Risk No.	Risk Name	Factors	Likelihood	Severity
1	Vendors	A number of parts are supplied to MDC through single source vendors. There are a number of reasons for this including quality of product, availability of vendors and vendor qualification process. Not all vendors have gone through the MDC vendor qualification process. This is due, in part, to MDC's inability to get some vendors to submit to the qualification process.	2	3
2	Biohazard	The used products are considered a biohazard (due to contact with human blood) and therefore must be disposed of properly. However, since the products used in the clinical trials must be saved for some time, there is some risk of exposure to employees who handle them. It is reported, however, that all employees who come into contact with these products are warned of the potential hazards and given the appropriate vaccinations.	1	1
3	Staffing	MDC is reported to be understaffed, especially when compared to companies of similar size. This is causing many people to take on multiple jobs in order to meet production and research demands. This also results in minimal training and may also cause people to take shortcuts in order to complete their business tasks. Finally, there is some concern that burnout could occur to key individuals who have multiple responsibilities. (See Risk 13).	4	2
4	Culture	MDC's organizational culture is seen as critical to their success. The company is seen as entrepreneurial, which allows it to respond quickly to changes and encourages risk taking. Many employees feel that this is the attitude that is need to succeed, and why they came to work here. A change in this culture (either by management, or by MDC being acquired by a larger corporation) would probably result in loss of a number of key individuals and a delay in getting their products approved and marketed.	2	3
5	Patient Recruitment	While Phase 1 of the clinical trials is completed, difficulty in patient recruitment was noted. In fact, patients from a non-United States hospital were used to complete the study. Phase 2 will require even more patients and hospitals. MDC may have a difficult time in getting enough patients into the trials. Without adequate patients the study will be slowed, and would delay approval and marketing of the product. In the worst case, the study would be halted.	2	4

Risk No.	Risk Name	Factors	Likelihood	Severity
6	Key Employees	There are a number of key employees throughout the organization. While loss of one of these persons would have some short-term consequences, it is felt that long-term consequences would be minimal. However, loss of more than one at the same time could have serious short and long-term consequences.	2	3
7	Management Structure	The current management structure is felt to be adequate for MDC as it now exists. However, as the company grows, the management structure needs to grow with it, and there is some concern on how this will be accomplished. (See Risk 8)	2	2
8	Geography	MDC's location has made it difficult to recruit some high level personnel. This is especially true in the marketing area, as the Marketing Manager's job is still unfilled (it was reported that a highly qualified candidate for that post turned the job down due to the job's location.)	2	2
9	Product Acceptance	There are a limited number of doctors (specialists) and hospitals around the USA that are receptive to the Product and its associated procedure. This does, at least initially, limit acceptance and use of the product throughout the USA. Further, since MDC does not have a marketing manager (at the time the interviews were conducted), there is limited visibility within the medical community. Finally, there will need to be a paradigm shift within the medical community in order to get the Product accepted on a widespread basis. Thus, it is conceivable that the product can operate as designed and save lives, but if there is no widespread acceptance of the product in the medical community MDC could end up bankrupt.	2	4
10	Improper Medical Advice	MDC employees are on hand for all procedures involving the Product. These employees are available to provide advice to the doctor performing the procedure, should they request assistance. It was reported that MDC employees are not allowed to touch the patient or the device, nor are they allowed to speak with the patient or the patient's family. Failure to follow these procedures could embroil MDC in a lawsuit(s) that have serious negative consequences with regard to the clinical trials.	1	4

Risk No.	Risk Name	Factors	Likelihood	Severity
11	Off-Label Use	The Product is approved for specific uses during the clinical trial period. Any use of the product, which is beyond the scope of the established protocol, could have serious consequences with the FDA, up to and including discontinuance of the clinical trials.	1	3
12	Support Staff (Hospitals)	Recruitment and training of hospital support staff (e.g. nurses) is viewed as an important step in gaining the acceptance of the Product. Once the device is in-place, patient care becomes the responsibility of the support staff. If the staff does not understand the device, or how to properly care for a patient, acceptance of the device/procedure is unlikely.	2	3
13	Human Resources	MDC does not currently have a full-time Human Resources Manager, with the function divided among several employees. Compounding the problem is the fact that the number of employees has doubled in the past year, and training needs are becoming critical. Formal HR policies and procedures are almost non-existent, including how to deal with temporary employees. This could lead to any number of employee related issues including increased product defects, increased workers' compensation claims, and employee practices liability.	4	3
14	Financial Reporting Systems	MDC appears to have several internal financial reporting systems, which do not work well together. In addition, MDC must move from a research accounting system to a cost accounting system in order to capture their manufacturing costs. They need to do this quickly in order to establish a "cost of manufacture" for the Product. Once established, MDC will then be able to recover these costs in Phase 2 trials by charging hospitals and/or investigators for the cost of the product.	3	2
15	IT Operations	MDC does not have a full-time IT person on staff. Thus, when the LAN or other system components "go down", they are scrambling to get them up and running again. Further, the lack of an IT professional on site hampers MDC's ability to get databases and other needed software up and running.(See Risk 17)	4	1

Risk No.	Risk Name	Factors	Likelihood	Severity
16	Business Plan	The business plan has been lagging behind expectations. Going forward, if the plan continues to fall behind schedule, it could have an effect on financing for MDC, including a proposed IPO.	3	4
17	Production Bottleneck	Manufacturing operations are critically dependent upon the operation of the Clean Room. There is currently no contingency plan "in-place" for the Clean Room (a production bottleneck) or any other operations. Thus, MDC would have to develop/implement a contingency plan "on the fly" that would delay re-starting operations and add additional costs to the recovery process. Restoration to current operating levels and specifications at this or an alternative site (which would take significant planning and require certification) would be difficult. In addition, the Clean Room and part of the building are not sprinkler protected, and fire detection is limited. (See Risk 25)	3	4
18	Manufacturing Space	The current facility has limited room to expand. The arrangement is not conducive to a large scale manufacturing operation. Further, storage space is limited, which could force MDC to rent additional storage space off-site.	4	1
19	Tools and Dies	The various vendors MDC works with own the drawings for the tools and dies used to manufacture parts for the Product. It is uncertain if these drawings would be available in an emergency to get new tools and dies made (in some cases where the drawings are actually located is uncertain, as are the availability of backup drawings). Further, it is unclear who is responsible for the tools and dies in the event they are lost or damaged. If MDC and the vendor were to get into a dispute over these items in the event of loss or damage, it could result in significant downtime to MDC. (See Risk 25)	3	3
20	Special Coating	The special coating is manufactured to MDC specifications, but the coating manufacturer owns the actual formula. MDC does not have access to the formula, thus if the vendor goes out of business, or suffers a loss, it may be difficult for MDC to quickly find another vendor for the coating. (See Risk 25)	3	3
21	Product Fails Trials	The clinical trial protocols (particularly Phase 2) are setup to prove that the Product will accomplish certain objectives for a specific group of patients. This information is also included in the FDA application. Failure of the product to accomplish the objectives in the protocol would probably result in the product being rejected by the FDA.	1	4

Risk No.	Risk Name	Factors	Likelihood	Severity
22	Communication	While MDC has an entrepreneurial culture which fosters research and development, there appears to be some lapses in communication within MDC and with outside organizations. Without proper oversight of communications, a climate may develop where it is possible small problems would go unnoticed until they had developed into serious problems with potentially significant consequences. It is also possible that information obtained from clinical trial sites that may be important to MDC, does not get fed back to the appropriate management within MDC. As an example, it was learned that there were some possible conflicts of interest between one of the clinical trial sites and investors/owners of MDC. This problem may have been known within MDC, but it was not brought to the attention of the appropriate management level within the organization. Such a conflict of interest could be devastating to MDC should an FDA audit uncover any improprieties.	4	4
23	Competition	While MDC does not believe they have any real competition for the Product, it is possible that another organization is developing a similar product. Should such an organization exist, and they "leap-frog" MDC with their device, it could conceivably put MDC out of business.	1	4
24	CE Mark	There appears to have been some confusion over the use of the CE mark in the past. This has caused some products to go out with the mark when they were not eligible, and for some products that were eligible for it not to have it. Part of this problem can be traced back to staffing deficiencies within the Marketing Department.	2	2
25	Contingency Planning	The survivability of MDC may depend upon the speed and efficiency to recover from a catastrophic event. Presently, there are no formal plans in-place for MDC's critical business components, e.g., Manufacturing, IT Operations, Key Personnel and Vendor Sourcing.	2	4