Attachment Nº A.1

Non-Technical Summary of IPPC Licence Application

Contents

Section

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1. Introduction

Howmedica International S. de R.L. is a medical device company operating on a site of approx. 18.75 acres located in the Raheen Business Park, Limerick. Raheen Business Park is located on the edge of Limerick City on the main Limerick to Cork road, in close proximity to other industrial facilities and agricultural land.

The plant was established in 1972 at the present location as a replica of the Howmedica International Inc. US facility for the casting and machining of. orthopaedic implants (hips/knees). The company formed part of the Pfizer Corporation until December 1998, at which point it was acquired by the Stryker Corporation.

The original plant began operations in 1972 in a 70,000sqft facility and has developed on a phased basis since that date:

- 1979 – Addition of Technical Centre housing research and product development activities
- 1984 – Addition of extension housing Canteen, Stores and Production areas
- 1990-94 Addition of Simplex bone cement manufacturing facilities and processes
- 1993 – Addition of extension housing calcium phosphate coating processes
- 1998 – Sale of Howmedica by Pfizer to Stryker Corporation based in Kalamazoo, Michigan, US
- 2001 – Bone substitute manufacturing and extension housing Stryker Biotech operations for testing, packaging and distribution of osteogenic protein
- 2004 – Manufacture of new Triathlon knee
- 2004 – Branding and name change of Stryker Howmedica group to Stryker Orthopaedics

Currently the plant employs approx. 560 people, operating primarily on a two-cycle shift, 5 days per week, with limited production during weekend periods. However if production demands increase the plant may operate in future on a 24hr, three-cycle shift, 7 days per week. The plant is manned by contract Security personnel on a 24/7 basis.

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2. Facility Operations & Environmental Impacts

Today the plant manufactures a range of medical device products including Knee, HMRS and other implants, Simplex Bone Cement, Peri-apatite coated implants. The Stryker Limerick plant is the site for the testing, packaging and distribution of the Osigraft/OP-1 product recently introduced in the European and Australian markets, and also manufactures a range of Bone Substitute products.

The facility comprises the following buildings housing manufacturing and support activities:

- Recon manufacturing building (57,600sqft) for the casting, machining and final packaging of a wide variety of orthopaedic implants including Knees, Hips (Foundry casting only), HMRS (modular replacement system), Instruments and plastic components such as inserts, centralizes. This building also houses the Toolroom for the manufacture of all moulds, tools and fixtures, and Stores receiving are for receipt of goods.
- Simplex/Biomaterials manufacturing building (40,000sqft) for the manufacture, testing and packaging of Simplex bone cement, bone substitute products and Peri-Apatite (calcium phosphate) coated implants. This building also houses the Stryker Biotech Operations group responsible for the testing, packaging and distribution of Osigraft/OP-1 implant (manufactured in US) for European and Australian markets and the manufacture of other bone substitute products.
- Main administration building (13,000sqft) housing support functions including IT, HR, Logistics and Plant Engineering.
- Technical Centre administration building (7,900sqft) housing support functions including QA/RA, Finance and Advanced Operations.
- External facilities include Maintenance workshop, bulk chemical storage tanks/compounds, waste storage compounds, natural gas/LPG compounds, nitrogen/compressed gas compounds, Effluent Treatment Plant, plant dust collectors and staff car-parking.

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A. Recon Manufacturing Process & Environmental Impacts

The Recon manufacturing plant is divided into product-focused Business Units as follows:

- Foundry
- Hips & Other Joints (HOJ)
- Triathlon Knee Femoral
- Standard Knee Femoral
- Duracon Femoral
- Knee Baseplates
- Plastics
- Packaging

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The manufacturing process commences in the Foundry, which is responsible for the manufacture of Vitallium metal castings using the Shell investment casting process. The process splits after the Foundry into the product-focused Business Units which are responsible for the finishing of the metal castings into the final product. Finally all finished components pass through the Packaging Business Unit which is responsible for the cleaning, passivation and packaging of the final product. The following is a summary of the main activities in each of the Recon Business Units.

Foundry

Metal castings are manufactured in the Foundry from Vitallium metal (cobalt/chrome) alloy by the lost wax or investment casting process. Wax patterns are firstly produced by injecting molten wax into pre-manufactured moulds on wax injection machines. The individual wax patterns are assembled on a central post with ceramic pouring cup to produce a 'case' for further processing. The cases are cleaned by immersing in baths containing a water-based detergent and a hydrocarbon solvent and then undergo 'shelling' to apply several layers of a ceramic shell mix to the cases by manual and robotic technologies. The cases are heated in a steam autoclave to melt and remove the wax from the shell cases and are then fired in a furnace to a temperature of approx. 2000F. Casting of the metal is performed by heating a charge of metal alloy to its molten state in a crucible heated by induction coils on a rollover unit, clamping the furnace fired case and inverting the rollover unit to enable the flow of molten metal into the cavity of the shell mould. Following casting the cases are cooled and the shell is removed from the metal by a vibratory hammer. Any residual ceramic is removed by immersing the metal castings in ultrasonic baths containing hot caustic solution to leach out the ceramic. The metal castings are subjected to a 'cut-off' operation which removes individual metal parts from the central post; the gate where the parts were attached to the post is removed by a mixture of manual and robotic belting and grinding operations. All metal castings undergo an X-ray inspection process to identify any internal defects using a licensed X-ray source and digital imaging system. The final step in the Foundry process is 'heat treatment' which is designed to improve the mechanical properties of the metal and improve fatigue life. This is performed in one of three available vacuum furnaces which are electrically heated and use inert gases such as nitrogen and argon to quench the metal from a temperature of 2225F to ambient.

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Product Focused Metal Finishing Cells

Product focused finishing cells - HOJ, Standard Femoral, Triathlon Femoral, Duracon Femoral and Knee Baseplates - transform the raw metal castings produced in the Foundry into the highly polished final product. The manufacturing process employed in these cells consists of a variety of finishing techniques including CNC milling/grinding, abrasive belting, stoning, blasting and laser marking of traceability codes. Products are inspected for surface cracks and defects by immersing the product in a fluorescent dye penetrant which is subsequently examined under UV light

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to highlight any defects. All products are subjected to in process cleaning and final cleaning prior to leaving the cell using water-based cleaning agents to remove residual machine oils/coolants, polishing media etc.

Plastics Cell

Plastics inserts and other products are manufactured from ultra high molecular weight polyethylene. The UHDP is purchased as billets and machined on CNC milling machines to produce inserts and other products.

Final Clean & Passivate/Packaging

All metal products undergo final cleaning and passivation prior to packaging. The product is automatically conveyed through a series of clean tanks to remove any residual contaminants, and immersed in heated nitric acid baths to produce a protective passivation layer on the product. The product is rinsed and dried and transported to an adjacent clean room for packing in sealed double blisters, followed by final packaging in an outer carton which is shrink wrapped and sent off-site for gamma sterilization by an approved vendor,

All plastic products are cleaned, packed in double blisters within a nitrogen environment, final packed and sent off-site for sterilization. A different design of plastic insert, referred to as 'X3', is packed using a different process. The product is packed in double blisters and is then sterilized by gas plasma sterilization using hydrogen peroxide in a dedicated sterilizer chamber.

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Significant Environmental Impacts

The Foundry lost wax investment casting process produces wax and shell ceramic wastes which are recycled off-site using approved recycling routes. The remaining metal alloy following cut-off of metal components referred to as 'revert' is returned to the supplier of the alloy based in the US for reprocessing with virgin metal. The Casting process employs a natural gas fired rotary hearth and batch furnace to fire the shell cases to the required temperature for casting. Any residual wax attached to the cases is burnt off in the furnaces and passes through an afterburner to remove VOCs and particulate. Metal grinding operations using robotic and manual machines are connected to externally sited dust collectors which remove the dust from the extracted air and collect the dust in hoppers for subsequent off-site recycling. Caustic lye tanks used to leach out ceramic from metal castings are periodically cleaned to remove solids. The caustic sludge is sent off-site as hazardous waste for specialized treatment. The X-ray developing process in the Foundry now employs a digital developing system that eliminates the use of chemicals and discharge of effluent containing silver/other chemicals associated with the previous 'wet' developing process.

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Product focused finishing cells generate the following waste streams from a variety of surface finishing operations:

- Machine oils/coolants from machining centers which are drummed and disposed of off-site as hazardous waste through approved vendors
- Dust from various grinding, belting and polishing processes which are extracted to externally sited dust collectors which remove the dust from the extracted air and collect the dust in hoppers for subsequent off-site recycling
- Metal and plastic swarf/turnings from the machining of metal implants and plastic inserts which are recycled off-site with approved vendors
- Wash water from dye penetrant inspection process which is discharged to sewer at SE-1 in accordance with the conditions of our current IPC Licence. The dye penetrant liquid that is approved for use consists of alcohol ethoxylates that carry an R50 risk phrases 'very toxic to aquatic organisms'. However previous toxicity testing of effluent containing dye penetrant washings has shown that toxicity levels are significantly below IPC Licence limits of 10 toxic units. Also we are currently investigating an alternative dye penetrant for this process that does not carry an environmental hazard.
- Cleaning solutions containing detergents for cleaning of metal implants and plastic inserts which are discharged to sewer at SE-1 in accordance with the conditions of our current IPC Licence. The wash water discharged will contain residual oils, coolants and polishing compounds present on the implant or insert following machining and surface finishing.
- Lapping oil and colloidal silica from a specific lapping and polishing process for mobile bearing surfaces of Baseplates which are drummed for off-site disposal as hazardous waste.
- Sodium nitrate based sludge from the electrochemical grinding of metal implants which is drummed for off-site disposal as hazardous waste.

The Final Clean and Passivation line generates small volumes of nitric acid waste when the tanks are cleaned on a quarterly basis. Cleaning solutions containing detergents are neutralized and discharged to sewer biweekly. The Passivation line is equipped with a water scrubber to remove any nitric acid in the extract from the nitric acid tanks. The scrubber is dosed with caustic to maintain pH neutral and the treated air is emitted to atmosphere through the scrubber stack. It is planned to install a second identical Passivation line in the near future for capacity reasons. The existing scrubber will be employed to treat nitric acid vapours from the second Passivation line. The X3 sterilization process uses hydrogen peroxide, however any peroxide used in the process is treated within the sterilizer chamber and there are no significant environmental impacts from the process.

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B. Simplex Manufacturing Process & Environmental Impacts

The Simplex manufacturing process is divided into the following areas:

- Simplex Liquid manufacturing line
- Simplex Powder manufacturing line
- Simplex Antibiotic manufacture
- Simplex final packaging

Simplex Liquid Manufacture

Methyl methacrylate is delivered in 200litre drums and blended with small volumes of two other components in a 200litre blending vessel. The blended liquid is chilled to below its flash point and pumped through filters to feed an ampoule filling process which fills 20mls of blended liquid into glass ampoules under class 100 sterile conditions. The filled ampoules are leak tested, inspected visually and blister packed and sent off-site for ethylene oxide sterilization by an approved vendor.

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Simplex Powder Manufacture

Methyl methacrylate is delivered in 200litre drums and polymerized in a reactor vessel containing mixture of industrial methylated spirits and water. The polymerization reaction is initiated by the addition of a catalyst to the reaction mixture and occurs over a period of approx. 60hrs. The reaction mixture is then re-slurried and transferred under nitrogen to a filter dryer vessel. The polymer is collected in the filter dryer vessel by means of a filter and the mother liquor is transferred to an externally site waste solvent tank. The polymer is repeatedly washed with deionised water – the first wash is also transferred to the waste tank, while the last two washes of the filter cake are discharged to sewer in accordance with the conditions of our current IPC Licence. The polymer is then dried and tested prior to further processing.

The polymer powder is milled to the correct particle size in a hammer mill and blended with two other powder components in a rotary blender to produce the final blended Simplex bone cement powder. The blended powder is filled and packed into double pouches and sent off-site for gamma sterilization using an approved vendor.

A second identical reactor vessel, filter dryer and hammer mill were installed as Simplex 2 polymerization plant following the granting of the existing IPC Licence in 1996.

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Simplex Antibiotic Manufacture

Antibiotic bone cement is manufactured by blending standard bone cement powder with specific antibiotics, either Tobramycin or Erythromycin. The blended powder is then filled into pouches and sealed - all operations are performed in a dedicated sterile isolator. Prior to manufacturing the antibiotic bone cement the isolator is sterilized using a specialized vaporized hydrogen peroxide process. Following manufacturing the inside of the isolator and all associated equipment are cleaned using IPA cleaning solutions.

Simplex Final Packaging

Simplex Liquid ampoules and Simplex Powder pouches are assembled and packaged as the final product. Assembly is fully automated and conducted in a non classified clean area. The assembly operation is performed using a Langenpac packaging assembly machine. The final packed product is then shipped off-site for global distribution.

Other Simplex manufacturing lines are also established to produce bone cements which are variations of the standard product. The processes and technologies employed are similar to those described above.

Simplex Laboratory Testing

QA testing of raw materials, WIP and final product is performed using standard laboratory equipment in a number of laboratory facilities.

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Significant Environmental Impacts

Methyl methacrylate which is used in the manufacture of Simplex Liquid and Powder components is highly flammable. All manufacturing rooms handling bulk liquid are fitted with sprinkler and foam fire protection systems. The ampoule filling isolator is also fitted with manual and automatic CO2 fire extinguishing systems. All Simplex manufacturing areas have been assessed from explosion hazard perspective in accordance with the ATEX Directive and recommendations identified in this risk assessment are currently being implemented. External storage tanks containing methyl methacrylate (MMA) and IMS are fitted with a fire deluge system.

Floor containment is provided in Polymerization and Liquid Blending rooms to contain any spills of bulk solvents. All external storage tanks are also provided with containment bunds to contain >110% of tank contents in the event of a spill.

The Simplex Liquid manufacturing process generates waste MMA/glass ampoules which are drummed for off-site disposal as hazardous waste. Prior to ampoule filling the isolator is fumigated using 200mls of 35-40% formaldehyde/methanol solution which is evaporated over approx. 60mins on a hot plate. Following evaporation the sterilant is allowed to penetrate all surfaces of the isolator. At the end of this phase the extract fan to the isolator is turned on to ventilate the isolator and any formaldehyde/methanol vapours are extracted to atmosphere. Following ampoule filling the entire isolator and associated equipment are cleaned down using 70% IPA solution.

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Mother liquor and first wash from Simplex 1 and 2 filter dryers collected in the 25,000litre waste solvent tank are disposed of off-site as hazardous waste. The subsequent two washes of the filter cake containing IMS/water and residual MMA are discharged to the foul sewer at SE2. The washes discharged comply with current IPC Licence limits of <10%v/v ethanol. Any off-specification batches arising from the manufacture of Simplex Powder, either in the blended or un-blended form, are disposed of as non-hazardous waste to landfill.

Waste from the Simplex Antibiotic manufacturing process in the form of scrap powder containing antibiotic or packaging are disposed of off-site as hazardous waste.

Laboratory testing of Simplex raw materials, WIP and product generates chlorinated and non-chlorinated waste solvents which are segregated and disposed of off-site as hazardous waste. Clean room facilities for the manufacture of Simplex (and other clean rooms provided for Recon Packaging and bone substitute manufacture) are cleaned using 70% IPA. Approx. 60-70litres of IPA is used per week which is released as fugitive emissions from the plant. Clean room facilities are also subjected to a routine fumigation procedure using 6% formaldehyde/IPA solution. Approx. 30litres of 6% formaldehyde solution is used and released as fugitive emissions on a quarterly basis.

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C. Peri-Apatite Coating/Biomaterials Manufacturing Process & Environmental Impacts

Peri-Apatite coating is a process by which hydroxyapatite (calcium phosphate) is manufactured and applied as a thin layer to beaded surfaces of metal implants. The process is performed using two identical coating machines. Implants are masked, fixtured and loaded into the coating machine. The hydroxyapatite is manufactured in the process tank by reacting solutions of calcium acetate and ammonium phosphate under controlled conditions of temperature and pH. As the hydroxyapatite forms, it precipitates out of solution and adheres to the beaded surfaces of the implants. Following coating, the coating composition and thickness are tested using standard laboratory test equipment, and the parts are sent for packaging.

The Biomaterials facility is responsible for the manufacture of calcium phosphate based osteoconductive bone substitute products for such applications as cranial defects, orthopaedic applications, bone void filler for trauma or surgically created defects.

Hydroset Injectable HA Bone Substitute is a two component product. The powder component is manufactured on-site by blending two calcium phosphate powders, tetra calcium phosphate (TTCP) and di-calcium phosphate dehydrate (DCPD) which is then combined with a third powder component, tri-sodium citrate. DCPD is manufactured on-site by reacting orthophosphoric acid with calcium carbonate and magnesium oxide. TTCP is manufactured on-site by mixing calcium carbonate and di-calcium phosphate anhydrous (DCPA) and sintering in an electrically heated furnace at 1550C. The powders are processed through a series of powder milling, mixing and blending steps to prepare the final Hydroset powder component. Hydroset powder is packaged and sent to an outside approved vendor for final packaging with the Hydroset sodium phosphate based liquid component.

Bonesource Bone Substitute is manufactured by blending TTCP and DCPA powders using similar processing steps to that described above. The Bonesource powder component is filled into bowls, packed into unit cartons and final packed with the sodium phosphate based liquid component which is purchased from an outside vendor.

Calstrux (TCP Putty) bone substitute product is also manufactured on –site in an adjacent clean room. Tri-calcium phosphate is blended with Polyvinyl Pyrrolidone (PVP) and Polyethylene Glycol (PEG), dried, sieved to produce material with correct particle size and sintered in an electrically heated furnace at approx. 1100C. The product is filled into vials with carboxymethylcellulose (CMC), final packed and sent off-site for gamma sterilization by an approved vendor.

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Significant Environmental Impacts

The process waste from the PA Coating process consists of aqueous solutions of ammonium acetate, nitric acid and ammonium hydroxide which are pH neutralized in local effluent tanks prior to discharge. The process waste contains high concentrations of ammonia which is discharged on a batch basis typically 5-6 discharges over two shifts or 16hr period. An extract fan is fitted to each of the PA Coating machines which extract any ammonia vapours released from the process to atmosphere during the coating cycle of approx. 3-4hrs duration.

There are no significant environmental impacts from the Hydroset and Bonesource manufacturing processes. Any waste water from cleaning of powder blending/sieving etc equipment will not contain any appreciable levels of calcium phosphate or other chemicals. Waste materials/packaging discarded from the process is disposed of as non-hazardous waste.

The Calstrux manufacturing process generates hazardous waste in the form of waste TCP/PEG discarded from the process because of the strict particle size requirements. Sintering of a batch of blended TCP/PEG/PVP in the furnace burns off approx. 5kgs of PEG/PVP which is extracted from the furnace through a series of carbon filters to remove the organic contaminants and is emitted to atmosphere.

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D. Stryker Biotech Operations – OP-1 Implant/Osigraft

The Stryker Biotech Operations group is responsible for the testing, packaging and distribution of OP-1 implant/Osigraft to the European and Australia markets. The product is manufactured in the Stryker Biotech manufacturing facility in the US. OP-1 implant is a bone morphogenic protein used for the treatment of non-union bone defects. On receipt of the product in Limerick OP-1 implant/Osigraft is placed in a quarantine refrigerated storage unit to maintain the product at 2-8C. Chemical testing and biological assay are performed in Biotech laboratory facilities. On completion of testing the product is packed and shipped to the customer by courier.

Significant Environmental Impacts

OP-1 Implant/Osigraft is manufactured in the Stryker Biotech US facility. Testing of the product in the laboratory facilities generates waste solvents and bio-hazardous waste which are drummed and disposed of off-site as hazardous waste.

E. Plant Services/Utilities/Storage

The Toolroom supports the Recon manufacturing plant by manufacturing all moulds used by the Foundry Wax Injection process. The moulds are manufactured from aluminium primarily, using a variety of CNC machining and manual lathe/milling operations. The Toolroom is also responsible for the manufacture of various tooling/fixtures required by manufacturing.

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The plant Maintenance group consists of electrical and mechanical technicians who provide preventative and routine maintenance support for manufacturing. External contractors provide additional electrical and mechanical support when required.

The main utilities/services used by the facility include:

- Electricity supplied by medium voltage supply 10KV stepped to low voltage through three 16KVA transformers.
- Natural gas supplied to the site via an underground pipeline to an external gas compound and is then piped into the plant. Main gas users include the rotary hearth and batch furnace in the Foundry, plant boilers, 23 no. roof mounted air handling units and laboratories.
- LPG is supplied from two Calor LPG bullets located in an external gas compound. LPG is used in the ampoule filling isolator and bench top bunsen burners in the Foundry Wax Assembly area.
- Water is provided by town water mains supply (80%) and site well (20%) which is pumped from underground well to the plant.
- Compressed air is provided by three Atlas Copco compressors with combined capacity of 1100cfm at 8bar.
- Cooling water for the compressors and vacuum furnaces/Inductotherm unit in the Foundry is provided by three independent closed-loop systems which consist of a re-circulation ring main type cooling system, using an externally sited air blast cooler, pump & tank assemblies to provide cold water.
- Dust extraction for all Recon grinding, polishing and surface finishing operations is provided by total of eight dust collectors which are essentially bag filters which filter the dust from the extract air and collect the dust in hoppers.
- Nitrogen is provided from an externally sited bulk storage tank which is piped to the main site users including Simplex Powder manufacturing, Foundry and Packaging areas.
- Total of six natural gas fired boilers are used for space heating and hot water supply.
- Total of 23 no. roof mounted gas-fired air handling units provide space heating and cooling for the Recon manufacturing plant and adjoining offices. A significant number of electrically/hot water heated air handling units provide air conditioning for clean rooms/controlled areas in Recon, Simplex, Biomaterials and Biotech areas.
- Effluent pH treatment of process effluent discharged at SE-1 is provided by an underground effluent balancing tank equipped with pH probes and dosing systems.
- External contractors provide key services on-site including landscaping, waste management, facility cleaning, security.

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Externally, facilities are provided and maintained for the storage of materials including:

- Compressed gas compound for storage of compressed gases including argon, acetylene and oxygen.
- Waste compound for the segregation and storage of non-hazardous and solid wastes for off-site recycling and disposal.
- Hazardous waste compound for the storage and containment of drummed hazardous waste.
- Raw materials store for the storage and containment of bulk drummed chemicals.
- Simplex waste effluent tanks for the storage and containment of waste IMS/water from the Simplex powder manufacturing process.

Significant Environmental Impacts

Electricity and natural gas usage represent the major energy use on site. In 2005 total of 11374MWhr of electricity and 533,000M3 of natural gas were used on site, in addition to total of 70772M3 of water. The six gas-fired boilers and 23 roof mounted gas-fired air handling units employed are <350KW capacity, therefore any environmental impact is minimal.

Each of the eight dust collectors have an emission to atmosphere downstream of the bag filter which are monitored on an annual basis under the existing IPC Licence. These dust collectors also represent the only significant external noise emission from the facility.

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3. Raw Materials and Product

Details of major raw materials used in the manufacturing process and products manufactured are provided in Section 2 of this non-technical summary under Facility Operations & Environmental Impacts. A full list of raw materials is provided in Section G of the IPPC Application under Resource Use & Energy Efficiency.

4. Emissions to Atmosphere

Details of emissions to atmosphere from plant activities are summarized in Section 2 of this non-technical summary under Facility Operations & Environmental Impacts. Major air emission points are summarized as follows:

A2 - 1	Midac Carter Extractor No. 1	E	155,269.936	152,859.974
A2 - 2	Midac Carter Extractor No. 2	E	155,272.930	152,858.700
A2 - 3	Midac Carter Extractor No. 3	E	155,269.207	152,858.557
A2 - 4	Ammerpulse Extractor No. 4	E	155,266.957	152,857.990
A2 - 5	Midac Carter Extractor No. 5	E	155259.873	152847.728
A2 - 6	Midac Carter Extractor No. 6	E	155,249.425	152,828.568
A2 - 7	Midac Carter Extractor No. 7	E	155,243.888	152,830.539
A2 - 8	Midac Carter Extractor No. 8	E	155,229.480	152,825.430

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A full evaluation of emissions to atmosphere including an assessment of environmental impact is included in Section D of the IPPC Application under Emissions & Environmental Impact.

5. Emissions to Sewer

Details of emissions to sewer from plant activities are summarized in Section 2 of this non-technical summary under Facility Operations & Environmental Impacts. Stryker discharges to the sewer in Raheen Business Park at two emission points, SE-1 and SE-2 (ref. Attachment B2 for locations of SE-1 and SE-2). The majority of process effluent from the facility discharges to sewer at SE-1 and is treated prior to discharge by pH balancing and neutralization in an underground tank equipped with agitation, pH monitoring and pH control.

All foul effluent from toilet and canteen facilities on site discharge to the sewer at SE-2. The Canteen waste passes through a grease trap prior to discharge. No other treatment is undertaken. Process effluent discharging to SE2 includes:

- Effluent from the Simplex bone cement manufacturing process which consists of the Simplex Liquid and Simplex Powder manufacturing lines. Principally effluent is discharged from the Simplex Powder process and specifically the second and third ethanol/water washes from the filter dryer vessel.
- General lab rinsings from Simplex test laboratories.

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6. Emissions to Water

Surface water from the Stryker site discharges to the main Raheen Business Park storm water system at three emission points, SW-1, SW-2 and SW-3 (ref. Attachment B2 for locations of SW-1, SW-2 and SW-3). Surface water from Raheen Business Park discharges to the nearby Barnakyle stream and subsequently to the Ballynaclogh River. There are no process discharges into the surface water collection system on the Stryker site. Any water collected arises from run-off from buildings, car-parks, road-ways, service yards and other developed areas of the site.

7. Emissions to Ground

There are no emissions to ground from the Stryker operation.

8. Noise Emissions

The main sources of environmental noise on the site arise from the operation of eight dust collectors at the rear of the site which provide extraction and dust collection for various metal finishing activities in the Recon manufacturing plant. Specific noise limits have been prescribed for four of these dust collectors in the existing IPC Licence. Stryker has undertaken an annual noise survey of environmental noise on the site in accordance with the conditions of the existing IPC Licence which involves monitoring noise emissions adjacent to the eight dust collectors, and monitoring noise levels at a number of boundary locations around the site (ref. Section D5 for details of noise emissions). As the Stryker site is located in an industrial park bounded by other industrial units, no noise sensitive locations have been identified and no environmental noise limits are specified for the site.

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9. Waste Management

All hazardous and non-hazardous waste from the facility is managed and disposed of by approved waste contractors in accordance with the conditions of the site's existing IPC Licence and European/Irish waste legislation. Full details of the waste generated, volumes and methods of recovery/recycling/disposal are provided in Stryker's Annual Environmental Report. Stryker works with waste vendors on a continuous basis to explore opportunities for the recovery or recycling of waste off-site.

Hazardous waste generated on site is drummed and stored in the Waste Chemical store pending collection by approved waste contractors. This storage compound is designed with adequate spill containment in compliance with the conditions of the site's IPC Licence. In addition, IMS/water waste from the Simplex powder manufacturing process is collected in a 25,000litre bulk tank and removed off-site by tanker. The site has recently completed the construction of a new waste compound for the storage of all solid and non-hazardous waste on site. Stryker is currently working with its waste contractor to commence operations in the new compound. The compound is designed with an isolation valve and oil interceptor/containment tank to remove any oil residue from water run-off and enable any contaminated water in the compound to be collected for analysis and treatment if necessary.

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10. Sampling and Monitoring

A detailed environmental monitoring program is established on the Stryker site to comply with the conditions of the existing IPC Licence and ensure the quality of the surrounding environment is not impacted. The monitoring program includes:

Air emissions:

- A2-1 – A2-8 Dust Collectors
  Isokinetic sampling and monitoring of particulates and metal constituents in emissions form each of the eight dust collectors on site on an annual basis as prescribed by the site's existing IPC Licence.
- A3-3 and A3-4 Foundry furnaces/afterburners
  Monitoring of emissions from rotary hearth and batch furnaces/afterburners in the Foundry for particulates, total VOCs/TOC, NOx during start-up and validation of furnaces.
- A3-9 Passivation scrubber
  Monitoring of emissions from scrubber for nitric acid, NOx during start-up and validation of Passivation line.
- Other monitoring of vents from processes on site periodically for characterization, impact assessment etc.

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Emissions to Sewer:

- SE-1A Process Effluent Composite
  24hr flow proportional composite sampling of process effluent discharging to sewer at SE-1 and analysis for listed parameters in existing IPC Licence.
- SE-1B Process Effluent pH and flow continuous monitoring
  Continuous pH and flow monitoring of process effluent discharging to sewer at SE-1 using pH probe/meter and ultrasonic flow meter and flume.
- SE-2A Simplex 1 powder manufacturing
  Sampling of second and third washes discharged from Simplex no. 1 filter dryer on a batch basis and analysis for ethanol, methyl methacrylate, sulphite and sulphate.
- SE-2B Simplex 2 powder manufacturing
  Sampling of second and third washes discharged from Simplex no. 2 filter dryer on a batch basis and analysis for ethanol, methyl methacrylate, sulphite and sulphate.

Emissions to Surface Water:

- SW-1/SW-2/SW-3
  Grab sampling of surface run-off from the site on a weekly basis and analysis for COD/pH.

Noise Emissions:

- N-1 – N-8
  Monitoring of sound pressure levels 3 metres directly in front of dust collectors as part of an annual noise survey.
- AN-1 – AN-7
  Environmental noise measurements at boundary locations during daytime and night time as part of an annual noise survey.

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11. Energy Efficiency

Electricity and natural gas are the major sources of energy on the Stryker site. In 2005 the following annual usage was recorded:

	Electricity	Natural Gas
2005	11374MWhr	533,000M3

The major users of electricity on site include the dust collectors (8), Foundry inductotherm power pack unit and the vacuum furnaces (3). The major users of natural gas on site include the 23 no. roof mounted air handling units servicing the Recon plant and the rotary hearth/batch furnaces in the Foundry.
An energy audit has not been completed for the site in the recent past. However energy efficiency and energy reduction projects are key priorities for Stryker led by the site's Facilities team. A number of specific energy reduction projects have been included in the site's Environmental Management Program for 2006 which sets clear objectives and targets for the site to improve environmental performance. Further details of the site's energy management program are provided in Attachment G.

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12. Accident Prevention and Emergency Response

The surface water collection system collects surface water run-off from the site and discharges to the main Raheen Business Park surface water drain. Firewater retention penstock valves are installed on two of the three surface water discharge points. Should an accidental spill of chemicals occur on site that has the potential to enter the surface water run-off from the site, then the penstock valves can be closed to contain the contaminated liquid. The liquid can then be analyzed and drummed for appropriate waste disposal.

All chemical storage areas on site are provided with spill containment designed to contain 110% of the largest container or 25% of the total volume stored, whichever is the greater. Procedures are in place for the inspection and analysis of bund water prior to discharge to the foul sewer. All bunds are subjected to a 3-yearly bund integrity test in accordance with existing IPC Licence conditions.

The facility operates to documented emergency response procedures for potential emergency scenarios which include the prevention of environmental damage. The site Emergency Response Team are fully trained in a number of emergency scenarios including fire, chemical spill, confined space, search and rescue etc and operate over both working shifts. Full details of the site's emergency procedures are provided in Attachment F1.

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13. Environmental Management

Overall responsibility for environmental, health and safety matters on site rests with the General Manager. The Environmental, Health and Safety Manager is appointed as the Management Representative responsible for developing, maintaining and continuously improving the site's EHS systems and procedures to ensure compliance with all legal obligations and improve the site's overall environmental, health and safety performance. In addition to the EHS Manager, environmental matters are managed by two environmental specialists, who co-ordinate the various environmental programs and projects. The site has operated under an IPC Licence since 1996, and is certified to the ISO14001:2004 environmental management system standard.

14. Decommissioning

In the event that the facility ceases production, Stryker will take all necessary measures to ensure that:

- All process equipment is decontaminated and/or removed from the site.
- All hazardous and non-hazardous wastes are disposed of in accordance with relevant waste legislation.
- All raw materials and finished products are removed from the site.
- Any residual level of hazardous materials, remaining after closure, will be at a level that will not cause harm to human health or the environment.

Stryker has not prepared a formal Residuals Management Plan as this was not a condition of the site's existing IPC Licence. Any future plans will be developed in accordance with the EPA Guidance on Environmental Liability, Risk Assessment, Residuals Management Plans and Financial Provision.

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