

# URGENT FIELD SAFETY NOTICE

No. : FCO-US-14-0002Z  
Control No. : QAU 14-127  
Type of Action : Recall  
December, 2014

## Information about unsealed Sterile Puncture Adapter

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### Dear customer,

We regret to inform you that unsealed sterile puncture adapters were found in circulation.  
This document contains important information for the continued safe and proper use of the product.

### Details of Affected Devices :

Product Name :

- Sterile Puncture Adapter EZU-PA5V  
(24 sterile puncture adapters for single use)
- Sterile Puncture Adapter EZU-PA5U  
(24 sterile puncture adapters for single use,  
and transrectal probe EUP-U531 contains one box of EZU-PA5U as standard composition.)
- Sterile Puncture Adapter EZU-PA7V  
(24 sterile puncture adapters for single use)

Lot No. :

- EZU-PA5V : 13088~13093 13098~13102 13104~13108 13112~13114 13121~13123  
13126~13129 13136~13138 14005~14009 14016~14018
- EZU-PA5U : 13U25
- EZU-PA7V : 13705

### Description of problem :

Some products were delivered with incomplete sealing in their individual packaging.

“Sterile products are unsterile if Package is damaged or opened” is indicated on the instruction manual and label of the individual bag of this sterile puncture adapter.

If the user finds abnormal condition of the individual bag, this product must not be used.

Following this advice should eliminate the possibility to cause serious health damage to the patient.

So far no information on any health damage has been received.

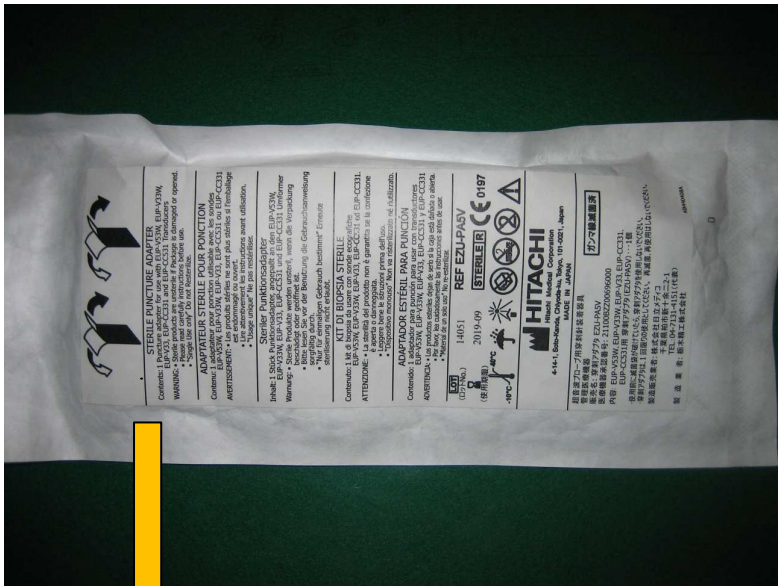
### <Normal PA5V sealed sterilization bag>



<Failed PA5V unsealed sterilization bag>



<Warning label : Sterile products are unsterile if Package is damaged or opened >



**Advise on action to be taken by the user:**

To use the products safely, please make sure of the following:

- Please confirm if the individual bag is appropriately sealed before breaking a seal.
- If you find the improper sealing condition on the individual bag,
  - 1) do not use the product of improper condition.
  - 2) please contact us as we will exchange the improper product for the new one.

**Transmission of this Field Safety Notice:**

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

**Geographic Distribution :**

Japan, EU, China, Singapore, Philippines, Jordan, Turkey, India, Viet Nam, Mexico, Peru

**Contact reference person:**

Please find your local contact person on the cover letter of our local sales organization to this "Urgent Field Safety Notice".

We confirm that this item has been reported to the responsible National Competent Authority.

Yours sincerely

HITACHI MEDICAL CORPORATION.