

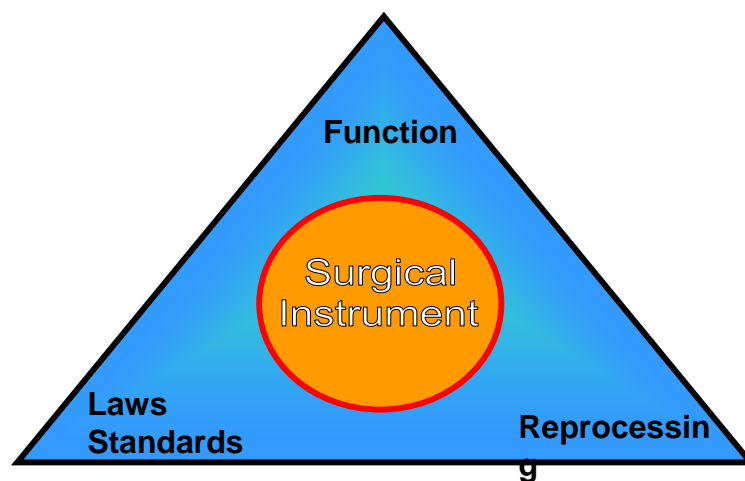
Reinigbare MIC-Instrumenten: een uitdaging voor de ontwerper



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R&D Electronic / Steriltechnology / Endoscopy

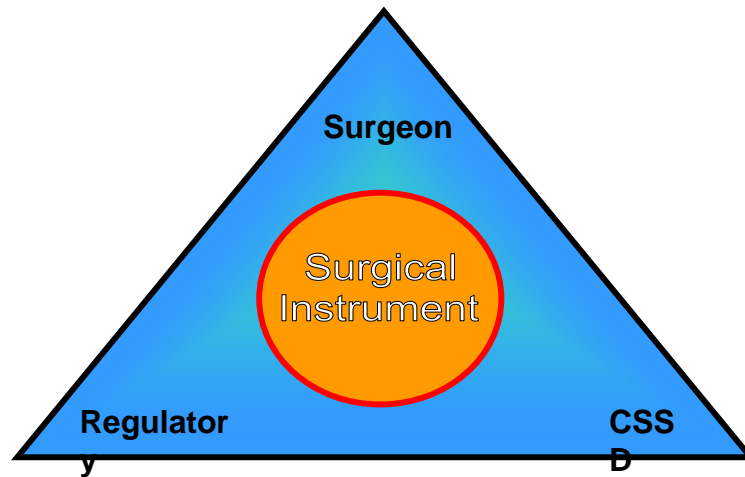
Am Aesculap-Platz
78532 Tuttlingen
Germany

REQUIREMENTS

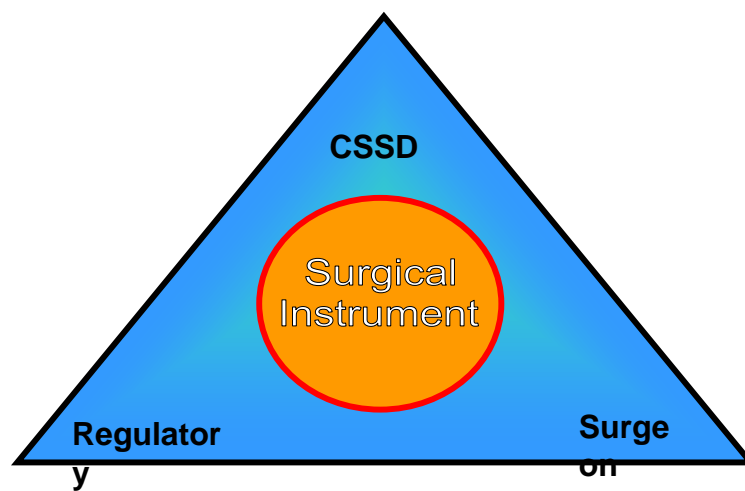




REQUIREMENTS



REQUIREMENTS



MIS Instrument

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

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

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



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
 - ✓ production technology

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development was dominated
by the surgeon and the technology



the
technician



risk analysis was done by
doctor not by the

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Start of MIS

Endoscopes are available

adequate function

easy to clean

but

**no
sterilization**

Cidex



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**the
answer**



NEW

Autoklavierbare Arthroskope

NEW

Autoclavable Arthrosopes

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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?





Scheren
Scissors

AESCULAP®

MERKMALE

- METZENBAUM-Scheren mit eingesetzten Hartmetall-Schneiden bieten:
 - hervorragende Schnithaltigkeit
 - lange Lebensdauer
- Möglichkeit der Präparation von Gewebeschichten und Freilegen von Gefäßen durch die schlank zulaufenden und abgerundeten Scherenblätter der METZENBAUM-Scheren
- 360° drehbare Instrumentenspitzen gewährleisten ein optimales operatives Vorgehen
- Perfektes Instrumentenhandling durch
 - Einhandbedienung der drehbaren Instrumente
 - optimierte Platzierung des monopolar HF-Anschlusses
 - ergonomisches Design der Handgriffe



FEATURES

- METZENBAUM scissors with inlaid tungsten carbide blades:
 - excellent cutting accuracy
 - long service life
- Possibility of preparation of tissue layers and exposure of vessels owing to the slim tapered and rounded scissor blades of the METZENBAUM scissors
- Instrument tips rotatable through 360° guarantee an optimal operative procedure
- Perfect instrument handling owing to
 - single-hand control of the rotatable instruments
 - optimised positioning of the monopolar HF connection
 - ergonomic design of the handles

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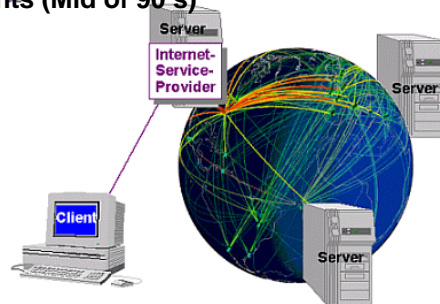
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Requirement list

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

- ☐ Function
- ☐ Reliable
- ☐ Reprocessing
- ☐ Production by CNC Machines
- ☐ Regulatory (MDD 1st January 1995, Operators Ordinance 7th July 1998)



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Result

- ❑ Detachable Instrument to have a safe sterilization
- ❑ Electrical Isolation by PEEK Tubes

Aesculap Endoscopic Technology AdTec® monopolar



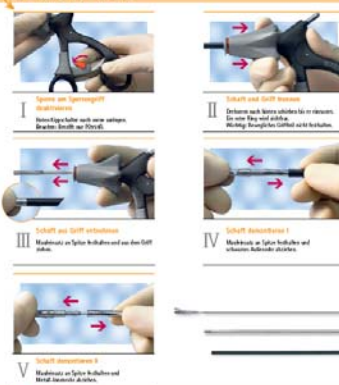
Anleitung zur Demontage und Montage

Aesculap Endoscopic Technology

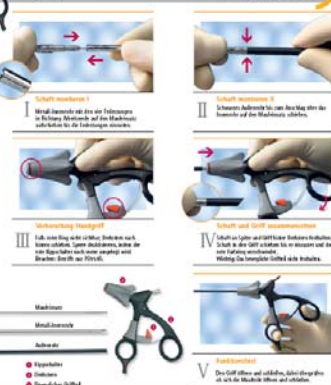


AESCULAP®

DEMONTAGE



MONTAGE



PFLEGE

Instrumente nach jeder Sterilisation und Reinigung sterilisieren und in der Sterilisation lagern.



AUTOREPAIRING & ZUBEHÖR

- 1. Fernschleifen-Produkte sind ebenfalls erhältlich.
- 2. Das Produkt kann sowohl im originalen als auch in einem anderen Zustand verwendet werden.
- 3. Das Produkt ist in der Lage, die Instrumente zu reparieren, die bei der Verwendung beschädigt wurden.
- 4. Alle Instrumente sind in der Lage, die Instrumente zu reparieren, die bei der Verwendung beschädigt wurden.
- 5. Zubehör und Ersatzteile sind separat erhältlich.

REPARATUR

Reparaturen sollten nur von einem qualifizierten Techniker durchgeführt werden, der eine entsprechende Ausbildung hat. Bei der Reparatur sollten die Originalteile verwendet werden, die bei der Herstellung des Instruments verwendet wurden.

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 CJD*

Adresse	http://www.rki.de/EN
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ROBERT KOCH INSTITUT



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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)

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Aesculap Single Use Surgical Instruments Pack per case

Procedure sets



0062010 Thorax Drainage Set, large



Contents	pieces	Contents	pieces
Nettic tray, 64 x 38 x 3 cm	1	Sterican Kanüle size 12, Ø 22 x 1 1/4, Ø 0.70 mm, 30 mm, black	1
Krape, 75 x 90 cm	1	Disposable scalpel size 11	1
surgical gloves, size 7.5, powder free	1	SUSI Bovie forceps, sharp, 145 mm	1
Kauze compress, 10 x 10 cm, 12-fold (ply)	8	SUSI Metzenbaum dissecting scissors, 180 mm	1
alt compress, 10 x 10 cm, 12-fold (ply)	2	SUSI needle holder Mayo-Hegar, 150 mm	1
low, round, 250 ml	1	SUSI tubing clamp, 135 mm	1
SUSI dressing forceps, curved, 265 mm	1	Suture Synthofil green Ø (3.5), 75 cm, 1 x ØS 30	1
Krape, 75 x 100 cm, self adhesive	2	Suture Durlon blue 2/0 (2), 75 cm, 1 x ØS 19	1
injection syringe, Luer, 10 ml	1	Suture Durlon blue 2/0 (2), 75 cm, 1 x ØS 19	1
American cannula size 1, Ø 20 x 1 1/4, Ø 0.90 mm, 40 mm, yellow	1	Adaline fix fixation platelet, 15 x 30 cm	2
American cannula, LL, Ø 18 x 1 1/4, Ø 0.90 mm, 40 mm, pink	1		
American cannula, LL, Ø 20 x 2 1/4, Ø 0.90 mm, 70 mm, yellow	1		

Order unit: PAK = Pack of 20 sets
Developed in cooperation with:
Dr. med. Thomas Fritze, Klinikum Oldenburg
Eberplatz 12, 77654 Oldenburg, Germany

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Alkaline 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

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The Acculap® 3Ti offers:

- Reliability
- Power
- Intuitive operation
- Ergonomic design
- Titanium housing
- Mechanical cleaning with Eccos®

■ Drill and reamer GA672

- Universal use with attachments for acetabular reaming, drilling and K-wire applications. Different gearing attachments adapt the Acculap® 3Ti for various applications – high-speed for precise drilling, high torque for reaming
- Easy to change attachments with innovative Acculap® 3Ti coupling
- A special adapter allows mechanical cleaning of the 4.0-mm cannulation

■ Drill and reamer attachments

- Drill attachments with AO, Jacobs chuck or Aesculap hexagon adapter available, as well as reamer attachments for AO and Harris tools
- Suitable for mechanical cleaning, the special Eccos® fixation allows rising through the cannulation, thus ensuring optimal reprocessing results
- Easy identification of different drill and reamer attachments through color code on the unlocking sleeve
Drilling – Black
Reaming – Blue



Requirement list

3. Generation of MIS Instruments (2004)

- ☐ Function
- ☐ Reliable
- ☐ Validated reprocessing
- ☐ Regulatory
- ☐ Production process



Result (Reusable Instrument)

- ☐ Detachable Instrument
- ☐ Fragile
- ☐ Electric Isolation by PEEK
- ☐ Validated Reprocessing
- ☐ Limitation of Life cycles



Aesculap Endoscopic Technology AdTec® bipolar

THE BLUE (R)EVOLUTION



A new standard for your safety and safety of your patients



Result (Single Use Instrument)

Tactile

Strong

Electric Isolation by heat
shrinking tube

Reprocessing not possible



AdTec® Single Use

Bipolar single use instruments

- Excellent coagulation results
- Jaw parts feature ceramic insulation
- Insulated to the tips

All Aesculap endoscopy products
on our Internet homepage:



...just a click away!

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AESCULAP®

Result (Reusable Needle Holder)

☐ Non Detachable Instrument

☐ Strong

☐ Electric Isolation by PEEK

☐ Validated Reprocessing

☐ No control of cleaning




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AdTec® needle holder
Expertise in Surgery

			Carrying handle Artikulationsarm
DURCOP® Needle holder straight Nadelhalter gerade	5 mm/210 mm		PL407B
	5 mm/270 mm		PL404B
DURCOP® Needle holder curved left Nadelhalter links gebogen	5 mm/210 mm		PL408B
	5 mm/270 mm		PL405B
DURCOP® Needle holder curved right Nadelhalter rechts gebogen	5 mm/210 mm		PL413B
	5 mm/270 mm		PL410B
DURCOP® Acute needle holder, 2 x 3 teeth Acute Nadelhalter, 2 x 3 Zähne	5 mm/210 mm		PL409B
CROCOTOM® DURCOP® Needle holder rivet-tipped DURCOP® Nadelhalter gefestigt	5 mm/210 mm		PL410R
CROCOTOM® DURCOP® Needle holder crimped DURCOP® Nadelhalter gestampft	5 mm/210 mm		PL411B
DURCOP® Needle holder curved left Nadelhalter links gebogen	10 mm/270 mm		PL412B

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SHARING EXPERTISE



DIN EN ISO 17664:2004

□ requires a validated process

but not a special validated process

the process is the choice of the
manufacturer

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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



DIN EN ISO 17664

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>

