

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.

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.

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