

# TactiCath Quartz catheter for percutaneous radiofrequency ablation in atrial fibrillation

Medtech innovation briefing

Published: 23 March 2016

[www.nice.org.uk/guidance/mib60](http://www.nice.org.uk/guidance/mib60)

## Summary

TactiCath Quartz is a single-use cardiac ablation catheter with a deflectable distal section and a contact force sensor at the tip. It is used to treat cardiac arrhythmias, such as atrial fibrillation, by delivering radiofrequency energy during ablation procedures. It may also be used to map the electrical activity of the heart, pace or confirm electrical isolation.

TactiCath Quartz differs from standard ablation catheters by providing a real-time measurement of the contact force applied by the catheter tip to the heart wall during the ablation procedure. The evidence from 3 comparative studies is of limited quantity and quality. In the TOCCASTAR randomised controlled trial, TactiCath achieved non-inferior efficacy and safety outcomes compared with pulmonary vein isolation using a non-contact force-sensing catheter. The list price of TactiCath Quartz is £3,565 (excluding VAT), but additional components are needed for the ablation procedure.

NICE has also published a medtech innovation briefing on the [ThermoCool SmartTouch catheter](#).

<b>Product summary and likely place in therapy</b>	<b>Effectiveness and safety</b>
<ul style="list-style-type: none"><li>• TactiCath Quartz is a single-use radiofrequency ablation catheter with a deflectable distal section and a contact force sensor at the tip.</li><li>• It delivers radiofrequency ablation as well as providing real-time contact force measurements during cardiac ablation procedures. TactiCath Quartz may also be used to map the electrical activity of the heart, pace or confirm electrical isolation.</li><li>• It would be used in people with cardiac arrhythmias requiring ablation, including people diagnosed with symptomatic atrial fibrillation, and would replace conventional radiofrequency ablation catheters without contact force-sensing technology.</li><li>• NICE has also published a medtech innovation briefing on the <a href="#">ThermoCool SmartTouch catheter</a>.</li></ul>	<ul style="list-style-type: none"><li>• The published evidence summarised in this briefing used the TactiCath catheter (the predecessor to TactiCath Quartz) and is limited in quantity and quality. The main evidence comes from 510 patients across 1 randomised controlled trial, 1 non-randomised prospective comparative study and 1 non-randomised retrospective comparative study.</li><li>• The TOCCASTAR randomised controlled trial compared TactiCath (n=152) with a non-contact force-sensing catheter (n=146). This study showed non-inferiority of TactiCath in device and procedural safety and effectiveness at 12 months.</li><li>• A non-randomised study which compared TactiCath (n=32) with a non-contact force-sensing catheter (n=35) showed a statistically significant reduction in total procedural time (78 minutes compared with 96 minutes) for the TactiCath catheter, but no statistically significant difference in recurrence of atrial fibrillation at 6 or 12 months.</li><li>• A non-randomised study involved a retrospective analysis of local registry data, comparing TactiCath (n=31) with a non-contact force-sensing catheter (n=112). The analysis showed a statistically significant reduction in total procedural time (128 minutes compared with 158 minutes) and a statistically significant reduction in the recurrence of atrial fibrillation at 12 months (16.1% compared with 36.6%) using the TactiCath catheter.</li></ul>

Technical and patient factors	Cost and resource use
<ul style="list-style-type: none"><li>• TactiCath Quartz would be used in the cardiac catheterisation laboratory of a secondary or tertiary care hospital. It would be used by cardiac electrophysiologists who have appropriate training.</li><li>• The TactiCath Quartz catheter must be used with the TactiSys Quartz system to visualise the contact force applied. The manufacturer recommends a contact force between 10 g and 30 g during a cardiac ablation procedure.</li><li>• NICE has published interventional procedures guidance on <a href="#">percutaneous radiofrequency ablation for atrial fibrillation</a>.</li></ul>	<ul style="list-style-type: none"><li>• The list price of a single-use TactiCath Quartz catheter is £3,565. A steerable introducer sheath may also be needed which costs from £1,178 to £1,364. A TactiSys Quartz system is also necessary and costs £25,730 (excluding VAT).</li><li>• A compatible radiofrequency generator and irrigation system are also needed for the ablation procedure, although they may be readily available in cardiac catheterisation laboratories.</li><li>• Conventional radiofrequency ablation catheters without contact force-sensing technology are available from St. Jude Medical, ranging in cost from £1,147 to £3,255. Separate circular mapping catheters (to confirm electrical pulmonary vein isolation) are also available from St. Jude Medical, ranging in cost from £1,550 to £2,170.</li><li>• No evidence on cost effectiveness or resource consequences was identified from the literature review.</li></ul>

## Introduction

Atrial fibrillation is the irregular and rapid beating of the upper 2 chambers of the heart (the atria), caused by the disruption of the electrical signals that control the heartbeat. In many cases of atrial fibrillation, extra electrical signals start in the area around the opening of the pulmonary veins (the large blood vessels that return blood from the lungs to the left atrium) causing the heart to beat erratically. It is 1 of the most common causes of abnormal heart rhythm with an estimated prevalence of 2% in England (Zoni-Berisso et al. 2014). Atrial fibrillation is associated with a 4- to 5-fold increase in the risk of stroke (British Heart Foundation 2015), and people with atrial fibrillation may be prescribed anticoagulants to minimise their risk of having a stroke (see the NICE guideline on [the](#)

management of atrial fibrillation).

People with atrial fibrillation may be asymptomatic or experience symptoms such as palpitations, dizziness, breathlessness and fatigue (NHS Choices 2015). Atrial fibrillation can be classified as paroxysmal (an intermittent episode of atrial fibrillation which spontaneously terminates within 7 days, and usually within 48 hours), persistent (an episode lasting longer than 7 days) or permanent. Paroxysmal atrial fibrillation can progress to the permanent form (Jahangir et al. 2007).

Treatment options for atrial fibrillation include medication to control the rate or rhythm of the heart, or electrical cardioversion in which an electric current is used to restore a normal regular heart rhythm. Catheter ablation is recommended for patients when they cannot have drug therapy (January et al. 2014). It is used to block the erratic electrical signals. Pulmonary vein isolation (PVI) is the most commonly used catheter ablation technique. PVI is usually done using laser energy, radiofrequency energy or intense cold to ablate (destroy) a small area of tissue in the left atrium of the heart at the opening of the pulmonary veins. The resulting scar tissue prevents electrical signals originating from the cells within the pulmonary veins entering the heart. This process is conducted around the opening of the pulmonary veins. A mapping catheter positioned in each pulmonary vein is used to confirm entrance and exit block of the electrical signals after ablation. Pulmonary vein mapping and isolation is usually confirmed using a separate circular mapping catheter.

For PVI using ablation, clinicians must estimate the amount of contact force necessary to create effective scar tissue around the pulmonary veins. Failure to create durable scar tissue may allow the electrical signals to reconnect with the left atrium, which increases the likelihood of atrial fibrillation recurring (Neuzil et al. 2013). However, the application of too much force increases the risk of tissue injury or perforation of the wall of the heart, which can lead to serious complications. Catheters measuring real-time contact force during ablation procedures provide clinicians with direct feedback and may improve both the efficacy and safety of ablation procedures (Gerstenfeld 2014).

## Technology overview

This briefing describes the regulated use of the technology for the indication specified, in the setting described, and with any other specific equipment referred to. It is the responsibility of healthcare professionals to check the regulatory status of any intended use of the technology in other indications and settings.

## About the technology

### CE marking

Endosense SA was awarded a CE mark for the original TactiCath force-sensing ablation catheter as a class III device in 2009. This was superseded by the third generation TactiCath Quartz ablation catheter, which was CE-marked in 2012.

Endosense SA was acquired by St Jude Medical in August 2013. St. Jude Medical was awarded a CE mark for the TactiCath Quartz in 2014, with the current certification dated October 2015.

The TactiCath Quartz catheter requires the TactiSys Quartz system with analysis software and display workstation to visualise the contact force information. Endosense SA was awarded a CE mark for the TactiSys Quartz system as a class IIb device in 2012.

Current certifications for TactiCath Quartz and the TactiSys Quartz system expire in January 2019 and September 2017 respectively.

### Description

TactiCath Quartz is a flexible catheter with a deflectable distal section and a contact force sensor at the tip which is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and cardiac ablation to treat supraventricular arrhythmias, including atrial fibrillation. It provides a real-time measurement of the contact force applied by the catheter tip to a patient's heart wall during an ablation procedure, using white light interferometry. This is designed to give clinicians more control than with a standard catheter by monitoring and modifying the applied force in order to create more effective scar tissue, and prevent accidental damage, during ablation procedures.

TactiCath Quartz is a single-use device with an overall length of 115 cm. It has a 7 Fr outer diameter and is available with either a 65 mm or 75 mm deflectable distal section. It consists of the following components:

- A deflectable distal section which includes 4 platinum-iridium electrodes, a 3.5 mm tip electrode and 3 ring electrodes (spaced 2 mm, 5 mm, 2 mm apart). All of the electrodes can be used for stimulating and recording (for electrophysiological mapping), so a separate cardiac mapping catheter is not needed when using TactiCath Quartz for ablation. The tip electrode also delivers the radiofrequency current to the desired ablation site and is irrigated.
- A hand-piece that controls the deflection of the distal section.
- A thermocouple temperature sensor embedded in the tip electrode.
- A tri-axial optical force sensor embedded in the distal section of the catheter. This has a resolution and sensitivity of approximately 1 g and measures the contact force magnitude and orientation every 100 milliseconds.
- A saline input port with a standard luer fitting at the proximal end of the catheter. This allows the injection of isotonic saline solution to 6 holes located at the tip of the catheter to irrigate and cool the tip electrode and ablation site during the ablation phase of the procedure.

The TactiSys Quartz system connects the radiofrequency generator, the computer with proprietary analysis software (TactiSoft) and the TactiCath Quartz catheter. TactiCath Quartz has separate electrical and optical connectors which plug into the TactiSys Quartz system. Light emitted by the TactiSys Quartz system through the ablation catheter is reflected through cavities in the catheter tip, creating interference between light beams. The pattern of interference changes when contact force is applied by the catheter. These patterns are returned through the catheter and then analysed by the TactiSys Quartz system. The software calculates both the magnitude and orientation of the contact force applied (in a similar manner to Fabry-Perot interferometry, Liu et al. 2012) and are displayed on a screen.

Additional software from St. Jude Medical is needed for 3D mapping of the signal data. This consists of either:

- TactiSoft software on a standalone computer and display screen (included in the TactiSys Quartz system), or
- EnSite contact force module, which integrates the contact force information into the EnSite velocity cardiac mapping system (which includes a display workstation), which may already be in use in a cardiac catheterisation laboratory.

Additional components needed for the ablation procedure include:

- A compatible radiofrequency generator (only the Ampere generator, St. Jude Medical or the Stockert 70 Generator with software version 1.037, Stockert Medical Solutions are compatible).
- A compatible irrigation pump and irrigation tubing, such as the Cool Point, irrigation pump (St. Jude Medical) or COOLFLOW pump (Biosense Webster), which connects to the catheter saline port's luer fitting.
- An introducer sheath with a minimum diameter of 8.5 Fr to insert the catheter into a large central blood vessel, usually the femoral vein. A steerable introducer sheath may be used to aid catheter handling.
- A separate disposable dispersive pad (indifferent patch electrode) which completes the ablation circuit. This usually connects to the patient's back, but can be placed at other locations to permit maximal skin contact.

TactiCath Quartz is inserted through the introducer sheath and manually moved through the blood vessels in order to map the site of the abnormal heart rhythm. Fluoroscopy and electrocardiograms are used to aid catheter positioning. When the site is identified, the same TactiCath Quartz catheter is used to carry out the ablation and deliver radiofrequency energy (at a recommended contact force of 10 g to 30 g. This blocks the electrical path that causes the abnormal heart rhythm. TactiCath Quartz transmits contact force information (calculated by the TactiSys Quartz system) to the clinician throughout the procedure, using the TactiSoft software on a standalone computer or the EnSite Velocity cardiac mapping system. TactiCath Quartz is also used to confirm entrance and exit block of the electrical impulse (that is successful PVI) during the procedure. The catheter is removed after treatment. In some cases the clinician may prefer to use a separate mapping catheter to identify the site of the abnormal heart rhythm and confirm electrical isolation of the pulmonary veins. A separate mapping catheter can be used simultaneously, sequentially or interchangeably with TactiCath Quartz.

## Setting and intended use

TactiCath Quartz would be used in a cardiac catheterisation laboratory during percutaneous PVI. It would be used by cardiac electrophysiologists trained in cardiac ablation who have appropriate training on TactiCath Quartz and the TactiSys Quartz system. The procedure is usually done with the patient under local anaesthesia and

sedation, although PVI can also be done under general anaesthesia according to patient or centre preference.

TactiCath Quartz and its additional components are indicated for catheter-based cardiac ablation when used with a compatible radiofrequency generator, and also for cardiac electrophysiological mapping.

Contraindications for use are similar to other cardiac ablation catheters, and include: cardiac surgery within previous 4 weeks; artificial heart valves; active systemic infection; use in coronary vasculature; myxoma (a heart tumour) or intracardiac thrombus (blood clot); trans-septal approach in patients with an interatrial baffle or patch; and retrograde trans-aortic approach in patients with aortic valve replacement.

## Current NHS options

NICE guidance on the [management of atrial fibrillation](#) recommends offering people a personalised care package of information and prompt referral for specialised management if treatment fails to control symptoms at any stage. Recommended interventions include anticoagulation medications to reduce the risk of stroke, and heart rate and rhythm control (antiarrhythmic) medications or electrical cardioversion. Left atrial catheter ablation is recommended for people with paroxysmal atrial fibrillation, and considered in people with persistent atrial fibrillation, in whom drug treatment has failed to control their symptoms or is unsuitable. NICE interventional procedures guidance on [percutaneous radiofrequency ablation](#) states that the evidence for the safety and efficacy of this treatment for atrial fibrillation is adequate to support its use in appropriately selected patients, provided that normal arrangements are in place for audit and clinical governance. The guidance also states that clinicians should ensure that patients fully understand the potential complications, the likelihood of success and the risk of recurrent atrial fibrillation associated with this procedure. The guidance further recommends that the procedure should only be done in specialist units and with arrangements for cardiac surgical support in the event of complications, and should only be done by cardiologists with extensive experience of other types of ablation procedures. Other cardiac ablation procedures are described in related interventional procedures guidance (see [relevance to NICE guidance programmes](#)). Other available interventions include surgical lesions (by sternotomy, thoracoscopy or minimally invasive approaches) used alone or in combination with valve or revascularisation surgery to control heart rate.

NICE is aware of the following CE-marked devices that appear to fulfil a similar function to



TactiCath Quartz (and its additional components):

- [ThermoCool SmartTouch and SmartTouch SF](#) used with the CARTO 3 navigation system (Biosense Webster)
- [Artisan Extend Control Catheter](#) used with the Sensei X2 Robotic System (Hansen Medical).

NICE has produced a medtech innovation briefing on the [ThermoCool SmartTouch catheter](#).

## Costs and use of the technology

St. Jude Medical has provided the following list prices (excluding VAT) for each component of the TactiCath system:

- TactiCath Quartz ablation catheter: £3,565
- TactiSys Quartz system (including TactiSoft software): £25,730
- EnSite contact force module (which integrates with EnSite Velocity cardiac mapping system which may already be in use in the cardiac catheterisation laboratory): £21,700
- Optional steerable introducer sheath: £1,178 to £1,364.

These costs can be reduced for customised NHS contracts depending on volume and contract duration.

A radiofrequency generator (for example the Ampere generator, St. Jude Medical; £31,000), and irrigation pump (for example Cool Point Irrigation Pump, St. Jude Medical; £12,400) are also needed. These components could be used for other ablation procedures and may already be present in some cardiac catheterisation laboratories. A dispersive pad (not supplied by St. Jude Medical) is also needed.

TactiCath Quartz catheters are single-use and have been validated for a 2-year shelf-life. The TactiSys Quartz system has an anticipated lifespan of 7 years and comes with a 12-month warranty. It requires a force measurement calibration check every 450 days, which would normally be done by St Jude Medical product specialists.

Onsite training in the use of TactiCath Quartz and the TactiSys Quartz system is routinely provided by St. Jude Medical personnel or accredited trainers at no cost.

## Likely place in therapy

TactiCath Quartz would be used in people diagnosed with symptomatic atrial fibrillation when drug treatment has failed to control their symptoms (NICE guidance on the [management of atrial fibrillation](#)). It would replace conventional radiofrequency ablation catheters without contact force-sensing technology, which are typically used with a separate mapping catheter. The overall care pathway would not be changed.

## Specialist commentator comments

All 4 specialist commentators highlighted that the degree of contact between tissue and catheter is critical for successful pulmonary vein isolation. One specialist commentator noted that real-time dynamic contact force feedback during cardiac ablation procedures would enable operators to adjust catheter position, improve procedure efficacy and increase safety by avoiding the application of excessive force. One specialist commentator noted that only 1 published study (EFFICAS-II) has demonstrated that using the device leads to durable lesions by confirming PVI at follow-up. The study did not define how to achieve lesion durability but suggested a threshold contact force above which better outcomes were obtained. One specialist commentator noted that the consistent message from general published evidence is that contact force-guided ablation results in better isolation of the pulmonary veins, and improvement in clinical outcomes in addition to other surrogates such as procedure time and radiation dose, when compared with non-contact force-guided ablation.

A reduction in fluoroscopy time was highlighted as being important by another specialist commentator given the hazards associated with ionising radiation to both patients and operators.

One specialist commentator highlighted that contact force capability should allow more effective and safer ablation of complex arrhythmia substrates, and should not be restricted to treating atrial fibrillation.

One specialist commentator stated that contact force is 1 of several variables that affect ablation delivery. Cardiac perforation has been shown with force above 40 g; however,

energy delivery not only involves contact force but also ablation time and radiofrequency power output. Tissue thicknesses differ between different areas of the atrium and the atrium is surrounded by structures such as the oesophagus posteriorly which may be particularly sensitive to heating. The specialist commentator noted that some data exists that may define efficacy, but none currently exists to define a safe contact force range. Another commentator agreed that what constitutes good contact and sufficient force is less well defined in the literature.

One specialist commentator advised that most centres in which atrial fibrillation ablation is done are within teaching hospitals, and being able to directly observe the force a trainee is exerting (during an ablation procedure) is invaluable but unlikely to be measured in a clinical trial.

The manufacturer states that the patient having had a ventriculotomy or atriotomy within the preceding 4 weeks and the presence of a prosthetic valve are contraindications for using TactiCath Quartz. However, 1 specialist commentator indicated that these patient groups may need ablation treatment for arrhythmias, and that using a contact force-recording catheter in these patients is advantageous.

One specialist commentator noted that TactiCath Quartz handles less well than they would expect for a catheter used for atrial fibrillation ablation, and stated that they heard the same from other clinicians. The specialist commentator indicated that as a consequence, TactiCath Quartz is frequently used with a steerable introducer sheath (for example Agilis), which incurs an additional cost. The specialist commentator noted that St. Jude Medical is planning to combine the tip technology of TactiCath Quartz with its new catheter platform (Flexibility), which would provide better catheter handling.

## Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance, NICE aims to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women

- eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

The risk of atrial fibrillation increases with age, and is more common in men than women. PVI catheter ablation is typically done under fluoroscopy guidance and therefore not recommended in people who are pregnant. Age, sex and pregnancy are protected characteristics under the Equality Act 2010.

## Evidence review

### Clinical and technical evidence

#### Regulatory bodies

A search of the Medicines and Healthcare Products Regulatory Agency website revealed no manufacturer Field Safety Notices or Medical Device Alerts for TactiCath Quartz.

A search of the US Food and Drug Administration database: Manufacturer and User Device Facility Experience (MAUDE) for 'TactiCath' between 2009 and 2015 identified 106 records, each describing the use of TactiCath Quartz (or its predecessor technology, TactiCath) in cardiac ablation procedures (but not explicitly for atrial fibrillation). Reported events occurred after October 2014, with the most recent in October 2015. Reported events included injury (96), death (7) and malfunction (2), with event type for 1 record not reported.

Common issues reported:

- Known risks associated with the procedure (91 records) including pericardial effusion, cardiac perforation, tamponade, pericarditis, atrial-oesophageal fistula, cerebrovascular events, steam pop and death.
- Product defects (13 records), including short circuits caused by fluid leaks, loss of contact force-sensing, deflection issues, no flow through the catheter and device error message.

- Incorrect usage (2 records), specifically excessive force and accessing the left side of the heart in a retrograde fashion.

The manufacturer has stated that design and process changes have since been incorporated in the manufacture of TactiCath Quartz.

The MAUDE database houses reports on medical devices that were submitted because of suspected device-associated deaths, serious injuries and malfunctions. Reports are submitted by mandatory reporters such as manufacturers, importers and facilities where the devices are used and voluntary reporters such as health care professionals, patients and consumers.

It should be noted that the MAUDE database is a passive surveillance system and potentially includes incomplete, inaccurate, untimely, unverified or biased data. The incidence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about frequency of device used.

## Clinical evidence

A systematic literature search identified 7 studies that reported on the TactiCath ablation catheter (the predecessor to TactiCath Quartz) for radiofrequency ablation in patients with atrial fibrillation. This included 1 multicentre randomised controlled trial (Reddy et al. 2015), 1 non-randomised comparative study (Wakili et al. 2014), 1 non-randomised comparative study that used retrospective data from a local registry (Wutzler et al. 2014), and 3 prospective single-arm multicentre interventional studies (Kautzner et al. 2015, Kuck et al. 2012, Reddy et al. 2012). The remaining study was a prospective, single-arm, single-centre interventional study (Vaccari et al. 2014). This has not been included in this briefing because it was considered to provide lower quality evidence.

The TOCCASTAR randomised controlled trial (Reddy et al. 2015) was done across 17 global study centres and enrolled 317 patients. It was powered to assess the non-inferiority of a contact-sensing catheter (TactiCath, intervention arm; final group size n=155) compared with a standard ablation catheter (ThermoCool, control arm; final group size n=145). Different navigation systems were used in the 2 arms (EnSite NavX in the TactiCath arm and CARTO in the control arm). The primary outcome was a combination of short-term ablation success (complete isolation of all pulmonary veins), longer-term effectiveness (prevention of symptomatic arrhythmia without drugs) and safety (device-related serious

adverse events). Long-term ablation success (at 12 months) was achieved in 67.8% of patients with TactiCath and 69.4% of patients with ThermoCool ( $p < 0.05$  for non-inferiority, 15% margin allowed for effectiveness). Device-related serious adverse events were seen in 1.97% of patients with TactiCath and 1.40% patients with ThermoCool ( $p < 0.05$  for non-inferiority, 9% margin allowed for safety). The authors concluded that TactiCath met the safety and effectiveness end points. The authors also reported that the contact force achieved by operators using TactiCath was highly variable, and that only 33% (12/36) of the operators achieved optimal contact force (where 90% or more of the lesions in a single patient were created using a contact force of 10 g or more). However, through retrospective threshold analysis, the authors were able to confirm that optimal contact force, achievable by using TactiCath, improved effectiveness outcomes. An overview and summary of the results can be found in [tables 1 and 2](#) of the appendix.

A non-randomised single-centre study in Germany (Wakili et al. 2014) compared ablation using a contact force-sensing catheter (TactiCath,  $n=32$ ) with ablation using a standard ablation catheter (ThermoCool,  $n=35$ ) and analysed procedural parameters and clinical outcomes. A separate circular catheter was used for mapping in both arms. The study found that compared with a standard ablation catheter, contact force-guided ablation resulted in fewer energy applications needed to isolate the pulmonary vein (34 compared with 44,  $p < 0.05$ ), greater reduction in impedance in the first 10 seconds (9.09 ohm compared with 6.58 ohm,  $p < 0.001$ ), shorter left atrial procedure time (78 minutes compared with 96 minutes,  $p < 0.05$ ), and shorter fluoroscopy time (33 minutes compared with 51 minutes,  $p < 0.001$ ). Freedom from atrial fibrillation was not statistically significantly different between the groups; 62.5% compared with 62.9% (at 6 months) and 59.4% compared with 62.9% (at 12 months) for contact force-sensing and standard ablation catheters respectively. Similar complication rates were seen in both groups, but none was considered to be severe. An overview and summary of the results can be found in [tables 3 and 4](#) of the appendix.

A single-centre comparator study in Germany (Wutzler et al. 2014) retrospectively analysed data from a local atrial fibrillation ablation registry, in order to determine if atrial fibrillation recurrence rate differed in PVI ablation procedures done with contact force-sensing catheters (TactiCath,  $n=31$ ) and non-contact force-sensing catheters (control group, CoolPath,  $n=112$ ). Both arms used the same navigation system (EnSite NavX). A separate circular mapping catheter was used in both arms to confirm pulmonary vein isolation after the ablation. The authors reported that at 12-month follow-up atrial fibrillation had recurred in 36.6% (41/112) of patients with CoolPath and 16.1% (5/31) of patients with TactiCath ( $p=0.031$ ). Additionally, the total procedure time

was significantly shorter in the TactiCath group (128 minutes) compared with the CoolPath group (158 minutes,  $p=0.001$ ). No other significant differences in ablation time, total ablation energy or fluoroscopy time were reported between the groups. One minor complication was reported in the TactiCath group, and 1 major and 3 minor complications were reported in the CoolPath group (in the absence of contact force measurement). An overview and summary of the results can be found in [tables 5 and 6](#) of the appendix.

Three prospective, single-arm, multicentre studies described the use of TactiCath in patients with paroxysmal atrial fibrillation (Kautzner et al. 2015, Kuck et al. 2012, Reddy et al. 2012). A total of 58 patients were included in these studies (with 2 studies reporting outcomes on the same patients). The TOCCATA study (Kuck et al. 2012) reported serious adverse events in 12% (4/34) of patients (including tamponade, sinus bradycardia, groin bleeding and stroke), with audible steam pops reported in 12% (4/34) of patients. At 3 months after the procedure, mild pulmonary vein stenosis was reported in 12% (4/34) of patients. At 12 months after the procedure, 26% (9/34) of patients experienced serious adverse events related to arrhythmia recurrence. The study by Reddy et al. (2012) included the same paroxysmal atrial fibrillation subgroup as the TOCCATA study. Of the 32 patients followed up until the end of the study, 17 were categorised as having a successful initial ablation procedure. In the 10 patients with an average contact force greater than 20 g recorded during the ablation procedure, 80% (8/10) had no atrial fibrillation recurrence or atrial fibrillation recurrence with confirmed durable PVI. However, all 5 patients having ablation with an average contact force of less than 10 g experienced atrial fibrillation recurrence at 12 months. The EFFICAS-II study (Kautzner et al. 2015) reported durable PVI at 3 months in 85% of cases (77/91 pulmonary veins from 24 patients), compared with 72% (73/103 pulmonary veins from 26 patients) in the earlier EFFICAS-I study ( $p=0.037$ ). This study also used a separate circular catheter to confirm PVI isolation after the ablation. Two patients (8.3%) experienced tamponade related to the procedure using TactiCath; 1 patient needed pericardiocentesis and the other needed surgery despite the site of perforation not being identified. A summary of results can be found in [table 7](#) of the appendix.

## Recent and ongoing studies

One ongoing trial on TactiCath was identified in the preparation of this briefing:

- [TactiCath contact force ablation catheter study for atrial fibrillation post approval study \(TactiCathPAS\)](#) – This is a prospective, multicentre, interventional study to collect confirmatory evidence on the safety and effectiveness of TactiCath Quartz for treating symptomatic paroxysmal atrial fibrillation using contact force-assisted irrigated radiofrequency ablation. The expected primary completion date for the study is stated as July 2016, but according to St. Jude Medical the primary completion date is February 2017.

## Costs and resource consequences

TactiCath Quartz would replace conventional catheters without contact force-sensing technology used in radiofrequency ablation for atrial fibrillation. Conventional radiofrequency ablation catheters without contact force-sensing technology are available from St. Jude Medical, ranging in cost from £1,147 to £3,255. Separate circular mapping catheters (to confirm electrical PVI) are also available from St. Jude Medical, ranging in cost from £1,550 to £2,170.

When compared with standard ablation catheters, using TactiCath Quartz and the additional components needed (the TactiSys Quartz system and additional software either integrated or non-integrated into a dedicated workstation) would pose an additional expense to the NHS. However, this could be offset if the device is associated with a long-term reduction in atrial fibrillation recurrence (fewer healthcare visits, reduced medications), reduction in procedure and fluoroscopy time, and reduced complications.

No published evidence on resource consequences was identified.

## Strengths and limitations of the evidence

The evidence to support the use of TactiCath Quartz in managing atrial fibrillation is limited in terms of quantity, with only 2 prospective (Reddy et al. 2015, Wakili et al. 2014) and 1 retrospective (Wutzler et al. 2014) comparative trials being identified. The TOCCASTAR study by Reddy et al. (2015) was the only randomised controlled trial and the largest study reviewed. It compared the TactiCath contact force-sensing catheter with a non-contact force-sensing catheter (ThermoCool) in patients with symptomatic paroxysmal atrial fibrillation. This study was statistically powered to show non-inferiority of TactiCath and included various definitions of procedural success in order to compare outcomes with previously published studies. The authors did not provide information



about why a non-inferiority trial was selected rather than a superiority trial. A superiority trial could have demonstrated improved efficacy or safety for TactiCath. This was a multicentre study (17 centres), and the variations between the study centres (for example treatment differences) was accounted for using multivariate analysis. The authors acknowledged several limitations and potential sources of bias in the study, including: the lack of strict contact force guidelines in the TactiCath (intervention) group in the study protocol; the high variability in contact force measurements achieved by operators (not accounted for in the multivariate analysis); and that the use of 2 ablation catheters from 2 different manufacturers needed 2 different mapping systems (with the operators having less experience with 1 of the systems). The authors accepted that the small differences in outcomes may have been attributable to the different ablation catheter designs. This study did not include a UK centre and was highly selective in its recruitment of patients so it is not clear how generalisable it is to UK practice.

Both studies by Wutzler et al. (2014) and Wakili et al. (2014) evaluated ablation procedures done with and without contact force-sensing catheters, allowing the potential benefits of contact force to be compared with standard practice in a population with atrial fibrillation. The study by Wakili et al. (2014) was prospective but not randomised, with the standard catheter (ThermoCool) being used in the first 35 consecutive patients and TactiCath being used in the next 32 consecutive patients, which introduces the potential for selection bias. The study by Wutzler et al. (2014) retrospectively analysed observational data from a local atrial fibrillation registry and had the potential for selection bias and confounding. Although Wutzler et al. (2014) and Wakili et al. (2014) reported that using a contact force-sensing catheter reduced total procedural time, as well as left atrial procedure time and fluoroscopy time respectively, it is unclear whether these reductions were clinically important. Furthermore, both studies reported no statistically significant difference in ablation time between groups. Both studies also had the potential for reporting bias. Major limitations of both studies include the use of multiple models of catheters (ThermoCool in the Wakili et al. [2014] study, and CoolPath in the Wutzler et al. [2014] study) in the intervention and control arms, and the use of different mapping systems between arms (in the Wakili et al. [2014] study), making it difficult to attribute outcomes to the TactiCath catheter alone.

## Relevance to NICE guidance programmes

NICE has issued the following related guidance:

- [Atrial fibrillation: management](#) (2014) NICE clinical guideline 180. Date for review: September 2016
- [Percutaneous balloon cryoablation for pulmonary vein isolation in atrial fibrillation](#) (2012) NICE interventional procedure guidance 427
- [Percutaneous endoscopic catheter laser balloon pulmonary vein isolation for atrial fibrillation](#) (2011) NICE interventional procedure guidance 399
- [Percutaneous \(non-thoracoscopic\) epicardial catheter radiofrequency ablation for atrial fibrillation](#) (2009) NICE interventional procedure guidance 294
- [Thoracoscopic epicardial radiofrequency ablation for atrial fibrillation](#) (2009) NICE interventional procedure guidance 286
- [Percutaneous radiofrequency ablation for atrial fibrillation](#) (2006) NICE interventional procedure guidance 168

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# Appendix

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Table 7: Summary of 3 prospective single-arm multicentre studies

### Table 1 Overview of the Reddy et al. (2015) study

Study component	Description
Objectives/ hypotheses	To determine the safety and effectiveness of TactiCath in the treatment of patients with paroxysmal atrial fibrillation (AF).

<p>Study design</p>	<p>TOCCASTAR study. Randomised controlled trial.</p> <p>Patients randomised in 1:1 ratio to a contact force sensing catheter (TactiCath<sup>a</sup>, intervention) or standard catheter without contact force sensing technology (ThermoCool, control).</p> <p>Different navigation systems were used in each arm: EnSite NavX with TactiCath, CARTO with ThermoCool.</p> <p>3 month blanking period included after initial procedure, with a maximum of 2 repeated ablation procedures allowed with the initial catheter type assigned.</p>
<p>Setting</p>	<p>Multicentre – 17 study centres (USA, Czech Republic, France, Switzerland)<sup>b</sup>. Dates of enrolment and follow-up not reported.</p>
<p>Inclusion/exclusion criteria</p>	<p>Inclusion criteria: patients with symptomatic, paroxysmal AF refractory or intolerant to at least 1 class I to IV antiarrhythmic drug (AAD), planned for catheter ablation, at least 1 documented episode of AF &gt;30 seconds, minimum of 3 episodes documented by history within 12 months before enrolment.</p> <p>Exclusion criteria: persistent AF, myocardial infarction within 3 months prior to intervention, prior left atrial ablation (surgical or catheter), left atrial diameter &gt;5 cm, left ventricular ejection fraction &lt;35%, contraindications to long-term antithrombotic therapy, severe pulmonary disease.</p>

<p>Primary outcomes</p>	<p>Short-term ablation success defined as complete isolation of all pulmonary veins (PVs) at the end of the initial procedure.</p> <p>Long-term ablation success defined as freedom from recurrence of symptomatic AF, atrial tachycardia or atrial flutter at 12 months after the initial procedure and off AADs, with the exclusion of 3-month blanking period. Any acute procedural failure, retreatment with ablation, use of class I or III AAD or symptomatic recurrence documented by transtelephonic monitoring (TTM) or electrocardiogram (ECG) after the blanking period constituted treatment failure. Additional outcome of clinically relevant success required AAD use after blanking period to be associated with documentation of arrhythmia through TTM (with at least 3 positive TTMs) or ECG.</p> <p>Secondary outcomes: device-related serious adverse events occurring within 7 days of the initial procedure or hospital discharge (whichever was later). Events were classified as primarily device- or procedure-related and adjudicated by an independent clinical events committee. Subgroup analysis of intervention cohort; optimal contact force (CF) group with <math>\geq 90\%</math> of lesions created with CF <math>\geq 10</math> g, and non-optimal CF group with patients with <math>&lt; 90\%</math> of lesions created with CF <math>\geq 10</math> g.</p>
<p>Statistical methods</p>	<p>Study powered to evaluate the non-inferiority of intervention compared to control catheter. Power calculation assumed treatment success rate of 55% in both groups, 80% power, non-inferiority margin of 9% for safety and 15% for effectiveness, one-sided 5% significance level, and 10% attrition.</p> <p>Categorical variables compared with Fisher's exact test. Continuous variables compared with Mann-Whitney U test. One-sided tests used in comparisons involving the optimal CF group, 2-sided tests used otherwise. A p value <math>&lt; 0.05</math> was considered to be statistically significant. Logistic regression analysis for treatment success was conducted to investigate potential treatment differences across study centres.</p>

Patients included	<p>Total of 317 patients enrolled; 17 were considered roll-in patients to allow for initial familiarisation with the TactiCath device, and the ablation catheters were not introduced in 5 patients. The 295 remaining patients were included in safety analysis (TactiCath intervention group n=152, control group n=143).</p> <p>A further 15 patients were excluded from effectiveness analysis; PVI was not attempted in 5 patients and in 10 there was a major deviation from protocol. The 280 remaining patients were included in the effectiveness analysis (TactiCath intervention group n=146, control group n=134).</p>
Results	<p>Short-term ablation success was achieved in 100% of the patients in both groups. Long-term ablation success (at 12 months) achieved in 67.8% and 69.4% of the intervention and control groups respectively (p=0.0073). Long-term clinically relevant success achieved in 78.1% and 80.6% of the intervention and control groups respectively (p=0.659). In the intervention group long-term success was achieved in 75.9% and 58.1% of the optimal CF and non-optimal CF subgroups (p=0.018).</p> <p>Device-related serious adverse events occurred in 1.97% and 1.40% of intervention and control groups respectively (p=0.0004).</p>
Conclusions	<p>CF ablation catheter met the primary safety and effectiveness endpoints. Additionally, optimal CF was associated with improved effectiveness.</p>
<p>Abbreviations: AAD, antiarrhythmic drug; AF, atrial fibrillation; CF, contact force; ECG, electrocardiogram; g, grams; n, number of patients; PV, pulmonary vein; PVI, pulmonary vein isolation; TTM, transtelephonic monitoring.</p> <p><sup>a</sup> The manufacturer has informed NICE that this study used TactiCath Quartz, although this is not stated in the paper.</p> <p><sup>b</sup> Not explicitly stated but assumed from author affiliations.</p>	

**Table 2 Summary of results from the Reddy et al. (2015) study**

	<b>Intervention:</b> <b>Catheter ablation with contact force (TactiCath)</b>	<b>Control:</b> <b>Catheter ablation without contact force (ThermoCool)</b>	<b>Analysis</b>

Randomised	n=155	n=145	
Efficacy	n=146	n=134	
Primary outcome: short-term ablation success (initial procedure)	30 min waiting time PV reconnection rate: 10.4% Final PV isolation rate: 100%	30 min waiting time PV reconnection rate: 13.8% Final PV isolation rate: 100%	p=0.206
Selected secondary outcomes:			
Repeat ablation procedures	During blanking period: n=6 After blanking period: n=16	During blanking period: n=6 After blanking period: n=17 (including 1 subject who required a third procedure)	
Long-term ablation success (12 months)	67.8%	69.4%	Absolute difference: -1.6% Lower 95% confidence interval: -10.7% (which is within the predefined 15% non-inferiority margin) p=0.0073 for non-inferiority
Long-term clinically relevant success (12 months)	78.1% (85.5% in the optimal CF subgroup and 67.7% in the non-optimal CF subgroup, p=0.009)	80.6%	p=0.659



Quality of life	Significant changes were observed in both groups with a non-significant trend for the intervention versus control group.		
Safety	n=152	n=143	
Procedure time, median	Fluoroscopy: 27.0 min	Fluoroscopy: 23.0 min	p=0.044
	Radiofrequency ablation: 46.5 min	Radiofrequency ablation: 53.0 min	p=0.018
Serious adverse events	Overall: 7.2% (11/152) Device related: 1.97% (3/152)	Overall: 9.09% (13/143) Device related: 1.40% (2/143)	Absolute difference: 0.57% Upper 1-sided 95% CI: 3.61% (which is within the predefined 9% non-inferiority margin) p=0.0004 for non-inferiority
Abbreviations: CI, confidence interval; min, minutes; n, number of patients; PV, pulmonary vein.			

**Table 3 Overview of the Wakili et al. (2014) study**

Study component	Description
Objectives/hypotheses	To compare procedural parameters and clinical outcomes between pulmonary vein isolation (PVI) ablation procedures conducted using a contact force-sensing catheter (TactiCath) and a standard ablation catheter.
Study design	Prospective non-randomised interventional study. The first 35 patients were included in the standard ablation catheter group, the subsequent 32 patients were included in the TactiCath group.
Setting	Single-centre (Germany). Consecutive patients enrolled (dates of enrolment and follow-up not reported).

Inclusion/ exclusion criteria	<p>Inclusion criteria: patients with AF undergoing circumferential PVI for all pulmonary veins.</p> <p>Exclusion criteria: circumferential isolation of all pulmonary veins with additional ablation lines or complex fractionated atrial electrogram ablation.</p>
Primary outcomes	<p>Freedom from AF at 6- and 12-month follow-up. Recurrence of AF was defined as at least 1 episode &gt;30 s documented either in baseline ECG or Holter ECG recordings, or clear AF-related symptoms (palpitations or tachyarrhythmias), or atypical atrial flutter or atrial tachycardia reported after a blanking period of 12 weeks after PVI.</p> <p>Secondary outcomes: left atrial procedure time (time from first to last ablation to achieve complete isolation), number of energy applications needed to achieve isolation, total fluoroscopy time, absolute decrease in impedance during first 10 s of every energy application (serving as a potential index of lesion efficiency).</p>
Statistical methods	<p>Unpaired Student's t-test used for 2-group comparisons. One-way ANOVA with post-hoc Bonferroni correction used for multivariate analysis. Calculation of correlation performed using Pearson correlation coefficient. p-values &lt;0.05 considered statistically significant.</p>
Patients included	<p>Total of n=67 consecutive patients underwent PVI n=32 underwent catheter ablation with TactiCath (with contact force), n=35 underwent ablation using a standard catheter, ThermoCool (without contact force).</p> <p>An additional decapolar catheter was used in the coronary sinus for reference and a lasso catheter for anatomical mapping for each patient.</p>
Results	<p>Freedom of AF similar between the groups: 62.5 vs. 62.9% after 6 months, 59.4 vs. 62.9% after 12 months for the TactiCath and standard ablation catheter groups, respectively.</p> <p>A significant reduction in left atrial procedural time (78.08 vs. 92.52 min, p&lt;0.05) and fluoroscopy time (33.0 vs. 51.4 min, p&lt;0.0001) was found in the TactiCath group.</p>
Conclusions	<p>Use of contact force-sensing catheters in PVI has a beneficial effect on procedural parameters.</p>

Abbreviations: AF, atrial fibrillation; ANOVA, analysis of variance; ECG, electrocardiogram; min, minutes; n, number of patients; PVI, pulmonary vein isolation; s, seconds.

**Table 4 Summary of results from the Wakili et al. (2014) study**

	<b>Catheter ablation with contact force (TactiCath)</b>	<b>Standard ablation catheter (ThermoCool)</b>	<b>Analysis</b>
Randomised	Not applicable	Not applicable	
Efficacy	n=32	n=35	
Primary outcome: freedom from AF	62.5% at 6 months	62.9% at 6 months	p=0.864
	59.4% at 12 months	62.9% at 12 months	p=0.780
			Increased freedom from AF after 12 months in paroxysmal AF patients: 73.7 vs. 48.1% for paroxysmal and persistent AF patients respectively, p<0.05]
	Paroxysmal AF at 12 months: 72.2%	Paroxysmal AF at 12 months: 71.4%	p=0.734
	Persistent AF at 12 months: 50.0%	Persistent AF at 12 months: 42.9%	p=0.585
Selected secondary outcomes:			

Impedance reduction in first 10 s ( $\Omega$ ; mean $\pm$ SD)	9.09 $\pm$ 0.53	6.58 $\pm$ 0.33	p<0.001
Number of energy applications required to isolate pulmonary vein	34.06 $\pm$ 3.11	44.20 $\pm$ 3.67	p<0.05
Safety	n=32	n=35	
Procedure times (min <sup>a</sup> ; mean $\pm$ SD)	Left atrial procedure: 78.08 $\pm$ 7.23	Left atrial procedure: 95.52 $\pm$ 7.35	p=0<0.05
	Fluoroscopy: 33.0 $\pm$ 2.7	Fluoroscopy: 51.4 $\pm$ 3.3	p<0.001
Force per energy application (mean $\pm$ SD)	Contact force: 17.4 $\pm$ 1.04 g Force-time integral: 713.35 $\pm$ 44.64 gs	Not applicable	
Complications	Severe complications: None Total complication rate: 6.3%	Severe complications: None Total complication rate: 5.7%	Two patients (1 patient in each group) showed small pericardial effusion without indication for pericardiocentesis and 2 patients (1 patient in each group) showed femoral arteriovenous fistula or aneurysm with indication for intervention.
Abbreviations: AF, atrial fibrillation; g, grams; gs, gram-seconds; min, minutes; n, number of patients; s, seconds; SD, standard deviation. <sup>a</sup> Units not explicitly reported but assumed to be minutes.			

**Table 5 Overview of the Wutzler et al. (2014) study**

Study component	Description
Objectives/ hypotheses	To evaluate the impact of catheter contact force monitoring during pulmonary vein isolation (PVI) on AF recurrence rate.
Study design	Non-randomised comparator study using data from a local prospective AF ablation registry.
Setting	Single-centre (Germany). Consecutive patients enrolled between 2010 and 2012.
Inclusion/ exclusion criteria	Inclusion criteria: patients with drug refractory symptomatic AF. Procedures conducted by physicians with at least 4 years' experience in interventional electrophysiology, performing >100 PVI procedures a year. Exclusion criteria: repeat procedures, cases where alternative ablation strategies (linear lesions, ablation of complex fractionated atrial electrograms) or alternative techniques (cryoblation, 'single-shot' devices, robotic ablation), patients with left ventricular ejection fraction <45%, post-surgical valve replacement.
Primary outcomes	Recurrence of AF within 12 months. Secondary outcomes: Ablation time, total procedure time, total ablation energy, fluoroscopy time, procedural complications, total number and reason for non-scheduled healthcare visits at 12-month follow-up and additional medications prescribed during 12-month follow-up.
Statistical methods	Categorical data analysed using the Chi <sup>2</sup> test. Continuous variables analysed using the 2-sample t-test for normally distributed data, and the Wilcoxon rank sum test for skewed data. A p-value of <0.05 considered to be statistically significant.
Patients included	143 patients underwent catheter ablation for symptomatic drug refractory AF. n=31 underwent catheter ablation with contact force (TactiCath group), n=112 underwent catheter mapping and ablation without the use of contact force using CoolPath, St Jude Medical catheters (control group) <sup>a</sup> .

Results	AF recurrence occurred in 36.6% (41/112) of patients in the control group and in 16.1% (5/31) of patients in the TactiCath group (p=0.031). As significant reduction in total procedure duration was seen in the TactiCath group (128.4±29 min vs. 157.7±30.8 min, p=0.001).
Conclusions	PVI conducted with the use of contact force information results in shorter procedure duration and a lower rate of AF recurrence after 12 months compared with conventional PVI without this information.
Abbreviations: AF, atrial fibrillation; min, minutes; n, number of patients; PVI, pulmonary vein isolation. <sup>a</sup> 19 (61.3%) of the TactiCath group and 85 (75.9%) of the control group had paroxysmal AF. Diagnosis of the remaining patients is not reported.	

**Table 6 Summary of results from the Wutzler et al. (2014) study**

	Catheter ablation with contact force (TactiCath)	Catheter ablation without contact force (CoolPath)	Analysis
Randomised	Not applicable	Not applicable	
Efficacy	n=31	n=112	
Primary outcome: atrial fibrillation recurrence at 12 months	16.1% (5/31)	36.6% (41/112)	p=0.031
Selected secondary outcomes:			
Complete PVI verified by bidirectional block (at procedure)	100% (31/31)	100% (112/112)	
Contact force (g; mean±SD)	26.8±10.7	Not applicable	
Force-time integral (gs; mean±SD)	1449.4±415	Not applicable	
Safety	n=31	n=112	

Procedure time (min; mean±SD)	Ablation: 38.6±12.7	Ablation: 45.2±16.5	p=0.13
	Total procedure: 128.4±29.0	Total procedure: 157.7±30.8	p=0.001
	Fluoroscopy: 39.7±11.3	Fluoroscopy: 43.8±14.5	p=0.5
Total energy delivered: (Ws, mean±SD)	71964.4±17894.8	78579.3±45534	p=0.9
Major complications	None	1 pericardial effusion (0.9%)	
Minor complications	1 femoral haematoma (3.2%)  No steam pops were reported	3 femoral haematoma (2.7%)  No steam pops were reported	p=0.75
Unscheduled visits <sup>a</sup>	9.7% (3/31)	17.9% (20/112)	p=0.27
Abbreviations: g, grams; gs, gram-seconds; min, minutes, n, number of patients; PVI, pulmonary vein isolation; s, second; SD, standard deviation; Ws, watt-seconds. <sup>a</sup> Assumed unscheduled outpatient visits but not explicitly stated.			

**Table 7 Summary of data from 3 prospective single-arm multicentre studies**

<b>A novel radiofrequency ablation catheter using contact force sensing: TOCCATA study (Kuck et al. 2012)</b>	
Design	<p>TOCCATA study. Prospective, single-arm, multicentre interventional study.</p> <p>The purpose was to evaluate the device- and procedure-related safety of the TactiCath force-sensing catheter during percutaneous ablation for the treatment of cardiac arrhythmias. Two study groups including confirmed paroxysmal atrial fibrillation cohort.</p> <p>Only results of the paroxysmal atrial fibrillation group will be reported in this summary table, n=34.</p>

Efficacy	Variable number of patients
Primary outcome: contact force during ablation	<p>During mapping, significant differences in the forces applied in the left atrium were observed between the 12 investigators (<math>p &lt; 0.0001</math>), with mean values ranging from 12 to 39 g.</p> <p>During ablation, a high variability was seen in the forces applied both between investigators (<math>p &lt; 0.0001</math>) and within individual investigators (coefficient of variability=72.1). The differences in the contact force between pulmonary vein sites were statistically significant (<math>p &lt; 0.0001</math>).</p>
Selected secondary outcomes:	
Number of valid contact force records (stable contact force for 15 consecutive seconds)	<p>529 valid records (90%) during mapping.</p> <p>71% valid records during ablation.</p>
Safety	n=34
Serious adverse events (SAE)	<p>During the procedure: 4 patients with audible steam pops (12%).</p> <p>3 months: 4 mild pulmonary vein stenosis (12%), 1 tamponade (3%), 1 bradycardia (3%), 1 groin bleeding (3%), 1 stroke (3%).</p> <p>12 months: 9 SAE related to arrhythmia recurrence (26%)<sup>a</sup>.</p>
<p><sup>a</sup> Note only 31 patients were followed-up for the full 12-month period due to 3 patients withdrawing consent prior to the study end, therefore the briefing authors conclude that 29% (9/31) of patients experienced serious adverse events.</p>	
<p><b>The relationship between contact force and clinical outcome during radiofrequency catheter ablation of atrial fibrillation in the TOCCATA study (Reddy et al. 2012)</b></p>	
Design	<p>Prospective, single-arm, multicentre, interventional study.</p> <p>The study aimed to determine the relationship between contact force parameters during ablation for paroxysmal atrial fibrillation and clinical recurrence at 12-month follow-up.</p> <p>Study participants were the same confirmed paroxysmal atrial fibrillation group reported in the TOCCATA study (Kuck et al. 2012).</p>



Efficacy	Variable number of patients
Primary outcome: procedural success	<p>Procedural outcome: all pulmonary veins successfully isolated in 100% of study patients (34/34).</p> <p>12-month follow-up: PVI considered successful in 53% (17/32). Atrial fibrillation recurrence defined as sustained atrial fibrillation, atrial flutter or atrial tachycardia for over 30 seconds.</p>
Selected secondary outcomes:	
Contact force	<p>Number of valid contact force records (stable contact force for 15 consecutive seconds): 1017 of 1458 records (70%).</p> <p>35% (351/1017) of ablation lesions were performed with low contact force (&lt;10 g).</p> <p>Overall, patients received ablations with an average contact force of 17.2±13.5 g.</p> <p>The difference in contact force between pulmonary vein sites were statistically significant (p&lt;0.001). On average, the highest contact force was applied at the right anterior inferior site, and the lowest contact force was applied at the left anterior inferior ridge and right carina site.</p> <p>Intermittent contact (contact force reaching 0 g at every diastole for at least 200 ms) correlated with low contact force (p&lt;0.001).</p> <p>Subgroup analysis: all 5 patients treated with an average contact force &lt;10 g were categorised as 'ablation unsuccessful' at 12 months. However 8/10 (80%) of patients treated with an average contact force &gt;20 g were categorised in 'ablation successful'.</p>
Force-time integral	<p>Mean FTI &lt;500 gs predicted a success rate of 25% (2/8) at 12 months.</p> <p>Mean FTI &gt;1000 gs predicted a success rate of 60% (9/13), p=0.03.</p>
Safety	Not reported
<b>EFFICAS-II: optimization of catheter contact force improves outcome of pulmonary vein isolation for paroxysmal atrial fibrillation (Kautzner et al. 2015)</b>	

Design	<p>EFFICAS-II study. Prospective single-arm, multicentre, interventional study.</p> <p>The aim of this study was to assess the impact of contact force guidance for an effective reduction PVI gaps prospectively, and to compare outcomes with the previous EFFICAS-I study.</p>	
Efficacy	n=24	
Primary outcome: pulmonary vein isolation at 3 months	85% (77/91 pulmonary veins)	This was a significant increase from 72% (73/102) reported in the EFFICAS-I study (p=0.037).
Selected secondary outcomes:		
Contact force	<p>Pulmonary vein segments with conduction gaps:</p> <p>Minimum – 13.1 g</p> <p>Average – 28.8 g</p> <p>Successfully isolated pulmonary vein segments:</p> <p>Minimum – 11.4 g (p=0.22)</p> <p>Average – 9.2 g (p&lt;0.01)</p>	Contact force between 10 and 30 g was achieved in 68% of ablations, which is a significant increase from 49% reported in the EFFICAS-I study (p<0.001).

Force-time integral	<p>Pulmonary vein segments with conduction gaps:</p> <p>Minimum – 223 gs</p> <p>Average – 868 gs</p> <p>Successfully isolated pulmonary vein segments:</p> <p>Minimum – 290 gs (p=0.48)</p> <p>Average – 704 gs (p=0.03)</p>	Force time integral greater than 400 gs was achieved in 78%, which is a significant increase from 55% in the EFFICAS-I study (p<0.001).
Total number of ablations	<p>Pulmonary vein segments with conduction gaps: 6</p> <p>Successfully isolated pulmonary vein segments: 6 (p=0.52)</p>	For equal setting of radiofrequency power, there was a 15% reduction in the number of ablations (1372 ablations in EFFICAS-II vs. 1818 in EFFICAS-I, p=0.05).
Safety	n=24	
Patients reporting serious adverse events	<p>8.3% (2/24 patients)</p> <p>Tamponade: 8.3% (2/24 patients)</p>	
Abbreviations: FTI, Force-time integral; g, grams; gs, gram-seconds; n, number of patients; PVI, pulmonary vein isolation; SAE, serious adverse events.		

# Search strategy and evidence selection

## Search strategy

The search strategy was designed to identify evidence on the clinical and cost effectiveness of the TactiCath catheter in people with drug refractory, recurrent, symptomatic atrial fibrillation (AF).

The strategy was developed for MEDLINE (Ovid interface). The strategy was devised using a combination of subject indexing terms and free text search terms in the title, abstract and keyword heading word fields. The search terms were identified through discussion within the research team, scanning background literature, browsing database thesauri and use of the [PubMed PubReMiner tool](#). The strategy reflected the nature of the MIB assessments as rapid evidence reviews, with a relatively pragmatic approach being taken. The performance of the draft MEDLINE strategy was assessed by checking retrieval of 7 known, relevant studies identified by the research team at the project start; the draft strategy successfully retrieved all the known, relevant studies.

The main structure of the search strategy comprised 3 concepts:

- AF
- catheter ablation
- contact force.

The search concepts were combined as follows:

- AF AND catheter ablation AND contact force.

The strategy also combined a line on catheter contact with AF terms, manufacturer terms with the AF and contact force terms, and included standalone search lines on device name-related terms. These were designed to identify studies that might be missed by the 3 concept approach.

Search concepts were captured using subject headings and textword searches in title, abstract and keyword heading word fields.

The strategy excluded animal studies using a standard algorithm. Non-English language publications were also excluded from the search results. The search was restricted to studies published from 2009 to date. This date reflected the date the original version of the device was CE marked.

The MEDLINE strategy was translated appropriately for the other databases searched. The PubMed search was limited to records not fully indexed for MEDLINE.

The following databases were searched:

- Cochrane Central Register of Controlled Trials (Cochrane Library, Wiley)
- Cochrane Database of Systematic Reviews (Cochrane Library, Wiley)
- Database of Abstracts of Reviews of Effects (Cochrane Library, Wiley)
- Embase (Ovid SP)
- Health Technology Assessment Database (Cochrane Library, Wiley)
- MEDLINE and MEDLINE in Process (Ovid SP)
- NHS Economic Evaluation Database (Cochrane Library, Wiley)
- PubMed.

## Evidence selection

A total of 482 records were retrieved from the literature search. After removal of duplicates, 279 records remained and were sifted against the inclusion criteria at title and abstract level.

Records were sifted independently by 2 researchers. Any disagreements were discussed and agreement was reached in all cases, so a third independent arbiter was not required. The first sift removed 250 records based on the following exclusion criteria:

- articles of poor relevance against search terms
- publication types that were out of scope
- non-English language studies

- conference abstracts
- review articles.

Full articles were retrieved for the remaining 29 studies and a full text assessment was done independently by 2 researchers to identify relevant primary research addressing the key clinical outcomes of interest. Twenty two studies were excluded for the following reasons:

- Device not used: 9
- Multiple contact force devices used and results could not be separated: 4
- Review studies/editorials: 3
- Meta-analyses with primary studies already included: 2
- Incorrect comparator: 2
- Threshold analysis studies: 1
- Proof-of-concept study: 1
- Total: 22

A total of 7 studies remained that reported on the TactiCath catheter and addressed the key clinical outcomes of interest (Kautzner et al. 2015; Reddy et al. 2015; Vaccari et al. 2014; Wakili et al. 2014; Wutzler et al. 2014; Kuck et al. 2012; Reddy et al. 2012).

## About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and **are not formal NICE guidance**.

## Development of this briefing

This briefing was developed for NICE by the Newcastle and York External Assessment Centre. The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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Newcastle and York External Assessment Centre

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### Specialist commentators

The following specialist commentators provided comments on a draft of this briefing:

- Dr John P Bourke (Consultant Cardiologist and Electrophysiologist and Senior Lecturer, Newcastle upon Tyne Hospitals NHS Foundation Trust)

- Dr Benjamin Brown (Consultant Cardiologist and Electrophysiologist, University Hospital of South Manchester NHS Foundation Trust)
- Professor G Andre Ng (Consultant Cardiologist and Electrophysiologist and Professor of Cardiac Electrophysiology, University Hospitals of Leicester NHS Trust)
- Dr Ewen Shepherd (Consultant Cardiologist, Newcastle upon Tyne Hospitals NHS Foundation Trust).

## Declarations of interest

- Professor G Andre Ng has a consultancy agreement with St Jude Medical acting as International EP Curriculum Director (with paid lecture fees), and Biosense Webster for Proctorship and Educational activity. He is also supervisor to a Clinical Research Fellowship funded by St. Jude Medical. He was also a Specialist Adviser to the NICE Interventional Procedures Programme (2010–2013).
- Dr John Bourke, Dr Benjamin Brown, Dr Ewen Shepherd – No relevant interests declared.

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ISBN: 978-1-4731-1772-3