



Nova Z Fiducial Marker

Instructions for Use

RX ONLY

Caution: Federal law restricts this device to sale to, or on the order of a physician.

DESCRIPTION

Each Nova Z Fiducial Marker consists of a sealed polyether ether ketone (PEEK) polymer capsule containing a zirconium oxide insert sealed within the device. The length of the polymer capsule is 5.5 mm, and the diameter is 1.0 mm. Each Nova Z Fiducial Marker has a PEEK protrusion at one end, this measures up to 1.0 mm in length and 0.2 mm in diameter.

PART NUMBERS

Pre-sterilization

F-02-04-0011 Nova Z Fiducial Marker

Post-sterilization

F-02-04-0111 Nova Z Fiducial Marker Needle Assembly

INTENDED USE

The Nova Z Fiducial Marker is intended to identify the location of normal or diseased tissue for future evaluation or treatments. The device is placed at or near the treatment or evaluation site through commercially available compatible needles and can be visualized in subsequent magnetic resonance imaging (MRI), computed tomography (CT) or x-ray studies.

INDICATION FOR USE

The Nova Z Fiducial Marker is indicated to be implanted into the body in situations where the location of specific anatomy, normal or diseased, needs to be marked for a future medical procedure. The device can be visualized using MRI, CT or x-ray, and provides a reference from which other procedures can be guided.

CONTRA-INDICATIONS

There are no known or anticipated contra-indications.

PRECAUTIONS

Single use only - DO NOT reuse.

DO NOT use if the package is or appears to be damaged or opened.

DO NOT use damaged product.

The Nova Z Fiducial Marker must be sterilized before use. The Nova Z Fiducial Marker may be sterilized by either gamma radiation or ethylene oxide.

NEEDLE LOADING

The Nova Z Fiducial Marker is intended to be implanted into a patient through commercially available, compatible needles. Only use FDA cleared needles.

- 1. Follow the instructions for use and handling of the needles used for loading.
- 2. Ensure the bevel of the needle is plugged to prevent the Nova Z Fiducial Marker from passing through before implantation.
- 3. Insert the Nova Z Fiducial Marker lengthwise, with PEEK protrusion first, into the proximal end of the implant needle.
- 4. Use the stylet from the implant needle to advance the Nova Z Fiducial Marker to the distal end of the implant needle so that it rests on the inner surface of the plug.
- 5. Place the stylet within the lumen of the needle.
- 6. Advance the stylet until it is resting on the proximal end of the Nova Z Fiducial Marker.
- 7. Ensure the stylet is locked to prevent ejection of the Nova Z Fiducial Marker prior to patient implantation.

STERILIZATION

Warning: Nova Z Fiducial Markers should not be sterilized in a glass vial and should be sterilized using FDA cleared accessories. The Nova Z Fiducial Marker should not be steam sterilized.

Nova Z Fiducial Markers must be subject to a validated gamma or ethylene oxide sterilization process once placed in an implant needle and before being implanted into a patient.

Sterilizers vary in design and performance characteristics. Cycle parameters and the load configuration should always be verified against the sterilizer manufacturer’s instructions. The gamma radiation or ethylene oxide sterilization process utilized must be validated to achieve a sterility assurance level (SAL) of 10⁻⁶ (no more than one non-sterile unit in one million units).

Ethylene Oxide (EO) Sterilization

The following values have been validated in a 3M Steri-Vac 8XL Ethylene Oxide Gas Sterilizer.

Ethylene Oxide Sterilization Parameters		Values
Temperature		51°C
Relative Humidity		65-80%
Gas Concentration		680-840mg/L
Ethylene Oxide Gas Type		100% EO
Cycle Time (Gas exposure time, full cycle)		120 minutes
Minimum In-chamber Aeration Time		0 minutes

Follow the manufacture's recommendations for the ethylene oxide sterilization equipment being used and allow any specified aeration time to fully elapse prior to use.

Gamma Sterilization

For the Nova Z Fiducial Marker, the minimum exposure for routine sterilization is 25 kGy and the maximum exposure for routine sterilization is 40 kGy. This provides a sterility assurance level (SAL) of 10^{-6} .

PATIENT IMPLANTATION

Instructions for Patient Implantation

1. Remove the implant needle containing the Nova Z Fiducial Marker from its packaging.
2. Insert the needle into the target location in the patient.
3. Retract the needle cannula while holding the stylet in place to deposit the Nova Z Fiducial Marker in position.
4. Dispose of the needle according to standard procedures.

MR IMAGING

MRI Safety Information

Non-clinical testing has demonstrated that the Nova Z Fiducial Marker is MR Conditional. A patient with this device can be safely scanned in an MRI system meeting the following conditions:

- Static magnetic field of 1.5 or 3.0 T only
- Maximum spatial gradient magnetic field of 3,640 gauss/cm (36.40 T/m)
- Maximum MRI system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Mode)

Image Artifact

In non-clinical testing, the image artifact caused by the Nova Z Fiducial Marker extends less than 2 mm when imaged with a gradient echo pulse sequence in a 1.5T MRI system or 3.0T MRI system.

RF Heating

Under the conditions of this testing but with the application of a limitation to a SAR of 4.0 W/kg, the largest expected differential temperature rise is 1.3°C and 0.4°C, respectively for 1.5T and 3.0T. This level of heating is not expected to be associated with any adverse physiological effect.

ADVERSE EVENTS

There are no known or anticipated adverse events.











STORAGE CONDITIONS

Store between 68° - 77°F (20° - 25°C).

HOW SUPPLIED

After sterilization individual Nova Z Fiducial Marker Needle Assemblies, each containing a single Nova Z Fiducial Marker, are provided in a primary heat sealed pouch. Up to ten pouched Nova Z Fiducial Marker Needle Assemblies can be placed into a secondary protective carton. This carton is supplied in an outer shipping box.

SYMBOL IDENTIFICATION

	MR Conditional
	Manufacturer
	Catalog Number
	Date of Manufacture
	Shelf Life
	Consult Instructions for Use
	Single Use Only / Do Not Reuse
	Batch Code
	Temperature Limitation
	Sterilized with Ethylene Oxide

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