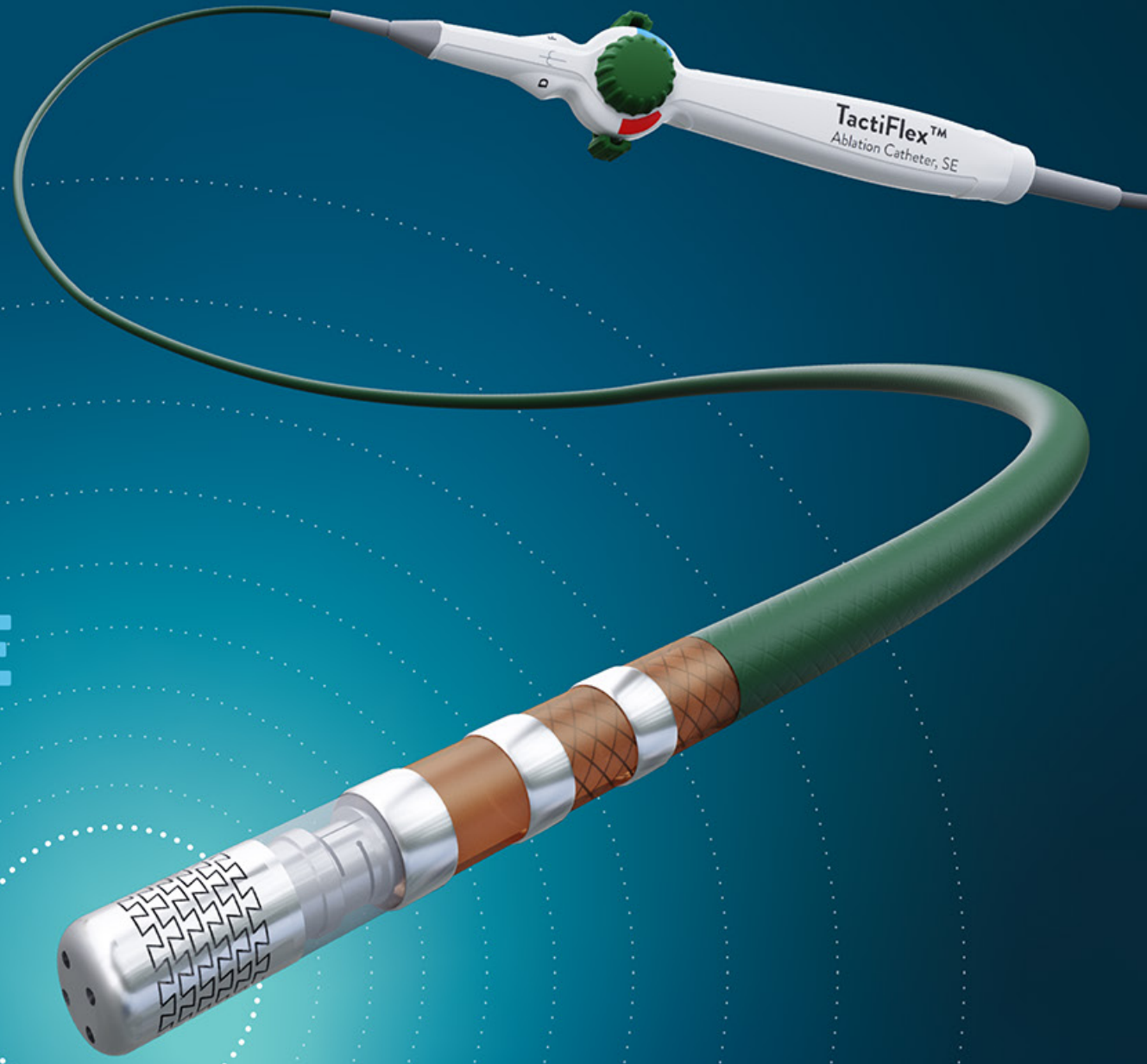
Abbott

TACTIFLEX™ ABLATION CATHETER,
SENSOR ENABLED™

# ECONOMIC VALUE PROPOSITION



TACTIFLEX™ ABLATION CATHETER, SENSOR ENABLED™

# EVOLUTION OF ADVANCED **ABLATION TECHNOLOGY**

## IRRIGATED TIP

FLEXABILITY™
ABLATION CATHETER

THERMOCOOL ST‡

## CONTACT FORCE

TACTICATH™
ABLATION CATHETER,
SENSOR ENABLED™

THERMOCOOL
SMARTTOUCH SF‡

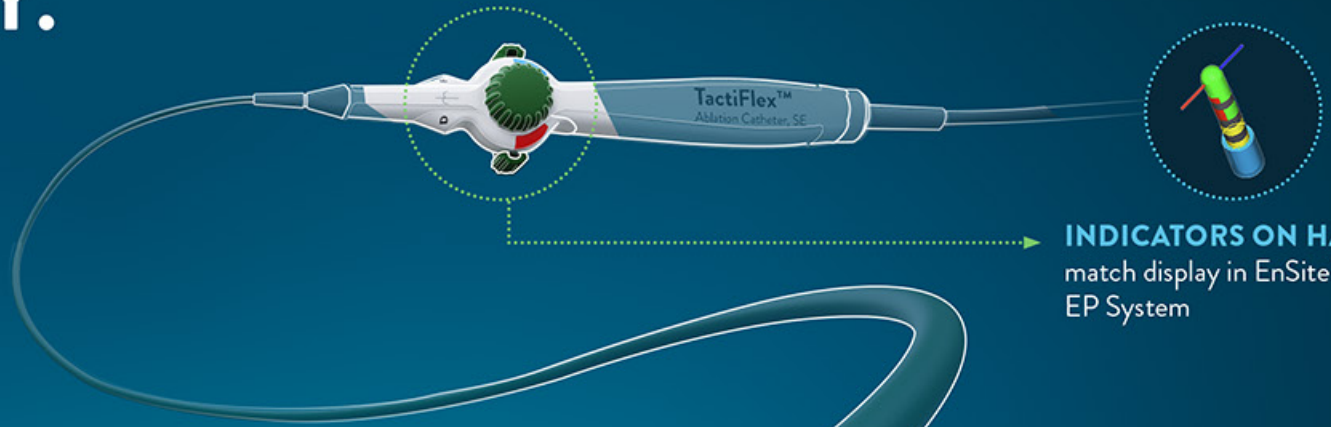
## CRYO

## HIGH-POWER SHORT DURATION

QDOT‡

TACTIFLEX™
ABLATION CATHETER,
SENSOR ENABLED™

# PERFORM HIGH-POWER ABLATION* WITH **SAFETY AND STABILITY, CONFIDENCE AND EFFICIENCY.**

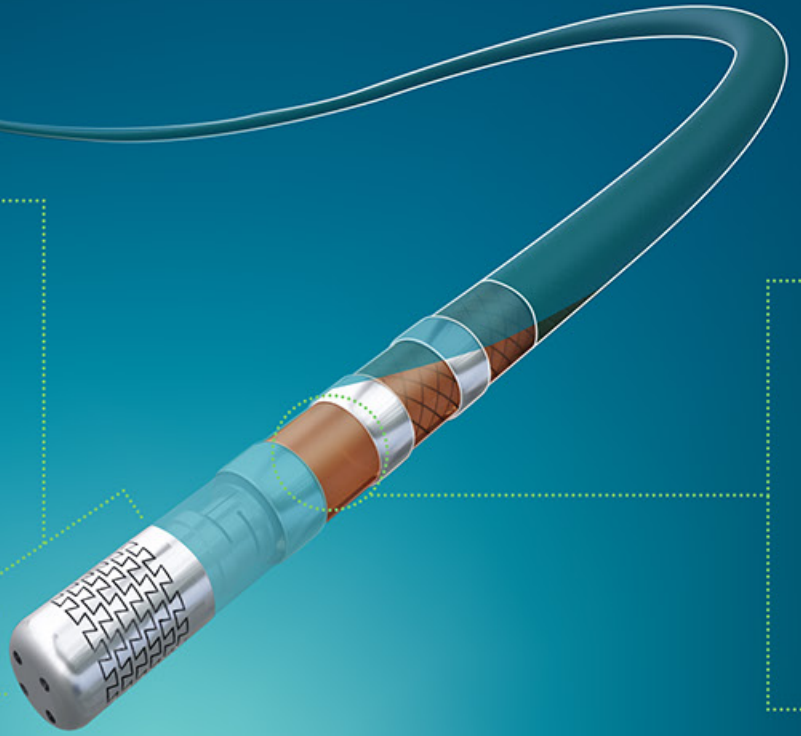





**INDICATORS ON HANDLE**
match display in EnSite™ X EP System

The only catheter with a **FLEX TIP** and a **CONTACT FORCE SENSOR**

**EXCELLENT SIGNAL QUALITY AND TIP STABILITY**[2,5]



**2-2-2 RING SPACING**


Two magnetic sensors allow display of **FORCE DIRECTION ARROW AND DEFLECTION INDICATOR**

# ECONOMIC VALUE PROPOSITION

## PROCEDURAL EFFICIENCY[7]

from intuitive handling and usability with full EnSite™ X EP System integration

- **REDUCE PVI ABLATION TIMES BY AS MUCH AS 70%*** ** with high-power short-duration ablation[1]
- Usability and predictability with **INTUITIVE CONTACT FORCE ARROW** and deflection direction indicator[2]
- Monitor lesion creation with **EXCELLENT ELECTROGRAM SIGNAL QUALITY** even during RF[3]

## DESIGNED FOR OPTIMAL SAFETY[7] AND STABILITY[5]

through a flexible laser-cut tip design

- Apply **DIRECTED IRRIGATION FLOW**[4] to the tip-tissue interface, effectively cooling tissue for safe transmural ablation
- Lower irrigation rate** while ablating up to 50W to **REDUCE FLUID LOADING**
- Experience **SUPERIOR STABILITY** with a unique, flexible, laser-cut tip - up to **2X GREATER STABILITY** than conventional 56-hole catheters[5]

## COST BENEFITS

Procedural efficiency creates opportunity for additional case revenue

- EP lab cost savings estimated at **$1,740 PER HOUR**[6]
- Time savings affords opportunity for **ADDITIONAL CASE VOLUME**
- Potential for **SAME DAY DISCHARGE** reduces hospital cost and provides opportunity for additional procedures requiring an overnight stay

ACUTE RESULTS: INCLUDING ALL POWER LEVELS UP TO 50W

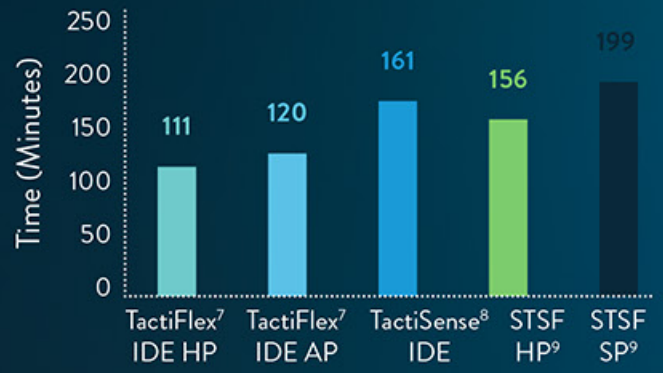
# PROCEDURAL EFFICIENCY

TactiFlex™ Ablation Catheter, Sensor Enabled™ vs. TactiCath™ Ablation Catheter, Sensor Enabled™ vs. SmartTouch SF‡

## REDUCE PROCEDURE TIME

by an average of

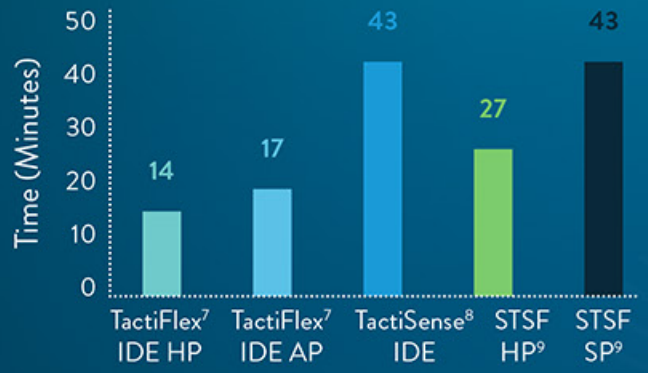
**50 MINUTES***




## REDUCE TOTAL RF TIME

for PV ablation by an average of

**29 MINUTES***




## BENEFITS

### PROCEDURAL TIME GAINS

- **50 MINUTES** savings translates to EP lab cost savings of **$1,450** per procedure**[6]
- **2.5-HOUR** savings per day based on average of 3 cases per day, resulting in additional procedure per day for the hospital creating additional revenue opportunity = **$23,481**

*TactiFlex Ablation Catheter, SE HP vs TactiCath Ablation Catheter, SE
**Using the average of other catheter times compared to TactiFlex Ablation Catheter, SE times

TactiFlex IDE data includes a 20-minute waiting period, and TactiSense IDE data includes a 30-minute waiting period. The TactiSense IDE was the PAF IDE study for TactiCath Ablation Catheter, Sensor Enabled.
SmartTouch SF[1] procedure time data includes a 30 min waiting period

ACUTE RESULTS: HIGH-POWER GROUPS

# PROCEDURAL EFFICIENCY

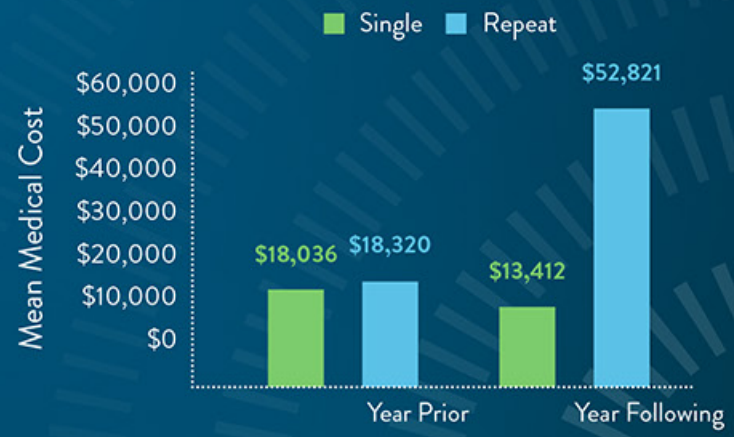
**HIGH-POWER**
(TIME-AVERAGED POWER SETTING ≥40W)

**81.8%**
FIRST PASS SUCCESS[7]

**1.3%**
RATE OF REPEAT ABLATION IN BLANKING PERIOD[10]

## BENEFITS

- FPI predicts clinical success, with FPI success on at least one set of PV a leading predictor of clinical success with **88%** freedom from AF recurrence at one year[11]
- Current rate of repeat ablations within 1 year is **17.2%**[12]
- A reduction of just **1%** in the rate of repeat procedures can result in cost savings of nearly **$30 MILLION** per year to the U.S. healthcare system[12]
- Incremental cost associated with having a repeat procedure was **$39,409**[12]

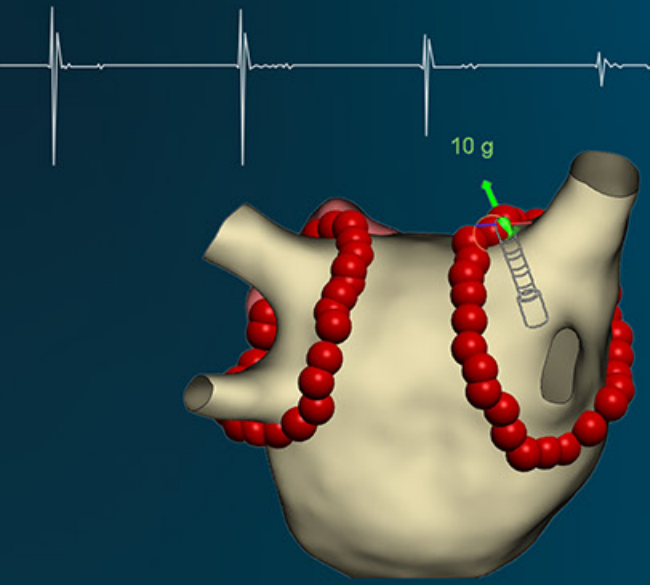


ENSITE™ X EP SYSTEM MAPPING INTEGRATION

# PROCEDURAL EFFICIENCY

## EXCELLENT SIGNAL QUALITY AND TIP STABILITY

Noise free signals allow for better resolution of signal attenuation during ablation, a reliable predictor of durable lesions[19]




## DEFLECTION INDICATORS ON HANDLE

More efficient and intuitive catheter manipulation of the catheter

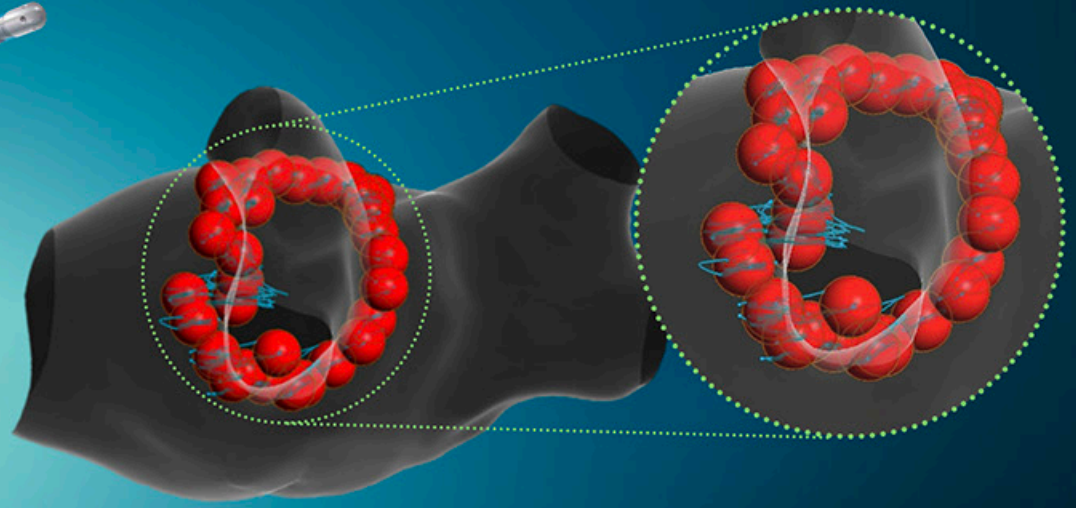

## FORCE DIRECTION ARROW AND DEFLECTION INDICATOR

More efficient and intuitive force application helps determine true direction of contact force

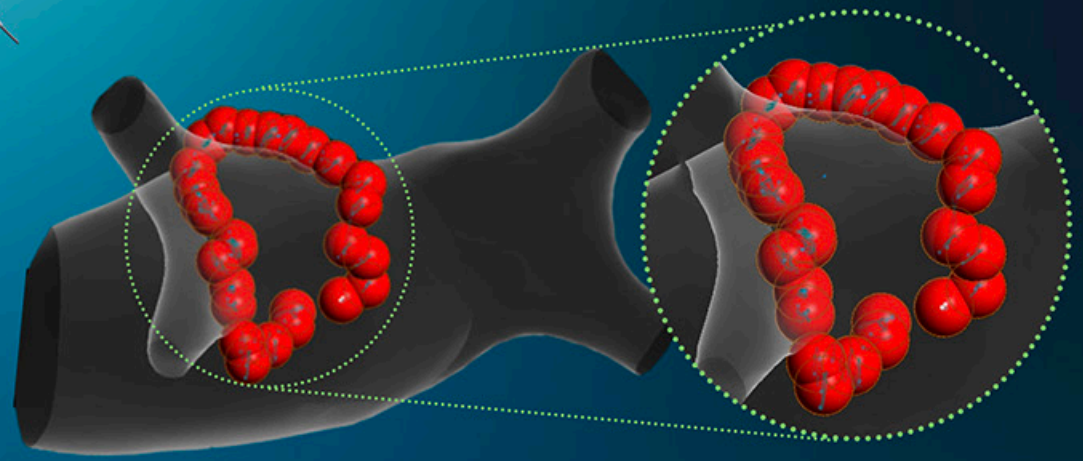
# ABLATE EFFICIENTLY WITH PREDICTABILITY AND CONFIDENCE:

THE **FIRST** AND **ONLY** CONTACT FORCE CATHETER WITH A FLEXIBLE TIP.

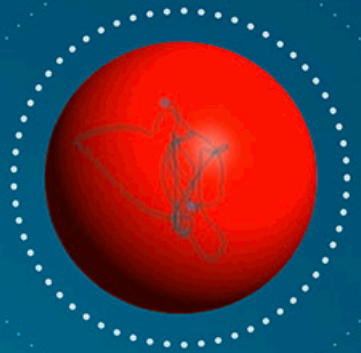
**TACTICATH™** ABLATION CATHETER, SENSOR ENABLED™



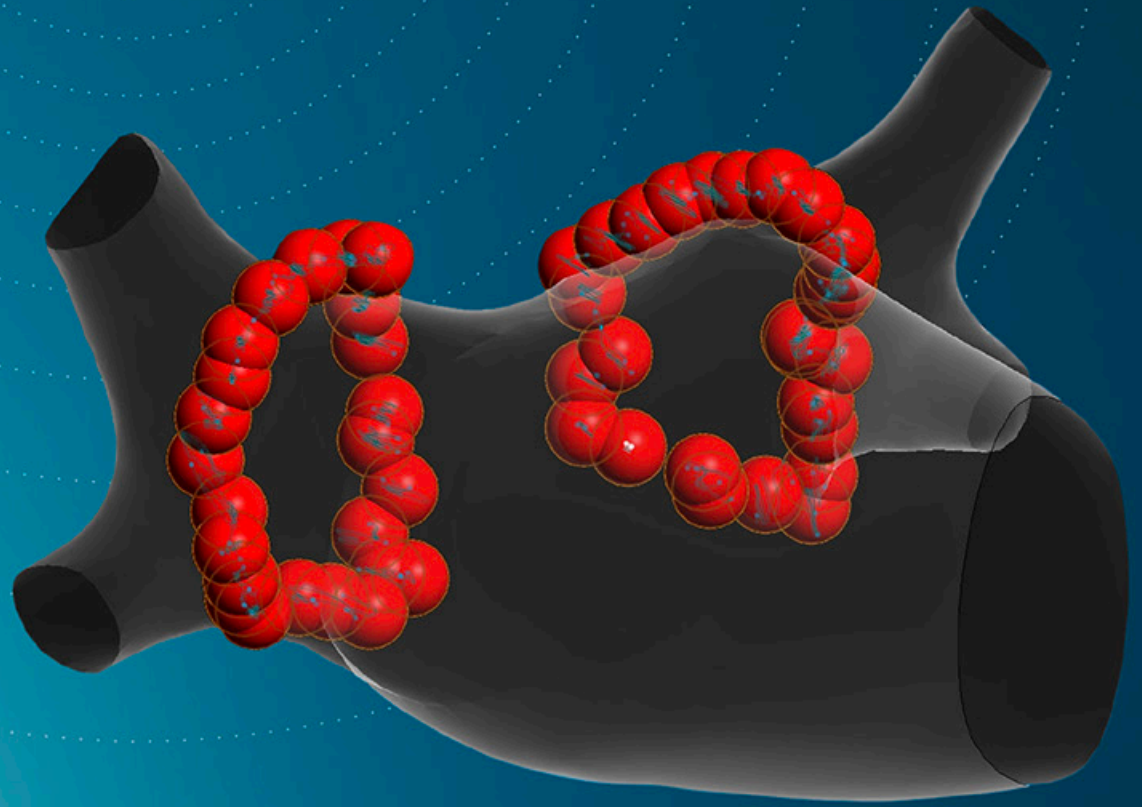
**TACTIFLEX™** ABLATION CATHETER, SENSOR ENABLED™



# STABILITY VISUALIZED



AUTO TRACK SOFTWARE
DEMONSTRATES
**SUPERIOR STABILITY**
DURING RF APPLICATION



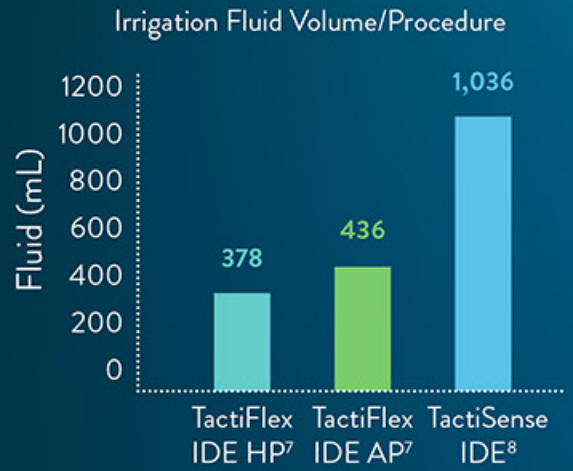
SAFETY

# FINANCIAL IMPACT OF SAME-DAY DISCHARGE (SDD)

TactiFlex™ Ablation Catheter, Sensor Enabled™ **HIGH-POWER** vs. TactiCath™ Ablation Catheter, Sensor Enabled™

## REDUCE IRRIGATION FLUID VOLUME

By an average of **63%***




## BENEFITS

- Excess fluid loading during RF can cause **VOLUME OVERLOAD** occasionally causing HF[20]
- **PROLONGED POST-PROCEDURE RECOVERY** is a significant barrier to SDD[13]
- SDD could have occurred in **63%** of patients if avoidable barriers were addressed[13]
- The financial gain from SDD would have ranged from **$1,110,096** (assuming discharge of 63% of eligible patients) to **$1,480,128** (assuming 80% discharge) over the course of a year[13]

HP: High-power (40-50W)
AP: All power levels up to 50W
*TactiFlex Ablation Catheter, SE IDE HP vs TactiSense IDE

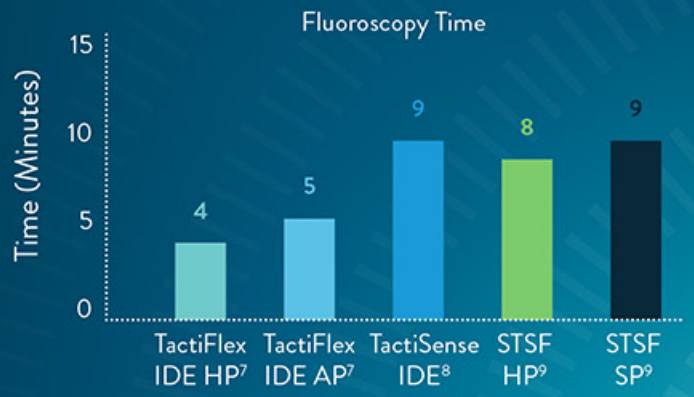
SAFETY

# LOWER CANCER RISK WHILE MINIMIZING THE RISK OF ORTHOPEDIC INJURIES[22]

TactiFlex™ Ablation Catheter, Sensor Enabled™ vs. TactiCath™ Ablation Catheter, Sensor Enabled™ and SmartTouch SF‡

## REDUCE FLUOROSCOPY TIME

By an average of **55%***




## BENEFITS

WEARING RADIATION PROTECTIVE APPAREL IS CAUSING INTERVENTIONALIST DISC DISEASE[14,15]

Among interventionalists and support staff:

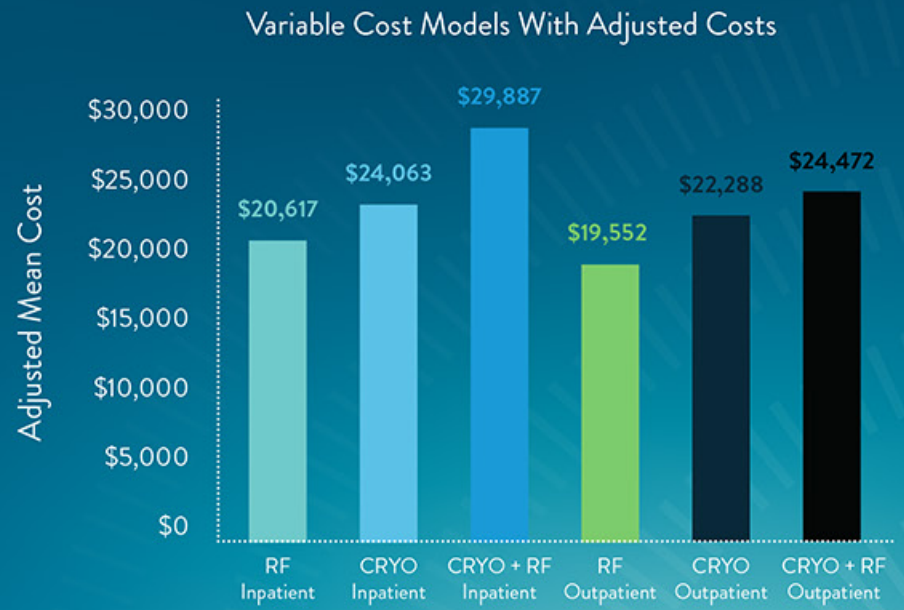
**44-62%** respectively, suffered from musculoskeletal pain[14]

**25%** had work-limitations due to spine problems[15]

*TactiFlex Ablation Catheter, SE HP vs TactiCath Ablation Catheter, SE and SmartTouch SF‡ SP

# COST COMPARISON OF RADIOFREQUENCY CATHETER ABLATION **VERSUS** CRYOABLATION FOR ATRIAL FIBRILLATION IN HOSPITALS USING **BOTH TECHNOLOGIES**

- A total of **2,537** procedures (**514** inpatient and **2023** outpatient) were identified in 13 hospitals
- The allocation of procedures by cohort was **1,261** RF and **1,276** Cryo, with the Cryo cohort comprised of **60.8%** (776 patients) having Cryo ablation only and **39.2% (500 PATIENTS) REQUIRING ADDITIONAL RF ABLATIONS**




Hunter et al. Journal of medical economics, 2016 vol. 19, no. 10, 959–964

# ECONOMIC VALUE PROPOSITION

| | SAFETY | EFFICIENCY | COST |
|---|---|---|---|
| **PATIENT** | • Decreased fluid requirements reduces risk of fluid overload in patients<br>• Contact force reduces risk of esophageal fistulas & phrenic nerve stimulation[21] | • Patient experience improves due to shorter procedures and increased potential for same-day discharge | • Cost to patient is reduced due to **SHORTER PROCEDURE TIMES,** lower complications, shorter anesthesia times, and the potential for same day discharge<br>• High rate of first pass isolation decreases reintervention rates |
| **PROVIDER** | • **55% DECREASED** x-ray time for physicians, staff and patients<br>^TactiFlex Ablation Catheter, SE HP | • **81.8%** first pass isolation<br>• **50 MINUTE** reductions/procedure<br>• Signal quality during ablation<br>• Catheter stability<br>^TactiFlex Ablation Catheter, SE HP | • Additional case volume revenue =**$23,481/ PROCEDURE**[6]<br>• Return **50 MINUTES** of time to MD for patient care and RVU billing |
| **PAYOR** | • Lower complication rates<br>• Reduced readmissions | • Only 1.3% needed additional ablation within the first 90 days<br>• Potential for same day discharge | • Cost of RF catheter ablations is **SIGNIFICANTLY LESS THAN CRYO**<br>• Potential for shorter length of stay |

* Up to 50W
** Compared to TactiCath Ablation Catheter, Sensor Enabled flow rates at all power levels and compared to SmartTouch SF‡ flow rates above 30W.
*** Compared to standard power ablation (50W vs. 30W)


1. Ptaszek LM et al. Safe and effective delivery of high-power, short-duration radiofrequency ablation lesions with a novel, flexible-tip radiofrequency ablation catheter [abstract]. In: Heart Rhythm 2021: July 28-31, Boston. Heart Rhythm Volume 18, Issue 9, Supplement. Elsevier; 2021. Abstract nr B-PO02-109.
2. Compared to TactiCath SE and EnSite Precision™. Abbott reports 90486839 and 90773365.
3. Abbott report 90486839.
4. Abbott report 90906650.
5. Ambrosius Nick, Fish Jeffrey, Tranter John, Abbott Laboratories. Flexible, kerfed ablation catheter tip provides superior stability in a bench model [abstract]. In: APHRS 2018: Abstract Book;
6. Creating a 5-step Process to Improve EP Lab Efficiency Sri Sundaram et al. EP Lab Digest
7. CL1017540 TactiFlex PAF IDE PMA Report
8. Abbott report CL1021674.
9. Dhillon et al. J Cardiovasc Electrophysiol. 2019;30:357–365.
10. CL1019990 TactiFlex PAF IDE As Treated Repeat Procedure Details.
11. Osorio et al. J Cardiovasc Electrophysiol. 2021;32:1814–1821
12. Mansour et al JACC 2017
13. Chu et al. Pacing Clin Electrophysiol. 2021;44:711–719
14. Orme N, et al.. J Am Coll Cardiol 2015;65:820–6
15. Klein L, et al. J Vasc Interv Radiol 2009; 20:147–153
16. De Potter, T. Temperature- Controlled Catheter Ablation for Paroxysmal Atrial Fibrillation: The QDOT-MICRO Workflow Study. Journal of Atrial Fibrillation. 2021; 13(6).
17. Lepillier, A., et al. Impact of Ablation Index Settings on Pulmonary Vein Reconnection. Journal of Interventional Cardiac Electrophysiology. 2022; 63: 133-142.
18. Muller, J., et al. Acute Oesophageal Safety of High-Power Short Duration with 50W for Atrial Fibrillation Ablation. Europace. 2022; 24: 928-937.
19. Mulder, M et al. Radiofrequency ablation to acheive durable pulmonary vein isolation. Europace. 2021; 00:1-13.
20. Sato T, Yoshimoto I, Oketani N, Okui H, Iriki Y, et al. (2019) Predictors of Heart Failure Caused by Volume Overload Using an Irrigation Catheter during Catheter Ablation for Atrial Fibrillation. Int J Clin Cardiol 6:155. doi.org/10.23937/2378-2951/1410155
21. Reduced esophageal heating in high-power short-duration atrial fibrillation ablation in the contact force catheter era; VASSALLO et al, Pacing Clin Electrophysiol. 2021;44:1185–1192.
22. Casella M, et al. (2015). Near zero fluoroscopic exposure during catheter ablation of supraventricular arrhythmias: the NO-PARTY multicentre randomized trial. Europace (2016) 18, 1565–1572. doi:10.1093/europace/euv344.


**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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