



## Stellar™ Intermediate Catheter

### Instructions for Use (IFU)

**Carefully read entire instructions prior to use.**

#### INDICATIONS FOR USE

The Stellar Intermediate Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

#### DEVICE DESCRIPTION

The Stellar Intermediate Catheter is a single-lumen, flexible, variable stiffness composite catheter. The distal tip of the catheter shaft includes a marker band while the proximal end of the catheter has a luer fitting to allow attachment of accessories and infusion of liquids through the system. The Stellar Intermediate Catheter distal shaft has an external hydrophilic coating which provides a lubricious surface during use (Figure 1).

The Stellar Intermediate Catheter is visible under fluoroscopy. The Stellar Intermediate Catheter dimensions are included on the individual device label. The Stellar Intermediate Catheter is offered in various sizes to accommodate physician preferences and anatomical variations.

A peelable split introducer sheath is provided in the package to provide support and facilitate the introduction of the distal tip of the Stellar Intermediate Catheter into an appropriate vascular sheath (Figure 2).

The catheter and introducer sheath are provided sterile, non-pyrogenic, and are intended for single use only.

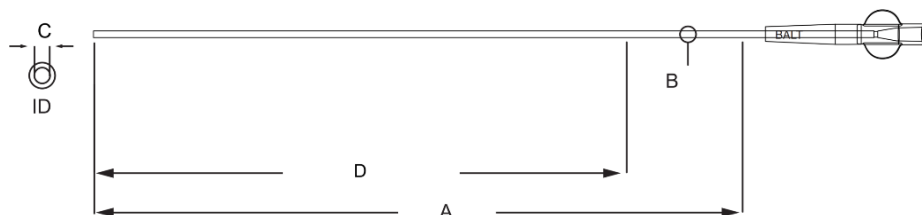


**Figure 1 – Stellar Intermediate Catheter**

**Table 1.** Referenced Dimensions for the Stellar Intermediate Catheter

|              | A              | B                   | C                   | D                          |
|--------------|----------------|---------------------|---------------------|----------------------------|
| Model Number | Usable Lengths | Outer Diameter (OD) | Inner Diameter (ID) | Hydrophilic Coating Length |
| STLR071105   | 105cm          | 0.083"<br>(2.11 mm) | 0.071"<br>(1.80 mm) | 60 cm                      |
| STLR071110   | 110 cm         |                     |                     |                            |
| STLR071115   | 115cm          |                     |                     |                            |
| STLR074105   | 105 cm         | 0.086"<br>(2.18 mm) | 0.074"<br>(1.88 mm) |                            |
| STLR074110   | 110 cm         |                     |                     |                            |
| STLR074115   | 115cm          |                     |                     |                            |

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One Stellar Intermediate  
Catheter One Introducer  
Sheath

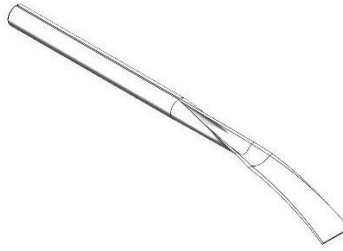


**Figure 2 – Introducer Sheath**

### COMPATIBILITY

The Stellar Intermediate Catheters are compatible with the following guide sheaths and guidewires (Table 2).

**Table 2.** Compatibility for the Stellar Intermediate Catheter

| Stellar Guide Catheter | Guide Sheath Inner Diameter         | Guidewire                           |
|------------------------|-------------------------------------|-------------------------------------|
| 071 Catheter           | $\geq 0.088''$<br>( $\geq 2.24$ mm) | $\leq 0.035''$<br>( $\leq 0.89$ mm) |
| 074 Catheter           | $\geq 0.091''$<br>( $\geq 2.31$ mm) |                                     |

Refer to product label for device dimensions.

Refer to labeling provided with other medical technologies to determine compatibility.

### DISPOSAL

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

### CONTRAINDICATIONS

There are no known contraindications.

### CAUTION

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

### WARNINGS

- The device is intended for single use only. Do not resterilize or reuse. After use, dispose in accordance with hospital and/or local government policy.
- Do not use kinked or damaged devices. Do not use if pouch is open or damaged. Product will remain sterile for the labeled shelf life if stored under the recommended conditions as long as the packaging is not compromised or damaged.
- Do not use automated high-pressure contrast injection equipment with the Stellar Intermediate Catheter as it may damage the device and injure the patient.

## **Stellar Intermediate Catheters**

### **Instructions for Use (IFU)**

- Exercise care when manipulating the device through tortuous anatomy. Do not advance or withdraw the Stellar Intermediate Catheter or accessory/adjunctive devices against resistance without careful assessment of the cause under fluoroscopy. If the cause cannot be determined, withdraw all devices. Excessive manipulation or torquing the device against resistance may result in damage to the vasculature or the device.
- The distal portion of the catheter has a lubricious hydrophilic coating and should be hydrated per steps in this IFU with heparinized saline before inserting the catheter into the patient. Failure to abide by this warning may result in damage to the device coating, which may necessitate intervention or result in serious adverse events.
- To avoid the introduction of embolic fibers, do not use fabric/cloth/gauze to hydrate or wipe down the catheters. Catheters should be hydrated through short immersion in a bath of heparinized saline.
- Inspect the Stellar Intermediate Catheter prior to use. Do not use the device if any damage or irregularities are observed.
- Do not use the Stellar Intermediate Catheter System with Ethiodol or Lipiodol based contrast media as this may cause damage to the device.
- Do not use organic solvents as this may cause damage to the device.
- The Introducer Sheath is not intended for use inside the patient's body. Ensure that the Introducer Sheath is removed from the Stellar Intermediate Catheter once the distal shaft of the Stellar Intermediate Catheter is placed inside the patient's body.
- Use caution when manipulating, advancing, or withdrawing the Stellar Intermediate Catheter through needles, metal cannulas, stents, or other devices with sharp edges, or through tortuous or calcified blood vessels. Manipulation, advancement, or withdrawal past sharp or beveled edges may result in destruction or separation of the outer coating, which may lead to clinical adverse events, resulting in coating material remaining in the vasculature or device damage.

### **PRECAUTIONS**

- Use prior to the "Use By" date specified on the product package.
- Prior to use, ensure that the dimensions (e.g. diameter and length) of accessory/adjunctive devices to be used in the procedure are compatible with each other and appropriate for the target vasculature.
- Use the Stellar Intermediate Catheter in conjunction with fluoroscopic visualization.
- Note: Sufficient shielding, reduced fluoroscopy times, and modified X-ray technical factors should be used when possible, to limit patient and physician exposure to X-ray radiation doses.
- The appropriate anti-platelet and anti-coagulation therapy should be administered in accordance with standard medical practice.
- Inspect the catheter system before use to verify that its size and condition are suitable for the specific procedure.
- Manually flush heparinized saline through the catheter lumen prior to insertion.
- Maintain a constant infusion of appropriate flush solution. If using a heparinized flush solution, care should be taken to account for the additional heparin being administered via the flush solution. Failure to do so can result in coagulopathy and excessive bleeding at the access site.
- If flow through the catheter becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device.
- Avoid using alcohol, antiseptic solutions, or other solvents to pre-treat the device as 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 the Preparation and Use section to avoid any potential impact to the coating performance. Once the catheter is hydrated, do not allow it to dry.

## Stellar Intermediate Catheters

### Instructions for Use (IFU)

- Avoid pre-soaking devices for extended durations when the device is not in use, as this may impact coating safety and performance. Soaking time should not exceed one (1) hour.
- Hydrophilic coating may swell when exposed to excessive aqueous media resulting in a tight fit of introduced devices.
- The safety and effectiveness of the coated device has not been established, or is unknown, in vascular regions other than those specifically indicated.

#### **POTENTIAL COMPLICATIONS**

*Potential adverse events include, but are not limited to, the following:*

- acute occlusion
- allergic reaction and anaphylaxis from contrast media
- kidney damage from contrast media
- air embolism
- device malfunction
- distal embolization
- emboli/embolic stroke
- false aneurysm formation
- infarction/necrosis
- pseudo aneurysm
- seizure
- sterile inflammation or granulomas at access site
- additional surgical intervention
- arteriovenous fistula
- hematoma or hemorrhage at puncture site
- infection, sepsis
- fever
- inflammatory responses
- intracerebral/intracranial hemorrhage
- cerebral infarct
- ischemia
- neurological deficits including stroke
- vessel spasm, thrombosis, dissection or perforation
- thrombus formation
- tissue necrosis, transient or long-lasting
- death

**Potential Risks Associated with X-ray Exposure:** This device requires fluoroscopy, which presents potential risks associated with X-ray exposure. The risks of angiographic and fluoroscopic X-ray radiation doses to the patient include risks such as alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia that increase in probability as procedure time and the number of procedures increase. Operators should take all necessary precautions to limit X-ray radiation doses to patients and themselves by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors whenever possible.

#### **PREPARATION AND USE**

1. Gently remove the Stellar Intermediate Catheter and packaging hoop from the pouch by grasping the packaging hoop and slowly pulling the hoop with catheter out of the pouch.
2. Flush the packaging hoop with heparinized saline before removing the catheter to hydrate the hydrophilic coating.
3. Remove the Stellar Intermediate Catheter from the packaging hoop.
4. Inspect the Stellar Intermediate Catheter for kinks or other damage. If any damage is observed, replace with a new device.

**WARNING:** Do not use the device if any damage or irregularities are observed.

5. Connect a rotating hemostasis valve (RHV) to the hub of the Stellar Intermediate Catheter and flush the inner lumen with heparinized saline. Set up the line for perfusion of heparinized saline through the side port of the RHV.
6. Prior to introducing the Stellar Intermediate Catheter into the vasculature, ensure an appropriate guidewire (refer to compatibility section above and Table 2) is placed inside the distal tip of the Stellar Intermediate Catheter.

## Stellar Intermediate Catheters

### Instructions for Use (IFU)

- Introduce the Stellar Intermediate Catheter and guidewire into a RHV connected to the proximal hub of a guide sheath (refer to compatibility section above and Table 2). If the peelable introducer sheath is used, remove the tool from the vascular sheath after introducing the catheter, then peel away from the catheter shaft.

**WARNING:** The introducer sheath is not intended for use inside the patient's body. Ensure that the introducer sheath is removed from the Stellar Intermediate Catheter once the distal shaft of the Stellar Intermediate Catheter is placed inside the patient's body.

- Under fluoroscopic guidance and using conventional catheterization techniques, advance the system over an appropriate guidewire (refer to compatibility section above and Table 2) until the Stellar Intermediate Catheter reaches the desired position.
- Remove the guidewire prior to the introduction of compatible devices (refer to compatibility section above and Table 2).

#### SYMBOL GLOSSARY

|                                                                                                                   |                                                                                                                                                     |
|-------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|
|  Lot Number                      |  Use-by Date                                                       |
|  Catalog Number                  |  Date of Manufacture                                               |
|  Keep Away From Sunlight         |  Caution                                                           |
|  Sterilized Using Ethylene Oxide |  Keep Dry                                                          |
|  Do Not Reuse                    |  Do Not Use If Package Is Damaged                                  |
|  Manufacturer                  |  Consult Instructions for Use                                    |
|  Prescription Only             |  Do Not Re-sterilize                                             |
|  Non-Pyrogenic                 |  Single Sterile Barrier System with Protective Packaging Outside |

Region specific approved language(s) from the selected device's Instructions for Use (IFU) are available for download at [balt.eifu.com](http://balt.eifu.com) or through [www.baltgroup.com](http://www.baltgroup.com) and using the "Instructions for Use and Safety Information" link under the "Our Products" menu. Using the selected website to access the eIFU, select your country and language, then select the "Product" icon, then select the device from the list. The device information can be located using its accompanying labeling. The resulting Electronic Instructions for Use (eIFU) will be displayed in Portable Document Format (PDF) and is accessible from any device with internet browsing capability.

If you require printed copies of the device's IFU, please send your request to Balt Customer Service ([customerservice@baltgroup.com](mailto:customerservice@baltgroup.com)), identifying the device and the language required. The provided IFU package includes printed copies of translations required for countries that do not accept eIFU alone. Not all products may be available in all markets since product availability is subject to regulatory requirements for individual markets. Please contact your Balt representative if you have questions about the availability of Balt's products in your area.

#### STORAGE

Store the Stellar Intermediate Catheter in a cool, dry, place at room temperature. Avoid exposure to water, sunlight, extreme temperatures and high humidity during storage. See the product label for the device shelf life. Do not use the device beyond the labeled shelf life.

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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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US and International patents are pending.



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