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## Urgent Field Safety Notice

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**Commercial name/Model:** Gauze Swabs with X-RAY Thread

**FSCA-identifier:** FSCA2020001

**Type of action:** Recall

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2020-08-19

**Attention:** [\[Laboratoire Tetra Medical\]](#)  
[\[Medline Int'l France SAS\]](#)

Dear Sir or Madam,

This letter is intended to provide you with information as following:

**Details on affected devices:** Gauze Swabs with X-ray Thread

Please refer to the attachment-- [2&3-Number of Medical Device Concern to Recall in Healthcare update](#)

### **Description of the problem:**

Based on feedback from our other customer, it became known that under tension the x-ray contrast threads in gauze compresses with x-ray contrast thread can break and fray at individual points. the affected devices please refer to the attachment- [2&3-Number of Medical Device Concern to Recall in Healthcare update](#) recall product list.

We inform Medline Int'l France SAS and Laboratoire Tetra Medical to isolate affected devices in the warehouse.

Theoretically, small pieces of thread could occur when the x-ray thread breaks or frays. This could, for example, lead to inflammation and/or granuloma formation when remaining in the body.

### **Advise on action to be taken by the Hospital administrator:**

1. Please pass this Notice to all those who need to be aware within your organization or to any organization where the potentially affected device(s) have been transferred.
2. Please stop using, we will recall the affected products that sold but not used.

### **Advise on action to be taken by the distributor:**

1. Please pass this Notice to all those who need to be aware within your organization or to any organization where the potentially affected device(s) have been delivered.....
2. Isolate the affected devices located in the warehouses immediately.
3. Please stop selling, we will recall the affected products that sold but not used.

### **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(s) have been transferred.

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Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

We would be grateful if you could confirm receipt of this letter. Please fill in below Acknowledgement Form and return via E-mail or Fax.

**Contact reference person:**

We apologize for the inconvenience caused by this situation. If you have any questions, please contact with your local General Manager of Quality –Vince Tian

Organization: Allmed Medical Products Co.,Ltd

Tel: 0086- (0) 717- 4215906

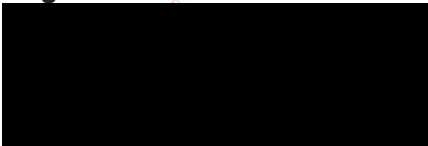
Fax: 0086- (0) 717-4215989

Email: vince@allmed.cn

This Notice has been notified the appropriate Regulatory Agency.

(Closing paragraph)

**Signature:**

A solid black rectangular box used to redact the signature of the General Manager.

General Manager, Quality Center

No.18 Qixing Road, Majiadian Town, 443200 Zhijiang City, Hubei Province, China

Tel: 0086-(0)717- 4215906

Fax: 0086-(0)717-4215989

Email: vince@allmed.cn

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## Acknowledgement Form

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**Confirmation of Receipt of Field Safety Notice**  
**Affected Products : please refer to the attachment- 2&3-Number of Medical Device**  
**Concern to Recall in Healthcare update**  
**FSCA : FSCA2020001**  
**Type of FSCA : Recall**

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**Please fill in this form and return this confirmation by E-mail or Fax immediately.**

**Fax:** 0086-(0)717-4215989  
**Email:** vince@allmed.cn

Name: Vince Tian

Tel. No.: 0086-(0)717- 4215906

E-mail address: vince@allmed.cn

Date and Signature: Vince Tian

数字签名: Vince Tian  
DN: cn=Vince Tian, o=Allmed Medical Products Co., Ltd., ou=Quality & Regulatory, email=vince@allmed.cn, c=CN  
日期: 2020.08.19 15:56:08 +0800

Address of the Organization:

No.18 Qixing Road, Majiadian Town, 443200Zhijiang City, Hubei Province,China

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Since the products are our customer's brand, as the distributor of the products, the following information will be collected by Medline and Tetra.

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**1. List of ...which distributed with equipments**

Country	Equipment S/N	Commercial name/Model	Distributor/Hospital	Contact person	Address	Telephone	Email

**2. List of ....individual distributed**

Country	Commercial name/Model	Affected quantity	Distributor/Hospital	Contact person	Address	Telephone	Email