



## PureCeption™ Sperm Separation Media

For laboratory procedures only; other uses must be qualified by the end user.

| Product Description   | REF Number | Unit Size  |
|---|------------|------------|
| PureCeption™ 40%  | ART-2040   | 100 mL     |
| PureCeption™ 80%  | ART-2080   | 100 mL     |
| PureCeption™ 100% Isotonic Solution                         | ART-2100   | 100 mL     |
| PureCeption™ 4-Determination Kit with Sperm Washing Medium  | ART-2004   | 3 x 12 mL  |
| PureCeption™ 16-Determination Kit with Sperm Washing Medium | ART-2016   | 12 x 12 mL |
| PureCeption™ 24-Determination Bi-Layer Kit                  | ART-2024   | 12 x 12 mL |

### DESCRIPTION

An 40% (v/v), 80% (v/v), or 100% (v/v) sterile colloidal suspension of silica particles stabilized with covalently bound hydrophilic silane supplied with HEPES-buffered Human Tubal Fluid (HTF). The components of this kit will allow for the highly efficient separation of motile sperm from the ejaculate of most semen specimens. It is fast, cost-effective, and needs very little equipment or expertise to perform.

### MATERIALS PROVIDED IN THE SPERM SEPARATION MEDIA KIT

#### 1. Lower Phase Gradient:

80% PureCeption™ with HEPES-buffered Human Tubal Fluid (HTF-HEPES).

#### 2. Upper Phase Gradient:

40% PureCeption™ with HEPES-buffered Human Tubal Fluid (HTF-HEPES).

### 3. Sperm Washing Medium\*:

HEPES-buffered Human Tubal Fluid with Human Serum Albumin, 5 mg/mL.

\*Sperm Washing Medium is not included in the 24-determination kit (available as Quinn's Sperm Washing Medium, REF ART-1005/1006).

### PACKAGING, STORAGE, AND EXPIRATION

PureCeption™ is assembled in 4-, 16-, and 24-determination kits. Each determination uses 2.0 mL of Upper Phase (40%) and 2.0 mL of Lower Phase (80%). Sperm Washing Medium may also be supplied. PureCeption™ gradients are also available in 100-mL volumes.

ART-2004 is assembled with 1 x 12-mL PureCeption™ 40% (v/v), 1 x 12-mL PureCeption™ 80% (v/v), and 1 x 12-mL Sperm Washing Medium.

ART-2016 is assembled with 4 x 12-mL PureCeption™ 40% (v/v), 4 x 12-mL PureCeption™ 80% (v/v), and 4 x 12-mL Sperm Washing Medium.

ART-2024 is assembled with 6 x 12-mL PureCeption™ 40% (v/v) and 6 x 12-mL PureCeption™ 80% (v/v).

All PureCeption™ components must be stored at 2°C to 8°C. The product is stable until the expiration date shown on the label or within 30 days of the Date of First Use provided that proper aseptic procedures have been observed by the user:

- Remove desired volume of product using aseptic procedures.
- Once product has been removed from the original container, reseal the container to ensure a tight seal. Write the date the product was first opened on the product label. Do not use product longer than 30 days after opening the container.
- Once removed, do not return any volume of product to the original container.

D. Once the product has been opened, store the sealed container at 2°C to 8°C.

E. Do not use if the product becomes discolored, cloudy, turbid, or shows any evidence of microbial contamination.

One-cell MEA tested and passed with 80% or greater blastocyst. USP Endotoxin gel clot tested and passed with <1 EU/mL.

A Certificate of Analysis is available for this product.

### USER QUALITY CONTROL

- Examine the PureCeption™ solutions. Do not use any medium that appears discolored. Upper Phase (40%) and Lower Phase (80%) PureCeption™ should have normal opalescent appearance.
- To avoid contamination:
  - Enter all bottles using sterile technique within a suitable sterile environment.
  - Do not use the same sterile pipette or needle to reenter a bottle of medium.
  - When entering a bottle through the stopper via a needle, use a sterile needle. Wipe the stopper with alcohol and air dry. Use a new sterile needle for each gradient.

### MATERIALS REQUIRED BUT NOT PROVIDED

- Sterile disposable polystyrene 15-mL conical centrifuge tube.
- Sterile 5-mL disposable pipettes (graduated/transfer) or 3-cc syringes with 15°/21g needles.
- Centrifuge/fixer or horizontal. Must be able to operate for up to 30 minutes at 250g to 750g.
- 37°C incubator or water bath.
- Counting chamber.
- Microscope with x10 and x20 objectives.

### PROCEDURE FOR FRESH SEMEN SAMPLES

- Bring all components of the kit and the semen sample to room temperature before using. This will avoid a cold "shock" to the spermatozoa.
- To prepare the single bilayered gradient:
  - Transfer 2.0 mL of Lower Phase (PureCeption™ 80%) into the conical tube.
  - Using a pipette or syringe, layer 2.0 mL of Upper Phase (PureCeption™ 40%) on top of the Lower Phase. This is done by carefully contacting the surface of the Lower Phase with the tip of the pipette or syringe needle.
  - Allow only the tip of the pipette or bevel of the needle to remain submerged. Slowly dispense the Upper Phase by lifting the pipette or needle up the side of the tube as the level of the Upper Phase rises. An interface separating the two layers will be observed. This single bilayered gradient is stable for 1 hour.

**NOTE:** Use the PureCeption™ gradient within 1 hour after creating it. Otherwise, the two phases will eventually blend into each other and a sharp interface will not exist. Considerable particulate debris accumulates at the Upper/Lower Phase interface. This is considered a valuable part of the PureCeption™ system.
- Gently place up to 2.5 mL of liquefied semen onto the Upper Phase using a pipette or syringe.
- Centrifuge for 20 minutes at 350g to 400g (or up to 750g for highly viscous samples). When first centrifugation is completed, you may not be able to see a pellet but it is essential to continue the procedure.
- Following centrifugation, remove all layers except the lowest portion (approximately 0.3 mL).

6. Add 2 to 3 mL of Sperm Washing Medium and resuspend the pellet.
7. Centrifuge for 4 to 8 minutes at 250g. The higher number of sperm will require the maximum 8-minute centrifugation time to ensure a complete and thorough sperm wash.
8. Remove supernatant and resuspend the pellet in 0.5 mL of Sperm Washing Medium.
9. Sample is now ready for recount and estimate of motility.

## PROCEDURE FOR FROZEN SPERM SAMPLES

Frozen-thawed sperm tend to be less vigorous than fresh sperm. For this reason, use 1.5 mL of Upper and Lower Phases instead of 2.0 mL volumes recommended for fresh sperm.

1. Bring all components of the kit and the semen sample to room temperature before using. This will avoid a cold “shock” to the spermatozoa.
2. To prepare the single bilayered gradient:
  - a. Transfer 1.5 mL of Lower Phase (PureCeption™ 80%) into a conical tube.
  - b. Using a pipette or syringe, layer 1.5 mL of Upper Phase (PureCeption™ 40%) on top of the Lower Phase. This is done by carefully contacting the surface of the Lower Phase with the tip of the pipette or syringe needle.
  - c. Allow only the tip of the pipette or bevel of the needle to remain submerged. Slowly dispense the Upper Phase by lifting the pipette or needle up the side of the tube as the level of the Upper Phase rises. An interface separating the two layers will be observed. This single bilayered gradient is stable for 1 hour.

**NOTE:** Use the PureCeption™ gradient within 1 hour after creating it. Otherwise, the two phases will eventually blend into each other and a sharp interface will not exist. Considerable particulate debris accumulates at the 40%/80% interface. This is considered a valuable part of the PureCeption™ system.

3. Gently place the thawed semen sample onto the Upper Phase using a pipette or syringe.
4. Centrifuge for 20 minutes at 350g to 400g. When first centrifugation is completed, you may not be able to see a pellet but it is essential to continue the procedure.
5. Following centrifugation, remove all layers except lowest portion (approximately 0.5 mL).
6. Add 2 to 3 mL of Sperm Washing Medium and resuspend the pellet.
7. Centrifuge for 8 minutes at 250g.
8. Remove supernatant and resuspend the pellet to 0.5 mL of Sperm Washing Medium.
9. Sample is now ready for estimate of count and motility.

**Each laboratory should make its own determination of which medium and protocol to use for each particular procedure.**

Information on specific aspects of IVF and embryo culture is available in our Product Catalog (cat. #80572).

## TROUBLESHOOTING

1. Occasionally, samples that do not liquefy properly and remain too viscous to pass through the gradient will be encountered. Increasing the centrifugal force up to but no more than 750g will aid in separating the sperm in these cases. Pelleting motile sperm from highly viscous semen does not usually present a problem using the PureCeption™ system.

2. The most important semen parameter contributing to a pellet of highly motile sperm is sperm progression. The higher the number of progressively motile sperm in the initial sample, the greater the number of sperm you will have in the final pellet. If sperm percent motility or progression is below WHO guidelines for normal semen parameters, you may be able to compensate for shortcomings in the initial semen analysis by using 1.0 mL of both 40% and 80% PureCeption™ instead of 2.0 mL of each. You may also want to leave the last 0.5 to 0.7 mL of the postcentrifugation Lower Phase above the pellet and wash the sperm caught in transit through this portion of the Lower Phase. If this is done, be sure to double the volume of Sperm Washing Medium in order to dilute out this remaining Lower Phase material.

## QUALITY CONTROL

All PureCeption™ solutions are tested using one-cell mouse embryo culture and endotoxin assays to ensure quality and safety. However, it is recommended that in-house quality control be performed with each lot.

## PRECAUTIONS AND WARNINGS

PureCeption™ comes packaged with tamper-proof seals and caps. If the seal is broken or the cap loose, do not use product.

PureCeption™ has a naturally cloudy appearance. Do not use product if it shows any evidence of particulate matter or contamination. This may be evident by extreme cloudiness or discoloration.

PureCeption™ should remain tightly capped when placed in a CO<sub>2</sub> incubator to avoid pH changes.

When using this product you must use aseptic techniques to avoid contamination.

This product contains albumin, a derivative of human blood. All donors used in its manufacture were individually tested and found to be nonreactive for

hepatitis B surface antigen (HBsAg) and antibodies to hepatitis C virus (HCV) and human immunodeficiency virus (HIV) by approved testing methods. Donors of the source material have been screened for Creutzfeldt-Jakob disease (CJD). Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of CJD is also considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

**Caution:** Federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

## RELATED PRODUCTS

SAGE Assisted Reproduction Products™ has a full line of products for the Reproductive Medicine Specialist. Please call or write for specific information or to receive a copy of our current catalog. For technical questions, or to reach our Customer Service Department, call the SAGE Support Line at the number below.

PureCeption™ is a trademark of CooperSurgical, Inc.  
**Patrick Quinn, PhD, HCLD, SAGE IVE, Inc.**

Call the **SAGE SUPPORT LINE** at:  
**1-800-243-2974 or 1-203-601-5200**



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