1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN 2021-00**1**
FSN Date*	08 April 2021
Product/ Device name*	See Appendix 01
Product Code(s)	See Appendix 01
Batch/Serial Number (s)	See Appendix 01

2. Customer/Distributor/Importer Details	
Company Name*	*Details will be entered by each end user in the different destination countries*
Account Number	*Details will be entered by each end user in the different destination countries*
Address*	*Details will be entered by each end user in the different destination countries*
Shipping address if different to above	*Details will be entered by each end user in the different destination countries*
Contact Name	*Details will be entered by each end user in the different destination countries*
Title or Function	*Details will be entered by each end user in the different destination countries*
Telephone number	Phone + *Details will be entered by each end user in the different destination countries* Mobile + *Details will be entered by each end user in the different destination countries*
Email	*Details will be entered by each end user in the different destination countries*

3. Return acknowledgement to BTC Medical Europe	
Email	……
Postal Address	Strada Statale Sud, 169, 41037 Mirandola MO - Italy
Web Portal	http://www.sidamgroup.it
Deadline for returning the Customer/Distributor/Importer reply form*	5 Calendar days

Dear Customer/Distributor/Importer,

Recently Sidam has become aware of a quality issue raised by SterilMilano, one of our Ethylene Oxide contract sterilizers, who highlighted potential quality issues related to the data handling of the cycle graphs and treatment certificates falsifications, to make them in compliance with quality and validation cycle requirements.

We are reaching you since SterilMilano is in charge for the sterilization cycle of some of the products we delivered to you.

As soon as we received the notification by SterilMilano, we blocked the supply of the products sterilized by them and we have been starting a product quality impact assessment on the records of the sterilization batches affected by this issue.

1. PATIENT RISK

The falsification of relevant data especially linked to the preconditioning cycle and the sterilization cycle could play a crucial role respectively in the functionality and in the effectiveness of the sterilization processes of the devices. The ineffective sterilization of the devices used for infusion of drugs or devices with direct contact with tissues could have consequences for patient's health with potential side effects linked to unsterile products, patient infection and worsening of their health conditions. The falsification of the degassing cycle may have consequences in the Ethylene Oxyde residues and thus a potential risk for operators, users and patient's health, even if it has to be highlighted that the gas residues disappear after few days from sterilization phase. Being the devices placed on the market since years, this risk is considered negligible.

2. CORRECTIVE ACTION

Based on the evaluation and sterility test performed, as conservative approach and as a protective measure in order to maintain patient health, we decided to recall the devices listed in Annex 01.

The Field Safety Notice identifies the problem, the affected product, the risk factors and the actions that must be taken by the users and distributor.

3. ACTION TO BE TAKEN BY THE USER

Once received this official notification, in order to prevent potential impact of the medical therapy, each user shall:

1) Identify and segregate all items listed in Annex 01, still available at their premises,
2) Fill-in this acknowledgment letter, including the number of received devices, used devices and remaining devices (see Table 1),
3) Within 5 calendar days from receiving the official notification, return all the segregated nonconforming devices to ....., at Sidam premises, Strada Statale Sud, 169, 41037 Mirandola MO, Italy

As required, we have provided this notification to the relevant Regulatory Agencies of the countries where the devices have been distributed.

Please refer to your local sales agent for any further information you may need or, in alternative, contact directly Sidam customer service at telephone number 0535 25523 or mail FSCA@sidamit.it

We apologize for any inconvenience.

Yours sincerely,

……..	……
Chief Executive Officer	QA Manager
Sidam S.r.l. a Socio Unico	Sidam S.r.l. a Socio Unico
Mirandola (MO), Italy	Mirandola (MO), Italy

……

4. Distributors/Importers (Tick all that apply)		
☐	I confirm the receipt, the reading and understanding of the Field Safety Notice.	Customer/Distributor/Importer to complete, sign or enter N/A
☐	I have checked my stock and quarantined inventory	Customer/Distributor/Importer to complete, sign or enter N/A
☐	I have identified all Healthcare organization and all end users where the devices listed in Table 1 have been shipped and on which this action has an impact that received or may have received this device	Customer/Distributor/Importer to complete, sign or enter N/A
☐	I have attached Healthcare organization and all end users list	Customer/Distributor/Importer to complete, sign or enter N/A
☐	I have informed the identified Healthcare organization and all end users of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified Healthcare organization and all end users	Date of receiving last communication:
☐	I have filled-in the mapping provided in the excel file attached to the email communication, with the number of received devices, used devices and remaining devices at each Healthcare organization and each end users	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	I have returned affected devices - *enter number of devices returned and date complete*.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	I have destroyed affected devices – enter number destroyed and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	Neither I nor any of our Healthcare organization and end users has any affected devices in inventory	
Print Name*		
Signature*		Customer/Distributor/Importer sign Here
Date *		

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.
Your organisation's reply is the evidence we need to monitor the progress of the corrective action

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