Subdural Evacuation System

Integra™ Subdural Evacuation System

see also Subdural Evacuating Port System.

The Integra™ Subdural catheter provides a new and simplified approach for the treatment of chronic subdural hematomas.

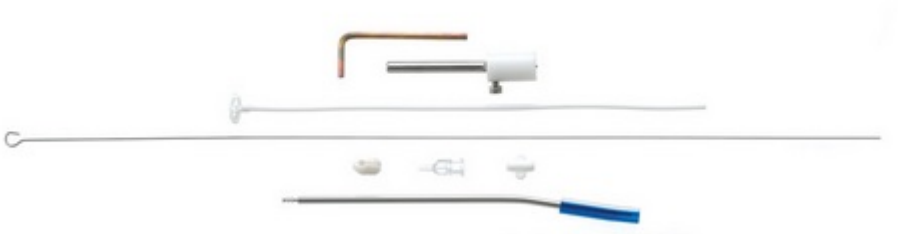
Low profile catheter tip allows placement through a 5mm burr hole.

Right Angle Guide prevents catheter crimping while sealing burr hole.

25cm catheter length allows for easy subcutaneous tunneling.

Expanded catheter tip maintains shape while anchoring safely into effusion.

Kit



This Kit Contains:

Allen wrench

5mm drill bit with adjustable stop

25cm subdural catheter

Right angle guide

Luer lock connector

Butterfly Suture Clamp

Subcutaneous passer

Indication

The Integra Subdural Drainage Catheter is intended for drainage of extraventricular fluid collections, such as hygromas and chronic subdural hematomas, into an external drainage system (such as the Suction Reservoir or the EDS or IDS Systems from Integra NeuroSciences) or implanted catheter communicating with an appropriate drainage site. The patient clinical pathology dictates whether the Subdural Drainage Catheter is connected to an internal or external drainage system.

Warnings

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.

Contraindications

The use of the Integra Subdural Catheter is contraindicated in patients with acute or subacute subdural hematoma and in patients undergoing anticoagulant therapy.

Side Effects

In addition to the risks associated with any brain surgical procedure, such as possible bleeding, transient headaches, damage to surrounding brain tissue, stroke, or death, the following complications may occur: Foreign body reactions, obstruction of the system by kinking or plugging with blood clots or bone particles; disconnection of the system; bacterial contamination of the wound, increased with the passage of time if an externalized system is used; wound abscess, fistula formation, and herniation of tissues at the site where the drain exits; seizures may be associated to brain surgery, pneumochephalus. These complications, as well as the persistent or relapse of the 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 his own judgment, based on patient condition and relative risks, to determine whether removal of the fragment is necessary.

MAUDE Adverse Event Report

INTEGRA NEUROSCIENCES SUBDURAL DRAINAGE CATHETER KIT CATHETER, DRAINAGE Back to Search Results Catalog Number 951-310 Event Date 10/13/2007 Event Type Malfunction Event Description

A subdural drain was placed by the surgeon for the patient's acute and chronic subdural hematoma. The subdural drain was not draining, so a second surgeon, who was taking calls for all neurosurgery cases, attempted to pull the drain. When the drain was pulled, it remained stuck until the end/tip of the catheter dislodged and was left in the cranial cavity. Since the patient's condition warranted a second surgery, the patient was taken back for a second craniotomy, removal of the tip, and replacement of the subdural drain