

ProteX™

Semen Collection Cup



CLINIC INSTRUCTIONS FOR USE

- 1  Ensure outer packaging is sealed & intact.
- 2  Provide ProteX™ and the ProteX™ patient identification label to a sperm producing patient or partner.
- 3  When receiving the collected specimen from the patient or partner in the ProteX™ cup, ensure the lid of the ProteX™ cup is securely closed and verify the patient identifying information according to your internal specimen acceptance procedures.
- 4  Upon completion of sample evaluation, analysis, and/or processing, discard the ProteX™ cup in accordance with your clinics and/or local or state's biological specimen disposal regulations.

INTENDED USE

ProteX™ is a single-use semen specimen collection cup intended to collect, contain, and transport a semen specimen for laboratory evaluation or assisted reproduction.

DEVICE DESCRIPTION

ProteX™ is an insulated cup that incorporates a holding well designed to reduce the effects of the temperature decrease from specimen collection through processing. It is used to collect and contain ejaculate samples for laboratory evaluation or assisted reproduction.



PRECAUTIONS

- Do not use if packaging is damaged. Damaged packaging could indicate a loss of sterility, or could result in a damaged ProteX cup. Using a ProteX cup from damaged packaging could impact ProteX performance and/or the semen sample.
- Practice universal precautions when handling human body fluids.
- Do not re-sterilize ProteX. ProteX could become damaged if re-sterilized, which could impact ProteX performance and/or the semen sample.
- Do not re-use ProteX. Re-using ProteX will result in a contaminated semen sample.
- Avoid direct contact between the inside of the ProteX collection cup and the genitals. Touching the ProteX cup to genitalia could introduce skin-based bacteria to the semen sample and contaminate the sample.
- Do not refrigerate the semen sample collected in the ProteX cup. Refrigerating the semen sample will reduce sample quality.

STORAGE & REPORTING

Store unused devices in a clean, dry location away from direct sunlight and temperature extremes, following the package label.

To report a product issue, complaint, or adverse event associated with the use of ProteX™, contact RSI at 800-465-0368 | support@reproductive.solutions | rsifertility.com

STERILIZATION

ProteX is sterilized using gamma radiation.

LEGAL MANUFACTURER:



RSI Technology Group, LLC
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Frisco, Texas 75034
Rsifertility.com

Glossary of Symbols

Source: ISO 15223-1 and ISO 7000

	Manufacturer
	Date of Manufacture
	Country of Manufacture
	Batch Code
	Catalog Number

	Sterilized using irradiation
	Do not resterilize
	Do not use if package is damaged and consult instructions for use
	Keep dry
	Unique device identifier

	temperature limit
	Do not reuse
	Consulting instructions for use or consult electronic instructions for use
	Caution
	Medical Device

