Biosense Webster®
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QDOT MICRO™
Catheter

The Value of QDOT MICRO™ Catheter Technology

ADVANCEMENT IN RADIOFREQUENCY CATHETER ABLATION OF ATRIAL FIBRILLATION

Radiofrequency (RF) catheters with irrigation and contact force technology are the most advanced and most commonly used technologies for the ablation of atrial fibrillation (AF), providing superior performance as compared to other available modalities.[1-5] However, technological advancement that enables shortening the duration of ablation via use of high-power (>40W) and short duration (4s) ablations has the potential to further enhance procedural efficiency and improve patient outcomes.[6]

Effective RF ablation of AF is dependent on catheter stability, contact force, power output, ablation time, and temperature.[4] Measurements of the temperature at the catheter-tissue interface may fluctuate and require operators to carefully control RF power output to ensure safe tissue temperatures and achieve optimal outcomes.[5]

Standard RF ablation procedures are conducted at 20W-40W,[7;8] which may lead to lengthy **procedure times.**[1-3]

Lengthy application of low RF power may **increase the risk of damage to surrounding tissues**, such as the esophagus, which may increase the risk of atrioesophageal fistula.[7-11]

Fluctuations in temperature measurement and conservative use of RF power may **increase the risk of imprecise lesion formation.**[7;12-14]

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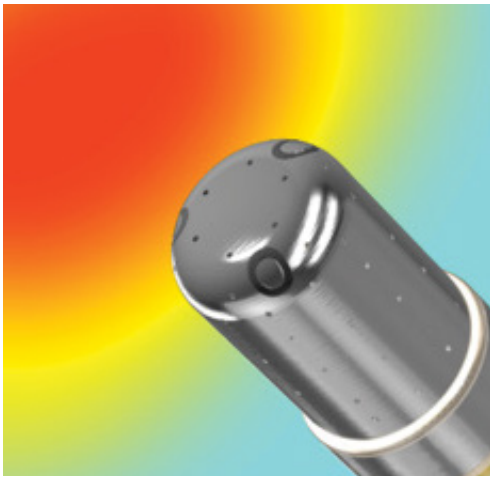
QDOT MICRO™ TECHNOLOGY: INNOVATION IMPROVING OUTCOMES

QDOT MICRO™ Technology enables automation of key ablation parameters to standardize and optimize RF energy delivery, which is enabled by thermocouples providing real-time feedback on catheter surface temperature. This technology provides temperature control, enables a high power, short duration workflow and allows for high-resolution substrate mapping capabilities.

OPTIMIZED TEMPERATURE CONTROL

QDOT MICRO™ Technology has been designed to **provide temperature control through automatic adjustment of power and fluid output** based on real-time temperature measurement. Use of higher average RF power with QDOT MICRO™ Technology is safely enabled by this precise temperature control.[1-7;15-16]

HIGH POWER, SHORT DURATION ABLATION



The temperature control of QDOT MICRO™ Technology allows for the **safe use of higher RF power (up to 90 Watts)** in short bursts (up to 4 seconds) in QMODE+™ Ablation Mode to improve ablation efficiency without compromising safety.[7;11;16-18]

Compared to conventional contact force sensing catheters, high-power short duration (vHP-SD, 90 W/4 s) QDOT MICRO™ Catheter (QMODE+™ Ablation Mode based PVI) provides comparably safe and effective PVI.[6;15-18]

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VALUE OF QDOT MICRO™ TECHNOLOGY

Innovative QDOT MICRO™ Technology enables improved procedure efficiency, allows for very low complication rates, facilitates the reduction of fluid delivery and fluoroscopy time, while providing excellent efficacy.

IMPROVED EFFICIENCY

60MIN
PROCEDURE DURATION WITH QMODE+™ ABLATION MODE[6;16-20]

Ablation with the QDOT MICRO™ Catheter has demonstrated a **median procedure duration of ~60 minutes** as compared to a median ~105 minutes with conventional CF-sensing catheters.[6;16-20]

UP TO 49%
SHORTER PROCEDURE TIME[2-3;11;16;21-22]

Ablation using QDOT MICRO™ Catheter can **reduce procedure time by up to 49%** as compared to standard contact force catheters. [1-3;11;16;23-24*] QDOT MICRO™ Technology is also compatible with VISITAG SURPOINT™ Module (i.e. Ablation Index), which may allow for a greater potential reduction in procedure time.[6;22]

Comparison of QDOT MICRO™ Technology to other studies of conventional contact force (CF) catheters for total procedure time.

* Data for conventional CF catheters is the average (204.7 min) of THERMOCOOL SMARTTOUCH® SMART-AF (Natale *et al*, 2014; n=160, 222.0 min), THERMOCOOL SMARTTOUCH® SMART-SF (Chinitz *et al*, 2018; n=159, 181.1 min), and TactiCath TOCCATA (Reddy *et al*, 2012; n=34, 211.0 min).

** QDOT QFFICIENCY (Osorio *et al* 2022) reported a median procedure time, whereas all other studies reported mean procedure times.

† QDOT QFFICIENCY (Osorio *et al*, 2022), and TactiCath TOCCASTAR (Reddy *et al*, 2015), studies report a median procedure time, whereas the other studies ported in this graph report mean procedure times.[6;11;16;22;29]

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REDUCED ABLATION TIME

UP TO 62%
SHORTER ABLATION TIME WITH QMODE+™ ABLATION MODE
11;16;21-22;24-25

Total ablation time with QDOT MICRO™ Technology in QMODE+™ (very high power, short duration RF bursts) was **up to 62% shorter** than with conventional contact force catheter ablation technologies[11;16;21-22;24-25]

† Based on a weighted average of the procedure time with QDOT MICRO™ Technology in QMODE+™ Ablation Mode (129.8 min; N = 42) and in QMODE+™ Ablation Mode (105.2 min; N = 52), and the weighted average of the procedure time with irrigated, contact force RF catheters (202.8 min; 5 studies, N = 622).[1-3;11;26-27]
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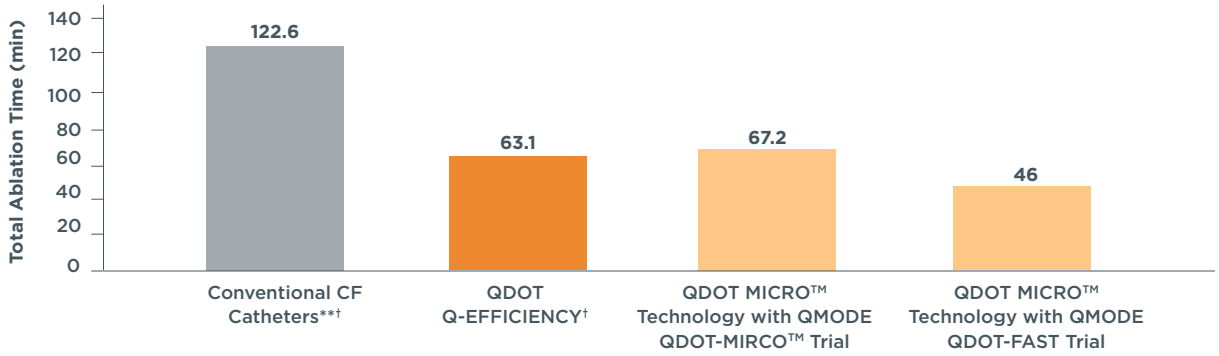


Comparison of QDOT MICRO™ Technology to other studies of conventional contact force (CF) catheters for total ablation time.

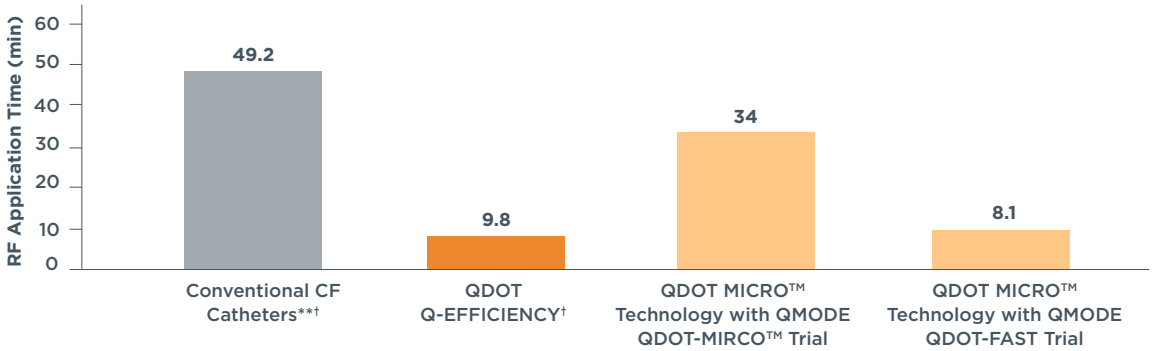
* Data for conventional CF catheters is the average (122.6 min) of THERMOCOOL SMARTTOUCH® SMART-AF (Natale *et al*, 2014; n=160, 121.5 min), THERMOCOOL SMARTTOUCH® SMART-SF (Chinitz *et al*, 2018; n=159, 104.3 min), TactiCath TOCCATA (Reddy *et al*, 2012; n=34, 218.0 min), and TactiCath TOCCASTAR (Reddy *et al*, 2015; n=152, 46.5 min).

** QDOT QFFICIENCY (Osorio *et al*, 2022) and TactiCath TOCCASTAR (Reddy *et al*, 2015) studies reported a median total ablation time, whereas all other studies reported mean total ablation times.[6;11;16;22;29]

REDUCED RF APPLICATION TIME

UP TO 84%
REDUCTION IN RF APPLICATION TIME WITH QMODE+™ ABLATION MODE 3;11;16;21-22

In the QDOT QFFICIENCY trial, QDOT Technology had **up to 84% shorter RF application time** than conventional contact force catheters.[3;11;16;21;28]



Comparison of QDOT MICRO™ Technology to other studies of conventional contact force (CF) catheters for RF application time.

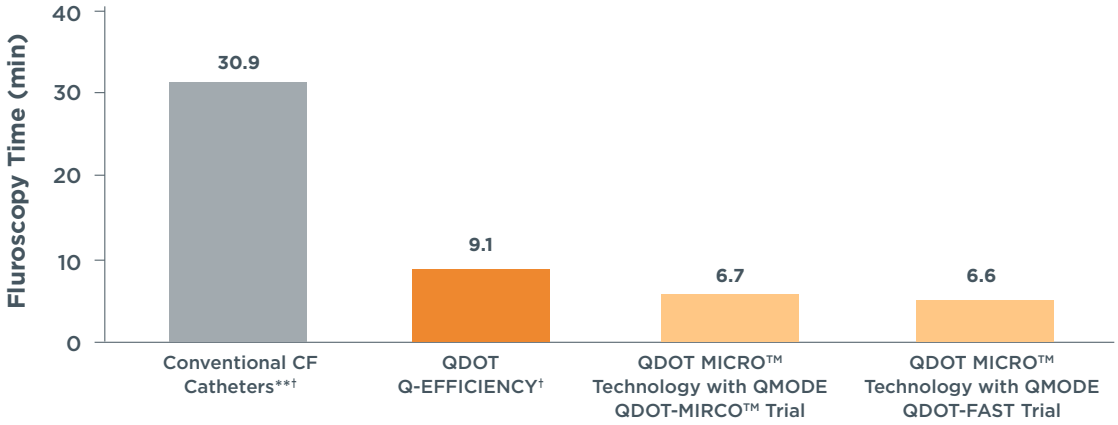
* Data for conventional CF catheters is the average (49.2 min) of THERMOCOOL SMARTTOUCH® SMART-AF (Reddy *et al*, 2019, n=160, 60.6 min), THERMOCOOL SMARTTOUCH® SMART-SF (Chinitz *et al*, 2018; n=159, 49.5 min), and TactiCath TOCCATA (Reddy *et al*, 2012, n=34, 37.6 min).

** QDOT QFFICIENCY (Osorio *et al*, 2022)) reported a median RF application time, whereas all other studies reported mean RF application times[6;11;16;22;29]

REDUCED FLUOROSCOPY EXPOSURE

UP TO 79% SHORTER MEAN FLUOROSCOPY TIME
1-3;11;16;19;21-22;27;29;33

RF ablation with QDOT MICRO™ technologies had **up to 79% shorter mean fluoroscopy time** compared to conventional contact force catheters.[1-3;11;16;19;21-22;26-27]



Comparison of QDOT MICRO™ Technology to other studies of conventional contact force (CF) catheters for fluoroscopy time.

* Data for conventional CF catheters is the average (30.9 min) of THERMOCOOL SMARTTOUCH® SMART-AF (Natale *et al*, 2014; n=160, 41.5 min), THERMOCOOL SMARTTOUCH® SMART-SF (Chinitz *et al*, 2018; n=159, 18.6 min), TactiCath TOCCATA (Reddy *et al* 2012; n=34, 36.3 min), and TactiCath TOCCASTAR (Reddy *et al*, 2015, n=150, 27.0 min).

** QDOT QFFICIENCY (Osorio *et al*, 2022) and TactiCath TOCCASTAR (Reddy *et al*, 2015) studies reported a median fluoroscopy time, whereas all other studies reported mean fluoroscopy times.[6;11;16;22;29]

PROCEDURES PERFORMED UNDER MILD CONSCIOUS SEDATION[19]

In a retrospective study 90% of patients treated with very high-power short duration (vHPSD) ablations were **successfully performed under mild conscious sedation**.[19]

LOW COMPLICATION RATE

Very high-power, short duration ablation **may help to reduce the incidence of complications** associated with poor catheter stability and tip-to tissue contact.[11]

EXCELLENT SAFETY PROFILE WITH QDOT MICRO™ TECHNOLOGY[16-19]

In prospective, non-randomized, multicenter studies, **catheter ablation with QDOT MICRO™ Technology** was associated with no incidence of steam pops or charring. Use of QMODE+™ Ablation Mode was associated with **no incidence of stroke, atrioesophageal fistula, and PV stenosis.**[1;2;6;11;23;26]

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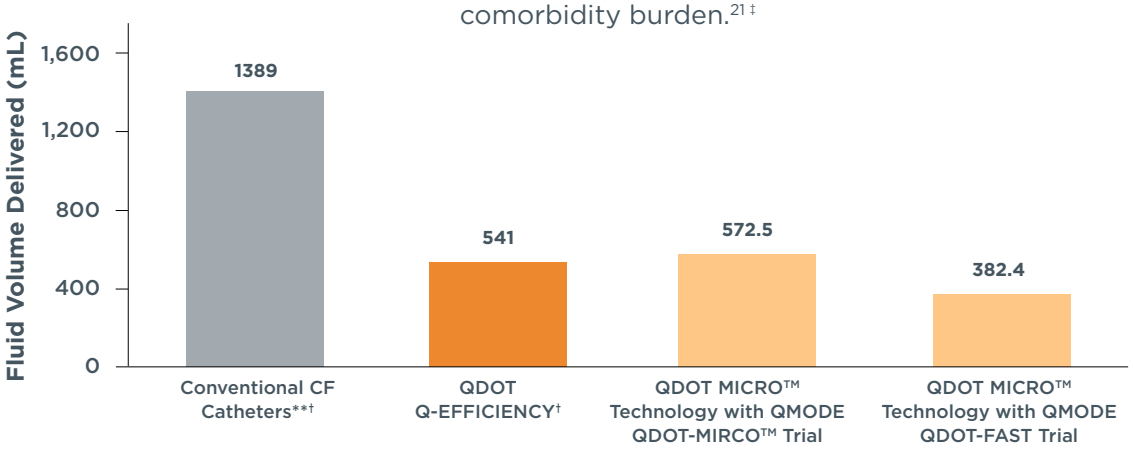
REDUCED FLUID DELIVERY

Excessive fluid delivery during RF ablation can increase the risk of complications, including fluid overload, heart failure, acute exacerbation of heart failure, acute respiratory distress, hypoxia, and pulmonary edema.[35-38]

UP TO 72%
LESS FLUID DELIVERED WITH QMODE MICRO™ TECHNOLOGY[11;16-17;21-22;29]

QDOT MICRO™ Technology delivered 72% less fluid with QMODE+™ Ablation Mode and **59% less fluid** with QMODE™ Ablation Mode than conventional contact-force catheter ablation technology.[11;16-17;21-22;26*†]

Delivery of less fluid during ablation may reduce the risk of complications, particularly in patients with a high comorbidity burden.[21 ‡]



Comparison of QDOT MICRO™ Technology to other studies of conventional contact force (CF) catheters for fluid volume.

* Data for conventional CF catheters is the average (1389.0 mL) of THERMOCOOL SMARTTOUCH® SMART-AF (Natale *et al,* 2014; n=158, 1879.6 mL) and THERMOCOOL SMARTTOUCH® SMART-SF (Chinitz *et al*, 2018; n=156, 898.4 mL).

** QDOT QFFICIENCY (Osorio *et al,* 2022) reported a median fluid volume, whereas all other studies reported mean fluid volumes.[6;11;16;22;29]

EFFICACY

HIGHER
PROBABILTY OF FIRST PASS ISOLATION[39]

A prospective study (156 patients) using very high-power short duration (vHPSD) ablation was associated with a higher probability of first-pass isolation compared to low-power long-duration (LPLD) ablation (OR = 2.90, p = 0.014).[39]

FREEDOM FROM ARRHYTHMIA AT 12 MONTHS

86%
OF PATIENTS ARE ARRHYTHMIA-FREE AT 12 MONTHS[16]

In a retrospective analysis, **86.6% of patients were free from recurrence of atrial arrhythmia** after ablation procedures using QMODE+™ ablation mode.[11;16;18-20;29]

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QDOT MICRO™ Uni-Directional Navigation Catheter Biosense Webster
The Biosense Webster QDOT MICRO™ Uni-Directional Catheter is a steerable multi-electrode luminal catheter with a deflectable tip designed to facilitate electrophysiological mapping of the heart and to transmit radiofrequency (RF) energy to the catheter tip electrode for ablation purposes.

Indications for Use
The Biosense Webster QDOT MICRO™ Uni-Directional Navigation Catheter and related accessory devices are indicated for catheter-based cardiac electrophysiological mapping (stimulating and recording) and, when used in conjunction with a compatible radiofrequency generator, for cardiac ablation. The Biosense Webster QDOT MICRO™ Uni-Directional Navigation Catheter
provides a real-time measurement of temperature and contact force between the catheter tip and heart wall, as well as location information when used with the CARTO™ 3 System.

Contraindications
Do not use this catheter:
1. If the patient has had a ventriculotomy or atriotomy within the preceding eight weeks because the recent surgery may increase the risk of perforation.
2. In patients with a myxoma or an intracardiac thrombus as the catheter could precipitate an embolus.
3. In patients with prosthetic valves as the catheter may damage the prosthesis.
4. In the coronary arterial vasculature due to risk of damage to the coronary arterial vasculature.
5. In patients with an active systemic infection because this may increase the risk of cardiac infection.
6. Via the transseptal approach in a patient with an interatrial baffle or patch because the opening could persist and produce an iatrogenic atrial shunt.
7. Via the retrograde trans-aortic approach in patients who have had aortic valve replacement.
8. With a long sheath or short introducer < 8.5 F in order to avoid damage to the catheter shaft.

Warnings and Precautions
Do not use excessive force to advance or withdraw the catheter when resistance is encountered during catheter manipulation through the sheath. Do not manually pre-shape the distal shaft of the catheter by applying external forces intended to bend or affect the intended shape or curve of the catheter. Prior to use, the catheter must be warmed up as specified in the Directions for Use section. If the catheter has not reached a steady state condition, there is potential for a zero-offset drift to occur which could result in an inaccurate contact force reading.

For all product details please consult the IFU (instruction for use) of this product.

For product details such as indications, contraindications, warnings and precautions please consult the IFU. This publication is not intended for distribution outside of the EMEA region.
This summary has been written by Biosense Webster (Europe), a division of Johnson & Johnson Medical NV/SA based on the referenced article, and is provided for information purposes only.
Important information: Prior to use, refer to the instructions for use supplied with the device for indications, contraindications, side effects, warnings and precautions.

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