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Quality Management**

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

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

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

Bankverbindungen:
Deutsche Bank AG Tuttlingen
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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Manual cleaning/ disinfection as listed in the currently valid instructions for use is no longer applicable for neuro applications.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 [°C/°F]	t [min]	Conc. [%]	Water quality	Chemical
I	Cleaning	RT (cold)	>15	1	D-W	B. Braun Stabimed® fresh
II	Rinsing	RT (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 ultrasound¹⁾

Phase	Step	T [°C/°F]	t [min]	Water quality	Chemical
I	Prerinse	<25/77	3	D-W	-
II	Cleaning	55/131	10	FD-W	Dr. Weigert neodisher® SeptoClean Application solution 1 % ²⁾
III	Neutralization	>10/50	2	FD-W	B. Braun Helimatic® Neutralizer C 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 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

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).

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">1. Correction of reprocessing processes to be used, since a different cleaner must be listed2. Split of Annex 1 into parts a and b to separate the single use products, as they must be excluded from reprocessing

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

Material	Material Description
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

Material	Material Description
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

Material	Material Description
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

Material	Material Description
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

Material	Material Description
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

Material	Material Description
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

Material	Material Description
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

Material	Material Description
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)**

Material	Material Description
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