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## Professional Profile

Ms. Ciccarelli's has over 20 years of experience in medical device consulting that spans the total product lifecycle. She has extensive experience in establishing international medical device retrieval programs in accordance with ASTM F561 and ISO 12891. She develops customized programs and procedures regarding the collection, investigation, and analysis of devices in the context of marketing applications (e.g. IDE studies), post approval studies, and as part of post market surveillance (e.g. 522 orders) and quality management activities. In addition, she assists clients with a variety of preclinical testing programs to support a number of research and development and regulatory objectives.

Ms. Ciccarelli is experienced in training internal client teams and external clinical investigation sites in retrieval programs in compliance with ISO 14155, Clinical investigation of medical devices for human subjects – Good Clinical Practice.

## Academic Credentials & Professional Honors

M.S., Biomedical Engineering, Drexel University, 2009

B.S., Biomedical Engineering, Drexel University, 2004

## Licenses and Certifications

ISO 14155:2020 Medical Device Standard from Biopharma Institute

## Publications

Siskey R, Ciccarelli L, Lui MKC, Kurtz SM. Are PEEK-on-ceramic bearings an option for total disc arthroplasty? An in vitro tribology study. Clin Orthop Relat Res 2016; 474(11): 2428-2440.

Kurtz SM, Ciccarelli L, Harper ML, Siskey R, Shorez J, Chan F. Comparison of in vivo and simulator-retrieved metal-on-metal cervical disc replacements. International Journal of Spine Surgery 2012; 6(1):145-156.

Kurtz SM, Toth JM, Siskey R, Ciccarelli L, MacDonald D, Isaza J, Lanman T, Punt I, Steinbeck M, Goffin J, van Ooij A. The latest lesson learned from retrieval analyses of ultra-high molecular weight polyethylene, metal-on-metal, and alternative bearing total disc replacements. Seminars in Spine Surgery 2012; 24(1):57-70.

Kurtz SM, Patwardhan A, MacDonald D, Ciccarelli L, van Ooij A, Lorenz M, Zindrick M, O'Leary P, Isaza J, Ross R. What is the correlation of in vivo wear and damage patterns with in vitro TDR motion

response? Spine 2008; 33(5):481-489.

Kurtz SM, van Ooij A, Ross ERS, de Waal Malefijt J, Peloza P, Ciccarelli L, Villarraga ML. Polyethylene wear and rim fracture in total disc arthroplasty. Spine 2007; 7(1):12-21.

Bove R, Fisher J, Ciccarelli L, Cargill R, Moore T. The Effects of anthropometry on driver position and clearance measures. SAE 2006-01-0454, presented at the SAE World Congress, Detroit, MI, April 3-6, 2006.

Kurtz SM, Siskey R, Ciccarelli L, van Ooij A, Peloza J, Villarraga ML. Retrieval analysis of total disc replacements: Implications for standardized wear testing. Journal of ASTM International 2006; 3(6):1-12.

### **Conference Papers and Abstracts**

Kuzel MJ, Heller MF, Sala JB, Ciccarelli L, Gray R. An analysis of real-world accidents involving distracted pedestrians. Proceedings, XXth Annual International Occupational Ergonomics and Safety Conference, Chicago, IL, 2008.

Heller M, DiJorio S, Kuzel M, Ciccarelli L, Carhart M. Effect of shoe type on stair negotiation in women. Proceedings, International Conference on Contemporary Ergonomics, Nottingham, United Kingdom, Paper W0109, 2008.

Kurtz SM, Ebert M, Siskey R, Ciccarelli L, Reitman M, Harper ML, Chan FW. Natural and accelerated aging of polyurethanes in the Bryan cervical disc. Poster No. P158, Transactions of Spineweek 2008, Geneva, Switzerland, May 26-31, 2008.

Siskey R, Kurtz SM, Ciccarelli L, Harper M, Chan F. A validation of ISO-standard wear testing using retrieved metal-on-metal cervical disc replacements. Paper No. 30, 8th Annual Meeting of the Spine Arthroplasty Society, Miami Beach, FL, May 6-9, 2008.

Kurtz SM, Ebert M, Siskey R, Ciccarelli L, Reitman M, Harper ML, Chan FW. Natural and accelerated aging of polyurethanes in the Bryan cervical disc. Poster No. 118, 8th Annual Meeting of the Spine Arthroplasty Society, Miami Beach, FL, May 6-9, 2008.

Siskey R, Kurtz SM, Ciccarelli L, Harper M, Chan F. Validation of ISO-standard wear testing with retrieved metal-on-metal cervical disc replacements. Poster No. 1927, 54th Annual Meeting of the Orthopaedic Research Society, San Francisco, CA, March 2-5, 2008.

Kurtz SM, MacDonald D, Ciccarelli L, van Ooij A, Isaza J, Ross R, Bowden A, Patwardhan A. Are one-sided wear patterns predictive of greater clinical wear in mobile bearing TDRs? Proceedings, 22nd North American Spine Society, Poster #151, Austin, TX, October 23-27, 2007.

Ciccarelli L, MacDonald D, Siskey R, Kurtz S, Villarraga M. International spine implant retrieval program. Philadelphia Spine Research Symposium, October 9, 2007.

Kurtz SM, Powell M, Ciccarelli L, Siskey R, White S, Chan F. Correlation of in-vivo and simulator-retrieved metal-on-metal cervical disc replacements. Proceedings, Eurospine 2007, Paper No. 10, Brussels, Belgium, October 2-6, 2007.

Kurtz SM, Heller J, Goffin J, Powell M, Ciccarelli L, Rouleau J, White S, Chan F. In vivo deformation and wear of retrieved Bryan cervical disc arthroplasties. Proceedings, Eurospine 2007, Paper No. 12, Brussels, Belgium, October 2-6, 2007.

Kurtz SM, Powell M, Ciccarelli L, Siskey R, White S, Chan F. Correlation of in-vivo and simulator-retrieved metal-on-metal cervical disc replacements. 7th Annual Meeting of the Spine Arthroplasty Society, Paper No. PA-WE08, Berlin, Germany, May 1-4, 2007.

Kurtz SM, MacDonald D, Ciccarelli L, van Ooij A, Isaza J, Ross R, Bowden A, Patwardhan A. Are one-sided wear patterns predictive of greater clinical wear in mobile bearing TDRs? 7th Annual Meeting of the Spine Arthroplasty Society, Paper No. PA-WE09, Berlin, Germany, May 1-4, 2007.

Kurtz SM, Heller J, Goffin J, Powell M, Ciccarelli L, Rouleau J, White S, Chan F. In vivo deformation and wear of retrieved Bryan cervical disc arthroplasties. 7th Annual Meeting of the Spine Arthroplasty Society, Poster No. 109, Berlin, Germany, May 1-4, 2007.

Kurtz SM, Patwardhan A, van Ooij A, Lorenz M, Zindrick M, O'Leary P, Pelozo J, Ciccarelli L, Villarraga ML. What is the correlation of in vivo wear and fracture patterns with in vitro TDR motion response? 74th Annual Meeting of the American Academy of Orthopaedic Surgeons, San Diego, CA, Paper No. 437, February 14-18, 2007.

Kurtz SM, van Ooij A, Ross R, de Waal Malefijt J, Isaza J, Pelozo J, Ciccarelli L, MacDonald D, Villarraga ML. Clinical significance of polyethylene oxidation for total disc arthroplasty. Transactions of the Orthopaedic Research Society 2007; Vol. 32, Poster No. 1130.

Kurtz SM, van Ooij A, Ross ER, Ciccarelli L, Villarraga ML. Analysis of textured endplates and bone ongrowth in retrieved charité total disc replacements. Proceedings, North American Spine Society, Poster #113, Seattle, WA, September 26-30, 2006.

Kurtz SM, Patwardhan P, van Ooij A, Lorenz M, Zindrick M, O'Leary M, Pelozo J, Ross ER, Ciccarelli L, Siskey R, Villarraga ML. What is the correlation of in vivo wear and fracture patterns with in vitro TDR motion response? Proceedings, North American Spine Society, Special Interest Poster #87, Seattle, WA, September 26-30, 2006.

Kurtz SM, Patwardhan P, van Ooij A, Lorenz M, Zindrick M, O'Leary M, Pelozo J, Ross ER, Ciccarelli L, Siskey R, Villarraga ML. What is the correlation of in vivo wear and fracture patterns with in vitro TDR motion response? Annual Meeting of the Spine Society of Europe (Eurospine 2006), Paper No. SP31, Istanbul, Turkey, October 25-28, 2006.

Kurtz SM, van Ooij A, Pelozo J, Ross ER, Ciccarelli L, Siskey R, Villarraga ML. Impact of in vivo oxidation on the clinical performance of total disc replacements. 13th International Meeting on Advanced Spine Techniques (IMAST), E-Poster No. 495, Athens, Greece, July 12-15, 2006.

Kurtz SM, Patwardhan P, van Ooij A, Lorenz M, Zindrick M, O'Leary M, Pelozo J, Ross ER, Ciccarelli L, Siskey R, Villarraga ML. What is the correlation of in vivo wear and fracture patterns with in vitro TDR motion response? 13th International Meeting on Advanced Spine Techniques (IMAST), Paper No. 38, Athens, Greece, July 12-15, 2006.

Kurtz SM, Patwardhan P, van Ooij A, Lorenz M, Zindrick M, O'Leary M, Pelozo J, Ciccarelli L, Villarraga ML. What is the Correlation of In Vivo Wear and Fracture Patterns with In Vitro TDR Motion Response? 6th Annual Meeting of the Spine Arthroplasty Society, Montreal, Canada, May 9-12, 2006. 2006 Spine Education in Research Award.

Kurtz SM, van Ooij A, Ciccarelli L, Villarraga ML. Analysis of textured endplates and bone ongrowth in retrieved charité total disc replacements. 6th Annual Meeting of the Spine Arthroplasty Society, Montreal, Canada, May 9-12, 2006.

Kurtz SM, van Ooij A, Pelozo J, Ciccarelli L, MacDonald D, Topper J, Villarraga ML. The impact of polyethylene oxidation on the long-term clinical performance of total disc replacements. 6th Annual Meeting of the Spine Arthroplasty Society, Montreal, Canada, May 9-12, 2006.

Kurtz SM, van Ooij A, Pelozo J, Ciccarelli L, Villarraga ML. Polyethylene wear and rim fracture in total disc arthroplasty. 73rd Annual Meeting of the American Academy of Orthopaedic Surgeons, Paper No.

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Kurtz SM, McCombe P, Ciccarelli L, Villarraga M, Chan F. Analysis of in vivo wear mechanisms in maverick total disc arthroplasty. 73rd Annual Meeting of the American Academy of Orthopaedic Surgeons, Poster No. P398, Chicago, IL, March 22-26, 2006.

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Kurtz SM, McCombe P, Ciccarelli L, Villarraga M, Chan F. Retrieval analysis of short-term implanted maverick total disc arthroplasty. Proceedings, North American Spine Society, Paper #124, Philadelphia, PA, September 28-October 1, 2005.

Kurtz S, van Ooij A, Pelozo J, Ciccarelli L, Zeiger A, Villarraga M. Central core and rim damage in retrieved polyethylene total disc replacement components. Proceedings, North American Spine Society, Paper #17, Philadelphia, PA, September 28-October 1, 2005.

Kurtz S, van Ooij A, Pelozo J, Ciccarelli L, Zeiger A, Villarraga M. Polyethylene wear and rim fracture of retrieved total disc arthroplasty. Annual Meeting of the Spine Society of Europe, Paper #41, Barcelona, Spain, September 21-24, 2005.

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Kurtz SM, McCombe P, Ciccarelli L, Villarraga M, Chan F. Analysis of in vivo wear mechanisms in a retrieved total disc arthroplasty. 5th Annual Meeting of the Spine Arthroplasty Society, New York, NY, May 4-7, 2005.

Edidin AA, Villarraga ML, Herr MP, Ciccarelli L, Hozack W, Turner J, Kurtz SM. Relationship between clinical performance and mechanical behavior of retrieved UHMWPE acetabular liners. Transactions of the Society for Biomaterials 2002; 25:25.

Edidin AA, Hozack W, Villarraga M, Ciccarelli L, Kurtz SM. Evaluation of wear in short term implanted highly-crosslinked UHMWPE inserts. Transactions of the Society for Biomaterials 2002; 25:27.

Kurtz SM, Villarraga ML, Herr MP, Ciccarelli L, Bergstrom J, Rimnac C, Edidin AA. Effect of temperature and crystallinity on the mechanical behavior of highly crosslinked UHMWPE. Transactions of the Society for Biomaterials 2002; 25:57.

Villarraga ML, Kurtz SM, Ciccarelli L, Herr MP, Rimnac C, Edidin AA. The Role of shear in the wear mechanism of UHMWPE. Transactions of the Society for Biomaterials 2002; 25: 186, 2002.

Villarraga ML, Kurtz SM, Herr MP, Ciccarelli L, Edidin AA. The effect of body temperature on the multiaxial fatigue behavior of virgin and highly crosslinked UHMWPE. Transactions of the Society for Biomaterials 2002; 25:402.

Villarraga M, Kurtz S, Herr M, Ciccarelli L, Edidin A. Multiaxial fatigue behavior of virgin and highly crosslinked UHMWPE at body temperature. Transactions of the Orthopaedic Research Society 2002; 27:1035.

Kurtz S, Villarraga M, Herr M, Ciccarelli L, Bergstrom J, Rimnac C, Edidin A. Thermomechanical behavior of highly crosslinked UHMWPE: effect of remelting vs. annealing. Transactions of the Orthopaedic Research Society 2002; 27:1026.