

Disposable Endoscopic Suction and Suction-Irrigation Sets
Instructions for use

Ref. no.: 0208-SXC30007SS05; 0208-SXC30007SS10; 0208-SIC05G; 0208-SIC10G; 0208-SIC05E; 0208-SIC10E, 0208-SIC05GB, 0208-SIC10GB, 0208-XXC05, 0208-XXC10, 0208-XXC05B, 0208-XXC10B

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Attention:

These Instructions For Use cannot be used as a surgical manual describing the use of suction and suction-irrigation sets. As needed, please contact our company or your authorized distributor. You should acquaint yourself with appropriate technical instructions, review the professional medical literature, and obtain formal graduate training under the supervision of a surgeon experienced in minimally invasive surgical techniques. We recommend thoroughly reviewing all information in this IFU; inattention to the instructions provided below may have serious clinical consequences such as patient injury, contamination, cross-infection, or death.

Indications:

Disposable endoscopic suction-irrigation sets are indicated for fluids removal as well as irrigation of body cavities during endoscopic surgery. Disposable endoscopic suction sets are indicated for fluids removal from body cavities during endoscopic surgery in the procedures where irrigation is not necessary.

Description:

Endoscopic suction and suction-irrigation sets are intended for single patient and procedure use. They are available as 5 and 10 mm versions to be used with the most popular endoscopic trocar sizes. Index B at the end of reference number indicates bariatric 45 cm long version. Spare suction-irrigation cannulas (0208-XXC05, 0208-XXC10, 0208-XXC05B, 0208-XXC10B) are available for cannula replacement, if necessary. Endoscopic suction-irrigation sets 0208-SIC05G, 0208-SIC05GB and 0208-SIC10G, 0208-SIC10GB are equipped with ergonomic handle with suction and irrigation valves operated by colour coded buttons – white for suction and blue for irrigation. Integral tubing allows for easy connection with irrigation fluid bags and suction source. Endoscopic suction-irrigation sets 0208-SIC05E and 0208SIC10E are economy versions of suction sets with option of irrigation with high volume syringe (syringe not included) via side luer-lock port. Endoscopic suction sets 0208-SXC30007SS05 and 0208-SXC30007SS10 are intended for suction only and are equipped with 3 m tube for easy connection with suction source.

Contraindications:

1. The use of disposable endoscopic suction and suction-irrigation sets is contraindicated whenever endoscopic surgical techniques are contraindicated for any reason.
2. This device is not intended for use except as indicated.

Instructions for use:

1. Open the package by using standard aseptic technique.
2. Connect free female connector of a suction tube with suction canister.
3. Set desired suction force.

When using 0208-SXC30007SS05 or 0208-SXC30007SS10:

1. Close the clamp on the tube.
2. Insert suction cannula through the trocar and advance it to the area of fluid pool to be evacuated.
3. Open the clamp to start suction.
4. After suction is completed close the clamp and remove cannula back through the trocar.

When using 0208-SIC05E or 0208-SIC10E:

1. Close the clamp on the tube.
2. Ensure that cap of the side luer-lock port remains closed.
3. Insert suction-irrigation cannula through the trocar and advance it to the area of fluid pool to be evacuated or to the area of irrigation.
4. If suction is to be performed:
 - open the clamp to start suction,
 - close the clamp when suction is completed.
5. If irrigation is to be performed:
 - open the cap of side luer-lock port and connect syringe filled with physiological solution and administer it to the desired area,
 - open the clamp, disconnect syringe and close side luer-lock port with the cap,
 - remove irrigation fluid from the body cavity by suction,
 - close the clamp when suction is completed.
6. After suction and/or irrigation is completed remove cannula back through the trocar.

When using 0208-SIC05G, 0208-SIC05GB or 0208-SIC10G, 0208-SIC10GB:

1. Insert the spikes into the irrigation bags. If the second irrigation bag is not in use, clamp the irrigation tube which is not in use with the attached occlusion clamp to eliminate the loss of irrigation fluid.
2. Hang irrigation bags about 1 meter above patient body.
3. Open the clamp of one of the irrigation bottles.
4. Depress blue button on the handle to open irrigation valve and prime irrigation line.
5. Depress white button on the handle to check if suction line is patent.
6. Insert suction-irrigation cannula through the trocar and advance it to the area of fluid pool to be evacuated or to the area of irrigation.
7. Depressing blue button opens irrigation valve, releasing it closes the valve automatically.
8. Depressing white button opens suction valve, releasing it closes the valve automatically.
9. After suction and/or irrigation is completed remove cannula back through the trocar

Spare suction-irrigation cannulas compatibility:

Spare suction-irrigation cannulas 0208-XXC05, 0208-XXC10, 0208-XXC05B, 0208-XXC10B are compatible with any of the following suction-irrigation sets 0208-SIC05G, 0208-SIC10G, 0208-SIC05GB, 0208-SIC10GB

Additional warnings and precautions:

1. Minimally invasive surgery should be performed only by physicians who are thoroughly trained in minimally invasive techniques.
2. To avoid injury to internal organs, a pneumoperitoneum must be maintained during the use of disposable endoscopic instrumentation.
3. Verify that the devices are compatible with other products that will be used in surgery prior to the procedure.
4. When suction is not in use, ensure that:
 - suction valve of 0208-SIC05G, 0208-SIC05GB and 0208-SIC10G, 0208-SIC10GB does not remain depressed
 - clamps of 0208-SIC05E, 0208-SIC10E, 0208-SXC30007SS05 and 0208-SXC30007SS10 does not remain opened
 so as to minimize loss of pneumoperitoneum.
5. When using 0208-SIC05E or 0208SIC10E for irrigation, it is important to open the clamp before disconnecting syringe to avoid that fluid from the cannula would blow out through the side luer-lock port due to positive pressure in the peritoneal cavity.
6. When one bottle with irrigation fluid is connected, ensure that clamp on the irrigation tube which is not in use remains closed to eliminate the loss of irrigation fluid.
7. Dispose of all opened instruments whether used or unused.
8. Use immediately after opening.
9. This product is intended for single patient and procedure use. Resterilization, reuse, modification may lead to serious consequences with death of patient included.
10. To be used by qualified physician only
11. Take care of proper product and packing disposal after use in accordance with hospital waste disposal practices.



STERILE EO



Keep dry



Caution, consult accompanying documents



Consult instructions for use



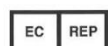
Do not resterilize



Manufacturer



Do not use if package is damaged



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