

# APPENDIX

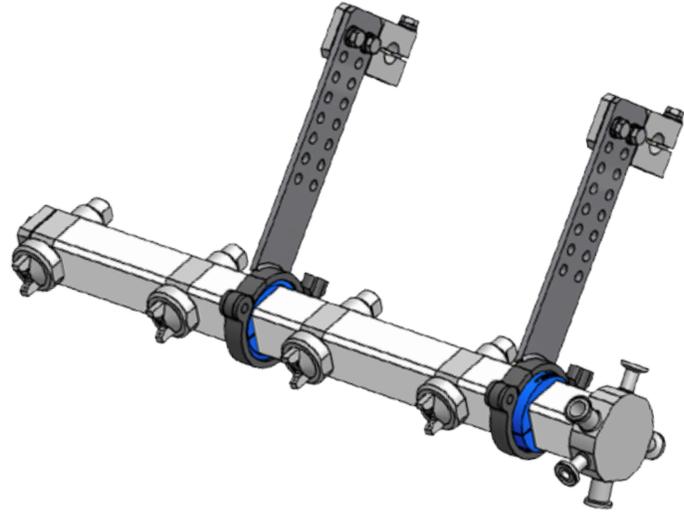
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## ACCESSORIES

**SANITARY MOUNTING CLAMP FOR  
54000 MODULAR MANIFOLDS**

## PRODUCT OVERVIEW

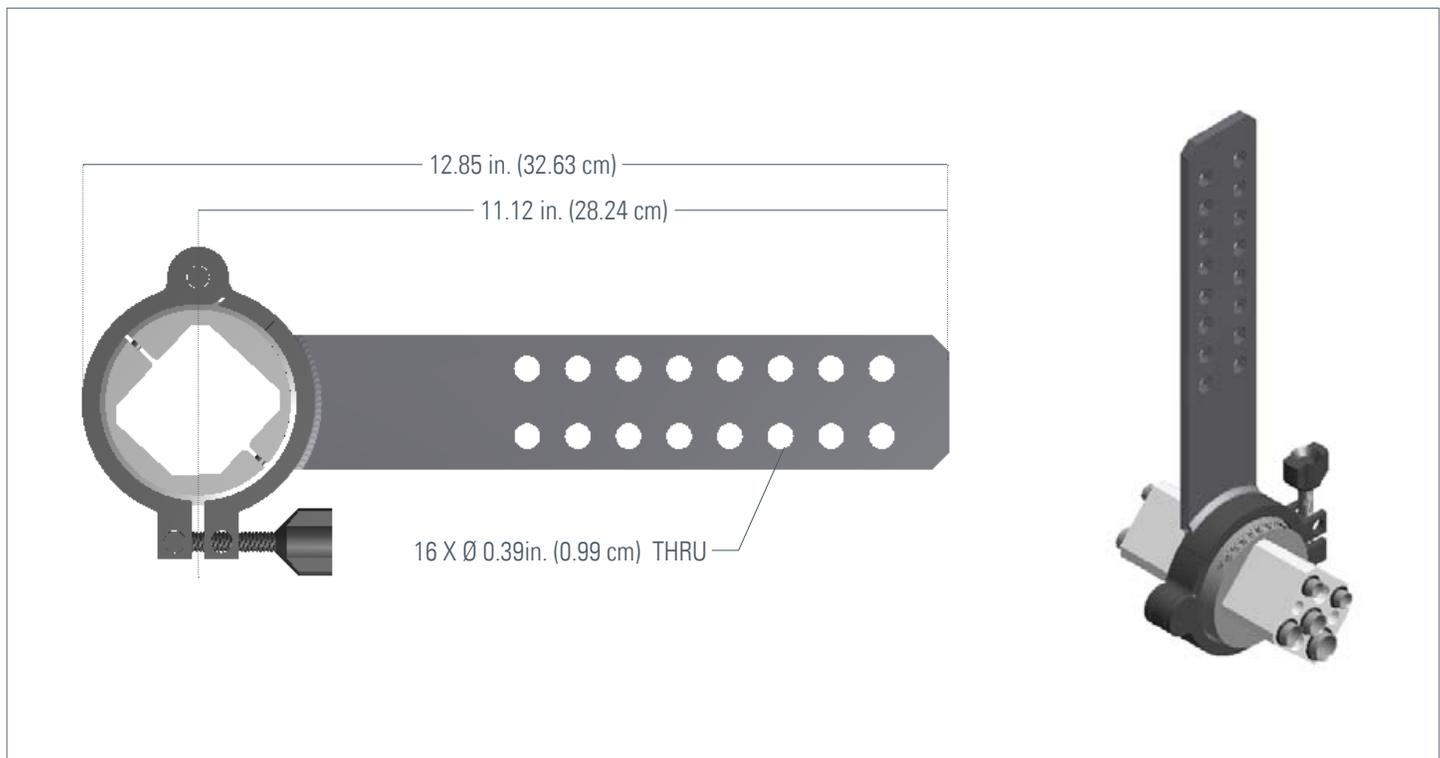
The sanitary mounting clamp system for 54000 Modular Manifolds is a set of stationary clamps which attach to the spacer blocks of the manifold. The clamps stay in place, but allow the manifold to index a full 360° inside the coater without the need to reposition the entire manifold.



## FEATURES AND BENEFITS

- Clamp can index a full 360°, permitting the manifold to be positioned exactly as needed
- Can be used for both 54000 and 54000LC manifolds
- Allows manifold to be positioned for optimal coating results

## DIMENSIONS



## ACCESSORIES

## O-RING KITS, TUBE FITTINGS AND MORE

## O-RING KITS

For our line of air atomizing/tablet coating products, we offer spare O-ring kits and more. Each O-ring kit consists of all of the different sizes of O-rings required for operation of the given product, eliminating the need for you to source and purchase larger-than-necessary quantities of multiple sizes of O-rings, saving time and money.

## AVAILABLE KITS (FOR TABLET COATING PRODUCTS)

54200 VMAU Lab Coater Spray Nozzle	51460 JAUSF Spray Nozzle	54000 Modular Air Atomizing Manifolds	54000LC Modular Air Atomizing Manifolds	P-Series Anti-Bearding Spray Set-Ups
54200-300-VIFDA-KIT		54028-200-VIFDA-KIT (for Tube Holder Assemblies)	54028-700-VIFDA-KIT (for Tube Holder Assemblies)	
54200-300-EPRFDA-KIT	54008-700-VIFDA-KIT	54028-200-EPRFDA-KIT (for Tube Holder Assemblies)	54028-700-EPRFDA-KIT (for Tube Holder Assemblies)	52533-VIFDA-KIT
28945-007-316SS (Rod Mount Kit)	54008-700-EPRFDA-KIT	54008-700-VIFDA-KIT (for Needle Actuators)	54008-700-VIFDA-KIT (for Needle Actuators)	52533-EPRFDA-KIT
		54008-700-EPRFDA-KIT (for Needle Actuators)	54008-700-EPRFDA-KIT (for Needle Actuators)	

## TUBE FITTINGS AND CONNECTIONS

In addition to O-Ring kits and other accessories, we also offer ferrule type and push-in tube fittings for all of our spray nozzles, lances, and modular manifolds to ensure that your installation and set-up is as simple as possible. Instead of sourcing the numerous components required to connect and install a system from multiple vendors, let us serve you as your single-source supplier for all of your spray system needs.

For information on available fittings and connections, [click here](#) ► or contact your local sales representative.

## GLOSSARY

**Active Coating-** A coating that contains active ingredients (APIs).

**API-** Active Pharmaceutical Ingredient (see also **active coating**), or active - is the part of a pharmaceutical drug that is biologically active. This is the ingredient that triggers the desired pharmacological reaction in a patient's body. To formulate a dosage form (e.g., tablet) that could be efficiently produced and delivered to the body, some inactive ingredients (see also **excipient**) are often added to the formulation. Most commercial dosage forms typically consist of both API(s) and excipients.

**ASME BPE-** The American Society of Mechanical Engineers Bio Processing Equipment (ASME BPE) Standard standardizes specifications for the design, manufacture, installation, inspection and acceptance of equipment used in the pharmaceutical and biological products industries.

**ASME BPVC Section IX-** The American Society of Mechanical Engineers Boiler Pressure and Vessel Code. Section IX defines welding procedures and how the procedures and welders are qualified.

**Autogeneous Welding-** A fusion welding process using heat without the addition of filler metal to join two pieces of the same metal.

**Biopharmaceutical-** A pharmaceutical derived from biological sources and especially one produced by biotechnology. A therapeutic product created through the genetic manipulation of living things, including (but not limited to) proteins and monoclonal antibodies, peptides, and other molecules that are not chemically synthesized along with gene therapies, cell therapies and engineered tissues.

**Batch-** The amount of product being processed at hand. Batches can be processed either individually (single batch) or continuously (continuous batch).

**Batch Record-** Documents prepared for each processed batch which include all ingredients, process details and equipment used to make the product. Manufacturers of regulated drug products are also required to prepare a master batch record. An approved master batch record is the source document for all individual batch records, which are prepared and executed each time a new batch of the given product is manufactured.

**cGMP-** Current Good Manufacturing Practices. Good Manufacturing Practice guidelines (GMPs) are published by the FDA and are used by pharmaceutical, medical device, and food manufacturers as they produce and test products that people use.

**Change Control Record-** A record which documents any changes made to the master batch record for the manufacture of a product. The change must be supported, documented and approved by management personnel responsible for the manufacture and release of the product to the public.

**CIP-** Clean-in-Place, equipment and techniques that allow process equipment to be cleaned without dismantling or manual cleaning.

**Drug-** A drug is a substance intended for use in the diagnosis, cure, treatment or prevention of a disease or to otherwise affect or modify the function or behavior of any part of the body.

**Electropolishing-** A method of importing brilliance to a surface by removing a thin surface layer. It is an electro-chemical process, sometimes called "super passivation," capable of improving surface finish by up to 50%.

**Enteric Coating-** A barrier applied to an oral medication that controls the location in the digestive system where it is absorbed. Enteric refers to the small intestine; enteric coatings are manufactured to prevent release of medication before reaching the small intestine.

**Excipient-** Generally a pharmacologically inactive substance used as a carrier (or enhancer, stabilizer, modifier, etc.) for the active ingredients of a medication. Some of the types of excipients may include anti-adherents, binders, coatings (those that do not contain "active drugs"), flavors, lubricants, preservatives, etc.

**Formulation-** A mixture of structures prepared according to a specific procedure (a "formula").

**Full Penetration-** Describes the type of weld wherein the weld metal extends through the complete thickness of the parts being joined.

**Functional Coating-** see **Modified Release Coating**.

**HPC-** Hydroxypropyl cellulose, a type of coating polymer.

**HPMC-** Hydroxypropyl methylcellulose, an early – and still commonly used – tablet coating material. In modern coating systems (formulations), additional substances are added to it as plasticizers, anti-tacking agents, etc. but it still remains a main component of many coatings. It is used in many complete coating systems, for instance Opadry® by Colorcon®.

**Installation Qualification (IQ)-** Documents which establish that the critical components of a system are installed correctly and in accordance with design documentation requirements (i.e. specifications, purchase orders, contracts, bid packages, etc).

**Modified Release Coating-** film coatings applied to the solid dose form (tablet, bead, capsule) to alter the release of API in a dosage form after it is ingested. The drug release characteristics of time, course, and/or location (in the GI tract) are chosen to accomplish therapeutic or convenience objectives not offered by conventional dosage forms. Examples of modified release functionality could be: sustained release coating, enteric coating (see **enteric coating**).

**MTR-** Mill test report, a quality assurance document in the steel industry that certifies a material's compliance with appropriate ASTM standards and applicable dimensions as well as physical and chemical specifications.

**Non-Functional Coatings** (also referred to as conventional coatings)- film coatings applied to tablets for improved product appearance (color, gloss), improved handling (e.g. moisture and UV protection), etc.



## GLOSSARY (CONTINUED)

**Operational Qualification (OQ)**- Documents which establish, through testing, that all critical components and “direct impact” systems are capable of operating within established limits and tolerances.

**Orbital Welding**- Automatic or machine welding of tubes or pipe-in-place with the electrode rotating (or orbiting) around the work.

**Passivation**- The formation of the protective layer of nickel and chromium oxides that prevent the formation of iron oxide (rust). Stainless steel self-passivates when exposed to air. The process known as passivation is actually an acid cleaning process that removes surface contaminants and allows the stainless steel to form the integral passive layer when exposed to air. Passivation doesn't change the appearance or surface finish.

**Potency**- a measure of drug activity expressed in terms of the amount required to produce an effect of given intensity. A highly potent drug evokes a larger response at low concentrations, while a drug of lower potency evokes a small response at low concentrations.

**Process Qualification (PQ)**- Process qualification is the final qualification activity before process validation. PQ integrates procedures, personnel, systems, and materials to verify that the given pharmaceutical grade utility, environment, equipment, or support system produces the required output.

**PVA**- Polyvinyl alcohol. Used in certain coating systems (complete coating formulations).

**Quality Control**- A process by which a given entity (e.g. the FDA) reviews the quality of all factors involved in production of a given drug, product or compound.

**Quarantine**- The compulsory isolation of a person, animal or substance, typically to contain the spread of something considered dangerous, often (but not always) disease.

**Riboflavin Test**- In cases of organic residues in vessels, a common practice is to spray the inner surfaces with a solution of riboflavin (vitamin B6), which adheres to the residue. When the surfaces of the vessel are exposed to UV light, adhering riboflavin fluoresces, indicating which areas need to be cleaned.

**Rouge**- A form of pitting corrosion found in pharmaceutical water for injection (WFI) systems. It must be removed chemically, either by electropolishing or repassivation.

**Seal Coat or Base Coat**- First layer of coating sprayed on the tablet. This first barrier is then used as a foundation to apply additional coatings.

**SIP**- Steam-in-place, heating or chemical sterilization of process equipment.

**Solid Dosage**- Term used in the pharmaceutical industry to refer to drugs that are intended for ingestion (vs. injection). Types of solid dosage drugs include tablets, capsules, granules, and powders.

**SOP**- Standard Operating Procedure.

**Sterilization**- a term referring to any process that removes or kills all forms of life present on a surface, contained in a fluid, in medication, or in a compound.

**Surface Finish**- There are three primary means of classifying surface finish. The first is called the standard mechanical sheet finish and is given with a number and a letter that indicates a process sequence used in the manufacture of stainless steel sheets. The second type of classification is by grit or mesh size. The third is by surface finish measurement using a device such as a profilometer.

**Turnover Package**- A package prepared to identify documentation that will readily allow operating companies to demonstrate that the vendor/contractor provided goods and services in compliance with good manufacturing and good laboratory practices for licensed products. The TOP provides the information that will allow the owner to validate, qualify, operate and maintain the equipment and facilities.

**USP**- United States Pharmacopeia, a drug regulating agency.

**Validation**- As it relates to the spray equipment, the process of validation involves the qualification of the manufacturing process to insure that it is stable and reliable so that the corresponding manufactured drugs meet specifications. Once an equipment or a process is validated, a new validation is required if any change is made.

**Welder Certificates**- (also known as welder qualifications)- specially designed tests to determine a welder's skill and ability to deposit sound weld material. The test consists of many variables, including the specific welding process, type of metal, thickness, joint design, position, and others. Most often, the test is conducted in accordance with a particular code.

**Weld Maps**- An isometric drawing showing the location and numerical identification of each weld used in the construction of a process piping system. Each weld, when completed, is labeled with the weld number indicated on the weld map, the date completed, and the welder/welding operator identification number or code.

**WFI**- Water for injection (RO- reverse osmosis, DI- deionized water)

**316L Stainless Steel**- 316SS contains 0.08% carbon. It may develop a heat-affected zone that is sensitized. If this area is exposed to active electrolytes, inter-granular corrosion may occur. 316LSS contains 0.03% carbon, which minimizes this problem.

## TERMS AND CONDITIONS OF SALE

### (1) Modification of Terms

Seller's acceptance of any order is expressly subject to Buyer's assent to each and all of the terms and conditions set forth below and Buyer's assent to these terms and conditions shall be conclusively presumed from Buyer's receipt of this document without prompt written objection thereto or from Buyer's acceptance of all or any part of the goods ordered. No addition to or modification of said terms and conditions shall be binding upon Seller unless specifically agreed to by Seller in writing. If Buyer's purchase order or other correspondence contains terms or conditions contrary to or in addition to the terms and conditions set forth below, acceptance of any order by Seller shall not be construed as assent to such contrary or additional terms and conditions or constitute a waiver by Seller of any of the terms and conditions.

### (2) Price

Unless otherwise specified: (a) all prices, quotations, shipments and deliveries by Seller are f.o.b. Seller's plant; (b) all base prices, together with related extras and deductions, are subject to change without notice and all orders are accepted subject to Seller's price in effect at the time of shipment; and (c) all transportation and other charges are for the account of Buyer, including all increase or decrease in such charges prior to shipment. Payment of said price shall be due at the remittance address shown on the Seller's invoice 30 days after the date of Seller's invoice. Interest will be charged at a rate of 1 to 1-1/2% per month on all balances outstanding more than 30 days after the date of the invoice.

### (3) Minimum Billing

The minimum billing by the Seller for any order shall be \$50.00.

### (4) Warranties

Seller warrants that its products will conform to and perform in accordance with the products' specifications. Seller warrants that the products do not infringe upon any copyright, patent or trademark. **THE FOREGOING WARRANTIES ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THOSE CONCERNING MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.**

### (5) Limitation on Liabilities

Because of the difficulty of ascertaining and measuring damages hereunder, it is agreed that, except for claims for bodily injury, Seller's liability to the Buyer or any third party, for any losses or damages, whether direct or otherwise, arising out of the purchase of product from Seller by Buyer shall not exceed the total amount billed and billable to the Buyer for the product hereunder. **IN NO EVENT WILL SELLER BE LIABLE FOR ANY LOSS OF PROFITS OR OTHER SPECIAL OR CONSEQUENTIAL DAMAGES, EVEN IF SELLER HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.**

### (6) Quality Assurance

Seller shall have no obligation to ensure that any goods purchased from Seller meet any special Buyer quality assurance specifications and/or other special Buyer requirements unless such specifications and/or other requirements are specifically set forth in Buyer's purchase order and expressly accepted by Seller. In the event that any such goods supplied by Seller in connection therewith, are applied to an end use without the appropriate specification and/or other requirement therefore having been set forth in Buyer's purchase order and expressly accepted by Seller, Buyer shall indemnify and hold Seller harmless against any and all damages or claims for damages made by any person for any injury, fatal or nonfatal, to any person or for any damage to the property of any person incident to or arising out of such application.

### (7) Claims

Claims respecting the condition of goods, compliance with specifications or any other matter affecting goods shipped to Buyer must be made promptly and, unless otherwise agreed to in writing by Seller, in no event later than one (1) year after receipt of the goods by Buyer. In no event shall any goods be returned, reworked or scrapped by Buyer without the express written authorization of Seller.

### (8) Default in Payment

If Buyer fails to make payments on any contract between Buyer and Seller in accordance with Seller's terms, Seller, in addition to any other remedies available to it, may at its option, (i) defer further shipments until such payments are made and satisfactory credit arrangements are re-established or (ii) cancel the unshipped balance of any order.

### (9) Technical Assistance

Unless otherwise expressly stated by Seller: (a) any technical advice provided by Seller with respect to the use of goods furnished to Buyer shall be without charge; (b) Seller assumes no obligation or liability for any such advice, or for any results occurring as a result of the application of such advice; and (c) Buyer shall have sole responsibility for selection and specification of the goods appropriate for the end use of such goods.

### (10) Cancellation of Special Orders

Special orders or goods specially manufactured for Buyer cannot be canceled or modified by Buyer, and releases cannot be held up by Buyer, after such goods are in process except with the express written consent of the Seller and subject to conditions then to be agreed upon which shall include, without limitation, protection of Seller against all loss.

### (11) Patents

The Seller shall not be liable for any costs or damages incurred by the Buyer as a result of any suit or proceeding brought against Buyer so far as based on claims (a) that use of any product, or any part thereof, furnished hereunder, in combination with products not supplied by the Seller or (b) that a manufacturing or other process utilizing any product, or any part thereof furnished hereunder, constitute either direct or contributory infringement of any patent of the United States. The Buyer shall hold the Seller harmless against any expense or loss resulting from infringement of patents or trademarks arising from compliance with Buyer's designs or specifications or instructions.

### (12) Complete Agreement

The terms and conditions set forth herein, together with any other documents incorporated herein by reference constitute the sole and entire agreement between Buyer and Seller with respect to any order superseding completely any oral or written communications. No additions to or variations from such terms and conditions whether contained in Buyer's purchase order, any shipping release or elsewhere shall be binding upon Seller unless expressly agreed to in writing by Seller.

### (13) Governing Law

All orders are accepted by Seller at its mailing address in Wheaton, Illinois, and shall be governed by and interpreted in accordance with the laws of the State of Illinois.

### (14) Customer Return Policy

We recognize that at times it is necessary for our customers to return products for a variety of reasons. Returns are a normal part of an on-going business relationship. To make the process as straightforward and fair as possible, our policy is based upon the following:

- An error on our part: Seller will credit you for the product and shipping costs, up to one year from ship date.
- An error on your part: Standard products can be returned for full credit, freight prepaid, also up to one year from date of shipment. There is the normal restocking charge of 20%.

Returns are subject to inspection.

For quick handling and authorization of returns, contact your local sales office.

**Spraying Systems Co. reserves the right to make changes in specifications or design of the products shown in the catalog or to add improvements at any time without notice or obligation.**