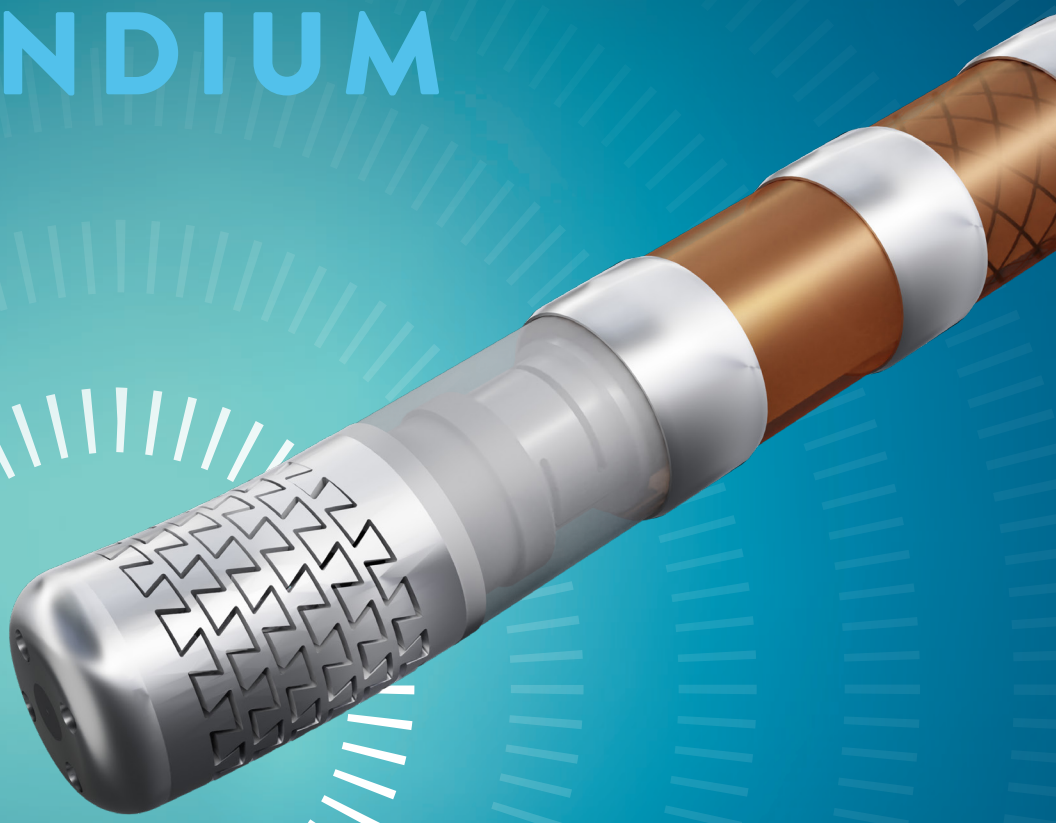
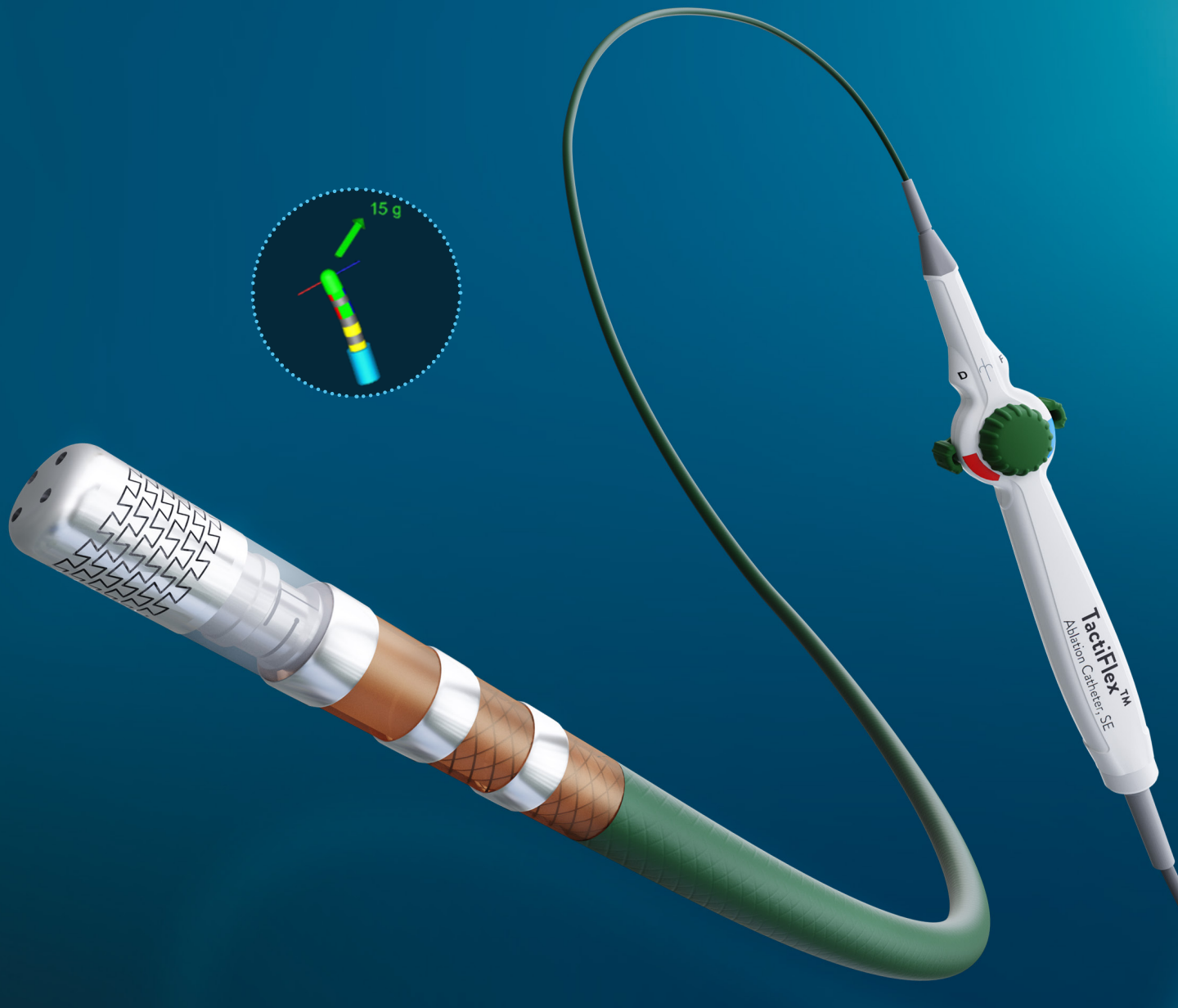
Abbott

TACTIFLEX™ ABLATION CATHETER,
SENSOR ENABLED™

CLINICAL COMPENDIUM



The TactiFlex™ Ablation Catheter, Sensor Enabled™ is the **FIRST AND ONLY** ablation catheter with contact force measuring capability and a flexible tip. The unique design of the **FLEXIBLE, LASER-CUT TIP PROVIDES SUPERIOR STABILITY** when compared to conventional 56-hole catheters[1]. Initial results from the investigational device exemption (IDE) study show that ablation with the TactiFlex Ablation Catheter, SE is not only **ACUTELY SAFE AND EFFECTIVE TO TREAT PAROXYSMAL ATRIAL FIBRILLATION** but also **INCREASES PROCEDURAL EFFICIENCY[2].** This compendium summarizes the initial clinical evidence and pre-clinical and bench data supporting the use of the TactiFlex Ablation Catheter, SE, to treat paroxysmal atrial fibrillation.



SUMMARY OF TACTIFLEX™ ABLATION CATHETER, SENSOR ENABLED™ IDE FOR PAROXYSMAL ATRIAL FIBRILLATION[3]

ACUTE TRIAL RESULTS

PAROXYSMAL ATRIAL FIBRILLATION ABLATION WITH A NOVEL FLEXIBLE TIP RADIOFREQUENCY CATHETER INCORPORATING CONTACT FORCE SENSING: ACUTE RESULTS OF THE TACTIFLEX AF IDE TRIAL.[2]

The primary objective of this study was to demonstrate that ablation with the TactiFlex Ablation Catheter, SE is safe and effective for the treatment of drug refractory, symptomatic paroxysmal atrial fibrillation. Acute results and study design are reviewed below.

- Prospective, non-randomized trial
- 355 de novo patients
- Pulmonary vein isolation (Other ablation lines as indicated)
- CTI-line ablation if indicated (or at operator discretion)
- Contact force: 5-20g (Recommended 20-50W with specified durations)

OVERALL ANALYSIS[2]

99.4%
ACUTE SUCCESS[4]

80.5%
FIRST PASS SUCCESS[5]

2.4%
RATE OF REPEAT ABLATION IN BLANKING PERIOD (0 – 90 DAYS)

4.3%
SUBJECT WITH PRIMARY SAFETY ENDPOINT EVENT AT 90 DAYS[6]

KEY TAKEAWAYS

The acute data results indicate that TactiFlex Ablation Catheter, SE, is **ACUTELY SAFE AND EFFECTIVE** for ablation of paroxysmal atrial fibrillation.

SUMMARY OF TACTIFLEX™ ABLATION CATHETER, SENSOR ENABLED™ IDE FOR PAROXYSMAL ATRIAL FIBRILLATION[3]

ACUTE TRIAL RESULTS

PROCEDURAL METRICS COMPARISON

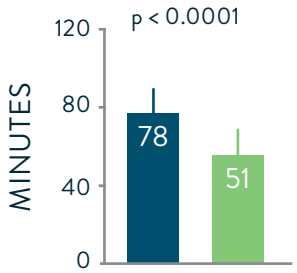
Initial results from the TactiFlex PAF IDE Study[2] (n=334) were compared to results from its predecessor, TactiCath™ Ablation Catheter, Senor Enabled™, in the TactiSense IDE (n=156).[7] The comparison showed that ablation procedures performed using the TactiFlex Ablation Catheter, SE decreased four important procedural metrics, shown below:

TactiSense IDE
Waiting period defined as 30 minutes.

TactiFlex IDE
Waiting period defined as 20 minutes.

TOTAL PV ABLATION TIME

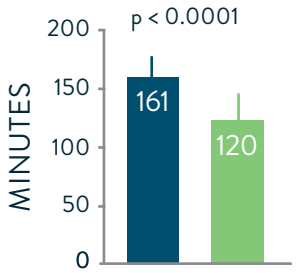
Includes a waiting period, time noted in key



35%

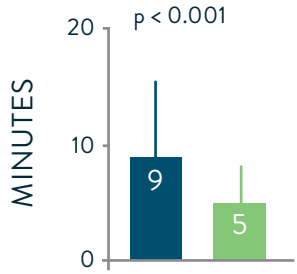
TOTAL PROCEDURE TIME

Includes a waiting period, time noted in key



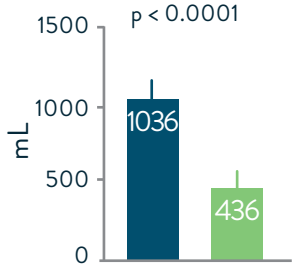
25%

TOTAL FLUOROSCOPY TIME



44%

TOTAL IRRIGATION FLUID VOLUME



58%

KEY TAKEAWAYS

IMPROVED PROCEDURAL METRICS are a significant benefit of the TactiFlex Ablation Catheter, SE.

SUMMARY OF TACTIFLEX AF IDE TRIAL FOR THE TREATMENT OF PAROXYSMAL ATRIAL FIBRILLATION[3]

AS-TREATED SUBGROUP ANALYSIS

Acute results of a novel flexible tip radiofrequency catheter incorporating contact force sensing – IDE Analysis: comparison of as-treated subgroups

The primary objective of the IDE study was to demonstrate that ablation with the TactiFlex Ablation Catheter, SE is safe and effective for the treatment of drug refractory, symptomatic paroxysmal atrial fibrillation. The study protocol was designed to investigate these outcomes broadly, across the entire study population, and by ablation power level. High-power short duration (40 to 50W) ablation has a strong body of pre-clinical and clinical evidence to support its safety and efficacy.[8-16]

TWO AS-TREATED SUBGROUPS:

HIGH-POWER (n=225)
- Time-averaged power setting 40-50W

81.8%
FIRST PASS SUCCESS[2,5]

1.3%
RATE OF REPEAT ABLATION IN BLANKING PERIOD[17]

4.1%
SUBJECTS WITH PRIMARY SAFETY ENDPOINT EVENT AT 90 DAYS[2,6]

LOW-POWER (n=97)
- Time-averaged power setting <40W

77.3%
FIRST PASS SUCCESS[2,5]

5.2%
RATE OF REPEAT ABLATION IN BLANKING PERIOD[17]

5.2%
SUBJECTS WITH PRIMARY SAFETY ENDPOINT EVENT AT 90 DAYS[2,6]

KEY TAKEAWAYS

The acute data results indicate that TactiFlex Ablation Catheter, SE, is **ACUTELY SAFE AND EFFECTIVE** with both high and low-power for ablation of paroxysmal atrial fibrillation.

SUMMARY OF TACTIFLEX AF IDE TRIAL FOR THE TREATMENT OF PAROXYSMAL ATRIAL FIBRILLATION[2,3]

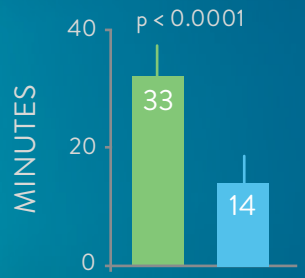
AS-TREATED SUBGROUP ANALYSIS

PROCEDURAL METRICS

Important procedural metrics from the TactiFlex Ablation Catheter, SE IDE acute data were compared between the two as-treated subgroups, with outcomes shown below[17]:

Low-Power (n=97) High-Power (n=224)

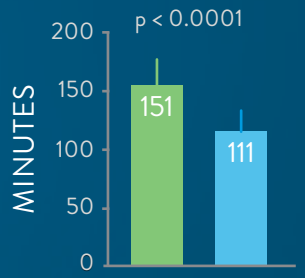
TOTAL RF TIME FOR PV ABLATION



58%

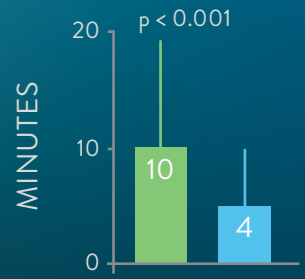
TOTAL PROCEDURE TIME

Includes a 20-minute waiting period



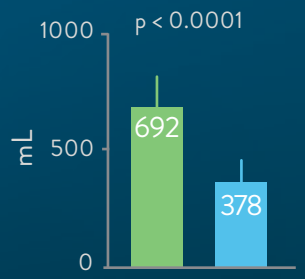
26%

TOTAL FLUOROSCOPY TIME



60%

TOTAL IRRIGATION FLUID VOLUME



45%

KEY TAKEAWAYS

The acute results indicate that using TactiFlex Ablation Catheter, SE at high-power **IMPROVES MULTIPLE PROCEDURAL METRICS** compared to low-power.

SUMMARY OF TRANSLATIONAL SCIENCE COMPLETED WITH TACTIFLEX™ ABLATION CATHETER, SENSOR ENABLED™*

BENCH AND PRE-CLINICAL DATA

UNDERSTANDING LESION CHARACTERISTICS

Lesion Size and Adverse Event Profile of the TactiFlex™ Ablation Catheter, Sensor Enabled™ in a Porcine Thigh Model[18]

- ✓ The purpose of the pre-clinical in vivo testing was to compare lesion size and adverse events using TactiFlex Ablation Catheter, SE and FlexAbility™ Irrigated Ablation Catheter, Sensor Enabled™
- ✓ RF ablations were performed in 5 swine at nominal or maximum settings:
  - Nominal: 30W for 60s; N=44 per catheter
  - Maximum: 50W for 10s; N=37 per catheter
- ✓ Trials were balanced between parallel and perpendicular tip orientations
- ✓ TactiFlex Ablation Catheter, SE and FlexAbility Irrigated Ablation Catheter, SE produced lesions equivalent in depth and width (Equivalence interval +/-1.67mm, Figures 1 and 2)

INTERVAL PLOT OF MAXIMUM LESION DEPTH (MM)
95% CI for the mean

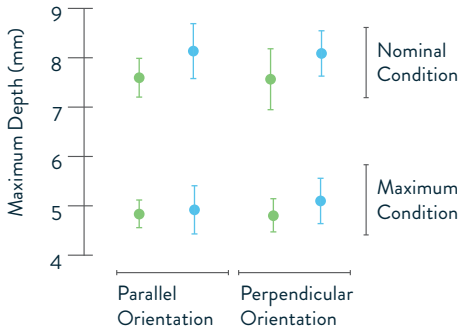


Figure 1

INTERVAL PLOT OF MAXIMUM LESION WIDTH (MM)
95% CI for the mean

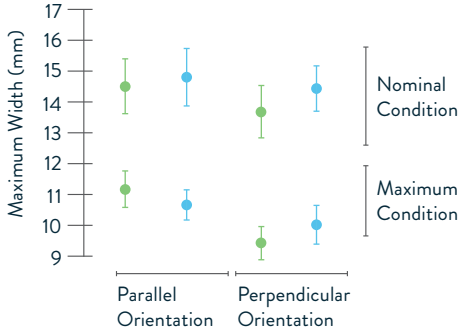


Figure 2

Test Input Conditions: N=161 Total

Power	30W 60s (nominal) 50W 10s (maximum)
Contact Force	20g
Irrigation	13ml/min

- ✓ TactiFlex Ablation Catheter, SE was non-inferior to FlexAbility Irrigated Ablation Catheter, SE for rate of coagulum and char (20% non-inferiority margin,Figures 3 and 4)
- ✓ No steam pops occurred with either catheter

COAGULUM RATE (%)

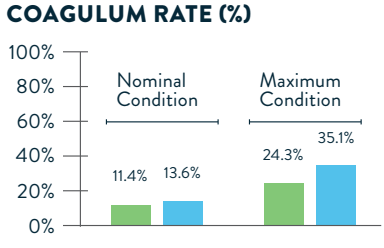


Figure 3

CHAR RATE (%)

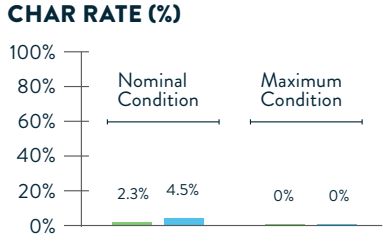


Figure 4

KEY TAKEAWAYS

TactiFlex Ablation Catheter, SE creates similar lesions to FlexAbility Ablation Catheter, SE, a catheter with a history of **SAFE AND EFFECTIVE ABLATION**

SUMMARY OF TRANSLATIONAL SCIENCE COMPLETED WITH TACTIFLEX™ ABLATION CATHETER, SENSOR ENABLED™*

BENCH AND PRE-CLINICAL DATA

UNDERSTANDING LESION CHARACTERISTICS

Investigation of Comparative Lesion Dimension Between Abbott TactiFlex™ Ablation Catheter, Sensor Enabled™ and TactiCath™ Ablation Catheter, Sensor Enabled™[19]

- ✓ The purpose of the preclinical bench testing was to explore range of settings in a non-perfused bovine ventricular tissue model for both the TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™ and the TactiFlex Ablation Catheter, SE and compare lesion dimensions
- ✓ RF ablations were performed at various power/duration combinations (20-50W, 5-60s) with contact forces of 5g and 15g
    - Ablations were performed in parallel and perpendicular orientations
- ✓ There was no significant difference in lesion width between the two catheters
- ✓ TactiFlex Ablation Catheter, SE produced slightly shallower lesions for a given power/duration combination
- ✓ The aspect ratio of lesions created using TactiFlex Ablation Catheter, SE was slightly greater than using TactiCath Ablation Catheter, SE (P=0.002, Figure 5)
    - This suggests that the slightly shallower lesions may decrease the risk of adverse events without compromising lesion continuity

WIDTH/DEPTH ASPECT RATIO BETWEEN TACTICATH SE AND TACTIFLEX SE
95% CI for the Mean

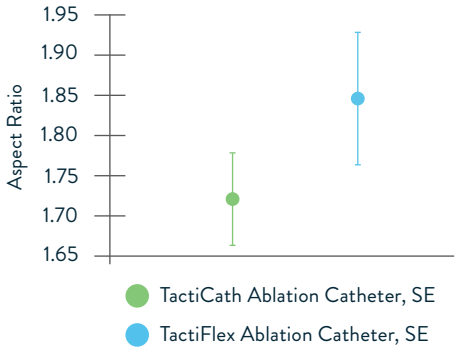


Figure 5

KEY TAKEAWAYS

The aspect ratio of lesions created by TactiFlex Ablation Catheter, SE **MAY PREVENT ABLATION IMPACT ON EXTRACARDIAC STRUCTURES** without compromising lesion continuity in clinical practice

SUMMARY OF TRANSLATIONAL SCIENCE COMPLETED WITH TACTIFLEX™ ABLATION CATHETER, SENSOR ENABLED™*

BENCH AND PRE-CLINICAL DATA

ANALYZING CATHETER STABILITY

A Flexible, Laser-cut Ablation Catheter Tip Provides Superior Stability in a Bench Model[1]

- ✓ The purpose of the pre-clinical bench testing was to compare the stability of a flexible, laser-cut ablation tip to a conventional 56-hole RF ablation tip
- ✓ Relative catheter tip-tissue movement was measured in bovine ventricular tissue
  - Catheters were mounted parallel or perpendicular to the endocardial surface
  - Contact force was applied at 5, 10, and 20g
  - 10 trials of each catheter type and condition were performed
- ✓ The flexible tip catheter required greater displacement force compared to the control for all conditions except 5g perpendicular (Figure 7)
- ✓ This observation was more pronounced at higher contact forces
- ✓ These results suggest that a flexible tip will be more stable within clinically relevant range of contact

DISPLACEMENT FORCE OF CATHETER ON LV TISSUE

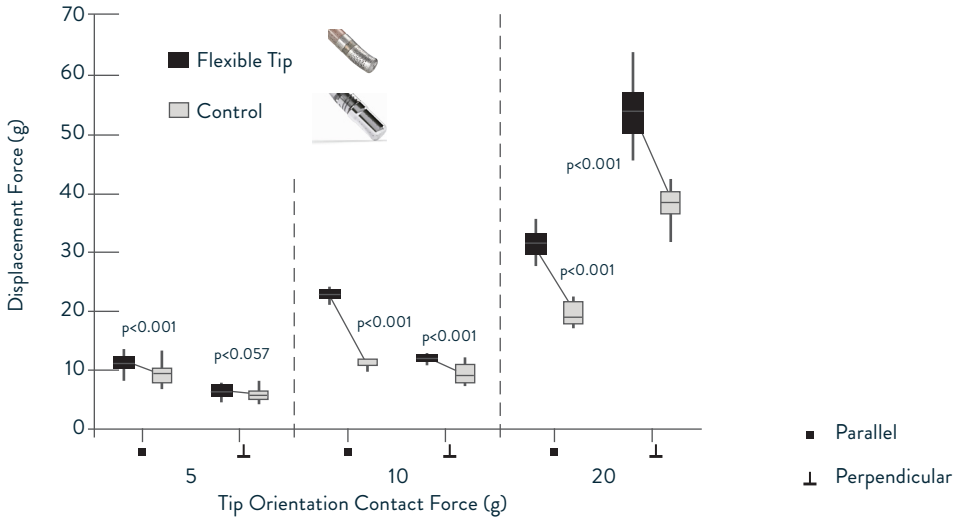


Figure 7

KEY TAKEAWAYS

- A flexible ablation catheter tip provided up to 2x superior stability vs. a conventional 56-hole smooth tip in a bench study, and this may translate to superior stability in clinical use
- Greater stability may make the catheters easier to operate and may lead to a more predictable lesion size

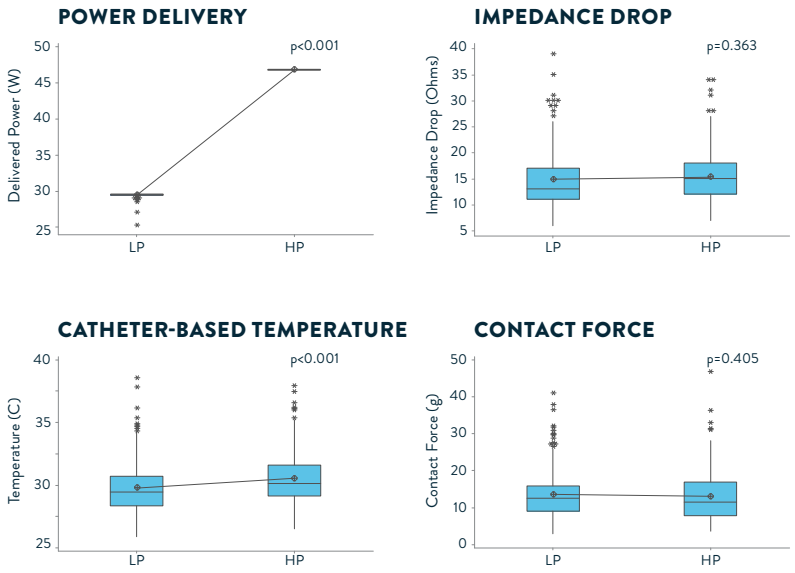
SUMMARY OF TRANSLATIONAL SCIENCE COMPLETED WITH TACTIFLEX™ ABLATION CATHETER, SENSOR ENABLED™*

BENCH AND PRE-CLINICAL DATA

COMPARING HIGH AND LOW POWER ABLATION

Safe and Effective Delivery of High-Power, Short-Duration Radiofrequency Ablation Lesions with a Flexible-Tip Ablation Catheter[20]

- ✓ The purpose of the pre-clinical study was to evaluate the in-vivo safety and efficacy of the TactiFlex Ablation Center, SE at various power settings
- ✓ Left-sided pulmonary vein isolation was performed in 12 canines. Each subject had 1 pulmonary vein ablated at high-power and 1 at low-power (total of 12 veins treated at both protocols)
  - The high-power protocol was 50W delivered for 10 sec
  - The low-power protocol was 30W delivered for up to a maximum of 60 seconds
  - Both groups had contact force targets of 5-20g
- ✓ The ablation time to achieve pulmonary vein isolation was 3-fold shorter in the high-power group compared to the low-power group
- ✓ The rates of steam pop formation were not statistically different between the high-power and low-power groups (HP 95% CI 0.000-0.015, LP 95% CI 0.001-0.024)
- ✓ There was no significant difference in the rate of pulmonary vein isolation after the acute 30-min waiting period and at a post-ablation study at 28±3 days
- ✓ Successful pulmonary vein isolation was achieved in both the high-power and low-power RF ablation protocol groups



Comparison of measured ablation parameters for high-power (HP) and low-power (LP) RF ablation lesions.

Figure 8

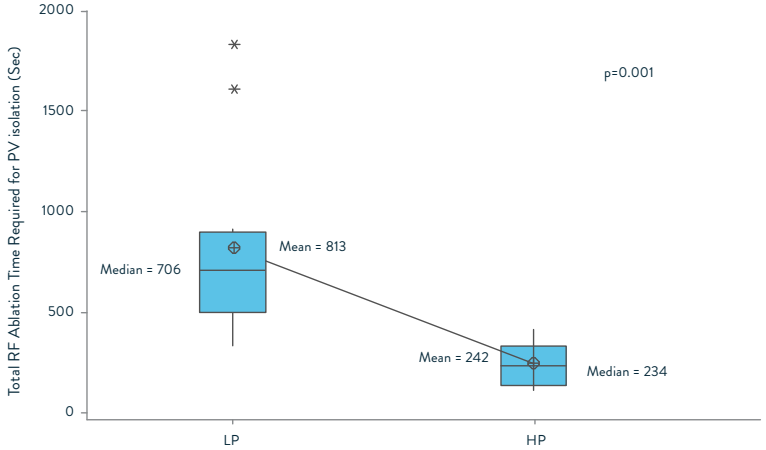


Figure 9

KEY TAKEAWAYS

- Both high-power and low-power ablation protocols led to **SUCCESSFUL PVI USING TACTIFLEX ABLATION CATHETER, SE** in a preclinical model
- The ablation **TIME TO ACHIEVE PVI WAS 3X SHORTER IN THE HIGH-POWER GROUP COMPARED TO THE LOW-POWER GROUP** with no statistical differences in steam pops or acute and long-term PVI

SUMMARY OF TAKEAWAYS FROM TACTIFLEX™ ABLATION CATHETER, SENSOR ENABLED™ CLINICAL AND PRE-CLINICAL DATA

CLINICAL DATA:

PAROXYSMAL ATRIAL FIBRILLATION ABLATION WITH A NOVEL FLEXIBLE TIP RADIOFREQUENCY CATHETER INCORPORATING CONTACT FORCE SENSING: ACUTE RESULTS OF THE TACTIFLEX AF IDE TRIAL[2,7]

- The acute data results indicate that TactiFlex Ablation Catheter, SE, is acutely **SAFE AND EFFECTIVE** for ablation of paroxysmal atrial fibrillation.
- Ablation procedures performed using the TactiFlex Ablation Catheter, SE **DECREASED TOTAL PROCEDURE TIME, FLUOROSCOPY TIME, TOTAL PV ABLATION TIME, AND TOTAL IRRIGATION FLUID VOLUME** compared to results from its predecessor, TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™ in the TactiSense IDE
- This comparison shows that the **MULTIPLE IMPROVED PROCEDURAL METRICS** are significant benefits of the TactiFlex Ablation Catheter, SE.

ACUTE RESULTS OF A NOVEL FLEXIBLE TIP RADIOFREQUENCY CATHETER INCORPORATING CONTACT FORCE SENSING – IDE ANALYSIS: COMPARISON OF AS-TREATED SUBGROUPS USING TACTIFLEX ABLATION CATHETER, SE[2,17]

- The acute data results indicate that TactiFlex Ablation Catheter, SE, is **ACUTELY SAFE AND EFFECTIVE AT BOTH HIGH AND LOW-POWER** for ablation of paroxysmal atrial fibrillation.
- **FIRST PASS ISOLATION IS ACHIEVED IN THE MAJORITY OF PATIENTS,** regardless of operator power choice
- The acute data results indicate that using TactiFlex Ablation Catheter, SE with high-power **IMPROVES MULTIPLE PROCEDURAL METRICS** compared to low-power

BENCH AND PRE-CLINICAL DATA:

UNDERSTANDING LESION CHARACTERISTICS USING TACTIFLEX ABLATION CATHETER, SE[18,19]

- TactiFlex Ablation Catheter, SE creates similar lesions to FlexAbility Ablation Catheter, SE, a catheter with a history of **SAFE AND EFFECTIVE ABLATION**
- The aspect ratio of lesions created by TactiFlex Ablation Catheter, SE may **PREVENT ABLATION IMPACT ON EXTRACARDIAC STRUCTURES** without compromising lesion continuity in clinical practice

ANALYZING CATHETER STABILITY USING A FLEXIBLE LASER-CUT TIPPED ABLATION CATHETER[1]

- A flexible ablation catheter tip provided up to **2X GREATER STABILITY** compared to a conventional 56-hole smooth tip in a bench study, and this may translate to superior stability in clinical use
- Greater stability may make the catheters easier to operate and may lead to more predictable lesion creation

SAFE AND EFFECTIVE DELIVERY OF HIGH-POWER, SHORT-DURATION RADIOFREQUENCY ABLATION LESIONS WITH A FLEXIBLE-TIP ABLATION CATHETER[20]

- **TACTIFLEX ABLATION CATHETER, SE ACHIEVED SUCCESSFUL PULMONARY VEIN ISOLATION PRE-CLINICALLY** using either high-power or low-power RF ablation protocols
- **HIGH-POWER ABLATION RESULTED IN SIGNIFICANT IMPROVEMENTS IN EFFICIENCY** compared to the low-power group with no statistical differences in steam pops or acute and long-term PVI
    - High-power ablation defined in this study as 50W
    - Low-power ablation defined in this study as 30W

VISIT OUR WEBSITE FOR MORE INFORMATION

*Pre-clinical data disclaimer:

- Each Ablation model (bench, thigh, intracardiac) is different and thus LESIONS CREATED IN EACH MODEL ARE NOT NECESSARILY EQUIVALENT FOR MATCHING ABLATION INPUT CONDITIONS.
- LESIONS CREATED IN BENCH, THIGH, AND INTRACARDIAC TESTING ARE NOT NECESSARILY REPRESENTATIVE OF CLINICAL LESION SIZES, but each model can be used to compare ablation performance and lesion sizes across varying ablation conditions and between catheter types.
- Data comparing lesion sizes between TactiFlex™ Ablation Catheter, Sensor Enabled™ and TactiCath™ Ablation Catheter, Sensor Enabled™ showcases a model for lesion sizes based on ablations at a range of settings to aid in range finding for ablation settings. This data shows lesion sizes beyond recommended ablation durations and for power levels that do not include specific duration recommendations in the TactiFlex Ablation Catheter, SE IFU. THIS IS NOT A SUGGESTION TO ABLATE BEYOND IFU RECOMMENDATIONS, PLEASE REMEMBER TO ALWAYS ADHERE TO IFU RECOMMENDATIONS.
- Initial studies provided general data comparison to set ablation recommendations, the TactiFlex Ablation Catheter, SE IFU ablation recommendations are based on GLP and should be adhered to.

1. Ambrosius Nick, Fish Jeffrey, & Tranter John. Flexible, Kerfed Ablation Catheter Tip Provides Superior Stability in a Bench Model APHRS 2018: Abstract Book; 2018, October 17-18; Taipei, Taiwan. Abstract nr 1170.
2. CL1017540 TactiFlex PAF IDE PMA Report
3. NCT04356040
4. Acute success in this study was defined as isolation of all pulmonary veins, confirmed by entrance block, by the end of the procedure.
5. First-pass success in this study was defined as isolation of all pulmonary veins, confirmed by entrance block after a minimum 20-minute waiting period, without any PV reconnection after initial PVI.
6. The full list of primary safety outcomes can be found at clinicaltrials.gov/ct2/show/NCT04356040
7. CL1021674
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17. CL1019990 TactiFlex PAF IDE As Treated Repeat Procedure Details
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Rx Only. Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use.

United States: Required Safety Information

Indications: The TactiFlex™ Ablation Catheter, Sensor Enabled™ is indicated for use in cardiac electrophysiological mapping and for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation and concomitant atrial flutter, when used in conjunction with a compatible RF generator and three-dimensional mapping system. **Contraindications:** Do not use for any of the following conditions: recent ventriculotomy or atriotomy heart surgery; prosthetic valves; active systemic infection; use in coronary vasculature; myxoma or intracardiac thrombus, transseptal approach with an interatrial baffle or patch; retrograde trans-aortic approach in patients with aortic valve replacement; patients unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation. **Warnings:** The temperature data transmitted by the sensor in this catheter is representative of the irrigated electrode only and does not provide tissue temperature data. Application of RF energy on the left atrial posterior wall exceeding 40 W in power, or use of contact force ≥15g, increases the risk of esophageal perforating complications including atrio-esophageal fistula and death. Application of RF energy outside of the power and duration recommendations may increase the likelihood of steam pop occurrence. Patients undergoing septal accessory pathway ablation are at risk for complete AV block which requires the implantation of a permanent pacemaker. Implantable pacemakers and implantable cardioverter/defibrillator (ICDs) may be adversely affected by RF current. The combination of intracoronary placement of the ablation catheter and RF energy application has been associated with myocardial infarction and death. Inspect tubing, connections, and saline irrigation for air bubbles prior to and throughout its use in the procedure. Air or bubbles in the saline irrigation may cause emboli, potential injury, or fatality. Increased contact force may increase the risk for perforation during manipulation of the catheter. Contact force in excess of 20 g may not significantly change the characteristics of lesion formation. Contact force accuracy above 50 g has not been established. Caution should be taken when placing lesions in the proximity of the specialized conduction system. To avoid thromboemboli, intravenous heparin should be used when entering the left heart during ablation. Always maintain a constant saline irrigation flow to prevent coagulation within the lumen of the catheter. When using the catheter with conventional EP lab system (using fluoroscopy to determine catheter tip location) or with a 3D navigational system, careful catheter manipulation must be performed, especially when used in combination with a long sheath, in order to avoid cardiac damage, perforation, or tamponade. **Precautions:** Always straighten the catheter tip before insertion or withdrawal. If irrigation flow is interrupted, immediately inspect and re flush the catheter outside of the patient. Re-establish irrigation flow prior to placing catheter in the body. Irrigated ablation systems have been shown to create larger lesions than standard radiofrequency ablation catheters. Be careful when ablating near electrically vulnerable, thin walled, or other arterial structures. **Potential Adverse Events:** Potential adverse events include, but are not limited to, cardiovascular related complications, including hematoma, pericardial effusion and infection. More serious complications are rare, which can include damage to the heart or blood vessels; blood clots (which may lead to stroke); tamponade; severe pulmonary vein stenosis; heart block; myocardial infarction; esophageal fistula, or death.

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