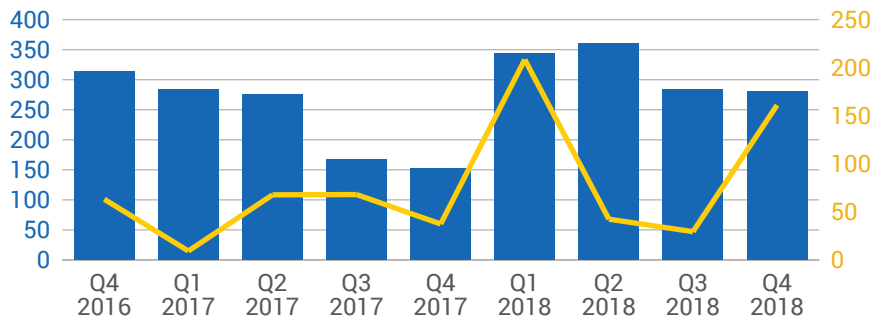


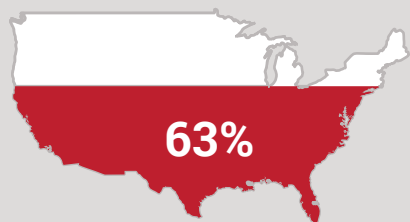
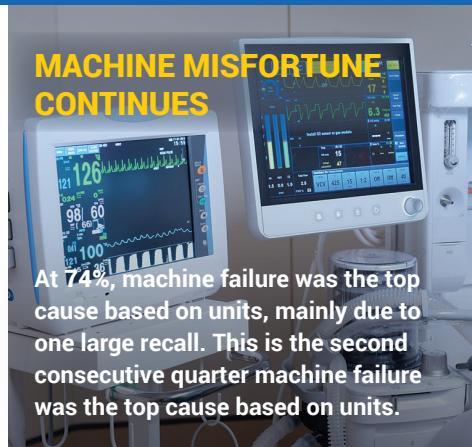
SNAPSHOT: Device Recalls Q4 2018

MEDICAL DEVICE RECALLS & UNITS (in millions)



MACHINE MISFORTUNE CONTINUES

At 74%, machine failure was the top cause based on units, mainly due to one large recall. This is the second consecutive quarter machine failure was the top cause based on units.



OF MEDICAL DEVICE RECALLS WERE NATIONWIDE

AVERAGE CLASS I UNITS RECALLED PER QUARTER

Q2 2018
599,165

Q3 2018
14,035,195

Q4 2018
1,380,706

CONNECTING THE DOTS

- The average recall size was 575,449 – the second highest quarter since Q3 2006.
- At 28%, software was the top cause based on recalls for the eleventh consecutive quarter. No other cause was responsible for more than 15% of recalls.
- Five companies reported 10 or more recalls in Q4 2018. This is the highest number since Q3 2016 and the second highest since Q3 2013.

TOP RECALL CAUSES BASED ON NUMBER OF EVENTS



Software Issue

79



Mislabeling Issue

43



Quality Issue

36



Sterility

27