



## V

### Intended Use

The drill is intended to be used with an external drainage and monitoring system in selected patients to reduce intracranial pressure (ICP), to monitor CSF, to provide temporary drainage of CSF, and to monitor ICP. The drill is intended for single use only.

## VI

### Technological Comparison To Predicate Devices

Item	CNS Cranial Drill	PS Medical Kit Drill	Camino Kit Drill
1. Hand Drill	Fiskars Twist Drill	Fiskars Twist Drill	Fiskars Twist Drill
2. Drill Bit Included with Drill	Yes	Yes	Yes
3. Integral Bit	Yes	Yes	NA
4. Adjustable Depth Guard	Yes	Yes	No
5. Set Screw with Hex Wrench	No	Yes	Yes
6. Packaging	Sterile, CSR Wrap in Peel Pouch	Sterile, CSR Wrap in Tray and Header Bag	Sterile, in Lidded Tray

## VII

### Test Data

The following tests were performed to ensure acceptable performance of the Clinical Neuro Systems Interchangeable Bit Cranial Drill.

<u>Test</u>	<u>Result</u>
Sterility	Acceptable
Performance	Acceptable
Cytotoxicity	Acceptable
Comparative Evaluation	Acceptable