












## Water for Assisted Reproductive Technologies (A.R.T.) Use

Catalog No. 9307

1 L

For assisted reproductive procedures.

### Glossary of Symbols\*:

	Catalog Number
	Lot Number
	Sterilized using aseptic processing techniques (filtration)
	Expiration: Year - Month - Day
	Caution, consult accompanying documents
	Consult instructions for use
	Storage Temperature: 15-30°C
	Manufacturer
	U.S. Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

\*Symbol Reference - EN ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labeling.

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### **INDICATION FOR USE**

Water for ART is intended for use in ART laboratory procedures requiring a non-pyrogenic high purity grade of water. Water for ART use is produced from sterile Ultra-Pure water that meets "Water for Injection" criteria in accordance with USP 24.NF 19.

### **DEVICE DESCRIPTION**

Sterile filtered distilled water. See Certificate of Analysis for specifications.

### **QUALITY ASSURANCE**

Water for ART which is membrane filtered and aseptically processed according to manufacturing procedures which have been validated to meet a sterility assurance level (SAL) of  $10^{-3}$ .

Each lot of Water for ART is tested for:

- Endotoxin by LAL methodology
- Biocompatibility by Mouse Embryo Assay
- Sterility by the current USP Sterility Test <71>

All results are reported on a lot-specific Certificate of Analysis which is available upon request.

### **DIRECTIONS FOR USE**

NOT INTENDED FOR INJECTION BY USUAL PARENTERAL ROUTES IN HUMANS OR ANIMALS.

For additional details on the use of this product, the laboratory should consult its own standard procedures and protocols which have been specifically developed and optimized for the individual medical program.

### **STORAGE INSTRUCTIONS AND STABILITY**

Store the unopened bottles at room temperature for up to six months from date of manufacture. When stored as directed, the product is stable until the expiration date shown on the bottle.

1. Aspirate desired volume using aseptic procedures.
2. Once the desired volume has been removed from original bottle, do not return any volume of product to the original bottle.
3. Tightly reseal bottle.
4. After opening, bottle should be tightly re-sealed and stored at room temperature, away from light.

### **PRECAUTIONS AND WARNINGS**

Do not use any bottle of water that shows evidence of particulate matter or microbial contamination.

To avoid problems with contamination, practice aseptic techniques and discard minimal amounts of excess product remaining in the bottle.