



Environmental Protection and Growth Management Department
POLLUTION PREVENTION, REMEDIATION AND AIR QUALITY DIVISION – AIR QUALITY
One North University Drive, Suite 203, Plantation, Florida 33324
954-519-1260 • FAX 954-519-1495

ISSUED TO:

PERMITTEE:

Authorized Representative:

Mr. Roberto Perez, Production Manager
Deputy Synthes Products LLC.
3260 Executive Way
Miramar, Florida 33025

AIRS ID NO: 0112746

Permit Number: 0112746-001-AC

Issue Date: April 9, 2014

Expiration Date: February 18, 2015

Facility Name: Deputy Synthes Products LLC. is located at 3260 Executive Way, Miramar, Broward County, Florida.

Project Description: After-the-fact construction permit for a medical devices manufacturing and assembly operation. SIC Code: 3841. NAICS: 339112.

Lat/Long: 25°58' 27.44" N / 80°17'09.1752"

UTM: Zone 17; 571.4 Km. E; 2873.4 Km. N

Statement of Basis: This permit is issued under the provisions of Chapter 403, Florida Statutes (F.S.) Florida Administrative Code (F.A.C.) Rules 62-4 and 62-210 through 62-297 (permitting requirements) and Broward County Code, Chapter 27 (emission limitations) and in conformance with all existing regulations of the Florida Department of Environmental Protection (FDEP). The above named Permittee is hereby authorized to perform the work or operate the facility shown on the application and approved drawing(s), plans, and other documents attached hereto or on file with the Broward County Pollution Prevention, Remediation and Air Quality Division (PPRAQD) and made a part hereof.

This permit is organized by the following sections.

1. Facility Description
2. General Conditions
3. Facility-wide Conditions
4. Emissions Unit Specific Conditions

Executed in Broward County, Florida

Lorenzo Fernandez, P.E., Manager
Environmental Assessment, Remediation and Air Quality
Broward County Pollution Prevention, Remediation and Air Quality Division

1. FACILITY DESCRIPTION

This facility is engaged in the manufacture and assembly of medical devices, which consist of access devices that are micro catheters and balloon catheters; and devices positioning units (DPUs) that are coil delivery systems. The volatile organic compounds (VOCs) and hazardous air pollutant (HAPs) emissions resulting from this operation are unconfined (fugitive) in nature. The potential emissions of volatile organic compounds (VOCs) and hazardous air pollutants (HAPs) are 11.36 tons per year and 0.014 tons per year, respectively. This facility is a natural minor source. Isopropyl alcohol at 70% is used for cleaning purposes. Hydrochloric acid at 25% is used in the soldering operation.

The manufacturing operation consists of:

1. Access Devices Processes:

Extrusion: Polymer pellets are received as raw material. This process includes the preparation of polymers for the use in catheters. 70% Isopropyl alcohol is used for cleaning the exterior surface of assembly after the polymer segment had been fused.

Braiding: It takes fine wires, received as raw material, and intertwines them over the micro catheter body. This process provides varying degrees of torque for the micro catheters. 70% isopropyl alcohol is used for cleaning purposes.

Coating: It provides lubricity to the micro catheter, guiding catheter, and balloon catheter assemblies. Hydromer coating topcoat solution 6-TS-51, hydromer coating solution 5-TS-72P, hydromer coating solution 2-TS-96, hydromer coating solution 3-TS-12, hydromer coating 3-TS-12; and hydromer coating 55106-01 are used. After coating, the catheters are dried, in an oven, for a specified amount of time.

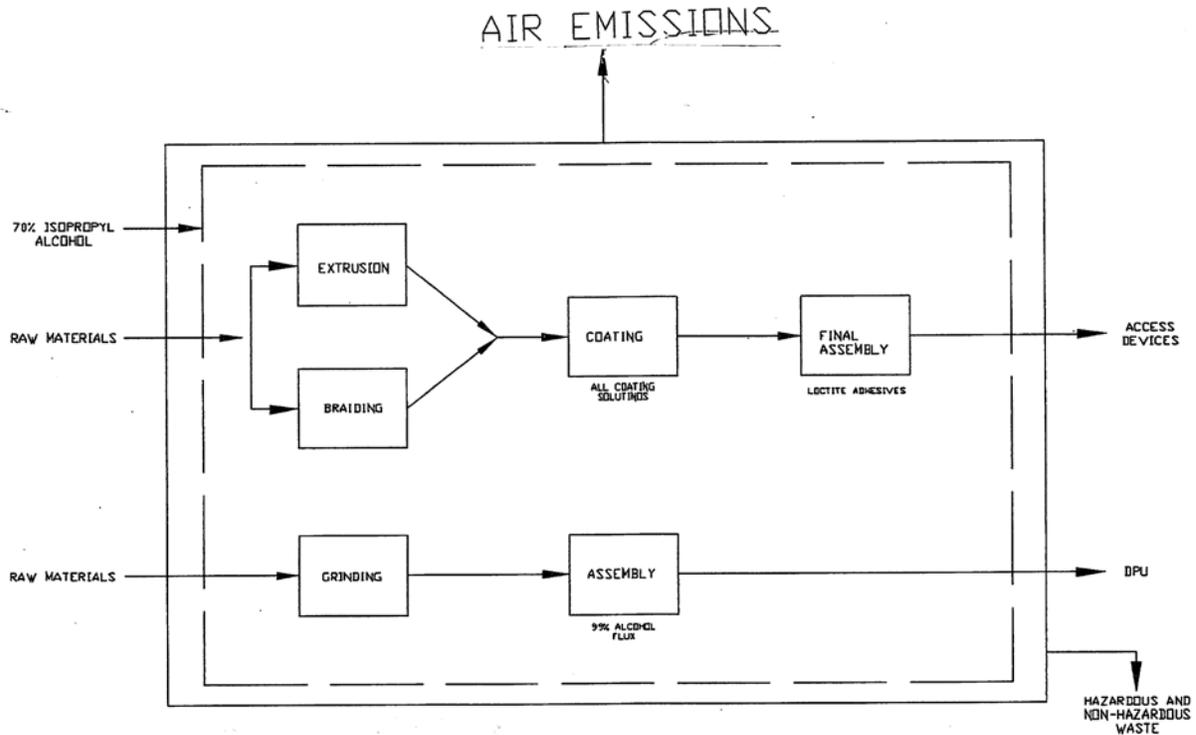
Final Assembly and Packaging: This process includes a variety of steps where the catheter polymer segment fused using high heat. The wire mandrels are removed and components, such as hubs and balloons, are added using a variety of adhesives. The adhesives used in the process are: Loctite 4014, 4011 and 4161. 70% isopropyl alcohol is used for cleaning and 99% isopropyl alcohol for leak testing,

2. Device Positioning Unit (DPU) Processes:

Grinding: Stainless steel core wires are received as raw material. The core wires are prepared through grinding and the tip of the wires are tapered to the optimum diameter. The core wire is cleaned using 99% isopropyl alcohol and dried in ambient air.

Assembly: This is the majority of the DPU process. It includes the following major sub-processes: coil winding, attaching connectors, attaching strain relief, marking bands, tip coils and packaging. 70% isopropyl alcohol is used for cleaning purposes.

The figure below depicts the process flow diagram:



The emissions unit is as follows:

E.U. ID No.	Brief Description
001	Component manufacturing process which consists of access devices that include extrusion, braiding, coating, final assembly and packaging; and device positioning units (DPUs) that are grinding, assembly, coil winding, attaching connectors, attaching strain relief, marking bands, tip coil; and packaging. There are no exhaust stacks. Air emissions are fugitive in nature.

2. GENERAL CONDITIONS

1. Terms of Permit. The terms, conditions, requirements, limitations and restrictions set forth in this permit, are “permit conditions” and are binding and enforceable pursuant to Sections 403.141, 403.727, or 403.859 through 403.861, F.S. The Permittee is placed on notice that the PPRAQD will review this permit periodically and may initiate enforcement action for any violation of these conditions. [Rule 62-4.160 (1), F.A.C.]
2. Permit Validity. This permit is valid only for the specific processes and operations applied for and indicated in the approved drawings or exhibits. Any unauthorized deviation from the approved drawings,

exhibits, specifications, or conditions of this permit may constitute grounds for revocation and enforcement action by the PPRAQD.

[Rule 62-4.160 (2), F.A.C.]

3. Disclaimer. As provided in subsections 403.087(6) and 403.722(5), F.S., the issuance of this permit does not convey any vested rights or exclusive privileges. Neither does it authorize any injury to public or private property or any invasion of personal rights, or any violations of federal, state or local laws or regulations. This permit is not a waiver of or approval of any other permit that may be required for other aspects of the total project which are not addressed in this permit.

[Rule 62-4.160 (3), F.A.C.]

4. Disclaimer. This permit conveys no title to land or water, does not constitute State recognition or acknowledgment of title, and does not constitute authority for the use of submerged lands unless herein provided and the necessary title or leasehold interest have been obtained from the State. Only the Trustees of the Internal Improvement Trust Fund may express State opinion as to title.

[Rule 62-4.160 (4), F.A.C.]

5. Liability. This permit does not relieve the Permittee from liability for harm or injury to human health or welfare, animal, or plant life, or property caused by the construction or operation of this permitted source, or from penalties therefore; nor does it allow the Permittee to cause pollution in contravention of Florida Statutes and FDEP rule, unless specifically authorized by an order from the PPRAQD.

[Rule 62-4.160 (5), F.A.C.]

6. Operation and Maintenance. The Permittee shall properly operate and maintain the facility and systems of treatment and control (and related appurtenances) that are installed and used by the Permittee to achieve compliance with the conditions of this permit, as required by county and state rules. This provision included the operation of backup or auxiliary facilities or similar systems when necessary to achieve compliance with the conditions of the permit and when required by PPRAQD and FDEP rules.

[Rule 62-4.160 (6), F.A.C.]

7. Onsite Inspection Activities. The Permittee, by accepting this permit, specifically agrees to allow authorized PPRAQD personnel, upon presentation of credentials or other documents as may be required by law and at reasonable times (depending on the nature of the concern being investigated), access to the premises where the permitted activity is located or conducted to:

- (a) Have access to and copy any records that must be kept under conditions of the permit;
- (b) Inspect the facility, equipment, practices, or operations regulated or required under this permit; and
- (c) Sample or monitor any substances or parameters at any location reasonably necessary to assure compliance with this permit or PPRAQD and FDEP rules.

[Rule 62-4.160 (7), F.A.C.]

8. Notice of Noncompliance. If, for any reason, the Permittee does not comply with or will be unable to comply with any condition or limitation specified in this permit, the Permittee shall immediately provide PPRAQD with the following information:

- (a) A description of and cause of noncompliance; and
- (b) The period of noncompliance, including dates and times, or, if not corrected, the anticipated time the noncompliance is expected to continue, and steps being taken to reduce, eliminate, and prevent recurrence of the noncompliance. The Permittee shall be responsible for any enforcement action by PPRAQD for penalties or for revocation of this permit.

[Rule 62-4.160 (8), F.A.C.]

9. Reporting Noncompliance. The Permittee shall report any periods of noncompliance to the PPRAQD immediately by phone at 954-519-1499 or by Email at EPDHOTLINE@broward.org. This also applies

when the period of non-compliance is first determined after normal business hours or on weekends and holidays.

[Rules 62-4.130 and 62-4.070(3), F.A.C.]

10. Evidence Materials. By accepting this permit, the Permittee understands and agrees that all records, notes, monitoring data and other information relating to the construction or operation of this permitted facility or activity, that are submitted to the PPRAQD, may be used by the PPRAQD as evidence in any enforcement proceeding arising under the Florida Statutes or F.A.C. rules, except where such use is prohibited by Section 403.111 and 403.73, Florida Statutes. Such evidence shall only be used to the extent it is consistent with the Florida Rules of Civil Procedure and appropriate evidentiary rules.
[Rule 62-4.160 (9), F.A.C.]
11. Rule Changes. The Permittee agrees to comply with changes in Florida Department of Environmental Protection rules and Florida Statutes after a reasonable time for compliance; provided, however, the Permittee does not waive any other rights granted by Florida Statutes or FDEP rules.
[Rule 62-4.160 (10), F.A.C.]
12. Permit Transfer. This permit is transferable only upon PPRAQD approval in accordance with Rule 62-4.120 and 62-730.300 F.A.C., as applicable. The Permittee shall be liable for any non-compliance of the permitted activity until the transfer approved by the PPRAQD.
[Rule 62-4.160 (11), F.A.C.]
13. Work Site Copy. This permit or a copy thereof shall be kept at the work site of the permitted activity.
[Rule 62-4.160 (12), F.A.C.]
14. Miscellaneous Compliance Requirements. The Permittee shall comply with the following:
 - (a) Upon request, the Permittee shall furnish all records and plans required under FDEP rules. During enforcement actions, the retention period for all records will be extended automatically unless otherwise stipulated by the PPRAQD.
 - (b) The Permittee shall hold at the facility or other location designated by this permit records of all monitoring information (including all calibration and maintenance records and all original strip chart recording for continuous monitoring instrumentation) required by the permit, copies of all reports required by this permit, and records of all data used to complete the application for this permit. These materials shall be retained at least three years from the date of the sample, measurement, report, or application unless otherwise specified by PPRAQD rule.
 - (c) Records of monitoring information shall include:
 1. The date, exact place, and time of sampling or measurements;
 2. The person responsible for performing the sampling or measurements;
 3. The dates analyses were performed.
 4. The person responsible for performing the analyses;
 5. The analytical techniques or methods used;
 6. The results of such analyses.
 [Rule 62-4.160 (14), F.A.C.]
15. Information Submittal. When requested by the PPRAQD, the Permittee shall within a reasonable time furnish any information required by law which is needed to determine compliance with the permit. If the Permittee becomes aware the relevant facts were not submitted or were incorrect in the permit application or in any report to the PPRAQD, such facts or information shall be corrected promptly.
[Rule 62-4.160 (15), F.A.C.]

16. Rules Adoption. Chapters 62-4, 62-204, 62-210, 62-212, 62-213, 62-296 and 62-297, as amended, are adopted by Broward County Code, Sec. 27-173.
[Broward County Code, Sec. 27-173]

3. FACILITY-WIDE CONDITIONS

17. Objectionable Odor. No person shall cause, suffer, allow or permit the discharge of air pollutants which cause or contribute to an objectionable odor.
[Rule 62-296.320(2), F.A.C.]
18. Volatile Organic Compound Emissions or Organic Solvent Emissions. No person shall store, pump, handle, process, load, unload or use in any process or installation volatile organic compounds or organic solvents without applying known and existing vapor emission control devices or systems deemed necessary and ordered by the PPRAQD.
[Rule 62-296.320(1), F.A.C., Rule 62-4.070(3), F.A.C. and Broward County Code, Sec. 27-175(f)]
19. General Visible Emissions. No person shall cause, let, permit, suffer or allow being discharged into the atmosphere any air pollutants from sources, the opacity of which is equal to or greater than 20 percent. If the presence of uncombined water is the only reason for failure to meet visible emission standards given in this section, such failure shall not be a violation of this prohibition.
[Rule 62-296.320(4) (b), F.A.C. and Broward County Code, Section 27-175(i)]
20. Concealment. No person shall build, erect, install, or use any article, machine, equipment or other contrivance, the use of which will conceal any emission which would otherwise constitute a violation of any provisions of Broward County Codes.
[Rule 62-4.070(3), F.A.C. and Broward County Code, Sec. 27-175(b)]
21. Circumvention. No person shall circumvent any air pollution device, or allow the emission of air pollutants without the applicable air pollution control device operating properly.
[Rule 62-210.650 F.A.C and Broward County Code, Sec. 27-175(c)]
22. Maintenance. No person shall operate any air pollution control equipment or systems without proper and sufficient maintenance to assure compliance with Broward County Codes.
23. Unconfined Emissions of Particulate Matter. The permittee shall take reasonable precautions to control emissions of fugitive particulate matter. Reasonable precautions may include but shall not be limited to the following:
- a) Paving and maintenance of roads, parking areas and yards;
 - b) Application of water or chemicals to control emissions from such activities as demolition of buildings, grading roads, construction, and land clearing;
 - c) Removal of particulate matter from roads and other paved areas under the control of the owner or operator of the source to prevent reentrainment, and from buildings or work areas to prevent particulate matter from becoming airborne;
 - d) Landscaping or planting of vegetation
 - e) Use of hoods, fans, filters and similar equipment to contain, capture and/or vent particulate matter;
 - f) Enclosure or covering of conveyor systems
 - g) Sanders and grinders equipped with vacuum collection systems
- [Rule 62-296.320(4) (c) F.A.C.; Broward County Code Section 27-177(b)]

- 24. Special Compliance Tests. When PPRAQD, after investigation, has good reason (such as complaints, increased visible emissions or questionable maintenance of control equipment) to believe that any applicable emission standard contained in a PPRAQD rule or in a permit issued pursuant to those rules is being violated, it shall require the owner or operator of the emissions unit to conduct compliance tests which identify the nature and quantity of pollutant emissions from the emissions unit and to provide a report on the results of said tests to the PPRAQD.
[Rule 62-297.310(7) (b), F.A.C.]
- 25. Annual Operation Report (AOR). The AOR shall be submitted to the PPRAQD by April 1 of the following year. If the permittee elects to use FDEP’s electronic annual operation report software (EAOR), the report must be submitted directly to FDEP and there is no requirement to submit a copy to PPRAQD.
[Rule 62-210.370(3), F.A.C.]
{Permitting Note. Information on the EAOR submittal is available at <http://www.dep.state.fl.us/air/emission/eaor/default.htm>}
- 26. Operating Permit. Sixty days before the expiration date of this construction permit, the permittee shall apply for a permit using the forms incorporated by reference in the specific rule chapter for this type of permit.
[Rule 62-4.090 F.A.C.]
{Permitting Note: The permittee may also elect to submit the application electronically using the Electronic Permit Submittal and Processing system (EPSAP) via the <http://www.dep.state.fl.us/air/emission/apds/default.htm> website, along with the processing fee established in Rule 62-4.050(4), F.A.C. , [62-4.090(1) and 62-4.050(4), F.A.C.

4. EMISSIONS UNIT SPECIFIC CONDITIONS

Subsection A. This section addresses the following emissions units.

E.U. ID No.	Description of Emissions Unit
001	Component manufacturing process which consists of access devices that include extrusion, braiding, coating, final assembly and packaging; and device positioning units (DPUs) that are grinding, assembly, coil winding, attaching connectors, attaching strain relief, marking bands, tip coil; and packaging. There are no exhaust stacks. Air emissions are fugitive in nature.

Emission Limiting Standards

- 27. Facility-Wide VOC, Total HAP and Individual HAP Emissions. The volatile organic compounds (VOCs) emissions shall be less than 12 tons in any consecutive twelve month period, the individual and total hazardous air pollutant (HAP) emissions shall be less than 1 ton in any consecutive twelve month period.
[Rule 62-4.070(3) F.A.C., Rule 62-213.4220(3)(c) 1, construction permit application received January 29, 2014]

Recordkeeping and Reporting Requirements

28. VOC Content: The owner or operator shall determine the VOC content of all solvent based materials, coatings, and solvents used, and shall monitor the usage of such materials at the referenced emission unit by recording and maintaining the following information:
- The VOC content for each material containing or emitting VOC.
 - The material utilization rate on a monthly basis, for all materials containing or emitting VOC used at the referenced emission unit.
 - The total monthly VOC emission rates for each material, calculated from the monthly material utilization rates and the VOC content, calculated for the preceding month no later than 20 days after the end of that month.
 - A rolling consecutive 12-month total emission rate for VOC, calculated from the monthly totals for the previous twelve calendar months.
 - Maintain Material Safety Data Sheets (MSDS) for all volatile materials utilized.
- [Rule 62-4.070(3), F.A.C.]
29. Total and Individual HAP Content: The owner or operator shall determine the total and individual HAP contents of all solvent based materials, coatings, and solvents used, and shall monitor the usage of such materials at the referenced emission unit by recording and maintaining the following information:
- The individual and total HAP contents for each material containing or emitting HAPs.
 - The material utilization rate on a monthly basis, for all materials containing or emitting HAPs used at the referenced emission unit.
 - The individual and total monthly HAP emission rates for each material, calculated from the monthly material utilization rates and the individual and total HAP content, calculated for the preceding month no later than 10 days after the end of that month.
 - A rolling consecutive 12-month total emission rate for individual and total HAPs, calculated from the monthly totals for the previous twelve calendar months.
 - Maintain Material Safety Data Sheets (MSDS) for all volatile materials utilized.
- [Rule 62-4.070(3), F.A.C.]
30. The permittee shall maintain the records required by this permit for a period of five (5) years from the date the records were created and be made available for PPRAQD staff review, if necessary.
[Rule 62-4.070(3), F.A.C.]
31. The permittee shall notify PPRAQD of any change in products and submit new material safety data sheets (MSDS) for approval prior to use.
[Rule 62-4.070(3), F.A.C.]