thermoscientific

Instructions for Use Nunc™ IVF ICSI Dish

These instructions are valid for:

Nunc™ IVF ICSI Dish

REF 150265

GTIN 00866630000410

Intended Use

Intended purpose/use	The Nunc™ IVF ICSI Dish is intended for holding oocytes and sperm during fertilization via intracytoplasmic sperm injection (ICSI).
Indications for use	In cases with male infertility, where there is a defect in sperm quality or sperm have difficulty penetrating the egg, IVF with intracytoplasmic sperm injection (ICSI) may be used.
Intended user group	Healthcare professionals.
Use environment	Hospitals, IVF clinics and laboratories.
Intended patient population	Females suited for *in vitro* fertilization.
Contraindications	No known contraindications have been identified. However, IVF should not be performed in women who have a significant risk of morbidity and mortality of pregnancy if IVF were successful.

Instructions for Use

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

Conditions of use

Nunc™ IVF ICSI Dish	
Transportation conditions	Ambient temperature (-40°C to 50°C or -40°F to 122°F)
Storage conditions	Room temperature (20°C to 26°C or 68°F to 77°F)

Limitation of use

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

Technical information

Disposal of the device must be handled according to local regulations.

This medical device complies with Medical Device Regulation (EU) 2017/745 Article 120.

Declaration of Conformity is available from the manufacturer.

⚠ Warnings and precautions

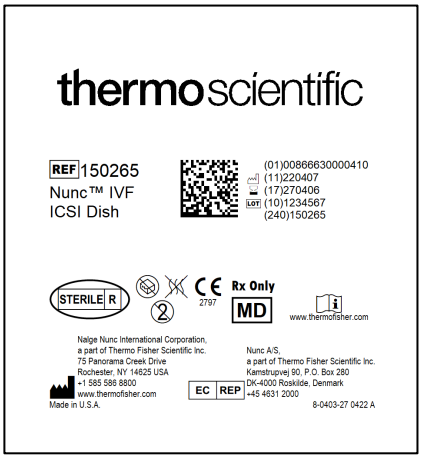
To ensure correct usage, familiarise yourself with the following warnings before using the device.

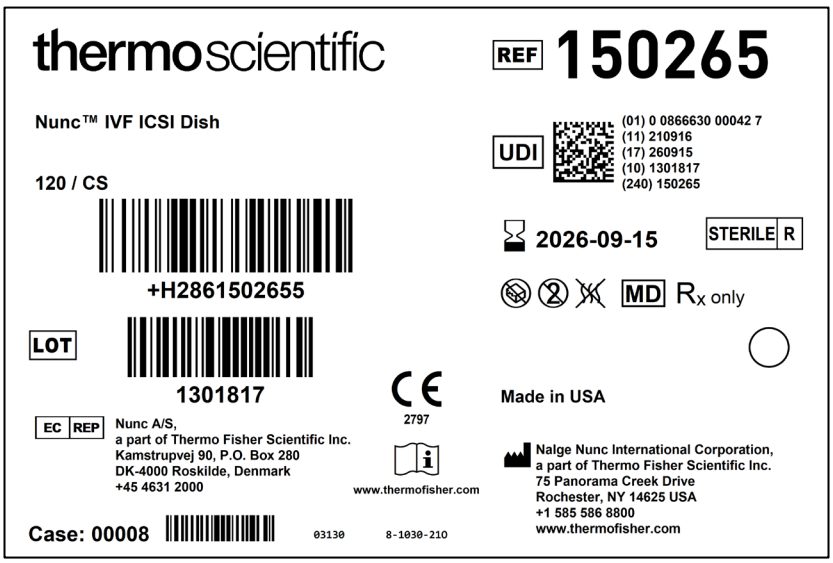
1. Disinfectants, such as alcohol, are known to reduce readability of the package printing. Consequently, we recommend assessing the suitability of your disinfecting solution, or documenting important product traceability information contained on the packaging prior to disinfection.
2. Federal Law (USA) 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.
5. Do not use after expiry date.
6. Do not use Hydrogen Peroxide with this product.

Report to the manufacturer and local competent authority if you experience unexpected operation or serious incident with the device during or because of its use. The manufacturer will support and if relevant report it to the competent authorities.

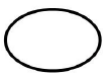
Quality Control Specifications

TEST	RELEASE LIMIT(S)
Pyrogen (endotoxin)	< 0.5 EU/mL
Irradiation Cert. Review	18.0 – 30.0 kGy
Mouse Embryo Assay	a) ≥ 70% 1-cell control embryos → blastocyst in 96hr b) ≥ 80% test embryos → 1-cell to 2-cell in 24hr c) ≥ 80% test embryos → 1-cell to blastocyst in 96hr **All must be met for beginning, middle and end for acceptance**.
Human Sperm Survival Assay	a) Control and test sperm initial forward progressive motility ≥ 79% b) Control and test sperm progressive motility at 24hr ≥ 70% **All must be met for beginning, middle and end for acceptance**.





Symbols Glossary in accordance with ISO 15223-1:2021 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.	Reg (EU) 2017/745
	*Medical device*	Indicates the item is a *medical device*.	5.7.7
	Non-pyrogenic	Indicates a medical device that is non-pyrogenic.	5.6.3
	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information.	5.7.10
	Single *sterile* barrier system	Indicates a single barrier system.	5.2.11
	Date of Manufacture	Indicates the date the medical device was manufactured.	5.1.3