



World Federation for  
Hospital Sterilisation Sciences

**DGSV**

Deutsche Gesellschaft für  
Sterilgutversorgung e.V.

WORLD CONFERENCE  
CENTER FOR  
reprocessed and altered medical devices

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# Agenda



- 1) statement of affairs
- 2) processing and modification of medical devices
- 3) examples of substantial modified medical devices



## 1) statement of affairs

- medical devices do not only bear the company logo, European law also requires information<sup>1</sup>, such as article number, batch or production identification and CE identification
- according to the above mentioned law<sup>2</sup>, the operator is responsible for the maintenance of the medical devices

<sup>1</sup> See EC Directive "Medical Devices" 93/42/EEC, Annex 1, Paragraph 13.3, Section 6 MPG

<sup>2</sup> See Section 3 MPBetreibV



## 1) statement of affairs

- in order to ensure conformity of the medical device and the validity of the processing instructions, repairs always need to be performed by authorized service providers. This is also obligatory to maintain claims from the guarantee which is assumed by the original manufacturer
- These requirements are generally not met by medical devices which are processed or repaired by unauthorized service providers.



## 2) processing and modification of the medical devices

reworked and/or modified medical devices may no longer correspond with the requirements of the original distributor.

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graph TD; A[reworked and/or modified medical devices may no longer correspond with the requirements of the original distributor.] --> B[As a result, these medical devices are no longer covered by the guarantee promise of the original distributor.]; B --> C[Loss of the manufacturers liability.];
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As a result, these medical devices are no longer covered by the guarantee promise of the original distributor.

**Loss of the manufacturers liability.**



## 2) processing and modification of medical devices

- If a medical device is substantially modified, it may no longer fulfill the legal security requirements which apply at the time of first being placed on the market
- In such case, the technical processor can become the “[...] manufacturer for this specific reconditioned medical device according to European law (MPG)”<sup>3</sup> and is thereby constrained to possess the documentation which is relevant for authorization

<sup>3</sup> See Böckmann/Frankenberger, Durchführungshilfen zum Medizinproduktegesetz Schwerpunkt Medizintechnik und In-vitro-Diagnostik [Implementation Aids to the Medical Devices Act, Focus on medical technology and in vitro diagnostics]



## 2) processing and modification of the medical devices

- By means of a professional hygienic processing and proper use in accordance with the instructions for use of the original distributor, maintenance measures can be kept low and the quality of the medical devices remains high



### 3) examples of significantly modified medical devices

#### Bipolar forceps

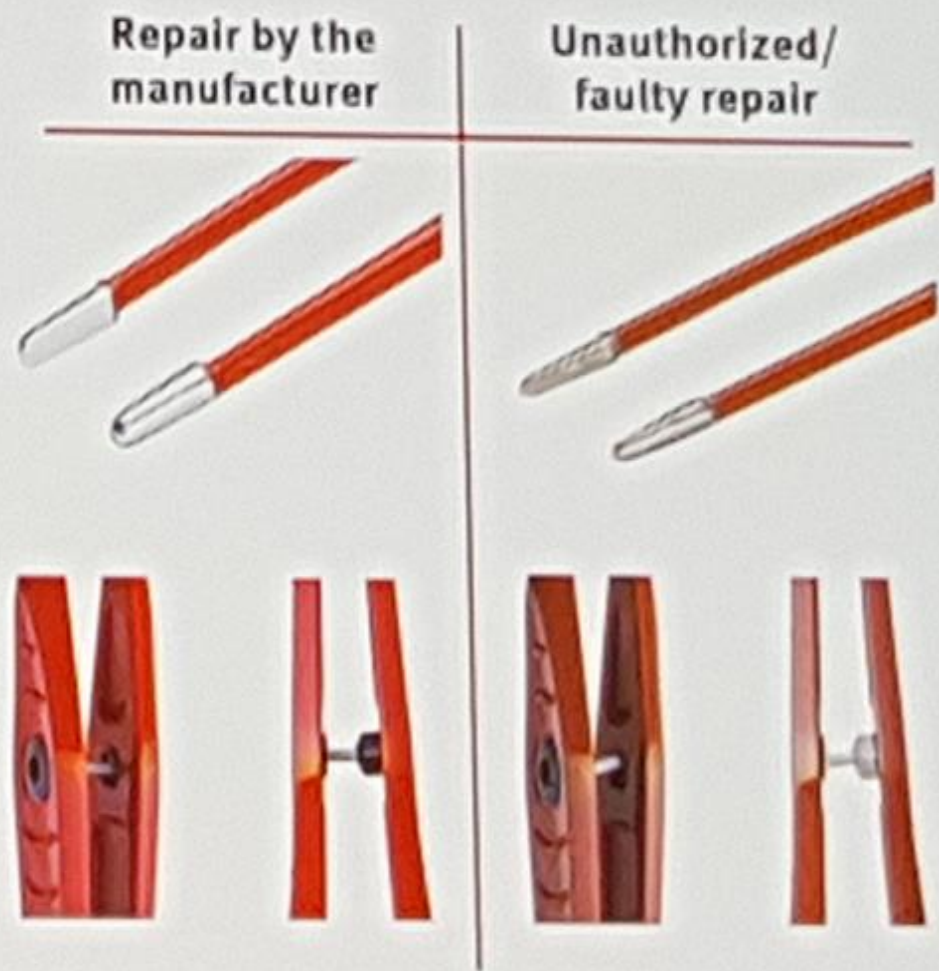
Bipolar forceps are used to prepare, grasp, manipulate and coagulate tissue.

Possible problems in the event of improper repair:

- Replacement of the insulation with non-validated materials
- Replacement of the guide sleeve and connectors with unauthorized spare parts
- Reworked geometry of the workload peaks can lead to a different bearing surface

#### Result:

- Danger to the patient and the user
- Uncontrolled flashovers and burns
- Stress resistance and biocompatibility cannot be guaranteed





### 3) examples of significantly modified medical products

#### Recoilless mallets

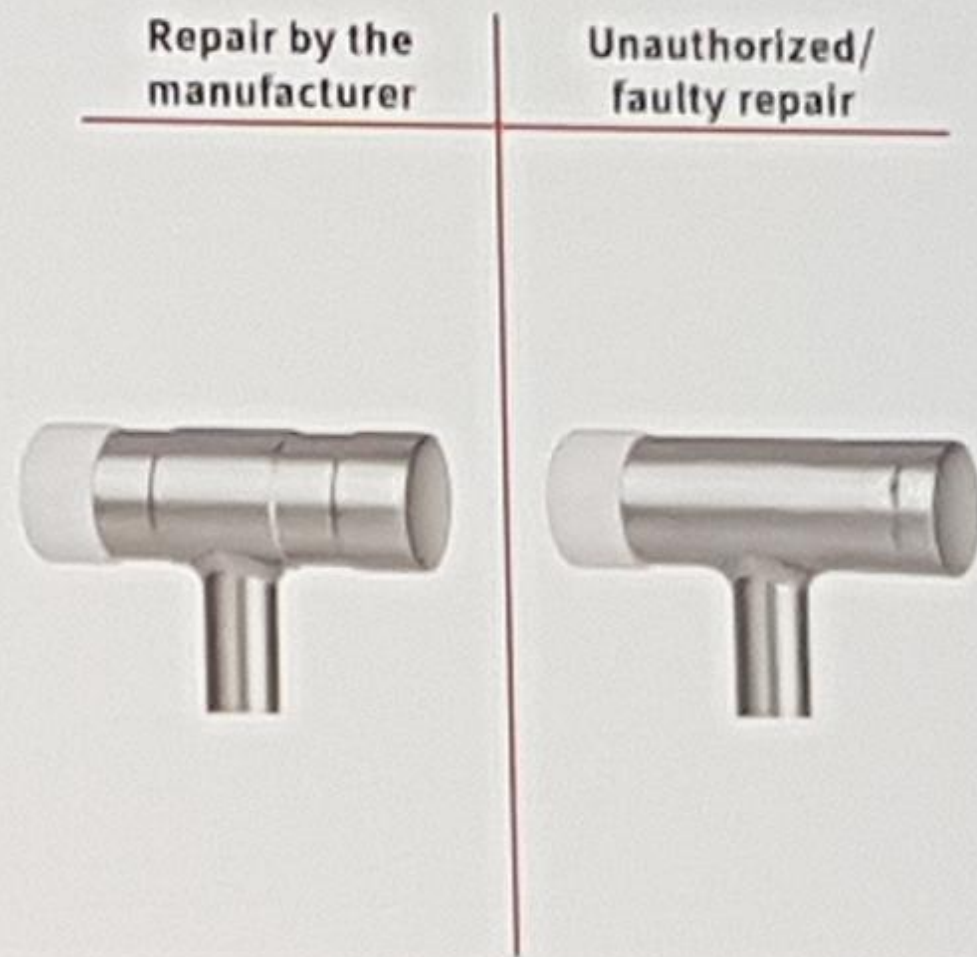
In combination with other medical devices, mallets are used to prepare bones or to insert nails into them, for example.

Possible problems in the event of improper repair:

- Change or renewal of the original weldseam
- Reworked surfaces with too much material removal
- Resulting in a weak weldseam

Result:

- Risk of fracture or rupture
- Exposition and loss of the filling material into the operation field
- Hygienic problem through carry over
- Increased risk of infections
- Consequential damages





### 3) examples of significantly modified medical products

#### Suction flushing pipe

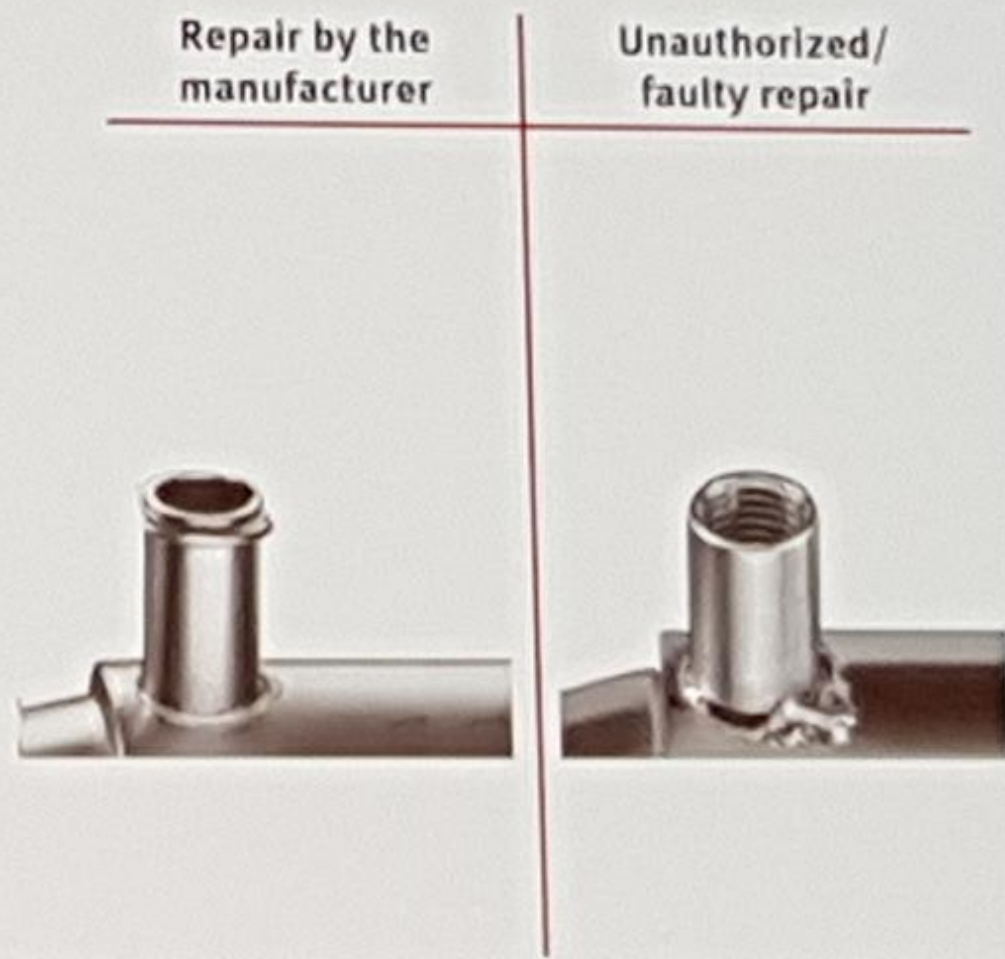
Aspirators are used in medical applications to remove various liquids from the operating field, such as secretion, blood, fat or saline solutions.

#### Possible problems in the event of improper repair:

- Deficient solder connection
- Leakage, not fully functional, uncontrolled discharge of flushing fluid

#### Result:

- Risk of fracture
- Hygienic problem through carry over
- Increased risk of infections
- Consequential damages





### 3) examples of significantly modified medical products

#### Forceps

Forceps are used to hold and grip tissue, organs, medical supplies and materials.

Possible problems in the event of improper repair:

- The spring part is not properly reworked

Result:

- Forceps break during surgery
- Forceps do not grip when closing
- carryover in the gap of the spring part
- proper hygienic cleaning is impossible

Repair by the  
manufacturer

Unauthorized/  
faulty repair





### 3) examples of significantly modified medical products

#### Needle holders

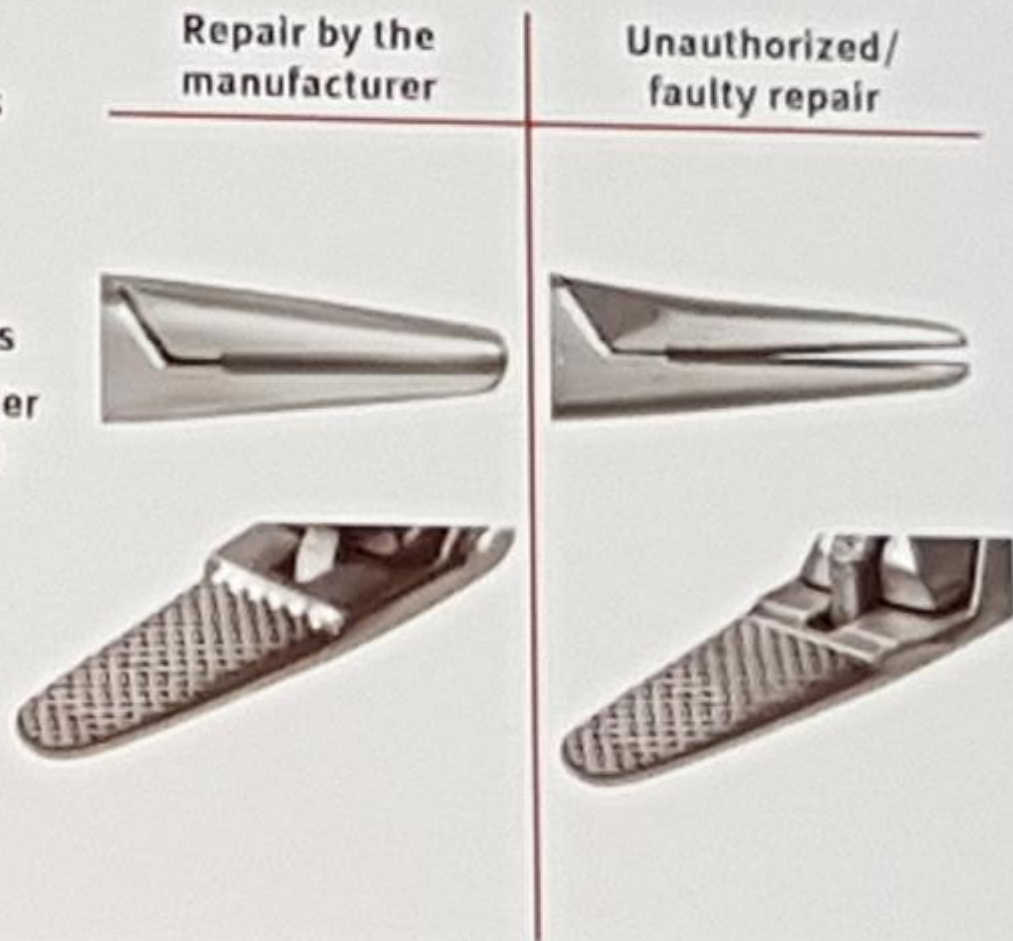
Needle holders are used to grip and hold surgical suture needles during an operation.

Possible problems in the event of improper repair:

- Faulty solder joints, inadequately positioned jaw and arm parts
- Easy onset for corrosion, needle can fall out of the needle holder during operation, small parts of the TC inserts can rupture and land in the operation field during the suturing process

#### Result:

- Patient injury through not firmly fixed needle during suturing process
- Aborted TC inserts can access the open operating field
- proper hygienic cleaning is impossible





### 3) examples of significantly modified medical products

#### Motor systems

Motor systems are used in surgery, e.g. for drilling or sawing works.

Possible problems in the event of improper repair:

- Improper repair of connecting cable
- Motor system no longer functional

Result:

- Motor system may fail during surgery

Repair by the  
manufacturer



Unauthorized/  
faulty repair





### 3) examples of significantly modified medical products

#### Boards

Boards are used in various medical devices, e.g. HF Devices.

Possible problems in the event of improper repair:

- Improper effort during disassembly, use of unsuitable tools (slipped down with oversized screwdriver)
- Board no longer functional

Result:

- Medical device may fail during surgery

Repair by the  
manufacturer



Unauthorized/  
faulty repair





Thank you very much  
for your attention

