CONSUMABLES



EZ-GRIP[®]

Instructions For Use



INDICATIONS FOR USE

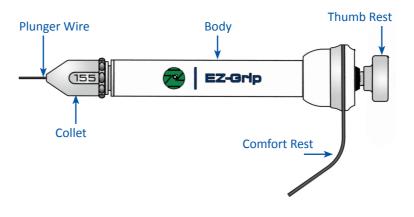
The EZ-Grip provides aspiration and expulsion capabilities to plastic pipettes when fitted during assisted reproductive procedures.

- **CAUTION:** US Federal law restricts this device to sale by or on the order of a physician.
- The EZ-Grip should only be used by qualified personnel approved by relevant authorised bodies.
- The introduction of the EZ-Grip for routine clinical use should be risk assessed prior to use.
- Pressing the plunger fully will activate the blow-out capacity.
- Do not attempt to use the EZ-Grip with fewer than the required three seals.

HOW TO USE

PREPARATION FOR USE

- RECOMMENDED: Clean and/or sterilise before first use, clean and sterilise at regular intervals as required or when contaminated. Please refer to the "Reprocessing Instructions" for full cleaning and sterilisation instructions.
- The EZ-Grip and Comfort Rest is ultrasonic and autoclave safe.
- Providing maintenance is conducted as required, there is no limit to the number of times the device may be reused.

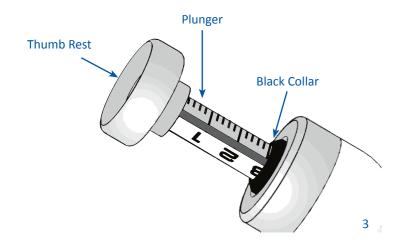


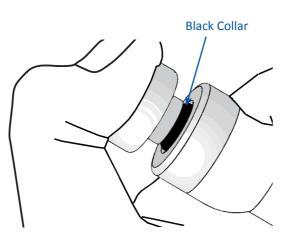
FITTING AN EZ-TIP®

- Ensure the collet is tightened down to its stop before continuing. The collet cannot be over-tightened past this stop.
- Press the plunger until the plunger wire becomes visible and is long enough to easily fit an EZ-Tip.
- Using the plunger wire as a guide, load the EZ-Tip onto the plunger wire and into the collet until resistance is met by the seals. Push it past this initial resistance until the EZ-Tip cannot be pushed any further ie it has reached the internal stop.

NORMAL USE

- Press the thumb rest to a suitable position to allow the aspiration and expelling of samples.
- Do not continue pressing the thumb rest past the black collar as this activates the blow-out capacity of the EZ-Grip. This will make it difficult to use later.
- Immerse the tip of the EZ-Tip into the sample media with the thumb rest still depressed.
- Release the thumb rest slowly to draw up some media and sample as required.
- To expel sample, press the thumb rest until there is no longer any media in the EZ-Tip or alternatively use the blow-out capacity. (See blow out capacity)



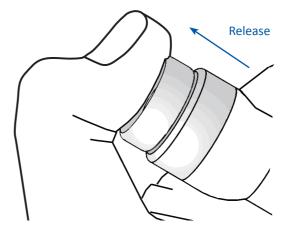


BLOW-OUT CAPACTITY

- The EZ-Grip has a maximum blow-out capacity of 1.4µl over the aspiration setting.
- To expel any remaining sample media from an EZ-Tip, press the thumb rest until it cannot be moved any further. Then release.
- The blow out capacity will be activated if the black collar is depressed also. Care should be taken to avoid the black collar during normal use unless the blow out capacity is intended to be used.

REMOVING AN EZ-TIP

- If any sample media is still present in the EZ-Tip, the blow-out capacity can be utilised.
- Before removing a pipette, check to ensure that the sample has been expelled safely.
- Press the thumb rest until there is at least 10mm of plunger wire visible inside the EZ-Tip.
- Using the plunger wire as a guide, hold the pipette firmly between your fingers and pull it carefully out of the collet.





REF 7-72-2800

INVENTORY

EZ-Grip

- 1x EZ-Grip
- Spares kit including: 1x set of 3 replacement seals 1x M2.5 hexagon key 1x replacement plunger wire
- Instructions For Use

EZ-Grip & Comfort Rest

- All of the above plus
- Comfort Rest

Plunger wire - 1-Cell MEA: ≥80% hatched blastocysts at 120h.







REF 7-72-2802

Sold Nor Sterile

Store in dry conditions

Manufacture



Research Instruments Ltd

SYMBOL GLOSSARY

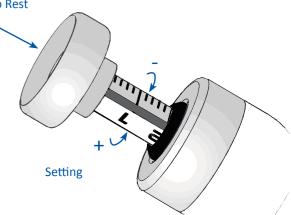
Source: ISO15223-1:2012

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7-72-2800UM, Issue 7, DRF 510K, 05/01/2017

Thumb Rest

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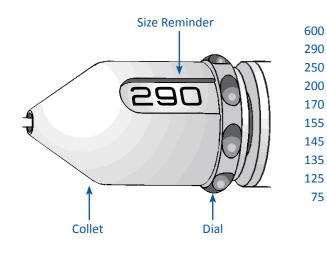


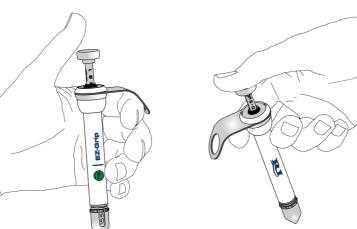
ADJUSTING VOLUME

- The EZ-Grip is preset to aspirate a maximum actuation volume of $3\mu l$ of media.
- Turning the thumb rest clockwise decreases (anti-clockwise increases) the setting.
- The settings are in increments of 0.2µl, with 3, 2 and 1µl marked as shown.
- To return the EZ-Grip to its maximum setting, turn the thumb rest anti-clockwise until the internal stop is reached.

USING THE COMFORT REST

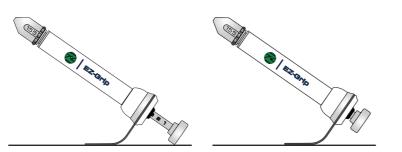
MAINTENANCE





EZ-TIP SIZE INDICATOR DIAL

- The EZ-Grip incorporates a manual size indicator dial on the collet. This dial may be used as a reminder of the size of EZ-Tip fitted. Or left blank if preferred.
- Fitting an EZ-Tip to the EZ-Grip will not automatically change the indication dial from what is shown to the size being fitted. Refer to the size indicated by the EZ-Tip packaging prior to use.

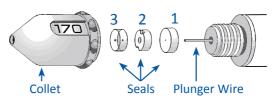


A replacement spares kit, including seals and a plunger wire, may be •

ordered from Research Instruments **REF** 5-72-2000.

REPLACING THE SEALS

- Remove the EZ-Tip from the EZ-Grip and unscrew the collet.
- Remove the old seals from the plunger wire, or from the inside of the collet if they have become stuck (the blunt end of a used EZ-Tip is ideal for this purpose), and dispose of them.



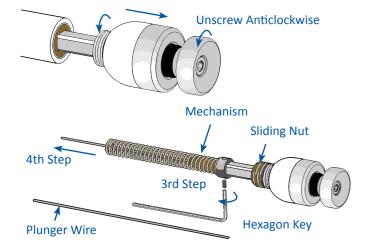
- Fit the seals over the plunger wire in this following order only:
 - 1. White rubber seal with smallest hole.
 - Plastic seal with two notches facing away from the body of the EZ-Grip.
 - 3. Translucent seal with largest hole.
- Fitting the seals in any other quantity, order or orientation than that described above will result in the EZ-Grip not functioning.
- See 'Reprocessing Instructions' as necessary.
- See 'Device Check' to ensure correct operation.

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REPLACING THE PLUNGER WIRE (CONTNUED)

- Test the EZ-Grip to ensure smooth movement and repeat steps as necessary.
- See 'Reprocessing Instructions' as necessary.
- See 'Device Check' to ensure correct operation.



REPROCESSING INSTRUCTIONS

CLEANING YOUR EZ-GRIP

- Prepare a neutral PH cleaner (eg Neutrad¹) bath per manufacturer's specifications (20 mL/L).
- 2. Submerge the assembled devices in the cleaner² bath and ultrasonicate for (20) minutes.
- 3. Rinse device under USP Purified Water until no visible evidence of cleaner remains.
- Check for visible soil. If visible soil is observed repeat cleaning steps.
- 5. Allow to dry completely before use.
- 6. See 'Device Check' to ensure correct operation.

STERILIZING YOUR EZ-GRIP

- Place the assembled³ devices into a sealed pouch^{7,8}, onto a rack⁴, into a autoclave⁴ at 135°C for 3 minutes on moist heat, pre-vacuum, 10 minutes dry time cycle. Use pouches^{5,7,8} as per manufacturer's instruction.
- Remove and allow to cool completely before use (minimum 30 minutes)⁶.
- 3. See 'Device Check' to ensure correct operation.
- 1. Neutrad detergent was used to validate this cleaning protocol
- A Fisher Scientific Model FS220 ultrasonic cleaner was used to validate this cleaning protocol.
 There is no requirement to dissemble prior to sterilisation. The validation was carried out with
- an assembled device.
 DO NOT place the device in its sealed pouch directly on the floor of the autoclave. DO NOT stack the pouches on top of each other in the autoclave.
- The validation was carried out with the device sealed in a pouch on a rack within the autoclave.
 A Steris AMSCO Lab 250 pre-vacuum steam steriliser was used to validate this sterilisation
- protocol. 7. Propper Chex-All II Pouches, dimensions 7" x 12" were used to validate this sterilisation protocol
- FDA-cleared sterilisation packaging materials should be used for sterilising procedures.

DEVICE CHECK

After reprocessing or replacing of seals or plunger wire, check your EZ-Grip is operating correctly by:

- Pressing the thumb rest so that the plunger activates the blow out function, then releasing it. Does it return to its original position?
- Rotating the thumb rest to the minimum aspiration setting, then returning it to the default (or your previous) setting. Does it rotate smoothly?
- Fitting an EZ-Tip and by holding the tip, suspend the EZ-Grip over an unused work surface for 15 seconds. Does the EZ-Grip remain suspended without dropping from the EZ-Tip?
- Fitting an EZ-Tip and following the NORMAL USE instructions. Is media aspirated and expelled?

If you answer 'no' to any of these questions, it may be that the device was reprocessed incorrectly, or it is not completely dry. If the EZ-Grip continues to malfunction, contact Research Instruments.

DISPOSAL

Dispose of the EZ-Grip in a suitable container.

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REPLACING THE PLUNGER WIRE

- Remove the EZ-Tip from the EZ-Grip.
- Unscrew the collet
- Remove all three seals.
- Unscrew the wider end of the EZ-Grip body anti-clockwise until it is free to move up the plunger.
- Turn the thumb rest anti-clockwise to unscrew the mechanism from the body.
- Using the hexagon key (supplied), gently loosen the two grub screws until the plunger wire becomes free.
- Remove the plunger wire.
- Locate the new plunger wire in the small hole in the mechanism and gently push it in, ensuring at least 60mm remains exposed.
- Tighten the two grub screws to firmly secure the new plunger wire.
- Next carefully thread the brown sliding nut back into the main body of the EZ-Grip by turning the thumb rest clockwise.
- Turn the thumb rest clockwise until at least 10mm of the plunger wire is left exposed from the collet ensuring proper alignment.
- Thread the wider end of the EZ-Grip body clockwise back into place in the 10mm recess left exposed in end of the EZ-Grip.
- Turn the thumb rest anti-clockwise until it stops to return the aspirate volume setting to its maximum 3µl.
- Replace the three seals and collet.

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TROUBLE SHOOTING GUIDE

PROBLEM	POSSIBLE REASON	ACTION
EZ-Tip does not fit	Incorrect pipette size being used	Only use 0.9mm outer diameter plastic pipettes
	Seals fitted incorrectly	Follow instructions (See pg 12)
	Plunger not depressed	Follow instructions (See pg 5)
	Plunger wire damaged	Replace plunger wire (See pg 13 & 14)
	Pipette damaged	Select new pipette
Poor control of sample	Pipette incorrectly fitted	Follow instructions (See pg 4)
	Pipette damaged	Select new pipette
	Seals damaged	Replace seals (See pg 12)
	Plunger wire damaged	Replace plunger wire (See pg 13 & 14)
	Plunger wire loose	Secure plunger wire (See pg 13 & 14)
	Sample delivery set to zero	Reset sample delivery to 1 - 3µl (See pg 8)
	Collet too loose	Tighten collet (See pg 4)
Plunger does not depress	Thumb rest tightened to body	Reset sample delivery to 1 - 3µl (See pg 8)
	Plunger wire damaged	Replace plunger wire (See pg13 & 14)
	Seals damaged	Replace seals (See pg 12)
	Plunger wire loose	Secure plunger wire (See pg 13)
	Pipette incorrectly fitted	Follow instructions (See pg 4)
Cannot adjust aspiration volume	Maximum or minimum reached	Follow instructions (See pg 8)
	Incorrectly maintained	Follow instructions (See pg 13)
	EZ-Grip damaged	Contact Research Instruments