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FIELD SAFETY NOTICE

Products: All variants of the fiducial markers Goldlock and Beammarks

FSCA-identifier: FSCA-CA-18-003

Type of action: Update of instructions for use due to misleading information on

reuse.

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Date: 2018-06-08

Affected devices: All variants of the fiducial markers Goldlock and Beammarks.

Description of the problem: The current version of the instructions for use indicate that fiducial markers can be reused if they are surgically removed, washed and resterilized. This is, however, not in line with the intended use of these single-use products.

To prevent accidents, the instructions for use will be updated and the misleading text removed.

Advice on action to be taken by the user: No action is necessary, but markers should not be reused.

Transmission of this Field Safety Notice:

Please transfer this notice to:

- People who use the products or may use them in the future
- Staff who make decision on use of the product

Contact reference person:

Hadi Ghane Beampoint AB c/o Karo Pharma AB Nybrokajen 7 111 48 Stockholm

beampoint@medcore.se

The undersigned confirms that this notice has been notified the appropriate Regulatory Agencies.

Hadi Ghane