



DISTEK

Part Number
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DISTEK[®]
CREATING A STIR[™]

Product Brochure

Evolution Series

6100 & 6300

Distek continues setting the industry standard with the Evolution Series of Dissolution Systems. Available in your choice of bathless or bath-based configurations, the Evolution Series is designed to meet today's demanding requirements. The advanced features combined with the intuitive user interface result in measurable productivity gains and increased control over the dissolution test.

USP<711> Tolerance Checking

- Dissolution test parameters are monitored against USP requirements and reported to confirm compliance for speed and temperature.

Patented Embedded Temperature Sensor in Each Shaft*

- Permits precise control over the individual heater jackets on the bathless 6100 and the thermocirculator for the 6300.
- Allows continuous temperature monitoring in each vessel.

Patented Bathless Technology* (Evolution 6100 Only)

- Virtually maintenance free. Eliminates the time required for bath cleaning.
- Improves overall system reliability and eliminates a potential source of system vibration.
- Heats media from ambient to 37°C in less than 15 minutes, reducing overall test time and increasing throughput.

USP<711> Compliant Detachable Paddles and Baskets

- Permanently installed common shafts are used for both paddle and basket tests.
- The automatic height adjustment block combined with the detachable stirring elements offer rapid conversion between apparatus 1 and 2.

Method Storage with Audit Trail

- Stores and sorts up to 100 methods by name and create date.
- Records the last 50 changes made to each method.

Auto Detection of Shaft Raising and Lowering

- Senses when a shaft is raised out of or lowered into the media.
- Simplifies the start of staggered drop basket tests.

Small Volume Dissolution (Evolution 6300 Only)

- Convert from a standard apparatus 1 and 2 configuration to small volume dissolution by removing the paddle blade or basket adapter from the shaft and installing the small volume stirring element.

*US Patent No. 5589649.
Related foreign patents apply.

6100



6300



DISTEK



Evolution 4300

The Evolution 4300 is an advanced, feature rich dissolution sampler combining an intuitive user interface with state-of-the-art electronics to control the proprietary syringe pumps. The Evolution 4300 offers unmatched functionality and flexibility.

The unique dual bath configuration has the ability to run two independent methods simultaneously from one autosampler saving time, money, and bench space. The system comes equipped with many attractive features like media recycling, media replacement, dilution of collected samples, and pH or volume adjustments in the dissolution vessel.

Independent Dual Bath Programming

- Utilization of the dual syringe pump configuration permits the running of two different and independent dissolution methods increasing productivity, saving time and money.

Positive Displacement Syringe Pumps

- Allow for highly accurate volume collections of 100µl to 20ml.
- Proprietary syringe plunger design significantly reduces carry-over between sampling intervals.

Septum Piercing

- The dual sleeved needle design vents back pressure created when sampling into sealed test tubes or vials.
- Sampling into sealed vials improves results by minimizing evaporative loss.

Dilution of Collected Samples

- User defined volumes of diluent can be programmed for individual time points or entire profiles, saving time and reducing errors.

Volume Addition and pH Adjustment

- Additional media can be added to each vessel to perform a pH adjustment or to increase the final test volume in each vessel.

Media Recycling and Media Replacement

- The system will automatically return media removed from the vessel during the sample collection process as well as replace the volume lost equal to the volume collected.

5 Minute Sampling

- The EVO 4300 is ideally suited for immediate release profiling when a sampling of five minutes* between time points is required.

*Sample parameters will affect minimal time intervals.

US Patent No. 6948389.
Related foreign patents apply.

Model 2100C

Distek's Model 2100C is the fourth generation of the same rugged 2100 series that has been faithfully serving the dissolution market for over 17 years. The 2100C's simple yet efficient design offers the most flexibility and value of any bath on the market.

Maximum Flexibility and Versatility

- 6, 7, or 8 vessel position layout for all application types.
- Choice of 100mL, 200mL, 1L, 2L, and 4L vessels.

USP<711> Compliant Detachable Paddles and Baskets

- Switch from paddle to basket tests without removing the shaft.
- Easier conversion between apparatus 1 and 2 with less chance of damaging vessels.

Automatic Height Adjustment for Baskets or Paddles

- Built in calibration spacer eliminates the need for manual height adjustment.
- Increases productivity and reduces the chance of operator error during set up.

High Volume "Hideaway" Thermocirculator

- Ensures even water distribution and temperature stability throughout the bath.
- Rapid bath equilibration saves time and increases throughput.
- Small footprint saves bench space.
- Drift-free temperature control ensures vessel-to-vessel uniformity within $\pm 0.1^{\circ}\text{C}$.





User Interface



Universal Wash Nozzle



Particulate Trap



VIP 4400 Vessel Washer

The VIP 4400 addresses one of the most time consuming and least productive aspects of the dissolution test: vessel clean-up. Customers employing the Distek VIP 4400 will virtually eliminate the tedious process of removing, draining, and cleaning the dissolution vessels. The use of the VIP 4400 is guaranteed to save time, reduce cost, and increase the output of the dissolution laboratory by performing these functions in-situ:

Patent Pending "Cyclone" Wash

- By integrating the drain and the "Cyclone" wash nozzle into one assembly the VIP 4400 offers a full 360° wash to provide a more efficient cleaning of the entire vessel.

Self-Adjusting Drain

- The spring loaded, self-adjusting drain automatically compensates for vessel height variations, minimizing residual wash water remaining in the vessel after cleaning, when using USP compliant 1L and 2L vessels.

Low Noise

- Whisper quiet pumps produce less than 65dB noise, minimizing the VIP 4400's contribution to laboratory noise.

ezfill 4500 Media Preparation Station

The ezfill 4500 is compact, transportable, and easy-to-use. The unique integration and control of critical functions like heating and vacuum degassing allow the unit to prepare and accurately dispense media in approximately 90 seconds* for volumes as large as 1000mls.

The ezfill 4500 provides tight control over key volume and temperature parameters with accuracies of $\pm 1\%$ for volume and $\pm 2^{\circ}\text{C}$ for temperature, meeting compendia requirements. The high precision glass vacuum chamber and piston are used to create the conditions for fast and effective de-aeration and media dispensing where up to 3 ppm of dissolved oxygen can be removed.

Compact Design

The ezfill can easily fit on the bench or be used with the optional mobile cart or autofill.

Automation Ready

Utilization of the autofill permits the unattended processing of up to 8 dissolution vessels.

In-line Heating

Eliminates time delays and wasted energy associated with immersion heaters used in bulk media tanks. The system is ready to prepare media immediately upon power up.

Precision Vacuum Chamber

The piston controlled vacuum chamber creates a high vacuum for effective de-aeration and delivers precise media volumes accurate to within 1% of the set volume.

Variable Dispense Volumes

User selectable volume settings from 250 ml to 1000 ml in 5 ml increments allow for quick and easy volume changes without the need for system recalibration.

MDC - Multiple Dispensing Cycle

The system will process multiple vessels simultaneously when volumes are set at or below 500 ml.

Variable Temperature

User selectable temperatures from ambient to 45°C .

Surfactant Capable

Process dissolution media containing up to 2% surfactants eliminating foaming issues seen in other media preparation systems.

*Cycle time is volume and temperature dependent





Mobile Cart
p/n 2600-0105

Mobile Cart

The Mobile Cart is specifically designed for use with the ezfill which will securely attach to the top shelf of the cart. The open bottom shelf will accommodate most common carboy containers or other pre-packaged dissolution media up to 50L. The mobile cart permits the easy transportation of the ezfill and media directly to the dissolution baths. It also reduces the potential for chemical spills, increasing safety in the dissolution laboratory.



Remote Dispensing Nozzle
p/n 2800-0169

Remote Dispensing Nozzle

When interfaced with the ezfill, on the bench or installed on the mobile cart, the Remote Dispensing Nozzle allows for the delivery of media directly into vessels in the dissolution bath. All key functions of the ezfill can be performed directly from the dispensing nozzle in a hands free operation.



autofill
p/n MODEL AUTOFILL
(Shown with ezfill)

autofill

The autofill is an 8 position carousel processing station for the unattended filling of up to 8 1L USP compliant dissolution vessels.

Opt-Diss™

UV Fiber Optics

Taking the analysis to the vessel where the dissolution occurs is the heart of the Opt Diss™, UV fiber optic system. Eliminating the need for sample removal brings improved precision and accuracy while eliminating errors. The Opt Diss™ greatly increases the number of data points that can be taken along a dissolution profile, providing greater flexibility and characterization in dissolution profile analysis. The scientific grade CCD detector permits the simultaneous collection of the entire UV spectral range.

G2 ARCH™ and mini-ARCH Probes

- Provide full light transmittance without the need for mirrors or prisms.
- Virtually eliminates the potential for trapping air bubbles and particulate build-up.
- Resident stationary probes do not require a cumbersome raising and lowering manifold.

Rapid Spectral Collections

- Simultaneous collection of the entire UV spectrum (190-400) from up to 12 vessels with a minimum 5 second interval improves profile analysis.

21 CFR part 11 Compliance

- Compliant software provides the security required for today's strict controls and audit trail requirements.

Small Volume Dissolution Capable

- Using mini-ARCH or Dip Type probes allows for the same benefits of traditional USP apparatus to be applied to small volume dissolution tests.
- Improves precision and accuracy of the test measurements where sample removal and evaporative loss are critical.

Distek Bath Control

- Key bath parameters are configured using the Opt Diss software making system setup simple.
- Integrates bath parameters and test results into a single report.

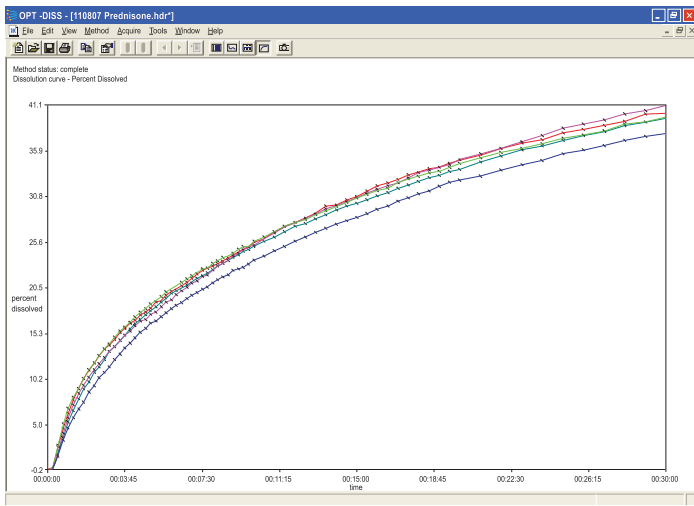


Figure 1. Dissolution Profile

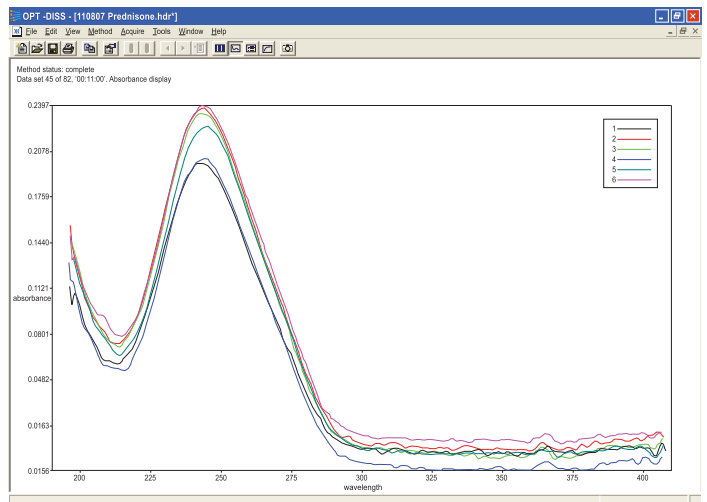


Figure 2. Spectral View



8453 UV-Vis

Agilent UV-Visible Spectroscopy Solutions

Distek has teamed up with global leader Agilent Technologies as a Premier Solution Partner since 1991 to offer you the 8453 UV-Visible Spectroscopy® System.

Featuring:

- A variety of sampling options ranging from manual offline through full automation of up to four baths each running different methods.
- 21 CFR part 11 compliance.
- 4th generation diode array technology offers robust, quick, and absolute wavelength resetability that can't be matched by traditional linear-scanning instruments.
- Customized reports from ChemStation software.
- Seamless integration/communication with Distek Dissolution Test Systems.
- Large capacities for data handling and fast evaluation with 32-bit platform.

On-Line HPLC Dissolution

Distek and Waters have joined forces to offer a superior on-line HPLC Dissolution System. This compliance ready system automates the entire test from starting the dissolution test, acquiring samples, performing analysis, and calculating the results. The Alliance™ system synchronizes the scheduling of sample collection, injection, and data acquisition minimizing the time required to complete a test and eliminating the guess work.

Maximum Productivity

- The 2695D can control and sample from up to two dissolution baths as well as operate in a stand-alone mode as a conventional HPLC without the need for re-configuration.

Dissolution Wizard

- The easy-to-use dissolution sample set wizard allows you to enter all of the dissolution test parameters in an easy-to-follow, step-wise fashion.

Dissolution Software

- Waters Empower or Millennium³² Dissolution Software automates the entire dissolution, sample analysis, and reporting process. Calculations are performed online without the need for an external spreadsheet. All of the equations used to calculate results are validated and available for viewing.
- The built-in relational database gives you the power to organize, store, and retrieve data quickly and easily with full 21 CFR part 11 compliance.
- Key dissolution parameters, such as RPM and Temperature, are captured, stored and reported.



Cipher Dissolution Software

Cipher dissolution control software is a Windows .NET based application designed and developed by Distek, emerging from our many years of experience serving the dissolution market.

Cipher can be installed locally or networked providing full access to any Distek Evolution 6100, 6300, 4300 or Model 2100C instrument on the network. The software is an easy to use, intuitive and user friendly application. Its many features make preparing, running, monitoring, and reporting the result of a dissolution test quick and easy. Cipher offers the flexibility to set the level of security appropriate for your laboratory. It monitors and reports the continuous temperature readings from the waterbath or from within the vessel when using the Evolution 6100 or 6300 as well as RPM. Simple, advanced and custom test reports are user selectable and user definable to include all pertinent information.

21 CFR part 11 Compliance

When enabling all available security features and audit trails, and combined with the appropriate customer policies, Cipher balances the requirements of compliance with limited intrusion on user activities.

eSignatures

The use of electronic signatures guarantees that only approved methods can be used and reports released.

Audit Trail

Event, system and method changes are tracked with a computer generated date and time stamp. Additional information logged includes the user, old and new values, and the reason for change.

Instrument Networking

Users are able to log on to a client work station and view the current status of any Distek system on the network permitting real time, remote instrument setup and monitoring.

LIMS Compatible

When configuring the system, two clicks of the mouse permit the automatic exporting of result files in an ASCII format for access and use by a LIMS package.

Method Wizard

The user is walked through method setup for a dissolution unit and attached sampler (if applicable).

Compendia Alerts

The user can set the specific tolerance parameters for RPM and temperature requiring the system to alert the user should a reading fall outside the acceptable range.

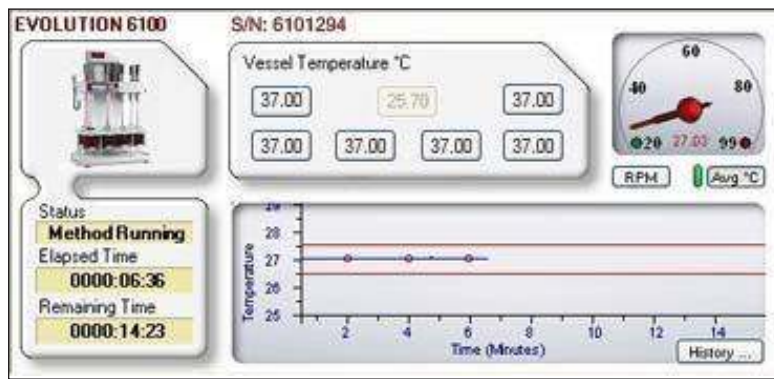


Figure 1. Dissolution Unit Monitoring with Temperature Plot

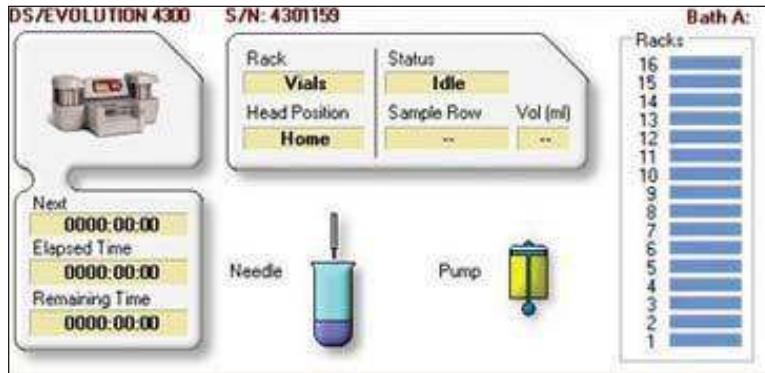


Figure 2. Dissolution Sampler Status Screen

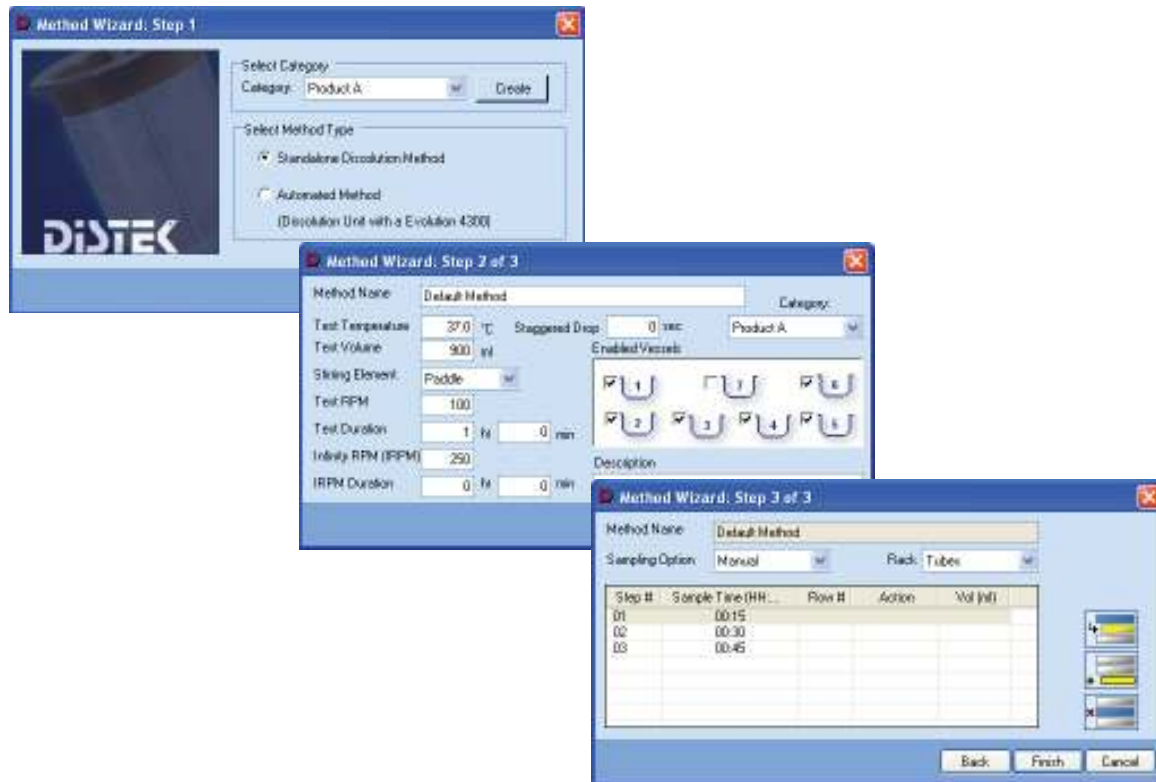


Figure 3. Method Wizard

3100 Series

3104



3102



3106



Distek advances disintegration testing by incorporating patented bathless technology into the state-of-the-art 3100 Series. This series offers a configurable layout of 2, 4, or 6 positions, to match your laboratory's workload, in a space saving semi-circular design.

The advanced features of the 3100 Series provide superior performance and functionality. With fast media warm-up (less than 8 minutes), the 3100 Series increases throughput by offering rapid changeover between tests.

Innovative Bathless Design

- Eliminates common problems associated with standard water baths, including evaporative loss and algae growth.

Integrated Temperature Sensors

- Enable the system to continuously monitor and document individual beaker temperatures for improved regulatory compliance.

Independent Test Stations

- Each position can be initiated in unison or run individually to greatly increase flexibility and productivity.



Validation

Distek's Validation Services Business Unit utilizes highly skilled chemists and technicians dedicated to meeting your needs with an unparalleled commitment to customer satisfaction. Our product is our people. Each validation service professional undergoes comprehensive training and certification in all aspects of validation service including cGMP and GLP. All measuring tools used are calibrated and traceable to NIST standards and comprehensive documentation will be provided for each instrument serviced.

Our Validation Services Business Unit offers the following services on a one time and annual contract basis.

Installation Qualification (IQ)

- Assures that the system is received in good condition and as ordered and will verify the system meets specifications and is ready for operational qualification.

Operational Qualification (OQ)

- Verifies the system is functioning and that all critical operational parameters are within specification. This will certify the mechanical performance of the system and that the system is ready for performance qualification.

Performance Qualification (PQ)

- Verifies and certifies that the instrument meets the system suitability requirements per the USP <711> guidelines using calibrator tablets.

Preventative Maintenance (PM)

- Assures that the system continues to operate properly and no component becomes incompatible due to wear and tear.

Certified Dissolution Accessories

- 2800-0165-SN-CERT
Standard Length Shaft, 316 SS, With O-Ring.
- 3221-0165-SN-CERT
Standard Length Shaft, 316 SS, Without O-Ring.
- 2800-0334-CERT
Extended Length Shaft, 316 SS.
- 2800-0338-CERT
Extended Length Shaft with Evolution Style Basket Adapter.
- 2800-0500-EXT-CERT
Extended Length Shaft and Machined Paddle Blade, 316 SS.
- 3251-1050-SN-CERT
Paddle Blade, Machined, 316 SS.
- 2800-0032-SN-CERT
Basket, 40 Mesh, Evolution Style.
- 3200-0038-SN-CERT
Basket Adapter for Evolution Style Basket.
- 2821-0460-SN-CERT
Basket and Basket Adapter, 40 Mesh, Evolution Style.
- 3010-0093-CERT
Vessel, 1L Clear Glass with Acculign Ring.
- 3010-0096-CERT
Vessel, Premier 1L Clear Glass.

*Please contact Distek for a current list of available certified accessories.

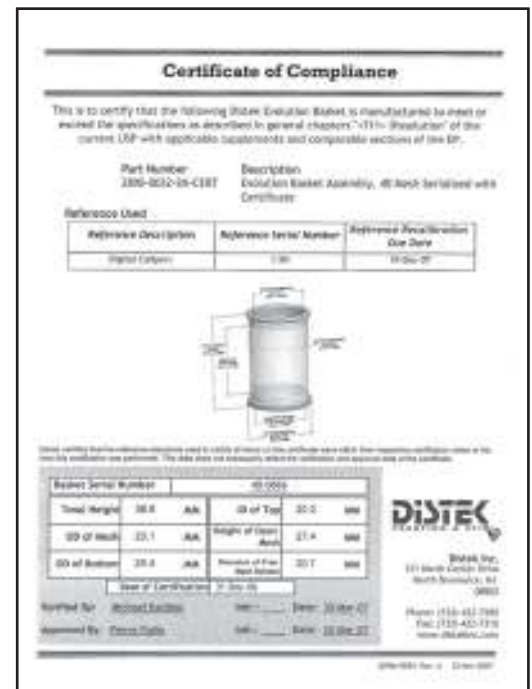


Figure 1. Example Certificate

Dissolution Kits and Accessories

Standard and Mini Intrinsic Dissolution

2800-0066-6
Intrinsic Dissolution Apparatus, Paddle Over Stationary Disk.

2800-0183-6
Small Volume Mini Intrinsic Dissolution Apparatus, Paddle Over Stationary Disk, 100 ml.

2800-0182-6
Small Volume Mini Intrinsic Dissolution Apparatus, Paddle Over Stationary Disk, 200 ml.



Small Volume Dissolution

2800-0600-6
Small Volume Conversion Kit for 6300 and 2100 Series Dissolution System, 100 ml.

2800-0601-6
Small Volume Conversion Kit for 6300 and 2100 Series Dissolution System, 200 ml.

2800-0061
Quad Stir for 2100B/C. Includes Quad Stir Drive Box, Square Hole Adapter Plate, and 4 Each Mini Paddles, 100 ml Vessels, Covers and Shaft Collars with Thumb Screw.



Apparatus 5

0500-0488
Apparatus 5 Paddle Over Disc Assembly, Stainless Steel Support Disc, 304 SS Mesh with Solid Outer Ring. 47 mm Diameter, 125 Mesh.

TD-190-093
Apparatus 5 Transdermal Sandwich, Set of 6.



Apparatus 6

3200-0142
Apparatus 6 Rotating Cylinder, 2 inch, Set of 6. Can Use Extension Adapter p/n 3200-0144.

3200-0143
Apparatus 6 Rotating Cylinder, 2 Inch, Set of 6.

3200-0144
Apparatus 6 Rotating Cylinder, 2.25 Inch Extension Adapter, Set of 6.



DISTEK®

Our qualified staff is always ready to assist you
with technical and application support.
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