THERAGENICS CORPORATION®

INSTRUCTIONS FOR USE

C20® SEED CARTRIDGE

9019 / 556006 Rev. F Effective June 2012

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

DESCRIPTION

The **C20** cartridge consists of a two-piece assembly that is capable of holding up to 20 brachytherapy sources (seeds) per cartridge (Fig. 1). The **C20** cartridge assembly is to be used in conjunction with the Mick® 200-TP, 200-TPV applicators or equivalent. A visual seed count indicator appears on the stem of the cartridge assembly. Radioactive seeds are loaded into the appropriate number of **C20** cartridges per the customer's order. Loaded cartridges are shipped in the FlatPack™ stainless steel shipping shield. A Loose Seed Kit containing a glass vial is provided with the product to contain excess loose, unused seeds. Please refer to the below sections for additional information for use and handling.

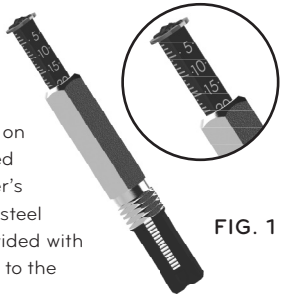

FIG. 1

PHYSICAL CHARACTERISTICS

The **C20** is constructed of a molded plastic lower housing and a stainless steel upper housing with internal metal spring.

CLINICAL INDICATIONS

The **C20** cartridge is indicated for use with the Mick® 200-TP, 200-TPV applicators or equivalent to facilitate the deployment and insertion of radioactive seeds into soft tissue organs within the body.

WARNINGS AND PRECAUTIONS

- The **C20** cartridge is designed to function with the Mick 200-TP, 200-TPV applicators or equivalent only. It is not recommended for use with other applicator systems.
- The **C20** cartridge accommodates seed geometries of 0.8 mm diameter by 5 mm length maximum. It is not recommended for use with other seed geometries.
- Loaded **C20** cartridges are provided non-sterile and must be autoclave sterilized prior to use. See guidance below.
- It is the user's responsibility to maintain the applicator in proper working condition. A poorly maintained applicator may not properly eject seeds from the **C20** cartridge. Please refer to the applicator's IFU for the recommended service interval.
- Do not partially push out seeds from cartridge until ready to insert into patient. Partially dislodged seeds may cause misalignment in cartridge resulting in ejection complications including but not limited to increased resistance during insertion and/or possible inability to eject/insert seeds.
- In the unlikely event that the cartridge should seize and/or stop working preventing insertion of seeds and/or removal of the cartridge from applicator place applicator over controlled area, invert applicator and carefully loosen upper stainless steel portion to release seeds out of cartridge. Cartridge may now be removed and reloaded for use.

- If cartridge is dropped, empty contents and inspect for damage.
- The **C20** cartridges are for single use only.
- Never use excessive force on seeds.
- It is recommended that the bottom seed in the cartridge be visually examined to ensure that it is aligned in the center of the cartridge prior to insertion of the cartridge into the applicator.
- Seeds lying diagonally in the magazine groove will prevent the next seed from dropping down, causing ejection complications.
- Use caution when disassembling the loaded cartridges as assembly is under spring tension.
- Do not over-tighten when reassembling the cartridge.

For appropriate **Warnings and Precautions** for the radioactive seeds please refer to the **Information For Physicians** for each seed type.

ADVERSE REACTIONS

There are no known adverse reactions to the patient from the handling or use of the **C20** cartridge.

INSTRUCTIONS FOR USE

Unpacking and Sterilization:

LOADED C20 CARTRIDGES ARE PROVIDED NONSTERILE AND MUST BE AUTOCLAVE STERILIZED PRIOR TO USE.

1. Remove plastic tray from shipping box.
2. Remove FlatPack (stainless steel shield) from plastic tray.
3. Remove plastic security shrink wrap from tray.
4. To inspect or assay cartridges/seeds. Place FlatPack on flat/level surface. Remove metal end cap. Cut autoclave tape and slide stainless steel tray out of housing to expose loaded cartridges (Fig. 2). Shield design allows User to expose only one cartridge at a time (Fig. 3) or all cartridges at once (Fig.4). Inspect/assay per established hospital procedures.
5. To remove seeds from cartridge, secure cartridge in Mick Loading V-Block (Mick Cat#7509) or equivalent per V-Block instructions for use. **Use caution when disassembling loaded cartridges, as assembly is under spring tension**. Carefully unscrew the upper stainless steel portion of the cartridge and place aside. Carefully remove seeds from cartridge using reverse action tweezers or equivalent. ***Use caution when handling radioactive seeds***. To reload the cartridges follow the reverse of the above steps. Finger-tighten the assembly until components are secure. **DO NOT OVER TIGHTEN**.

FIG. 2

6. To sterilize, return any loaded cartridges that were removed to the stainless steel tray. Slide stainless steel tray back into housing of FlatPack and secure in place using autoclave tape or equivalent. Place FlatPack containing loaded cartridges in sterilization wrap, pouch or equivalent per hospital recommendations.
7. Sterilize FlatPack containing loaded cartridges per hospital recommendations or per recommendations below. User may also use the standard Mick seed sterilizer (Mick Cat#: 7901) in lieu of the tray.

8. After sterilization, place in sterile field. Shield design allows User to expose only one cartridge at a time (Fig. 3) or all cartridges at once (Fig.4). Use cartridges as clinically indicated.
9. After use, empty cartridges and/or empty stainless steel shield may be discarded. Shield material contains no lead.

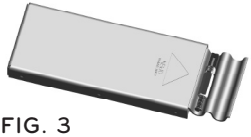

FIG. 3

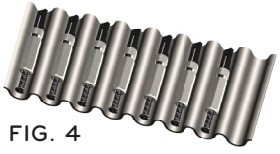

FIG. 4

STERILIZATION INFORMATION

VALIDATED STERILIZATION CYCLES

FLATPACK™

Standard Cycle:

Time	24 minutes
Temperature	250° F (121° C)
Pressure	15 psig

Flash Cycle:

Time	4 minutes
Temperature	270° F (132° C)
Pressure	27 psig

MICK STERILIZATION CARRIER

Standard Cycle:

Time	42 minutes
Temperature	250° F (121° C)
Pressure	15 psig

Flash Cycle:

Time	20 minutes
Temperature	270° F (132° C)
Pressure	27 psig

QUALITY ASSURANCE VERIFICATION INSTRUCTIONS

User may perform a QA check of the activity of seeds loaded in the **C20** cartridge using cartridge source holders provided by well chamber/dose calibrator manufacturers, such as the Standard Imaging Mick® Source Holder, REF # 70047. User must determine the appropriate "Correction Factor" to be applied to measurement of the loaded cartridge to verify seed activity. The correction factor is determined by comparing the measurement value of seeds loaded in the **C20** cartridge to the sum of the measurement value of each individual seed. For additional guidance in determining this factor, please refer to the Instructions for Use for your source holder. To check seeds loaded in the **C20** cartridge using a source holder, first expose all twenty seeds by unscrewing the upper housing until the numerical indicator reads 16 seeds (Fig. 5). This will allow full exposure of seeds to calibrator sensors. **All seeds must be visible to obtain proper radiation measurements**. Insert loaded cartridge into source holder per manufacturer's guidance. Place into well chamber/dose calibrator and obtain measurements.

Apply correction factor to obtain activity per seed. After measurement verification has been obtained for a cartridge, re-tighten the cartridge assembly until components are secure. **DO NOT OVER TIGHTEN**. Repeat above steps for each cartridge to be verified.

UNUSED SEEDS

If unused seeds remain in the **C20** cartridge after dispensing seeds, place cartridge containing seeds back into FlatPack shipping shield. Any loose, unused seeds should be placed into the glass vial provided in the Loose Seed Kit envelope of product packaging. Place vial containing seeds into FlatPack shipping container for storage/shielding purposes. Store unused seeds per established hospital protocol.

RETURNS FOR DISPOSAL

Seeds may be returned for disposal per Core Oncology's standard disposal policy. For excess seeds that are loaded in a **C20** cartridge and/or loose seeds, follow guidance in **UNUSED SEEDS** section above. Contact Core Oncology Customer Care for return authorization and shipping instructions.

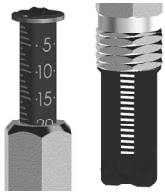

FIG. 5

CLEANING PROCEDURES

There are no special cleaning procedures for the **C20** cartridge, as it is a single-use, disposable device. Dispose when empty. **DO NOT REUSE**.

CUSTOMER SERVICE

For product information or to place an order, contact Theragenics® Customer Service at (877) 444-7333, Monday through Friday, 8:00 AM to 6:00 PM ET. Orders may also be submitted via facsimile at (800) 458-4303.

Defective, damaged, or out of specification product may be returned for credit with prior return authorization. *Please do not return product without first obtaining a return authorization.*