Barricade Coil System (BCS)
(Endovascular Embolization Coil)
Instructions for Use

DEVICE DESCRIPTION

The Barricade Coil System (BCS) is a series of specialized coils that are inserted into the cerebral vasculature under angiographic visualization to embolize cerebral aneurysms. The system is compatible with existing sub-3F microcatheter systems (for insertion through microcatheters with maximum IDs of .021" and target ID's of .0165"-.017"). The system is available in various implant shapes, lengths, and sizes. Upon positioning coils into the aneurysm, the coils are detached from the delivery pusher in serial manner until the aneurysm is occluded. However, after a device is deployed into the aneurysm, it can be repositioned prior to detachment from the delivery pusher if the location is not per physician preference. To accommodate a variety of clinical situations and aneurysm sizes and shapes, the system's devices are provided in a range of diameters (1 – 15mm) and lengths (1 – 50cm).

The Barricade Coil System (BCS) consists of an implantable coil attached to a delivery pusher. The delivery pusher is powered by the Blockade Detachment Controller (BDC) designed specifically for the BCS. A Handheld Detachment Cable may be incorporated in conjunction with the BDC to allow detachment control in the sterile field. The Barricade Coil System is comprised of a platinum embolization coil attached to a delivery pusher with radiopaque positioning marker. BCS Framer coils establish the initial framework in the treatment of the cerebrovascular aneurysm or lesion. Once the initial framework has been established by one or more Framer coils, additional BCS Framers, Filler and Finishing coils provide embolization of the cerebrovascular aneurysm or lesion. BCS Filler coils are used to fill aneurysm/lesion space within the framework established by the Framer coil. BCS Finishing coils used at the end of the procedure to complete the embolization at the aneurysm neck or lesion. Use of these coils is determined by the clinician. The BCS is available in several coil types based on the coil primary diameter and configuration (Frame, Fill and Finish). Within each coil type is a broad range of coil secondary (loop) diameters and lengths to meet the needs of the physician. These coil types include 10 and 18 compatible systems and are delivered through the following wire-reinforced microcatheters with the specified minimum ID:

Coil Type	**Microcatheter I.D.**	
	inches	**mm**
BCS-10	0.0165	0.42
BCS-18	0.0165	0.42

INTENDED PURPOSE

The Barricade Coil System is intended for purpose 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 Barricade Coil System (BCS) is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The BCS 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 embolization in the peripheral vasculature.

INTENDED USER

The device should only be used by physicians trained in interventional procedures and who have undergone training in technical aspects of coil embolization, including Interventional Neuro Radiologists (INRs), Endovascular Neurosurgeons, Interventional neurologists and Interventional radiologists. Users can be trained utilizing flow models, with support from trained Clinical Specialists/Managers and/or proctoring from physicians familiar with the system.

TARGET POPULATION

Barricade Coils are intended for use on adult patients, with no specificity in gender or race. Efficacy and safety in pediatrics, pregnant women, or children (under 10) have not been evaluated.

ADVERSE EVENTS

The Barricade Coil System (BCS) potential complications have been assessed as harm categories as per Balt USA's Risk Management provides the methodology to identify harm, hazard, hazardous situations, causes, risk controls and overall residual risk assessment and the risk analysis is documented.
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.

The known risks associated with Barricade Coil System (BCS) include:

- Risk of Infection, such as:
  - Inflammatory response
  - Patient infection (local and systemic)
  - Soreness
  - Redness
  - Pyrogenic response
- Risk of Patient Discomfort, such as:
  - User inconvenience
  - Pain
  - Hypertension
  - Hypotension
- Risk of Vessel Damage, such as:
  - Vessel or Artery damage
  - Dissection
  - Perforation
  - Puncture
  - Rupture
  - Aneurysm rupture
  - Tissue damage
  - Tear
  - Vasospasm
  - Stenosis
- Risk of Hematoma, such as:
  - Hemorrhage
  - Bleeding
- Inability to Treat
- Risk of Neurological Deficit, such as:
  - Stroke
  - Ischemia
  - Vessel spasm
  - Thrombosis (also known as: Emboli or Clot Formation)
  - Mass effect/Headaches
  - Hydrocephalus
  - Seizure
  - Nerve Damage
  - Neuropathy
  - Post-embolization syndrome
- Risk of Arrhythmia, such as:
  - Cardiac event
  - Organ Damage
  - Kidney failure
  - Organ failure
- Risk of Toxic Response, such as:
  - Allergic or irritant response
  - Allergic reaction
  - Pyrogenic response
  - Adverse response to device materials
  - Chemical aseptic meningitis
- Risk of Death

REQUIRED ADDITIONAL ITEMS

- Blockade Detachment Controller (BDC) with Battery (Supplied by Balt)
- Handheld Detachment Cable (Supplied by Balt)
- Microcatheter with 2 RO markers, with min ID .0165" and with a working length between 135cm to 150cm.• Guide catheter compatible with microcatheter
- Steerable guidewires compatible with microcatheter
- 2 rotating hemostatic Y valves (RHV)
- 1 three-way stopcock
- Sterile saline
- Pressurized sterile saline drip
- 1 one-way stopcock
- A sterile 20- or 22-gauge uncoated stainless steel hypodermic needle

WARNINGS AND PRECAUTIONS

Federal law (USA) restricts this device to sale by or on the order of a physician.

- The Barricade Coil System (BCS) is sterile and non-pyrogenic unless the unit package is opened or damaged.
- DO NOT USE THE DEVICE if the radiation indicator label on the package is yellow (must be red).
- The Barricade Coil System (BCS) is intended for single use only. Do not resterilize and/or reuse the device. Reuse of the device may result in re-infection or cross-infection. After use, dispose in accordance with hospital, administrative and/or local government policy. Do not use if the packaging is breached or damaged.
- The Barricade Coil System (BCS) 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 BCS and microcatheter from the patient.
- Flush Guide Catheter and Micro Catheter with Sterile solution prior to use to prevent particulate or harm to the patient and damage to the device.
- Follow the IFU directions to occlude aneurysm space and prevent patient harm.
- Do not advance the Delivery Wire past the Micro Catheter Tip after deployment to assure that the patient is not exposed to sharp surfaces.
- Verify coil location fluoroscopically, retrieval may be required if migration could cause patient harm or disrupts blood flow unintentionally.
- The Barricade Coil System (BCS) should only be used by physicians who have undergone pre-clinical training in all aspects of BCS procedures as prescribed by Balt.
- 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
- High quality, digital subtraction fluoroscopic road mapping is mandatory to achieve correct placement of the BCS Coils.
- Do not advance the delivery pusher with excessive force. Determine the cause of any unusual resistance, remove the BCS and check for damage.
- Advance and retract the BCS device slowly and smoothly. Remove the entire BCS if excessive friction is noted. If excessive friction is noted with a second BCS, 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 BCS coils, 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 BCS coils is usually required to achieve the desired occlusion of some aneurysms or lesions. The desired procedural endpoint is angiographic occlusion.
- The long-term effect of this product on extravascular tissues has not been established so care should be taken to retain this device in the intravascular space.
- Always ensure that at least two Blockade Detachment Controllers (BDC's) are available before starting a Barricade Coil System (BCS) procedure.
- The Barricade Coil System (BCS) cannot be detached with any power source other than a Blockade Detachment Controller (BDC).
- Always advance an appropriately sized guidewire through the microcatheter after detaching the coil and removing the pusher to ensure that no part of the coil remains within the microcatheter.
- Do NOT place the delivery pusher on a bare metallic surface.
- Always handle the delivery pusher with surgical gloves.
- Do NOT use in conjunction with radio frequency (RF) devices.

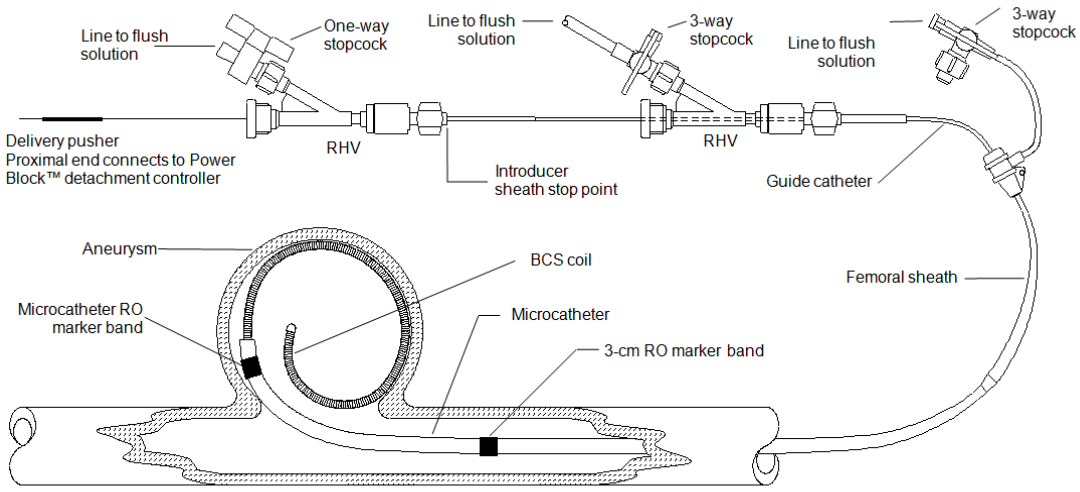


Diagram of BCS Setup

PREPARATION FOR USE

1. Refer to the set-up diagram.
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 the flush solution line 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, access 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 the appropriate inner diameter. 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 Barricade Coil System (BCS) effectiveness and patient safety. Occlusive efficiency is, in part, a function of compaction and overall coil mass. In order to choose the optimum BCS coil for any given lesion, examine the pre-treatment angiograms. The appropriate BCS 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 BCS FOR DELIVERY

11. Prior to using the device, remove the proximal end of the delivery pusher from the packaging hoop. Use care to avoid contaminating this end of the delivery pusher with foreign substances such as blood or contrast.

12. Remove the Barricade Coil System (BCS) from the packaging hoop by pulling the proximal end until the introducer exits the hoop.

13. Hold the device just distal to the white introducer locking tubing. Slide the introducer locking tubing proximally and completely off of the delivery wire to loosen the grip of the introducer sheath on the delivery wire.

14. Slowly advance the BCS implant Coil 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.**

15. 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 Barricade Coil System (BCS)

16. Open the RHV on the microcatheter just enough to accept the introducer sheath of the BCS.

17. Insert the introducer sheath of the BCS 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.

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

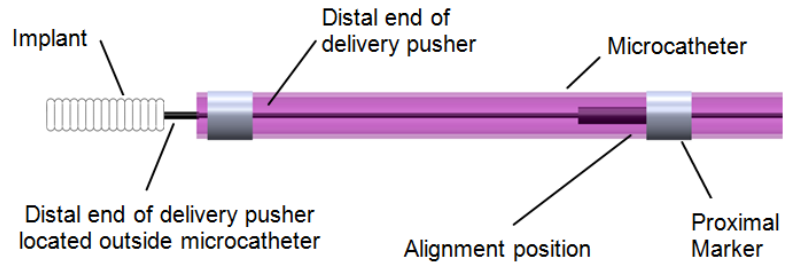
18. Push the coil into the lumen of the microcatheter. Use caution to avoid catching the coil on the junction between the introducer sheath and the hub of the microcatheter.

19. Push the Barricade Coil System (BCS) through the microcatheter until the proximal end of the delivery pusher meets the proximal end of the introducer sheath. Loosen the RHV. Retract the introducer sheath just out of the RHV. Close the RHV around the delivery pusher. Slide the introducer sheath completely off of the delivery pusher. Use care not to kink the delivery system.

20. Carefully advance the Barricade Coil System (BCS) until the delivery pusher is well inside the RHV on the hub of the microcatheter. Continue to advance the delivery wire into the microcatheter until the Warning Stripes approach the RHV. Upon reaching the RHV, the Warning Stripes indicate the implant coil position near the exit of the microcatheter tip. At this time, fluoroscopic guidance must be initiated.

21. Under fluoroscopic guidance, slowly advance the BCS coil out the tip of the microcatheter. Continue to advance the BCS coil into the lesion until optimal deployment is achieved. Reposition if necessary. If the coil size is not suitable, remove and replace with another device. 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. 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 BCS 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.

22. Advance the coil into the desired site until the radiopaque proximal marker on the delivery system is adjacent to the distal side of the proximal marker on the microcatheter. 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 system distally past the proximal marker on the microcatheter.**



Position of Marker Bands for Detachment

To minimize the potential risk of aneurysm or vessel rupture, **DO NOT** advance the proximal marker on the delivery system distally past the proximal marker on the microcatheter.

23. Tighten the RHV to prevent movement of the coil.

24. 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 delivery. Catheter tip movement could cause the aneurysm or vessel to rupture.

DETACHMENT OF THE Barricade Coil System (BCS) COIL

25. When the BCS detachable coil has been placed as desired, proceed with detachment per the following: **Do not use any power source other than the Blockade Detachment Controller (BDC) to detach the coil. The BDC is intended for multi-use. Do not sterilize.**

26. Insert a sterile needle (size 20G or 22 G = 0.7 mm or 0.9 mm, respectively at the shoulder (M. deltoideus) or at the patient's groin.

27. Insert the connector of the sterile Handheld Detachment Cable into the connector receptacle of the Blockade Detachment Controller (BDC).

28. Clip the connector end of the sterile black cable onto the sterile needle and then clip the connector end of the sterile red cable onto the proximal end of the delivery pusher. Ensure that the guiding system is resting on a dry, clean surface.

29. Confirm again under fluoroscopy that the positioning coil of the guiding system is just distal of the proximal marker of the microcatheter.

30. Switch "ON" the Blockade Detachment Controller (BDC) with the main switch on the device.

31. Start the detachment by pressing the green button on the BDC or Handheld Detachment Cable until the detachment lamp starts flashing.

32. A audible acoustic sound and "Detach" indicator flashes on the BDC, which indicates the detachment of the coil. BCS Coil shall detach within 3 detachment cycles of the controller.

33. At the end of the detachment cycle, an audible tone will sound, and the light will be constantly lit. This indicates that the detachment cycle is complete. If the coil does not detach during the detachment cycle, leave the BDC attached to the delivery pusher and attempt another detachment cycle.

34. When the battery becomes low the battery indicator light will turn red. **The Blockade Detachment Controller (BDC) will not start a detachment if the light is red.**

35. Verify detachment of the coil under fluoroscopy by first loosening the RHV valve, then pulling back slowly on the delivery system and verifying that there is no coil movement. If the implant did not detach, do not attempt to detach it more than two additional times. If it does not detach after the third attempt, remove the delivery system.

36. After detachment has been confirmed, slowly advance the delivery pusher to ensure the proximal end of the coil is outside the microcatheter. After this step is performed, slowly retract the delivery pusher back into the microcatheter. **Advancing the delivery pusher beyond the microcatheter tip once the coil has been detached involves risk of aneurysm or vessel rupture.**

37. After the coil is outside the microcatheter, pull the entire delivery system out of the microcatheter.

38. Verify the position of the coil angiographically through the guide catheter.

39. Prior to removing the microcatheter from the treatment site, place an appropriately sized guidewire completely through the microcatheter lumen to ensure that no part of the coil remains within the microcatheter.

40. Switch off the Barricade Detachment Controller (BDC).

41. Repeat the above steps if additional coil placement is required.

42. If the patient experiences pain at the site of the patient return electrode, or if detachment times are increasing, replace the needle with a new needle at a new insertion site.

After Detachment, Advance Delivery Pusher to Ensure the Coil is Outside the Microcatheter

The physician has the discretion to modify the coil deployment technique to accommodate the complexity and variation in embolization procedures. Any technique modifications must be consistent with the previously described procedures, warnings, precautions and patient safety information.

SPECIFICATIONS FOR BLOCKADE DETACHMENT CONTROLLER (BDC)

• Output Current: 2.0 mA.

• Maximum number of detachments per battery: 59

• Maximum time for detachment sequence: 180 seconds

• Cleaning, preventative inspection, and maintenance: The BDC is a non-sterile, multi-use device, preloaded with replaceable batteries. No inspection, or maintenance is required. If the device does not perform as described in the Detachment section of these Instructions, replace the batteries for BDC or replace it with a new unit.

• The BDC is a reusable device. It must not be sterilized.

• Once the procedure is complete, discard the Cable Set and store BDC in a clean, dry and secure place. The BDC may be cleaned with a damp cloth.

• Dispose of the batteries in accordance with hospital, administrative and/or local government policy. Remove the batteries when the BDC is not in use.

PACKAGING AND STORAGE

The Barricade Coil System (BCS) is placed inside a protective, plastic dispenser hoop and packaged in a pouch and unit carton. The BCS 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 Barricade Coil System (BCS) 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 in order to use the BCS. If the indicator is yellow, DO NOT USE THE DEVICE.

The Blockade Detachment Controller (BDC) is packaged separately in a protective carton. The BDC detachment controller has not been sterilized; Store at a controlled room temperature in a dry place.

SHELF LIFE

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

DISPOSAL

There are no special disposal requirements for the Delivery Wire and packaging after use, dispose in accordance with hospital, administrative and/or local government policy.

MRI COMPATIBILITY 

The Barricade® Coil System (BCS) implant materials have been determined to be MR conditional.

Non-clinical testing has demonstrated the Barricade Coil System (BCS) is MR Conditional. A patient with this device can be scanned safely under the following conditions:

- Static magnetic fields of 3 Tesla
- Maximum spatial gradient field of 4000 Gauss/cm (40 Tesla/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.9 W/kg for 15 minutes of scanning

Under the scan conditions defined above, the Barricade Coil System (BCS) is expected to produce a maximum temperature rise of 1.9°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 5 mm from the Barricade Coil System when imaged with a gradient echo pulse sequence and a 3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI MR scanner.

The artifact does not obscure the device lumen.

MATERIALS

The Barricade Coil System (BCS) does not contain latex or PVC materials.

COILS:

The Barricade Coil System (BCS) consists of an embolization coil implant comprised of platinum/tungsten affixed to a delivery pusher. The Implant Coil is made from medical grade polymers, and metals.

DELIVERY WIRE:

The Delivery Wire assembly is a stainless-steel guidewire and is soldered to the RO marker coil and has a polymeric jacket along its length. The Delivery Wire is made from medical grade polymers, and metals.

The Barricade Coil System (BCS) is comprised of commonly used medical grade materials and processes that are similar and or exact to other devices used in the same medical procedures that are manufactured by companies competing in the same medical market space. These Barricade Coil System (BCS) materials have undergone successful testing for Biocompatibility to ISO 10993 and have been proven safe for their intended purpose.

Description	**Material Description**
Introducer Sheath	
Introducer Sheath	Polyethylene
Barricade Coil System (BCS) - Implant	
Primary Wind Coil	Platinum alloy
PET Thread	Polyethylene thread
Engage Thread	Ethylene thread
Dymax UV Glue	Cyano acrylate adhesive
Barricade Coil System (BCS) – Delivery Wire	
Coupler Coil	Platinum alloy
Multi-Pitch Pt/W 479 Body Coil	Platinum alloy
Core Wire	304V (A2 Stainless steel / UNS S30400)
PET Jacket	Polyethylene tubing
Warning Mark PET, Black/White Zebra Print	Polyethylene tubing

Formed Heat Shrink	Polyethylene tubing
Gold Solder	Gold Solder
Dymax UV Glue	Cyano acrylate adhesive

The above table contains the list of material that is used in Barricade. The materials listed above are not carcinogenic, mutagenic, threat to reproducibility, or concentration that is less than 0.1 % weight by weight (w/w).

SYMBOLS

The following symbols are used:

LOT Lot Number	Use-by Date
REF Catalog Number	Date of Manufacture
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
Prescription	MR Conditional
Non-Pyrogenic	Consult Instructions for Use
Do Not Use if Package Is Damaged	Single Sterile Barrier System with Protective Packaging Outside
UDI Unique Device Identifier	MD Medical Device
Do not Resterlize	Latex Free
CE 0297 CE Mark	Keep Dry
Patient information website	

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 resterilized and makes no warranties, expressed or implied, including, but not limited to, merchantability or fitness for intended purpose, with respect to such device.

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

Barricade Coil System Basic UDI-Device Identifier Number: 0810068560014J

More information on this device, including a Summary of Safety and Clinical Performance, is available at the websites below:

www.baltgroup.com https://ec.europa.eu/tools/eudamed

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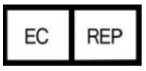

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