



URGENT MEDICAL DEVICE RECALL

Date: November 13, 2024

For the Attention of:

Kirwan Surgical Products LLC is conducting a voluntary recall on all 25-gauge disposable bipolar pencils with a sterile lot range from 220906 to 241002. Further details on the at-risk products are presented in the table below.

Product Name	Catalog No.	UDI	Expiration Date(YYYY-MM-DD)	Sterile Lot Range
Disposable Bipolar Pencil 25GA Straight	14-5011	Pouch – 00841019101049 Inner Pack – 10841019101046 Case - 20841019101043	2027-09-01 or later	220906 to 241002
Disposable Bipolar Pencil 25GA Straight, Long	14-5011L	Pouch – 00841019101056 Inner Pack – 10841019101053 Case - 20841019101050	2027-10-01	221020

Description of the Problem and Health Hazard(s):

On November 9th, 2024, Kirwan Surgical Products LLC initiated a voluntary recall for the European Union, Switzerland & United Kingdom. In the United States of America an adverse event occurred that required intervention to prevent permanent impairment /damage. The Device in question is a Kirwan brand disposable 25-gauge bipolar pencil, straight (14-5011). The protective sheath came off when the surgeon removed the instrument from the right eye. The sheath stayed in the eye and poked a hole in the retina. The sheath is made from 25GA stainless steel tubing. Medical intervention was performed and prevented permanent damage. Due to this fact, it has been determined that a recall of all at risk 25GA pencils out in the field shall be immediately implemented.

Upon review of this event report and upon review of similar customer complaints, this issue affects an overall small percentage of 25 Gauge bipolar pencils built (<0.1%), however there has been an increase in reported complaints over the past 6 months. There have been two injuries in total, one minor, and one serious that required intervention to prevent damage. The recent increase in occurrence and potential severity evidenced by trend analysis is cause for concern and is the impetus behind carrying out this recall.

Our records indicate you have been shipped product referenced in the table above.

Please Take the Following Actions:

1. We have asked that if the end user is in possession of any 25GA disposable bipolar pencils with the following SKUs (**14-5011, 14-5011L**) with a sterile lot range from 220906 to 241002, please quarantine devices in question & return it to the respective distributor.

Contact Information:

If you require further assistance, please contact:

Kirwan Contact	Contact Information	Areas of Support
Matthew R. Prario	781-834-9500 Mon-Fri 7:30AM to 4:00PM EST Email: mprario@ksp.com	General Follow-up Technical Questions

Local Contact	Contact Information	Areas of Support
	Phone: Email: Address:	General Follow-up

We apologize for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Sincerely,

Matthew R. Prario
Regulatory Affairs Manager