# National Institute for Health and Care Excellence

## IP1316/2 Biodegradable spacer insertion to reduce rectal toxicity during radiotherapy for prostate cancer

**IPAC date: 10th November 2022**

| Com. no. | Consultee name and organisation | Sec. no. | Comments | Response<br>Please respond to all comments |
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| 1 | Consultee 1<br>Boston Scientific | 1.1 | We welcome NICE's decision to revise the guidance to 'special arrangements', based on the detailed feedback provided by stakeholders as part of the consultation process. We are very pleased that this will result in patients in the UK having access to this procedure and the ability to participate in shared decision making with their healthcare provider, based on their individual needs. | Thank you for your comments and agreeing with the recommendation. |
| 2 | Consultee 1<br>Boston Scientific | 1.2 | The link to the audit tool does not appear to work. Could NICE please correct the link? 'File not found \| NICE' | Thank you for your comments.<br>The team amended the link to the audit tool in section 1.2 in the final guidance. |
| 3 | Consultee 1<br>Boston Scientific | 1.4 | We are pleased to see that NICE has recommended further research as we believe this will reinforce the existing evidence of safety and efficacy of SpaceOAR for patients undergoing radiotherapy treatment for prostate cancer.<br><br>We would like to bring to the attention of the Committee the following ongoing clinical trial sponsored by Boston Scientific: NCT04905069 - Effectiveness of the SpaceOAR Vue System in Subjects with Prostate Cancer being Treated with Stereotactic Body Radiotherapy (SABRE). It is anticipated that first data from this study will be published in 2026. | Thank you for your comments and bringing to our attention about an ongoing trial. NICE may update the guidance on publication of further evidence. |

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| 4 | Consultee 1<br>Boston Scientific | 3.5 | We are aware that prior to publication the Committee will once again review the evidence for SpaceOAR. We would like to draw their attention to a recent publication (Delphi Study) published in BMJ Open that focuses on patient selection.<br><br>https://bmjopen.bmj.com/content/12/7/e060506 | Thank you for your comments. The Delphi study has been presented to the committee and was considered as part of IPAC discussion. This has been added to the appendix in the overview. |
| 5 | Consultee 2<br>Prostate Cancer UK | **1** | "Prostate Cancer UK welcomes the draft recommendation for biodegradable spacer insertion to reduce rectal toxicity during radiotherapy for prostate cancer.<br><br>We agree that more robust and suitable data and evidence regarding the safety and efficacy of the procedure should be obtained and we agree that the recommendation of special arrangements is suitable at this stage.<br><br>We agree that further research through trials and also via outcomes reported from healthcare organisations should be sought to confirm how this procedure can improve quality of life and evidence the potential long term outcomes." | Thank you for your comments and agreeing with the recommendations. |
| 6 | Consultee 3<br>NHS professional<br>Sheffield Teaching Hospitals NHS Foundation Trust | | Perhaps now more commonly done under local anaesthesia | Thank you for your comments.<br>Section 2.5 in the draft guidance states that the procedure can be done under general, local or spinal anaesthesia.<br>Text in 2.5 has been amended slightly. |

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| 7 | Consultee 3<br>NHS professional<br>Sheffield Teaching Hospitals NHS Foundation Trust | 1.1 | Agree should be recommended with special measures to gain more data. Experience form this centre of n=26, shows an extremely well tolerated procedure, with minimal side effects. Prospective audit is ongoing and so far no significant adverse events. Prospective audit data will be reported when complete.<br><br>Recommend a national registry or some form of large scale database, with a view to picking up rare toxicity and providing more evidence of benefit in the contemporary RT era | Thank you for your comments, sharing your experience and agreeing with the recommendation.<br>Text in section 1.5 in the guidance has been amended about recommending data collection in the form of real-world evidence in line with NICE real-world evidence framework (RWEF). |
| 8 | Consultee 3<br>NHS professional<br>Sheffield Teaching Hospitals NHS Foundation Trust | 1.3 | Totally agree. Supporting clinicians to audit and publish data is very important | Thank you for your comments. |
| 9 | Consultee 3<br>NHS professional<br>Sheffield Teaching Hospitals NHS Foundation Trust | 1.4 | Agree. The high risk group continues to be very difficult to define | Thank you for your comments. |
| 10 | Consultee 3<br>NHS professional<br>Sheffield Teaching Hospitals NHS Foundation Trust | 3.5 | Agree, may wish to add Diabetes, Smokers, already with a history of rectal bleeding due to eg haemorrhoids | Thank you for your comments.<br>IPAC considered the comment but decided not to amend 3.5. The committee stated that there may be some groups that may benefit. |

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| 11 | Consultee 3<br>NHS professional<br>Sheffield Teaching Hospitals NHS Foundation Trust | 3.8 | Radio-opaque spacers for CT have considerable advantages, for both planning and delivering radiotherapy and should strongly be encouraged | Thank you for your comments.<br>IPAC slightly amended the wording in 3.8. |
| 12 | Consultee 4<br>Palette Life Sciences | 1.1 | We welcome the change in the provisional recommendation which will allow data on the patient and health care system benefits of spacers to continue to be collected. | Thank you for your comments and agreeing with the recommendation. |
| 13 | Consultee 4<br>Palette Life Sciences | 1.2 | Bullet points 1,2 and 3. We welcome the recommendations on shared decision-making and audit. In addition, we consider that a high-quality structured and ongoing clinician training programme is also a key element in ensuring the safety and efficacy of the procedure, and we ask that this recommendation is revised to include reference to training. For more information on the UK Barrigel training programme, please refer to the comments submitted by Palette Life Sciences during the first consultation.<br>Bullet point 4. We welcome the recommendations on data collection. However, the link in the recommendation to NICE's outcome audit tool is broken and, in any case, we understand that the tool was created some years before NICE developed its real-world evidence framework (RWEF). We ask that a more helpful and detailed recommendation is made specifically with reference to the RWEF to increase the likelihood that data collected will be of sufficient quality for use in future guidance development. | Thank you for your comments.<br>IPAC considered and included a recommendation about specific training and expertise in the procedure in section 1.4<br>The link to the audit tool in 1.2 has been updated in the guidance.<br>Text in section 1.5 in the guidance has been amended about recommending data collection in the form of real world evidence in line with NICE real-world evidence framework (RWEF). |

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| 14 | Consultee 4<br>Palette Life Sciences | 1.3 | We ask that this recommendation is also framed with specific reference to the NICE real-world evidence framework to promote high-quality data collection. | Thank you for your comments.<br>Text in section 1.5 in the guidance has been amended about recommending data collection in the form of real world evidence in line with NICE real-world evidence framework (RWEF). |
| 15 | Consultee 4<br>Palette Life Sciences | 2.5 | The description of techniques to effect the spacer procedure is incomplete, and is factually incorrect for Barrigel. We ask for this section to be updated to ensure that it is accurate and comprehensive. For more information, please refer to the comments submitted by Palette Life Sciences during the first consultation. | Thank you for your comments.<br>**IPAC considered and amended section 2.5 as follows:**<br>The procedure is usually done with the patient under general or local anaesthesia using transrectal ultrasound guidance , but it may also be done using spinal anaesthesia. The patient is placed in the dorsal lithotomy position. For gel injections, a needle is advanced percutaneously via a transperineal approach into the space between the prostate and the rectum. Hydrodissection with saline is may be used to separate the prostate and the rectum for some gels but is always not necessary. After confirming the correct positioning of the needle, gel is injected, filling the perirectal space. Some of the gels may polymerise to form a soft mass whereas some do not. The biodegradable gel absorb slowly over several months. Some gels are reversible and can be dissolved using enzymes.<br>For balloon spacer insertion, a small perineal incision is typically used to insert a dilator and introducer sheath. The dilator is advanced towards the prostate base over the needle, which is then removed. A biodegradable balloon is introduced through the introducer sheath and is filled with |

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| | | | | saline and sealed with a biodegradable plug. The balloon spacer degrades over several months. |
| 16 | Consultee 4<br>Palette Life Sciences | 3.6 | We note that the committee's comment about the incidence of rectal toxicity is unchanged from the first Interventional Procedures Consultation Document. During the first consultation, Palette Life Sciences submitted citations for 8 published studies across a range of radiotherapy techniques which demonstrate a significant risk of toxicity when no spacer is used. We are concerned that, because they are not included in the updated interventional procedures overview, they have not been assessed or considered by the committee. We ask that these studies, and their impact on the risk-benefit judgement for the spacer procedure, be properly considered. For more information, please refer to the comments submitted by Palette Life Sciences during the first consultation. | Thank you for your comments.<br>The additional studies about the risk of toxicity across a range of radiotherapy techniques (submitted during first consultation) have been reconsidered by the committee as part of IPAC 2 discussion. They have not been included in the updated overview as no spacers were used in these studies.<br>IPAC decided not to amend 3.6. |
| 17 | Consultee 5<br>NHS professional | 1 | I agree with the committee's recommendation that peri-rectal spacers should be used in the context of 'special arrangements'. Spacer devices have the potential to significantly improve the experience of prostate radiotherapy by reducing long term rectal complications, particularly for certain groups of men. This guidance will allow centres to continue to gather data so that we can define the specific groups of men that should be offered spacer insertion as a routine part of their radiotherapy treatment | Thank you for your comments and agreeing with the recommendation. |
| 18 | Consultee 5<br>NHS professional | 2.5, lay description | The comment that 'It is usually done under general anaesthesia' is no longer correct. The procedure can be done under general, regional or local anaesthesia. In our centre we have aimed to do all procedures under local anaesthesia for the last 2 years (over 80 | Thank you for your comments.<br>Section 2.5 in the draft guidance states that the procedure can be done under general, local or spinal anaesthesia. |

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| | | | procedures) and only once have had to abandon and rebook as a general anaesthetic.<br><br>The comment that the spacer breaks down and is absorbed by the body after about 6 months is true for SpaceOAR, but Barrigel takes much longer to break down and is usually still present even a year afterwards | Text in section 2.5 has been amended.<br><br>The sentence in lay description has been amended as follows:<br>'It is biodegradable, which means it breaks down and is absorbed by the body slowly over a number of months'. |
| 19 | Consultee 5<br>NHS professional | 1.1, 1.2 | I completely agree with this statement. All departments that carry out spacer implantation must collect prospective data and carry out regular audit and quality control. Peer review of spacer implant quality should also be encouraged | Thank you for your comments and agreeing with the recommendation. |

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