



CORONARY SHUNTS INSTRUCTIONS FOR USE

Catalog Number	Description
SHT-1210S	Vessel Shunt, 1.00mm Beveled Tip, 18.5mm Total Length, Tether Length 2.5"
SHT-1213S	Vessel Shunt, 1.25mm Beveled Tip, 18.5mm Total Length, Tether Length 2.5"
SHT-1215S	Vessel Shunt, 1.50mm Beveled Tip, 18.5mm Total Length, Tether Length 2.5"
SHT-1218S	Vessel Shunt, 1.75mm Beveled Tip, 18.5mm Total Length, Tether Length 2.5"
SHT-1220S	Vessel Shunt, 2.00mm Beveled Tip, 18.5mm Total Length, Tether Length 2.5"
SHT-1223S	Vessel Shunt, 2.25mm Beveled Tip, 18.5mm Total Length, Tether Length 2.5"
SHT-1225S	Vessel Shunt, 2.50mm Beveled Tip, 18.5mm Total Length, Tether Length 2.5"

Catalog Number	Description
SHT-1210S-C01	Vessel Shunt, 1.00mm Beveled Tip, 18.5mm Total Length, Tether Length 1.5"
SHT-1213S-C01	Vessel Shunt, 1.25mm Beveled Tip, 18.5mm Total Length, Tether Length 1.5"
SHT-1215S-C01	Vessel Shunt, 1.50mm Beveled Tip, 18.5mm Total Length, Tether Length 1.5"
SHT-1218S-C01	Vessel Shunt, 1.75mm Beveled Tip, 18.5mm Total Length, Tether Length 1.5"
SHT-1220S-C01	Vessel Shunt, 2.00mm Beveled Tip, 18.5mm Total Length, Tether Length 1.5"
SHT-1223S-C01	Vessel Shunt, 2.25mm Beveled Tip, 18.5mm Total Length, Tether Length 1.5"
SHT-1225S-C01	Vessel Shunt, 2.50mm Beveled Tip, 18.5mm Total Length, Tether Length 1.5"

Catalog Number	Description
SHB-1215S	Vessel Shunt, 1.50mm Bulb Tip, 15mm Total Length
SHB-1218S	Vessel Shunt, 1.75mm Bulb Tip, 15mm Total Length
SHB-1220S	Vessel Shunt, 2.00mm Bulb Tip, 19.5mm Total Length
SHB-1225S	Vessel Shunt, 2.50mm Bulb Tip, 19.5mm Total Length

Catalog Number	Description
SHB-1230S	Vessel Shunt, 3.00mm Bulb Tip Clear Flow, 12mm Shaft, 21mm Total Length
SHB-3020S	Vessel Shunt, 2.00mm Bulb Tip Clear Flow, 30mm Shaft, 36mm Total Length
SHB-3025S	Vessel Shunt, 2.50mm Bulb Tip Clear Flow, 30mm Shaft, 38mm Total Length
SHB-3030S	Vessel Shunt, 3.00mm Bulb Tip Clear Flow, 30mm Shaft, 39mm Total Length
SHB-3040S	Vessel Shunt, 4.00mm Bulb Tip Clear Flow, 30mm Shaft, 42mm Total Length

Product Description:

The Chase Coronary Shunt is composed of two silicone bulbs on the distal ends of a flexible silicone tubular shaft. A tab is attached to a tether as a reminder a shunt is present in the vessel. The size of the shunt is imprinted on the tab for ease of identification. The bulbs and tab of the shunt are radiopaque.

Sterile, Nonpyrogenic, Disposable, Single use only.

Indications For Use:

The Chase Coronary Shunt is intended to be used to internally shunt a blood vessel during an anastomosis. The shunt allows a dry field to be maintained during a vessel anastomosis procedure. The shunt also allows blood to be delivered distally past the anastomosis during vessel repair. The shunt is easily removed prior to the final sutures being tied.

Contraindications:

This device is not intended for use other than as indicated above.

Warnings:

- Protect from extreme temperature and humidity.
- **DO NOT REUSE OR RESTERILIZE.** Reuse or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Proper surgical procedures and techniques are the responsibility of the medical professional. The surgical team must evaluate the appropriateness of the procedure based on their experience. The outcome is dependent on many variables, including patient anatomy, pathology, surgical technique and anesthesia management.
- Although product has been carefully designed, manufactured and inspected or tested prior to sale, the product may fail to perform its intended function satisfactorily for a variety of reasons. Warnings contained in the product labeling and in this document provide more detailed information and should be read by the user prior to use of product.

Precautions:

- Federal U.S. laws restrict this device to sale, distribution, and use, by, or on the order of a physician.
- The Directions for Use are furnished for information purposes only.
- Product is Ethylene Oxide sterilized.
- Sterile unless package is opened or damaged.
- This device is a temporary device and cannot be implanted.

- Do not reinsert shunt once it has been removed as it may become occluded from stagnant blood left in the shunt.
- Due to the possible danger of damage because of the friability of some vessels, care must be used when dealing with these vessels.
- Intimal damage to the vessel must be guarded against. Never force the shunt into a vessel.
- Carefully choose the correct size shunt for each vessel.
- Do not remove by pulling on the tab or tether.
- Do not cut the tab or tether.

Adverse Effects:

None known.

Instructions For Use:

1. Carefully read instructions prior to use.
2. Inspect package and product for damage and expiration date prior to opening the package.
3. If undamaged and unexpired, open the package and transfer the product onto the sterile field utilizing aseptic technique.
4. Check the patency of the shunt by injecting a small amount of sterile saline through the center lumen.
DO NOT USE SHUNT IF LUMEN IS NOT PATENT.
5. Choose the appropriate shunt size based on the internal diameter of the vessel.
6. Hold the flexible shaft with forceps and pickups adjacent to the bulb to be inserted. See Figure 1. The shunt is designed to easily slide inside the vessel.
7. Insert the first bulb through the vessel opening and into one side of the vessel (Arterial Use: insert proximal side first which allows for back-bleeding and avoids introduction of air). See Figure 2.
8. Insert the second bulb in a similar manner. See Figure 3.
9. Ensure that the shunt shaft is straight.
10. Lay the tab to one side. Reposition as needed.
11. Remove the shunt prior to the final sutures being tied. Remove the distal end of the shunt first. Do not remove by pulling on the tab or tether. This may cause both bulbs to exit simultaneously and could cause vessel damage.
12. When finished, discard shunt(s) according to approved hospital procedures.



Figure 1

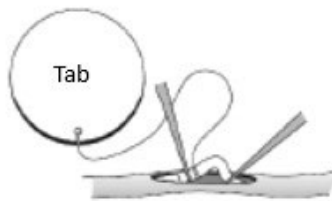


Figure 2



Figure 3

LIMITED WARRANTY AND DISCLAIMER OF LIABILITY












Chase Medical products (“Product”) are manufactured under carefully controlled conditions and Chase Medical warrants the Product will perform in accordance with its labeling and will be free from defects in material and workmanship under normal use for one year from the date of shipment.

Chase Medical’s sole liability shall be limited to replacement of, or credit for, any Product returned to Chase Medical and which Chase Medical determines, in its sole discretion, to have been defective in either material or workmanship at the time of shipment.

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Explanation of Symbols on Packaging Label

	Sterilized using Ethylene Oxide		SKU / Catalog Number
	Double Sterile Barrier System		Lot Number
	Manufacturer		Non-pyrogenic
	Date of Manufacture	Rx only	Prescription only / Caution: Federal (US) law restricts this device to sale by or on the order of a physician
	Use-by Date		Consult Electronic Instructions for Use
	Do Not Re-Use		Natural Rubber Latex is Not Present



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