



Date: January 15th, 2021

Attention: Biomedical department

RE: T34™ Syringe pump lead screw motor block remediation – Field Safety Notice MMS-19-1572

Dear Valued Customer,

Early in 2020, BD/CME issued a Field Safety Notice (MMS-19-1572) relating to the Lead Screw on 2nd and 3rd edition T34™ Ambulatory pumps. As part of the Field Action, BD has committed to remediating the leadscrew; the remediation will consist of providing a new stainless-steel lead screw block assembly (which can be replaced by Rockford. For certain T34™ pumps, where the replacement with new motor block is not feasible, Rockford will complete the remediation through providing a new BD Ambulatory Syringe pump (BD BodyGuard™ T).

BD/CME has made decision to replace the following pumps currently in operational use with a new BD BodyGuard™ T pump:

- T34™ devices manufactured prior to 2009 (under the brand name McKinley)
- CME T34™ 3rd edition pumps manufactured between September 2018 to May 2020.

The BD BodyGuard™ T pump will only be provided free of charge, in relation to the guidance in Appendix 1, with deliveries anticipated to commence in early 2021. This product is based on BD T34 3rd edition and will also include updated software to provide extended battery life as compared to current 3rd edition pump.

In the interim, until your T34™ pump is replaced, continue to follow the instructions within the Field Safety Notice (MMS-19-1572). If you identify white debris, contact your local BD representative immediately.

We are aware that many of our valued customers have mixed fleets of different editions of the T34™ pumps, and to clarify the remediation strategy for all the pumps, we have included a comprehensive remediation guide in Appendix 1. To assist with BD & Rockford Planning and preparation for the device exchange please complete the acknowledgement form attached and return to BDT34replacement@rockford.ie by **January 30th 2020**.

We thank you for your loyalty and welcome feedback on our products to help BD better meet customer expectations and improve patient care.

Country Business Leader

Name:

Signature

Appendix 1: Remediation Guide for T34™ devices

Production Date	Product Name/Brand/Specification	Lead screw remediation Guide
<p>Prior to 2009 (2nd edition)</p> 	<p>McKinley T34™ Old Lead Screw design - Initial Software</p>	<p>To be replaced by BD BodyGuard™ T, free of charge.</p> <p><i>Please return the acknowledgement form in appendix 2 to</i> BDT34replacement@rockford.ie</p>
<p>2009 to April 2018 (2nd edition)</p> 	<p>CME Medical T34™ (UK) - CME T34™ /CME Niki T34™ Old Lead Screw design - Initial software</p>	<p>Motor Block Assembly Change required.</p> <p><i>Please ensure you have responded to the previous Field Safety Notice MMS-19-1572 & BD will complete required actions.</i></p>
<p>September 2018 to May 2020 (3rd Edition)</p> 	<p>CME T34™ 3rd Edition Old Lead Screw design -Software Version: T34SW3.07D</p>	<p>To be replaced by BD BodyGuard™ T, free of charge.</p> <p><i>Please return the acknowledgement form in appendix 2 to</i> BDT34replacement@rockford.ie</p>
<p>May 2020 onwards (3rd Edition)</p>  <p>See Note 3 for further information</p>	<p>CME T34™ 3rd edition New Stainless Steel Lead Screw design Software Version: T34SW3.07D</p>	<p>No Customer action required – device contains stainless steel leadscrew (see note 3).</p> <p>BD will propose a software upgrade when available. Further information will be provided at a later stage</p>

Note 1: The device exchange proposed in the table page 2 are related exclusively to the Lead Screw remediation program only, under Field Safety Notice, MMS-19-1572, issued in February 2020.

Note 2: An example of serial number on reverse of T34 pump:



Note 3: For 3rd Edition Pumps manufactured from May 2020, the T34 will have the below sticker on the battery compartment.





Appendix 2

T34™ Ambulatory Syringe Pump, Lead screw remediation Exchange Program Customer Acknowledgement Form

Please complete the below information, scan and e-mail the completed form to BDT34replacement@rockford.ie.

Alternatively email the required information to BDT34replacement@rockford.ie.

1: How many units of the Mc Kinley T34™ Pumps (Prior 2009) does your organization have currently in operational use?

- Units: []
- *Please provide the serial numbers*

2: How many units of the CME T34™ pumps produced from September 2018 to May 2020 does your organization have currently in operational use

- Units: []
- *Please provide the serial numbers*

<p>Organisation Name:</p> <p>Name and Title:</p> <p>Date:</p> <p>Signature:</p>
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Upon reception of this acknowledgment form, Rockford will contact you in due course to plan device exchange.