



URGENT FIELD SAFETY NOTICE
PROTEK Duo ECLS Cannula 29Fr & PROTEK Duo ECLS Kit (Subset)
Labelling Check

Date: November 4, 2019

Attention: Customers and Distributor impacted by device(s) listed below

Dear Valued Customer,

The purpose of this letter is to inform you that Tandem Life¹ is initiating a corrective action potentially affecting six units of PROTEK Duo ECLS Cannula 29Fr & PROTEK Duo ECLS Kit, related to the labeling of the device.

Description of the issue addressed in this Letter:

Tandem Life identified incorrect Direction For Use (DFU) booklet and device identification labels were inserted into one unique device package.

Although the affected device could not be identified with certainty, it has been confirmed to be part of six units of PROTEK Duo ECLS Cannulae 29Fr or PROTEK Duo ECLS Kits delivered to the field.

You are receiving this communication because, according to our records, there is in your facility at least one of the six potentially affected units.

Details on affected devices:

The product package for one of the six potentially affected units listed in Table 1 contains incorrect DFU booklet and device identification labels:

Product Number	Name	Potentially Affected Lot Number	Number of units potentially affected
5140-4629EU	PROTEK Duo ECLS Cannula 29Fr	223272	2
5190-0020EU	PROTEK Duo ECLS Kit	00142278	1
		00142279	1
		00142280	1
		00142281	1

Table 1: Details on the 6 Potentially affected units

¹ CardiacAssist, dba TandemLife in one of LivaNova PLC, a U.K. holding company, wholly-owned subsidiaries. In this document, we refer to all entities using the brand name TandemLife.



Risk to health associated with this issue:

For the affected unit, incorrect precautions, indications and additional information on the product are available with the device.

Potential patient consequences could be a delay in the procedure, or, would the error not be detected, cannula misplacement in the vasculature.

No patient harm has been reported to date, due to this issue.

Action to be taken by the user:

Please complete the following actions:

1. Check your inventory for the presence of units listed in **Table 1**;
2. For each potentially affected unit, check labeling using detailed instructions in **Attachment 1**;
3. Fill and return the Customer Response Form in **Attachment 2**.

Transmission 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 sent, if applicable.

Contact reference person:

For questions regarding this Field Safety Notice, please contact your TandemLife distributor or Customer Quality organization at LivaNova.Fsca@livanova.com.

A copy of this Field Safety Notice has been provided to the appropriate Regulatory Agency in your country who is aware of this action.

Thank you for your cooperation in this matter. We are committed to providing quality products and we apologize for any inconvenience this may have caused.

Sincerely,



TandemLife
620 Alpha Drive
Pittsburgh, PA 15238





Attachment 1: Labeling check instructions
URGENT FIELD SAFETY NOTICE
PROTEK Duo ECLS Cannula 29Fr & PROTEK Duo ECLS Kit (Subset)

For each potentially affected unit in your inventory (**Table 1**), please follow the instructions 1 to 3:

1. Open the device packaging and locate the DFU booklet and device identity labels
2. Confirm the product information of the DFU booklet and device identification labels matches the product information on the packaging labels (eg. PROTEK Duo printed on both the DFU booklet on pouch and box labels):
 - a) an example of a correct DFU booklet and device identification labels is shown in **Figure 1**.



Figure 1 – Example of Matching DFU booklet cover, device identification labels, primary label, and secondary label for PROTEK Duo (clockwise from top left)



b) The cannula drawing in section 1.2 of the correct booklet DFU is shown in **Figure 2**.

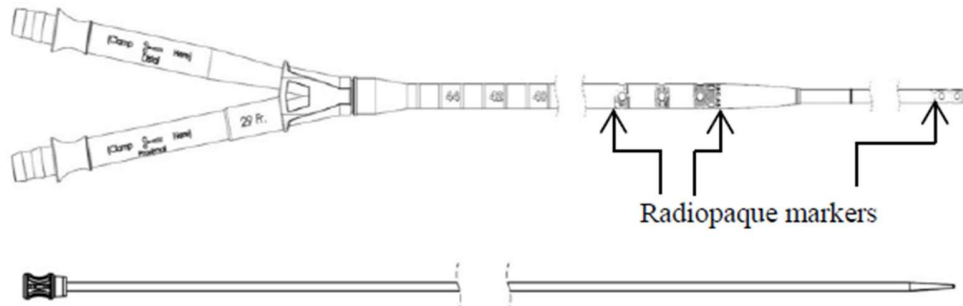


Figure 2 – Correct DFU - Picture of 5140-4629EU

3. Device / Labeling disposition:

- a) If the DFU booklet and device identification labels match the product information on the packaging labels (eg. PROTEK Duo printed on both the DFU booklet on pouch and box labels), the device is safe to use. No additional action is required except returning the Customer Response Form (**Attachment 2**).
- b) If the DFU booklet and device identification labels do not match the product information on the packaging labels (The cannula drawing in section 1.2 of the Incorrect booklet DFU is shown in **Figure 3**):
 - i) Discard the incorrect DFU booklet and incorrect device identity labels
 - ii) Include the correct DFU (**Attached to this communication - Attachment 3**) in the packaging
 - iii) Contact Tandem Life to obtain the correct device identity labels to be used with the device, and, in any case return the Customer Response Form (**Attachment 2**)
 - iv) With the correct DFU booklet, the device will be safe to use, and the corrective action will be completed.

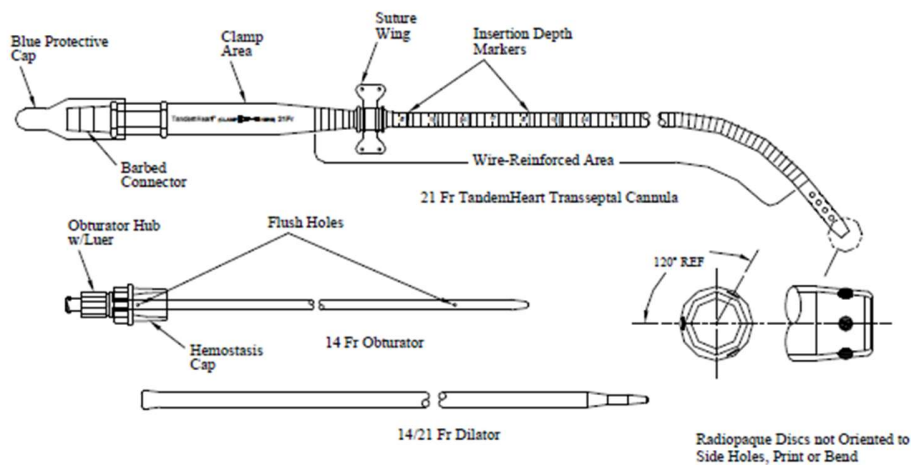


Figure 3 – Incorrect DFU - Picture of 5140-6221EU



**Attachment 2: Customer Response Form
URGENT FIELD SAFETY NOTICE
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Please complete this Customer Response Form and return it to Tandem Life - LivaNova.Fsca@livanova.com at your earliest convenience, and if possible, within two weeks after reception, to ensure timely execution of the corrective action and to avoid repeated notification of this information.

Adverse reactions or quality problems experienced with the use of this product may be reported to Tandem Life via LivaNova.Fsca@livanova.com.

We have reviewed and understood the attached Field Safety Notice. The information and required actions have been brought to the attention of all relevant users:

- Yes No

The result of our inventory check is:

Product	Lot Number	Nb of units	Nb in Inventory	Nb with Correct Labeling	Nb with INCORRECT Labeling	Comment
5140-4629EU / PROTEK Duo ECLS Cannula 29Fr	223272	2				
5190-0020EU / PROTEK Duo ECLS Kit	00142278	1				
	00142279	1				
	00142280	1				
	00142281	1				

The incorrect DFU booklet has been discarded and the correct DFU booklet has been placed into device package:

- Yes Not applicable

Next lines may be used for any question/request (Including device identification labels request) /comment to be submitted to Tandem Life:

Facility Name: _____

Customer Name & Title: _____

City & Country: _____

Contact information: _____

Signature

Date