

IZI Medical Products Inc.  
**IZI Gold Fiducial Markers**

Sterile, biocompatible interstitial needles containing solid gold marker(s) of various lengths

**DESCRIPTION:** The **IZI Gold Fiducial Markers** products are designed for use in conjunction with conventional radiation therapy methods. The products consist of one (1), or more, solid gold seed marker(s) loaded into a standard 17 or 18 gauge brachytherapy needle that has been preplugged with Bone Wax.

The patient contacting parts of the needle are made of 304 stainless steel. The markers are cast from solid gold (99.99% purity).

**INDICATIONS:** The needles are used for interstitial placement of gold seed markers. Once implanted, the gold markers serve as localization devices for the purpose of radiation therapy.

**ACTIONS:** N/A

**CONTRAINDICATIONS:** There are no known contraindications for using brachytherapy needles or for the implanted gold markers.

**WARNINGS and PRECAUTIONS:**

A **WARNING** indicates the potential for death, serious injury, or other serious adverse events due to use or misuse of the device.

- This product may only be used by a qualified health care professional.
- Single use only - DO NOT REUSE
- DO NOT RESTERILIZE
- DO NOT use if product is damaged

-  DO NOT USE IF PACKAGE IS DAMAGED

A **CAUTION** indicates the potential to damage the device as a result of use or misuse of the device.

- Federal (US) law restricts this device to sale by or on the order of a licensed healthcare practitioner.
- Before use, inspect the sterile package for seal integrity and other damage that may affect product sterility.
- Verify the product expiration date has not been exceeded.
- Use aseptic procedures to remove the needle(s) from the package.

**ADVERSE REACTIONS:** N/A

**HOW SUPPLIED:** The loaded needles are packaged individually or in groups of three or four. The packaged needles are sterilized via ethylene oxide.