

MEDIA RELEASE

NJM Presents Dara NFL/2 Aseptic Filling and Closing Machine for Ready-to-Use Syringes at Pack Expo

Streamlining small batch biopharmaceutical packaging

MONTREAL, September 27, 2022 – NJM, a <u>ProMach</u> product brand, presents the <u>Dara NFL/2</u> aseptic filling and closing machine for ready-to-use syringes at Pack Expo booth #W-17002 in the Healthcare Packaging Pavilion. Ideal for biotech companies and 503B pharmacies packaging suspensions, diagnostics, solutions and/or vaccines, the NFL/2 handles nests of pre-sterilized syringes as well as vials and cartridges. This fully servo-driven system simplifies small scale production to reduce capital costs, minimize floorspace requirements and speed up changeover.

"Biopharmaceutical manufacturers who are new to commercial production can rely on the Dara NFL/2 to maximize efficiencies during both the 'scale up' phase and small batch commercial manufacturing," said Thomas Kessler, Dara Product Manager at NJM. "By filling and closing syringes, vials and cartridges that are already sterilized and prepared for processing, the NFL/2 has eliminated the need for a washer and depyrogenation tunnel, which streamlines the packaging operation."

The NFL/2 fills and seals syringes while they remain in the nest. A vibratory hopper/circular feeder delivers the plungers to the pick-and-place stations, which places the plungers into the syringes using direct drive, servo-motion control. Changeover to another syringe size can be completed in less than 15 minutes with no tools required.

As a dual station system, the NFL/2 can fill and close up to 4,500 syringes per hour in a compact footprint that's only 6.6 feet (2 meters) long and 3.3 feet (1 meter) wide. For customers requiring faster throughput, the five-station NFL/5 handles up to 10,000 syringes per hour.

To maximize production versatility, the NFL/2 is available with a wide variety of options. Automatic loading and unloading of nested syringes is available, as well as automatic and semi-automatic debagging and delidding. The NFL/2 can be equipped with stainless steel or ceramic rotary piston pumps, which can achieve +/- 0.5 percent accuracy, or with peristaltic pumps, which can achieve +/- 1 percent accuracy. If sterile or ISO 5 environments are needed, laminar air flow (LAF), open or closed restricted access barrier systems (oRABS/cRABS) or high containment isolator systems are available. Vacuum-assisted cap insertion and gas flushing reduce O2 levels in the container, if required. Optional statistical process control and particulate counters help ensure final product quality. Clean-in-place (CIP) or sterilization-in-place (SIP) modules are also available.

NFL/2 utilizes servo-driven, X-Y motion to achieve repeatable performance, low maintenance, simple troubleshooting, fast changeovers and easy addition of new formats. An Allen-Bradley PLC controls the machine functions and a Beckhoff PC-based 15-inch (38 cm) color touchscreen presents a large and intuitive user interface. All production parameters, including dosing volumes and speeds, can be programmed via the HMI.

The NFL/2 can be equipped with data recording software to export the production data in compliance with 21 CFR Part 11. Featuring a 304 stainless steel frame and electro-polished 316 stainless steel product contact parts that meet FDA approval for use by pharmaceutical and biotech manufacturers, the NFL/2 is designed in compliance with cGMP.

NJM offers a "total solution" approach that includes IQ, OQ, FDS, FAT and SDS validation support as well as turnkey line integration services to seamlessly combine best-in-class technologies. NJM's world-class aftersales support includes standard and extended warranties, preventative maintenance programs and onsite installation, training and ongoing service.

About NJM

The world's proven, trusted, single-source provider of automated packaging machinery for pharmaceutical, nutraceutical and personal care products, NJM offers both stand-alone solutions and integrated systems for packagers of solid dose and liquid pharmaceuticals, biopharmaceuticals, vitamins and food supplements. As part of the ProMach Pharma business line, NJM helps our customers protect and grow the reputation and trust of their consumers. ProMach is performance, and the proof is in every package. Learn more about NJM at www.NJMPackaging.com.

About ProMach

ProMach is a family of best-in-class packaging solution brands serving manufacturers of all sizes and geographies in the food, beverage, pharmaceutical, personal care and household and industrial goods industries. ProMach brands operate across the entire packaging spectrum: filling and capping, flexibles, pharma, product handling, labeling and coding and end of line. ProMach also provides Performance Services, including integrated solutions, design/build, engineering services and productivity software to optimize packaging line design and deliver maximum uptime.

ProMach designs, manufactures, integrates, and supports the most sophisticated and advanced packaging solutions in the global marketplace. Its diverse customer base, from Fortune 500 companies to smaller, privately held businesses worldwide, depends on reliable, flexible, technologically advanced equipment and integrated solutions. ProMach is headquartered near Cincinnati, Ohio, with manufacturing facilities and offices throughout the United States, Canada,

Mexico, Brazil, Europe, United Arab Emirate and China. For more information about ProMach, visit www.ProMachBuilt.com.

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