



ORDER NO.	DESCRIPTION	EAN / GTIN CODES
IVX-NS-1040	Dornier Hoover - FANS Ureteral Access Sheath, 10/12 Fr x 40 cm	0106950203341063
IVX-NS-1050	Dornier Hoover - FANS Ureteral Access Sheath, 10/12 Fr x 50 cm	0106950203341438
IVX-NS-1140	Dornier Hoover - FANS Ureteral Access Sheath, 11/13 Fr x 40 cm	0106950203341308
IVX-NS-1150	Dornier Hoover - FANS Ureteral Access Sheath, 11/13 Fr x 50 cm	0106950203341322
IVX-NS-1240	Dornier Hoover - FANS Ureteral Access Sheath, 12/14 Fr x 40 cm	0106950203341148
IVX-NS-1250	Dornier Hoover - FANS Ureteral Access Sheath, 12/14 Fr x 50 cm	0106950203341445

PRODUCT DETAILS

FANS Ureteral Access Sheaths are composed of a guide sheath with flexible tip and a dilator. Both guide sheath and dilator are radiopaque and the surface coated with hydrophilic lubrication coating. The guide sheath joint includes a negative pressure suction port which can be connected with the negative pressure aspirator.

Intended use	FANS Ureteral Access Sheaths are used to establish a conduit to facilitate passage of endoscopes and other instruments into the urinary tract for the treatment of urinary stones or other urinary diseases during endoscopic procedures.
Sterilization	Yes. Method of sterilization: ethylene oxide.
Type of product	Single-use, disposable product. No reprocessing allowed.
Material / composition	Guide sheath catheter: Pebax, PTFE, Hydrophilic coating. Dilator catheter: PE, Hydrophilic coating.
Radiopacity	Yes, increased X-ray visibility of the tip (tungsten coil).
Packaging	Packed in a sterile pouch (paper/film). Labeled with lot number, expiration date, and sterilization method.
Minimum unit of sale	One box contains one sterile unit and an IFU (instruction for use). Each unit includes a dilator.
Product classification	According to Rule 5, paragraph 1 indent 2, Annex VIII of (EU) 2017/745 (MDR), Ureteral Access Sheath is class IIa.
Indwell time	Intended for continuous use of not more than 24 hours.

Dornier HOOVER

Technical Specifications

Notified body	CE 0197
Storage	Product must be kept in its original packaging, in a clean and dry place, and away from direct sunlight. Rotate inventory so that products are used prior to the sterilization expiration date on the package label.
Shelf life	Sterility is guaranteed for three years from the date of manufacture, provided that the indicated storage conditions are kept, and the packaging is not damaged. Do not use after the expiration date.

MANUFACTURER

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