



SAR HEALTHLINE (P) LTD

PureCeption™ Sperm Separation Medium

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

<u>Product Description</u>	<u>Catalogue Code</u>	<u>Unit Size</u>
PureCeption™ 40%	ART-2040	1 x 100mL
PureCeption™ 80%	ART-2080	1 x 100mL
PureCeption™ 100% Isotonic solution	ART-2100	1 x 100mL
PureCeption™ 24-Determination Bi-Layer Kit	ART-2024	12 x 12mL

INTENDED USE

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 *(not in the 24 determination kit)*

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

PACKAGING, STORAGE AND EXPIRATION

PureCeption™ is assembled in 24- determination kits. Each determination uses 12mL of Upper Phase (40%) and 12mL of Lower Phase (80%). PureCeption™ gradients are also available in 100mL volumes. **ART-2024** is assembled with 6 x 12mL PureCeption™ 40%(v/v), and 6 x 12mL PureCeption™ 80%(v/v). All PureCeption™ components must be stored at 2-8°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.

- A. Remove desired volume of product using aseptic procedures.
- B. 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.
- C. 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 2-8°C.
- E. Do not use if the product becomes discoloured, 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

1. Examine the PureCeption™ solutions. Do not use any medium that appears discoloured. Upper Phase (40%) and Lower Phase (80%) should have normal opalescent appearance.
2. To avoid contamination:
 - a. Enter all bottles using sterile technique within a suitable sterile environment.
 - b. Do not use the same sterile pipette or needle to re-enter a bottle of medium.
 - c. 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

1. QUINN'S® Sperm washing media.
2. Sterile disposable polystyrene 15-mL conical centrifuge tube.
3. Sterile 5-mL disposable pipettes (graduated/transfer) or 3-cc syringes with 1.5"/21g needles.
4. Centrifuge/fixed or horizontal. Must be able to operate for up to 30 minutes at 250g to 750g.