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HDR MRI Lumen Marker

Part Number: F-01-02-0001

INSTRUCTIONS FOR USE

Symbol Identification

	MR Conditional
	Manufacturer
	Catalog Number
	Date of Manufacture
	Use By Date
	Consult Instructions for Use
	Batch Code
	Temperature Limitation
	Non-sterile

How Supplied

The HDR MRI Lumen Marker is provided as a single unit contained within a protective pouch. Single unit pouches are packed within a primary protective box, with up to 5 individually pouched HDR MRI Lumen Markers per box. This protective box is provided within an outer shipping box. Each HDR MRI Lumen Marker is supplied with a stopper.

Manufactured for:
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C4 Imaging™ is a trademark of C4 Imaging LLC.

C-01-02-0014, REV B

Warnings

The HDR MRI Lumen Marker is intended to be used as an accessory to a remote controlled high dose rate (HDR) radionuclide applicator systems. In order to safely scan a patient, you must follow the MRI Safety information for all utilized system components.

Image Artifact

In non-clinical testing, the image artifact caused by the HDR MRI Lumen Marker extends less than 3 mm when imaged with a gradient echo pulse sequence in a 1.5T MR system and a spin echo pulse sequence in a 3.0T MR system.

RF Heating

Under the scan conditions defined above the HDR MRI Lumen Marker is expected to produce a maximum temperature rise of less than 1°C after 15 minutes of continuous scanning.

Adverse Events

There are no known or anticipated adverse events associated with the HDR MRI Lumen Marker.

Storage Conditions

Store between 68° - 77°F (20° - 25°C)

Disposal

Although HDR MRI Lumen Markers are not intended to come into direct contact with tissue or bodily fluids they are intended to facilitate the identification of HDR applicator treatment lumens that are placed into patients. It is recommended they are disposed of in a biohazard container.

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Rx Only

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

Description

The HDR MRI Lumen Marker is a sealed high-density polyethylene (HDPE) tube containing a cobalt chloride:N-Acetylcysteine saline solution. The HDPE tube is up to 350.0 mm in length and 1.0 mm in diameter. The distal end of the device is provided with an attached HDPE end-cap for handling. This end cap is approximately 5.0 mm in length.

The HDR MRI Lumen Marker is an accessory to remote controlled high dose rate (HDR) radionuclide applicator systems and facilitates the identification of lumens within MRI compatible HDR brachytherapy applicators. Each HDR MRI Lumen Marker is supplied with a stopper designed to hold the device in place once fully inserted into an applicator.

Intended Use

The HDR MRI Lumen Marker is intended to facilitate the identification of HDR applicator treatment lumens after placement into a patient.

Indication for Use

The HDR MRI Lumen Marker is indicated as an accessory for use with FDA Market Cleared remote controlled radionuclide applicator systems that are used to treat tumors that are indicated for treatment with high dose rate (HDR) brachytherapy. The HDR MRI Lumen Marker is indicated for temporary placement in HDR applicator lumens.

The HDR MRI Lumen Marker is intended to facilitate the identification of HDR applicator treatment lumens. It is intended to be non-patient contacting and only placed in applicators that are designed to prevent patient tissue or bodily fluids accessing the inner lumen.

Once placed in an HDR applicator lumen the HDR MRI Lumen Marker is intended to be imaged with MRI. It is removed after MR imaging and prior to the placement of a radioactive source. The HDR MRI Lumen Marker is intended for use in a single patient and can be re-used for a maximum of four (4) times if required for a single course of treatment in a single patient. Cleaning and storage instructions are provided in the Cleaning section below.

Contra-indications

There are no known or anticipated contra-indications for the HDR MRI Lumen Marker.

Precautions

DO NOT use if packaging is, or appears to be damaged or opened.

DO NOT use if HDR MRI Lumen Marker is, or appears to be damaged.

DO NOT use with more than one patient.

DO NOT use other than within an HDR applicator.

HDR MRI Lumen Marker Placement

Only use with FDA Market Cleared MRI compatible HDR applicators that are designed for use with FDA Market Cleared remote controlled radionuclide applicator systems.

The HDR MRI Lumen Marker is intended to be placed into applicator lumens with a minimum diameter of 1.0 mm and a maximum length of 320.0 mm.

1. Follow instructions for use and handling for the placement of the HDR applicator(s) prior to utilizing the HDR MRI Lumen Marker.
2. Open a pouch containing a single HDR MRI Lumen Marker, hold the device by the proximal tip and the distal end-cap and remove it from the pouch.
3. Before use visually inspect the HDR MRI Lumen Marker to ensure the contained MRI fluid is free of any bubbles that completely occlude the interior lumen of the device within a minimum distance of 7.0 mm from the proximal tip. If such bubbles are present in the fluid within 7.0 mm of the proximal tip dispose of the device according to the instructions described in Disposal below.
4. Advance the proximal tip of the HDR MRI Lumen Marker through the central hole of the stopper.
5. Insert the proximal tip of the device into the open lumen of the HDR applicator after it has been placed into the patient.
6. Advance the device until the proximal tip reaches the applicator's inner lumen tip.
7. As a secondary check of full insertion, measure the length of any protruding HDR MRI Lumen Marker (excluding the end-cap) to ensure the inserted length is equivalent to the length of the applicator.
8. Once the proximal tip of the HDR MRI Lumen Marker is fully advanced to the inner tip of the HDR applicator's lumen advance the stopper toward the distal end of the HDR applicator until it achieves a press fit, securing the HDR MRI Lumen Marker with the HDR applicator.
9. Repeat steps 2 – 8 to place additional HDR MRI Lumen Markers within additional HDR applicators if required.
10. Once the MR imaging procedure is complete, disengage each stopper and remove all HDR MRI Lumen Markers from the applicator(s).
11. The HDR MRI Lumen Marker may be used for further HDR applicator lumen imaging if required for the same patient and is within its labeled use by date. If not required, dispose of the device according to the instructions described below in Disposal.

12. If re-used in the same patient each HDR MRI Lumen Marker should be cleaned according to the instructions described below in Cleaning.
13. Before re-use visually inspect the HDR MRI Lumen Marker to ensure the contained MRI fluid is free of bubbles that completely occlude the interior lumen of the device within a minimum distance of 7.0 mm from the proximal tip. If such bubbles are present in the fluid within 7.0 mm of the proximal tip dispose of the device according to the instructions described below in Disposal.
14. If additional HDR applicator lumen imaging is required for the same patient follow steps 1 – 9.
15. If not required for further imaging the HDR MRI Lumen Marker should be disposed of according to the instructions described below in Disposal.

Cleaning

The HDR MRI Lumen Marker may be re-used up to 4 times if required for additional HDR applicator lumen imaging in a single patient. If re-use is required follow the cleaning steps below.

1. Each HDR MRI Lumen Marker that is to be re-used should be cleaned by wiping along the full length and the complete circumference with an isopropanol (isopropyl alcohol) wipe (30 – 60% isopropanol) between 7 and 12 times.
2. After wiping with isopropanol, the HDR MRI Lumen Marker should be placed on a clean surface and allowed to air dry before re-use.
3. If the HDR MRI Lumen Marker is not to be re-used immediately it should be cleaned following steps 1 and 2 and then sealed in a clean plastic bag until re-use is required. Once re-use is required, steps 1 and 2 should be repeated.

MR Imaging

MR Safety Information

Non-clinical testing has demonstrated that the HDR MRI Lumen Marker 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 Tesla (1.5T) or 3.0 Tesla (3.0T)
- Maximum spatial gradient magnetic field of 1900 gauss/cm (19.0 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode)