ISD - Instructions for Use (User Manual) - English

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Regulatory References	
ISO 13485:2016	4.2.3
ISO 20417:2021	All

User Manual ReSpindle

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Website: respindle.com
Basic UDI-DI: 87208929043ReSpindle4R

ReSpindle is a Class I medical device in accordance with Regulation (EU) 2017/745 (MDR).

Users can request a physical copy of the user manual by reaching out to the manufacturer's customer support: info@respindle.com

Symbol	Meaning	Reference
Manufacturer	Indicates the medical device manufacturer	ISO 15223-1:2021, 5.1.1
Date of manufacture	Indicates the date when the medical device was manufactured (software release date)	ISO 15223-1:2021, 5.1.3
Consult instructions for use	Indicates the need for the user to consult the instructions for use	ISO 15223-1:2021, 5.4.3
Caution	Indicates the need to consult the instructions for use for important cautionary information	ISO 15223-1:2021, 5.4.4
CE marking	Indicates conformity with applicable EU regulations	Regulation (EU) 2017/745, Article 20
Unique Device Identifier	UDI carrier as required by MDR	Regulation (EU) 2017/745, Article 27

Product Description

Intended Medical Indication

Oocyte meiotic spindle morphology scoring to provide supplementary information for embryo selection and prioritization in assisted reproductive technology procedures.

Characterization of User Profile

ReSpindle is intended for use by qualified clinical embryologists working in IVF laboratories. Users are expected to hold sufficient professional qualification to perform ICSI procedures in accordance with applicable national regulations. Standard ICSI procedure competency is required. No specific ReSpindle certification is required. Prior to first use, users receive product training consisting of a training webinar and the Instructions for Use provided via email. Training completion is documented per clinic.
Users interact with ReSpindle through a standard web interface during routine ICSI workflow — either by uploading a pre-recorded video or by initiating screen sharing to capture a video recording. The time spent using the software per analysis corresponds to the duration of the user's standard ICSI assessment workflow.

Characterization of Patient Population

IVF patients undergoing ICSI procedures. No restrictions are placed on patient age, clinical history, or other demographic attributes. The principal clinical requirement is that the patient is undergoing ICSI and that a suitable MII oocyte with visible meiotic spindle is available for imaging.

Characterization of Use Environment Including Software / Hardware

Physical environment: IVF laboratory.
Required equipment:

- Polarized light microscopy system (validated: Hamilton Thorne Oosight; in validation: Olympus, Zeiss, Nikon polarizers)
- Glass-bottom culture dishes
- Video recording capability during ICSI
- Internet connection for video upload

Software deployment: Cloud-based SaaS platform. Video upload via web interface; analysis results returned within minutes.
Compatible systems: Windows, macOS, or web browser access.

Exclusions

ReSpindle shall not be used:

- Outside of an IVF laboratory setting
- By persons who are not qualified clinical embryologists with ICSI competency
- As an autonomous diagnostic tool or for making clinical decisions without embryologist oversight

Safety Information

Contraindications

ReSpindle is contraindicated when:

- No compatible polarizer is installed on the microscope
- The MII meiotic spindle is not visible under polarized light

Warning and Remaining Risks

All results provided by ReSpindle are supplementary information only. The embryologist retains full clinical authority over embryo selection decisions. ReSpindle does not replace or modify mandatory morphological scoring protocols per clinic SOP.
In the event of inaccurate morphological scoring, the resulting embryo prioritization is equivalent to current practice without AI assistance, representing no additional risk to patients.
When video quality is insufficient for reliable analysis, the system provides a fallback response with the reason for non-scoring. Users should verify that video input meets quality requirements before relying on the output.
Do not upload video recordings containing patient-identifiable information. ReSpindle processes video data via encrypted transmission and does not store patient identifiers.

Reporting a Serious Incident

If you want to report a serious incident which occurred with this medical device, contact the manufacturer at: info@respindle.com
You can also report directly to your national competent authority:

- Netherlands: Dutch Health and Youth Care Inspectorate (IGJ) Website: www.igj.nl Email: meldpunt@igj.nl
- Germany: Federal Institute for Drugs and Medical Devices (BfArM) Website: www.bfarm.de Email: medizinprodukte@bfarm.de Phone: +49 228 207 5355

- Spain: Spanish Agency for Drugs and Medical Products (AEMPS) Website: www.aemps.gob.es Email: sgps@aemps.es Phone: +34 918 225 274
- Poland: Office for the Registration of Medical Products (URPLWMiPB) Website: www.urpl.gov.pl/en Email: incydenty@urpl.gov.pl Phone: +48 22 492 11 90
- For other EU member states, contact information for national competent authorities is available at: https://ec.europa.eu/health/medical-devices-sector/new-regulations/contacts_en

Language

The ReSpindle user interface is available in English. This Instructions for Use document is available in English and Dutch.

System Requirements

Hardware

- Computer with internet access and web browser (desktop or laptop connected to microscope workstation)
- Polarized light microscopy system (validated: Hamilton Thorne Oosight; in validation: Olympus, Zeiss, Nikon polarizers)
- Glass-bottom culture dishes
- Video recording capability during ICSI
- Internet connection for video upload

Software

- Windows, macOS, or web browser access
- No local software installation required (cloud-based SaaS)

IT-security Measures

User account credentials (email and password) are provided to the clinic by the manufacturer following contract conclusion. No personal data of individual embryologists is stored in the system. No cookies are tracked.
All data transmission between the user's browser and ReSpindle servers is encrypted. No patient identifiers are stored or processed. The user is not required to configure firewall settings, VPN, or other IT-security infrastructure.

Installation

No local software installation is required. ReSpindle is a cloud-based SaaS platform accessed via web browser. Following contract conclusion, the manufacturer provides the clinic with the web application URL and user account credentials (email and password). A successful installation is verified by successful user login. Prior to clinical use, users complete product training consisting of a training webinar and review of the Instructions for Use. Training completion is documented per clinic.

Safety and Maintenance

The software's lifetime is established to be three years. This is the maximum time expected until the implementation of a significant change, by which the manufacturer is able to react to relevant changes to the software device environment, such as SOUP changes, cybersecurity innovations, or the evolving technological or medical state of the art.

Software updates are deployed to the production environment with zero downtime. Clinics are notified at least 48 hours in advance of scheduled updates via email.
To report a malfunction, security concern, or any other issue, users can contact the manufacturer at info@respindle.com or via the in-app feedback form.

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Review & Approval

Activity	Date	Name (Role)
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