

Urgent Field Safety Notice (FSN)
Haemostatic forceps

For Attention of: **Users, Importers and Distributors of the affected device(s).**

Contact details of local representative (name, e-mail, telephone, address etc.)

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Dear Customer,

Aesculap AG as legal manufacturer of the device(s) Haemostatic forceps has updated the Instructions for Use (IFU). The content changes are provided in this Field Safety Notice (FSN) as preventive action to all affected economic operators globally.

1. Information on Affected Devices	
1.1	Device Type(s)
	<ul style="list-style-type: none">▪ Haemostatic forceps
1.2.	Commercial name(s)
	<ul style="list-style-type: none">▪ AESCULAP® Haemostatic forceps▪ Haemostatic clamps

1.3.	Part number(s)	Device Name
	BH100R	CARREL ARTERY FORCEPS 85MM
	BH104R	HARTMANN MOSQUITO FCSD DEL STR 100MM
	BH105R	HARTMANN MOSQUITO FCPSDEL CVD100MM
	BH108R	MICRO-HALSTED FORCEPS DEL STR125MM
	BH114R	HARTMANN MOSQUITO FCPSDELSTR1X2100MM
	BH115R	HARTMANN MOSQUITO FCPSDEL CVD1X2100MM
	BH118R	MICRO-HALSTED FCPS DEL STR 1X2125MM
	BH119R	MICRO-HALSTED FCPS DEL CVD 1X2125MM
	BH120R	HALSTED-MOSQUITO FCPSDELSTR1X2125MM
	BH121R	HALSTED-MOSQUITO FCPS DELCVD1X2125MM
	BH130R	PROVIDENCE-HOSP FCPS DEL STR140MM
	BH131R	PROVIDENCE-HOSP FCPS DEL CVD 140MM
	BH135R	KELLY FORCEPS DEL CVD 140MM
	BH139R	DANDY DELICATE FORCEPS CVD140MM
	BH140R	BABY CRILE FORCEPS DEL STR 140MM
	BH141R	BABY CRILE FORCEPSDEL CVD140MM
	BH143R	DANDY DEL FCPS LAT-CVD 1X2 140MM
	BH145R	CRILE FORCEPS CVD 140MM
	BH150R	BABY KOCHER FORCEPS STR.140MM
	BH151R	KOCHER FORCEPS DEL CVD 1X2140MM
	BH154R	CRILE FORCEPS DEL STR 1X2 140MM
	BH155R	CRILE FORCEPS DEL CVD 1X2 140MM
	BH160R	LERICHE DELICATE FORCEPS STR 150MM
	BH161R	LERICHE DELICATE FORCEPS CVD 150MM
	BH164R	RANKIN FCPS LONG KELLY DEL STR160MM
	BH166R	CRILE FORCEPS STR 160MM
	BH168R	DIXON LOVELACE STR.160MM
	BH170R	LERICHE DELICATE FORCEPS STR 1X2150MM
	BH171R	LERICHE DELICATE FORCEPS CVD1X2150MM
	BH176R	CRILE FORCEPS STR 1X2160MM
	BH177R	CRILE FORCEPS CVD 1X2 160MM
	BH178R	DIXON-LOVELACE ARTERY FCPS.1X2T.STR.160
	BH191R	DUNHILL ARTERIAL CLAMP CVD 190MM
	BH196R	BIRKETT ARTERY FORCEPS STR.185MM
	BH197R	BIRKETT DELICATE FORCEPS CVD185MM
	BH198R	FUCHSIG ARTERY FORCEPS CVD.190MM
	BH199R	NISSEN DELICATE FORCEPS CVD 185MM
	BH200R	ADSON DELICATE FORCEPS STR185MM
	BH201R	ADSON DELICATE FORCEPS CVD 185MM
	BH202R	HALSTED DELICATE FORCEPS STR 185MM
	BH203R	HALSTED DELICATE FORCEPS CVD 185MM
	BH205R	ADSON HEMOSTATIC FCPS CVD.215MM
	BH206R	HEISS DELICATE FORCEPS STR 200MM
	BH207R	HEISS DELICATE FORCEPS CVD 200MM
	BH210R	HALSTED-MOSQUITO FORCEPS DELSTR200MM
	BH211R	HALSTED-MOSQUITO FCPS DEL CVD 200MM
	BH212R	HALSTED-MOSQUITO FCPSDELSTR1X2185MM
	BH213R	HALSTED-MOSQUITO FCPSDEL CVD1X2185MM
	BH214R	HALSTED-MOSQ.FCPSDELSTR1X2 200MM
	BH215R	HALSTED-MOSQ.FCPSDEL CVD 1X2 200MM
	BH216R	HEISS DELICATE FORCEPS STR 1X2 200MM

BH217R	HEISS DELICATE FORCEPS CVD 1X2 200MM
BH224R	SAROT DELICATE FORCEPS 240MM
BH225R	CRAFOORD DELICATE FORCEPS CVD 245MM
BH227R	ARTERY FORCEPS CRAFOORD MODIF.240MM
BH228R	BENGOLEA DELICATE FORCEPS STR 245MM
BH230R	BRIDGE DELICATE FORCEPS STR 275MM
BH231R	BRIDGE DELICATE FORCEPS CVD 275MM
BH234R	SAROT DELICATE FORCEPS STR 1X2240MM
BH238R	BENGOLEA DEL CV FCPS STR W/1X2245MM
BH239R	BENGOLEA DEL CV FCPS W/1X2 245MM
BH300R	KROENLEIN ARTERY FORCEPS STR.130MM
BH302R	PEAN ARTERY FORCEPS STR.125MM
BH304R	PEAN ARTERY FORCEPS STRAIGHT 140MM
BH316R	PEAN ARTERY FORCEPS STR.165MM
BH318R	PEAN ARTERY FORCEPS STR.185MM
BH332R	SPENCER-WELLS FORCEPS STR130MM
BH333R	SPENCER-WELLS FORCEPS CVD 130MM
BH334R	SPENCER-WELLS FORCEPS STR 150MM
BH335R	SPENCER-WELLS FORCEPS CVD150MM
BH336R	SPENCER-WELLS FORCEPS STR 175MM
BH337R	SPENCER-WELLS FORCEPS CVD 175MM
BH338R	SPENCER-WELLS FORCEPS STR 200MM
BH339R	SPENCER-WELLS FORCEPS CVD 200MM
BH361R	SPENCER-WELLS ARTERY FORCEPS CVD.230MM
BH410R	PEAN FORCEPS STR 125MM
BH412R	PEAN FORCEPS DEL STR 130MM
BH413R	PEAN FORCEPS DEL CVD 130MM
BH414R	PEAN FORCEPS DEL STR 140MM
BH415R	PEAN FORCEPS DEL CVD 140MM
BH422R	PEAN FORCEPS STR130MM
BH424R	PEAN FORCEPS STR 140MM
BH425R	PEAN FORCEPS CVD 140MM
BH442R	ROCHESTER-PEAN FORCEPS STR 160MM
BH443R	ROCHESTER-PEAN FORCEPS CVD 160MM
BH444R	ROCHESTER-PEAN FORCEPS STR 185MM
BH445R	ROCHESTER-PEAN FORCEPS CVD 185MM
BH446R	ROCHESTER-PEAN FORCEPS STR 200MM
BH448R	ROCHESTER-PEAN FORCEPS STR 225MM
BH450R	ROCHESTER-PEAN FORCEPS STR 240MM
BH456R	ROCHESTER-PEAN FORCEPS STR.350MM
BH470R	PEAN FORCEPS STR240MM
BH471R	PEAN FORCEPS CVD 240MM
BH472R	PEAN FORCEPS STR 260MM
BH473R	PEAN FORCEPS CVD 260MM
BH474R	PEAN FORCEPS STR 280MM
BH610R	KOCHER ARTERY FORCEPS 1X2T.STR.145MM
BH612R	KOCHER DEL FCPS STR 1X2 130MM
BH615R	KOCHER FORCEPS CVD 1X2140MM
BH619R	ROCHESTER-OCHSNER FCPS CVD1X2140MM
BH642R	KOCHER-OCHSNER FORCEPS STR 1X2 160MM
BH643R	KOCHER-OCHSNER FORCEPS CVD 1X2 160MM
BH644R	KOCHER-OCHSNER FORCEPS STR 1X2 185MM

BH645R	KOCHER-OCHSNER FORCEPS CVD 1X2 185MM
BH646R	KOCHER-OCHSNER FORCEPS STR 1X2 200MM
BH647R	KOCHER-OCHSNER FORCEPS CVD 1X2 200MM
BH648R	KOCHER-OCHSNER FORCEPS STR 1X2 225MM
BH649R	KOCHER-OCHSNER FORCEPS CVD 1X2 225MM
BH650R	KOCHER-OCHSNER FORCEPS STR 1X2240MM
BH651R	KOCHER-OCHSNER FORCEPS CVD 1X2240.MM
BH652R	KOCHER-OCHSNER FORCEPS STR1X2260MM
BH653R	KOCHER-OCHSNER FORCEPS CVD1X2260MM
BH654R	OCHSNER FORCEPS STR 1X2280MM
BH655R	KOCHER-OCHSNER FORCEPS CVD 1X2280MM
BH800R	ROCHESTER-CARMALT FORCEPS STR160MM
BH801R	ROCHESTER-CARMALT FORCEPS CVD 160MM
BH804R	ROCHESTER-CARMALT FORCEPS STR 200MM
BH805R	ROCHESTER-CARMALT FORCEPS CVD 200MM
BH808R	CLAMP FICKLING 1X2T.ANG.SIDEW.180MM
BH812R	ARTERY FORCEPS STRAIGHT 250MM
BH814R	ARTERY FORCEPS CURVED 225MM
BH831R	MOYNIHAN SPECIAL FORCEPS CVD 230MM
BH833R	MOYNIHAN SPECIAL FORCEPS CVD 240MM
BH949R	MIKULICZ ARTERY FORCEPS 1X2T.CVD.185MM
BH951R	NEGUS TONSIL FORCEPS HVY-CVD 190MM
BH952R	NEGUS TONSIL FORCEPSX-HVY-CVD190MM
BH957R	SCHNIDT TONSIL FORCEPS SLT-CVD185MM
BH959R	SCHNIDT TONSIL FORCEPS CVD 185MM
BH961R	SCHNIDT TONSIL FCPSOPEN-RINGCVD 185MM
BH963R	SCHNIDT TONSIL FCPSOPEN-RINGCVD185MM
BH965R	WILSON TONSIL FORCEPS 190MM
BJ009R	BABY OVERHOLT DISS.A.LIGAT.FORCEPS 135MM
BJ015R	DISS.A.LIGAT.FORCEPS S-SHAPED CVD.185MM
BJ016R	DISS.A.LIGAT.FORCEPS S-SHAPED CVD.210MM
BJ017R	DISS.A.LIGAT.FORCEPS S-SHAPED CVD.215MM
BJ018R	DISS.A.LIGAT.FORCEPS S-SHAPED CVD.220MM
BJ019R	OVERHOLT MIXTER DISS.A.LIGAT.FCPS.205MM
BJ020R	OVERHOLT-GEISS SUTURE FCPS #0CVD195MM
BJ021R	OVERHOLT-GEISS SUTURE FCPS #1CVD205MM
BJ022R	OVERHOLT-GEISS SUTURE FCPS #2CVD220MM
BJ024R	OVERHOLT-GEISS SUTURE FCPS#4CVD220MM
BJ025R	OVERHOLT-GEISS SUTURE FCPS #5CVD230MM
BJ026R	OVERHOLT-GEISS SUTURE FCPS #6 CVD225MM
BJ031R	OVERHOLT-GEISS SUTURE FCPS#1CVD260MM
BJ032R	OVERHOLT-GEISS SUTURE FCPS#2CVD270MM
BJ033R	OVERHOLT-GEISS SUTURE FCPS#3CVD275MM
BJ034R	OVERHOLT-GEISS SUTURE FCPS#4CVD270MM
BJ035R	OVERHOLT-GEISS SUTURE FCPS #5CVD280MM
BJ037R	FORCEPS CVD DELICATE 145MM
BJ038R	FORCEPS CVD.DELICATE 185MM
BJ039R	FORCEPS CVD.DELICATE 235MM
BJ041R	RUMEL SUTURE FORCEPS SLT-CVD 240MM
BJ042R	RUMEL SUTURE FORCEPS CVD 240MM
BJ043R	RUMEL SUTURE FORCEPS MED-CV 240MM
BJ044R	RUMEL SUTURE FORCEPS HVY-CV 240MM

BJ045R	RUMEL SUTURE FORCEPS RT-ANG# 5 240MM
BJ047R	ZENKER SUTURE FORCEPS SLT-CVD 300MM
BJ048R	ZENKER SUTURE FORCEPS HVY-CVD 290MM
BJ050R	MIXTER-O'SHAUGNESSY FORCEPS CVD190MM
BJ051R	WIKSTROEM SUTURE FORCEPS RT-ANG 205MM
BJ052R	FINOCHIETTO SUTURE FCPCVDW/HOLE245MM
BJ055R	MIXTER SUTURE FORCEPS RT-ANG 230MM
BJ058R	KANTROWITZ THORACIC CLAMP 245MM
BJ059R	KANTROWITZ THORACIC CLAMP 275MM
BJ060R	LAHEY FORCEPS LONG-SERR 225MM
BJ061R	MIXTER FORCEPS LONG-SERR220MM
BJ062R	MIXTER FORCEPS LONG-SERR 250MM
BJ067R	O'SHAUGNESSY DISS.A.LIGAT.FORCEPS 220MM
BJ068R	LAHEY DISS.A.LIGAT.FORCEPS 230MM
BJ070R	LAWRENCE SUTURE FCPS DEL CVDD 270MM
BJ073R	MIXTER FORCEPS LONG-SERR 290MM
BJ080R	OVERHOLT FORCEPS # 0 CVD215MM
BJ081R	OVERHOLT FORCEPS # 1 CVD210MM
BJ082R	OVERHOLT FORCEPS # 2 CVD 220MM
BJ086R	OVERHOLT FORCEPS # 6 CVD 225MM
BJ090R	OVERHOLT FORCEPS # 0 CVD 295MM
BJ091R	OVERHOLT FORCEPS # 1 CVD 295MM
BJ096R	OVERHOLT FORCEPS # 6 CVD 300MM
BJ103R	GEMINI CLAMP RT-ANG200MM
BJ106R	GEMINI CLAMP RT-ANG 280MM
BJ120R	O'SHAUGNESSY DISS.A.LIGAT.FORCEPS 160MM
BJ121R	O'SHAUGNESSY DISS.A.LIGAT.FORCEPS 180MM
BJ122R	O'SHAUGNESSY DISS.A.LIGAT.FORCEPS 200MM
BJ123R	O'SHAUGNESSY DISS.A.LIGAT.FORCEPS 220MM
BJ124R	O'SHAUGNESSY DISS.A.LIGAT.FORCEPS 245MM
BJ130R	ZENKER DISS & LIG FCPSSLT-CVD 350MM
BJ131R	ZENKER DISS & LIG FCPS CVD 350MM
BJ132R	ZENKER DISS & LIG FCPSHVY-CVD 350MM
BJ500R	PHANEUF HYSTERECTOMY FORCEPS STR 210MM
BJ501R	PHANEUF HYSTERECTOMY FORCEPS ANG 205MM
BJ506R	WERTHEIM HYSTERECTOMY FORCEPS CVD.235MM
BJ507R	WERTHEIM HYSTERECTOMY FORCEPS CVD.235MM
BJ510R	HOLZBACH HYST FORCEPS STR 245MM
BJ511R	HOLZBACH HYST FORCEPS CVD245MM
BJ517R	MAINGOT HYSTERECTOMY CLAMPS 210MM
BJ519R	MAINGOT HYSTERECTOMY CLAMPS 250MM
BJ520R	HEANEY HYST FORCEPS GROOVED 205MM
BJ521R	HEANEY HYST FORCEPS GROOVED 250MM
BJ522R	HEANEY HYST FORCEPS GROOVED195MM
BJ524R	HEANEY-REZEK FCPSSSTR SER LGTH 210MM
BJ527R	WIENER HYST FORCEPS GROOVES 240MM
BJ530R	HEANEY HYSTERECTOMY FORCEPS STR 225MM
BJ531R	HEANEY HYSTERECTOMY FORCEPS CVD220MM
BJ532R	HEANEY HYSTERECTOMY FORCEPS CVD215MM
BJ534R	HYSTERECTOMY FOR.GWILLIAMSSSTR.205MM
BJ535R	HYSTERECTOMY FOR.GWILLIAMSCUR.205MM
BJ536R	MAINGOT HYSTERECTOMY FORCEPS STR.210MM


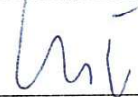
BJ537R	BERKELEY-BONNEY HYSTERECTOMY FCPS.205MM
BJ540R	SEGOND-LANDAU FCPSW/SCRWSTRSRR240MM
BJ541R	SEGOND FORCEPS W/SCREW CVDSERR240MM
BJ550R	WERTHEIM PARAMETRIUM CLAMP STR 250MM
BJ551R	WERTHEIM PARAMETRIUM CLAMP CVD 245MM
BJ552R	WERTHEIM PARAMETRIUM CLAMP CVD240MM
BJ553R	WERTHEIM PARAMETRIUM CLAMPHVY-CVD220MM
FB440R	DE'BAKEY ATR.MOSQUITO FCPS STR125MM
FB441R	DE'BAKEY ATR.MOSQUITO FCPS CVD 125MM
FB442R	DE'BAKEY ATR.MOSQUITO FCPS STR165MM
FB443R	DE'BAKEY ATR.MOSQUITO FCPS CVD165MM
FB444R	PEAN-DE'BAKEY ATR.FRCPS STR155MM
FB446R	DE'BAKEY-BAINBRIDGE ATR.FCPS STR 155MM
FB447R	DE'BAKEY-BAINBRIDGE ATR.FCPS CVD 155MM
FB448R	DE'BAKEY-BAINBRIDGE ATR.FCPS STR180MM
FB458R	GLOVER ATR.CLAMP CVD 215MM
FB459R	GLOVER ATR.CLAMP CVD 245MM
FB461R	GLOVER ATR.CLAMP 195MM
FB462R	GLOVER ATR.CLAMP 210MM
FB469R	LELAND-JONES PERIPHERAL CLMPSTR 195MM
FB483R	DE'BAKEY SUTURE FORCEPS 240MM
FB486R	DE'BAKEY-RUMEL SUTURE FORCEPS CVD245MM
FB487R	DE'BAKEY-RUMEL SUTURE FCPS CVD245MM
FB496R	DE'BAKEY-MC'QUIGG-MIXTER ATR.FCPS.210MM
FB497R	DE'BAKEY-MIXTER ATR.DISS./LIGAT.FORCEPS
FB498R	DE'BAKEY ATR.DISS./LIGAT.FORCEPS 210MM
FB499R	DE'BAKEY ATR.DISS./LIGAT.FORCEPS 230MM
FB526R	DE'BAKEY-PEAN ATR.FRCPS STR.60MM 200MM
FB527R	DE'BAKEY-PEAN ATR.FRCPS CVD 60MM200MM
FB533R	DE'BAKEY-PEAN ATR.FCPS CVD89MM260MM
FB534R	DE'BAKEY-PEAN ATR.FCPS STR 99MM 280MM
FB568R	COOLEY PEDIATRIC CLAMP 60DG 30/160MM
FB729R	COOLEY PEDIATRIC CLAMP 17MM 170MM
FB741R	COOLEY ATR.FORCEPS 140MM CVD.
FB742R	COOLEY ATR.FORCEPS 140MM
FB961R	SEMB SUTURE FORCEPS HVY-CVD 240MM
MB229R	JACOBSON MOSQUITO FCPSX-DEL CVD.130MM
MD464	COLLER ARTERY FORCEPS STR 145MM
MD468	COLLER ARTERY FORCEPS STR.180MM
MD469	COLLER ARTERY FORCEPS CVD.180MM
MD569	RIGHT ANGLE CLAMP 140MM
MD592	HEANY BALLENTINE HYST FCPS CVD.215MM
BH618R	ROCHESTER-OCHSNER FCPS STR1X2140MM
BH630R	KOCHER FORCEPS STR 1X2 150MM
BH631R	KOCHER FORCEPS CVD 1X2 150MM

1.4.	<p>Primary clinical purpose of device(s)</p> <p>As the device(s) are limited by their design of the jaw length, the use thereof is limited to the occlusion of minor blood vessels by design and size. The devices cannot be used for the occlusion of large blood vessels. To further emphasize the limited use the Intended Purpose of the device(s) is restricted to:</p> <p>“Haemostatic Clamps are used for clamping of tissue and small vessels.”</p>
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2. Reason for Field Safety Corrective Action	
2.1	<p>Description of the product problem</p> <p>According to market feedback, the Haemostatic forceps have been used according to indications which are currently not covered by the design (e.g. larger blood vessels or fixation of medical materials) leading to customer complaint cases related to the breakage of the device(s) during use caused by the failure mode “breakage of the box lock”.</p>
2.2	<p>Hazard giving rise to the FSCA</p> <p>By its design and the limits of the jaw opening, the Haemostatic forceps are designed and used in clinical practice for the occlusion of small blood vessels. In the event of the device failure “breakage of the box lock”, the functionality of the device(s) is lost, which may result in the blood vessel not being occluded properly and/or parts falling in the situs.</p> <p>In a rare worst-case scenario, the device(s) failure may cause long-term health consequences if the device(s) is used in conjunction with another device in a cardiopulmonary bypass as was uniquely reported in one customer complaint case.</p>
2.3	<p>Probability of problem arising</p> <p>Globally, the occurrence rates for both potential hazards (2.2) resulting from the product problem are as follows:</p> <ul style="list-style-type: none"> • Additional medical intervention: 0.00001% (maximum allowable rate: 0.05%) • Major critical blood loss: 0.000001% (maximum allowable rate: 0.00005%) <p>Therefore, the occurrence in clinical practice is considered “improbable”.</p>
2.4	<p>Predicted risk to patient/users</p> <p>The risk for patients resulting from small blood vessels not being occluded properly and/or parts falling in situs may be minor bleedings which have to be treated by additional medical intervention and may cause surgery delay.</p> <p>The risk from using the device(s) in conjunction with another device in a cardiopulmonary bypass may be immediate and long-term health consequences dependent on the surgical intervention during which the device(s) is used and possible clinical circumstances.</p>
2.5	<p>Further information to help characterise the problem</p> <p>N/A</p>
2.6	<p>Background on Issue</p> <p>N/A</p>
2.7	<p>Other information relevant to FSCA</p> <p>N/A</p>

3. Type of Action to mitigate the risk																				
3.1	Action To Be Taken by the User																			
	<p>The user is requested to promptly implement the new product-specific Instructions for Use (IFU), which is attached to this FSN, and to ensure the compliant use of the device(s) at patients. Additionally, the user must immediately implement the guidelines for verifying the safety and performance of the device(s) within the context of lifecycle monitoring during the reprocessing routine.</p> <p>The following adjustments have been made in the new product-specific Instructions for Use (IFU) Haemostatic forceps TA016590 - 2024-12 in comparison to the former IFU:</p> <table border="1"> <thead> <tr> <th>Chapter</th> <th>Chapter</th> <th>New content</th> </tr> </thead> <tbody> <tr> <td>2.1.1</td> <td>Intended purpose</td> <td rowspan="2">Haemostatic clamps are used for clamping of tissue and small vessels.</td> </tr> <tr> <td>2.1.2</td> <td>Intended use</td> </tr> <tr> <td>3.2</td> <td>Service life</td> <td>End-of-life indicators for these products are signs of corrosion, cracks as well as deformation in the jaw area and loss of tension.</td> </tr> <tr> <td>3.9.1</td> <td rowspan="2">Visual inspection</td> <td>Inspect the product carefully: The surface of the product shall be clean and free of any signs of corrosion and cracks.</td> </tr> <tr> <td></td> <td>Especially check the area of the joint and the jaw in open position from both sides. If in doubt, use magnification.</td> </tr> <tr> <td>3.9.2</td> <td>Functional test</td> <td>Check the jaw area for deformation and loss of tension.</td> </tr> </tbody> </table>	Chapter	Chapter	New content	2.1.1	Intended purpose	Haemostatic clamps are used for clamping of tissue and small vessels.	2.1.2	Intended use	3.2	Service life	End-of-life indicators for these products are signs of corrosion, cracks as well as deformation in the jaw area and loss of tension.	3.9.1	Visual inspection	Inspect the product carefully: The surface of the product shall be clean and free of any signs of corrosion and cracks.		Especially check the area of the joint and the jaw in open position from both sides. If in doubt, use magnification.	3.9.2	Functional test	Check the jaw area for deformation and loss of tension.
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3.2	By when should the action be completed?																			
	The Aesculap AG plans to complete this FSN within the next 9 months.																			
3.3	Is follow-up of patients or review of patients' previous results recommended?																			
	No																			
3.4	Is customer reply required?																			
	Yes. See point 4.3																			
3.5	Action Being Taken by the Manufacturer																			
	The new eIFU will be published from 16 th December 2024 on at https://eifu.bbraun.com globally.																			
3.6	Is the FSN required to be communicated to the patient /lay user?																			
	No																			
3.7	If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?																			
	N/A																			

4. General Information* / Allgemeine Informationen*	
4.1	FSN Type
	New
4.2	Manufacturer information
	(For contact details of local representative refer to page 1 of this FSN)
	Company Name/Name des Unternehmens
	Aesculap AG
	Address
	Postfach 40, 78501 Tuttlingen
	Website address
	http://www.aesculap.de

4.3	List of attachments/appendices:	Feedback Form
4.4	Name/Signature	
		Georg Erhard Safety Officer Quality Management
	Name/Signature	
		Christian von der Grün Director Post Market Surveillance Quality Management
Transmission of this Field Safety Notice (FSN)		
<p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.</p>		