IFU-022 Rev. B **English**
**Revised 2019-01**

# Ballast™ 088 Long Sheath

**Instructions for Use**

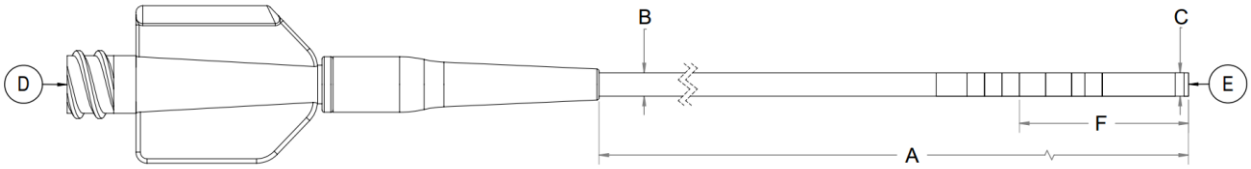
## *DEVICE DESCRIPTION*

The Ballast™ 088 Long Sheath is a single lumen, braid-reinforced, variable stiffness catheter with a radiopaque zone on the distal end and a luer hub on the proximal end. The Ballast 088 Long Sheath dimensions are included on the individual device label and listed below. The Ballast 088 Long Sheath is compatible with introducer sheaths appropriately sized for the outer diameter of the Ballast 088 Long Sheath.

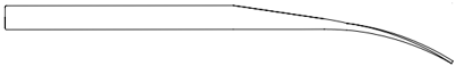
The catheter is provided sterile, non-pyrogenic, and is intended for single use only.

The Ballast 088 Long Sheath includes the Ballast 088 Long Sheath, Dilator, Introducer Sheath, 9F Rotating Hemostasis Valve (RHV) and 8F Hemostasis Valve Adapter (HVA).

The Dilator facilitates the percutaneous entry of the Ballast 088 Long Sheath by forming an atraumatic transition of distal sheath through the skin and subcutaneous tissue to the vessel while protecting the Ballast distal diameter integrity. The distal portion of the Ballast 088 Long Sheath is covered with a hydrophilic coating to aid in reducing friction. The hydrophilic coating length is provided in the table below.




| | A | B | C | D | E | F |
|---|---|---|---|---|---|---|
| PART NUMBER | USABLE LENGTH | PROXIMAL OD | DISTAL OD | PROXIMAL ID | DISTAL ID | Hydrophilic Coating |
| BALLAST80 | 80 cm | | | | | |
| BALLAST90 | 90 cm | | | | | |
| BALLAST100 | 100 cm | | | | | 20cm |
| BALLAST105 | 105 cm | 0.106" | 0.100" | 0.088" | 0.088" | |



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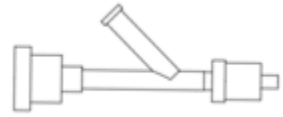

RHV



***INDICATIONS FOR USE***

The Ballast 088 Long Sheath is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

***CONTRAINDICATIONS***

There are no known contraindications.

***COMPATIBILITY***

The Ballast 088 Long Sheath can be used individually with a 0.038” guidewire or together with a 6F diagnostic catheter to access the desired anatomy. The Ballast 088 Long Sheath can be used for direct access to the vessel or through a short vessel access sheath. Refer to labeling provided with other medical technologies to determine compatibility.

***WARNINGS***

- The Ballast 088 Long Sheath should only be used by physicians who have received appropriate training in interventional techniques.
- Do not reuse. The device is intended for single use only. Discard the Sheath after one procedure. Structural integrity and/or function may be impaired through reuse or cleaning. Sheaths are extremely difficult to clean after exposure to biological materials and may cause adverse patient reactions if reused.
- This device is coated with a hydrophilic coating at the distal end. Please see table above for specific coating measurements. Please refer to the Instructions for Use section for further information on how to prepare and use this device to ensure it performs as intended. Failure to

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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.

***PRECAUTIONS***

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

- Store in a cool, dry, dark place.
- Do not use kinked or damaged devices.
- Do not use opened or damaged packages.
- Use prior to the "Use by date."
- Do not autoclave, resterilize or reuse. This device is intended for single use.
- Use the Ballast 088 Long Sheath in conjunction with fluoroscopic visualization.
- Inspect the product before use to verify that its size and condition are suitable for the specific procedure.
- Manually flush and hydrate Sheath prior to insertion.
- Do not advance or withdraw the Ballast 088 Long Sheath against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device.
- Moving or torqueing the device against resistance may result in damage to the vessel or device.
- Maintain a constant infusion of appropriate flush solution.
- If flow through the Sheath becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device.
- Extreme care must be taken to avoid damage to the vasculature through which the Sheath passes.
- The Sheath may occlude smaller vessels. Care must be taken to avoid complete blood flow blockage.
- Torqueing the Sheath may cause damage which could result in kinking and possible separation along the sheath shaft. Should the system become severely kinked, withdraw the entire system.
- An appropriate anticoagulation therapy should be applied per institutional guidelines.
- 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 hydrated as stated in this instructions for use to avoid any potential impact to the coating performance.

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**Instructions for Use**

- 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.
- Do not shape catheter tip.
- Hydrophilic coating may swell when exposed to aqueous media resulting in a tight fit of introduced devices.

## *POTENTIAL ADVERSE EVENTS*

*Possible complications include, but are not limited to, the following:*

- acute vessel occlusion
- allergic reaction
- air embolism
- death
- device malfunction
- distal embolization
- emboli
- false aneurysm formation (i.e. dissection)
- hematoma or hemorrhage at puncture site
- infection
- inflammatory responses
- Sterile inflammation or granulomas at the access site and tissue necrosis
- Intracranial hemorrhage
- ischemia
- neurological deficits including stroke
- vessel spasm, thrombosis, dissection or perforation
- This device requires the 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.

## *PREPARATION FOR USE (Sheath Configuration)*

1. Select an appropriately sized Ballast 088 Long Sheath based on the anatomy and length.
2. Gently pull the Ballast 088 Long Sheath and packaging card out of the pouch.
3. Remove the Ballast 088 Long Sheath from the packaging card by removing the hub from the card tabs before gently removing the Ballast 088 Long Sheath shaft.
4. Gently remove the Dilator from the packaging card by removing the hub from the card tabs before gently removing the Dilator shaft.
5. Inspect the Ballast 088 Long Sheath for kinks or other damage.
6. Attach the Hemostasis Valve Adapter (HVA) to the proximal end of the Ballast 088 Long Sheath.
7. Flush the HVA and Ballast 088 Long Sheath with heparinized saline through HVA stopcock.
8. Flush the Dilator lumen and wet the outer surface of the dilator with heparinized saline.
9. Insert the Dilator through the HVA of the Ballast 088 Long Sheath, snapping it into place at the hub.

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10. Introduce the angiographic needle into the vessel using aseptic technique. Holding the needle in place, insert the flexible end of a 0.038" guidewire through the needle and into the vessel. Gently advance the guidewire to the desired depth.
11. Holding the guidewire in place, withdraw the needle and apply pressure to the puncture site until the Ballast 088 Long Sheath is inserted into the vasculature.
12. Thread the Ballast 088 Long Sheath/Dilator assembly over the guidewire, grasping the Sheath close to the skin to prevent buckling. Using a rotating motion, advance the assembly through the tissue into the vessel.
13. Under fluoroscopy, advance the Ballast 088 Long Sheath over the 0.038" guidewire (always ensure the distal wire extends in front of the dilator tip) until a safe flushing position is achieved.
14. Detach the Dilator from the Sheath by releasing the snap-fit ring at the hub. Withdraw the guidewire and Dilator. To avoid damage to the Sheath, do not withdraw the Dilator until the Sheath is in the vessel.
15. Aspirate from the HVA to remove any potential air. After aspiration and flushing, consider establishing pressurized drip of heparinized saline solution or suitable isotonic solution via the HVA.
16. **If using a 6F diagnostic catheter** to navigate final position, select appropriate 6F catheter shape based on the target vessel and its surrounding anatomy.
    a. Insert the 6F diagnostic catheter into the Ballast 088 Long Sheath and advance the 6F catheter until the distal tip of the 6F diagnostic catheter is at the distal tip of the Ballast 088 Long Sheath.
    b. Appropriately aspirate and flush the 6F diagnostic catheter.
    c. Advance the 6F diagnostic catheter an appropriate distance beyond the tip of the Ballast 088 Long Sheath to properly navigate to the target vessels.
    d. Once the 6F diagnostic catheter is in the proper location, advance the Ballast 088 Long Sheath to the proper location.
17. **If using a 0.038" guidewire** instead of the 6F catheter, insert the 0.038" guidewire into the Ballast 088 Long Sheath and advance the guidewire until the distal tip of the wire is beyond the distal tip of the Ballast 088 Long Sheath.
    a. Advance the 0.038" guidewire an appropriate distance beyond the tip of the Ballast 088 Long Sheath to properly navigate to the target vessels. Advance the Ballast 088 Long Sheath and guidewire to the vascular site and remove the guidewire.
    b. Insert appropriately sized diagnostic or therapeutic catheters and advance products to the intended vasculature.
    c. In order to protect the distal tip of the sheath, the prepackaged Introducer Sheath may be used.
        i. To properly use the Introducer Sheath, advance the selected catheter assembly to the distal tip of Introducer Sheath.
        ii. Holding the Introducer Sheath and catheter assembly, advance into HVA.

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iii. Holding the Introducer Sheath with the left hand, advance the catheter assembly with the right hand with the Ballast 088 Long Sheath.

iv. After passing approximately 30 to 50cm of catheter assembly into the Ballast 088 Long Sheath, peel away the Introducer Sheath with the right hand while securing the catheter assembly with the left hand.

v. Aspirate and flush the HVA.

18. After the procedure, remove the Ballast 088 Long Sheath when clinically indicated by placing compression on the vessel above the puncture site and slowly withdraw the Ballast 088 Long Sheath. Discard the Ballast 088 Long Sheath appropriately.
19. Important: Upon removing the Ballast 088 Long Sheath, aspirate via the HVA to collect any fibrin that may have been deposited within or at the tip of the catheter.

***PREPARATION FOR USE (Guide Catheter Configuration)***

1. Select an appropriately sized Ballast 088 Long Sheath based on the anatomy and length.
2. Gently pull the Ballast 088 Long Sheath and packaging card out of the pouch.
3. Remove the Ballast 088 Long Sheath from the packaging card by removing the hub from the card tabs before gently removing the Ballast 088 Long Sheath shaft.
4. Gently remove the Dilator from the packaging card by removing the hub from the card tabs before gently removing the Dilator shaft.
5. Inspect the Ballast 088 Long Sheath for kinks or other damage. Flush the lumen and hydrate outer surface of the Ballast 088 Long Sheath with heparinized saline.
6. Attach the RHV to the proximal end of the Ballast 088 Long Sheath.
7. Flush the RHV and Ballast through RHV side port with heparinized saline.
8. Flush the Dilator lumen and wet the outer surface of the Dilator with heparinized saline.
9. Insert the Dilator through the RHV of the Ballast 088 Long Sheath to appropriate distal length then rotate RHV to secure Dilator in place.
10. Insert 0.038” guidewire into Dilator, diagnostic catheter, or directly into Ballast 088 as described above and advance the guidewire until the distal tip of the wire is beyond the distal tip of the Ballast 088 Long Sheath.
11. Introduce appropriate 8F or larger sheath into the vessel using aseptic technique.
12. Thread the Ballast 088 Long Sheath/Dilator/diagnostic catheter/0.038” guidewire assembly into the sheath, grasping Ballast 088 Long Sheath close to sheath to prevent buckling.
13. Under fluoroscopy, advance the Ballast 088 Long Sheath along with Dilator/diagnostic catheter/0.038” guidewire (always ensure the distal wire extends in front of the Dilator tip) until a safe flushing position is achieved.
14 Advance Dilator/diagnostic catheter/0.038” guidewire appropriate distance beyond tip of Ballast 088 Long Sheath to properly navigate to target vessels.
    a. Navigate Ballast 088 Long Sheath assembly to final position.

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15 Remove Dilator/diagnostic catheter/0.038” guidewire, then aspirate and flush the Ballast 088 Long Sheath

16 Insert appropriately sized diagnostic or therapeutic catheters and advance products to the intended vasculature.

17 In order to protect the distal tip of diagnostic or therapeutic catheters, the prepackaged Introducer Sheath may be used.

   a. To properly use the Introducer Sheath, advance the selected catheter assembly to the distal tip of Introducer Sheath.
   b. Holding the Introducer Sheath and catheter assembly together while advancing into RHV.
   c. Holding the Introducer Sheath with the left hand advance the catheter assembly with the right hand with Ballast 088 Long Sheath.
   d. After passing approximately 30 to 50cm of the catheter assembly into Ballast 088 Long Sheath, peel away the Introducer Sheath with the right hand while securing the catheter assembly with the left hand.
   e. Aspirate and flush RHV.

18 Important: Upon removing the Ballast 088 Long Sheath, aspirate via the RHV to collect any fibrin that may have been deposited within or at the tip of the catheter.

***STORAGE***

Store the Ballast 088 Long Sheath in room temperature. See the product label for the device shelf life. Do not use the device beyond the labeled shelf life.

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## *SYMBOL GLOSSARY*

| Symbol | Standard Reference | Symbol Title | Explanatory Text |
|---|---|---|---|
|  | ISO 15223-1 §5.1.4 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | Use-by date | Indicates the date after which the medical device is not to be used. |
|  | ISO 15223-1 §5.1.1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | Manufacturer | Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC. |
|  | ISO 15223-1 §5.1.3 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | Date of Manufacture | Indicates the date when the medical device was manufactured |
|   | ISO 15223-1 §5.2.3 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | Sterilized using ethylene oxide | Indicates a medical device that has been sterilized using ethylene oxide |
|  | ISO 15223-1 §5.6.3 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | Non-pyrogenic | Indicates a medical device that is non-pyrogenic. |
|   | 21 Code of Federal Regulations (CFR) sec. 801.109(b)(1) | Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. | Indicates a medical device that is a prescription device. |
|  | ISO 15223-1 §5.4.2 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | Do not re-use | Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure. |
|   | ISO 15223-1 §5.1.6 Medical devices — Symbols to be used with medical device labels, labelling and information | Catalogue number | Indicates the manufacturer's catalogue number so that the medical device can be identified. |

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| | | | |
|---|---|---|---|
| | to be supplied — Part 1: General requirements | | |
| LOT | ISO 15223-1 §5.1.5 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | Batch code | Indicates the manufacture's batch code so that the batch or lot can be identified. |
|  | ISO 15223-1 §5.4.3 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | Consult Instructions for Use | Indicates the need for the user to consult the instructions for use. |
|  | ISO 15223-1 §5.3.2 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | Keep Away from Sunlight | Indicates a medical device that needs protection from light sources. |
|  | ISO 15223-1 §5.3.4 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | Keep Dry | Indicates a medical device that needs to be protected from moisture. |
|  | ISO 15223-1 §5.2.8 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | Do not use if package is damaged | Indicates a medical device that should not be used if the package has been damaged or opened. |
|  | ISO 15223-1 §5.4.4 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | Caution | Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself. |
|  | ISO 15223-1 §5.2.6 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | Do not resterilize | Indicates a medical device that is not to be resterilized. |
| EC REP | ISO 15223-1 §5.1.2 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | Authorized representative in the European Community | Indicates the authorized representative in the European Community. |

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***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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