NICE advice

ThermoCool SmartTouch catheter for percutaneous radiofrequency ablation in atrial fibrillation

Medtech innovation briefing
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Summary

ThermoCool SmartTouch 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 mapping the electrical activity of the heart, delivering radiofrequency energy during ablation procedures, and confirming electrical isolation. ThermoCool SmartTouch 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. This briefing includes 10 studies of mixed quality, including 2 randomised controlled trials and 2 large comparative studies. The studies reported a higher mean contact force, fewer pulmonary reconnections and shorter procedural, ablation and fluoroscopy times with ThermoCool SmartTouch compared with radiofrequency ablation with contact force measurements blinded or with conventional catheters. The list prices for the ThermoCool SmartTouch uni- and bi-directional catheters

are £1,675 and £1,750 (excluding VAT) respectively, but additional components are needed for the ablation procedure.

NICE has also published a medtech innovation briefing on the TactiCath Quartz catheter.

Product summary and likely place in therapy	Effectiveness and safety
• ThermoCool SmartTouch is a single-use radiofrequency ablation catheter with a deflectable distal section and a contact force sensor at the tip. • It conducts cardiac mapping, delivers radiofrequency ablation and provides real-time contact force guidance during cardiac ablation procedures. • It would be used in people with symptomatic atrial fibrillation and would replace conventional radiofrequency ablation catheters without contact force-sensing technology. • NICE has also published a medtech innovation briefing on the TactiCath Quartz catheter.	• The relevant evidence summarised in this briefing includes 2 randomised controlled trials and 2 observational studies including 2,273 patients and is of mixed quality. Six non-randomised comparative studies have also been considered. There are several further studies in progress. • Two randomised controlled trials compared pulmonary vein isolation using ThermoCool SmartTouch with and without the contact force measurements being visible to the user. The first study (n=120) reported fewer acute and persistent pulmonary vein reconnections and a shorter procedural time in the contact force-guided group. The second trial (n=38) reported a higher mean contact force, a shorter procedural time and fewer residual connection gaps in the contact force-guided group. • A retrospective observational cohort study (n=1,515) compared the use of ThermoCool SmartTouch with a non-contact force-sensing catheter. The study reported lower fluoroscopy times, radiation doses and shorter procedural times with ThermoCool SmartTouch.

	• A retrospective observational study (n=600) compared the use of ThermoCool SmartTouch with non-contact force catheters. The study found that using ThermoCool SmartTouch independently predicted clinical success in ablation of paroxysmal atrial fibrillation but not non-paroxysmal atrial fibrillation.

Technical and patient factors	Cost and resource use
• ThermoCool SmartTouch 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. • The ThermoCool SmartTouch catheter must be used with the CARTO 3 navigation system to visualise the contact force applied. The manufacturer does not recommend a particular optimal contact force to be used during ablation procedures. • NICE has published interventional procedures guidance on percutaneous radiofrequency ablation procedures for atrial fibrillation.	• The list prices for single-use ThermoCool SmartTouch uni- and bi-directional catheters are £1,675 and £1,750 (excluding VAT) respectively. The CARTO 3 navigation system is also necessary and costs £129,999 (excluding VAT). • A Biosense Webster radiofrequency generator and irrigation system are also needed for the ablation procedure, although they may be readily available in cardiac catheterisation laboratories. • A conventional radiofrequency ablation catheter without contact force-sensing technology – ThermoCool Nav – is available from Biosense Webster, and has a list price of £1,250. Separate circular mapping catheters (to confirm electrical pulmonary vein isolation) are also available from Biosense Webster, with list prices ranging from £1,000 to £1,200. • No evidence on cost effectiveness or resource consequences was identified from the literature review.

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

ThermoCool SmartTouch is a class III medical device. The manufacturer, Biosense Webster, has a CE certification dated November 2015 that includes the following catheters:

- ThermoCool SmartTouch bi-directional catheter, first CE marked in December 2010.
- ThermoCool SmartTouch uni-directional catheter, first CE marked in February 2011.
- ThermoCool SmartTouch SF uni- and bi-directional catheters, first CE marked in May 2014.

ThermoCool SmartTouch catheters require the CARTO 3 navigation system to visualise the contact force information. Biosense Webster was awarded a CE mark for the CARTO 3 system as a class IIa device in November 2008.

The current certifications for ThermoCool SmartTouch and the CARTO 3 navigation system expire in May 2017 and January 2018 respectively.

Description

ThermoCool SmartTouch 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 a precision spring. 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.

ThermoCool SmartTouch is a single-use device with an overall length of 115 cm. Two types of ThermoCool SmartTouch catheter are available, with either a uni-directional tip (available with deflectable distal curves of 73.5 mm, 84.5 mm or 98.5 mm) or a bi-directional tip (available with symmetrical deflectable distal curves of 73.5 mm, 84.5 mm or 98.5 mm and asymmetrical deflectable distal curves of 73.5 mm/84.5 mm or 84.5 mm/98.5 mm). The catheters comprise several parts:

- A deflectable distal section containing several electrodes, including a 3.5 mm tip electrode. All of the electrodes may be used for stimulating and recording (required for electrophysiological mapping) so a separate cardiac mapping catheter is not needed when using ThermoCool SmartTouch for ablation. The tip electrode also delivers the radiofrequency current to the desired ablation site and is irrigated. The catheter shaft measures 7.5 Fr with 8 Fr ring electrodes.
- A hand-piece that controls the movement of the catheter and the uni-directional or bi-directional tip deflection. Tip deflection is controlled at the proximal end by a thumb-knob on the hand-piece. The shaft controls the plane of the curved catheter tip allowing it to be rotated for accurate positioning.
- A thermocouple temperature sensor embedded in the tip electrode.
- A location sensor and transmitter coil embedded in the distal section that sends location signals to the CARTO 3 navigation system.
- A precision spring embedded in the distal section that flexes in response to contact force, enabling software calculation of force in grams.
- A saline input port with a standard luer fitting at the proximal end of the catheter. This allows the injection of normal saline to irrigate and cool the tip electrode and ablation site during the ablation phase of the procedure.

In addition to the standard ThermoCool SmartTouch catheter, the company has produced an 'SF' (surround flow) variant with a modified irrigation tip. This is CE marked but not yet commercially available in the UK.

Additional components needed for the ablation procedure include:

- The CARTO 3 navigation system, with SmartTouch 3D software module and integrated display screen, designed to visualise the real-time calculated position and orientation of the catheter within the patient's heart. This may already be in use in a cardiac catheterisation laboratory.
- A compatible radiofrequency generator, such as the SMARTABLATE radiofrequency generator (Stockert Medical Solutions) or the Stockert EP Shuttle Generator (Stockert Medical Solutions).
- A compatible irrigation pump and irrigation tubing, such as the COOLFLOW irrigation pump (Biosense Webster) or the SMARTABLATE irrigation pump and tubing set (Stockert Medical Solutions), 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.
- Six disposable dispersive pads and an earthing pad which complete the ablation circuit. These are usually attached to the patient's chest, back and leg.

ThermoCool SmartTouch 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 ThermoCool SmartTouch catheter is used to carry out the ablation and deliver radiofrequency energy. This blocks the electrical path that causes the abnormal heart rhythm. Biosense Webster does not specify a target contact force or a force range for an ablation procedure. ThermoCool SmartTouch transmits contact force information to the clinician throughout the procedure using the CARTO 3 navigation system (which is commonly used in electrophysiology). ThermoCool SmartTouch 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 ThermoCool SmartTouch.

Setting and intended use

ThermoCool SmartTouch 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 ThermoCool SmartTouch. 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.

ThermoCool SmartTouch 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 8 weeks; artificial heart valves; active systemic infection; use in coronary vasculature; myxoma (a heart tumour) or intracardiac thrombus (blot clot); trans-septal atrial approach in patients with an interatrial baffle or patch; retrograde trans-aortic approach in patients with aortic valve replacement; and use with an introducer sheath of less than 8.5 Fr.

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 ThermoCool SmartTouch (and its additional components):

- TactiCath Quartz irrigated ablation catheter used with the TactiSys Quartz system (St Jude Medical).
- Artisan Extend Control Catheter used with the Sensei X2 Robotic System (Hansen Medical).

NICE has produced a medtech innovation briefing on the TactiCath Quartz catheter.

Costs and use of the technology

Biosense Webster has provided the following list prices (excluding VAT).

Each single-use ThermoCool SmartTouch costs £1,675 (uni-directional) or £1,750 (bi-directional).

This equipment is needed for mapping and ablation procedures using the ThermoCool SmartTouch catheter:

- CARTO 3 navigation system: £129,999
- CARTO 3 SmartTouch module: £35,000
- CARTO 3 system external reference patches (pack of 6): £595.

An introducer sheath greater than 8.5 Fr (not supplied by Biosense Webster) is also needed.

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

ThermoCool SmartTouch can only be used with Biosense Webster radiofrequency generators, such as the SMARTABLATE system with integrated irrigation pump (£35,000) or the Stockert EP Shuttle radiofrequency generator used with the separate COOLFLOW irrigation pump (£14,999 and £8,999 respectively). These components could be used for other ablation procedures and may already be present in some cardiac catheterisation laboratories.

ThermoCool SmartTouch ablation catheters are single-use and have an anticipated shelf-life of 12 months. The anticipated lifespan of the CARTO 3 navigation system, COOLFLOW irrigation pump and SMARTABLATE system are 7 years, 10 years and 10 years, respectively.

Biosense Webster offers a number of service contracts for hardware covering 1, 2 or 3 years, which cost:

- CARTO 3 navigation system: £12,000, £23,000, £32,000
- Stockert EP Shuttle: £500, £800, £900
- COOLFLOW irrigation pump: £900, £1,600, £2,100.

The manufacturer provides onsite training by a clinical support specialist as part of the overall service, at no cost.

Likely place in therapy

ThermoCool SmartTouch 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 in 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 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 the main difference between ThermoCool SmartTouch and previous navigation catheters is the ability to visualise the shaft electrodes using the CARTO 3 navigation system. This allows a representation of part of catheter to be seen within the mapping system and contributes to the reduced need for fluoroscopy during catheter manipulation.

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 which 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 ThermoCool SmartTouch. 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 highlighted that the 2 randomised trials only report early reconnection, but contact force technology is important not just to improve early reconnection rates but also to minimise late reconnection. This requires the integration of other variables than contact force into ablation delivery. A second specialist commentator

also indicated that although not all of the identified studies show an improvement in outcomes, the consistent message from the published data is that ablation guided by contact force results in better isolation of the pulmonary veins.

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

The Medicines and Healthcare products Regulatory Agency has published 3 Field Safety Notices for ThermoCool SmartTouch, 1 of which was for ThermoCool SmartTouch SF, and all of which were monitored to a satisfactory conclusion. No adverse incidents were received relating to the issues in the safety notices.

A US Food and Drug Administration (FDA) major product recall was posted in October 2014 and terminated in October 2015. The recall resulted in Biosense Webster providing

additional labelling for the safe and effective use of ThermoCool SmartTouch.

A search of the FDA database: Manufacturer and User Device Facility Experience (MAUDE) for 'SmartTouch' identified 939 records all describing the use of ThermoCool SmartTouch in cardiac ablation procedures. These reported events occurred after January 2012, with the most recent occurring in October 2015. The records were categorised by the following indications:

- atrial fibrillation (464 records)
- ventricular tachycardia, premature ventricular contractions (199 records)
- atrial flutter (29 records)
- atrial tachycardia (12 records)
- Wolff–Parkinson–White syndrome (3 records)
- multiple indications (5 records)
- indication undefined (227 records).

Reported event types for the 464 atrial fibrillation records included the following common issues:

- Injury/known risks associated with the procedure (283 records), including pericardial effusion, cardiac tamponade, atrioesophageal fistula, perforation, cerebrovascular accident and steam pop.
- Malfunction (172 records), including catheter damage, internal components exposed, noise on all signals, char on catheter tip, deflection issue, loss of contact force, temperature issue and clot formation.
- Death (9 records), including atrioesophageal fistula, cardiac tamponade, pericarditis, effusion and cerebrovascular accident.

Analysis by the manufacturer is ongoing in 132 cases and corrective actions have been started in 22 cases.

The FDA's major product recall for ThermoCool SmartTouch was ended on 31 October 2014. Of the 464 atrial fibrillation records, 190 were reported before this date and 273 were reported after (the event date of 1 record was not reported).

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 20 primary studies that reported on ThermoCool SmartTouch ablation catheter for radiofrequency ablation in patients with atrial fibrillation. The highest quality evidence was selected for inclusion in this briefing, including 2 randomised controlled trials (Nakamura et al. 2015, Kimura et al. 2014).
Two retrospective cohort studies (Lee et al. 2015, Jarman et al. 2015) were included because they recruited a large number of patients, were UK-based and used routine data. Ten additional non-randomised comparative studies were identified, but only 6 were prospective in design (Andrade et al. 2014, Itoh et al. 2015, Makimoto et al. 2015, Marijon et al. 2014, Martinek et al. 2012, Sciarra et al. 2014) and have therefore been summarised. The other studies were excluded from this briefing as they were judged to provide lower quality evidence.

The study by Nakamura et al. (2015) prospectively enrolled 120 consecutive patients who were randomly assigned to have contact force-guided circumferential pulmonary vein isolation (CPVI; contact force [CF] group, n=60) or CPVI with the operators blinded to the CF information (blind group, n=60). ThermoCool SmartTouch and the CARTO 3 navigation system was used in both groups. The CF group had fewer pulmonary vein reconnections (0.67±0.91 per patient compared with 1.16±1.16 per patient; p=0.007) and a shorter procedural time (50 minutes compared with 56 minutes; p=0.019) than the blind group. The mean contact force applied was higher in the CF group than the blind group (18.0 g compared with 16.1 g, p<0.001), with the most significant difference observed along the posterior right-sided pulmonary veins and anterior left-sided pulmonary veins. The arrhythmia-free survival rate at 12 months was not significantly different between the 2 groups (89.9% compared with 88.2%; p=0.624). The authors stated that the similar

clinical outcomes may have been a result of the learning effect from using the CF-guided technique and repeated stimulation of inactive pulmonary vein conduction. The authors concluded that contact force-guided CPVI could reduce pulmonary vein reconnections and the procedural time. An overview and summary of results can be found in table 1 and table 2 of the appendix.

The randomised controlled trial by Kimura et al. (2014) aimed to compare procedural parameters and outcomes between contact force-guided (n=19) and non-contact force-guided (n=19) CPVI in consecutive patients with atrial fibrillation (28 people with paroxysmal and 10 with non-paroxysmal). ThermoCool SmartTouch was used in both arms but operators were blinded to contact force information in the non-CF group. The CARTO 3 navigation system was used in both groups. In the CF group, the contact force was kept between 10 g and 20 g during the procedure. The mean contact forces observed in the CF and non-CF groups were 11.1±4.3 g and 5.9±4.5 g for left side CPVI ($p<0.001$) and 12.1±4.8 grams and 9.8±6.6 g for right side CPVI ($p<0.001$) respectively. The procedure time for CPVI in the CF group was 59±16 minutes and in the non-CF group was 96±39 minutes ($p<0.001$). The total number of residual connection gaps needing touch-up ablation was 2.8±1.9 in the CF group and 6.3±3.0 in the non-CF group ($p<0.001$). At 6-month follow-up, 94.7% of patients in the CF group and 84.2% in the non-CF group were free from any atrial tachyarrhythmias ($p=0.34$). The authors concluded that contact force-guided CPVI was effective in reducing residual conduction gaps that need touch-up ablation, and therefore reducing procedure time. They also stated that it may improve long-term outcomes, although further evidence is needed. A summary of the study can be found in table 3 and table 4 of the appendix.

The retrospective observational cohort study by Lee et al. (2015) aimed to determine the 'real-world' impact of ThermoCool SmartTouch for the treatment of AF when used with Carto 3.1 software on the CARTO 3 navigation system (n=510). This was compared with non-contact force-sensing catheters used alongside standard 3D-mapping CARTO-XP and EnSite NavX software (n=1,005). Patients having ThermoCool SmartTouch had a significantly lower fluoroscopy time (9.5 minutes compared with 41 minutes, $p<0.001$), radiation doses (1,044 mGy cm^2 compared with 3571 mGy cm^2, $p<0.001$) and shorter procedural time (195 minutes compared with 240 minutes, $p<0.001$) compared with the control group. However, no difference in the rate of cardiac complications following the procedure was found. An overview and summary of results can be found in table 5 and table 6 of the appendix.

The retrospective study by Jarman et al. (2015) matched procedures using contact

force-sensing catheters (n=200) to procedures without contact force-sensing (n=400), taking into account the type of atrial fibrillation (paroxysmal, persistent or long-lasting persistent). The authors did not describe the mapping systems used. They found that the use of contact force-sensing catheters independently predicted clinical success in ablation in paroxysmal atrial fibrillation (hazard ratio [HR] 2.24, 95% confidence interval [CI] 1.29 to 3.90, p=0.04), but not in non-paroxysmal atrial fibrillation (HR 0.73, 95% CI 0.41 to 1.30, p=0.289) in multivariate analysis. This study also reported a reduction in fluoroscopy time in the contact force-sensing group of 7.7 minutes (p<0.001) compared with the control group. An overview and summary of results can be found in table 7 and table 8 of the appendix.

Six prospective non-randomised controlled trials compared ThermoCool SmartTouch with non-contact force-sensing ablation (Andrade et al. 2014, Itoh et al. 2015, Makimoto et al. 2015, Marijon et al. 2014, Martinek et al. 2012, Sciarra et al. 2014). The non-contact force-sensing catheters included conventional catheters such as the standard ThermoCool, EZ steer ThermoCool or Navistar ThermoCool, and ThermoCool SmartTouch but with the operator blinded to contact force information. The studies included 418 patients, 186 having ThermoCool SmartTouch and 232 having non-contact force-sensing ablation for AF. Three studies showed a statistically significant reduction in atrial fibrillation recurrence in patients having ThermoCool SmartTouch at 12 months' follow-up (Andrade et al. 2014, Itoh et al. 2015, Marijon et al. 2014). Five of the 6 studies reported a statistically significant reduction in overall procedure time with contact force guidance, with 1 study reporting a significant increase in overall procedure time (Andrade et al. 2014). Three of the 5 studies that measured ablation times reported a statistically significant reduction in this outcome in patients having ThermoCool SmartTouch (Marijon et al. 2014, Martinek et al. 2012, Sciarra et al. 2014). Similarly, 3 of the 6 studies that measured fluoroscopy times reported a statistically significant reduction in patients having ThermoCool SmartTouch (Andrade et al. 2014, Itoh et al. 2015, Marijon et al. 2014). Only 1 study reported a significant increase in fluoroscopy time (Andrade et al. 2014). Procedural complications were reported in the ThermoCool SmartTouch group in 3 studies: 1 atrioventricular fistula and 1 pericardial tamponade (Martinek et al. 2012), 1 mild groin haematoma (Sciarra et al. 2014), 1 local haematoma and 2 pericardial effusions (Marijon et al. 2014). Only 1 study (Andrade et al. 2014) reported adverse events at 1-year follow-up, but the authors did not report in which group the complications occurred. A summary of results can be found in table 9 of the appendix.

Recent and ongoing studies

Ten ongoing or in-development trials on ThermoCool SmartTouch for atrial fibrillation were identified in the preparation of this briefing.

Completed trials

- NCT01677052: ThermoCool SmartTouch Registry – Designed to measure 'real-world' clinical use of contact force measurements during ablation procedures.

Active studies recruiting patients

- NCT02217657: SmartTouch catheter for left anterior line, smart line study – This prospective, randomised study will investigate whether information about the catheter force applied during ablation of a left anterior line reduces total radiofrequency application time by preventing ineffective lesions.
- NCT02485925: SMART China, a multicentre clinical registry study – This is a prospective effectiveness and safety assessment of the study device during radiofrequency ablation treatment of patients with drug-refractory symptomatic atrial fibrillation.
- NCT01730924: Comparison of pulmonary vein isolation using the SmartTouch catheter with or without real-time contact force data – The purpose of this study is to evaluate whether contact force information affects the time to perform the procedure, or the outcomes as a result of it.
- NCT02364401: Impedance versus contact force-guided atrial fibrillation ablation using an automated annotation system – The purpose of this study is to compare the efficacy of catheter ablation for atrial fibrillation between contact force-guided and impedance-guided annotation using an automated annotation system (Visitag).
- NCT01587404: Catheter contact force and electrograms – The purpose of the study is to examine how contact force affects the electrical behaviour of heart muscle tissue in atrial fibrillation.

- NCT01570361: Atrial fibrillation progression trial (ATTEST) – The objective of this study is to determine whether early radiofrequency ablation treatment in patients with paroxysmal atrial fibrillation delays progression of atrial fibrillation compared with drug therapy (either rate or rhythm control) using current atrial fibrillation management guidelines.

Active studies not recruiting patients

- NCT02359890: SMART-SF radiofrequency ablation safety study – This is a prospective safety assessment of the study device during radiofrequency ablation treatment of drug-refractory symptomatic atrial fibrillation.

Studies of unknown status

- NCT01630330: Contact force-sensing use in atrial fibrillation ablation – The purpose of the study is to determine whether the contact between the catheter tip and the inside of the heart wall improves the effectiveness of catheter ablation for atrial fibrillation patients.
- NCT01693107: Atrial fibrillation force contact ablation study (CAFCAS) – The purpose of the study is to assess the current force being used for ablation of symptomatic paroxysmal atrial fibrillation in a wide range of operators in different Canadian centres, with the operators being blinded to the contact force data, and to assess the efficiency of using ThermoCool SmartTouch.

Costs and resource consequences

ThermoCool SmartTouch 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 Biosense Webster and have a list price of about £1,250 (ThermoCool Nav). Separate circular mapping catheters (to confirm electrical PVI) are also available from Biosense Webster. The list prices range from £1,000 to £1,200, excluding VAT.

When compared with standard ablation catheters, using ThermoCool SmartTouch and the additional components needed (the CARTO 3 navigation 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

There are several published studies on the use of ThermoCool SmartTouch for atrial fibrillation. A systematic literature search identified 20 relevant articles, 4 of which were selected for full review and 6 that were summarised in the briefing. The 2 randomised controlled trials were both small single-centre studies and not done in the UK. However, the 2 retrospective studies recruited substantially more patients and were both done in UK hospitals. Although the 2 randomised controlled trials have an important contribution, they both suffer from the same flaw. The contact force measurements suggested reconnection early, during the index ablation procedure. However, they did not report on late reconnection, for example at 6-month follow-up.

The randomised controlled trial by Nakamura et al. (2015) was a slightly larger study with 120 consecutive patients randomised into either a contact force-guided CPVI group or non-contact force-guided CPVI group, where the operators were blinded to the contact force measurements. Four operators did the CPVI procedures for each group, reducing operator variability. The authors noted that a learning effect may have improved the operators' manipulation of the catheter, which may have negatively impacted the earlier reported outcomes in the intervention group. However, because all 4 operators performed both procedures, this could also have affected the non-CF-guided group. The authors highlighted that although the target contact force application was 20 g, the mean contact force applied was less than 20 g in certain segments, which was caused by technical difficulty in manipulating the catheter, particularly around the ridge between the left pulmonary veins and the left atrial appendage.

The randomised controlled trial by Kimura et al. (2014) was a relatively small study with only 38 consecutive patients included across the 2 groups. However, after completion of the trial, the authors attempted to validate the effectiveness of contact force between 10 g and 20 g in accomplishing CPVI in a separate cohort of 20 patients. Although consecutive patients were enrolled, limiting selection bias, no exclusion criteria were described within the report. The authors noted that despite a run-in period to improve operator familiarity with the device there was evidence of a learning effect, so it might be

expected that performance with ThermoCool SmartTouch would improve with time. Overall, the methodology of this randomised controlled trial was poor, as the authors did not calculate power, there were no prespecified primary outcomes and they only reported technical and surrogate outcomes.

The retrospective comparator study by Lee et al. (2015) reported data on the most patients of any included trial (n=510 using ThermoCool SmartTouch and n=1,005 in the control arm). Major limitations of this study include the use of multiple models of catheters and different mapping systems across the 2 arms, making it difficult to attribute outcomes to ThermoCool SmartTouch alone. Furthermore, the absolute numbers of cardiac complications were tabulated but no statistical comparisons were described (the odds ratios calculated by the authors of this briefing confirmed no statistical difference in individual or combined cardiac complication rates between groups). Because this was a UK study using routine data, the results are generalisable to current practice. However, the weakness lies in its internal validity which is intrinsic to the study design.

The retrospective observational study by Jarman et al. (2015) matched cases using ThermoCool SmartTouch in a 1:2 ratio to cases not having a contact force-sensing catheter, taking the type of atrial fibrillation into account during matching. The authors correctly accounted for differences in baseline characteristics between cases and controls by conducting multivariate analysis. As a result of the use of retrospective data in the chosen study design, the authors acknowledge that the results of this study are limited by selection bias and confounding from other variables is not recorded.

Relevance to NICE guidance programmes

NICE has issued the following guidance:

- Atrial fibrillation: management (2014) NICE guideline CG180
- 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

Contents

Data tables

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

Study component	Description
Objectives/ hypotheses	To compare the prevalence, characteristics and predictors of pulmonary vein reconnections (PVRs) and the clinical outcome between contact force (CF) guided and conventional circumferential pulmonary vein isolation (CPVI) of atrial fibrillation (AF).

Study design	Randomised controlled trial. Randomisation was performed in a 1:1 fashion based on a computer generated list of random numbers, in permuted blocks of 4, according to the presence or absence of the CF information during ablation and the sequential order of the CPVI.
Setting	Single centre (Japan). Patients were enrolled from April 2013 to April 2014.
Inclusion/ exclusion criteria	Inclusion criteria: consecutive patients scheduled to undergo an initial CPVI of symptomatic paroxysmal or persistent AF refractory to or intolerant of at least 1 antiarrhythmic drug, using a 3.5 mm tip externally irrigated ablation catheter equipped with a CF sensor (ThermoCool SmartTouch). Exclusion criteria: age of less than 20 years or more than 80 years, long-standing persistent AF with a duration of more than 1 year, left atrium (LA) diameter of greater than 55 mm in the parasternal long-axis view on transthoracic echocardiography, substrate modification of the LA in addition to CPVI, and previous cardiac surgery.
Primary outcomes	PVRs Procedural time Mean CF Predictors of PVRs Arrhythmia-free survival rate at 12 months
Statistical methods	Comparative analysis between the CF and blind groups was performed using Student's t test, Mann–Whitney's U test, or chi^2-test. The coefficient of variation was used to compare the variability in the distribution.
Patients included	120 patients enrolled were randomly assigned to undergo CF-guided CPVI with target CF of 20 g (n=60), or CPVI with operators blinded to CF information (n=60).

Results	The CF group had fewer PVRs, a lower incidence of persistent PVRs, and a shorter procedural time for the CPVI than the blind group. The mean CF was higher in the CF group than the blind group, with the most significant difference observed along the posterior right-sided PVs and anterior left-sided PVs. In logistic regression models, the mean CF was a negative predictor of PVRs along the P-RPVs and A-LPVs in the blind group, while no significant predictor was identified in the CF group or elsewhere in the blind group. The arrhythmia-free survival rate at 12 months was lower in the blind group, however, was not significant.
Conclusions	The authors concluded that CF-guided CPVI could reduce PVRs and the procedural time and could be particularly beneficial along regions where a relatively low CF tends to be applied: the P-RPVs and A-LPVs.
Abbreviations: A-LPVs, anterior-left pulmonary veins; AF, atrial fibrillation; CF, contact force; CPVI, circumferential pulmonary vein isolation; g, grams; LA; left atrium; n, number of patients; P-RPV, posterior-right pulmonary veins; PV, pulmonary vein; PVRs, pulmonary vein reconnections.	

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

	ThermoCool SmartTouch (CF) group	**Blind (non-CF) control group**	**Analysis**
Randomised	n=60	n=60	–
Efficacy	n=60	n=60	–
Primary outcome: Incidence of PVRs/patient (mean±SD)	0.67±0.91	1.16±1.16	p=0.007
Incidence of persistent PVRs	13.2%	41.2%	p<0.001
Selected secondary outcomes:			
Procedural time (min; IQR)	50.0 (42.0–60.5)	56.0 (47.5–70.5)	p=0.019

Mean CF (g)	18.0	16.1	p<0.001
Arrhythmia survival rate at 12 months (%)	89.9	88.2	p=0.624
Safety	n=60	n=60	–
Patients reporting serious adverse events	5% (3/60)	1.6% (1/60)	p=0.309
Air embolism during procedure	1.6% (1/60)	–	–
Femoral arteriovenous fistula	1.6% (1/60)	–	–
Late cardiac tamponade	1.6% (1/60)	–	–
Femoral haematoma	–	1.6% (1/60)	–
Abbreviations: CF, contact force; g, grams; IQR, interquartile range; min, minutes; n, number of patients; PVRs, pulmonary vein reconnections; SD, standard deviation.			

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

Study component	Description
Objectives/ hypotheses	To compare procedure parameters and outcomes between contact force-guided and non-contact force-guided circumferential pulmonary vein isolation (CPVI).
Study design	Randomised controlled trial.
Setting	Single centre (Japan). Dates of patient enrolment were not reported.
Inclusion/ exclusion criteria	Inclusion criteria: consecutive patients undergoing CPVI for AF. Exclusion criteria: not reported.

Primary outcomes	Contact force. Procedure and fluoroscopy times. Residual conduction gaps. Freedom from any tachyarrhythmias at 6 months.
Statistical methods	Statistical analysis of the categorical variables in the 2 groups was made by Fisher's exact test or chi-squared test. Statistical analysis of the continuous variables in the 2 groups was made by paired t test, analysis of variance, or Kruskal–Wallis test. All tests were 2-tailed with $p<0.05$ considered significant.
Patients included	CPVI was conducted using ThermoCool SmartTouch catheter in all patients, however patients were randomly assigned to a contact force-guided ablation group (CF information provided, n=19) or non-contact force-guided ablation group (CF information blinded, n=19).
Results	The mean±SD contact force observed in the contact force-guided and non-contact force-guided groups were 11.1±4.3 g and 5.9±4.5 g respectively, for left side CPVI, and 12.1±4.8 g and 9.8±6.6 g respectively, for right side CPVI (both $p<0.001$). The procedure time for CPVI in the contact force-guided and non-contact force-guided groups were 59±16 min and 96±39 min, respectively ($p<0.001$). The total number of residual connection gaps was 2.8±1.9 in the contact force-guided group and 6.3±3.0 in the non-contact force-guided group ($p<0.001$). At the 6 month follow-up, 94.7% of patients in the contact force-guided group and 84.2% in the non-contact force-guided group were free from any atrial tachyarrhythmias ($p=0.34$).
Conclusions	The authors concluded that the contact force-guided CPVI was effective in reducing procedure time and additional touch-up ablation. It may also improve long-term outcomes, although further evidence is needed in this regard.
Abbreviations: AF, atrial fibrillation; CF, contact force; CPVI, circumferential pulmonary vein isolation; g, grams; min, minutes; n, number of patients; SD, standard deviation.	

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

	ThermoCool SmartTouch group	Non-contact force control group	Analysis
Randomised	n=19	n=19	–
Efficacy	n=19	n=19	–
Primary outcome: Contact force (g; mean±SD)	Left: 11.1±4.3	Left: 5.9±4.5	p<0.001
	Right: 12.1±4.8	Right: 9.8±6.6	p<0.001
Selected secondary outcomes:			
Procedure time (min; mean±SD)	59±16	96±39	p<0.001
Total number of residual conduction gaps (mean±SD)	2.8±1.9	6.3±3.0	p<0.001
Freedom from any atrial tachyarrhythmias at 6 months	94.7% Paroxysmal only: 100%	84.2% Paroxysmal only: 84.0%	p=0.34 p=0.11
Safety	n=19	n=19	–
Fluoroscopy time (s; mean±SD)	9±20	22±63	p=not significant
Major complications	None	None	–
Abbreviations: g, grams; min, minutes; n, number of patients; s, seconds; SD, standard deviation.			

Table 5 Overview of the Lee et al. (2015) study

Study component	Description

Objectives/ hypotheses	To determine if contact force sensing using the SmartTouch catheter with Advance Catheter Location (ACL) software reduces fluoroscopy times and radiation exposure during atrial fibrillation (AF) ablation when compared to procedures performed without them.
Study design	Retrospective cohort study.
Setting	Single high-volume academic teaching hospital (UK). AF ablations performed between 2009 and 2014 were included in study.
Inclusion/ exclusion criteria	Inclusion criteria: patients with persistent or paroxysmal AF. Exclusion criteria: not reported.
Primary outcomes	Total fluoroscopy time, radiation dose. Secondary outcomes: procedure duration, total ablation time, cardiac complications.
Statistical methods	Comparisons between groups were performed with an unpaired Student's t-test or, where normal distribution could not be assumed, the Mann–Whitney U test. Categorical variables were compared with a Chi^2-test. A p value of <0.05 was considered statistically significant.

Patients included	n=510 SmartTouch group: AF ablations delivered via the unidirectional D or F curve ThermoCool SmartTouch catheter coupled with CARTO 3.1 software which includes additional ACL feature. n=1,005 control group: AF ablations delivered via the ThermoCool and ThermoCool Celsius catheters coupled with CARTO-XP and EnSite NavXsoftware. Both paroxysmal and persistent AF was treated with wide area circumferential ablation with lesions placed 1–2 cm outside the pulmonary vein (PV) ostia. An additional strategy for persistent AF patients included the following: complex or fractionated electrograms targeted throughout the left and right atrium. If remained in AF linear lesions were added at the mitral isthmus and roof. If patients had a history of typical atrial flutter, a cavotricuspid isthmus line was added. If at any point AF developed into atrial tachycardia, this was mapped and ablated. If sinus rhythm was not restored following these lesions, electrical cardioversion was performed.
Results	The SmartTouch group had a significantly lower fluoroscopy time (9.5 vs. 41 min, p<0.001), radiation doses (1,044 vs. 3,571 mGy cm^2, p<0.001) and shorter procedural time (195 vs. 240 min p<0.001) when compared to the control group. There was no difference in the rate of cardiac complications across groups.
Conclusions	SmartTouch CF-sensing catheter use with ACL during AF ablation significantly reduces fluoroscopy times by 77%, radiation dose by 71% and procedural time by 19% but does not improve overall safety or the risk of cardiac complications.
Abbreviations: ACL, advanced catheter location; AF, atrial fibrillation; CF, contact force; cm, centimetres; mGy, milligrays; min, minutes; PV, pulmonary vein.	

Table 6 Summary of results from the Lee et al. (2015) study

	ThermoCool SmartTouch Group	Non-contact force control group	Analysis

Randomised	n/a	n/a	–
Efficacy	n/a	n/a	–
Safety	n=510	n=1,005	–
Primary outcome: Median fluoroscopy time (min; IQR)	All patients: 9.5 (9.8)	All patients: 41 (28.8)	p<0.0001
	Subgroup analysis – Paroxysmal AF subgroup: 8 (6.5)	Subgroup analysis – Paroxysmal AF subgroup: 33 (113)	p<0.0001
	Persistent AF subgroup: 10.5 (11.3)	Persistent AF subgroup: 47.5 (33.0)	p<0.0001
			No statistical difference in fluoroscopy times or radiation dose was observed for de novo vs. redo ablation procedures in paroxysmal AF (p=0.22) or persistent AF (p=0.50) patients.
Median radiation dose (mGy cm^2; IQR)	All patients: 1043.5 (1050)	All patients: 3571 (4527)	p<0.0001
	Subgroup analysis – Paroxysmal AF subgroup: 923 (976)	Subgroup analysis – Paroxysmal AF subgroup: 2467 (2791)	p<0.0001
	Persistent AF subgroup: 1037.5 (2594.4)	Persistent AF subgroup: 2501.5 (2451.0)	p<0.0001

Median total procedure time (min; IQR)	All patients: 195 (60)	All patients: 240 (130)	p<0.0001
	Subgroup analysis – Paroxysmal AF subgroup: 200 (95)	Subgroup analysis – Paroxysmal AF subgroup: 240 (130)	p<0.0001
	Persistent AF subgroup: 238 (67.5)	Persistent AF subgroup: 288 (135)	p<0.0001
Median total ablation time (min; IQR)	All patients: 51.5 (46.0)	All patients: 42 (48.8)	p=0.802
	Subgroup analysis – Paroxysmal AF subgroup: 43 (40)	Subgroup analysis – Paroxysmal AF subgroup: 35 (45)	p=0.685
	Persistent AF subgroup:58 (58)	Persistent AF subgroup: 55.4 (58.3)	p=0.701
Cardiac complications	Pericardial effusion: 0.98%[a] (5/510)	Pericardial effusion: 1.49%[a] (15/1005)	No statistical comparison reported
	Cardiac tamponade: 0.78% (4/510)	Cardiac tamponade: 0.99% (10/1005)	

Abbreviations: AF, atrial fibrillation; CF, contact force; cm, centimetres; IQR, interquartile range; mGy, milligray; min, minutes.

[a]Calculated by the external assessment centre, not explicitly reported in study.

Table 7 Overview of the Jarman et al. (2015) study

Study component	Description
Objectives/ hypotheses	To determine if the use of a contact force sensing catheter is associated with lower fluoroscopy times and improved freedom from arrhythmia in the medium-term following first time paroxysmal and non-paroxysmal atrial fibrillation (AF) ablation.
Study design	Retrospective cohort study. Patients having ablation procedures between 2010 and 2012 were included in the study.
Setting	Four high-volume hospitals (UK).
Inclusion/ exclusion criteria	Inclusion criteria: patients undergoing first time radiofrequency AF ablation using 3.5 mm tipped open-irrigated catheters who had never previously undergone any left atrial ablation, and who completed at least 6 months follow-up. Exclusion criteria: none reported
Primary outcomes	Freedom from AF. AF defined as any ≥30 s period of atrial tachyarrhythmia (fibrillation, flutter or tachycardia) by symptoms and all electrocardiogram (ECG) recordings, at all follow-ups after a 3-month blanking period. Secondary outcomes: procedural fluoroscopy time, procedural complications. Complications were predefined as: death during admission or directly related to procedure, atrioesophageal fistula, sternotomy, pericardial drainage, PV stenosis, phrenic palsy, stroke, transient ischemic attack, atrioventricular block requiring permanent pacing, and femoral complication defined as significant by detection of atriovenous fistula or pseudoaneurysm, or requirement for intervention, blood transfusion, or readmission.

Statistical methods	Differences between populations were evaluated with Pearson's Chi^2-test. For categorical data, Mann–Whitney U test where ordinal with >2 categories, and Student's t-test for continuous data. Univariate relationship to outcome were evaluated within Pearson's Chi^2-test or Fisher's exact test for categorical data, Mantel–Haenszel test of trend where ordinal with >2 categories, and Student's t-test for continuous data. Tests were performed 2-tailed with $p<0.05$ considered statistically significant. As well as the use of a contact force sensing catheter, 19 possible explanatory variables were assessed as potential predictors of outcome. For the primary outcome, possible univariate explanatory variables were entered into multivariate stepwise binary logistic regression analyses in order of univariate significance, with primary outcome the dependent variable. Variables with $p<0.05$ in the presence of other selected variables were retained in the final model, and the c-statistic calculated. For the secondary outcome, non-categorical possible univariate explanatory variables were entered into a multiple regression analysis in order of univariate significance, with secondary outcome the dependent variable. Variables with $p<0.05$ in the presence of other selected variables were retained in the final model, and the r^2 calculated.
Patients included	Patients were selected by case-matching within each of the 3 AF types (paroxysmal, persistent, long-lasting persistent). Cases used the ThermoCool SmartTouch catheter and were matched 1:2 ratio to controls utilising a non-contact force-sensing catheter (undefined). In the control group, surround flow catheter technology was used in a minority of procedures, 9.8% (39/400) by a single operator. CF group: n=200 (including 92 paroxysmal and 108 non-paroxysmal AF). Non-CF group: n=400 (including 184 paroxysmal and 216 non-paroxysmal AF).

Results	The use of a contact force-sensing catheter independently predicted clinical success in ablation for paroxysmal AF (HR 2.24 [95% CI: 1.29 to 3.90], p=0.004) but not non-paroxysmal AF (HR 0.73 [0.41 to 1.30], p=0.289) in multivariate analysis. Among all cases, the use of contact force-sensing catheters was associated with reduced fluoroscopy time in multivariate analysis (reduction by 7.7 [5.0 to 10.5] min, p<0.001). Complication rates were similar in both groups.
Conclusions	At medium-term follow-up, contact force-sensing catheter technology is associated with significantly improved outcomes for first-time catheter ablation of paroxysmal AF, but not non-paroxysmal AF. Fluoroscopy time was lower when contact force-sensing technology was employed in all types of AF ablation procedures.
Abbreviations: AF, atrial fibrillation; CF, contact force; CI, confidence interval; ECG, electrocardiogram; HR, hazard ratio; min, minutes; s, seconds.	

Table 8 Summary of results from the Jarman et al. (2015) study

	ThermoCool SmartTouch group	**Non-contact force control group**	**Analysis**
Randomised	n/a	n/a	–
Efficacy	n=200	n=400	–
Primary outcome: Procedural success	Paroxysmal: 59% (54/92)	Paroxysmal: 46% (85/184)	p=0.05
	Non-paroxysmal: 43% (46/108)	Non-paroxysmal: 43% (92/216)	p=1.00

			The use of a contact force sensing catheter independently predicted clinical success in ablation for paroxysmal AF (HR 2.24 [95% CI: 1.29 to 3.90], p=0.004) but not non-paroxysmal AF (HR 0.73 [95% CI: 0.41 to 1.30], p=0.289) in multivariate analysis.
Safety	n=200	n=400	–
Fluoroscopy time (min; mean±SD)	26.6±15.1	34.7±18.7	p<0.0001 Among all cases, the use of contact sensing catheters was associated with reduced fluoroscopy time in multivariate analysis (reduction by 7.7 [95% CI: 5.0 to 10.5] min, p<0.001).
Complications	Overall complications: 3.5% (7/200)	Overall complications: 17 (4.25%)	p=0.163
	Complication related to ablation: 1% (2/200)	Complication related to ablation: 2.25% (9/400)	p=0.158
	Pericardial drains: 1.0%[a] (2/200)	Pericardial drains: 1.25%[a] (5/400)	
	Femoral complications: 2.0%[a] (4[a]/200)	Femoral complications: 1.75%[a] (7/400)	
	Transient ischemic attack: 0.50%[a] (1/200)	Atrioesophageal fistula leading to death: 0.25%[a] (1/400)	

		Stroke: 0.25%[a] (1/400)	
		Pulmonary vein stenosis: 0.25%[a] (1/400)	
		Phrenic palsies: 0.50%[a] (2/400)	

Abbreviations: min, minutes; n, number of patients.

[a]Calculated by EAC, not explicitly reported in study.

Table 9 Summary of data from 6 prospective non-randomised controlled studies

Pulmonary vein isolation using "contact force" ablation: The effect on dormant conduction and long-term freedom from recurrent atrial fibrillation – A prospective study (Andrade et al. 2014)			
	ThermoCool SmartTouch ablation	**Non-contact force guided ablation**	**Analysis**
Design	Prospective non-randomised controlled study. The purpose was to study the utility of CF-guided ablation using the ThermoCool SmartTouch catheter on immediate and long-term outcomes, when compared to non-CF-guided ablation using the standard ThermoCool catheter.		
Efficacy	n=25	n=50	–
Primary outcome: Dormant conduction	Patients: 4 (16%)	Patients: 26 (52%)	p=0.0029
	Pulmonary vein pairs: 4 (8%)	Pulmonary vein pairs: 35 (35%)	p=0.0004
Selected secondary outcomes:			
Procedural time (min; mean±SD)	235.4±89.9	179.1±59.1	p=0.0038

Ablation time (min; mean±SD)	58.8±22.1	56.4±24.0	p=0.5857
Freedom from recurrent atrial arrhythmias at 1 year	88%	66%	log rank p=0.047
Safety	n=25	n=50	–
Fluoroscopy time (min; mean±SD)	71.9±19.1	36.5±18.6	p=0.0001
Patients reporting serious adverse events	Not reported	Not reported	Complications included[a]: Tamponade requiring drainage: 1 Groin hematomas: 2 Cerebral thromboembolic event with full recovery: 1 Atrioventricular fistula requiring surgical repair: 1
[a] complications were not attributed to 1 or the other intervention groups.			
Reduced residual conduction gaps and favourable outcome in contact force-guided circumferential pulmonary vein isolation (Itoh et al. 2015)			
	ThermoCool SmartTouch ablation	**Non-contact force guided ablation**	**Analysis**

Design	Prospective non-randomised controlled study. The study assessed the safety and efficacy of CF-guided CPVI and compared the residual conduction gaps and long-term outcomes in patients undergoing CPVI by the ThermoCool SmartTouch catheter and EZ Steer ThermoCool catheter.		
Efficacy	n=50	n=50	
Primary outcome: Total number of residual gaps (mean±SD)	2.7±1.7	6.3±2.7	p<0.05
Selected secondary outcomes:	–	–	–
Procedural time (min; mean± SD)	160±30	245±61	p<0.001
Freedom from any atrial tachycardia (including AF recurrence) at 12 months	94% (47/50)	78% (39/50)	Log rank p=0.02
Freedom of AF recurrence at 12 month	96% (48/50)	82% (41/50)	Log rank p=0.02
Safety	n=50	n=50	–
Fluoroscopy time (min; mean±SD)	17±8	54±27	p<0.001
Complications	None reported	None reported	–
Comparison of contact force-guided procedure with non-contact force-guided procedure during left atrial mapping and pulmonary vein isolation: impact of contact force on recurrence of atrial fibrillation (Makimoto et al. 2015)			

	ThermoCool SmartTouch ablation	**Non-contact force guided ablation**	**Analysis**
Design	Prospective non-randomised controlled study The aim of the study was to evaluate the impact of contact force visualisation on the incidence of low and high CF during left atrial mapping and pulmonary vein isolation.		
Efficacy	n=35	n=35	–
Primary outcome: Contact force (% at each force category)	Low (<10 g): 13%	Low (<10 g): 38%	p<0.001
	High (≥40 g): 1.5% Excessive high (>100 g): none	High (≥40 g): 11% Excessive high (>100 g): 0.5%	p<0.0001
Recurrence of AF or atrial tachycardia	9 patients	12 patients	p value: NS
Selected secondary outcomes:			
Total procedural time (min; mean±SD)	133±42	152±33	p=0.04
Ablation time (min; mean±SD)	Right PV: 819±150	Right PV: 824±268	p=0.92
	Left PV: 786±213	Left PV: 794±255	p=0.88
Safety	n=35	n=35	–
Total fluoroscopy time (min; mean±SD)	13.5±6.6	15.7±6.5	p=0.16
Total fluoroscopy dose (cGy; mean±SD)	2047±973	2281±1229	p=0.38

Complications	None reported	None reported	–
Real-time contact force sensing for pulmonary vein isolation in the setting of paroxysmal atrial fibrillation: procedural and 1-year results (Marijon et al. 2014)			
	ThermoCool SmartTouch ablation	**Non-contact force guided ablation**	**Analysis**
Design	Prospective single-centre non-randomised controlled study The study aimed to establish whether continuous CF monitoring during PVI using the ThermoCool SmartTouch catheter could be associated with lower rate of AF recurrence and better maintenance of sinus rhythm, when compared with a conventional ablation catheter (EZ Steer ThermoCool).		
Efficacy	n=30	n=30	
Primary outcome: Procedural PVI success	80% (25/30)	37% (11/30)	p<0.0001
Acute PV reconnection (within 20 min)	10.0%	16.7%	–
Selected secondary outcomes:			
RF ablation time (min; mean±SD)	45.2±18.0	65.4±22.0	p=0.01
AF recurrence at 12 months (95% CI)	10.5% (1.38 to 22.4)	35.9% (12.4 to 59.4)	Log rank p=0.04
Safety	n=30	n=30	–
Fluoroscopy time (min; mean±SD)	20.1±4	26.7±5	p<0.01

Total radiation dose ($Gy \cdot cm^2$; mean±SD)	41.6±10	56.7±14	p=0.02
Immediate procedural complications	Local hematoma: 1 Pericardial effusions: 2	Local hematoma: 1 Arteriovenous fistula: 1 Pericardial effusions: 1	–
Clinical impact of an open-irrigated radiofrequency catheter with direct force measurement on atrial fibrillation ablation (Martinek et al. 2012)			
	ThermoCool SmartTouch ablation	**Non-contact force guided ablation**	**Analysis**
Design	Prospective non-randomised controlled study The study aimed to assess the impact of direct catheter force measurements on acute procedural parameters during RFCA using either a standard catheter (Navistar ThermoCool) or a CF-guided catheter (ThermoCool SmartTouch).		
Efficacy	n=25	n=25	
Primary outcome: Acute pulmonary vein reconnection	12% (3/25)	36% (9/25)	p=0.095
Selected secondary outcomes:			
RF ablation time (min; mean±SD)	39.0±11.0	50.5±15.9	p=0.007
Procedure time (min; mean±SD)	154±39	185±46	p=0.022
Total energy delivered (W; mean±SD)	58,510±14,655	70,926±19,470	p=0.019

Safety	n=25	n=25	–
Complications	AV fistula: 1 Pericardial tamponade: 1	AV fistula: 1 Pseudo-aneurysm: 1 Minimal pericardial effusion: 1	–
Fluoroscopy time (min; mean±SD)	23.6±13.1	28.6±17.4	p=0.312

Which is the best catheter to perform atrial fibrillation ablation? A comparison between standard ThermoCool, SmartTouch, and Surround Flow catheters (Sciarra et al. 2014)				
Design	Prospective non-randomised controlled trial The aim of this study was to analyse the impact of the SmartTouch and Surround Flow catheters on catheter ablation of paroxysmal AF in terms of feasibility and acute efficacy when compared to the conventional ThermoCool catheter.			
	ThermoCool SmartTouch (STc)	**ThermoCool SF (SFc)**	**Conventional ThermoCool catheter (TCc)**	**Analysis**
Efficacy	n=21	n=21	n=21	–
Primary outcome: Isolated PVs	83 (98%)[a]	80 (96%) [a]	81 (96%) [a]	p=NS
PVs isolated at 30 min after procedure	95%	95%	89%	p=0.05
AF recurrence	5 (23.8%)	5 (23.8%)	7 (33.3%)	–
Selected secondary outcomes:				

RF ablation time(min; mean±SD)	30±14	30±9	41±13	STc vs. TCc p=0.013 SFc vs. TCc p<0.01 STc vs. SFc p=NS
Total procedure time (min; mean±SD)	140±53	170±51	181±53	STc vs. TCc p<0.001 SFc vs. TCc p=NS STc vs. SFc p<0.001
Safety	n=21	n=21	n=21	–
Fluoroscopy time (min; mean±SD)	20±10	21±13	34±18	STc vs. TCc p<0.001 SFc vs. TCc p=0.02 STc vs. SFc p=NS
Complications	None	Mild groin haematoma: 1	None	–

Abbreviations: AF, atrial fibrillation; CF, contact force; CI, confidence interval; cm, centimetres; CPVI, circumferential pulmonary vein isolation; g, grams; Gy, grays; min, minutes; n, number of patients; NS, not significant; PV, pulmonary veins; RF, radiofrequency; RFCA, radiofrequency cardiac ablation; SD, standard deviation; SFc, SmartTouch SF catheter; STc, SmartTouch catheter; TCc, ThermoCool catheter; W, watts.

[a] Percentages calculated by EAC as 98.8%, 95.2% and 96.4% for the STc, SFc and TCc groups respectively.

Search strategy and evidence selection

Search strategy

The search strategy was designed to identify evidence on the clinical and cost effectiveness of ThermoCool SmartTouch catheter in people with drug-refractory, recurrent, symptomatic paroxysmal 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 (http://hgserver2.amc.nl/cgi-bin/miner/miner2.cgi). 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 9 known, relevant studies identified by the research team at project start; the draft strategy successfully retrieved all the known, relevant studies.

The main structure of the search strategy comprised three 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 stand-alone search lines on device name-related terms. These were designed to identify studies which might be missed by the 3 concept approach.

Search concepts were captured using subject headings and text word 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 2010 to date. This date is 1 year prior to the date when 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 (http://www.ncbi.nlm.nih.gov/pubmed).

Evidence selection

A total of 482 records were retrieved from the literature search. After de-duplication, 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 240 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 39 studies and a full test assessment was done independently by 2 researchers to identify relevant primary research addressing the key clinical outcomes of interest. Studies were excluded for the following reasons:

- Meta-analyses with primary studies already included: 3.
- Multiple contact force devices used and cannot disaggregate results: 3.
- Review studies/editorials: 3.
- Incorrect comparator: 3.
- Device not used: 2.
- Threshold analysis studies: 2.
- Indication for use out of scope: 2.
- Operators were blinded to contact force measurements (not valid intervention): 1.
- Total: 19.

A total of 20 studies remained which reported on the ThermoCool SmartTouch catheter and addressed the key clinical outcomes of interest. Because of the large evidence base, the highest quality evidence was selected for inclusion in this briefing. This included 2 randomised controlled trials (Kimura et al. 2014; Nakamura et al. 2015), 2 large retrospective cohort studies (Jarman et al. 2015; Lee et al. 2015). An additional 6 studies which were prospective in design (Andrade et al. 2014; Itoh et al. 2015; Makimoto et al. 2015; Marijon et al. 2014; Martinek et al. 2012; Sciarra et al. 2014) were summarised.

The remaining 10 studies included 5 non-randomised comparative studies which used historical controls (Haldar et al. 2013; Natale et al. 2014; Sigmund et al. 2015; Ullah et al. 2014; Wolf et al. 2015), 4 observational cohort studies (Nakagawa et al. 2013; Providencia et al. 2015; Sotomi et al. 2014; Stabile et al. 2015), and 1 multicentre pilot study (Stabile et al. 2014). All 10 studies were excluded from further analysis.

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 & methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

Project team

Newcastle and York External Assessment Centre

Medical Technologies Evaluation Programme, NICE

Peer reviewers and contributors

- Roseanne Jones, Research Scientist, Newcastle upon Tyne Hospitals NHS Foundation Trust
- Mick Arber, Information Specialist, York Health Economics Consortium
- Kim Keltie, Research Scientist, Newcastle upon Tyne Hospitals NHS Foundation Trust
- Derek Bousfield, Senior Clinical Technologist, Newcastle upon Tyne Hospitals NHS Foundation Trust
- Emma Belilios, Administrator, Newcastle upon Tyne Hospitals NHS Foundation Trust
- Iain Willits, Clinical Scientist, Newcastle upon Tyne Hospitals NHS Foundation Trust

- Helen Cole, Head of Service – Clinical Scientist, Newcastle upon Tyne Hospitals NHS Foundation Trust

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 with 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 (2010–13).
- Dr John P Bourke, Dr Benjamin Brown, Dr Ewen Shepherd – No relevant interests declared.

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