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Evaluation of the Cleaning Efficiency of an Aqueous Based Detergent System for Cleaning Metallic Medical Devices

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Evaluation of the Cleaning Efficiency

- Introduction
- Scope
- Approach
- Results
- Conclusions

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Introduction

- To ensure consistent removal of manufacturing materials 21 CFR 820-70 and other contamination to predefined limits.
- ISO 13485, Section 6.4 / ISO TIR 14969, Section 6.4.2.2 requires that controls be established where the manufacturing environment could adversely impact product.

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Evaluation of the dipping bath cascade

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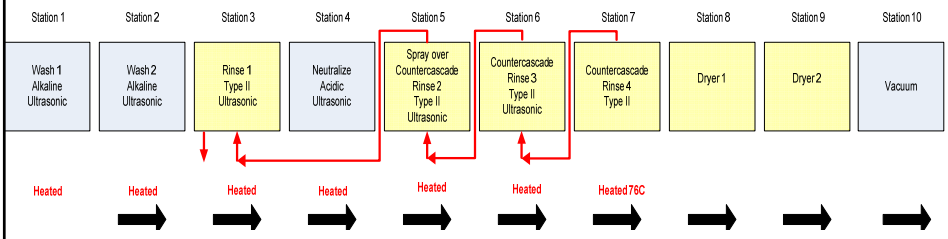
Robotic cleaning system



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Test methods used

- Approach and Methods
- Potentiometric Titration three times a week
- pH and Temperature measurement

Fig. Titrino & Autorepipet : tools used for the potentiometric titration

- Chemical Cleanliness Analysis of three different implants, three specimens per method: a total of 135 specimens analyzed

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Stability of the detergent?

	Content Decrease/ %		
	Bath 1	Bath 2	Bath 4
Week 1	10.4	10.8	17.7
Week 2	2.3	2.3	12.4
Week 3	3.9	4.1	11.9

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How do we ensure the detergent content?

- Systematic Deviation between potentiometric and visual Titration :

Calculated Top-up quantity*/ l	After 1 Week		After 2 Weeks	
	Pot Titation	Vis Titration	Pot Titration	Vis Titration
Bath 1	2.61	2.12	1.88	1.73
Bath 2	1.99	1.09	1.71	0.92
Bath 3	4.22	3.55	3.42	2.69

* Calculated from the Sodium Hydroxide/ Hydrochlorid Acid Usage and the multipliaction factor from the technical sheet

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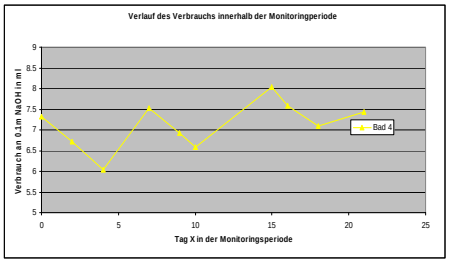
Cleanliness validation

Direct Analysis

Continuous Decrease of Detergent Concentration within a week.
Different Concentrations at the Beginning of the three weeks
After comparing the data: systematic deviation from the results of the visual Titrations



Product-related Analysis

With the actual life cycle, the required chemical cleanliness is generally assured.
No decrease of the chemical cleanliness was observed either within the week or three weeks.

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Cleanliness validation

Part Description & Characteristics	Chemical Cleanliness Prior to the Cleaning Step		Chemical Cleanliness After the Cleaning Step	
	Average in mg/ Part	Max Value in mg/ Part	Average in mg/ Part	Max Value in mg/ Part
Hip Cup / Challenging Surface	Organic Residue: 5.9 TOC: 0.21 Ionic Residue: 1.24 Particulate Residue: 15.7	Organic Residue: 6.0 TOC: 0.22 Ionic Residue: 1.30 Particulate Residue: 23.6	Organic Residue:<0.5 TOC: 0.07 Ionic Residue: 0.07 Particulate Residue: 0.6	Organic Residue:<0.5 TOC: 0.08 Ionic Residue: 0.08 Particulate Residue: 0.8
Hip Stem / High Production Rate, Challenging Geometry	Organic Residue:<0.5 TOC: 0.09 Ionic Residue: 0.14 Particulate Residue: 2.9	Organic Residue:<0.5 TOC: 0.11 Ionic Residue: 0.19 Particulate Residue: 3.7	Organic Residue:<0.5 TOC: 0.05 Ionic Residue: <0.05 Particulate Residue:<0.2	Organic Residue:<0.5 TOC: 0.06 Ionic Residue: <0.05 Particulate Residue:<0.2
Femur Component / Highly porous surface	Organic Residue: 2.6 TOC: <0.05 Ionic Residue: 0.09 Particulate Residue: 0.4	Organic Residue: 2.9 TOC: <0.05 Ionic Residue: 0.09 Particulate Residue: 0.4	Organic Residue:<0.5 TOC: <0.05 Ionic Residue:<0.05 Particulate Residue:<0.2	Organic Residue:<0.5 TOC: <0.05 Ionic Residue:<0.05 Particulate Residue:<0.2

Table 1: Average Results: Total Organic Carbon (TOC), Organic Residual, Ionic Residual, Particulate Residual

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Conclusions

1. Effect of the detergent concentration was studied by monitoring of the detergent baths. It was done via proven titration methods. Concentration of the detergent is important to ensure the cleanliness of the implants.
2. It is important to know the minimum and maximum concentration to meet the cleanliness requirements. This should be the starting point for the optimisation of a cleaning process.
3. Chemical residues on the implants are low after the cleaning process as expected.
4. An optimized cleaning process enhances consistancy and predicatbility of the cleanliness of implants in accordance with CFR 211.611.

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Thank you for your attention

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