

Instructions for use of the medical device

SG System Micropipettes for handling of human embryos and oocytes

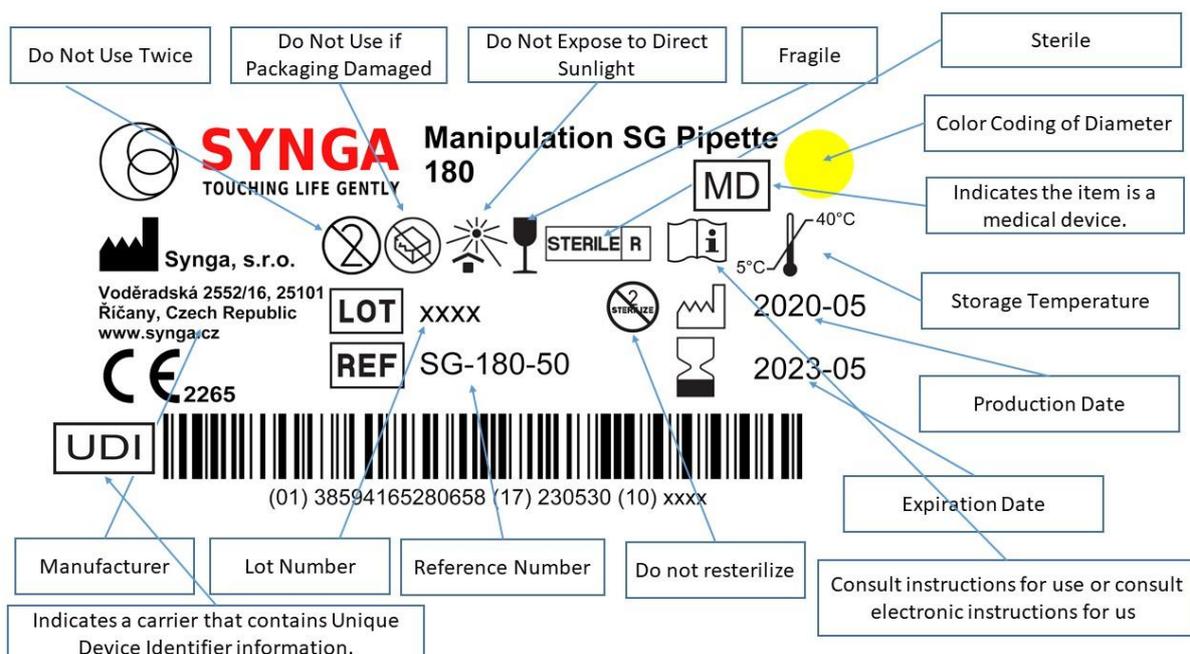
Model: Denudation SG Pipette, Manipulation SG Pipette, Blastocyst SG Pipette, SG Holding Pipette, SG ICSI Pipette, SG Biopsy Pipette, SG Flex Denudation Pipette, SG Flex Manipulation Pipette, SG Flex Blastocyst Pipette.

Intended Use: Made from glass and plastic, sterile, single-use pipettes for embryo/oocyte manipulation in vitro with defined inner diameter size.

Indication: Sterile pipettes for single use in the manipulation of human oocytes and embryos in vitro with a defined internal diameter for manipulation, vitrification and intracytoplasmic sperm injection (ICSI) or other assisted reproductive techniques. Target group: A man and a woman (couple) involved in the process of in vitro fertilization and embryo transfer. The product will only come into contact with gametes (oocytes, sperm) and embryos under in vitro conditions. User: Handling of devices (micropipettes) is only allowed in certified laboratories by certified embryologists according to certified SOPs (standard operating protocols). Medical conditions: Assisted reproductive techniques involving in vitro manipulation of human embryos/oocytes, vitrification and intracytoplasmic sperm injection (ICSI) or other methods. They are made of borosilicate glass or plastic (PC) and are intended for single use in health care or laboratories of other industries.

The SG System micropipettes for in vitro human embryo/oocyte manipulation must not be combined in units with other medical devices. However, it may be used in routine laboratory IVF practice along with other devices.

Labelling description:



Contraindications, adverse effects: Contraindications and adverse effects within the intended use are not known to the manufacturer.

Application Policy: The product is used under normal laboratory conditions.

Warning: The product must not be used twice - repeatedly. The packaging must be free from any signs of damage, opening or tampering.

The permissible temperature range for storage is 5-40 deg. C. Do not expose to sunlight. Do not use after the expiry date.

Vigilance: In the event of an adverse event, contact the manufacturer at mail@synga.cz. and the competent authority of the Member State.

The form is available here: <https://ec.europa.eu/docsroom/documents/41681>.

Disposal: Dispose of as hazardous waste in accordance with the legislative framework in the country of use.

Note to users: The manufacturer welcomes feedback from patients. Please send your experiences with the Micropipette SG System for in vitro human embryo/oocyte manipulation, whether positive or negative, and in particular any adverse reactions (incidents) and complaints to the manufacturer by email or to the address of the company headquarters.

Manufacturer: Synga, s.r.o., Voděradská 2552/16, Říčany, 25101, Česká republika

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