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CVC Syringe Failure Mode and Effects Analysis

Group: Jennifer Adams, Janet Chan, Evan Hill, Matt Wolf

Purpose: The FMEA is intended to provide a bottom-up analysis of the device components and the possible failures associated with each component.

Risk Classification:

	Severity			
Occurrence	Catastrophic	Dangerous	Marginal	Negligible
Frequent	iv	iv	iv	iii
Probable	iv	iv	iii	ii
Occassional	iv	iii	ii	ii
Remote	iii	ii	ii	i
Improbable	ii	ii	i	i
Incredible	ii	i	i	i

Always Acceptable	i
Acceptable	ii
Minimally Tolerable	iii
Unacceptable	iv

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Failure Mode and Effects Analysis:

Component	Failure Mode	Effect on System	Possible Hazards	Risk Index	User Detection	Applicable Controls
Needle Sheath	Material breaks or loses its rigidity	No affect on the overall function of the system	Needle sticks prior to insertion which could lead to infection	ii	Recognize missing or defective material	Design material, manufacturing accuracy, regular testing of products
Needle	Needle breaks	Device cannot draw blood and must be discarded for a new device	Needle sticks before and after insertion, infection due to multiple injections	iii	Inspect needle prior to use to ensure stability	Design materials, manufacturing accuracy, regular testing of products

Failure Mode and Effects Analysis Continued:

Pressure Sensor	Electrical circuit failure/ malfuction	Device cannot read pressure correctly	Catheterization of the artery, multiple injections, electrical shock	iii	Inspect sensor prior to use to check for unconnected components	Design criteria for sensor, careful packaging, regular product testing, tubing for manual pressure testing provided
	Blood Contaminates the circuit	Device cannot read any pressure	Catheterization of the artery, multiple injections	iii	Inspect connection prior to use	Design criteria for sensor, careful packaging, regular product testing, tubing for manual pressure testing provided
	Patient pressure is too low	Device cannot recognize a difference between venous and arterial pressure	Catheterization of the artery, multiple injections	iii	Recognize limitations of sensor and the patient's conditions	Design criteria for sensor, training of the clinicians prior to use of the device

Failure Mode and Effects Analysis Continued:

Support Handle	Material breaks	Connector falls out or material cracks causing device to be discarded	Multiple injections can lead to infection	ii	Inspect material prior to use for any cracks or loss of structural stability	Design material selection, manufacturing processes, regular product testing
Connector	Material breaks	Connector falls out or material cracks causing device to be discarded	Multiple injections can lead to infection	ii	Inspect material prior to use for any cracks or loss of structural stability	Design material selection, manufacturing processes, regular product testing
Connector Valve	Valve does not open or close properly	Guide wire cannot be slide through or blood can be lost	Blood can contaminate injection site and lead to infection	iii	Use thumb to prevent blood loss	Limiting manufacturing error, regular product testing
Guide Wire	Not marked properly	Guide wire can be over inserted into the patient	Heart puncture	iii	Check depth markings on guide wire to ensure correct placement before depending on markings	Design material for marker, limiting manufacturing error, regular product testing