English

# Optima Coil System

**Instructions For Use**

**Carefully read all instructions prior to use. Observe all warnings and cautions noted throughout these Instructions For Use (IFU). Failure to do so may result in complications.**

***CAUTIONS***

**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 neurovascular or peripheral vascular interventional technique and preclinical training on the use of this device.**

***DEVICE DESCRIPTION***

The Optima Coil System consists of an implantable embolization coil comprised of a platinum-tungsten alloy attached to a proximal stainless steel hypo-tube and distal body coil delivery pusher with a radiopaque distal positioning marker and a proximal fluorosafe marker.

The Optima Coil delivery pusher is 185cm in length. It is designed for use with the XCEL Detachment Controller. The XCEL Detachment Controller comes pre-loaded with batteries and is a sterile, handheld, single-patient-use device which should not to be reused, re-sterilized, opened or tampered with. The Optima Coil System and XCEL Detachment Controller(s) are sold separately. The Optima Coil achieves detachment by an internal heater element, which is powered by the XCEL Detachment Controller.

***DEVICE COMPATIBILITY*** (**not included)*

The following devices are required for use with the Optima Coil System:

- The XCEL Detachment Controller
- A delivery microcatheter with a minimum inside diameter (ID) of 0.0165in.(0.42mm) with **two** Radiopaque (RO) marker bands*

**OTHER REQUIRED ADDITIONAL DEVICES** (**not included)*

- Microcatheter* (see above)
- Guidewires compatible with microcatheter*
- Guide catheters compatible with microcatheter*
- Rotating hemostatic valves (RHV)*
- One-way stopcocks*
- Three-way stopcocks*
- Continuous sterile saline and heparin flush set*
- Femoral Sheath*

***INTENDED USE***

The Optima Coil System is intended for use in the peripheral and neuro-vasculature to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels.

***INDICATIONS FOR USE***

The Optima Coil System is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The Optima Coil System is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolizations in the peripheral vasculature.

***ADVERSE EVENTS***

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

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.

***WARNINGS AND PRECAUTIONS***

**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 neurovascular or peripheral vascular interventional technique and preclinical training on the use of this device as established by Balt.**

- The Optima 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 Optima Coil must not be used as this may result in patient injury.
- Do not use if sterile packaging has been compromised or damaged.
- The Optima 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 XCEL Detachment Controller is a sterile, handheld, single-patient-use device which should not to be reused, re-sterilized, opened or tampered with.
- The Optima Coil cannot be detached with any power source other than a XCEL 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 Optima 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 Optima 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 with 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 Optima Coil.
- 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.
- Do not advance the delivery pusher with excessive force. If excessive force is encountered, determine the cause of any unusual resistance and remove the Optima Coil and check for damage.
    - If excessive friction is noted with a second Optima 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 Optima Coil, the tortuous vascular pathways that lead to certain aneurysms and vessels, and the varying morphologies of intracranial aneurysms, 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 Optima 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 Optima Coil, 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 XCEL Detachment Controllers are available before starting a Optima 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 Optima Coil and may lead to detachment failure.
- Do not use in conjunction with radio frequency (RF) devices.

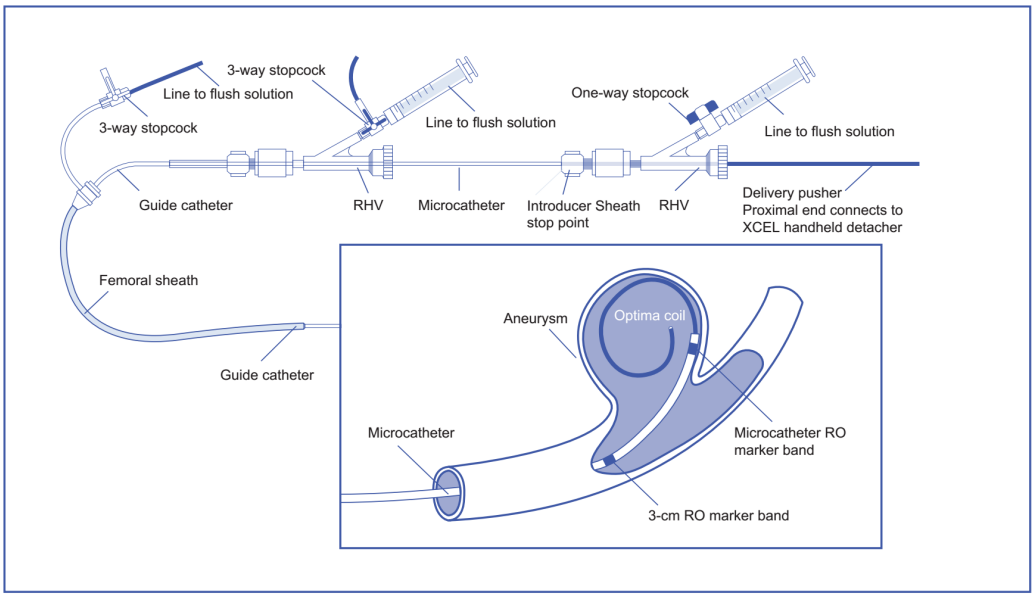


**Diagram 1.**

***PREPARATION FOR CONTINUOUS FLUSH***

1. Refer to the set-up in Diagram 1.
2. Attach a Rotating Hemostatic Valve (RHV) to the hub of the guiding catheter. Attach a 3-way stopcock to the side arm of the RHV and then connect a line for continuous infusion of flush solution.
3. Attach a second RHV to the hub of the microcatheter. Attach a 1-way stopcock to the sidearm of the second RHV and connect a line for continuous flushing of appropriate solution to the stopcock.
4. Open the stopcock and flush the microcatheter with sterile flush solution and then close the stopcock. To minimize the risk of thromboembolic complications, it is critical that a continuous infusion of appropriate sterile flush solution be maintained into the guide catheter, the femoral sheath and the microcatheter.

***CATHETERIZATION OF THE LESION***

5. Using standard interventional procedures, carefully catheterize the lesion by first accessing the vessel with a guide catheter. The guide catheter should have an inner diameter (ID) large enough to allow for contrast injection while the microcatheter is in place. This will allow for fluoroscopic road mapping during the procedure.
6. Select a microcatheter with 2 radiopaque markers with the appropriate inner diameter (0.0165”/ 0.42mm). After the microcatheter has been positioned inside the lesion, remove the guidewire.

***COIL SIZE SELECTION***

7. Perform fluoroscopic road mapping.
8. Measure and estimate the size of the lesion to be treated.
9. Select the appropriately sized coils.

10. Correct coil selection increases Optima Coil effectiveness and patient safety. Occlusive efficiency is, in part, a function of compaction and overall coil mass. To choose the appropriate Optima Coil for any given lesion, examine the pre-treatment angiograms. The appropriate Optima Coil size should be chosen based upon angiographic assessment of the diameter of the parent vessel, aneurysm dome and aneurysm neck. When accessing aneurysms, the diameter of the first and second coils should never be less than the width of the aneurysm neck or the propensity for the coils to migrate may be increased.

***PREPARATION OF THE OPTIMA COIL***

11. Verify the packaging is not damaged. Do not use an Optima Coil if the packaging is damaged.
12. Open the pouch containing the coil packaging hoop in the sterile field and remove the assembly from the pouch.
13. Locate the exposed delivery pusher in the dispensing hoop (See diagram 2)

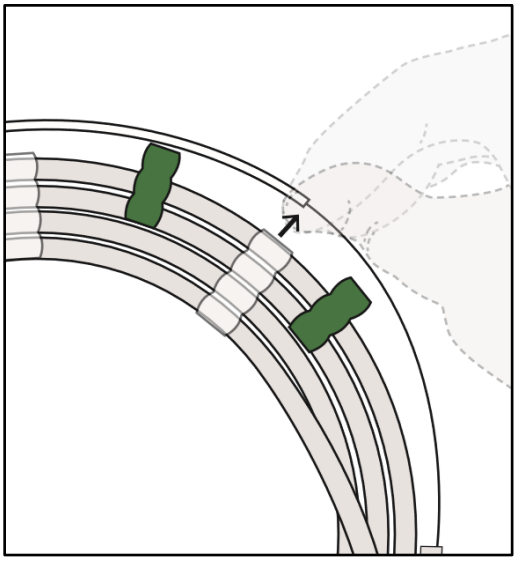

**Diagram 2.**

14. Carefully grasp the introducer sheath and the delivery wire in the section between the two retainer tabs.
15. Pull upwards to unlock it from the retainer tabs using care not to kink or damage the deliver pusher. (See diagram 2)
16. Once the delivery pusher is unlocked from the retainer tabs, carefully remove the entire device from the packaging hoop (protecting the gold connector on the proximal tip). (See diagram 3) Use care to avoid contaminating this end of the delivery pusher with foreign substances such as blood or contrast while taking caution not to damage the proximal gold tip connector during removal.

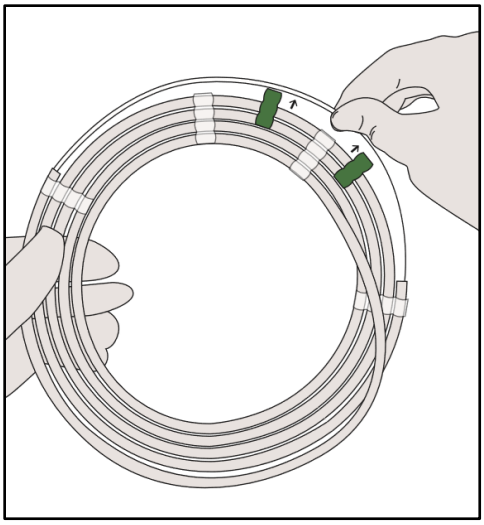

**Diagram 3.**

17. Inspect the proximal section of the delivery pusher for any damage or irregularities especially to the gold connector located at the proximal tip.
18. Do not use the Optima Coil if any irregularities or damage is found to the delivery pusher.
19. After removal of the device from the packaging hoop, carefully insert the proximal end of the delivery pusher into the XCEL Detachment Controller. If the XCEL Detachment Controller indicates a green light along with a single audible sound, remove the XCEL Detachment Controller from the proximal delivery pusher and continue to use the device.

    ***Warning: If the XCEL Detachment Controller indicates an alternating green and red light along with an audible sound, remove the delivery pusher from the XCEL Detachment Controller and attempt this step again. If an alternating green and red light continues to be indicated after multiple attempts, replace the Optima Coil with a NEW Optima Coil before insertion into the patient.***

    ****Also see Instructions For Use packaged with the XCEL Detachment Controller****

20. Slowly advance the Optima Coil implant out of the introducer sheath and inspect the coil for any irregularities or damage. If any damage to the coil or delivery pusher is observed, DO NOT use the system.
21. While holding the introducer sheath vertically, gently retract the coil back into the introducer sheath about 1 to 2 cm.

***INTRODUCTION AND DEPLOYMENT OF THE BALT OPTIMA COIL***

22. Open the RHV on the microcatheter just enough to accept the introducer sheath of the Optima Coil.
23. Insert the introducer sheath of the Optima Coil through the RHV. Seat the distal tip of the introducer sheath at the distal end of the microcatheter hub and close the RHV lightly around the introducer sheath to secure the RHV to the introducer. A slight buckling of the introducer sheath inside the RHV hub indicates proper positioning.

    ***Warning: Do not over-tighten the RHV around the introducer sheath. Excessive tightening could damage the device.***

24. Transfer the Optima Coil into the lumen of the microcatheter by advancing the coil delivery wire in a smooth, continuous motion. Use caution to avoid catching the coil on the junction between the introducer sheath and the hub of the microcatheter.

25. Continue to deliver the Optima Coil through the microcatheter until the proximal end of the delivery pusher meets the proximal end of the introducer sheath.

    ***Note: Make sure the proximal end of the delivery pusher is aligned within the introducer sheath so the proximal end or the gold connector is flush with the proximal end prior to removal of the introducer sheath***

26. Loosen the RHV and retract the introducer sheath just out of the RHV.
27. Close the RHV around the delivery pusher then remove the introducer sheath completely off the delivery pusher. Use care not to kink the delivery system.
28. Locate the fluorosafe markers towards the proximal end of the delivery pusher.

    ***Warning: If the fluorosafe markers are not visible on the delivery pusher, do not advance the coil without fluoroscopy.***

29. Carefully advance the Optima Coil until the delivery pusher is well inside the RHV on the hub of the microcatheter. Continue to advance the delivery pusher into the microcatheter until the fluorosafe markers approach the RHV. Once the fluorosafe markers reach the RHV, this indicates the implant coil is near the exit opening of the microcatheter tip (approximately 7cm). At this time, fluoroscopic guidance must be initiated. (See diagram 4.)

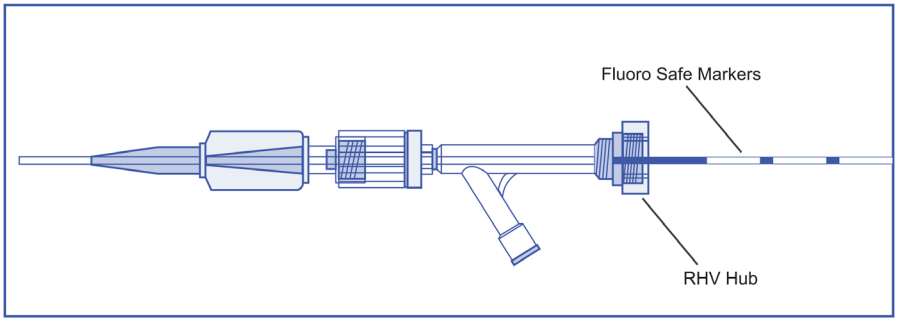


**Diagram 4.**

30. Under fluoroscopic guidance, slowly advance the Optima Coil out the microcatheter tip. Continue to advance the Optima Coil into the lesion until optimal deployment and desired placement is achieved. Reposition the Optima Coil as needed if necessary. If the coil size is not suitable, remove and replace with another Optima Coil.
31. If undesirable movement of the coil is observed under fluoroscopy following placement and prior to detachment, remove the coil and replace with another more appropriately sized coil.

    ***Warning: Movement of the coil may indicate that the coil could migrate once it is detached. DO NOT rotate the delivery pusher during or after delivery of the coil into the aneurysm. Rotating the Optima Coil delivery pusher may result in a stretched coil or premature detachment of the coil from the delivery pusher, which could result in coil migration. Angiographic assessment should also be performed prior to detachment to ensure that the coil mass is not protruding into the parent vessel.***

32. Continue to advance the Optima Coil into the desired site until the radiopaque marker on the delivery pusher is adjacent to the distal side of the proximal marker on the microcatheter.

    ***Notice: This alignment positions the proximal end of the coil outside the microcatheter. To minimize the potential risk of aneurysm or vessel rupture, DO NOT advance the proximal marker on the delivery pusher beyond the proximal marker on the microcatheter. (See diagram 5.)***

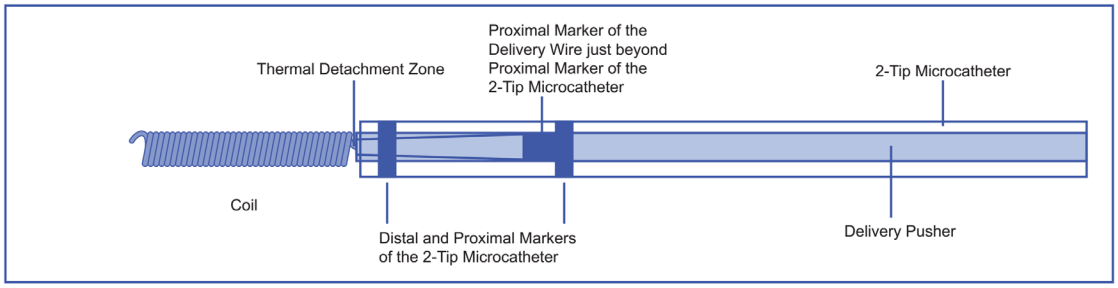


**Diagram 5.**

33. Once desired placement of the Optima Coil is achieved, tighten the RHV around the delivery pusher to prevent movement of the coil.
34. Verify repeatedly that the distal shaft of the delivery pusher is not under stress before coil detachment. Axial compression or tension could cause the tip of the microcatheter to move during coil detachment. Catheter tip movement could cause the aneurysm or vessel to rupture.

***DETACHMENT OF THE OPTIMA COIL***

***Notice: Refer to the XCEL Detachment Controller Instructions For Use contained with the XCEL Detachment Controller packaging for detailed information.***

35. When the Optima Coil has been placed as desired, proceed with detachment per the following instructions.

***Warning: Do not use any power source other than the XCEL Detachment Controller to detach the Optima Coil.***

36. The XCEL Detachment Controller comes pre-loaded with batteries. The XCEL Detachment Controller will activate when an Optima Coil delivery pusher is properly inserted and connected to the XCEL Detachment Controller funnel.
37. Confirm under fluoroscopy placement of the coil and the “3cm” radiopaque marker on the delivery pusher is properly positioned just distal of the proximal radiopaque marker of the microcatheter system.
38. Ensure the RHV is in the locked position around the Optima Coil delivery pusher prior to connecting the XCEL Detachment Controller to ensure the coil does not move.
39. Verify the gold connector on the proximal end of the Optima Coil delivery pusher is clear of any irregularities, is not damaged, and is free of any blood and/or contrast.

***Notice: Although the gold connecter on the proximal end of the Optima Coil delivery pusher is designed to be compatible with blood and contrast, keeping the gold connector free of these materials is important for the proper functionality of the XCEL Detachment Controller.***

40. Gently grasp the Optima Coil delivery pusher approximately 3cm from the proximal end. Keep the delivery pusher still.
41. Holding the XCEL Detachment Controller, gently slide the funnel of the XCEL Detachment Controller over the proximal end of the Optima Coil delivery pusher using care to minimize movement or placing tension on the delivery pusher.
42. Continue to slide the XCEL Detachment Controller over the delivery pusher while holding the delivery pusher steady until the proximal tip of the delivery pusher bumps against the inside of the XCEL Detachment Controller. If significant resistance is encountered during advancement of the XCEL Detachment Controller over the delivery pusher and the controller has not activated, gently remove the XCEL Detachment Controller from the delivery pusher and try connecting again.

43. Once the proximal tip of the delivery pusher bumps against the inside of the XCEL Detachment Controller and the delivery pusher and internal contacts of the controller are properly connected, a short single audible sound will be heard and a steady green light will be visible. This confirms that a proper connection of the XCEL Detachment Controller to the Optima Coil delivery pusher has been established. (See diagram 6.)

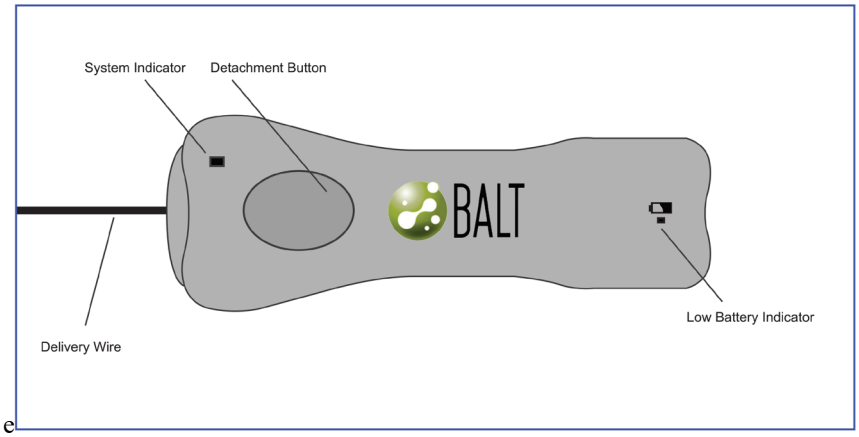


**Diagram 6.**

44. Re-confirm the visible steady green light. This indicates the XCEL Detachment Controller is ready to detach the Optima Coil.
45. At this point, press and release the white "DETACHMENT BUTTON" to begin the detachment process. A short audible sound will be heard along with a 3-burst flashing green light followed by a longer audible sound and a steady green light indicating a completed detachment cycle.
46. Gently slide the XCEL Detachment Controller off the proximal end of the delivery pusher.
47. Under fluoroscopy, verify the Optima Coil has successfully detached by loosening the RHV valve and slowly pull back on the Optima Coil delivery pusher to verify there is no coil movement.
48. Once coil detachment has been confirmed under fluoroscopy, slowly withdraw the delivery wire from the microcatheter. In the event the coil moves indicating a non-detachment of the coil from the delivery pusher, realign the delivery pusher and confirm coil placement then tighten the RHV over the delivery pusher and repeat the detachment procedure.
49. In the instance of 3 unsuccessful attempts to detach a coil with the XCEL Detachment Controller, remove the entire system.
50. Repeat the above steps if additional coil placement is required.

***SPECIFICATIONS FOR XCEL DETACHMENT CONTROLLER***

- Maximum number of detachments per controller: 60
- The XCEL Detachment Controller is a sterile single-patient use device.
- The XCEL Detachment Controller is not intended to be opened, tampered with, re-sterilized or re-used upon completion of surgery.
- Once the procedure is complete, dispose of the XCEL Detachment Controller in accordance with hospital, administrative and/or local government policy.

***PACKAGING AND STORAGE***

The Optima Coil is placed inside a protective, plastic dispenser hoop and packaged in a pouch and unit carton. The Optima Coil and dispenser hoop will remain sterile unless the package is opened, damaged, or the expiration date has passed. Store at a controlled room temperature in a dry place.

A small round indicator label has been affixed to the Optima Coil package so that it is visible before the sterile barrier is breached. This indicator turns from yellow to red upon exposure to radiation and must be red to use the Optima Coil. If the indicator is yellow, DO NOT USE THE DEVICE.

***SHELF LIFE***

See the product label for the device shelf life. Do not use the device beyond the labeled shelf life.

***MRI CONDITIONAL*** 


Non-clinical testing and MRI simulations were performed to evaluate the entire family (i.e., available diameters and lengths) of the Optima Coil System. Non-clinical testing demonstrated that the entire family of these embolization coils is MR Conditional. A patient with an implant from this family can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 4,000-gauss/cm (40-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence)

Under the scan conditions defined, the Optima Coil System is expected to produce a maximum temperature rise of 2.0°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the Optima Coil System extends approximately 5 mm from this device when imaged with a gradient echo pulse sequence and a 3-Tesla MR system. In addition, the use of an MRA pulse sequence at 3T, using an echo time of 3.5ms, generated a signal void artifact of 3 mm from the edge of the coil.

***MATERIALS***

The Optima Coil System does not contain latex or PVC materials.

***SYMBOLS***

The following symbols are used:

| | |
|---|---|
| LOT Lot Number | Use-by Date |
| REF Catalog Number | Do Not Use if Package is Damaged |
| CONT Content | Attention, Consult Accompanying Documents |
| STERILE R Sterilized Using Irradiation | Type BF Applied Part |
| Do Not Reuse | Power ON and OFF |
| Manufacturer | EC REP EC Representative |
| Rx Only Prescription | MR Conditional |
| Non-pyrogenic | Information for Use |
| LATEX Latex Free | Do Not Resterilize |

***WARRANTY***

Balt warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. Handling, storage, cleaning and sterilization of the device, as well as factors relating to the patient, diagnosis, treatment, surgical procedure and other matters beyond Balt's control, directly affect the device and the results obtained from its use. Balt's obligation under this warranty is limited to the repair or replacement of this device and Balt shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly, arising from the use of this device. Balt neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. Balt assumes no liability with respect to devices reused, reprocessed or re-sterilized and makes no warranties, expressed or implied, including, but not limited to, merchantability or fitness for intended use, with respect to such device.

Prices, specifications and model availability are subject to change without notice.







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