

STERIS®



February 13, 2015

Dear Valued Customer,

In response to recent requests, this letter will confirm that the validated Duodenoscopes listed below as well as on the SYSTEM 1E Device & Quick Connect Finder (also called the Device Wizard; please visit the link below) can be processed in the SYSTEM 1E® Liquid Chemical Sterilant Processing System. All applicable instructions must be followed for proper connection and placement in the tray; these are provided in the Instructions for Use, the Wall Chart and the Quick Reference Card that is attached to the Quick Connect used to connect the device to SYSTEM 1E.

MANUFACTURER	DEVICE TYPE	MODEL NUMBER	QUICK CONNECT	TRAY
Olympus	Duodenoscope	JF-140F	QLC1738E	C1160E
Olympus	Duodenoscope	JF-140R	QLC1738E	C1160E
Olympus	Duodenoscope	TJF-140F	QLC1738E	C1160E
Olympus	Duodenoscope	TJF-140R	QLC1738E	C1160E
Olympus	Duodenoscope	TJF-145	QLC1738E	C1160E
Olympus	Duodenoscope	TJF-160F	QLC1738E	C1160E
Olympus	Duodenoscope	TJF-160R	QLC1738E	C1160E
Olympus	Duodenoscope	TJF-160VF	QLC1738E	C1160E
Olympus	Duodenoscope	TJF-160VR	QLC1738E	C1160E
Olympus	Duodenoscope	JF-240	QLC1738E	C1160E
Olympus	Duodenoscope	TJF-240	QLC1738E	C1160E
Olympus	Duodenoscope	JF-260V	QLC1738E	C1160E
Olympus	Duodenoscope	TJF-260V	QLC1738E	C1160E
Olympus	Duodenoscope	TJF-Q180V	QLC1725E	C1160E

MANUFACTURER	DEVICE TYPE	MODEL NUMBER	QUICK CONNECT	TRAY
Pentax	Duodenoscope	ED-2900	QPC1669E	C1160E
Pentax	Duodenoscope	ED-3200	QPC1669E	C1160E
Pentax	Duodenoscope	ED-3400	QPC1669E	C1160E
Pentax	Duodenoscope	ED-3401	QPC1669E	C1160E
Pentax	Duodenoscope	ED-3410	QPC1669E	C1160E
Pentax	Duodenoscope	FD-29X	QPC1669E	C1160E
Pentax	Duodenoscope	FD-34X	QPC1669E	C1160E
Pentax	Duodenoscope	ED-2330	QPC1679E	C1160E
Pentax	Duodenoscope	ED-3230	QPC1679E	C1160E
Pentax	Duodenoscope	ED-3230K	QPC1679E	C1160E
Pentax	Duodenoscope	ED-3240	QPC1679E	C1160E

Pentax	Duodenoscope	ED-3430	QPC1679E	C1160E
Pentax	Duodenoscope	ED-3430K	QPC1679E	C1160E
Pentax	Duodenoscope	ED-3430T	QPC1679E	C1160E
Pentax	Duodenoscope	ED-3430TK	QPC1679E	C1160E
Pentax	Duodenoscope	ED-3440	QPC1679E	C1160E
Pentax	Duodenoscope	ED-3440T	QPC1679E	C1160E
Pentax	Duodenoscope	ED-3440TK	QPC1679E	C1160E
Pentax	Duodenoscope	ED-3270K	QPC1713E	C1160E
Pentax	Duodenoscope	ED-3280K	QPC1713E	C1160E
Pentax	Duodenoscope	ED-3470T	QPC1713E	C1160E
Pentax	Duodenoscope	ED-3470TK	QPC1713E	C1160E
Pentax	Duodenoscope	ED-3480TK	QPC1713E	C1160E
Pentax	Duodenoscope	ED-3485T	QPC1713E	C1160E
Pentax	Duodenoscope	ED-3490TK	QPC1713E	C1160E
Pentax	Duodenoscope	ED34-i10T	QPC1713E	C1160E
Pentax	Duodenoscope	ED-3670TK	QPC1713E	C1160E
Pentax	Duodenoscope	ED-3680TK	QPC1713E	C1160E

MANUFACTURER	DEVICE TYPE	MODEL NUMBER	QUICK CONNECT	TRAY
FUJINON/FUJIFILM	Duodenoscope	ED-250XL5	QFC1728E	C1160E
FUJINON/FUJIFILM	Duodenoscope	ED-250XL8	QFC1728E	C1160E
FUJINON/FUJIFILM	Duodenoscope	ED-250XT5	QFC1728E	C1160E
FUJINON/FUJIFILM	Duodenoscope	ED-250XT8	QFC1728E	C1160E
FUJINON/FUJIFILM	Duodenoscope	ED-450XL5	QFC1728E	C1160E
FUJINON/FUJIFILM	Duodenoscope	ED-450XL8	QFC1728E	C1160E
FUJINON/FUJIFILM	Duodenoscope	ED-450XT5	QFC1728E	C1160E
FUJINON/FUJIFILM	Duodenoscope	ED-450XT8	QFC1728E	C1160E
FUJINON/FUJIFILM	Duodenoscope	ED-530XT	QFC1728E	C1160E

Device Wizard Link: <http://www.steris.com/products/quickconnects/>

STERIS qualifies all instruments to be labeled for processing in SYSTEM 1E through a robust compatibility and efficacy validation testing program. Representative device (s) from this class have demonstrated both microbial efficacy and material compatibility in established testing protocols.

Within particular series of OEM instruments, STERIS tests the endoscope model(s) that, in our professional judgment, present the most challenging design of the series to liquid chemically sterilize. We ensure that efficacy is demonstrated on these “worst case” devices by achieving successful liquid chemical sterilization, including the device’s internal channels, over consecutive trials after inoculation with a known amount of the most resistant test organism (*G. stearothermophilus* spores).

Material compatibility is tested over numerous cycles in SYSTEM 1E on representative devices from the series. As part of our testing, the above-listed scopes were evaluated by an independent third party or the manufacturer. In each case, the scopes were found to have no functional or material cosmetic damage.

Please note that if a Quick Connect or tray is altered or damaged in any way, it cannot be used in the SYSTEM 1E and must be replaced. STERIS Corporation makes no claim of safety or liquid chemical sterilization efficacy when the Quick Connect or SYSTEM 1E tray is altered, nor when these items are used with or applied to devices and/or accessories other than those specified in the applicable STERIS Instructions for Use. Liquid chemical sterilization will not be achieved unless all flow unit components are functional, unrestricted and remain firmly attached to the device during and at the completion of processing.

Consult our website www.steris.com for additional validated devices or for periodic updates to this information. Please don't hesitate to contact STERIS at 1-800-548-4873 if you have any additional questions.

Best regards,

STERIS Corporation

A handwritten signature in black ink, appearing to read 'J.D. Bean', with a long horizontal flourish extending to the right.

Jason D. Bean, B.S., M.B.A.
Global Product Manager, Endoscopy