

General / intended use

GyPetto is a reusable cell handling instrument (pipettor) for use in the field of human assisted reproductive medicine. It is used for the treatment of cells or media transfer with suitable denaturation or handling pipettes (outer diameter 0.9 mm, e.g. Gynemed „DENU-Tips“). Not included in the scope of delivery.

The product may only be used by qualified personnel / medical professionals (biologists, laboratory technicians).

Check before use

- Before first use, it is recommended to clean and/or wipe-disinfect the product. The product should be cleaned and/or disinfected as required / at regular intervals or in the event of contamination (see section „Cleaning“).
- Make sure that the device has been properly maintained. Only then can it be ensured that the specified service life of 5 years is guaranteed (see section „Maintenance“). 5-year service life is guaranteed (see „Maintenance“ section).

Instruction for use

Attaching a denaturation pipette („Denu-Tip“)

- Loosen the tip of the GyPetto (approx. one turn) and press the thumb rest until the plunger wire becomes visible.
- Insert the Denu-Tip onto the plunger wire and into the tip until resistance is met.
- Push the tip past the initial resistance until it stops.
- Tighten the tip. Please note: Overtightening can affect the ability of the piston to slide.
- Check the hold before use by pressing the thumb rest several times.

Use

- Press the thumb rest to the first stop and hold it in this position so that the black ring remains visible.
- Immerse the tip of the Denu-Tip into the sample medium and slowly release the thumb rest to aspirate the medium/sample.
- Press the thumb rest to eject the sample or alternatively use the blowout capacity (see blowout capacity).

Volume adjustment

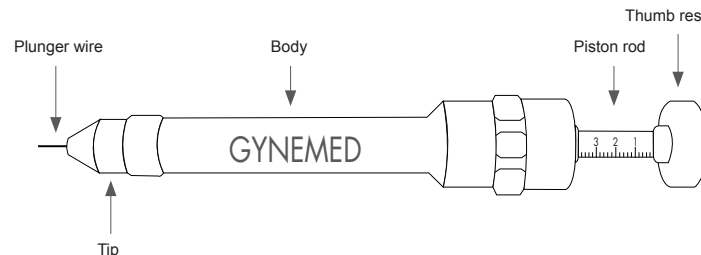
- Turning the thumb rest decreases (clockwise) or increases the volume (counterclockwise). The adjustment is stepless, the markings are for support.
- (Caution: do not turn beyond the value 3.4. This can lead to loosening of the piston rod).

Blow-out capacity

- The blow-out capacity for ejecting residual amounts is activated by pressing the thumb rest so that the black ring is no longer visible.

Removal of Denu-Tip

- First check that the sample has been safely ejected.
- Press the thumb rest until approximately 1 cm of plunger wire is visible inside the Denu-Tip.
- Using the plunger wire as a guide, hold the Denu-Tip firmly between your fingers and gently pull the Denu-Tip out of the tip.



⚠ Precautions and Warnings before use

- **Caution:** Do not turn the piston rod beyond the value of 3.4. This can lead to loosening of the piston rod and thus to the inoperability of the product.
- Do not attempt to use the GyPetto with fewer than the required three seals.
- Any serious incident (as defined in the European Medical Devices Regulation 2017/745) that has occurred should be reported to Gynemed GmbH & Co. KG and, where applicable, to the competent authority of the EU Member State where the user and/or patient is established will...

Cleaning

- The GyPetto is suitable for wiping with disinfectant cleaning. Allow to dry completely after cleaning and before use.
- Moisten a lint-free cloth with a suitable disinfectant.
- Observe the safety instructions and the exposure time of the disinfectant.
- Wipe all surfaces of the GyPetto with the damp cloth.
- Allow to dry completely before use.

Device Check

- After cleaning or replacing seals or the plunger wire, check that the GyPetto is working properly.

Go through the following points:

- Press the thumb rest all the way down and then release.
- Turn the thumb rest to the minimum volume setting and then back to 3.4.
- Insert a Denu-Tip and hold the GyPetto by the Denu-Tip just above a soft work surface for 5 seconds.
- When performing the above, if the piston returns to its original position, the thumb rest rotates smoothly, the GyPetto can be held in the air by the Denu-Tip, and the media is aspirated and ejected, your device is fully functional.
- If one of the points does not produce the desired result, the device is probably not assembled correctly or it is not completely dry. If the GyPetto malfunctions, contact Gynemed GmbH & Co. KG.

Maintenance

- A spare parts set consisting of a plunger wire, seals and an Allen key can be ordered from Gynemed GmbH & Co. KG.
- A service life of 5 years is guaranteed. Requirement: Maintenance is carried out as described below.

Replacement of Seals

Recommendation for replacement: every **six months**. A premature replacement may be necessary in the case of contamination, for example.

- Unscrew the GyPetto tip and remove all seals.

Install the new gaskets over the piston wire only in the following order:

1. Transparent seal with the smallest hole (towards the body).
2. White seal with funnel shaped hole (largest diameter towards tip).
3. Transparent seal with the largest hole (towards the top).

- Attaching the seals in a different quantity, order or orientation affects the functionality of the GyPetto.
- Screw the tip back on and check its functionality.

Replacement of Plunger wire

It may be necessary to change the plunger wire if it is damaged or if the GyPetto is no longer functional.

- To replace, remove the tip of the GyPetto and remove the seals.
- Unscrew the wider end from the base body in an anti-clockwise direction.
- Turn the thumb rest counterclockwise to separate the mechanism from the body and pull out the plunger wire.
- Using the hex wrench, carefully loosen the two grub screws until the plunger wire is free. Insert the new plunger wire into the small opening and gently push in until at least 6 cm is visible.
- Screw the new piston wire hand-tight with the two grub screws.
- Screw the copper colored plunger guide into the main body of the GyPetto by turning the thumb rest clockwise. Make sure the spring is inside the body and the plunger wire is passed through.
- Rotate the thumb rest clockwise until approximately 1 cm of plunger wire protrudes from the tip to ensure proper alignment.
- Screw the wider end of the base body clockwise back into the GyPetto without leaving any gaps.
- Turn the thumb rest counterclockwise until you feel resistance.
- Insert the three gaskets as described above and screw the tip back on.
- See „Device Check“ to ensure functionality.

Disposal

- The product must be disposed of in accordance with local regulations on the disposal of medical devices.

Technical Support

GYNEMED GmbH & Co. KG
Lübecker Straße 9 - 23738 Lensahn - Germany

Phone: +49 (0) 4363 90 32 90
Fax: +49 (0) 4363 90 32 9-19

E-Mail: info@gynemed.de
<http://www.gynemed.de>

Troubleshooting

Problem	Possible reason	Action
Tip does not fit	Incorrect pipette size being used	Use DENU-Tip with outer diameter of 0.9mm
	Seals fitted incorrectly	see „Replacement of Seals“
	Plunger not depressed	see „Use“
	Plunger wire damaged	see „Replacement of plunger wire“
	Pipette damaged	use new DENU-Tip
Poor control of sample	Pipette incorrectly fitted	see „Use“/“Removal of Denu-Tip“
	Pipette damaged	use new DENU-Tip
	Seals damaged	see „Replacement of Seals“
	Plunger wire damaged	see „Replacement of plunger wire“
	Plunger wire loose	see „Replacement of plunger wire“
	Sample delivery set to zero	see „Volume adjustment“
	Tip of GyPetto too loose	tighten tip
Plunger does not depress	Thumb rest tightened to tight	tighten tip
	Plunger wire damaged	see „Replacement of plunger wire“
	Seals damaged	see „Replacement of Seals“
	Plunger wire loose	see „Replacement of plunger wire“
	Pipette incorrectly fitted	see „Use“/“Removal of DENU-Tip“
Cannot adjust aspiration volume	Maximum or minimum reached	see „Volume adjustment“
	Incorrectly maintained	see „Cleaning“ and „Maintenance“
	GyPetto damaged	contact Gynemed

Glossary of Symbols

Symbole gemäß ISO 15223-1/ Symbols as defined in ISO 15223-1			
REF	Artikelnummer Catalogue number	SN	Seriennummer Serial number
MD	Hersteller Manufacturer	MD	Medizinprodukt Medical device
Country	Land der Herstellung/ Herstellungsdatum Country of manufacture/ Date of Manufacture	i	Gebrauchsanweisung beachten Consult instructions for use
Steril	Nicht steril Not sterile		
Symbole gemäß MDR 2017/745/ Symbol according to MDR 2017/745			
CE	CE-Kennzeichnung CE marking		