

SAFETY PARACENTESIS PROCEDURE TRAY

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION:

The Safety Paracentesis Procedure Tray is a sterile, single use kit containing devices designed to assist the clinician in draining fluid from body cavities.

INTENDED USE:

The Safety Paracentesis Procedure Tray is intended for drainage of fluid and specimen collection for diagnostic purposes or to remove excess fluid collections.

CONTRAINDICATIONS:

Thoracentesis
Pericardiocentesis

WARNINGS:

- During catheter insertion procedure, if resistance is encountered, the cause must be determined before continuing.
- Withdraw the introducer needle as soon as fluid is observed to avoid puncturing internal organs.
- Refer to Lidocaine Hydrochloride Instructions for Use included in the box for product use, contraindications, etc.
- All sharp instruments (needles, scalpels) should be handled with care.
- Activate the safety mechanism away from yourself or others.
- To help avoid infectious disease due to accidental needlesticks, contaminated needles should not be recapped or removed, unless there is no alternative or such action is required by a medical procedure.
- Used sharps are contaminated. Handle carefully. Dispose scalpel in accordance with all applicable local and national laws and regulations.

CAUTIONS:

- Read instructions prior to use.
- RX Only.
- Procedure must be performed by trained personnel.
- Practitioners must be aware of complications associated with paracentesis.
- Safety mechanism on the Monoject Magellan™ Safety Needles should not be deployed by placing hands in front of needle.
- After deployment do not attempt to override or defeat the safety mechanism on scalpel or needles.
- This device is for single use only. Do not resterilize or reuse.
- Store at controlled room temperature 15° to 30°C (50° to 86°F).
- Use lidocaine ampules only if the solution is clear.
- Do not Autoclave before use.

COMPLICATIONS / RISKS:

- Perforation of organs
- Infection
- Pain in region
- Risks normally associated with percutaneous interventional procedures.
- Air embolism
- Hematoma
- Bleeding

INSTRUCTIONS FOR USE:

Paracentesis is a sterile procedure which is typically performed with ultrasonic imaging, computed tomography imaging or fluoroscopic monitoring and guidance. The procedure should be performed using aseptic technique.

1. It is recommended that the patient empty the bladder prior to the procedure.
2. Open the paracentesis tray and unwrap the CSR wrap.
3. Prep the skin by using the skin cleansing agent.
4. Remove adhesive backing from the fenestrated drape and place it over the puncture site. If the patient is in an upright position, the adhesive along the edge of the drape may be used to secure upper portion.

5. Aspirate the lidocaine by using the 18 gauge Monoject Magellan™ Safety Needle. Twist syringe clockwise while holding the rigid sheath that covers the Monoject Magellan™ Safety Needle to seat the Safety Needle to the syringe. Remove the sheath from the Monoject Magellan™ Safety Needle while directing the needle away from you and others. Be certain not to touch the needle or the safety shield.
6. If necessary to transport the filled syringe to the point of administration, use a safe, passive recapping technique to cover the needle before transport. In accordance with OSHA standards, such recapping must be accomplished by a one-handed technique, i.e., do not hold the needle shield during the recapping process.
7. Replace the needle used in Step 5 by following the safety precautions mentioned in step 9.
8. Raise skin wheel with lidocaine by using the 25 gauge safety needle at puncture site. The 22 gauge safety needle may be used for deeper infiltration.
9. Immediately following injection procedure, lock the safety needle shield, using any of the following methods:
 - a. Push the safety shield forward in a single-handed manner to cover the needle and lock the shield. Keep your finger or thumb behind the needle tip --at all times.OR:
 - b. Press the safety shield, lever side down, onto a flat surface to cover the needle and lock the shield, i.e., bedside table.
 - The Monoject Magellan™ Safety Needle is locked once the needle tip is completely shielded. Verify locked position through audible, tactile, and/or visual feedback.
 - **Only grasp the colored hub to connect/disconnect needle and syringe.**
 - Once safety shield is locked, immediately discard the Monoject Magellan™ Safety Needle and syringe into the nearest sharps container following applicable regulations.
10. Puncture the skin with the One-Step™ Catheter assembly. A small incision may be made at the puncture site with the # 11 Futura® Safety Scalpel to ease catheter transition.
 - a. To Use Futura Safety Scalpel:
 - Push slide forward with thumb until blade locks.
 - Retract blade before passing scalpel or disposing scalpel. To retract apply pressure at the proximal end of the slide.
 - Scalpel is now ready for passing or disposal
11. When fluid flashback is observed, advance the catheter approximately one centimeter and withdraw the needle completely.
WARNING: The needle must be withdrawn as soon as fluid is observed to avoid puncturing internal organs.
12. The catheter may be repositioned during the procedure to facilitate drainage, which also might involve moving of the patient to a more convenient position for drainage.
13. Attach the three-way stopcock to the catheter. Laboratory samples may be withdrawn at this time. Aspirate fluid with the 60ml syringe and inject it into the 10ml specimen vials.
14. To drain fluid into a vacuum bottle, attach the tubing to the stopcock on the catheter device. Close the clamp down completely and pierce the vacuum bottle with the spike attached to the tubing.
15. Following the procedure, gently withdraw the catheter and dress the site accordingly.

Monoject Magellan™ is a trademark of Covidien AG



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