
Urgent Field Safety Notice

Commercial name/Model: Sterile Hypodermic Syringe for single use

FSCA-identifier: PA-W20201205

Type of action: 1ML

Feb.12, 2021

Attention: [Hospital/Distributor Name] 

Dear Sir or Madam,

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

Details on affected devices: Sterile Hypodermic Syringe for single use, batch number 20201205.

Description of the problem: Sterile Hypodermic Syringe for single use, batch number 20201205. When use this product, there is a foreign substance: After drawing up the solution, “fibrous particles / flakes” were discovered in these syringes.

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 the syringes!

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. Please stop using and selling the syringes!

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.

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 Customer Service Engineer or designated Technical Support Engineer.

Organization: Hunan Pingan Medical Device Technology Co., Ltd.

Tel: +86-736-3242188

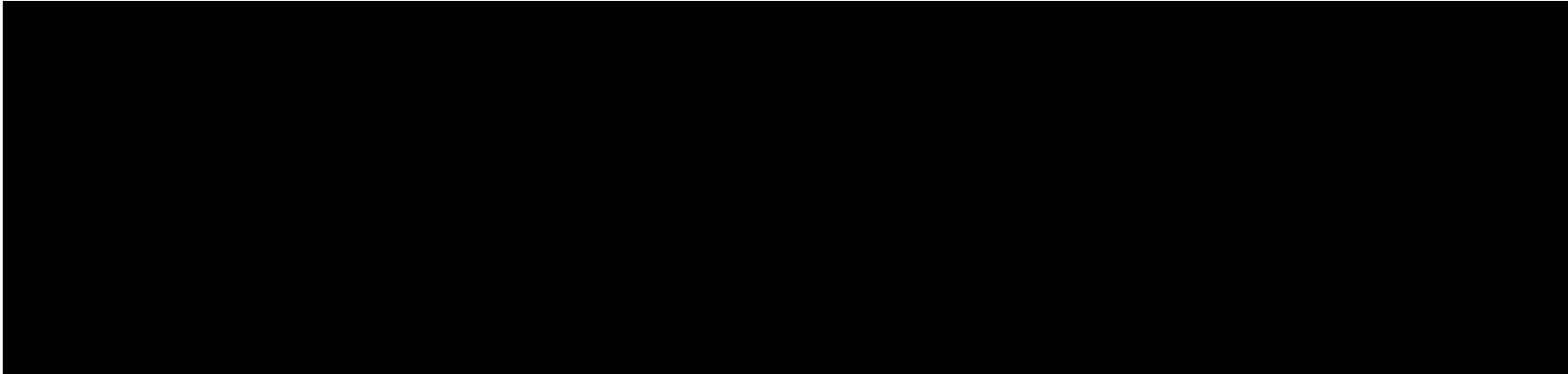
Fax: +86-736-3242188

Email: palyd998@163.com

This Notice is submitted to appropriate Regulatory Agency.

(Closing p

Signature:



Acknowledgement Form

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Confirmation of Receipt of Field Safety Notice

Affected Products :

FSCA :

Type of FSCA :

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

Fax:

Email:

Name:

Tel. No.:

E-mail address:

Date and Signature:

Address of the Organization:

1. List of ...which distributed with equipments

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

2. List ofindividual distributed

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