

Date/Datum: 2024-12-19

**UPDATE Urgent Field Safety Notice/**  
**Dringende Sicherheitsinformation (FSN)**  
**Haemostatic Forceps/Hämostatische Klemmen**

For Attention of\*: **Users, Importers and Distributors of the affected products.**

Zu Beachtung für\*: **Anwender, Importeure und Distributoren der betroffenen Produkte.**

Contact details of local representative (name, e-mail, telephone, address etc.)* Kontaktdaten des lokalen Vertreters (Name, E-Mail, Telefon, Adresse usw.)*
Aesculap AG Quality Management Postfach 40 78501 Tuttlingen Germany/Deutschland
<b>Quality Management</b> Dominik Neumeister FSCA Coordinator Phone: +49 7461-95 31139 email: vigilance_aag.de@aesculap.de
<b>Global Marketing &amp; Sales</b> Annabelle Haller Product Manager Surgical Instruments Phone: +49 7461-95 31462 email: annabelle.haller@aesculap.de

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. This update, following the initial FSN dated December 16, 2024, has become necessary because additional affected articles have been identified and added to this FSN.

*Geschätzter Kunde,*

*Aesculap AG als Hersteller der Produkt (hämostatische Klemmen) hat die Gebrauchsanweisung (IFU) aktualisiert. Die inhaltlichen Änderungen werden in dieser dringenden Sicherheitsinformation (FSN) als präventive Maßnahme für alle betroffenen Wirtschaftsbeteiligten weltweit bereitgestellt. Die Aktualisierung der ursprünglichen FSN vom 16. Dezember 2024 wurde notwendig, da zusätzliche betroffene Artikel identifiziert und in diese FSN aufgenommen wurden.*

<b>1. Information on Affected Devices/Angaben zu den betroffenen Produkten</b>			
1.1	<b>Device Type(s) / Produktgruppe(n)</b>		
	<ul style="list-style-type: none"> <li>▪ Haemostatic forceps / <i>Hämostatische Klemmen</i></li> </ul>		
1.2.	<b>Commercial name(s) / Handelsname(n)</b>		
	<ul style="list-style-type: none"> <li>▪ AESCULAP® Haemostatic forceps / <i>Aesculap Hämostatische Klemmen</i></li> </ul>		
1.3.	<b>Unique Device Identifier(s) / Eindeutige Gerätebezeichnung (UDI-DI)</b>		
	see 1.5.		
1.4.	<b>Primary clinical purpose of device(s) / Primärer klinischer Nutzen der Produkte</b>		
	<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> <p><i>Da die Produkte durch ihr Design in der Backenlänge begrenzt sind, ist ihre Verwendung auf den Verschluss kleinerer Blutgefäße durch Design und Größe beschränkt. Die Produkte können nicht für den Verschluss großer Blutgefäße verwendet werden. Um die eingeschränkte Verwendung weiter zu unterstreichen, wird die Zweckbestimmung der Produkte entsprechend eingeschränkt:</i></p> <p><i>„Hämostatische Klemmen werden zum Abklemmen von Gewebe und kleinen Gefäßen verwendet.“</i></p>		
1.5	<b>Part numbers/Artikelnummern</b>		
	<b>Unique Device Identifiers / Eindeutige Gerätebezeichnung (UDI-DI)</b>		
	BH100R	CARREL ARTERY FORCEPS 85MM	40392390000004722C
	BH104R	HARTMANN MOSQUITO FCSDDEL STR 100MM	40392390000004722C
	BH105R	HARTMANN MOSQUITO FCPSDEL CVD100MM	40392390000004722C
	BH108R	MICRO-HALSTED FORCEPS DEL STR125MM	40392390000004722C
	<b>BH109R*</b>	MICRO-HALSTED FORCEPS DEL CVD 125MM	40392390000004722C
	BH114R	HARTMANN MOSQUITO FCPSDELSTR1X2100MM	40392390000004722C
	BH115R	HARTMANN MOSQUITO FCPSDEL CVD1X2100MM	40392390000004722C
	BH118R	MICRO-HALSTED FCPS DEL STR 1X2125MM	40392390000004722C
	BH119R	MICRO-HALSTED FCPS DEL CVD 1X2125MM	40392390000004722C
	BH120R	HALSTED-MOSQUITO FCPSDELSTR1X2125MM	40392390000004722C
	BH121R	HALSTED-MOSQUITO FCPS DELCVD1X2125MM	40392390000004722C
	BH130R	PROVIDENCE-HOSP FCPS DEL STR140MM	40392390000004722C
	BH131R	PROVIDENCE-HOSP FCPS DEL CVD 140MM	40392390000004722C
	<b>BH134R*</b>	KELLY FORCEPS DEL STR 140MM	40392390000004722C
	BH135R	KELLY FORCEPS DEL CVD 140MM	40392390000004722C
	BH139R	DANDY DELICATE FORCEPS CVD140MM	40392390000004722C
	BH140R	BABY CRILE FORCEPS DEL STR 140MM	40392390000004722C
	BH141R	BABY CRILE FORCEPSDEL CVD140MM	40392390000004722C
	BH143R	DANDY DEL FCPS LAT-CVD 1X2 140MM	40392390000004722C
	<b>BH144R*</b>	CRILE FORCEPS STR 140MM	40392390000004722C

BH145R	CRILE FORCEPS CVD 140MM	4039239000004722C
BH150R	BABY KOCHER FORCEPS STR.140MM	4039239000004722C
BH151R	KOCHER FORCEPS DEL CVD 1X2140MM	4039239000004722C
BH154R	CRILE FORCEPS DEL STR 1X2 140MM	4039239000004722C
BH155R	CRILE FORCEPS DEL CVD 1X2 140MM	4039239000004722C
BH160R	LERICHE DELICATE FORCEPS STR 150MM	4039239000004722C
BH161R	LERICHE DELICATE FORCEPS CVD 150MM	4039239000004722C
BH164R	RANKIN FCPS LONG KELLY DEL STR160MM	4039239000004722C
BH166R	CRILE FORCEPS STR 160MM	4039239000004722C
BH168R	DIXON LOVELACE STR.160MM	4039239000004722C
BH170R	LERICHE DELICATE FORCEPS STR 1X2150MM	4039239000004722C
BH171R	LERICHE DELICATE FORCEPS CVD1X2150MM	4039239000004722C
BH176R	CRILE FORCEPS STR 1X2160MM	4039239000004722C
BH177R	CRILE FORCEPS CVD 1X2 160MM	4039239000004722C
BH178R	DIXON-LOVELACE ARTERY FCPS.1X2T.STR.160	4039239000004722C
BH191R	DUNHILL ARTERIAL CLAMP CVD 190MM	4039239000004722C
BH196R	BIRKETT ARTERY FORCEPS STR.185MM	4039239000004722C
BH197R	BIRKETT DELICATE FORCEPS CVD185MM	4039239000004722C
BH198R	FUCHSIG ARTERY FORCEPS CVD.190MM	4039239000004722C
BH199R	NISSEN DELICATE FORCEPS CVD 185MM	4039239000004722C
BH200R	ADSON DELICATE FORCEPS STR185MM	4039239000004722C
BH201R	ADSON DELICATE FORCEPS CVD 185MM	4039239000004722C
BH202R	HALSTED DELICATE FORCEPS STR 185MM	4039239000004722C
BH203R	HALSTED DELICATE FORCEPS CVD 185MM	4039239000004722C
BH205R	ADSON HEMOSTATIC FCPS CVD.215MM	4039239000004722C
BH206R	HEISS DELICATE FORCEPS STR 200MM	4039239000004722C
BH207R	HEISS DELICATE FORCEPS CVD 200MM	4039239000004722C
BH210R	HALSTED-MOSQUITO FORCEPS DELSTR200MM	4039239000004722C
BH211R	HALSTED-MOSQUITO FCPS DEL CVD 200MM	4039239000004722C
BH212R	HALSTED-MOSQUITO FCPSDELSTR1X2185MM	4039239000004722C
BH213R	HALSTED-MOSQUITO FCPSDEL CVD1X2185MM	4039239000004722C
BH214R	HALSTED-MOSQ.FCPSDELSTR1X2 200MM	4039239000004722C
BH215R	HALSTED-MOSQ.FCPSDEL CVD 1X2 200MM	4039239000004722C
BH216R	HEISS DELICATE FORCEPS STR 1X2 200MM	4039239000004722C
BH217R	HEISS DELICATE FORCEPS CVD 1X2 200MM	4039239000004722C
BH224R	SAROT DELICATE FORCEPS 240MM	4039239000004722C
BH225R	CRAFOORD DELICATE FORCEPS CVD 245MM	4039239000004722C
BH227R	ARTERY FORCEPS CRAFOORD MODIF.240MM	4039239000004722C
BH228R	BENGOLEA DELICATE FORCEPS STR 245MM	4039239000004722C
<b>BH229R*</b>	BENGOLEA DELICATE FORCEPS CVD 245MM	4039239000004722C
BH230R	BRIDGE DELICATE FORCEPS STR 275MM	4039239000004722C
BH231R	BRIDGE DELICATE FORCEPS CVD 275MM	4039239000004722C
BH234R	SAROT DELICATE FORCEPS STR 1X2240MM	4039239000004722C
BH238R	BENGOLEA DEL CV FCPS STR W/1X2245MM	4039239000004722C

BH239R	BENGOLEA DEL CV FCPS W/1X2 245MM	4039239000004722C
BH300R	KROENLEIN ARTERY FORCEPS STR.130MM	4039239000004722C
BH302R	PEAN ARTERY FORCEPS STR.125MM	4039239000004722C
BH304R	PEAN ARTERY FORCEPS STRAIGHT 140MM	4039239000004722C
BH316R	PEAN ARTERY FORCEPS STR.165MM	4039239000004722C
BH318R	PEAN ARTERY FORCEPS STR.185MM	4039239000004722C
BH332R	SPENCER-WELLS FORCEPS STR130MM	4039239000004722C
BH333R	SPENCER-WELLS FORCEPS CVD 130MM	4039239000004722C
BH334R	SPENCER-WELLS FORCEPS STR 150MM	4039239000004722C
BH335R	SPENCER-WELLS FORCEPS CVD150MM	4039239000004722C
BH336R	SPENCER-WELLS FORCEPS STR 175MM	4039239000004722C
BH337R	SPENCER-WELLS FORCEPS CVD 175MM	4039239000004722C
BH338R	SPENCER-WELLS FORCEPS STR 200MM	4039239000004722C
BH339R	SPENCER-WELLS FORCEPS CVD 200MM	4039239000004722C
BH361R	SPENCER-WELLS ARTERY FORCEPS CVD.230MM	4039239000004722C
BH410R	PEAN FORCEPS STR 125MM	4039239000004722C
BH412R	PEAN FORCEPS DEL STR 130MM	4039239000004722C
BH413R	PEAN FORCEPS DEL CVD 130MM	4039239000004722C
BH414R	PEAN FORCEPS DEL STR 140MM	4039239000004722C
BH415R	PEAN FORCEPS DEL CVD 140MM	4039239000004722C
BH422R	PEAN FORCEPS STR130MM	4039239000004722C
BH424R	PEAN FORCEPS STR 140MM	4039239000004722C
BH425R	PEAN FORCEPS CVD 140MM	4039239000004722C
BH442R	ROCHESTER-PEAN FORCEPS STR 160MM	4039239000004722C
BH443R	ROCHESTER-PEAN FORCEPS CVD 160MM	4039239000004722C
BH444R	ROCHESTER-PEAN FORCEPS STR 185MM	4039239000004722C
BH445R	ROCHESTER-PEAN FORCEPS CVD 185MM	4039239000004722C
BH446R	ROCHESTER-PEAN FORCEPS STR 200MM	4039239000004722C
<b>BH447R*</b>	ROCHESTER-PEAN FORCEPS CVD 200MM	4039239000004722C
BH448R	ROCHESTER-PEAN FORCEPS STR 225MM	4039239000004722C
<b>BH449R*</b>	ROCHESTER-PEAN FORCEPS CVD 225MM	4039239000004722C
BH450R	ROCHESTER-PEAN FORCEPS STR 240MM	4039239000004722C
<b>BH451R*</b>	ROCHESTER-PEAN FORCEPS CVD240MM	4039239000004722C
BH456R	ROCHESTER-PEAN FORCEPS STR.350MM	4039239000004722C
BH470R	PEAN FORCEPS STR240MM	4039239000004722C
BH471R	PEAN FORCEPS CVD 240MM	4039239000004722C
BH472R	PEAN FORCEPS STR 260MM	4039239000004722C
BH473R	PEAN FORCEPS CVD 260MM	4039239000004722C
BH474R	PEAN FORCEPS STR 280MM	4039239000004722C
BH610R	KOCHER ARTERY FORCEPS 1X2T.STR.145MM	4039239000004722C
BH612R	KOCHER DEL FCPS STR 1X2 130MM	4039239000004722C
<b>BH614R*</b>	KOCHER FORCEPS STR 1X2 140MM	4039239000004722C
BH615R	KOCHER FORCEPS CVD 1X2140MM	4039239000004722C
BH618R	ROCHESTER-OCHSNER FCPS STR1X2140MM	4039239000004722C

BH619R	ROCHESTER-OCHSNER FCPS CVD1X2140MM	4039239000004722C
BH630R	KOCHER FORCEPS STR 1X2 150MM	4039239000004722C
BH631R	KOCHER FORCEPS CVD 1X2 150MM	4039239000004722C
BH642R	KOCHER-OCHSNER FORCEPS STR 1X2 160MM	4039239000004722C
BH643R	KOCHER-OCHSNER FORCEPS CVD 1X2 160MM	4039239000004722C
BH644R	KOCHER-OCHSNER FORCEPS STR 1X2 185MM	4039239000004722C
BH645R	KOCHER-OCHSNER FORCEPS CVD 1X2 185MM	4039239000004722C
BH646R	KOCHER-OCHSNER FORCEPS STR 1X2 200MM	4039239000004722C
BH647R	KOCHER-OCHSNER FORCEPS CVD 1X2 200MM	4039239000004722C
BH648R	KOCHER-OCHSNER FORCEPS STR 1X2 225MM	4039239000004722C
BH649R	KOCHER-OCHSNER FORCEPS CVD 1X2 225MM	4039239000004722C
BH650R	KOCHER-OCHSNER FORCEPS STR 1X2240MM	4039239000004722C
BH651R	KOCHER-OCHSNER FORCEPS CVD 1X2240.MM	4039239000004722C
BH652R	KOCHER-OCHSNER FORCEPS STR1X2260MM	4039239000004722C
BH653R	KOCHER-OCHSNER FORCEPS CVD1X2260MM	4039239000004722C
BH654R	OCHSNER FORCEPS STR 1X2280MM	4039239000004722C
BH655R	KOCHER-OCHSNER FORCEPS CVD 1X2280MM	4039239000004722C
BH800R	ROCHESTER-CARMALT FORCEPS STR160MM	4039239000004722C
BH801R	ROCHESTER-CARMALT FORCEPS CVD 160MM	4039239000004722C
BH804R	ROCHESTER-CARMALT FORCEPS STR 200MM	4039239000004722C
BH805R	ROCHESTER-CARMALT FORCEPS CVD 200MM	4039239000004722C
<b>BH807R*</b>	CLAMP FICKLING ANG.SIDEW.180MM	4039239000004722C
BH808R	CLAMP FICKLING 1X2T.ANG.SIDEW.180MM	4039239000004722C
BH812R	ARTERY FORCEPS STRAIGHT 250MM	4039239000004722C
<b>BH813R*</b>	ARTERY FORCEPS CURVED 250MM	4039239000004722C
BH814R	ARTERY FORCEPS CURVED 225MM	4039239000004722C
BH831R	MOYNIHAN SPECIAL FORCEPS CVD 230MM	4039239000004722C
BH833R	MOYNIHAN SPECIAL FORCEPS CVD 240MM	4039239000004722C
BH949R	MIKULICZ ARTERY FORCEPS 1X2T.CVD.185MM	4039239000004722C
BH951R	NEGUS TONSIL FORCEPS HVY-CVD 190MM	4039239000004722C
BH952R	NEGUS TONSIL FORCEPSX-HVY-CVD190MM	4039239000004722C
BH957R	SCHNIDT TONSIL FORCEPS SLT-CVD185MM	4039239000004722C
BH959R	SCHNIDT TONSIL FORCEPS CVD 185MM	4039239000004722C
BH961R	SCHNIDT TONSIL FCPSOPEN-RINGCVD 185MM	4039239000004722C
BH963R	SCHNIDT TONSIL FCPSOPEN-RINGCVD185MM	4039239000004722C
BH965R	WILSON TONSIL FORCEPS 190MM	4039239000004722C
BJ009R	BABY OVERHOLT DISS.A.LIGAT.FORCEPS 135MM	4039239000004722C
BJ015R	DISS.A.LIGAT.FORCEPS S-SHAPED CVD.185MM	4039239000004722C
BJ016R	DISS.A.LIGAT.FORCEPS S-SHAPED CVD.210MM	4039239000004722C
BJ017R	DISS.A.LIGAT.FORCEPS S-SHAPED CVD.215MM	4039239000004722C
BJ018R	DISS.A.LIGAT.FORCEPS S-SHAPED CVD.220MM	4039239000004722C
BJ019R	OVERHOLT MIXTER DISS.A.LIGAT.FCPS.205MM	4039239000004722C
BJ020R	OVERHOLT-GEISS SUTURE FCPS #0CVD195MM	4039239000004722C
BJ021R	OVERHOLT-GEISS SUTURE FCPS #1CVD205MM	4039239000004722C

BJ022R	OVERHOLT-GEISS SUTURE FCPS #2CVD220MM	4039239000004722C
<b>BJ023R*</b>	OVERHOLT-GEISS SUTURE FCPS #3 CVD225MM	4039239000004722C
BJ024R	OVERHOLT-GEISS SUTURE FCPS#4CVD220MM	4039239000004722C
BJ025R	OVERHOLT-GEISS SUTURE FCPS #5CVD230MM	4039239000004722C
BJ026R	OVERHOLT-GEISS SUTURE FCPS #6 CVD225MM	4039239000004722C
BJ031R	OVERHOLT-GEISS SUTURE FCPS#1CVD260MM	4039239000004722C
BJ032R	OVERHOLT-GEISS SUTURE FCPS#2CVD270MM	4039239000004722C
BJ033R	OVERHOLT-GEISS SUTURE FCPS#3CVD275MM	4039239000004722C
BJ034R	OVERHOLT-GEISS SUTURE FCPS#4CVD270MM	4039239000004722C
BJ035R	OVERHOLT-GEISS SUTURE FCPS #5CVD280MM	4039239000004722C
BJ037R	FORCEPS CVD DELICATE 145MM	4039239000004722C
BJ038R	FORCEPS CVD.DELICATE 185MM	4039239000004722C
BJ039R	FORCEPS CVD.DELICATE 235MM	4039239000004722C
BJ041R	RUMEL SUTURE FORCEPS SLT-CVD 240MM	4039239000004722C
BJ042R	RUMEL SUTURE FORCEPS CVD 240MM	4039239000004722C
BJ043R	RUMEL SUTURE FORCEPS MED-CV 240MM	4039239000004722C
BJ044R	RUMEL SUTURE FORCEPS HVY-CV 240MM	4039239000004722C
BJ045R	RUMEL SUTURE FORCEPS RT-ANG# 5 240MM	4039239000004722C
BJ047R	ZENKER SUTURE FORCEPS SLT-CVD 300MM	4039239000004722C
BJ048R	ZENKER SUTURE FORCEPS HVY-CVD 290MM	4039239000004722C
BJ050R	MIXTER-O'SHAUGNESSY FORCEPS CVD190MM	4039239000004722C
BJ051R	WIKSTROEM SUTURE FORCEPS RT-ANG 205MM	4039239000004722C
BJ052R	FINOCHIETTO SUTURE FCPCVDW/HOLE245MM	4039239000004722C
BJ055R	MIXTER SUTURE FORCEPS RT-ANG 230MM	4039239000004722C
<b>BJ057R*</b>	KANTROWITZ THORACIC CLAMP 200MM	4039239000004722C
BJ058R	KANTROWITZ THORACIC CLAMP 245MM	4039239000004722C
BJ059R	KANTROWITZ THORACIC CLAMP 275MM	4039239000004722C
BJ060R	LAHEY FORCEPS LONG-SERR 225MM	4039239000004722C
BJ061R	MIXTER FORCEPS LONG-SERR220MM	4039239000004722C
BJ062R	MIXTER FORCEPS LONG-SERR 250MM	4039239000004722C
BJ067R	O'SHAUGNESSY DISS.A.LIGAT.FORCEPS 220MM	4039239000004722C
BJ068R	LAHEY DISS.A.LIGAT.FORCEPS 230MM	4039239000004722C
BJ070R	LAWRENCE SUTURE FCPS DEL CVDD 270MM	4039239000004722C
BJ073R	MIXTER FORCEPS LONG-SERR 290MM	4039239000004722C
BJ080R	OVERHOLT FORCEPS # 0 CVD215MM	4039239000004722C
BJ081R	OVERHOLT FORCEPS # 1 CVD210MM	4039239000004722C
BJ082R	OVERHOLT FORCEPS # 2 CVD 220MM	4039239000004722C
<b>BJ083R*</b>	OVERHOLT FORCEPS # 3 CVD 225MM	4039239000004722C
BJ086R	OVERHOLT FORCEPS # 6 CVD 225MM	4039239000004722C
BJ090R	OVERHOLT FORCEPS # 0 CVD 295MM	4039239000004722C
BJ091R	OVERHOLT FORCEPS # 1 CVD 295MM	4039239000004722C
BJ096R	OVERHOLT FORCEPS # 6 CVD 300MM	4039239000004722C
<b>BJ100R*</b>	GEMINI CLAMP RT-ANG140MM	4039239000004722C
<b>BJ102R*</b>	GEMINI CLAMP RT-ANG 180MM	4039239000004722C

BJ103R	GEMINI CLAMP RT-ANG200MM	4039239000004722C
<b>BJ104R*</b>	GEMINI CLAMP RT-ANG 230MM	4039239000004722C
BJ106R	GEMINI CLAMP RT-ANG 280MM	4039239000004722C
BJ120R	O'SHAUGNESSY DISS.A.LIGAT.FORCEPS 160MM	4039239000004722C
BJ121R	O'SHAUGNESSY DISS.A.LIGAT.FORCEPS 180MM	4039239000004722C
BJ122R	O'SHAUGNESSY DISS.A.LIGAT.FORCEPS 200MM	4039239000004722C
BJ123R	O'SHAUGNESSY DISS.A.LIGAT.FORCEPS 220MM	4039239000004722C
BJ124R	O'SHAUGNESSY DISS.A.LIGAT.FORCEPS 245MM	4039239000004722C
BJ130R	ZENKER DISS & LIG FCPSLT-CVD 350MM	4039239000004722C
BJ131R	ZENKER DISS & LIG FCPS CVD 350MM	4039239000004722C
BJ132R	ZENKER DISS & LIG FCPSHVY-CVD 350MM	4039239000004722C
BJ500R	PHANEUF HYSTERECTOMY FORCEPS STR 210MM	4039239000004722C
BJ501R	PHANEUF HYSTERECTOMY FORCEPS ANG 205MM	4039239000004722C
BJ506R	WERTHEIM HYSTERECTOMY FORCEPS CVD.235MM	4039239000004722C
BJ507R	WERTHEIM HYSTERECTOMY FORCEPS CVD.235MM	4039239000004722C
<b>BJ509R*</b>	WERTHEIM HYSTERECTOMY FORCEPS CVD.245MM	4039239000004722C
BJ510R	HOLZBACH HYST FORCEPS STR 245MM	4039239000004722C
BJ511R	HOLZBACH HYST FORCEPS CVD245MM	4039239000004722C
BJ517R	MAINGOT HYSTERECTOMY CLAMPS 210MM	4039239000004722C
BJ519R	MAINGOT HYSTERECTOMY CLAMPS 250MM	4039239000004722C
BJ520R	HEANEY HYST FORCEPS GROOVED 205MM	4039239000004722C
BJ521R	HEANEY HYST FORCEPS GROOVED 250MM	4039239000004722C
BJ522R	HEANEY HYST FORCEPS GROOVED195MM	4039239000004722C
BJ524R	HEANEY-REZEK FCPSSTR SER LGTH 210MM	4039239000004722C
BJ527R	WIENER HYST FORCEPS GROOVES 240MM	4039239000004722C
BJ530R	HEANEY HYSTERECTOMY FORCEPS STR 225MM	4039239000004722C
BJ531R	HEANEY HYSTERECTOMY FORCEPS CVD220MM	4039239000004722C
BJ532R	HEANEY HYSTERECTOMY FORCEPS CVD215MM	4039239000004722C
BJ534R	HYSTERECTOMY FOR.GWILLIAMSSTR.205MM	4039239000004722C
BJ535R	HYSTERECTOMY FOR.GWILLIAMSCUR.205MM	4039239000004722C
BJ536R	MAINGOT HYSTERECTOMY FORCEPS STR.210MM	4039239000004722C
BJ537R	BERKELEY-BONNEY HYSTERECTOMY FCPS.205MM	4039239000004722C
BJ540R	SEGOND-LANDAU FCPSW/SCRWSTRSRR240MM	4039239000004722C
BJ541R	SEGOND FORCEPS W/SCREW CVDSERR240MM	4039239000004722C
BJ550R	WERTHEIM PARAMETRIUM CLAMP STR 250MM	4039239000004722C
BJ551R	WERTHEIM PARAMETRIUM CLAMP CVD 245MM	4039239000004722C
BJ552R	WERTHEIM PARAMETRIUM CLAMP CVD240MM	4039239000004722C
BJ553R	WERTHEIM PARAMETRIUM CLAMPHVY-CVD220MM	4039239000004722C
FB440R	DE'BAKEY ATR.MOSQUITO FCPS STR125MM	4039239000004722C
FB441R	DE'BAKEY ATR.MOSQUITO FCPS CVD 125MM	4039239000004722C
FB442R	DE'BAKEY ATR.MOSQUITO FCPS STR165MM	4039239000004722C
FB443R	DE'BAKEY ATR.MOSQUITO FCPS CVD165MM	4039239000004722C
FB444R	PEAN-DE'BAKEY ATR.FRCPS STR155MM	4039239000004722C
FB446R	DE'BAKEY-BAINBRIDGE ATR.FCPS STR 155MM	4039239000004722C

FB447R	DE'BAKEY-BAINBRIDGE ATR.FCPS CVD 155MM	4039239000004722C
FB448R	DE'BAKEY-BAINBRIDGE ATR.FCPS STR180MM	4039239000004722C
FB458R	GLOVER ATR.CLAMP CVD 215MM	4039239000004722C
FB459R	GLOVER ATR.CLAMP CVD 245MM	4039239000004722C
FB461R	GLOVER ATR.CLAMP 195MM	4039239000004722C
FB462R	GLOVER ATR.CLAMP 210MM	4039239000004722C
FB469R	LELAND-JONES PERIPHERAL CLMPSTR 195MM	4039239000004722C
FB483R	DE'BAKEY SUTURE FORCEPS 240MM	4039239000004722C
FB486R	DE'BAKEY-RUMEL SUTURE FORCEPS CVD245MM	4039239000004722C
FB487R	DE'BAKEY-RUMEL SUTURE FCPS CVD245MM	4039239000004722C
FB496R	DE'BAKEY-MC'QUIGG-MIXTER ATR.FCPS.210MM	4039239000004722C
FB497R	DE'BAKEY-MIXTER ATR.DISS./LIGAT.FORCEPS	4039239000004722C
FB498R	DE'BAKEY ATR.DISS./LIGAT.FORCEPS 210MM	4039239000004722C
FB499R	DE'BAKEY ATR.DISS./LIGAT.FORCEPS 230MM	4039239000004722C
FB526R	DE'BAKEY-PEAN ATR.FRCPS STR.60MM 200MM	4039239000004722C
FB527R	DE'BAKEY-PEAN ATR.FRCPS CVD 60MM200MM	4039239000004722C
FB533R	DE'BAKEY-PEAN ATR.FCPS CVD89MM260MM	4039239000004722C
FB534R	DE'BAKEY-PEAN ATR.FCPS STR 99MM 280MM	4039239000004722C
<b>FB563R*</b>	COOLEY PEDIATRIC FORCEPS 24MM160MM	4039239000004722C
<b>FB567R*</b>	COOLEY PEDIATRIC CLAMP 30DG30/165MM	4039239000004722C
FB568R	COOLEY PEDIATRIC CLAMP 60DG 30/160MM	4039239000004722C
<b>FB569R*</b>	COOLEY PEDIATRIC CLAMP 90DG30/150MM	4039239000004722C
<b>FB570R*</b>	COOLEY PEDIATRIC FORCEPS 90MM200MM	4039239000004722C
FB729R	COOLEY PEDIATRIC CLAMP 17MM 170MM	4039239000004722C
<b>FB730R*</b>	COOLEY PEDIATRIC CLAMP 20MM175MM	4039239000004722C
<b>FB736R*</b>	COOLEY PEDIATRIC CLAMP 74MM 185MM	4039239000004722C
<b>FB737R*</b>	COOLEY PEDIATRIC CLAMP 86MM 195MM	4039239000004722C
<b>FB738R*</b>	COOLEY PEDIATRIC CLAMP 108MM 260MM	4039239000004722C
FB741R	COOLEY ATR.FORCEPS 140MM CVD.	4039239000004722C
FB742R	COOLEY ATR.FORCEPS 140MM	4039239000004722C
FB961R	SEMB SUTURE FORCEPS HVY-CVD 240MM	4039239000004722C
MB229R	JACOBSON MOSQUITO FCPSX-DEL CVD.130MM	4039239000004722C
MD464	COLLER ARTERY FORCEPS STR 145MM	4039239000004722C
<b>MD465R*</b>	COLLER ARTERY FORCEPS CVD.145MM	4039239000004722C
<b>MD466R*</b>	COLLER ARTERY FORCEPS STR 160MM	4039239000004722C
<b>MD467R*</b>	COLLER ARTERY FORCEPS CVD.160MM	4039239000004722C
MD468	COLLER ARTERY FORCEPS STR.180MM	4039239000004722C
MD469	COLLER ARTERY FORCEPS CVD.180MM	4039239000004722C
MD569	RIGHT ANGLE CLAMP 140MM	4039239000004722C
<b>MD570R*</b>	RIGHT ANGLE CLAMP180MM	4039239000004722C
<b>MD591*</b>	HEANY BALLENTINE HYST FCPS STR.215MM	4039239000004722C
MD592	HEANY BALLENTINE HYST FCPS CVD.215MM	4039239000004722C

\*Articles added in this Updated Urgent Field Safety Notice

\* Neue Artikel in dieser aktualisierten Dringenden Sicherheitsmitteilung für das Feld



1.6	<b>Software version / Software Version</b>
	N/A
1.7	<b>Affected serial or lot number / Betroffene Serien- oder Chargennummern</b>
	N/A
1.8	<b>Associated devices / zugehörige Produkte</b>
	N/A

<b>2. Reason for Field Safety Corrective Action/ Grund für die Sicherheitskorrekturmaßnahme (FSCA)</b>	
2.1	<b>Description of the product problem / Problembeschreibung</b>
	<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> <p><i>Nach Rückmeldungen aus dem Markt wurden die hämostatischen Klemmen für Indikationen verwendet, die nicht durch das Design abgedeckt sind (z. B. große Blutgefäße oder Fixierung von medizinischem Material), was zu Kundenbeschwerden im Zusammenhang mit dem Bruch der Klemmen während der Anwendung aufgrund des Fehlerbildes „Bruch Box Lock“ führte.</i></p>
2.2	<b>Hazard giving rise to the FSCA / Gefahr, der Anlass für die FSCA ist</b>
	<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> <p><i>Hämostatische Klemmen sind durch ihre Konstruktion und die Begrenzung der Maulöffnung für den Verschluss kleiner Blutgefäße ausgelegt und werden in der klinischen Praxis entsprechend eingesetzt. Im Falle des Fehlerbildes „Bruch Box Lock“ geht die Funktionalität des Instruments verloren, was dazu führen kann, dass das Blutgefäß nicht richtig verschlossen wird und/oder Teile in den Situs fallen.</i></p> <p><i>In seltenen, kritischsten Fällen kann ein Produktversagen zu langfristigen gesundheitlichen Folgen führen, wenn das Produkt zusammen mit einem anderen Produkt für einen Herz-Lungen-Bypass verwendet wird, wie in einem einzelnen Kundenbeschwerdefall berichtet wurde.</i></p>
2.3	<b>Probability of problem arising / Auftretenswahrscheinlichkeit des Problems</b>
	<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"> <li>• Additional medical intervention: 0.00001% (maximum allowable rate: 0.05%)</li> <li>• Major critical blood loss: 0.000001% (maximum allowable rate: 0.00005%)</li> </ul> <p>Therefore, the occurrence in clinical practice is considered “improbable”.</p> <p><i>Die Häufigkeit des Auftretens der beiden möglichen Gefährdungen (2.2), die sich aus dem Produktproblem ergeben, stellt sich wie folgt dar:</i></p> <ul style="list-style-type: none"> <li>• <i>Zusätzliche medizinische Intervention: 0,00001% (maximal zulässige Rate: 0,05%)</i></li> <li>• <i>Schwerer kritischer Blutverlust: 0,000001% (maximal zulässige Rate: 0,00005%)</i></li> <li>• <i></i></li> </ul> <p><i>Das Auftreten in der klinischen Praxis wird daher als „unwahrscheinlich“ eingestuft.</i></p>

2.4	<b>Predicted risk to patient/users / Risiko Prognose für Patienten/Endanwender</b>
	<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> <p><i>Das Risiko für den Patienten, dass kleine Blutgefäße nicht ordnungsgemäß verschlossen werden und/oder Teile in den Situs fallen, kann zu kleineren Blutungen führen, die zusätzliche medizinische Maßnahmen erfordern und den chirurgischen Eingriff verzögern können.</i></p> <p><i>Das Risiko, das sich aus der Verwendung der Produkte in Kombination mit anderen Produkten in einem kardiopulmonalen Bypass ergibt, kann zu sofortigen und langfristigen gesundheitlichen Folgen führen, die von dem chirurgischen Eingriff, bei dem die Produkte verwendet werden, und den möglichen klinischen Umständen abhängen.</i></p>
2.5	<b>Further information to help characterise the problem / Weitere Informationen zur Charakterisierung des Problems</b>
	N/A
2.6	<b>Background on Issue / Hintergrund zu dem Problem</b>
	N/A
2.7	<b>Other information relevant to FSCA / Weitere relevante Informationen zur FSCA</b>
	N/A

	<b>3. Type of Action to mitigate the risk / Art der Maßnahme zur Minderung des Risikos</b>																			
3.1	<b>Action To Be Taken by the User / vom Anwender zu ergreifender Maßnahme</b>																			
	<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) on 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 rowspan="2">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>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> <p><i>Der Anwender wird aufgefordert, die neue produktspezifische Gebrauchsanweisung (IFU), die dieser FSN beigelegt ist, unverzüglich umzusetzen und die vorschriftsmäßige Anwendung des/der Produkte(s) am Patienten sicherzustellen. Darüber hinaus ist der Anwender verpflichtet</i></p>		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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<p><i>unverzüglich die Vorgaben zur Überprüfung der Sicherheit und Leistungsfähigkeit des/der Produkte(s) im Rahmen der Lebenszyklusüberwachung in der Aufbereitungsroutine umsetzen.</i></p> <p><i>In der neuen produktspezifischen Gebrauchsanweisung TA016590 - 2024-12 Hämostatische Klemmen wurden folgende Anpassungen gegenüber der bisherigen Gebrauchsanweisung vorgenommen:</i></p>		
<i>Kapitel</i>	<i>Kapitel</i>	<i>Neue Inhalte</i>
2.1.1	Zweckbestimmung	Hämostatische Klemmen werden zum Abklemmen von Gewebe und kleinen Gefäßen verwendet.
2.1.2	Bestimmungsgemäße Verwendung	
3.2	Lebensdauer	Indikatoren für das Ende der Lebensdauer der Produkte sind Anzeichen von Korrosion und Rissen sowie Verformungen im Maulbereich und Spannungsverlust.
3.9.1	Visuelle Prüfung	Das Produkt sorgfältig auf Folgendes hin prüfen: Die Oberfläche des Produkts muss sauber und frei von Anzeichen von Korrosion und Rissen sein. Insbesondere den Bereich des Gelenks und des Mauls von beiden Seiten in geöffneter Position prüfen. Im Zweifelsfall eine Vergrößerungshilfe verwenden.
3.9.2	Funktionsprüfung	Den Maulbereich auf Verformung und Spannungsverlust prüfen.
3.2	<b>By when should the action be completed?</b>	The Aesculap AG plans to complete this FSN within the next 9 months.
	<b>Bis wann muss die Maßnahme abgeschlossen sein?</b>	Die Aesculap AG plant diese FSCA innerhalb der nächsten 9 Monate abzuschließen.
3.3	<b>Is follow-up of patients or review of patients' previous results recommended?</b>	
	<b>Wird eine Nachsorge der Patienten oder eine Überprüfung der früheren Ergebnisse der Patienten empfohlen?</b>	
	No / Nein	
3.4	<b>Is customer reply required?</b>	Yes. See point 4.3
	<b>Ist eine Antwort des Kunden erforderlich?</b>	Ja. Siehe Punkt 4.3
3.5	<b>Action Being Taken by the Manufacturer / Vom Hersteller ergriffene Maßnahme</b>	
	The new eIFU be published from 16 <sup>th</sup> December 2024 on at <a href="https://eifu.bbraun.com">https://eifu.bbraun.com</a> globally.	
	Die neue eIFU wurde am 16.Dezember 2024 weltweit unter <a href="https://eifu.bbraun.com">https://eifu.bbraun.com</a> veröffentlicht .	
3.6	<b>Is the FSN required to be communicated to the patient /lay user?</b>	No
	<b>Muss die FSN dem Patienten/Laienbenutzer übermittelt werden?</b>	Nein
3.7	<b>If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?</b>	
	<b>Falls ja, hat der Hersteller zusätzliche Informationen für den Patienten/Liegenutzer in einem Informationsschreiben/Blatt für den Patienten/Liegenutzer oder den nicht berufsmäßigen Nutzer bereitgestellt?</b>	
	N/A	

<b>4. General Information* / Allgemeine Informationen*</b>	
4.1	<b>FSN Type / FSN Typ</b> <span style="float: right;">New / Neu</span>

4.2	<p><b>Manufacturer information</b>          (For contact details of local representative refer to page 1 of this FSN)  <b>Angaben zum Hersteller</b>          (Die Kontaktdaten des Herstellers finden Sie auf Seite 1 dieses FSN)</p>	
	<p><b>Company Name/Name des Unternehmens</b></p>	<p>Aesculap AG</p>
	<p><b>Address/Adresse</b></p>	<p>Postfach 40, 78501 Tuttlingen</p>
	<p><b>Website address/Homepage</b></p>	<p>http://www.aesculap.de</p>
4.3	<p><b>List of attachments/appendices:          Liste der Anlagen/Anhänge:</b></p>	
		<p>Feedback Form / Rückmeldeformular</p>
4.4	<p><b>Name/Signature/Unterschrift</b></p>	
		<p>Georg Erhard          Safety Officer          Quality Management</p>
	<p><b>Name/Signature/Unterschrift</b></p>	
		<p>Christian von der Grün          Director Post Market Surveillance          Quality Management</p>
<p><b>Transmission of this Field Safety Notice/Übermittlung dieses Sicherheitshinweises (FSN)</b></p>		
<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> <p><i>Dieser Hinweis muss an alle Personen in Ihrem Unternehmen übermittelt werden oder an alle Unternehmen/Einrichtungen, wohin die eventuell betroffenen Produkte geliefert wurden (wie jeweils zutreffend).</i></p> <p><i>Bitte leiten Sie diesen Hinweis an andere Unternehmen/Einrichtungen weiter, auf die diese Maßnahme Auswirkungen hat (wie jeweils zutreffend).</i></p> <p><i>Bitte sorgen Sie über einen angemessenen Zeitraum dafür, dass dieser Hinweis berücksichtigt wird und bekannt ist, um die Wirksamkeit der Korrekturmaßnahme zu gewährleisten.</i></p>		

<p><i>Bitte melden Sie dem Hersteller, Händler oder lokalen Vertreter sowie gegebenenfalls der zuständigen nationalen Behörde alle Vorfälle im Zusammenhang mit dem Produkt, da dies eine wichtige Rückmeldung darstellt. *</i></p>
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