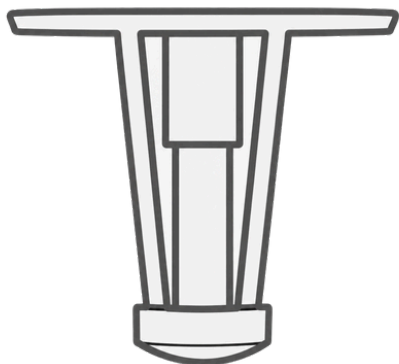




PREPARATION:

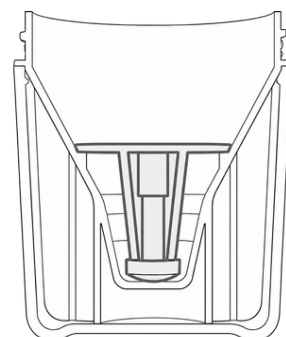
Place the ProteX™ Semen Collection Cup with the previously collected semen sample in it on a stable, flat, undisturbed location in the laboratory to prevent cup movement during NovoSort® device insertion and semen sample processing.

Determine the correct quantity of media to be added to NovoSort® by referring to Table 1.

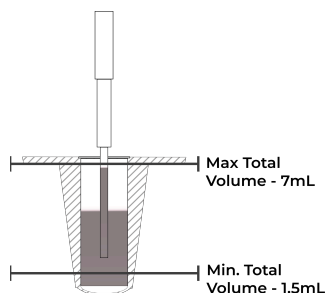
NovoSort® Media Chart	
Total Semen Volume (mL)	Media Added to Novosort (mL)
1.5 - <2.0mL	0.75mL
2.0 - <3.0mL	1.00mL
3.0 - <4.0mL	1.25mL
4.0 - <7.00mL	1.50mL

Table 1

- Total semen volume= native specimen only or native specimen with 1mL of media.
- Max processing volume = 7mL. If above, pipette off enough sample to below 7mL.
- Min processing volume = 0.5mL. Must add 1mL of media to achieve a total of 1.5mL.



- 1 Ensure NovoSort® packaging is sealed & intact.
- 2 Carefully open the NovoSort® package.
- 3 While holding NovoSort® in one hand, use the other hand to pipette and dispense the determined volume of media into the center inlet.
 - Note: Media must be inside of NovoSort® prior to placing NovoSort® into the semen sample.
- 4 Gently place the NovoSort® device into the semen sample within the ProteX™ Semen Collection Cup.
 - Note: DO NOT jostle the cup during processing as it can disturb the surface tension, which may result in less than expected recovery of motile sperm.
- 5 Allow sample to process undisturbed for the desired time based on the procedure to be conducted with the sperm sample:
 - ICSI = 15 minutes
 - IUI = 30 minutes
 - Max processing time = 60 minutes
- 6 Withdraw the volume of highly motile sperm for treatment from the middle of the NovoSort® using a retrieval pipette.
 - Best practice includes gently inserting the pipette until you find the bottom of the NovoSort® device. Then pull back slightly, landing the middle of the column to withdraw the sperm.
 - Note: DO NOT pull your specimen from the very top or the very bottom of the device. Doing so may result in a less than desired concentration of motile sperm.
 - Note: Ensure the retrieval pipette does not make contact with the NovoSort® mesh. Doing so may break the liquid surface tension, causing a mixing of fluids and less than expected recovery of motile sperm.
 - Note: RSI recommends using a gentle transfer pipette, glass pipette, micropipette, multi-channel pipette, or IUI catheter to draw up the processed sample.



- Upon completion of semen sample processing, discard the NovoSort® and ProteX™ cup in accordance with clinic and/or local or state biological specimen disposal requirements.

INTENDED USE

NovoSort® is intended to isolate motile sperm from other components of a fresh (i.e. not previously frozen) semen specimen prior to use in intrauterine insemination (IUI) and intracytoplasmic sperm injection (ICSI) procedures.

DEVICE DESCRIPTION

NovoSort® is a sterile, single-use plate insert designed for exclusive use with the ProteX™ Collection Cup to isolate motile sperm from other components of a fresh (i.e. not previously frozen) semen specimen prior to use in intrauterine insemination (IUI) and intracytoplasmic sperm injection (ICSI) procedures.

During operation, NovoSort® applies controlled fluid movement and separation principles to process a human semen specimen and facilitate the isolation of a sperm fraction enriched in motile sperm. The resulting sperm preparation may be used in subsequent intrauterine insemination (IUI) or intracytoplasmic sperm injection (ICSI), an assisted reproductive technology (ART) procedure.

PRECAUTIONS



- NovoSort® must be used only by properly trained operators.
- Do not use if packaging is damaged. Damaged packaging could indicate a loss of sterility, or could result in a damaged NovoSort®. Using a NovoSort® from damaged packaging could impact NovoSort® performance and/or the semen sample.
- Practice universal precautions when handling human body fluids.
- Do not re-sterilize NovoSort®. NovoSort® could become damaged if re-sterilized, which could impact NovoSort® performance and/or the semen sample.
- Do not re-use NovoSort®. Re-using NovoSort® will result in a contaminated semen sample.

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 NovoSort®, contact RSI at 800-465-0368 | support@reproductive.solutions | rsifertility.com

STERILIZATION

NovoSort® is sterilized using gamma radiation.



LEGAL MANUFACTURER:
RSI Technology Group, LLC
2601 Network Blvd, Suite 202
Frisco, Texas 75034
Rsifertility.com

Glossary of Symbols
Source: ISO 15223-1 and ISO 7000

	Manufacturer
	Date of Manufacture
	Country of Manufacture
	Use by date
	Batch Code
	Catalog Number
	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner

	Sterilized using irradiation
	Single Sterile barrier system
	Do not resterilize
	Do not use if package is damaged and consult instructions for use
	Fragile, handle with care
	Keep dry
	Unique device identifier

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