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Q3 Recalls Snapshot: Number Of Recalls Ticks Up For Third Consecutive Quarter; Recalled Units Spike An Incredible 1013%

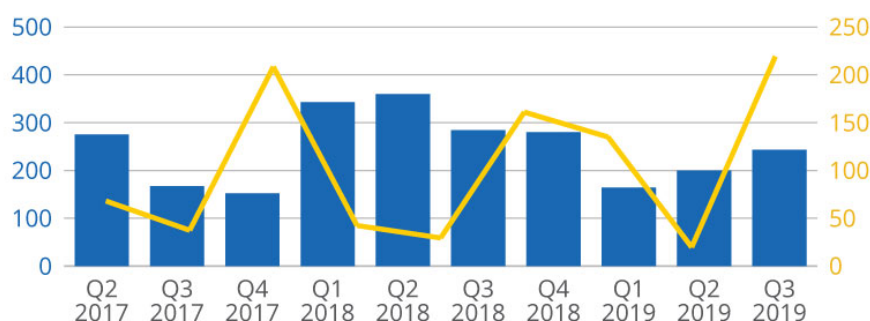
by [Shawn M. Schmitt](#)

Device makers initiated 243 recalls in the third quarter of 2019 – a modest 1% increase over Q2's 200 recalls. Interestingly, the number of recalled device units skyrocketed a whopping 1013%, from 19.7 million in Q2 to 219.2 million in Q3. Check out our Q3 recalls infographic.

For the second quarter in a row, the number of medical devices recalled by manufacturers has increased, consulting firm Stericycle says in its most recent [recalls index](#). Industry initiated 243 recalls in the third quarter of 2019, a modest 1% increase over [Q2](#)'s 200 recalls. Interestingly, the number of recalled device units skyrocketed a whopping 1013%, from 19.7 million in Q2 to 219.2 million in Q3. "While this is the greatest number of units impacted in a quarter since at least 2005, the anomaly is largely due to one recall that accounted for 83% of all recalled units," Stericycle explains.

SNAPSHOT: Device Recalls Q3 2019

MEDICAL DEVICE RECALLS & UNITS (in millions)



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

54



Quality Issue

34



Device Failure

33



Sterility/Parts Issue/
Outside Of Specs

20

Source: Stericycle ExpertSOLUTIONS Q3 2019 Recall Index

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