# National Institute for Health and Care Excellence

## IP1847 Aortic remodelling hybrid stent insertion during surgical repair of an acute type A aortic dissection

**IPAC date: 12 May**

| Com. no. | Consultee name and organisation | Sec. no. | Comments | Response<br>Please respond to all comments |
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| 1 | Consultee 1<br>Artivion, Inc. | Lay description | à change to “a superhelical nitinol stent with PTFE material sewn on one end (hybrid stent)”.<br><br>"Tube" gives the impression that it has no stent openings, which is false as the open stent structure allows uninhibited flow to supra aortic vessels. | Thanks for your comment.<br><br>‘Tube’ has been changed to ‘stent’ in the lay description. |
| 2 | Consultee 1<br>Artivion, Inc. | 1.5 | We request reference to randomised controlled trials (RCT) be excluded. RCTs are not standard practice for aortic dissection and to our knowledge there are no RCTs for any treatments involving acute aortic dissection. | Thanks for your comment.<br><br>The committee has considered this comment but has decided not to exclude RCT and changed ‘and’ to ‘or in section 1.5: “*Further research could include randomised controlled trials* ***or*** *analysis of registry data*...” |
| 3 | Consultee 1<br>Artivion, Inc. | 3.2 | We suggest quality of life be excluded. There have been no QoL surveys administered for patients treated with AMDS or in other studies of acute aortic dissection, likely due to the emergent nature without prior symptoms, and high mortality rates if not immediately treated surgically. | Thanks for your comment.<br>The committee has considered this comment but has decided not to remove quality of life from the key efficacy outcomes (section 3.2). As detailed in the evidence and/or professional expert questionnaires, some outcomes are related to quality of life, such as stroke, renal failure, and |

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| | | | | peripheral malperfusion (i.e. leg ischemia). |
| 4 | Consultee 1<br>Artivion, Inc. | 3.5 | We recommend clarifying this statement to read "managing dissections…that extend into the aortic arch, SAV's, and descending aorta." | Thanks for your comment.<br><br>Section 3.5 has been changed to: *"The committee was informed that acute type A aortic dissection is a rare condition with a high mortality, and this procedure has a role in managing* ***type A*** *dissections* ***that extend into the aortic arch, supra-aortic vessels and descending aorta****."* |
| 5 | Consultee 1<br>Artivion, Inc. | Lay description | change to "a superhelical nitinol stent with PTFE material sewn on one end (hybrid stent)".<br>"Tube" gives the impression that it has no stent openings, which is false as the open stent structure allows uninhibited flow to supra aortic vessels. | Thanks for your comment.<br><br>Please see response in comment 1. |
| 6 | Consultee 1<br>Artivion, Inc. | General | • Page 1: Replace "a small metal tube with felt sewed on one end (hybrid stent)" with "a superhelical nitinol stent with PTFE material sewn on one end (hybrid stent)". "Tube" gives the impression that it has no stent openings, which is incorrect, as the open stent structure allows uninhibited flow to supra aortic vessels.<br>• Page 4 - We request mention of randomized controlled trial (RCT) to be removed. This is not standard practice for aortic products for dissection and to our knowledge there are no RCTs for any treatments involving acute aortic dissection.<br>• Page 6, section 3.2 - QoL is listed as a key efficacy outcome. There have been no QoL surveys administered for patients treated with AMDS or in other studies of acute aortic dissection, likely due to the emergent nature without prior symptoms, and high mortality rates if not immediately treated surgically. Therefore, we suggest it be excluded. | Thanks for your comments.<br><br>Page 1: please see response in comment 1.<br>Page 4: please see response in comment 2.<br>Page 6 section 3.2: please see response in comment 3.<br>Page 6 section 3.3: the committee has discussed this comment but decided not to remove 'bleeding' from the key safety outcomes (section 3.3).<br>Page 6 section 3.5: please see response in comment 4. |

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| | | | • Page 6 section 3.3 – Bleeding is included as a key safety outcome. To date, bleeding has not been included as a primary or secondary safety endpoint.<br>• Page 6 Section 3.5 - Recommend clarifying the following statement to read “managing dissections…that extend into the aortic arch, SAV’s, and descending aorta.” | |
| 7 | Consultee 1<br>Artivion, Inc. | (Over view | • Page 1- Replace “a small metal tube with felt sewed on one end (hybrid stent)” with “a superhelical nitinol stent with PTFE material sewn on one end (hybrid stent)”. “Tube” gives the impression that it has no stent openings, which is incorrect, as the open stent structure allows uninhibited flow to supra aortic vessels.<br>• Page 5 and 6 - TL and FL diameter sections reference “when comparing to baseline”, as if the TL and FL baseline is the same as what was previously described for the TAD baseline. The baselines were different. Also, for TL and FL, the baseline was preoperative CT.<br>• Page 5 – In the phrase “and from 16.13 mm to 19.34” replace “19.34” with “19.43mm in the mid-descending aorta.”<br>• Page 8 – W suggest adding a section on “device safety” that includes the that there was no spinal cord ischemia or aortic injury associated with device implantation. No stent fracture, distal stent-induced new entry tear, or device-related reintervention reported in DARTS study.<br>• Page 10 and 14 - There are two (2) ClinicalTrials.gov records for the DARTS I study. NCT03397251 is currently listed and is the record for sites in Germany and NCT03035643 is the record for sites in Canada<br>• Page 11, 2nd paragraph - The denominator should be 46 vs. 47; the % values are correct.<br>• Page 11 - The following is incorrect: “Median cerebral perfusion duration (minutes): 3.0 (range 2.0 to 5.0)”. This is either meant to be Median cerebral perfusion duration (minutes): 30.5 (IQR 23.0, 37.8) OR Median AMDS implantation time (minutes): 3.0 (IQR 2.0, 5.0).<br>• Page 23/24: Add | Thanks for your comments.<br>Page 1: please see response in comment 1.<br>Pages 5 and 6: ‘the preoperative CT was used as a baseline’ has been added.<br>Page 5: ’19.34’ has been changed to ’19.43’.<br>Page 8: this information is described in study 1 (DARTS), page 13.<br>Pages 10 and 14: NCT03397251 with enrolment at 5 institutes in Canada and 1 in Germany is described in Bozso 2019, 2021). To avoid confusion, the trial ID number has been removed.<br>Page 11. 2nd paragraph: ‘47’ has been changed to ‘46’.<br>Page 11: the information has been changed to:<br>• Median AMDS implantation time (minutes): 3.0 (IQR 2.0 to 5.0)<br>• Median cerebral perfusion duration (minutes): 30.5 (IQR 23.0 to 37.8) |

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| | | | o There is an ongoing registry study investigating the clinical benefits of the AMDS to treat patients with acute DeBakey type I dissections and/or intramural hematomas (IMH) involving the ascending aorta and aortic arch through open surgical repair and the study is referred to as the DARTS Registry (ClinicalTrials.gov reference: NCT03894033). The study is an observational, prospective study. The study will target up to 100 patients; sites will be located in Europe (currently Germany only) and in Canada. The study will follow all enrolled patients through 5-years following the AMDS procedure. The primary outcomes at early (30-days) and late (1+ years) are mortality, disabling permanent stroke, paralysis/ paraplegia, aortic injury associated with the implantation of the device and aortic arch vessel branch patency.<br>o There is an ongoing and recently approved (December 2021) US IDE Study investigating the safety and efficacy of AMDS and the study is referred to as the PERSEVERE Study (ClinicalTrials.gov reference: NCT05174767). The study is a prospective, non-randomized, single-arm, multicenter interventional study. The study will target 93 enrolled patients with acute DeBakey type I dissection with evidence of radiographic and/or clinical malperfusion; all sites will be located in the United States. The study will follow all enrolled patients through 5-years following the AMDS procedure. The primary objective is to demonstrate a clinically meaningful reduction (31%) in the percent of patients who experience at least one of the following MAEs within 30-days post-procedure: all-cause mortality, new disabling stroke, new onset renal failure requiring dialysis, myocardial infarction; published clinical outcomes after the standard of care (hemiarch procedure) were used to estimate a performance goal. The co-primary objective is to demonstrate a clinically meaningful increase (40%) in the percent of patients who have true lumen expansion ≥ 6.0 mm by 1- year; published aortic remodeling outcomes after the standard of care (hemiarch procedure) were used to estimate a performance goal. | Page 23/24: NCT03894033 was listed in the ongoing trials; NCT05174767 has been added to the overview. |

*understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."*