

OSTEOMED
DuraKnife
Dura Cutting Instrument
Product Information and Instructions for Use

Device Description

The **OSTEOMED DuraKnife** is designed to isolate and cut the dura through a single small incision. The knife allows cutting of the dural meningeal layer while retracting it away from underlying neurovascular structures thus protecting the cortical surface and cortical vasculature from the instrument's cutting surface.

Materials

The DuraKnife is comprised of a dural knife blade and footplate made from surgical grade stainless steel and the blade cover and handle are made from medical grade plastic.

Indications for Use

The **OSTEOMED DuraKnife** is indicated for opening the dura in certain cranial procedures. The **OSTEOMED DuraKnife** is intended for single patient use only. OsteoMed single use devices cannot be reused and/or reprocessed. The product has been labeled as single use only for patient safety. The design of the device and the intricacies of the surfaces may not facilitate cleaning and sterilization after contact with body tissues or fluids, so there is an increased risk of contamination if reused. This may lead to potential risks of cross infection/contamination associated with using inadequately cleaned and sterilized devices. The cutting efficacy may be reduced requiring the surgeon to use increased force that might cause patient harm. Because this product has not been validated for multiple uses, OsteoMed cannot guarantee the safety and effectiveness of the device if it is used on more than one patient.

Maintaining Device Effectiveness

- The Surgeon should have specific training, experience and thorough familiarity with the use of the **OSTEOMED DuraKnife**. A DuraKnife Surgical Technique Guide (030-1829) is available at no charge from OsteoMed.
- Failure to use dedicated, unique OsteoMed components for every step of the surgical procedure may compromise the outcome of the procedure, leading to subsequent patient injury.
- OsteoMed recommends the use of OsteoMed products in a sterile environment.

Storage

- The sterile packaged **DuraKnife** should be stored at controlled room temperature.
- Product package should be inspected prior to use for signs of damage or tampering.

Sterility

- The **OSTEOMED DuraKnife** is packed **STERILE** (Gamma Sterilized).
- DO NOT USE IF STERILE PACKAGE IS DAMAGED.**
- DO NOT USE AFTER EXPIRATION DATE.**
- DO NOT AUTOCLAVE THE INSTRUMENT, THE HANDLE WILL MELT.**

Caution

- Federal Law (USA) restricts this device to sale by or on the order of a medical practitioner licensed to do so.
- Do not attempt a surgical procedure with faulty, damaged, or suspect OsteoMed devices. Inspect all components preoperatively to assure utility.

Warnings

- Avoid contact of the **DuraKnife** blade with hard surfaces or other instruments to prevent damage to the cutting surface of the blade.
- Keep the **DuraKnife** blade protected by the blade cover when the device is not in use to avoid accidental injury to the patient or staff.
- Do Not use the **DuraKnife** on tissue other than dura.

Possible Complications

Possible complications specific to the device may include:

- Accidental injury to the pia mater, arachnoid mater or the brain
- Cerebrospinal fluid leakage if the above injury occurs

Accidental puncturing of a meningeal vein or artery which could result in a subdural or epidural hematoma

Instructions for Use:

Patient Preparation:

The patient is placed in the appropriate position and is prepped and draped in the usual manner. Hemostasis is achieved according to the surgeon's preference.

Surgical Technique:

- After obtaining access to the dura, make a small 5mm incision with a scalpel in order to create the starting location for cutting of the dura.
- Remove the blade cover from the **OSTEOMED DuraKnife** by pulling and sliding the cover away from the handle.
- Introduce the **OSTEOMED DuraKnife** into the incision with the footplate underneath the dura.
- Elevate and separate the dura from the brain with the foot plate
- With the **OSTEOMED DuraKnife** blade positioned perpendicular to the dura, begin cutting through the dura in the same direction as the incision made with the scalpel until the desired length of cut is attained.

NOTE: The **OSTEOMED DuraKnife** will cut up to an 8 inch opening in the dura.

NOTE: If the **OSTEOMED DuraKnife** does not cut the dura or does not cut it as intended, or it inadvertently cuts the brain or other vital tissue, discontinue its use and use an alternate method.

- The **OSTEOMED DuraKnife** is then removed, the blade cover is placed over the blade and the surgeon proceeds with the chosen procedure.



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Class Is instrument

Symbols and Definitions

	Single Use Only	REF	Catalogue Number
	Use By (Date)		Do not use if sterile package is damaged
	Date of Manufacture (MFG DATE)		Manufacturer (MFR)
	Batch Code (Lot Number)		Authorized Representative in the European Community
	Federal Law (U.S.A.) Restricts this device to sale by or on the order of a physician.		Sterile, Method of Sterilization Using Irradiation