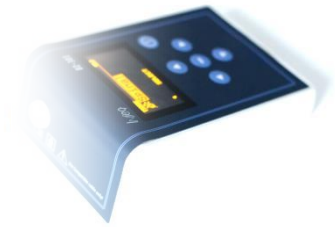
IQ-Needle for Lumbar Puncture

Immediate alert as needle tip touches Spinal Fluid
High quality Spinal Fluid sample*



Benefits

Injeq BZ-301 alerts immediately when the tip of the Injeq IQ-Needle™ touches the Spinal Fluid (CSF). The alert provides for a smoother and faster puncture which increases comfort for both physician and patient. Real-time analyzer also provides information about the puncture for the observer in a training situation.

With immediate CSF alert procedural benefits may be argued:

- Helps to avoid unnecessary needle movements close to spinal nerves
- The repeated stylet removal and reinsertion for observing CSF flow can be reduced
- The risk of passing through subarachnoid space and causing multiple punctures to dura is reduced
- *)Reduced tissue damage should contribute to high quality CSF sample
- Use of the device may also decrease risk of complications related to stylet re-insertion or unintentional tip movement causing damage

Indications for use

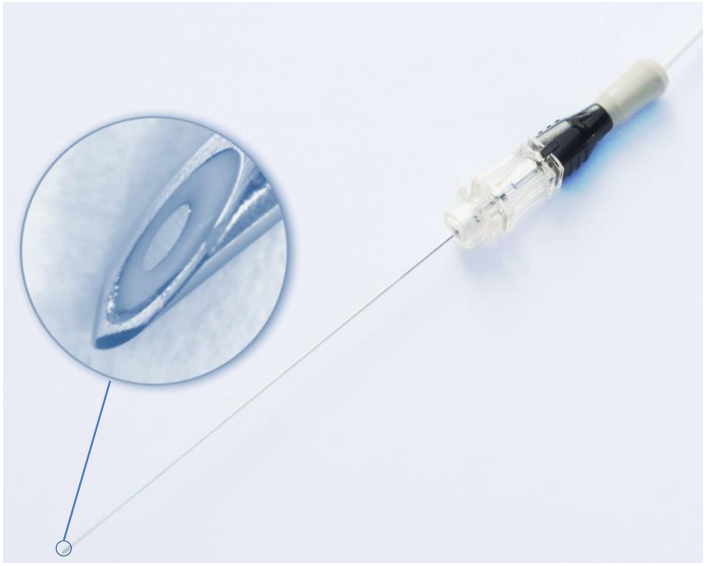
Injeq IQ-Needle™ is indicated for use in lumbar puncture aiming for cerebrospinal fluid (CSF) collection or spinal anesthesia. The device detects CSF in immediate proximity of the needle tip based on bio-impedance measurement and real-time tissue analysis. The device is suitable for physicians with variety of puncture experience.

The greatest benefits could be expected with:
- Physicians that perform lumbar punctures only occasionally for diagnostic or treatment purposes (e.g. neurologists, pediatrics)
- Spinal punctures to patients with subdued tactility of tissues
- Training situations
- Clinical research

Image courtesy of Wikipedia / Bobjgalindo

Injeq Device Specifications

Injeq IQ-Needle™



Gauge	Color code	Length (mm)	Code
22	Black	40 90	BIPN-22040-0001 BIPN-22090-0001
27	Gray	90	BIPN-27090-0001

Injeq single use Injeq IQ-Needle™ is compliant with relevant medical standards including ISO 6009, ISO 10993-1, ISO 9626, ISO 15223, ISO 7864 and ISO 594-1

Bipolar impedance measurement is integrated to the K-3 Lancet tip of the needle. Excellent needle hub for grip and tactile feedback. IQ-Needle™ be used independently as a typical hypodermic needle, but it provides the best results when used together with BZ-301 Analyzer.

Injeq BZ-301 impedance analyzer

Injeq BZ-301 Impedance Analyzer is designed for real-time tissue identification with Injeq IQ-Needle™.

The performance of Cerebrospinal Fluid (CSF) identification has been clinically validated. In addition to CSF the device also indicates non-validated tissues such as ***muscle*** or ***fat*** which may be combined to tactile feel and used as indicative reference of needle position.

Hardware

Type BF, Class IIa medical device
DSP based real-time architecture
Single-fault-safe design
Optimized for live tissue measurement
Measurement band 1-349kHz
Measurement precision 98%
Designed for indoor use (IP40)
5 x AA (LR6) Alkaline or NiMH (6-10 hours continuous use)

Software

Real-time DSP software

- Multi-frequency impedance spectrum
- Bayesian classification

Parametric configuration

- One language per configuration, independent from tissue models
- Proven performance in Clinical research (CSF Sensitivity 100%, Confidence interval 89.1% - 100.0%)

User interface

Simple graphical user interface on high contrast OLED display. Visual and auditory alerts for target tissue

Compatible

Designed for hospital environment
Can be used to enhance ultrasound guidance (e.g. hip joint)

Disinfection by wiping with ethanol based products

BZC-03 Cable disinfection with ethanol based products. Cable can also be sterilized by steam autoclave

Compliant with IEC 60601, IEC 62304, IEC 62366, MDD 93/42/EEC. ISO 13485, ISO 14971.

Products are available for clinical research on contract basis. Contact info@injeq.com