

LumiCoil™ Platinum Fiducial Marker

REFER TO THE DEVICE DIRECTIONS FOR USE FOR COMPLETE INSTRUCTIONS ON DEVICE USE. RX ONLY.
CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Compatibility

Compatible with the Boston Scientific 22 ga Expect™ Slimline (SL) Endoscopic Ultrasound Aspiration Needle.

The risks associated with LumiCoil Marker placement in procedures other than Endoscopic Ultrasound have not been evaluated.

User Information

The intended user is a physician properly trained in interventional EUS procedures.

INTENDED USE / INDICATIONS FOR USE

The LumiCoil Platinum Fiducial Marker is indicated for use to radiographically mark soft tissue for future therapeutic procedures.

CONTRAINDICATIONS

None known.

WARNINGS

The fiducial should slide freely inside the needle. Do not force the fiducial into the needle.

The fiducial placement procedure should only be performed where possible hemorrhage will not present a danger to patients. The device should be used with caution and only after careful consideration in patients with elevated bleeding times or coagulopathies.

PRECAUTIONS

- Do not use plungers, introducers, or fiducials that have been damaged.
- Do not advance the fiducial with force if the fiducial becomes lodged within the needle or introducer. Determine the cause of resistance and replace the needle and fiducial if necessary.

MRI Safety Information

Non-clinical testing has demonstrated that the LumiCoil™ Platinum Fiducial Marker is MR Conditional. A patient with this device can be safely scanned under the following conditions:

- Static magnetic field 3 Tesla or less.
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40 T/m).

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- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of < 4 W/kg (First Level Controlled Operating Mode). Under the scan conditions defined above, the fiducial is expected to produce temperature rise of less than 2.0 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends less than 2 mm from the fiducial when imaged with a gradient echo pulse sequence in a 3T MRI System.

ADVERSE EVENTS

The complications that may result from fiducial marker placement may include, but are not limited to:

- Bleeding
- Perforation
- Pancreatitis
- Infection
- Peritonitis
- Inflammation
- Fever
- Allergic Reaction
- Tumor Seeding
- Pain
- Fiducial Migration
- Foreign body reactions necessitating medical intervention