ASSET® MEDICAL

Ikitelli OSB Mahallesi, 17. Cadde, No:17
Basaksehir, Istanbul - Türkiye

Phone : +90 212 494 27 27
Fax : +90 212 494 34 37

info@assetmedical.com | www.assetmedical.com

FSN & FSCA Ref: 24FA001
Date: 28.02.2024

Urgent Field Safety Notice

FLOWART® NEEDLE FREE VALVE SET WITH 1.2 MICRON FILTER

For Attention of*:all affected distributors and users

Contact details of local representative (name, e-mail, telephone, address etc.)*
Krypton Chemists Ltd. P: +356 21378888 M: +356 99030904 A: Ta' Cantrija Complex, Triq it-Targa, Maghtab, NXR 6613 matthew@kryptonchemists.com Asset Medical İkitelli OSB Mah., 17.Cad., No:17 Basaksehir, Istanbul, TÜRKİYE info@assetmedical.com

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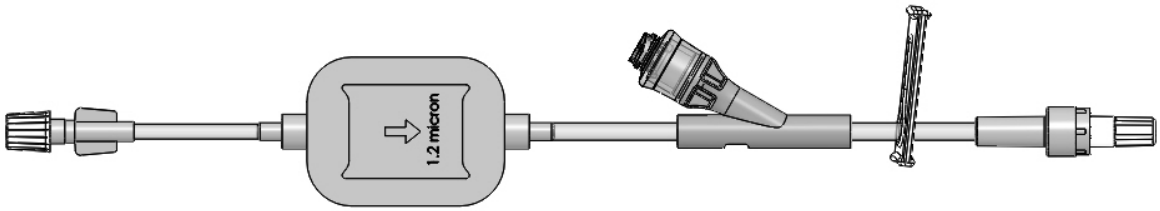
Risk addressed by FSN

Urgent Field Safety Notice (FSN)

FLOWART® NEEDLE FREE VALVE SET WITH 1.2 MICRON FILTER

Risk Addressed by FSN

1. Information on Affected Devices*
1.1. Device Type(s)*
Flowart® Needle Free Valve Set with 1.2 micron Filter is a sterile infusion therapy device equipped with a Y-site needle-free valve and an adult size 1.2 micron filter. Needle-free valve has a fully transparent clear housing with an integrated flat silicone seal and internal fluid pathway that protects the patient and nursing staff from exposures. 
1.2. Commercial name(s)
Flowart® Needle Free Valve Set with 1.2 micron Filter
1.3. Unique Device Identifier(s) (UDI-DI)
08699443581164
1.4. Primary clinical purpose of device(s)*
FlowArt® 1.2 micron filter set is used for administration of fluids and medication during intravenous therapy. Filter sets remove air, particles, fungi, and fungal spores..
1.5. Device Model/Catalogue/part number(s)*
AF6012
1.6. Software version
N/A
1.7. Affected serial or lot number range
Z20230731025
1.8. Associated devices
N/A

2 Reason for Field Safety Corrective Action (FSCA)*
2.1. Description of the product problem*
The product problem involves kinking of the plastic tubing between the filter and the Y-site needle-free valve, which was observed in the packed product
2.2. Hazard giving rise to the FSCA*
The greatest hazard to both the patient and the end-user stemming from the observed kinking of the plastic tubing between the filter and the Y-site needle-free valve lies in the potential obstruction of fluid flow during intravenous therapy administration. This obstruction poses a significant risk of interrupting or impeding the delivery of essential fluids and medications to the patient. If the advice/action provided in the Field Safety Notice (FSN) is taken, which involves rectifying the kinking issue or replacing affected components, the residual risk is significantly mitigated.
2.3. Probability of problem arising

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2 Reason for Field Safety Corrective Action (FSCA)*

Given that the cause of kinking, which was attributed to the wrong size primary packaging, has been eliminated through the implementation of a larger version, the likelihood of the problem recurring is significantly reduced. Incident data or prospective modeling would likely indicate a minimal likelihood of kinking occurrences once the packaging size has been appropriately adjusted. This adjustment addresses the root cause of the issue and mitigates the risk associated with kinking of the plastic tubing between the filter and the Y-site needle-free valve. Therefore, the probability of the problem arising again would be considerably low, providing assurance in the product's improved safety and reliability.

2.4. Predicted risk to patient/users

The predicted risk to patients and users following the correction of the primary packaging size is substantially reduced. With the elimination of the root cause of kinking—incorrectly sized primary packaging—the likelihood of the tubing issue recurring is greatly diminished. Consequently, the risk of interrupted or impeded fluid flow during intravenous therapy, which could potentially jeopardize patient treatment, is significantly mitigated.

2.5. Further information to help characterise the problem

While specific statistics pertaining to the incidence rate of kinking in the plastic tubing between the filter and the Y-site needle-free valve may vary, it's essential to highlight the potential seriousness of the issue. Even though the occurrence of such incidents may be relatively rare, the consequences can be severe, particularly in the context of intravenous therapy administration.

For instance, research suggests that interruptions or restrictions in fluid flow during intravenous therapy can lead to adverse outcomes for patients. These consequences may include delayed or inadequate medication delivery, compromised treatment efficacy, and increased risk of complications or adverse events. In severe cases, such disruptions could even result in patient harm or medical emergencies.

Furthermore, the impact of such incidents extends beyond individual patient outcomes. Healthcare providers may also experience increased workload, potential delays in patient care, and heightened resource utilization in addressing and mitigating the consequences of fluid flow interruptions.

2.6. Background on Issue

Asset became aware of the issue through an incident report received by the Malta Medicines Authority, with an internal reference code IR035-2024, on 20.02.2024. This report detailed the observed kinking of plastic tubing between the filter and the Y-site needle-free valve during intravenous therapy administration. Following this notification, the manufacturer initiated an investigation to assess the scope and root cause of the issue.

While specific details of relevant incidents may vary, it's likely that reports of interrupted or impeded fluid flow during intravenous therapy prompted the investigation. The incident was identified through post-market surveillance mechanisms, such as adverse event reporting systems and customer complaints.

The root cause of the observed kinking issue was determined to be the use of incorrectly sized primary packaging for the product. This packaging inadequacy likely exerted pressure on the tubing during storage or transportation, resulting in kinks that could potentially obstruct fluid flow.

In response to the identified issue, Asset implemented containment measures to address the problem specifically within affected devices. This involved halting distribution or recalling products with the incorrect primary packaging size to prevent further distribution and usage.

Overall, Asset's response to the incident involved a multi-faceted approach aimed at containing the problem, mitigating immediate risks, and implementing measures to prevent recurrence, thus safeguarding patient safety and product quality.

2.7. Other information relevant to FSCA

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3. Type of Action to mitigate the risk*	
3.1. Action To Be Taken by the User* ☒ Identify Device ☒ Destroy Device	
3.2. By when should the action be completed?	Specify where critical to patient/end user safety
3.3. Particular considerations for: **Choose an item.** **Is follow-up of patients or review of patients' previous results recommended?** **No** The issue primarily pertains to the packaging and integrity of the product rather than its direct interaction with individual patients. While the kinking of the plastic tubing could potentially impact patient care during intravenous therapy, the root cause of the problem lies in packaging deficiencies rather than inherent product defects. The incident affects a specific batch of products with incorrectly sized primary packaging. Therefore, the number of patients directly impacted by the issue is limited. It's reasonable to assume that patients /healthcare personnel who received products from unaffected batches does not experience adverse effects related to the observed kinking issue. Asset's containment measures, such as halting distribution or recalling affected products, are aimed at preventing further distribution and usage of potentially compromised devices. By addressing the root cause and containing the problem at the source, the immediate risk to patients is mitigated. Without patient-specific data or adverse event reports directly linking the packaging issue to patient harm, individual patient-level follow-up is not deemed necessary. The focus of remedial actions is on correcting the packaging deficiency and ensuring product integrity rather than monitoring individual patient outcomes.	
3.4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.5. Action Being Taken by the Manufacturer **☒ Product Removal**	
3.6. By when should the action be completed?	**immediately**
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	

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4. General Information*	
4.1. FSN Type*	New
4.2. For updated FSN, reference number and date of previous FSN	No
4.3. For Updated FSN, key new information as follows:	
Summarise any key difference in devices affected and/or action to be taken.	
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:	
4.6. Anticipated timescale for follow-up FSN	
4.7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
a. Company Name	Asset Medikal Tasarim San. Tic. A.S.
b. Address	
c. Website address	www.assetmedical.com
4.8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.9. List of attachments/appendices:	-
4.10. Name/Signature	
	Ebru Sirali Manager, Quality Assurance

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.*