

OPS[®] Art of Prodimed[®]

Warning

Read the complete directions before use.

- Failure to properly follow the instructions, warnings and cautions may lead to serious surgical consequences or injury to the patient.
- These procedures should only be performed by persons having adequate training and familiarity with these techniques.
- Consult medical literature regarding techniques, complications and hazards prior to performance of these procedures.
- To be used by or under the direction of qualified persons in line with local guidelines governing Assisted Reproductive Techniques, if applicable.

STERILE: Contents sterile unless package has been opened or damaged. Discard if product or packaging is damaged.

Description

Order code	AOPSV-80	AOPS-80
Designation	OPS[®] Art of Prodimed[®] with valve	OPS[®] Art of Prodimed[®] without valve
Units per box	5	5
Flushing valve	Yes	No
Needle	Triple bevel - Simple flow Usable length 30 cm External diameter 1.4 mm Internal diameter 1 mm 5 mm laser marked echogenic zone	
Collector tube	Usable length 80 cm External diameter 2 mm Internal diameter 1.1 mm PU	
Vacuum tube	Usable length 100 cm External diameter 5.6 mm Internal diameter 3.8 mm PU	
Bung	Fitting 10 ml Falcon [®] type collector tube	
Connection to pump	Luer-lock	

The OPS[®] Art of Prodimed[®]:

- A simple flow, triple bevel needle, with a 5 mm laser marked echogenic zone before the beveled tip.
- A thin PU catheter connecting the needle to a soft cap. The latter fits on a collector tube, such as the Falcon[®], sterilized by irradiation.
- A triple channel valve (for the model concerned) between the collection needle and the cap to use either to aspirate or rinse the follicles.
- An aspiration tube connecting the soft cap to the vacuum source.

Class IIa medical device, complying with Directive 2007/47/CE.

CE 0120 Marking.

U.S. Federal law restricts this device for sale by or on the order of a physician.

Single use: Discard after single use.

Latex free.

Individually sterile package.

Sterilized by irradiation. Do not resterilize.

Indications

In percoelioscopic or ultrasound-guided (transvesical, transvaginal, per urethral and endovaginal) oocyte collection, the OPS[®] Art of Prodimed[®] is used to:

- collect a maximum of oocytes rapidly and without trauma
- limit the risk of fracturing the zona pellucida by controlling the aspiration
- provide optimum storage conditions for the oocytes during the collection, particularly by being able to maintain the vials at an appropriate temperature using heating systems

Contraindications

The device should not be used:

- in the presence of chronic cervical infection
- in the presence of or after recent pelvic inflammatory disease

Caution

Prior to use:

- All devices coming in contact with gametes should be checked for integrity and rinsed with appropriate biological media.
- The system must be tested to ensure all connections are sound and flow can be achieved.

Instructions for use

- Check the integrity of the device (bevel sharpness, connection parts, tubing).

- Rinse the system with a biological medium adapted to the collection.
- Check the soft cap is tightly connected to the collector tube.
- Collect the oocytes under controlled negative pressure to limit the risks of zona pellucida rupture.
- The triple lumen valve in the model with tap, which can be connected to a 10 ml syringe, is used to flush the follicles under low pressure.
- Once the collector tube is full, it can be easily replaced by the next one.
- At the end of the procedure, rinse the OPS[®] Art of Prodimed[®] to make sure there is no oocyte left inside the catheter or the needle.
- Discard the device in accordance with local medical hazardous waste practices.