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CANADIAN MEDICAL DEVICES SECTOR INITIATIVE

March 1991

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Medical Devices Sector Initiative Science and Technology Profile

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March 1991

Medical Devices Sector Initiative Science and Technology Profile

By NGL Consulting Inc.

Health Care Products Directorate
Chemicals and Bio-Industries Branch
Industry and Science Canada

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PREFACE

To maintain our standard of living, Canadians will have to succeed in a number of high value-added industries. Like many other sectors of that description, medical devices represent an area where Canada has an ample research base but precious little of any of the other ingredients required for industrial success.

As befits a "science and technology profile", this report identifies the cities and highlights the research centres where medical device work of high quality is being done. In analyzing case studies of attempts at commercialization, in Canada and elsewhere, certain features of the commercialization process are noted to be characteristic of the medical device sector, particularly the tendency for the clinician and/or his or her technical colleague to create the device in response to an immediate practical need.

This report goes on to point out the steps which could be taken if Canada decided that it required an active medical device industry. These steps give no guarantee of success. As the report indicates, Canada is a country with virtually no real venture capital, no major firms in the medical device field, a fragmented and difficult market and a relatively short history of entrepreneurial culture. Apart from efforts in the province of Quebec, these problems have never been systematically tackled by any Canadian government.

The complex, difficult and risky efforts outlined in this document are not the only possible actions, of course. The government could enter into a Memorandum of Understanding with a large Canadian company in a related sector or with a foreign company in the medical device field,

permitting that company to locate a major facility in Canada and providing it with a large amount of patient, cheap capital. This approach is not currently in ideological favour and would carry with it considerable financial and political risk.

While it makes sense that a country that pays for such a large amount of medical research should derive commercial benefits therefrom, it is clear that there are many other necessary ingredients to such success, virtually all of which would need to be created almost from scratch. This paper does not argue that such steps must be taken or that they would guarantee success. Depending upon how important a medical device sector is thought to be with respect to Canada's strategic interest, the program described herein represents a sensible way to go about building such an industry.

Stuart L. Smith, M.D.
President
RockCliffe Research & Technology Inc.

EXECUTIVE SUMMARY

Canada spends about $35 million per year on institutional research on medical devices. This research is undertaken within a broader health care research activity which is funded by government at a level somewhat higher than that in France, Germany, Britain and Japan but much lower than that in the United States.

The areas of Canadian research strengths are:

- diagnostics, which is responsible for more than 40% of the sector expenditures; and
- implants, imaging and assistive devices, which together account for another 40% of the expenditures

There are geographical concentrations of activity. Some 50% of the activity is in Ontario and there are 12 Canadian cities with the capability to support medical device R&D.

While Canada has the research base in medical devices needed to generate a significant level of commercial activity, a major problem is transferring the technology from the research environment to the commercial sphere. Through 35 case studies in six specific sub-sections, it was possible to establish that medical devices are developed principally by health care provider (e.g. doctors, surgeons) and their associates (e.g. biomedical engineers). Although the health care providers are the users of the devices, they have little interest in commercializing their innovations. Research papers and presentations at conferences are hit-and-miss approaches to marketing new medical devices.

To overcome this difficulty, universities and some hospitals in Canada have set in place technology transfer units whose responsibility is to commercialize technology emerging from the research environment. For a number of reasons, including the fact that Canada is a relatively late comer at setting in place mechanisms to systematically commercialize research undertaken in publicly-funded institutions, these units are not as well developed and do not have the sustained support that they appear to have in Europe and the U.S.A. Moreover, the Canadian technology transfer units are, by and large, not as aggressive in promoting their services as their foreign counterparts. This was reflected in the case studies where it was found that technology transfer units were used in only 20% of the Canadian cases while they were used in 78% of the foreign cases.

What is needed in Canada is a pro-active medical devices technology transfer body. It is recommended that ISTC support the establishment of such an entity which would undertake the following functions:

- extract medical device ideas and products from the research community;

- promote the undertaking of market studies related to the above medical devices;
- promote the development of business plans to support promising medical devices
- present the business plan to the financial community and to existing firms;
- maintain the information data base service described in Section 8.3;
- assist firms to get financial support through government programs (e.g. IRAP, PEMD, etc.)

This "technology broker" would be the sector's focal point and would interact with other groups, such as those within university and hospitals to provide services which they require to effectively transfer technology. A private sector approach is recommended, using sound business principles.

In support of this principal recommendation, ISTC should also act in the following complementary areas:

- provide financial support to individual researchers wishing to undertake market studies to develop business plans. Such studies could be undertaken by business consultants.
- commission the publication of a manual for medical researchers on do-it-yourself market studies and creation of business plans;
- support the inclusion of marketing and other commercial topics as part of scientific meetings and as articles in appropriate journals. These should include successful case histories of technology transfer;
- encourage large buyers to make their needs known at medical conferences, workshops and trade fairs;
- support local initiatives (e.g. technology brokerage, awareness) which encourage closer contacts between university medical researchers and the local industrial and financial communities. ISTC has supported similar initiatives in the past through the Technology Outreach Program;
- support one major medical device trade fair;
- provide financial support for the development of prototypes; and

- provide financial assistance to meet regulatory requirements.

The above recommendations would help to extract technology from the research environment. However, given that the medical devices sector is fragmented, that initial production is in small quantities and that there are few sizeable firms to receive the technology, it would be advantageous to have a "umbrella" marketing and distributing company which could bring the innovations to market. The Technical Aids and Systems for the Handicapped Inc. (TASH Inc.) is such a company in a niche area and provides a model for the type of mechanism needed. It is recommended that ISTC consider supporting the establishment of a broad based medical device marketing company.

1.0 INTRODUCTION

Industry, Science and Technology Canada (ISTC) is working towards the development of a coherent national strategy for the medical devices industry in Canada.

ISTC initiatives have included:

a) the signing of a Memorandum of Understanding with the national association of medical device manufacturers (MEDEC) setting out specific objectives for increasing research and development and export to world markets from Canadian based manufacturing firms

b) the establishment of the Technology Institute for Medical Devices Canada (TIMEC) as a source of intelligence about technology, products, markets, sources of technology, recipient firms and potential partners to serve the scientific and industrial communities

The current phase, of which this study is a part, is to develop a coherent national sector strategy in close consultation with the scientific community, industry, the purchasers of medical devices, all levels of government and other interested parties.

The specific studies commissioned by ISTC as part of the current phase include:

a) the development of a science and technology profile

b) a strategic analysis of the industry

c) options for improving the business climate

d) the development of improved means of measuring sector performance

This study relates to (a) above.

2.0 OBJECTIVES

The principal objectives of the "Science and Technology Profile" for the Canadian Medical Devices sector are four-fold:

(1) to develop institutional science and technology for the benefit of the sector;

(2) to consider mechanisms by which government and other parties can catalyze the exploitation of this science and technology for the development of the sector;

(3) to suggest ways in which technology transfer processes in Canada can be improved;

(4) to bring Canadian research and development into the global arena.

Achieving these four objectives will help the sector to meet growth targets in both domestic and international markets for the year 2000, as set down in the ISTC/MEDEC Memorandum of Understanding;

(1) to increase sales from $600 million to $2.4 million

(2) to boost exports from $200 million to $1 billion

3.0 METHODOLOGY OF THE STUDY

3.1 Overall Work Plan

The work plan, as outlined in the proposal and accepted by ISTC consisted of three major parts

(1) the inventory of relevant institutional research
(2) the analysis of the technology transfer processes
(3) the strategic analysis; options and action plans

3.2 The Inventory of Relevant Institutional Research

An extensive computer-based analysis of grants to institutional researchers was conducted. The primary information sources were the MRC Reference List 1989-90, 1990-91, the NSERC Annual Report 1989-90, the DSS R&D bulletin 1989, and the survey of individual expertise, research units, and research projects in 30 top institutions. It is important to understand that this initial inventory is based on a sample which represents at least 50% of the financing for institutional medical device related research and development.

The information was then analyzed to develop an inventory of relevant institutional research.

The study was further extended during the course of work to capture broader fields of relevant research.

Details of the TIMEC methodology may be found in Appendix A.

3.3 The Analysis of the Technology Transfer Process

The analysis of the technology transfer process was conducted at two levels:

(1) Macro Level Analysis

The macro level analysis was based on the knowledge of the consulting team, an analysis of technology transfer process in Canada and an analysis of four

comparable foreign regions to determine the main factors behind their significant industrial development through technology transfer in the medical device sector.

The four international regions selected were:

i) Minneapolis-St. Paul, in the U.S.A.
ii) Montpellier, in France
iii) Rhône-Alpes, a region of France
iv) Baden-Wuerttemberg, a region of Germany

The reasons for the choice of these regions are given in Section 5.5.

(2) Micro Level Analysis

For the micro level analysis, it was proposed to conduct 36 case studies; 30 in Canada and 6 abroad. Eventually, 35 case studies were conducted; 26 in Canada, 2 in the U.S.A. and 7 in Europe. As agreed to by ISTC during the study, meetings with two venture capitalists and a technology transfer office at an American university were also undertaken in lieu of two case studies.

The listing of the case studies can be found in Section 5.0.

3.4 Strategic Options and Action Plans

Based on the analysis of the data generated and on the significant expertise of the consulting team in technology transfer and in developing strategic plans, a number of strategic options were identified and studied. The preliminary list of options was presented at the Kananaskis meeting on February 4th, 1991 for discussion. Based on the consensus of the participants and further analysis and refinement of the data, additional recommendations based on possible options have been included in this report.

4.0 THE RESEARCH BASE

4.1 Current Inventory

4.1.1 Policies for the Support of Research

For reasons of economic structure, geography as well as the federal/provincial division of powers and responsibilities for education and research, Canadian universities conduct most of Canada's basic research.

Over the past several years, federal government support for science and engineering, and medical sciences in the universities has increased by about 8% per annum. There has been an increasing concern in Canada about the low level of privately supported research, the growth of which has lagged that of other developed countries.

Accordingly, the federal government has strongly encouraged, and provided financial support through the Natural Sciences and Engineering Research Council and the Medical Research Council to establish university/industry co-operative research activities. Since co-operative research has become the fastest growing segment of the Councils' operating grants programs, universities are actively marketing their research capabilities, and have been establishing offices of research services, including allied technology transfer groups. In addition, research parks and innovation centres which provide physical infrastructure for co-operative university/industry endeavours in research and its commercialization.

The Councils have also established categories of "strategic" grants to enable a stronger focus on research areas of importance to federal economic and social objectives. The concepts of the university/industry co-operative project and strategic grant have further evolved into the Network of Centres of Excellence program of the federal government, which links outstanding university researchers across the country with industry partners in specific areas of research. Some of these proposed centres' areas of concentration were related to the health sciences (See Exhibit 4-1).

The provinces in turn have been emphasizing support for innovation, i.e. the transfer of research results from the universities and their application in industry. They finance in a somewhat sporadic and haphazard fashion, applied research, intellectual property protection, and market research. In no case, however, has there been a strong focus on medical device-related research. Provincial interest in the health sciences and medical device-related research however is growing. British Columbia, Manitoba, Quebec and especially Alberta have all indicated strong interest in the sector.

Both federal, and provincial governments are fostering research partnerships between industry and universities in certain areas, such as artificial intelligence and robotics,

Exhibit 4-1
Networks of Centres of Excellence
Proposals in Health Care Fields Related to Medical Devices

NAME OF PROPOSAL	LEAD	CONTACT
Institute for Telecommunications Research*	McGill	Dr. M.L. Blostein
Neural Regeneration and Functional Recovery*	McGill/Université de Montréal	Dr. A.J. Aguayo
Respiratory Health Network of Centres of Excellence*	McGill	Dr. P.T. Macklem
Institute for Robotics and Intelligent Systems*	PRECARN Associates Inc.	Dr. G.M. MacNabb
Photodynamics	U.B.C.	Dr. D.H. Dolphin
Advanced Photothermal Research Diagnostics and Applications	U. of T.	Dr. A. Mandelis
Medical Imaging Science and Technology Network (MISTNET)	U. of T.	Dr. M.J. Bronskill
Immunoconjugates for Diagnostic Imaging and Therapy of Cancer	U. of T.	Dr. A. Marks
University-Industry Plan for Orthopaedic Research and Technology	Queen's	Dr. C. Sorbie
Research and Development in Advanced Robotic Technology and Applied to Health Care	Ecole Polytechnique	Dr. G. Drouin
A Network of Centre of Excellence in Nursing Informatics	Calgary General	Dr. K.J. Hannah
Studies in the Engineering, Medical and biological Aspects of Cardiovascular Devices (SEMBAC)	U. of O.	Dr. W. Keon
New Frontiers in Disease Diagnosis: Real Time Monitoring of Molecular Function in Health and disease	U.B.C.	Dr. P. Hochachka
A National Network for Research for Affordable Health Care	MDS Health Group Limited, Etobicoke, Ontario	Dr. E.K. Rygiel
Radiopharmaceuticals	Frosst Radiopharmaceuticals Montréal	Dr. R. Flanagan
Heart Health Science and Technology Network	Dalhousie University	Dr. T.F. McDonald
Un réseau de Centres d'excellence en recherche sur l'irradiation et ses applications	Institut Armand Frappier	Dr. M. Gagnon
Biomaterials	U. of T.	Dr. D.C. Smith
Isotopes in the Physical, Biological and Biomedical Sciences and their Industrial Applications	Queen's	Dr. J.W. Kamphuis

* Funded

advanced materials, and aspects of biotechnology. The underlying premise is that industry and the universities must become close allies in research and development, teaching, and continuing education.

4.1.2 International Comparisons in the Health Care Field

As a % of Gross Domestic Product (GDP), government support for health care research and development (R&D) is 1/3 that of the U.S.A., but between 1.15 times that of France and 3 times that of Japan.

Exhibit 4-2 compares government expenditure on health care R&D in Canada and other selected countries. The figures for government include provincial governments. The following observations can be made:

- The share of Gross Expenditures on Research and Development (GERD) financed by governments in Canada (45.8%) is somewhat less than the U.S. (50.8%) and France (52.9%)
- The fraction of Health Care R&D / Total R&D financed by governments in Canada (7.9%) and the U.S. (11.9%) is 2 to 3 times higher than other countries , e.g. U.K. (4.3%), France (3.6%) and Japan (2.4%)
- Government support for health care R&D in Canada at $224 million (US) is almost 10% less than that of F.R.G. ($246 million), Japan ($240 million).
- All countries' expenditures on health R&D are 1/25 of the U.S.A.'s or less.

Exhibit 4-2
International Comparisons (1987)

	GERD (US $ million)	GERD/GDP (%)	R&D Share Financed by Gov'ts (%)	Health Care R&D Share of Gov't Financed R&D (%)	Health Care R&D Financed by Gov't (US $ million)	Gov't Financed Health Care R&D / GDP (%)
Canada	6200	1.40	45.8	7.9	224	.050
France	16200	2.27	52.9	3.6	308	.043
F.R.G.	22900	2.81	33.6	3.2	246	.032
Japan	46100	2.87	21.7	2.4	240	.015
U.K.	15500	2.36	38.9	4.3	259	.039
U.S.	120300	2.69	50.9	11.9	7271	.163

Sources: OECD, NSF, Statistics Canada

4.1.3 Gross Expenditures on R&D (GERD) in the Health Care Field in Canada

In 1990, based on data prepared for the Medical Research Council of Canada by Statistics Canada, health care GERD in Canada was estimated to be as follows:

	Millions	(%)
Federal Government	$ 294	28.2
Provincial Governments	$ 101	9.7
Industry	$ 223	21.4
University	$ 260	24.6
Foundations	$ 134	13.0
Foreign	$ 30	3.0
GERD	$1,042	100.0

Federal government health care R&D and total R&D expenditures over the past three years, were as follows:

Federal Government R&D Expenditures ($ millions)			
Year	Total	Health Care	Health Care / Total (%)
1988-1989	2800	250	8.9
1989-1990	3000	267	8.8
1990-1991	3200	287	9.0

Thus federal government expenditure on health care R&D is approximately 9% of total federal government R&D expenditure and is just under 30% of the total Canadian R&D expenditures in the health care field.

4.2 Institutional Medical Device-Related R&D - Strengths

4.2.1 Sources of Funding

The focus of the inventory of Medical Device-Related Research was on institutional research. It identified amounts provided to research institutions from various funding sources as indicated in Exhibit 4-3;

Exhibit 4-3
Funding Sources of Medical Device-Related Institutional Research in Canada during 1989-1990

	$ (Cdn)
Medical Research Council of Canada	14 181 491.
Natural Sciences & Engineering Research Council	4 200 583.
Heart and Stroke Foundation	2 529 209.
National Cancer Institute of Canada	2 309 389.
Fonds de la recherche en santédu Québec	1 401 311.
Science Council of British Columbia	1 079 356.
Health and Welfare Canada	1 069 204.
Alberta Cancer Board	919 983.
Ontario Ministry of Health	918 867.
B.C. Health Care Research Foundation	826 039.
Physicians' Services Incorporated Foundation	789 570.
National Defence	729 718.
Heart Institute Research Corporation	650 924.
Telecommunications Research Institute of Ontario	433 360.
National Research Council	399 607.
Arthritis Society	383 515.
Rick Hansen Man in Motion World Tour Society	293 372.
Muscular Dystrophy Association of Canada	188 117.
Canadian Cystic Fibrosis Foundation	158 081.
Alberta Research Council	150 000.
Ontario Ministry of Labour	130 151.
Kidney Foundation of Canada	119 880.
Energy, Mines and Resources	116 474.
Multiple Sclerosis Society of Canada	104 847.
Board of Trustees of Red Deer Hospital	100 000.
Baxter Corporation	93 000.
Canadian Foundation for Ileitis and Colitis	70 000.
Juvenile Diabetes Foundation Canada	60 600.
RP Eye Research Foundation	59 760.
Canadian Paraplegic Association	54 600.
Ontario Mental Health Foundation	42 500.
Meadox Medical Inc.	37 047.
Lung Associations	30 194.
Manitoba Health Research Council	29 000.
Institut de recherche en santé et sécurité du travail de Québec	28 000.
Ottawa Civic Hospital Foundation	11 613.
Ontario Ministry of Colleges and Universities	8 047.
Alberta Foundation for Nursing Research	6 000.
University of Ottawa	5 300.
Employment and Immigration	2 600.
Advanced Mobility Systems Corporation	2 300.
TOTAL:	$ 34 723 609.

- 41 funding sources provided $35 million;
- 10 sources provided 85% of the funding;
- 2 federal agencies, NSERC ($14.2 million) and MRC ($4.2 million) together provided $18.4 million, or more than 50% of the funding.

4.2.2 Institutional Research Strengths by Sector and Region

Research strengths by sector and region are set out in Exhibit 4-4;

- **43% of research is in the diagnostic sector**
- **43% of research is nearly equally divided amongst three other sectors**
  - implants, imaging, assistive devices

The research activity by region can be summarized as follows:

- 50% of research is in Ontario
- 22% of research is in Quebec
- 12% of research is in Alberta
- 10% of research is in British Columbia
- 4% of research is in Nova Scotia

4.2.3 Institutional Research Strengths by City

As can be seen from Exhibit 4-5, there are strong research capabilities in 12 cities across Canada, being or capable of being directed to the support of four medical device sectors;

- Assistive Devices: Montreal, Toronto, Edmonton, Kingston, Vancouver
- Diagnostics: Toronto, Montreal, Hamilton, Halifax, Sherbrooke, Calgary
- Imaging: Montreal, Edmonton, Vancouver, London, Ottawa
- Implants: Toronto, Ottawa, London, Vancouver, Quebec, Kingston

Research in these 12 cities constitutes more than 75% of the medical device-related institutional research in Canada.

Exhibit 4-4
Sector Strengths by Region
Medical Device-Related Institutional Research 1989-1990
(in dollars)

	B.C.	Alta.	Sask	Man.	Ont. (W)	Ont. Tor.	Ont. (E)	P.Q.	N.B.	Nfld	N.S.	TOTAL
Assistive	296 852	702 074		38 000	114 137	540 920	495 406	1 890 898	83 797		28 500	4 174 084
Diagnostic	566 721	1 257 530	57 000	132 818	2 210 041	5 901 923	1 008 827	3 059 367	96 679	43 047	773 084	15 041 408
Equipment	645 592	645 592		231 600	235 377	667 222	133 890	515 814	29 000		57 886	2 795 961
General	207 135			101 609	80 802	103 385	105 000	292 878	212 258		34 849	1 055 158
Imaging	727 533	1 322 853		46 295	692 810	551 868	513 571	1 174 145	9 248		1 174 145	5 149 735
Implants	465 519	391 057			994 894	1 737 161	929 454	742 846	12 000		742 846	5 582 982
Surgical	404 054	132 350				387 877						924 281
Total	3 413 406	4 085 444	57 000	550 322	4 328 061	9 890 356	3 186 148	7 675 948	178 095	43 047	1 315 782	34 723 609

Sources:

MRC Reference List 1989-90, 1990-91
NSERC Annual Report 1989-90
DSS R&D Bulletin 1989 - 90
TIMEC Survey

Exhibit 4-5
Medical Device-Related Institutional Research 1989-1990
Sector Strengths by City

	Assistive	Diagnostics	Equipment	General	Imaging	Implants	Surgical	Total
Toronto	540 920	5 901 923	667 222	103 385	551 868	1 737 161	387 877	9 890 356
Montréal	1 750 651	2 120 356	487 014	292 878	1 159 361	297 627		6 107 887
Vancouver	296 852	524 481	645 592	307 135	727 533	465 519	404 054	3 371 166
Edmonton	518 278	555 601	24 580		1 149 853	255 757	132 350	2 636 419
Hamilton		1 982 725	122 055	80 802	115 809	217 105		2 518 496
Ottawa	45 901	772 799	118 970	105 000	513 571	894 944		2 451 185
London		50 404	50 000		577 001	754 479		1 431 884
Halifax	28 500	773 084	57 886	34 849	111 412	310 051		1 315 782
Calgary	18 796	701 929	5 000		173 000	135 300		1 199 025
Québec	140 247	313 859	28 800			411 804		894 710
Kingston	449 505	236 028	14 920			34 510		734 963
Sherbrooke		625 152			14 784	33 415		673 351
Winnipeg	38 000	132 818	231 600	101 609	46 295			550 322
Waterloo	114 137	129 520	63 322			23 310		330 289
Red Deer			250 000					250 000
Fredericton	67 297	31 051	29 000	29 500	9 248	12 000		178 095
Saskatoon		57 000						57 000
Guelph		47 392						47 392
St. John's		43 047						43 047
Victoria		42 240						42 240
Total	4 174 084	15 041 408	2 795 961	1 055 158	5 149 735	5 582 982	924 281	34 723 609

4.2.4 Research Strengths by University

Basic research support for industrial research development and commercialization are concentrated in 10 universities, each receiving more than $1 million per year for research related to medical devices, as follows:

University	Medical Devices ($ 000)
Toronto	7,630
Alberta	2,640
McMaster	2,520
McGill	2,510
British Columbia	2,490
Ottawa	2,210
Montreal	1,900
Western Ontario	1,430
Dalhousie	1,280
Calgary	1,200
	$ 25,810

These 10 universities received nearly 75% of the research support identified by TIMEC.

Further details of the relative ranking of hospitals, foundations, and other universities are shown in Exhibit 4-6.

4.2.5 Strengths by University and Area of Specialization

The following listing of research strengths by university and area of specialization is not all inclusive but is representative. A more refined picture can be obtained from the regional overview section (see Appendix C), and the individual research listings (see Appendix B).

These areas of specialization represent strong basic research capabilities in the various research centres listed below, which could be more strongly focused on medical device-related research through the formation of new, or the strengthening of existing biomedical engineering groups or institutes and by linking individuals in such groups into national university/industry R&D consortia.

Exhibit 4-6
Medical Device-Related Research 1989-1990
Leading Organizations during the 1989-1990 Period

	$ (Cdn)
University of Toronto	
University of Alberta	7 627 338.
McMaster University	2 636 419.
McGill University	2 518 496.
University of British Columbia	2 510 769.
University of Ottawa	2 494 060.
Université de Montréal	2 208 568.
University of Western Ontario	1 906 409.
Dalhousie University	1 431 884.
Ontario Cancer Institute	1 227 282.
University of Calgary	1 239 757.
Université Laval	1 194 025.
Université de Sherbrooke	894 710.
Queen's University	754 340.
Sunnybrook Medical Centre	734 963.
Institut de réadaptation de Montréal	574 835.
Ecole Polytechnique	512 292.
Waterloo University	355 736.
Simon Fraser University	330 289.
Red Deer Hospital	267 769.
Concordia University	250 000.
Hugh MacMillan Medical Centre	240 224.
Institut Nationale de la Recherche Scientifique	231 464.
Institut de cardiologie de Montréal	229 953.
University of New Brunswick	207 865.
University of Victoria	207 095.
University of Manitoba	205 068.
Carleton University	203 944.
St. Boniface General Hospital Research Centre	186 063.
Manitoba Cancer Treatment & Research Foundation	186 000.
Cancer Control Agency of B.C.	160 378.
Hospital for Sick Children (Toronto)	147 085.
B.C.'s Children's Hospital	144 488.
Quadra Logic Technologies Inc.	95 213.
Vancouver General Hospital	60 400.
University of Saskatchewan	57 975.
Arbutus Society for Children	57 000.
Guelph University	53 050.
Memorial University of Newfoundland	47 392.
Technical University of Nova Scotia	43 047.
Hôpital Notre-Dame (Montréal)	38 500.
Canadian Memorial Chiropractic College (Toronto)	34 650.
Ottawa Civic Hospital	31 914.
G.F. Strong Rehabilitation Centre	30 000.
Surrey Place Centre	28 886.
Canadian Red Cross Society	26 127.
Mount Sinai Hospital	17 000.
Royal Ottawa Regional Rehabilitation Centre	14 433.
Glenrose Rehabilitation Centre	9 554.
British Columbia Ministry of Health	5 000.
	3 900.
TOTAL:	$ 34 723 609.

Exhibit 4-7
Selected Research Strengths by University and Area of Specialization

UNIVERSITY	DESCRIPTION
University of British Columbia University of Victoria	- molecular biology, protein engineering and applications to disease detection, immunodiagnostics, medical imaging and therapy, transplants, rehabilitation engineering, photodynamic therapy.
University of Alberta University of Calgary Red Deer Hospital	- structure and function of muscle proteins and enzymes, lasers for cancer diagnosis and treatment, monoclonal antibody technology, pharmaceuticals, rehabilitation neurosciences, medical imaging, diagnostic radiomaterials, NMR spectroscopy and imaging, biomaterials, pharmaceutical robotics
Canadian Aging and Rehabilitation Product Development Centre; St. Boniface General Hospital and University of Manitoba	- assistive devices for the disabled and elderly, medical imaging, pharmaceutical robotics
University of Western Ontario University of Waterloo McMaster University	- cardiovascular and neural imaging, bioprosthetic valves, hip prostheses, implant fixation - orthopedic implants, EMG - nerve regeneration, neurophysiology, blood/material interactions, radio-immuno therapy
University of Toronto	- biomaterials for dental and orthopedic implants and cardiovascular applications, biosensor, rehabilitation engineering, imaging, diagnostic probes, biomedical engineering

Exhibit 4-7
Research Strengths by University and Area of Specialization
(cont'd)

UNIVERSITY	DESCRIPTION
University of Ottawa and Carleton University	- cardiovascular imaging and assistive devices, portable power sources for medical devices, transcutaneous energy transfer, multi-media medical communications, medical information systems; blood substitutes, ultra and micro-filtration, reverse osmosis vascular grafts, biomaterials, blood/material interactions, fracture fixation devices
Queens University	- implanted knee prostheses, surgical lasers, neurophysiology (stimulation, regeneration) biomaterials
Université de Montreal	- cardiac electrophysiology, medical imaging, biomechanics/biomaterials /rehabilitation engineering
Université de Sherbrooke	- radiopharmaceuticals for nuclear medicine and diagnostics, toxicity of inhaled substances, cochlear implants
Ecole Polytechnique	- medical instrumentation
McGill University	- Artificial cells, immobilized cells, microencapsulation; adsorbents including charcoal, resins, biosorbents and immunosorbents; blood substitutes, drug delivery systems; artificial kidney; artificial liver; detoxifier
Université Laval	- neurophysiology, oculomotor systems, single cell motor mechanics, laser scanning, multisensor perception for robotic control, biomechanics, orthopedic devices, biomaterials
University of New Brunswick	- myoelectric control
Dalhousie University	- dental implants, cardiological imaging and monitoring

4.3 Identification of Canadian Champions

Using existing published information, and the survey of research units, individual research expertise, and research projects, some dozen "champions" were identified during the course of the study. Champions were found amongst those researchers receiving more than $50,000 per year in peer-reviewed financing, and in biomedical engineering groups in hospitals. Since the sector is not yet generally recognized as a separate academic discipline and much of this work is engineering design and development, few biomedical engineers receive peer-reviewed funds directly. The cost of the work that they do is covered mainly by hospital operating funds.

The criteria established for selecting champions were a demonstrated record of successful interaction with industry, transfer of technology to an existing company, or involvement in a start-up, and holding patents or receiving patent royalties.

The persons identified as champions were reluctant to be singled out as such. Many felt it would be more appropriate to recognize teams. Therefore, "champions" are not included in the main body of this report.

5.0 TECHNOLOGY TRANSFER PROCESS - FINDINGS

5.1 The Case Studies - The Sample: 35 Case Studies

The sample comprises 35 case studies of innovation in medical devices. These case studies were divided over the six main categories of medical devices as defined by Medical Devices Canada (MEDEC).

Assistive Devices

Limbs
Bathroom Aids
Contact Lens
Electronic Therapy
Hearing Aids
Incontinence
Orthotics
Rehabilitation
Mobility Aids and Seating Systems

Hospital Equipment

Dialysis
Stimulators, Electronic
Furniture, Mobiles
Laser Therapy
Monitoring Equipment
Operating Room
Robotics
Sterilizing

Medical Imaging Therapy

Software (Healthcare information)
Imaging (Ionized/X-Ray)
Therapy (Non-ionized)
Ultrasound MSS

Medical Surgical Supply

Disposables
Instruments
Laser
Respiratory (Gas)
Wound Care

Diagnostic

Biotechnology
Instrumentation
Laboratory Equipment
Nuclear Equipment
Reagents
In-Vitro

Implants

Cardiovascular
Drug Delivery System
Ophthalmic
Neurological Stimulus
Orthopaedic
Sutures

The 35 case studies are listed in Exhibit 5-1. They include 30 successes and 5 failures. The successes include recent technology transfers and established commercial successes. Details of the case studies can be found in Appendix D.

Exhibit 5-1
Completed Case Studies

Note: 1 Technology Transfer Done 2 Commercial Success

I. CANADA	SUCCESS	FAILURE
ASSISTIVE DEVICES:		
- Bar Grip	1	
- Body Lifting Device	1	
- Geriatric Mobile Chair	1	
- Crib for Handicapped Parent(s)	1	
- Hand Rehabilitation	1	
DIAGNOSTICS:		
- Blood Serum Analyzer	1	
- Gradient Maker	2	
- Urodynamics Analyzer	1	
- EEG Radio Telemetry	1	
- Hand Vein Compliance Device		X
- Telemetry Set	1	
HOSPITAL EQUIPMENT:		
- Blood Plasma Defroster	2	
- Electrical Bed	2	
- Video System	1	
- Patient Controlled Analgesic Infuser	1	
- Evacuation Sled		X
IMPLANTS:		
- Spinal Fixation Plate	2	
- Self Aligning Knee	1	
- Miller/Galante Knee	2	
MEDICAL IMAGING:		
- X-ray Machine	2	
- Cardio Map II		X
- Cardiac Mapping		X
- Pump to Calibrate Ultra Sound	1	
- Radio Therapy Imaging	2	
MEDICAL SURGICAL SUPPLY:		
- Safety Cap for Needle		X
- Elastic Bandages	1	

Exhibit 5-1
Completed Case Studies
(cont'd)

Note: 1 Technology Transfer Done 2 Commercial Success

II. FOREIGN	SUCCESS	FAILURE
ASSISTIVE DEVICES:		
(France)		
- Remote Control System for Handicapped	1	
DIAGNOSTICS:		
(France)		
- Electronic Sensor for Breathing Capacity	1	
(Switzerland)		
- Arterial Sensor	1	
(U.K.)		
- Non Radioactive Immunoassay System	2	
IMPLANTS:		
(France)		
- Artificial Bone Graft	2	
(U.S.A.)		
- Implantable Infusion Pump	2	
MEDICAL SURGICAL SUPPLY:		
(U.K.)		
- Glass Ionamer Cement	2	
(U.S.A)		
- Vascular Access Catheter	1	
ULTRASOUND:		
(France)		
- Ultrasound for destroying kidney stone	2	

As indicated in Exhibit 5-1, 26 Canadian case studies spread across the 6 medical device segments were undertaken based on a common interview guide. Of the total, 5 were classified as failures - no transfer had taken place. Fourteen products were considered to be Stage 1 successes - the technology was transferred but no evidence of market launch or success existed (i.e. no sustained commercial activity). The remaining 7 were not only transferred but were considered to be Stage 2 successes (i.e. the product was launched on the market and had a sales volume and income flow which would allow for full recovery of commercialization within 5 years).

The 9 foreign cases were developed using the same interview guide as the Canadian studies. Because of the willingness of potential respondents to only mention successes and not failures, all the foreign cases included only successes. Over half these cases (5/9) were Stage 2 commercial successes, the remaining cases (4/9) were Stage 1 successes.

5.2 Sources of Innovation

Exhibits 5-2 and 5-3 identify the locus of demand and of technical development for the 9 international and the 26 Canadian case studies respectively.

Exhibit 5-4 summarizes the data presented in Exhibits 5-2 and 5-3. This summary table indicates that in 64% of the Canadian cases, the main sources of medical device innovation were health care providers (clinicians and health care researchers such as bio-medical engineers). In the foreign cases, the overall pattern is similar except that a higher percentage of the ideas originated with health care researchers and fewer with clinicians. (The reader should keep in mind the small foreign sample size.)

The first major conclusion emerging from our case studies is that the principal source of innovation in this sector is the heath care provider who identifies the need or sees an opportunity for the application of a technology. This is similar to what occurs in other high-technology sectors where a technically oriented individual is often the source of innovation.

Innovations are based on the technical knowledge of the health care provider and their research associates. They pick from the pool of available technology with which they are familiar, to develop their innovations. Attempts to encourage, through policy measures, the use of specific but unfamiliar technologies in the development of medical devices is not likely to be very successful.

Exhibit 5-2
Idea vs. Development
Results from International Case Studies

COUNTRY, REGION	DEVICE	RECOGNITION OF DEMAND BY	DEVELOPMENT OF TECHNICAL CAPABILITY
France, Lyon	Ultrasound equipment for destroying kidney stones	Institut National de la Santè et de la Recherche Mèdicale (INSERM)	Technomed (private company)
France, Montpellier	Electronic sensor for breathing capacity	Entrepreneur	Firm in an incubator (Cap Alpha)
France, Paris region	Artificial bone graft	Orthopedic research lab	Biocoral (private company) ANVAR/CRITT support
France, Dijon	Remote Control System for handicap equipment	University (Marseille)	Proteor (private company) ANVAR support
Switzerland, Lausanne	Arterial sensor	University Researcher	University Researcher
U.K. Chalfont Bucks	Non-radioactive Immunoassay System	Wolfson Research Lab	Amersham (private firm)
U.K. Teddington, Middlesex	Glass Ionamer Cements	Lab of Government Chemist (LGC)	LGC; support from British Technology Group
Minneapolis, St. Paul	Implantable Infusion Pump	Surgeon	Bio Med Department
Minneapolis, St. Paul	Vascular Access Catheter	Bio Med Department	Bio Med Department/Manufacturer

(1) ANVAR: Agence Nationale pour la Valorisation des Applications de Recherche

(2) CRITT: Centre Régional d'Innovation et de Transfer Technologique

Exhibit 5-3
Idea Versus Development
Research from Canadian Case Studies

CASE STUDY	RECOGNITION OF DEMAND BY:	DEVELOPMENT OF INNOVATION BY:
Assistive Devices:		
Bar Grip	Research Centre for Studies in Aging (Sunnybrook Hospital)	Lifestyle Innovations Inv. (Sunnybrook Hospital)
Body Helping Device	Research Sunnybrook Hospital	Lifestyle Innovations Inv. (Sunnybrook Hospital)
Geriatric Mobile Chair	Dept. of Rehab Engineering	Sunnybrook Hospital
Crib For Handicapped Parent(s)	Clinical Physician & University Researcher	Dept. of Rehab Engineering
Hand Rehabilitation		Hospital & University
Diagnostics:		
Blood Serum Analyzer	Lab Biochemist	Lab Biochemist
Gradient Maker	University Researcher	University Researcher
EEG Radio Telemetry	EEG Dept.	EEG Dept.
Hand Vein Compliance Device	Hospital Researcher	Bio Engineering Dept
Urodynamics Analyzer	Clinical Physicians	Commercial Firm
Telemetry Set	Business Person	Commercial Firm
Hospital Equipment:		
Blood Plasma Defroster	Red Cross	NRC & Red Cross
Electrical Bed	Commercial Firm	Commercial firm & Govemment Dept Hospital
Video System	Business Person & Hospital Cardiology Dept.	Commercial firm & Cardiology Dept
Patient Controlled Analgesic Infuser	Nurses	Bio Engineering Dept
Evacuation Sled	Bio Engineering Dept	Bio Engineering Dept
Implants:		
Special Fixation Plate	Clinical Physician & Researcher	Ottawa Civic and NRC
Self Aligning Knee	Clinical Physician	Orthopedic Research Unit & Commercial Firm
Miller/Galante Knee	Clinical Physician	Orthopedic Research Unit & Commercial Firm
Medical Imaging:		
X-Ray Machine	Former Dept Head	Start up
Cardio Map II	Researcher	Hospital
Cardiac Mapping	Researcher	Bioengineering Dept
Ultra Sound Pump	Researcher	Roberts Institute
Radio Therapy Imaging	Clinician	Roberts Institute
Medical Surgical Supply:		
Safety Cap For Needle	Clinical Physician	Clinical Physician
Elastic Bandages	Entrepreneur	Commercial Firm

Exhibit 5-4
Sources of Innovation

	CANADA		FOREIGN	
	#	%	#	%
Health Care Provider	6	23.2		
Health Care Researcher	5	19.3	5	55.5
Joint: Health Care Provider and Researcher	3	11.5	1	11.1
Researcher	3	11.5	2	22.2
Researcher - Better Tools	3	11.5		
Patient/User	3	11.5		
Corporate/Entrepreneur	3	11.5	1	11.1
TOTALS	26	100.0	9	100.0

5.3 The Nature of Medical Device Innovation

The analysis of the case studies also shows that device innovation in both Canada and abroad focuses on incremental as opposed to breakthrough innovation (see Exhibit 5-5).

Exhibit 5-5
Degree of Innovation Embodied in the Successful Case Studies

	CANADA		FOREIGN	
	#	%	#	%
"Breakthrough" to provide radical new capabilities stemming from basic research	--	--	--	--
Major Improvement in Functionality	12	58	7	78
Minor Improvement in Functionality	9	42	2	22
TOTAL	21	100	9	100

Innovation is largely derived from clinical applications and the "tinkering" of health care providers and researchers. Devices are thus modified and upgraded.

5.4 The Technology Transfer Process in Canada

5.4.1 From Idea to Product

The innovation process in the medical devices field resembles that in other high technology sectors in that a technological idea (in this instance an incremental improvement) is engineered into a prototype by the innovator or another entity, usually one close to him/her (see Exhibit 5-4). The prototype is then commercialized through a new or existing firm. As indicated in Exhibit 5-6, in more than 75% of the Canadian and foreign cases, the device was transferred to a commercial partner.

Exhibit 5-6
Type of Recipient of Technology

TYPE OF INITIAL TRANSFER	CANADA		FOREIGN	
	#	%	#	%
To firm within medical industry Domestic Foreign	 5 3	31	2	22
To firm outside medical industry Domestic Foreign	 4 --	15	1	11
Start up	6	23	4	45
Within an existing corporation	2	8	--	--
Other/Not Identified	--	--	2	22
Not Transferred	6	23	--	--
TOTAL	26	100	9	100

This dynamic is in contrast with innovation in the pharmaceutical sector where products are the result of systematic long-term research in large organizations.

Our case studies were spread over the six main categories of medical devices so that important differences in the innovation process among these six categories could be identified. In all categories, except implants, the innovation process proceeded as described above. In the case of implants, the innovator (surgeon) was usually the prime mover throughout the developmental process. He/she did not pass the development of the innovation to the biomedical engineers. As well, there was the need for clinical trials in this case.

In five of our case studies no transfer of a technology had taken place (i.e. failures). The lack of legal protection of the concept or product was the cause of failure in two cases. These products were developed elsewhere. In two cases, there were no market assessments and in one, there was a lack of perceived advantage over products already in the market.

One major inhibition to the transfer of technology is the cost of developing a prototype which is often beyond the scope of internal funds. A working prototype is usually needed to interest a venture capitalist or commercial firm. Only rarely is a transfer effectively made based on technical descriptions and drawings. In the case of implants, there is the added cost of clinical trials.

5.4.2 The Role of Technology Transfer Units

The research environment in the medical devices field is in keeping with the overall research environment in most universities. Researchers view their jobs as doing research to obtain new knowledge and to solve problems. In general, they do not see themselves as business people, nor do they have much interest in business. Their research is undertaken to meet academic and technical criteria.

Because of this tendency, some universities and a few hospitals have set in place technology transfer units to play a catalytic role in bringing new technology to the market place. A listing of university based Technology Transfer Offices can be found in Exhibit 5-7. Some of these units also serve related teaching hospitals. But as noted by the Science Council[1], few of these offices have been fully accepted within their university and given the resources necessary to operate effectively. This has led the Science Council to recommend that technology transfer be acknowledged as an aspect of the mission of Canadian universities.

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[1] Science Council of Canada; Winning in a World Economy; University-Industry Interaction and Economic Renewal in Canada: Report 39, April 1988.

Exhibit 5-7
Technology Transfer Offices at Canadian Universities

University of Alberta
University Hall
Edmonton, Alberta
T6G 2J9
TEL: (403) 432-5360

University of Calgary
2500 University Drive N.W.
Calgary, Alberta
T2N 1N4
TEL: (403) 220-4652

University of Guelph
Guelph, Ontario
N1G 2W1
TEL: (519) 824-4120, Ext. 3429

Université Laval
Sainte-Foy, Québec
G1K 7P4
TEL: (418) 656-5375

McGill University
3550 University Street
Montréal, Québec
H3A 2A7
TEL: (514) 398-4201

Memorial University of Newfoundland
St. John's, Newfoundland
A1B 3X5
TEL: (709) 737-4448

University of Ottawa
115 Wilbrod Street, Room 207
Ottawa, Ontario
K1N 6N5
TEL: (613) 564-3282

Université de Sherbrooke
Pavillon central, bureau 043
2500, boul. Université
Sherbrooke, Québec
J1K 2R1
TEL: (819) 821-7555

Simon Fraser University
University/Industry Liaison Office
Burnaby, British Columbia
V5A 1S6
TEL: (604) 291-3842

Technical University of Nova Scotia
P.O. Box # 1000
Halifax, Nova Scotia
B3J 2X4
TEL: (902) 429-8300

University of Victoria
Victoria, British Columbia
V8W 2X2

York University
4700 Keele Street
North York, Ontario
M3J 1P3

University of British Columbia
2194 Health Sciences Mall
Suite 331, IRC Building
Vancouver, British Columbia
V6T 1W5
TEL: (604) 224-8580

Dalhousie University
Halifax, Nova Scotia
B3H 4H6
TEL: (902) 424-6513

Lakehead University
Thunder Bay, Ontario
P7B 5E1
TEL: (807) 343-8124

University of Manitoba
208 Administration Building
Winnipeg, Manitoba
R3J 2N2
TEL: (204) 474-9404

McMaster University
Health Sciences Centre, Room 3N7
Hamilton, Ontario
L8N 3Z5
TEL: (416) 525-9140 Ext. 2873

Université de Montréal
C.P. 6128, succursale A
Montréal, Québec
H3C 3J7
TEL: (514) 343-6786

Queen's University
Fleming Hall
Kingston, Ontario
K7L 3N6
TEL: (613) 545-2342

University of Saskatchewan
Room 50, Murray Building
Saskatoon, Saskatchewan
S7N 0W0
TEL: (306) 966-8751

Université du Québec à Montréal et Université Concordia
C.P. 8888, succursale A
Montréal, Québec
H3P 3P8
TEL: (514) 282-3535

University of toronto
27 King's College Circle
Toronto, Ontario
M5S 1A1
TEL: (416) 978-5588

University of Waterloo
Office of Research, Needles Hall
Waterloo, Ontario
N2L 3G1
TEL: (519) 888-4515

The tenuous relationship between technology transfer units and universities/hospitals is reflected in the findings in our case studies. As Exhibit 5-8 indicates, in only 20% of the cases did a technology transfer unit become involved in the commercialization process. By contrast, in the foreign cases, there was a much higher incidence of support from a technology transfer unit.

As well, Canadian technology transfer units are called upon to carry out other functions, such as soliciting, negotiating and monitoring research contracts. To find a role, they often become multifunctional offices, which dilutes their original purpose. Their role is further eroded by the six or so U.S. based technology transfer groups which regularly visit researchers to obtain recently developed products.

Some research institutions have, however, begun to set in place dedicated technology transfer units which can be models for others. A case in point is Sunnybrook Hospital in Toronto. Sunnybrook's holding company, Sunnybrook Health Services Ltd., recently established the Centre for Studies in Aging Inc. (CSAI), as a non-profit organization, to hold the technology developed by the researchers at its Centre for Studies in Aging (CSA) and the associated group at the University of Toronto. In turn, CSAI has established a Lifestyle Innovations Inc., a for-profit subsidiary to exploit its technology. Royalties flow back to CSA to support its research program and to the inventors of assistive products.

Another example is the recently established University Technology International (U.T.I.), a for-profit technology commercialization company at the University of Calgary. The University of Calgary is currently the sole shareholder but shares have been offered to the University of Alberta and Vencap, an Alberta based venture capital group. While U.T.I. covers all areas of technology, one person is dedicated full time to medical technology.

In summary then, university based technology transfer units are by and large struggling to do an effective job. Other approaches are emerging but it is yet too early to evaluate their performance.

5.4.3 Commercializing Products

Given the largely indifferent research environment in which the technology transfer process must operate, it is not surprising to find that commercialization of medical device technology is a hit-and-miss affair.

Exhibit 5-8
Type of Technology Transfer Support Provided

TYPE OF TECHNOLOGY TRANSFER SUPPORT PROVIDED	CANADA		FOREIGN	
	#	%	#	%
None	18	69	2	22
Technology Transfer Unit/Patent Dept.	5	19	7	78
Independent Consultant	3	12	--	--
TOTAL	26	100	9	100

Researchers interested in transferring technology use one of three types of search strategy in looking for a commercial partner for their products:

i) Limit the search to people and firms known to the researcher; e.g. friends, associates and firms with specific expertise known to the researcher (this approach is the least likely to identify many interested firms).

ii) Attend conventions and meetings - meet people and present papers (This approach is better but is hit or miss in that good prospects may not attend that convention or meeting or the researcher may not present the case in a manner which instills confidence).

iii) Conduct complete industry searches, identify possible prospects and promote the product on a systematic basis using professional business and marketing expertise - e.g. use of computerized data banks and professional mailings (This type of search is now beginning to be conducted by some institutional technology transfer offices in Canada).

A Canadian researcher looking for a commercial sponsor in Canada for his/her product is likely to be disappointed and frustrated for any of several reasons:

i) Medical device venture capitalists such as those active in the United States are not numerous in Canada.

ii) Although large multinational medical device firms do look at some medical devices, almost all of the devices are transferred to medium to small firms, some of which were not principally in the medical device industry.

iii) Although the technology may have been transferred to a firm, the product may not have been placed in commercial production because of the limited resources of the firm and/or an absence of preproduction orders. The lack of royalties to the researcher from the dormant product may hinder improvements and/or other projects.

Venture capitalists may play a key role in commercializing products, especially as start ups, but they have problems dealing with researchers and technology transfer departments. The venture capitalist and researcher may have differing understanding of each other's needs. Although the technology transfer offices can be helpful, venture capitalists see some of them as being too cumbersome and slow moving. By demanding market ready products (to be on the market within a year) the venture capitalists put pressure on the researcher and the technology transfer office move in directions they might not otherwise choose (see Appendix D for details).

Although some technology transfer people view the venture capitalists goal of annual return on investment of 40 percent as exorbitant, the target is typical of high risk new technology ventures where the few successes must also pay for the many failures.

Several of the case studies indicated the benefits of well thought out joint research projects between non-commercial research units and the business community. The advantages of this type of venture include:

1) the selection of partners who have the specific expertise lacking within the non-commercial research environment;

2) the existence of a firm which will commercialize the product once the plans are formulated;

3) in some agreements between universities/hospitals and firms, there can be an added benefit of an initial order for the product by the hospital which funded the research unit. This initial order will help to cover manufacturing start up costs and to demonstrate that the product works as designed.

Many of the above observations and conclusions are similar to those identified by the Commercialization sub-Working Group of the Federal-Provincial-Territorial Working Group on Increasing Canadian Value Added of Medical Devices (see Appendix E). They illustrate the difficulty of commercialization because of the differing perceptions and values between researchers and business people.

5.5 Technology Transfer in Selected International Areas

The regions of Montpellier and Rhône-Alpes, France, Baden-Wuerttemberg, Germany and Minneapolis-St.Paul, U.S.A. were chosen for comparative analysis for the reasons mentioned below.

5.5.1 Montpellier, France

This French city was chosen because, like Ottawa and London, Ontario, it has given the medical/medical-device sector a priority and has set in place mechanisms to assist in the technology transfer process.

The Montpellier initiative, called "Pôle Euromédecine", has at its base a local technology engine with the following characteristics:

- the oldest University Medical Faculty in Europe, established in 1289;
- the third largest hospital centre in France (4,000 beds);
- a variety of related research centres such as l'Institut National de la Santé et de la Recherche Médicale (INSERM), le Centre National de la Recherche Scientifique (CNRS), Elf-Aquitaine and SANOFI
- close industry-laboratory links in biomedical engineering;
- an annual "Euromédecine" congress which attracts over 18,000 people from 20 countries; and
- a "Euromédecine" TechnoPark which currently has about 100 firms with some 3,700 employees.

The technology transfer process in Montpellier, as in any other regions of France, is encouraged through a variety of government support programs, which cover every aspect of the innovation cycle. However, the city of Montpellier has established the "Montpellier L.R. Technopole" as an organization to assist firms to access these and other programs. This organization has within it a group of people whose mandate is to assist in establishing and nurturing firms in the medical/medical device sector (i.e. - Pôle Euromédecine). This sectoral group provides the "brokerage" services offered by most local economic development offices (e.g. - finding financial, technical, human resources marketing and other assistance).

One particular initiative of the "Montpellier L.R. Technopole" worth mentioning is Cap Alpha, an incubator mall (pépinière) dedicated to technology start-ups in Montpellier

under a European Community program which has spawned some 60 such incubators across Europe by 1989. Cap Alpha offers services (e.g. business plan development, physical space, technical assistance) on a fee for service basis, but payable only if the start-up becomes a successful enterprise (i.e. refundable as a % of sales). Cap Alpha has within it its own venture capital firm, Mistral Investissements, which can provide between $25,000 to $125,000 per venture. Cap Alpha encourages discipline within start-ups through monthly meetings where actual performance is evaluated against business plan projections.

DATALINK, one of our international case studies, is being subjected to this discipline as a tenant of Cap Alpha. Cap Alpha has a vested interest in ensuring the success of the firms on its premises, since it gains financially.

In summary, the city of Montpellier has set in place enabling support structures to encourage and assist the transfer of technology. The "Pôle Euromédecine" is one of five high-technology "pôles"[2] that Montpellier has chosen as developmental priorities. All "pôles" are supported through similar mechanisms because of similar core technology transfer dynamics among the sectors.

5.5.2 Rhône-Alpes, France

The Rhône-Alpes region was chosen because, with its 5.2 million people, it represents about 10% of French economic activity and has the highest concentration of S&T resources after Paris. Lyon and Grenoble, the two major cities in the region, each represent about 45% of S&T activities and are recognized for their high technology thrusts including biological/medical engineering. These characteristics are similar to those in Canada's more important provinces.

The Lyon area has been assigned the priority or "pôle" for biological and medical engineering because of its concentration of medical research organizations (e.g. INSERM[3], WHO International Cancer Research Centre) and related industry with firms, such as Spécia, Institut Mérieux, Bellon, Roussel, Uclaf and Borion, which provide some 30,000 jobs in the area.

The focus on regional "pôles" for technology development in France is driven by a regionalization process that began in earnest with legislation passed in 1982. S&T is an explicit priority in Rhône-Alpes given the concentration of resources. The elected

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[2] The other four pôles are New Media, Informatics Agri-Business and Tourism.

[3] The product idea of our Lyon case study originated at INSERM (see Exhibit 5-2).

Regional Council has appointed a Vice-President for Research who is responsible for 2.5% (1990) of the region's budget. These financial resources are used to develop new S&T infrastructure (e.g. technical pôles, major laboratory equipment) and specific programs linking universities with industry to encourage local technology transfer.

Regional S&T financial resources are also matched with national level resources to co-finance activities that relate to:

- the development of regional technology "pôles";
- technology transfer operations through the Centres régionaux d'innovation et de transfert technologique (CRITT);
- a network of local technology counsellors, part of which is similar to the NRC field network;
- education and training.

This "top-down" devolution of S&T structures meets the "bottom-up" municipal level S&T structures through 12 local Chambres de Commerce et d'Industrie (CCI). While the CCIs have a broad mandate, a priority is given to S&T because of its importance to the region. The CCIs are very active and powerful because they have the authority to tax local firms to provide needed services.

The local CCIs in Rhône-Alpes have grouped themselves into a regional federation which is supported financially by the Regional Council. The federation's principal task is to promote the region externally and to obtain international intelligence related to possible strategic partnerships of investment possibilities and so on. Rhône-Alpes has set up an office in Montreal to promote the region in Canada and to encourage technology partnerships.

Rhône-Alpes, like other regions in Europe, is aggressively seeking international technology transfer possibilities. The region has joined with Baden-Wuerttemberg, Lombardy and Catalonia to set up the Association of "The Four Motors of Europe" for marketing purposes. The Province of Ontario has signed co-operation agreements, including joint technology development, with these regions.

In summary, Rhône-Alpes, has given technology development an explicit priority and has set in place structures to encourage technology transfer and commercialization. Through a focus on technology "pôles", including one on biological and medical engineering, the region can marshall its resources around "niche" technology areas and through this process gain access to key national support programs and international opportunities.

5.5.3 Baden-Wuerttemberg, Germany

Baden-Wuerttemberg was chosen because, with its population of 9 million, it is the most highly industrialized state in Germany. As such, it resembles our larger provinces of Ontario and Quebec. Moreover, it has the highest density of research institutes in Europe and has set in place interesting mechanisms to stimulate technology transfer from this research base.

Baden-Wuerttemberg accounts for some 25% of West Germany's sales in electric /electronic equipment and 42% of sales in precision instruments. It has major companies such as BOSCH and ZEISS in each sector respectively, which stimulate the development of supplier firms in many technology-intensive sectors including medical devices.

Technology transfer is given a special status in Baden-Wuerttemberg because of the potential for the commercialization of technology developed within the State's extensive research base. The government has appointed a "Commissioner for Technology Transfer of the State of Baden Wuerttemberg" who co-ordinates and encourages any measures taken by industry in the State to strengthen its technological base.

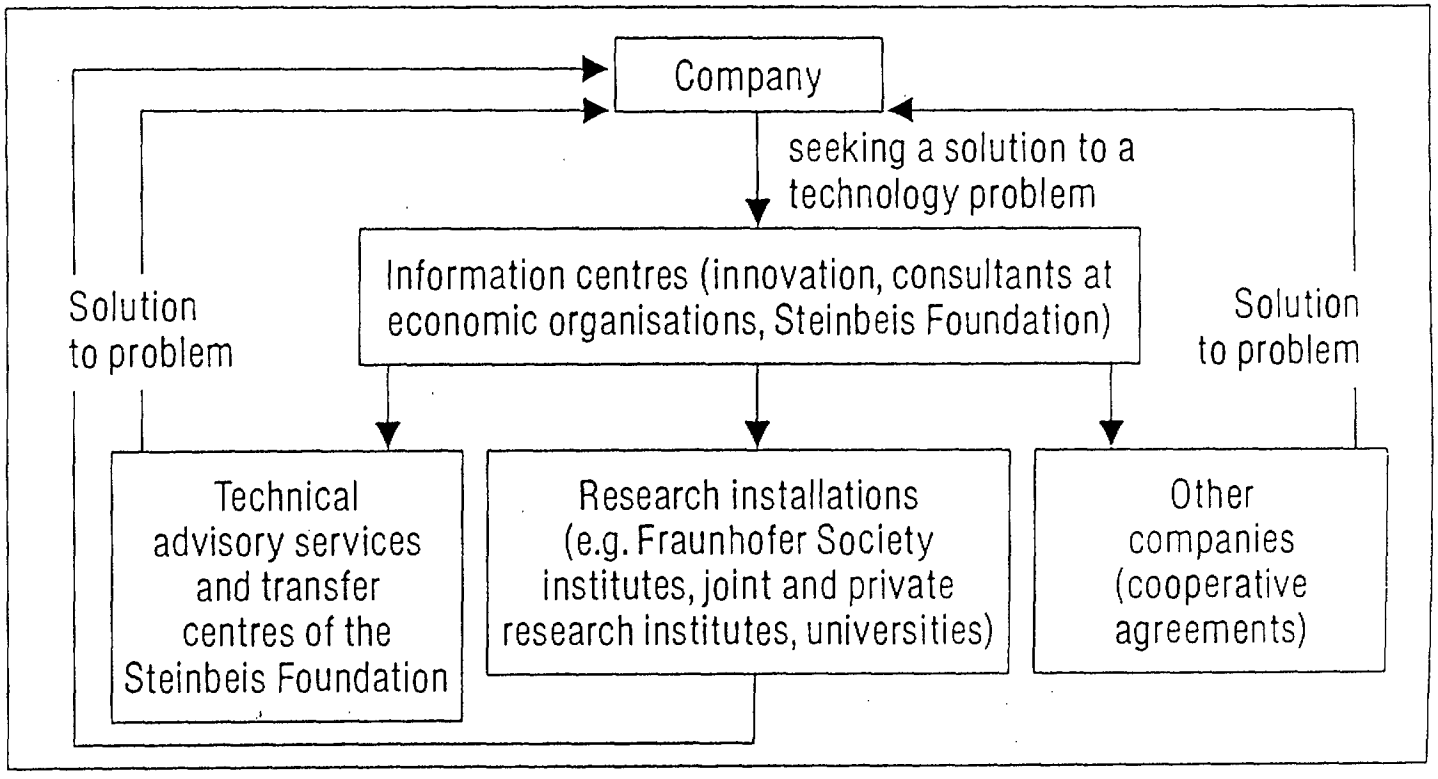
The Commissioner is also Chairman of Steinbeis Foundation which, was established in 1971. With its 100 local technology transfer centres and 2,372 employees is the most important technology transfer agency in the State. Most technology transfer centres are established in co-operation with local universities and industry. The Foundation's budget of DM 64.5 million (1989) is made up of principally interest on its endowment (3.1%), government grants (2.3%) and from advisory services (70.8%) provided. The government contribution is very small.

More than 15,000 specific projects were carried out in 1989, 80% of them in firms with fewer than 500 employees. The Foundation's mandate is principally to stimulate the adoption of new technology by existing industry and to exploit new ideas emerging from the research base.

Complementing this activity are those of innovation consultants attached to local Chambers of Commerce and the Fraunhofer Society institutes and other research organizations.

In summary, then, the technology transfer process is highly institutionalized and works as shown in Exhibit 5-9. The process works well, as evidenced by the fact that the Steinbeis Foundation's income from consultancy increased 10-fold between 1983 and 1989.

Exhibit 5-9
Technology Transfer in Baden-Württemberg



5.5.4 Minneapolis-St. Paul, U.S.A.

The twin cities of Minneapolis-St. Paul, the major urban centre in Minnesota, were included in the study because of their success in developing new medical devices and in attracting commercial medical device manufacturers. Minnesota ranks tenth in the number of medical devices registered with the FDA. In 1988, Minnesota's medical device manufacturing employment was 246 percent higher than the U.S.A. national average. Minnesota, which has between 400 and 600 major medical and health care product manufacturers, is third in the United States in the concentration of medical manufacturing employment.

The success of the twin cities in the medical device industry is the result of the interaction of several drivers:

(a) Conducive Climate for Innovation

An entrepreneurial spirit exists in Minnesota. People are prepared to take the risk of starting an operation.

This entrepreneurial spirit, in part, is supported by a good supply of venture capital in the region. The state ranks tenth in the United States in terms of venture capital dollars per capita. The venture capitalists are knowledgeable in medical devices and in medicine. This source of funding has been available in Minnesota since the 1970s. The fact that a major source of funding is venture capitalists who want to quickly (usually within one year) move the product to the market drives the researchers to be efficient and creative in converting concepts into commercial products.

Another facilitator of the entrepreneurial spirit is a private firm called Medtronic, Inc., sometimes referred to as the "University of Medtronics". Many people have worked at this manufacturer of pace makers and artificial hearts, learned their skills and then left to start their own business, usually in the medical industry. It is estimated that at least 24 companies, including St. Jude Medical which has become a very large medical device firm have spun off from Medtronic. Medtronic, itself, is a model of entrepreneurial success. It started operation in a garage and has become, over time, a billion dollar corporation. Medtronic's growth is in part due to the acquisition of smaller, successful companies, such as Bio Medicus, the world's leading producer of implantable blood pumps.

(b) Health Care Infrastructure Has Achieved Critical Mass

The region has a skilled labour pool not only including researchers and production people but legal experts, marketing personnel and other needed skilled people who have experience and knowledge relating to the health care industry.

Health care professionals are attracted to the area because of the professional environment which enables them to easily interact and consult with their peers and to stimulate creative thought.

On a more formal basis the health care research infrastructure in the state centres around three poles:

i) University of Minnesota ranks fifth in the United States in terms of university patents (of all types) between 1986 and 1989. The number of patents applied for by the University of Minnesota has increased dramatically since 1983. There is a sufficient number of innovations to be processed that a person has been assigned to cover medical devices;

ii) The university and its researchers are able to obtain significant amounts of research funding;

iii) Medtronics, a large private firm, has a blend of academic doctors and private engineers working together in an environment which has led to many start-up firms.

5.6 Comparative Analysis with Canada

The major lessons that can be extracted from our international case studies are the following:

- regions which have an extensive S&T base give technology development a high and sustained priority (i.e. Montpellier, Rhône-Alpes, Baden-Wuerttemburg, Minneapolis). This can also be said of the Province of Quebec and the Ottawa area, for example;

- regions where there is a concentration of medical research activity recognize the potential of this activity (i.e. "pôles" in Montpellier and Lyon and Minneapolis). This is similar to the recognition of the medical research strengths in the Ottawa and London, Ontario regions;

- regions which appreciate the commercial potential of their S&T resources, including medical research/medical devices, set in place significant and sustained programs and activities to stimulate technology transfer; i.e.

  - dedicated brokerage function centered on medical technology, leverage of national funds and incubator mall in Montpellier;

- brokerage function, Chamber of Commerce, special infrastructure programs and leverage of national funds in Rhône-Alpes;
- the Commissioner for Technology Transfer and the Steinbeis Foundation in Baden-Wuerttemberg;
- Medtronics in Minneapolis.

° while it can be argued that similar programs and activities do take place in Canada (e.g. - IRAP, university technology transfer offices, local level promotion), the priority given, scale and sustainability levels do not appear to be comparable (see for example Section 5.4.2 on the issues related to Technology Transfer Units).

° regions which have a mix of both large and small firms encourage the development of close relationships between those firms (i.e. Rhône-Alpes, Baden-Wuerttemberg and Minneapolis-St. Paul). Such relationships are largely lacking in Canada because the lack of large firms in many technology areas including medical devices and the need for small high-technology firms to export most of their production;

° the more "hands-on" approach to technology transfer by intermediaries (e.g. Montpellier, Rhône-Alpes, Baden-Wuerttemberg) differs from the largely "hands-off" advisory approach of Canadian intermediaries;

° while venture capital is a relatively new phenomenon in Europe to stimulate technology transfer, it has become an important source of financing as evidenced from our case studies. In fact, in 1989, the average venture capital financing for a Canadian technology company was $657,000, only 65% of that for a French company, 52% of that for a U.K. company, and only 30% of U.S.A. technology companies.[4]

In conclusion, then, while Canada seems to nominally have some of the mechanisms and programs that are found abroad, the level of commitment and importance given to technology commercialization does not appear to be equivalent to that found in Europe and the U.S.A.

It was found in our case studies, for example, that technology transfer bodies in the foreign health care research systems seem to play a more important role in the commercialization of medical devices than in Canada (see Exhibit 5-8).

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[4] Venture Economics Ltd.

6.0 MODELLING THE TECHNOLOGY TRANSFER PROCESS

6.1 The Sources of Innovation

The innovator in the medical devices sector is principally the health care provider, usually in association with the biomedical engineer (see Exhibit 5-4). This finding, along with the fact that the innovations are incremental in nature (see Exhibit 5-5) lead to a different pattern of innovation than what is suggested by the traditional model of innovation.

The traditional model of the innovation cycle suggests that the transfer from the realm of technical ideas to the reality of commercial products is a seamless ribbon from basic research to the market place with different people exercising different functions at each step in the cycle (see Exhibit 6-1). However, in the medical devices sector, the idea comes principally from the health care provider (e.g. doctor/surgeon) who then develops a prototype in partnership with the biomedical engineer.

Although other researchers are also a source of innovation (over 20% in our case studies - see Exhibit 5-4), they follow the more traditional model of innovation by passing off their research findings to others for development, since they are mainly interested in basic research.

6.2 Commercialization of the Technology

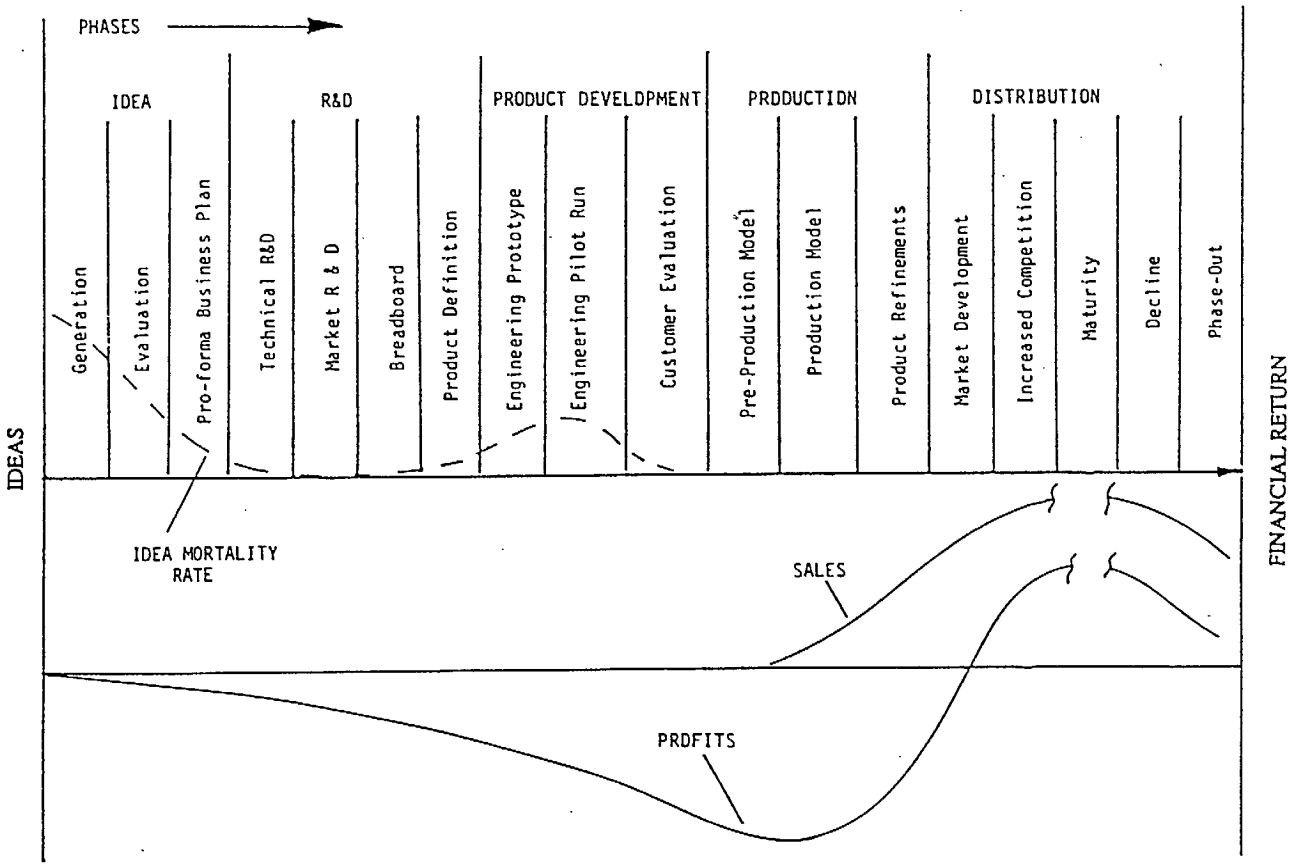
Because the innovator is, by and large, not especially interested in commercializing his/her medical device, the sophistication of the technology transfer intermediary is central to the effective transfer of the technology. However, as we have seen in Section 5.4.2, these bodies are generally not very well developed in Canada and are often by-passed in the commercialization process.

As well, the quality of the recipient company, be it either an existing firm or a start-up, will determine the success or failure of the technology transfer. Initially, the recipient would produce small volumes for first-time buyers who purchase experimental quantities. If the product penetrates the market, then commercial scale can then be achieved either through expansion of the recipient firm or through alliances with major firms.

In the commercial realm, large firms have two principal advantages in directing the technology transfer process:

- they often contribute funding to projects to keep abreast of developments of interest (e.g. Zimmer and the Miller Gallante knee).

Exhibit 6-1
The Innovation Cycle



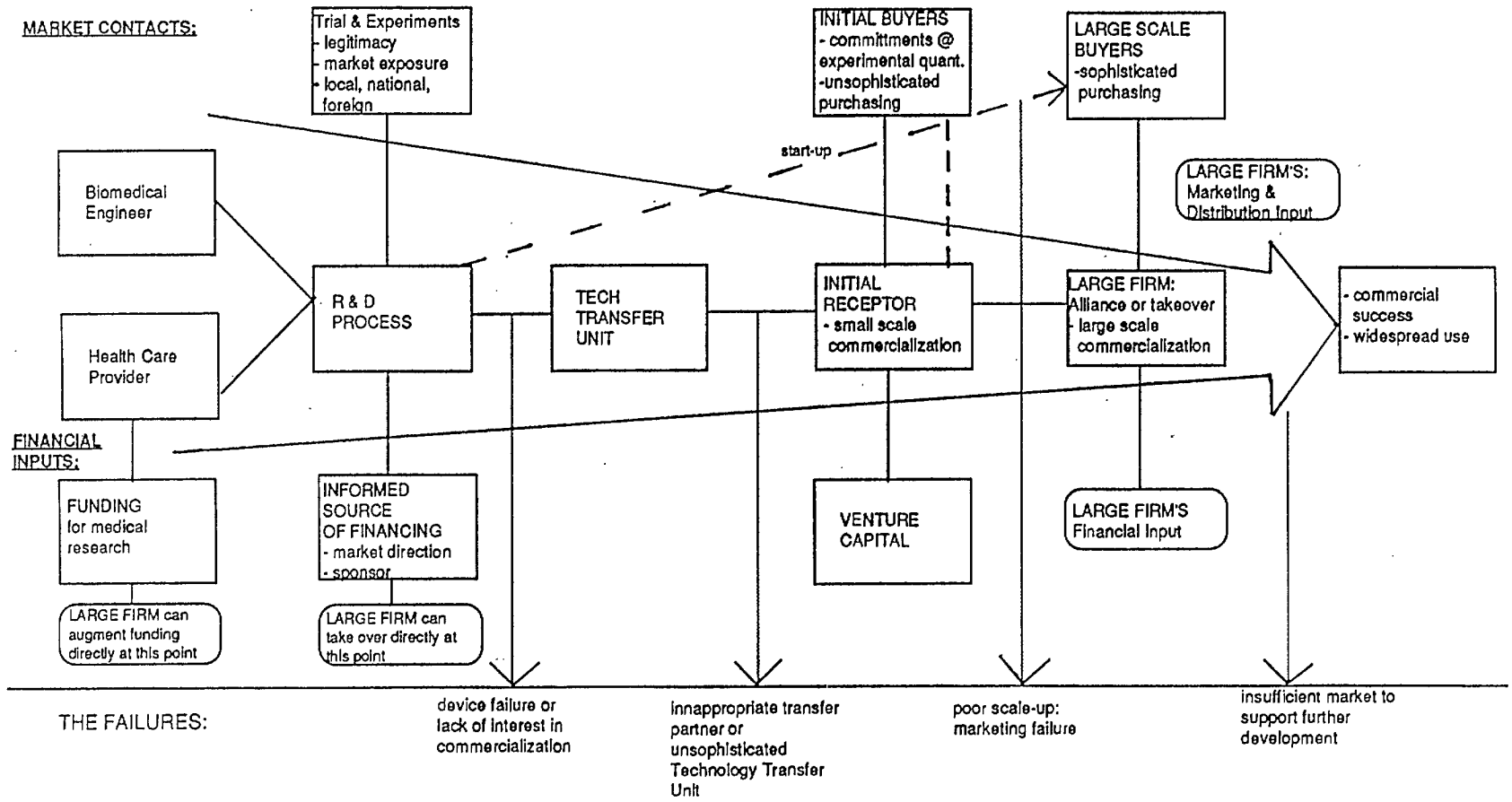
- they have the production capability to ensure economies of scale. This capability is particularly well suited to medical devices where the improvements are largely incremental necessitating only a variety of adjustments to the production line.

6.3 The Model

The essential features of the technology transfer process in medical devices are summed up in the model presented in Exhibit 6-2. The model highlights the following essential features:

- the partnership between health care providers and biomedical engineers
- the key roles played by various sources of funding:
  - at the research level
  - at the scale of initial commercialization
  - at the level of large scale commercialization
- the central role of technology transfer units
- the multiple levels of marketing
  - at the trial and experimentation stage
  - at the level of the first users
  - at the level of large scale buyers
- the powerful lever of marketing and distribution muscle which can reach back to any stage of the process and appropriate innovations even at the source
- the many points at which good technology can fail to enter the market.

Exhibit 6-2
Medical Devices: The Technology Transfer Process



7.0 CONCLUSIONS

7.1 The Research Base

Canada spends about $35 million per year on institutional research in the medical device sector. This research is undertaken within a broader health care research activity which is funded at a level similar to or relatively higher than that in other selected industrialized countries, except the U.S.A. (see Exhibit 4-2).

The areas of research strengths are:

- diagnostics, responsible for more than 40% of the sector expenditures; and
- implants, imaging and assistive devices, together accounting for another 40% of the expenditures.

There are geographical concentrations of activity. Some 50% of the activity is in Ontario and there are 12 Canadian cities with the capability to support medical device R&D.

Canada has the research base needed to generate a significant level of medical device commercial activity.

7.2 Technology Transfer

In the medical devices sector, the technology transfer process is characterized by the following:

- the health care provider and the innovator are often one and the same
- transfer to market often begins with the publication of research papers.
- successful innovations are helpful to adapt to market realities by user feedback and by informed sources of financing
- Innovation is largely incremental, and thrives on continual feedback from actual medical practice
- technology transfer units can play a valuable catalytic role in the commercialization process
- the incremental nature of innovation means that a single product stands little chance against broad, established product-lines

- eventual absorption by large firms or strategic alliances with them is, by and large, the only viable means to commercialize most device innovations

- university hospitals can be centres of innovation. They combine, under one roof:

  - health care providers
  - biomedical engineers/researchers
  - windows to market exposure through an active publications process and in-house testing
  - technical transfer resources

The Canadian medical devices sector is every bit as innovative as its foreign counterparts. However, the sector suffers from the systemic, structural weaknesses of the Canadian market which are the following:

- Weak Canadian market-pull

  - a small domestic market

  - fragmented buying power: the provinces buy individually; furthermore, even within the provinces, institutions rarely buy as a group

  - a publicly funded health care system which tends to resist innovation (e.g. capital expenditures on innovative devices are infrequent and amortization is spread over a long time (e.g. - radiology equipment is amortized over 20 years)

  - few effective forums exist for doctors and other health care professionals to combine forces and play the role of demanding buyers

- Institutional Weaknesses

  - virtually no medical device oriented venture capitalists

  - limited sophisticated support structures (technology brokerage groups, incubators)

  - limited institutionalization of technology transfer functions

- Sector Weaknesses

  - the underdeveloped medical devices industry has a serious lack of large indigenous companies with which smaller firms can interact and where fledging entrepreneurs can learn the market realities of technical innovation.

8.0 STRATEGIC OPTIONS TO BE EVALUATED

8.1 Government Initiatives

Although a medical device researcher may apply to the usual granting organizations for research funds, there is no funding source for medical devices which might encourage development and direct it towards a commercially viable product.

Such a central focus could be provided by the Natural Science and Engineering Research Council of Canada (NSERC), if it were to classify medical devices as a strategic area in the Strategic Grants Program.

By elevating medical devices to a strategic area:

1. A sum of money would be set aside specifically for medical device research

2. Researchers would receive a message as to the importance of this area and would be encouraged to give it higher priority. Competition for funding would lead to better proposals and ultimately to innovative devices

3. As part of the application and review process, NSERC could require evidence that a private sector firm is interested in commercializing any products developed as the result of the grant (it is implied that, if a firm is interested, it has conducted at least a preliminary market study).

ISTC could, in concert with NSERC and MRC, encourage the formation of university-industry consortia to develop specific medical devices in areas of strength. Canada is beginning to have some experience in consortium building with the federal and Ontario Centres of Excellence programs and the Ontario Technology Fund, for example.

This approach follows from the understanding that the transfer of an invention that is market driven is more likely to be a commercial success than one which is "research pushed".

8.2 Medical Technology "Showcase"

The concept of a technology showcase which allows researchers, venture capitalists and commercial firms to interact at one place is sound.

There are several annual American conferences and expositions where medical devices are shown to buyers and users. The only activity in Canada that was identified was London's Medtech show. The success of this concept in a Canadian setting is confirmed

by the fact that 14 technology transfer deals were apparently made as the result of the last Medtech.

In order to achieve Canada's objective of increasing exports for the medical device industry , the technology showcase must be aimed at firms and venture capitalists who are committed to producing the acquired technology in Canada. Inviting representatives from firms throughout the world who may acquire the technology for production elsewhere might serve to enhance Canada's reputation as a center for medical device development and might bring in royalties, but it will not create a Canadian growth industry.

Because the level of medical device activity in Canada is low compared to the U.S.A. and since it is desirable to have new products and concepts for each showcase event, it is suggested that initially the exhibition be held every two years, at the same time of year and at the same location. People should know, for example, that the exhibition will take place in the last week of October in every odd numbered year. At some later time, should the level of development of medical devices increase significantly, then at that time consideration could be given to an annual exhibition.

Given London's (Ontario) existing initiative, it seems the logical place for the exhibition. It may be argued that London is inconvenient because of the lack of many direct flights from other parts of Canada. However, more than two thirds of the medical research activity is in Ontario and Quebec and London is within reach in terms of travel time and cost for most researchers and businesses. As well, the previous London-based trade shows were considered to be successful.

One very strong point in favour of retaining London as the location for the bi-annual exhibition is the large core of dedicated volunteers who successfully organized the previous exhibitions. Similarly, the moral and financial support of the City of London is an important factor.

The organizing committee (or board of directors) should include representatives from each of the interested publics:

a) the federal government
b) the City of London
c) the medical device research community
d) the Canadian commercial medical device community
e) the financial community

Any organization which is dedicated to the growth of the commercial Canadian medical device industry should also be represented.

It would be reasonable that the funding sources represent half of the committee and that other interested groups constitute the remainder of the committee.

Although a major aspect of the Medtech concept is to show ideas and products to potential commercial partners, a second important component is the associated scientific symposium which allows the exchange of ideas and concepts. Because the medical device industry draws on technology from diverse sources, this type of focused communication should be continued.

8.3 Information Data Base

As a strategic option, consideration was given to the development of a database of current research, technologies (including general ones with potential application in the medical device field), and available prototypes. To this end, the following was undertaken:

a) review of UNIRES (an inventory of university research projects reported by federal government agencies) by the Canadian Institute for Scientific and Technical Information (CISTI);

b) review of a study entitled "Towards a National Data Base of University Research (1986)" undertaken by the Corporate Higher Education Forum

c) interviews with selected people with experience in the development and maintenance of such systems;

d) examination of the difficulties in adopting the classification systems for a computerized inventory of multi-disciplinary research and technologies; and

e) consideration of the utility of an information system from a marketing perspective and in terms of: a) simplifying the technology transfer process, and b) fostering an indigenous medical-device related sector

From the survey and review of the literature, there appears to be a need to improve the methods for exchange of timely, accurate information on medical device-related research, technologies, markets and services. Feedback from researchers and technology transfer officers suggested that the following areas needed attention;

- better information flow between industry and university concerning needs and resources;

- improved access to timely information on likely sources of funding for

applied research, including venture capital funding for start-up companies;

- affordable access to market information for technology transfer and production of products;
- improved information support for technology transfer people at medical facilities; and
- better awareness of local expertise

In the case studies, timely access to information and market analysis was instrumental to the process of successfully transferring technology from the research lab to industry and then to the marketplace. Failures could have been avoided if timely information is available to the researcher or technology transfer officer early in the marketing process.

Technology transfer initiatives will increasingly depend on the ability of stakeholders (researchers, research institutions, government and industry) to support an information system in this sector. Many of the existing information systems in various jurisdictions appear under-utilized, but might under appropriate conditions, benefit the sector. These data stores include:

a) MRC Reference list:

b) NSERC: List of Scholarships and Grants in Aid of Research;

c) Business Opportunities Sourcing System (BOSS) within ISTC;

d) inventories of funding sources (Investment Canada, AUCC, Federal and Provincial Granting Agencies).

Many custodians of these systems are effectively using information technology to facilitate in-house processes, but the movement of information which might simplify the technology transfer process is relatively primitive, considering advances in data storage, processing and data communication. The traditional approach to this challenge is to integrate such systems using mainframe database solutions. These require substantial resources for computing hardware, programming, data conversion and maintenance. In a 1986 study,[5] an initial hardware investment of between $300K to $800K was estimated to be required while updating and maintenance would cost approximately $500K per year.

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[5] Corporate Higher Education Forum: Towards a National Data Base of University Research: University of Toronto, Number 1986.

The cost-effective solution to the information systems question is NOT to develop yet another database system, but rather to establish mechanisms which would allow an "information broker" to transfer electronic information (in a structured format) in the public domain to a workstation system for local processing, data retrieval and reporting. The "information broker" would add value to the data by repackaging it as an information service to meet the particular needs of industry or the research community.

The "information broker" could also be a suitable candidate to maintain the research inventory compiled during this study. These results could be repackaged and included as one of the services the "information broker" might offer, among which might include:

a) publishing a directory of sources of medical devices manufactured in Canada (in print and possibly electronically) to serve the particular needs of the medical technology sector;

b) providing an alternative source of access to domestic market statistics for the medical technology sector to be used as a common tool by marketing consultants, venture capitalists, inventors, entrepreneurs and users;

c) providing services to promoters of conferences and workshops in medical technology;

d) publishing listings of services and programs for medical technologies across Canada; and

The market demand for this approach to information needs to be fostered. A preliminary review suggests that the "information broker" might require start-up money in the form of contracts and contributions from various sectors to make the venture viable, particularly during the early stages of development.

This "information broker" function could be an element in the broader "technology broker" function recommended in the next section.

9.0 STRATEGIC DIRECTIONS AND RECOMMENDATIONS

A comprehensive and sustained sector strategy will be needed if the sectoral growth targets established by ISTC/MEDEC are to be met (see Section 2.0). The following suggests strategic directions that would bring the research and business communities closer to each other and makes specific recommendations in this regard. Other elements making up a comprehensive strategy would come from the other studies that have been undertaken (see Section 1.0).

9.1 Making Medical Devices a Strategic Research Sector

To bring the research effort closer to the market environment it is recommended that government, the research community and industry agree to designate the medical device sector as a strategic research sector so that it can be funded under the NSERC strategic grants program (see Section 8.1); the medical device sector would thus become a "pôle" to use a European concept. By raising the profile of the sector, more interest will be generated within both the research and business communities.

As well, ISTC should, in concert with NSERC and MRC, promote and subsidize the formation of university-industry research consortia related to the development of specific medical devices, especially in areas where there are known strengths (see Section 4.0). The benefits of such joint research are noted in Section 5.4.3.

9.2 Creating an Aggressive Commercially Oriented Technology Transfer Mechanism

9.2.1 The Problematique

This study has identified technology transfer has the major problem in the commercialization of medical devices for the following principal reasons;

- the health care providers and associated researchers are not, by and large, particularly interested in commercializing their innovations;
- the development of technology transfer mechanisms is not as advanced in Canada as in other countries in Europe and in the U.S.A.;
- by and large, existing university/hospital based technology transfer units do not, at present have the sustained commitment and resources from their institutions to do an effective job;
- the lack of large indigenous firms, and the presence of only a limited number of

small firms in the sector are constraints on the technology transfer process (i.e. - few viable recipients are available to accept the technology).

These characteristics are not unlike those found in other high technology sectors in Canada.

9.2.2 Developing A Pro-active Approach

Many of the mechanisms set in place in Canada are passive in nature in that the expectation is that the business sector will initiate the search for technology as is done in the U.S., for example. The classic case was the now defunct Canadian Patents and Development Ltd. (CPDL), the repository of innovations emerging from government laboratories and universities, which did not pro-actively market its innovations. The existing university/hospital based technology transfer units also suffer from this problem. Moreover, they are situated within a research culture which is not particularly interested in commercialization of its findings. So, it is not surprising that, to date, these bodies have only had limited success. Hopefully some of the emerging approaches (e.g. Sunnybrook, U.T.I.) will be more successful.

Because the Canadian business sector does not interact closely with the research community, an intermediary is needed to introduce the innovations emerging from publicly funded research institutions to the private sector. A pro-active approach works! A case in point is the experiment conducted in Saskatchewan in 1983. Mr. Denzil Doyle, President of Doyletech Inc. was retained by the Saskatchewan government to pro-actively search out innovations within that province's publicly funded research institutions and other sources of technology and present them to the business community.

Within a six month period over 100 potential business opportunities were reviewed and approximately half resulted in business plans which were considered to be worthy of presentation to investors. About a quarter of these resulted in new business ventures within that six month period or very shortly thereafter.

Over a four year period, that strategy produced the following results:

Year	1982	1986
Number of Firms	39	142
Sales	$ 81M	$400M
Employment	1,097	2,735

It has also created a greater awareness of the incubation process within both the scientific and investment communities. This has led to greater teamwork and an

acceleration of the technology diffusion process generally.

This experiment was repeated in New Brunswick, beginning in 1988, where an Innovation Centre was established, under the Canada-New Brunswick Industrial Innovation and Technology Development Agreement, to commercialize technology which exists within the province. As in Saskatchewan, the Innovation Centre team of four people, sought out promising technical ideas within the research community and elsewhere, undertook market studies and developed business plans, which were then presented to the business community in New Brunswick and in other parts of Canada. The Innovation Centre raised the awareness of the potential for technology transfer in New Brunswick and improved contacts between the research and business communities. Its three year mandate terminated in March 1991 and future directions are currently under review.

These experiments are modest compared to the institutionalized approaches in Europe (e.g. - Steinbeis Foundation in Baden-Wuerttemberg) and large business ventures in the U.S. (e.g. Medtronics). They do, however, indicate a way to follow in an emerging sector in Canada where the industrial structure is not well developed and hence the financial resources available are limited.

9.2.3 A Technology Transfer Mechanism for the Canadian Medical Devices Sector

Because the technology transfer process is not particularly well developed in Canada, for all the reasons mentioned earlier, it is recommended that:

- ISTC support the establishment of a private sector technology transfer company who would be an intermediary between the research community in the medical devices sector and the financial and industrial sectors. This "technology broker" would:
  - extract medical device ideas and products from the research community;
  - promote the undertaking of market studies related to the above medical devices;
  - promote the development of business plans to support promising medical devices;
  - present the business plans to the financial community and to existing firms;
  - maintain the information data base service described in Section 8.3; and
  - assist firms to get financial support through government programs (e.g. IRAP, PEMD, etc.).

This "technology broker" would be the sector's focal point and would interact with other groups, such as those within university and hospitals to provide services which they require to effectively transfer technology. A private sector organization operating on sound business principles is recommended.

9.3 Other Recommendations in Support of Technology Transfer

ISTC should also act in the following complementary areas:

- provide financial support to individual researchers wishing to undertake market studies to develop business plans. Such studies could be undertaken by business consultants;
- commission the publication of a manual for medical researchers on do-it-yourself market studies and creation of business plans;
- support the inclusion of marketing and other commercial topics as part of scientific meetings and as articles in appropriate journals. These should include successful case histories of technology transfer;
- encourage large buyers to make their needs known at medical conferences, workshops and trade fairs;
- support local initiatives (e.g. technology brokerage, awareness) which encourage closer contacts between university medical researchers and the local industrial and financial communities. ISTC has supported similar initiatives in the past through the Technology Outreach Program;
- support one major medical device trade fair;
- provide financial support for the development of prototypes; and
- provide financial assistance to meet regulatory requirements.

9.4 Facilitating Commercialization

All the above recommendations relate to transferring technology out of the research environment. Further assistance is needed once the technology has been imbedded into a product which is ready to be commercialized.

Because the medical devices sector is fragmented and initial production is in small quantities, it would be advantageous to have a "umbrella" marketing and distribution company which could undertake the necessary marketing and selling functions as well as contract out production to manufacturing firms. A model for such a body exists. The Technical Aids and Systems for the Handicapped Inc. (TASH Inc.) develops, markets and distributes technologically sophisticated electronic products for the rehabilitation of handicapped people. The actual manufacturing of specialized products is undertaken largely by Canadian suppliers. TASH purchases over $1 million of goods from local Canadian industry and exports some 60% to the U.S. and Europe. TASH has the ability to aggregate a number of small volume product lines.

Given the nature of the medical devices market (i.e. small volumes to be sold over a large international market) a broad-based marketing group, along the lines of TASH, would help create market pull for Canadian medical devices.

It is recommended that ISTC consider supporting the establishment of such a marketing company.

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