Symbol Identification

	MR Conditional
	Manufacturer
	Catalog Number
	Date of Manufacture
	Use By Date
	Consult Instructions for Use
	Single Use Only / Do Not Reuse
	Batch Code
	Temperature Limitation
	Non-sterile

How Supplied
The Sirius MRI Marker NS is provided in packs of up to 250 units within a primary container, which is contained within a secondary protective barrier. The pack is supplied within an outer box.

Manufactured for:
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C-01-99-0014, REV 3

SIRIUS™
MRI MARKER

Sirius™ MRI Marker NS

Part Number: F-01-01-0011

INSTRUCTIONS FOR USE

C4 | IMAGING

Sirius™ MRI Marker NS

Part Number: F-01-01-0011

Rx Only

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

The Sirius MRI Marker NS should only be used according to a physician prescribed treatment plan.

Description

The Sirius MRI Marker NS consists of a sealed polyether ether ketone (PEEK) polymer capsule containing a cobalt chloride:N-Acetylcysteine solution. The Sirius MRI Marker NS is used as an accessory to radionuclide sources (seeds) during prostate brachytherapy procedures.

Intended Use

The Sirius MRI Marker NS is a component device indicated as an accessory for use in conjunction with brachytherapy seed carrier sleeves and radionuclide brachytherapy seeds containing one of the following isotopes: Iodine 125 (^{125}I), Palladium 103 (^{103}Pd) or Cesium 131 (^{131}Cs). It is indicated for permanent interstitial implantation in the prostate of patients with confirmed prostatic malignancy.

The Sirius MRI Marker NS is intended to be implanted immediately adjacent to seeds within a brachytherapy seed carrier sleeve. It is intended to be implanted into the prostate via 17- or 18-gauge brachytherapy implant needles using a perineal template according to a physician approved brachytherapy dosimetry plan. The Sirius MRI Marker NS is recommended for use with legally marketed brachytherapy seed carrier sleeves. It is intended to be imaged under MRI within sixty (60) days of implantation.

The Sirius MRI Marker NS is supplied non-sterile and will need to be sterilized by the end-user using either gamma radiation or ethylene oxide.

Sirius MRI Marker NS and the brachytherapy seed carrier sleeve assembly, including the brachytherapy sources, in which they are loaded, must be subject to a validated gamma or ethylene oxide sterilization process before being delivered according to the instructions of the treating physician or licensed medical facility.

Indication for Use

The Sirius MRI Marker NS is a component device indicated as an accessory for use in conjunction with brachytherapy seed carrier sleeves and radionuclide brachytherapy sources containing one of the following isotopes: Iodine 125 (^{125}I), Palladium 103 (^{103}Pd) or Cesium 131 (^{131}Cs). It is indicated for permanent interstitial implantation in the prostate of patients with confirmed prostatic malignancy.

RF Heating

The radio frequency (RF) induced heating results are summarized in Tables 1 and 2. At 1.5T and 3.0T, the results indicated that 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. This level of heating is not expected to be associated with any adverse physiological effect.

Table 1 – Summary of 1.5T field strength RF induced heating results

Test Sample	Probe	Probe Location	ΔT [°C]	ΔT Scaled to Control SAR	ΔT – Control ΔT
Control*	1,2	Control	0.9	—	—
	3	Contralateral	0.3	—	—
Device	1	Head	1.4	1.4	0.5
	2	Foot	1.2	1.2	0.3
	3	Contralateral	0.9	0.9	0.6

Table 2 – Summary of 3.0T field strength RF induced heating results

Test Sample	Probe	Probe Location	ΔT [°C]	ΔT Scaled to Control SAR	ΔT – Control ΔT
Control*	1,2	Control	1.5	—	—
	3	Contralateral	0.7	—	—
Device	1	Head	1.6	1.6	0.1
	2	Foot	1.8	1.8	0.3
	3	Contralateral	1.0	1.0	0.3

*Control represents the average of probes 1 and 2

Adverse Events

None known or anticipated.

Storage Conditions

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

3. Disengage the stylet lock.
4. Hold the stylet in place with one hand, retract the needle over the stylet with the other hand, leaving the brachytherapy seed carrier sleeve containing seeds and Sirius MRI Marker NS in position.
5. Dispose of the needle and stylet according to standard procedures.

MRI Imaging

MRI Safety Information
Non-clinical testing has demonstrated that the Sirius MRI Marker NS is MR Conditional. A patient with this device can be safely scanned in an MR 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 MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Mode)

Warnings:
The Sirius MRI Marker NS is intended to be used in conjunction with brachytherapy seeds. In order to safely scan a patient, you must follow the MRI Safety information for all of the treatment components.

Under the scan conditions defined above the Sirius MRI Marker NS is expected to produce a maximum temperature rise of less than 2°C after 15 minutes of continuous scanning.

Imaging Techniques for Visualization of the Sirius MRI Marker NS
The Sirius MRI Marker NS is best visualized within sixty (60) days of implantation using the body coil and T1-weighted pulse sequence with the following scan parameters:

1. A field view on the order of 16 cm x 16 cm with a 256 x 256 acquisition matrix interpolated to 512 x 512.
2. Slice thickness of 2.5 mm interpolated to 1.25 mm.
3. The shortest available echo time (<3 ms) to minimize T2* relaxation effects associated with Sirius MRI Marker NS and adjacent seeds.
4. High bandwidth (>3.8 ppm per pixel) to minimize off-resonance distortions and signal loss associated with the presence of brachytherapy seeds.
5. Use an acquisition time of 10 minutes.

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

The Sirius MRI Marker NS is intended to facilitate the anatomical localization of seeds after they have been implanted in the prostate of a patient with confirmed prostatic malignancy. It is intended to be imaged under MRI within sixty (60) days of implantation.

The Sirius MRI Marker NS is supplied non-sterile and will need to be sterilized by the end-user using either gamma radiation or ethylene oxide.

Contra-indications

The Sirius MRI Marker NS should not be used for prostate implantation along with radioactive seeds unless they are stranded, linked, or connected in an approved brachytherapy seed carrier sleeve. The Sirius MRI Marker NS should not be used during cardiovascular or neurological procedures.

Precautions

Prepare and use Sirius MRI Marker NS according to a brachytherapy treatment plan prepared under the guidance and approval of a licensed physician.

Single use only - DO NOT reuse.

DO NOT use Sirius MRI Marker NS if package (pouch or vial) is, or appears to be damaged or opened.

DO NOT use damaged product.

The Sirius MRI Marker NS, the brachytherapy source and the carrier sleeve must be sterilized prior to implantation into the patient. The Sirius MRI Marker NS may be sterilized by either gamma radiation or ethylene oxide.

Warning: The Sirius MRI Marker NS should not be sterilized in the glass vial, and should be sterilized using FDA cleared accessories/sterilization pouch.

Needle Loading

Warnings:
Do not handle radioactive materials without necessary personal radioactive monitoring devices, such as direct reading pocket dosimeters, film, and ring badges.

Follow the principals of **ALARA**. Always keep radiation exposure **As Low As Reasonably Achievable**.

DO NOT load radioactive seeds without proper shielding. The loading of radioactive seeds into the carrier sleeve and implant needles should be done behind a protective lead-glass L-Shield.

DO NOT touch or pick-up radioactive seeds with your fingers. Use reverse action tweezers when handling radioactive seeds.

Instructions for Needle Loading

Only use FDA approved brachytherapy seed carrier sleeves, radioactive seeds and implant needles.

The Sirius MRI Marker NS is intended to be implanted into the prostate via 17- or 18-gauge brachytherapy implant needles

1. Follow the instructions for use and handling of the other components used in loading.
2. Use established techniques to transfer the Sirius MRI Marker NS to a brachytherapy seed carrier sleeve and the implant needle that will be used to place the Sirius MRI Marker NS in to a patient.
3. Use reverse action tweezers to pick up the Sirius MRI Marker NS in the sequence defined by the approved treatment plan.
4. Insert Sirius MRI Marker NS lengthwise into the proximal end of the brachytherapy seed carrier sleeve one by one.
5. Use the stylet from the implant needle being loaded to individually advance each Sirius MRI Marker NS to the distal end of the brachytherapy seed carrier sleeve. Ensure the distal Sirius MRI Marker NS and seed is not ejected from the distal end of the brachytherapy seed carrier sleeve.
6. Advance each Sirius MRI Marker NS until it is seated on top of the previous seed or Sirius MRI Marker NS within the brachytherapy seed carrier sleeve.
7. Ensure the bevel of each implant needle is plugged to prevent the brachytherapy seed carrier sleeve assembly passing through.
8. Use reverse action tweezers to place the brachytherapy seed carrier sleeve assembly into the implant needles.
9. Ensure the brachytherapy seed carrier sleeve assembly is advanced to the distal end of the implant needle.
10. Place the stylet within the bore of the needle.
11. Advance the stylet until it is resting on the proximal end of the brachytherapy seed carrier sleeve assembly.
12. Place a stylet lock on the implant needle to prevent ejection of the brachytherapy seed carrier sleeve assembly prior to patient implantation.

Sterilization

Warning: Sirius MRI Marker NS should not be sterilized in the glass vial, and should be sterilized using FDA cleared accessories/sterilization pouch.

Sirius MRI Marker NS must be subject to a validated gamma or ethylene oxide sterilization process once loaded into a brachytherapy seed carrier sleeve assembly and placed in a brachytherapy implant needle and prior to being delivered according to the instructions of the treating physician or licensed medical facility.

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 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 conditions have been validated for sterilizing Sirius MRI Marker NS in a pre-loaded brachytherapy needle configuration utilizing a 3M Steri-Vac 5XL Ethylene Oxide Gas Sterilizer.

Ethylene Oxide Sterilization Parameters	Values
Temperature	37°C
Relative Humidity	60%
Gas Concentration	736 mg/L
Ethylene Oxide Gas Type	100% EO
Cycle Time (Gas exposure time, full cycle)	480 minutes
Minimum Aeration Time	0 minutes

Follow the manufactures recommendations for the ethylene oxide sterilization equipment being used and allow any specified aeration time to fully elapse prior to use. Only FDA-cleared sterilization accessories should be used.

Gamma Sterilization

For the Sirius MRI Marker NS, 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

Warnings:

Do not handle radioactive materials without necessary personal radioactive monitoring devices, such as direct reading pocket dosimeters, film, and ring badges.

Follow the principals of **ALARA**. Always keep radiation exposure **As Low As Reasonably Achievable**.

Follow the principles of radiation protection; **Minimum time, Maximum distance and Maximum shielding**.

Instructions for Patient Implantation

1. Remove the implant needles from the transport packaging according to the instructions of the supplier of the needles and seeds.
2. Insert the needles into the prostate under trans-rectal ultrasound guidance by placing each needle through the perineal template at the designated location.