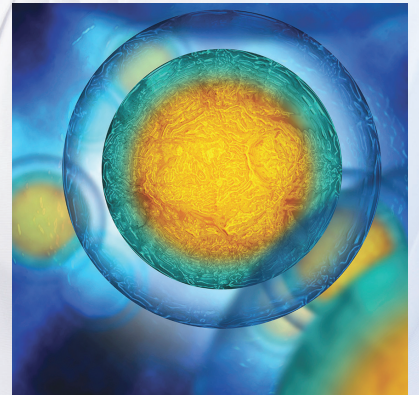


# Falcon® *In Vitro* Fertilization Products

Prepare. Store.  
Manipulate. Culture.  
Transfer.

*With Confidence*



**FALCON®**

*A Corning Brand*



# Reliable Products for a Consistent Process

## Specially designed for IVF and other assisted reproduction applications

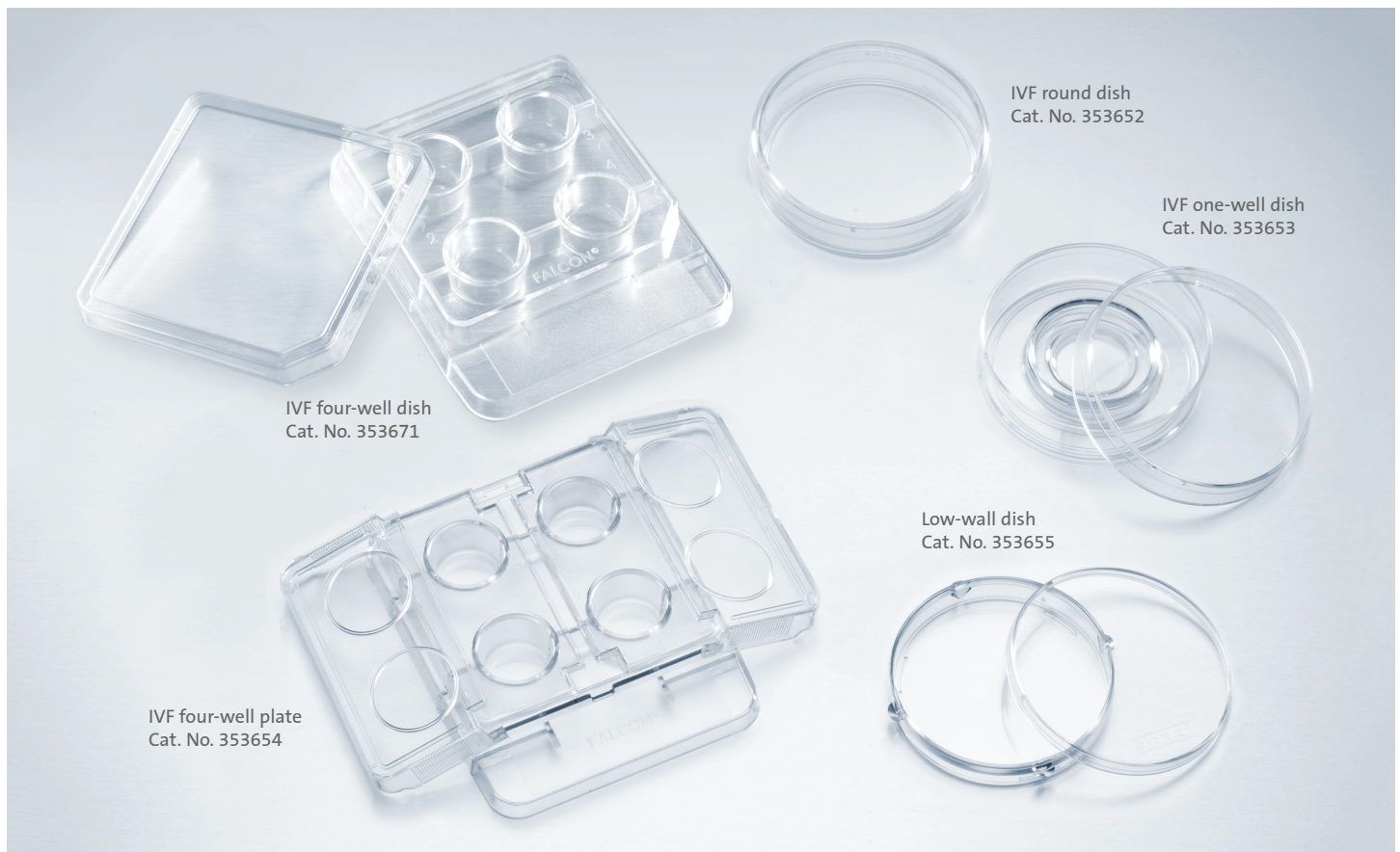
Due to the sensitive nature of *in vitro* fertilization (IVF) work, you must have precise, consistent, and highly reliable products that are designed to help you achieve normal growth and development, and ultimately, successful results.

Our innovative Falcon® IVF plasticware designs feature a sterile, flat, optically clear, single-use device for optimum manipulation and observation of ova and embryos. Falcon IVF dishes and four-well plates are designed to control heat transfer, keeping temperatures stable while you work.

The unique lid design of the IVF plate (Cat. No. 353654) reduces the risk of contamination and minimizes evaporation by providing access to two wells at a time, while two remain covered. Our IVF 4-well dish (Cat. No. 353671) has a single piece lid for easy removal. The wells are numbered, and a large writing patch allows clear sample identification. The four-well dish and plate are packaged in individual peel-open trays for sterile presentation. The Falcon IVF lids are designed for aseptic manipulation and consistent venting to maintain humidification (with the exception of the tight-fit lid of the Falcon low-wall dish).

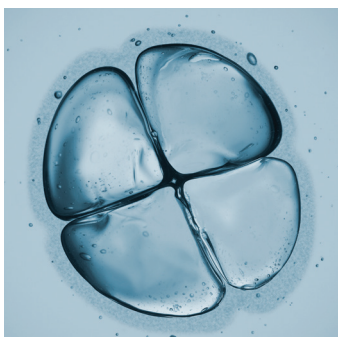
The Falcon low-wall dish has many of the same features as the other IVF products, except the dish is non-tissue culture (TC)-treated (non-wettable), for optimal media droplet consistency. The Falcon low-wall dish also makes the micromanipulation procedure easier to perform. This product is packaged in individually sealed blister compartments so one dish can be accessed at a time, and the remaining dishes are kept protected. Procedures requiring long term incubation are not recommended in the Falcon low-wall dish due to the tight lid fit, which results in low gas exchange rates.

Falcon IVF products were designed and created in partnership with embryologists, to ensure safe and reliable products, for sophisticated IVF and other assisted reproduction applications.



Products may not be available in all markets.

# Certified and Tested to Protect Your Precious Work



Pre-tested Falcon® IVF products were the first plasticware available certified sterile, nonpyrogenic, noncytotoxic, and nonembryotoxic. These pre-tested products save you time and expense in complying with the College of American Pathologists and the American Society for Reproductive Medicine recommended standards for IVF labs.

## Performance Tested

Each lot of Falcon IVF product is subjected to a performance test for growth with a mammalian cell line. A minimum of 90% confluency within 72 hours is required for lot acceptance.

## Quality Management and Control

Falcon IVF products are manufactured in compliance with the current version of the EN ISO 13485 Standard, the Medical Device Directive (MDD) 93/42/EEC as amended with 2007/47/EEC, and the FDA CFR 21 Part 820 and current Good Manufacturing Practices (cGMP).

## Medical Device Classification

- ▶ US FDA 510(k) cleared Class II medical device
- ▶ CE marked in compliance with the European Medical Devices Directive 93/42/EEC as Class IIa medical device

## Embryotoxicity

Each lot of Falcon IVF product is tested for embryotoxicity using the one-cell mouse embryo assay. A minimum of 75% of both test and control embryos must reach the hatched and/or expanded blastocyst stage in order for our products to be deemed nonembryotoxic and acceptable for product release.

## Sterility

Falcon IVF products are irradiated and dosimetrically released per the requirements of ANSI/AAMI/ISO 11137 and meet a minimum Sterility Assurance Level (SAL) of  $10^{-6}$ .

## Nonpyrogenic

Each lot of Falcon IVF product is tested and meets the criteria established in United States Pharmacopeia (USP) Chapter <85>, "Bacterial Endotoxins Test." The acceptance level for product is less than 0.1 EU/mL or 5 EU/device.

## Cytotoxicity

Thorough testing is conducted to qualify material resins to USP Class VI. Products are also tested and qualify as noncytotoxic per the requirements of ISO 10993-5, *Biological evaluation of medical devices – Tests for in vitro cytotoxicity*.

## Genotoxicity, Carcinogenicity, and Reproductive Toxicity

Products have been tested and demonstrated to be non-mutagenic and non-genotoxic per the requirements of ISO 10993-3, *Biological evaluation of medical devices: Tests for genotoxicity, carcinogenicity, and reproductive toxicity*.

Individual certificates, containing actual test results, are available for each lot by contacting your local Corning Life Sciences office after you receive your order.

# Supporting Preparation Through Fertilization and Transfer

Falcon® IVF plasticware is manufactured from virgin crystalline polystyrene that is tested for USP Class VI cytotoxicity and is ideal for applications like oocyte preparation as well as fertilization, culture, and transfer. You can feel confident in Falcon IVF products because they are certified and tested to ensure your embryo's viability during a complex process.

## Falcon IVF products feature:

- ▶ Flat dish bottoms for distortion-free optics and temperature stability and control
- ▶ Dish bottoms raised slightly to reduce abrasions and ensure optical clarity
- ▶ Bevel around interior perimeter to prevent settling in the corner (four-well plate and four-well dish)
- ▶ Lids designed for aseptic manipulation and consistent venting to maintain humidification
- ▶ Lids designed for consistent gas exchange except low-wall, tight fit lid which limits gas exchange
- ▶ Packaged in peel-open, medical-style packaging (four-well plate, four-well dish, and low-wall dish)
- ▶ Multi-unit bags have reseal tabs (60 mm dishes)

## Falcon IVF products are:

- ▶ Tissue culture (TC)-treated for a consistent hydrophilic surface with the exception of the low-wall dish, which is non-TC-treated (non-wettable) for optimal media droplet consistency
- ▶ Single-use
- ▶ Nonembryotoxic\*
- ▶ Nonpyrogenic
- ▶ Noncytotoxic
- ▶ Non-genotoxic
- ▶ Non-mutagenic
- ▶ Sterility Assurance Level (SAL) of  $10^{-6}$

\*Falcon IVF lids are not tested or certified for embryotoxicity.

## Ordering Information

### Falcon IVF Plasticware

Cat. No.	Description	Well Area (cm <sup>2</sup> )	Well Volume (mL)	Qty/Pk	Qty/Cs
353652	60 x 15 mm IVF round dish	24.1	23.0	20	500
353653	60 x 15 mm IVF one-well dish	2.45	2.5	20	500
353655	50 x 9 mm IVF low-wall dish, non-TC-treated	18.3	—	4	100
353654	17 x 11 mm IVF four-well plate	1.4	1.8	1	100
353671	17 x 11 mm IVF four-well dish (one piece lid)	1.4	1.8	1	100

**NOTE:** The lids of the Falcon IVF products are not certified nonembryotoxic.

**Warranty/Disclaimer:** For a listing of US medical devices, regulatory classifications or specific information on claims, visit [www.corning.com/resources](http://www.corning.com/resources). Products may not be available in all markets.

# CORNING

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