

SeQuent Please balloon catheter for in- stent coronary restenosis

Medical technology guidance

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1 Recommendations

NICE medical technologies guidance addresses specific technologies notified to NICE by manufacturers. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This case is reviewed against the evidence submitted and expert advice. If the case for adopting the technology is supported then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.

- 1.1 The case for adopting SeQuent Please balloon catheter in the NHS, when used as described in 1.2 and 1.3, is supported by the evidence. The need for subsequent re-intervention for coronary stenosis is reduced as is the duration of clopidogrel therapy, compared with paclitaxel-eluting stent. SeQuent Please balloon catheter is associated with a cost saving of £467 per patient compared with paclitaxel-eluting stent.
- 1.2 SeQuent Please balloon catheter should be considered for use in patients with in-stent restenosis in bare metal coronary artery stents.
- 1.3 SeQuent Please balloon catheter can also be considered as an option for patients with in-stent restenosis in any type of coronary artery stent if:
- there are clinical reasons to minimise the duration of clopidogrel treatment (for example, there is concern about an increased risk of bleeding or there is the need for surgical intervention) or
 - placement of further stents is not technically possible.
- 1.4 Further research is recommended in a UK setting to compare the outcomes of patients treated with SeQuent Please balloon catheter with the outcomes of patients treated with other types of drug-eluting balloon catheter and stent. This research should report long-term outcomes (for example, after 3 years), including clinical outcomes and details of further revascularisation required for subsequent restenosis. Research should investigate the use of SeQuent Please balloon catheter for restenosis in drug-eluting coronary artery stents and in de novo coronary stenosis where stenting is either technically difficult or is associated with an increased risk of complications. If research shows that SeQuent Please balloon catheter reduces the rate of restenosis in patients with

drug-eluting stents or in native coronary arteries, compared with other technologies, then the number of patients for whom it might be suitable would increase significantly.

2 The technology

Description of the technology

- 2.1 SeQuent Please (B Braun Medical) is a balloon catheter for percutaneous transluminal coronary angioplasty. The balloon is coated with the antimetabolic drug paclitaxel, with the aim of reducing restenosis.
- 2.2 The balloon section of the catheter is coated with paclitaxel at a dose of 3 microgram/mm². When the balloon is expanded, paclitaxel is released into the vessel wall. Using paclitaxel reduces smooth muscle cell proliferation that can give rise to restenosis and recurrence of symptoms. The aim of targeted delivery is to achieve a high local concentration of drug in the vessel wall with minimal systemic release. The balloon catheter is also coated in iopromide, an X-ray contrast medium which aims to improve the solubility and transfer of paclitaxel to the vessel wall. After treatment, antiplatelet therapy with clopidogrel is recommended for 3 months in addition to aspirin to reduce the risk of thrombosis.
- 2.3 The cost of a SeQuent Please balloon catheter is approximately £800 ± 150. The cost of SeQuent Please balloon catheter may vary because of differences in purchasing contracts.

Current management

- 2.4 Current treatment options for patients with in-stent restenosis include balloon angioplasty, repeat stenting (usually using a drug-eluting stent), cutting balloon angioplasty, directional coronary atherectomy, rotational coronary atherectomy and brachytherapy.
- 2.5 After implantation of a drug-eluting stent, antiplatelet therapy with clopidogrel and aspirin is usually continued for 12 months.
- 2.6 Various paclitaxel and other drug-eluting balloon catheters are available.

3 Clinical evidence

Summary of clinical evidence

- 3.1 The main clinical outcomes for treatment of in-stent restenosis with SeQuent Please balloon catheter are successful revascularisation, the occurrence of restenosis, and the avoidance of major adverse cardiac events, including death, myocardial infarction and stroke. Further restenosis is assessed angiographically by measuring late lumen loss at the site of intervention or by the presence of coronary stenosis greater than 50% (binary restenosis), and by determining target lesion revascularisation or target vessel revascularisation. Full details of all clinical outcomes considered by the Committee are available in the [assessment report](#).
- 3.2 The PEPCAD II trial was a randomised controlled trial (RCT) of 131 patients with a single restenosis in a bare metal stent treated by SeQuent Please balloon catheter or paclitaxel-eluting stent. PEPCAD II reported binary in-stent restenosis rates of 7% (4/66) with SeQuent Please balloon catheter and 17% (10/65) with paclitaxel-eluting stent at 12-month follow-up ($p = 0.17$). The ISR I and II trials included 108 patients with a single restenotic lesion in a bare metal stent or drug-eluting stent treated by SeQuent Please balloon catheter or an uncoated balloon catheter. This RCT showed a significant difference in binary in-stent restenosis rates of 6% (3/54) with SeQuent Please balloon catheter and 49% (24/54) with uncoated balloon catheter at 6-month follow-up ($p = 0.001$). In the PEPCAD I trial, a non-randomised controlled study of 118 patients with a single de novo lesion in a native small calibre coronary artery, the binary restenosis rate (in-lesion) was 6% (4/82) for patients treated with SeQuent Please balloon catheter and 41% (12/32) in patients treated by SeQuent Please balloon catheter plus bare metal stent implantation at 12-month follow-up.
- 3.3 The PEPCAD II trial has reported in-stent late lumen loss of 0.19 ± 0.39 mm for SeQuent Please balloon catheter compared with 0.45 ± 0.68 mm for paclitaxel-eluting stent at 6 months ($p = 0.01$). The ISR I and II trials reported combined in-stent late lumen loss of 0.14 ± 0.46 mm for SeQuent Please balloon catheter and 0.81 ± 0.79 mm for uncoated balloon catheter at 6 months ($p = 0.001$). The PEPCAD I trial reported in-lesion late lumen loss of 0.18 ± 0.38 mm for SeQuent Please balloon catheter and 0.73 ± 0.74 mm for SeQuent Please balloon catheter plus bare metal stent implantation at 6-month follow-up ($p < 0.0001$).

- 3.4 The ISR I and II trials reported target lesion revascularisation rates of 6% (3/54) for SeQuent Please balloon catheter and 37% (20/54) for uncoated balloon catheter at 24-month follow-up ($p = 0.001$). The PEPCAD II trial reported target lesion revascularisation rates of 6% (4/66) for SeQuent Please balloon catheter and 15% (10/65) for paclitaxel-eluting stent at 12-month follow-up ($p = 0.15$). For patients with bifurcation lesions, the PEPCAD V study reported a target lesion revascularisation rate of 4% (1/28) at 9 months. The mean target lesion revascularisation rate for all 118 patients with small coronary arteries in the PEPCAD I trial was 12% (14/118) at 12-month follow-up. In this study, target lesion revascularisation rate was reported in 5% (4/82) of patients treated with SeQuent Please balloon catheter and 28% (9/32) of patients treated with SeQuent Please balloon catheter plus additional bare metal stent at 12-month follow-up ($p < 0.0001$; as-treated analysis).
- 3.5 The rate of major adverse coronary events was significantly lower at 24 months for patients treated with SeQuent Please balloon catheter compared with patients treated with the uncoated balloon catheter (11% [6/54] vs 46% [25/54]) in ISR I and II ($p = 0.001$). Major adverse coronary events at 12-month follow-up in the PEPCAD II trial were 8% in patients treated with SeQuent Please balloon catheter compared with 17% after treatment by drug-eluting stent ($p = 0.17$) (intention-to-treat analysis). Major adverse coronary events rates at 6-month follow-up were reported as 6% for patients treated with SeQuent Please balloon catheter and 38% for patients treated with SeQuent Please plus bare metal stent in the PEPCAD I trial ($p \leq 0.0001$). The PEPCAD V study had an associated major adverse coronary event rate of 11% at 9 months. A lower major adverse coronary event rate was associated with SeQuent Please balloon catheter use compared with the uncoated balloon catheter at 24 months in ISR I and II, although the reductions were not statistically significant. PEPCAD II reported death in 3% (2) of patients treated with SeQuent Please balloon catheter and 5% (3) of patients treated with paclitaxel-eluting stent at 12-month follow-up. Among these patients, non-cardiac death occurred in 1 and 3 patients respectively and there was one cardiac death in the SeQuent Please balloon catheter group, compared with no deaths in the drug-eluting stent group. Myocardial infarction was reported in 1 patient in the drug-eluting stent treatment group. At 12 months, the PEPCAD I trial reported no deaths in either patient group, with myocardial infarction rates of 1.3% for the SeQuent Please balloon catheter group and 3.1% for the SeQuent Please

balloon catheter plus bare metal stent group. The PEPCAD V trial reported no deaths at 9-month follow-up.

Committee considerations

- 3.6 The Committee considered that the available evidence, although limited in quantity and relatively short term, supported a lower incidence of restenosis after treatment of in-stent restenosis by SeQuent Please balloon catheter compared with paclitaxel-eluting stents and uncoated balloon catheters, and that there was a consistent trend towards a reduced need for re-treatment and major adverse cardiac events. The Committee noted that an important aspect of the clinical utility of the technology was the effective treatment of in-stent restenosis when the passage and delivery of another stent is not technically possible. It was noted that in the PEPCAD II trial, an RCT of 131 patients with a single restenosis in a bare metal stent treated by SeQuent Please balloon catheter or paclitaxel-eluting stent, inserting a paclitaxel-eluting stent was not possible in five patients. Of these five patients, four were successfully treated with SeQuent Please balloon catheter.
- 3.7 The Committee recognised that the majority of evidence was on in-stent restenosis within a bare metal stent and not a drug-eluting stent. The Committee judged that the evidence was insufficient to recommend SeQuent Please balloon catheter for in-stent restenosis within drug-eluting stent at the present time. This is reflected in the guidance recommendation 1.2.
- 3.8 The recommended duration of clopidogrel therapy after using SeQuent Please is 3 months compared with 12 months after using a drug-eluting stent. One study protocol specified that patients treated with SeQuent Please balloon catheter would receive 3 months of clopidogrel therapy and two study protocols specified 1 month of clopidogrel therapy after treatment with SeQuent Please balloon catheter. The Committee was advised that reducing the duration of clopidogrel therapy may have clinical advantages in terms of safety, where there are special concerns about an increased risk of bleeding or need for surgical intervention. This is reflected in the guidance recommendation 1.3.
- 3.9 The Committee was advised that other indications for SeQuent Please balloon catheter might include stenoses in small coronary arteries and complex coronary disease (for example, stenoses at vessel bifurcations). Indications

might also include situations where using stents is difficult or undesirable, for example in calcified or tortuous vessels, or in people with diabetes. The Committee concluded that data on these subgroups would be useful (see section 1.4).

- 3.10 The Committee noted that none of the trial data were from the UK and it debated the generalisability of the evidence to the UK NHS. The Committee was advised that the restrictions of a trial environment meant that the data could not be assumed to apply to the generality of UK cardiology practice.
- 3.11 The Committee noted that there are ongoing trials of SeQuent Please balloon catheter in other countries.
- 3.12 The Committee considered that there was no evidence to suggest that SeQuent Please balloon catheter is harmful. Because no permanent scaffold or polymer is left in the vessel and the overall dose of paclitaxel delivered by the SeQuent Please balloon catheter is less than with the paclitaxel-eluting stent, the Committee considered that theoretical concerns about long-term safety were unlikely to exceed those for drug-eluting stent implantation, although longer-term data would be useful.

4 NHS considerations

System impact

- 4.1 There is evidence to suggest that SeQuent Please balloon catheter reduces the incidence of restenosis and therefore the costs associated with subsequent re-intervention for coronary stenoses, and the costs of more prolonged clopidogrel therapy compared with paclitaxel-eluting stent. The most significant savings to the NHS are likely to be associated with a reduction in re-intervention compared with paclitaxel-eluting stent.
- 4.2 The Committee was advised that if re-intervention is required for subsequent in-stent restenosis, there would be a wider range of options available after treatment with SeQuent Please balloon catheter than after stenting, because of the absence of an additional metallic scaffold.

Committee considerations

- 4.3 The Committee considered that reductions in restenosis requiring medical treatment, readmission and re-intervention would have long-term cost savings if these reductions were maintained. The anticipated savings would only be realised if the beneficial results of SeQuent Please balloon catheter shown in the studies were maintained beyond the current 1-year follow-up intervals, and the Committee saw no reason to believe that this would not be the case.

5 Cost considerations

Cost impact evidence

- 5.1 The main aspects of the cost impact evidence for treatment of in-stent restenosis with SeQuent Please balloon catheters are presented below. Full details of all cost impact evidence and modelling considered by the Committee are available in the [assessment report](#).
- 5.2 The manufacturer submitted a Markov model to assess the costs and consequences of use of SeQuent Please balloon catheter compared with paclitaxel-eluting stent. Costs included those associated with buying the balloon catheter, staff and other costs associated with the procedure, necessary medication, serious complications and survival from the perspective of the NHS and Personal Social Services. The model used a 1-year time horizon, with monthly Markov cycles and applied a half-cycle correction. The model used a 'within-trial' approach, using the PEPCAD II trial with a 12-month time horizon. There was no extrapolation from this short-term time horizon to the long-term, therefore longer term cost impact could not be assessed.
- 5.3 All of the costs for the procedures and adverse events were taken from the National Tariff 2010–2011. The External Assessment Centre considered that this approach was appropriate. The cost of a percutaneous coronary intervention was based on the HRG code EA31Z which refers to PCI involving 0–2 stents. The percutaneous coronary intervention cost was applied similarly for both treatment arms, with a cost differential of £200 associated with the device being added to the SeQuent Please balloon catheter arm. The External Assessment Centre considered that more information justifying the £200 price differential needed to be provided and although an increased price differential of £300 was investigated, reducing the potential cost saving by just over £100, further sensitivity analysis around the price differential would have been informative.
- 5.4 The cost of antiplatelet therapy using clopidogrel was applied per cycle (that is, every month), based on prices derived from 'Prasugrel for the treatment of acute coronary syndromes with percutaneous coronary intervention' (NICE technology appraisal guidance 182), and applied for the corresponding durations: 3 months for SeQuent Please balloon catheter and 12 months for

paclitaxel-eluting stent. Total costs of clopidogrel were £108 and £430, respectively. The External Assessment Centre questioned whether these treatment durations reflected real-world practice because, based on the PEPCAD II trial, the percentages of patients taking clopidogrel after SeQuent Please balloon catheter treatment were 29% at 6 months and 18% at 12 months, and after paclitaxel-eluting stent were 65% at 6 months and 42% at 12 months. These differing treatment durations and proportions of patients were not incorporated in the model or addressed in the sensitivity analysis. The External Assessment Centre carried out additional sensitivity analysis assuming 7 months of clopidogrel therapy in the SeQuent Please balloon catheter arm and 8 months in the paclitaxel-eluting stent arm. This changed the potential saving to £187.

- 5.5 The manufacturer's submission stated that the model used transition probabilities based on the rates of target lesion revascularisation or target vessel revascularisation. These were proposed by the manufacturer to be the main cost drivers, however, a cost model using target lesion revascularisation was not presented in the manufacturer's submission. The transition probabilities were derived from the PEPCAD II trial, in addition to two studies on coronary artery bypass grafting for probabilities related to bleed-related mortality. In the base case it was assumed that transition probabilities did not vary according to time.
- 5.6 Probabilistic sensitivity analysis was not submitted by the manufacturer. Deterministic sensitivity analysis was undertaken, which investigated the following model parameters:
- mortality rates
 - target vessel revascularisation rates
 - anti-platelet therapy (clopidogrel) duration
 - cost of SeQuent Please balloon catheter
 - cost of target vessel revascularisation and myocardial infarction
 - time dependence for events (that is, time-dependent transition probabilities).

- 5.7 The sensitivity analysis identified the key drivers of the results to be target vessel revascularisation rates, co-medication costs and initial revascularisation costs.
- 5.8 The cost model submitted by the manufacturer, using target vessel revascularisation rates in the base case, reported an average per-patient cost over the 1-year horizon of £4134 for the SeQuent Please balloon catheter treatment arm and £4873 for the paclitaxel-eluting stent arm. Therefore SeQuent Please balloon catheter was associated with a cost saving of £739 per patient compared with paclitaxel-eluting stent.
- 5.9 Target vessel revascularisation and target lesion revascularisation were considered by the Committee to be legitimate clinical outcomes for trial analysis. The cost impact of an intervention resulting in either target vessel revascularisation or target lesion revascularisation is comparable as both involve a repeat procedure. The External Assessment Centre identified that the target vessel revascularisation rates used in the base-case model were obtained from different study populations so considered it appropriate to construct a model based on target lesion revascularisation rates from the PEPCAD II trial at 12-month follow-up. Target lesion revascularisation rates of 6% (4/65) for SeQuent Please balloon catheter and 15% (10/63) for paclitaxel-eluting stent were applied. Further details of this cost model are available in the External Assessment Centre's [supplementary report](#).
- 5.10 The cost model by the External Assessment Centre using a target lesion revascularisation instead of target vessel revascularisation parameter reported an average per-patient cost over the 1-year time horizon of £3856 for the SeQuent Please balloon catheter treatment arm and £4323 for the paclitaxel-eluting stent arm. Therefore SeQuent Please balloon catheter was associated with a cost saving of £467 per patient compared with paclitaxel-eluting stent. This is the cost saving quoted in section 1.1.
- 5.11 The results reported in the manufacturer's submission indicated that SeQuent Please balloon catheter is likely to be cost-saving over the 1-year time horizon for patients with in-stent restenosis. These findings are sensitive to target vessel revascularisation rates, co-medication costs and initial revascularisation costs.

- 5.12 In the revised cost model developed by the External Assessment Centre and based on target lesion revascularisation costs, SeQuent Please remained cost saving when event rates were varied $\pm 20\%$.

Committee considerations

- 5.13 The Committee noted that cost data were restricted to the comparison of SeQuent Please balloon catheter and paclitaxel-eluting stent in patients with in-stent restenosis, over a 1-year time horizon.
- 5.14 The Committee noted that although only one comparator (paclitaxel-eluting stent) was used in the cost model, this was likely to be the most relevant comparator for this technology, and was therefore appropriate for the model.
- 5.15 The Committee was advised by the External Assessment Centre that the use of target lesion revascularisation rates from the two arms of the same trial population in the base-case model was more robust than the use of target vessel revascularisation data from different trial populations. The Committee considered the cost saving using target lesion revascularisation instead of target vessel revascularisation to be more robust. On this basis, SeQuent Please balloon catheter was associated with a cost saving of £467 per patient compared with paclitaxel-eluting stent. This is quoted in section 1.1.
- 5.16 The Committee considered the evidence on clopidogrel duration included in the model. It noted in particular the sensitivity analysis carried out by the External Assessment Centre. Even when the assumptions on the duration of clopidogrel therapy that were most unfavourable to SeQuent Please balloon catheter were applied, it remained cost saving.

6 Conclusions

- 6.1 The Committee recognised that there are uncertainties in the clinical evidence and cost model, but the available data support a cost saving associated with use of SeQuent Please balloon catheter under the conditions set out in sections 1.2 and 1.3.

- 6.2 There may be additional advantages related to reduced duration of clopidogrel therapy and increased treatment options if further restenosis occurs, compared with the use of stenting for in-stent restenosis.

7 Implementation

7.1 NICE has developed tools to help organisations put this guidance into practice (listed below). These are available on our website (www.nice.org.uk/guidance/MTG1).

- Slides highlighting key messages for local discussion.
- Costing template and report to estimate the national and local savings and costs associated with implementation.
- A podcast with Peter Groves (clinical expert on the Medical Technologies Advisory Committee) and Katie Worrall (NICE implementation adviser).

8 Related NICE guidance

Published

- Prasugrel for the treatment of acute coronary syndromes with percutaneous coronary intervention. NICE technology appraisal guidance 182 (2009). Available from www.nice.org.uk/guidance/TA182
- Drug-eluting stents for the treatment of coronary artery disease (part review of NICE technology appraisal guidance 71). NICE technology appraisal guidance 152 (2008). Available from www.nice.org.uk/guidance/TA152
- Guidance on the use of coronary artery stents. NICE technology appraisal guidance 71 (2003). Available from www.nice.org.uk/guidance/TA71

Andrew Dillon

Chief Executive

December 2010

Appendix A. Committee members and NICE lead team

A Medical Technologies Advisory Committee members

The Medical Technologies Advisory Committee is a standing advisory committee of NICE. A list of the committee members who took part in the discussions for this guidance appears below.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each Medical Technologies Advisory Committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Professor Bruce Campbell (Chair)

Consultant Vascular Surgeon, Exeter

Dr Peter Groves

Consultant Cardiologist, Cardiff and Vale NHS Trust

Dr Allan Swift

Director of Quality and Regulatory Affairs, Gen-Probe Life Sciences

Professor Peter Gaines

Consultant Interventional Radiologist, Sheffield Vascular Institute and Sheffield Hallam University

Professor Karl Claxton

Professor of Economics, University of York

Mr Harry Golby

Head of Commissioning, Acute, Access and Diagnostics, Salford NHS

Professor Tony Freemont

Professor of Osteoarticular Pathology, University of Manchester

Matthew Hill

Lay Member

Susan Bennett

Lay Member

Mrs Gail Coster

Radiography Manager, Strategy, Planning and Governance, Yorkshire NHS Trust

Dr Daniel Clark

Head of Clinical Engineering, Nottingham University Hospitals NHS Trust

Mrs Jacqui Nettleton

Programme Director, Long Term Conditions, West Sussex PCT

Dr Paul Knox

Reader in Vision Science, University of Liverpool.

Professor Stephen Westaby

Consultant Cardiac Surgeon, John Radcliffe Hospital, Oxford

Dr Susanne Ludgate

Clinical Director, Devices Medicines & Healthcare Products Regulatory Agency

Professor Bipin Bhakt

Charterhouse Professor in rehabilitation Medicine and NHS Consultant Physician, University of Leeds

Dr Keith Blanshard

Consultant Radiologist, Leicester Royal Infirmary

Mrs Catherine Leonard

Reimbursement Manager, Medtronic UK

Dr (Robert) Martyn Bracewell

Senior Lecturer in Neurology and Neuroscience, Bangor University

Professor Christopher McCabe

Professor of Health Economics, Institute of Health Sciences, University of Leeds

Dr Alex Faulkner

Senior Research Fellow, Centre for Biomedicine & Society, King's College London

Dr Janelle York

Lecturer & Researcher in Nursing, University of Salford

Professor Sharon Peacock

Professor of Clinical Microbiology, University of Cambridge

Dr Dilly Anumba

Senior Clinical Lecturer/Honorary Consultant Obstetrician and Gynaecologist, University of Sheffield

B NICE lead team

Each medical technology assessment is assigned a lead team of a NICE technical analyst and technical adviser, a clinical expert, a representative of the External Assessment Centre, and a non-expert member of the Medical Technologies Advisory Committee.

Suzi Peden

Technical analyst

Dr Peter Groves

Clinical expert

Professor Chris McCabe

Non-clinical expert

Professor John Hutton

External Assessment Centre representative

Lizzy Latimer

Technical adviser

Appendix B. Sources of evidence considered by the Medical Technologies Advisory Committee

A The External Assessment Centre report for this assessment was prepared by York Health Economic Consortium:

Whitehead S, Hutton J, Glanville J SeQuent Please coronary balloon catheter with paclitaxel release for coronary artery disease for the treatment of in-stent restenosis or stenoses of small calibre coronary arteries (May 2010).

B Submissions from the following manufacturer/sponsors:

- Braun Medical

C The following people gave their expert personal view on SeQuent Please balloon catheter for in-stent coronary restenosis by providing their expert comments on the draft scope, assessment report and medical technologies consultation document.

- Dr Peter Groves, Medical Technologies Advisory Committee, clinical expert

The following individuals gave their expert personal view on SeQuent Please balloon catheter in writing by completing a patient questionnaire or expert adviser questionnaire provided to the Committee.

- Dr Martin Been nominated by British Cardiovascular Intervention Society, clinical expert
- Dr Mark de Belder nominated by British Cardiovascular Intervention Society, clinical expert
- Dr Stephen Campbell nominated by British Cardiovascular Intervention Society, clinical expert
- Dr Sagar Doshi nominated by British Cardiovascular Intervention Society, clinical expert
- Dr Simon Eccleshall nominated by British Cardiovascular Intervention Society, clinical expert
- Mr Liam Hughes nominated by British Cardiovascular Intervention Society, clinical expert
- Mr Ken Timmis President of Heart Care Partnership UK, the patient arm of the British Cardiovascular Society, patient expert
- Dr John Townend nominated by British Cardiovascular Intervention Society, clinical expert

About this guidance

NICE medical technology guidance addresses specific technologies notified to NICE by manufacturers. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This 'case' is reviewed against the evidence submitted and expert advice. If the case for adopting the technology is supported, then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.

This guidance was developed using the NICE [medical technologies guidance process](#).

We have produced a [summary of this guidance for the public](#). [Tools](#) to help you put the guidance into practice and information about the evidence it is based on are also available.

Changes after publication

April 2015: minor maintenance

April 2012: minor maintenance

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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