BRONSON
Battle Creek

Cancer Care Center

Affix Patient Label

ACCELERATED PARTIAL BREAST IRRADIATION CONSENT

Name_____ Date of Birth_____

This information is given to you so that you can make an informed decision about having **Accelerated Partial Breast Irradiation** therapy for cancer.

Reason and Purpose of the Procedure:

- For this treatment a balloon catheter (SAVI® Brachy, Contura, MammoSite®) is placed in the space where the tumor was removed. This can be done during surgery or after surgery. You may have an x-ray or ultrasound to check the placement. During treatment the balloon is filled with normal saline. Treatments will last between 15 minutes and hour. At the end of your treatment session the radiation is removed from the catheter. You will have treatment twice a day for the length of your treatment. Treatment may last for up to eight days. After the radiation therapy, the device will be deflated and removed.

Benefits of this Procedure:

You might receive the following benefits. Your doctor cannot promise you will receive any of these benefits. Only you can decide if the benefits are worth the risk.

- Delay or prevent spread of cancer.
- Improve symptoms**.**
- Increase chance of a cure.

Risks and discomforts of this procedure:

No procedure is completely risk free. Some risks are well known. There may be risks not included in the list that your doctor cannot expect.

- Infection
- Bleeding
- Loss of nerve function. You may have numbness.
- Swelling
- Blood clotting
- Fluid build-up around the place catheter was placed
- Catheter may move from the place it was inserted
- Allergic reaction
- Small scar or mark where the applicator was placed.

After the catheter is implanted, it is possible that the position may not be right for radiation. It may need to be removed. A different treatment may be needed. Complications arising from the delivery of brachytherapy (radiation treatment) include, but are not limited to:

- Infection
- Loss of nerve function. You may have numbness.
- Swelling (edema)
- Scarring
- Rib fracture
- Chest wall pain
- Skin ulceration and tissue death
- Scarring
- Firmness, tenderness, pain or deformity in the treated area of the breast may develop in the future.

- The safety and effectiveness of the MammoSite® RTS or Contura or Savi® as a replacement for radiation therapy of the whole breast in the treatment of breast cancer has not been shown to the same degree as standard external beam radiation.
- I understand that all these side effects are possible. I may experience no side effects, some of them, or most of them.
- The side effects of radiation therapy depend on where the radiation is aimed and may not be the same for each person.
- Side effects tend to be worse if radiation and chemotherapy are given together.
- Often these side effects go away shortly after treatment.

Risks specific to you:

_____

_____

_____

After Treatment:

- Follow-up visits will be scheduled with your doctor.
- CT scan X-rays and ultrasound imaging may be done to confirm the size, shape and location of the balloon. This will confirm that you should receive radiation therapy with the MammoSite® RTS or Contura or Savi® device.

Alternative Treatments:

- Observation
- Chemotherapy
- Surgery

If you choose not to have this treatment:

- Your cancer may get worse.

IMPORTANT INFORMATION FOR WOMEN OF CHILDBEARING AGE:
I understand that the MammoSite or Contura or Savi is not intended for use in women who are pregnant. To the best of my knowledge, I am not currently pregnant. To confirm this, a pregnancy test may be done. I agree to take precautions to avoid becoming pregnant during treatment.

By signing this form I agree:

- I have read this form or had it explained to me in words I can understand.
- I understand its contents.
- I have had time to speak with the doctor. My questions have been answered.
- I want to have this procedure:_____.

Patient Signature _____

Relationship ☐ Patient/parent of minor☐Closest Relative/Relationship ☐ Guardian/POA Healthcare

Interpreter's Statement: I have translated this consent form and the doctor's explanation to the patient, a parent, closest relative or legal guardian.

_____ _____ _____

Interpreter (if applicable) *Date* *Time*

For provider use only:
I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options and possibility of complications and side effects of the intended intervention. I have answered questions and patient has agreed to procedure.

Provider Signature_____Date_____Time_____

Teach Back

Patient shows understanding by stating in his or her own words:
____Reason(s) for the treatment/procedure:_____
____Area(s) of the body that will be affected: _____
____Benefit(s) of the procedure :_____
____Risk(s) of the procedure: _____
____Alternative(s) to the procedure: _____

or
____Patient elects not to proceed_____(patient signature)

Validated/Witness_____ Date_____Time _____