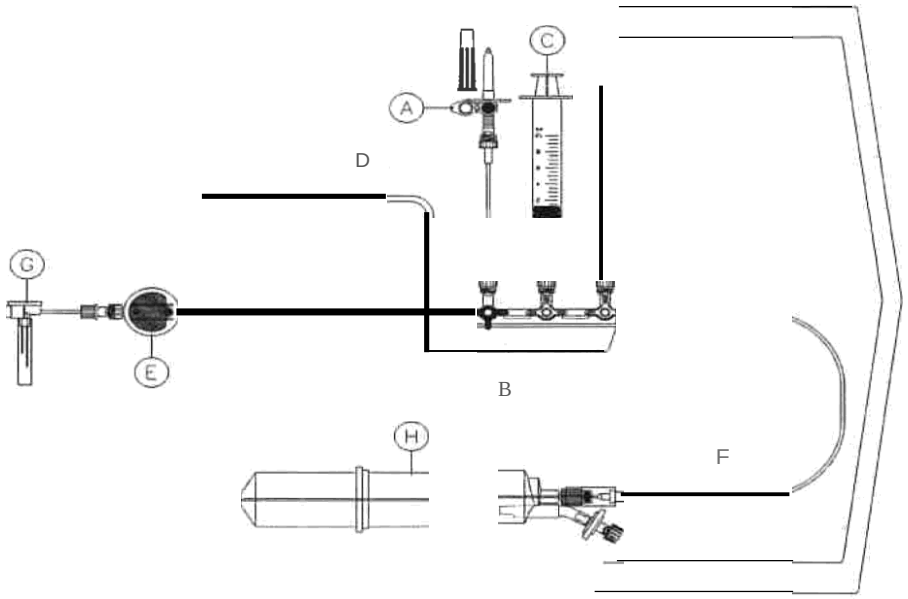
Urgent Field Safety Notice Dispensing Kit Clio

For Attention of:

……,
Comecer S.p.A. (Exclusive Distributor)
Via Maestri del Lavoro, 90,
1-48014 Gastel Bolognese (RA), ltaly

Urgent Field Safety Notice (FSN)
Dispensing kit Clio
Risk addressed by FSN

1. **Information on Affected Devices***	
1.	1. **Dispensing kit** A dispensing device tor radiopharmaceuticals.  Figure1: parts of the *" Dispensingkit Clio"*
1.	2. Commercial name(s Dispensing Kit Clio
1.	3. Uni ue Device Identifier s UDI-01 Not yet available
1.	**4.** Prima clinical ur ose of device s * Dispensing kit Clio devices, kit for dispensing of radiopharmaceuticals solutions.
1.	5. Device Model/Catalo ue/ art number s * **CODE** **DESC PTION** 29A2E2000 1.01 Dispensing kit Clio
1.	6. Software version Not relevant

1. 7. Affected serial or lot number range

Table 1:

CODE	DESCRIPTION	LOTNR	Expiry Date
29A2E20001.01	Dispensing gamma kit Clio	FA00388	2024/04
29A2E20001.01	Dispensing gamma kit Clio	FA01074	2024/07

1. 8. Associated Devices

The above listed devices are intended to be used in association with the equipment for dispensing radiopharmaceuticals solutions, placed on the market by Comecer S.p.A.

2 Reason *tor* Field Safet Corrective Action FSCA *

2. 1. Descri tion of the roduct roblem

BTC has become aware of a possible defect on certain lots of "Dispensing kit clio" due to the presence of halo on stainless-steel needle inside the rigid chamber, component H (see Figure 1).

If any halos exist, can be associated to stainless steel corrosions and they can be identified by visual inspection, as shown in the detailed photo below:

Figure 2: Halo on the stainless-steel needle inside the rigid chamber, component H

Corrective actions are being implemented to eliminate the defect from occurring.

2.	2. Hazard giving rise to the FSCA
	The exposure to the chemical elements could lead to compromised renal or hepatic functions. The exposure to the molecules generated via the reactions of the elements in hydrophilic solution is not predictable, but the toxicological evaluation of the NOAEL, "No Observed Adverse Effect Level", of each molecule has been evaluated and found to be less than the potential amount of exposure, leading to toxicological concerns about the release of contaminants from the halos.
2.	3. Probability of problem arising
	As results of the Health Hazard Evaluation, less than the 4 % of the devices wilt arise the issues.
2.	**4.** Predicted risk to patient/users
	From the Health Hazard Evaluation, exposure to the chemical elements could lead to compromised renal or hepatic functions. The estimated likelihood to cause serious injury is remote (1/1000 < Pharm < 1/10000).
2.	5. Further information to help characterise the problem
	The exposure to the molecules generated via the reactions of the elements in hydrophilic solution is not predictable, but the toxicological evaluation of the NOAEL, No Observed Adverse Effect Level", of each molecule has been evaluated and found to be less than the potential amount of exposure, leading to toxicological concerns about the release of contaminants from the halos.
2.	6. Background on Issue
	The likelihood of a halo on the stainless-steel needle is remote and BTC have received no reports of patient injury. Being clearly visible, the halo has been always detected by the users before the filling of the kit as the visual inspection is part of routine clinical setting of the product.
2	7. Other information relevant to FSCA
	The events and the related injury to patients have been evaluated. The estimated likelihood to cause serious injury is remote (1/1000 < Pharm < 1/10000). Furthermore, the risks have been weighed against the patients benefits to receive the treatment with the radiopharmaceuticals mixture, considering also the unavailability of other or equivalent dispensing kits at the health care facilities.

	3. Type of Action to mitigate the risk*
3.	**1. Action To Be Taken by the User***
	181 Identify Device 181 Quarantine Device 181 Return Device D Destroy Device
	181 On-site device modification/inspection
	D Follow patient management recommendations
	D Take note of amendment/reinforcement of Instructions For Use (IFU)
	!XI Other D None

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

1) Identify and segregate all items listed in Table 1, still available at their premises,
2) Conduct an accurate visual inspection on each Dispensing kit Clio, on 100 % of the needle surface, rotating the rigid chamber 180°, in order to identify kit with the halo visible on the stainless-steel needle, inside the rigid chamber, component H (see Figure 1),
3) First Visual Inspection: Segregate all the Dispensing kit Clio having **the visible halo** on the stainless-steel needle (non-conforming products), from the Dispensing kit Clio without the visible halo on the stainless-steel needle, (conforming devices),
4) Second Visual Inspection: Make sure thatjust before use, also the Dispensing kit Clio without the visible halo on the stainless-steel needle, (conforming devices from previous inspection) are visually re-inspected, on 100 % of the needle surface, rotating the rigid chamber 180°, in order to identify kit with the halo visible on the stainless-steel needle, inside the rigid chamber, component H (see Figure 1),
5) Fill the acknowledgment letter provided in the attachment 1, including the number of selected Dispensing kit Clio, number of non-conforming kit and number of conforming devices,
6) Within four months from receiving the official notification, return all the segregated nonconforming devices to Mr. Saverio Caria, at Comecer premises, Via Maestri del Lavoro, 90, 1-48014 Gastel Bolognese (RA), Italy, who will replace as soon as possible the received item with conforming products.
7) The exclusive distributor, Comecer, return all the received "FSN concerning dispensing kit clio, customer reply" and nonconforming devices to Mr Marco Tognolo, at BTC, operative site via 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 as Medical Devices.

Please refer to your local sales agent for any further information you may need or, in alternative, contact directly COMECER Quality at telephone number 0546 656375 or email: comecerquality@comecer.com

3 2. By when should the action be completed?

Within 5 (five) months from the issue date

ID#	Actions description	Bv when
1	Identify and segregate all items listed in Table 1, still available at their premises,	Immediately or within 1 calendar day

2	Conduct an accurate visual inspection on each Dispensing kit Clio, on 100 % of the needle surface, rotating the rigid chamber 180°, in order to identify kit with the halo visible on the stainless-steel needle, inside the rigid chamber, component H (see Figure 1),	Within 1 week or in any case before the use of the Dispensing kit Clio	
3	First Visual Inspection: Segregate all the Dispensing kit Clio having **the visible halo** on the stainless-steel needle (non-conforming products), trom the Dispensing kit Clio without the visible halo on the stainless-steel needle, (conforming devices),	Within 1 week or in any case before the use of the Dispensing kit Clio	
4	Second Visual Inspection: Make sure that just before use, also the Dispensing kit Clio without the visible halo on the stainless-steel needle, (conforming devices trom previous inspection) are visually re-inspected, on 100 % of the needle surface, rotating the rigid chamber 180°, in order to identify kit with the halo visible on the stainless-steel needle, inside the rigid chamber, component H (see Figure 1),	Just before use of the Dispensing kit Clio	
5	Fill the acknowledgment letter provided in the attachment 1, including the number of selected Dispensing kit Clio, number of non-conforming kit and number of conforming devices,	When all the Dispensing kit Clio have been used	
6	Return all the segregated nonconforming devices to Mr. Saverio Caria, at Comecer premises, Via Maestri del Lavoro, 90, 1-48014 Castel Bolognese (RA), Italy, who will replace as soon as possible the received item with conforming products.	Within four months trom receiving the official notification	

		7	The exclusive distributor, Comecer, return all the received "FSN concerning dispensin,g kit clio, customer reply" and nonconforming devices 'to Mr Marco. Tognolo , at BTC, operative site via Strada Statale Sud, 169 41037 Mirandola MO ltaly.	Within 1 month from conclusion of Action 6
3.	3. Particular considerations for: Not Applicable			
3.	4. Is customer Reply Required? See Customer Reply in Attachment 1, to be returned within 4 months from the issue date			
3.	**5. Action Being Taken by the Manufacturer** D Product Removal 181 On-site device modification/inspection D Software upgrade D IFU or labelling change D Other D None In order to ensure the product performance and safety, we decided to implement actions to ensure a 100 % inspection by the users, for all the devices listed in **Table 1.** This decision is based on our risk-based approach and the need of users to have sufficient devices, to allow patients benefits to receive the medica! treatment with radiopharmaceuticals, compounded using the Dispensing kit Clio. No other alternative disposable kit are available at the Health Care facilities. BTC has sent a Field Safety Notice to all interested customers, through Comecer, its exclusive distributor. 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	6. By when should the action be completed?	Before 5 months from the issue date (See point 2 below for additional detail)		
3.	7. Is the FSN required to be communicated to the patient /lav user?	No		
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lav 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	NA
4.	3. For Updated FSN, key new information as follows:	
	NA	
4.	4. Further advice or information already expected in follow-up FSN? *	Choose an item. No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	NA	
4	6. Anticipated timescale for follow-up FSN	NA
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSNJ	
	a. Comoanv Name	BTC Medical Europe s.r.l.
	b. Address	37067 VALEGGIO SUL MINCIO (VR)-VIA DEL LAVORO 10 (ITA) - ltaly
	c. Website address	http://www.btcmedicaleurope.it/
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. Yes	
4.	9. List of attachments/appendices:	1. **ATTACHMENT 1: Customer Reply** 2. **ATTACHMENT 2: Acknowledgment letter of Distributor**
4.	3. Name/Signature	Insert Name and Title here and signature below **……..** ……

	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 and to all users 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.