New Technique or Device Risk Matrix

For Red - Score of 15 - 25	High risk	High
For Amber - Score of 4 - 12	Medium risk	Moderate
For Green - Score of 1 - 3	Low risk	Low Risk

v0.2

Assessment 1 - Patient Risk

Q1	How much is this tried and tested?	1	Tried and tested and in widespread use through UK with CE mark	L
		2	Tried and tested but not yet used widely in UK with CE mark	L
		3	Evolution of a tried and tested product with CE mark	L
		4	Innovative technique or device with CE mark	M
		5	Untried and untested technique or device via REC or custom made	H
Q2	How iterventional is this?	1	Non interventional(Class (wheel chair)	L
		2	Interventional (Class I) (Reuse surg instr, sigmoidoscope)	L
		3	Interventional (Class Iia) (Invasive surgical, dental)	L
		4	Interventional (Class Iib) (Implants - THR)	M
		5	Interventional (Class III) (Bioactive, cardiac, CNS)	H

	Q1 - How much tried and tested?				
Q2 - How Interventional?	**1**	**2**	**3**	**4**	**5**
1	**1**	**2**	**3**	**4**	**5**
2	**2**	**4**	**6**	**8**	**10**
3	**3**	**6**	**9**	**12**	**15**
4	**4**	**8**	**12**	**16**	**20**
5	**5**	**10**	**15**	**20**	**25**

Assessment 2 - Training

		How much additional training is required?		
Q3	How much additional training is required?	1	None, utilises pre-existing training	L
		2	Clinician requires minor modification of existing skills	L
		3	Clinician and support staff require in house training	M
		4	New skills are required and substantial training	H
		5	Mentorship required	H

Assessment 3 - Finance

Q4	What is the unit cost?	1	<£50	L
		2	£50 - £499	L
		3	£500 - £4999	L
		4	£5000 - £10,000	M
		5	>£10,000	H
Q5	How many per year?	1	<10	L
		2	10 to 49	L
		3	50 to 99	L
		4	100 - 500	M
		5	> 500	H

	Q4 - What is unit cost?				
Q5 - How many/year?	**1**	**2**	**3**	**4**	**5**
1	**1**	**2**	**3**	**4**	**5**
2	**2**	**4**	**6**	**8**	**10**
3	**3**	**6**	**9**	**12**	**15**
4	**4**	**8**	**12**	**16**	**20**
5	**5**	**10**	**15**	**20**	**25**

Notes: Product of these defines risk level

Lee to set risk levels for trust,

Impact - financial
What replacing