Indications:
- Percoelioscopic or ultrasound-guided oocyte collection.

Directions for use:
1. Before commencing the procedure, stick the traceability label in the patient's records.
2. Check the integrity of the device (needle, connections, tubing).
3. Remove the needle's protective sleeve and check the integrity of the bevel.
4. Rinse the system with a biological medium suitable for punctures.
5. Make sure no connections present any leakage and that the cap is sealed at the manifold.
6. Position the endovaginal probe to visualise the ovary and the follicles.
7. Localise the blood vessels in and around the ovary and determine a direct trajectory to the follicles to aspirate.
8. Introduce the needle in the guide of the endovaginal probe.
9. Proceed with the oocyte retrieval (on the single needle model, the arrow on the hub shows the direction of the bevel).
10. Collect the oocytes under a controlled negative pressure of 120 to 180 mm Hg in order to limit the risks of the zona pellucida rupturing.
11. After the aspiration procedure is completed, rinse the needle with the appropriate solution to ensure that no oocytes remain inside the tubing or needle.
12. Discard the needle in an appropriate container and follow the waste disposal process.
13. In the event of a problematic rupture, carefully replace the needle protective sleeve and store the device to have it checked by the manufacturer.

Contraindications:
- Untreated lower genital tract infections.
- All counterindications of the range of application are applicable as they are assumed to be known for such retrievals according to medical practice regulations.
- Pregnancy.
- Do not use in patient presenting a cervical (chronic) infection.
- Do not use in patient presenting or having recently presented a pelvic inflammatory disease.
- These devices are intended for adult women (over 18 years of age).

Complications:
1. Perforation of a neighbouring organ, e.g.:
- Ureteral wound,
- Ureterovaginal fistula,
- Urine leaking in the abdominal cavity due to a bladder lesion,
- Bladder wound resulting in hematuria or even clot retention.

2. Hemorrhage:
- Abdominal hemorrhage (through the vagina),
- Vaginal bleeding.

3. Infections:
- Genital infection, e.g. tubo-ovarian infection,
- Ovarian abscess,
- Peritonitis.

Precautions of use:
- In patients with clotting disorders, take usual precautions.
- The procedure must be stopped if the needle cannot be seen on the ultrasound screen.
- Maintain the tip of the needle inside the follicle until the end of aspiration.
- In the event of bleeding, apply direct pressure.
- The patient must be monitored for a few hours after the puncture procedure (hemoperitoneum, bleeding, etc...).
- In patients with ovarian hyperstimulation, the evaluation of the extent of intraperitoneal bleeding after the puncture procedure must be based on changes in the RBC count and hematocrit rather than on the estimated volume of peritoneal fluid.
- Retrievals of this kind are to be carried out exclusively by health professionals qualified.
- Make sure the packaging is not open or damaged before use and check the expiry date.
- These instruments has been expressly made for single use, these devices may not be re-used after a single application. The quality of materials, coatings and adhesive joints may deteriorate. A secure application is no longer guaranteed. These products are not designed for cleaning and sterilization processes after a single use. The sterility of the single-use device is therefore not guaranteed if re-used. The risk of unintentional injuries or infections increases unmeasurably. PRODIMED does not claim responsibility in case of resterilization and reuse of the device.

Storage conditions:
- Do not use after the expiry date printed on the packaging.
- Do not use if primary packaging is opened or damaged.
- Store in a dry place, protected from sunlight.

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AIGUILLES ET SETS POUR PRELEVEMENT OVOCYTAIRE

NEEDLES AND SETS FOR OOCYTE RETRIEVAL

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