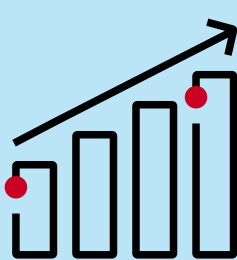
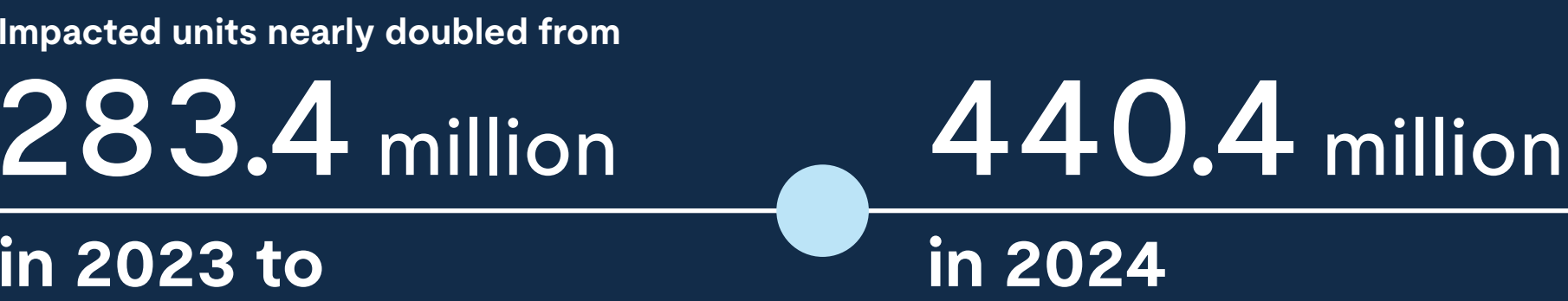
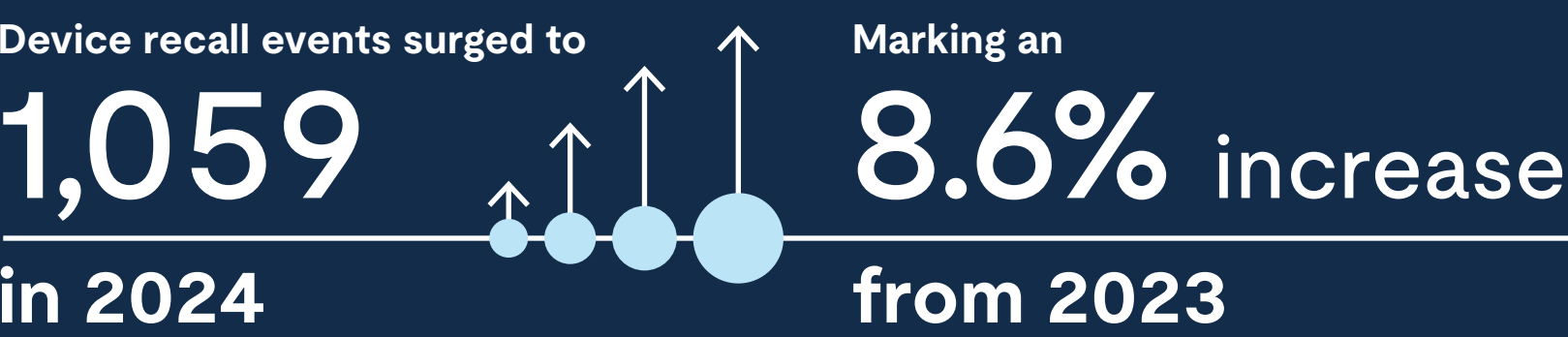


# Medical device recalls: Highlights from 2024



## Alarming recall numbers



Class I device recalls hit a **15-year high**



## Leading causes of recall

### 01 Recall events

**Device failure**  
A five-year high comprising **11.1%** (118) of total recall events.

- The next four common reasons for recall events:
- Quality
  - Software
  - Mislabeling
  - Parts issues

### 02 Recalls by unit

**Parts-related failure**  
Comprising **28%** of total impacted units.

- The next four common reasons for unit recalls:
- Device failure
  - Quality issues
  - Device expiration
  - Instructions updates



## Recall insights from Q4 2024

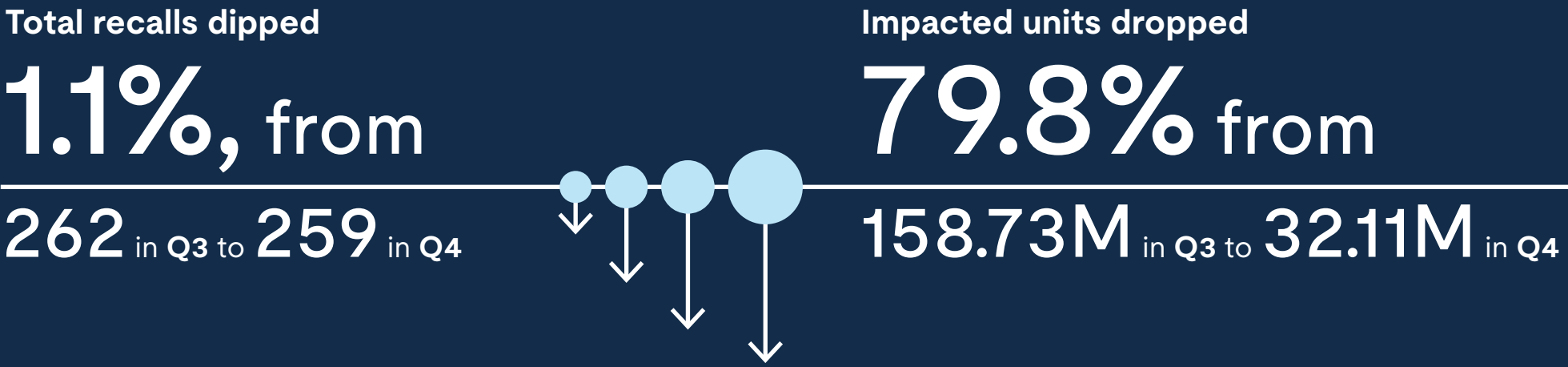
### 04 Top recall causes

- Device failure**  
44 events
- Software issues**  
31 events
- Mislabeling and manufacturing**  
27 events each

### 03 Units recalled by volume

- Safety concerns**  
5.32 million dental aligners
- Parts issues**  
4.44 million dialysis transfer sets
- Leakage**  
5.31 million units

## Promising trends



\*Data attributed to: Sedgwick Brand Protection. 2025. "State of the Nation 2025 Product Safety and Recall United States Edition."