



CVC Syringe Risk Management Summary

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

Purpose: The Risk Management Summary provides a comprehensive list of the complications that can occur during the CVC procedure and the associated level of risk. This document also provides an analysis of how the new method of CVC placement addresses the complications.

Risk Classification:

Occurrence	Severity			
	Catastrophic	Dangerous	Marginal	Negligible
Frequent	iv	iv	iv	iii
Probable	iv	iv	iii	ii
Occasional	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



Risk Management Summary:

Hazard ID (FTA)	Hazard	Severity	Cause	Probability of Occurrence	Risk	Method of Control	Design Measures	Modified Probability of Occurrence	Modified Risk
1.1	Pressure sensor failure	Dangerous	Decreased sensor sensitivity	Occasional	iii	Design	Highest sensitivity and testing	Remote	ii
1.2		Dangerous	Increased sensor sensitivity	Occasional	iii	Design	Highest sensitivity and testing	Remote	ii
1.3		Marginal	Complete failure	Occasional	ii	Design	Highest sensitivity and testing	Remote	ii
2.1	Valve Failure	Marginal	Valve manufacturing error	Remote	ii	Manufacturing	Minimize production error	Improbable	i
2.2		Marginal	User error	Occasional	ii	Labels	Warning on proper placement of handle within connector	Remote	ii



Risk Management Summary Continued:

3.1	Mechanical Failure	Marginal	Material stress/strain failure	Remote	ii	Design	Select appropriately strong materials	Improbable	i
3.2		Marginal	Material manufacturing error	Remote	ii	Manufacturing	Conduct appropriate material tests	Improbable	i
4.1	Infection	Dangerous	Unsterile device or materials	Probable	iv	Packaging and Manufacturing	Maintain sterile package and manufacturing	Occasional	iii
4.2		Dangerous	User Error	Probable	iv	Labels	Warning about sterile and accurate placement	Occasional	iii
4.3		Dangerous	Valve Failure	Occasional	iii	Labels and manufacturing	Warning about handle Insertion and reduce manufacturing error	Improbable	ii



Risk Management Summary Continued:

5.1	Needle Sticks	Marginal	Unprotected needles	Occassional	ii	Packaging	Provide proper sheaths for all needles	Remote	ii
5.2		Marginal	User Error	Occassional	ii	Lables	Warn about needle safety	Remote	ii
6.1	Guide Wire Insertion	Dangerous	User Error	Improbable	ii	Lables	Markings on the guide wire indicating depth	Incredible	i
7.1	Electrical Shock	Dangerous	Current Leakage	Occassional	iii	Design	Insulation	Remote	ii