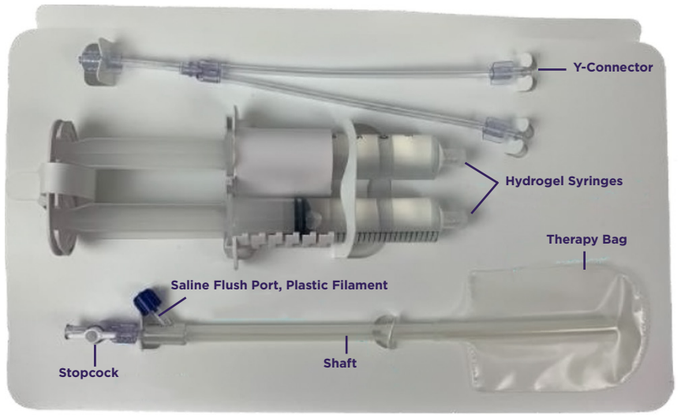
PACKAGING CONTENTS:



CAUTION:

Federal (United States) law restricts this device to sale by or on the order of a physician.

PRECAUTIONS:

- Please read and comprehend all warnings before operating this device.
- The device is for Single Patient Use and is a Single Use Device (SUD) only. The device is not sterilized, nor is it compatible with sterilization procedures.
- The device is designed to be used with external fixation for the brachytherapy treatment applicator. An external fixator was used with the applicator during clinical testing of the device.
- If any component of the packing system is damaged, do not use and discard according to your facility policy.
- The BrachyGel Vaginal Hydrogel Packing System device should not remain inserted into the patient for any time longer than required for radiation treatment.
- If the patient cannot tolerate the device during treatment due to pain, stop and remove the device as described in the “INSERTION, INSTALLATION AND REMOVAL” section.
- A new subsequent treatment planning scan and treatment plan may be required after removal of the device per Physician’s orders.
- The BrachyGel Hydrogel Vaginal Packing System is not sterilized, nor is it compatible with sterilization procedures.

INTENDED USE AND PRODUCT INTRODUCTION:

The BrachyGel Vaginal Hydrogel Packing System is a single-use, non-sterile, disposable, non-powered, self-expanding hydrogel positioning device, intended to be used on a daily treatment basis for the temporary positioning of the vaginal wall and adjacent pelvic tissues during radiation treatment.

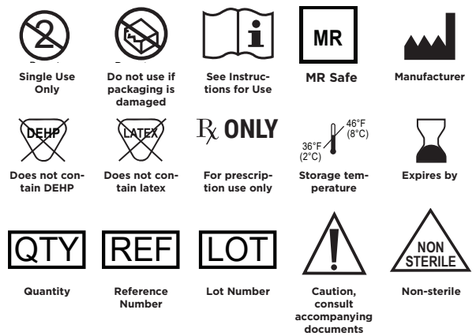
INDICATIONS FOR USE:

The BrachyGel Vaginal Hydrogel Packing System is a single-use, non-sterile, disposable, non-powered positioning device that delivers self-expanding hydrogel that forms and expands within the vaginal cavity. The purpose of this device is to displace the vaginal wall and adjacent pelvic tissues during radiation therapy planning and delivery, to reduce dose to adjacent tissues by attenuation of radiation dose, and to stabilize radiation treatment equipment during radiation therapy planning and delivery. The placement of the hydrogel device requires a physician or physician directed healthcare professional, and is performed as a separate procedure outside of brachytherapy applicator insertion, computed tomography and/or magnetic resonance imaging exam, radiation treatment planning, and radiation treatment delivery. This device is not intended to be inserted into the uterine cavity or rectum. This device is intended to be in place temporarily and removed after less that 24 hours.

TRANSPORTATION AND STORAGE:

During transportation, the device can be at temperatures ranging from -30C to +50C (-22 to 122F). The device should be stored in refrigeration, 2C to 8C (36F to 46F).

SYMBOLS:



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CQ MEDICAL™

Instructions for Use

BrachyGel Vaginal Hydrogel Packing System

143-326 Rev. A
02/2024

CONTRAINDICATIONS:

Unresolved vaginal laceration or tear.
Excessive vaginal bleeding.
Any standard contraindications recognized for vaginal packing devices.
BrachyGel is contraindicated for use in patients who cannot tolerate, including allergy or Hypersensitivity, any polymer which contains urethane or the polymers thiol THIOCURE ETTMP1300 and poly(ethylene glycol) diacrylate(PEGDA).

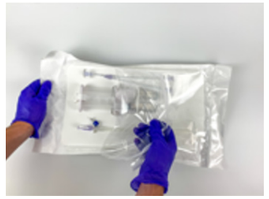
WARNINGS:

Do not fill bag with foreign fluids.
Failure to perform the standard imaging position verification protocol may cause the device to not perform as intended.
Do not apply excessive pressure/force on the device tubing.

INSERTION AND INSTALLATION:

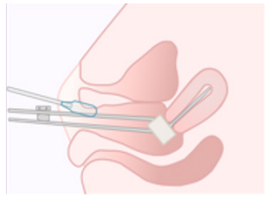
1. Position patient, insert brachytherapy treatment applicator, and attach applicator to external fixation per facility protocol.
2. Put on gloves. Aseptically, open packaging and remove device contents.
3. Lubricate the device bag as desired per facility protocol.
4. Hold device by the shaft.
5. Gently insert the device to desired depth anterior or posterior to the brachytherapy treatment applicators.
6. If desired, insert a second device to desired depth anterior or posterior to the brachytherapy treatment applicators.
7. Attach the Y-connector tubing to the device stopcock.
8. Remove syringe caps from syringes and attach the split ends of the Y-connector to each male luer connector on the hydrogel syringes.
9. Turn the stopcock to the open position and infuse contents from syringes to desired fill volume (50mL max). Infuse syringe contents over 1 minute or less to prevent clogging. Turn the stopcock to the closed position.
10. If a second device was placed, repeat Steps 7 through 9 for the second device.
11. Assess adequate packing by physical exam and visual inspection. During fraction planning, use a 3D imaging method to verify presence and position of the applicator and BrachyGel Vaginal Hydrogel Packing System device.
12. With the balloon filled and stopcock turned to the closed position, perform treatment according to facility protocols.
13. The use of saline for removal of the device is optional. Physician will assess the degree of tension when initiating removal of the device (I.e., caudal force on the device) to determine if the use of saline is needed. See Steps 14 through 15 for instructions on the use of saline.
14. Unscrew Saline Port Cap and withdraw attached plastic filament.
15. Connect a 10mL Luer lock syringe (not supplied) to the Saline Port. Based on physician assessment, infuse a maximum of 10mL saline into the port to cause separation of the hydrogel into two or more pieces.
16. Gently remove the device from the patient and dispose per facility protocol.

INSTALLATION:



1. Aseptically, open packaging and remove device contents.

2. Lubricate the device bag as desired per facility protocol. Hold device by the shaft.

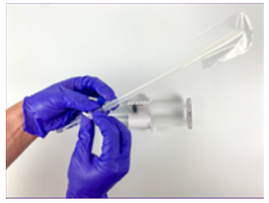


3. Gently insert the device to desired depth anterior or posterior to brachytherapy treatment applicators.

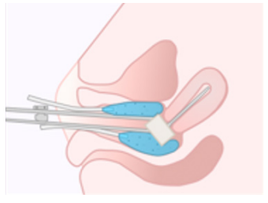
4. Attach the Y-connector tubing to the device stopcock.

5. Remove syringe caps

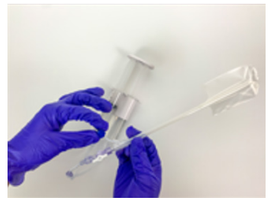
6. Attach the split ends of the Y-connector to each male luer connector on the hydrogel syringes.



7. Turn the stopcock to the open position and infuse contents from syringes to desired fill volume (50mL max). Turn the stopcock to the closed position.



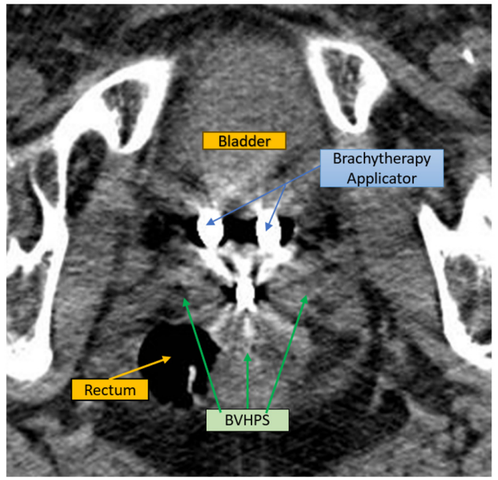
8. With the balloon filled and stopcock turned to the closed position, perform treatment according to facility protocols.



9. Unscrew Saline Port Cap and withdraw attached plastic filament. Gently remove the device from the patient and dispose per facility protocol.

IMAGING:

Axial CT image (see below) with brachytherapy applicator and BVHPS in place (marked with arrows). The BVHPS may be challenging to define visually with image artifact from the metal brachytherapy applicator.



NOTES:

□ Use one set of dual syringes (50mL total) with each reaction bag. The nominal fill volume of the reaction bag is 50mL.
□ Monitor patient tolerance of the first device prior to filling a second device.
□ Take proper steps to maintain the position of the brachytherapy treatment applicators during device placement.
□ If the device fails to work as intended, remove the device as per Steps 13 through 16 and proceed with institution's clinical standard practice for packing with other FDA cleared products for this intended use.
□ The maximum time between infusion and gelation is approximately 5 minutes.
□ The device may be left in place for up to 5 hours. Device performance over 5 hour duration has not been validated.

RECOMMENDATIONS:

Scheduling Physicians and/or other healthcare providers should inform the patient that the device will be inserted for the procedure.