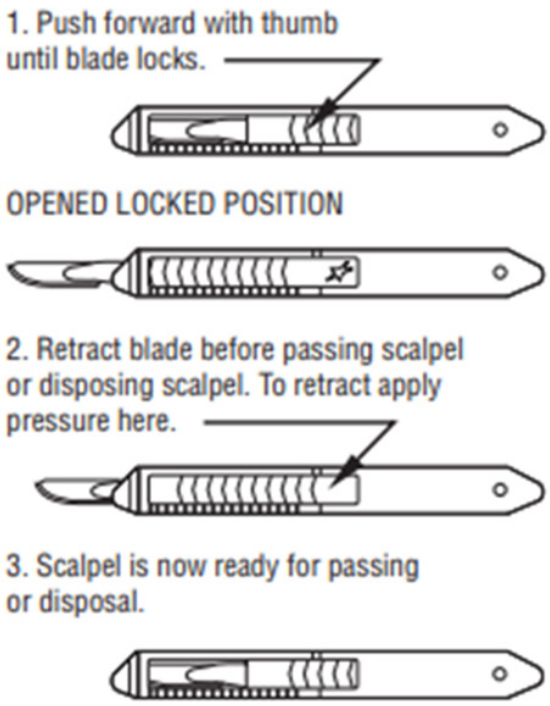
Futura® Safety Scalpel

INSTRUCTIONS FOR USE

℞ ONLY: Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician trained and/or experienced in the use of this device.

DESCRIPTION
Futura Safety Scalpels are a line of disposable scalpels that incorporate a retractable stainless-steel blade to be used during diagnostic or interventional procedures.

INSTRUCTIONS FOR USE



INTENDED PURPOSE/USE
Intended for use in procedures that require a sharp blade to puncture, cut, or separate tissues.

DEVICE LIFETIME
The device lifetime is intended to cut tissue up to 24 inches.

PATIENT POPULATION
The Futura Safety Scalpel is intended to be used in patients who require tissue separation, puncture, or cut.

INTENDED USERS
For use by clinicians trained to perform procedures that necessitate different incision and dissection techniques for soft tissues.

CLINICAL BENEFITS
Futura scalpels provide an indirect benefit to patients by facilitating the puncturing, cutting, and separation of tissue as required to conduct a medical procedure.

WARNINGS
- Warning: This product contains Cobalt. Please consider the risk and impact of using this device, especially in children, pregnant and breastfeeding women, or other vulnerable patient groups.
- The Merit Futura Safety Scalpel should be used by persons knowledgeable of the risks involved and qualified in the procedures performed.
- Used sharps are contaminated
- Handle carefully
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practice and with applicable local, state, and federal laws and regulations
- Ruler shown on scalpel handle should be used as an indicator only, and not for accurate measurements
- Do not use product if contains a dull and/or detached blade.
- If blade becomes dull or breaks, dispose and replace product
- Do not use product if product is damaged or particulate is found in sterile packaging

CONTRAINDICATIONS
There are no contraindications identified for this device.

CAUTIONS
- Read instructions prior to use.
- This device is intended for single use only.
- In the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable Member State.

HOW SUPPLIED
The product is supplied sterile unless the package has been opened or damaged. Sterilized using Gamma sterilization. For single patient use only. Do not reuse. Do not resterilize.

STORAGE CONDITIONS
Store in a cool, dark and dry place.

SAFE DISPOSAL
After use, dispose of the products used in the procedure per institutional protocol.

REUSE PRECAUTION STATEMENT
For single patient use only. Do not reuse or reprocessing may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse or reprocessing may also create a risk contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

The basic UDI-DI for the Futura Scalpel is 0884450BUDI571Q7

SYMBOL	DESIGNATION
	Caution
	Do Not Use If Package is Damaged and Consult Instruction for Use
REF	Catalog number
LOT	Batch code
MD	Medical Device
UDI	Unique Device Identifier
	Single use
	Do not resterilize
	Non-pyrogenic
	Consult Instructions for Use. For electronic copy scan QR code, or go to www.merit.com/ifu and enter IFU ID. For printed copy, call U.S.A. or EU Customer Service
STERILE	Sterilized using Gamma sterilization
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Single Sterile Barrier System
	Use by date: YYYY-MM-DD
	Date of Manufacture: YYYY-MM-DD
	Manufacturer
EC REP	Authorized Representative in European Community
	Keep away from Sunlight
	Keep Dry
	Contains Cobalt

MERIT MEDICAL®

www.merit.com

Manufacturer:
Merit Medical Systems, Inc.
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1-801-253-1600
U.S.A Customer Service 1-800-356-3748

EC REP Authorized Representative:
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