

Rev 1: 22-09-2026
FSN Ref: FSN-NL-PR-000000117-2026-01
FSCA Ref: FSCA-NL-PR-000000117-2026-01

Date: 22-09-2026

Urgent Field Safety Notice

Custom Procedure Trays
with specific article numbers

For attention of
All personnel involved in handling the affected Custom Procedure Trays, including those responsible for unpacking the trays from the outer shipping carton, manually moving the trays, and removing the immediate packaging (header bag) prior to use, should be made aware of this notice and take the actions described herein.

Contact details of local representative (name, e-mail, telephone, address etc.)
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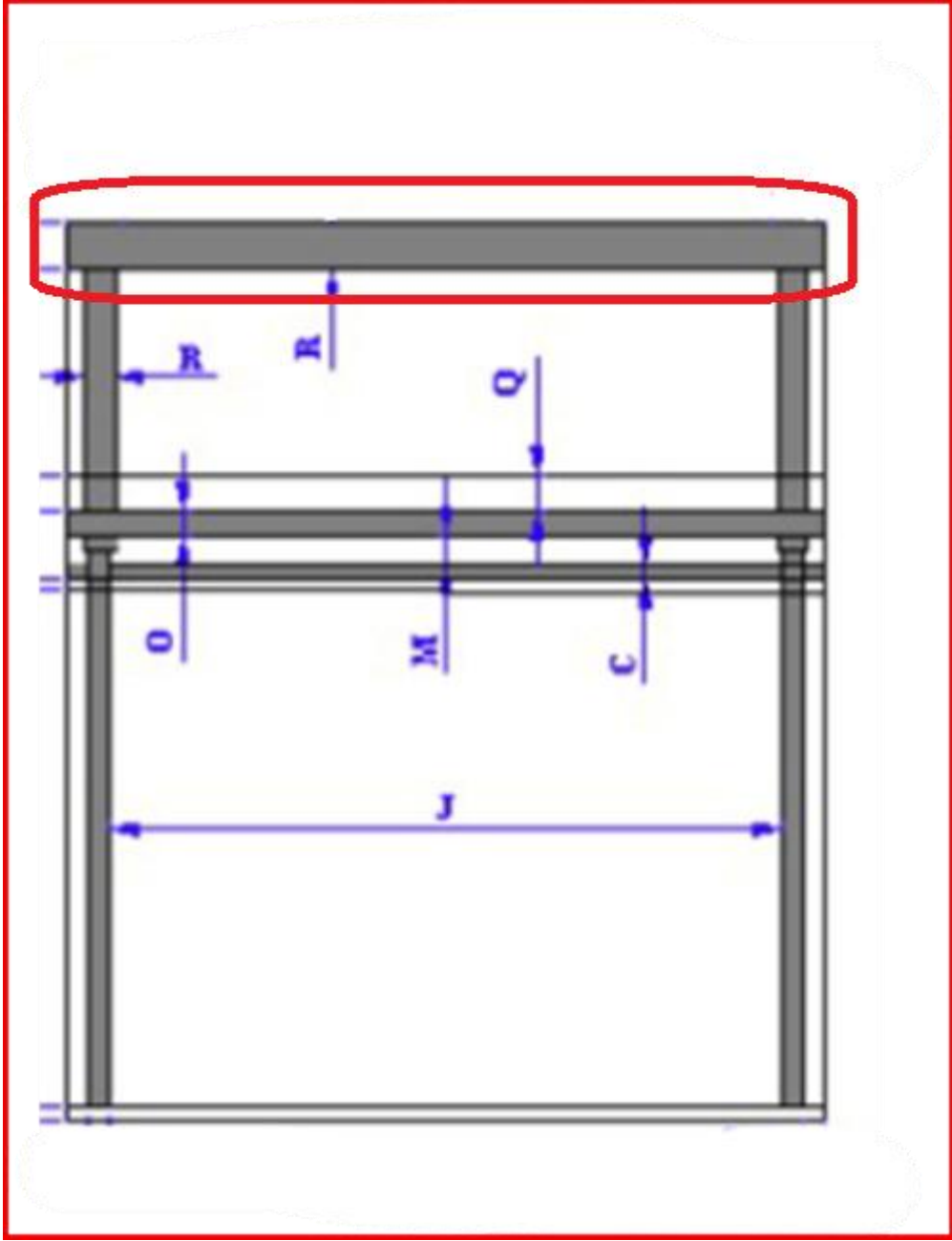
Custom Procedure Trays
 with specific article numbers

Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s) The affected device is a sterile, single-use Custom Procedure Tray (CPT) containing a predefined set of medical devices and accessories intended to support specific clinical procedures. The tray is supplied sterile within a sealed header bag and is subsequently packaged in an outer shipping carton. Product identification can be verified using the product label, article number, and lot number displayed on the packaging.
1.	2. Commercial name(s) See appendix 1
1.	3. Unique Device Identifier(s) (UDI-DI) See appendix 1
1.	4. Primary clinical purpose of device(s) Custom procedure trays provide ready-to-use (medical) devices, to be used during surgical procedures or other medical interventions as intended by their legal manufacturer.
1.	5. Device Model/Catalogue/part number(s) See appendix 1
1.	6. Software version Not applicable
1.	7. Affected serial or lot number range All available lot numbers
1.	8. Associated devices Not applicable

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem A potential defect has been identified affecting the seal integrity of the header bag of certain Custom Procedure Trays. The seal on the header side (white paper side) may open unintentionally before use, resulting in a compromised sterile barrier. The drawing below indicates the specific seal affected by this issue.

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2.	2. Hazard giving rise to the FSCA The primary hazard is the potential loss of sterility of the Custom Procedure Tray due to unintended opening of the header bag seal. This may expose the sterile contents to environmental contamination and could increase the risk of infection for the patient if an affected tray is used. The risk is primarily to the patient; no additional risk to the user has been identified. When the recommendations in this FSN are followed and trays with compromised packaging are not used, the residual risk is considered acceptable and reduced to a negligible level.

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2.	3. Probability of problem arising Based on complaint data received during the past week, four complaints were reported from three different users, involving a total of nine Custom Procedure Trays with an unintentionally opened header bag seal. The issue has therefore been confirmed to occur in the field. The exact occurrence rate is currently under investigation as the total number of affected products distributed has not yet been fully assessed. However, the probability of occurrence is considered low, although the issue may not be readily detectable until the tray is removed from the outer carton or handled prior to use.
2.	4. Predicted risk to patient/users The predicted risk to patients is considered low. If the header bag seal opens unintentionally, the sterile barrier may be compromised, potentially leading to contamination of the tray contents. If an affected tray is used despite a compromised sterile barrier, there is a potential risk of infection to the patient. No direct health risk to the user has been identified. Based on the severity of the potential harm and the low probability of occurrence, the overall risk is considered low.
2.	5. Further information to help characterise the problem The issue is limited to the integrity of the header bag seal and does not affect the contents of the Custom Procedure Tray. To date, no patient injuries, infections, or other adverse health consequences have been reported. The condition may only become apparent during removal from the outer carton or subsequent handling prior to use.
2.	6. Background on Issue Medica Europe became aware of the issue following repeated customer complaints regarding unintended opening of the header bag seal, resulting in the initiation of a CAPA investigation. The investigation linked the issue to a single lot of one specific header bag size used as the sterile barrier system for certain Custom Procedure Trays. All affected products remaining under the control of Medica Europe underwent a 100% seal integrity inspection, and the header bag manufacturer is conducting a root cause investigation and implementing corrective actions to prevent recurrence.
2.	7. Other information relevant to FSCA The issue has been traced to the seal applied by the manufacturer of one specific size of header bag used by Medica Europe as the immediate sterile barrier system for certain Custom Procedure Trays. The affected condition is limited to a single lot number of this header bag. Although only one header bag lot is involved, the material was used in the production of multiple Custom Procedure Tray product codes distributed to multiple customers. Since 15 September 2026, Medica Europe has received four complaints from three separate customers reporting unintended opening of the header bag seal. To date, no reports of patient injury, infection, or other adverse health consequences associated with this issue have been received. Based on the available information, the issue appears to be limited to the affected header bag lot; however, this Field Safety Corrective Action is being initiated as a precautionary measure to prevent the potential use of products with a compromised sterile barrier.

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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 Users should identify all affected Custom Procedure Trays by verifying the product code and lot number against the information provided in this Field Safety Notice. Prior to use, the integrity of the header bag seal should be inspected. Particular attention should be paid when removing trays from the outer shipping carton and during manual handling. Any tray found with a partially or fully opened header seal should not be used as a sterile product and should be segregated according to local procedures. As an immediate containment measure, all affected products that had not yet been distributed underwent a 100% inspection of the header bag seal integrity. Products that successfully passed this inspection were released for distribution and have been clearly identified with a green sticker stating "Pakket voorzichtig uitnemen" ("Remove package carefully") applied to both the Custom Procedure Tray and the outer shipping carton. Please inform all relevant personnel involved in the handling and preparation of the affected Custom Procedure Trays of the contents of this notice and ensure that the above precautions are followed.	
3.	2. By when should the action be completed?	The actions described in this Field Safety Notice should be implemented immediately upon receipt of this communication. Affected Custom Procedure Trays should be inspected prior to use until all affected stock has been identified and managed in accordance with this notice.
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No	

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	No patient-level follow-up is required. The issue relates to the integrity of the sterile barrier system and can be identified prior to use through inspection of the header bag seal. Products with a compromised seal should not be used as sterile products and should be segregated according to local procedures. As no affected product is intended to be used once the defect is identified, and no patient harm has been reported, no specific patient follow-up measures are considered necessary.	
3.	4. Is customer Reply Required?	Yes. Customers are requested to acknowledge receipt of this Field Safety Notice by e-mail to qa@medica-europe.nl within 7 calendar days of receipt.
3.	5. Action Being Taken by the Manufacturer ☐ Product Removal ☐ Software upgrade ☐ Other ☒ On-site device modification/inspection ☐ IFU or labelling change ☐ None Medica Europe has initiated a Field Safety Corrective Action related to a single lot of one specific header bag size used as the immediate sterile barrier system for certain Custom Procedure Trays. The issue has been traced to the seal applied by the header bag manufacturer. As an immediate containment measure, all affected products remaining under the control of Medica Europe underwent a 100% inspection of the header bag seal integrity. Products with a compromised seal were segregated and withheld from distribution. Products that successfully passed the inspection were released for distribution and were identified with a green sticker stating "Pakket voorzichtig uitnemen" ("Remove package carefully") applied to both the Custom Procedure Tray and the outer shipping carton. In addition, customers are being informed of the issue and instructed to inspect the header bag seal integrity prior to use, with particular attention during removal from the outer shipping carton and during manual handling. Any tray with a partially or fully opened header seal should not be used as a sterile product and should be segregated according to local procedures. As an additional risk mitigation measure for future production batches using the current header bag design, Medica Europe will apply a second seal to the header bag to reinforce the integrity of the sterile barrier system. This additional seal significantly reduces the likelihood of unintended seal opening during handling and transportation. As a consequence, users will need to open two seals instead of one before the Custom Procedure Tray can be removed from the header bag. For these CPTs to be produced the green stickers will no longer be applied. The header bag manufacturer has been notified, and an investigation into the root cause of the seal integrity issue is ongoing. Appropriate corrective actions will be implemented to prevent recurrence.	

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	Once header bags with improved seal strength and higher resistance to opening forces become available, the additional reinforcement seal applied by Medica Europe will no longer be required. At that time, Custom Procedure Trays will again be supplied in their standard packaging configuration as currently familiar to customers.	
3	6. By when should the action be completed?	The actions described in this Field Safety Notice should be implemented immediately upon receipt and applied to all affected Custom Procedure Trays prior to use.
3.	7. Is the FSN required to be communicated to the patient /lay user?	N/A
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?	
	Choose an item. Choose an item.	
	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant
4.	3. For Updated FSN, key new information as follows:	
	Not applicable	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Not applicable	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	See page 1
	b. Address	See page 1
	c. Website address	See page 1
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	9. List of attachments/appendices:	n/a
4.	10. Name/Signature	

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	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.

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Appendix 1 - Affected Product Codes and UDI-DIs

Article nr.	Article name	UDI-DI
100507BH	LAP.PELVIC TRAY	08710685136032
103801AD	PROCUREMENT PACK A+B+C	08710685072699
105265AD	BOTEXPL. FASE D	08710685120314
105847BI	CARDIO TRAY	08710685144747
111237AP	HEUP TRAY ANTERIEUR	08710685137657
116136AL	CENTRALE PROCEDURE TRAY	08710685142699
118466AF	CARDIOVASCULAIR TRAY	08710685124701
119478AF	PT ANTERIOR HEUP	08710685145362
119481AG	KNIEPROTHESE TRAY	08710685141913
119925AH	LAMBIK CARDIO SET CV	08710685147144
119941AE	HEUP ANTERIEUR SET ORTHO	08710685141296
119942AE	HEUP POSTERIEUR SET	08710685141074
119943AE	KNIE SET ORTHO	08710685142972
121135AA	CABG TRAY	08710685148462