

Design Failure Modes and Effects Analysis								
Item	Failure Mode	Failure Effects	SEV	Causes	OCC	Controls	DET	RPN
Ratchet Wheel	Wheel Slips	Sudden Loss of Torque Transfer	5	Teeth Shear Prematurely	1	Material Inspection, Structural Analysis	2	10
		Inability to Transfer Torque	3	Teeth Mate Improperly	2	Dimensional Inspection	1	6
Pawl	Fails to Hold Wheel	Sudden Loss of Torque Transfer	5	Counter Support Deforms under Load	2	Structural Analysis (FEA)	2	20
		Unable to Transfer Rated Torque	3	Teeth Mate Improperly	2	Dimensional Inspection	1	6
			2	Pawl Sticks in Neutral	2	Prototype Testing	2	8
		Sudden Loss of Torque Transfer	5	Teeth Shear Prematurely	1	Material Inspection, Structural Analysis	2	10
Detent	Doesn't hold Pawl in gear	Intermittent Direction Changes	2	Spring Force too Low	2	Prototype Testing	2	8
			2	Worn Detent Cone	2	Prototype Testing	2	8
Ratchet Main Body	Handle Breaks	Can't operate the ratchet and hand may slip causing injury	5	Working Limit Exceeded	2	Establish Safety Margin	1	10
			5	Fatigue Cracks	1	Structural Analysis to keep Stress Below Endurance limit	3	15
			5	Material out of spec	2	Material Inspection	1	10

Guidelines For Failure Modes And Effects Analysis For Medical Devices

JS Bruner



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