

# **Bentec Dilator**

## **DESCRIPTION**

The thermoplastic **Bentec Dilator** is designed for percutaneous introduction and exchange of Biliary catheters used for drainage of benign and malignant biliary obstructions.

## **INDICATIONS**

The **Bentec Dilator** is recommended for placing or exchanging **Biliary Stents** utilized for the management of both benign and malignant biliary obstructions. The Stent is used to prevent or relieve sepsis, to relieve symptoms of obstruction such as pruritis, and to maintain a pathway for bile flow into the bowel for digestive function.



## **CONTRAINDICATIONS**

The use of the **Bentec Dilator** and biliary stents in very small ducts of the biliary system may be contraindicated because of the possibility of irreparable damage to the duct mucosa.



## **INSTRUCTIONS FOR USE**

A variety of surgical techniques may be employed during the placement of a **Biliary Stent** with a **Bentec Dilator**; therefore, the surgeon is best advised to use the method, which his/her own practice and discretion dictate to be best for the patient.

The placement technique is at the discretion of the physician and should be dependent on the intended use if the device and particular patient requirements.

The device should be tested for patency and integrity prior to use.

A **Bentec Dilator** of appropriate size is lubricated and placed through the silicone stent tube so that the tapered tip extends 5-6 cm coaxially beyond the end of the tube. The stent tube and dilator are then advanced coaxially over the guidewire. The stent is also lubricated to facilitate passage through the liver and reduce patient discomfort.

When the tip of stent is in the duodenum or small bowel, the **Bentec Dilator** and guidewire are removed.

## **HOW SUPPLIED**

Supplied in peel-open packages, sterilized by Ethylene Oxide. Intended for one-time use. Sterile if package is unopened or undamaged. Do not use product if there is any doubt of sterility. Store in a cool, dry place.



## **WARNINGS**

The surgeon must verify the compatibility of the **Bentec Dilator** with any other instruments or devices to be used together in the surgical technique, prior to attempting stent placement; the internal diameter of the commonly used accessory instruments vary according to manufacture and date production.



## **PRECAUTIONS**

**To assure a successful outcome, read the following with care:**

- Meticulous care should be exercised in the handling, connecting and insertion of the device.
- Each device should be examined prior to insertion and continuously monitored throughout the insertion procedure to ensure that the structural integrity of the device is not compromised in any way.
- This device should not be inserted following any modification to its original design. A device which has not been damaged, or on which repairs have been attempted, should not be inserted. **A standby device should be available at the time of operation.**

## **RETURNED GOODS POLICY**

### **U.S. Customers**

A **Returned Goods Authorization** must be received from **Bentec Medical, Inc.**, prior to the return of the merchandise. Merchandise returned must have all correct seals intact and **Bentec Medical, Inc.**, must be notified within 30 days of invoice date to be eligible for credit or replacement. Any explanted device should be returned to **Bentec Medical, Inc.**, and include the authorization number provided. Returned products may be subject to restocking charges. **Bentec Medical, Inc.**, does not accept returns on **Special Order Devices**.

### **International Customers**

A **Returned Goods Authorization** for return of merchandise must be obtained from your respective dealer. Other conditions noted above also apply.

**PRODUCT ORDER INFORMATION DISCLOSURE**



*Bentec Medical, Inc., has exercised reasonable care in the choice of material and the manufacture of this product. **Bentec Medical, Inc., excludes all warranties, whether expressed or implied by operation of law or otherwise, including, but not limited to any implied warranties of merchantability or fitness. Bentec Medical, Inc., shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from the use of this product. Bentec Medical, Inc., neither assumes nor authorizes any other or additional liability or responsibility in connection with this device.***

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P/N 102346, Rev. B  
August 2008

**Product Order Information**

**U.S. Customers**

To order directly in the USA or for information on special devices, please contact the **Bentec** Customer Service Department at **Bentec Medical, Inc.,** 1380 East Beamer Street, Woodland, California 95776. Telephone: (800) 767-9175, Fax: (530) 406-3306, e-mail [bentec@bentecmed.com](mailto:bentec@bentecmed.com)

**International Customers**

For product information or to order directly, contact your local **Bentec Medical, Inc.,** product distributors or the International Customer Service Department at **Bentec Medical, Inc.,** 1380 East Beamer Street, Woodland, California 95776 USA. Telephone: (530) 406-3333, Fax: (530) 406-3306, e-mail [bentec@bentecmed.com](mailto:bentec@bentecmed.com)

For technical information on this product or on **Special Order Devices,** please call (toll free) the **Bentec Medical, Inc.** Customer Service Department at (800) 767-9175.

**CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.**

**RE-ORDER INFORMATION**

REF	DESCRIPTION	SIZE
AAD5FR	BENTEC DILATOR	5 Fr
AAD6FR	BENTEC DILATOR	6 Fr
AAD7FR	BENTEC DILATOR	7 Fr
AAD8FR	BENTEC DILATOR	8 Fr
AAD9FR	BENTEC DILATOR	9 Fr
AAD10FR	BENTEC DILATOR	10 Fr

