

INSTRUCTIONS FOR USE : IMANLAP MAGNETIC GRASPING FORCEPS

1. DESCRIPTION AND ASSEMBLY



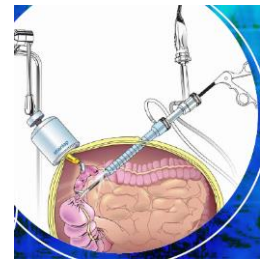
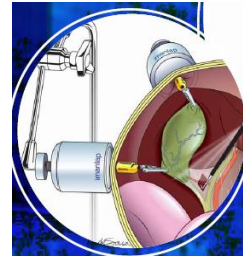
- IMANLAP magnetic grasping forceps Ø12
Ref:03.120.00



- External magnet with adjustable force
Ref:03.100.00



- Assembly



The magnetic grasping forceps and the external magnet are class I devices that are **CE** approved since 2014. The magnetic forceps for endoscopic surgery are to be placed on an organ, tissues or an extraction bag which can thus be moved inside the abdominal cavity or be extracted from it. The magnetic grasping forceps are used as standard laparoscopic grasping forceps without damage to the abdominal wall, skin, fat, muscle or peritoneum. They can be moved within the abdominal cavity, using the external magnet with adjustable force (Ref: 03.100.00). This feature is especially useful when the procedure takes place in different quadrants, for example in gallbladder or appendix surgeries or in laparoscopic abdominal explorations. The use of magnetic grasping forceps allows to limit the number of incisions or, if they cannot be avoided, helps choosing the most appropriate location. The magnetic grasping forceps are intended to be used through ports or trocars of 12mm diameter or higher.

2. INDICATIONS

The IMANLAP magnetic grasping forceps are an intracavitary device that, when used in association with the external magnet, allows to retract (statically or dynamically), mobilize or triangulate organs, tissues or prosthetic bags during single-port or multi-port, trans vaginal, trans umbilical and NOTES (Natural Orifice Transluminal Endoscopic Surgery) laparoscopic surgeries. The device can be used to improve surgical field visualization.

3. CONTRAINDICATIONS

The magnetic devices must NOT be used in:

- Patients for whom laparoscopic surgery is contraindicated
 - Pregnant patients, regardless of the stage of pregnancy
 - Children under 4 years old
 - Patients with temporary or permanent pacemakers
 - Patients with implanted hearing aids or ferromagnetic prostheses
 - In case of absence or failure to achieve adequate pneumoperitoneum
- If in doubt, contact FRANCEMED.

4. GENERAL INSTRUCTIONS FOR USE



CAUTION:

- As in any laparoscopic surgery, it is necessary to use the device with the proper technique, to proceed with caution and to strictly follow the recommended steps to avoid any damage to the internal organs.
- Needles inside and outside of the abdomen can be attracted to the magnet. Keep this fact in mind when moving the external magnet or the magnetic graspers if they are used in combination with suture or other ferromagnetic devices.

- How the device works

The IMANLAP magnetic grasping forceps can be moved over the entire anterior wall of the abdominal cavity by means of the external magnet. The forceps can thus be moved from one side of the abdomen to the other if needed. The device can be applied and repositioned as many times as needed.

The device has, in one of its branches, a free orifice into which a commercial suture can be inserted. This safety link allows to easily retrieve the graspers if they are to fall into the abdominal cavity.

- Insert the suture percutaneously, under direct and continuous laparoscopic vision. Proceed with caution to avoid damaging any organ.
- Pull out the suture through the trocar.
- Cut the needle from the thread.
- Tie the thread and adjust it to the forceps.
- Insert the magnetic grasping forceps into the abdominal cavity through the trocar.



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- Insertion into the cavity

Once the access port to the abdominal cavity is in place, use a laparoscope to check that the abdomen is adherence-free and bleeding-free and that adequate pneumoperitoneum has been achieved.

- Place the external magnet (placed in a sterile bag) where you want to attract the magnetic grasping forceps.
- Hold the back of the forceps using traditional grasping forceps and insert the device, **tip first**, into the abdominal cavity through an incision or trocar of 12mm diameter or higher.
- Under laparoscopic vision, position the magnetic forceps the zone where the external magnet is. The forceps will be oriented with more force as they approach the external magnet. The forceps part of the device will remain free and the magnet part will be attracted to the peritoneum.
- Under laparoscopic vision, using traditional grasping forceps, move the magnetic grasping forceps and apply them on the desired organ.
- Once in place, the traction force between the magnetic forceps and the external magnet can be adjusted in order to obtain a clear exposition of the surgical field.
- The device exerts an externally adjustable force on the element it holds: from 0 if the external magnet is not applied on the patient to 800 grams in lift or retraction (depending on the thickness of the patient's abdominal wall).
- To reposition the magnetic grasping forceps, grasp them with traditional forceps and move them to the desired location.

- Extraction of the device

Prior to the extraction maneuver, remove the external magnet and make sure that there is no external magnetic field around the patient.

- **Option 1:** Hold firmly the tip of the magnetic forceps with standard forceps and, without losing your grip, extract the device through the incision or the trocar under direct vision. Make sure that no foreign body inside the trocar obstructs the passage of the device.
- **Option 2:** Insert the device in a retrieval bag while it still holds the tissue sample to be extracted. Retrieve the bag through the orifice by the usual method and when outside of the abdomen, make sure that the magnetic forceps are inside the bag.

Recommendations :

- Use retrieval bags with thick walls such as Endobag™ and Endo catch™ (Covidien)
- Never try to remove the device from the cavity if the pneumoperitoneum is not established.
- In case of unexpected event, such as a complication of anesthesia or a cardiac event (arrhythmia, cardiac arrest), extract the device from the patient's abdomen only if the cavity is inflated by pneumoperitoneum and if the patient's condition allows it. In case of an emergency, it is not necessary to remove the device in order to follow the standard procedure for laparoscopic surgery (deflate the pneumoperitoneum even though the magnetic forceps are still in the cavity) and stabilize the patient. In any case, the external magnet must be moved away from the patient. Once stabilization is achieved and if the laparoscopic surgery resumes, the magnetic forceps can still be used only if pneumoperitoneum can be obtained. Otherwise, remove the device by other means (incision).
- If, for any reason, the device should break inside the abdominal cavity, proceed as follows: insert a retrieval bag and put inside every part of the device. If, for any reason, a part of the device cannot be located, use dynamic X-rays to locate it within the abdomen.
- It is possible to use several magnetic forceps simultaneously. However, in this situation, the risk of shocks between the forceps and the risk of untimely movements are increased. This practice should thus be restricted to surgeons who master the surgical technique and the use of the device.
- It is recommended to always have at least two magnetic forceps ready for use during surgery in case the first one became unusable.

Always check that the WHOLE device is outside the patient before closing the abdomen.

5. WARNINGS AND PRECAUTIONS

- The magnetic forceps must only be used by surgeons appropriately trained for their use.
- Always check the electrical, mechanical and magnetic compatibility of every device of every manufacturer to be used with the magnetic forceps.
- As in any laparoscopic surgery, it is necessary to use the device with the proper technique, to proceed with caution and to follow strictly the recommended steps to avoid any damage to the internal organs. See related literature for more information on safe techniques.
- In order to use the device correctly, strictly follow the insertion, use and extraction steps described in the present document.
- As usually necessary for laparoscopic surgery, make sure the abdominal cavity is always distended with the adequate pneumoperitoneum. This point is essential to ensure proper and safe use of the device. **DO NOT** use the device if the proper conditions for its use have not been met.



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- The abdominal wall is different for each patient: its thickness can vary even within the same patient and this can affect the force of the forceps. The thinner the wall, the greater the force of the magnet.
- If used properly, the device will not damage the abdominal wall. The device is coated with polyamide to avoid direct contact between the magnet and the peritoneum. If, for any reason, this capsule breaks, the device and all the broken pieces should be retrieved.
- The device **MUST NOT** be used if it has been modified or transformed by any means.
- Except in case of an emergency, never deflate the abdominal cavity while the device is inside.
- Always monitor the safe extraction of the device under direct laparoscopic vision. It is possible to use laparoscopes with different degrees of vision.
- Never put the device next to the heart or brain of the patient or the user.
- This device is for medical use only and must not be used for other purposes.
- Dispose of the device that came into contact with the patient in accordance with current regulations.
- Do not use the device near another magnet or ferromagnetic equipment.
- When using the device, it is recommended to always have X-ray equipment available in the operating room.
- Magnetic grasping forceps (ref: 03.120.00) are intended for continuous use for a maximum of 60 minutes and can be reused a maximum of two times. External magnet (ref: 03.100.00) can be reused many times.
- Store at room temperature and avoid exposure to temperatures higher than 80°C. Store in a clean and dry area, away from any other ferromagnetic or magnetic items. It is recommended to store the device in the container provided by Francemed.
- Always be aware that needles with thread and any other ferromagnetic item can be attracted to the magnetic grasping forceps or by the external magnet. Take all appropriate health precautions to minimize risks.

6. INTERFERENCES WITH OTHER DEVICES AND MEDICAL TESTS OR TREATMENTS

- Never use the device in a room that contains magnetic resonance equipment.
- The device does not affect X-rays and it is possible to perform dynamic or static X-ray imaging on the patient if required, for example to study the gallbladder or for a cholangiography.
- The device can appear on X-ray images since it is radio-opaque and this can interfere with the desired image. In such a situation, safely move the forceps or direct the X-rays accordingly if needed or, if that is impossible, retrieve the magnetic forceps, perform the x-ray and re-insert the device. Before this, make sure the device is still sterile. If in doubt, use other sterile magnetic forceps.

If in doubt, contact FRANCEMED.

7. IMPORTANT INFORMATION REGARDING HANDLING OF DEVICES CONTAINING A MAGNET

The device contains a powerful neodymium magnet. Take all appropriate measures to prevent hurting the patient or the user and damaging other equipment.



Keep devices containing magnets out of reach of children.



Neodymium magnets conduct electricity. Keep away from potential power sources.



The magnet Ref: 03.100.00 has a very strong attractive force. Unsafe handling could cause jamming of fingers or skin in between magnets. This may lead to contusions and bruises.



Magnets could affect the functioning of pacemakers and implanted heart defibrillators. A pacemaker could switch into test mode and cause illness. A heart defibrillator may stop working. If you wear these devices keep sufficient distance to magnets. Warn others who wear these devices from getting too close to magnets.



Magnets produce a far-reaching, strong magnetic field. Keep a safety distance of at least 30cm between magnets and electronic devices. They could damage TVs and laptops, computer hard drives, credit and ATM cards, data storage media, mechanical watches, hearing aids and speakers.



Magnets have coatings that contain nickel. Some people have an allergic reaction when they come into contact with nickel.

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Airfreight: Airfreight magnets only in packaging with sufficient magnetic shielding. Magnets are generally considered dangerous goods, which can only be forwarded by airfreight under certain circumstances. Correct classification requires accurate measurements.

A shipment with magnets falls under one of three categories:

1. Air-freight forbidden (magnetic field too large)

If the package with the magnets (including magnetic shielding packaging) creates a magnetic field of more than 0.00525 gauss (=5.25 mG = 0.525 μ T) at a distance of 4.6 meters (in any direction), the transport of the package via air freight is generally forbidden.

2. Shipment unproblematic (magnetic field very small)

The second and stricter test requires that at a distance of 2.1 meters from the package a magnetic field of less than 0.002 gauss (2 mG = 0.2 μ T) is created.

If the package passes this test, the content is considered "not magnetized" for transport purposes and the package can be shipped. In that case it is recommended to attach a shipping declaration that confirms that the package passed the stricter test and therefore can be viewed as non-magnetic. This can avoid possible delays due to inspections by authorities.

3. Shipment as a declared dangerous good (for all other cases)

If the package falls between the two categories, meaning the first test was passed but not the stricter second one, the package has to be declared a dangerous good, which will lead to higher shipping costs and additional work. Also, there are certain airports that cannot be used in this case.

If in doubt, contact FRANCEMED.




Postage: Magnetic fields of improperly packaged magnets could cause disturbances in sorting machines and damage fragile goods in other packages. Use a large box and place the magnet in the middle surrounded by lots of padding material. Arrange magnets in a package in a way that the magnetic fields neutralize each other. If necessary, use sheet iron to shield the magnetic field.

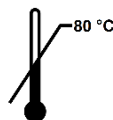


Exposing the device to temperatures of 80°C or higher can alter the device and its functioning.

8. HANDLING AND STORAGE

This system includes two powerful neodymium magnets. They are affected by humidity, acid and dust and must thus be stored in a clean and dry area at room temperature (neodymium magnets lose part of their adhesive force permanently at a temperature of 80°C). Do not store magnets near electrical and ferromagnetic equipment. The magnetic force of the devices can attract all nearby ferromagnetic equipment and injure the people who are using it. Handle with care. Store the devices in the non-magnetic packaging provided by FRANCEMED.

 : Fragile, handle with care

 : Upper limit of temperature: 80°C

9. STERILITY



: Non sterile

• Products delivered non-sterile:

The products are delivered non-sterile. They are delivered in a protective bag which cannot be used as sterile packaging. Before using the IMANLAP magnetic grasping forceps and the external magnet, they must be cleaned and decontaminated by hand at a temperature below 80°C. The magnetic grasping forceps must then be sterilized. We recommend sterilization with STERRAD® system. However, the external magnet must not be sterilized but must be placed in a sterile bag.

10. MEANING OF THE SYMBOLS

 Catalogue number	 Manufacturer	 Consult instructions for use	 Batch code
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For additional information, please contact us or your dealer or consult the videos and documentation available at our website www.medicalex.info