B BRAUN

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Your Reference	Our Reference	Tel (603)	Fax (603)	Date
	OSS.17320.2.25	03-7841 4200		17 February 2025

Dear Sir/Madam

Urgent Field Safety Notice (FSN) – ORTHOPILOT CAP SINGLE-USE MARKERS

Issue Description: Aesculap AG, the legal manufacturer of the device(s) ORTHOPILOT CAP SINGLE-USE MARKERS has initiated a volunteer recall. If the Orthopilot® CAP marker are not recognized by the camera, a new marker has to be used. This will result in a delay of surgery of less than 15 minutes. As a consequence of the mentioned failure mode, the OrthoPilot® CAP markers must be replaced during the surgery. If no further markers are available in the hospital the surgeon has to switch to non-navigated Knee Arthroplasty Surgery.

Actions to be Taken:

1. The affected batch will be recalled.
2. Confirm receipt of this FSN and adherence to the stated contents by filling up and returning the Feedback Form FSCA No.290 – enclosed.

For any questions or further assistance, please contact the local representatives as listed in our FSN. We apologize for any inconvenience this may cause and appreciate your prompt attention to this matter.

Thank you for your cooperation.

Yours sincerely
B. BRAUN MEDICAL SUPPLIES SDN BHD

Veronica Chong
Sales Manager

Min Xai Sing
General Manager
(Marketing & Biz. Dev.)

FSCA Ref: 290

Date: 2025-02-17

Urgent Field Safety Notice/Dringende Sicherheitsinformation (FSN)
ORTHOPILOT CAP SINGLE-USE MARKERS
ORTHOPILOT CAP EINMAL-MARKER

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: **Regulatory Affairs** Ms Chan Jeh Huei Manager Phone: +603-78414200 Email: jeh_huei.chan@bbraun.com Ms Rima Efriani Rusli Executive Phone: +603-78414200 Email: rima_efriani.rusli@bbraun.com **Marketing & Sales** Veronica Chong Sales Manager Phone: +60126666028 Email: veronica.chong@bbraun.com **Marketing & Biz. Dev** Min Xai Sing General Manager Phone: +60128368803 Email: min_xai.sing@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(s)**
	OrthoPilot® CAP Single-use navigation marker
1.2.	**Commercial name(s)**
	▪ OrthoPilot®
1.3.	**Unique Device Identifier(s) (UDI-DI)**
	40392390000014262C (FS618SU) 40392390000014262C (FS619SU)
1.4.	**Primary clinical purpose of device(s)**
	The purpose of the OrthoPilot® CAP marker is to retro-reflect infra-red light and thus enabling the OrthoPilot® System to locate the marker's optical center in three dimensions. OrthoPilot® CAP markers used on instruments having Aesculap passive sphere mounting posts are required to enable the device, in combination with approved OrthoPilot® application software, to calculate the position and orientation of these instruments in three-dimensional space. The OrthoPilot® CAP marker is a patient non-contact, single use, disposable device to be used by qualified professional medical personnel. It is indicated for any medical condition in which the use of navigated surgery may be considered to be safe and effective.
1.5	**Part numbers/ Unique Device Identifiers (UDI-DI)**
	FS618SU; FS619SU
1.6	**Software version**
	N/A
1.7	**Affected serial or lot number**
	FS618SU 24912226D7; 24913618D5; 24915526D7; 24917126D7; 24919226D7; 24912326D7; 24913718D5; 24915626D7; 24917726D7; 24919326D7; 24912426D7; 24914326D7; 24915826D7; 24917826D7; 24919726D7; 24912718D5; 24914426D7; 24915926D7; 24917926D7; 24919826D7; 24912818D5; 24914526D7; 24916326D7; 24918026D7; 24919926D7; 24912918D5; 24914826D7; 24916426D7; 24918326D7; 24920426D7; 24913018D5; 24914926D7; 24916526D7; 24918426D7; 24920526D7; 24913118D5; 24915026D7; 24916626D7; 24919026D7; 24920626D7; 24913418D5; 24915126D7; 24916926D7; 24919126D7; 24920726D7; 24913518D5; 24915226D7; 24917026D7 **FS619SU** 24917226D7
1.8	**Associated devices**
	N/A

2. Reason for Field Safety Corrective Action (FSCA)	
2.1	**Description of the product problem**
	It's being reported that individual Orthopilot® CAP markers cannot be identified by the OrthoPilot® camera.
2.2	**Hazard giving rise to the FSCA**
	If the Orthopilot® CAP marker are not recognized by the camera, a new marker has to be used. This will result in a delay of surgery of less than 15 minutes. As a consequence of the mentioned failure mode, the OrthoPilot® CAP markers must be replaced during the surgery. If no further markers are available in the hospital the surgeon has to switch to non-navigated Knee Arthroplasty Surgery.
2.3	**Probability of problem arising**
	In the fourth quarter of 2024, the manufacturer's post-market monitoring system identified an increase in incidents involving the affected OrthoPilot® CAP markers during trend evaluation. An internal investigation revealed that the current occurrence rate of 0.0774% reported from the market exceeds the maximum acceptable occurrence rate of 0.001% for this failure mode. Therefore, the probability of this failure mode occurring during use is rated as 'occasional'.
2.4	**Predicted risk to patient/users**
	OrthoPilot® CAP markers are single-use products, and multiple markers are used in each surgery. Therefore, it is highly likely that additional markers are available in the hospital. All orthopedic surgeons are trained in non-navigated knee arthroplasty surgery. Additionally, every hospital that performs navigated knee arthroplasty surgery is equipped with the necessary instruments for non-navigated surgeries.
2.5	**Further information to help characterise the problem**
	N/A
2.6	**Background on Issue**
	N/A
2.7	**Other information relevant to FSCA**
	N/A

	3. Type of Action to mitigate the risk	
3.1	**Action To Be Taken by the User** Identify Device ☒ Return Device ☒	
3.2	**By when should the action be completed?**	The Aesculap AG plans to complete this FSCA 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 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	http://www.aesculap.de
4.3	**List of attachments/appendices:**	Feedback Form
4.4	**Name/Signature**	
		Ms Chan Jeh Huei Manager - Regulatory Affairs
	Name/Signature	
		Ms Rima Efriani Rusli Executive - Regulatory Affairs
	Transmission of this Field Safety Notice	
	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) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. 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. *	