

Welcome!





Agenda

- My journey into Healthcare
- A brief overview of my Healthcare work
- Connection between mind & heart, body & soul
- Some practical examples
- What can I do today and how to overcome obstacles



My journey

into Healthcare

Crossroad



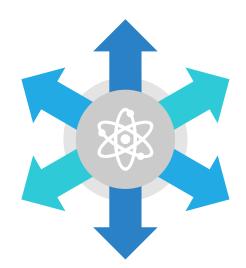


Spojená škola Tvrdošín

"Neučíme sa pre školu, ale pre život."















A brief overview

Healthcare work

Timeline





MedtronicFort Worth, Texas



YVFWC Yakima, Washington



SWHRDallas, Texas

2007

2014

2015

2019

2020

YKHC

Bethel, Alaska



HNsP Trstena Trstena, Slovakia





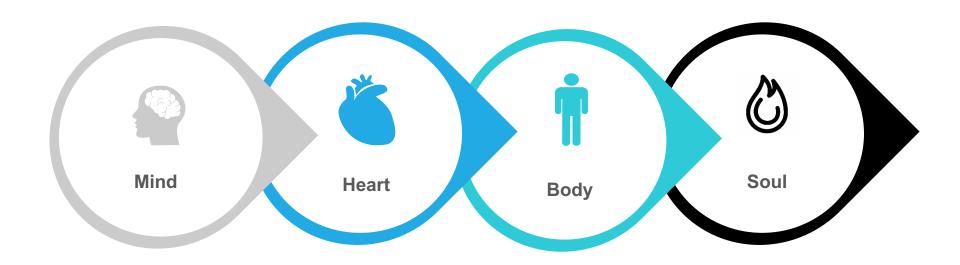


Connection between

mind and heart, body and soul

Holistic approach









Practical examples

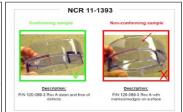
work assignments

Reactive work assignments | 1/2





Supplier Quality > Nonconformance Communication









CORRECTIVE ACTION REPORT	CAR No.:	CAR 06-0092
(CAR) FORM	⊠ CA □	PA

	Initi	ation/Background	Information (CAPA Coordina	itor / Owner)	
Product Description / Quality System	Part	#100-580-4	(Length Dimer	nsion) for	CAR Initiation Date	10/11/06
	CA	R Source			Initial Risk Asset	sment
Management Review P Quality Review Board Complaint No. NCR No		CAPA System Re Investigation (Inv. Department Mana Other:	No)	RAW #: (Attach cop)	NA- v of risk assessment)	□ R1 □ R2 □ R3 □ R4
Root or Probable Cause (If CAR source is not an Investigation)	CAR #06-0 failed incor limit of .314 for this dim	R source is an Investigatic—` 012 was issued to ning inspection beca !". The initial implem ension was not succe ts with a proper lenger	after use the overall ler entation plan to p essful. The capat	ngth on 17 p erform 1009 pility o	arts fell below the % inspection on all nanu	00-580-4 and one lot lower specification subsequent parts cess to
CAR Owner		500.00 100.00	Responsib	le Departn	ent Quality Ass	surance
		CAR Imple	mentation Plan	1 (Owner)		
Description of Corrective/ Preventive Action to be implemented: OR Attach a CAR Plan it the activities required are complex.	determin necessar months of be requir	will begin capturing t es for the length dim ed from the data and y. The current of production. Once ed by s for the length dimer	ension on the 100 copropriate actio iventory levels begins many to provide	0-580-4 part. ons will be ta for the 100- anufacturing de in-proces	. The capability of	the process will be capability as sufficient for 3 to 4 rts again, they will
Implementation Due Date	05/31/0	7 te to CAPA Coordinator with	- 14 1			ion Due Date Extended
Additional Team Men Requested? Yes (The Addition of Team Mem Requires ORB Approval)	nbers No	Name	Department		Name	Department
Proposed Criteria to Determine CAR Effectiveness	Th by manufac dimensio	tured fo The	xt three production	on lots of the	100-580-4 parts t	n must be provided hat are n-conforming length
	Initial Plan	Approval (Owner, Ov	wner's Supervisor, & C/	APA Coordinate	runless resources added)	
Owner		-	-		10/25/200	6
R&D			-			
Manufacturing			_			
Quality			_		10/25/06	
Other			_		1 1/00	
RA*			-			
CAPA Coordinator	Ci	udes delles		10	laston	
		Previde Original to	CAPA Coordinato	r After Appr	oval	

Reactive work assignments | 2/2



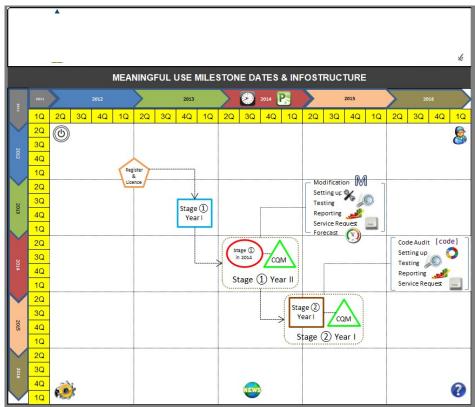
Problem Statement	Project Y	Path Y's (If ne	Path Y's (If needed)				
Diamond coating yields at diamond coater, are below 96% causing shortages, affecting to meet customer demands	Production yield (PY>97%)	Rolled Throughpu	ut Yield				
Project Goal	Scope						
Increase diamond coating yields at I to greater than 97 % by August 2011	Scope includes: Diamond coating process through receiving inspection at Medtron Scope excludes: Transit, stem material, Medtronic packaging Do not harm: Dimension of the product, durability of diamond coating						
Resources	Business Impact ar	nd Benefits					
Project Team:	Schedule: -Project start date: January, -Estimated project completio -Estimated date when benefit Benefits:	n date: August, 2011	31K				

		Lean Six Sig	ma l Production Proje	ect			
		January-May 2011 (F	rior Improve Phase)	June - August 2011 (Current State)			
L NCR Reduction	1	Quantity (No.)	Cost(\$)	Quantity (No.)	Cost(\$)		
	ľ	4	3485	0	0		
II. Scrap Reduction	F	January-May 2011 (F	Prior Improve Phase)	June - August 2011 (Current State)			
	2	Quantity (pos)	Average Srap (%)	Quantity (pos)	Average Scrap (%)		
		1868	4.684	1305	2.087%		
		January-May 2011 (F	rior Improve Phase)	June - August 2	011 (Current State)		
II. Component Quantity	3	Quantity (pos)	Average monthy receipts (pcs)	Quantity (pos)	Average monthy receipts (pos)		
,		49327	9865	61284	20428		
IV. Savings	4		Savings	Medtronic Inc. Saving			
iv. Javings	*	400 pcs X \$6 > \$	2400 per month	400 pcs X \$10 >\$4000 per month			
V. Other	٠				-		
> MPSS Inspection time	5	Receiving inspection fo	or curve burrs the same	Receiving inspection for curve burrs improved (Ultrasonic cleaning process			
Rework process	6	AVG Feb-May 2011 (Over	plated, Sparse) 9.08%	AVG June-August 2011 (Overplated, Sparse) 2.47%			
> Inspection method variation	7	No visual methods of inspection est	ablished between MPSS & Di-Coat	Visual methods of inspection established & alligned			
. Operational & process metrics	8	Operational & proce	ss metrios the same	Weekly meetings / Data colle	ction / Data analysis established		
What's next?	Ī	Complete drawing revisions	Drive excellence to improve Op. 40	Continue focus on XOMED curve burrs	Complete transfer to Plant No. 3		

Proactive work assignments | 1/2

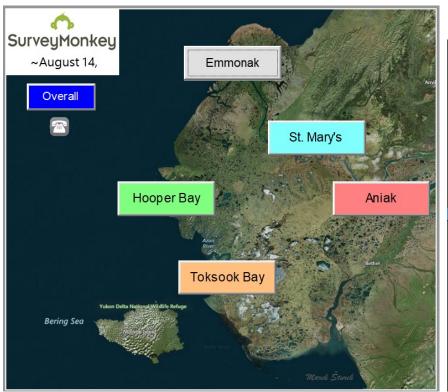


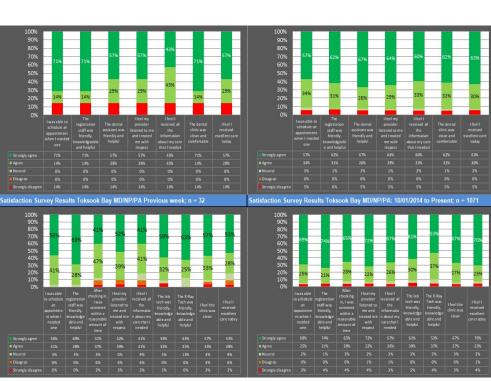
		RISK AN		3	RISK ANALYSIS TRACKING NO:	RAW07-	0013	Rev.NEW
		Works	HEET		NCR / COMPLAIN	r#/OTHER	07-017	8
INITIATOR:						DA	TE INIT	TATED: 2/8/07
Primary Event Descr (Include how the event was di and the facts surrounding the	scovered	Lubricant prior to instal	ation. 2. Als	o, step	093800-10. 1. O-Ring w 4 of work instruction, insiddle of step 3 before ins	serting collet	housing i	into
Primary Event Source	e: (selec	t one)						
☑ Internal Source	and the second			Extern	al Source			
State Failure Effects:	1. O-Ring o	Attached could become damaged e effect is associated to			ence.		į.	
State Potential Clinical Effects:	See A	Attached clinical effect of either s	ituation 1 o	r 2. The	risk is completely transp	parent to the	doctor ar	nd patient.
State Potential Event Cause(s):	See A	Attached rror - not following work	instructions.		2			
SEVERITY 4-Critical 3-Major 2-Minor 1-Negligible	purpose. T 2. Inserting	a: cose of the O-Ring on the here is no risk to the doo the collet housing into the collet performance. N	tor or paties he compres	nt. sion nu	f prior to inserting cellet	arrier into o	let hous	ing has NO
FREQUENCY 4-Frequent 3-Occasional 2-Remote	Rationale Work instra	a: uctions are provided for a	perator at	every w	ork station, but human e	rror is occasi	onal.	
1-Improbable	Rational	e: Ring is cut, it may not be	detectable	to the o				
DETECTABILITY 3-Not Detectable 2-May be Detectable 1-Readily Detectable	1. If the O-	rang assembly steps out of	f order wou	ld not b	e detectable unless four	d during an	audit.	
DETECTABILITY	1. If the O-	raing assembly steps out o	f order wau	ld not b	e detectable unless four	d during an	audit.	
DETECTABILITY	1. If the O- 2. Perform	ing assembly steps out of	f order would be seen and the	R1	e detectable unless four	ust be mit	gated	
DETECTABILITY 3 -Not Detectable 2 -May be Detectable 1 -Readily Detectable Calculate RPN Severity X Frequency)	1. If the O- 2. Perform	ing assembly steps out of	f order would be seen a seen	R1 R2	Intolerable Risk; n	ust be mit	igated nitigate	d per Table 4
DETECTABILITY 3-Not Detectable 2-May be Detectable 1-Readily Detectable Calculate RPN	1. If the O- 2. Perform	ing assembly steps out of	f order would be seen and the	R1	e detectable unless four	ust be mit must be r ble; may r	igated nitigate equire	d per Table 4 mitigation
DETECTABILITY	1. If the O- 2. Perform (Detectab	lity = RPN	≥ 24 12-23 5-11 1-4	R1 R2 R3 R4	Intolerable Risk; m Unacceptable risk Marginally accepta Acceptable; mitiga	nust be mit must be rable; may ration not re	igated nitigate equire i quired	mitigation
DETECTABILITY 3 -Not Detectable 2 -May be Detectable 1 -Resettly bectable Calculate RPN Saverity X Frequency 1 X 3 X 3 = Approved By: (Extern	1. If the O- 2. Perform (Detectab	ing assembly steps out of	≥ 24 12-23 5-11 1-4	R1 R2 R3 R4	Intolerable Risk; m Unacceptable risk Marginally accepta Acceptable; mitiga	nust be mit must be rable; may ration not re	igated nitigate equire i quired	mitigation ality ory signature)
DETECTABILITY S-Not Detectable 2-May be Detectable 1-Readily Detectable Calculate RPN Severity X Frequency 1 X 3 X 3 = Approved By: (Extern Egigne Department	1. If the O- 2. Perform (Detectab	lity = RPN	≥ 24 12-23 5-11 1-4	R1 R2 R3 R4	Intolerable Risk; m Unacceptable risk Marginally accepta Acceptable; mitiga	nust be mit must be r able; may r tion not re Sources rec act requires	igated nitigate equire i quired uire Qua Regulate Da	mitigation ality ory signature)
DETECTABILITY 3 -Not Detectable 2 -Niky be Detectable i -Readily Detectable i -Readily Detectable Calculate RPN Severity X Frequency > 1 X 3 X 3 = Approved By: (Externess Engineering Department Ouality Engineering	1. If the O- 2. Perform (Detectab 9 nat Sources rering, Manuf	lity = RPN	≥ 24 12-23 5-11 1-4	R1 R2 R3 R4	Intolerable Risk; m Unacceptable risk Marginally accepta Acceptable; mitiga	nust be mit must be r able; may r tion not re Sources red act requires	igated nitigate equire quired pure Qui Regulate Da	mitigation ality ory signature)
DETECTABILITY S-Not Detectable 2-May be Detectable 1-Readily Detectable Calculate RPN Severity X Frequency 1 X 3 X 3 = Approved By: (Extern Egigne Department	1. If the O- 2. Perform (Detectab 9 nat Sources rering, Manuf	lity = RPN	≥ 24 12-23 5-11 1-4	R1 R2 R3 R4	Intolerable Risk; m Unacceptable risk Marginally accepta Acceptable; mitiga	nust be mit must be r able; may r tion not re Sources rec act requires	igated nitigate equire quired pure Qui Regulate Da	mitigation ality ory signature)



Proactive work assignments | 2/2

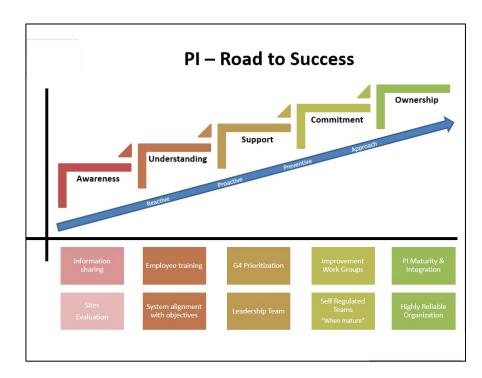


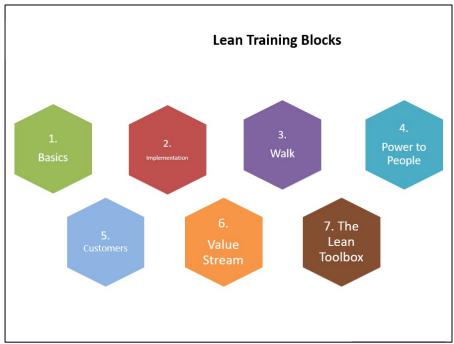




Preventive work assignments | 1/2

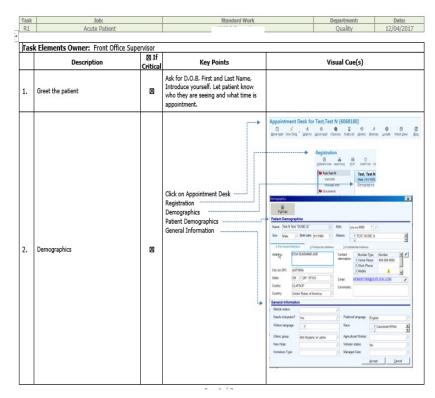






Preventive work assignments | 2/2





HFMEA Subprocess Step Title and Number														
		HFMEA Step 4 - Ha							Ţ.		HFMEA Step 5 - Identi	fy Actions and Outcomes		
Failure Mode: First Evaluate failure mode before determining potential causes	Po	otential Causes	Severity	Probability 0	Haz Score	-	Existing ois Control u Measure?	Detectability N	Proceed?	Action Type (Control Accept, Eliminat e)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management
		•	Major	Frequent	12	N	N	N	Y					
(spa	1	Gender, Age in same room	Moderate	Frequent	8	Υ	N	N	Y	N/A	State and Joint Committion regulations			
ER 2 b	2	Hight volume of patient	Moderate	Frequent	8	N	N	N	Y	Control	Review staffing plan for North Wing and ER in order to establish more effective patient service	Effective patient service measured by Patient Satisfaction, Decreased length of stay	Carrine, Rachelle, Jeff	Barba , Ray
beds,	3	Staffing	Moderate	Frequent	8	N	N	N	Y	Control	> Create guidelines for addmition > Review staffing plan on North Wing > Training status			
atient 3	4	Lack of guards	Minor	Occasional	3	N	N	N	N	Accept				
ty (Inp	5	Intoxication (High acquity)	Major	Frequent	12	N	N	N	Y	Accept				
alibili	6	Insufficient # of room	Major	Frequent	12	N	N	N	Y	Control				
Bed avalibility (Inpatient 3 beds, ER 2 beds)	7	Mechanical issue	Moderate	Uncommon	4	N	N	N	Y	Control				
ď	8	Standardization	Moderate	Occasitonal	6	N	N	N	Y	Control				
	9	Waiting Judge, API Response, BH clinicial	oderate	requent	8	N	N	N	Y	Accept				



What can I do

how to overcome obstacles

8 steps according to JOHN KOTTER

- Urgency of change
- Coalition supporting change
- Clear vision
- Communication of vision
- Stronger employee engagement
- Short wins
- Support of next change
- o Hardwiring change





Thank you & Questions