

Sorisole, 2025-05-08

TILBAGEKALDELSE/RECALL

Bemærk: Ansvarligt organ, laboratorieleder, brugere/operatører.

Kære Milestone Partners,

Milestone s.r.l. udsteder denne Field Safety Corrective Action (FSCA) for at informere dig om en Field Action relateret til REF 51461 Formalin, 10% v/v (4% w/v), 10000ml Cubitainer.

Berørte lot-/batchnumre:

- 202024170
- 252024210
- 312024020
- 362024060
- 452024080

Beskrivelse

Milestone har modtaget en advarsel om mulig lækage af reagens mellem forbindelsesstykket og beholderen.

Råd om øjeblikkelig handling

Kontakt straks din distributør.

Hvis LOT/BATCH-nummeret angivet på kassen er det samme som dem nævnt ovenfor:

1. Brug ikke og distribuer ikke REF 51461 Formalin, 10 % v/v (4 % w/v), 10.000 ml Cubitainer;
2. Opbevar Cubitaineren (pakassen) med forbindelsesstykket vendt opad;
3. 3. Kontakt straks din distributør eller Milestone s.r.l..

Vi advarer om, at du bør bortskaffe eventuelle Cubitainere, der stadig er på lager og endnu ikke er blevet brugt.

Milestone vil erstatte dem med nye enheder.

Identifikation af LOT/batchnummer:

Videresendelse af denne sikkerhedsmeddelelse (Field Safety Notice):

Denne meddelelse skal videregives til alle, der bør informeres i din organisation, samt til enhver organisation, hvortil de potentielt berørte enheder er blevet overført.

Venligst videresend også denne meddelelse til andre organisationer, som kan blive berørt af denne handling.

Bevar venligst opmærksomheden omkring denne meddelelse og de tilhørende tiltag i en passende periode for at sikre, at den korrigerende handling er effektiv.

Rapportér alle enhedsrelaterede hændelser til Milestone s.r.l. (på den e-mail, der er noteret nedenfor), distributøren eller den lokale repræsentant og den nationale kompetente myndighed, hvis det er relevant, da dette giver vigtig feedback.

Hvis du har yderligere spørgsmål, er du velkommen til at kontakte os på: regulatory@milestonesrl.com

Tak og med venlig hilsen.

Returrapport om sikkerhedsrelaterede korrigerende handlinger

Angiv venligst mængden af REF 51461 Formalin, 10% v/v (4% w/v), 10000ml Cubitainer, der ikke er brugt og til stede på lager:

REF 51461 LOT **202024170**: Cubitainer antal:

REF 51461 LOT **252024210**: Cubitainer antal:

REF 51461 LOT **312024020**: Cubitainer antal:

REF 51461 LOT **362024060**: Cubitainer antal:

REF 51461 LOT **452024080**: Cubitainer antal:

Bekræft venligst bekræftelsen ved at markere nedenstående felter:

- ☐ Jeg har læst og forstået Sikkerhedskorrigerende handling
- ☐ Jeg har bortskaffet HELE den mængde Cubitainer, der er rapporteret ovenfor
- ☐ Cubitainer LOT/batch til stede i organisationen, rapporteret ovenfor.

Navn på sundhedsorganisation:	
Kontakt navn:	
Titel eller funktion:	
Afdeling:	
Telefonnummer:	
Adresse forsendelse:	Adresse: _____

	Postnummer, By: _____, _____
	Stat: _____
Underskrift:	

Udfyld og returner returrapporten for korrigerende sikkerhedsforanstaltninger inden for 15 arbejdsdage til din lokale Milestone-distributør eller:

Certification and Regulatory Affairs Department

e-mail: regulatory@milestonesrl.com

Hvis du har yderligere spørgsmål, så tøv ikke med at kontakte os: regulatory@milestonesrl.com

Tak og venlig hilsen.

MILESTONE S.r.l.

Certification and Regulatory Affairs Department

Email: regulatory@milestonesrl.com

Website: www.milestonemed.com

FSN 2025-00001

Milestone Srl – Via Fatebenefratelli, 1/5, 24010 Sorisole (BG) – Italy. Tel +39 035 4128264 – Fax +39 035 575498

REF 51461 Formalin – 10 L Cubitainer

Sorisole, 2025-05-08

RECALL

Attention to: Responsible Body, Laboratory Manager, Users/operators.

Dear Milestone Partners,

Milestone s.r.l. is issuing this Field Safety Corrective Action (FSCA) to inform you about a Field Action related to the REF 51461 Formalin, 10% v/v (4% w/v), 10000ml Cubitainer.

Affected Lot/batch numbers:

- 202024170
- 252024210
- 312024020
- 362024060
- 452024080

Description

Milestone received the alert of possible reagent leakage between the connector and the container.

Advice on immediate action to take

Contact immediately your distributor.

If the LOT/BATCH number reported on the box is the same as the ones reported above:

1. **do not use, neither distribute, REF 51461 Formalin, 10% v/v (4% w/v), 10000ml Cubitainer;**
2. **maintain the cubitainer (carton-box) with slippage connect on the side up;**
3. **Contact immediately your distributor, or Milestone s.r.l..**

We warn you to dispose of the Cubitainer present in your stock and not used yet.

Milestone will replace them with new ones.

Identification of the LOT/batch number:



Transmit of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please transfer this notice to other organizations on which this action has an impact.

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 Milestone s.r.l. (at the e-mail address reported below), distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

If you have further questions, do not hesitate to contact us: regulatory@milestonesrl.com

Thank you and best regards.

MILESTONE S.r.l.
Certification and Regulatory Affairs Department
Email: regulatory@milestonesrl.com
Website: www.milestonemed.com

Field Safety Corrective Action Return Report

Please report the amount of the REF 51461 Formalin, 10% v/v (4% w/v), 10000ml Cubitainer not used and present in your stock:

REF 51461 LOT **202024170**: Cubitainer quantity:

REF 51461 LOT **252024210**: Cubitainer quantity:

REF 51461 LOT **312024020**: Cubitainer quantity:

REF 51461 LOT **362024060**: Cubitainer quantity:

REF 51461 LOT **452024080**: Cubitainer quantity:

Please confirm acknowledge by checking the boxes below:

- ☐ I have read and understood Field Safety Corrective Action
- ☐ I have disposed ALL the quantity of Cubitainer reported above
- ☐ Cubitainer LOT/batch present in organization, reported above.

Healthcare Organization Name:	
Contact Name:	
Title or Function:	
Department:	
Telephone number:	
Address shipment:	Address: _____ _____ Postal code, City: _____, _____ State: _____
Signature:	

Please complete and return the Field Safety Corrective Action Return Report within **15 working days** to your Milestone local distributor or:

Certification and Regulatory Affairs Department

e-mail: regulatory@milestonesrl.com

If you have further questions, do not hesitate to contact us: regulatory@milestonesrl.com

Thank you and best regards.

MILESTONE S.r.l.

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