MammoSite®

Radiation Therapy System

Silicone Balloon
INSTRUCTION MANUAL

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HOLOGIC®

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

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MammoSite® Applicator Tray

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

SYMBOLS KEY

The following symbols may appear on the label or carton:

SYMBOL	DEFINITION
	Caution
	Use-by date
	Batch code
	Sterilised using irradiation
	Do not resterilise
	Do not re-use
	Manufacturer
	Catalog number
	Non-sterile
	Do not use if package is damaged

MammoSite products and their packaging are latex-free.

MammoSite Applicator Models

- **REF 2456**
  Variable 4 cm–5 cm spherical

Accessory Components

(Supplied in individual non-sterile packages):

- **REF 9010**
  Varian® VariSource™ HDR afterloader connectors with obturators
- **REF 9011**
  Nucletron™ HDR afterloader connectors with obturators
- **REF 9012**
  Varian® GammaMed® HDR afterloader connectors with obturators

PRODUCT DESCRIPTION

The MammoSite applicator is used to position tissue and the radioactive source during breast brachytherapy treatments. It consists of a multi-lumen silicone catheter with an inflatible balloon assembly at its distal end. The MammoSite applicator is illustrated in Figures 1 and 2: A.

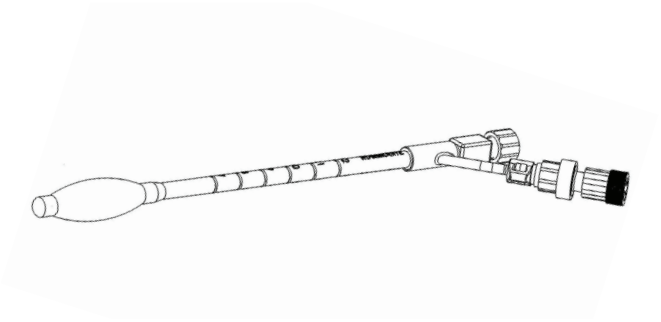


Figure 1. Illustration of MammoSite Applicator (deflated)

The MammoSite device is available in spherical 4–5 cm.

A.

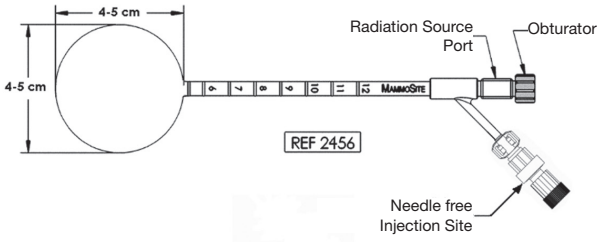


Figure 2: Illustration of MammoSite variable 4–5 cm spherical balloons (inflated).

4 GENERAL INFORMATION

INTENDED USE/INDICATIONS

The MammoSite device is intended to provide brachytherapy when the physician chooses to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer.

CONTRAINDICATIONS

- The MammoSite device should not be implanted if the shape and size of the resected tumor cavity is not consistent with the shape and size of the balloon and the fill volume ranges listed, per balloon size, in Table 10.
- Do not deliver radiation if the minimum distance from the balloon surface to the skin surface is less than 5 mm; or if the distance from the balloon surface to the skin surface is 5 mm over a continuous length greater than 1 cm on the surface of the skin.
- Do not implant the MammoSite device in patients with extreme or unusual anatomical features, e.g., extreme rib curves or very unequal amounts of breast tissue around the lumpectomy cavity. This may cause the MammoSite applicator to become asymmetrical, thereby affecting the conformal delivery of the radiation dose to the target tissue. Ensure the necessary tissue-to-balloon conformance prior to proceeding with radiation therapy.

WARNINGS

The safety and effectiveness of the MammoSite Radiation Therapy System (RTS) as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.

- The timing of the MammoSite applicator placement and radiation therapy should be planned so that the therapy and applicator removal are complete within 29 days of the MammoSite device implant.
- Never fill the system with more fluid than the maximum specified system volumes, per balloon size, listed in Table 10. Overfilling of the balloon could result in rupture of the balloon and/or failure of the device.
- Do not use the MammoSite device if any leaks are observed and/or if the balloon does not resemble the approximate size and shape illustrated in Figure 2: A, per appropriate balloon size.

- Do not implant the MammoSite device if the cavity is not visualized by breast imaging technique or if the cavity is too small for the MammoSite balloon implantation. Imaging should verify a minimum distance of 5 mm from balloon surface to skin surface; however a minimum distance of 7 mm from balloon surface to skin surface is recommended.
- Verify balloon placement and inflation using imaging prior to delivering each brachytherapy fraction. If the balloon diameter changes by greater than ten percent, re-evaluate treatment planning prior to delivering a brachytherapy fraction.
- Altering patient position after CT may affect skin spacing, tissue-to-balloon conformance and dose distribution, which may result in an inappropriate patient treatment. Ensure analogous patient positioning from CT through delivery of all fractions.
- Verify treatment parameters per High Dose Rate (HDR) manufacturer's instructions prior to proceeding with radiation therapy.
- Only medical personnel trained and authorized in the safe operation of HDR remote afterloaders should deliver brachytherapy using the MammoSite device.
- Do not use excessive force to implant or remove the MammoSite device. If the MammoSite device balloon or shaft becomes bound to the breast tissue, through tissue adhesion, the physician should consider surgical removal.
- For enhanced imaging purposes, the balloon may be filled with a sterile saline/contrast solution not to exceed the maximum fill volume ranges, per balloon size, listed in Table 10.
- For optimal balloon imaging and to minimize potential radiation dose attenuation, less than 10% contrast per fluid volume is recommended[1].

[1]Kassas B, Mourtada F, Horton JL, and Lane RG. Contrast effects on dosimetry of a partial breast
irradiation system. *Med Phys.*, 31: 1976-1979, 2004.

- This device has been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices particularly those with long and small lumina, joints, and/or crevices between components are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications.
- For patients who have or may have an allergic reaction to iodinated materials, consider using a non-ionic contrast agent.
- Healthcare practitioners should avoid using latex gloves to prevent possible allergic reactions by patients who are allergic to latex.

PRECAUTIONS

- The MammoSite RTS should be used only by physicians trained in catheter placement, treatment planning and radiation delivery prior to the use of the device.
- Do not use the contents if there is any evidence of damage to the package or package seal that could compromise sterile integrity. Do not resterilize. Single-use device.
- Keep catheter away from foreign materials at all times. Exercise extreme caution when handling the MammoSite balloon prior to and during implantation. Silicone materials are susceptible to damage by sharp objects/instruments and excessive pulling or pushing.
- Avoid contact of the product with glove talc, lint, particulate matter, soaps, oils, detergents or other surface contaminants. Caution should be used to avoid contamination of the MammoSite device.
- Store product at ambient temperature. Storage of product at high temperature and high humidity may damage the package.
- Use needle-free syringes (provided) when inflating or deflating the MammoSite applicator. For proper inflation and deflation, ensure inflation lumen is not kinked or twisted.

- Exercise caution when handling the device to avoid excessive bending of the applicator shaft. Bending or coiling of the shaft to extreme angles could result in kinking of the radiation source pathway and/or failure of the device.
- To avoid possible contamination by foreign particulate do not remove the obturator or stylet from the radiation source port during device placement.
- Forceps should not be used during implantation of the balloon. Forceps can damage the balloon.
- During closure of the cavity, both deep and superficial, the balloon must be completely deflated and retracted out of the cavity to avoid needle puncture or abrasions which could lead to deflation of the balloon and/or failure of the device.
- During all levels of closure, suture knots should be rotated away from the lumpectomy cavity to avoid puncture of the balloon by suture ends. When possible, place a layer of breast tissue between the balloon surface and the deepest line of suture to avoid suture abrasion on the balloon which could lead to deflation of the balloon and/or failure of the device.
- Do not use surgical marking clips in conjunction with the MammoSite device to avoid puncture of the device.
- The MammoSite RTS has only been tested using commercially available ^{192}Ir HDR sources. It is not recommended for use with HDR equipment other than those manufactured by Nucletron™ or Varian®.
- Expose afterloader connectors to ambient conditions 72 hours prior to use or length modification.
- Ensure that the afterloader connector is fully seated within the radiation source port luer connection of the applicator.
- Always replace the luer cap after accessing the needle-free injection site to avoid contamination by foreign particulate and leakage from the injection site.
- The needle-free injection site should only be accessed for catheter inflation and deflation.
- The afterloader connector pathway must be clear and patient movement minimized during radiation treatment to prevent kinking of the catheter.

- If an incorrect connection is made to the fluid port rather than the radiation source port, fluid will flow out of the afterloader connector, indicating an incorrect connection. If undetected, fluid may backflow into the afterloader resulting in temporary operation suspension of the afterloader.
- In case of balloon deflation/rupture, carefully inspect the device upon removal to ensure that no fragments remain within the lumpectomy cavity.

MAMMOSITE CLINICAL STUDY

4–5 cm Spherical Balloon

DESIGN AND OBJECTIVE

A clinical study was conducted using the MammoSite variable 4–5 cm spherical balloon to demonstrate that the MammoSite RTS could be safely used to deliver a specific dose of radiation to the surgical margins following lumpectomy for breast cancer. The study objectives were to evaluate the performance of the MammoSite RTS applicator in patients with breast cancer, and in addition, to evaluate the safety of the MammoSite RTS in patients with breast cancer. This is an ongoing study in which enrollment has closed and the continued annual follow-up of patients is occurring. The protocol and median 63 month (1–74 month range) data are provided here to assist treating physicians in understanding the effects of using this device in patients to provide brachytherapy when choosing to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer.

STUDY ENDPOINTS

The primary short-term safety endpoint was related to the applicator performance and its ability to deliver the specified treatment plan. This endpoint was defined as the ability of the applicator to deliver the final prescribed brachytherapy dose.

To demonstrate the short-term effects of the device, there are three key factors that were examined. These three factors are:

- The ability of the MammoSite device to be implanted and remain implanted throughout the duration of the radiation therapy.

- The ability of the balloon to inflate and maintain its integrity throughout the treatment as measured by the volume of fluid infused compared to the volume of fluid retrieved at the end of therapy and the ability of the MammoSite device to provide an unobstructed pathway for positioning of the radioactive source.
- The ability of the MammoSite applicator to be explanted without tissue damage that necessitates surgical reopening of the entry path to repair the damage.

The secondary safety endpoint was defined as the incidence rate of serious adverse events attributable to the MammoSite RTS that occur during the study. Data continues to be collected in order to understand the use of this device in lieu of external beam therapy. The data being collected includes an annual evaluation of the following: cosmetic evaluation (Harvard scale and digital photo), patient satisfaction, disease recurrence, systemic therapy and adverse events.

PATIENT ENROLLMENT AND DEMOGRAPHICS

The study was designed to enroll at least 25 patients completing brachytherapy. A total of 70 patients were enrolled, 54 patients were implanted with the device and a total of 43 patients completed brachytherapy. Eleven patients did not complete brachytherapy because of: cavity size being too small or too large (7), patient age (1), pathology (1) and inadequate skin spacing (2). Of the 43 that completed brachytherapy, 34 patients continue to be followed. Two patients died after receiving treatment with the device due to breast cancer metastases. One patient died due to non Hodgkin's lymphoma. Six patients were either unable to return or did not return for follow-up.

PATIENT SELECTION CRITERIA

The patient selection criteria was as follows:

INCLUSION CRITERIA

Patients selected to participate in this clinical investigation must:

- Be at least 45 years of age
- Be a T1, $\leq$ 2 cm, N0, M0 AJC Classification
- Should have a cavity size $\geq$3 cm in one dimension determined at the time of implant
- Have negative surgical margins (NSABP definition) after final surgery

- Applicator must be placed within ten weeks of the final lumpectomy surgery provided that ultrasound confirms the presence of a cavity just prior to implantation.

EXCLUSION CRITERIA

Patients selected to participate in this clinical investigation should not:

- Have a serious medical illness or condition that may effect the study or the use of the MammoSite applicator
- Be pregnant or breast-feeding (If appropriate, patient must use birth control during the study.)
- Have collagen-vascular disease
- Have extensive intraductal component (Harvard Definition, >25% DCIS)
- Have infiltrating lobular histology
- Have pure DCIS
- In addition, patients were excluded if the distance from cavity edge to skin surface was < 5mm.

PATIENT POPULATION DEMOGRAPHICS

The average age of the patients enrolled in the MammoSite study was 69 years. The majority of the patients (95%) were postmenopausal. The breast sizes treated in this study included A, B, C and D+ cup. The average tumor size was 1.07 cm. All patients enrolled in the study had T1, N0 and M0 staging. The patients' ER/PR and her2neu status were not collected and are not available.

BRACHYTHERAPY TREATMENT

All eligible patients received an HDR brachytherapy dose of 34 Gy to a 1 cm distance from the balloon surface, treating the lumpectomy cavity walls. This dose was fractionated over ten fractions, generally twice a day at least six hours apart. Each fraction lasted approximately 10–15 minutes, and the patients were able to go home between treatment fractions.

PATIENT FOLLOW-UP

For short-term efficacy, the primary endpoints were related to the applicator performance and its ability to deliver the specified treatment plan. All patients were followed at 24 hours, one week and again one month after the completion of brachytherapy treatment. The protocol was subsequently amended to allow for the continued follow-up of the patients at least annually for 10 years. Follow-up data for

the original 43 patients ranging from 1 to 74 months post-treatment (median 63 months) is provided here.

PATIENT ACCOUNTABILITY

Thirty-four of the 43 treated patients are participating in the long term follow-up study. The median length of follow-up for these patients is 63 months with a range of 1 month to 74 months.

STUDY RESULTS

SHORT-TERM SAFETY: PRIMARY ENDPOINT RESULTS

Table 1

Device Performance and Endpoint Evaluation at Time of Treatment	
	N (%)
Number Enrolled	**70**
Number Evaluable	**42***
Primary Endpoint	**42 (100.0)**
The ability of the MammoSite to be implanted and remain implanted throughout the duration of radiation therapy	**42 (100.0)**
The ability of the balloon to inflate and maintain its integrity throughout the treatment as measured by the volume of fluid infused compared to the volume of fluid retrieved at the end of therapy and the ability of the MammoSite to provide an unobstructed pathway for positioning of the radioactive source	**42 (100.0)**
The ability of the MammoSite applicator to be explanted without tissue damage that necessitates surgical reopening of the entry path to repair the damage	**42 (100.0)**
*** One patient was enrolled, implanted and completed brachytherapy. The patient met all study endpoints; however, was determined to be ineligible due to skin and balloon surface spacing distance and was therefore inevaluable.**	

There were some instances of device malfunctions that occurred during the clinical study. See the Device Malfunctions section of this manual for complete details.

SHORT-TERM SAFETY: SECONDARY ENDPOINT RESULTS

There have been 13 serious events reported that occurred after device removal. For a complete description of these events, refer to the Adverse Events section of this manual.

OTHER STUDY RESULTS

At each follow-up visit, a cosmetic evaluation using the Harvard Scale was performed. The criteria was defined as follows:

Excellent – The treated breast looks essentially the same as the opposite breast.

Good – Mimimal but identifiable effects of radiation on the treated breast.

Fair – Significant effects of radiation on the treated breast.

Poor – Severe normal tissue sequelae secondary to irradiation.

In addition, an ultrasound of the cavity was performed and the cavity healing was assessed by the study investigator using the following criteria:

Good – Seroma completely resolved, equal to or smaller than previous ultrasound;

Fair – Seroma larger than previous ultrasound, however, patient is not symptomatic;

Poor – Seroma larger and patient is symptomatic.

COSMETIC RESULTS

Cosmetic results that were assessed by the study investigator are reported in Table 2.

Table 2–Cosmetic Results

Harvard Scale[2]	Excellent/Good N (%)	Fair N (%)	Poor N (%)
At last follow-up n=43 [95%CI]	35 (81%) [66%–91%]	8 (19%) [9%–34%]	0 (0%) [0%–10%]
12 Months (0 Mo-12 Mo) n=43 [95% CI]	41 (95%) [83%–99%]	2 (5%) [0%–17%]	0 (0%) [0%–10%]
24 Months (>12 Mo–24 Mo) n=36 [95% CI]	32 (89%) [73%–96%]	4 (11%) [4%–27%]	0 (0%) [0%–12%]
36 Months (>24 Mo–36 Mo) n=37 [95% CI]	31 (84%) [67%–93%]	6 (16%) [7%–33%]	0 (0%) [0%–12%]
48 Months (>36 Mo–48 Mo) n=32 [95% CI]	29 (91%) [74%–98%]	3 (9%) [2%–26%]	0 (0%) [0%–13%]
60 Months (>48 Mo–60 Mo) n=28 [95% CI]	23 (82%) [61%–93%]	5 (18%) [7%–38%]	0 (0%) [0%–16%]
Over 60 Months (>60 Mo) n=24 [95% CI]	18 (75%) [53%–89%]	6 (25%) [11%–47%]	0 (0%) [0%–17%]

The results of the cavity healing assessment are shown in Table 3.

Table 3

Internal Cavity Healing			
Cavity Healing Scale	24 Hour (n=26)	1 Week (n=26)	1 Month (n=26)
Good	19 (73%)	22 (85%)	17 (65%)
Fair	6 (23%)	3 (11%)	8 (31%)
Poor	0 (0%)	1 (4%)	0 (0%)
Not Reported	1 (4%)	0 (0%)	1 (4%)

[2]Rose M, et al. Conservative surgery and radiation therapy for early stage breast cancer. Long term cosmetic results. *Arch. Surg.* 124:153-157; 1989.

ADVERSE EVENTS

The summary of the adverse events is provided in Table 4.

Table 4—Adverse Events During Study

Adverse Event Description	Patient Incidence N=43 N (%)
Erythema	31 (72.1%)
Catheter Site Drainage	24 (55.8%)
Breast Fibrosis	24 (55.8%)
Breast Pain	22 (51.2%)
Telangiectasia	17 (39.2%)
Ecchymosis	15 (34.9%)
Breast Seroma	14 (32.6%)
Induration	14 (32.6%)
Breast Edema	12 (27.9%)
Skin Discoloration	10 (23.3%)
Breast Retraction	9 (20.9%)
Dry Skin	8 (18.6%)
Dry Desquamation	7 (16.3%)
Axillary Pain	7 (16.3%)
Paresthesia	7 (16.3%)
Pruritis	6 (14.0%)
Fatigue	5 (11.6%)
Nausea	4 (9.3%)
Asymptomatic Fat Necrosis	4 (9.3%)
Skin Irritation	3 (7.0%)
Moist Desquamation	3 (7.0%)
Hematoma	3 (7.0%)
Rash	2 (4.7%)
Lymphedema	2 (4.7%)
Breast Infection	2 (4.7%)
Blister/Breast	2 (4.7%)

The following occur in less than 2.3% of cases: abdominal pain, accidental injury, anorexia, anxiety, arm pain, arrhythmia, arthralgia, asthma, axillary infection, breast abscess, breast cyst, breast firmness, bursitis, carcinoma lung, chills, chronic inflammation, colon carcinoma, diagnostic test reaction, dizziness, dry cough, dyspepsia, embolus, eschar, facial rash, fever, gastroenteritis, hip pain, hypotension, hypoxia, incision firmness, post-operative infection, insomnia, joint disorder/ shoulder, mastitis, nipple retraction, pharyngitis, rash breast, renal failure, rhinitis, scar pain, shoulder pain, skin carcinoma, skin melanoma, skin thickening/ breast, subcutaneous tissue change, vasodilatation/ lumpectomy, ulceration/ breast.

LOCAL TISSUE EFFECTS

Summarized in Table 5 are the local tissue effects and their overall patient incidence and duration.

Table 5

Event	Subject Incidence Overall n=43		Subject Incidence With Resolution n=43		Resolution Duration (Days)		Subject Incidence Without Resolution n=43	
	N	%	N	%	Mean	Range	N	%
Erythema	31	72.1	26	60.5	266.9	3–1372	5	11.6
Catheter Site Drainage	24	55.8	24	55.8	6.5	0–48	0	0.0
Breast Fibrosis	24	55.8	4	9.3	482.7	186–1083	20	46.5
Breast Pain	22	51.2	20	46.5	160.6	0–834	2	4.7
Telangiectasia	17	39.5	2	4.7	497.6	92–926	15	34.9
Ecchymosis	15	34.9	15	34.9	12.9	1–36	0	0.0
Breast Seroma	14	32.6	13	30.2	199.8	0–504	1	2.3
Induration	14	32.6	7	16.3	336.0	49–878	7	16.3
Breast Edema	12	27.9	12	27.9	162.6	2–581	0	0.0
Skin Discoloration	10	23.3	8	18.6	486.2	100–1829	2	4.7
Breast Retraction	9	20.9	1	2.3	162.0	162–162	8	18.6
Dry Skin	8	18.6	8	18.6	260.4	9–668	0	0.0
Dry Desquamation	7	16.3	7	16.3	100.3	6–167	0	0.0
Axillary Pain	7	16.3	6	14.0	43.3	0–228	1	2.3
Pruritus	6	14.0	5	11.6	90.4	3–186	1	2.3
Asymptomatic Fat Necrosis	4	9.3	2	4.7	367.0	0–734	2	4.7
Skin Irritation	3	7.0	3	7.0	106.3	61–137	0	0.0
Moist Desquamation	3	7.0	3	7.0	16.3	10–28	0	0.0
Hematoma	3	7.0	3	7.0	138.0	14–295	0	0.0
Breast Infection	2	4.7	2	4.7	112.5	36–189	0	0.0
Blister/Breast	2	4.7	2	4.7	33.0	3–63	0	0.0
Axillary Infection	1	2.3	1	2.3	12.0	12–12	0	0.0
Chronic Inflammation	1	2.3	1	2.3	110.0	110–110	0	0.0
Ulceration Breast	1	2.3	1	2.3	185.0	185–185	0	0.0
Breast Abscess	1	2.3	1	2.3	5.0	5–5	0	0.0
Rash Breast	1	2.3	1	2.3	2.0	2–2	0	0.0
Breast Firmness	1	2.3	1	2.3	267.0	267–267	0	0.0
Mastitis	1	2.3	1	2.3	140.0	14–267	0	0.0
Vasodilatation/Lumpectomy	1	2.3	1	2.3	140.0	140–140	0	0.0
Scar Pain	1	2.3	1	2.3	266.0	266–266	0	0.0
Skin Thickening Breast	1	2.3	1	2.3	162.0	162–162	0	0.0
Eschar	1	2.3	1	2.3	17.0	17–17	0	0.0
Incision Firmness	1	2.3	1	2.3	774.0	774–774	0	0.0
Nipple Retraction	1	2.3	1	2.3	126.0	126–126	0	0.0
Breast Cyst	1	2.3	1	2.3	5.0	5-5	0	0.0
Subcutaneous Tissue Change	1	2.3	0	0.0	-	-	1	2.3

LATE LOCAL TISSUE EFFECTS

Summarized in Table 6 are the late local tissue effects and their overall patient incidence that were reported 90 days after device removal. None of the events classified as related to the device were unanticipated.

Table 6

	Subject Incidence	
	n=42*	
Adverse Event Description	N	%
Breast Fibrosis	**22**	**52.4**
Telangiectasia	**17**	**40.5**
Induration	**13**	**31.0**
Breast Pain	**11**	**26.2**
Breast Retraction	**9**	**21.4**
Erythema	**7**	**16.7**
Skin Discoloration	**7**	**16.7**
Breast Seroma	**7**	**16.7**
Breast Edema	**6**	**14.3**
Asymptomatic Fat Necrosis	**4**	**9.5**
Dry Skin	**2**	**4.8**
Hematoma	**2**	**4.8**
Chronic Inflammation	**1**	**2.4**
Pruritus	**1**	**2.4**
Axillary Pain	**1**	**2.4**
Breast Cyst	**1**	**2.4**
Skin Irritation	**1**	**2.4**
Dry Desquamation	**1**	**2.4**
Ulceration Breast	**1**	**2.4**
Breast Firmness	**1**	**2.4**
Mastitis	**1**	**2.4**
Scar Pain	**1**	**2.4**
Skin Thickening Breast	**1**	**2.4**
Incision Firmness	**1**	**2.4**
Nipple Retraction	**1**	**2.4**
Subcutaneous Tissue Changes	**1**	**2.4**
***There were 42 subjects enrolled in the study after 90 days of follow-up**		

SERIOUS ADVERSE EVENTS

There were thirteen serious events reported in the course of the study. These events are summarized in Table 7.

Table 7

	Subject Incidence Overall	
Serious Adverse Event	N	(%)
Breast Seroma	**3**	**(7.0)**
Breast Abscess	**1**	**(2.3)**
Breast Infection	**1**	**(2.3)**
Accidental Injury	**1**	**(2.3)**
Colon Carcinoma	**1**	**(2.3)**
Embolus	**1**	**(2.3)**
Hypotension	**1**	**(2.3)**
Hypoxia	**1**	**(2.3)**
Post-operative Infection	**1**	**(2.3)**
Renal Failure	**1**	**(2.3)**
Lung Carcinoma	**1**	**(2.3)**

DEVICE MALFUNCTIONS

There were fourteen device complications reported in the clinical study. None of these complications caused an adverse event. A description of the events is included in Table 8.

Table 8

Event	#	Description	Resolution
Balloon Deflation	2	Surgical clips in cavity	Replaced MammoSite, Brachytherapy completed.
Balloon Deflation	1	Needle Stick post implant.	Replaced MammoSite, Brachytherapy completed.
Balloon Deflation	2	Needle Stick during implant.	Replaced MammoSite, Brachytherapy completed.
Balloon Asymmetry	1	Pre-implant inflation test.	Replaced MammoSite, Brachytherapy completed.
Balloon Asymmetry	3	Asymmetrical at the time of CT imaging.	MammoSite explanted. Patients received a different method of radiation therapy.
Balloon Inflation Luer	1	Barbed luer injection port slipped off the catheter.	Replaced MammoSite, Brachytherapy completed.
Balloon Inflation Luer	1	Radiation source port was injected with saline.	Replaced MammoSite, Brachytherapy completed.
Fluid Cap Removed	1	Fluid port cap was removed. A loss of ~10 cc of fluid.	Fluid loss did not change the diameter. Patient's brachytherapy completed.
Source Pathway Kink	1	The source pathway became kinked during brachytherapy due to the patient's wound dressing.	The MammoSite was manipulated to resolve the kink and brachytherapy completed.
Tip of MammoSite Pulled Off	1	During the implantation, forceps broke the tip of the MammoSite as it was being implanted.	Replaced MammoSite, Brachytherapy completed.

PATIENT COUNSELING INFORMATION

The patient and/or her representative should be informed of the warnings, precautions and possible complications associated with the use of this product.

HOW SUPPLIED

CAUTION: Store product at ambient temperature. Storage of product at high temperature and high humidity may damage the package.

CAUTION: Do not use the contents if there is any evidence of damage to the package or package seal that could compromise sterile integrity. Do not resterilize. Single-use device.

- The MammoSite applicator tray contains a MammoSite applicator, four 30 cc syringes, one 10 cc syringe, one trocar (8 mm diameter), one scalpel with #11 knife blade, one obturator and one stylet. An instruction manual and chart stickers are also provided.
- All MammoSite applicator trays are supplied in sterile packaging. Each package should be examined carefully prior to opening.
- Afterloader connectors and additional obturators are packaged separately in individual non-sterile packages.

DEVICE SPECIFICATIONS

The MammoSite applicator body is a multi-lumen extrusion of a silicone elastomer. The central lumen provides the radioactive source pathway. The source pathway's lumen diameter is sized to accommodate commercially available HDR radioactive sources. The balloon assembly consists of a silicone balloon that inflates into a spherical configuration based on the specified size of the inflated MammoSite balloon. The balloon fill volume ranges are listed, in Table 10.

Graduation marks are printed on the applicator body to assist in placement of the applicator. The marks are measured at 1 cm intervals.

HDR afterloader connectors are available to enable connection to commercially available HDR remote afterloading systems.

MAMMOSITE DEVICE PLACEMENT PROCEDURE

The MammoSite device may be placed using a percutaneous technique up to ten weeks after lumpectomy. Proper patient selection must be determined by the physician. Patient selection criteria have been set forth by both surgical (American Society of Breast Surgeons) and radiation oncology (American Brachytherapy Society) professional organizations to guide in the appropriate selection of breast brachytherapy candidates[3,4]. Considerations include tumor type, size and histology, nodal status and patient age.

At the time of implant, balloon shape, size and fill volume that best approximates the cavity should be identified. In addition, imaging should be performed as specified in the Intended Use section of this manual to confirm appropriate tissue-to-balloon conformance and adequate skin spacing.

MAMMOSITE BALLOON SELECTION

Prior to proceeding with MammoSite device placement, the appropriate balloon fill volume range should be identified. The following guidelines provide direction for choosing appropriate fill volume.

1. Using Table 10, determine the balloon fill volume that is at least as large as and best fits the cavity to be implanted.

Table 10—Balloon Fill Volume

REF Number	Balloon Shape	Balloon Configuration	Balloon Fill Volume
2456	Spherical	4–5 cm	35–70 cc

SYSTEM VERIFICATION

WARNING: Never fill the system with more fluid than the maximum specified system volumes, per balloon size, listed in Table 10. Overfilling of the balloon could result in rupture of the balloon and/or failure of the device.

WARNING: Do not use the MammoSite device if any leaks are observed and/or if the balloon does not resemble the approximate size and shape illustrated in Figure 2: A.

CAUTION: Use needle-free syringes (provided) when inflating or deflating the MammoSite applicator. For proper inflation and deflation, ensure inflation lumen is not kinked or twisted.

[3] Arthur et. al. Accelerated partial breast irradiation: an updated report from the American Brachytherapy Society. *Brachytherapy*, 1:184-190,2003.

[4] Revised consensus statement for accelerated partial breast irradiation. The American Society of Breast Surgeons. Available at http://www.breastsurgeons.org

CAUTION: Exercise caution when handling the device to avoid excessive bending of the applicator shaft. Bending or coiling of the shaft to extreme angles could result in kinking of the radiation source pathway and/or failure of the device.

CAUTION: Always replace the luer cap after accessing the needle-free injection site to avoid contamination by foreign particulate and leakage from the injection site.

CAUTION: The needle-free injection site should only be accessed for catheter inflation and deflation.

CAUTION: Keep catheter away from foreign materials at all times. Exercise extreme caution when handling the MammoSite balloon prior to and during implantation. Silicone materials are susceptible to damage by sharp objects/instruments and excessive pulling or pushing.

CAUTION: Avoid contact of the product with glove talc, lint, particulate matter, soaps, oils, detergents or other surface contaminants. Caution should be used to avoid contamination of the MammoSite device.

Immediately prior to implantation of the MammoSite device, complete the following procedure under sterile conditions.

1. Place catheter on a surgical instrument stand or other area clear of all surgical instrumentation.
2. Remove luer cap on needle-free injection site. Assemble the syringe to the applicator injection site and withdraw any air. Remove the syringe from the injection site while maintaining negative pressure.
3. Use Table 10 to identify the appropriate fluid fill volume range, per balloon size, and fill the syringe with normal sterile fluid solution. Do not exceed the maximum fill volume indicated.
4. Assemble the fluid-filled syringe to the injection site.
5. Slowly inject the sterile fluid solution into the applicator.
6. Repeat steps 3–5, as necessary, to fill the applicator balloon to its required fill volume.
7. Observe the balloon to ensure that it resembles the approximate size and shape illustrated in Figure 2: A.
8. While continuing to fully depress the syringe, check the balloon, applicator and injection site for any signs of leaks.

9. A small amount of air may be observed within the balloon. This is normal and will dissipate shortly.
10. Once it has been determined that the MammoSite device is functioning properly, remove all of the fluid from the balloon by withdrawing the plunger of the syringe. Repeat as necessary to ensure all fluid is removed from applicator.

APPLICATOR PLACEMENT

WARNING: Never fill the system with more fluid than the maximum specified system volumes listed in Table 10. Overfilling of the balloon could result in rupture of the balloon and/or failure of the device.

WARNING: Do not use excessive force to implant or remove the MammoSite device. If the MammoSite device balloon or shaft becomes bound to the breast tissue, through tissue adhesion, the physician should consider surgical removal.

WARNING: For patients who have or may have an allergic reaction to iodinated materials, consider using a non-ioinic contrast agent.

WARNING: Healthcare practitioners should avoid using latex gloves to prevent possible allergic reactions by patients who are allergic to latex.

CAUTION: Keep catheter away from foreign materials at all times. Exercise extreme caution when handling the MammoSite balloon prior to and during implantation. Silicone materials are susceptible to damage by sharp objects/instruments and excessive pulling or pushing.

CAUTION: Use needle-free syringes (provided) when inflating or deflating the MammoSite applicator. For proper inflation and deflation, ensure inflation lumen is not kinked or twisted.

CAUTION: Exercise caution when handling the device to avoid excessive bending of the applicator shaft. Bending or coiling of the shaft to extreme angles could result in kinking of the radiation source pathway and/or failure of the device.

CAUTION: To avoid possible contamination by foreign particulate do not remove the obturator or stylet from the radiation source port during device placement.

CAUTION: Do not use surgical marking clips in conjunction with the MammoSite device to avoid puncture of the device.

The placement of the applicator may be accomplished through a variety of techniques. Implantation techniques are at the discretion of the physician.

The following are descriptions of one surgical placement method and one post-surgical placement method for the MammoSite applicator. For both placement methods, the obturator may be removed and replaced with the stylet for easier MammoSite device insertion.

Surgical Placement (See Figure 3: A–D):

WARNING: The timing of the MammoSite applicator placement and radiation therapy should be planned so that the therapy and applicator removal are complete within 29 days of the MammoSite device implant.

WARNING: Do not implant the MammoSite device if the cavity is not visualized by breast imaging technique or if the cavity is too small for MammoSite balloon implantation. Imaging should verify a minimum distance of 5 mm from balloon surface to skin surface; however a minimum distance of 7 mm from balloon surface to skin surface is recommended.

WARNING: For enhanced imaging purposes, the balloon may be filled with a sterile saline/contrast solution not to exceed the maximum fill volume ranges, per balloon size, listed in Table 10.

WARNING: For optimal balloon imaging and to minimize potential radiation dose attenuation, less than 10% contrast per fluid volume is recommended[5].

WARNING: For patients who have or may have an allergic reaction to iodinated materials, consider using a non-ioinic contrast agent.

CAUTION: Forceps should not be used during implantation of the balloon. Forceps can damage the balloon.

[5] Kassas B, Mourtada F, Horton JL, and Lane RG. Contrast effects on dosimetry of a partial breast irradiation system. *Med Phys*., 31: 1976-1979, 2004.

CAUTION: During closure of the cavity, both deep and superficial, the balloon must be completely deflated and retracted out of the cavity to avoid needle puncture or abrasions which could lead to deflation of the balloon and/or failure of the device.

CAUTION: During all levels of closure, suture knots should be rotated away from the lumpectomy cavity to avoid puncture of the balloon by suture ends. When possible, place a layer of breast tissue between the balloon surface and the deepest line of suture to avoid suture abrasion on the balloon which could lead to deflation of the balloon and/or failure of the device.

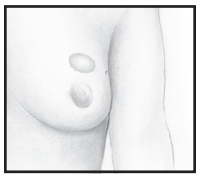
CAUTION: Do not use surgical marking clips in conjunction with the MammoSite device to avoid puncture of the device.

CAUTION: The needle-free injection site should only be accessed for catheter inflation and deflation.

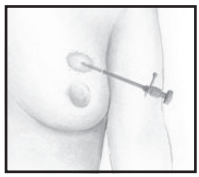
1. Place catheter on a surgical instrument stand or other area clear of all surgical instrumentation.
2. Choose an entry point away from the surgical incision. (The physician should select a location for entry that provides the optimum pathway for the applicator/balloon placement into the resected tumor cavity.)
3. To create a pathway for device implantation, make a small nick in the skin using the knife blade included in the MammoSite applicator tray.
4. Through the skin nick, advance the trocar included in the MammoSite applicator tray into the surgical cavity.
5. Once the surgical cavity is penetrated, remove the trocar and advance the MammoSite applicator along the same trocar tract until the tip is touching the distal edge of the resected surgical cavity.
6. Inflate the balloon with sterile saline/contrast solution to the desired fill volume, per balloon size volumes listed in Table 10, to position the balloon in the resected tumor cavity. Syringes are provided to allow for solution delivery into the MammoSite balloon.
7. Fully deflate the balloon and retract out of the lumpectomy cavity prior to suturing to avoid balloon puncture or abrasion during closure.

8. Perform closure. It is recommended that suturing be done at a second level 1 cm or more below the surface. The additional line of suture will aid in obtaining the necessary distance between the balloon and the skin surface (>5 mm). This distance is important to minimize the potential for radiation skin effects. Complete closure using standard surgical suturing of the incision.
9. Position the balloon in the cavity and fully inflate the applicator with sterile saline/contrast solution to the previously determined fill volume. Fluid fill volume may be adjusted, per balloon size fill volume range (Table 10), to achieve desired cavity conformance and skin distance.
10. Recap the needle-free injection site with blue luer cap provided.
11. If the stylet has been used, remove and replace it with the obturator to prevent kinking of the applicator shaft between treatments.

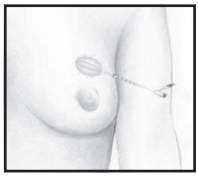
Figure 3. Illustrations of MammoSite Device Placement



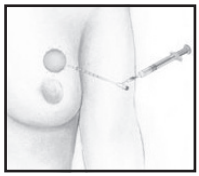
A: Lumpectomy cavity is created



B: Trocar used to create pathway to cavity



C: Un-inflated MammoSite device is advanced into the cavity through the trocar path



D: MammoSite balloon is inflated to position the tissue to receive radiation therapy

12. Dress the applicator exit site. Avoid kinking the applicator shaft while dressing the site.
13. Record the balloon fill volume on the chart stickers provided in the MammoSite applicator box and adhere to patient's chart.

Post-Surgical Placement (See Figure 3: A–D):

WARNING: The timing of the MammoSite applicator placement and radiation therapy should be planned so that the therapy and applicator removal are complete within 29 days of the MammoSite device implant.

WARNING: Do not implant the MammoSite device if the cavity is not visualized by breast imaging technique or if the cavity is too small for the MammoSite device implantation. Imaging should verify a minimum distance of 5 mm from balloon surface to skin surface; however a minimum distance of 7 mm from balloon surface to skin surface is recommended.

WARNING: For enhanced imaging purposes, the balloon may be filled with a sterile saline/contrast solution not to exceed the maximum fill volume ranges, per balloon size, listed in Table 10.

WARNING: For optimal balloon imaging and to minimize potential radiation attenuation, less than 10% contrast per fluid volume is recommended[6].

WARNING: For patients who have or may have an allergic reaction to iodinated materials, consider using a non-ioinic contrast agent.

CAUTION: The needle-free injection site should only be accessed for catheter inflation and deflation.

1. Locate the lumpectomy cavity, using breast-imaging techniques, e.g., ultrasound.
2. Place catheter on a surgical instrument stand or other area clear of all surgical instrumentation.
3. Determine the entry point for insertion of the MammoSite device.
4. Administer local anesthesia to the trocar entry point and the planned applicator insertion pathway.
5. To create a pathway for device implantation, make a small nick in the skin using the knife blade included in the MammoSite applicator tray.
6. Through the skin nick, advance the trocar included in the MammoSite applicator tray into the surgical cavity.

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[6] Kassas B, Mourtada F, Horton JL, and Lane RG. Contrast effects on dosimetry of a partial breast
irradiation system. *Med Phys*., 31: 1976-1979, 2004.

7. Once the surgical cavity is penetrated, drain any fluids that have collected in the cavity.
8. Remove the trocar and advance the MammoSite device along the same trocar tract, using ultrasound guidance, until the tip of the applicator is touching the distal edge of the resected surgical cavity.
9. Inflate the balloon with sterile saline/contrast solution to the desired fill volume, per balloon size volumes listed in Table 10, to position the balloon in the resected tumor cavity and confirm applicator placement using ultrasound imaging. Syringes are provided to allow for solution delivery into the MammoSite balloon. Fluid fill volume may be adjusted per balloon size fill volume ranges (Table 10) to achieve desired cavity conformance and skin distance.
10. Recap the needle-free injection site with blue luer cap provided.
11. If the stylet has been used, remove and replace it with the obturator to prevent kinking of the applicator shaft between treatments.
12. Dress the applicator exit site. Avoid kinking the applicator shaft while dressing the site.
13. Record the balloon fill volume on chart stickers provided in MammoSite applicator box and adhere to patient's chart.

RADIATION THERAPY DELIVERY

WARNING: Verify balloon placement and inflation using imaging prior to delivering each brachytherapy fraction. If the balloon diameter changes by greater than ten percent, re-evaluate treatment planning prior to delivering a brachytherapy fraction.

WARNING: Altering patient position after CT may affect skin spacing, tissue-to-balloon conformance and dose distribution, which may result in an inappropriate patient treatment. Ensure analogous patient positioning from CT through delivery of all fractions.

WARNING: Only medical personnel trained and authorized in the safe operation of HDR remote afterloaders should deliver brachytherapy using the MammoSite device.

WARNING: Verify treatment parameters per HDR manufacturer's instructions prior to proceeding with radiation therapy.

WARNING: For patients who have or may have an allergic reaction to iodinated materials, consider using a non-ionic contrast agent.

CAUTION: The MammoSite RTS has only been tested using commercially available 192Ir HDR sources. It is not recommended for use with HDR equipment other than those manufactured by Nucletron™ or Varian®.

CAUTION: Expose afterloader connectors to ambient conditions 72 hours prior to use or length modification.

CAUTION: Ensure that the afterloader connector is fully seated within the radiation source port luer connection of the applicator.

CAUTION: The afterloader connector pathway must be clear and patient movement minimized during radiation treatment to prevent kinking of the catheter.

CAUTION: If an incorrect connection is made to the fluid port rather than the radiation source port, fluid will flow out of the afterloader connector, indicating an incorrect connection. If undetected, fluid may backflow into the afterloader resulting in temporary operation suspension of the afterloader.

CAUTION: In case of balloon deflation/rupture, carefully inspect the device upon removal to ensure that no fragments remain within the lumpectomy cavity.

ASSESSMENT OF BALLOON CONFORMANCE

- Prior to radiation therapy, conformance of the lumpectomy cavity to the balloon surface should be assessed using CT imaging. Ensure the necessary cavity-to-balloon conformance prior to proceeding with radiation therapy.
- Trained medical personnel should review these images. The conformance of the lumpectomy cavity walls to the balloon surface should be analyzed. The conformance of the lumpectomy cavity to the balloon surface should be at least 90% to allow for adequate radiation therapy coverage of the targeted treatment area.
- The MammoSite inflation volume may be adjusted to improve the conformance. If adequate conformance cannot be obtained, the MammoSite device should not be used for radiation therapy delivery.
- Dosimetry calculations have been made assuming the balloon takes the shape of a sphere and therefore, the device should only be used in lumpectomy cavities that can be made to conform to the spherically shaped balloons.

The radiation oncologist develops a treatment plan designed to deliver a prescribed dose of radiation to the targeted treatment volume. Treatment planning is completed using commercially available planning software and should be based on the shape and inflated size of the implanted MammoSite balloon. Delivery of an optimized radiation dose is readily achievable with the spherical devices using a single dwell position.

Radiation therapy is delivered using a commercially available HDR radiation source. When delivering radiation using HDR remote afterloading, the MammoSite applicator connects to the HDR remote afterloader by attaching the red banded luer end of the specified HDR afterloader connector to the red banded radiation source port of the MammoSite device, and the other end to the afterloader's transfer/guide tube or indexer per manufacturer's instructions.

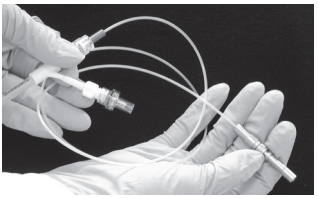
Table 11 below identifies the appropriate afterloader connector devices to be used in conjunction with each type of HDR afterloader. Both the MammoSite device and the appropriate afterloader connector are available through Hologic, Inc. The transfer guide tube, quick connector or clamping adapter (accessory type is dependent on HDR afterloader model) are available through the HDR afterloader manufacturer. Contact the HDR afterloader manufacturer for information on the appropriate model number and instructions for use specific to each afterloader model.

Table 11

HDR Afterloader Model	Afterloader Connector (Hologic, Inc.)	Type of Transfer Guide Tube Required*	Type of Connector Required *
Varian®– VariSource™ ID	REF 9010 – Varian® VariSource™ HDR afterloader connectors	n/a	Standard VariSource D model quick connector
Varian®– VariSource™ 200	REF 9010 – Varian® VariSource™ HDR afterloader connectors	n/a	Standard VariSource 200 model quick connector
GammaMed®– MammoSource	REF 9012 – Varian® GammaMed® HDR afterloader connectors	n/a	Clamping adapter GMplus for ø 1.8 mm catheter
GammaMed*plus* / GammaMed*plus* 3/24	REF 9012 – Varian® GammaMed® HDR afterloader connectors	n/a	Clamping adapter GMplus for ø 1.8 mm catheter
GammaMed12i(t)	REF 9012 – Varian® GammaMed® HDR afterloader connectors	n/a	Clamping adapter for catheter ø 1.8 mm, GammaMed 12i(t)
Nucletron™	REF 9011 – Nucletron™ HDR afterloader connectors	6F Flexible Implant Transfer Tube	Push-fit coupling

* Available through the HDR manufacturer, not provided by Hologic, Inc.

Example of the MammoSite afterloader connection to a quick connector

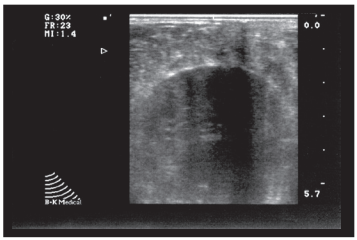


NOTE: The MammoSite device does not require special fixation to the tissue or skin to maintain its position within the lumpectomy cavity. The expansion of the MammoSite balloon fully fills the lumpectomy cavity. Perform the twice daily imaging using CT, x-ray or ultrasound to verify that the MammoSite device has not migrated.

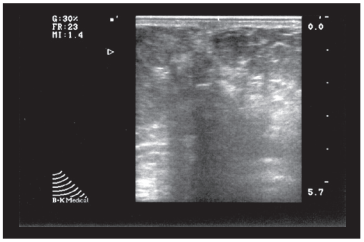
In addition, verify that the MammoSite positioning markers located on the catheter shaft are at the same depth. If it appears that the device has migrated, perform imaging to determine the exact positioning of the MammoSite device and refer to the Troubleshooting Guidelines section of this manual.

The pre-clinical and clinical studies have shown that the spherical MammoSite device did not rotate within the cavity. Therefore, there is no need to assess rotation of the MammoSite device.

In addition to verifying that the MammoSite device/balloon has not migrated, use twice daily imaging (CT, x-ray or ultrasound) to verify that the balloon diameter has not changed. If balloon diameter changes by greater than 10%, re-evaluate treatment planning prior to delivering the brachytherapy fraction. If it is determined that the balloon integrity has been compromised, refer to the Troubleshooting Guidelines, Balloon Compromise, in this manual. See images below.



Ultrasound image of inflated MammoSite balloon



Ultrasound image of deflated MammoSite balloon

Adhere to the HDR manufacturer's instructions concerning use of the radiation source. It is recommended that a test run be conducted prior to treatment to ensure the source is adequately positioned and functioning properly with the MammoSite applicator.

The MammoSite afterloader connectors may be cut to the appropriate length for use with various models of HDR remote afterloaders. Follow the remote afterloader manufacturer's recommendations for trimming and measuring the connectors and transfer tubes. Exposure to ambient conditions 72 hours prior to use or length modification is recommended to allow for any change in connector length due to temperature and humidity.

Timing of radiation therapy delivery (afterloading) is at the discretion of the physician, but should be planned so the therapy and applicator removal are complete within 29 days of MammoSite device placement.

MammoSite device removal procedure

WARNING: Do not use excessive force to implant or remove the MammoSite device. If the MammoSite device balloon or shaft becomes bound to the breast tissue, through tissue adhesion, the physician should consider surgical removal.

Once the radiation therapy is completed, withdraw all fluid residing in the MammoSite balloon and carefully remove the applicator. Caution should be exercised when removing the MammoSite device from the resection cavity. Dispose of the MammoSite device as medical waste.

TROUBLESHOOTING GUIDELINES

Below are troubleshooting guidelines for potential device malfunctions. If any device malfunction is suspected, please call:

Hologic, Inc. • 800-442-9892

Balloon Compromise

1. In the event of a suspected compromise of the balloon integrity, image the MammoSite device using CT. The size of the balloon should be noted.
2. In the event the balloon integrity has been compromised, the compromised MammoSite device may be removed and a new MammoSite device inserted.
3. The new MammoSite device may be inserted using the same pathway as the previous MammoSite device. Refer to the Post-Surgical Placement section of this manual for complete instructions on implanting the MammoSite device.
4. The compromised MammoSite device should be returned to Hologic, Inc. for analysis.
5. CT imaging of the new MammoSite device should be performed to reassess treatment plan and conformance. Follow the instructions in the Radiation Therapy Delivery section of this manual.
6. Proceed with radiation therapy in accordance with the instructions in the Radiation Therapy Delivery section of this manual.

MammoSite Shaft Kink

1. In the event of a kink in the catheter shaft, manually attempt to straighten the catheter shaft.
2. If unable to manually straighten the catheter shaft, use a stylet from the MammoSite applicator tray to open up or straighten the catheter shaft. The stylet should be inserted into the source pathway while manually straightening the catheter in the kinked section.
3. If the stylet does not open up or straighten the catheter shaft, deflate and replace the kinked MammoSite device with a new MammoSite device.

4. The new MammoSite device may be inserted using the same pathway as the previous MammoSite device. Refer to the Post-Surgical Placement section of this manual for complete instructions on implanting the MammoSite device.
5. The kinked MammoSite device should be returned to Hologic, Inc. for analysis.
6. CT imaging of the new MammoSite device should be performed to reassess treatment plan and conformance. Follow instructions in the Radiation Therapy Delivery section of this manual.
7. Proceed with radiation therapy in accordance with the instructions in the Radiation Therapy Delivery section of this manual.

Obstruction of the Radiation Source Pathway

1. In the event of an obstruction in the MammoSite shaft, attach a dry syringe to the source pathway, pull a vacuum and attempt to draw out the obstruction.
2. If this does not move the obstruction, attempt to push the obstruction past the dwell position point using the syringe loaded with air or the stylet from the MammoSite applicator tray.
3. If the MammoSite device remains obstructed, remove and replace the MammoSite device.
4. The new MammoSite device may be inserted using the same pathway as the previous MammoSite device. Refer to the Post-Surgical Placement section of this manual for complete instructions on implanting the MammoSite device.
5. The obstructed MammoSite device should be returned to Hologic, Inc. for analysis.
6. CT imaging of the new MammoSite device should be performed to reassess treatment plan and conformance. Follow instructions in the Radiation Therapy Delivery section of this manual.
7. Proceed with radiation therapy in accordance with the instructions in the Radiation Therapy Delivery section of this manual.

Contamination of the Radiation Source Pathway

1. In the event that a contamination of the radiation source pathway is suspected, remove and replace the MammoSite device.
2. The new MammoSite device may be inserted using the same pathway as the previous MammoSite device. Refer the Post-Surgical Placement section of this manual for complete instructions on implanting the MammoSite device.
3. The contaminated MammoSite device should be returned to Hologic, Inc. for analysis.
4. CT imaging of the new MammoSite device should be performed to reassess the treatment plan and conformance. Follow the instructions in the Radiation Therapy Delivery section of this manual.
5. Proceed with radiation therapy in accordance with the instructions in the Radiation Therapy Delivery section of this manual.

MammoSite Device Dislodgement/Migration

1. In the event the MammoSite device dislodges or migrates out of the cavity, imaging should be performed. The imaging should be analyzed for the effect of the migration on the treatment plan and target volume.
2. If appropriate based on the imaging analysis, the device should be repositioned into its original position.
3. If it cannot be repositioned, remove and replace the MammoSite device.
4. The new MammoSite device may be inserted using the same pathway as the previous MammoSite device. Refer to the Post-Surgical Placement section of this manual for complete instructions on implanting the MammoSite device.
5. The MammoSite device should be returned to Hologic, Inc. for analysis.
6. CT imaging of the new MammoSite device should be performed to reassess treatment plan and conformance. Follow instructions in the Radiation Therapy Delivery section of this manual.
7. Proceed with radiation therapy in accordance with the instructions in the Radiation Therapy Delivery section of this manual.

FOR MORE INFORMATION

For technical support or reorder information in the United States, please contact:

Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752 USA
Phone: 877-371-4372
www.hologic.com

WARRANTY

Except as otherwise expressly stated in the Agreement: i) Equipment manufactured by Hologic is warranted to the original Customer to perform substantially in accordance with published product specifications for one (1) year starting from the date of shipment, or if Installation is required, from the date of Installation ("Warranty Period"); ii) digital imaging mammography x-ray tubes are warranted for twenty-four (24) months, during which the x-ray tubes are fully warranted for the first twelve (12) months and are warranted on a straight-line prorated basis during months 13-24; iii) replacement parts and remanufactured items are warranted for the remainder of the Warranty Period or ninety (90) days from shipment, whichever is longer; iv) consumable Supplies are warranted to conform to published specifications for a period ending on the expiration date shown on their respective packages; v) licensed Software is warranted to operate in accordance with published specifications; vi) Services are warranted to be supplied in a workman-like manner; vii) non-Hologic Manufactured Equipment is warranted through its manufacturer and such manufacturer's warranties shall extend to Hologic's customers, to the extent permitted by the manufacturer of such non-Hologic Manufactured Equipment. Hologic does not warrant that use of Products will be uninterrupted or error-free, or that Products will operate with non-Hologic authorized third-party products.

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