Health Line International Corporation
5675 West 300 South
Salt Lake City, Utah, 84104, USA
Tel: 1-801-773-7798
Fax: 1-855-228-1336
www.hlic.net

FSN Reference: FSN-20-001

FSCA Reference: FSCA-20-001

Date: 18 December 2020

URGENT FIELD SAFETY NOTICE (FSN)
Synergy CT PICC™ Dual Lumen Catheter

For Attention of: Risk Management/ Recall Coordinator/ Inventory Manager/ Responsible of Medical Device Vigilance/ Distributors/ Clinicians Material Procurement/ Supply Chain

Contact details of local representative (name, e-mail, telephone, address etc.)

Dear Customer,

Thank you for being a loyal Health Line International Corp. (HLIC) customer and crucial partner in growing the vascular access space with us. Patient safety and positive outcomes is at the core of everything we do at HLIC. Please follow the instructions detailed in the below FSN. We apologize for any inconvenience that this issue may cause, and we thank you in advance for helping us resolve this matter as quickly and effectively as possible.

For further information, assistance or reporting of any adverse health consequences related to the issue described in this Field Safety Notice FSN, please contact your local HLIC representative or Emergo Europe.

European Representative	HLIC Contact Information
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands Tel: (31) (0) 70 345-8570 Email: EmergoVigilance@ul.com	**Customer Service** Between the hours of 9:00am to 5:00 pm MST +1-877-847-4542 Customerservice@hlic.net

Sincerely,

Gracie Sierra
Quality Assurance Manager
Health Line International Corp.

Aaron Faulkner
Director of Regulatory and Quality
Health Line International Corp

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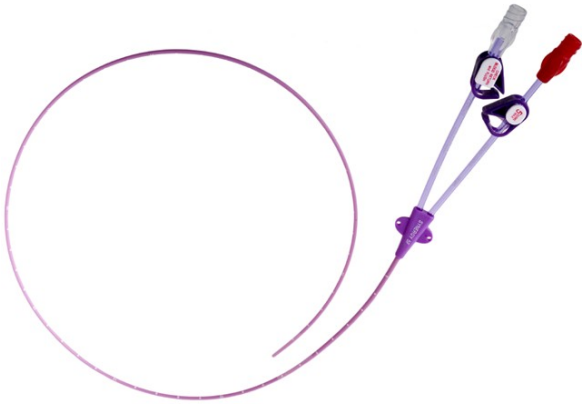
Synergy CT PICC™ Dual Lumen Catheter
Risk Addressed by FSN

	1. Information on Affected Devices
1.	**1. Device type(s)**
	The Synergy CT PICC™ 5 Fr Dual Lumen Catheter is a sterile, single use device intended for short or long term (less than or greater than 30 days) peripheral access to the central venous system. The catheter has two extension tubes intended for infusion, intravenous therapy, blood sampling and power injection of contrast media. The proximal end of one of the tubes is identified by a clear uer lock connector, and the other by a red luer lock connector. 
1.	**2. Commercial name(s)**
	Synergy CT PICC™ 5Fr Dual Lumen Catheter Basic Kit Synergy CT PICC™ 5Fr Dual Lumen Catheter Nursing Kit
1.	**3. Unique Device Identifier(s) (UDI-DI)**
	00876604001183 00876604000704
1.	**4. Primary clinical purpose of device(s)**
	The SYNERGY™ CT PICC is indicated for short or long term (less than or greater than 30 days) peripheral access to the central venous system for infusion, intravenous therapy, blood sampling and power injection of contrast media.
1.	**5. Device Model/Catalogue/Part Number(s)**
	A14-05260 A14-05260-N
1.	**6. Software version**
	N/A – This device is not a software device, nor does it incorporate software.
1.	**7. Affected serial or lot number range**
	A004805 A004861 A004960 A004999 A005296 A005330 A005381

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	A005425 A005551
1.	**8. Associated devices**
	CT Peripherally Inserted Central Catheter (PICC) Kits Contains Synergy™ CT PICC, 7cm x 21ga Safety Needles With Echo Tip, 0.015" x 75cm Twisted Wire Stylet, 0.018" x 45cm Nitinol Guidewire, 5.5Fr Tearaway Introducer, 10cc Syringe, Tape Measure, Needle Free Valves, Safety Scalpel, Securement Device.

	2 Reason for Field Safety Corrective Action (FSCA)
2.	**1. Description of the product problem**
	The red luer lock connector, at the proximal end of the extension tube, may dislodge (separate) from the extension tube during the use.
2.	**2. Hazard giving rise to the FSCA**
	If the red luer lock connector dislodges (separates) from the proximal end of the extension tube, the potential risk for air embolism, blood loss (exsanguination), contamination or infection increases. The possible adverse events that could be caused by such risks include discomfort, low blood pressure, dizziness, irregular heartbeat, breathlessness, chest pain, blurred vision, anxiety. HLIC has not received any complaints related to the risks and adverse events listed above by customers for affected products.
2.	**3. Probability of problem arising**
	HLIC has determined that 6 events have occurred out of a total of 1809 units placed in the market. Based on HLIC's analysis the probability of the occurrence is approximately 3.3% or less giving a low probability of the problem arising.
2.	**4. Predicted risk to patient/users**
	Given the hazard has a significant severity and a low possible occurrence, it is predicted a moderate-low risk to patients and users.
2.	**5. Further information to help characterize the problem**
	HLIC has determined the product affected is limited to two (2) specific models with lots and quantities clearly identified.
2.	**6. Background on Issue**
	Six (6) complaints were reported on the catheter device with no adverse events to any patient or user. The determination of the root cause is continuing to be investigated. From initial data collected it is believed to be only affecting the red luer lock connector. For the foreseeable future, HLIC has established a 100% inspection of all products currently in production before being released to finished goods.
2.	**7. Other information relevant to FSCA**
	To attain HLIC's responsibilities as a manufacturer, this FSCA-20-001 is being implemented to return any unused product on the market via the appointed distributors. The number of devices affected by this issue is 1809 units, although it is likely that the majority have been already used.

	3. **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

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	☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None This action affects all Synergy CT PICC catheters with lot numbers identified on section 1.7. Further distribution or use of any remaining affected product should cease immediately. For devices already implanted, please see section 3.3. Please confirm that you have received this communication and undertaken the required actions by completing and returning the attached "Customer Response" form. Ensure relevant staff members are informed of this action. If this device has been transferred/supplied to another facility or organization, please let them know of the action immediately by providing a copy of this FSN.	
3.	**2. By when should the action be completed?**	Immediately discontinue use of the Synergy CT PICC product reported in the list on section 1.7 and return all affected units from your inventory, regardless of where these units are stored in your facility. Segregate the units in a secure place, pending return to your distributor or HLIC.
3.	**3. Particular considerations for:** Implanted Device **Is follow-up of patients or review of patients' previous results recommended?** No. HLIC recommends verifying any patient's catheter condition if they are known to be affected with the LOTs identified in section 1.7 and replacing the catheter as soon as possible. Discard per institutional guidelines.	
3.	**4. Is customer Reply Required?** (If yes, form attached specifying deadline for return)	Yes, please return the verification form
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Further actions, including additional testing, are being undertaken to allow return of the device to the market.	
3.	**6. By when should the action be completed?**	FSN-20-001 from customers completed by January 31, 2021 FSCA-20-001 closure by March1, 2021
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?**	
	N/A	

	4. General Information	
4.	**1. FSN Type**	New
4.	**2. For updated FSN, reference number and date of previous FSN**	N/A – This is a new FSN

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4.	**3. For Updated FSN, key new information as follows:**	
	N/A – This is a new FSN	
4.	**4. Further advice or information already expected in follow-up FSN?**	N/A – Follow-up FSN not expected.
4.	**5. If follow-up FSN expected, what is the further advice expected to relate to:**	
	N/A – Follow-up FSN not expected.	
4.	**6. Anticipated timescale for follow-up FSN**	N/A – Follow-up FSN not expected.
4.	**7. Manufacturer information** (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Health Line International Corporation
	b. Address	5675 West 300 South Salt Lake City, Utah 84104, USA
	c. Website address	www.hlic.net
4.	**8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.**	
4.	**9. List of attachments/appendices:**	Customer Response Form
4.	**10. Name/Signature**	
		Gracie Sierra Quality Assurance Manager Health Line International Corporation

	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 organizations 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. 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 actions and that you have received the FSN.

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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	FSN-20-001
FSN Date	18/12/2020
Product/ Device name	Synergy CT PICC™ 5Fr Dual Lumen Catheter Basic Kit Synergy CT PICC™ 5Fr Dual Lumen Catheter Nursing Kit
Product Code(s)	A14-05260 A14-05260-N
Batch/Serial Number (s)	A004805 A004861 A004960 A004999 A005296 A005330 A005381 A005425 A005551

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different from above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
☐	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		N/A	Comments:	

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☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:
		Qty	Lot/Serial Number:
		N/A	Comments:
☐	No affected devices are available for return/ destruction	Customer to complete or enter N/A	
☐	Other Action (Define):		
☐	I do not have any affected devices.	Customer to complete or enter N/A	
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query	
Print Name*		Customer print name here	
Signature*		Customer sign here	
Date*			

4. Return acknowledgement to Sender	
Email	
Customer Helpline	
Postal Address	
Web Portal	
Fax	
Deadline for returning the customer reply form *	January 31, 2021

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 actions and that you have received the FSN.