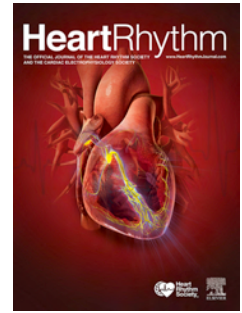


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A second chance to make a first impression – Parylene C residuals staining the surface of cardiac implantable electronic devices

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1 **A second chance to make a first impression – Parylene**
2 **C residuals staining the surface of cardiac implantable**
3 **electronic devices**

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25 **Research letter**

26 Cardiac implantable electronic devices (CIEDs) malfunctions are rare but concerning¹. We report a
27 series of three devices, where new cardiac resynchronization therapy defibrillators (CRT-Ds) appeared
28 stained. As per Swiss law, analysis of these devices did not require ethical approval.

29 We observed this issue for the first time during a CRT-D generator replacement. When the new
30 generator was unpacked, its surface appeared stained and scratched (Fig. 1, panel 1 and 2). The
31 discolorations could neither be palpated nor removed using a textile drenched in saline solution. Device
32 interrogation revealed no unusual findings. Nevertheless, the new device was discarded due to concerns
33 regarding sterility and electrical integrity (mechanical stress during the manufacturing causing
34 unapparent damage could not be excluded).

35 Within a week, we observed two similar cases, all affecting a CRT-D device family of a specific
36 manufacturer (Quadra Assura CRT-Ds with IS1/DF1/IS4 and IS1/DF4/IS4 headers, Abbott Medical,
37 Chicago, Illinois, United States). All devices were returned to the manufacturer for analysis.

38 The manufacturer performed scanning electron microscopy (Fig. 1, panel 4) and X-ray spectroscopy
39 (Fig. 1, panels 5-7). The analysis revealed that there was no damage of the titanium housing. X-ray
40 spectroscopy demonstrated that the stains contained a significant amount of chlorine and carbon,
41 whereas – at the same sites – the titanium signature (metal housing) was attenuated (Fig. 1, panels 5-
42 7). The discolorations matched the chemical composition of Parylene C (Fig. 1, central illustration), an
43 electrical insulator. To test electrical integrity, all devices were assessed on the bench in a 37°C heated
44 saline-filled tank. Leads were connected to the devices, which were then interrogated. High-voltage
45 impedances of all devices and different shock configurations were within normal ranges (32-38Ω) since
46 the residuals only cover a small amount of the overall device surface.

47 Parylene is a common name for poly-(para-xylylene), a group of translucent, hydrophobic, inert,
48 thermally stable polymers used to coat medical implants². Parylene C provides excellent
49 biocompatibility², reduces friction (i.e. between the generator and CIED leads in the pocket) and may
50 minimize the risk for device infections³. However, after its vapor deposition on the CIED surface, it must
51 again be removed partially as the metallic can of a CIED is electrically active and Parylene is electrically
52 insulating. Only the device's edges are intended to remain covered since the mechanical interactions of
53 leads and generator seem to be most pronounced there, justifying additional protective Parylene
54 coating. Parylene removal can be performed by different etching processes or laser ablation⁴. In our

55 case series, the removal of the Parylene on the device's central portion by laser ablation was incomplete,
56 causing the inhomogeneity of the device surface.

57 Similar findings (unpublished) have been observed at other sites in Singapore and the UK, but the
58 reported incidence of these findings seems very low (0.06‰ according to the manufacturer). However,
59 the affected devices were produced more than one year apart and at different manufacturing sites, thus,
60 underreporting seems likely. Meanwhile, we observed again similar issues in two other devices. Due to
61 the findings of the manufacturer, these devices were implanted and showed normal behavior. Based on
62 the received complaints, the manufacturer is reviewing ablation parameters at each production site and
63 revising manufacturing protocols.

64 To conclude, maculate CIED surfaces are unusual findings. In the case of several stained Abbott CRT-
65 D models, these findings appear benign – based on the limited testing performed at this time.

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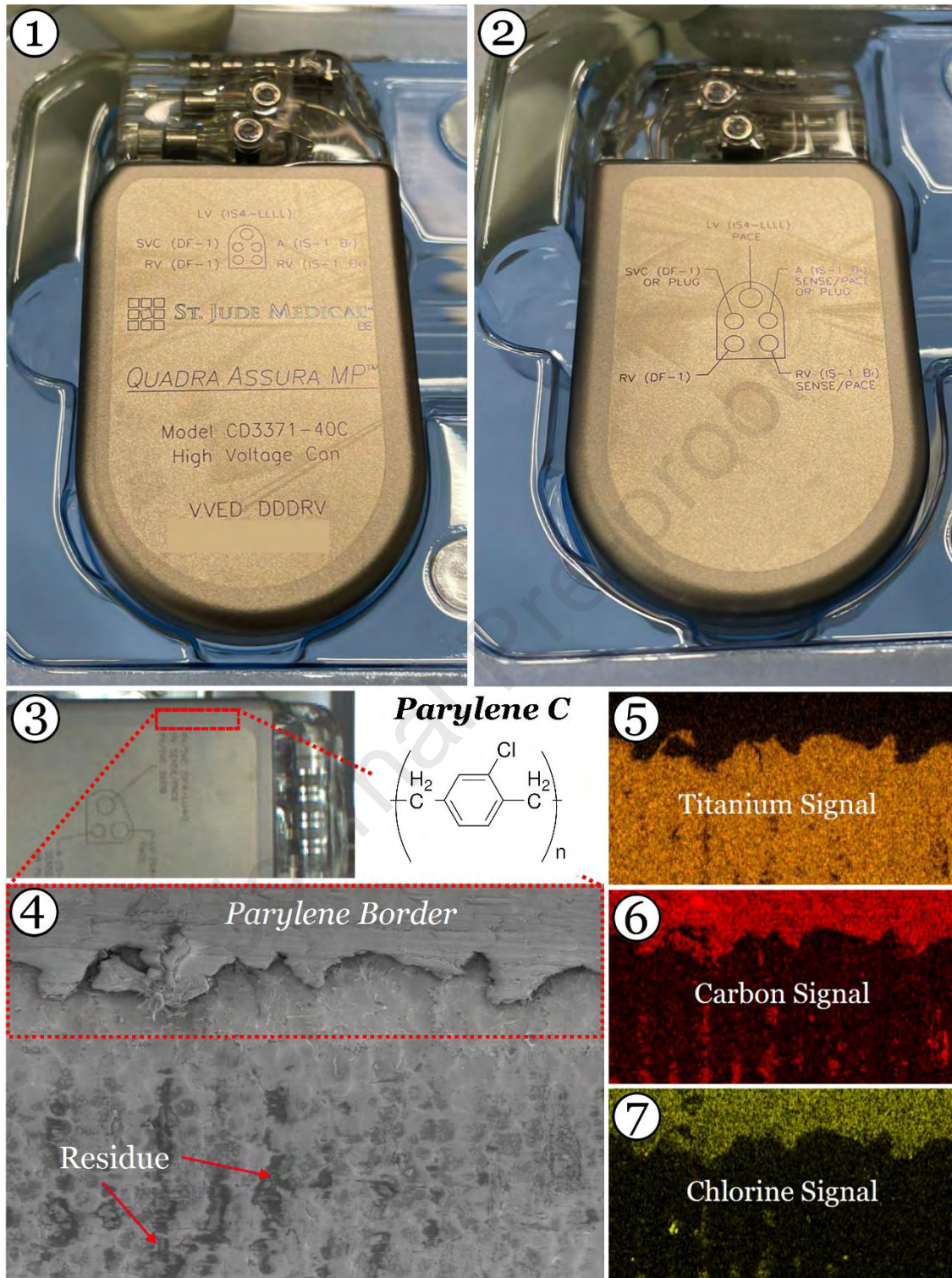
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69

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73 **Figure**

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75 **Fig. 1:** Parylene C residuals on CIED generators. Panel 1 and 2 show the stained surface of a Quadra
 76 Assura CRT-D (Abbott Medical, Chicago, Illinois, US). Panel 4 shows the electron microscopy image of
 77 the border, where Parylene C covers the edges of an affected device (panel 3). Residuals can be seen
 78 in the lower part of panel 4, where the Parylene C should have been removed from the titanium surface.

79 *Panels 5-7 are X-ray spectroscopy images of the respective border (courtesy Abbott Medical). Panel 5*
80 *shows residual coating (black) on the titanium surface (orange). The primary elements identified in the*
81 *residuals were carbon and chlorine (panel 6 and 7), matching the composition of Parylene C (chemical*
82 *formula shown as central illustration).*

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