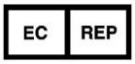
INVOTEC INTERNATIONAL, INC.®

General Instructions for Single Use Disposables

General Handling:	• Any contamination of the product must be avoided. • The product must be kept in its sealed protective packaging. • Examine packaging for damage before opening since damaged packaging may impair the sterility of the product. • Do not open the protective packaging until just before implantation of the product. In addition, the product must be visually checked for damage. • **This product is intended for single use only**. Reuse of this device may expose the patient to infection or contamination risks. Once the seal of the sterile packaging has been torn open its contents will not be taken back by the manufacturer.	
Packaging & Sterility:	The packaging of the product consists of: • Sterile packaging (primary packaging) • The packaging meets the provisions of the European Standards. Intact packaging protects the product form environmental influences and ensures sterile storage.	
Handling of Sterile Packaging:	Please ensure that the relevant aseptic instructions are complied with when removing the product from the packaging.	
Re-Sterilization:	Re-sterilization after expiry of the use-by date as well as re-sterilization of unsterile uncontaminated products is prohibited. Manufacturer and distributor will assume no liability for products that have been re-sterilized by the user.	
Storage:	Store in a dry environment at room temperature. After expiry of the use-by date the product may no longer be used.	
Symbols & Definitions:		Manufacturer: Indicates the medical device manufacturer, as defined in EU directives 90/385/EEC, 93/42/EEC, and 98/79/EC
		Authorized representative in the European Community: This symbol shall be accompanied by the name and address of the authorized representative in the European Community, adjacent to the symbol.
		Use By date: Indicates the date after which the medical device is not to be used.
		Batch Code: Indicates the manufacturer's batch code so that the batch or lot can be identified.
		Catalog Number: Indicates the manufacturer's catalog number so that the medical device can be identified.
		Sterilized using Ethylene oxide: Indicates a medical device that has been sterilized using ethylene oxide.
		Do not resterilized: Indicates a medical device that is not to be resterilized.
		Do not use if package is damaged: Indicates a medical device that should not be used if the package has been damaged or opened.
		Do not re-use: Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Invotec International, Inc.®
6833 Phillips Industrial Blvd. • Jacksonville, FL 32256 USA Tel: 800-998-8580/ 904-880-1229 • Fax: 904-886-9517 • www.invotec.net
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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.

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