

07 May 2019 | News

Q1 Recalls Snapshot: Device Corrections & Removals Are Down, But Recalls Of High-Risk Class I Units Remain A Concern

by [Shawn M. Schmitt](#)

Corrections & removals of medical devices were down 41% in the first quarter of 2019, the lowest number of recalls recorded in a quarter since Q4 2017. There was one dark spot, though: Q1 was the third consecutive quarter in which more than 1 million high-risk class I units were recalled. Check out our Q1 recalls infographic.

Good news for industry: Corrections & removals of medical devices were down 41% in the first quarter of 2019, the lowest number of recalls recorded in a quarter since Q4 2017. There were 164 recalls in Q1, compared to the 280 noted in [Q4 2018](#). And there were just under 135 million units recalled in Q1 (down 16% from Q4's 161 million), consulting firm Stericycle says in its most recent [recalls index](#). However, there was one dark spot: It was the third consecutive quarter in which more than 1 million high-risk class I units were recalled. Meanwhile, problems with quality was the No. 1 reason for recalled units – the first time quality troubles was the top recall cause since Q3 2016.

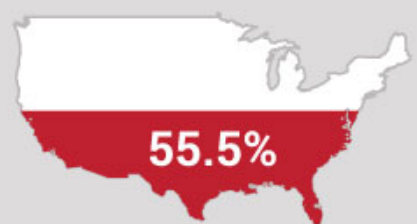
SNAPSHOT: Device Recalls Q1 2019

MEDICAL DEVICE RECALLS & UNITS (in millions)



MEDICAL DEVICE MALADIES

There were more than 1 million class I units recalled for the third consecutive quarter. The last time there were three consecutive quarters with at least 1 million units each was Q2 to Q4 2014.



55.5%
OF MEDICAL DEVICE
RECALLS WERE NATIONWIDE

AVERAGE CLASS I UNITS RECALLED PER QUARTER

Q3 2018

14,035,195

Q4 2018

1,380,706

Q1 2019

1,388,655

CONNECTING THE DOTS

- The average recall size was 823,126 – the highest quarter since 2006.
- At 51%, quality issues was the top recall cause based on UNITS, mostly due to one large recall. This is the first time quality issues was the top cause since Q3 2016.
- For the first time since Q3 2017, no company reported 10 or more recalls in the quarter.

TOP RECALL CAUSES BASED ON NUMBER OF EVENTS



Software Issue

37



Mislabeling Issue

31



Quality Issue

21



Sterility

15

Source: Stericycle ExpertSOLUTIONS Q1 2019 Recall Index

Design: Janet Haniak

Get a PDF of this infographic [here](http://medtech.citeline.com/MT125058).