Instruction for Use

D-TIP DENUDATION PIPETTES

Description:

Sr. No.	Device Name	Product Code
1	D-TIP Denudation Pipettes	D-TIP 125µm
2	D-TIP Denudation Pipettes	D-TIP 130µm
3	D-TIP Denudation Pipettes	D-TIP 135µm
4	D-TIP Denudation Pipettes	D-TIP 140µm
5	D-TIP Denudation Pipettes	D-TIP 145µm
6	D-TIP Denudation Pipettes	D-TIP 155µm
7	D-TIP Denudation Pipettes	D-TIP 170µm
8	D-TIP Denudation Pipettes	D-TIP 175µm
9	D-TIP Denudation Pipettes	D-TIP 200µm
10	D-TIP Denudation Pipettes	D-TIP 275µm
11	D-TIP Denudation Pipettes	D-TIP 300µm

Intended use:
D-TIP pipettes are intended to be used for denudation i.e. to remove cumulus oocytes complexes from oocytes before Intracytoplasmic Sperm Injection (ICSI) procedure and handling or manipulating of oocytes and embryos in Assisted reproduction technique (ART).

Indications for Use:
The medical condition is infertility and genetic disease.

Patient Target Group:
Couples, whose fertility is impaired and require assisted reproduction treatments to improve their chances of a healthy pregnancy.

Contraindications:
No known contraindication

Complications:
No Known Complication

Clinical benefit:
D-TIP pipette, lies in its ability to enhance the quality and viability of oocytes during Assisted Reproductive Technology (ART) procedures. By effectively removing cumulus cells from oocyte
complexes, the pipette ensures that oocytes are optimally prepared for fertilization techniques like Intracytoplasmic Sperm Injection (ICSI). This precise denudation process not only improves the accessibility of the oocyte for sperm injection but also contributes to better embryo development and implantation rates, ultimately increasing the chances of successful pregnancies in patients undergoing fertility treatments.

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

Warning / Precaution:
- Check that the package has not been damaged. Do not use if package has been compromised. (Medical device provides the sterile barrier).
- Denudation pipette should be used only with pipettors compatible with the proximal dimensions.
- Check the pipette TIP under microscope to ensure it is clear in dimension.
- If the appropriate TIP is not selected sample damage is possible during IVF procedure.
- These tools are intended for one time use only and must remain covered until ready to use in order to maintain both sterility and prevent contamination.
- The user is warned to follow safe established laboratory practices in order to prevent accidental DNA contamination after the D-TIP has been removed from its protective covering.
- Do not reuse.
- Do not resterilize.
- This device is supplied sterile and intended for single use only
- The intended users of the device are skilled medical professional specializing in Assisted Reproductive Technique (ART).

Performance characteristics:
- Sterilised by gamma irradiation to a Sterility Assurance Level (SAL) of 10^{-6}.
- 1-Cell MEA: ≥80%
- Non-Pyrogenic (Limulus Amebocyte Lysate [LAL] Test), Pass Level: ≤20 EU/device.
- Depending on the size of the TIP the volumetric capacity of the EZ-TIP is 15.9 - 25.4µl.

Instructions for Use:
D-TIP Denudation Pipette is a class IIa device and it is a legacy device. D-TIP Denudation Pipette is based on existing technology. Intended user of the D-TIP Denudation Pipette are medical specialists trained in fertility treatment. D-TIP Denudation Pipette can be used safely without any such instruction, so instruction for use is not required.

Storage:
- The device should be stored in a clean, dry area.
- Do not expose to organic solvents, ionizing radiation or ultraviolet light.
- The devices must be used prior to the sterilization expiration date on package.

How Supplied:
The D-TIP Denudation is provided sterile by gamma sterilization and is intended for single use only.

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.

EU REP
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Single Sterile Barrier system with protective packaging inside

CE 0123

UDI Unique Device Identification

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