Cultivate

A PARASOL MEDICAL PRODUCT

How clean are your testing supplies?

USP Chapter <797> & <800> Testing Supplies

The first aseptic products built to minimize risk—
starting with the packaging itself

Smarter, Cleaner, Convenient…Cultivate™

USP General Chapter <797>
Pharmaceutical Compounding - Sterile Preparations

The purpose of this guide is to show how Cultivate™ products support a pharmacist's goal of complying with United States Pharmacopeia Chapter <797>. In this case, USP's focus is on specific quality assurance activities involving compounded sterile preparations (**CSPs**). According to USP: "The intent of this chapter is to prevent harm and fatality to patients that could result from microbial contamination (nonsterility), excessive bacterial endotoxins, large content errors in the strength of correct ingredients, and incorrect ingredients in CSPs."

Cultivate™ products target the prevention/detection of microbial contamination and the detection of excessive bacterial endotoxins. Areas addressed are personnel training, evaluation of aseptic manipulations, air and surface quality testing of the compounding environment, sterility testing, and detection of excessive bacterial endotoxins (pyrogen).

Area to be tested	Cultivate™ Product(s)
Personal Aseptic Sampling System	PASS™ Kits
Media Fill Process Validations	Clear Check™
Environmental Monitoring	Contact™
Gloved Fingertip testing	Contact™
Sterility Testing, Membrane Filtration	Transfer Test™, TTJunior™, TTMicro™
Sterility Testing, Direct Inoculation	Double Check™, Clear Check™
Beyond-Use Dating Validation	See "Sterility Testing" Above
Filter Integrity Testing	Cultivate™ Syringe Filters
Sterility testing, 70% IPA	Membrane Filtration or Direct Inoculation

USP <797> puts pharmacy prepared CSPs into 3 categories based on the difficulty of maintaining sterility and potential for patient harm: Low-risk, medium-risk, and high-risk. Refer to the definitions in <797> to determine which category describes a particular compounding operation. The frequency and complexity of Quality Assurance procedures are driven by the highest risk level. USP <797> describes the minimum QA procedures that are required. Many pharmacies routinely exceed the minimums to increase patient safety of their CSPs.

Cultivate™ Products
Frequently Asked Questions

Contact™ Test Kits

1. ***How long should Contact™ agar paddles be exposed to air in a laminar flow hood, barrier isolator, clean, and buffer room areas?***

   We suggest an exposure time of 1 hour in hoods and other areas. Exposing any Contact™ products longer than 1 hour in the air flow has the potential of drying the media. It is most important to be consistent in the exposure duration.

2. ***Moisture and water droplets occasionally appear on the inside of Contact™ housing. Does this have any effect on performance or shelf life?***

   Moisture on the inside of the housing does not harm Contact™ products. This moisture comes from the agar. Agar is mostly water and the atmosphere inside the housing stabilizes the 100% humidity.

3. ***How should a pharmacist purposely contaminate a Contact™ product if they want to demonstrate microbial growth?***

   Minimizing touch contamination is a primary goal of aseptic technique testing. Pressing finger tips on the Contact™ agar is an excellent way to inoculate the media. It also demonstrates how easily contamination can occur during a lapse in aseptic technique.

4. ***Can the Contact™ media paddle be used for testing sterile gloved finger tips for microbial contamination?***

   The Contact™ media paddle is an excellent choice for finger tip testing. The unique sealed cap with agar on paddles helps eliminate false positives often found with Petri dish media.

Clear Check™

1. ***Why are several repetitions of media transfers necessary to pass a validation or "competency test" of aseptic technique?***

   Multiple repetitions are necessary to stimulate the most complex aseptic manipulations encountered during normal workloads. Many repetitions induce the boredom that can lead to lapses in good aseptic technique.

2. ***Why is Clear Check™ media offered in a variety of vials and bags?***

   Media transfer validations should stimulate the actual manipulations typically encountered in a particular pharmacy. Examples include syringe transfers from vials to minibags, multiple additive procedures, syringe filling, and use of automated compounders. Multiple repetitive transfers from Clear Check™ vials to Clear Check™ minibags is an excellent example of a simulation of an actual procedure.

3. ***How important is it to exactly follow the Directions for Use that come with each box of PASS™ and PASS2™ kits?***

   The DFUs are written as suggestions only. They can be modified to more closely mimic the most difficult aseptic manipulations performed by a particular operator or pharmacy.

Transfer Test™, TTJunior™, and TTMicro™ Systems

1. ***If the IV admixture has already been infused into the patient by the time the QA Pharmacist knows the results from the contamination test, why bother?***

   Regular use of the Cultivate™ end-product testers is intended to confirm that aseptic technique is being maintained. Since it is impractical to test, quarantine, and then release every admixture, the supervising pharmacist must watch for trends in the contamination testing program. If several tests exhibit turbidity over a short period of time, it would trigger an investigation. A rare, random positive would probably be tolerated. The supervisor would check to see if the multiple positives were prepared by the same pharmacist or technician. The point is to watch for trends and detect problems in validated procedures.

2. ***How soon after mixing a sterile drug product should sterility testing begin?***

   An important study determined that sterility testing should begin within 40 to 60 minutes after preparation of intravenous admixtures. Testing that began after 60 minutes decreased the recovery of Staphylococcus epidermidis and lead to increased false negatives. Contact Cultivate™ Technical Service to receive a free reprint of this research article.

3. ***Why should the Transfer Test™ be used with a compounder, pump, vacuum bottle, or vacuum bell when testing 3in1 TPN?***

   Commercial fat emulsions contain a substantial number of particles that are larger than 1 micron. These large particles can eventually occlude the Transfer Test™ filter. Compounders and vacuum systems maintain a pressure difference across the filter. This pressure overcomes the resistance caused by the large fat particles.

4. ***Doesn't the residual fat emulsion in the Transfer Test™ cloud the TSB media and make seeing microbial-caused turbidity difficult?***

   Residual fat emulsion in the filter chamber would be a problem if we didn't have an effective procedure for removing it. The bag of Clear Check™ media that comes with each Transfer Test™ contains approximately 100mL of sterile TSB. After filtering the admixture, an operator can perform a rinse of the filter chamber using the sterile media. This eliminates most of the residual fat emulsion. The last 20mL of TSB is left in the filter chamber to grow potential microbial contaminates.

5. ***How frequently should a pharmacist test IV admixtures?***

   Refer to USP Chapters <71> and <797> for the appropriate sampling tables.

6. ***Can the Transfer Test™, TTJunior™, or TTMicro™ be used to detect microbial contamination in antibiotics?***

   Yes. The biggest concern is reducing the concentration of residual antibiotic agents in the tester's fluid path to a level where it does not interfere with culturing possible microbiological contaminates. USP suggests rinsing the filter sufficiently to remove these trace amounts of antibiotic agents.

   Transfer Test™'s and TTJunior™'s unique filter design helps the rinsing process. The filter membrane is held in the plastic support by insert molding. During manufacturing, molten plastic fills the microscopic pores around the filter's edges. Filling these pores prevents residual traces of antibiotics from being trapped in the filter's edge during rinsing.

7. ***Which sterility test products meet the USP's definition of "Membrane Filtration", described as the method of choice in chapter <797>?***

   The Transfer Test™, TTJunior™, or TTMicro™ are "Membrane Filtration" sterility test devices. Examples of the second choice for sterility testing, "Direct Inoculation of the Culture Medium", are the Double Check™ and Clear Check™ products.

Double Check™

1. *What is the purpose of the Double Check™?*

Double Check™ (#TL100) detects microbial contamination in sterile admixtures that contain suspensions or emulsions. Suspensions and emulsions are naturally turbid. That prevents visualizing microbial growth in the liquid media. Double Check™ reduces this problem by having sterile agar paddles inside the bottle of media, separate from the liquid media, on which growth can be observed.

Clear Check™ 10mL Tubes

1. *What is the purpose of the 10mL tubes of TSB (#TT010) if the preferred method of testing for sterility in compounded medications is "full titration"?*

Some drugs are dispensed in containers where it is difficult to transfer the contents through a filter test device. Respiratory drugs and eye drops are good examples. These drugs can be carefully transferred into the 10mL tubes by removing and replacing the screw cap. Some viscous drugs can not be filtered using a 0.22 micron membrane. They can be injected directly into the TSB media via the needle access port on the top of the screw cap.

Incubation of Samples

1. *Which Cultivate™ products require incubation at other than room temperature, 20 to 25°C?*

Clear Check™ liquid media may yield faster results at elevated temperatures but incubation is not needed for consistent, reliable results. Refer to USP Chapter <797> for more details. Contact™ products should be incubated between 30 to 35°C.

2. *How long do samples have to remain in the incubator in order to yield reliable results?*

According to USP <797> the TouchScience should be incubated at 30 to 35°C and observed for 48 to 72 hours.

USP recommends incubating sterility tests using Soybean-Casein Digest Medium (TSB), like the Double Check™, Transfer Test™, TTJunior™, TTMicro™, and all Clear Check™ units at 22.5°C +/- 2.5°C. They should be examined at 48 hours and daily thereafter.

Positives should be removed immediately. Units not showing growth should remain in the incubator for not less than 14 days.

Testing 70% Isopropyl Alcohol (IPA)

1. *Which Cultivate™ products are appropriate for periodically testing sanitizing agents like IPA for microbial contamination?*

Introduce an aliquot of the sanitizing agent directly into TSB media like the Clear Check™ #TT010 tube or the #TV020 vial. Observe for growth for not less than 14 days.

Contact™

Microbial Contamination Monitoring System for Surfaces Testing and Gloved Fingertip Testing

Cultivate
A PARASOL MEDICAL PRODUCT

Important Benefits

- Easy to test uneven and difficult to reach surfaces
- Test gloved fingertips
- Finger grips on contact plate allow for easy handling and sampling
- Hinged paddle bends to fit even surfaces
- Long shelf life while being stored at room temperature
- Use for growth of common bacteria, yeast, & fungi

Contact™

Environmental Monitoring System

Product Information and Kit Options:

Catalog No.	Description	Kit Components
TD100	Double sided TSA (trypticase soy agar) growth media paddles for surface testing and gloved fingertip testing. Targets bacterial contamination. Per USP Chapter <797> media contains lecithin and polysorbate 80 formulated to inactivate many antimicrobial compounds.	10 Paddle Testers, 10 gummed labels, directions for use, and result log
MD300	Double sided MEA (malt extract agar) growth media paddles for surface testing and gloved fingertip testing. Targets bacterial contamination. Per USP Chapter <797> media contains lecithin and polysorbate 80 formulated to inactivate many antimicrobial compounds.	10 Paddle Testers, 10 gummed labels, directions for use, and result log

Refer to USP General Chapter <797> for recommended incubation times and temperatures

Contact™ Media Paddles

Directions for Use

Cat. #TD100

Figure 1

Glove Fingertip Sampling

Press fingertips and thumbs of both hands with enough pressure to create a light impression in the agar. Note: do not disinfect gloves directly before sampling.

Figure 2

Contact Inoculation

Press each side of the paddle firmly against the solid surface to be tested. Complete contact with the surface is accomplished with the hinged design.

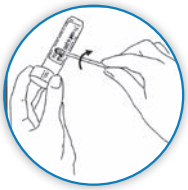


Figure 3

Swabbing

A sterile swab moistened with sterile water can be used to sample hard to reach surfaces. Rotate the swab while moving it over the sample area to pick up as much sample as possible. Then, firmly roll the swab over both agar surfaces.

Figure 4

Impaction Air Testing

Using the cap as a pedestal, position one side of the paddle to be perpendicular to the air flow. Use the same exposure duration every time the test is performed. Exceeding 2 hours may dry out the agar.

Incubation

After the paddle has been inoculated or exposed, carefully put it back into the vial and firmly secure the cap. Incubate at (USP<797>) 30°-35°C for 48 to 72 hours.

Interpretation of Results

Carefully pull the paddle out of the vial and visually examine under good lighting. Count the number of discrete colonies, if any, and record as colony forming units (CFUs). In order to make quantitative conclusions, the same sampling technique under similar conditions must be used for subsequent tests. The agar media promotes the growth of most aerobic fungi, yeast, and bacteria.

Storage, Stability and Destruction

Contact™ kits should be kept unopened at room temperature and protected from light. Do not allow the paddles to freeze. Any unused paddles showing microbial growth and all used paddles should be discarded in accordance with State and Federal regulations.

Solid Surface Sampling

Press each side of the paddle firmly against the solid surface to be tested. Complete contact with the surface is accomplished with the hinged design. Do NOT drag the agar across the surface.

Difficult to Reach Surface Sampling

A sterile swab moistened with sterile water can be used to sample hard to reach surfaces. Rotate the swab while moving it over the sample area to pick up as much sample as possible. Then, firmly roll the swab over both agar surfaces.

Staff Training

To demonstrate the importance of handwashing, press unwashed finger tips on one side of a Contact™ Media Paddle. Wash hands and press clean finger tips on other side of the paddle. Incubate and compare results.

TSA Media Ingredients: Tryptose, Yeast Extract, Dextrose, Agar Lecithin - Inactivates quaternary ammonium compounds. Polysorbate 80 - Inactivates phenolics, hexachlorophene and formaldehyde. Lecithin & Polysorbate 80 - synergistic effect that inactivates ethanol.

Certificate of Analysis -Available upon request.

Contact™ Media Paddles

Directions for Use

Cat. #MD300

Figure 1

Glove Fingertip Sampling

Press fingertips and thumbs of both hands with enough pressure to create a light impression in the agar. Note: do not disinfect gloves directly before sampling.

Figure 2

Contact Inoculation

Press each side of the paddle firmly against the solid surface to be tested. Complete contact with the surface is accomplished with the hinged design.

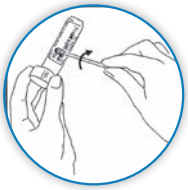


Figure 3

Swabbing

A sterile swab moistened with sterile water can be used to sample hard to reach surfaces. Rotate the swab while moving it over the sample area to pick up as much sample as possible. Then, firmly roll the swab over both agar surfaces.

Figure 4

Impaction Air Testing

Using the cap as a pedestal, position one side of the paddle to be perpendicular to the air flow. Use the same exposure duration every time the test is performed. Exceeding 2 hours may dry out the agar.

Incubation

After the paddle has been inoculated or exposed, carefully put it back into the vial and firmly secure the cap. Incubate at (USP<797>) 26°-30°C for 120 to 168 hours (5 to 7 days).

Interpretation of Results

Carefully pull the paddle out of the vial and visually examine under good lighting. Count the number of discrete colonies, if any, and record as colony forming units (CFUs). In order to make quantitative conclusions, the same sampling technique under similar conditions must be used for subsequent tests. The agar media promotes the growth of most yeasts, molds, and fungi.

Storage, Stability and Destruction

Contact™ kits should be kept unopened at room temperature and protected from light. Do not allow the paddles to freeze. Any unused paddles showing microbial growth and all used paddles should be discarded in accordance with State and Federal regulations.

Solid Surface Sampling

Press each side of the paddle firmly against the solid surface to be tested. Complete contact with the surface is accomplished with the hinged design. Do NOT drag the agar across the surface.

Difficult to Reach Surface Sampling

A sterile swab moistened with sterile water can be used to sample hard to reach surfaces. Rotate the swab while moving it over the sample area to pick up as much sample as possible. Then, firmly roll the swab over both agar surfaces.

Staff Training

To demonstrate the importance of handwashing, press unwashed finger tips on one side of a Contact™ Media Paddle. Wash hands and press clean finger tips on other side of the paddle. Incubate and compare results.

MEA Media Ingredients: Malt Extract, Dextrose, Peptone, Agar, Lecithin – Inactivates quaternary ammonium compounds. Polysorbate 80 – Inactivates phenolics, hexachlorophene and formaldehyde. Lecithin & Polysorbate 80 – synergistic effect that inactivate ethanol. Chloramphenicol - Increases the inhibitory properties of Malt Extract Agar to inhibit bacterial overgrowth while permitting successful selective isolation of fungi and yeasts

Certificate of Analysis – Available upon request.

Clear Check™

Aseptic Technique Training & Validation Aids

Cultivate
A PARASOL MEDICAL PRODUCT

Important Benefits

- Key to continuous quality improvement in IV pharmacies
- Pre-packaged media avoids mixing mess and false positives
- Available in several sizes and container types
- Test manual and automated processes
- Sensitive to a wide range of contaminates
- Access ports available to needle, IV, spike or luer lock connections
- Custom configurations to fit any QA program

Clear Check™

Aseptic Technique Training & Validation Aids

Product Information and Kit Options:

Catalog No.	Description	Kit Components
TBV120	PASS™ TSB media, 20mL vials, 100mL bags	5 vials, 5 bags
TBVA123	PASS 2™ TSB media, 3mL ampules, 20mL vials, 100mL bags	5 ampules, 5 vials, 5 bags
TA003	TSB media, 3mL glass ampule	20 ampules
TT010	TSB media, 10 mL glass tube, screw cap and needle access port	20 tubes
TV020	TSB media, 20mL vial, needle port	20 vials
TB100	TSB media, 100mL bag, needle & spike access ports	10 bags
TV100	TSB media, 100 mL vial, needle port	10 vials
TB500	TSB media, 500 mL bag, covered needle port & spike access port	10 bags
TS005	TSB media, 5cc syringe, luer lock	10 syringes
EV020	Sterile, empty 20mL vial, needle port	20 vials
EV100	Sterile, empty 100mL vial, needle port	10 vials

Each case contains special gummed labels and results log.

PASS™

Personal Aseptic Sampling System

For Low and Medium Risk Levels

Cat. #TBV120

1. This test requires 1 Clear Check™ partially filled minibag and 1 Clear Check™ 20 mL vial, each containing TSB. The test involves adding 20 portions of the vial to the minibag and is one of the more complicated procedures the operator will perform.

2. Using standard procedures, sanitize the work area and swab the vial and bag ports.

3. If the test is to be performed within a laminar flow hood, protect the injection ports of the containers by placing them at least 6 inches within the work area. Take caution not to interrupt the clean air flow.

4. Select a sterile 3, 5, or 6cc disposable syringe. Remove the syringe from its packaging and place it in the work space. Select 20 sterile needles (18G x 1" or smaller as appropriate).

5. Aseptically attach a needle to the syringe. Withdraw 1 mL of TSB from the vial and inject it into the minibag. Change the needle.

6. Repeat step (#5) 19 times, using 19 different needles with the same syringe and receiving minibag. After the final transfer there will be approximately 120 mL in the minibag.

   The complexity of the above procedure can be increased by transferring the contents of the minibag into another empty container at the end of step (#6). The receiving container should be a frequently used size. The transfer is accomplished using gravity and a standard sterile pharmacy tubing set.

7. Immediately inspect the TSB in the final container for particulates, corings, and fibers. These particles should not be recorded as microbial growth.

8. Label the final container and incubate at a temperature of 20° - 25°C or 30° - 35°C for 14 days.

9. Examine the TSB daily for turbidity. If turbidity is observed, the test is positive. A positive test sample indicates that the operator has introduced microorganisms into the "product" and has failed the test. If the TSB is clear, the test is negative and the operator has passed the test.

10. After 14 days, complete the required data in the PASS™ log.

11. Reevaluation should take place using the procedure above. The frequency of which depends upon the risk level being simulated.

PASS 2™

Personal Aseptic Sampling System

For Low and Medium Risk Levels

Cat. #TBVA123

1. This test requires 1 Clear Check™ ampule, 1 Clear Check™ partially filled minibag and 1 Clear Check™ 20 mL vial, each containing TSB. The test involves transferring the contents of an ampule to a vial and then adding 20 portions of the vial to the minibag. It is one of the more complicated procedures the operator will perform.

2. Using standard procedures, sanitize the work area and swab the vial and bag ports.

3. If the test is to be performed within a laminar flow hood, protect the injection ports of the containers by placing them at least 6 inches within the work area. Take caution not to interrupt the clean air flow.

4. Select a sterile 3, 5, or 6cc disposable syringe. Remove the syringe from its packaging and place it in the work space. Select 20 sterile needles (18G x 1" or smaller as appropriate).

5. Aseptically attach a needle to the syringe.

6. Draw up contents of the ampule and inject into the vial. Shake to mix indicator dye.

7. Withdraw 1 mL of TSB from the vial and inject it into the minibag. Change the needle.

8. Repeat step (#7) 19 more times, using 19 different needles with the same syringe and receiving minibag. After the final transfer there will be approximately 120 mL in the minibag

   The complexity of the above procedure can be increased by transferring the contents of the minibag into another empty container at the end of step (#6). The receiving container should be a frequently used size. The transfer is accomplished using gravity and a standard sterile pharmacy tubing set.

9. Immediately inspect the TSB in the final container for particulates, corings, and fibers. These particles should not be recorded as microbial growth.

10. Label the final container and incubate at a temperature of 20° - 25°C or 30° - 35°C for 14 days.

11. Examine the TSB daily for turbidity. If turbidity is observed, the test is positive. A positive test sample indicates that the operator has introduced microorganisms into the "product" and has failed the test. If the TSB is clear, the test is negative and the operator has passed the test.

12. After 14 days, complete the required data in the PASS™ log.

13. Reevaluation should take place using the procedure above. The frequency of which depends upon the risk level being simulated.

TTMicro™ System

Nondestructive, full filtration systems for testing small volume sterile drug products

Cultivate
A PARASOL MEDICAL PRODUCT

Important Benefits

- Prevents waste of expensive drugs
- Syringe to syringe or syringe to sterile container transfers
- Available in TSB or FTM media

TTMicro™ System

Product Information and Kit Options:

Catalog No.	Description	Kit Components
TF7S005	0.22u TTMicro hydrophilic filter units with female luer lock inlet and female luer lock outlet 5cc syringes of TSB growth media	10 filters, 10 Syringes w/5cc TSB Media, labels & log sheet
FF7S005	0.22u TTMicro hydrophilic filter units with female luer lock inlet and female luer lock outlet 5cc syringes of FTM growth media	10 filters, 10 Syringes w/5cc FTM Media, labels & log sheet

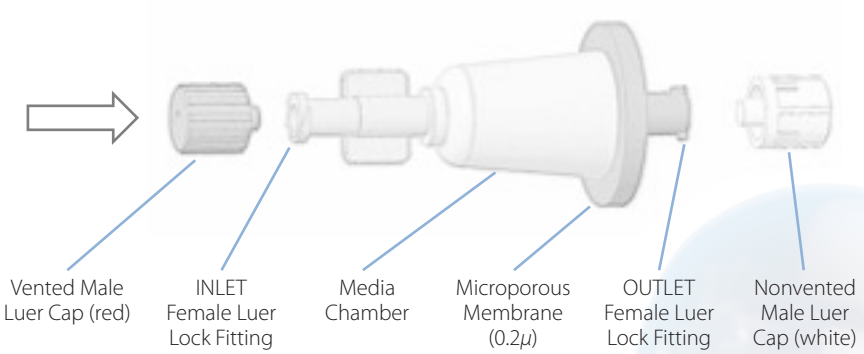
Each case contains special gummed labels, directions for use, and results label.

TTMicro™ System

Directions for Use

Cat. #TF7S005 – TSB Growth Media
Cat. #FF7S005 – FTM Growth Media

Use for testing IV solutions for microbial contamination under the conditions of growth described in the Directions For Use and for verifying aseptic technique.



- Single use only
- Manipulation should be performed in a controlled environment
- Use in hospital and homecare IV pharmacy Quality Assurance & Improvement programs
- Use aseptic techniques where appropriate
- For testing up to 120cc of liquid
- Use for testing clear solution, emulsions will not pass through the filter

Directions for Use

1. Remove and discard RED Vented Male Luer cap on INLET Female Luer Lock fitting on F700 Micro Filter.

2. Attach syringe containing fluid to be tested to the INLET Female Luer Lock fitting.

3. Remove and save WHITE Nonvented Male Luer cap from OUTLET Female Luer Lock fitting. Carefully position in laminar air flow to avoid contamination of inner surface of Male Luer cap.

4. Firmly attach a sterile, empty (receiving) syringe to the OUTLET Female Luer Lock. The empty syringe must have a capacity equal to or greater than the volume of solution in the syringe being tested.

5. Press plunger on syringe containing solution to be tested to transfer fluid through the F700 Micro Filter into the receiving syringe. Pull back syringe plunger slightly and press again to transfer any solution remaining in the filter housing.

6. Carefully remove and cap receiving syringe.
   Note: F700 Micro Filter is not intended to filter-sterilize (cold sterilize) contaminated solutions or admixtures made from non-sterile ingredients.

7. Replace WHITE cap on OUTLET Female Luer Lock fitting.

8. Remove empty syringe from INLET Female Luer Lock fitting

9. Attach syringe containing ClearCheck™ growth media to the INLET Female Luer Lock fitting.

   Note: The Soybean-Casein Digest and Fluid Thioglycollate Medium growth media are formulated according to current USP requirements for performing microbiological sterility tests.

10. Press plunger on growth media syringe to fill chamber on F700 Micro Filter.

    NOTE:
    Point syringe DOWN while pressing plunger. This will remove air from filter chamber

11. Leave growth media syringe attached to the F700 Micro Filter.

12. Complete, then attach gummed label to ClearCheck™ syringe.

13. Incubation, USP Chapter Sterility Test Method
    Soybean-Casein Digest Medium (TSB) Incubate at 22.5+/-2.5˚C for not less than 14 days.
    Fluid Thioglycollate Medium (FTM) Incubate at 32.5+/-2.5˚C for not less than 14 days.
    If the test is positive before 14 days of incubation, further incubation is not necessary.

14. Remove gummed label from F700 Micro Filter and record results in TTMicro™ log.

15. Discard used F700 Micro Filters in a safe manner.

    IMPORTANT:
    Do not use to test blood, blood products, or emulsions.
    Do not use if protective covers are missing or not in place.
    Do not use for direct infusion into patient.
    Do not resterilize or reuse, discard after use.

Cultivate™ Syringe Filters

High Performance Syringe Filters

Cultivate
A PARASOL MEDICAL PRODUCT

Important Benefits

- High Flow Rate
- Filter more liquid before clogging
- Male and female luer lock fittings
- Non-leaching EtO residuals
- Protects valuable solutions
- Secure connections prevent leaking of hazardous or expensive drugs
- Custom color housing prevents using incorrect filter

Cultivate™ Syringe Filters

Sterile High Performance hydrophilic filters

Specifications:

Housing material: Modified acrylic (blue)

Pore size: 0.2 micron

Effective filtration area: 2.8 cm2

Maximum pressure: 75 psi

Inlet connection: Female luer lock

Flow Direction: Bidirectional

Membrane material: Polyethersulfone

Diameter: 25mm

Fluid Retention: <0.05mL

Bubble Point (water): >45 psi

Outlet Connection: Male luer lock

Packaging: Blister pack

Product Information and Kit Options:

Catalog No.	Description	Kit Components
HP1002	0.22µ hydrophilic filter with female luer lock inlet and male luer lock outlet, blue housing color	50 Filters

Cultivate™ Syringe Filter

Directions for Use

Cat. #HP1002-0.22µ Hydrophilic Filter

Quality Standards

Syringe Filters designed for rapid filtration, high throughputs, low protein binding and extensive drug compatibility to assure quality control in drug preparation and intravenous, epidural and subcutaneous syringe bolus drug administration. Non-pyrogenic and non-cytotoxic.

Sterilization: Gamma irradiation
Membrane: Low protein binding polyethersulfone
Biocompatibility: Meets USP Biological Reactivity Testing in vivo <88>
Usage: Sterile, singe use only

Directions for Use

1. Prior to drawing your solution, draw 1mL of air into a 10-20mL syringe. The air will minimize fluid retention within the filter. CAUTION: Syringes smaller than 10mL can cause excess pressure on the filter which can exceed the maximum operating pressure.
2. Remove the seal and attach the filled syringe to the filter (avoid over tightening).
3. Applying gentle pressure helps assure maximum throughput. *CAUTION: If particulate accumulates on the filter causing excessive resistance, apply a new filter to avoid a housing rupture which results in particulate to contaminate the filtrate*

Integrity Test using Bubble Point Method

Note: The following procedure was developed for testing Cultivate™ hydrophilic filters. Refer to a filter manufacturer's specifications when testing any other filter.

1. Use a Cultivate™ Syringe Filter that was previously used in the process of sterilizing.
2. Fill a 10-20mL syringe with 5-10mL of clean water and flush the used filter.
3. Disconnect the flushed filter from the syringe and connect it to the male luer of the PSI gage.
3. Draw approximately 10mL of air into the syringe and attach to the female luer of the PSI gage.
4. Slip the tubing over the filter's male luer, then immerse tubing end into a beaker of water.
7. Hold syringe in down position, applying pressure until a steady stream of bubbles emerge.
8. If it reaches the bubble point beyond 45 PSI than the filter has passed the integrity test.
9. If it reaches the bubble point before 45 PSI than the filter has failed the integrity test.

Cultivate™ Vial Adapters

Safely fill syringes without needles

Cultivate
A PARASOL MEDICAL PRODUCT

Important Benefits

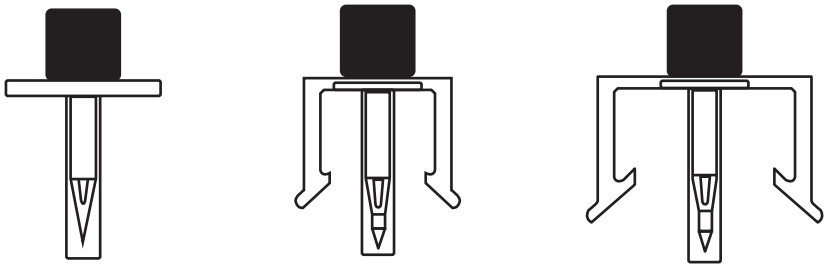
- Fits all multi-dose vials
- Needle-free access when filling syringes
- Convenient lock on vial improves aseptic technique
- Expedites solution transfer with large lumen

Cultivate™ Vial Adapters

Product Information and Kit Options:

Catalog No.	Description	Kit Components
N001	Universal vial adaptor with female luer slip outlet, no locking flanges (for use on any single or multi-dose vial)	50 vial adaptors
N002	Small vial adaptor, female luer slip outlet with locking flanges (for use on vials with ½ inch, 13mm tops)	50 vial adaptors
N003	Large vial adaptor, female luer slip outlet with locking flanges (for use on vials with ¾ inch, 20mm tops)	50 vial adaptors

Shown actual size



N001 **N002** **N003**

PARASOL MEDICAL LLC

SPECIALTY MEDICAL DEVICES FOR THE EVER-CHANGING HEALTHCARE INDUSTRY

Parasol Medical is a premier developer of specialty medical devices designed to serve the ever-changing healthcare industry. Our greatest priority is making the lives of healthcare workers easier and improving patient outcomes.

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Smart, safe solutions to protect patients and facilities from the problems associated with falls

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PARASOL MEDICAL LLC

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