



New Boston Scientific facility on the Maple Grove campus.

Boston Scientific, Maple Grove, Minnesota, USA

Breakthrough medical device site uses PSP® to safely handle corrosive fume exhaust

Headquartered in Natick, Massachusetts, Boston Scientific has research and manufacturing facilities in the U.S., Ireland, Asia and Europe. One of the revolutionary products they manufacture is the stent, a mechanical spring-like device inserted into an artery to keep it open after balloon angioplasty. The stent is made of stainless steel; it is laser cut, deburred and polished to the required "surgical" finish necessary for insertion into the human body.

Background:

While stents have virtually eliminated many of the complications of abrupt artery closure, another problem remained: restenosis, or re-blocking. Boston Scientific was one of the first companies to develop a solution to the restenosis problem with the introduction of drug-eluting stents. Sometimes referred to as a "coated" or "medicated" stent, a drug-eluting stent is a normal metal stent that has been chemically etched (roughening of the surface) and then coated with a drug that is known to interfere with the process of restenosis. Coated stents have proven to be so successful in reducing re-blocking that it is predicted the demand for these

products will double the current world market for stents to \$5 billion annually. Given this fact, it's easy to understand Boston Scientific's need for additional stent manufacturing capacity.

A new facility in Minnesota:

The Boston Scientific Cardiology Group, located in the Minneapolis suburb of Maple Grove, develops medical technologies for interventional cardiologists, interventional radiologists, and vascular surgeons. Weaver Lake 3 is a new 150,000 square foot building located on the Maple Grove campus, providing space for up to 600 new employees. It is one of two locations where Boston Scientific manufactures its TAXUS™ Express paclitaxel-eluting coronary stent system, and the new building will house primary research and development laboratories and cleanrooms. Construction began in the fall of 2004 and is expected to be completed by the fall of 2005. Led by Boston Scientific engineers, the project design/build team consisted of: Kraus Anderson Construction Co., Hagen, Christensen & McIlwain Architects, Michaud Cooley Erickson Engineers and Metropolitan Mechanical Contractors.

The new facility is a two-story building incorporating a "mid-story" interstitial level for handling utilities. Long used in semiconductor facilities, interstitial floors are gaining acceptance in pharmaceutical, biotech and medical device manufacturing. Working in this mid-story space, engineers can bring order to a complex tangle of pipes, conduits, fire-suppression piping, clean air ducts and specialized corrosive exhaust ducting.

From a mechanical standpoint, attention was focused on clean environments and laboratory spaces. These areas have stringent Food and Drug Administration (FDA) requirements for temperature and humidity, which must be maintained at all times. And just as cleanrooms necessitate the intake of clean, filtered air, they also require the careful removal of fumes and emissions.

Stent manufacturing employs many of the same chemistries and protocols used in semiconductor production. Chemical cleaning after laser cutting, and later, etching the stainless steel to prepare it for

drug "coating" require the use of aggressive chemicals. These hazardous materials must be monitored and safely controlled to prevent accidental release. On the Weaver Lake 3 project, the interstitial space was equipped with an exhaust system with variable speed fans and top of the line Fab-Tech fluoropolymer coated stainless steel was selected for the safe handling of their corrosive exhaust.

Successful history with Fab-Tech:

Boston Scientific used Fab-Tech's coated stainless steel previously in its manufacturing facilities. Coated stainless steel has great appeal and benefit due to its FM approved fire and smoke rating in addition to not requiring future maintenance costs. Boston Scientific had previously used highly flammable polypropylene plastic duct, and the switch to coated stainless steel was seen as a significant leap forward in fire safety.

Fab-Tech's product, called PermaShield Pipe (PSP®) has been used for nearly two decades in the semiconductor industry as the premier product for exhausting corrosive fumes. Their 300 series stainless steel duct with proprietary fluoropolymer integrally bonded to interior surfaces delivers exactly what Boston Scientific needed; unparalleled corrosion protection, structural integrity and ease of installation without the need for internal sprinklers. One of the critical factors in selecting PSP® was its FM rating. Factory Mutual (FM) is an affiliate of FM Global, the world's largest insurance company. FM is specifically devoted to reducing commercial and industrial property losses. PSP® has earned the FM Approval mark as stipulated in Factory Mutual Research Standard No. 4922.

Conclusion:

Over 1,800 feet of coated stainless steel exhaust duct, ranging from 12 inch to 40 inch diameter, was delivered on schedule and efficiently installed by Metropolitan Mechanical Contractors, Inc. of Eden Prairie, MN. "We had a very aggressive time table for the initial mechanical rough-in and the Fab-Tech duct coming in right on time was a big help," commented Vern Ackerman, general foreman for Metropolitan on the project. "The fit-up went very well and working with Mike Baranski of Fab-Tech was

a real plus. Boston Scientific was very pleased with both the Fab-Tech product and Metropolitan's installation", Ackerman added.



Interstitial level of Weaver Lake 3 facility with PSP® duct shown in the foreground with connection to horizontal header.

The demand for drug-eluting stents will explode as both the devices themselves and procedures for stent implantation advance. The real winners are the patients, with additional benefits of reduced expense and the potential of repeat procedures also vastly reduced. Fab-Tech is proud to play a contributing role with Boston Scientific in this vital, life saving and revolutionary technology in coronary care.

