injeTAK® ADJUSTABLE TIP NEEDLE

STERILE AND NON-PYROGENIC — SINGLE USE ONLY
DO NOT RESTERILIZE AND DO NOT REUSE

Intended Use
The injeTAK® Adjustable Tip Needles are intended to be used to deliver a variety of legally marketed drugs into tissues or structures during cystoscopic procedures. They are provided sterile for single use only.

Description
DIS198: injeTAK® Adjustable Tip Needle for Rigid Cystoscope Use, 35cm, 25g/6FR, adjustable tip length 0mm, 2mm, 3mm, 5mm.
DIS199: injeTAK® Adjustable Tip Needle for Rigid Cystoscope Use, 35cm, 23G/4.8FR, adjustable tip length 0mm, 2mm, 3mm, 4mm, 5mm.
DIS200: injeTAK® Adjustable Tip Needle for Flexible Cystoscope Use, 70cm, 23g/6FR , adjustable tip length 0mm, 2mm, 3mm, 5mm.
DIS201: injeTAK® Adjustable Tip Needle for Flexible Cystoscope Use, 70cm, 23G/4.8FR , adjustable tip length 0mm, 2mm, 3mm, 4mm, 5mm.

Sterilization Method
Devices sterilized with Ethylene Oxide Gas (EO).

Supplied Items
Individually packed sterile disposable needles per mini-pack box. Quantity varies.

Compliant to Standards
- EN 20594-1 (1994) and EN 1707 (1997) – Conical fittings for needles and syringes.
- EN ISO 14644-5 (2004) – Cleanroom manufacturing
- EN ISO 11607-1 (2009) and EN ISO 11607-2 (2006) – Sterile packaging
- EN ISO 15223-1 (2012) - Labeling Symbols
- ANSI/AAMI ST72 (2011) – Passes the LAL Kinetic Chromogenic tests
- ASTM F1140-07 (2007) – Internal Pressurization failure resistance of unrestrained packages
- ASTM F1929-98 (2004) – Seal leak detection in porous medical packaging by dye penetration
- ASTM F88/F88M-09 (2009) – Seal strength of flexible barrier materials
- ASTM F1980-07 (2011) – Accelerated aging of sterile barrier systems
- EN ISO 10993-1(2009) Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a risk management process
- EN ISO 10993-5 (2009) Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- EN ISO 10993-7 (2008) Biological Evaluation of Medical Devices - Part 7: Ethylene oxide sterilization residuals
- EN ISO 10993-10 (2010) Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- ANSI/AAMI ST72 (2011) Bacterial endotoxins - Test methodologies, routine monitoring, and alternatives to batch testing
- Refer to Declaration of Conformity for additional standards

Treating and Disposing of Product after Use
After use, discard the product and its packaging according to your institution's standard operating procedures on medical waste handling.
NOTE: Each batch of the device carries a unique LOT# printed on all packaging labels for traceability and is registered in a computerized tracking system.

Caution
Federal law restricts these devices to sale by or on the order of a licensed physician.

Warnings
- **Read instruction sheet carefully before use.**
- These devices are **single use only** and are intended to be used only by trained physicians who are familiar with associated pathologies and possible complications.
- **The devices are identified as single use only and cannot be reused or resterilized**. Reuse, reprocessing or resterilization could lead to failure of the devices and create a risk of cross-infection and/or cross-transmission of infectious disease(s) from one patient to another. Result of sterilization failure could lead to cross infection and/or cross-transmission of infectious disease from one patient to another.

Warnings (continued…)
- Do not use if package has been opened, or damaged, or if it presents any fault due to improper transport, storage, or handling that could in any way hamper its use.
- To reduce the possibility of sterilization contamination before use, Tyvek® packaging is used.
- Do not bend or fold the Tyvek packaging as this may compromise product sterility.
- To prevent damage at joint section of connector, avoid using large volume or heavy syringes (>15cc) with the needle.
- Avoid excessive bending force or angle (preferably -60°<α<60°) on the needle shaft.
- Always wear protective gloves, gown, and/or mask during procedures.
- Drug leaks should be flushed and drained from injection spot immediately.
- Leak is prevented in design by placing a seal rubber O-ring between the moving handle and distal end of needle hub.
- The needles are not recommended for delivering drugs with a viscosity over 4cP.
- To minimize the potential of unexpected needle tip movement, ensure the lock-pin is secured in place at the pre-set length.
- Always prime the needle before performing injection procedure.
- Always check the expiry date printed on packaging before use.
- To minimize tissue damage or pain sensation, needle tip angle is designed for bladder injection with consideration of the nature of the human bladder wall.
- To minimize patient discomfort**,** the needle gauges are designed to be as large as possible while maintaining patient safety.
- To minimize tissue damage and pain, needle point bevel angles are designed to be as sharp as possible to allow precise tissue puncture.
- To reduce the possibility of leaks from inside and connector dislodging, the needle is tested under high fluid pressure (DIS198 and DIS200 >250 psi; DIS199 and DIS201 >50 psi).
- To prevent accidental needle tip detachment or dislodged materials, the needle uses an integral needle cannula elongating from the needle hub to the free end throughout the sheath.
- To minimize the chance of producing cores, the needle tip is designed specifically with "Anti-coring" in mind. In addition, the chance of producing "cores" or dislodging material is minimal as needle port is open and in parallel with the needle tip.
- To minimize bio-contamination, the injeTAK® is non-pyrogenic.
- To reduce the possibility of bio-incompatibility, the needles are tested according to EN 10993 and manufactured using bio-compatible materials (medical grade plastics, stainless steel).
- To help prevent the needle from accidentally passing through the bladder wall, the needle tip has a small black contrast mark and is clearly visible under the Cystoscope monitor.
- To ensure connection to any medical syringe with a standard male luer connector, the needle is designed with a female luer lock connector in compliance with standard EN 20594 -1(1994) and EN 1707(1997).
- Use of the injeTAK® adjustable tip needle outside of its stated intended use is not supported by LABORIE Medical Technologies Canada ULC.
- Local/general anaesthetic may or may not be employed at the discretion of the physician.
- Physician should explain risks of the procedure to the patient. It is recommended any anticoagulation medicine is stopped 5 days prior to start of procedure.
- Physician should be knowledgeable and qualified in applying the appropriate sterile technique during the intended use of the device. The use of prophylactic antibiotics is at the discretion of the physician and the policies of the institution.
- The device is specifically designed for bladder wall injection with multiple tip length options (0mm, 2mm, 3mm, 4mm, 5mm) based on the nature of the bladder wall (normal thickness 3 ± 1mm), where "0mm" is for patient /Cystoscope protection when injection is in standing by status; "2mm" is for injection in dome area of bladder; "3mm" or "4mm" is for injection in the side area of bladder; "5mm" is for injection at the bottom of bladder or prostate injection.
- The injeTAK® Adjustable Tip Needles are identified as single-use only and cannot be reused or re-sterilized. Reuse, reprocessing or re-sterilization could lead to failure of the devices and create a risk of cross-infection and/or cross-transmission of infectious disease(s) from one patient to another. Re-use, re-processing or re-sterilization may compromise the structural integrity of the needle and/or lead to device failure. It may also lead to a decrease in sharpness of the needle, which can result in increased pain to the patient during insertion. If the injeTAK® needles are re-used, re-processed and/or re-sterilized, it may lead to slow material degradation of the needle cannula (i.e. stainless steel) and insulation.

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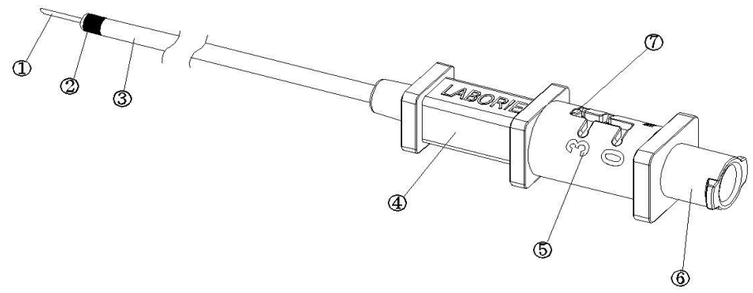
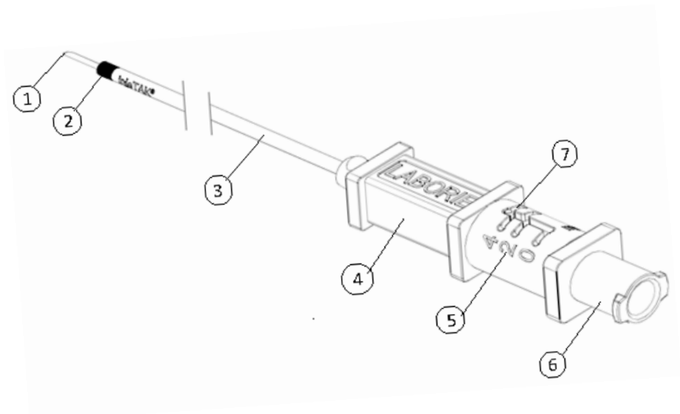
Instructions for Use - DIS198 and DIS200

1. Remove a needle from the pouch and protective sleeve.
2. Fill a syringe with drug solution.
3. Attach the syringe to the luer-tip [⑥] of the needle. Set needle tip [①] to “3” or “5” at the handle. Prime and remove any air bubbles from the needle cannula [①].
4. Set needle tip [①] to “0”; insert it into the working channel of the Cystoscope until the contrast marker [②] can clearly be seen through the Cystoscope eyepiece or visional system.
5. Select a suitable needle tip length (2, 3, 5mm) at the handle [⑤] according to the targeted injection location and operator’s experience.
6. Move the needle or Cystoscope to puncture the targeted tissue and perform the injection at an appropriate speed.
7. Upon completion of the procedure retract the needle tip [①] back to position “0” and withdraw the entire needle out of the Cystoscope and dispose of the needle in a safe location.



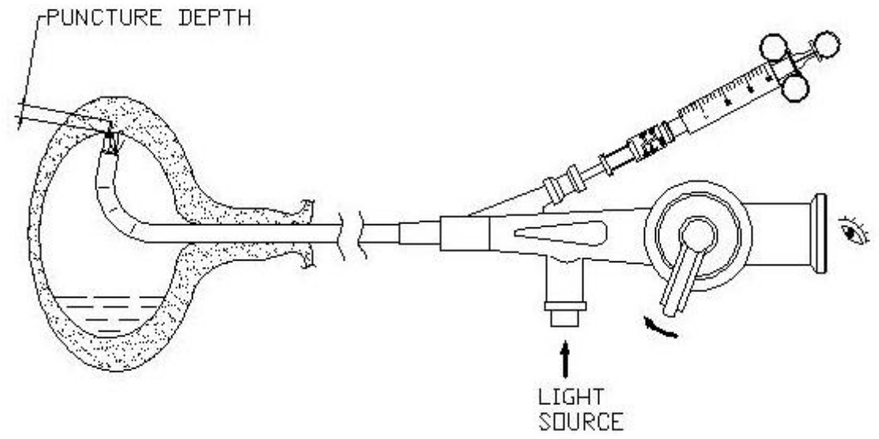
Instructions for Use - DIS199 and DIS201

1. Remove a needle from the pouch and protective sleeve.
2. Fill a syringe with drug solution.
3. Attach the syringe to the luer-tip [⑥] of the needle. Set needle tip [①] to “4” or “5” at the handle. Prime and remove any air bubbles from the needle cannula [①].
4. Set needle tip [①] to “0”; insert it into the working channel of the Cystoscope until the contrast marker [②] can clearly be seen through the Cystoscope eyepiece or visional system.
5. Select a suitable needle tip length (2, 3, 4, 5mm) at the handle [⑤] according to the targeted injection location and operator’s experience.
6. Move the needle or Cystoscope to puncture the targeted tissue and perform the injection at an appropriate speed.
7. Upon completion of the procedure retract the needle tip [①] back to position “0” and withdraw the entire needle out of the Cystoscope and dispose of the needle in a safe location.

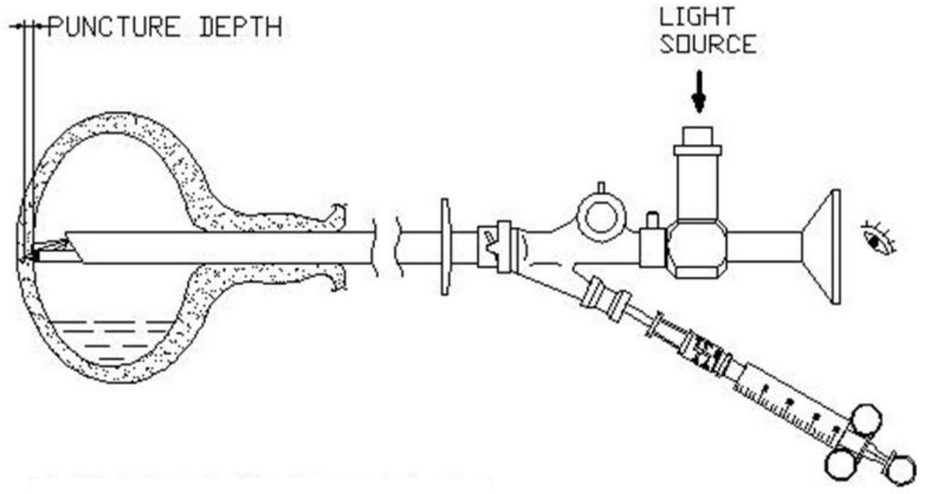


① Needle tip/point ② Contrast marker ③ Needle sheath ④ Handle ⑤ Length set of needle tip (unit: mm) ⑥ Female luer-tip connector ⑦ Needle lock-pin/tip length indicator

Bladder Injection



With flexible Cystoscope and injeTAK® needle DIS200, DIS201



With rigid Cystoscope and injeTAK® needle DIS198, DIS199

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