Reinigbare MIC-Instrumenten: een uitdaging voor de ontwerper

Friedrich-Wilhelm Oertmann
Director Group Project Management
R&D Electronic / Steriltechnology / Endoscopy

Am Aesculap-Platz
78532 Tuttlingen
Germany

REQUIREMENTS

Function

Surgical Instrument

Laws Standards

Reprocessing
MIS Instrument

- **SURGON**
  - function
  - tactile
  - strong

- **CSSD**
  - reprocessable
  - easy to clean
  - good for washing machine
  - steam sterilizable
  - all chemicals

- **Regulatory**
  - substantial requirements
  - risk management

**Easy to clean**

**Tactile**

**Strong**

**Price**

**Function**

**Risk**

**Steam sterilizable**

**Build**

**Function**

**Easy to clean**

**Tactile**

**Strong**

**Price**

**Risk**

**Steam sterilizable**

**Build**
Development always means to take into consideration:

- the time period
  - the legal environment
  - the main business market
  - the medical setting
  - exceptional events
  - state of technology
  - material knowledge

Development was dominated by the surgeon and the technology.

Risk analysis was done by the doctor not by the technician.
Start of MIS

Endoscopes are available
adequate function
easy to clean
but
no sterilization

the answer
Requirement list

1. Generation of MIS Instruments (End of 80’s)

- Function
- Reliable
- steam sterilizable
- Regulatory
- Production process

Result

- Non Detachable Instrument
- Jaw parts „hand made“
- Electric Isolation by heat shrinking tube (electric breakdown)
- steam sterilizable
- cleaning?
Requirement list

2. Generation of MIS Instruments (Mid of 90's)

- Function
- Reliable
- Reprocessing
- Production by CNC Machines
Result

- Detachable Instrument to have a safe sterilization
- Electrical Isolation by PEEK Tubes
Development was affected by 2 very different events

- Medical Device Directive becomes effective
- Creutzfeldt-Jacob-Disease (vCJD)

Medical Device Directive

Reusable products must have statements of adequate reprocessing procedures for example cleaning, disinfection and sterilization procedures...
vCJD

Diseases up to 2001:
- 94 in UK
- 3 in France
- 1 in the Republic of Ireland

In Germany up to 2005 no case of vCJD*

To get instruments free of prions that time there was no idea how to get it today?

RKI Task force report 2002:
- Autoclave 134° for 18 min is not enough
- Additional alkaline cleaning above 55° C

→ SUSI (Single Use Surgical Instruments)
Alcaline Cleaning

Alkaline cleaning is a must since that time for all new instruments - in Europe not in the US -

that means

- no aluminum
- reduction of polymers
- special technique for joining parts
**Requirement list**


- Function
- Reliable
- Validated reprocessing
- Regulatory
- Production process
Result (Reusable Instrument)

- Detachable Instrument
- Fragile
- Electric Isolation by PEEK
- Validated Reprocessing
- Limitation of Life cycles
Result (Single Use Instrument)

- Tactile
- Strong
- Electric Isolation by heat shrinking tube
- Reprocessing not possible

Result (Reusable Needle Holder)

- Non Detachable Instrument
- Strong
- Electric Isolation by PEEK
- Validated Reprocessing
- No control of cleaning
DIN EN ISO 17664:2004

- requires a validated process

but not a special validated process

the process is the choice of the manufacturer
DIN EN ISO 17664

- allows

very special cleaning procedures
very special sterilizing procedures
(for example 143° 18 min, gravity process for 40 min)

It is important to know the reprocessing parameters before buying the instrument

Instruction of Use according DIN EN ISO17664 does not guarantee to fulfill

YOUR

Requirements for the Reprocessing Process
Welcome to Aesculap Extranet

Instruction of Use

Have a look in the Instructions of Use

AESCULAP Extranet:

http://www.aesculap-extra.net

Thank you for your attention!