Eclipse 2L Safety & Warnings

Contraindications

The ECLIPSE 2L and COPERNIC 2L catheters are contraindicated when, in the medical judgment of the physician, use of such product may compromise the patient's condition.

- Not intended for embolectomy or angioplasty procedures.
- Not intended for use in coronary vessels.
- Not intended for pediatric or neonatal use.

Potential Complications

Potential complications associated with the use of balloon catheters or with the endovascular procedures include but are not limited for:

- Complications at entry site,
- Allergic reaction,
- Aneurysm rupture,
- Neurological deficit,
- Transient ischemic attack
- Vessel occlusion,
- Vessel perforation or aneurysm perforation
- Vasospasm
- Hematoma at entry site,
- Embolism, Ischemia
- Haemorrhage
- Pseudo aneurysm
- Epilepsy crisis
- Stroke
- Infection
- Vessel dissection
- Thrombosis
- Death

US (Additional):

• This device requires use with fluoroscopy. Potential complications related to angiographic and fluoroscopic X-ray radiation doses include, but are not limited to, alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia. The probability of occurrence of complications may increase as procedure time and number of procedures increase.

• Adverse reaction to contrast media

Precautions for Use

-  Do not use if the pouch is open or damaged. These products are sterile when the packaging is not damaged.

- This product is intended for single use only. Do not reuse. Any reuse of the device cause a high risk of microbiological contamination for the patient as well as a risk of loss of the device characteristics.

- Do not resterilize.

- Store in a dry place at room temperature and away from light.

- Do not use the product after the expiry date.

- These products must be used by specialist physicians in interventional neuroradiology and / or specialist physicians in interventional radiology. Physician must be familiar with percutaneous, intravascular techniques and possible complications associated with the procedure.

- Check the size of the vessel under fluoroscopy. Ensure that the balloon catheter is suitable with the vessel size

- Compatibility or use of balloon catheter with liquid agent embolic agents have not been tested except Onyx® (Ev 3) and Squid® (Emboflu A.G.).

- Do not exceed the maximum recommended inflation volume indicated on the label as balloon rupture may occur.

- Viscosity and concentration of contrast affect balloon inflation and deflation times.

- During preparation, do not deflate the balloon unless the distal tip is submerged in saline or contrast to prevent air from entering

balloon.

- Do not attach any high pressure devices to the balloon inflation port as this may rupture the balloon.

- Do not inflate the balloon with air or any other gas while in the body.

- Improper preparation can result in air getting into system. This can inhibit proper fluoroscopic visualization.

- If back-loading the balloon catheter over a guidewire, ensure distal tip of the balloon catheter is not damaged.

- Do not over-tighten the RHV around the balloon catheter. Over-tightening could delay balloon inflation and deflation.

- Do not advance the balloon catheter or guidewire against resistance. If resistance is felt, assess the source of resistance using fluoroscopic means.

- Always inflate and deflate under fluoroscopic visualization control to ensure patient safety.

- After balloon preparation and before use, re-inflate to nominal volume to inspect the balloon catheter prior to use for any irregularities or damage. Do not use if any defects are observed.

- Verify balloon catheter compatibility when using other ancillary devices commonly used in intravascular procedures.

- The balloon catheter has a hydrophilic surface and should be hydrated prior to use. Once the balloon catheter is hydrated, do not allow it to dry.

- Exercise care in handling the balloon catheter to reduce the chance of accidental damage. Do not expose the balloon catheter surface to organic solvents, which might damage the balloon catheter and/or coating on the surface.

- Verify prior to use that the diameter of any guidewire or accessory device that is used is compatible with the inner diameter of the balloon catheter as claimed on the label.

- Take precaution when manipulating the balloon catheter in tortuous vasculature to avoid damage. Avoid advancing or withdrawal against resistance until the cause of resistance is determined.

- Presence of calcifications, irregularities, or existing devices can damage the balloon catheter and potentially affect its insertion or removal.

- The balloon catheter does not contain materials in latex or in PVC.

US :

- Store in a dry place at room temperature and away from light.
- Do not use the product after the expiry date.
- These products must be used only by physicians who have received appropriate training in interventional techniques.
- After balloon preparation and before use, re-inflate to nominal volume to inspect the balloon catheter prior to use for any irregularities or damage. Do not use if any defects are observed.
- Verify balloon catheter compatibility when using other ancillary devices commonly used in intravascular procedures.
- The balloon catheter has a hydrophilic surface and should be hydrated prior to use. Once the balloon catheter is hydrated, do not allow it to dry.
- Exercise care in handling the balloon catheter to reduce the chance of accidental damage. Do not expose the balloon catheter surface to organic solvents, which might damage the balloon catheter and/or coating on the surface.
- Verify prior to use that the diameter of any guidewire or accessory device that is used is compatible with the inner diameter of the balloon catheter as claimed on the label.
- Take precaution when manipulating the balloon catheter in tortuous vasculature to avoid damage. Avoid advancing or withdrawal against resistance until the cause of resistance is determined.
- Presence of calcifications, irregularities, or existing devices can damage the balloon catheter and potentially affect its insertion or removal.
- The balloon catheter is not made with natural rubber latex.
- Avoid wiping the device with dry gauze as this may damage the device coating.
- Avoid excessive wiping of the distal segment containing hydrophilic coating.
- Avoid using alcohol, antiseptic solutions, or other solvents to pre-treat the device because this may cause unpredictable changes in the coating which could affect the device safety and performance.
- Ensure that the device is rinsed as stated in this instructions for use to avoid any potential impact to the coating performance.
- Limit the exposure to X-ray radiation doses to patients and physicians by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors when possible.
- Avoid pre-soaking devices for extended durations when the device is not in use, as this may impact coating safety and performance.

Warnings

EU:

WARNING: if back-loading the balloon catheter over a guidewire, ensure distal tip of the balloon catheter is not damaged.

WARNING: viscosity and concentration of contrast solution will affect balloon inflation and deflation times.

WARNING: ensure that the contrast fluid does not reach the distal purge orifices of the balloon before evacuation of the whole air while maintaining vertical with distal end upward.

WARNING: during air-purging process, inject fluid slowly otherwise balloon may rupture.

WARNING: Keep balloon catheter hydrated during preparation procedure by periodically submerging in physiological solution as required.

WARNING: Do not attach any high pressure devices to the balloon inflation port as this may rupture the balloon.

WARNING: Do not inflate the balloon with air or any other gas.

WARNING: Improper preparation may result in air getting into system. This may inhibit proper fluoroscopic visualization.

WARNING: Do not over-tighten the RHV around the balloon catheter. Over-tightening could delay balloon inflation and deflation.

WARNING: Do not advance the balloon catheter or guidewire against resistance. If resistance is felt, assess the source of resistance using ftuoroscopic means.

WARNING: Do not exceed the maximum recommended inflation volume as balloon rupture may occur.

WARNING: inflate and deflate always the balloon while visualizing under fluoroscopy to ensure patient safety.

US :

Contents supplied STERILE using an ethylene oxide (EO) process. Non-pyrogenic. Do not use if sterile barrier is damaged. If damage is found, call your Balt USA representative.

For single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

- This product is intended for single use only. Do not reuse. Any reuse of the device may cause a high risk of microbiological contamination for the patient as well as a risk of loss of the device characteristics.
- Do not resterilize or reuse. This device is intended for single use. This device is coated with a hydrophilic coating at the distal end. Please see Instructions for Use for specific coating measurements. Please refer to the Directions for Use section for further information on how to prepare and use this device to ensure it performs as intended. Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.
- ECLIPSE 2L should only be used with DMSO based liquid embolic agents for the proper neurovasculature indication.
- Check the size of the vessel under fluoroscopy. Ensure that the ECLIPSE 2L is suitable for the vessel size.
- Do not exceed the maximum recommended inflation volume indicated on the label as balloon rupture may occur.
- Do not use if the pouch is open or damaged. These products are sterile when the packaging is not damaged.
- Viscosity and concentration of contrast mixture affect balloon inflation and deflation times.
- During preparation, do not deflate the balloon unless the distal tip is submerged in saline or contrast mixture to prevent air from entering balloon.
- Do not attach any high-pressure devices to the balloon inflation port as this may cause the balloon to rupture.
- Do not inflate the balloon with air or any other gas while in the body.
- Improper preparation may result in air getting into system. This can inhibit proper fluoroscopic visualization.

- Pressure in the working lumen should not exceed the maximum pressure of 300 psi. Excessive pressure may cause leakage or rupture of the catheter.
- If back-loading the ECLIPSE 2L over a guidewire, ensure distal tip of the balloon catheter is not damaged.
- Do not over-tighten the RHV around the balloon catheter. Over-tightening could delay balloon inflation and deflation.
- Do not advance the balloon catheter or guidewire against resistance. If resistance is felt, assess the source of resistance using fluoroscopic means.
- Always inflate and deflate under fluoroscopic visualization control to ensure patient safety.
- Ensure that the contrast mixture fluid does not reach the distal purge hole before air is fully evacuated. This can be achieved by maintaining the balloon in a vertical position with distal end upward while purging.
- During the air-purging process, inject fluid slowly. Otherwise, the balloon may rupture.
- Keep the ECLIPSE 2L hydrated during the preparation procedure by periodically submerging in saline solution as required.