Disposable Trocar
Instructions for use

Ref. No.: DTK3; DTK5; DTK10S; DTK12; DTK5X2; DTK10SX2; DTK12X2; DTK510SX4VE

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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.

Indications:
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 3, 5, 10 and 12 mm diameter with transparent cannula. 3 and 5 mm Trocar has pyramidal tip only while 10 and 12 mm is available with pyramidal tip or sharp linear cutting edge with shield. Upon entry into a free space in the abdominal cavity, the shield advances to cover cutting edge, reducing the potential for injury to internal structures. All the Trocars are available with standard length of 100 mm.

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

Instructions for use (Trocar):
1. 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 way to ensure that an adequate incision is made is to press the unarmed Trocar cannula against the body wall, making round impression, and then incise the diameter of the impression plus an appropriate additional amount to accommodate the cannula, eg., 2, 5 and 7 mm for the 5, 10 and 12 mm Trocar respectively.
3. Insert the obturator into the Trocar canula and close insufflation port if equipped.
4. Position the Trocar at the appropriate angle to the abdomen wall.
5. Squeeze down on the top of the obturator placing it close to cannula top activating shield this way.
6. While maintaining compression of the handle, introduce the Trocar through the skin incision. Apply continuous downward pressure during entry of the trocar. The red flag in the indicator window shows the position of the shield relative to the cutting edge. When insertion is performed, the shield indicator moves from the shield ON position (cutting edge shielded) to the shield OFF position (cutting edge exposed). Once the front end of the cannula has passed through the body wall into free space, the shield will spring forward. The red flag will return to the ON position showing that the sharp cutting edge is shielded.
7. When the instrument is in the desired position within the abdominal cavity, remove the obturator from the Trocar cannula, leaving cannula in place.
8. Connect an insufflation tube and open insufflation port if necessary.

Instructions for use (Veress Needle of DTK510SX4VE):
1. Inspect the instrument handle to ensure the safety indicator slides proximally toward the stopcock when blunt stylet is pressed. This action indicates the retraction of the blunt stylet and exposure of the sharp needle for penetration. Once the blunt stylet is free of tension from tissue, safety indicator reseats itself in the distal portion of the handle.
2. Close, open and close again 2-way stopcock to ensure it works properly and to ensure it will remain closed during insertion.
3. Make small incision to insert Veress Needle.
4. Grasp Veress Needle handle between the thumb and forefinger and advance it through the incision. Pay attention to the movement of safety indicator which at the beginning of insertion goes upwards, than returns to its original position in the distal portion of the handle. Slight “click” is audible. Resetting of safety indicator in its original position indicates that peritoneal cavity was penetrated.
5. Test to ensure Veress Needle is in the peritoneal cavity.
6. Connect an insufflation tube to luer lock connector of the Veress Needle, open 2-way stopcock and inflate the peritoneal cavity.
7. Following insuflation, remove the Veress Needle from the abdomen and proceed with the endoscopic procedure.

Instructions for use (Retrieval Bag of DTK510SX4VE):
1. Roll Retrieval Bag tightly and insert it through a 10-12 mm trocar using a blunt laparoscopic instrument, such as the MaxiGrip or atraumatic fenestrated grasper.
2. When the bag is deployed, unroll it. by using the tip of a blunt laparoscopic instrument, such as the MaxiGrip or atraumatic fenestrated grasper.
3. Place specimen into the Retrieval Bag. Ensure that the entire specimen fits within the confines of the bag.
4. Once the specimen is completely within the bag, grasp nylon thread and pull it out through the trocar until the leading edge of the bag is inside the tip of the Trocar.
5. Remove the Retrieval Bag and trocar from the body using one of the following two methods:
   Method 1:
   - Withdraw trocar together with Retrieval Bag until the whole Trocar becomes visible outside the body. Remove the Trocar.
   - While holding the orifice of the Retrieval Bag above body surface push the nylon thread forward. This will allow the Retrieval Bag to be easily opened.
   - Take out the excised tissue from the Retrieval Bag using appropriate surgical instrument such as the MaxiGrip or atraumatic fenestrated grasper. Take extreme care not to damage the bag.
   - After the excised tissue is taken out, pull the Retrieval Bag out.

   Method 2 (allows an intact tissue specimen removal):
   - Withdraw trocar together with Retrieval Bag and remove from the access site together.
   - If the bag with the specimen cannot be removed, carefully enlarge the access site to facilitate easy bag removal.

Additional warnings and precautions:
1. Minimally invasive procedures should be performed only by persons 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.
2. 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.
3. 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 is not compromised.
4. Failure to establish and maintain appropriate pneumoperitoneum in abdominal procedures may reduce available free space, thereby impeding the advancement of the shield and increasing the risk of injury to internal structures.
5. Adhesions, anatomical anomalies, or other obstructions may prevent or delay advancement of the shield, leaving the sharp pyramidal tip uncovered, exposing internal structures to injury.
6. Do not attempt to to insert the trocar if the red flag in the safety indicator does not move from the ON to the OFF position, as the trocar tip will not be exposed for body wall penetration.
7. The incorrect trocar insertion may result in aortic puncture. Anatomy changes relative to patient’s position should be always taken into consideration.
8. Do not attempt to insert the Veress Needle if the safety indicator in the handle does not slide back toward the stopcock, as this indicates the needle point will not be exposed for insertion.
9. Do not attempt to insert the Veress Needle if the safety indicator in the handle does not returns to its original position in the distal portion of the handle, as this indicates the blunt stylet will not protect intraabdominal organs from injury due to the needle point which will remain exposed after insertion.
10. While checking Veress Needle blunt stylet mobility never press the stylet with a finger to avoid injury by the needle sharp point.
11. The stopcock should be closed during insertion of Veress Needle to prevent the abdominal pressure from equilibrating with the ambient pressure, when penetration of the peritoneum occurs.
12. After removing the Trocar or Veress Needle from the abdominal cavity, always inspect the site for hemostasis. Bleeding can be controlled by electrocautery or surgical sutures.
13. Retrieval Bag is not intended for use with any tissue that will not fit within the confines of the specimen bag and allow complete closure of the bag.
14. Once Retrieval bag is cinched, the specimen bag cannot be readily reopened in situ.
15. Do not attempt to remove the Retrieval Bag with specimen through the trocar as this may lead to bag rupture and spillage of contents.
16. Do not use morcellators with Retrieval Bag.
17. Care should be taken to avoid contact of the Retrieval Bag with sharp instruments, cutting devices, electrocautery and laser or other instruments.
18. Excessive forces should be avoided during Retrieval Bag extraction.
19. If the Retrieval Bag with specimen cannot be removed through the access site, carefully enlarge the access site to facilitate easy bag removal. Do not force the bag through the access site as this may lead to bag rupture and spillage of its contents.
20. Dispose of all opened instruments whether used or unused.
21. Use immediately after opening.
22. The instrument requires appropriate disposal after use in accordance with all applicable local regulations including, without limitation, those pertaining to human health and safety and the environment.
23. This product is intended for single patient and procedure use. Resterilization, reuse, reprocessing, modification may lead to serious consequences with death of patient included.
24. Product is intended to be used exclusively by qualified medical staff.

Keep dry

Caution, consult accompanying documents

Consult instructions for use

Do not resterilize

Manufacturer

Do not use if package is damaged