

Date: 2025.08.28

Urgent Field Safety Notice (FSN)
REUSABLE TROCAR SYSTEM 10MM, 12MM

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

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

B. Braun Medical Supplies Sdn. Bhd
Crown Penthouse, Plaza IBM,
8, First Avenue, Persiaran Bandar Utama,
47800 Petaling Jaya, Selangor,
Malaysia.

Contact Points:

Quality Management

Ms Chan Jeh Huei
Manager
Phone: +603-78414200
Email: jeh_huei.chan@bbraun.com

Muhammad Zaim Mohd Shairy
Executive
Phone: +603-78414200
Email: muhammad_zaim.mohd_shairy@bbraun.com

Global Marketing & Sales

Ms Cheng Meow Yu
Senior Product Manager
Phone: +60126756227
Email: meow_yu.cheng@bbraun.com

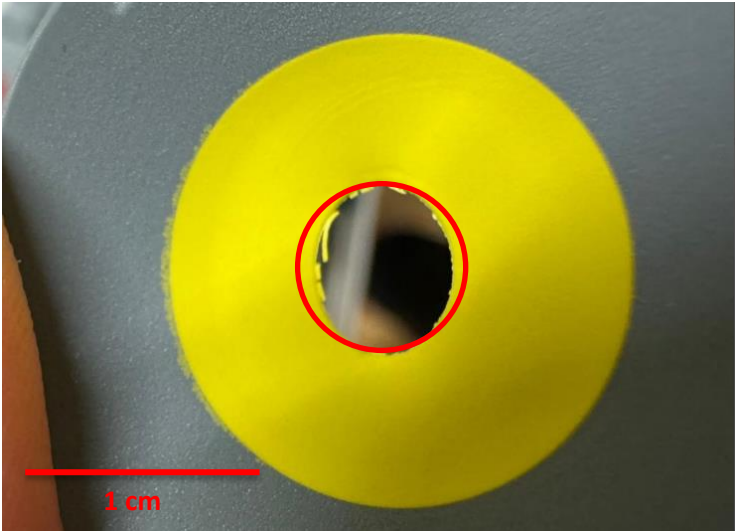
Mr Mohd Shahril Hisyam Mohd Sata
Business Unit Manager
Phone: +60126096336
Email: shahril_hisyam.sata@bbraun.com


Dear Customer,

Aesculap AG as a legal manufacturer has voluntarily decided to recall the affected products under point 1.7 as a precaution due to the risk scenario mentioned below.



1. Information on Affected Devices																																								
1.1	Device Type																																							
	REUSABLE TROCAR SYSTEM 10MM, 12MM																																							
1.2.	Commercial names																																							
	REDUCING CONVERTER 10/12MM TO 5MM SEALING CAP FOR 10/12MM TROCARS SEALING UNIT F/10/12MM TROCARS W.REDUCER SEALING UNIT FOR 10/12MM TROCARS																																							
1.3.	Unique Device Identifier																																							
	4039239000013372C																																							
1.4.	Primary clinical purpose of devices																																							
	The REUSABLE TROCAR SYSTEM 10MM, 12MM is used in laparoscopic operations in general surgery, gynecology and urology. It serves to create and maintain an approach to the operating field for instruments and endoscopes in laparoscopic operations. Endoscopic instruments of 5 - 10 mm diameter (10-mm trocar) and 5 -12 mm diameter (12-mm trocar) can be inserted.																																							
1.5	Article numbers																																							
	EK087P; EK085P; EK083P; EK086P																																							
1.6	Software version																																							
	N/A																																							
1.7	Affected lot numbers																																							
	<table border="1"> <thead> <tr> <th>Article Numbers</th> <th>Device Names</th> <th>Lot Numbers</th> </tr> </thead> <tbody> <tr> <td>EK083P</td> <td>SEALING UNIT F/10/12MM TROCARS W.REDUCER</td> <td>52978946</td> </tr> <tr> <td>EK083P</td> <td>SEALING UNIT F/10/12MM TROCARS W.REDUCER</td> <td>52991996</td> </tr> <tr> <td>EK083P</td> <td>SEALING UNIT F/10/12MM TROCARS W.REDUCER</td> <td>53002275</td> </tr> <tr> <td>EK083P</td> <td>SEALING UNIT F/10/12MM TROCARS W.REDUCER</td> <td>53004669</td> </tr> <tr> <td>EK083P</td> <td>SEALING UNIT F/10/12MM TROCARS W.REDUCER</td> <td>53006807</td> </tr> <tr> <td>EK083P</td> <td>SEALING UNIT F/10/12MM TROCARS W.REDUCER</td> <td>52941286</td> </tr> <tr> <td>EK083P</td> <td>SEALING UNIT F/10/12MM TROCARS W.REDUCER</td> <td>52956527</td> </tr> <tr> <td>EK083P</td> <td>SEALING UNIT F/10/12MM TROCARS W.REDUCER</td> <td>52956740</td> </tr> <tr> <td>EK083P</td> <td>SEALING UNIT F/10/12MM TROCARS W.REDUCER</td> <td>52956952</td> </tr> <tr> <th>Article Numbers</th> <th>Device Names</th> <th>Lot Numbers</th> </tr> <tr> <td>EK083P</td> <td>SEALING UNIT F/10/12MM TROCARS W.REDUCER</td> <td>52957393</td> </tr> <tr> <td>EK083P</td> <td>SEALING UNIT F/10/12MM TROCARS W.REDUCER</td> <td>52967167</td> </tr> </tbody> </table>	Article Numbers	Device Names	Lot Numbers	EK083P	SEALING UNIT F/10/12MM TROCARS W.REDUCER	52978946	EK083P	SEALING UNIT F/10/12MM TROCARS W.REDUCER	52991996	EK083P	SEALING UNIT F/10/12MM TROCARS W.REDUCER	53002275	EK083P	SEALING UNIT F/10/12MM TROCARS W.REDUCER	53004669	EK083P	SEALING UNIT F/10/12MM TROCARS W.REDUCER	53006807	EK083P	SEALING UNIT F/10/12MM TROCARS W.REDUCER	52941286	EK083P	SEALING UNIT F/10/12MM TROCARS W.REDUCER	52956527	EK083P	SEALING UNIT F/10/12MM TROCARS W.REDUCER	52956740	EK083P	SEALING UNIT F/10/12MM TROCARS W.REDUCER	52956952	Article Numbers	Device Names	Lot Numbers	EK083P	SEALING UNIT F/10/12MM TROCARS W.REDUCER	52957393	EK083P	SEALING UNIT F/10/12MM TROCARS W.REDUCER	52967167
Article Numbers	Device Names	Lot Numbers																																						
EK083P	SEALING UNIT F/10/12MM TROCARS W.REDUCER	52978946																																						
EK083P	SEALING UNIT F/10/12MM TROCARS W.REDUCER	52991996																																						
EK083P	SEALING UNIT F/10/12MM TROCARS W.REDUCER	53002275																																						
EK083P	SEALING UNIT F/10/12MM TROCARS W.REDUCER	53004669																																						
EK083P	SEALING UNIT F/10/12MM TROCARS W.REDUCER	53006807																																						
EK083P	SEALING UNIT F/10/12MM TROCARS W.REDUCER	52941286																																						
EK083P	SEALING UNIT F/10/12MM TROCARS W.REDUCER	52956527																																						
EK083P	SEALING UNIT F/10/12MM TROCARS W.REDUCER	52956740																																						
EK083P	SEALING UNIT F/10/12MM TROCARS W.REDUCER	52956952																																						
Article Numbers	Device Names	Lot Numbers																																						
EK083P	SEALING UNIT F/10/12MM TROCARS W.REDUCER	52957393																																						
EK083P	SEALING UNIT F/10/12MM TROCARS W.REDUCER	52967167																																						

	EK085P	SEALING CAP FOR 10/12MM TROCARS	52987668
	EK085P	SEALING CAP FOR 10/12MM TROCARS	52993442
	EK085P	SEALING CAP FOR 10/12MM TROCARS	53001930
	EK085P	SEALING CAP FOR 10/12MM TROCARS	53008562
	EK085P	SEALING CAP FOR 10/12MM TROCARS	53013543
	EK085P	SEALING CAP FOR 10/12MM TROCARS	52948710
	EK085P	SEALING CAP FOR 10/12MM TROCARS	52954233
	EK085P	SEALING CAP FOR 10/12MM TROCARS	52957528
	EK085P	SEALING CAP FOR 10/12MM TROCARS	52966111
	EK085P	SEALING CAP FOR 10/12MM TROCARS	52979586
	EK086P	SEALING UNIT FOR 10/12MM TROCARS	52968398
	EK086P	SEALING UNIT FOR 10/12MM TROCARS	52975386
	EK086P	SEALING UNIT FOR 10/12MM TROCARS	52988022
	EK086P	SEALING UNIT FOR 10/12MM TROCARS	52993532
	EK086P	SEALING UNIT FOR 10/12MM TROCARS	53008999
	EK086P	SEALING UNIT FOR 10/12MM TROCARS	53009000
	EK086P	SEALING UNIT FOR 10/12MM TROCARS	53009001
	EK086P	SEALING UNIT FOR 10/12MM TROCARS	53009417
	EK087P	REDUCING CONVERTER 10/12MM TO 5MM	52974276
	EK087P	REDUCING CONVERTER 10/12MM TO 5MM	52952133
	EK087P	REDUCING CONVERTER 10/12MM TO 5MM	52954633
	EK087P	REDUCING CONVERTER 10/12MM TO 5MM	52959357
	EK087P	REDUCING CONVERTER 10/12MM TO 5MM	52964442
	EK087P	REDUCING CONVERTER 10/12MM TO 5MM	52968887
	EK087P	REDUCING CONVERTER 10/12MM TO 5MM	52972214
	EK087P	REDUCING CONVERTER 10/12MM TO 5MM	52977427
	EK087P	REDUCING CONVERTER 10/12MM TO 5MM	52981208
	EK087P	REDUCING CONVERTER 10/12MM TO 5MM	52985519
	EK087P	REDUCING CONVERTER 10/12MM TO 5MM	52988828
	EK087P	REDUCING CONVERTER 10/12MM TO 5MM	52992514
	EK087P	REDUCING CONVERTER 10/12MM TO 5MM	52993617
	EK087P	REDUCING CONVERTER 10/12MM TO 5MM	52997919
	EK087P	REDUCING CONVERTER 10/12MM TO 5MM	53002094
	EK087P	REDUCING CONVERTER 10/12MM TO 5MM	53004347
	EK087P	REDUCING CONVERTER 10/12MM TO 5MM	53006380
	EK087P	REDUCING CONVERTER 10/12MM TO 5MM	53007625
	EK087P	REDUCING CONVERTER 10/12MM TO 5MM	53010869
	EK087P	REDUCING CONVERTER 10/12MM TO 5MM	53013557
1.8	Associated devices		
	N/A		

2. Reason for Field Safety Corrective Action (FSCA)	
2.1	Description of the product problem
	<p>Aesculap AG identified that the yellow sealing component of the affected REUSABLE TROCAR SYSTEM 10MM, 12MM exhibits uneven edges with visible silicone fragments (see Figure 1). There is the potential risk that silicone fragments detach from the yellow sealing component during use.</p>  <p>Figure 1: Uneven edges with visible silicone fragments of yellow sealing component</p>
2.2	Hazard giving rise to the FSCA
	<p>Due to the described product problem, there is a potential risk that the silicone fragments could fall in situ when an instrument is inserted through the yellow sealing component. In case the fragments detach intraoperatively, they will likely remain unnoticed due to the restriction of the field of view due to the endoscopic procedure and the small size of the fragments. In case suction devices are applied at the site where the fragments are located, there is the possibility that they may be retrieved.</p> <p>The short-term hazard posed by the unsighted fragments is considered negligible due to the small weight force of the fragments. Yet, the fragments might lead to long term health consequences resulting from the fragments serving as a foreign body stimulus. They pose a risk for:</p> <ul style="list-style-type: none"> - Inflammation or infection - Encapsulation or adhesion formation
2.3	Probability of problem arising
	<p>Within the past five years (August 15, 2020 - August 14, 2025), three product complaints related to the RESUABLE TROCAR SYSTEMS 10MM, 12MM were reported to the manufacturer, all involving the same described product issue.</p> <p>The actual occurrence rate of 0.004% exceeds the maximum acceptable limit of 0.001%, as defined in the current product risk analysis. As a result, the associated risk is considered not acceptable.</p>

<p>2.4</p>	<p>Predicted risk to patient/users</p> <p>The clinical impact on the patient depends on several variables such as the severity of the symptoms, the affected organs or tissues, and available treatment options. Typical symptoms of foreign body reactions include swelling and/or pain at the site of the foreign body, fever, fatigue, and swollen lymph nodes.</p> <p>In a worst-case scenario, albeit remote, a foreign-body reaction can lead to permanent tissue damage. For instance, encapsulation or adhesion formation in immediate vicinity to the ureters can lead to kidney damage in untreated cases of clinically significant (sustained) ureteral obstruction.</p> <p>Furthermore, patients with a silicone allergy are most at risk as they will display more pronounced foreign body reactions if exposed to the material compared to the general population.</p> <p>The potential patient harm to patients is therefore classified as “critical”.</p>
<p>2.5</p>	<p>Further information to help characterise the problem</p> <p>Affected products were manufactured between September 30, 2024, and July 29, 2025. Users can identify the affected products by verifying the batch number on the label of the product’s primary packaging (see Figure 2).</p>  <p>Figure 2: Example – Label Primary packaging</p>
<p>2.6</p>	<p>Background on Issue</p>
<p></p>	<p>N/A</p>
<p>2.7</p>	<p>Other information relevant to FSCA</p>
<p></p>	<p>N/A</p>

3. Type of Action to mitigate the risk	
3.1	Action To Be Taken by the User
	Identify Device <input checked="" type="checkbox"/> Return Device <input checked="" type="checkbox"/>
3.2	By when should the action be completed?
	The Aesculap AG plans to complete this FSCA within the next 12 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 affected products are recalled.
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	
4.1	FSN Type New
4.2	Manufacturer information (For contact details of local representative refer to page 1 of this FSN)
	Company Name Aesculap AG
	Address Postfach 40, 78501 Tuttlingen
	Website address/Homepage http://www.aesculap.de
4.3	List of attachments Feedback Form
4.4	Name/Signature  Ms Chan Jeh Huei Manager - Regulatory Affairs
	Name/Signature  Muhammad Zaim Mohd Shairy Executive - Regulatory Affairs
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>