



Date: XX August 2023

Olympus reference: QIL FY24-EMEA-15-FY24-OSTA-03

URGENT FIELD SAFETY NOTICE

Removal of Veran Devices

Products (Please see attachment for details)	Lot Number
ig4 Image Guided System	All serial numbers and all lot numbers
SPiN Thoracic Navigation System	
SPiN Planning Laptop Workstation	
SPiN Thoracic Navigation System and all associated navigation instruments	

Attention: Endoscopy Department, Pulmonary Department

Dear Healthcare Professional:

Veran Medical Technologies, a wholly owned subsidiary of Olympus Corporation of the Americas (“Olympus”), is writing to inform you of a removal action of the Veran (“Veran device”) devices referenced above. The attached product list details the systems and their instruments used for navigation-assisted interventional radiological procedures, peripheral bronchoscopy, and transthoracic needle aspiration (TTNA).

Risk to Patient Health:

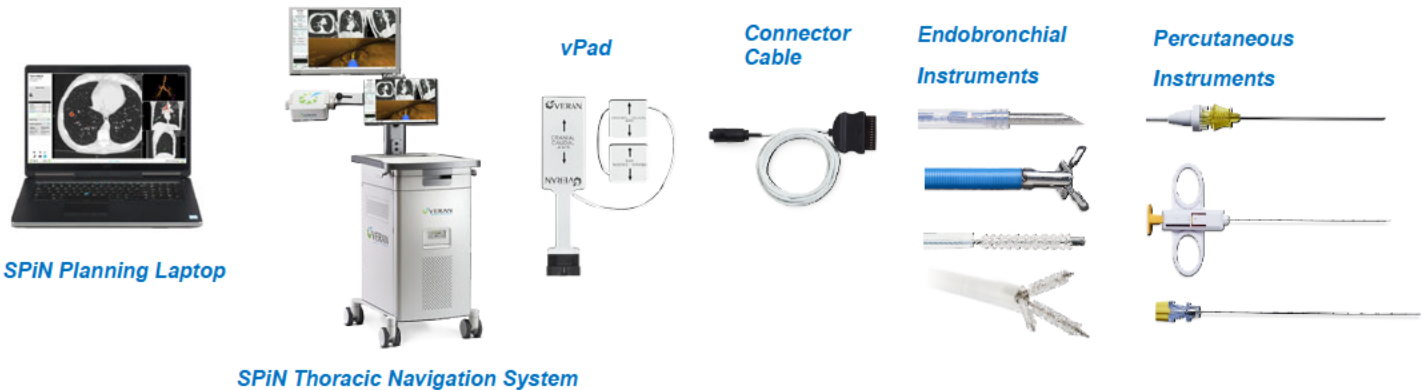
This removal action is being taken after Veran conducted a retrospective review of manufacturing records. This review revealed non-conformances in Veran device manufacturing to design requirements and insufficient evidence to demonstrate adequate electromagnetic compatibility (EMC). EMC is the ability of electrical equipment and systems to function acceptably without interference and to not interfere with other devices within its operating environment.

The risks to health due to insufficient electromagnetic compatibility included: Prolonged Surgery and Delay to Treatment/Therapy. Considering the manufacturing non-conformances, as well as insufficient evidence to demonstrate electromagnetic compatibility, Veran has determined to remove all Veran devices from the market. This action affects Veran single-use instruments and hardware systems.

Action steps to be taken by the end user:

Our records indicate that your facility has purchased one or more Veran devices. Veran requests you to take the following actions:

1. Inspect your inventory and identify any Veran models. Please check all areas of the hospital to determine if any of these devices remain in inventory. The Veran devices are illustrated in the following picture.



2. If you have further distributed this product, identify your customers, and forward them this Field Safety Notice. Please appropriately document your notification process and let us know the end-customer feedback accordingly.
3. Indicate on the Reply Form that you have received and understood this Field Safety Notice by filling out and returning the completed enclosed Reply Form back to your local Olympus representative **XXX** latest by **XXX**.
4. Your local Olympus representative will contact you to arrange return and appropriate reimbursement.

Your National Competent Authority has been informed of this Field Safety Notice.

Veran regrets any inconvenience this action may have caused and fully appreciates your prompt cooperation.

Sincerely

[SIGNATORY]

[Contact Name]

Attachment

Detailed Product List:

Type	Model Number	Description	UDI
EMN Hardware	SYS-1000	ig4 Image Guides System	N/A
EMN Hardware	SYS-2000	ig4 Image Guides System	00815686020064
EMN Hardware	SYS-3000	SPiN Thoracic Navigation System	00815686020088
EMN Hardware	SYS-3230	SPiN Thoracic Navigation System - 230V 50Hz	00815686020095
EMN Hardware	SYS-4000	SPiN Thoracic Navigation System	00815686020101
EMN Hardware	SYS-4230	SPiN Thoracic Navigation System - 230V 50Hz	00815686020118
EMN Hardware	SYS-0185	SPiN Planning Laptop Workstation	00815686020033
EMN Accessory	INS-0048	vPad Connector Cable	00815686020392
EMN Accessory	INS-0050	vPad Patient Tracker, 5/Bx	00815686020408
EMN/SPiN Vision Accessory	INS-7150	SPiN Vision Scope Adapter	N/A
EMN Endobronchial	INS-0352	Always-On Tip Tracked (AOTT) Brush, 15mm L, 1.8mm OD, 5/Bx	00815686020538
EMN Endobronchial	INS-5410	SPiN Flex® ANSO® Needle, 22ga, 1.8mm OD, 5/Bx	00815686020637
EMN Endobronchial	INS-0362	AOTT Oval Cup Forceps, 1.8mm OD, 5/Bx	00815686020538
EMN Endobronchial	INS-0372	AOTT Serrated Forceps, 1.8mm OD, 5/Bx	00815686020576
EMN Endobronchial	INS-0382	AOTT 19ga Needle, 12mm L, 1.8 OD, 5/Bx	00815686020590
EMN Endobronchial	INS-0392	AOTT 21ga Needle, 12mm L, 1.8mm OD, 5/BX	00815686020613
EMN Endobronchial	INS 5450	SPiN Xtend® 21ga, 1.8 OD, 5/Bx	00815686020651
EMN Endobronchial	INS-5300	Always-On Tip Tracked® Triple Needle Brush, 12mm L, 1.8mm OD, 5/Bx	00815686021207
EMN Endobronchial	INS-5411	0.016" Stylet, 1235 mm L, 10/Bx	00815686021191
EMN Endobronchial	INS-5900	SPiN Access Catheter® 90 Degree for use w/ Olympus Scopes	00815686021153
EMN Endobronchial	INS-5905	SPiN Access Catheter® 180 for use w/ Olympus Scopes	00815686021269
EMN Endobronchial	INS-5910	SPiN Access Catheter® 90 for use w/ Olympus 190 Scopes	00815686021276
EMN Endobronchial	INS-5915	SPiN Access Catheter® 180 for use w/ Olympus Scopes	00815686021290
EMN Percutaneous	INS 5610	SPiN Perc® Localization Needle - 1cm, 5/Bx	00815686021139
EMN Percutaneous	INS 5611	SPiN Perc® Localization Needle - 2cm, 5/Bx	00815686021146
EMN Percutaneous	INS-5600	SPiN Perc® Biopsy Needle Guide Kit, 5/Bx (includes INS-5029)	00815686020736
EMN Percutaneous	INS 5620	SPiN Perc® Biopsy Needle Guide Kit - 20cm, 5/Bx (includes INS-5028)	00815686021122
EMN Endobronchial	INS-0304	Always-On Tip Tracked Guidewire, 1.0mm, 735mm	00815686020439
EMN Endobronchial	INS-0305	Always-On Tip Tracked Guidewire, 1.0mm, 950mm	00815686020446
EMN Endobronchial	INS-0322	View Peripheral Catheter, 3.2mm OD, 2.0mm WC	00815686020477
EMN Percutaneous	INS-5016	17ga x 155mm Tip Tracked Bx Needle	00815686020217

Type	Model Number	Description	UDI
EMN Percutaneous	INS-5017	17ga x 155mm Tip Tracked Bx Needle	00815686020224
EMN Percutaneous	INS-5023	17ga 100mm Always-On Tip Tracked Biopsy Needle, Chiba point	00815686020248
EMN Percutaneous	INS-5024	17ga 150mm Always-On Tip Tracked Biopsy Needle, Chiba point	00815686020255
EMN Percutaneous	INS-5032	19 UTW 150mm Always-On Tip Tracked Biopsy Needle, Chiba point	00815686020330
EMN Percutaneous	INS-5034	17 UTW Lg 123mm Always-On Tip Tracked Biopsy Needle, Chiba point	00815686020354
EMN Percutaneous	INS-5036	22 UTW 125mm Always-On Tip Tracked Biopsy Needle, Trocar point	00815686020361
EMN Percutaneous	INS-5039	Always-On vTrack Universal Tracker, SM/CL, 12-18ga	00815686020699
EMN Percutaneous	INS-5040	Always-On vTrack Universal Tracker, LG 7-12ga	00815686020705
EMN Accessory	INS-5323	Sliding stopper	00815686020712
EMN Endobronchial	INS-5440	View Peripheral Catheter, 3.8mm OD, 2.5mm WC	00815686020644
EMN Endobronchial	INS-5500	View Optical Probe	00815686020729
EMN Endobronchial	INS-5700	SPiN EWC Biopsy Guide Kit	00815686021108
EMN Endobronchial	INS-5920	SPiN Access Catheter® 90 Degree for use w/ Pentax Scopes	00815686021306
EMN Endobronchial	INS-5925	SPiN Access Catheter® 180 Degree for use w/ Pentax Scopes	00815686021313



REPLY FORM – QIL FY24-EMEA-15-FY24-OSTA-03

URGENT FIELD SAFETY NOTICE Removal of Veran Devices
[Name & Address of Hospital/Medical Facility]
[Dept/Attn]
[Date]

Dear Sirs or Madams,

I herewith confirm the receipt of your Field Safety Notice.
Further I confirm that I have transferred the content of the attached FSN to all affected departments on which this action has an impact. I understand the necessity to follow the steps.

Name (Signature) _____

Name (Print) _____

Position _____

Please scan / email your completed paper form response to **XXXXXXX**