

Supplementary Table 1. Specific device related reports

Operational failure	Count	%	Mechanical failures	Count	%	Quality problems	Count	%
Activation failure	1461	41.87	Break	346	9.92	Patient-device incompatibility	4	0.11
Positioning failure	219	6.28	Difficult to open or close	165	4.73	Use of device problem	2	0.06
Device operates differently than expected	172	4.93	Detachment of device or device component	89	2.55	Component or accessory incompatibility	1	0.03
Activation, positioning or separation problem	138	3.96	Material deformation	80	2.29	Device contamination with chemical or other material	1	0.03
Migration or expulsion of device	126	3.61	Difficult to remove	44	1.26	High readings	1	0.03
Difficult or delayed positioning	67	1.92	Physical resistance	40	1.15	Human-device interface problem	1	0.03
Occlusion within device	39	1.12	Separation failure	37	1.06	Incorrect device or component shipped	1	0.03
Positioning problem	39	1.12	Physical resistance/Sticking	33	0.95	Unexpected therapeutic results	1	0.03
Migration	36	1.03	Material twisted/Bent	27	0.77			
Sticking	33	0.95	Detachment of device component	18	0.52			
Difficult to position	24	0.69	Fracture	17	0.49			
Unintended movement	21	0.60	Material separation	14	0.40			
Unintended ejection	16	0.46	Mechanical problem	11	0.32			
Collapse	15	0.43	Kinked	8	0.23			
Retraction problem	14	0.40	Entrapment of device	5	0.14			
Malposition of device	13	0.37	Device slipped	4	0.11			
Failure to advance	12	0.34	Deformation due to compressive stress	3	0.09			
Premature activation	9	0.26	Device dislodged or dislocated	3	0.09			
Flaked	6	0.17	Material rupture	3	0.09			
Leak/Splash	6	0.17	Nonstandard device	3	0.09			
Stretched	6	0.17	Structural problem	3	0.09			
Difficult to advance	4	0.11	Difficult to insert	2	0.06			
Improper or incorrect procedure or method	4	0.11	Folded	2	0.06			
Delamination	3	0.09	Inadequacy of device shape and/or size	2	0.06			
Device inoperable	3	0.09	Material invagination	2	0.06			
Disconnection	3	0.09	Bent	1	0.03			
Extrusion	3	0.09	Defective device	1	0.03			
Infusion or flow problem	3	0.09	Material fragmentation	1	0.03			
Peeled/Delaminated	3	0.09	Material frayed	1	0.03			
Restricted flow rate	3	0.09						
Failure to disconnect	2	0.06						
Obstruction of flow	2	0.06						
Incorrect measurement	1	0.03						

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Operational failure	Count	%	Mechanical failures	Count	%	Quality problems	Count	%
Communication or transmission problem	1	0.03						
Difficult or delayed activation	1	0.03						
Failure to discharge	1	0.03						
Improper flow or infusion	1	0.03						
Inflation problem	1	0.03						
Insufficient flow or under infusion	1	0.03						