<p>The risk of using a non-OEM power cord includes electrical shock and fire, as we have received reports of electrical issues such as sparking and arcing, which have occurred during operations.</p> <p>Non-OEM power cords may lack proper electrical compatibility, safety certifications, and mechanical fit, increasing the risk of device failure and safety standards. Their use, often unnoticed by clinical staff, is further compromised by environmental stress in hospital settings.</p> <p>Prior to use, visually inspect the product, check labeling/documentation, to ensure you are using an I-Sheng OEM power cord as identified in figure 1.</p> <p>Use of an OEM power cord compliant with IEC 60601 standards effectively mitigates these risks.</p>
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Actions Required of the Customer:	<ol style="list-style-type: none"> 1. REVIEW your inventory for the above-mentioned product codes to ensure that an I-Sheng OEM power cord is used. 2. COMMUNICATE the risks of using non-OEM power cords. 3. POST a copy of this notification in your storeroom and clinical areas. 4. NOTIFY any customers to whom you may have distributed/forwarded affected product (or to whom you intend to distribute/forward product) about this medical device product advisory and share a copy of this notice. 5. RETURN the enclosed acknowledgment form by following the directions on the form.
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Available Customer Assistance:	<p>If you have any questions regarding this field safety notice, please contact your local sales representative, or local sales office.</p>
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Additional Information:	<p><u>Regulatory Notification</u> The applicable regulatory agencies are being notified that Cardinal Health is voluntarily taking this action.</p>
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We apologize for any inconvenience this communication may cause. We know that you place high value in our products, and we appreciate your cooperation in this matter. Cardinal Health is committed to maintaining your confidence in the safety and quality of the products that we supply.

Respectfully yours,



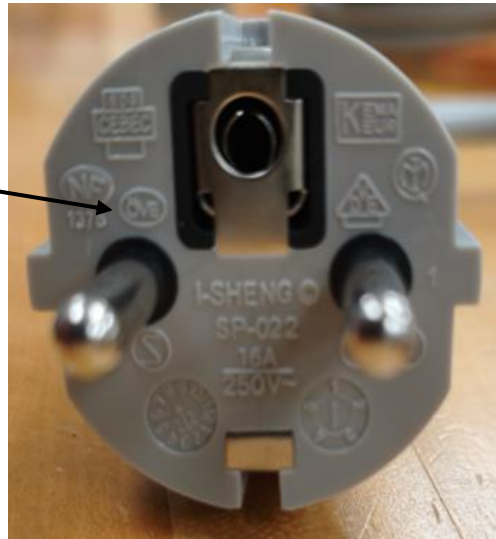
Hector Rocha

Figure 1.

OEM US/Japan Power cord manufactured by I-Sheng



OEM EU Power cord manufactured by I-Sheng



OEM UK Power cord manufactured by I-Sheng



OEM India Power cord
manufactured by I-Sheng

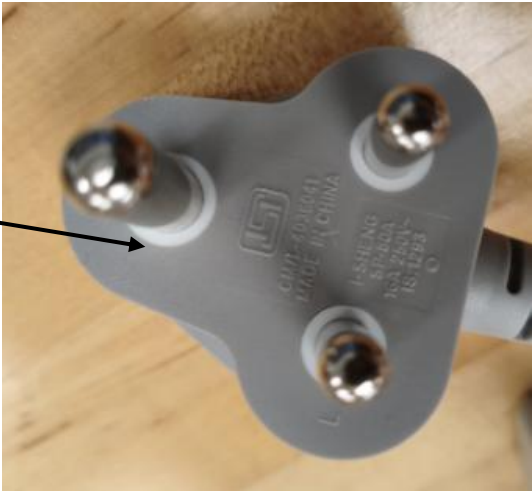


Figure 2 - OEM Power Cord Part Numbers

DESCRIPTION	ORDER PART NUMBER
Power Cord Cover Assembly	PT00111589
Power Cord, US/Japan	93120-SP
Power Cord, Brazil	1030183-SP
Power Cord, India	1046854-SP
Power Cord, Europe	F090704-SP
Power Cord, UK	F090705-SP
Power Cord, Australia/New Zealand	F090706-SP