National Institute for Health and Care Excellence

IP1012/2 – Subcutaneous implantable cardioverter defibrillator insertion for preventing sudden cardiac death

IPAC date: 13th October 2017

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Specialist Adviser	**General**	Dear Sir/Madam I am writing to offer some feedback on this consultation document. I think that overall the documents are all excellent and very accurately reflect the data that is currently available.	Thank you for your comment.
2	Specialist Adviser	**3.2**	I have a few minor comments on the procedure consultation document itself. On page 4, section 3.2, the suggestion is that the procedure uses no fluoroscopy at all. However, practice has changed slightly and it is now usual to use a few seconds of fluoroscopy through the procedure. This is still very minimal compared to a transvenous ICD and almost negligible in terms of exposure to x-ray, but the document is currently not strictly correct.	Thank you for your comment. Section 3.2 of the guidance has been changed to ‘’ The implantation procedure is carried out with the patient under general anaesthesia, or with local anaesthesia and sedation. Implantation is guided by anatomical landmarks with or without the use of fluoroscopy or other medical imaging. A subcutaneous pocket for the generator is created on the left side of the chest. The lead is tunnelled subcutaneously from the pocket to a small incision at the lower end of the sternum. Then, it is tunnelled to the upper end of the sternum so that the sensing ring electrodes and shocking

				coil lie alongside the sternum. The lead can be secured using either a 2- or 3-incision technique, and is then connected to the generator in the pocket. Finally, the incisions are closed and the sensing and recording functions of the subcutaneous ICD are adjusted using an external programmer. Ventricular fibrillation is induced to test that the subcutaneous ICD can appropriately detect and correct it.''
3	Specialist Adviser	**3.2**	Also the description of the technique in this section is what is referred to as a '3 incision' technique by implanters of the S-ICD. However, many operators are now using predominantly a '2 incision' technique that does not require the 'second small incision at the upper end of the sternum' as mentioned in this section of the document. Again, purely for factual correctness it would be appropriate to say that there are 2 techniques and the 2 incision one is increasingly the one used.	Thank you for your comment. Section 3.2 of the guidance has been changed to: '' The implantation procedure is carried out with the patient under general anaesthesia, or with local anaesthesia and sedation. Implantation is guided by anatomical landmarks with or without the use of fluoroscopy or other medical imaging. A subcutaneous pocket for the generator is created on the left side of the chest. The lead is tunnelled subcutaneously from the pocket to a small incision at the lower end of the sternum. Then, it is tunnelled to the upper end of the sternum so that the sensing ring electrodes and shocking coil lie alongside the sternum. The lead can be secured using either a 2- or 3-incision technique, and is then connected to the generator in the pocket. Finally, the incisions are closed and the sensing and recording functions of the

				subcutaneous ICD are adjusted using an external programmer. Ventricular fibrillation is induced to test that the subcutaneous ICD can appropriately detect and correct it.''
4	Specialist Adviser	**6.2**	In section 6.2 the committee's comment that 'patients with a subcutaneous implantable cardioverter defibrillator may develop psychological disturbance, including anxiety and fear of shocks' is of course equally applicable to patients with a transvenous ICD. As it is currently written there is an implication that this is specific to the S-ICD which I am sure the committee did not mean or intend. Thank you very much for allowing us to comment on the IPG. Kind regards Dr [redacted] Consultant Cardiologist & Electrophysiologist Cardiac Department [redacted] [redacted]	Thank you for your comment. Section 6.1 of the guidance has been changed to**:** ''*The committee recognised that patients with implantable cardioverter defibrillators of any kind may develop psychological disturbance, including anxiety and fear of shocks*.'' Please refer to comments 20 and 26.
5	Specialist Adviser British Heart Rhythm Society and the British Cardiovascular Society	**General**	Dear NICE, I am responding on behalf of the British Heart Rhythm Society and the British Cardiovascular Society to the above guidance. Both organisations are happy with the provisional guidance and would support its further development and implementation. Regards,	Thank you for your comment. The consultee agrees with main recommendation.

			[redacted] Consultant Cardiologist [redacted] [redacted] [redacted]	
6	Company Boston Scientific	**General**	When using an acronym for the subcutaneous implantable cardioverter-defibrillator, we would suggest using the term â€œS-ICDâ€ or â€œsubcutaneous ICDâ€ in order to clearly differentiate it from a transvenous implantable cardioverter-defibrillator, rather than the term â€œICDâ€ alone. The use of the acronym â€œICDâ€ alone, as currently used in a number of places in the document is often ambiguous as it could refer to either of these technologies. We would suggest the term â€œS-ICDâ€ is used in the following places: first box (page 1), sections 3.1 and 3.2 (page 4), section 4.1 (page 5) and section 5.1 (page 7).	Thank you for your comment. The term ‘’subcutaneous’’ has been added to the term ‘’ICD’’ in sections 3.1 and 3.2. In the other places mentioned by the consultee, the term ‘’subcutaneous’’ was already present.
7	Company Boston Scientific	**Lay description**	First box: The term â€œarrhythmiasâ€ can refer to fast or slow, irregular or regular heartbeats. We would propose that the second sentence is changed as follows so the terms are used correctly: â€œIt detects and treats fast heartbeats called tachyarrhythmias.â€	Thank you for your comment. The lay description of the procedure in the overview has been changed to**:** ‘’ A subcutaneous implantable cardioverter defibrillator (ICD) is a device that is placed under the skin of the chest. It detects and treats fast heartbeats called tachyarrhythmias. The device uses electrical shocks to help control life-threatening arrhythmias that can cause sudden cardiac death.’’

8	Company Boston Scientific	**1.1**	We agree with the conclusions drawn by the NICE committee that the evidence on S-ICD implantation shows the procedure to be safe and efficacious and support the recommendation for standard arrangements for this procedure.	Thank you for your comment. The consultee agrees with main recommendation.
9	Company Boston Scientific	**3.1**	In order to accurately reflect the type of electrodes found on the subcutaneous ICD lead, which are ring electrodes, we would suggest that the second sentence in this section is changed as follows: â€œThis single lead comprises 2 sensing ring electrodes and a shocking coil.â€	Thank you for your comment. Section 3.1 of the guidance has been changed to**:** ‘’An entirely subcutaneous implantable cardioverter defibrillator (ICD) differs from a transvenous ICD in that a single lead is placed subcutaneously. This single lead comprises 2 sensing ring electrodes and a shocking coil. The ICD senses cardiac signals, but the lead is not directly attached to the heart. Also, unlike a conventional transvenous ICD, the subcutaneous device is not designed to provide long-term pacing.’’
10	Company Boston Scientific	**3.2**	Current practice in the UK varies, with some centres using fluoroscopy or imaging to confirm lead positioning with others relying on anatomical landmarks alone. For accuracy, we would propose the second sentence in this section is changed as follows: â€œImplantation is guided by anatomical landmarks with or without the use of fluoroscopy or other medical imaging.â€	Thank you for your comment. Section 3.2 of the guidance has been changed to: ‘’The implantation procedure is carried out with the patient under general anaesthesia, or with local anaesthesia and sedation. Implantation is guided by anatomical landmarks with or without the use of fluoroscopy or other medical imaging. A subcutaneous pocket for the generator is created on the left side of the chest. The lead is tunnelled subcutaneously from the pocket to a

				small incision at the lower end of the sternum. Then, it is tunnelled to the upper end of the sternum so that the sensing ring electrodes and shocking coil lie alongside the sternum. The lead can be secured using either a 2- or 3-incision technique, and is then connected to the generator in the pocket. Finally, the incisions are closed and the sensing and recording functions of the subcutaneous ICD are adjusted using an external programmer. Ventricular fibrillation is induced to test that the subcutaneous ICD can appropriately detect and correct it. ‘’ Please also refer to comment 2.
11	Company Boston Scientific	**3.2**	We would like to note that in light of recent clinical advances in the implantation technique, the current description for tunnelling of the lead, which describes only a three-incision technique, is out of date. We would propose the text is changed as follows to reflect the current practice in terms of implantation of the lead and the additional clarification around the type of electrode used by the lead: â€œThe lead is tunnelled subcutaneously from the pocket to a small incision at the lower end of the sternum. Then, it is tunnelled to the upper end of the sternum so that the sensing ring electrodes and shocking coil lie alongside the sternum. The lead can be secured using either a two- or three-incision technique as per the deviceâ€™s labelling. The lead is then connected to the generator in the pocket.â€□	Thank you for your comment. Section 3.2 of the guidance has been changed to: ‘’The implantation procedure is carried out with the patient under general anaesthesia, or with local anaesthesia and sedation. Implantation is guided by anatomical landmarks with or without the use of fluoroscopy or other medical imaging. A subcutaneous pocket for the generator is created on the left side of the chest. The lead is tunnelled subcutaneously from the pocket to a small incision at the lower end of the sternum. Then, it is tunnelled to the upper end of the sternum so that the

				sensing ring electrodes and shocking coil lie alongside the sternum. The lead can be secured using either a 2- or 3-incision technique, and is then connected to the generator in the pocket. Finally, the incisions are closed and the sensing and recording functions of the subcutaneous ICD are adjusted using an external programmer. Ventricular fibrillation is induced to test that the subcutaneous ICD can appropriately detect and correct it. ‘’ Please also refer to comment 3.
12	Company Boston Scientific	**3.2**	In order to accurately reflect the functions of the subcutaneous ICD device, which does not include pacing, we would suggest the second to last sentence in this section is changed as follows: â€œFinally the incisions are closed and the sensing and recording functions of the S-ICD are adjusted using an external programmer.â€□	Thank you for your comment. Section 3.2 of the guidance has been changed to: ‘’The implantation procedure is carried out with the patient under general anaesthesia, or with local anaesthesia and sedation. Implantation is guided by anatomical landmarks with or without the use of fluoroscopy or other medical imaging. A subcutaneous pocket for the generator is created on the left side of the chest. The lead is tunnelled subcutaneously from the pocket to a small incision at the lower end of the sternum. Then, it is tunnelled to the upper end of the sternum so that the sensing ring electrodes and shocking coil lie alongside the sternum. The lead can be secured using either a 2- or 3-

				incision technique, and is then connected to the generator in the pocket. Finally, the incisions are closed and the sensing and recording functions of the subcutaneous ICD are adjusted using an external programmer. Ventricular fibrillation is induced to test that the subcutaneous ICD can appropriately detect and correct it. ‘’
13	Company Boston Scientific	**4**	"We are pleased to confirm that the international EFFORTLESS registry mid-term paper has now been published in the Journal of the American College of Cardiology and can be found online via the following link: http://www.onlinejacc.org/content/accj/70/7/830.full.pdf?download=true Given the relevance of this study in terms of the number of patients and length of follow-up, we would propose that the key efficacy outcomes from this paper are also added to the guidance document for completeness as follows: â€¢ 99.5% patients had a successful conversion of induced VT/VF at implant â€¢ 10.6% of patients had 278 appropriately treated VT or VF episodes â€¢ 1 and 5 year rates of appropriate shock were 5.8% and 13.5% respectively â€¢ Discrete episode conversion success was 97.4% overall (88.5% converted on 1st shock, and 97.4% within 5 shocks available)	Thank you for your comment. The Boersma (2017) paper which is a 5-year follow-up of the Effortless registry has been added to table 2.

			â€¢ Mean time to therapy was 15.1s (+/- 3.5s) for induced vs. 18.4s (+/-4.3s) for spontaneous episodes (p=<0.001). o Time to therapy for MVT episodes was 17.4 +/-3.8s o Time to therapy for PVT epsisodes was 19.8 +/-4.9s"	
14	Company Boston Scientific	**5**	"We are pleased to confirm that the international EFFORTLESS registry mid-term paper has now been published in the Journal of the American College of Cardiology and can be found online via the following link: http://www.onlinejacc.org/content/accj/70/7/830.full.pdf?download=true Given the relevance of this study in terms of the number of patients and length of follow-up, we would propose that the key safety outcomes from this paper are also added to the guidance document for completeness as follows: â€¢ S-ICD system and procedure complication rate at 30 days 4.1%, and 8.4% at 360 days â€¢ S-ICD complication rates were 0.3% at 30days and 2.0% at 360days o Most common S-ICD complications were cardiac oversensing (1.1%) and discomfort (0.8%) â€¢ Inappropriate shock rate was 8.1% year 1 and 11.7% after 3 years* author notes similar to historical TV-ICD studies of 7-10% in first year rising to 18% by year 5. Second generation S-ICD detection algorithms may reduce inappropriate shocks.	Thank you for your comment. The Boersma (2017) paper which is a 5-year follow-up of the Effortless registry has been added to table 2.

			â€¢ Inappropriate shock rate for AF or SVT â€“ 1st year 1.5%, overall 2.3% for average 3 year follow-up â€¢ Few device extractions â€“ 1.4% patients - due to change in indication: need for ATP (5), CRT (4) and brady pacing (1) â€¢ Infections requiring device removal 2.4%"	
15	Company Boston Scientific	**5**	We believe that given the relevance of the UK registry data from NICOR, as reported under study 9 in the â€œIP overviewâ€, the complication rates reported should be included in the main guidance document and would propose the addition of a further section after section 5.16 to report the findings as follows: â€œA UK registry reported complications in 1.1% (2/181) of patients receiving a subcutaneous ICD. This rate is similar to the reported rate of 1.8% in conventional transvenous ICD implants recorded in this registry.â€	Thank you for your comment. The committee decided not to make this change. Section 5 is intended as a summary of the key safety issues and is not intended to provide comparative data. A full summary of the registry data from NICOR can be found in the overview and will be published alongside the final guidance.
16	Company Boston Scientific	**5.13**	The Burke et al (2015) study referred to in this section reported 7 events of electrode movement occurred in 5 patients. The text here should be corrected as it is currently wrong.	Thank you for your comment. Section 5.13 of the guidance has been corrected as follows: ‘’Electrode movement was reported in 5 patients in the case series of 889 patients. The lead complication rate was statistically significantly lower in the subcutaneous ICD group than in the transvenous ICD group in the retrospective propensity-matched cohort study of 280 patients (1% versus 12%; p=0.03). The only lead complication reported in the subcutaneous ICD group was lead displacement, which occurred in 1 patient out of 140.’’

17	Company Boston Scientific	**5.13**	The Brouwer et al (2016) study referred to in this section reported a lead complication rate of 0.8% for the subcutaneous ICD group (versus 11.5% in the transvenous ICD group) and not 5%. This should be corrected in the text.	Thank you for your comment. Section 5.13 of the guidance has been corrected as follows: ''Electrode movement was reported in 5 patients in the case series of 889 patients. The lead complication rate was statistically significantly lower in the subcutaneous ICD group than in the transvenous ICD group in the retrospective propensity-matched cohort study of 280 patients (1% versus 12%; p=0.03). The only lead complication reported in the subcutaneous ICD group was lead displacement, which occurred in 1 patient out of 140.'' Table 2 of the overview has also been corrected.
18	Company Boston Scientific	**5.17**	Given the recent publication of the EFFORTLESS mid-term follow-up study, we feel it may be helpful to quantify the comment made by specialist advisers regarding discomfort around the device as follows: â€œFor this procedure, specialist advisers listed the following anecdotal adverse event: discomfort around the device (reported at a rate of 0.8% (8/985) of patients in an international registry of 994 patients).â€	Thank you for your comment. Section 5.17 is the opinion of the Specialist Advisers and will not be changed.
19	Company Boston Scientific	**6.1**	We note that the discussion on registries during the committee meeting and the comment here relate only to the international EFFORTLESS registry and hence find the comment slightly misleading. We would	Thank you for your comment.

			propose the comment is amended as follows to account for the presence and use of the UK NICOR registry: "The committee noted that not all insertions of a subcutaneous implantable cardioverter defibrillator were being recorded in the international EFFORTLESS registry. However, procedures being conducted in the UK should be recorded in the UK Central Cardiac Audit Database."	Section 6.1 of the draft guidance has been removed. The committee has already recommended in section 1.2 of the guidance that ‘’*Clinicians should enter details about all patients having subcutaneous implantable cardioverter defibrillator insertion for preventing sudden cardiac death onto a register by submitting data to the National Audit of Cardiac Rhythm Management database at the UK National Institute for Cardiovascular Outcomes Research (NICOR), and should review local clinical outcomes*’’.
20	Company Boston Scientific	**6.2**	Based on our recollections of the discussions in the committee meeting and in line with the commentary provided in section 4.5 (page 6), we would like to clarify that there are no significant differences in physical or mental quality of life between a subcutaneous ICD and a transvenous ICD, and that with either device evidence shows patients see an improvement in quality of life after implantation. At present, we feel that the comment in section 6.2 may be misinterpreted as implying a decrease in quality of life of patients after receiving such a device and/or that patientsâ€™ concerns after implantation are unique to a subcutaneous ICD and may not be the same for patients receiving a transvenous ICD. As such, we would propose that this comment is changed as follows to reflect the fact that the impact to patients would occur for any type of defibrillator, not only a subcutaneous defibrillator: "The committee recognised that patients with any type of implantable	Thank you for your comment. Section 6.1 of the guidance has been changed to**:** ‘’*The committee recognised that patients with implantable cardioverter defibrillators of any kind may develop psychological disturbance, including anxiety and fear of shocks*.’’ Please refer to comment 4 and 26.

			cardioverter defibrillator (ICD), including a subcutaneous ICD, may develop psychological disturbance, including anxiety and fear of shocks but that overall their quality of life is expected to improve after receiving such a device."	
21	Resuscitation Council (UK)	3.1	This section could be improved by making clearer the potential advantages and potential limitations of (and therefore the potential indications for considering) a subcutaneous ICD over a transvenous ICD system.	Thank you for your comment. Section 3.1 reads: '' An entirely subcutaneous implantable cardioverter defibrillator (ICD) differs from a transvenous ICD in that a single lead is placed subcutaneously. The lead comprises 2 sensing electrodes and a shocking coil. The ICD senses cardiac signals, but the lead is not directly attached to the heart. Also, unlike a conventional transvenous ICD, the subcutaneous device is not designed to provide long-term pacing.''
22	Resuscitation Council (UK)	3.2	This section also states correctly that the device is not designed to provide long-term pacing, but the document goes on later to refer to a pacing function, without explaining this (to clinicians without a detailed understanding of indications for and modes of pacing) apparent disparity. It would be useful to include a succinct and clear explanation of the need for transvenous leads to provide pacing for cardiac resynchronisation, dual chamber pacing for bradycardia, atrial pacing for bradycardia or reliable, tolerable long-term ventricular pacing for bradycardia.	Thank you for your comment. The word ''pacing'' has been removed from section 3.2. of the guidance.
23	Resuscitation Council (UK)	5.11	The wording should be "…inadequate or **delayed** healing" (not prolonged healing)	Thank you for your comment.

				Section 5.11 has been changed to include the results of a systematic review of 5,380 patients recently published as follows: ‘’ *Delayed wound healing was reported in less than 1% of patients (range 0% to 19%, 7 events, 1,145 patients from 7 studies) in the systematic review of 5,380 patients*.’’
24	Resuscitation Council (UK)	5.13	The terms “electrode movement” and “electrode displacement” are used as if they are different, when in fact they are being used synonymously.	Thank you for your comment. Both terms are used in the same section, which means they are used to describe the same complication as 1 section describes 1 complication. Section 5.13 reports on 2 different papers which used 2 different terms to describe the same complication. The term ‘’ displacement’’ has been changed to ‘’movement’’ in section 5.13 of the guidance.
25	Resuscitation Council (UK)	5.14	“Near syncope, dizziness, shortness of breath or confusion were reported in 1 patient in the international registry of 472 patients.” This statement (using the words “or” and “were”) doesn’t make sense. Which of these four symptoms was/were reported by this single patient?	Thank you for your comment. The lambiase (2014) paper has been replaced by the Boersma (2017) paper which is a longer follow-up of the Effortless registry. The final guidance document has been changed accordingly.
26	Resuscitation Council (UK)	6.2	The committee should acknowledge here that this risk is not specific to subcutaneous ICDs; a similar risk exists in people with transvenous ICD systems.	Thank you for your comment. Section 6.1 of the guidance has been changed to: ‘’*The committee recognised that patients with a subcutaneous*

				implantable cardioverter defibrillators of any kind may develop psychological disturbance, including anxiety and fear of shocks.'' Please refer to comments 4 and 20.
27	Resuscitation Council (UK)	General	The guidance directs people to the home page of the NICE website for 'related NICE guidance' but does not provide a link to or list of relevant guidance, making it difficult for people to be aware of what related guidance is available and to obtain access easily to relevant documents.	Thank you for your comment. The list of related NICE guidance can be found in the NICE IP overview.
28	Resuscitation Council (UK)	General	The NICE-accredited guidance on ICDs within the following publication is as relevant to subcutaneous ICDs as it is to transvenous systems, so an opportunity has been missed to promote clinical excellence by helping people to find such relevant guidance easily. Pitcher D, Soar J, Hogg K, et al. Cardiovascular implanted electronic devices in people towards the end of life, during cardiopulmonary resuscitation and after death: guidance from the Resuscitation Council (UK), British Cardiovascular Society and National Council for Palliative Care Heart 2016;102:A1–A17.	Thank you for your comment. This guidance has been added to the list of existing assessments of this procedure in the overview.

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