

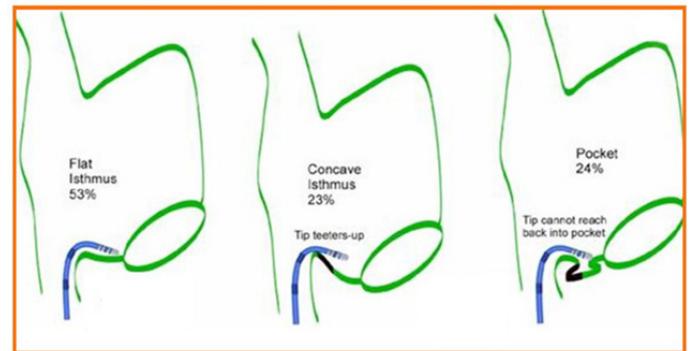
Essential elements to increase efficient use of remote magnetic navigation

Use in conjunction with established best practices in EP ablation to evaluate outcomes

CTI Ablation Procedure

Background

- RF Ablation of CTI dependent flutter is a standard procedure in current EP practice. The success rate of this procedure type is reportedly very high with short procedure times. The CTI procedure presents a unique challenge to the physician when using a magnetic catheter.
 - The NaviStar® RMT Thermocool® catheter has an ablation tip of 3.5cm in length.
 - The superior safety profile of the flexible catheter shaft may require additional positioning adjustments. Some of these adjustments could involve sheath manipulation.
- Many physicians who are expert in the use of magnetically guided ablation report success rates for CTI ablations with magnetic catheter navigation similar to those of their manual experience.
- Whether a manual or magnetic approach is chosen, the variability of CTI morphology directly impacts the time required for success. User experience as well as peer reviewed literature suggests that longer and anatomically more complex CTI requires more RF applications and longer cumulative RF times.
- CTI can be classified based on morphology, as depicted in the panel.
- It is important to notice that features are not related to age, gender or race.
- These findings further suggest that detailed mapping prior to performing ablation of a CTI dependent flutter with a magnetic catheter may be helpful in determining the most appropriate ablation strategy.



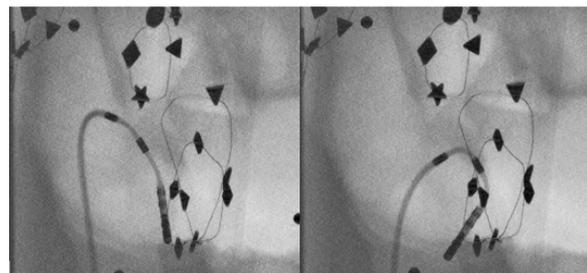
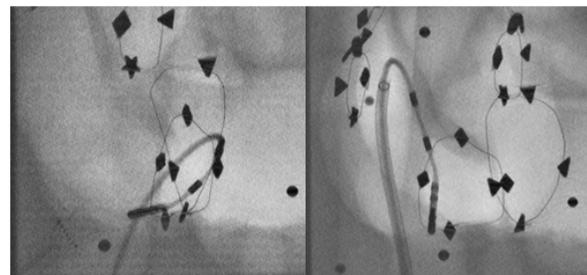
Set Up

- Place an 8.5F SL-0 sheath low in the inferior vena cava. A sheath position that is too high may prevent navigation at the Eustachian ridge.
- Using a separate CS catheter and a 10-20 pole diagnostic catheter in place of a single diagnostic catheter for both atrium and CS signals helps prevent this single diagnostic catheter from potentially blocking the proximal ablation line.

*Essential elements to increase efficient use of remote magnetic navigation
Use in conjunction with established best practices in EP ablation to evaluate outcomes*

Mapping

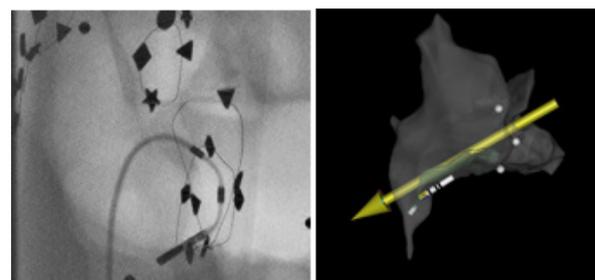
- A CARTO® 3 system FAM resolution of 20 will provide a detailed map of the isthmus. Collecting FAM surface with high resolution takes more time, but limiting the area of mapping to the isthmus, will keep the mapping time acceptable. Use respiratory gating to enhance the map.
- Place the ablation catheter at the distal aspect of the tricuspid annulus. Apply a vector that is directed at least 45° toward the tissue surface. Set CAS step size to 2mm and retract to the IVC.
- Initial high-resolution mapping provides sufficient information to identify the type of isthmus present in order to determine if multiple lines, vector changes or ablating while advancing the catheter is appropriate.
- In the presence of a concave or pocketed isthmus, loop the magnetic catheter or advance the sheath to the high right atrium as described in the image.
- Looping the catheter is an effective way to access concaved structures at the isthmus.
 - Advance the catheter until the shaft curves between the distal and middle magnet in the right atrium and the magnets are aligned with the current vector.
 - Sweep the isthmus distal to proximal looking for depressions or ridges by alternating between CAS advancement and retraction to contact the tissue surface. Adjust the vector when the tip is retracted away from the tissue surface and ablate when the tip is advanced to the tissue surface.
 - This looping technique has been reported to be instrumental in achieving success in CTI ablations by expert users of magnetic catheter navigation.



Essential elements to increase efficient use of remote magnetic navigation
Use in conjunction with established best practices in EP ablation to evaluate outcomes

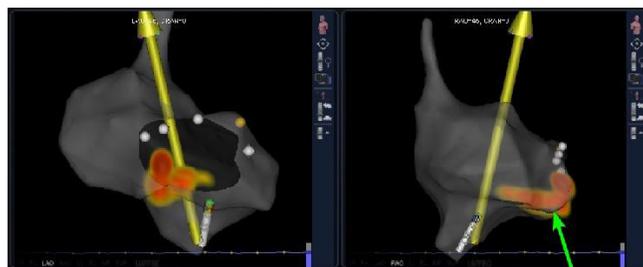
Treatment

- Physicians experiencing success with CTI ablation report using power settings in a range between 45 and 50 Watts, advancing the catheter when desired EGM attenuation is achieved.
- A 2mm CAS step size and 5° vector movement supports maintaining the desired position on the contiguous lesion line. If available, employ the Ablation History feature in Navigant® to visualize and immediately address gaps.
- Alternating frequently between the two *Navigant* 3D Mapping Windows described below informs the physician whether a CAS or vector movement is required.
 - Map View 1: RAO (or RL) projection shows a profile view of the isthmus, visualizing the process of directing the vector toward the tissue.
 - Map View 2: INF (inferior) projection shows the ablation line in a vertical orientation, visualizing when a CAS movement is required.
- In procedures with more complex CTI morphology, reducing the CAS step size to 1mm and using small vector movements helps stabilize the catheter supporting a contiguous lesion line. Conversely, excess vector steering or large CAS step size movements can result in undesired catheter jumps due to high amounts of stored energy.
- Use looping and/or high sheath position to access crenulations at the ablation line.



Confirm Treatment Effect

- Assess acute bi-directional block according to standard EP pacing practice. Ablation History data in *Navigant* and the magnetic catheter tip can assist in this process.
- If gaps in treatment exist, use Ablation History data in *Navigant* to assist in identifying these areas.



Isthmus with a pouch

Further Reading

- Anatomical variations of the right coronary artery may be a source of difficult block and conduction recurrence in catheter ablation of common-type atrial flutter
Hanno U. Klemm
(Europace (2010) 12, 1608–1615)
- Elimination of cavotricuspid isthmus conduction by a single ablation lesion: observations from a maximum voltage-guided ablation technique.
Posan et al
(Europace (2007) 9, 208–211)
- Cavotricuspid isthmus angiography predicts atrial flutter ablation efficacy in 281 patients randomized between 8 mm- and externally irrigated-tip catheter
A. Da Costa et al.
(European Heart Journal (2006) 27, 1833–1840)

Stereotaxis' Best Practices material is only intended to provide general information relating to use of Stereotaxis' products and is not a substitute for medical training or certification. Drs. J. Peter Weiss, MD, MSc and William H. Spear, MD, FACC, FHRS contributed to and support the Stereotaxis Best Practice Program.

Stereotaxis does not provide or evaluate physician credentialing. Users of Stereotaxis' products, for example the Niobe® ES magnetic navigation system, are responsible for obtaining sufficient training and having the skill and experience necessary to protect the health and safety of the patient.

For technical information, including full cautions and warnings on using the products, please refer to the system user manual. Read all instructions carefully. Failure to properly follow instructions, labeling, notes, cautions, warnings and danger messages associated with Stereotaxis' products may lead to serious injury to users or patients, or patient complications including death, or damage to the products. While clinical studies support the use of Stereotaxis' products as an effective tool for procedures specified in the labeling, individual results may vary.

© 2014 Stereotaxis, Inc. All rights reserved.

Navigant and Niobe are trademarks of Stereotaxis, Inc., registered in the United States, the European Community, and Japan. All other brand names, product names, or trademarks are the property of their respective owners.

Mastering Micro-movements with Magnetic Catheters

If more than two vector moves are employed without associated tip response, remove the vector input(s) to eliminate high amounts of stored energy. Subsequently, retract the catheter until the attitude of the tip changes, and then re-apply the desired vector.

If more than two CAS moves are employed without associated tip response retract CAS inputs until the attitude of the tip changes, and then adjust vector to regain tip control.

CARTO 3 System FAM Mapping Resolution Settings with Magnetic Catheters

Physicians who are expert in the use of the CARTO 3 system with magnetic catheters and FAM mapping state that they prefer a FAM resolution of 16 or 17. Resolutions lower than 16 produce excessive interpolation between independent catheter positions resulting in a map that looks complete but lacks sufficient fidelity. Conversely, resolutions greater than 17 produce a high fidelity map but display many holes in the map surface unless additional time is taken to ensure all independent catheter positions are close enough to each other to fill holes. Thus, selecting a FAM resolution of 16 or 17 best supports efficiently creating a high fidelity map.

Variables Influencing Efficient Ablation with a NaviStar® RMT ThermoCool® Catheter (power, time, force)

- When using a magnetic catheter, the amount of force applied to the tissue remains relatively constant throughout the cardiac cycle at a median level of approximately 10 grams¹.
- With this relatively constant level of force, the remaining variables that can be adjusted are power and time. Increasing power (rather than time) is the most efficient way to heat tissue to desired temperature levels.
- During manual ablations, physicians have the ability to increase force if initial RF energy applications result in rising edema. Physicians who are expert in magnetic catheter ablation minimize risk of edema by increasing power during the **initial** delivery of RF energy.
- With more than 75,000 Stereotaxis magnetic procedures completed to date, increasing power is common best practice of physicians.

¹Nakagawa et al., 2014 AF Symposium