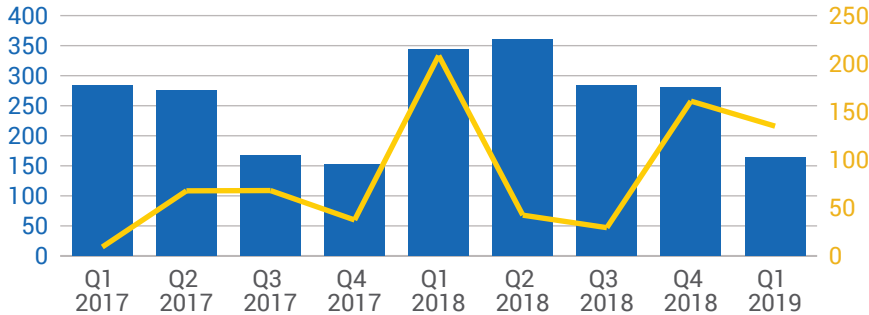


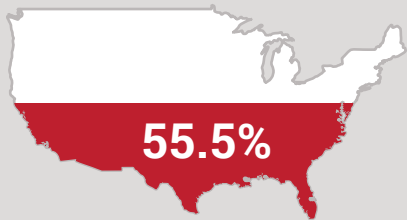
SNAPSHOT: Device Recalls Q1 2019

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.



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