	Title: FSN: Acetabular Cup Size/Label Mismatch – Lot 25070154 / 25070274		
	Version: 1	**FSN Ref.:**	FM-00909
	Effective Date:	**FSCA Ref:**	FSCA-2026-00902

Date: 2026-07-29

Field Safety Notice

VarioCup, TPS Coating, Three-hole, 58mm/RR

VarioCup, TPS Coating, Three-hole, 52mm/pp

For Attention of*:Distributor, Hospitals

Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages.

Field Safety Notice (FSN)

VarioCup, TPS Coating, Three-hole, 58mm/RR and 52mm/pp

Risk of surgical delay or case interruption due to a confirmed label/product mismatch between Lot 25070154 (52mm) and Lot 25070274 (58mm) acetabular cup components.

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Acetabular Cup Component, for cementless use, sterile
1.	2. Commercial name(s)*
	VarioCup, TPS Coating, Three-hole, 58mm/RR / VarioCup, TPS Coating, Three-hole, 52mm/PP
1.	3. Unique Device Identifier(s) (UDI-DI)
	4251795500565, 4251795500596
1.	4. Primary clinical purpose of device(s)*
	Acetabular component for total hip arthroplasty
1.	5. Device Model/Catalogue/part number(s)*
	A1402-0-2052 (52mm), A1402-0-2058 (58mm)
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	LOT 25070154, LOT 25070274
1.	8. Associated devices
	None

2. Reason for Field Safety Corrective Action (FSCA)*

2.	1. Description of the product problem*
	A confirmed labelling/product mix-up has been identified between Lot 25070154 (52mm) and Lot 25070274 (58mm). The implant contained within the sterile packaging does not correspond to the external package label for units within these two lots.
2.	2. Hazard giving rise to the FSCA*
	Due to the sterile packaging, the implant cannot be visually verified against the external label prior to opening. As press-fit acetabular components, an incorrect size cannot be implanted undetected, as intraoperative reaming and trial components would reveal a size mismatch before use of the final implant. The primary risk is surgical delay or case interruption if the correct size is not otherwise available on site. Residual risk after following this FSN advice is considered low.
2.	3. Probability of problem arising
	Full physical verification of all remaining stock has confirmed that the mismatch is limited to Lot 25070154 and Lot 25070274 and affects the entirety of both lots.
2.	4. Predicted risk to patient/users
	Surgical delay or case interruption if no correctly matched alternative implant is available intraoperatively, potentially requiring rescheduling of the procedure under renewed anaesthesia. Implantation of an incorrect size is not expected to occur undetected, given standard intraoperative trial/reaming verification for press-fit components.
2.	5. Further information to help characterise the problem
	Lot 25070154 and Lot 25070274 each comprise 40 units per Device History Record (DHR).
2.	6. Background on Issue
	The mismatch was identified through a customer complaint and confirmed through internal investigation. The exact origin of the mismatch is still under investigation.
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 ☒ Quarantine Device ☒ Return Device ☐ Destroy Device

☐ On-site device modification / inspection

☐ Follow patient management recommendations

☐ Take note of amendment / reinforcement of Instructions For Use (IFU)

☐ Other ☐ None

- Provide further details of the action(s) identified.

Please contact Supply Chain SC@aap-joints.com to arrange return of affected units and receive return shipping instructions. For any further questions regarding this notice, please contact Regulatory Affairs regulatory@aap-joints.com.

3.	2. By when should the action be completed?	Immediately upon receipt of this notice.

3. 3. Particular considerations for: Implantable device

- Is follow-up of patients or review of patients' previous results recommended?

No

- Provide further details of patient-level follow-up if required or a justification why none is required.

Not required: as press-fit components, an incorrect size cannot be implanted without detection during intraoperative trial/reaming; no follow-up of already-treated patients is indicated at this time.

3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes

3. 5. Action Being Taken by the Manufacturer*

☒ Product Removal ☐ On-site device modification/inspection

☐ Software upgrade ☐ IFU or labelling change

☐ Other ☐ None

Provide further details of the action(s) identified.

3.	6. By when should the action be completed?	Collection/return of remaining affected stock from customers and distributors is to be completed by 2026-08-14.
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3.	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	

	• No Not appended to this FSN

4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	3. For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4.	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	aap Joints GmbH
	b. Address	Wilhelm-von-Siemens-Str. 23, Aufgang F, 12277 Berlin, Germany
	c. Website address	www.aap-joints.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. YES	
4.	9. List of attachments/appendices:	Customer/Distributor Reply Form (Template-00396/00397)
4.	10. Name/Signature	Norman Popp-Lange, Quality Management Representative

	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.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.