Risk Management in Medical Device Design

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What this lecture is about

- Introduction to Risk Analysis of Medical Device
- Methodology to help assess the risks of Medical Device
- Examples

Risk Assessment

- A step in Risk Management
  - Analysis and Reduction of Risks
- There are many types of risk assessments used in various industries:
  - Information Security
  - Project Management
  - Supply Chain
  - Megaprojects
  - NUS Research Labs

Risk Assessment in BN3101

- Methodology
- How to apply principle to:
  - Project Management (Design Phase)
  - Design Qualification (Design Phase)
  - Design Verification (FDA Phase)
  - Design Validation (Post market)

DFMEA – Design Failure Mode and Effect Analysis

Methodology

- Quantify Severity S (alternate L=Loss)
- Quantify Probability P (alternate p=probability of a particular incidence occuring)
- For a specific incident the **Risk** is $R_i = S_i \times P_i$
- **Total Risk** $= \sum S_i P_i$

Surgifile

What we do in practice?

Failure Mode

Analysis

Mitigation

SurgiTech	TEMPLATE						Document Number:	DHF-002-0026-02			
	RISK ANALYSIS (DFMEA)						Project Scope Reference:	DHF-002-0232-02	TMP 73007 REV B		
PROJECT NAME:	Disposable rasp & reusable reciprocating transmission						Project Responsibilities Reference:	DHF-002-0006-02			
INITIAL RISK ASSESSMENT				INIITAL RISK			Risk Control / Mitigation Measures	RISK REDUCTION (required for Risk ≥ 8)	RESIDUAL RISK		
RA #	Failure Mode	Failure Cause	Failure Consequence (Harm)	Severity (S)	Probability (P)	Risk (S x P)		Verification & Validation	Severity (S)	Probability (P)	Risk (S x P)
	Describe the product characteristic that can fail	Describe the root cause of the failure mode	Describe the potential harm to a person, property or environment				Reduce risks in priority order: 1) Inherent safety by design 2) protective measures 3) information for safety	Describe method for verifying or validating that risk control measure is effectively implemented			
1	**Operational Hazards** (function, use of the device, use error)										
1.1	Vibrations of the device reduces good control of the instrument	Excessive vibrations of the reciprocating mechanism or excessive friction in the disposable tip	Inconvenience for the surgeon	2	2	4	Measure of acceleration by internal protocol, benchmarking of existing devices				
1.2	Noise of the device is uncomfortable for the operating team	Excessive noise produced by the reciprocating mechanism or the disposable tip	Discomfort for the surgeon	2	2	4	Benchmarking of existing devices				

Tool = DFMEA Matrix

Probability
of failure due to specific cause

1 **Remote:** Failure unlikely

2 **Low:** Relatively few

3 **Moderate:** Occasional

4 **High:** Repeated failures

5 **Extreme:** Almost inevitable

Severity: Safety vs Function

RATING	Patient Safety Severity Evaluation Criteria
1	**No Health Hazard**: ▪ No physical effect of the physiological complaints anticipated
2	**Limited Health Hazard:** ▪ Extended Procedure Time ▪ Physiological complaints ▪ Temporary minor physical effect
3	**Moderate Health Hazard:** ▪ Additional procedure required ▪ Temporary but significant physical effects ▪ Permanent minor physical effects
4	**Severe Health Hazard:** ▪ Permanent significant physical effects
5	**Catastrophic:** ▪ Life Threatening

Use This

RATING	Device Functionality Severity Evaluation Criteria
1	**Insignificant**: ▪ Cosmetic defect ▪ The failure will not have any perceptible effect on the performance of the product
2	**Low Significance:** ▪ User nuisance ▪ Dissatisfaction on the part of the end user ▪ Product may be operable at reduced performance
3	**Moderate Significance:** ▪ Compromised function / loss of minor function ▪ The user may notice a negative impact on the product or system performance
4	**High Significance:** ▪ Compromised function / loss of major function ▪ Loss of system function - device completely unusable
5	**Extreme Significance:** ▪ Regulatory issue ▪ Involves non-compliance with government regulations

What is acceptable Risk?
Rule of Thumb is <8

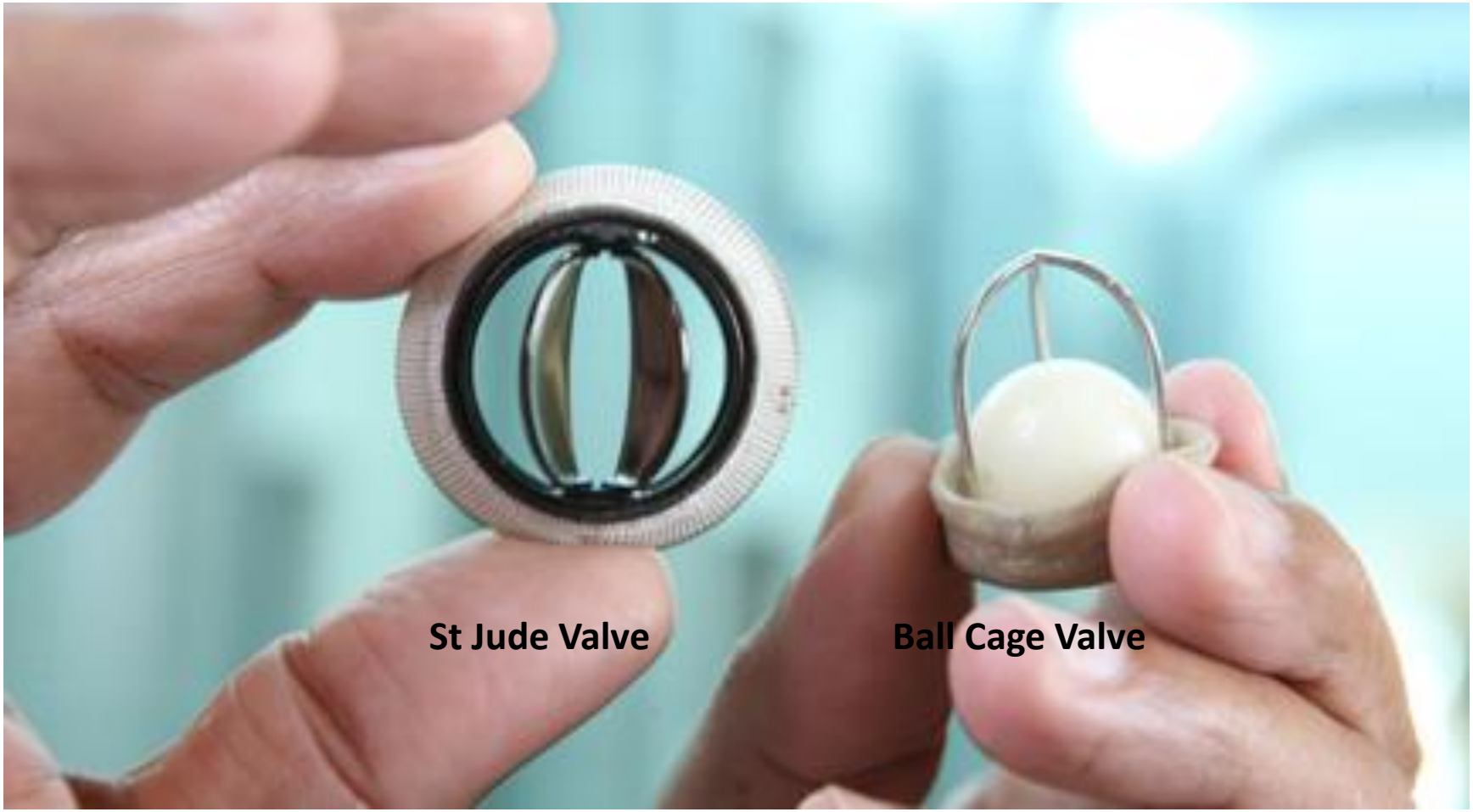
LIKLIHOOD		CONSEQUENCE				
		Minor - minor injury / adverse health outcome	Moderate - moderate injury / adverse health outcome	Serious - major injury / adverse health outcome	Major - death	Catastrophic - multiple deaths
		1	2	3	4	5
Rare – not expected to happen, but is possible	1					
Unlikely – could occur occasionally	2					
Likely – could occur in many circumstances	3					
Expected – is expected to occur in most circumstances	4					
Certain – will occur on every occasion	5					

High Risk	Medium Risk	Low Risk

Risk Assessment BN3101

Failure Mode	Cause of Failure	Harm	Initial Risk
Unable to come up with an acceptable concept			
Unable to complete to complete design			
Unable to make working prototype			

Risk Management is Specific to Design



Risk Assessment

Failure Mode	Cause of Failure	Harm	Initial Risk
Fracture of Cage Strut	Metal Fatigue	Initially there may be some leakage, failure of other struts may be accelerated.	
Fragmentation of Ball	Brittleness of material, fatigue	1. Small fragmetation may cause leaks. 2. Large fragmentation may cause immediate death	

Design Process

1. Understand the user need and clinical context
2. Background Information (depends on 1)
   - Industry Bench Marking, Patents, Adverse Events, Focus Group, Consultations
3. Design Specifications (User Specifications 1,2)
4. Concept Selection (Go back to 2 and 3)
5. Risk Management (2,3,4)
6. Detail Design (2,3,4,5)
7. Design Qualification (6,5,2,3)
8. Design Verification (Design output meets Design Input)

Risk Assessment for Design Verification

- Come up with the top 5 Risks
- Preferably all be less than 8
- Fully document them in terms of mitigations and verifications of mitigation

Design Rationale and Design Verification

- Continue on with your Design Rationale and Design Verification online lecture
- Take the assessment which will open from Thursday to Sunday