Charles S. Carignan, M.D.
Vice President, Clinical Affairs and Medical Director
Endosurgery

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760

****Revised as of January 2003****

EDUCATION

Doctor of Medicine
Columbia University, College of Physicians and Surgeons — New York, New York

Bachelor of Arts
Yale University — New Haven, Connecticut

PROFESSIONAL LICENSES & CERTIFICATIONS

Maryland State License
New York State License
Drug Enforcement Agency
Controlled Dangerous Substances License to Dispense
Diplomat, National Board of Medical Examiners
Advanced Trauma Life Support
Advanced Cardiac Life Support

EMPLOYMENT

Boston Scientific Corporation
Natick, MA
Vice President, Clinical Affairs, and Medical Director, Endosurgery — January 2003-Present

Responsible for Clinical and Medical Affairs for the Endosurgery Group of companies covering therapeutic areas of Gastroenterology, Pulmonology, Gynecology and Women's Health, Urology, Oncology and Venous Access. Designs and implements clinical trials testing the safety and effectiveness of new medical devices and surgical procedures. Evaluates new companies and technologies for possible acquisition. Develops strategies, prepares submissions for, and interfaces with US, European, Asian, Canadian, and Australian regulatory authorities and notified bodies. Oversees protocol design, statistical analysis design, oversees clinical affairs staff, monitoring staff, data collection, including electronic data collection and data reporting and analysis. Responsible for all clinical data report writing. Has responsibility for reviewing all device and procedure related complaints and interfacing with physicians to resolve problems.

Conceptus, Inc. — San Carlos, CA
Vice President, Clinical Research and Medical Affairs — July 2000-January 2003

As an officer of the corporation, participated in overall leadership of the company. Responsible for the clinical trials leading to the approval of Essure, a new female contraceptive device. Co-wrote the PMA that

was granted expedited review status, presented at the CDRH OB/GYN Panel 3 months after PMA submission and received approval in less than 7 months from submission. Designed and implemented clinical trials testing the safety and effectiveness of new medical devices and surgical procedures. Also responsible for developing a physician training program for new market introduction in Australia, Europe and Singapore. Oversaw protocol design, statistical analysis design, clinical monitoring staff, data collection, including electronic data collection and data reporting and analysis. Responsible for all clinical data report writing. Developed strategies, prepared submissions for, and interfaced with US, European, Asian, Canadian, and Australian regulatory authorities and notified bodies. Had responsibility for reviewing all device and procedure related complaints and interfacing with new physicians to resolve problems. Presented new data at medical meetings, wrote journal articles, served on board of Reproductive Health related organizations, and was involved in establishing distribution contracts and alliances with partners. As a consultant helped develop the clinical and regulatory strategy, designed the clinical trials and interact with and train investigators in the study. Collaborated in development of Direct-to-Physician and Direct-to-Patient marketing programs.

Stanwood Associates **Baltimore, Maryland**
President **November 1997- July 2000**

Stanwood Associates was devoted to making new reproductive health technologies available through direct development and by providing consulting services to other organizations developing new technologies. Experience in both drugs and devices, in Phase I, II and III. Experience managing clinical investigators and CRAs. Familiarity with the FDA particularly in the OB/GYN division of both devices and drugs. Expertise for the design and implementation of clinical trials in the U.S., Europe and developing countries, including protocol development; device and drug design; participant recruitment; site selection and development; and data collection and analysis**.** Stanwood Associates also works to design and implement programs to improve access and quality of health care services in developing countries. Areas of expertise are clinical operations research; training, accreditation and certification of health care providers and systems; quality improvement; service delivery design, organization and management; and guideline and policy development. Content areas are primary health care, reproductive health and family planning.

EngenderHealth (Formerly AVSC International) **New York, New York**

Vice President **June 1996- November 1997**
Medical Director

Acting Medical Director **August 1995 - June 1996**
Deputy Medical Director **July 1994 - August 1995**
Associate Medical Director **July 1993 - July 1994**
Senior Medical Associate **November 1997- May 1998**

As a Vice President, responsible for developing and implementing a reorganization of the agency involving restructuring, team development and change management; oversee the development and management of the agency wide budget; strategic planning; and marketing of the technical assistance capability of the organization. As Medical Director, responsible for overseeing the medical and training staff and those components of AVSC's international programs including the technical resources and materials needed to support this TA including curricula, policies, clinical operations research and evidence based guidelines. Supervisory responsibilities for professional staff in all regions with direct oversight of several international regions. Research and writes publications related to reproductive health and family planning and particularly in the area of sterilization. Provides direct technical assistance in areas of clinical training in sterilization and temporary methods of contraception, STDs/HIV, quality assurance, medical monitoring and supervision,

development of protocols and standards, and development of service delivery programs. Provides technical assistance on the development of new contraceptive techniques. Participates on WHO and USAID committees for new technology development.

Columbia-Presbyterian Medical Center **New York, New York**
Resident in General Surgery
The Population Council **New York, New York**
Research Associate

CONSULTANCIES

Industry

Conceptus, Inc.
Ethicon
Ethicon Endo-Surgery
Gynecare
Gynetics

Non-governmental organizations

EngenderHealth
JHPIEGO
ISTI
Pathfinder International
Institute for Reproductive Health, Washington, D.C.
International Planned Parenthood Federation, London, UK.
Family health International, Research Triangle Park, North Carolina.
PPFA National Medical Committee.

Co-Founder of WHO Advisory Committee on Laparscopic Training. Geneva. 1996-98.

Served on World Health Organization Committee on Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Contraceptive Use. Geneva, May 15-19, 1995.

Served on USAID Technical Guidance Working Group of the Maximizing Access and Quality Project. Washington, D.C. 1994-present.

Drafted *Medical Eligibility Criteria for Sterilization* for the World Health Organization, Improving Access to Quality Care in Family Planning. September 1994.

PUBLICATIONS

Cooper JM, **Carignan CS**, Cher D, and Kerin JF. Safety and Effectiveness of micro-insert non-incisional hysteroscopic sterilization in a multicenter trial. Obstetrics and Gynecology.

Kerin JF, Cooper JM, Price T, Van Herendael BJ, Cayuela-Font E, Cher D, and **Carignan CS**. Non-incisional hysteroscopic sterilization: results of a multicenter phase II study.
Journal of Human Reproduction

Pollack AE **Carignan CS**. Female and Male Sterilization, chapter 22. In *Contraceptive Technology, 18h, revised edition*. In Press.

Kerin JF, **Carignan CS**, Cher D.
The safety and effectiveness of a new hysteroscopic method for permanent birth control: results of the first Essure pbc clinical study.Aust N Z J Obstet Gynaecol Suppl. 2001 Nov;41(4):364-70.

Valle RF, **Carignan CS,** Wright TC.
Tissue response to the STOP microcoil transcervical permanent contraceptive device: results from a prehysterectomy study.
Fertil Steril. 2001 Nov;76(5):974-80.

Carignan CS, Pati S and Pollack AE. Update on Female Sterilization. Contemporary OB/GYN (1998).

Carignan CS, Pat S and Pollack AE. Update on Vasectomy. Contemporary OB/GYN (1998).

Stewart GK and **Carignan CS**. Female and Male Sterilization, chapter 22. In *Contraceptive Technology, 17th, revised edition*. Hatcher et al. Ardent Media, Inc. New York, 1998.

Female and male sterilization: Contraceptive Technology Update Series. Family Health International, Research Triangle Park, 1998.

Carignan CS and Pati S. Findings of the CREST Study: implications for providers. Medscape, Women's Health Network. November 1997.

Female Sterilization and Vasectomy in *Recommendations for updating selected practices in contraceptive use volume II.* Technical Guidance? Competence Working Group. United States Agency for International Development. 1997

Carignan, CS. *No Scalpel Vasectomy Curriculum.* AVSC International, New York, 1997.

No-scalpel vasectomy: an illustrated guide for surgeons, second edition. Carignan CS and Harper PB, eds. AVSC International, New York, 1997.

Huezo, C. and **Carignan, CS**. *Medical and Service Delivery Guidelines for family planning., second edition*. International Planned Parenthood Federation in collaboration with AVSC International. IPPF Medical Publications, London, 1997.

Carignan CS, Pollack AE and Moore C. male and Female Sterilization. *In Family Planning handbook for health professionals: the sexual and reproductive health approach*. Evans I and Huezo C editors. IPPF, London, 1997.

Findings of the 1996 CREST Study: AVSC Technical Statement. AVSC International, New York, 1996.

Carignan, CS, Falk, S., and Pollack, A. 1994. *Medical Eligibility Criteria for Sterilization*. Background document for World Health Organization Committee on eligibility criteria for contraception.

Carignan, CS, Rogow, D., and Pollack, A. 1994. The quinacrine method of nonsurgical sterilization: Report of an experts meeting. *AVSC Working Paper, No. 6*, New York.

Pollack, A., and **Carignan, CS** 1994. Association for Voluntary Surgical Contraception: A technical statement on quinacrine pellets for nonsurgical contraception. *Advances in Contraception* 10:43-50.

Pollack, A., and **Carignan, CS** 1994. The use of quinacrine pellets for nonsurgical sterilization. *Reproductive Health Matters* 2:119-22.

Winikoff, B., **Carignan, CS**, et al. 1991. Medical services to save mother's lives: Feasible approaches to reducing maternal mortality. *Programs Division Working Paper No. 4*. New York: The Population Council.

PRESENTATIONS

Multiple presentations at International and National professional meetings, societies, training, and committees including FDA CDRH OB/GYN panel. Details available on request.

LANGUAGES

Proficient Spanish; minimal fluency in French.

ASSIGNMENT COUNTRIES

Short-term technical assistance:
Asia: Bangladesh, India, Indonesia, Nepal, Philippines, Vietnam
Sub-Saharan Africa: Kenya, Tanzania, Zimbabwe, Malawi, Nigeria, Ghana, Mali, Guinea, Uganda
North Africa and Middle East: Morocco, Turkey, Egypt, Jordan
Latin America and Caribbean: Mexico, Peru, Guatemala, Jamaica
Russia and Former Soviet Union: Russia, Kazakhstan, Kyrgyzstan, Ukraine, Uzbekistan

PROFESSIONAL ASSOCIATIONS

American Medical Association
American Public Health Association
Regulatory Affairs Professional Society
Association for Reproductive Health Professionals
Fellow of the American College of Physician Executives