thermoscientific

Instructions for Use of the Nunc™ IVF Center Well Dish and Nunc™ IVF ICSI Dish

REF 150260

REF 150265

Intended Use

Nunc™ IVF Center Well Dish

The Nunc™ IVF Center Well Dish is intended for preparing and culturing gametes or embryos for use in *In Vitro* Fertilization (IVF), gamete intrafallopian transfer (GIFT), or other in vitro fertilization procedures.

Nunc™ IVF ICSI Dish

The Nunc™ IVF ICSI Dish is intended for holding oocytes and sperm during fertilization via intracytoplasmic sperm injection (ICSI).

Instructions for Use

The use of these dishes must be defined and implemented by the standard operating procedures and policies of the IVF clinics to whom they are sold to.

Storage

Store at room temperature

Quality Control Specification

Parameter	Specification
USP <85> Limulus Amebocyte Lysate (LAL) Endotoxin	< 20 EU/device (0.5 EU/ mL)
Mouse Embryo Assay (MEA) 1-cell Mouse Embryo Assay (% blastocysts at 96 hours of culture)	≥ 80%
Human Sperm Survival Assay (HSSA) Test article sample spermatozoa initial forward progressive motility Test article sample spermatozoa with progressive motility at 24 hours	 ≥ 79% ≥ 70%

Precautions and Warnings

1. Disinfectants, such as alcohol, are known to reduce readability of the package printing. Consequently, we recommend assessing the suitability of your disinfecting solution, or documenting important product traceability information contained on the packaging prior to disinfection.
2. Federal Law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
3. Do not use the product if the product packaging is unsealed or damaged.
4. For single use only. Do not use after expiry date.
5. Do not use Hydrogen Peroxide with this product.

CE 2797 STERILE R Rx Only

www/thermofisher.com

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Made in USA

Symbols Glossary in accordance with ISO 15223-1:2016 and other standards

Symbol	Title of Symbol	Description of Symbol	Reference Number
	Manufacturer	Indicates the medical device manufacturer as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	5.1.1
	Authorized representative in the European Community	Indicates the authorized representative in the European Community	5.1.2
	Use-by date	Indicates the date after which the medical device is not to be used.	5.1.4
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	5.1.6
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation	5.2.4
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened	5.2.8
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure	5.4.2
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	5.4.3
	By Prescription Only for US	Indicates that US Federal Law restricts this device to sale by or on the order of a licensed practitioner	21 CRF 801.15(c)(1)(i)F
	European Conformity Mark	Indicates European technical conformity	768/2008/EC MDD