BRACHYTHERAPY NEEDLE PRODUCT INSERT

BRACHYTHERAPY NEEDLE SET
Sterile Interstitial Needles

DESCRIPTION
CP Medical Brachytherapy needles are used for interstitial placement of radioactive seeds in cancer therapies or for the placement of gold markers that serve as localization devices for the purpose of aiding in radiation therapy.

The device is comprised of four basic elements; a wire stylus with plastic handle, a plastic needle hub, a protective needle sleeve and the hollow steel needle. The shaft of the needle and hub are bonded together after the fashion of hypodermic or spinal needles. The hub tapers smoothly down to the inside diameter of the needle to facilitate the insertion of the radioactive seeds and stylus. The barrel of the needle may be etched externally with a series of evenly spaced bands from tip to hub. These bands will correspond to the locations of the radioactive seeds, spacers and/or markers once they are loaded within the needle cannula. A single or multiple seeds, spacers, or markers may be placed by the physician as desired.

INDICATIONS
The CP Brachytherapy needle is a manual radionuclide applicator system intended to apply a radionuclide source into the body for radiation therapy.

ACTIONS
(N/A)

CONTRAINDICATIONS
This device is not intended for use in central nervous or circulatory system applications.

The particular medical condition and anatomy of the patient may dictate the implantation procedure to be used.

WARNINGS & PRECAUTIONS
Do not use if package is open or damaged or if the expiration date has been exceeded. Discard open, unused needles.

Do not resterilize or reuse; this is a single use product.

This product may only be used by qualified physicians. Federal (U.S.) law restricts this device to sale by or on order of a licensed health care practitioner.

Needles are to be used in soft tissues only; care must be taken not to contact hard surfaces, such as bone, during insertion as such contact may break or bend the needle while still in the body, causing tissue damage or needle fragments left behind as the needle is removed.

ADVERSE REACTIONS
Bone wax is used as a terminal plug in the needle to retain radioactive seeds prior to implantation. Bone wax contains natural beeswax. Some reaction to bone wax may occur, such as an allergic reaction or foreign body reactions (e.g. granulomas), as bone wax is a minimally resorbable implantable substance.

PROCEDURE
Needles provided by CP Medical do not contain radioactive seeds; therapeutic seeds must be obtained from licensed sources and subsequently loaded into the needles.

NEEDLE INSERTION
1. Ensure the stylert is intact to prevent accidental displacement of components during needle placement.
2. Insert loaded needles via the grid into the treatment area as indicated by the treatment plan. The needle must be discarded if penetration is not possible or if the needle comes into contact with a bony construction.
3. Repeat for each needle required by the treatment plan. (see Warnings & Precautions)

NEEDLE REMOVAL
1. Upon completion of source delivery, remove and collect all treatment needles.
2. Check the needles for radioactive contamination as required by facility radiation procedures.
3. Dispose of needles in accordance with facility procedures for biohazardous materials and sharps.

HOW SUPPLIED
These needles are available in various gauges either pre-waxed or non-waxed. Waxed needles are also available with a gold fiduciary marker(s) and spacers of absorbable material.

SYMBOL DEFINITIONS

Do Not Use If The Package Is Open Or Damaged
Manufacturer
Sterilized By Ethylene Oxide

See Instructions For Use.
Lot Number
Expiration Date
Do Not Reuse
Do Not Resterilize

CP Medical
803 NE 25th Ave.
Portland, OR 97232 USA
Tel. (503) 232-1555

MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

CP Medical
803 NE 25th Avenue
Portland, OR 97232 USA
Phone 503 232-1555
Fax 503 230-9993
www.cpmedical.com