SFDA Commissioner Shao Mingli meets Director General of the Center for Genetic Engineering and Biotechnology of Cuba  On October 28, 2011, Shao Mingli, Commissioner of SFDA, met with the visiting delegation led by the Director General of the Center for Genetic Engineering and Biotechnology of Cuba. The two sides exchanged views on biotechnology collaboration between both countries.  (October 28, 2011)

SFDA Commissioner Shao Mingli meets Belgian Vice Prime Minister and Minister of Foreign Affairs and Institutional Reform  On October 24, 2011, the Belgian delegation led by Mr. Steven Vanackere, Vice Prime Minister and Minister of Foreign Affairs and Institutional Reform of Belgium, visited SFDA. Shao Mingli, Commissioner of SFDA, had a cordial and friendly conversation with Mr. Steven Vanackere. Both sides had an extensive and in-depth discussion on relevant laws and regulations on drug and medical device supervision and other issues of common interest.  (October 25, 2011)

SFDA Commissioner Shao Mingli meets U.S. Department of Commerce Biotechnology and Life Sciences Trade Mission to China  On October 14, 2011, Shao Mingli, Commissioner of SFDA, met with the U.S. Department of Commerce Biotechnology and Life Sciences Trade Mission to China led by Mr. Francisco J Sanchez, U.S. Under Secretary of Commerce. Both sides had an in-depth discussion on the development of biomedical industry, market access, management of orphan drugs and other issues.  (October 15, 2011)

SFDA Commissioner Shao Mingli meets Deputy Minister of the Syrian Ministry of Health  On the morning of September 23, 2011, Shao Mingli, Commissioner of SFDA met with the visiting Dr. Rajwa Jbeily, Deputy Minister of the Syrian Ministry of Health, and her entourage. Both sides introduced the drug supervision situation respectively and expressed the intention to cooperate in the field of drug supervision.  (September 24, 2011)

SFDA Deputy Commissioner Wu Zhen meets the Head of Iran's Innovation and Technology Cooperation Center  On the morning of September 6, 2011, Wu Zhen, Deputy Commissioner of SFDA, met with the visiting Mr. Hamidreza Amirinia, Head of Innovation and Technology Cooperation Center of Iran. Both parties exchanged views on enhancing mutual exchanges and understanding, and promoting cooperation in the field of traditional Chinese medicine and biopharmaceuticals.  (September 7, 2011)

SFDA Deputy Commissioner Bian Zhenjia meets Vice Minister of Health of Vietnam  On the afternoon of November 1, 2011, Bian Zhenjia, Deputy Commissioner of SFDA, met with Mr. Cao Minh Quang, Vice Minister of Health of Vietnam, and his entourage. Both sides exchanged views on such topics as registration of traditional Chinese medicine, certification management, clinical trails, adverse reaction monitoring, and quality management of Chinese crude drugs.  (November 4,2011)

China-ASEAN Drug Safety Forum & Food and Drug Administration Director Conference held in Nanning  The “China-ASEAN Drug Safety Forum & Food and Drug Administration Director Conference”, jointly organized by the State Food and Drug Administration and the People's Government of Guangxi Zhuang Autonomous Region, was held in Nanning. SFDA Commissioner Shao Mingli introduced the general condition of China's drug safety regulation and the major tasks and measures for China's drug administration in the future. Heads of the Food and Drug Administration Departments from Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Singapore, Thailand and other countries also delivered their keynote speeches.

The theme of China-ASEAN Drug Safety Forum is: Strengthen Communication, Protect Drug Safety, and Seek Common Development --- Drug Safety Cooperation Along with the Development of China-ASEAN Free Trade Zone. The Forum is of great significance for the ASEAN countries to build a communication platform, share experiences and achievements of drug administration, further promote drug safety cooperation, and promote the healthy and sustainable development of pharmaceutical economy and trade.

The 150 Participants of the Forum also include leaders of the relevant SFDA departments and Food and Drug Administration departments of 31 provinces (autonomous regions and municipalities), as well as representatives of pharmaceutical enterprises. The Forum was co-hosted by the Food and Drug Administration department of Guangxi Zhuang Autonomous Region, China Center for Pharmaceutical International Exchange, and the China - ASEAN Expo Secretariat.  (October 21, 2011)
National Medical Device Adverse Event Monitoring On-Site Meeting Held

In order to promote the in-depth development of national medical device adverse event monitoring, the 2011 National Medical Device Adverse Event Monitoring On-Site Meeting was held in Shandong Province from September 27 to 28, 2011. SFDA Deputy Commissioner Bian Zhenjia attended the meeting and delivered a speech.

At the meeting, Deputy Commissioner Bian Zhenjia fully affirmed the achievements attained by China’s whole food and drug administration system in recent years through their earnest implementation of the “Requirements for Medical Device Adverse Event Monitoring and Re-evaluation (Interim)”, and vigorous promotion of medical device adverse event monitoring and re-evaluation. He comprehensively analyzed the current situation and tasks, and raised specific requirements for the forthcoming works. Deputy Commissioner Bian Zhenjia pointed out that: we should grasp the overall situation and transform our ideas to further improve our awareness of the importance of medical device adverse event monitoring; face up to the status quo, find the drawbacks to effectively and conscientiously implement medical device adverse event monitoring; improve emergency response mechanism to enhance emergency response capabilities; and we should lay extra emphasis on and further implement the re-evaluation of medical devices.

Principal leaders of the SFDA Department of Medical Device Supervision and the National Center for Adverse Drug Reaction Monitoring delivered their work reports respectively, 16 food and drug administration units from Shandong, Beijing, Hunan, Zhejiang, Anhui Province and Linyi in Shandong exchanged their field experience.

(October 12, 2011)

SFDA Exposed Four Illegal Medical Device Advertisements

Recentely, SFDA exposed four illegal medical device advertisements for "Super Radiation Therapy Devices" produced by Qingdao Wu Long Biotechnology Co., Ltd., the "Devices for Hypertension" by Dalian Xiongwei Electronics Co., Ltd., the "Chiyu Magnetic Therapeutic Shoes" by Chiyu Science Industrial and Trading Co., Ltd. (Group), and the "Nano-Silver Anti-Bacterial Gel Series (for hemorrhoids)" by Changchun Kexin Institute of Biochemical Medical Devices. The contents of the four medical device advertisements have overstepped the approved contents stipulated by Food and Drug Administration departments, containing unscientific assertions and guarantees of the efficacy and functions of products, etc., and serious deceived and misled the consumers.

As per the "Provisions for Medical Device Advertising Inspection", the Food and Drug Administration departments have meted punitive measures on the aforementioned medical devices and manufacturers with illegal advertising, which have been transferred at the same time to Industrial and Commercial Administrative Departments for investigation and disposal. SFDA warned consumers with corresponding diseases to seek treatment under the guidance of doctors, and ignore all illegal advertisements.

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(September 7, 2011)
Online Promulgation of the "Guidelines for the Clinical Trial of Coronary Drug-Eluting Stents" (Draft for Approval)

To further clarify the scientific nature and rationale of the clinical trials of these products, ensure safe and effective clinical trials, and guide manufacturers and clinical trial institutions to conduct standardized clinical trials, Center for Medical Device Evaluation of SFDA drafted the "Guidelines for the Clinical Trial of Coronary Drug-Eluting Stents". Through three consecutive online comments solicitations and repeated discussions & revisions of Experts Conferences, a consensus has been achieved now to form the Draft for Approval. To enable the manufacturers to have more timely and accurate access to the work of medical device adverse events monitoring, and to better guide the manufacturers to carry out clinical trials, the Draft for Approval of the Guidelines is hereby promulgated in the central website of CMDE. Meanwhile the manufacturers are recommended to regulate the implementation of clinical trials and the preparation of application dossiers according to the Draft for Approval of the Guidelines. (September 23, 2011)

Guidelines for Medical Device Adverse Event Monitoring (Trial Implementation) Issued

In order to comprehensively promote the work of medical device adverse event monitoring, standardize and guide all related works of adverse event monitoring, in accordance with the Requirements for Medical Device Adverse Event Monitoring and Re-evaluation (Interim) and other relevant regulations, SFDA organized the formulation of the “Guidelines for Medical Device Adverse Event Monitoring (Trial Implementation)”, which was promulgated for implementation on September 16, 2011.

PREFACE

The Guidelines are applicable to all the medical device manufacturing enterprises, distributing enterprises, user units, the requirements for medical device adverse events reporting for the individuals, corporate bodies, other relevant social organizations, and requirements and working specifications for medical device adverse events monitoring agencies as well as the annexes.

I. MEDICAL DEVICE MANUFACTURING ENTERPRISES

(1) The responsibilities and obligations

1. Act as the legal responsible person for the safety and efficacy of medical devices;
2. One of the entities responsible for medical devices adverse events reporting;
3. Establish and carry out the management system of medical devices adverse events monitoring within the manufacturing enterprises; the corresponding systems also shall be built by the manufacturers of Class II and III medical devices to ensure the traceability of products;
4. Organize and disseminate relevant rules and to have more timely and accurate access to the development process of the Guidelines, ensure safe and effective clinical trials, and guide manufacturers and clinical trial institutions to conduct standardized clinical trials, Center for Medical Device Evaluation of SFDA drafted the "Guidelines for the Clinical Trial of Coronary Drug-Eluting Stents". Through three consecutive online comments solicitations and repeated discussions & revisions of Experts Conferences, a consensus has been achieved now to form the Draft for Approval. To enable the manufacturers to have more timely and accurate access to the work of medical device adverse events monitoring, and to better guide the manufacturers to carry out clinical trials, the Draft for Approval of the Guidelines is hereby promulgated in the central website of CMDE. Meanwhile the manufacturers are recommended to regulate the implementation of clinical trials and the preparation of application dossiers according to the Draft for Approval of the Guidelines. (September 23, 2011)

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and regulations on medical devices adverse events monitoring formulated by the enterprises;

5. Designate full-time (part-time) personnel to take the responsibility of the medical devices adverse events monitoring within the enterprises;

6. Take the initiative to find out, collect, investigate, analyze and control all the suspected adverse events related to the medical devices manufactured, and report the adverse events that may cause serious injuries or death to the competent authorities timely.

7. Build and keep all the records related to medical devices adverse events monitoring for archiving;

8. The manufacturing enterprises of Class I medical devices shall establish an annual summary system of medical devices adverse events monitoring for the future reference; manufacturing enterprises of Class II, Class III medical devices shall establish an annual summary system of medical devices adverse events monitoring for reporting;

9. Be active to cooperate with regulatory department on the handling of the adverse event, and provide relevant data unconditionally.

10. Other responsibilities.

(II) Requirements for the designated agencies and staffing

1. One of departments in the organizations of medical devices quality management system shall be designated by the medical device manufacturing enterprises for being responsible for the medical devices adverse events monitoring, and the person in charge should be at least at the position of the deputy to the chief of an office within the enterprise.

2. A full-time (part-time) personnel in charge of medical devices adverse events monitoring designated by medical device manufacturing enterprises shall meet the following requirements:
   (1) of strong sense of responsibility and duty;
   (2) be familiar with relevant rules and regulations on medical devices adverse events monitoring;
   (3) with a background of majoring in medical science or medical devices;
   (4) know well about the relevant information on the products; and,
   (5) be good at communication and coordination.

3. Medical device manufacturing enterprises shall provide necessary resources and facilities for the routine operation of monitoring.

(III) Main monitoring system and procedures shall be established

Relevant monitoring system and procedures of medical devices adverse events shall be established by medical device manufacturing enterprises, and incorporated into the corresponding quality management system.

1. The responsibilities medical devices adverse events monitoring, and the responsibilities of the departments and personnel at all levels;

2. The dissemination of regulations, training and incentive system of medical devices adverse events monitoring;

3. The procedures for the finding, collecting, investigating, analyzing, evaluating, reporting and controlling the suspected medical devices adverse events;

4. The prerequisite for initializing the reevaluation of the medical devices, as

3. 建立并履行本企业医疗器械不良事件监测管理制度，第二类、第三类医疗器械的企业应当建立产品可追溯制度。
4. 积极组织贯彻医疗器械不良事件监测相关法规，
5. 指定机构并配备专人（兼）职人员负责本企业医疗器械不良事件监测工作，
6. 主动发现、收集、调查、分析和控制所生产医疗器械发生的所有可疑不良事件，并报告导致或者可能导致严重伤害或死亡的不良事件；
7. 建立并保存医疗器械不良事件监测记录，形成档案。
8. 第一类医疗器械生产企业应建立年度医疗器械不良事件监测情况总结备案制度，第二类、第三类医疗器械生产企业应建立年度医疗器械不良事件监测情况总结报告制度。
9. 积极主动配合监管部门对干预“事件”的处理，并无条件提供相应资料。
10. 其他相关职责。

（三）指定机构与人员配备要求

1. 医疗器械生产企业应当在其建立的医疗器械质量管理体系组织机构中指定部门负责人负责医疗器械不良事件监测工作，并建议由企业的副职及以上人员担任负责人。
2. 医疗器械生产企业应当配备相对稳定的专（兼）职人员负责医疗器械不良事件监测工作，其应具备以下基本条件：
   (1) 具有较强的责任心和使命感；
   (2) 熟悉医疗器械不良事件监测工作相关法规；
   (3) 具有医学、医疗器械相关专业背景；
   (4) 熟悉本企业产品的相关信息；
   (5) 具有较强的沟通和协调能力。
3. 医疗器械生产企业应当配置适宜的资源以保障监测工作的开展。

（三）应建立的主要监测制度和程序

医疗器械生产企业应当建立医疗器械不良事件监测管理制度和工作程序，并将其纳入建立的医疗器械质量管理体系之中。
1. 医疗器械不良事件监测工作职责，包括部门及各级人员职责；
2. 医疗器械不良事件监测法规宣贯、培训和激励制度；
3. 可疑医疗器械不良事件的发现、收集、调查、分析、评价、报告和控制工作程序。
well as the procedures and methods;
5. The contingency plan for the unexpected and mass adverse events;
6. The management system for the preserving of the files related to the medical devices adverse events monitoring;
7. The management system serves to the traceability of products;
8. Other relevant systems.

(IV) The requirements for the main procedures

1. The finding and collecting of medical devices adverse events

(1) Medical device manufacturing enterprises shall take the initiative to collect all the suspected medical devices adverse events related to the medical devices listed from the distributing enterprises and user units, other options for collecting medical devices adverse events are the complaints from the customers, literature reports and information disclosed by regulatory agencies from home and abroad.

(2) A convenient and efficient reporting channel (telephone, facsimile, written report, and online report, etc.) shall be established by the medical device manufacturing enterprises, for the user’s convenience to report medical devices adverse events.

(3) A reporting information system (in the language of Chinese) for medical devices adverse events shall be established by manufacturing enterprises of Class III implantable devices, the methods and channels for the reports collecting shall be depicted in the user’s manual, and inform the customers of the system while in the process of selling. When necessary, technical training on the reporting information system for the users shall be provided.

2. The investigation and evaluation of medical devices adverse events

(1) The medical device manufacturing enterprises shall attach great importance to the medical devices adverse events collected, all the events are subject to the analysis, investigation and evaluation conducted by designated personnel to determine whether these events are or shall be reported as adverse events according to the extent of severity and urgency.

(2) The medical devices reevaluation shall be carried out in good time according to the reevaluation initiation conditions, evaluation procedures and methods of medical devices previously formulated by medical device manufacturing enterprises.

3. The reporting of medical devices adverse events

The medical device manufacturing enterprises shall establish a user credential in the national medical devices adverse events monitoring system for the routine operation of the system, and report all related adverse events according to the principle of reporting all the suspected adverse events through the system.

(1) Case report (reporting of suspect medical devices adverse events)

Whereas the suspected medical device adverse events that caused death being reported, the medical device manufacturing enterprises shall fill the Report Form for Suspected Medical Device Adverse Events (see Annex 1) and report to the local medical device adverse events monitoring agencies within 5 working days since the date of finding or knowing for events causing death.

For the medical devices adverse events may cause serious injuries, or may possibly cause serious injuries or death, medical device manufacturing enterprises shall fill the Report Form for Suspected Medical Device Adverse Events and...
report to the local medical device adverse events monitoring agencies within 15 working days since the date of finding or knowing for events causing serious injuries or death.

The medical device manufacturing enterprises shall integrate the enterprise information, follow up information of the event and product information, etc. after submit the report for suspected medical devices adverse events, and fill the Supplementary Report Form for Medical Device Adverse Events (see Annex 2) in allusion to the subsequent event handling, investigation, the cause the event and the issues not specified in Report Form for Suspected Medical Device Adverse Events.

If the analysis of the cause in the report of suspected medical device adverse events is deemed as the final report by medical device manufacturing enterprises, while no Supplementary Report Form for Medical Device Adverse Events will be necessary, however, a statement of final report in the Report Form for Suspected Medical Device Adverse Events shall be attached.

If the analysis of the cause in the supplementary report of medical device adverse events is deemed as the final report by medical device manufacturing enterprises, a statement of final report in the Supplementary Report Form for Medical Device Adverse Events shall be attached. Otherwise, the supplementary report of medical device adverse events shall be submitted again, until the final report is achieved.

The medical device manufacturing enterprises shall fill the Supplementary Report Form for Medical Device Adverse Events within 20 working days after submitting the report of suspected medical device adverse events, and report to the local technical institutions for medical device adverse events monitoring.

In case of any other conditions beyond all the description in report of suspected medical device adverse events and supplementary report of medical device adverse events, the medical device manufacturing enterprises shall submit relevant supplementary information to local technical institutions for medical device adverse events monitoring when further measures should be adopted.

The medical device manufacturing enterprises shall submit the supplementary information promptly according to the specified requirements and time limits in the written notice issued by provincial technical institutions for medical device adverse events monitoring for submitting the supplementary information on suspected medical devices adverse events.

(2) The reporting of unexpected and mass medical devices adverse events

Whereas the unexpected and mass medical devices adverse events being reported, the medical device manufacturing enterprises shall report to local provincial food and drug administration departments, health bureaus and medical device adverse events monitoring agencies, and fill and submit the Report Form for Suspected Medical Device Adverse Events within 24 hours.

When necessary, cross reporting shall be adopted by the medical device manufacturing enterprises, which could directly report to the senior superior departments, while the superior provincial food and drug administration departments, health bureaus and medical device adverse events monitoring agencies that shall be informed timely.

(3) Annual summary report

The manufacturing enterprises of Class I medical device shall make
Conference Report

Seminar on YY0505 and Other Standards Held in Chongqing

From September 28 to 30, 2011, Medical Device Standards Management Center of SFDA organized the convening of the Seminar on YY0505 and Other Standards in Chongqing. More than 50 participants from the SFDA Department of Medical Device Supervision, Center for Medical Device Evaluation of SFDA, Medical Device Supervision Divisions and Centers for Medical Device Evaluation of some provincial Food and Drug Administrations, national and some provincial medical device testing centers, special standardization technical committees or sub-technical committees of active medical devices, and other domestic and foreign large and medium-sized enterprises attended the Seminar.

The Seminar introduced the international and domestic background and the development & revisions of YY0505 Standard, relevant units of various provinces and cities exchanged information about EMC laboratory construction, the preparation for the implementation of YY0505 Standard, and the overall situation of the YY0505-2005-based detection and rectification. Focusing on the specific contents, the necessity and the feasibility of implementation, the relevant issues in specific implementation and other topics, the participants held in-depth discussions and put forward their relevant views and suggestions. In addition, the Seminar also discussed the relevant issues after the implementation of YY0709-2009 Standard. (October 8, 2011)

The Second International Symposium on the Quality Control of Biomaterials and Tissue Engineering Products Held in Chengdu

Sponsored by the National Institutes for Food and Drug Control, and co-hosted by relevant units, the Second International Symposium on the Quality Control of Biomaterials and Tissue Engineering Products was held on September 8, 2011 in Chengdu.

Focusing on the “Safety Evaluation and Risk Control” of biomaterials and tissue engineering products, the Symposium is divided into two plenary sessions on Valves, and Related Laws & Regulations; and two sub-topics on Biological Materials & Tissue Engineering, and Nano-materials & Stents.

The Symposium has constructed a mutual learning, exchange & cooperation platform for China's drug administration departments, testing and inspection institutions, universities and colleges, other scientific research institutions and related enterprises. (September 12, 2011)

YY0505等标准研讨会在中国召开

2011年9月28至30日，国家食品药品监督管理局医疗器械标准管理中心在重庆组织召开了YY0505等标准研讨会。国家食品药品监督管理局医疗器械监管司、医疗器械技术审评中心、部分省局器械处和审评中心、国家级及部分省级医疗器械检测中心、有源类医疗器械专业标准化技术委员会或分技术委员会以及国内外大中型企业等相关部门代表50余参加了研讨会。

会议介绍了YY0505的国际、国内背景及制修订情况，各省市交流了有关ECM实验室建设和实施YY0505标准的前期准备情况以及开展YY0505-2005检测与整改的大体情况，并围绕标准的具体内容、实施的必要性和可行性、具体实施中的相关问题等主题以及YY0709-2009实施后的情况进行了讨论。

（2011年10月8日）

第二届生物材料与组织工程产品质量控制国际研讨会召开

2011年9月8日，由华中国食品药品检定研究院主办、相关单位协办的“第二届生物材料与组织工程产品质量控制国际研讨会”在成都召开。

大会以生物材料与组织工程产品的“安全性评价与风险控制”为主题，聚焦和相关法规两个全体会议以及生物材料与组织工程和纳米材料与血管支架两个分议题进行。

会议为我国药品监督管理部门、检验检测机构、大专院校、其他科研机构及相关企业搭建了互相学习、交流与合作的平台。

（2011年9月12日）
China's Medical Device Industry Has Great Potential with Four Major Development Trends

In 2010, China's medical device market growth rate was 23%, the market scale reached to 120 billion yuan. In the first quarter of 2011, China’s total medical device market revenue was 1.961 billion yuan, an increase of 40.06% over the previous terms. By 2015, China’s entire medical device and equipment market is expected to reach $53.7 billion, the compound annual growth rate of Chinese medical device industry will remain at 20%-30%, and the industry has great development potential.

The great potential of China's medical device industry is mainly manifested in two aspects:

First, the people’s ever rigidly growing demand for healthcare and rehabilitation medical devices, as well as China’s increasing support on the technology innovation of medical devices will become the fundamental driving force for the rapid development of China’s medical device industry;

Second, along with the rapid development of computer technology, the information technology and networking of the health sector led to growing demands for imaging, digital and other high-tech, precise and cutting-edge medical devices, and brought considerable market space to medical device manufacturers;

Third, with the grand background of China’s vigorous promotion of health care reform and the development of basic health care insurances, the market demand for medical equipment, instruments, and materials will witness an unceasing grow, and primary health care institutions will be an important market for medical devices.

S&P Consulting pointed out that the future trends of China’s medical device industry will present in four aspects:

First, automation. Medical devices featuring automated integration and precise operation, such as medical equipment assembly, laboratory automation and electronic assembly, etc., have attracted more and more attention;

Second, TCM-based. The integration of traditional Chinese medicine with medical device products will become a trend, such as digital diagnostic device, through intelligent analysis technology, TCM-based diagnosis, interpretation and syndrome differentiation can be achieved;

Third, miniaturization. Miniaturized medical devices have merits of portability, easy use, fast application, etc., they can conduct tests and examinations for patients at any time, saving time and space;

Fourth, extensive application of medical software, which shall be widely applied in the sales and management information systems of pharmaceutical industry, and shall become an indispensable part of medical devices in modern pharmaceutical industry.

(September 27, 2011)

China’s Medical Electronics Industry Boosted Significantly

Under the impact of the recovering economy, the acceleration of hospital informatization, the support of national policy and other favorable factors, China’s medical electronics industry is rapidly emerging as a new industry in the Chinese market. Based on an in-depth study of the medical electronics industry, CCID Consulting released in August 2011 the "Research on the Strategies of Chinese Medical Electronics Industry in 2011.”

According to the research, the rapid release of medical electronic products, high-end products, and integrated products can meet the rapid expansion of the medical electronics market.

Medical electronic products are the industry’s key factor and the industry’s future trend as well.

2010年，我国医疗器械市场增长率为23%，市场规模达1200亿元。2011年一季度，我国共有营业收入19.61亿元，同比增长40.06%。预计到2015年，中国整个医疗仪器与设备市场将达到537亿美元。中国医疗器械行业复合增长率将维持在20%-30%，行业发展潜力巨大，发展趋势显现。

发展趋势主要表现在：

一、随着计算机技术的快速发展，医疗领域的信息化和网络化引发了对影像化、数字化等高精尖医疗设备的需求增长，给医疗器械生产企业带来一定的市场空间；

二、在国家大力推进医疗、发展基础医疗保障的大背景下，市场对医疗设备、仪器、材料的需求量将不断增长，基层医疗机构将是医疗器械重要市场。

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四、随着计算机技术的快速发展，医疗领域的信息化和网络化引发了对影像化、数字化等高精尖医疗设备的需求增长，给医疗器械生产企业带来一定的市场空间；

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of China’s market demands for medical electronics has maintained the fast growth of the overall market size. In 2010, China’s medical electronics market reached 40.31 billion yuan, an increase of 21.1% over the previous terms.

The research report shows that the first, the regional distribution of the medical electronics industry is quite evident, with the major cluster areas of medical electronic device manufacturers locating in East, South, Northeast and North China. The second, medical electronics semiconductor manufacturers are mainly located in Beijing and Shanghai, and formed a cluster area of medical electronics semiconductors with foreign funded enterprises taking the lead. The third, medical electronics software enterprises in the coastal regions of East, South and North China have boomed and formed a cluster area with a trend of large-scale development.

1. Regional Distribution of Medical Electronic Device Manufacturers

**Northeast:** Omron (Dalian) Co., Ltd., Shenyang Neusoft Medical Systems Co., Ltd.


**North China:** Wandong Medical Equipment Co., Ltd., Toshiba Medical Systems Co., Ltd., Hitachi Medical Co., Ltd., Hangwei General Electric Appliance Medical System Co., Ltd., Jingjing Medical Equipment Co., Ltd., Tianjin Andon Health Medical Electronics Co., Ltd., and Tianjin Maida Medical Science and Technology Co., Ltd., etc.


2. Regional Distribution of Medical Electronic Semiconductor Manufacturers

**North China:** Toshiba, Hitachi, Hangwei General Electric Appliance Medical System Co., Ltd., Panasonic, Freescale Semiconductor Co., Ltd.


**South China:** Siemens electronics, etc.

3. Distribution of China’s Medical Electronic Software Enterprises

**North China:** Shenyang Neusoft Medical Systems Co., Ltd., Brainsoft Co., Ltd., ZKML Technology Co., Ltd., TomTec, IBM, ReadHengda Medical Software Co., Ltd., etc.

**East China:** Kingstar Winning Software Inc., Co., Ltd., Kingdeer Health Software Technology Co., Ltd., SAP, Shandong LANSOFT Co., Ltd., B-soft, etc.

**South China:** Mindray Bio-Medical

![Figure: The growth and market size of China’s medical electronics market in 2006-2010](image)

**Figure:** The growth and market size of China’s medical electronics market in 2006-2010

**Path:** 2006—2010年中國醫療電子市場規模與增長

**Source:** CCID Consulting
In addition, the report shows that, in the context of the overall growth of the market size of medical electronics, the market of portable medical electronics enjoys a more robust growth momentum. In 2010, China’s portable medical electronics market reached 20.87 billion yuan, an increase of 28.5% over the previous terms. From the perspective of market structure, the market share of household portable medical electronics reached 65.0%, which is the most influential component of China’s portable medical electronics market.

Figure: The product structure of China’s portable medical electronics market in 2010

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Market Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>Portable Medical Electronics</td>
<td>65%</td>
</tr>
<tr>
<td>Medical Electronics</td>
<td>34.4%</td>
</tr>
<tr>
<td>Other</td>
<td>0.6%</td>
</tr>
</tbody>
</table>

Source: CCID Consulting

Special column

The Magnetic Navigation in the Interventional Therapy for Cardiovascular Diseases

The development of science and technology witnesses the rapidly emerging of interventional therapy. Its acceptance by the clinicians and patients continues to expand, and the range of its application is increasingly wide. In the field of interventional cardiology, the conventional cardiac intervention always goes with long operating time and large amount of radiation, which may compromise the health of both the operators and patients. Since 2002, the clinical application of Magnetic Navigation Systems (MNS) has significantly reduced the time of X-ray exposure to the doctors and patients, and has changed the surgical operation methodology of interventional cardiology, thus having expanded the indications for surgery and improved the therapeutic effects.

Basic principles: MNS consists of two parts basically, namely the magnetic navigation and the X-ray imaging system. In addition to magnetically shielded, the basic performance of X-ray imaging system is identical to that of the X-ray angiography machine, but with high resolution and low radiation. The basic principle of MNS: a hemispherical magnet is placed on each side of patients lying on the cardiac catheterization bed. A very small magnet is embedded in the catheter tip which has been implanted in patients. The operator, following the computer program instructions, can change the relative position of magnets on both sides of the thorax, calculate and change the integrated vector surrounding the spherical magnetic field of the heart, and preset and adjust the bending and rotation of the body magnetic tube, and its direction of advance and retreat, to achieve the control operation of interventional devices, and the purpose of quickly locating the catheter. In the assist of the cardiac physiological three-dimensional positioning system, it can accurately guide the electrode to perform the mapping and ablation to the arrhythmias.

With the development of image processing function, MNS also can be combined with CT or MRI and other imaging systems, and reconstruct the three-dimensional model of quickly locating the catheter. In the assist of the cardiac physiological three-dimensional positioning system, it can accurately guide the electrode to perform the mapping and ablation to the arrhythmias. In the assist of the cardiac physiological three-dimensional positioning system, it can accurately guide the electrode to perform the mapping and ablation to the arrhythmias.

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Source: CCID Consulting

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Special column

磁导航技术在心血管介入治疗中的应用

近年来，随着科学技术的进步，介入诊疗技术飞速发展，被临床医生和病人接受的程度不断增大，应用范围越加广泛。在心脏介入医学领域，常规心导管介入治疗时间长，射线辐射量大，对术者和病人的不利。2002年以来，数字平板磁导航血管成像系统（磁导航系统，Magnetic Navigation Systems，MNS）的临床应用大幅度减少了心血管医生和病人的X线暴露时间，改变了介入心脏病学的手法术学，从而扩展了手术适应症，提高了治疗效果。

基本原理：MNS基本构成有两部分，磁导航部分和X线成像系统。其中X线成像系统除了具有防磁功能外，其基本性能与现在广泛使用的X线血管影像机相同，但分辨率提高，射线量降低。磁导航部分的基本原理是于平躺在心导管床上的患者身体两侧各安装一个半球形磁铁，植入病人体内的导管前端包裹一块非常小的磁铁，操作者可以通过计算机程序指令，变换两侧导管体的相对位置，计算与改变包绕心脏磁成像的综合向量，预设和调整体内磁性导管的弯曲、旋转和进退方向，实现对接入器械的遥控操作。达到快速定位导管的目的。在该系统配套的心脏电生理立体定位系统辅助下，可以精确引导导电杆进行心律失常的标测和消融。随着图像处理技术的发展，MNS...
image of patients' coronary. In the coronary interventional therapy, you can use the "virtual angiography" to lead the guide wire to pass through the complex, or even total occlusion of coronary artery, make the coronary interventional techniques easily handle an acute angle, bifurcation lesion or diffuse disease of the distal coronary vein branches, and even make the treatment of total chronic coronary occlusion (CTO) easier. Thus, some experts predict that this system will bring about revolutionary advances in the interventional treatment.

The application of MNS in the treatment of cardiac arrhythmias with catheter ablation: in the pre-clinical period, animal studies have shown that the magnetic catheter can pass through the radio frequency and create the linear block in the atrial and ventricular endocardium, even for the region which is very difficult to predict, as well, such as the trabecular muscles. The application of MNS in four chambers of heart should be safe. Because the magnetic catheter can precisely move (during the remote operation, the minimum movement distance is 1mm, and the smallest rotation angle is 1°), it makes the electrophysiology catheter be correctly and repeatedly navigated to the target in the heart model. Owing to its flexibility and ability to rotate in any direction, the ablation of complex arrhythmias can be accurately and easily completed. Clinical studies have shown that the MNS makes the curative ablation in the treatment of atrial fibrillation (AF) more convenient, and it can reduce the X-ray exposure to the operators and patients. Studies have found that the radiation time that the operator underwent when using MNS is only one-third of that patient underwent.

When it was applied in the ativoventricular nodal reentrant tachycardia, it can reduce the risk of surgery and shorten the operation time. For the complex anatomy of the heart, if there is a slow channel in the persistent left superior vena cava (SCV), by using the radio frequency catheter, it can quickly complete the ablation, without any complication. It can be used for the left ativoventricular reentrant tachycardia RF ablation as well. The catheter, guided by MNS in the endocardium and epicardium, is used to map the scar-related ventricular tachycardia, such as myocardial infarction, dilated cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy, hypertrophic cardiomyopathy, etc., which all can obtain an excellent efficacy. Besides, MNS can be used to perform the percutaneous transluminal septal myocardial ablation in the hypertrophic obstructive cardiomyopathy patients.

The application of MNS in the coronary intervention: the referred report on the application of MNS in the coronary intervention is rare. Clinical studies have confirmed that the MNS can safely lead the guide wire to pass through the complex coronary artery lesion which the traditional surgical methods have failed. For adapting to different types of coronary artery lesion, there are special guide wires for MNS and the hardness of the guide wires are different. The improvement of these devices simplifies the treatment of total occlusion vessels, restenosis lesions after the coronary artery bypass graft and the treatment of difficult lesions with multiple branches or acute angles. For the total occlusion vascular lesions in patients with acute myocardial infarction, it can shorten the reperfusion time. Hence, it can treat the vessel which cannot be passed by the conventional interventional methods, to save lives and avoid the enormous trauma caused by surgery. The findings of the domestic clinical observations: the average time from the...
magnetic guide wire passing through the target lesion and reaching the distal vessel is less than 1 minute, which is much shorter than that needed by the normal coronary intervention. Operators once successfully performed 25 cases interventional treatment in patients with coronary heart disease, and released various bare-metal stents and drug-eluting stents with different lengths, without any complications.

The application of MNS in the implant of cardiac pacing electrodes: the cardiac resynchronization therapy (CRT) effectively improves the hemodynamics of patients with heart failure and bundle branch block. Clinical studies have shown that the implantation of left ventricular pacing electrode through the coronary sinus, by using MNS, is safe and quick, and does not require any guide sheath of coronary sinus. The operation time, and the time of X-ray exposure to the operator and patient are all significantly reduced, and the related complications on the coronary sinus perforation are also decreased.

In summary, MNS has been a new talent in the rapid development of interventional techniques in cardiovascular disease. As for the clinical application, it can be used to stabilize the remote access point or target of the catheter to make the mapping more accurate, which greatly improves the efficiency of both cardiac electrophysiological surgery and ablation.

[Notes: All Chinese information in Newsletter extracted from Newspapers and Internet. All English articles are the translations from the Chinese version.]

[备注: Newsletter中所有中文信息摘自报刊及网络，英文为中文翻译。]