SNAPSHOT: Device Recalls Q3 2019

MEDICAL DEVICE RECALLS & UNITS (in millions)

| | Q2 2017 | Q3 2017 | Q4 2017 | Q1 2018 | Q2 2018 | Q3 2018 | Q4 2018 | Q1 2019 | Q2 2019 | Q3 2019 |

404 SYSTEM ERROR

SOFTWARE WOES

Software issues remained the top cause for recalls for the **14th consecutive quarter,** but impacted fewer than **1%** of all units recalled.

65.8%

OF MEDICAL DEVICE RECALLS WERE NATIONWIDE

UNITS RECALLED BY CLASS

Class I

201,244,136

Class II

14,816,297

Class III

3,123,777

CONNECTING THE DOTS

- The average number of units per recall was 901,993 – the largest number in a quarter since 2005. However, this was an anomaly resulting from one recall that accounted for 83% of all recalled units.

- At 85%, quality issues was the top recall cause based on units for the third consecutive quarter. Prior to Q1 2019, the last time quality issues was the top cause was in Q3 2016.

TOP RECALL CAUSES BASED ON NUMBER OF EVENTS

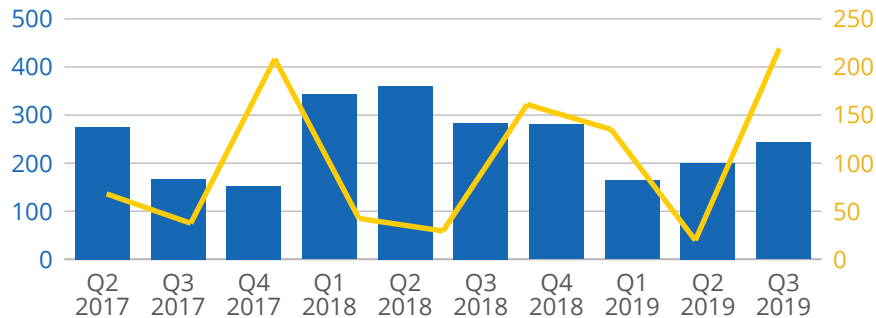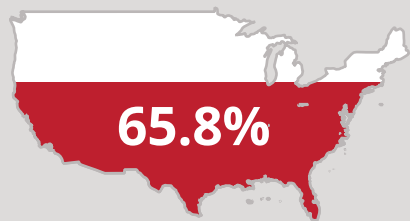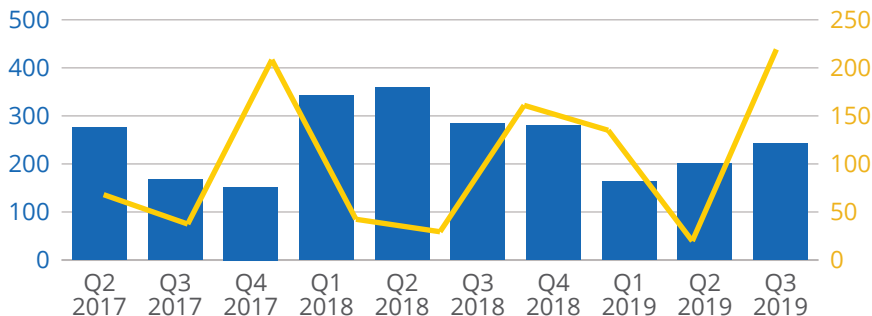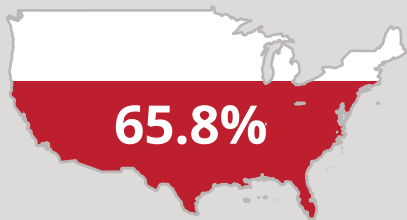| Software Issue	Quality Issue	Device Failure	Sterility/Parts Issue/ Outside Of Specs
54	34	33	20

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Source: Stericycle ExpertSOLUTIONS Q3 2019 Recall Index

Design: Janet Haniak / Informa Pharma Intelligence Design Team

Medtech Insight
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