法兰克曼医疗
FRANKENMAN MEDICAL

Field Safety Notification

April 27th 2023

Frankenman reference: FI20230417

Product: Ultrasonic Soft Tissue Cutting and Sealing System

Type of action: Product Recall

Dear OR Supervisors, Materials Management Personnel, and Chief of Surgery：

Frankenman Medical has initiated a voluntary product recall (removal) of U-sonic Generator which is one main part of the product. The finished product consist of five parts as below table 1, and Generator is related for the recall only.

Table 1: Ultrasonic Soft Tissue Cutting and Sealing System

Product or trade name	**Ultrasonic Soft Tissue Cutting and Sealing System**	
Model number	Foot Switch	FU-FSW01
	Generator	**FU-01M**
	Transducer	FU-02(15), FU-02(26), FU-12(26)
	Ultrasonic Shear	FU A45/ FU B45;FU A36/ FU B36;FU A23/ FU B23;FU A18;FU A14/ FU B14
	Cart (Optional)	FU-P01

Frankenman Medical has identified a rare condition in some U-sonic generators that the leakage current may exceed the allowable values. The problem products with specific Serial Numbers as below：

21110010002 ; 21110010003 ; 21110010004 ; 21110010007 ; 21110010009 ;

21110010010 ; 21110010011 ; 21110010014 ; 21110010015 ; 21110010019 ;

21110010021 ; 21110010023 ; 21110010024 ; 21110010025 ; 21110010026 ;

21110010027 ; 21110010030

To date, Frankenman Medical has not received any reports of adverse events associated with the issue that led to this recall. Frankenman Medical has determined the root cause of this issue, identified the specific U-sonic generators, and implemented corrective actions to address the issue and upgrade the safety of U-sonic generators.

PLEASE DISTRIBUTE THIS URGENT INFORMATION THROUGHOUT YOUR FACILITY WHO USE FRANKENMAN'S U-SONIC GENERATOR.

EFFECTIVE IMMEDIATELY – DO NOT USE OR DISTRIBUTE THESE U-SONIC GENERATORS WITH SPECIFIC SERIAL NUMBERS AS MENTIONED ABOVE.

Recommendations on action to be taken by the user

1. Examine your inventory immediately to determine if you have product subject to this recall on hand and quarantine such product(s) as quickly as possible.
2. Communicate the issue to relevant operating room or materials management personnel, or anyone else in your facility who needs to be informed.
3. If any product subject to this action has been forwarded to another facility, contact that facility to arrange return. Please consider including a copy of this recall letter when communicating.
4. Customers are required to return affected U-sonic generators subject to this recall that are in their inventory immediately.
5. Keep this notice visibly posted for awareness until all product subject to this recall has been returned to the authorized distributor and franchise. While processing your returns, please maintain a copy of this notice with the product subject to this recall and keep a copy for your records.

Contact reference person:

At Frankenman, our first priority is to our customers and their patients, and that includes the safe and effective use of our products. We apologize for any inconvenience this may cause.

If you have additional questions regarding this voluntary product recall or require any assistance with returning product, please contact: leon.guan@frankenman.com

If you have any further questions related to this notice or if you need any additional communications, please contact your local business partners.

Yours sincerely,

Huiying Fan

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QA Head

苏州法兰克曼医疗器械有限公司

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