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19th February 2016

URGENT: FIELD SAFETY NOTICE
RECALL: RENASYS[®] GO External Power Supply Units
FIELD SAFETY NOTICE: 19th February 2016

Affected Product: External Power Supply Units for RENASYS[®] GO
FSCA reference: 19th February 2016
FSCA action: Recall: Device Exchange / Device Destruction
Details of affected product: See below

Customer Name
Device Name
Street Address
City, State, Zip Code

Dear Device Customer/Distributor,

Smith & Nephew informs you of a voluntary Field Safety Corrective Action (FSCA) in relation to the External Power Supply Units ('the External Power Units') for the RENASYS[®] GO Negative Pressure Wound Therapy (NPWT) System.

Following a review of complaint data concerning the External Power Units, Smith & Nephew have identified a risk that some External Power Units have the potential to overheat and induce an electric shock whilst in use with the Renasys[®] GO NPWT Pump. Only certain External Power Units, as detailed in Tables One and Two are affected by this issue

The scope of this FSCA is limited to the External Power Units and not to the Renasys[®] GO NPWT Pumps or the power leads that connects the External Power Unit to the mains electricity. Figure One illustrates the affected item of this FSCA.



Figure One – The affected External Power Units

The purpose of this Field Safety Notice is to provide information to identify the affected External Power Units and to communicate the necessary actions to be undertaken by customers and distributors.

Details on affected devices:

The affected External Power Units in scope of this FSCA are sold as either a separate item or as part of the Renasys[®] GO NPWT Pump system. The affected External Power Units supplied as a separate item or as part of the Renasys[®] GO NPWT Pump system are detailed in Tables One and Two.

| External Power Unit Part Number | Affected Serial Numbers |
|---------------------------------|--|
| 66800161 | External Power Units that have a Serial Number Less than 144500875 |

Table One –The Serial Numbers of the affected External Power Units.

| Renasys [®] GO NPWT Pumps Part Number which the External Power Unit Part Number (66800161) is included within | Affected Serial Numbers |
|--|--|
| 66800164 | External Power Units that have a Serial Number Less than 144500875 |
| 66801244 | |

Table Two – The Renasys[®] GO NPWT Pumps Part Number which the External Power Unit Part Number (66800161) included within

Figure Two illustrates the location of the Serial Number on the External Power Unit. All other External Power Units in use with the RENASYS[®] GO NPWT Pumps remain unaffected by this issue.

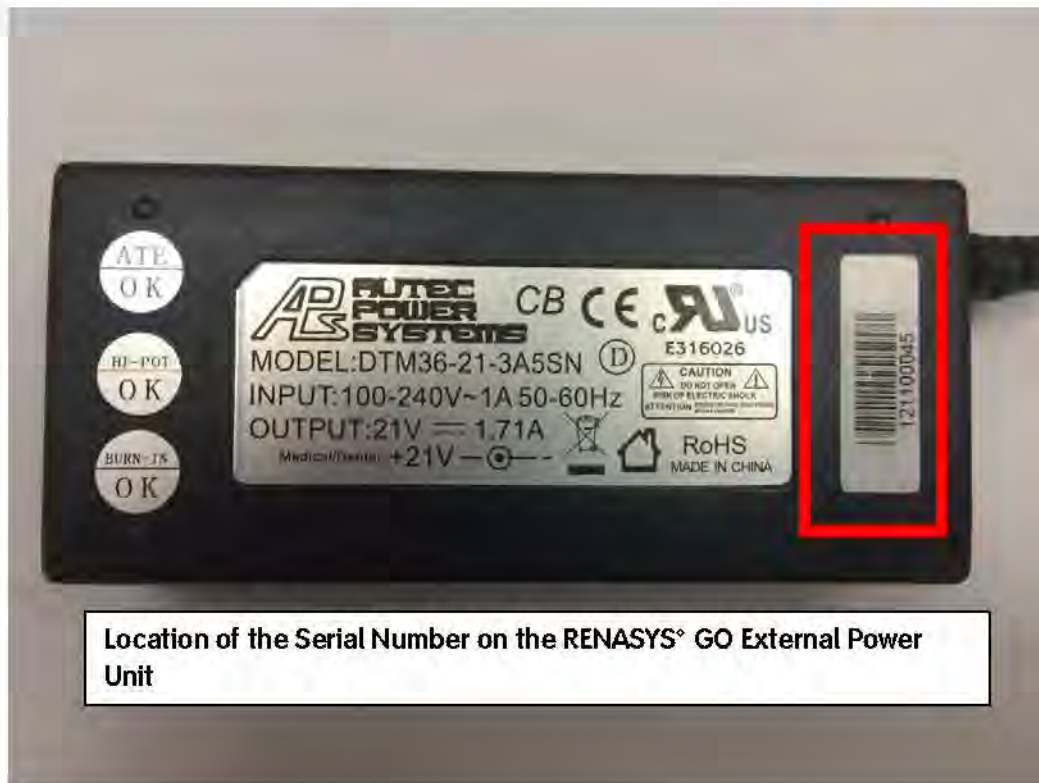


Figure Two – Location of the Serial Number on the External Power Unit.


Description of the problem:

Smith & Nephew investigated complaints received concerning the External Power Units for the RENASYS® GO NPWT Pumps. The complaints received related to the External Power Unit overheating and inducing of electric shocks. Figure One depicts the affected item.

Smith & Nephew concluded that the receptacle for the External Power Units were not adequately supported during the manufacturing process and this had the potential to damage the External Power Units' solder joints whereby electrical arcing became possible between the damaged solder joints.

A partially broken connection of this type, leading to electrical arcing could lead to heat build-up, degradation and even ignition of the External Power Supply Unit's (PSU) Printed Circuit Board Assembly and/or casework). Upon the identification of the root cause, Smith & Nephew have implemented a corrective action.

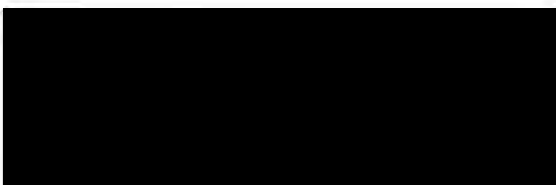
Actions to be taken by customers and distributors

| No. | Actions to be undertaken |
|-----|---|
| 1 | <p>Identify users of the affected External Power Supply Units for RENASYS[®] GO NPWT Pumps. This requires you to identify all users of Smith & Nephew RENASYS[®] GO NPWT system, who may be in possession of an affected External Power Unit and who need to be made aware of this issue and actions to be executed in this Field Safety Corrective Action. Users may be distributors, healthcare professionals, home care workers or patients. Provide copies of this notice to all identified users as soon as is reasonably practicable.</p> |
| 2 | <p>Users are instructed to immediately inspect the Serial Numbers for all External Power Units with any RENASYS[®] GO NPWT Pumps. The figure below illustrates where the Serial number is located on the External Power Unit.</p> <div data-bbox="236 846 1286 1626" style="text-align: center;">  <p data-bbox="320 1451 1225 1543">Location of the Serial Number on the RENASYS[®] GO External Power Unit</p> </div> |
| 3 | <p>Users are instructed to immediately disconnect all affected External Power Units from the mains electricity supply. The pump will continue to provide NPWT treatment as the device will run off its internal battery.</p> <p>Users must switch to an unaffected External Power Unit while the device is in battery mode to avoid discontinuing NPWT therapy. NPWT therapy will no longer be provided by the pump once the RENASYS[®] GO internal battery runs out.</p> |

| | |
|---|---|
| | <p>If an unaffected External Power Unit is not available, patients should consult their responsible Health Care Professional for determining an alternative treatment</p> <p>Users <u>must not</u> use non-Smith & Nephew External Power Units with the RENASYS® GO NPWT Pump.</p> |
| 4 | Users are instructed to quarantine all affected External Power Unit located |
| 5 | <p>Users are instructed to return all affected External Power Units to Smith & Nephew</p> <p style="text-align: center;">or</p> <p>Users are instructed to dispose all affected External Power Units in accordance with local requirements.</p> |
| 6 | <p>Users must complete the Acknowledgement, Receipt and Confirmation of Return / Disposal Form attached with this notice and return to your local Smith & Nephew Contact as soon as reasonably practicable.</p> <p>An 'Acknowledgement, Receipt and Confirmation of Disposal' Form must be return even if you do not have any affected product in your inventory. If necessary, your Smith & Nephew contact can assist you in completing the form</p> |
| 7 | Users must contact the local Smith & Nephew contact to coordinated any replacement External Power Units |
| 8 | Users must ensure this safety information is passed on to all those who need to be aware of it within your organization |
| 9 | Users must maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action |

If you have any questions, please contact your local Smith & Nephew subsidiary on the details listed below.

| |
|--|
| Contact Details of Subsidiary / Distributor: |
|--|



IMPORTANT - MEDICAL DEVICE FIELD SAFETY NOTICE RESPONSE
Acknowledgement, Receipt and Confirmation of Return / Disposal Form
 Response is required within 15 days

Customer Information:

Customer Name
 Street Address
 Town, State, Zip Code

RENASYS® GO External Power Supply

I have read and understood the information contained in this letter and have distributed copies to all relevant users, as defined in the instructions.

PLEASE SELECT THE APPROPRIATE OPTION IN TABLE A

Table A

| | |
|---|--------------------------|
| I have checked inventory for the affected products listed in the Field Safety Notice and confirm zero inventory remaining IF YOU TICK THIS BOX PLEASE PROCEED TO THE APPROVAL SECTION | <input type="checkbox"/> |
| I have checked inventory for the affected products listed in the Field Safety Notice and can confirm inventory remaining IF YOU TICK THIS BOX PLEASE ALSO COMPLETE TABLE B | <input type="checkbox"/> |

PLEASE SELECT THE APPROPRIATE OPTION IN TABLE B

| | |
|---|--------------------------|
| I want to return the affected products listed in the Field Safety Notice back to Smith & Nephew IF YOU TICK THIS BOX PLEASE ALSO COMPLETE TABLE C | <input type="checkbox"/> |
| I want to dispose the affected products listed in the Field Safety Notice in accordance with local requirements IF YOU TICK THIS BOX PLEASE ALSO COMPLETE TABLE D | <input type="checkbox"/> |

Table C - ONLY COMPLETE THIS TABLE IF YOU HAVE IDENTIFIED AFFECTED PRODUCTS LISTED IN THE FIELD SAFETY NOTICE IN YOUR LOCATION AND WANT TO RETURN IT TO SMITH & NEPHEW.

| External Power Unit Part number | Serial number(s) | Quantity of product returned |
|---------------------------------|------------------|------------------------------|
| 66800161 | | |

ADD ADDITIONAL ROW IF REQUIRED.

Table D - ONLY COMPLETE THIS TABLE IF YOU HAVE IDENTIFIED AFFECTED PRODUCTS LISTED IN THE FIELD SAFETY NOTICE IN YOUR LOCATION AND WANT TO DISPOSE OF IT

| External Power Unit Part number | Serial number(s) | Quantity of product discarded |
|---------------------------------|------------------|-------------------------------|
| 66800161 | | |

ADD ADDITIONAL ROW IF REQUIRED.

Please provide any additional information, if applicable.

Approval

| | |
|----------------------|--|
| Name | |
| Signature | |
| Title | |
| Telephone | |
| Email address | |

PLEASE FAX OR MAIL THE COMPLETED RESPONSE FORM TO: YOUR LOCAL SMITH & NEPHEW CONTACT