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Saga evaluation With HUS Testbed

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Smarter solutions for fluid collection, disposal and management.



Rely on the essential in fluid collection



Serres Suction Bag System

Creating value disposal-by-disposal



Serres Nemo



Serres Saga

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Serres Saga

Pioneering surgical flows









Background

Previously performed at hospitals in an office environment, or in our office in Espoo with intended users (Operating room nurses):

- Validation of user needs
- Concept/Prototype evaluation with intended users
- Formative usability evaluation
- Summative usability testing
 - Testing risk reduction measures



Problems:

Some questions remained unanswered

- About the use of space, visibility and lightening
- About connection from the operating site
- About cleanability of the device

Are alarm colors visible enough in the ambient lighting conditions in the OR?

Is it possible to position Saga close enough to the patient / surgeon?

Connection of Saga from the operating site with relevant instruments Cleaning procedures between patients

Are we missing something, are we ready for clinical investigation?



HUS Testbed solution



Additional evaluation in a real operating room setting with intended users but without patient

Scope of the evaluation

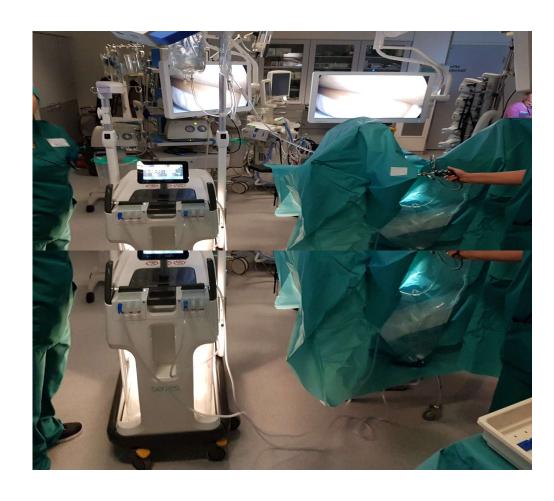
- Testing of Saga training procedure
- Usage of Saga in a simulated surgery
- Review of the device for cleanability



Results

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- Training procedure approved by intended users
- Minor problems revealed triggering immediate couple of product changes
 e.g. too sensitive suction alarms, too intense lightening, wrong hook shape
- Input for clinical investigation plan
- Input for improvement opportunity
- Confidence in device readiness for clinical use
 - HUS Testbed evaluation 15.2.2019
 - Clinical investigation started 22.3.2020
 - Serres Saga received CE certificate 22.8.2019



Experience with HUS Testbed



- Able to accommodate specific needs and mobilize users based on needed profile (e.g. experience with certain surgical specialty)
- Able to accommodate tight schedule
- Nurses participating in the evaluation very experienced and professional
- Nurses able to reflect more objectively on the device usage when in their normal working environment instead of office environment
- Motivation boost for the development team to see the device in the intended operating room environment





Serres is the progressive leader in smart fluid management solutions



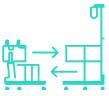


Focused

on high quality fluid management solutions.



1973 founded.



Pioneer

in safe and smart solutions around surgical suction.



Finland

HQ, design & manufacturing.



200

employees.



Environmental

by being smart across the lifecycle.



Global

distribution network with sales in 50+ countries.



30M€

turnover.