Ref. no.: 0213-DTKKP05100, 0213-DTKKS05100, 0213-DTKKB05100, 0213-DTKKP10100, 0213-DTKKS10100, 0213-DTKKB10100, 0213-DTKKP12100, 0213-DTKKP12100, 0213-DTKKB12100



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IFU-DTKK-ENG-05

Important:

This instruction cannot be used as a manual for surgical techniques used during the work with Trocar. To learn adequate knowledge about surgical technique it is necessary to contact our company or authorized distributor and to acquaint with appropriate technical instructions, professional medical literature and graduate proper training under supervision of surgeon experienced in techniques of microinvasive surgery. Before use we recommend reading precisely all information included in this manual. Not being obedient to this information may lead to serious surgical consequences such as patient injury, contamination, infection, cross-infection or death.

Disposable Trocar is used in gynecologic and abdominal endoscopic procedures for establishment of a port of entry for instrumentation.

Description:

Disposable Trocar is available in 5, 10 and 12 mm diameter with thin wall metal cannula. Trocars are available with pyramidal (DTKKP), pencil point sharp (DTKKS) or pencil point blunt (DTKKB) tips. All the Trocars are available with standard lengths of 100 mm. Fixing ring and adhesive tape allows to fix cannula to the body surface.

- **Contraindications:** Do not use in the area of local inflammation.
- Do not use if endoscopic techniques are contraindicated.

Ilustracja narzędzia (rys. 1):

A. Obturator

B. Cannula

D. Insufflation port

E. Seal

F. Silicone ring

Instructions for use:

- Create pneumoperitoneum in the abdomen prior to insertion of the Trocar.
- 2 Prepare the abdominal cavity for Trocar insertion by making an adequate incision to accommodate cannula circumference. One of the ways to ensure that an adequate incision is made is to press the unarmed Trocar cannula against the body wall, making oval impression, and then incise the major axis of the impression.
- 3. Insert the obturator into the Trocar cannula (pic. 2) and close insufflation port with an integral cap (pic. 2) or fix one-way stopcock supplied with the device. If stopcock is used close it before trocar insertion.

Warning: when inserting a sharp edged obturator, take care not to damage cannula seal with obturator blade.

C. Cap

- Move silicone sling along the cannula to the position reflecting intended depth of Trocar insertion.
- Position the Trocar at the appropriate angle to the abdomen wall (pic. 3).
- Squeeze down on the top of the obturator placing it close to cannula top.

 While maintaining compression of both parts of the Trocar, introduce the Trocar through the skin incision (pic. 3). Apply continuous downward pressure during entry of the trocar.
- When the instrument is in the desired position within the abdominal cavity, remove the obturator from the Trocar cannula, leaving cannula in place (pic. 4). 8.
- To fix cannula to the body surface remove main part of adhesive tape cover from fixing tape (pic. 5). Two rectangular tape covers at the edge of the tape should be used as holders to avoid sticking the tape to gloves. After main part of adhesive tape cover is removed, position tape above silicone ring and stick it to the skin and ring. Remove two rectangular adhesive tape covers and stick both tips of adhesive tape to the skin (pic. 6)

Warning: do not touch bottom of adhesive tape after cover is removed.

As an option, sutures can be applied to fix silicone ring to the body surface.

- 10. Connect an insufflation tube to an insufflation port or one-way stopcock, if required. If stopcock is used open it to commence insufflation.
- 11. If 10 or 12 mm cannula is to be used with 5 mm instruments reducer (included in the package) should be fixed on the cannula head to prevent losing pneumoperitoneum. DO NOT remove cannula seals to fix reducer.
- To dessuflate, disconnect insuflation tube. If one-way stopcock is used open it after insufflation tube is removed or disconnect stopcock from cannula.

Additional warnings and precautions:

- Minimally invasive procedures should be performed only by physicians having adequate training and familiarity with minimally invasive techniques. Consult medical literature
- relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.

 Minimally invasive instruments may vary from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure. Failure to do this can result in loss of pneumoperitoneum or inability to perform surgery.
- Direct contact of sharp instrument components with the silicone seals of the trocar should be avoided, as this may damage seals and pneumoperitoneum would be lost.
- A thorough understanding of the principles and techniques involved in laser, electrosurgical, and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Ensure that electrical insulation or grounding of co-used devices is not compromised.
- 5. Failure to establish and maintain appropriate pneumoperitoneum in abdominal procedures may reduce available free space, thereby impeding the advancement of the device and increasing the risk of injury to internal structures.
- Adhesions, anatomical anomalies, or other obstructions may obstruct advancement of the device exposing internal structures to injury
- The incorrect trocar insertion may result in aortic puncture. Anatomy changes relative to patient's position should be always taken into consideration.
- After removing the Trocar from the abdominal cavity, always inspect the site for hemostasis. Bleeding can be controlled by electrocautery or surgical sutures. 8.
- Dispose of all opened instruments whether used or unused.
- Use immediately after opening.
- Take care to discard the product and packing after use, as well as unused but opened devices in accordance with hospital waste disposal practices and local regulations including, without limitation, those pertaining to human health and safety and the environment.

 This product is intended for single patient and procedure use. Resterilization, reuse, reprocessing, modification may lead to serious consequences with death of patient included.
- Product is intended to be used exclusively by qualified medical staff. 13.
- If any serious incident has occurred in relation to the device it should be reported to the manufacturer and the competent authority of the Member State.

