



## Risk Assessment form

<b>FSCA Reference:</b>	
<b>Medical Device Name:</b>	
<b>Manufacturer:</b>	

### Severity

Value	Level	Description
5	Catastrophic	Loss of limb; life-threatening injury or death
4	Critical	Severe; long-term injury; potential disability
3	Serious	Short-term injury or impairment requiring additional medical intervention to correct (e.g. Reoperation)
2	Minor	Slight customer inconvenience; little to no effect on product performance, non-vital fault
1	Negligible	No or negligible risk to patient

### Probability of harm

Value	Level	Description
5	Frequent	> 1 in 10
4	Probable	1 in 11 to 100
3	Occasional	1 in 101 to 10,000
2	Remote	1 in 10,001 to 1,000,000
1	Improbable	< 1 in 1,000,000

Fill the fields below:

Severity	Probability	Risk Value

Risk Level	Value Range
High	10 - 25
Medium	5 - 9
Low	1 - 4

### Health Risk Index Table

Probability of harm × Severity	Negligible (1)	Minor (2)	Serious (3)	Critical (4)	Catastrophic (5)
<b>Frequent (5)</b>	5	10	15	20	25
<b>Probable (4)</b>	4	8	12	16	20
<b>Occasional (3)</b>	3	6	9	12	15
<b>Remote (2)</b>	2	4	6	8	10
<b>Improbable (1)</b>	1	2	3	4	5

I hereby confirm that I am the authorized person from the company listed below, and I am aware of SFDA Safety Alerts requirements, and I have verified the information provided in this document.

<b>Authorized Person Name:</b>	
<b>Company Name</b>	
<b>Date:</b>	
<b>Signature:</b>	