

07 May 2019 | News

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

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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.

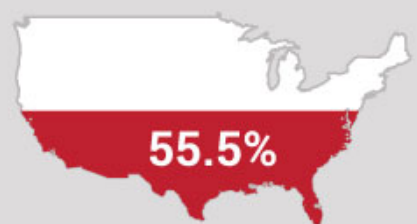
# SNAPSHOT: Device Recalls Q1 2019

## 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

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