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. • When disposing the, take all steps necessary to avoid risk of injury and infection. Contaminated products must be disposed of as hazardous waste and handled to avoid contamination of third parties. • Any serous incident that has occurred in relation to the device should be reported to Invotec International, Inc. MDSS GmbH, and the competent authority of the member state in which the user and/or patient is established.	
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
	EC REP	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.
	LOT	Batch Code: Indicates the manufacturer's batch code so that the batch or lot can be identified.
	REF	Catalog Number: Indicates the manufacturer's catalog number so that the medical device can be identified.
	STERILE EO	Sterilized using Ethylene oxide: Indicates a medical device that has been sterilized using ethylene oxide.

 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

EC REP
MDSS GmbH
Sciffgraben 41
30175 Hanover, Germany

	STERILE R	Sterilized using irradiation: Indicates a medical device that has been sterilized using irradiation.
		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.
	MD	Medical Device Indicated
		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.

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.

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

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hanover, Germany