

## Prestige / Prestige Plus Safety & Warnings

### Potential Complications

Potential complications include, but are not limited to:

- Allergic reaction
- Aneurysm rupture
- Arrhythmia
- Clot formation
- Coil migration or misplacement
- Dissection
- Emboli
- Hemorrhage
- Incomplete aneurysm filling
- Infection
- Ischemia
- Neurological deficits including stroke and possibly death
- Parent artery occlusion
- Post-embolization syndrome
- Puncture site hematoma
- Revascularization
- Vasospasm
- Vessel perforation
- Vessel rupture
- Vessel thrombosis

### Precautions for Use

**Federal law (USA) restricts this device to sale, distribution, and use by or on the order of a physician.**

**This device should be used only by physicians who have received appropriate training in peripheral vascular interventional technique and preclinical training on the use of this device as established by Balt.**

- The Prestige Coil, the dispenser hoop, and the introducer sheath are in a sterile, non-pyrogenic, unopened and undamaged package. The packaging should be checked for potential damage prior to use. A damaged Prestige Coil must not be used as this may result in patient injury.
- Do not use if sterile packaging has been compromised or damaged.
- The Prestige Coil is intended for single use only.

- Reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death.
- The Ultra Detachment Controller is a sterile, handheld, single-patient-use device which should not be reused, re-sterilized, opened or tampered with.
- The Prestige Coil cannot be detached with any power source other than an Ultra Detachment Controller.
- Damage to the delivery pusher may cause detachment failures, vessel injury or unpredictable distal tip response during coil deployment. If the delivery pusher is damaged at any point during the procedure, do not attempt to straighten or repair it. Do not proceed with the deployment or detachment of the coil. Remove the entire coil system and replace with a new coil.
- Damage to the coil implant may affect coil delivery, stability and overall performance possibly resulting in coil migration and/or stretching.

The Prestige Coil must be delivered only through a wire-reinforced microcatheter with a PTFE inner surface coating. Damage to the device may occur and necessitate removal of both the Prestige Coil and microcatheter from the patient.

- The fluorosafe marker on the delivery pusher is designed for use with a Rotating Hemostatic Valve (RHV) on a 150cm length catheter. If used without an RHV or a shorter catheter, the distal end of the coil may be beyond the alignment marker when the fluorosafe marker reaches the microcatheter hub.
- If the fluorosafe marker is not visible on the proximal end of the delivery pusher, do not advance the coil delivery pusher without the use of fluoroscopy.
- High quality, digital subtraction fluoroscopic road mapping is mandatory to achieve correct placement of the Prestige Coil.
- Do not advance the delivery pusher with excessive force. If excessive force is encountered, determine the cause of any unusual resistance and remove the Prestige Coil and check for damage.
  - If excessive friction is noted with a second Prestige Coil, check the microcatheter for damage or kinking.
- If repositioning is necessary, take special care to retract the coil under fluoroscopy in a one-to-one motion with the delivery pusher. If the coil does not move in a one-to-one motion with the delivery pusher, or if repositioning is difficult, the coil may have become stretched and could possibly break. Gently remove and discard the entire device.
- Due to the delicate nature of the Prestige Coil, in the tortuous vascular pathways that lead to certain aneurysms and vessels, and the varying morphologies of aneurysms and lesions, a coil may occasionally stretch while being maneuvered. Stretching is a precursor to potential coil breakage and migration.
- If resistance is encountered while withdrawing a coil that is at an acute angle relative to the microcatheter tip, it is possible to avoid coil stretching or breaking by carefully repositioning the distal tip of the catheter at, or slightly inside, the ostium of the aneurysm. By doing so, the aneurysm and artery act to funnel the coil back into the microcatheter.

- Delivery of multiple Prestige Coils are usually required to achieve the desired occlusion of some aneurysms or lesions. The desired procedural endpoint is angiographic occlusion.
- Prior to detachment and/or after detachment of the Prestige Coil in an aneurysm, verify there is no coil loop protrusion into the parent vessel. Coil protrusion into the parent vessel after detachment may result in thromboembolic events.
- Advancing the delivery pusher beyond the microcatheter tip after detachment of a coil may result in aneurysm or vessel perforation.
- Always ensure that at least two Ultra Detachment Controllers are available before starting a Prestige Coil procedure.
- Always handle the delivery pusher with surgical gloves.
- Do not use the product after the “Use by” date recorded on the device packaging
- Do not place the delivery pusher on a bare metallic surface.
- It is recommended to keep the proximal end of the pusher dry. Moisture (i.e. saline or blood) may disrupt the electrical current required to detach the Prestige Coil and may lead to detachment failure.
- Do not use in conjunction with radio frequency (RF) devices.
- 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.
- Limit the exposure of X-ray radiation doses to patients and physicians by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors when possible. This device may create local field inhomogeneity and susceptibility artifacts during magnetic resonance angiography (MRA), which may degrade the diagnostic quality to assess effective lesion treatment.