



APBI FOR EARLY-STAGE BREAST CANCERS

A STANDARD OF CARE OPTION FOR BREAST CONSERVING THERAPY



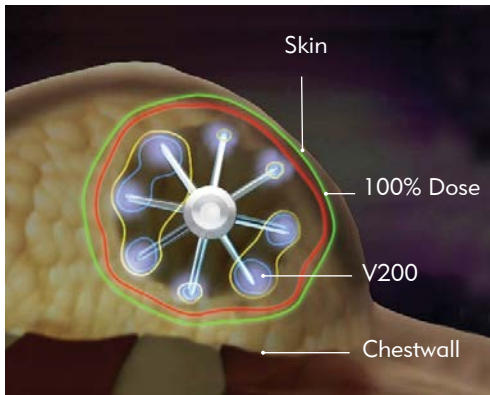
- Proven Efficacy¹³
- Excellent Tolerability
- Unparalleled Cosmesis
- Treatment in 2–5 Days*

*based on clinicians' preferred treatment protocol.
Ask us about a 2-day treatment regimen¹²





“Accelerated Partial Breast Irradiation (APBI) brachytherapy is an attractive treatment approach with a high level of **precision, versatility** and **flexibility**. The benefits of APBI brachytherapy include an at least **four-fold reduction in total radiation exposure to healthy surrounding tissue and nearby structures...preservation of future treatment options; and a notably shorter course of therapy.**”²



SAVI Sculpt Dosing with Unique, Strut-Based, Open Architecture

“Strut based applicators are significantly more effective in keeping skin and rib dose constraints under 125 and 100% when compared to any balloon based applicator and also achieve a significantly better D90.”⁷

Proven Efficacy¹³

GEC-ESTRO Brachytherapy vs. WBI Phase 3 Clinical Trial³

No difference in local recurrence, disease-free survival or survival at 5 years

5-year results of accelerated partial breast irradiation using sole interstitial multicatheter brachytherapy versus whole-breast irradiation with boost after breast-conserving surgery for low-risk invasive and in-situ carcinoma of the female breast: a randomized, phase 3, non-inferiority trial.

Vratislav Strnad, MD, Csaba Polgar, MD, et al. – GEC-ESTRO¹ The Lancet, October 2015

Objective: to prove the hypothesis that local control rate is non-inferior with brachytherapy compared to WBI

5-Year Results	Brachy	WBI	p-value [†]
Number of patients	633	551	–
Local recurrence	1.4%	0.9%	0.42
Disease-free survival	95%	94.5%	0.79
Overall survival	97.3%	95.6%	0.11

“Our results confirm that adjuvant APBI using multicatheter brachytherapy after breast-conserving surgery is as effective as adjuvant whole-breast irradiation for carefully selected patients with early breast cancer.”

[†]Groupe Européen de Curiethérapie of European Society for Radiation And Oncology
[‡]p-value <0.05 indicates statistical significance

Less Toxicity*

Favorable Toxicity Rate^{4,5,6}

	Yashar, et al ASTRO 2014 ⁱ	Strasser, et al ASTRO 2014 ⁱⁱ	Yashar, et al IJROBP 2010 ⁱⁱⁱ
# of Pts/Follow-up	200 pts/ 56.9 mo.	596 pts/ 39 mo.	102 pts/ 21 mo.
Telangiectasia	1.6%	1.0%	1.9%
Symptomatic Seroma	3.2%	3.0%	1.9%
Fat Necrosis	0.5%	0.8%	1.9%

*as compared to WBI

Toxicity rates defined by CTCAE v.3

- i. Yashar C et al. Outcomes for APBI with Strut-Based Brachytherapy: First 200 Patients (5-Year Report). Poster session presented at the American Society for Radiation Oncology Annual Meeting, September 14-17, 2014.
- ii. Strasser J, et al. Outcomes for APBI with Strut-Based Brachytherapy: 596 Patients with 39-Month Median Follow-Up. Poster session presented at the American Society for Radiation Oncology annual meeting, September 14-17, 2014.
- iii. Yashar C, Scanderbeg D, et al. Initial Clinical Experience with the Strut-Adjusted Volume Implant (SAVI) Breast Brachytherapy Device for Accelerated Partial-Breast Irradiation (APBI): First 100 Patients with More than 1 Year of Follow Up. Int J Radiat Oncol Biol Phys. 2011 Jul 1; 80(3): 765-70.

Preserve Future Treatment Options

“In the case of a tumor recurrence, breast cancer treatment can be performed a second time with APBI brachytherapy allowing the breast to still be preserved and avoiding mastectomy.”¹²



Excellent Cosmetic Results

Limited fibrosis and skin toxicity, providing excellent cosmetic results.¹¹ Catheter placement can be planned to hide the scar.

APBI Patient Selection Criteria

Professional Medical Society Consensus Statement: Patient Selection Criteria for Accelerated Partial Breast Irradiation					
	ABS ¹	ASBS ⁹		ASTRO ¹⁰	
				Suitable	Cautionary
Age	≥45	≥45	≥50	≥50	40–49
Diagnosis	All invasive subtypes and DCIS	Invasive ductal carcinoma	DCIS	Invasive ductal/DCIS	Pure DCIS ≤3cm EIC ≤3cm
Tumor Size	≤3cm	≤3cm		≤2cm	2.1–3.0cm
Surgical Margins	Negative (Invasive—no tumor on ink; DCIS—≥2mm)	Negative microscopic surgical margins of excision		Negative by at least 2mm	Close (<2mm)
Nodal Status	NØ	NØ		NØ (i-, i+)	

Convenient

The short treatment course (five days or less) allows patients to get back to their routines more quickly.⁸



Visit us at [CiannaMedical.com](https://www.CiannaMedical.com) or contact your your local Account Representative and find out how we can help you deliver efficient, patient-focused, and cost-effective care.

Experience the SAVI® Advantage



With SAVI, customized catheter sizing helps to increase the number of women who may be eligible for treatment.

- Innovative design of the SAVI Applicator combines the precise dosimetry of interstitial brachytherapy with the ease and convenience of single-entry devices.
- Provides targeted radiation where it's needed most while minimizing dose to healthy tissue—decreases toxicity and lowers the risk of cosmetic side effects.¹¹
- 'SAVI Sculpt Dosing' delivers customized radiation based on patient-specific anatomy which may increase the number of women who are eligible for treatment with APBI.



The SAVI Prep™ Catheter is a simple, easy to use tool for sizing and selection of the proper SAVI applicator size.



The SAVI Prep 01 Catheter is an option for use in the OR to preserve the cavity and track.

References

1. Shah C, Vicini F, Shaitelman SF, Hepel J, Keisch M, Arthur D, Khan AJ, Kuske R, Patel R, Wazer DE. The American Brachytherapy Society consensus statement for accelerated partial-breast irradiation. *Brachytherapy*. 2017. 2. Cianna Medical press release, New Data Demonstrate Accelerated Partial Breast Irradiation using Multicatheter Brachytherapy is Clinically Equivalent to Whole Breast Irradiation in Treating Early Stage Cancer, October 2015. 3. Strnad V, Ott OJ, Hildebrandt G, et al. 5-year results of accelerated partial breast irradiation using sole interstitial multicatheter brachytherapy versus whole-breast irradiation with boost after breast-conserving surgery for low-risk invasive and in-situ carcinoma of the female breast: a randomised, phase 3, non-inferiority trial. *Lancet*. 2016;387(10015):229-38. 4. Yasher C et al. Outcomes for APBI with Strut-Based Brachytherapy: First 200 Patients (5-Year Report). Poster session presented at the American Society for Radiation Oncology Annual Meeting, September 14-17, 2014. 5. Strasser J et al. Outcomes for APBI with Strut-Based Brachytherapy: 596 Patients with 39-Month Median Follow-Up. Poster session presented at the American Society for Radiation Oncology Annual Meeting, September 14-17, 2014. 6. Yasher C, Scanderberg D, et al. Initial Clinical Experience with the Strut-Adjusted Volume Implant (SAVI) Breast Brachytherapy Device for Accelerated Partial-Breast Irradiation (APBI): First 100 Patients with More than 1 Year of Follow Up. *Int J Radiat Oncol Biol Phys*. 2011 Jul 1;80(3): 765-70. 7. Zaker R, Nasr NM, Lorio V et al. Comparative dosimetric findings using accelerated partial breast irradiation across five cathetersubtypes. *Radiat Oncol*. 2015 Jul 31;10:160. doi: 10.1186/s13014-015-0468-7. 8. Orecchia R, Fossati P. Partial breast irradiation: ready for routine? *The Breast* 2007; 16:S89-S97. 9. Consensus statement for accelerated partial breast irradiation. *The American Society of Breast Surgeons*. August 2011. 10. American Society of Radiation and Oncology Consensus Statement of Partial Breast Irradiation. July 2009. 11. Khan, Atif J. et al. Three-Fraction Accelerated Partial Breast Irradiation (Apbi) Delivered With Brachytherapy Applicators Is Feasible And Safe: First Results From The Triumph-T Trial. *International Journal of Radiation Oncology*. 2019. Online publication. 12. Victor, Brant. Interview 2018. https://www.ciannamedical.com/cianna_press/preserving-future-treatment-options-retreatment-with-savi-brachy/ 13. Yasher et al. Initial clinical experience with the Strut-Adjusted Volume Implant brachytherapy applicator for accelerated partial breast irradiation. *Brachytherapy* 8 (2009).

Before using refer to Instructions for Use for indications, contraindications, warnings, precautions, and directions for use.



Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, Utah 84095
Main: +1.801.253.1600
Customer Service: +1.801.208.4300

Merit Medical Europe, Middle
East, & Africa (EMEA)
Amerikalaan 42, 6199 AE
Maastricht-Airport
The Netherlands
+31 43 358 82 22

Merit Medical Ireland Ltd.
Parkmore Business Park West
Galway, Ireland
+353 (0) 91 703 733

merit.com
ciannamedical.com

©2019 Merit Medical Systems, Inc. All rights reserved.

405106001_002 ID082819