RI Saturn 5™ Laser Systems

User Manual

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℞ Only

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SECTION 1 - PREFACE

Thank you for choosing the RI Saturn 5 Laser System.

This manual provides all necessary information to use the Research Instruments Ltd RI Saturn 5 Laser System. The system should be operated by trained personnel only. All sections of this manual should be read and understood fully before any operation of the system. Please see the Intended Use for more information.

If the operator is unsure of any of the information contained in this manual, they should contact Research Instruments Ltd or an appointed representative before attempting to use this equipment.

In no event does Research Instruments Ltd (RI) assume the liability for any technical or editorial errors of commission, or omission; nor is Research Instruments Ltd liable for direct, indirect, incidental, or consequential damages arising out of the use or inability to use this manual.

RI Saturn 5™ and RI Viewer™ are trademarks of Research Instruments Ltd. All other brand names are trademarks of their respective owners.

Patents - please go to this web page to see the patents that protect this product: www.RI patents.com

The information in this manual is current at the time of publication. RI is constantly updating its products, and, therefore, reserves the right to introduce changes in design, equipment and technical features at any time. The latest version of the User Manual as well as RI Viewer software can be downloaded from software.research-instruments.com.

The RI Saturn 5 Laser System manual belongs with the laser and should be passed on with the RI Saturn 5 Laser System if relocated to another clinic.

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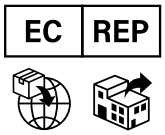

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The Netherlands

SECTION 2 - INTRODUCTION TO THE RI SATURN 5 LASER SYSTEM

Intended Use

18. The RI Saturn Laser System is intended to ablate a User defined section of a gamete or embryo within ART.

Indication for Use

18. For use in assisted reproduction procedures to ablate or thin the zona pellucida of an embryo to facilitate assisted hatching or recovery of cells for pre-implantation genetic diagnosis (blastomeres). The device can also be used on blastocyst stage embryos for biopsy of trophectoderm cells for pre-implantation diagnosis procedures, and blastocyst collapse prior to vitrification procedures.

Applicable indications for use are subject to the regulations of the country into which the device is sold.

Intended User

Trained clinical professional with locally relevant qualifications

Intended Patient Population

Patients seeking treatment for reproductive medicine

Clinical Benefits

To facilitate treatment of a patient by manipulation or modification of the patients' reproductive cells and/or tissue in vitro

Applicable Part Numbers

18.

6-47-500	RI Saturn 5 Active Laser System
6-47-501	RI Saturn 5 Fixed Laser System

Microscope Compatibility

Zeiss Axiovert 40/100/200/Observer

Nikon TMD, Diaphot 200/300, TE200/300, TE2000, Ti, Ti2

Leica DMIRB, DMI3000B/4000B/6000B, DMIL, DMi8

Olympus IMT2, IX50/70, IX51/71/81, IX53/73/83

Installation

18. The PC is an intrinsic part of the RI Saturn 5 Laser System. It may be connected to a Local Area Network (LAN) only. Only install RI Viewer software. We recommend PC security features such as anti-virus software/firewall be installed consistent with the facility's IT policy and that each user of the system has a password protected user profile assigned to the PC in order to prevent unauthorized access.

The RI Viewer software must be installed on a Windows computer and requires .NET Framework. It connects to a RI Saturn 5 Control Unit, and optional RI Saturn 5 Motor Module, via USB to operate the movement and firing of the laser.

Connecting the computer running RI Viewer to an IT network or to other equipment could result in previously unidentified risks to patients, operators or third parties. Users should identify, analyze, evaluate and control these risks. Changes to the IT network could introduce new risks that require additional analysis; these changes may include changes in network configuration, connection of additional items, disconnection of items, update of software or upgrade of equipment.

Installation of the RI Saturn 5 Laser System should be carried out by a Research Instrument technician or other Research Instrument authorized personnel. Incorrect installation could result in reduced power output, laser misalignment or laser malfunction. Relocation of this system should be treated as a re-installation and should, therefore, be carried out by authorized personnel.

Please note that installation and servicing is covered separately in the RI Saturn 5 Laser System Installation Manual (6-47-500IM), which is available to service providers.

Once installed, the RI Viewer application can be started by double clicking the RI Viewer icon on the desktop.

SECTION 3 - RI SATURN 5 LASER SYSTEMS SAFETY WARNINGS

Cautions and Warnings

Laser radiation is present within the Control Unit, the fiber optic patch lead and through the microscope to output at the objective. The RI Saturn 5 Laser System has been designed to ensure that emission of laser radiation at any point is within the limits stipulated by international safety standards, IEC 60825-1:2014, and US 21 CFR 1040.10 for unprotected viewing (Class 1). As an extra precaution, an infrared blocking filter has been incorporated into the optical path leading to the eyepieces to reduce laser emission by a further 99%.

For a description of controls and for the location of laser aperture on Control Unit, "Section 4 - RI Saturn 5 Laser Systems Product Overview" on page 8

Warnings

WARNING: The microscope itself must be maintained to a high standard. Problems such as worn focus mechanisms or an insecure video camera may lead to unreliable focus and image stability, and could lead to embryo damage.

WARNING: DO NOT disassemble or modify any part of the RI Saturn 5 Laser System, or substitute any component for any other. Doing so may result in exposure to dangerous levels of laser radiation. This voids the warranty and/or service contract.

WARNING: The embryo may be damaged if objectives other than the red RI Saturn 5 Laser System objective are used.

WARNING: Do not operate the pilot laser with an embryo in the field of view. Exposure to the pilot laser may damage the embryo.

WARNING: Not to be used in a patient environment.

WARNING: Before performing any procedure, the pilot laser must be used to check the alignment of the Active positioning system. The system must be re-aligned when necessary. See Section 8 How to Check Laser Target Alignment.

WARNING: Thermal lensing is a defocusing of the laser beam caused by changes to the refractive index of the medium as it is heated. The degree of defocus depends on the total beam energy deposited in the medium. While slight defocus has no effect on the drilling properties, this effect may become a problem for higher beam energies. To eliminate any significant effects from thermal lensing, we recommend that the pulse width be kept below 1000µs for clinical Laser Assisted Hatching (LAH) zona drilling.

WARNING: Only a single opening should be made in the zona pellucida. Multiple openings or those that are too small may prevent embryo hatching or lead to abnormal development.

WARNING: In the event of a cyber security incident, shut down the computer, then contact the manufacturer.

WARNING: To avoid the risk of electric shock, this equipment must only be connected to a mains supply with protective earth.

Cautions

CAUTION: Federal law restricts this device to sale by or on the order of a physician or a practitioner trained and certified in its use.

CAUTION: DO NOT operate the laser unless it is properly mounted to a microscope.

CAUTION: The system should be operated by qualified and trained personnel only.

CAUTION: Where an ITO glass heated stage is fitted, do not fire the laser with the microscope focussed into the ITO glass surface as this may damage the ITO coating.

CAUTION: Hazardous radiation exposure may occur through the use of controls, executing adjustments or the performance of procedures other than those specified herein. Servicing and adjustment other than that specified in this manual should only be carried out by RI or RI authorized agents.

CAUTION: ONLY use the power cable and power supply adaptor supplied with the system.
The cable to the power supply is the Disconnect Device for this equipment. To remove all electrical power from this product, disconnect the power cable from the electrical outlet. Equipment should be positioned so as to allow easy access to the power cable. The appliance coupler or mains plug is used as the disconnect and must remain readily operable.

Cautions and Warnings also appear in this format throughout this manual.

Precautions

- To minimize the risk of damage to blastomeres, administer as few laser pulses as possible at the lowest energy levels possible to achieve the prescribed zona drilling or thinning effect.
- Direct the laser beam toward a section of the zona pellucida where the adjacent perivitelline space is widest or next to an area of fragmentation.
- A holding pipette should be used during laser treatment to minimize the risk of embryo movement.
- Small openings in the zona pellucida may lead to embryo constriction and abnormal development.
- To date there are no known reports showing a greater occurrence rate of major or minor defects in children derived from laser-hatched embryos. Long-term follow-up data on children born from laser-hatched embryos does not yet exist. A study of 134 such babies* found no increase in the major congenital malformations, chromosomal aberrations or minor congenital malformations between the LAH treated group and all deliveries at their hospital.
- The device is not affected by and does not present any reciprocal interference to the microscope.
- During normal use there is no contact with patient/sample.

**Kanyo, K., Konc, J. "A follow-up study of children born after diode laser assisted hatching." European Journal of Obstetrics and Gynaecology. 110: 176-180 (2003).*

Electromagnetic Compatibility (EMC)

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential ENVIRONMENT (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

The RI Saturn 5 Laser System may be used alongside RFID readers operating at 13.56MHz. Where alternative frequencies are used, confirm correct operation of the RI Saturn 5 Laser System prior to use.

USA Only

Compliance with the emissions requirements of CISPR 22 Class A requires the following warning: "This is a class A product. In a domestic environment this product may cause radio interference in which case the user may be required to take adequate measures."

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Glossary of Safety and Information Symbols

Source: ISO 15223-1 and ISO 60601-1+A12

Symbol	Meaning
CE 2797	In accordance with Annex II of the European Medical Device Directive 93/42/EEC, as amended by Directive 2007/47/EC
Rx Only	Caution: US Federal law restricts this device for sale to or on the order of a licensed healthcare practitioner
EC REP	Authorized representative in the European Community
	Consult instructions for use
	Consult instructions for use
	WARNING: Indicates a potentially hazardous situation which, if not avoided, could result in serious injury or death
	CAUTION: Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury
	Manufacture
	Date of Manufacture
GB	Country of Manufacture
REF	Catalogue or Part number
	Distributor

Symbol	Meaning
SN	Serial Number
MD	Medical Device
UDI	Unique Device Identifier
	Do not dispose of product with normal waste. Dispose of in accordance with the EU WEEE Directive. (See Care and Maintenance section.)
	Direct current (DC)
CLASS 1 LASER PRODUCT	Class 1 laser product (IEC60825-1:2014)
	This way up
	Fragile, handle with care
3	Stacking limited to 3 units
	Keep dry
	Importer

SECTION 4 - RI SATURN 5 LASER SYSTEMS PRODUCT OVERVIEW

Welcome to the RI Saturn 5 Laser System User Manual. This manual covers the set-up, operation and maintenance of the system.

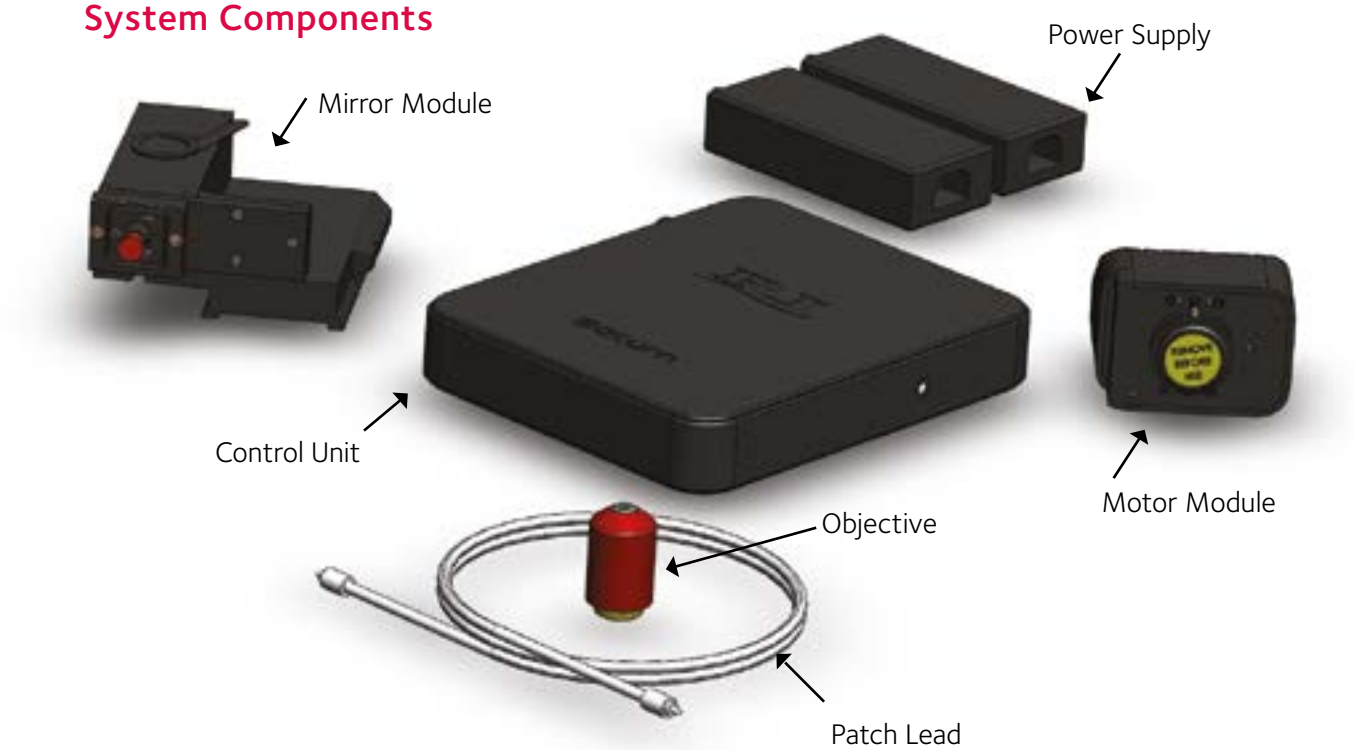
This device is for use in assisted reproduction procedures to ablate or thin the zona pellucida of an embryo to facilitate assisted hatching or recovery of cells for pre-implantation genetic diagnosis (blastomeres). The device can also be used on blastocyst stage embryos for the biopsy of trophectoderm cells for pre-implantation diagnosis procedures, and blastocyst collapse prior to vitrification procedures.

The system is used with an inverted microscope, PC and camera to provide an optical system and means of firing a laser. The system cannot be used without a PC or RI Viewer software.

The RI Saturn 5 Laser System is offered in two options, Fixed or Active models. The Active model allows the user to move the position of the laser to the target area on the sample. The Fixed model has the laser in a fixed position and the user moves the sample to the target.

All laser movement (Active model only) and laser firing is user controlled.

System Components



Note: Actual components may differ from those shown.

The RI Saturn 5 Laser System comes supplied with the following parts: a Control Unit containing the lasers, a Mirror Module, armoured Patch Lead and a special Objective. If you have a RI Saturn 5 Active Laser System then an additional Motor Module will be supplied. The laser beams are delivered to the specimen through a fiber optic Patch Lead, Collimator Module (that is part of the Mirror Module for a Fixed system or the Motor Module for an Active system) and the special Objective.

A foot pedal for firing the laser is available as an optional extra. This is attached to the PC by a USB cable.

The Motor Module receives coordinates via the USB which moves the motors to those coordinates. The Control Unit then receives commands from the software to fire for a specific length of time.

The following tables give part numbers of system components and microscope adaptors.

RI Saturn 5 Laser System Component Part Numbers

Part Number	Description
5-47-010	Control Unit with 1.5m Patch Lead
5-47-011	Control Unit with a 1.5m Patch Lead (RI Saturn 5 Fixed)
5-47-100	Motor Module (RI Saturn 5 Active Laser System)
1-10-133	12V 3.3A Medical PSU
5-45-500	Laser Objective (red) 40x
5-45-507	Laser Objective (red) 20x*

RI Saturn 5 Active Laser System Mirror Module Part Numbers

Part Number	Description
5-46-163	Mirror Module for Olympus IX53/73/83 left
5-46-150	Mirror Module for Olympus IX50/70 left
5-46-160	Mirror Module for Olympus IX50/70 right
5-46-151	Mirror Module for Olympus IX51/71/81 left
5-46-152	Mirror Module for Olympus IX51/71/81 right
5-46-159	Mirror Module for Olympus IMT2
5-46-135	Mirror Module for Nikon TMD
5-46-132	Mirror Module for Nikon Diaphot 200/300
5-46-130	Mirror Module for Nikon TE 200/300
5-46-140	Mirror Module for Nikon TE2000 with Integra Ti
5-46-141	Mirror Module for Nikon TE2000 without Integra Ti
5-46-142	Mirror Module for Nikon Ti with Integra Ti
5-46-144	Mirror Module for Nikon Ti with X-Y
5-46-146	Mirror Module for Nikon Ti2 with Integra
5-46-148	Mirror Module for Nikon Ti2 with XY stage
5-46-110	Mirror Module for Zeiss Axiovert 200/Observer
5-46-120	Mirror Module for Leica DMIRB
5-46-121	Mirror Module for Leica DMI4000B/6000B
5-46-122	Mirror Module for Leica DMI3000B fluorescence
5-46-123	Mirror Module for Leica DMI3000B non-fluorescence
5-46-124	Mirror Module for Leica DMi8

**Not cleared for use in USA market.*

RI Saturn 5 Laser System Collimator Module Part Numbers

5-45-163	Collimator Module for Olympus IX53/73/83
5-45-387	Collimator Module for Olympus IX71
5-45-301	Collimator Module for Nikon Diaphot 300/TE300
5-45-545	Collimator Module for Nikon TE2000/Ti/Ti-E
5-45-547	Collimator Module for Nikon Ti2
5-45-011	Collimator Module for Zeiss Ax200/Observer
5-45-470	Collimator Module for Leica DMIL
5-45-463	Collimator Module for Leica DMi8

Specifications

Laser Specifications	**Ablation Laser**	**Pilot Laser**
Output wavelength	1480nm	650nm
Power output from patch lead	400mW	180µW (max)
Maximum pulse width	2.0ms	None
Laser Safety Classification*	Class 1	Class 1

* IEC 60825-1:2014, US 21 CFR 1040.10

Objective Specifications

Magnification	40x	20x*
N.A.	0.49	0.25
Working distance	2.5mm	2.5mm
Parfocal distance	45mm (adaptor supplied for Nikon CFI60 systems)	

**Not cleared for use in USA market.*

40x or 20x is a nominal figure. Actual magnification will vary slightly when fitted to different microscopes.

Manufacturer	Actual Magnification
Olympus	40x, 20x
Nikon (CFI60)	36x, 18x
Leica	36x, 18x
Zeiss	44x, 22x

RI Saturn Active Specifications

Range of Movement	Approx. 370µm (40x), 740µm (20x)
Accuracy	1µm within calibration area, 3µm outside (40x) (see page 31) 2µm within calibration area, 6µm outside (20x) (see page 31)

Electrical Specifications
Mains Adaptor for Control Unit and Motor Module

Input	100-240VAC, 50-60Hz, 1.0 - 0.5A
Output Power (maximum)	40W
Voltage	12VDC
Current (maximum)	3.3A

Dimensions

Control Unit	220mmx180mmx34mm (8.6"x7.1"x1.3")
Weight	1.2Kg

Operating Conditions

Temperature	10°C (50°F) to 42°C (108°F)
Humidity	15% to 85% RH (Non-condensing)
Pressure	Pressure Range: 70kPa. to 108kPa

SECTION 5 - RI VIEWER

Introduction

RI Viewer is the software that interacts with the RI Saturn 5 Laser System for use within an ART laboratory. Connected to a camera attached to a microscope, it provides on-screen images of samples under the microscope. It can record video and store still images from the microscope in a PC's file system. End users should ensure their own PCs are certified compliant to IEC 62368-1.

The operator should be positioned to easily access the microscope and also view the image on the PC monitor.

RI Viewer software can be downloaded from http://software.research-instruments.com

Once installed, the RI Viewer application can be started by double clicking the RI Viewer icon on the desktop.

User Interface Icons

Icon	Meaning	Icon	Meaning
	Take Picture		Increase/Decrease Zoom Level
	Take Video		Laser Control
	Stop Video Recording		General Settings
	Open RI Viewer Gallery		Additional Camera Settings
	Device not connected or fault		Take Measurements
	Device requires attention		Display Rulers Tool
	Device OK		Instructions For Use
	Choose Objective Magnification		Open Image Details

How to Zoom & Pan the Image

There are three ways to zoom into an area on the screen.

1. Place the mouse at a point on the screen and click and hold the right mouse button, then release. This will zoom into the spot where the mouse is placed. To zoom out, click and hold the right mouse button.
2. Place the mouse at a point on the screen and use the scroll wheel on the mouse (if available).This will give the user control over how much digital zoom is given.
3. Using the tool bar at the bottom of the screen, click the **+** icon to zoom in incrementally. To zoom out by the same amount, click on the **-** icon on the tool bar. The magnifying glass icon will zoom in and out by the preset zoom.

Whilst using digital zoom, a thumbnail image of the screen will appear in the top left of the screen. At the top of this panel is the amount of magnification you are using. When zoomed out fully, this panel will not appear on the screen.

Zooming in and zooming out can also be achieved using the foot pedal. (See page 16)

How to Set the Preset Zoom

1. Click the **Additional Camera Settings** icon on the tool bar.
2. Drag the **Preset Zoom** slider to the required zoom.

How to Select Cameras

1. Click the **General Settings** icon on the tool bar. The Video Source drop-down box will have a list of camera names referring to the cameras connected to the PC.
2. Click on the drop-down box to allow the selection of cameras. Clicking on the required camera in the list will change the live image to that of the selected camera.

Note: The list of available cameras is automatically populated to show the attached devices. Camera names in this list cannot be altered by the user.

When using a Dazzle video converter

When connected to an analogue camera (e.g. Watec) and digital converter (e.g. Dazzle), there can be flickering artefacts at the top and bottom of the image. RI Viewer masks these by covering over two rows of pixels along the top and bottom of the image.

If this behaviour is not desired it can be disabled, please contact CooperSurgical for instructions on how to do so.

Camera Flipping

1. Click the **General Settings** icon on the tool bar.
2. Tick **Flip Video Horizontal** (for camera devices that support these options).
3. Tick **Flip Video Vertical** (for camera devices that support these options).

Camera flipping is for microscopes where the camera image may be required to be inverted. This is carried out during installation where a camera port requires camera flipping to show the image correctly on the screen. This will be carried out by a trained CooperSurgical Service Engineer or company representative. When camera flipping is required it is recommended to carry out Laser Target Alignment as per instructions before carrying out any procedure.

Changing Camera Settings

Clicking the **Additional Camera Settings** icon on the tool bar will show a panel indicating the camera name and frames per second (fps). Clicking on **Additional Settings** will allow the user to adjust settings on the video source. Only settings available to the video source chosen will appear.

Objectives

Objectives can be changed on the microscope to enable the user to get a better field of view or better magnification. If you require accurate measurements of the image, the objective chosen in RI Viewer must be the same magnification as the objective in use on the microscope.

How to Select Objectives

1. Click the **Choose Objective Magnification** icon on the tool bar.
2. Click the required objective magnification.

How to Add Objectives

1. Click **Display Rulers Tool** icon on the tool bar.
2. Click the **Objective Calibration** button.
3. Click **New Objective**. The magnification will be the same as the current magnification.
4. Click the required objective to edit Objective Magnification and Fine Adjustment values.

How to Remove Objectives

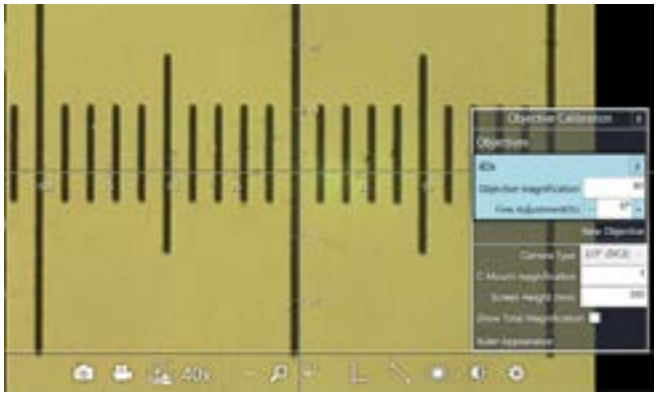
1. Click **Display Rulers Tool** icon on the tool bar.
2. Click the **Objective Calibration** button.
3. Click **X** next to the objective to be removed.

How to Check Objective Calibration

1. Click the **Display Rulers Tool** icon on the tool bar. 

2. Click the **Objective Calibration** button to open the Objective Calibration panel.
3. Place an object of known dimensions (a stage micrometer is supplied with each system for this purpose) in the field of view. Ensure that the objective selected in RI Viewer matches that being used on the microscope

4. The stage micrometer supplied measures 100µm between the longer lines. For best accuracy, position each end point of the line at exactly the same relative position on the scale, for example at the right hand edge of each vertical line.
5. Drag the rulers to the point where the stage micrometer is going to be measured from and use the fine adjustment up and down until the ruler scale matches the stage micrometer.



How to Configure the Foot Pedal/Keyboard

1. Click the **General Settings** icon on the tool bar.
2. From the Settings panel click the **Keyboard/Foot Pedals Shortcuts**.
3. Click the corresponding edit button to assign a shortcut.
4. Hold down the key or press the foot pedal to assign.
5. Click **Save and Quit**.

Once the shortcuts are set up, press the shortcut keys or the corresponding foot pedal to activate the command.

How to Perform Measurements

1. Click the **Take Measurements** icon on the tool bar.
2. Click on the screen to select a start point for the measurement.
3. Click on the screen a second time to select an end point for the measurement.

The ends of the line can be dragged to change the measurement.

Lines can be removed by clicking the cross in the context window.

Lines are shown during laser operation but cannot be dragged or created and no measurements will be displayed.

Lines and measurements are shown on an image when images are taken in line mode or laser mode.

How to Take a Picture

1. Click the **Take Picture** icon on the tool bar.
2. A camera icon will flash briefly in the centre of the screen to let the user know that an image has been taken.

Images can be stored in a .bmp file format or .jpg file format. This is configurable from the Settings menu by checking Compress Images. If this box is ticked the images are saves as .jpg files, if not they are are saved as .bmp files.

Images are named by default (date and time) yyyymmddhhmmss.bmp. For example, a picture taken on the 3rd of January 2012 at 10:35:02 would be named 20120103103502.bmp.

How to Record Video

1. Click the **Take Video** icon on the tool bar.
2. Whilst video is being captured, a recording notification will flash in the top left corner of the screen.
3. Click the **Stop Video Recording** icon on the tool bar and the recording notification will stop.

   Each video recording can last for a maximum of one hour. This eliminates the problem of accidentally leaving the software recording with the possibility of rendering the computer unusable.
4. When Freeze Frame is set as keyboard shortcut, the live image can be paused. A second press of the shortcut key will restart the live image.

Recorded videos are stored in a .wmv file format

Recorded videos are named by default (date and time) yyyymmddhhmmss.wmv. For example, a video taken on the 3rd of January 2012 at 10:35:02 would be named 20120103103502.wmv.

Image Details

Image Details allows details of the current patient and sample such as Patient ID, Patient Name, Reference and Comment, to be entered. There are two purposes for this:

When images or videos are captured, they will be assigned in the Gallery to the current patient.

A setting can be enabled to save the details as an overlay on the image, to better support photo printers.

To open the Image Details panel, click the button on the button bar:

Use the Image Details panel to fill out the details of the patient and the sample:

The details entered will appear in a bar at the top of the RI Viewer window:

Pre-select patient for Gallery assignment

With a Patient ID entered, when an image or video is captured by RI Viewer, it will automatically be assigned in the Gallery to that patient. See Section 5 “RI Viewer Gallery – Patient Details”.

If the Patient Name, Reference and Comment fields have been entered, those details will automatically be added to the file. See Section 5 “RI Viewer Gallery – Edit Details”.

Capture patient/embryo details over images

The details entered can be saved as an overlay on captured images.

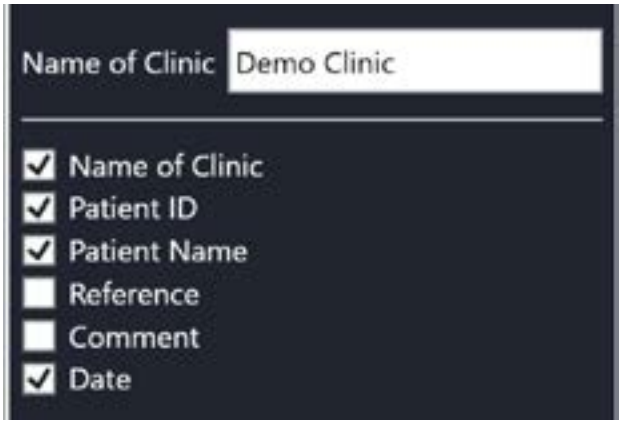
To enable this, click Settings on Image Details to open the Image Details Settings panel.

Then check the box 'Print details on images':

When an image is taken (Section 5 "How to Take a Picture"), the enabled fields will be captured over the image.

The elements included in the overlay can be customised on the Settings panel:

- When Patient ID, Patient Name, Reference or Comment are disabled, they will not appear on the Image Details panel.
- All enabled fields will be included in the overlay, even if they are not filled out.



Additional custom fields can be added; these will appear on the Image Details panel so they can be filled out and will be added to the image overlay:

- Click the 'plus' button to add a custom field, then enter the name.
- Click the 'minus' button next to a custom field to delete it.

- Fill out the custom fields on the Image Details panel:

RI Viewer Gallery

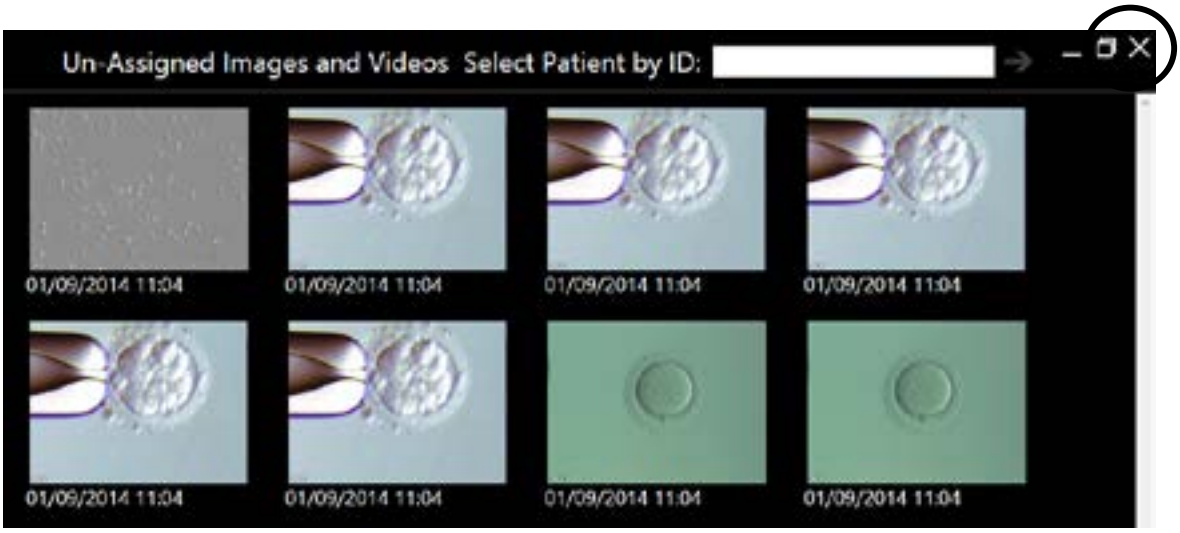
The RI Viewer Gallery is used to review, store and add comments to images and videos taken using RI Viewer. The RI Viewer Gallery icon can be found on the tool bar.

RI Viewer Gallery

When images and videos are taken with RI Viewer, they are saved to the pre-configured storage folder. This is configured from the Settings screen of RI Viewer. The RI Viewer Gallery shows all of the images and videos in this folder. It allows them to be reviewed and then printed, deleted or assigned to a patient. Once they have been assigned to a patient, they can also have references and comments added. These can then be printed alongside the images.

The **Gallery** icon  in RI Viewer is used to open RI Viewer Gallery. The first screen displayed is the Un-Assigned Images screen below.

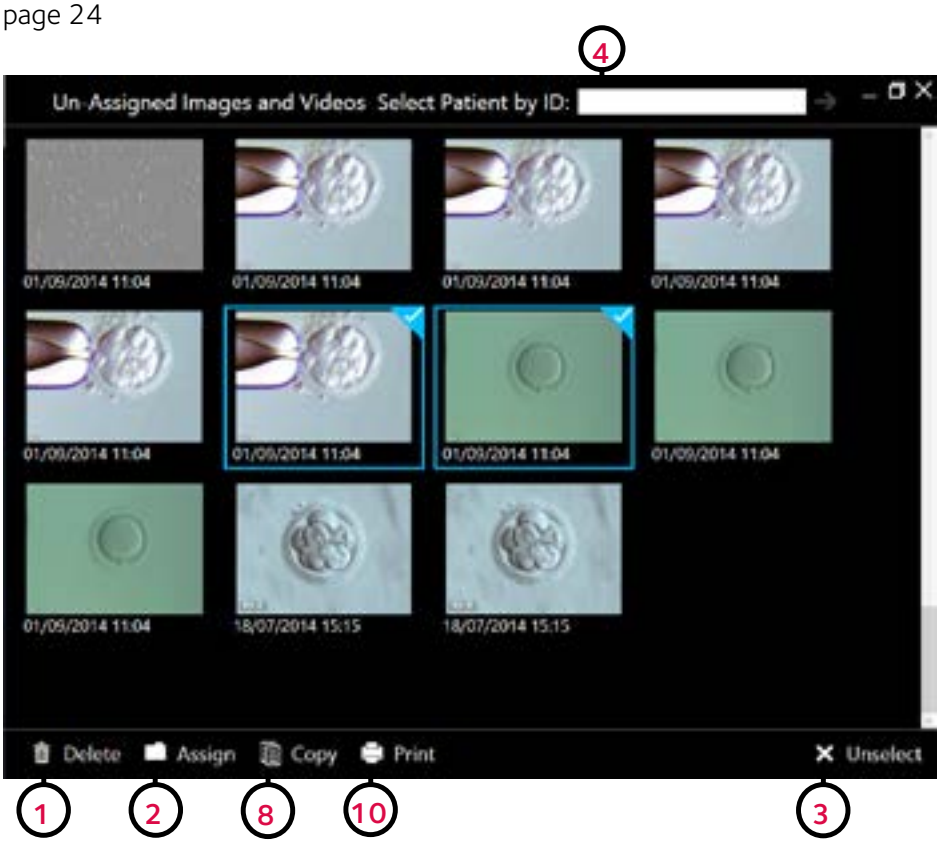
To return to RI Viewer, close the Gallery using the cross in the top-right corner.



Un-Assigned Images and Videos

The Un-Assigned Images and Videos screen shows all of the images and videos that are saved in the default folder as configured in RI Viewer.

- To select an image or video either right-click on it or hold the Ctrl key and left-click. The selected images are indicated by the coloured border.
- A single left-click will open the image or video in a full-screen view. See "9. Full Screen View" on page 24

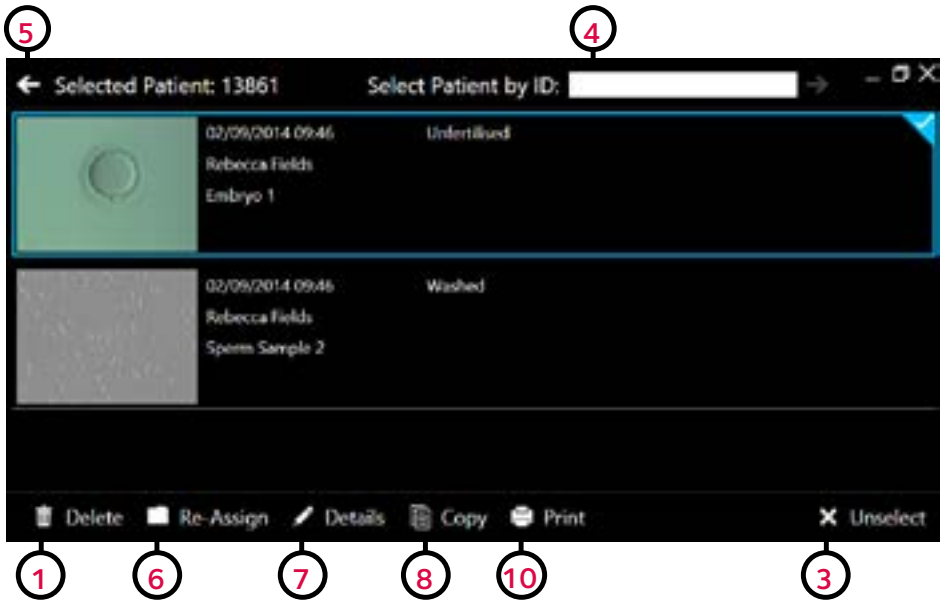


Patient Details

The Patient Details screen shows the images that have been assigned to the selected patient along with the patient name, reference and comments that have been entered for each image.

The Delete, Print, Image Selection and Unselect functions all work in the same way.

RI Viewer Gallery Functions:



1. Delete
2. Assign
3. Unselect
4. Select Patient
5. Return to Unassigned Images and Videos or Patient Details
6. Re-Assign
7. Edit Details
8. Copy
10. Print Preview (Images only)

1. Delete

Delete

To delete an image or video, first select it, then press the delete icon. A confirmation screen will appear, allowing the user to confirm whether the images and videos listed should or should not be deleted.

2. Assign

Assign

Assign is used to assign the selected images and videos to a patient using a unique ID number. The image or video will be moved to the patient folder.

3. Unselect

Unselect

Unselect will de-select all of the images and videos that have been selected.

4. Select Patient

Select Patient by ID:

Once images or videos have been assigned to a Patient ID, they are no longer shown on the Un-Assigned screen. To view the images and videos assigned to a patient click the **Select Patient** button to show the Select Patient box. Then enter the patient ID number into the box and click the arrow to go to the Patient Details screen for that patient. See "Patient Details" on page 21

5. Return to Un-Assigned Images and Videos or Patient Details

To return to the Un-Assigned Images and Videos or Patient Details screen click

6. Re-Assign

Re-Assign

If the Patient ID was assigned incorrectly click Re-Assign A pop-up box will appear in which the correct patient details relating to the image or video can be input. Click **OK** to save.

7. Edit Details Details

Edit Details is used to enter a patient name, reference and a comment. These are saved with each image and are displayed on the Patient Details screen.

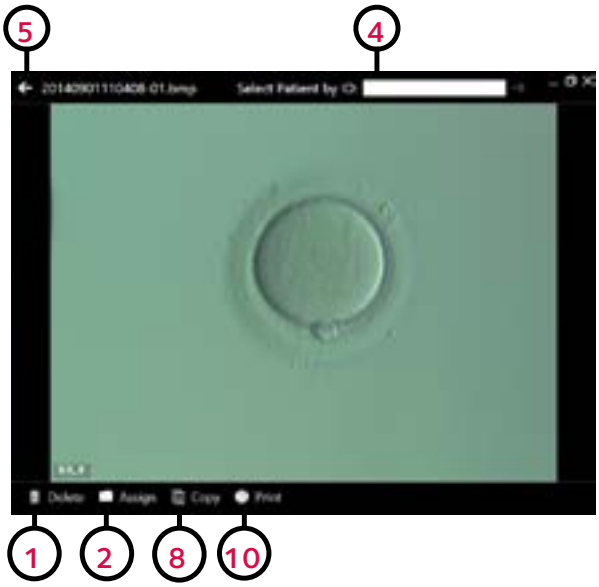
If a different patient name, reference or comment has been entered across a selection of images, the Edit Details screen will display (multiple values) for these fields. Changing this will alter the value for all of the selected images.

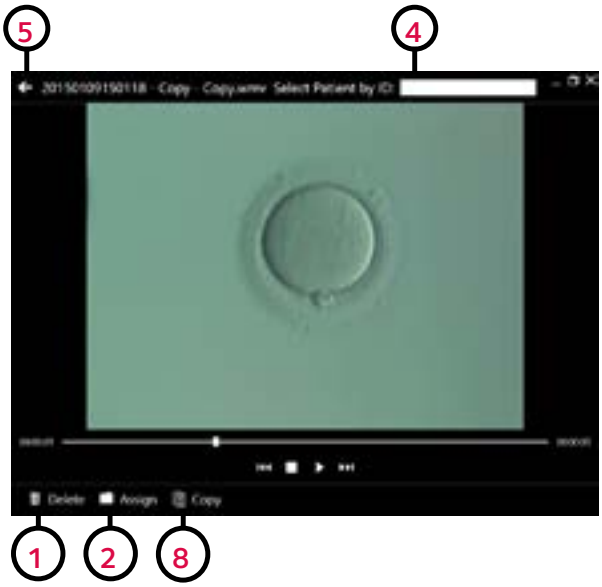
8. Copy Copy

This copies the selected images and videos to the clipboard. These images can then be pasted to a new location such as a USB drive or into another application such as a word processor.

9. Full Screen View

A single left-click on an image or video will open it in a full-screen view. Delete, Assign, Re-Assign, Copy and Print can all be actioned from this view. To return to the Un-Assigned Images and Videos or Patient Details screen click





10. Print Preview

To preview the image before printing, first select the image. Then press **Print**. This will open the Print Preview Functions.

A. Print
B. Print Setting

A. Print

The **Print** button will print the selected images with the current settings. See "B. Print Settings" below.

B. Print Settings

Select the printer, paper size, page range, etc required for printing the selected images. Press **OK** to save the changes and return to Print Preview or **Cancel** to discard your changes.

Advice for Use

All images and videos should eventually be moved out of the Un-Assigned list so that it only contains newly captured images and videos. If there are any that you do not wish to delete permanently or assign to an existing patient, then a patient ID of 'miscellaneous' or similar can be created to assign them to.

Whenever one or more videos are selected, either in addition to a number of images or by themselves, the print command is unavailable.

Transfer images to MedITEX database

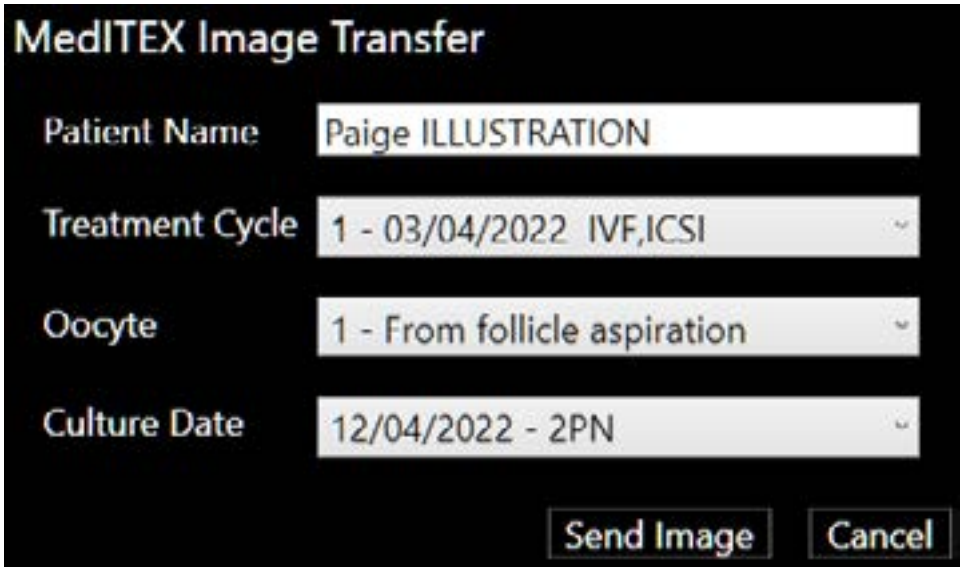
For clinics that use the MedITEX database, RI Viewer Gallery can transfer images into MedITEX using an API provided by Critex; please contact them for advice on installing and configuring the API, then follow the process below:

1. Open RI Viewer and open the Settings panel.
2. Enter the URL of the MedITEX API (given by Critex) and click Save:

NOTE: We recommend the use of HTTPS to secure the communication between RI Viewer Gallery and the MedITEX API.

3. Open RI Viewer Gallery and choose a patient with assigned images.
4. Open an image by left clicking, or right click to select multiple images.
5. The MedITEX button will appear on the button bar:

6. Click this button to open the Image Transfer dialog.
7. Enter the Patient Name if needed.
8. Select the appropriate cycle, oocyte and culture date.
9. Click Send Image to transfer the images to the MedITEX database.



10. A dialog will show if the transfer was successful or failed.

SECTION 6 - RI SATURN 5 LASER SYSTEM INDICATIONS FOR USE

Laser Assisted Hatching

Note: Assisted Hatching is not recommended for routine use in all ART patients.

The aim of Laser Assisted Hatching (LAH) is to locally weaken the zona pellucida. The specimen is viewed along the optical axis and the laser creates a trench in the zona pellucida which extends above and below the apparent hole.

Circle shows hole as viewed through microscope

To minimize the risk of damage to blastomeres, users should administer as few laser pulses as possible at the shortest pulse widths possible to achieve prescribed zona drilling or thinning effects.

The optimum diameter of the hole is determined by the thickness and/or hardness of the zona. Larger holes are necessary in thicker zona. Smaller holes are preferable for thin zona. The hole may fully breach the zona, whilst some users prefer to ablate only a fraction of the zona thickness, but across a wider area. This process is commonly referred to as zona thinning.

Only a single opening should be made in the zona pellucida. Multiple openings or those that are too small may prevent embryo hatching or lead to abnormal development.

The site chosen for the hole should be a section of the zona pellucida where the adjacent perivitelline space is widest or next to an area of fragmentation. This will minimize possible damage due to heating of adjacent blastomeres. The Exclusion Zone display can help with this.

To achieve a zona opening of 15µm, select a pulse width which will result in a hole size of 9.3µm to 9.5µm. A minimum of 4 shots should be applied to breach the inner and outer layers of the zona pellucida. Hole sizes of up to 10.5µm may be used without affecting blastocyst development rate.

Embryo Biopsy Procedure

The aim of embryo biopsy is to remove a part of the whole embryo which can then be analysed for chromosomal or genetic abnormalities.

The RI Saturn 5 Laser System is only to be used for the uses stated in the Indications for Use section of this manual.

WARNING: Repeated exposure to laser energy can cause the cells to harden making extraction of the biopsy cells more difficult to perform. A combination of laser shots, aspiration and gentle manipulation is recommended to separate the biopsy from the embryo.

Cleavage Stage Blastomere Biopsy

This biopsy is generally performed at the 6-8 cell stage of embryo development and typically 1 or 2 cells (blastomeres) are removed for analysis.

A hole should be made around two thirds the size of the cell to be taken (see published papers for exact dimensions) and care should be taken to drill the zona pellucida where there are no cells close by.

Again, smaller holes will give less heat exposure, so as a guideline we recommend individual hole sizes of between 5-10µm in diameter. The laser pulse widths required to make these hole sizes will vary a little from set-up to set-up, but will be anything in the range of between 15-1000µs (see Hole Size Selection, page 29).

For blastomere biopsy, the resultant hole made in the zona should be approximately 20µm and the opening should be made in between two blastomeres after the embryo is rotated and the cells selected for biopsy are positioned. A hole size setting of 9-10µm should be selected and 4-6 shots are usually sufficient to make an opening of around 20µm.

Firing the laser to make an opening in between two cells means the cells will have less exposure to the heat generated; therefore, there will be a reduction in the chance of cell lysis and other cells in this vicinity (above or below) being affected. The embryo should be held at the bottom of the dish when the laser shots are being applied to maximise laser efficiency.

Trophectoderm/Blastocyst Biopsy

The aim of this biopsy is to take 5-10 trophectoderm (TE) cells from the embryo at blastocyst stage, without causing damage to the inner cell mass (ICM). Laser assisted hatching (LAH) is performed on day 3 or early day 5 to create a weak point in the zona pellucida through which the trophectoderm cells can start to herniate.

If creating a hole on day 3, the hole size created should be 15µm as described for Assisted Hatching. At day 5/6 of embryo development there should be sufficient compaction of the ICM creating herniation of the TE. If the herniated cells are safely away from the ICM, TE cells can be aspirated with a biopsy pipette (20-30µm ID).

If creating a hole on day 5/6, an opening of approximately 15-20µm is adequate. In this instance the opening should be made on the side opposite to the ICM whilst the blastocyst is being held by a holding pipette and often an immediate collapse of the blastocoelic cavity will result. The biopsy pipette should be projected towards the collapsed trophectoderm and a few TE cells aspirated and pulled towards the opening of the zona. To dissociate the TE cells from the remaining embryo, suction from the biopsy pipette to the TE cells and from the holding pipette to the embryo should continue to be gently and firmly applied to allow the laser pulses to effectively penetrate and puncture the extended TE layer. Laser pulses of 0.4-0.8ms can be applied with a maximum of 4 shots at a time to sever the TE cells. This series of shots can be repeated if needed.

A maximum of 5-10 cells should be aspirated when performing trophectoderm biopsy.

Blastocyst Collapse

Blastocyst collapse is a procedure to remove the blastocoelic fluid of the embryo prior to vitrification to inhibit ice crystal formation in the cell during the freezing process. The procedure is similar to that performed for trophectoderm biopsy at day 5/6, that is, it should be performed on expanded blastocysts and an opening of approximately 15-20µm is adequate. The laser should be fired at the junction between two trophectoderm cells and should be made on the side opposite to the inner cell mass (ICM). An immediate collapse of the blastocoelic cavity will result.

SECTION 7 - LASER ABLATION PROCEDURE

1. Select the red laser objective on the microscope and check the objective calibration settings.

> **WARNING:** The embryo may be damaged if objectives other than the red RI Saturn 5 Laser System objective are used.

2. Check the Laser Target Alignment before each procedure.
3. Check the temperature of the specimen (37°C).
4. Focus at the mid-plane of the embryo.
5. Position the embryo against the surface of the Petri dish using a micromanipulator and holding pipette to minimize embryo movement.
6. Choose a suitable location for the laser shot.
7. The first attempt to make a hole in the zona pellucida should be made with a short pulse. If the hole is too small, then use progressively longer pulses until the desired hole size is achieved.

Hole Size Selection

For safe and effective treatment, we recommend that pulses used are in the range 15 to 1000µs.

Pulses that are very short may be ineffective and pulses that are too long may damage the embryo. For this reason, a warning will appear on the **Fire** button when pulse width is 15µs or below and when the pulse width is greater or equal to 1000µs.

When the warnings are shown, the laser can still be fired.

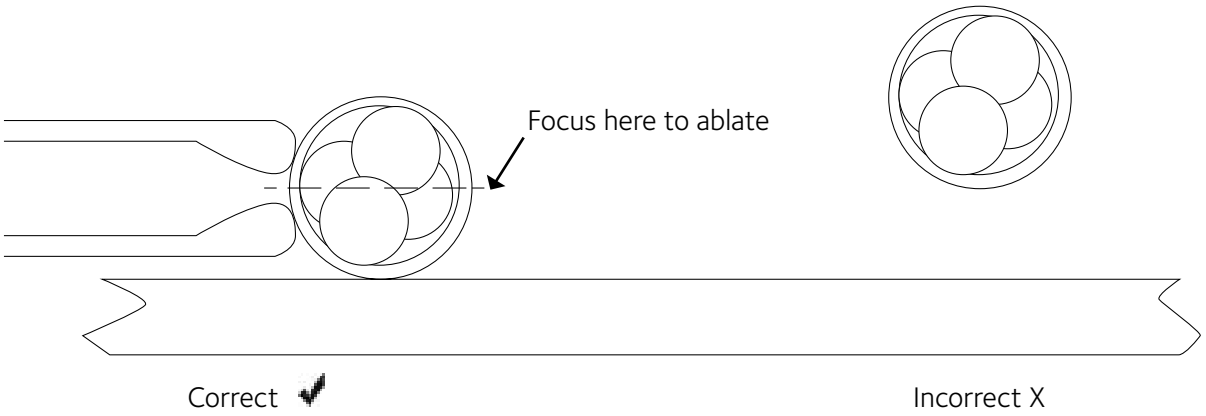
Ablation Procedure

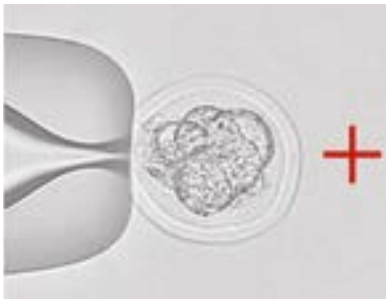
Focus on the surface of an empty Petri dish and ensure that the target is correctly aligned to the pilot laser spot. Place the dish with the specimen on the microscope stage and hold the specimen on the bottom of the dish with a holding pipette. Check you are using the red RI Saturn 5 Laser System objective. To ablate the zona, the focal plane must be at the mid section of the embryo. Refocus the microscope until the image of the zona is sharp.

Pilot laser brightness: The brightness of the pilot laser can be adjusted by turning the control knob on the rear panel to obtain the clearest image in the target alignment procedure.

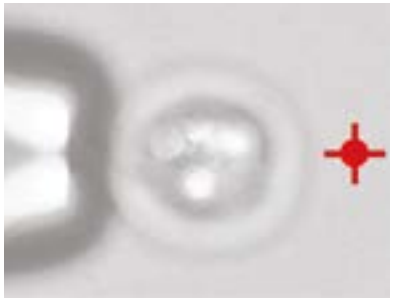
The light on the front of the Control Unit indicates that the Control Unit is operational. If the unit is plugged in and the light is not on, contact CooperSurgical for assistance.

Side view showing embryo on dish surface



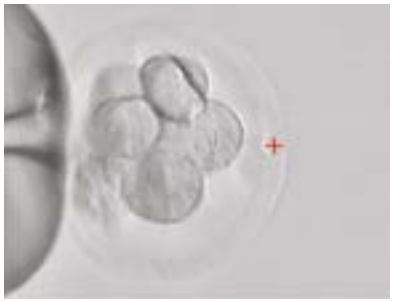


Correct focus - specimen is sharply focussed.



Incorrect focus for drilling.

Using a RI Saturn 5 Fixed Laser System, move the specimen into the field of view. Select a short pulse width using the RI Viewer controls. The different settings do not vary the power of the laser; they control the length of time that the laser is fired. If using a RI Saturn 5 Active Laser System move the target on the screen by clicking the position required with the mouse button.



Click on the zona pellucida where you want the hole to appear. Fire the laser by clicking the **Fire** button in RI Viewer. A small hole should appear in the zona. If a larger hole is required, increase the laser pulse time and fire again.

To create larger holes and for zona thinning the area should be ablated using a series of small diameter holes that overlap slightly, joining to form one larger hole or channel.

CAUTION: Do not attempt to make a large hole with just one shot of the laser. Although this will not cause damage to the instruments, it could potentially damage the embryo due to the greater heating effect of the long pulse width.

For further information on the methodology of laser ablation, refer to the many published scientific papers on the subject, or seek advice from a practitioner who is experienced in the technique.

SECTION 8 - RI SATURN 5 LASER OPERATION

How to Start Up

There is no power button for the RI Saturn 5. Once the device has been plugged into the power outlet and the power outlet is switched on then the device is active and can be used.

1. Plug the device into the power outlet
2. Ensure outlet is switched on

How to Configure the Laser for a New Procedure

1. Check objective calibration, see page 15
2. Check laser target alignment, see below
3. Check hole size calibration, see page 33

How to Check Laser Target Alignment for the RI Saturn 5 Active System

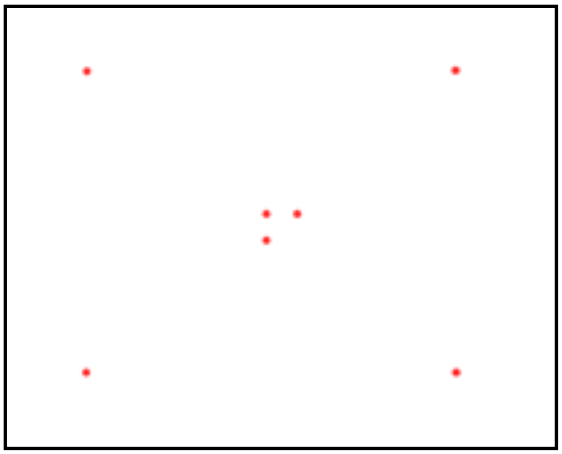
If the laser has not been aligned before then when you start RI Viewer the alignment procedure will start automatically.

Laser alignment of the RI Saturn 5 Active Laser System can be checked by following these steps.

1. If the RI Saturn laser system is expecting a Motor Module and one is not connected the connected devices icon will be red. Connect and power on a Motor Module
2. If this is the first time the motor has been connected or if the power has been off to the motor since last use, click the control panel button to start hardware alignment. The motor will start a self-diagnostic test
3. Once the hardware alignment test is complete it is safe to continue with the laser target alignment. Any errors during the hardware alignment will be displayed and should be conveyed to RI service
4. Click next to start laser target alignment
5. Ensure there are no embryos in the field of view
6. Using an empty Petri dish or a slide adjust the focus of the pilot laser to ensure the pilot laser spot is as small as possible. The brightness of the pilot laser can be adjusted
7. Click **Align Laser**
8. The motor will carry out a 7-point alignment at various points on the screen. At each motor position click the screen at the exact centre of the pilot laser
9. Click **Next** to proceed to the next alignment point
10. When the final alignment point is finished, click on the screen to drive the motor to the selected point and test the alignment by looking at the distance between the selected point and the actual position of the pilot laser. If the alignment is acceptable press Finish to close the alignment window and turn off the pilot laser, or press Align Laser to repeat the process
11. The laser positioning is accurate to 1µm or better within the area bounded by the four outer calibration points (see diagram on the right). For optimum use of the laser, place the section of your specimen to be ablated within this area. Outside this area the accuracy is not guaranteed to be better than 3µm

The diagram (below) represents the 7 calibration points on the screen

The exact position of the points on the screen will vary depending on the field of view and on the individual microscope



How to connect a Motor Module

To connect a Motor Module to a Saturn 5 Laser System:

1. Plug in and power up the Motor Module.
2. Start RI Viewer.
3. See How to check Laser Target Alignment for the Saturn 5 Active System.

How to remove a Motor Module

If a Motor Module is being removed from a Saturn 5 Laser System, the expectation of the motor will need to be removed from the software:

1. Unplug and disconnect the Motor Module.
2. Start RI Viewer.
3. Connected Devices panel will show Motor Module Not connected.
4. Open the Settings panel.
5. Click System Information.
6. Click Remove under Motor Module.

How to Check Laser Target Alignment for RI Saturn 5 Fixed Laser System

1. Click the **Laser Control** icon
2. Click **Laser Settings**
3. Click **Align Laser**
4. Ensure embryos have been removed from the field of view
5. Using an empty Petri dish or a slide adjust the focus of the pilot laser to ensure the pilot laser spot is as small as possible. The brightness of the pilot laser can be adjusted
6. Click the centre of the pilot laser
7. Click **Finish**

How to Check Hole Size Calibration

The laser objective must be calibrated correctly for the Hole Size Indicator to work correctly.

The actual size of hole a laser produces may vary depending on the type of Petri dish and media, the characteristics of the embryo and other factors. For this reason, the Hole Size Indicator may be calibrated.

To calibrate the Hole Size Indicator, you must be using the red laser objective and select the 40X or 20X objective in RI Viewer depending which magnification laser objective is installed. A suitable test specimen (which will be drilled) should be in the laser target area.

1. Click the Laser Settings button on the Laser Control panel
2. Click the Hole Size Calibration button.
3. Put the laser target on top of the specimen.
4. Fire the laser and ablate an area of the sample specimen.
5. Click the up and down arrows next to Adjust Hole Size to match to the size of the drilled hole.
6. Click the **Save Point** button when you are happy that the sizes match.
7. Repeat for a number of pulse widths to create a curve on the graph.

CAUTION: Repeated hole size calibration can sometimes introduce incorrect points on the graph. The graph should normally be a straight line or smooth curve with a positive (increasing) gradient. If a point leads to a negative gradient then a warning will be displayed on the chart. This should be corrected as it will imply two different pulse widths for a given hole size, and may lead to unexpected hole sizes.

How to Remove a Point from the Hole Size Calibration Graph

1. Click the point you wish to remove.
2. Click the **Remove** button.

The warning will disappear as soon as the negative gradient has been resolved.

Laser Target

RI Viewer displays a laser target on the image. This indicates where the laser beam is focused, and thus where the hole will appear.

Note: To use the laser system, the specimen must be viewed with the red laser objective.

The target will only be shown when the system is in laser mode.

The appearance and size of the laser target can be modified. The Target Appearance Setting is displayed in the Laser Settings panel. You can change its appearance by adjusting the sliders. This is also where the size of the laser Exclusion Zone can be set.

Hole Size Indicator

The circle that is displayed indicates the estimated size of the hole that will be created when the laser is fired. Actual hole sizes may vary due to natural differences between specimens.

The Hole Size Indicator can be turned on or off from the Target Appearance panel on the Laser Settings panel.

Exclusion Zone

The laser generates heat which has the potential to damage critical cells. The Exclusion Zone provides a measuring tool to show whether critical cells are close to the laser ablation area and therefore may be affected by the heat. The target point should be as far away from these critical cells as is possible to avoid unnecessary damage and it is ultimately the responsibility of the user to define a safe distance. The default exclusion zone setting is 5µm. This can be adjusted via the Target Appearance panel using the slider or input box.

How to Adjust Hole Size/Pulse Width

1. Hold the left mouse button down and drag until the desired size is reached (Fixed laser systems only).
2. For Active systems the option to click and drag can be turned off in the **General Settings.**
3. Click and drag the slider on the **Laser Control** panel.
4. Fine adjustment can be made using the **up down** keys.

Preset Pulse Widths

Preset pulse widths are 0.350ms, 0.400ms and 0.450ms and these preset values can be changed using RI Viewer.

Choose the preset by clicking the **+** or **-** buttons.

To change a preset, select the preset, set the desired value using the slider, and click the **Save** button.

Hole sizes can also be chosen by clicking on the screen and dragging a hole of the size you need. The pulse width will be calculated automatically to create the size of hole required.

How to Fire the Laser (Single Pulse)

Find the sample under the microscope using an objective with wide field of view (for example the 4x objective).

1. Hold the sample with a holding pipette at the bottom of the dish.
2. Switch to the laser objective and focus on the sample.
3. Click the **Laser Control** icon on the tool bar.

4.a Fixed System - position the sample such that the desired hole location is under the target.

4.b Active System - position the sample in the field of view. Click on the desired position of the hole.

5. Click the **Fire** button. The Control Unit will beep to confirm that the laser has fired

In some installations, the field of view is larger than the range of movement of the laser. If the cursor is moved to a position on the screen where the laser cannot reach, the unreachable area will be highlighted. The target cannot be placed in this area.

Biopsy Mode

Biopsy Mode is available with the RI Saturn 5 Active Laser System only and can be used for assisted hatching and embryo biopsy procedures. It allows the user to deliver a series of 4-6 shots along a predetermined line automatically and has no behavioral differences to a succession of single shots; that is, it is as safe as single shot mode. This predetermined line can be straight or curved. When using this mode care must be taken:

- not to draw a line where you do not want a hole to be drilled
- not to move the sample while firing the laser
- to check the laser settings and alignment prior to firing
- to fire in between two cells so that the cells are less exposed to the heat generated and to reduce the chance of cell lysis and other cells around this vicinity (above or below) also being affected by the heat.

How to Enable Biopsy Mode

1. Click the **General Settings** icon on the tool bar.
2. Tick **Enable Biopsy Mode.** (this option is available only with RI Saturn 5 Active Laser System).

How to Fire the Laser (Biopsy Mode)

1. Switch to the laser objective.
2. Focus on the sample.
3. Click the **Laser Control** Icon on the tool bar.
4. Check the sample is just on the bottom of the dish.
5. From the Laser Control Panel, click **Biopsy**. You will be taken to the Laser Biopsy panel.
6. Click where you want the first hole to be. The line will follow your cursor.
7. Click where you want the last hole to be. The holes to be drilled are overlaid on the image.
8. The size and number of holes can be changed by moving the two sliders on the panel.
9. The line can be lengthened or shortened by dragging the line end.
10. A point in the middle of the line can be dragged to create a curved line.
11. Press **Start Firing** to begin the firing procedure. The laser will then drill each hole in sequence.

If Biopsy Mode needs to be stopped at any stage press **Stop.**

How to Shut Down

1. Close RI Viewer software.
2. Unplug the device from the power outlet.

SECTION 9 - TROUBLESHOOTING FOR RI SATURN 5 LASER SYSTEM

Problem	Possible Cause	Solution
No lights on Control Unit	No power input	Check the power supply is plugged in to the mains and switched on
	Incorrect power supply	Use only the power supply provided
No video image	Camera not connected	Make sure camera is connected to PC and to power supply if appropriate
	Incorrect camera settings	Check brightness/contrast settings (section How to view live image)
	Microscope camera port not selected	Select camera port
Laser having no effect	Wrong objective used	Only use the red RI Saturn 5 Laser System objective
	Target misaligned	Check alignment
	Port selector misaligned	Check port selector is in correct position*
	Dirt on fiber optic	Service required
	Embryo above dish surface	Check the embryo is touching the dish surface
	Dirt on fiber optic	Service required
Hole size smaller than expected	Kinked fiber optic	Straighten fiber optic patch lead - minimum bend radius 50mm
	Embryo too cold	Check temperature should be 37°C
	Dirt/oil on objective	Clean objective
Hole size larger than expected	Excessive pulse width	Choose smaller hole size
	Hole Size Indicator not calibrated	Check calibration. Check for negative gradient
Laser position inaccurate	Port selector misaligned	Check port selector is in correct position*
	Calibration not done	Calibrate each time unit is switched on

*Some microscope port selectors do not return to exactly the same position when moved. Check the target alignment each time the port selector is moved.

SECTION 10 - CARE AND MAINTENANCE

Cleaning

We recommend that a non PVC dust cover is placed over the microscope when not in use.

WARNING: Plasticisers commonly used in PVC are toxic to embryos.

The Control Unit case should be cleaned with a cloth moistened with isopropyl alcohol or mild detergent solution only. If any liquids are spilt over the Control Unit switch off immediately and remove the power connector. Clean the spill and ensure that the unit is completely dry before switching on. If it is suspected that any liquids have gone inside the case contact CooperSurgical for advice before switching on.

Routine maintenance simply involves ensuring that all optical components are kept clean. The lens on the end of the RI Saturn 5 Laser System objective should be cleaned occasionally by wiping gently with a dry lens cloth.

Every six months the Collimator Module should be removed and the dichroic mirror cleaned with a dry lens cloth. This should be done by CooperSurgical or an appointed representative as the laser alignment must be checked and readjusted after removing the Collimator Module.

For further advice on microscope cleaning, please contact CooperSurgical or your microscope supplier.

Servicing

CAUTION: We recommend that the system undergoes a routine service at least every twelve months. This can normally be carried out by your distributor.

Regular servicing by an RI authorized technician will help to ensure that your system performs at its best. We recommend a minimum of one annual inspection and service. However, this may need to be more frequent if systems are heavily used. Contact your distributor or RI's service team directly to arrange servicing. Where necessary, RI will provide all technical information required to assist in resolving problems.

For all maintenance requirements, contact your distributor or RI 's service team directly.

In the event that you have a problem with the RI Saturn 5 Laser System, first look at the Troubleshooting section. If you require any further help, contact your distributor or RI's service team direct. We will try to resolve the problem as quickly as possible.

Servicing should be carried out by authorized personnel, there are no user-serviceable parts.

Disposal of Electrical and Electronic Equipment

CooperSurgical have taken the necessary steps to comply with the EC directive 2012/19/EU on waste electrical and electronic equipment (WEEE).

Environmental implications: WEEE contains materials that are potentially hazardous to the environment and to human health. Therefore, when this instrument has reached its end of life it must be collected and recycled separately from other waste according to national requirements. Please contact a local CooperSurgical distributor for instructions. Do not dispose of with 'normal' waste.

SECTION 11 – WARRANTY INFORMATION AND LIMITS ON LIABILITY

CooperSurgical Inc, warrants that this item will be free from defects in materials and workmanship for one year from the date of installation. If CooperSurgical determines that the product fails to conform to that warranty during the one-year period, CooperSurgical will repair or replace the product, at CooperSurgical's discretion, free of charge.

To return the product to CooperSurgical, a customer must comply with CooperSurgical's Returned Goods Policy described in this manual and the warranty requires the customer to return the product to CooperSurgical in accordance with the CooperSurgical Returns Instruction. CooperSurgical will return products (that it repaired or replaced under warranty) to the same customer who returned those products, at CooperSurgical's expense F.O.B. the customer's facility. Under all other circumstances, CooperSurgical will return products to the same customer who returned those products at the customer's expense.

CooperSurgical's warranties do not cover damage caused by misuse, improper care, improper use of chemicals or cleaning methods, loss, theft, use of non-authorized parts, servicing by non-authorized personnel or negligent or intentional conduct on the part of the owner or user of the product, nor do they cover normal wear and tear or general maintenance. Any modifications or changes to a product will void that product's warranty. CooperSurgical's warranties do not apply to any single-or-limited-use, disposable or consumable components or items.

CooperSurgical is not responsible for, and the owner and operator of the product shall defend, indemnify and hold harmless CooperSurgical from and against, all claims, damages, and other losses resulting from the improper servicing, maintenance, repair, use or operation of the product or the owner or operator's negligence or willful misconduct, and use of inadequate packing and packaging when returning product for repair.

The above warranties are in lieu of, and CooperSurgical hereby disclaims, all other warranties, express or implied, written or oral, with respect to CooperSurgical products, including the warranties of merchantability and fitness for a particular purpose. No terms, conditions, understandings or agreements that purport to modify the above warranties or that make any additional warranties for any CooperSurgical product shall have any legal effect unless made in writing and signed by an authorized CooperSurgical corporate officer.

CooperSurgical shall not under any circumstances be liable for lost profits, damages from loss of use or lost data, or indirect, special, incidental or consequential damages under its warranties or otherwise for any claim related to CooperSurgical products, even if CooperSurgical has been advised, knew or should have known of the possibility of such damages. CooperSurgical's liability with respect to a product covered by a warranty or otherwise shall be limited in all circumstances to the purchase price of that product.

SECTION 12 - RETURNING PRODUCT FOR REPAIR

Please refer to the 'Troubleshooting' section in this manual before returning product. If the problem continues with the device, please follow these instructions:

Returned Goods Policy

Goods will be accepted for return for the following reasons:

- If shipment was made without the customer's authorization or order
- If incorrect items were shipped
- If defective items were shipped
- If defective goods are covered by the standard warranty

To return product, please contact Customer Service for a Returned Merchandise Authorization (RMA) number. Items will not be accepted without an RMA number. Please have the following information:

- Reason for returning the goods
- Quantity, description, part number, serial number of the goods
- Date of receipt of order
- Customer's purchase order and the RI or Origio invoice number

All used products must be cleaned and sterilized prior to shipment. A signed decontamination declaration may be required.

All products should be carefully and adequately packed, preferably in original packaging. Replacement items or additional repairs will be invoiced.

All packaging should be clearly labeled with the RMA number and statement "Urgent – Returned Items for Repair".

Shipment must be sent prepaid by the customer and insured for their full value during shipping. Freight collect shipments will not be accepted, and goods will be returned to sender.

If Customer intends to return equipment ordered in error, the following restocking charges and terms will apply:

- 25 percent within 60 days from date of shipment
- Goods must be returned unused, in the original carton, and in marketable condition
- Refurbishing and replacement charges will be added to the restocking charges for damaged or missing items
- No return after 60 days
- No refund on sterile, single-use disposable products

Customer Service Contact Details

Tel: +45 46 79 02 02

Fax: +45 46 79 03 02

E-mail: sales@coopersurgical.com

fertility.coopersurgical.com

Contact Details for Customers in the USA

Tel: 800-243-2974

Fax: 800-262-0105

fertility.coopersurgical.com

Obligation to Inform

Any serious incident that has occurred in relating to this device should be reported to CooperSurgical via phone number +1 203-601-5200 Ext 3100 or by email at ProductSurveillance@coopersurgical.com and to the local Health Authority in your country. A serious incident may have caused or contributed to a death, a delay in a procedure which resulted in death or serious injury, or a malfunction that could have caused an adverse event.