Subdural Evacuation System
A new approach in the treatment of chronic subdural effusions
Subdural Evacuation System

The unique design of the Subdural catheter provides a new and simplified approach for the treatment of chronic subdural hematomas
- Easy to implant and explant
- Stable catheter placement
- Catheters sold in procedure-ready complete kits or individually

Low profile catheter head allows placement through a small 5mm burr hole

Right Angle Guide prevents catheter crimping while plugging burr hole

25cm catheter length allows for easy subcutaneous tunneling

Expanded catheter head maintains shape while anchoring safely into effusion
Implantation Technique Summary
(Consult Directions For Use for Complete Implantation Technique)

1. Administer anesthesia. Place patient in supine position.

2. Expose the skull over the fluid collection by making a small linear incision.

3. Make a burr hole using the 5mm drill bit and Manual Drill (Figure 1).

4. Using an electro coagulator, make an opening in the dura just large enough for the Subdural Catheter passage.

5. Place the introducing rod into the Subdural Catheter.

6. Hold the introducing rod with one hand. With the other hand grasp the catheter at the base of the cage and pull firmly along the introducing rod, so as to deform the cage to its extended configuration.

7. While maintaining the cage extended, introduce it through the burr hole (Figure 2).

8. Remove the Introducing Rod. Verify adequate CSF flow. (Caution: Do not attempt to restraighten the catheter with the introducer while in vivo. The introducer could accidentally slide out of the cage. If repositioning is necessary, remove the catheter by gently pulling it out and proceed from step 5).

9. Grab the free end of the catheter and pass it through the central channel of the Right Angle Guide.

10. With one hand, gently pull on the catheter while the other hand pushes the Right Angle Guide until it plugs the burr hole (Figure 3).

11. The catheter cage is now against the dura.

12. Tunnel the catheter subcutaneously to an exit wound away from the burr hole incision, using subcutaneous passer.

13. Confirm correct position of the catheter with X-rays (Figure 4). (Warning: regularly check the collection resorption progress. The catheter should be explanted before completion of the collection resorption to prevent any risk of tissue adhesion to the device).
951-310
- Allen wrench
- Disposable 5 mm drill bit with adjustable stop
- 25 cm subdural catheter
- 35 cm stylet
- Right angle guide
- Luer lock connector
- Suturable tubing clamp
- Subcutaneous passer

INS-030
- Manual hand drill

910-500
- Suction reservoir and extension tubing

Convenience Kit
(US ONLY)
31223
Complete procedure-ready kit, includes
- 951-310
- INS-030
- 910-500

Convenience Kit
(US ONLY)
31253
Complete procedure-ready kit, includes
- 951-310
- INS-SHND*
- 910-500

* Cranial Access kit, no Lidocaine

Precautions
Single use only. Ethylene Oxide sterilization. Do not use if package is opened or damaged. Use device prior to the “Use Before” date on label. Do not resterilize.

Contraindications
Use is contraindicated in patients with acute or subacute subdural hematoma and in patients undergoing anticoagulation therapy.

Side Effects
In addition to risks associated with any brain surgical procedure, such as possible bleeding, transient headaches, damage to surrounding brain tissue, stroke, or death, the following may occur: foreign body reactions, obstruction of system by kinking or plugging with blood clots or bone particles, disconnection of system, bacterial contamination of wound (increased with time if externalized system is used), wound abscess, fistula formation, and herniation of tissue at site where drain exits; seizures, pneumocephalus. These complications, as well as persistent or relapse of chronic subdural effusion or inadequate initial catheter placement, may lead to re-surgery.

Caution
Care must be taken to affect the complete removal of the catheter. As with any drainage catheter left in place for an extended period, on rare occasions during withdrawal a fragment of the device may remain at the site due to tissue ingrowth. The surgeon should use their own judgment, based on patient condition and relative risks, to determine whether removal of the fragment is necessary.