INTEGRA NEUROSCIENCES™

Sundt Internal and External Carotid Endarterectomy Shunts

Sterile For Single Use Only

STERILE EO

CE 0123

NL850-5065	NL850-5066	NL850-5067	NL850-5060	NL850-5061	NL850-5062	NL850-5063
NL850-5070	NL850-5071	NL850-5072	NL850-5076	NL850-5077	NL850-5078	NL850-5079

Description

The Integra NeuroSciences Sundt internal and external (Loop) Carotid Endarterectomy Shunts are designed to provide temporary carotid bypass for cerebral circulation during carotid endarterectomy procedures.

The Sundt internal and external Carotid Endarterectomy shunts are constructed of silicone elastomer with stainless steel spring reinforcement to minimize kinking and occlusion of the cannula lumen and to aid in the ease of insertion of the proximal and distal ends. The ends of the shunts have cone-shaped bulbs to facilitate fixation of the shunt in the vessel. Quite frequently in the internal type shunt a distal tourniquet is not required because, if the proper shunt size is selected, the bulb fits firmly enough against the wall of the vessel that there is no bleeding around the distal bulb. A tourniquet is always required on the proximal end of both the external and internal shunts and usually on the distal end of the external shunt.

The internal shunt is 10cm long and designed for placement within the artery, the external shunt is 30cm in length to allow formation of an external loop.

Both shunts are available in three different diameters: small, medium and large which are detailed in the Dimensioned Illustrations section. Vessels which appear somewhat small on angiography and at surgery usually will accommodate the medium sized shunt. The small shunt is reserved for vessels which appear very small on the angiography and at surgery. Flow values through the small shunts have been reported to be adequate for cerebral perfusion and have delivered an adequate amount of flow for cerebral protection during the period of endarterectomy.

Internal and external shunts are also available in models with a 1cm non-reinforced segment near the midway point of the shunt to allow the surgeon to selectively occlude blood flow through the shunt with an appropriate clamping device and to facilitate simple shunt removal.

The 1cm non-reinforced shunts are available in four different diameter which are detailed in the Dimensioned Illustration section.

Indications

These carotid endarterectomy shunts are indicated for temporary carotid artery bypass during carotid endarterectomy procedures in order to help protect the cerebral hemispheres from ischemia during the period of carotid artery occlusion. These shunts are designed as temporary indwelling catheters and are not intended for permanent placement.

There is considerable controversy in the literature regarding advisability of routine shunting, monitoring with elective shunting, or “rapid endarterectomy without shunting.” Each surgeon must make a judgement regarding the use of a shunt in medical practice and each physician must bear the responsibility for technical complications which arise from the use or non-use of a shunt during the period of carotid occlusion. The risks of not using a shunt with inadequate cerebral protection during the period of occlusion must be weighed against the risks of shunt use.

Contraindications

There are no true contraindications for use of a shunt during endarterectomy other than diffuse atherosclerosis in the vessel which prevents adequate placement of the shunt. It is always necessary that the lumen of the internal carotid artery be visualized distal to the plaque prior to placement of the shunt. In the common carotid artery it is necessary that the arteriotomy be extended proximal to the most severe area of atherosclerosis and that the proximal bulb of the shunt be placed very carefully in the common carotid artery so that the wall of the atherosclerotic intima will not be elevated and that loose debris will not float into the lumen of the shunt.

The insertion of a carotid endarterectomy shunt at the site of infection is contraindicated. It is advisable to avoid shunting procedures if infection is present anywhere in the body.

Existence of preoperative risk factors may contraindicate carotid endarterectomy. It is necessary that clinical judgement be exercised in the process of patient selection but this does not relate to a judgement regarding use of the shunt.

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Instructions For Use

A variety of surgical techniques may be used in the insertion of either the external or internal shunts; therefore, the surgeon is best advised to use the method which his/her own practice and training dictate to be best for the patient.

How Supplied

The Sundt Internal and External Carotid Endarterectomy Shunts are each supplied in several sizes and are individually packaged sterile. The product is supplied sterile, in a double-wrap, pyrogen-free packaging system. The double-wrap system facilitates the preferred method of sterile product transfer from the circulating area to the sterile field.

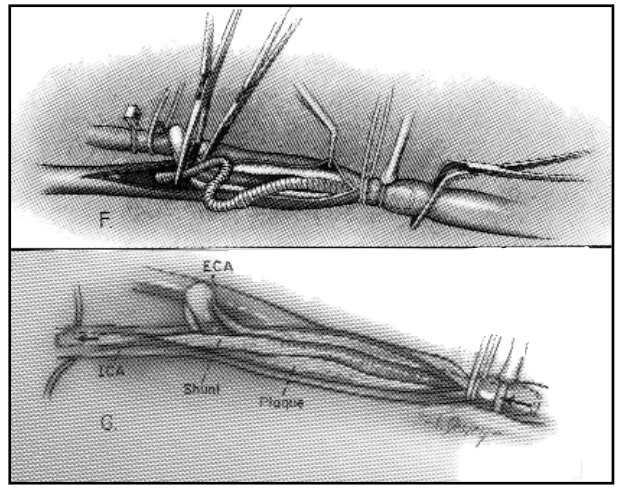
Do Not Resterilize

This product is for **single use only.**

Warnings

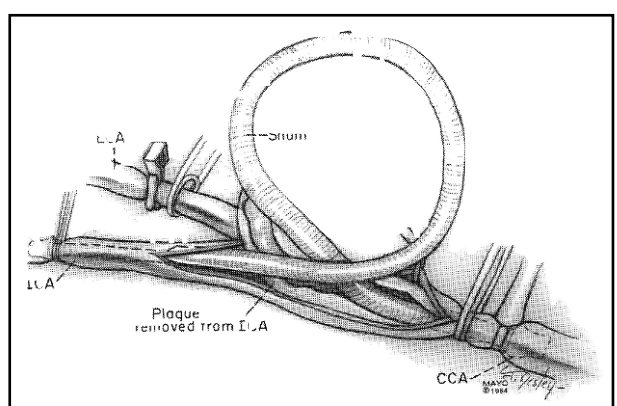
The Carotid Endarterectomy shunts are intended for single use only. Repeated use is not recommended and will usually result in unavoidable damage to the stainless steel spring portion of the shunt, which may affect the lumen size.

These silicone elastomer carotid endarterectomy shunts are soft and pliable. They should not be handled with pointed, toothed or sharp-cornered instruments, as punctures, surface cuts, nicks, crushing or overstress can lead to tearing or warping and subsequent disintegration of the shunt at the point of damage. If instruments are used to handle or occlude the shunt, it is recommended that only instruments with soft silicone or rubber protective inserts be used. The shunt should be held gently taking care not to crush, kink, or occlude the spring-reinforced shunt tubing. Models which provide a non-reinforced segment should only be occluded at the specified 1cm non-reinforced location and special care should be employed to prevent damage to or puncture of the shunt tubing. If instruments have been used, careful inspection of the shunt tubing must be made prior to the opening of the proximal clamp to ensure the shunt tubing has not been crushed, kinked, or otherwise damaged and that the lumen



Placement of Internal Sundt Shunt

Distal end of shunt is inserted into endarterectomized internal carotid artery. It is seldom necessary to place a distal tourniquet when using the internal shunt. However, in some patients, there is some bleeding around the shunt which requires slight pressure from the vessel loop which can be achieved by using a single strand on either side of the loop brought together and approximated with a vascular clip. The remaining portion of the endarterectomy is completed and the vessel repaired with a saphenous vein patch graft.



Placement of External (Loop) Sundt Shunt

The use of the Sundt external or loop shunt differs somewhat from the internal shunt in that the distal end of the shunt must be secured with a tourniquet to prevent its dislodgement from the internal carotid artery. In all other respects, the placement of this shunt is similar.

of the shunt has not been compromised by instrument usage.

Precautions

To minimize the possibility of shunt contamination or sepsis, very careful aseptic technique should be observed during the inspection, placement and maintenance of the shunt.

Prior to a carotid endarterectomy, patients or their representatives should be informed of the possible complications associated with a carotid endarterectomy in general and specifically problems referable to the ischemic tolerance of neural tissue during the operative procedure and methods undertaken to protect the brain during the period of carotid occlusion. The patient should be informed that a bypass shunt will be used if this is the surgeon's practice or that a bypass shunt may be required if his or her monitoring techniques indicate its necessity.

Risk factors of carotid endarterectomy are discussed thoroughly in the literature. The following are considered the medical, neurologic, and angiographically determined risk factors which are of importance in grading a patient for surgery. These risk factors are provided by T.M. Sundt, Jr., M.D. based on his experience with carotid endarterectomy:

Medical Risk Factors

Patients demonstrating any of the following symptoms should be carefully evaluated before undergoing carotid endarterectomy:

1. Coronary artery disease (angina pectoris) or a myocardial infarction of less than 6 months duration;

2. Severe hypertension (blood pressure greater than 180/110);

3. Chronic obstructive pulmonary disease;

4. Physiologic age of more than 70 years; or

5. Severe obesity.

Neurologic Factors

Patients demonstrating any of the following neurologic deficits should be carefully evaluated before undergoing carotid endarterectomy:

1. A progressive neurologic deficit;

2. A neurologic deficit less than 24 hours old;

3. Frequent daily transient ischemia attacks; or

4. Multiple neurologic deficits secondary to multiple cerebral infarction.

Angiographically Determined Vascular Risk Factors

Patients demonstrating any of the following angiographically determined risk factors should be carefully evaluated prior to carotid endarterectomy:

1. Stenosis if the internal carotid artery in the siphon area;

2. Extensive involvement of the vessel to be operated with plaque extending more than 3cm distally in the internal carotid artery or 5cm proximally in the common carotid artery;

3. Bifurcation of the carotid artery at the level of the second cervical vertebra in conjunction with a short, thick neck;

4. Occlusion of the opposite internal carotid artery; or

5. Evidence of soft thrombus extending from the ulcerative lesion.

Complications

There are three primary risks of complications from the use of a carotid endarterectomy shunt:

1. Physical damage to the intima with placement of a shunt. The distal bulb in the Sundt internal and external carotid endarterectomy shunts has been designed to minimize this risk.

Rigorous attempts to place too large a shunt into the internal carotid artery can result in damage to the intima. For this reason three separate sizes of shunts have been provided and the surgeon is encouraged to use the size shunt which most closely fits the distal internal carotid artery.

2. Embolization through the shunt. This has been reported and remains an inherent risk of shunt usage. It is necessary that the patient be heparinized prior to placement of the shunt in order to minimize the formation of thrombi in the shunt during the period of shunt use. Thrombi are more likely to form in the external shunt than the internal shunt because the external shunt is three times the length of the internal shunt. If xenon cerebral blood flow measurement facilities are available, flow through the shunt can be measured intermittently during the period of shunt use and this decreases the hazard of this complication developing undetected.

3. Embolization through the shunt from damage to the common carotid artery proximal to the point of shunt placement. "(See **Instructions for Use**.)" Cholesterol material in the shunt can be directly visualized at surgery and the tapered distal end of the internal shunt helps to trap large emboli from passage. If cholesterol material is identified in the shunt, it should be removed, flushed, and reinserted. However the shunt should only be replaced after the proximal common carotid artery has been allowed to bleed freely for a brief period in order to remove soft debris from trapped segments of the artery.

Complications which may result from the use of this product include the risks associated with the medication and methods utilized in the surgical procedures, as well as the patient's response, reaction or degree of intolerance to any foreign object placed in contact with the body.

Product Information Disclosure

Integra NeuroSciences has exercised reasonable care in the choice of materials and manufacture of this product. Integra NeuroSciences excludes all warranties, whether expressed or implied by operation of law or otherwise, including, but not limited to any implied warranties of **merchantability or fitness**. Integra NeuroSciences shall not be liable for any **incidental or consequential loss, damage, or expense**, directly or

indirectly arising from use of this product. Integra NeuroSciences neither assumes or authorizes any other person to assume for it, any other or **additional liability or responsibility** in connection with this device.

Product Order Information

All products can be ordered through your Integra NeuroSciences Neuro Specialist or customer service representative or by contacting :

Integra NeuroSciences
311 Enterprise Drive
Plainsboro, NJ 08536 USA
Telephone: 1-800-654-2873
Outside the US: 1-609-275-0500
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or

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Hampshire SP10 4DR England
Tel: +44(0) 1264-345-700
Fax: +44 (0) 1264-332-113

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Do not use if the package has been opened or damaged.

Symbols Used On Labeling


See instructions for use


Expiration date


Do not reuse after opening

Lot number

Sterile unless package is opened or damaged. Method of sterilization-ethylene oxide.

Product complies with requirements of directive 93/42/EEC for medical devices.

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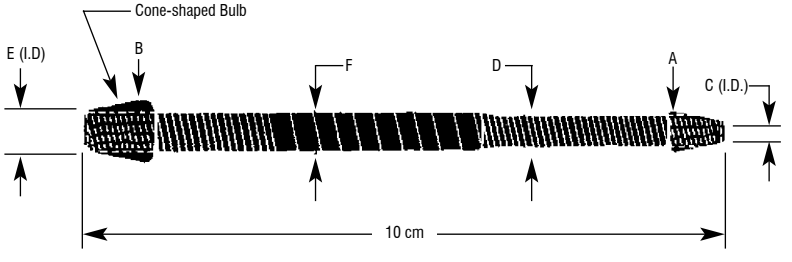
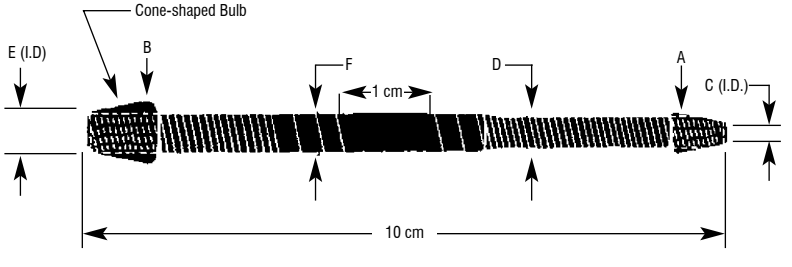
Dimensional Illustrations (All dimensions are nominal)

Catalog Number	Nominal Size (O.D. of Cannula)	Dimensions A (Distal)	B (Proximal)	Distal C (I.D.)	D (O.D.)	Proximal E (I.D.)	F (O.D.)
Sundt Internal Shunt							
NL850-5065	3mm x 4mm	3.8mm	5.5mm	1.3mm	2.7mm	2.1mm	3.9mm
NL850-5066	3mm x 5mm	4.6mm	6.3mm	1.6mm	2.8mm	3.1mm	4.6mm
NL850-5067	4mm x 5mm	5.5mm	6.3mm	2.1mm	3.9mm	3.1mm	4.6mm
Sundt Internal Shunt with Non-Reinforced Segment							
NL850-5060	3mm x 4mm	3.8mm	5.5mm	1.3mm	3.0mm	2.2mm	4.0mm
NL850-5061	3.5mm x 5mm	4.5mm	6.4mm	1.6mm	3.5mm	3.1mm	5.0mm
NL850-5062	4mm x 5mm	5.5mm	6.4mm	2.2mm	4.0mm	3.1mm	5.0mm
NL850-5063	3.5mm x 4mm	4.5mm	5.5mm	1.6mm	3.5mm	2.1mm	4.0mm
Sundt External Shunt							
NL850-5070	3mm x 4mm	3.8mm	5.5mm	1.3mm	2.7mm	2.1mm	3.9mm
NL850-5071	3mm x 5mm	4.6mm	6.3mm	1.6mm	2.8mm	3.1mm	4.6mm
NL850-5072	4mm x 5mm	5.5mm	6.3mm	2.1mm	3.9mm	3.1mm	4.6mm
Sundt External Shunt with Non-Reinforced Segment							
NL850-5076	3mm x 4mm	3.8mm	5.5mm	1.3mm	3.0mm	2.2mm	4.0mm
NL850-5077	3.5mm x 5mm	4.5mm	6.4mm	1.6mm	3.5mm	3.1mm	5.0mm
NL850-5078	4mm x 5mm	5.5mm	6.4mm	2.2mm	4.0mm	3.1mm	5.0mm
NL850-5079	3.5mm x 4mm	4.5mm	5.5mm	1.6mm	3.5mm	2.1mm	4.0mm

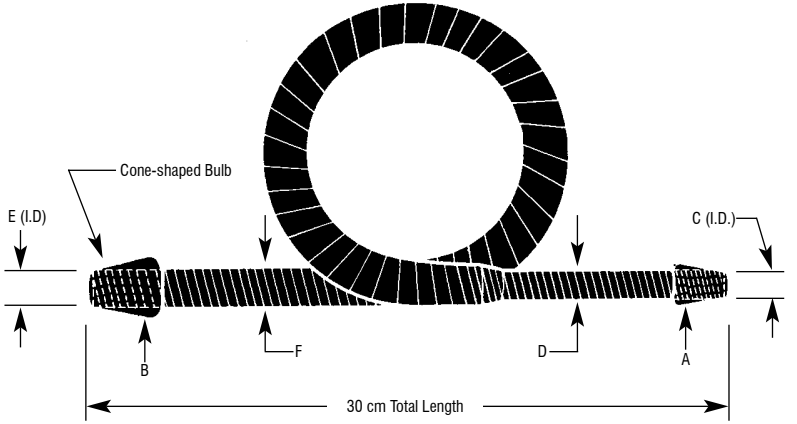
Sundt Internal Shunt



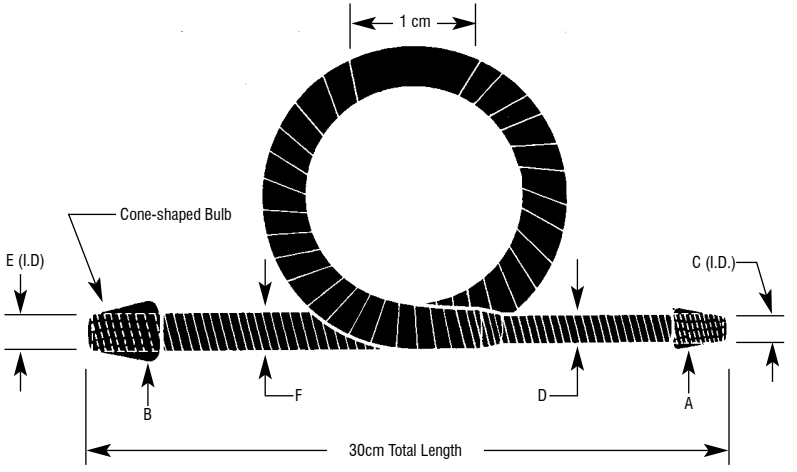
Sundt Internal Shunt with Non-Reinforced Segment



Sundt External Shunt



Sundt External Shunt with Non-Reinforced Segment



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