

1 Appendix I: Schedule of study procedures and evaluations

Activity	Screening	Enrollment	Observation	Discharge
Eligibility assessment	X			
Informed consent and comprehension checklist	X			
Assign participant ID	X			
Demographics	X	X		
Medical history		X	X	X
Maternal pregnancy history		X		
Medications use		X		
Placement of reference and/or investigational device(s)		X	X	
Collection of vital signs		X	X	X
Video tape recording and/or photographs			X	

Track clinical care and non-study activities			X	X
Safety assessment			X	
End of study questions				X
Removal of investigational and/or reference device(s)				X

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