

CARTO VISITAG™

Module with Ablation Index

Extend your Senses



**THE SINGLE PROCEDURE SOLUTION
FOR YOUR AFIB PATIENTS**

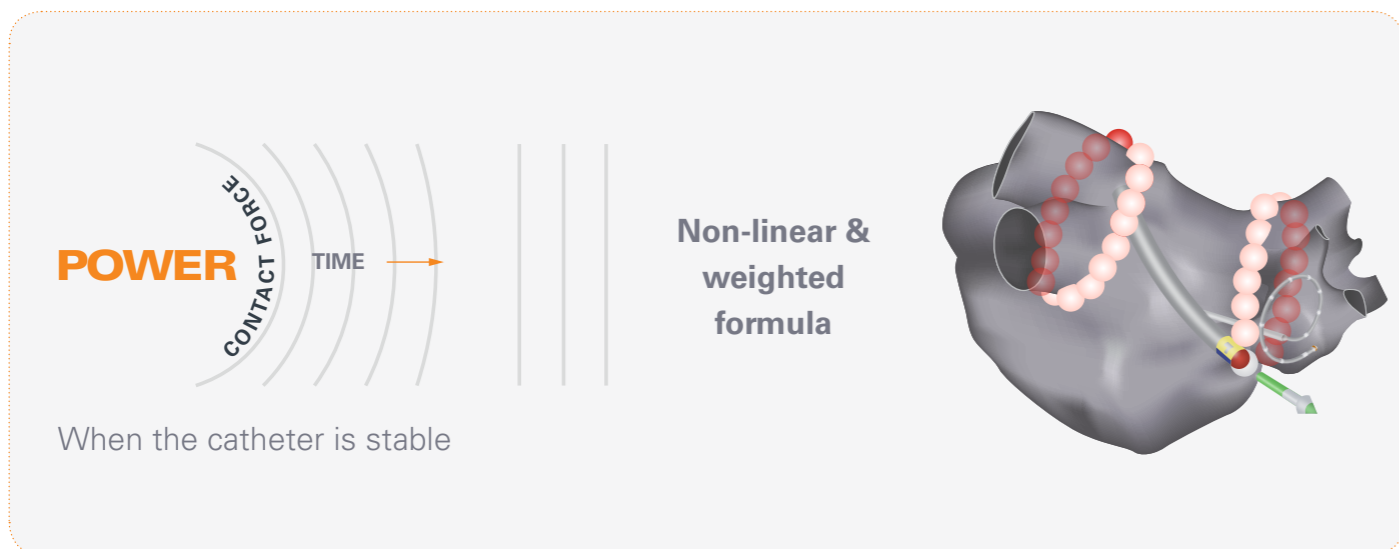
 **Biosense Webster®**
PART OF THE *Johnson & Johnson* FAMILY OF COMPANIES

Real World Clinical Experiences using an Optimized Workflow with Ablation Index



“ We can finally offer our patients a single procedure solution in less than 2 hours procedural time with up to 92% success rate at 1 year follow-up. ”

Prof. Duytschaever (Bruges, Belgium)



“ ...revolutionize the treatment of patients with AF, just as the iPod and iPhone revolutionized their respective markets. ”

Dr Wright (London, UK)



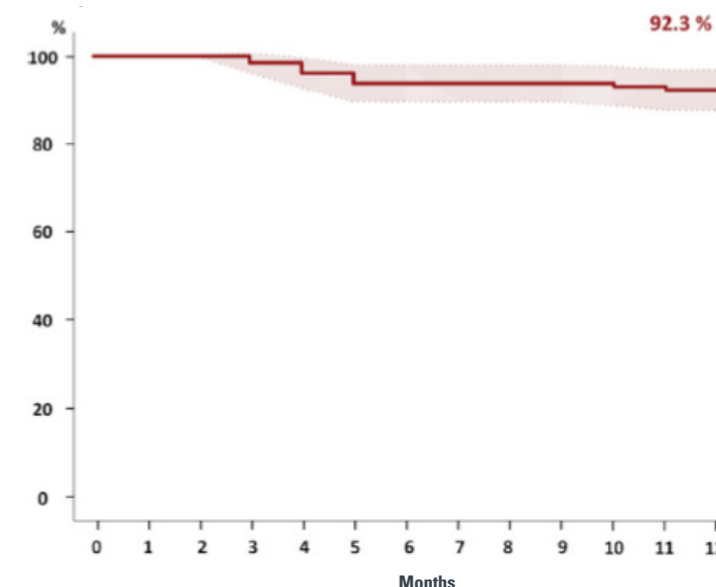
Now you can **REPRODUCE** your own successful ablation strategy in a **STANDARD** and **SIMPLE** way with **up to 92%** single procedure success rate at 1 year follow-up^{1*}

REPRODUCIBILITY

With different operators in the same center (92.3 ± 1.3%)¹

- 91.3% off AAD (n=104)
- 96.2% on AAD (n=26)

Freedom from documented AF/AT/AFL in all patients (n=130)

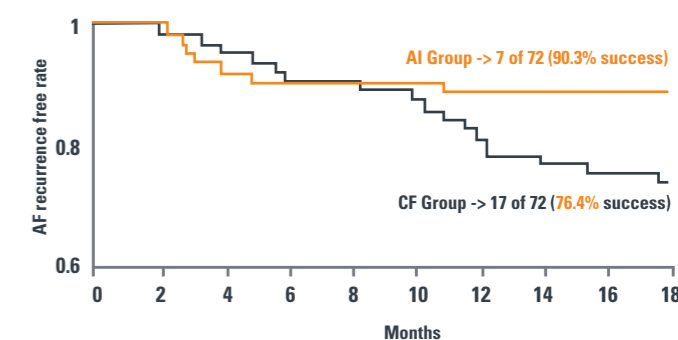
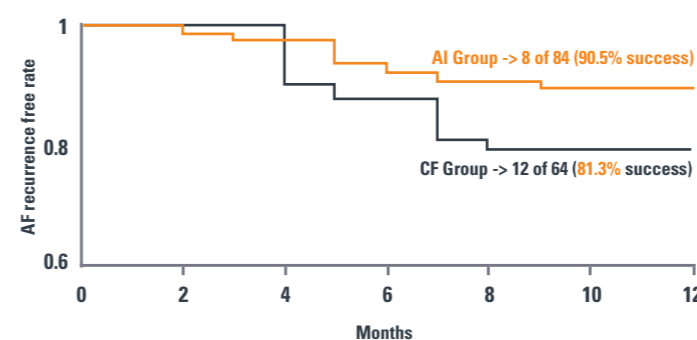


STANDARDIZATION

In different centers^{1,5,6}

Multi-center study (n=148), 1 year follow-up^{5†}

Single-center study (n=144), 1 year follow-up^{6†}



*Results are coming from single-center studies

†Data are coming from abstracts presented at international congresses

SIMPLIFICATION



22%
reduction in
procedural
time^{1,2}



36%
reduction in
RF time^{1,2}

CF vs AI

	Conventional CF group (n=50)	CLOSE group (n=50)	P-value
PV isolation, n	50 (100%)	50 (100%)	>0.99
Procedure time (min)	192±42	149±33	<0.001
Total RF time (min)	56±11	36±7	<0.001
Freedom from documented AF/AT/AFL in patients off ADT at 1 year	75%	91%	

-22%

-36%



RF ablation offers the locational versatility **not afforded by the single-shot tools** as well as the flexibility to alter its individual components for truly individualized RF lesion creation.

While the journey towards achieving **>90% single procedure success rates** with ablation for paroxysmal AF has been long and arduous, the destination **is now in sight**. The force is with us.³



Dr Gupta (Liverpool, UK)

NEW EXPERIENCES COMING FROM DIFFERENT CENTERS¹²:

- >90% Success Rate,
- Less Than 2 Hours Procedural Time Achievable
- Minimal Fluoroscopy Time
- Safe

	Ablation Index group (n=156)* ¹²
Success rate at mean follow-up 14±6 months	91% (PAF patients, n=124), 78% (Ps AF patients, n=32)
Mean procedural time (min)	95±30
Mean fluoroscopy time (min)	5±6
Mean ablation time (min)	26±10
Complications	3 (1.9% minor complications)

*using THERMOCOOL SMARTTOUCH® SF Catheter



Right First Time:

We are now absolutely sure that each spot is fully treated, before we move on to the next spot.

This is real progress, analogous to a leap made in manufacturing industry at the start of this century....

Compared to our experience with One Shot technology, our procedural time using Point by Point approach guided by Ablation Index **varies less**: total procedural time is still slightly longer (in any case less than 2 hours), but the standard deviation is now lower.

This means that Point by Point approach guided by Ablation Index is much more reproducible and allow us to get each point of ablation right and consequently get each procedure **right on the first procedure**.

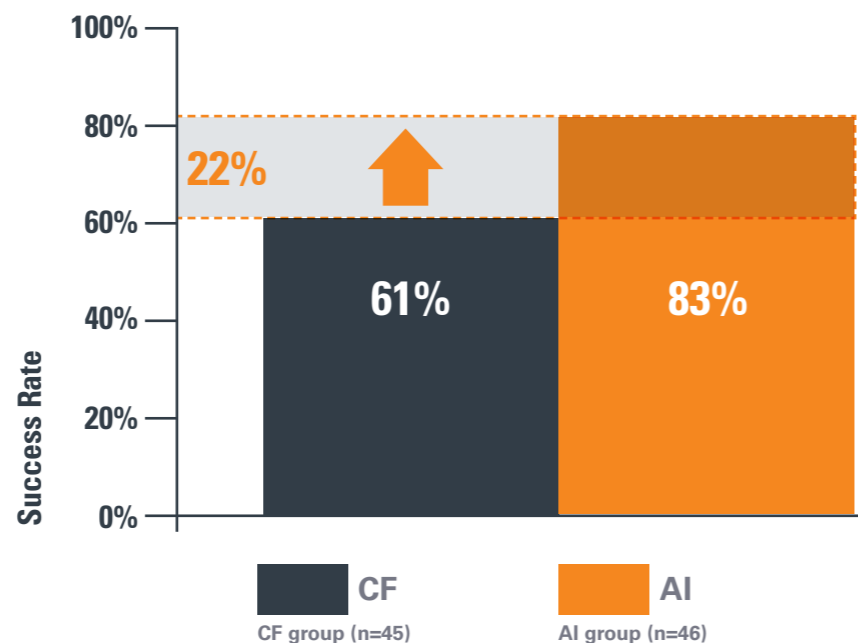


Dr Gallagher (London, UK)

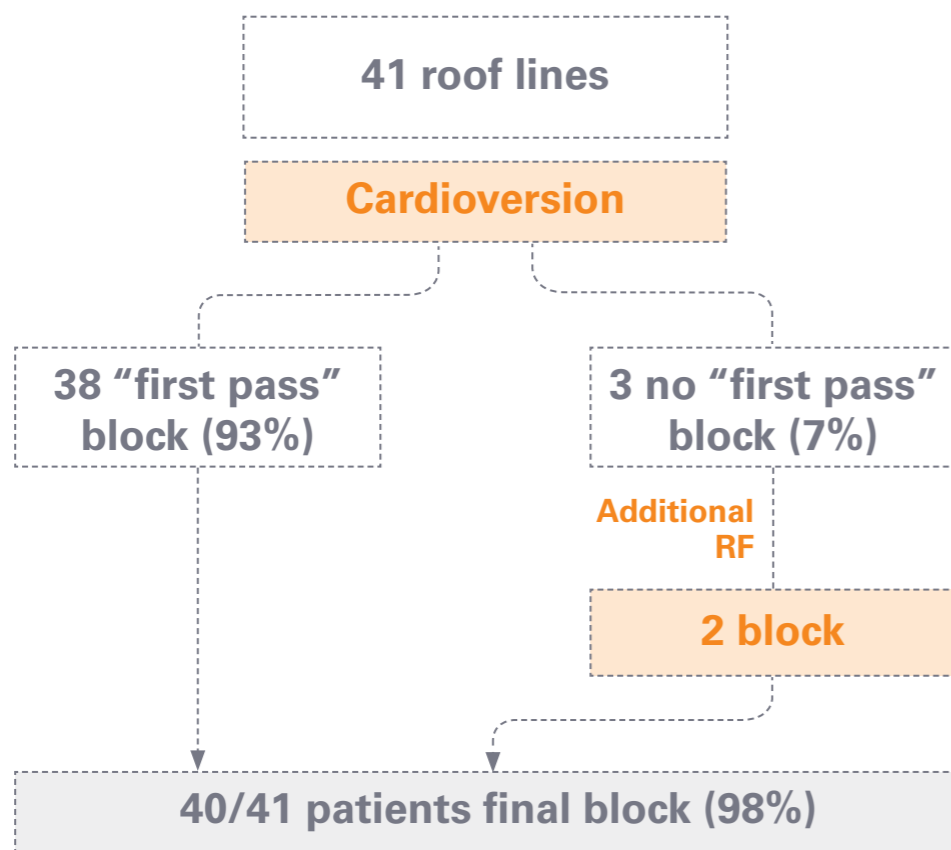
■ PERSISTENT AF

+22% success rate in **Persistent Atrial Fibrillation⁷**

Success rate at **1 year follow-up** in Persistent Atrial Fibrillation (Ps AF)



93% «first-pass» rate for bidirectional block at the roof line⁸



■ OPTIMIZED WORKFLOW



↑ +45% success rate at 1 year follow-up with point by point vs dragging technique⁹

- N=120
- THERMOCOOL SMARTTOUCH™ Catheter

↓ -61% reduction in mapping time with LASSO® Catheter vs THERMOCOOL SMARTTOUCH™ Catheter¹⁰

According to Expert Consensus

“Electrical isolation of the PVs is recommended during all AF ablation procedures” and “Achievement of electrical isolation requires, at a minimum, assessment and demonstration of entrance block into the PV.”¹¹



■ Ordering Information

The Ablation Index Software is fully supported and controlled through the existing CARTO VISITAG™ Module, which seamlessly integrates into the trusted CARTO® 3 System and THERMOCOOL SMARTTOUCH™ Catheter technologies.

KT5400490 & KT5400490U	CARTO VISITAG™ Module Ablation Index kit*
KT5400158 & KT540050U	CARTO VISITAG™ Module Ablation Index kit* (including Workstation)

* CARTO VISITAG™ Module with Ablation Index requires CARTO SMARTTOUCH™ Module.

■ References

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4. Wright, M. AF Ablation Simplicity is the Answer. JACC 2017 Jan;4(1):109-111
5. P748 Impact of a novel lesion target on clinical outcome of paroxysmal atrial fibrillation ablation De Ruvo, et al presented "at EHRA 2018", pending formal publication
6. B-P002 -128 - Ablation Index: A Standardized Technique To Reach Higher AF Treatment Effectiveness In A Single-centre Experience Dello Russo, Casella, Natale, et al presented "at HRS 2018", pending formal publication
7. Hussein, A. et al. Prospective use of Ablation Index targets improves clinical outcomes following ablation for atrial fibrillation. J Cardiovasc Electrophysiol 2017 Sep;28(9):1037-1047.
8. Wolf, M. et al. Evaluation of left atrial linear ablation using contiguous and optimized radiofrequency lesions: the ALINE study. Europace (2018) 0, 1–9
9. Tofiq, B. et al. Recurrence after pulmonary vein isolation is associated with low contact force. Scandinavian Cardiovascular Journal, 52:1, 28-33,
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11. 2017HRS/EHRA/ECAS/APHS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation: Executive summary
12. Solimene F, et al.; Safety and efficacy of atrial fibrillation ablation guided by Ablation Index module; J Interv Card Electrophysiol. 2018; doi: 10.1007/s10840-018-0420-5

Important Information: Prior to use, refer to the instructions for use supplied with this device for indications, contraindications, side effects, warnings and precautions.

This product can only be used by healthcare professionals in EMEA.

The CARTO VISITAG™ Module provides access to data collected during the application of RF energy. The data does not indicate the effectiveness of RF energy application. Refer to the CARTO® 3 System Instructions for use and Optimum Device Performance Guide for proper recommendations and settings.

Tag Index values can only be compared when created with the same CARTO VISITAG™ Module settings.

The Tag Index values should not be used to replace standard handling precautions or other clinically accepted endpoints for RF applications such as reduction of IC signals, impedance drop, force, etc.

Tag Index values do not represent clinical outcome.

Manufacturer: Biosense Webster Inc. For more details go to www.biosensewebster.com

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