	Task:	Hazard-Related Use Scenario:	Harm:	Severity:	Occurrence:	Mitigation(s):	Risk Level:
Risk Category:							
Indicator function	Patient bleed monitoring	User attempts to assess level of patient bleeding and misinterprets indicator meaning	Delayed or incorrect treatment	3	1	•Indicator meaning labeled on device •Abrasive alarm for "level 3" bleed encourages action regardless of interpretation of indicator •IFU informs user on how to interpret indicator •Users must complete training	3
Indicator function	Patient bleed monitoring / applying device in incorrect environment	Indicator light(s) goes undetected due to ambient light in the room	Delayed or incorrect treatment	3	2	•Abrasive alarm for "level 3" bleed encourages action •Alarm for device error •Only use device in intended environment with proper lighting •Indicator lights should contrast with ambient light color of intended environment of use	6
Interface design	User interface interaction (intentional or unintentional)	User accidentally toggles power button resulting in the device being turned off	Delayed or incorrect treatment	3	1	•Power button is non-functional after device is on for 5 minutes •Power button is tactile and in a "low-traffic" location •Power button must be engaged for 3 seconds to toggle power •Green indicator light for "on" position and red for "off" position •Transient alarm sound whenever button is toggled to reduce ambiguity	3
Interface design	User interface interaction (intentional or unintentional)	User accidentally toggles sound button resulting in deactivated alarm	Delayed or incorrect treatment	3	1	•Design such that sound button is ineffective unless alarm is actively occurring •Design such that power button is ineffective after use of device has begun •IFU instructs user to interpret output (or lack of output) from device with clinical judgement •Move buttons to lower risk location (eg: side of device) •Convert button to a tactile, hardware buttons to reduce ambiguity •Increase time duration to hold button to cause toggle •Reduce button size •Increase force required to push button •Transient alarm sound whenever button is toggled to reduce ambiguity	3
Alarm function	Patient bleed monitoring	Alarm has insufficient intensity to be reliably noticed by user	Delayed or incorrect treatment	3	2	•Usability testing to ensure that alarm is designed with sufficient intensity •Alarm increases intensity over time	6
Alarm function	Patient bleed monitoring	Indistinguishable tone/pitch to be reliably noticed by the user	Delayed or incorrect treatment	3	2	•Usability testing to ensure tone/pitch are sufficiently distinguishable in ambient noise	6
Alarm function	Patient bleed monitoring	Too many false alarms resulting in alarm fatigue	Delayed or incorrect treatment	3	2	•Alarm only sounds when action is necessary rather than whenever a bleed happens (highest threshold)	6
User overreliance	Patient bleed monitoring	User attempts to assess level of patient bleeding and over relies on possibly erroneous information instead of using it to aid clinical judgement	Delayed or incorrect treatment	3	3	•IFU informs user of confidence interval of device •IFU instructs user to interpret output from device with clinical judgement	9
Device handling	Advancing, withdrawing, or otherwise handling introducer sheath/dilator	User's control of introducer sheath compromised due to its material having insufficient grip	Injury to patient	4	2	•Usability testing to ensure that grip is sufficient even when compromised by liquid •Introducer sheath has ergonomic grip	8

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Device assembly	Advancing, withdrawing, or otherwise handling introducer sheath/dilator	Leading edge on distal end of the sheath improperly inserted in into tapered dilator	Injury to patient	4	2	•Device design initiates an audible and tactile "snap" upon correct insertion •Users must complete training •IFU informs user of risk	8
Device application	Patient bleed monitoring	Internal bleeding occurs prior to introduction of insertion sheath resulting in an erroneous bioimpedance measurement being accepted	Delayed or incorrect treatment	3	3	•Design such that if blood detected upon insertion, an indicator is activated •IFU instructs user to interpret output from device with clinical judgement	9
Device Compatibility	Catheter or interventional device selection	Catheter or interventional device with diameter smaller/larger than that of Early Bird Introducer sheath selected and used	Injury to patient	4	2	•Label on sheath indicating compatibility •Color or shape coding in line with industry convention •Users must complete training •IFU informs user of risk	8
Device assembly	Advancing, withdrawing, or otherwise handling introducer sheath/dilator	Sheath withdrawal or advancement without guidewire and dilator in place	Injury to patient	4	2	•Device labeled with guidewire and dilator instructions •IFU instructs user to advance sheath only with guidewire and dilator in place	8
Device assembly	Advancing, withdrawing, or otherwise handling introducer sheath/dilator	Advancing sheath while dilator improperly secured in hemostasis valve housing	Injury to patient	4	2	•audible and tactile "snap" upon correct insertion •Users must complete training •IFU informs user of risk	8
Device application	Advancing, withdrawing, or otherwise handling introducer sheath/dilator	Difficulties with sheath insertion results in kinking of device, user still applies device	Injury to patient	4	2	•Select sheath material with minimal susceptibility to kinking during use •IFU instructs user to remove and replace the device if kinking occurs •Packaging should discourage kinking	8
Device application	Device operation	User re-uses device which is designed for single use only	Injury to patient	4	1	•After 5 minutes of device being on, power button is non-functional including after procedure •IFU informs user that device is designed for single use only •On-device label of "For single use only"	4
Device application	Applying device in inappropriate environment	Device used in incorrect electromagnetic environment or without fluoroscopic guidance	Delayed or incorrect treatment	3	2	•IFU informs user of intended environment for use •Device labeled with specifications for intended environment	6
Device application	Using compromised device	Use of an improperly stored device	Injury to patient	4	2	•IFU clearly states directions for storage •Analog indicator for water damage	8
Device application	Using compromised device	Use of an expired device	Injury to patient	4	2	•Expiration date clearly stated on device •Maximum storage duration stated in IFU	8

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		OCCURENCE OF HARM				
		Improbable	Remote	Occasional	Probable	Frequent
SEVERITY OF HARM		1	2	3	4	5
Catastrophic	5	5	10	15	20	25
Critical	4	4	8	12	16	20
Serious	3	3	6	9	12	15
Minor	2	2	4	6	8	10
Negligible	1	1	2	3	4	5
		Intolerable				
		As Low As Reasonably Practical				
		Acceptable				