MPTP Milestones

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1 ☑ Developmental Material Creation	2 ☑ Developmental Material Testing and Industry Evaluation	3 ☑ Extensive Developmental Material Data Published	4 ☑ Transition Protocol Material Creation	5 ☑ Transition Protocol Material Testing and Industry Evaluation	6 ☑ Extensive Transition Protocol Material Data Published
7 ☑ MPTP Package Creation and Sterilization	8 Phantom Protocol Testing	9 MPTP Package Testing	10 Extensive MPTP Package Data Published	11 Global Commercial Launch After Regulatory Affirmation of Functional Equivalence	12 Interchangeability Between Current Tyvek® and Transition Protocol Material

Regulatory Milestones

☑ U.S. FDA Transition Protocol Reviewed and Accepted by the CDRH at the U.S. FDA	☑ Guidance Received from Six Notified Bodies in Europe	☑ Guidance Received from Three-party Committee in Japan	☑ CFDA-Jinan Quality Supervision and Inspection Center for Medical Devices Issued Final Report with Results of Functional Equivalence	☑ Guidance Received from Health Canada	U.S. FDA Affirmation of Functional Equivalence (Expected 3Q 2015)

MDM Actions

1 Change/Risk Management Assessment and Documentation	2 Supply Chain Assessment and Documentation	3 Implementation of Risk Assessment Testing (as necessary)	4 Regulatory Engagement (as necessary)