# National Institute for Health and Care Excellence

## 1015 – Arthroscopic radiofrequency chondroplasty for discrete chondral defects of the knee

## Consultation Comments table for 1st consultation (21 November 2013 to 19 December 2013)

## IPAC date: Friday 17 January 2014

| Com. no. | Consultee name and organisation | Sec. no. | Comments | Response<br>Please respond to all comments |
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| 1 | Consultee 1:Chief Technology Officer (Manufacturer) | **1** | In the opening paragraph RF Chondroplasty is described as “using heat to smooth and contour” Heat is not the mechanism used to remove tissue with RF bipolar devices. Â The ablation and debridement process involves passage of radiofrequency energy through saline solution to produce a plasma field around the tip of the device. Â It is the energised particles within this plasma field that ablate the tissue through a chemical etching process resulting in tissue removal. Â Direct passage of some electrical current through the conductive media may lead to the dissipation of thermal energy that is a by-product of the process but not the mechanism of action. Â (See supporting references). Â Â Heat inside the joint can be minimised with the proper delivery of energy, and it is preferred to utilise devices that include technology to actively monitor the intra-articular temperature during the procedure. Â Users must also ensure proper fluid flow within the joint.7 Not all RF devices are the same. Â RF devices most commonly used in arthroscopic surgery can be split into two groups. | Thank you for your comment. Revised consultation document issued.<br><br>The Committee was advised that the primary mechanism of tissue destruction employed by radiofrequency probes is the deposition of heat within the tissue; however, section 3.2 has been changed to:<br><br>“Under arthroscopic guidance, a radiofrequency probe is then used to smooth the edge of the chondral defect using irrigation to stabilise temperature and flush any debris” |

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| 2 | Consultee 1:Chief Technology Officer (Manufacturer) | **1 (continued)** | 1. Monopolar Diathermy: Â These systems operate using a non conductive medium, like glycine, and generate very high temperature to ablate tissue through a thermal process. 2. Plasma mediated RF surgical devices utilise generation of a high frequency electrical field across a saline solution to produce plasma. Â A non thermal plasma is created around the active electrode(s) and acts on the tissue to chemically dissociate the molecular bonds within the tissue. a. With monopolar devices, a grounding pad is applied to the patient and acts as a return electrode. Â RF current energy has to pass through tissue. Â Passage of current through tissue can lead to higher tissue temperature and more tissue alterations. b. With Bipolar Plasma generating RF, both active and the return electrode are located on the device, allowing electrical field to be localized to a smaller volume, creating a smaller, controlled, and precise energy field. Â The plasma acts on the tissue to chemically dissociate the molecular bonds within the tissue. Â As much less current flows through tissue, Bipolar Plasma generating RF is associated with lower tissue temperatures and less depth of energy penetration into the targeted tissue. Â Bipolar technology is most commonly used in arthroscopic surgery. | Thank you for your comment. Revised consultation document issued.<br><br>**Refer to comment 1** |

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| 3 | Consultee 1:Chief Technology Officer (Manufacturer) | **1 (continued)** | 1. Stalder KR, Woloszko J, Brown IG, Smith CD "Repetitive plasma discharges in saline solutions" Applied Physics Letters 2001, 79(27): 4503-4505. 2. Woloszko J, Stalder K,. R and Brown I. G. "Plasma Characteristics of Repetitively-Pulsed Electrical Discharges in Saline Solutions Used for Surgical Procedures" IEEE Trans. On Plasma Sciences, 30(3), June 2002, 1376-1383. 3. Stalder Kenneth R, McMillen Donald F and Woloszko Jean. Â "Electrosurgical plasmas" J. Phys. D: Appl. Phys. 38 (2005) 1728–1738 4. Stalder K.R. , Woloszko J. Â "Some Physics and Chemistry of Electrosurgical Plasma discharges". Â Contrib. Plasma Phys., 47, NÂ°1-2, 64-71 (2007) 5. Jean Woloszko, Ashley Endler, Thomas P. Ryan and Kenneth R. Stalder. – "Clinical Applications of Plasma Based Electrosurgical Systems". Energy-based Treatment of Tissue and Assessment VII, edited by Thomas P. Ryan, Proc. of SPIE, Vol. 8584, 85840Q •February 2013 6. Kenneth R. Stalder, Thomas Ryan and Jean Woloszko. - Some Physics and Chemistry of CoblationÂ® Electrosurgical Plasma Devices. Â Energy-based Treatment of Tissue and Assessment VII, edited by Thomas P. Ryan, Proc. of SPIE, Vol. 8584, 85840P •February 2013 7. Zoric BB; Horn N, Braun S, Millett PJ. Factors Influencing Intra-Articular Fluid Temperature Profiles with Radiofrequency Ablation. J Bone Joint Surg. 2009; 91(10):2448-2454. | Thank you for your comment. Revised consultation document issued.<br><br>**Refer to comment 1**<br><br>Papers cited by the consultee are not included in the overview: these papers explore the technical parameters of radiofrequency probes and do not report any clinical or patient reported outcomes related to radiofrequency chondroplasty |

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| 4 | Consultee 1:Chief Technology Officer (Manufacturer) | **3** | Proper use of these devices typically does not require “short, intermittent bursts of thermal energy”. Â Again, heat is not the mechanism used to remove tissue. Â Instead, the recommended surgical technique typically involves the device to be in close proximity or in contact with the tissue to be ablated, and kept in continuous motion while activated. Â This allows the plasma to form efficiently, and maintain consistency for the most precise tissue removal (ex. Diseased Cartilage) with minimal effect on surrounding tissue (ex. Healthy Cartilage). | Thank you for your comment. Revised consultation document issued.<br><br>The procedure description has been changed to:<br><br>“Under arthroscopic guidance, a radiofrequency probe is then used to smooth the edge of the chondral defect using irrigation to stabilise temperature and flush any debris”. |
| 5 | Consultee 1:Chief Technology Officer (Manufacturer) | **5** | As with any medical device, proper surgical training on the safe and effective use is required. Â The cited works in the NICE guidance contained here describe the efficacy of RF-based energy devices in arthroscopic surgery. Â The published, peer-reviewed literature counters the theoretical adverse events specifically related to avascular necrosis and chondrocyte death when the device is used properly. Â The data shows equivalence and/or superiority to the current “gold standard’ treatment with mechanical instruments. 4. Osteonecrosis of the medial femoral condyle was observed in 4% (2/50) of patients at a follow-up assessment that occurred at least 6 months after treatment, in a prospective case series of 50 patients. | Thank you for your comment. Revised consultation document issued.<br><br>Section1.2 highlights the need for adequate training.<br><br>The overview/guidance highlights any adverse events, identified in the literature or stated by specialist advisers, which can be associated with the procedure, regardless of the technique used. |

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| 6 | Consultee 1:Chief Technology Officer (Manufacturer) | **5 (continued)** | No clinical consequences were reported as a result of this From Cetik O, Cift H, Comert B, Cirpar M. (2009) Risk of osteonecrosis of the femoral condyle after arthroscopic chondroplasty using radiofrequency: a prospective clinical series. Knee Surgery Sports Traumatology Arthroscopy 17: 24-29 In Cetik's 2009 prospective clinical trial, arthroscopic chondroplasty was performed in 50 patients with degenerative changes of the knee articular cartilage, stage II and III. This study searches for an answer whether surgical arthroscopic modalities using RF energy (VAPR-DePuy) causes osteonecrosis. Â RF energy was found to be superior to mechanical techniques in smoothening the articular surface (chondroplasty), limiting injury to adjacent untreated cartilage tissue, reducing blood loss, having an easier avoidance of iatrogenic damage, and that the defective cartilage can be more rapidly and easily countered which results in shortened operative time. There is no clinical evidence in the literature supporting that RF causes osteonecrosis. Until now RF energy was not clearly defined as a cause for osteonecrosis, and according to this study it was concluded that bipolar RF energy used for arthroscopic chondroplasty does not cause subchondral osteonecrosis if proper surgical techniques are carried out. | Thank you for your comment. Revised consultation document issued.<br><br>**Refer to comment 5** |

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| 7 | Consultee 1:Chief Technology Officer (Manufacturer) | **5 (continued)** | In addition, regarding the 2006 Barber study referenced in the guidance, it is important to note the Conclusion that, “The primary endpoint was to look for AVN (This also coincides with their Cetik safety question (5.2). Â No subchondral bone effects attributable to either mechanical shaving or radiofrequency energy were noted. The secondary endpoint was a clinical evaluation. Both groups showed significant improvements in pain and function outcomes with no discernible differences between groups. The use of monopolar radiofrequency as an adjuvant to mechanical chondroplasty with a shaver for the treatment of grade III chondral lesions did not affect MRI findings or pain and function outcomes when compared with mechanical chondroplasty by use of a shaver only. Â Monopolar devices were shown in the barber study to be no different than mechanical shavers. Â In the Spahn and Voloshin studies, bipolar devices were shown to be the superior form of treatment. Â It should be noted that published literature has never shown a direct correlation between AVN and uses of bipolar RF-based devices. | Thank you for your comment. Revised consultation document issued.<br><br>**Refer to comment 5.** |