

Ovum Pickup Needles

Description:
**1) ACE Single Lumen Ovum Pickup Needle
(B Bevel Type Needle)**

REF	Needle Gauge & Length	Aspiration Line	Vacuum Line
A-OVM-SL16/30	16g & 30cm	100cm	40cm
A-OVM-SL16/35	16g & 35cm	100cm	40cm
A-OVM-SL17/30	17g & 30cm	100cm	40cm
A-OVM-SL17/35	17g & 35cm	100cm	40cm
A-OVM-SL18/30	18g & 30cm	100cm	40cm
A-OVM-SL18/35	18g & 35cm	100cm	40cm

**2) OVUMPICK Double Lumen Ovum Pickup Needle
(B Bevel Type Needle)**

REF	Needle Gauge & Length	Aspiration Line	Vacuum Line	Flush Line
OVM-DL16/30	16g & 30cm	100cm	40cm	75cm
OVM-DL16/35	16g & 35cm	100cm	40cm	75cm
OVM-DL17/30	17g & 30cm	100cm	40cm	75cm
OVM-DL17/35	17g & 35cm	100cm	40cm	75cm

**3) ACE-FL Single Lumen Ovum Pickup Needle with Flushing Line
(B Bevel Type Needle)**

REF	Needle Gauge & Length	Aspiration Line	Vacuum Line
A-OVM-SL16/30-FL	16g & 30cm	100cm	40cm
A-OVM-SL16/35-FL	16g & 35cm	100cm	40cm
A-OVM-SL17/30-FL	17g & 30cm	100cm	40cm
A-OVM-SL17/35-FL	17g & 35cm	100cm	40cm
A-OVM-SL18/30-FL	18g & 30cm	100cm	40cm
A-OVM-SL18/35-FL	18g & 35cm	100cm	40cm

**4) ACE-M Manual Single Lumen Ovum Pickup Needle
(B Bevel Type Needle)**

REF	Needle Gauge & Length
A-OVM-SL16/30-M	16g & 30cm
A-OVM-SL16/35-M	16g & 35cm
A-OVM-SL17/30-M	17g & 30cm
A-OVM-SL17/35-M	17g & 35cm
A-OVM-SL18/30-M	18g & 30cm
A-OVM-SL18/35-M	18g & 35cm

Indications for Use:

Allwin Ovum Pickup Needles are used for laparoscopic or ultrasound guided transvaginal retrieval of oocytes from ovarian follicles.

Note:

One Cell MEA $\geq 80\%$

Bacterial Endotoxins (LAL) ≤ 20 EU/device.

Contraindications:

Ovum pick-up needle should not be used:

- In the presence of or after recent pelvic inflammatory disease
- For intra-fallopian procedures
- Active vaginal or intrauterine infection
- Sexually transmitted disease

- Recent Uterine perforation

Complications:

- Hematuria
- Extravasation of urine
- Infection
- Vaginal bleeding

Caution:

Federal (USA) law restricts this device to sale by or on the order of a physician.

Ensure that the ultrasound unit has good resolution for better visibility.

Warning/ Precaution:

- Do not use if package is opened or damaged.
- Test the system to ensure all connections are sound and flow can be achieved. Failure to test the system may result in failure to obtain the required sample and/or tissue damage.
- Failure to use ultrasound to locate the follicles may result in failure to obtain the required sample and/or tissue damage.
- Storage temperature between 5°C to 30°C.
- Dispose in accordance with recognized medical practice and under observance of applicable law and regulation.
- This device is supplied sterile and intended for single use only.
- Attempt to resterilize a single use device may compromise its structural integrity and/or lead to device failure which may result in patient injury or illness.
- Only experienced surgeon should use this device.

Instruction for Use:
Ultrasound Guided Procedure

1. The procedure should be performed under either general anesthesia or analgesia.
2. Position the patient in the lithotomy position, using aseptic technique prepare the patient and cover the area in sterile drapes. Introduce the ultrasound transducer into the vagina and scan the pelvis to establish the position of the uterus, the development of the endometrium and the number and position of follicles to be aspirated.
3. Remove the Ovum pickup needle from its packaging and insert the needle into the needle guide of the ultrasound transducer, ensuring that there is smooth movement along its length. Ensure no kinks in the tubing.
4. a) For **1, 2 & 3** – Connect vacuum pump to the luer connector on the vacuum line and a sterile collection tube to the silicone bung designed to fit 15ml Falcon tube. The vacuum pressure required varies with the gauge and the type of needle. The vacuum pressure selection is at the discretion of the performing clinician but should not exceed -500mm HG.
b) For **4** – Attach a sterile syringe to the needle for aspiration

REF Catalogue Number **LOT** Batch Code  Date of Manufacture  Use By  Do not re-use  Do not Re-Sterilize **R_x only**

 Consult Instruction for use  Do not use if Packing is damaged  Caution  Keep out of sunlight  Keep Dry **STERILE EO** Sterilized using ethylene oxide

Caution: Federal Law restricts this device to sale by or on the order of a physician or a practitioner trained in its use.

5. If Flushing is required :
 - a) For **2** – A 10ml syringe containing flushing media can be connected to the luer connector of flushing line, and flushing of the follicle performed. Aspiration of the follicle should then be repeated.
 - b) For **3** – To activate flushing line, turn the 3 way stopcock valve and attach a syringe containing flushing media to 3rd face of stopcock and perform flushing.
6. Insert the ultrasound transducer and needle into the vagina and direct the probe towards the posterolateral aspect of the vaginal fornix. Manipulate the probe until the follicles appear in close proximity to the needle.
7. Advance the needle into the nearest follicle. If the ovaries are mobile apply pressure suprapubically and enter the follicles with a stabbing movement. When the tip of the needle can be seen in the follicle, aspirate the contents until empty.
8. Repeat for all follicles within the ovary. To minimize trauma and possible bleeding keep the needle tip within the ovary between aspirations.
9. Remove the collection tube from the silicon bung when full. Replace with a new sterile collection tube.
10. When all the follicles in one ovary have been aspirated, repeat the procedure with the other ovary.
11. At the end of the procedure ensure to rinse the needle with flushing solution and discard as per standard procedure.

Laparoscopic Procedure

1. Under standard laparoscopic procedure advance the needle in the follicles.
2. Aspirate and / or flush the follicle to obtain all the oocytes from ovary.

Do not reuse, reprocess & resterilize:

Reuse, Reprocessing & resterilization may compromise the structural integrity, can also create risk of contamination & may not give desired result or create complications, infections which may result in injury, illness or death.

Limited Express Warranty:

The limited express warranty as set forth herein is exclusive and in lieu of all warranties of merchantability and fitness for use, remedies, obligations and liabilities for consequential damages. The products are being sold only for the purpose described herein and such limited express warranty runs only to the original user. In no event shall ALLWIN be liable for any breach of warranty in any amount exceeding the purchase price of the product. ALLWIN reserves the right to make design changes to products without liability to incorporate said changes in ALLWIN products previously designed or sold.

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 Consult Instruction for use	 Do not use if Packing is damaged	 Caution	 Keep out of sunlight	 Keep Dry	 STERILE EO	Sterilized using ethylene oxide	

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