

Igla za punkcijo foliklov**Indikacije**

Igla za punkcijo foliklov je namenjena aspiraciji foliklov iz jajčnikov, za namen postopka oploditve z biomedicinsko pomočjo.

Kontraindikacije

Izdelek se ne sme uporabljati na pacientkah, katere so preobčutljive na uporabljene materiale. Uporaba izdelka ni dovoljena ob prisotnosti vaginalne infekcije, spolno prenosljivih bolezni, nedavni perforaciji maternice ali s pacientkami, katere so trenutno noseče. Uporaba izdelka je dovoljena le ob soglašanju pacientke s postopkom aspiracije foliklov. Maksimalen čas uporabe 60 minut.

Možni stranski učinki

Pri uvajanju igle skozi nožnico pride lahko do krvavitve iz nožnice, okužbe sečil ali maternice, poškodb notranjih organov kot so črevesje, sečni mehur, sečevod, maternica ali jajčniki, krvne žile ali do nastanka notranjih brazgotin, kot posledica postopka punkcije. Po postopku aspiracije foliklov lahko pacientka čuti rahle bolečine v predelu trebuha, rahlo utrujenost kot posledico anestezije. Lahko se pojavijo izcedki iz nožnice, rdeče ali rjave barve. Stranski učinki se pri aspiraciji foliklov lahko pojavijo, pri tem ni razloga za dodatno skrb, razen če se stanje poslabša. V primeru poslabšanja stanja takoj poiskati zdravniško pomoč! Pacientke je potrebno pred postopkom aspiracije foliklov seznaniti s vsemi zgoraj naštetimi tveganji.

Uporabljeni materiali

Nerjavno jeklo AISI 304, politetrafluoroetilen (PTFE), silikon, polietilen (PE), medicinski PVC brez ftalatov (PVC DEHP-FREE), metakrilat-butadien-stiren (MBS).

Navodila za uporabo

1. Pred uporabo izdelka pripravite roke v skladu s higienskimi navodili.
2. Preverite, da izdelku ni potekel rok sterilnosti in da embalaža ni odprta ali poškodovana.
3. Sterilen ovoj previdno odprite na predvidenem mestu z uporabo aseptične tehnike.
4. Izdelek vzemite iz ovoja, ga vizualno pregledajte, da ni mehansko poškodovan in ga takoj uporabite.
5. Silikonski zamašek na povezovalnih ceveh spojite z epruveto za zbiranje tekočine (silikonski zamašek se uporablja v kombinaciji s 15 ml Falcon epruveto).
6. Povezovalno cevko z Luer lock priključkom priključite na aspirator s kontrolno vleka. Pri tem pazite na trdnost spoja.
7. Prehodnost izdelka lahko preverite z aspiriranjem približno 5 ml medija. Če je postopek uspešen, zbirno epruveto zamenjajte, v nasprotnem primeru pa zamenjajte iglo.
8. Z uporabo ultrazvoka določite folikle, katere boste aspirirali.
9. Iglo uvajajte skozi vodilo ultrazvočne sonde in pričnite z aspiriranjem. Pri tem pazite, da povezovalne cevi niso prepognjene in s tem neprehodne.
10. Če je po končanem postopku aspiriranja potrebno izpiranje kanile in povezovalne cevi, uporabite izpiralno iglo. Povlecite iglo iz vodila ultrazvočne sonde, odstranite silikonski zamašek iz epruvete in vstavite izpiralno iglo v povezovalno cevko z oblikovanim (razširjenim) koncem. Luer brizgalko z izpiralnim medijem priključite na izpiralno iglo in izperite sistem v epruveto.
11. Po končanem postopku izdelek zavrzite v skladu z medicinsko prakso.

Previdnostni ukrepi

Izdelek je namenjen samo za enkratno uporabo. V primeru ponovne uporabe obstaja tveganje okužbe z boleznimi prenosljivimi s krvjo in ostalimi telesnimi tekočinami. Uporabiti samo, če je embalaža nepoškodovana. Po uporabi je potrebno izdelek zavreči v skladu z medicinsko prakso.

Opozorilo!

Igla za punkcijo foliklov sme uporabljati samo ustrezno usposobljeno medicinsko osebo s poznavanjem tehnike aspiracije foliklov.

Skладиščenje


Pred uporabo mora biti izdelek shranjen v originalni embalaži v čistem in suhem prostoru pri temperaturi med 5 °C in 40 °C. Izdelek je potrebno zaščititi pred direktno sončno svetlobo. Če je izdelek pravilno skladiščen in embalaža ni odprta ali poškodovana je rok sterilnosti 5 let.

Proizvajalec: TIK d.o.o., Proizvodnja medicinskih pripomočkov
Goriška cesta 5b
5222 Kobarid, Slovenija
Tel: +386 (0)5 389 07 00
E-mail: info@tik.si


**Razlaga grafičnih simbolov:**

STERILE EO Sterilizirano z etilen oksidom

 Za enkratno uporabo

 Rok uporabnosti

 # Količina v embalaži

 Ne uporabljaj če je embalaža poškodovana

LOT Številka serije

REF Kataloška številka

 Datum izdelave


 Hraniti na suhem


 Opozorilo


 Ne resteriliziraj


 Proizvajalec


 Premer

 Prazno embalažo odvrzi na primerno mesto

 Ne vsebuje lateksa

 Ne vsebuje DEHP

 Dolžina

 Ne izpostavljalj sončni svetlobi

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Follicle aspiration needle**Indications**

The follicle aspiration needle is indicated for ultrasonic guided, transvaginal harvesting of oocytes from follicles for IVF.

Contraindications

The product should not be used on patients with known hypersensitivity to any of the materials employed. The product should not be used on patient with an active vaginal or intrauterine infection, sexually transmitted diseases, a recent uterine perforation, a recent caesarean section, or who is currently pregnant. The product is not intended for use with uncooperative patient. Maximal time of use 60 minutes.

Possible side effects

At the passing of the needle through the vagina towards the ovaries it can appear a vaginal bleeding, an urinary tract infection or an uterine infection, damage to organs like a bowel, a bladder, an ureter, an uterus or an ovaries, a blood vessels and an internal scarring caused by the procedure. Post-egg retrieval effects are a slight tender in the abdomen, maybe a little fatigue caused by anaesthesia and red or brown vaginal spotting. All those consequences are normal and there is no reason for worry, unless they get worse. In that case, the patient should immediately contact the doctor! Patients should be informed before procedure for all complication listed above.

Materials used

Stainless steel AISI 304, polytetrafluoroethylene (PTFE), silicone, polyethylene (PE), medical grade PVC with no phthalates (PVC DEHP-FREE), methacrylate-butadiene-styrene (MBS).

Instructions for use

1. Prepare hands before use of the product by following hygiene instructions.
2. Check the sterilisation expiry date. Prior to use, ensure that the packaging is not opened or damaged.
3. Carefully open the peel pack on the marked place using the aseptic technique.
4. Visually inspect the product for any damage and use it immediately.
5. Attach the silicone cork with the sampling tube (design to fit 15 ml Falcon tube).
6. Connect the connecting tube with Luer lock connector on the vacuum pump. Make sure that all connections are well secured.
7. The follicle aspiration needle can be tested for patency by placing the needle tip in a spare sampling tube, containing approximately 5 ml of culture medium and then applying vacuum. If the procedure is successful, replace the sampling tube with new one, otherwise replace the needle.
8. Introduce ultrasound transducer to identify the follicles. Determine a direct puncture path into the ovarian follicles to be aspirated.
9. Insert the needle into the needle guide on the ultrasound probe. Be careful, that connecting tubes are not kinked during the procedure.
10. If flushing of cannula and connecting tube after finishing the aspiration procedure is needed, use ablation needle. Remove the needle from the ultrasound guide, detach the sampling tube from the silicone cork and insert the ablation needle into the connecting tube with formed (spreaded) end. Attach a Luer syringe with flushing media to the ablation needle and flush it into the sampling tube.
11. After use disposed the product in accordance with clinical practice for medical hazardous waste.

Precautions



















The product is intended for single use only. In case of re-use there exists a risk of infection with diseases transmitted by blood or other body fluids. Use only if package is undamaged. After single use, discard the product in accordance with clinical practice for medical hazardous waste. Attention! Follicle aspiration needle should be used only by medical person qualified in gynaecological and follicle aspiration procedures.

Storage

Before use the product should be stored in original packaging in a clean, dry place at temperature between 5 °C and 40 °C. The product should be protected of direct sun light. Sterility is assured for 5 years unless package is opened or damaged.

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**General graphic symbols explanation:**

 Sterile using ethylene oxide	 Batch code	 Caution	 Latex free
 Single use	 Catalogue number	 Do not resterilize	 DEHP free
 Use by	 Date of manufacture	 Manufacturer	 Length
 Quantity	 Keep dry	 Diameter	 Keep away from sunlight
 Do not use if package is damaged		 Dispose of this carefully and thoughtfully	

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