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**NEURO-BALLOON RETRACTOR**  
**ATTENTION OPERATING SURGEON**  
**ALL INSTRUCTIONS MUST BE READ CAREFULLY PRIOR TO CLINICAL USE**

**DESCRIPTION**

The Neuro-Balloon Retractor is a single use, sterile packaged, silicone balloon catheter device intended to be used as an instrument to gently retract, elevate and/or hold neural tissues during surgery. The device is designed to enhance microsurgical techniques and help provide atraumatic exposure, and avoid retraction trauma by minimizing injury to neural structures. The device is delivered with two separately packaged cards in each box. Each card contains one balloon/ catheter assembly and one syringe.

**INDICATIONS**

The Neuro-Balloon Retractor is intended to assist neurosurgeons when opening natural fissures and sulci in the brain. The device can also be used to gently retract dissected neural tissue so the surgeon can maintain access to deeper structures within the brain.

**CONTRAINDICATIONS**

Not intended for use as a tissue dissector.

**WARNINGS**

1. **Do not over-inflate balloon**, doing so could damage the balloon. See chart below for recommended fill volumes.
2. Use extreme care when using sharp objects such as forceps and scissors near the balloon.
3. Only grasp balloon at the junction with the catheter using forceps to avoid damaging the balloon.

**SUGGESTIONS FOR PROPER TIP PLACEMENT AND INFLATION**

1. Dissect a small insertion hole into the tissue, use forceps to advance the balloon tip into the hole being careful to grab the balloon only at the catheter/ balloon junction.
2. Fill the syringe with saline solution to the maximum suggested volume listed below.

Balloon Size *	6mm	9mm	12mm	15mm
Maximum Fill Volume	0.5 ml	0.75 ml	1.0 ml	1.25 ml

\*Balloon sizes are based on nominal dimensions between seals. Actual balloon length will vary.

3. Once the balloon is in the desired location, use the syringe to inflate the balloon. Disconnect the syringe to leave the balloon in the inflated state.
4. Carefully dissect the surrounding tissues with forceps or scissors.
5. Deflate the balloon, advance it and repeat the aforementioned step until the desired dissection depth has been reached
6. Once the desired depth has been achieved, two balloons spaced slightly apart can be inflated to retract and hold tissues to provide a hole through which surgery can be performed.

**STERILITY**

The Neuro-Balloon retractor is provided sterile by exposure to Gamma irradiation. Do not use after expiration date. The device is intended for single patient use only. Do not resterilize this product. Biomet Microfixation assumes no liability for products that have been resterilized by a Health Care Facility.

**Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.**

**Operating Surgeons and all personnel involved with handling these products are responsible for attaining appropriate education and training within the scope of the activities with which they are involved in the handling and use of this product.**