

**Aesculap AG  
Quality Management**

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Date: March 23, 2020

***Urgent Field Safety Notice***  
***(Updated version 2)***

**Various surgical instruments for use at the central nervous system  
(see appendix 1 – list of affected products)**

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This safety information corresponds to version 2 and replaces version 1 of 11.03.2020.  
We only ask you to acknowledge receipt of this letter (version 2).

We have internally determined that a number of our surgical instruments are used at the central nervous system. For some of these instruments, this is part of the intended use. Please refer to the list of affected products in appendix 1 (a / b).

Related to the reprocessing of the affected products, we draw your attention to the valid legal regulations with regard to special types of diseases, of which compliance is also pointed out in the current instructions for use.

Proceed as described in the following to reprocess the affected surgical instruments:

Vorsitzender des Aufsichtsrates:  
Prof. Dr. Heinz-Walter Große

Vorstand:  
Dr. Joachim Schulz  
(Vorsitzender)  
Dr. Jens von Lackum  
(Stellv. Vorsitzender)  
Dr. Katrin Sternberg

Sitz der Gesellschaft: Tuttlingen  
Reg. Gericht: Stuttgart HRB 726261  
USt. Id.-Nr. DE812160059  
WEEE-Reg.-Nr. DE 65109852

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Hausanschrift:  
Aesculap AG  
Am Aesculap-Platz  
78532 Tuttlingen  
Deutschland

**Remark:**

Manual cleaning/ disinfection as listed in the currently valid instructions for use is no longer applicable for neuro applications.

**Mechanical cleaning/ disinfection with manual pre-cleaning**

Part 1 – Manual pre-cleaning

Applies to bipolar forceps and suction cannulas/ Dissecting suction tube

**Manual pre-cleaning with a brush**

*Note*

*Only applies to suction cannulas and bipolar forceps.*

| Phase | Step            | T<br>[°C/°F] | t<br>[min] | Conc.<br>[%] | Water<br>quality | Chemical                 |
|-------|-----------------|--------------|------------|--------------|------------------|--------------------------|
| I     | <b>Cleaning</b> | RT<br>(cold) | >15        | 1            | D-W              | B. Braun Stabimed® fresh |
| II    | <b>Rinsing</b>  | RT<br>(cold) | 1          | -            | D-W              | -                        |

D-W: Drinking water  
 RT: Room temperature

**Phase I**

- ▶ Clean the product with a suitable cleaning brush in the solution until all discernible residues have been removed from the surface.
- ▶ If applicable, brush through non-visible surfaces with an appropriate cleaning brush for at least 1 min.
- ▶ Mobilize non-rigid components, such as set screws, links, etc. during cleaning.
- ▶ Thoroughly rinse through these components with the cleaning disinfectant solution (at least five times), using a disposable syringe (20 ml).

**Phase II**

- ▶ Rinse/flush the product thoroughly (all accessible surfaces) under running water.
- ▶ Mobilize non-rigid components, such as set screws, joints, etc. during rinsing.

Part 2 – Mechanical cleaning/ disinfection

Applies to all surgical instruments in Annex 1a, including those already manually pre-cleaned products from Part 1

**Mechanical alkaline cleaning and thermal disinfecting**

Machine type: single-chamber cleaning/disinfection device without ultrasound<sup>1)</sup>

| Phase | Step                  | T<br>[°C/°F] | t<br>[min] | Water<br>quality | Chemical                                                                    |
|-------|-----------------------|--------------|------------|------------------|-----------------------------------------------------------------------------|
| I     | Prerinse              | <25/77       | 3          | D-W              | -                                                                           |
| II    | Cleaning              | 55/131       | 10         | FD-W             | Dr. Weigert neodisher® SeptoClean<br>Application solution 1 % <sup>2)</sup> |
| III   | Neutralization        | >10/50       | 2          | FD-W             | B. Braun Helimatic® Neutralizer C<br>Application solution 0,15 %            |
| IV    | Intermediate rinse I  | >10/50       | 1          | FD-W             | -                                                                           |
| V     | Intermediate rinse II | >10/50       | 1          | FD-W             | -                                                                           |
| VI    | Thermal disinfection  | 90/194       | 5          | FD-W             | -                                                                           |
| VII   | Drying                | -            | -          | -                | According to the program for cleaning<br>and disinfection device            |

D-W: Drinking water

FD-W: Fully desalinated water

1) The following cleaning and disinfection device was used to verify cleanability: Miele 7836 CD

2) Prion-inactivating detergent (see Technical information Dr. Weigert neodisher® SeptoClean)

- ▶ Place the product on a tray that is suitable for cleaning (avoid rinsing blind spots).
- ▶ Place the product on the tray with all product links and joints open.
- ▶ Connect components with lumens and channels directly to the rinsing port of the injector carriage.
- ▶ Check visible surfaces for residues after mechanical cleaning/disinfecting.

## Sterilization

### Applies to all items listed in appendix 1a

- ▶ Check to ensure that the sterilizing agent will come into contact with all external and internal surfaces (e.g., by opening any valves and faucets).
- ▶ Validated sterilization process
  - Steam sterilization using fractional vacuum process
  - Steam sterilizer according to DIN EN 285 and validated according to DIN EN ISO 17665
  - Sterilization using fractionated vacuum process at 134 °C,, holding time 18 minutes for prion inactivation
- ▶ If several devices are sterilized at the same time in the same steam sterilizer: Ensure that the maximum permitted load according to the manufacturers' specifications is not exceeded.

The internal validations of the affected products confirm the suitability and applicability of the specified procedures. An increased patient risk is therefore **not** expected.

To confirm that you have taken note of this safety information, please return the feedback form attached to this letter.

If you have any further questions regarding the content of this safety information, please contact your responsible sales specialist or one of the following contact persons:

Alexander Kerle  
Product Manager Neurosurgery  
☎ + 49 7461 95-2270  
☎ + 49 175 2776532  
[alexander.kerle@aesculap.de](mailto:alexander.kerle@aesculap.de)

Insert local responsible person  
Position  
☎ Phone number  
☎ Cell phone number  
[Email](#)

Please ensure in your organization that all users of the affected products and other persons to be informed are aware of this safety information.

If you have handed over the product to third parties, please forward a copy of this information or inform Aesculap AG ( [vigilance\\_aag.de@aesculap.de](mailto:vigilance_aag.de@aesculap.de) ).

The Federal Institute for Medicinal Products and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) has received a copy of this safety information.

Yours sincerely

Aesculap AG

i.V.

i.V.

Jacqueline Liebers  
Vice President Quality Management

Georg Erhard  
Director Quality Management International Affairs

This document is computerized made and valid without signature

Change history

| Version | Change description                                                                                                                                                                                                                                                          |
|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1       | Initial creation                                                                                                                                                                                                                                                            |
| 2       | <ol style="list-style-type: none"><li>1. Correction of reprocessing processes to be used, since a different cleaner must be listed</li><li>2. Split of Annex 1 into parts a and b to separate the single use products, as they must be excluded from reprocessing</li></ol> |

**FEEDBACK FORM**  
**Field Safety Notice**  
**Version 2**  
**Surgical instruments for use at the central nervous system**

Please return this form by fax or e-mail to:

**Department QMV**

**Fax +49 7461-95 1555**

**vigilance\_aag.de@aesculap.de**

We confirm adherence to the contents of the field safety notice.

HOSPITAL \_\_\_\_\_ LOCATION \_\_\_\_\_

NAME \_\_\_\_\_ DEPARTMENT \_\_\_\_\_ PHONE \_\_\_\_\_

SIGNATURE \_\_\_\_\_ DATE \_\_\_\_\_

**Appendix 1a: List of affected products – Reprocessing**

| <b>Material</b> | <b>Material Description</b>             |
|-----------------|-----------------------------------------|
| FD481B          | MICRO SCISSORS CVD.BL/SH 140MM          |
| FD482B          | MICRO SCISSORS CVD.SH/SH 140MM          |
| FD483B          | MICRO SCISSORS CVD.SH/SH 170MM          |
| FD484B          | MICRO SCISSORS STR.SH/SH WL:100MM 225MM |
| FD485B          | MICRO SCISSORS CVD.BL/SH WL:100MM 225MM |
| FD488B          | MICRO FORCEPS STR.0.3MM 140MM           |
| FD489B          | MICRO FORCEPS STR.0.3MM 170MM           |
| FD490B          | MICRO FORCEPS STR.0.3MM 210MM           |
| FD493B          | MICRO NEEDLE HOLDER STR.0.5MM 150MM     |
| FD494B          | MICRO NEEDLE HOLDER CVD.0.5MM 170MM     |
| FD495B          | MICRO NEEDLE HOLDER CVD.0.5MM 210MM     |
| FD510B          | MICRO FORCEPS RND HANDLE BAY.45DG 210MM |
| FD511B          | MICRO FORCEPS RND HANDLE BAY.90DG 210MM |
| FF341R          | TOENNIS TUMOR GRASPING FORCEPS SMALL    |
| FF342R          | TOENNIS TUMOR GRASPING FORCEPS MEDIUM   |
| FF343R          | TOENNIS TUMOR GRASPING FORCEPS LARGE    |
| GF005B          | NOIR THUMB CONTROL MODULAR              |
| GF025B          | NOIR SUCTION TUBE 4FR 80MM              |
| GF026B          | NOIR SUCTION TUBE 6FR 80MM              |
| GF027B          | NOIR SUCTION TUBE 8FR 80MM              |
| GF030B          | NOIR SUCTION TUBE LE.CVD.6FR 100MM      |
| GF031B          | NOIR SUCTION TUBE RI.CVD.6FR 100MM      |
| GF032B          | NOIR SUCTION TUBE LE.CVD.8FR 100MM      |
| GF033B          | NOIR SUCTION TUBE RI.CVD.8FR 100MM      |
| GF035B          | NOIR SUCTION TUBE 4FR 100MM             |
| GF036B          | NOIR SUCTION TUBE 6FR 100MM             |
| GF037B          | NOIR SUCTION TUBE 8FR 100MM             |
| GF038B          | NOIR SUCTION TUBE W/HOLES 6FR 100MM     |
| GF039B          | NOIR SUCTION TUBE W/HOLES 8FR 100MM     |
| GF045B          | NOIR SUCTION TUBE 4FR 120MM             |
| GF046B          | NOIR SUCTION TUBE 6FR 120MM             |
| GF047B          | NOIR SUCTION TUBE 8FR 120MM             |
| GF048B          | NOIR SUCTION TUBE W/HOLES 6FR 120MM     |
| GF049B          | NOIR SUCTION TUBE W/HOLES 8FR 120MM     |
| GF055B          | NOIR SUCTION TUBE 4FR 140MM             |
| GF056B          | NOIR SUCTION TUBE 6FR 140MM             |
| GF057B          | NOIR SUCTION TUBE 8FR 140MM             |
| GF058B          | NOIR SUCTION TUBE W/HOLES 6FR 140MM     |
| GF059B          | NOIR SUCTION TUBE W/HOLES 8FR 140MM     |

| <b>Material</b> | <b>Material Description</b>              |
|-----------------|------------------------------------------|
| GF235R          | THUMB PLATE MODULAR SUCTIONS TEAR DROP   |
| GF240R          | SUCTION ATTM.MALLEAB.TAPERED 3FR 100MM   |
| GF241R          | SUCTION ATTM.MALLEAB.TAPERED 4FR 100MM   |
| GF242R          | SUCTION ATTM.MALLEAB.TAPERED 5FR 100MM   |
| GF243R          | SUCTION ATTM.MALLEAB.TAPERED 6FR 100MM   |
| GF244R          | SUCTION ATTM.MALLEAB.TAPERED 7FR 100MM   |
| GF245R          | SUCTION ATTM.MALLEAB.TAPERED 8FR 100MM   |
| GF246R          | SUCTION ATTM.MALLEAB.TAPERED 9FR 100MM   |
| GF247R          | SUCTION ATTM.MALLEAB.TAPERED 10FR 100MM  |
| GF248R          | SUCTION ATTM.MALLEAB.TAPERED 12FR 100MM  |
| GF250R          | SUCTION ATTM.MALLEAB.TAPERED 3FR 115MM   |
| GF251R          | SUCTION ATTM.MALLEAB.TAPERED 4FR 115MM   |
| GF252R          | SUCTION ATTM.MALLEAB.TAPERED 5FR 115MM   |
| GF253R          | SUCTION ATTM.MALLEAB.TAPERED 6FR 115MM   |
| GF254R          | SUCTION ATTM.MALLEAB.TAPERED 7FR 115MM   |
| GF255R          | SUCTION ATTM.MALLEAB.TAPERED 8FR 115MM   |
| GF256R          | SUCTION ATTM.MALLEAB.TAPERED 9FR 115MM   |
| GF257R          | SUCTION ATTM.MALLEAB.TAPERED 10FR 115MM  |
| GF258R          | SUCTION ATTM.MALLEAB.TAPERED 12FR 115MM  |
| GF260R          | SUCTION ATTM.MALLEAB.TAPERED 3FR 140MM   |
| GF261R          | SUCTION ATTM.MALLEAB.TAPERED 4FR 140MM   |
| GF262R          | SUCTION ATTM.MALLEAB.TAPERED 5FR 140MM   |
| GF263R          | SUCTION ATTM.MALLEAB.TAPERED 6FR 140MM   |
| GF264R          | SUCTION ATTM.MALLEAB.TAPERED 7FR 140MM   |
| GF265R          | SUCTION ATTM.MALLEAB.TAPERED 8FR 140MM   |
| GF266R          | SUCTION ATTM.MALLEAB.TAPERED 9FR 140MM   |
| GF267R          | SUCTION ATTM.MALLEAB.TAPERED 10FR 140MM  |
| GF268R          | SUCTION ATTM.MALLEAB.TAPERED 12FR 140MM  |
| GF270R          | SUCTION ATTM.MALLEAB.TAPERED 3FR 165MM   |
| GF271R          | SUCTION ATTM.MALLEAB.TAPERED 4FR 165MM   |
| GF272R          | SUCTION ATTM.MALLEAB.TAPERED 5FR 165MM   |
| GF273R          | SUCTION ATTM.MALLEAB.TAPERED 6FR 165MM   |
| GF274R          | SUCTION ATTM.MALLEAB.TAPERED 7FR 165MM   |
| GF275R          | SUCTION ATTM.MALLEAB.TAPERED 8FR 165MM   |
| GF276R          | SUCTION ATTM.MALLEAB.TAPERED 9FR 165MM   |
| GF277R          | SUCTION ATTM.MALLEAB.TAPERED 10FR 165MM  |
| GF278R          | SUCTION ATTM.MALLEAB.TAPERED 12FR 165MM  |
| GF350R          | FERGUSSON SUCT.CANN D:1.5MM WORK.L.110MM |
| GF352R          | FERG-FRAZIER SUCT 7FR110MM WRK-LGT       |
| GF354R          | FERG-FRAZIER SUCT 12FR 110MM WRK-LGT     |
| GF355R          | FERGUSSON SUCT.CANN D:5.0MM WORK.L.110MM |

| <b>Material</b> | <b>Material Description</b>              |
|-----------------|------------------------------------------|
| GF360R          | FERGUSSON SUCT.CANN D:1.5MM WORK.L.130MM |
| GF361R          | FERGUSSON SUCT.CANN D:2.0MM WORK.L.130MM |
| GF362R          | FERGUSSON SUCT.CANN D:2.5MM WORK.L.130MM |
| GF363R          | FERGUSSON SUCT.CANN D:3.0MM WORK.L.130MM |
| GF364R          | FERGUSSON SUCT.CANN D:4.0MM WORK.L.130MM |
| GF365R          | FERGUSSON SUCTION CANNULA 5MM 130MM      |
| GF370R          | FERGUSSON SUCT.CANN D:1.5MM WORK.L.160MM |
| GF371R          | FERGUSSON SUCT.CANN D:2.0MM WORK.L.160MM |
| GF372R          | FERGUSSON SUCT.CANN D:2.5MM WORK.L.160MM |
| GF373R          | FERGUSSON SUCT.CANN D:3.0MM WORK.L.160MM |
| GF374R          | FERGUSSON SUCT.CANN D:4.0MM WORK.L.160MM |
| GF375R          | FERGUSSON SUCT.CANN D:5.0MM WORK.L.160MM |
| GF380R          | FERGUSSON SUCT.CANN D:1.5MM WORK.L.200MM |
| GF381R          | FERGUSSON SUCT.CANN D:2.0MM WORK.L.200MM |
| GF382R          | FERGUSSON SUCT.CANN D:2.5MM WORK.L.200MM |
| GF383R          | FERGUSSON SUCT.CANN D:3.0MM WORK.L.200MM |
| GF384R          | FERGUSSON SUCT.CANN D:4.0MM WORK.L.200MM |
| GF385R          | FERGUSSON SUCT.CANN D:5.0MM WORK.L.200MM |
| GF391R          | SUCTION TUBE TAPERED TEARDROP 3FR 180MM  |
| GF392R          | SUCTION TUBE TAPERED TEARDROP 4FR 180MM  |
| GF393R          | SUCTION TUBE TAPERED TEARDROP 5FR 180MM  |
| GF394R          | SUCTION TUBE TAPERED TEARDROP 6FR 180MM  |
| GF395R          | SUCTION TUBE TAPERED TEARDROP 7FR 180MM  |
| GF396R          | SUCTION TUBE TAPERED TEARDROP 8FR 180MM  |
| GF397R          | SUCTION TUBE TAPERED TEARDROP 9FR 180MM  |
| GF398R          | SUCTION TUBE TAPERED TEARDROP 10FR 180MM |
| GF399R          | SUCTION TUBE TAPERED TEARDROP 12FR 180MM |
| GF401R          | SUCTION TUBE TAPERED TEARDROP 3FR 165MM  |
| GF402R          | SUCTION TUBE TAPERED TEARDROP 4FR 165MM  |
| GF403R          | SUCTION TUBE TAPERED TEARDROP 5FR 165MM  |
| GF404R          | SUCTION TUBE TAPERED TEARDROP 6FR 165MM  |
| GF405R          | SUCTION TUBE TAPERED TEARDROP 7FR 165MM  |
| GF406R          | SUCTION TUBE TAPERED TEARDROP 8FR 165MM  |
| GF407R          | SUCTION TUBE TAPERED TEARDROP 9FR 165MM  |
| GF408R          | SUCTION TUBE TAPERED TEARDROP 10FR 165MM |
| GF409R          | SUCTION TUBE TAPERED TEARDROP 12FR 165MM |
| GF411R          | SUCTION TUBE TAPERED TEARDROP 3FR 205MM  |
| GF412R          | SUCTION TUBE TAPERED TEARDROP 4FR 205MM  |
| GF413R          | SUCTION TUBE TAPERED TEARDROP 5FR 205MM  |
| GF414R          | SUCTION TUBE TAPERED TEARDROP 6FR 205MM  |
| GF415R          | SUCTION TUBE TAPERED TEARDROP 7FR 205MM  |

| <b>Material</b> | <b>Material Description</b>              |
|-----------------|------------------------------------------|
| GF416R          | SUCTION TUBE TAPERED TEARDROP 8FR 205MM  |
| GF417R          | SUCTION TUBE TAPERED TEARDROP 9FR 205MM  |
| GF418R          | SUCTION TUBE TAPERED TEARDROP 10FR 205MM |
| GF419R          | SUCTION TUBE TAPERED TEARDROP 12FR 205MM |
| GF421R          | SUCTION TUBE TAPERED TEARDROP 3FR 230MM  |
| GF422R          | SUCTION TUBE TAPERED TEARDROP 4FR 230MM  |
| GF423R          | SUCTION TUBE TAPERED TEARDROP 5FR 230MM  |
| GF424R          | SUCTION TUBE TAPERED TEARDROP 6FR 230MM  |
| GF425R          | SUCTION TUBE TAPERED TEARDROP 7FR 230MM  |
| GF426R          | SUCTION TUBE TAPERED TEARDROP 8FR 230MM  |
| GF427R          | SUCTION TUBE TAPERED TEARDROP 9FR 230MM  |
| GF428R          | SUCTION TUBE TAPERED TEARDROP 10FR 230MM |
| GF429R          | SUCTION TUBE TAPERED TEARDROP 12FR 230MM |
| GF470R          | BENDING RESIST.MICRO SUCTION 4FR 80MM    |
| GF471R          | BENDING RESIST.MICRO SUCTION 6FR 80MM    |
| GF472R          | BENDING RESIST.MICRO SUCTION 8FR 80MM    |
| GF473R          | BENDING RESIST.MICRO SUCTION 4FR 100MM   |
| GF474R          | BENDING RESIST.MICRO SUCTION 6FR 100MM   |
| GF475R          | BENDING RESIST.MICRO SUCTION 8FR 100MM   |
| GF476R          | BENDING RESIST.MICRO SUCTION 4FR 120MM   |
| GF477R          | BENDING RESIST.MICRO SUCTION 6FR 120MM   |
| GF478R          | BENDING RESIST.MICRO SUCTION 8FR 120MM   |
| GF479R          | BENDING RESIST.MICRO SUCTION 4FR 140MM   |
| GF480R          | BENDING RESIST.MICRO SUCTION 6FR 140MM   |
| GF481R          | BENDING RESIST.MICRO SUCTION 8FR 140MM   |
| GF923R          | FRAZIER SUCTLUER-HUB9FR100MMWRK-LGTH     |
| GF925R          | FRAZIER SUCTLUER-HUB15FR5/100MM LGTH     |
| GF980R          | LANDOLT DISS SUCTION TUBE 3.2MM DIA      |
| GK595R          | BIPOL.FORCEPS AAG FL.STR.0.6MM 120MM     |
| GK596R          | BIPOL.FORCEPS AAG FL.STR.0.3MM 145MM     |
| GK597R          | BIPOL.FORCEPS AAG FL.CVD.0.6MM 110MM     |
| GK604R          | BIPOL.FORCEPS AAG FL.STR.0.9MM 160MM     |
| GK605R          | BIPOL.FORCEPS AAG FL.STR.0.9MM 185MM     |
| GK606R          | BIPOL.FORCEPS AAG FL.STR.0.9MM 200MM     |
| GK614R          | BIPOL.FORCEPS AAG FL.BAYO.F.0.7MM 160MM  |
| GK615R          | BIPOL.FORCEPS AAG FL.BAYO.F.1.0MM 185MM  |
| GK616R          | BIPOL.FORCEPS AAG FL.BAYO.F.1.0MM 200MM  |
| GK624R          | BIPOL.FORCEPS AAG FL.ANGL.0.9MM 160MM    |
| GK625R          | BIPOL.FORCEPS AAG FL.ANGL.0.8MM 200MM    |
| GK644R          | PRECIOUS METAL FORCEPS160MM 0.7MM        |
| GK645R          | PRECIOUS METAL FORCEPS 185MM 1.0MM       |

| <b>Material</b> | <b>Material Description</b>             |
|-----------------|-----------------------------------------|
| GK646R          | PRECIOUS METAL FORCEPS 200MM 1.0MM      |
| GK660R          | BIPOLAR COAGULATION FCPS 0.6MM 160MM    |
| GK670R          | BIPOLAR COAG.FORCEPS 0.6MM 200MM        |
| GK671R          | BIPOLAR FORCEPS INS.BAYO.9MM 200MM      |
| GK675R          | BIPOLAR COAGULATION FORCEPS.6MM220MM    |
| GK677R          | BIPOLAR COAGULATION FORCEPS.6MM 240MM   |
| GK679R          | BIPOLAR COAGULATION FORCEPS 0.9MM240MM  |
| GK690R          | BIPOLAR COAGULATION FORCEPS0.4MMX120MM  |
| GK700R          | COAGULATION FORCEPS INSUL.160MM STR.    |
| GK701R          | COAGULATION FCPS STR INS 160MM          |
| GK703R          | COAGUL.FORCEPS INSULATED 200MM STR.     |
| GK711R          | BIPOLAR COAGULATION FCPSIND.9MMX160MM   |
| GK713R          | COAG.FORC.INCUL 200MMWORK.PART ANGL     |
| GK720R          | BIPOLAR COAGULATION FORCEPS .6MMX160MM  |
| GK722R          | BIPOLAR COAGULATION FORCEPS .9MMX160MM  |
| GK723R          | BIPOLAR COAGULATION FCPSANG.9MMX160MM   |
| GK730R          | BIPOLAR COAGULATION FORCEPS 0.9MM200MM  |
| GK743R          | BIPOL.RING FCPS.RING D:5.0 WORK.L.75MM  |
| GK746R          | YASARGIL BIPOLAR FORCEPS 0.4X20/140MM   |
| GK747R          | YASARGIL BIPOLAR FORCEPS 0.7X20/140MM   |
| GK748R          | YASARGIL BIPOLAR FORCEPS 1.0X20/140MM   |
| GK749R          | YASARGIL BIPOLAR FORCEPS 1.3X20/140MM   |
| GK760R          | YASARGIL BIPOLAR FORCEPS 0.4MMX35/155MM |
| GK761R          | YASARGIL BIPOLAR FORCEPS 0.7X35/155MM   |
| GK762R          | YASARGIL BIPOLAR FORCEPS 1.0X35/155MM   |
| GK763R          | YASARGIL BIPOLAR FORCEPS 1.3X35/155MM   |
| GK764R          | YASARGIL BIPOLAR FORCEPS 0.4X55/175MM   |
| GK765R          | YASARGIL BIPOLAR FORCEPS 0.7X55/175MM   |
| GK766R          | YASARGIL BIPOLAR FORCEPS 1.0X55/175MM   |
| GK767R          | YASARGIL BIPOLAR FORCEPS 1.3X55/175MM   |
| GK768R          | YASARGIL BIPOLAR FORCEPS 0.4X75/195MM   |
| GK769R          | YASARGIL BIPOLAR FORCEPS 0.7X75/195MM   |
| GK770R          | YASARGIL BIPOLAR FORCEPS 1.0X75/195MM   |
| GK771R          | YASARGIL BIPOLAR FORCEPS 1.3X75/195MM   |
| GK772R          | YASARGIL BIPOLAR FORCEPS 0.4X95/215MM   |
| GK773R          | YASARGIL BIPOLAR FORCEPS 0.7X95/215MM   |
| GK774R          | YASARGIL BIPOLAR FORCEPS 1.0X95/215MM   |
| GK775R          | YASARGIL BIPOLAR FORCEPS 1.3X95/215MM   |
| GK777R          | YASARGIL BIPOLAR FCP45DG-UP7X95/215MM   |
| GK780R          | YASARGIL BIPOLAR FCP90DG-UP.4X95/215MM  |
| GK781R          | YASARGIL BIPOLAR FCP90DG-UP.7X95/215MM  |

| <b>Material</b> | <b>Material Description</b>              |
|-----------------|------------------------------------------|
| GK785R          | YASARGIL BIPOLR FCP90DG-DWN.7X95/215MM   |
| GK789R          | YASARGIL BIPOLAR FORCEPS 0.7X115/235MM   |
| GK790R          | YASARGIL BIPOLAR FORCEPS 1.0X115/235MM   |
| GK791R          | YASARGIL BIPOLAR FORCEPS 1.3X115/235MM   |
| GK793R          | YASARGIL BIPOLAR FORCEPS 0.7X135/255MM   |
| GK807R          | BIPOLAR COAGULATION FORCEPS 175MM        |
| GK808R          | BIPOLAR COAGULATION FORCEPS 220MM        |
| GK809R          | BIPOLAR COAGULATION FORCEPS 125MM        |
| GK822R          | BIPOL.FORCEPS STR.BAY.0.7MM 95MM         |
| GK823R          | BIPOL.FORCEPS 45°BAY.0.7MM 95MM          |
| GK824R          | BIPOL.FORCEPS STR.BAY.1.0MM 95MM         |
| GK825R          | BIPOL.FORCEPS 45°BAY.1.0MM 95MM          |
| GK826R          | BIPOL.FORCEPS STR.BAY.0.7MM 135MM        |
| GK827R          | BIPOL.FORCEPS 45°BAY.0.7MM 135MM         |
| GK828R          | BIPOL.FORCEPS STR.BAY.1.0MM 135MM        |
| GK829R          | BIPOL.FORCEPS 45°BAY.1.0MM 135MM         |
| GK831R          | BIPOLAR FORCEPS RING-TIP 2.3X235MM       |
| GK832R          | BIPOLAR FORCEPS RING-TIP 3.4X235MM       |
| GK833R          | BIPOLAR FORCEPS RING-TIP 4.5X235MM       |
| GK838R          | BIPOL.FCPS.W/SANO IRRIGATION 165MM 0.7MM |
| GK840R          | BIPOLAR FRCPS W/IRRIG CHANNEL.4MM180MM   |
| GK841R          | BIPOLAR FRCPS W/IRRIG CHANNEL.7MM180MM   |
| GK842R          | IRRIGATION FORCEPS 180MM 1.3MM TIP       |
| GK843R          | BIPOLAR FRCP W/IRRIG CHANNEL 0.4MM205MM  |
| GK844R          | BIPOLAR FRCP W/IRRIG CHANNEL .7MM205MM   |
| GK845R          | IRRIGATION FORCEPS 205MM 1.3MM TIP       |
| GK846R          | BIPOLAR FRCP W/IRRIG CHANNEL .4MM230MM   |
| GK847R          | BIPOLAR FRCP W/IRRIG CHANNEL.7MM230MM    |
| GK848R          | IRRIGATION FORCEPS 230MM1.3MM TIP        |
| GK871R          | BIP.RING IRRIG.FORCEPS RING D:5MM 235MM  |
| GK899R          | BIPOLAR COAGULATION FORCEPS 165/0.2MM    |
| GK900R          | CASPAR BIPOLAR FORCEPS 0.5X70/165MM      |
| GK910R          | CASPAR BIPOLAR FORCEPS 1.0X70/165MM      |
| GK920R          | CASPAR BIPOLAR FORCEPS 2.0X70/165MM      |
| GK929R          | BIPOLAR COAGULATION FORCEPS 195/0.2MM    |
| GK930R          | CASPAR BIPOLAR FORCEPS 0.5X100/195MM     |
| GK940R          | CASPAR BIPOLAR FORCEPS 1.0X100/195MM     |
| GK950R          | CASPAR BIPOLAR FORCEPS 2.0X125/195MM     |
| GK959R          | BIPOLAR COAGULATION FORCEPS 220/0.2MM    |
| GK960R          | CASPAR BIPOLAR FORCEPS 0.5X125/220MM     |
| GK970R          | CASPAR BIPOLAR FORCEPS 1.0X125/220MM     |

| <b>Material</b> | <b>Material Description</b>              |
|-----------------|------------------------------------------|
| GK972R          | GKSPAR BIPOLAR FCPS45DG-UP1.X125/220MM   |
| GK974R          | CASPAR BIPOLAR FCP45DG-DWN1.X125/220MM   |
| GK976R          | CASPAR BIPOLAR FCP90DG-UP 1.X120/215MM   |
| GK978R          | CASPAR BIPOLAR FCP90DG-DWN1.X120/215MM   |
| GK980R          | CASPAR BIPOLAR FORCEPS 2.0X125/220MM     |
| GL470R          | BIPROTECT PARTLY INSUL.TAB CON.195/0.4MM |
| GL471R          | BIPROTECT PARTLY INSUL.TAB CON.195/0.8MM |
| GL480R          | BIPROTECT PARTLY INSUL.TAB CON.215/0.4MM |
| GL481R          | BIPROTECT PARTLY INSUL.TAB CON.215/0.8MM |
| S61017          | SUCTION CANNULA                          |
| S67507          | COAG. FORCEPS                            |
| US161           | GOLDTIP BIPOLAR FCPS STR 220/95/0.5MM    |
| US162           | GOLDTIP BIPOLAR FCPS STR 220/95/1.0MM    |
| US163           | GOLDTIP BIPOLAR FCPS STR 220/95/1.5MM    |
| US164           | GOLDTIP BIPOLAR FCPS CVD-UP 220/95/0.5MM |
| US171           | GOLDTIP BIPOLAR FCPS STR 125/1.0MM       |
| US172           | GOLDTIP BIPOLAR FCPS STR 100/0.4MM       |
| US173           | GOLDTIP BIPOLAR FCPS STR 255/150/1.5MM   |
| US182           | CUSHING BIPOLAR FCPSBAYO,INS,1.0MM190MM  |
| US183           | CUSHING BIPOLAR FCPSBAYO,INS,1.5MM190MM  |
| US184           | HARDY BIPOLAR FORCEPS INS 1.0MM215MM     |
| US185           | HARDY BIPOLAR FORCEPS INS 1.5MM215MM     |
| US186           | HARDY BIPOLAR FORCEPS INS 2.0MM215MM     |
| US187           | HARDY BIPOLAR FORCEPS INS 0.5MM255MM     |
| US188           | HARDY BIPOLAR FORCEPS INS 1.0MM255MM     |
| US189           | HARDY BIPOLAR FORCEPS INS 1.5MM255MM     |
| US305           | CUSHING BIPOLAR FCPSBAYOINS2MM190MM      |
| US308           | CUSHING BIPOLAR FCPSBAYOINS0.7MM190MM    |
| US310           | HARDY BIPOLAR FORCEPS INS .5MM215MM      |
| US403           | GOLDTIP BIPOLAR FCPS STR 150/50/0.5MM    |
| US404           | GOLDTIP BIPOLAR FCPS STR 150/50/0.7MM    |
| US405           | GOLDTIP BIPOLAR FCPS STR 150/50/1.0MM    |
| US406           | GOLDTIP BIPOLAR FCPS STR 150/50/1.5MM    |
| US407           | GOLDTIP BIPOLAR FCPS STR 150/50/2.0MM    |
| US486           | GOLDTIP BIPOLAR FCPS STR 150/50/0.25MM   |
| US487           | GOLDTIP BIPOLAR FCPS STR 170/70/0.25MM   |
| US488           | GOLDTIP BIPOLAR FCPS STR 170/70/0.5MM    |
| US489           | GOLDTIP BIPOLAR FCPS STR 170/70/0.7MM    |
| US490           | GOLDTIP BIPOLAR FCPS STR 170/70/1.0MM    |
| US491           | GOLDTIP BIPOLAR FCPS STR 170/70/1.5MM    |
| US492           | GOLDTIP BIPOLAR FCPS STR 170/70/2.0MM    |

| <b>Material</b> | <b>Material Description</b>             |
|-----------------|-----------------------------------------|
| US493           | GOLDTIP BIPOLAR FCPS STR 190/90/0.25MM  |
| US494           | GOLDTIP BIPOLAR FCPS STR 215/115/0.25MM |
| US495           | GOLDTIP BIPOLAR FCPS STR 230/125/0.25MM |
| US496           | GOLDTIP BIPOLAR FCPS STR 255/150/0.25MM |
| US530           | GOLDTIP BIPOLAR FCPS STR 255/150/0.5MM  |
| US531           | GOLDTIP BIPOLAR FCPS STR 255/150/2.0MM  |
| US600           | GOLDTIP BIPOLAR FCPS STR 190/90/0.5MM   |
| US601           | GOLDTIP BIPOLAR FCPS STR 190/90/0.7MM   |
| US602           | GOLDTIP BIPOLAR FCPS STR 190/90/1.0MM   |
| US603           | GOLDTIP BIPOLAR FCPS STR 190/90/1.5MM   |
| US604           | GOLDTIP BIPOLAR FCPS STR 190/90/2.0MM   |
| US610           | GOLDTIP BIPOLAR FCPS STR 215/115/0.5MM  |
| US611           | GOLDTIP BIPOLAR FCPS STR 215/115/0.7MM  |
| US612           | GOLDTIP BIPOLAR FCPS STR 215/115/1.0MM  |
| US613           | GOLDTIP BIPOLAR FCPS STR 215/115/1.5MM  |
| US614           | GOLDTIP BIPOLAR FCPS STR 215/115/2.0MM  |
| US615           | GOLDTIP BIPOLAR FCPS STR 230/125/0.5MM  |
| US616           | GOLDTIP BIPOLAR FCPS STR 230/125/0.7MM  |
| US617           | GOLDTIP BIPOLAR FCPS STR 230/125/1.0MM  |
| US618           | GOLDTIP BIPOLAR FCPS STR 230/125/1.5MM  |
| US619           | GOLDTIP BIPOLAR FCPS STR 230/125/2.0MM  |
| US620           | GOLDTIP BIPOLAR FCPS STR 255/150/0.7MM  |
| US621           | GOLDTIP BIPOLAR FCPS STR 255/150/1.0MM  |
| XG601           | WFNS BASIC SET OF BIPOLAR COAGULATION   |

**Appendix 1b: List of affected products – Single Use Products  
(Non-reprocessible / sterilizable)**

| <b>Material</b> | <b>Material Description</b>              |
|-----------------|------------------------------------------|
| GK501SU         | GOLDTIP DISP.BIPOLAR FCPS 190/90/0,5MM   |
| GK502SU         | GOLDTIP DISP.BIPOLAR FCPS 190/90/1,0MM   |
| GK503SU         | GOLDTIP DISP.BIPOLAR FCPS 190/90/1,5MM   |
| GK504SU         | GOLDTIP DISP.BIPOLAR FCPS 215/115/0,5MM  |
| GK505SU         | GOLDTIP DISP.BIPOLAR FCPS 215/115/1,0MM  |
| GK506SU         | GOLDTIP DISP.BIPOLAR FCPS 215/115/1,5MM  |
| GK507SU         | GOLDTIP DISP.BIPOLAR FCPS 190/90/0.25MM  |
| GK508SU         | GOLDTIP DISP.BIPOLAR FCPS 215/115/0.25MM |
| GK509SU         | GOLDTIP DISP.BIPOLAR FCPS 190/90/0.7MM   |
| GK510SU         | GOLDTIP DISP.BIPOLAR FCPS 215/115/0.7MM  |