



IRRAS USA, INC.

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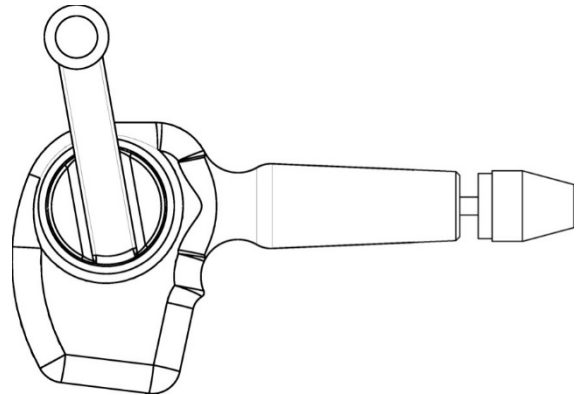
IC40D CRANIAL ACCESS KIT

IC40 CRANIAL ACCESS KIT (No Pharmaceuticals)

The Cranial Access Kit consists of various accessories used during a ventriculostomy procedure. The kit includes a hand drill with an adjustable chuck and drill bits, each with a drill bit collar.

The drill bit collar allows accurate, secure, and easy to use adjustment of drill bit depth.

Additional kit contents are listed on the package label.



DESCRIPTION

The Cranial Access Kit is single use disposable. Please refer to the kit label for specific contents.

INDICATIONS

The Cranial Access Kit allows for access to the subarachnoid space or the lateral ventricles of the brain. The kit is intended to be used with an external drainage and monitoring system in selected patients to reduce intracranial pressure (ICP), to monitor cerebral spinal fluid (CSF), to provide temporary drainage of CSF, and to monitor ICP.

CONTRAINDICATIONS

This product is not designed, sold, or intended for use except as indicated.

INSTRUCTIONS FOR USE

Prior to system use, it is necessary for all responsible personnel to understand the use and function of the system components, system preparation, and system controls.

The hand drill includes drill bits with an adjustable drill bit collar. The drill bits may be exposed to the desired depth by adjusting and securing the drill bit collar.

The selected drill bit is exposed and secured by following the steps noted in figure #1:

1. Set desired drill bit with drill bit collar in the drill chuck and securely tighten.
2. To adjust the penetration depth of the drill bit, loosen the drill bit collar set screw with the supplied hex wrench.

3. Set the desired penetration depth of the drill bit.
4. **Securely tighten** the drill bit collar set, screw in position with the supplied hex wrench.
5. Verify that the correct depth of drill bit is exposed and drill bit collar is securely tightened prior to use.

The drill bit collar assembly allows a maximum penetration depth of over 25mm (1.0”).

Cranial Access

WARNING: NEVER USE THE DRILL BITS PROVIDED WITHIN THE CRANIAL ACCESS KIT FOR BOLTED ICP CATHETERS.

Warning:

Ensure drill bit is secured in adjustable chuck prior to tightening drill bit collar.

Use extreme care when performing the drilling procedure to prevent damage to the dura.

A variety of surgical techniques may be used in performing the drilling procedures. The procedure used is at the discretion of the surgeon.

ICP Monitoring / CSF Drainage

Placement of a monitoring device and/or drainage system should be accomplished by following standard hospital procedure.

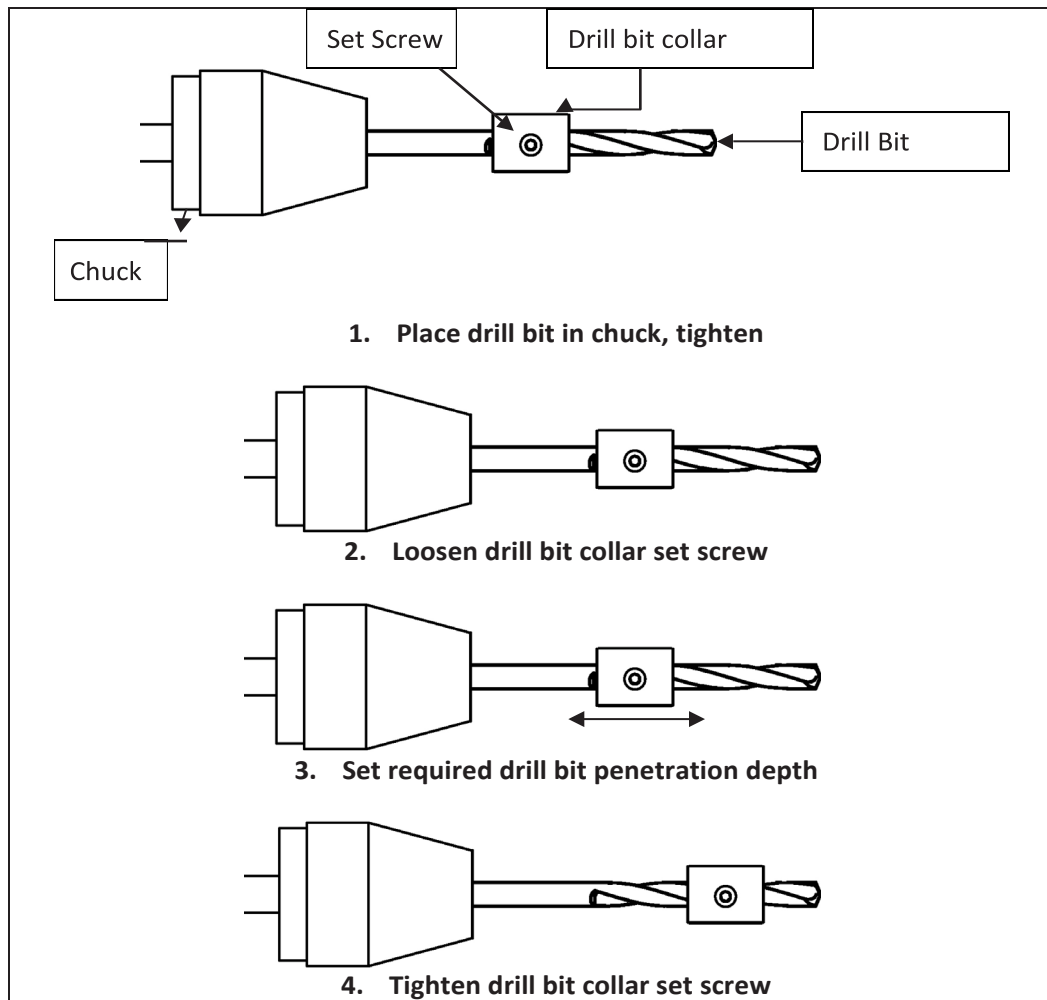


Figure 1

HOW SUPPLIED

The Cranial Access Kit is supplied sterile. The hand drill is pre-assembled with an adjustable chuck. The kit is supplied with drill bits, each with a drill bit collar.

RE-STERILIZATION

The components within the Cranial Access Kit are disposable devices. Never re-sterilize the Cranial Access Kit.

WARNINGS

Extreme care should be taken during the preparation and performance of the drilling procedure to maintain sterile technique.

The hand drill with adjustable chuck and drill bit assembly must be used properly to prevent penetration or damage to the dura.

Products within the kit may contain solutions (i.e. Povidone Iodine Solution, etc.) that may have expiration date(s). Note expiration dates and discard all expired contents.

PRECAUTIONS

Cranial Access components should avoid contact with lint, glove talc, and other surface contaminants.

Contents of the kit are sterile if the package is unopened and undamaged.

Use aseptic technique throughout this procedure.

The drill with adjustable chuck and drill bit with adjustable drill bit collar must be used properly in order to prevent drilling too deeply and causing injury or damage to the dura, cortex, and cortical vessels.

Maintain site per hospital protocol.

The kit is designed for single use only. Do not re-sterilize.

COMPLICATIONS

Improper use of the hand drill, including failure to properly secure the drill bit to the adjustable chuck, or failure to properly secure the drill bit collar to the drill bit, may result in serious injury.

PRODUCT INFORMATION DISCLOSURE

IRRAS USA has exercised reasonable care in the selection of materials and the manufacture of these products. IRRAS USA 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, since storage and handling of this device by the user, as well as other factors relating to the patient, the diagnosis, treatment, surgical therapy, and other matters beyond IRRAS USA's control directly affect this device and the results obtained from its use. IRRAS USA will not be liable for INCIDENTAL or CONSEQUENTIAL LOSS, DAMAGE, or EXPENSE directly or indirectly arising from the use of this device. IRRAS USA neither assumes, nor authorizes any other person to assume for it, any other or additional LIABILITY or RESPONSIBILITY in connection with this device.

RETURNED GOODS POLICY

Products must be returned in unopened packages with manufacturer's seals intact to be accepted for replacement or credit, unless returned due to a complaint or product defect. Determination of a product defect will be made by IRRAS USA, which determination will be final.

Products will not be accepted for replacement if they have been in the possession of the customer for more than 90 days.



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BY OR ON THE ORDER OF A PHYSICIAN**

Technical information on these products may be obtained from the IRRAS USA Distributor in your area or by contacting IRRAS USA directly.