

Please Read Carefully:

NOTE: THE MEDICAL PROFESSIONAL IS RESPONSIBLE FOR PROPER SURGICAL PROCEDURES AND TECHNIQUES. THE FOLLOWING INSTRUCTIONS ARE FOR INFORMATION ONLY. THE ATTENDING SURGEON MUST EVALUATE THE APPROPRIATENESS OF THE PROCEDURE BASED ON HIS/HER OWN MEDICAL TRAINING AND EXPERIENCE.

Indications

Invotec burs are indicated for use in incising or removing bone and cartilage during otologic, sinus and rhinology surgery.

Contraindications

There are no known contraindications.

Warnings:

- Use care when drilling close to the cochlea or ossicular chain as excessive noise may cause hearing damage.
- Without proper cooling excessive heat may buildup resulting in thermal injury to tissue.
- Excessive force may lead to bur damage. If the bur fractures or bends during use, laceration of body tissue may result. A bur which fractures inside a patient may also cause tissue injury and necessitate emergency procedure for extraction.
- Eccentricity of the bur can cause bur vibration and may result in excess tissue and bone destruction and hearing damage and handpiece damage.

Precautions:

- Test handpiece for vibration and proper function before inserting bur.
- Inspect burs under magnification before each use.
- Always ensure that the bur is securely engaged into the drill handpiece prior to operating the drill system.
- Always test operations of each bur in a handpiece before use. Operating certain burs at high speeds can cause vibration of the bur. The following are suggestions for reducing bur vibrations:

Instructions for use:

- Refer to the User's Guide for the particular handpiece/drill system for specific instructions.

Reuse and cleaning/Sterilization:

Invotec Burs are provided sterile. Burs must be cleaned and sterilized using the following process before each reuse.

DO NOT COLD SOAK IN GLUTARALDEHYDE, CHLORINE, OR AMMONIUM SOLUTIONS OR DRY HEAT STERILIZE AS DAMAGE TO THE BURS MAY OCCUR.

1. Promptly and thoroughly rinse the burs with deionized water after each use.
2. Thoroughly scrub burs with a soft instrument brush while the burs are submerged in a cleaning solution to remove blood and tissue.
3. Soak in lukewarm, mild enzymatic detergent, and deionized water for a minimum of two minutes. Clean ultrasonically in a lukewarm solution of mild detergent and deionized water for at least 30 seconds. Rinse thoroughly with deionized water and wipe dry.

Sterilization

Before sterilization, carefully inspect the bur tips and shafts under a microscope or magnifying glass for any irregularities or eccentricities. Discard any burs which show signs of damage or wear.

Steam Sterilization:	Gravity
Temp:	121° C
Time:	Not less than 30 minutes

Alternatively, any validated steam sterilization cycle with a temperature up to 135°C may be used.

IT IS THE RESPONSIBILITY OF EACH HEALTH CARE FACILITY TO VALIDATE THE STERILIZATION PROCESS WITH THEIR PARTIUCULAR EQUIPMENT AND PROCEDURES TO ASSURE STERILITY.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

Warranty

Invotec International, Inc. warrants that the product is free from defects in material and workmanship. Invotec will replace or provide a refund for any product found to be defective so long as the product is returned according to the Returned Goods instructions in the Sales Policy. Invotec shall not be liable for any consequential loss, damage or expense directly or indirectly arising from the use of, or inability to use, this product. THE FOREGOING WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, HOWEVER ARISING, INCLUDING MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AGAINST INFRINGEMENT OR OTHERWISE. Invotec International neither assumes, nor authorizes any person to assume for it, any other additional liability or responsibility with respect to this product.