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Purchasing of surgical instruments

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Introduction

- Frank Raymaekers
- Expert sterile medical devices
- Unitmanager material management



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Erasmus MC university medical center Rotterdam:



Primary function	<ul style="list-style-type: none"> ▪City Hospital ▪University Medical Center
Beds	1221
Employees	10.000
Number of admittances	36.204
Budget	€ 743.000.000
Organization	Sophia children's hospital Daniel den Hoed oncology Thoracic centre Centre location
Yearly production CSD	<ul style="list-style-type: none"> •Sets: 95.000 •Single instruments 110.000 •Yearly increase 2.7 procent (last two years)

Unit material management



Corebusiness:

- Material management
- Management of the Quality management system
- Consultancy
- Projectmanagement
- Troubleshooting

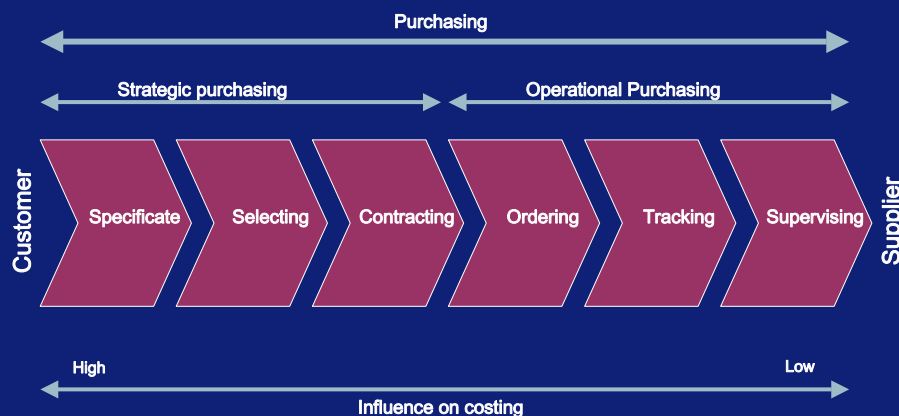
Material Manager: tasks in relation to purchasing

- The material manager is the intermediate between the purchasing department and the users of medical devices.
- "Translates" wishes and demands in Program of Demands
- Coordinates implementation
- Registers and coordinates faults and complaints regarding medical devices



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The professional purchasing process



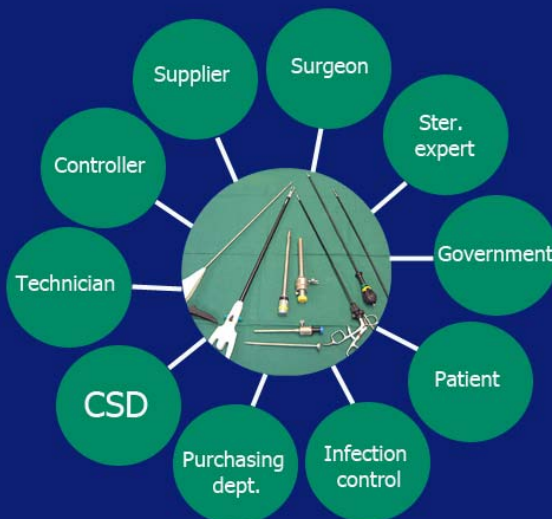
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Main objective of surgical instruments in the past

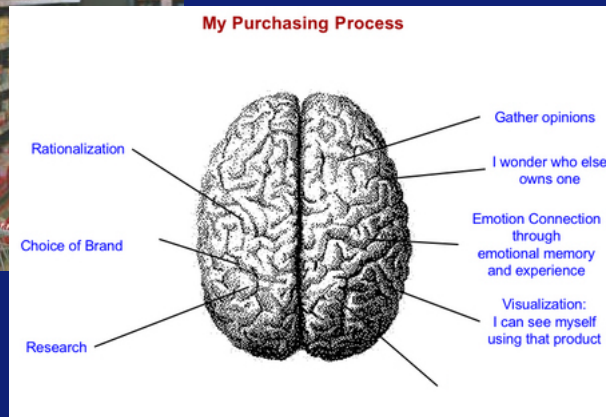
- “only conditions that brought patients near death warranted the risk of surgical intervention. If patients survived the operation, infection was nearly inevitable and death by overwhelming sepsis was knocking at their door”
- Instruments were made by blacksmiths or by surgeons themselves
- The primary purchasing demand was of course..... sharpness!



Stakeholders purchasing complex surgical instruments

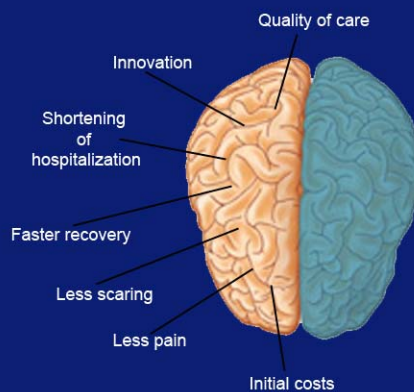


Personal choices



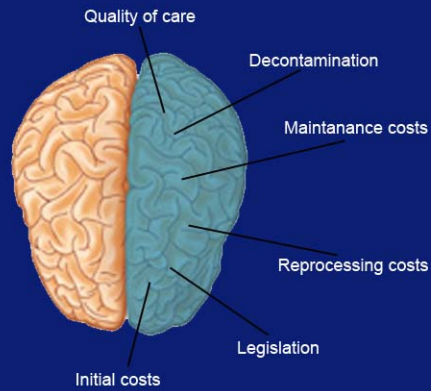
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The surgeon's purchasing demands



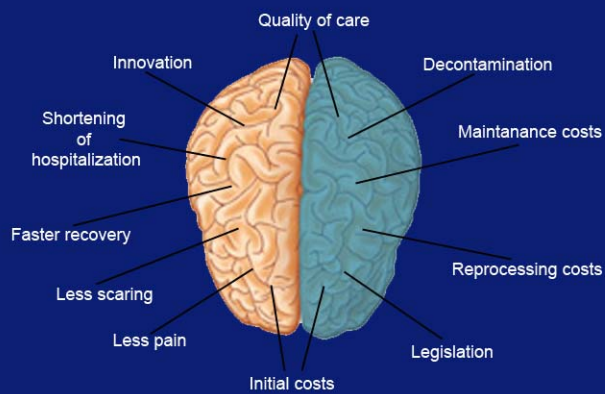
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The CSD's purchasing demands



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The combined purchasing demands



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Who's demands tips the scale?



- The surgeon?
- The CSD'?
- Infection prevention?
- Controller?

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Purchasing route:

- Buying is achieved through a direct contact between the customer and the Purchasing Department, without having a structured operational meeting related to the product
- Purchasing through multi – disciplinary consultations on the product that is needed.
 - A Program of Demands is an important aid!



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The Program of Demands is a structural list with conditions to which the offered solution must comply

- by describing the different expectations precisely
- making an inventory, structuring and there where necessary giving direction to the expectations
- keeping the oversight
- a means of communication between the team members, the buying and the selling party
- final selection, objective, measurable, transparent and simple
- exchange of Programs of Demands provides standardization, harmonization and “not inventing the wheel” time and time again
- the Program of Demands provides cost reduction and supports the discussion to go ahead with the purchase

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Conditions for the Program of Demands:

- no solution should be formulated
- space needs to be given to innovations, where wanted
- “hard” conditions based on validated data
- “soft” conditions must be made measurable
- conditions to be interpreted in a single manner
- prevent unwanted variations in the offerings
- all aspects of the product (functional) have to be covered

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Example

		Wegingsfactoren:	Scoren: *niet door lev				
g: gebruiker d: decubitus m: microbiologie a: AVM		3 = vereist, knock-off (wie hier niet aan voldoet valt af)	+2 = onvoldoende	Weging	score	-2	-1
		2 = vereist (geen knock-off criterium)	+1 = matig				
		1 = gewenst (geen knock-off criterium)	+1 = goed				
			+2 = uitstekend				
						1	2
		Het is vereist dat het AD-systeem					
AD-eigenschappen	g 1	dusdanig gebruiksvriendelijk is dat de toepassing geen nadelige effecten heeft op de behandeling en verzorging van de patiënten					
	g 2	zelfredzaamheid, mobiliteit van de patiënten, tijdens het verblijf op de AD, niet nadelig wordt beïnvloed					
	g 3	kans op					
	g 4	fixatie v					
	g 5	passen					
	d 6	maatvo					
	d 6	ligcomf					
	g 7	gewicht					
	g 8	een pos					
	g 8	door zijn uitvoering een positieve bijdrage levert aan het uitvoeren van onderzoek en behandeling					
	d 9	passen bij de op het moment van aanschaf geldende normen voor druk, schuif en wrijf (frictie) krachten, waarbij optimale drukverdeling en drukverlaging uitgangspunten zijn (geldende normen aangegeven door UMCG)					
	g 10	gebruik niet leidt tot verhoging of verlaging van de lichaamstemperatuur tenzij geïndiceerd					
	g 11	geen actieve bijdrage levert aan het zweten van de patiënt					
	g 12	electrische apparatuur geen resonantie geeft aan de bedden en een geluidsproductie heeft van max 40 dB gemeten op een afstand van 1 meter van de elektrische apparatuur					
	g 13	mogelijkheden bieden tot reanimatie, inclusief defibrillatie, met een aanvangstijd van maximaal 10 seconden					
	g 14	na reanimatie de uitgangssituatie van het matras binnen 1-3 minuten weer is bereikt					
	g 15	bij stroomonderbreking de werking van het systeem gedurende minimaal 2 uur op druk blijft					
	a 16	het gewicht van het AD valt binnen de geldende ARBO normen, m.b.t. tilgewichten					
	a 17	dienen gefabriceerd te zijn van brandveilige materialen en ook voorzien van een dusdanige verklaring					
		Totaal	103			3	2

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What can we learn from a PoD: The retractor

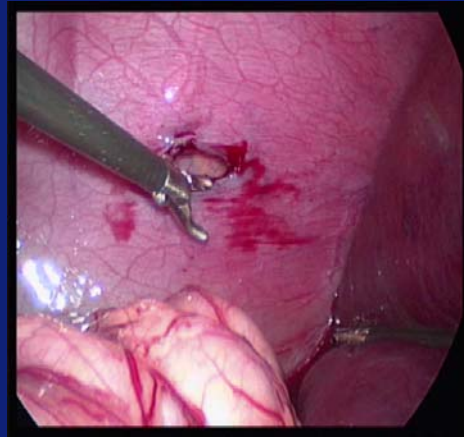
- Designed in the early nineties
- No more modifications since then



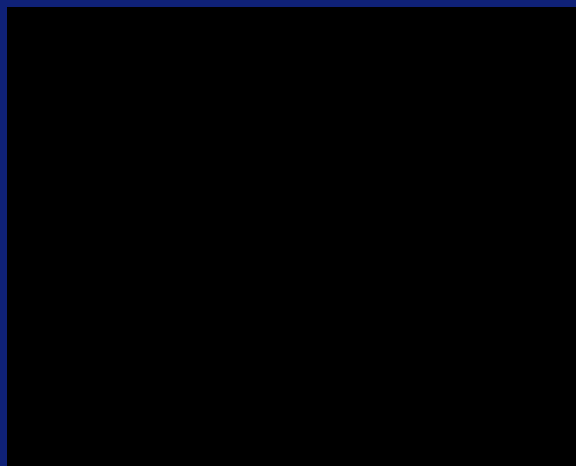
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Functional demands

- The retractor should not damage the tissue of a child more than conventional retractors used in adults.
- The product needs to retract a lung, stomach, liver, kidney or spleen without the help of other instruments.
- The functions of the product should be clear or comparable with existing instruments
- The retractor should lift at least 261 gr. (this is the right lob of the liver of a two year old, and is the biggest organ to be retracted)



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Legal demands

- The retractor complies to the Medical Directive 93/42
 - Thus complying to the essential requirements

1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

8. Infection and microbial contamination

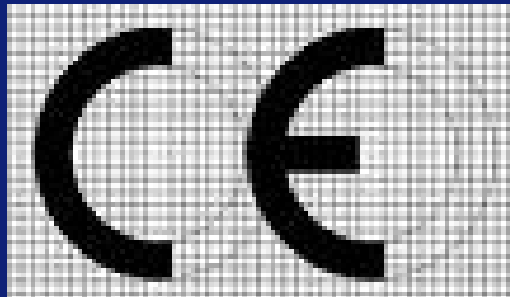
8.1. The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.

Legal demands: Classification

Rule 6

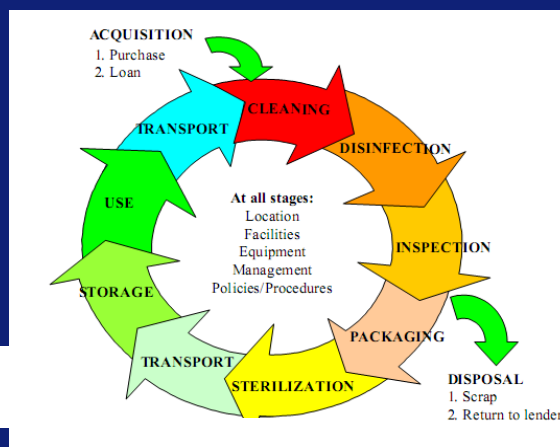
All surgically invasive devices intended for transient use are in Class IIa unless they are:

- Reusable surgical instruments, in which case they are in class I
- This means that the Technical Files regarding surgical instruments are not evaluated by Notified Bodies.



Decontamination demands

- The instrument must be suitable for decontamination
- The instrument must be compatible with the decontamination process on site.



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Decontamination instructions

Step 1	- 30 minutes of soaking in a detergent, - flush the lumen minimal 3 times with 50 cc, - Bring the instrument in a angulated position and wiggle the distal tip for a minimum of 3 times:	OR
Step 2	After cleaning rinse with aqua dest. Via the flush opening	
Step 3	20 minutes in a ultra soon	CSD
Step 4	After the ultra soon rinse again with aqua dest.	
Step 5	Automated disinfection isn't included in this instruction	
Step 6	Lubricate the instrument thoroughly every time	
Step 7	3 minutes of drying time before Autoclaving	
Step 8	Autoclaving	

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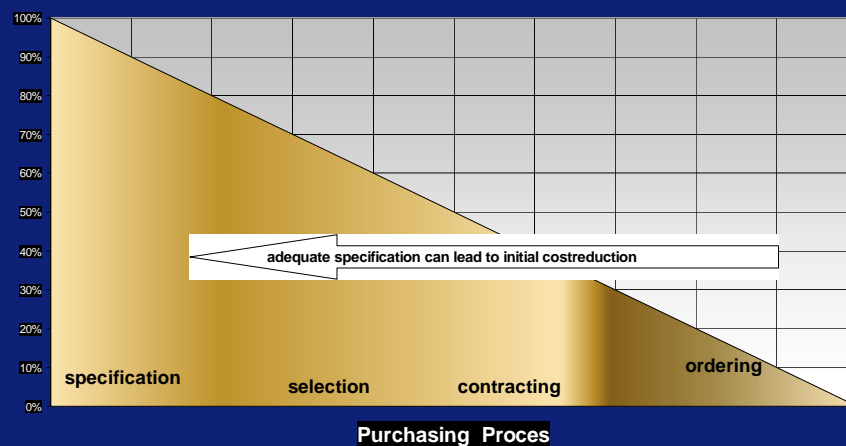
Commercial demands

- initial purchasing costs within budget
- Total Cost of ownership within budget



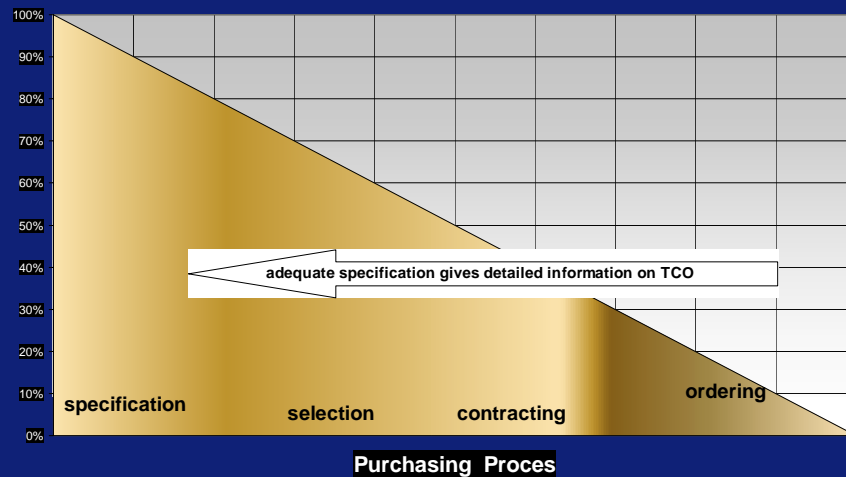
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Professional Purchasing Process



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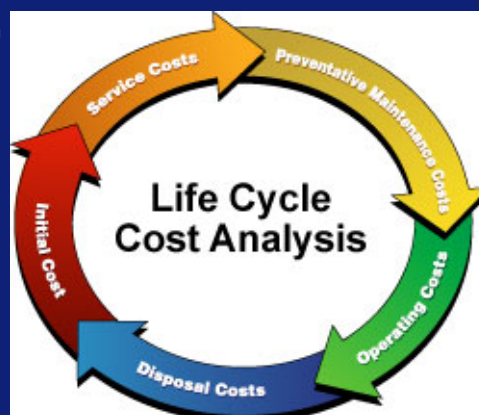
Insight on Total cost of ownership



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Total cost of ownership (TCO)

- Is a method of calculating both the direct and the hidden costs of an equipment purchase.
- In many cases a products hidden costs are greater than its actual purchase price.
 - Initial costs
 - Decontamination costs
 - Maintenance costs
 - Operating costs
 - Service costs
 - Disposal costs



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Developments

- Natural Orifice Translumenal Endoscopic Surgery (NOTES)
- Surgery for Obese
- Further development of Minimal invasive surgery
- Nanotechnology (coating of instruments)



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Keynotes

- A lot of stakeholders
- With a lot of different demands
- Therefore purchasing of surgical instruments can be complex and time-consuming
- Nevertheless it is necessary to gain insight prior to the purchase of instruments regarding:
 - Total cost of ownership
 - Consequences for other disciplines
 - CSD
 - OR staff
 - Logistics.
- A Program of Demands and a TCO analysis are important aids
- My recommendation is that a standardized PoD with the demands of the stakeholders is available for surgeons and OR's

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Thank you for your attention!

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