

## Endoscope Leak Testing



Proper leak testing is one of the most important reprocessing steps. Cross-infection is a risk if a leak is left unchecked. Proper leak testing is crucial for lowering the risks of cross-infection and minimizing fluid damage to the endoscopes. Early leak detection of endoscopes can extend the life of the instruments, reduce the high cost of instrument repairs, and improve patient care.

The industry and endoscope manufacturer’s recommended method for detecting leaks use the water immersion bubble test. Products that assist in leak detection using the water immersion method range from manual hand pump with a mechanical gauge to automated inflation systems with digital screens and pressure sensor.

The Knight EndoFlate GI is an automated inflation system used to pressurize the flexible endoscopes for leak testing. EndoFlate provides an easy-to-read digital screen with a numerical pressure value, timer, pressure bar, and date/time. A red screen indicator will notify the endoscopy technician of the liner’s failure to meet desired inflation pressure. In the event of a minor leak, the EndoFlate keeps the line inflated to prevent fluid ingress and allow the manual cleaning to be completed.

### EndoFlate GI Target Customers

- Target customers of: Bulb type inflation device and Olympus Mu-1
- Target endoscope repair service, medical device distributors, endoscopy OEM’s



### EndoFlate GI Benefits

For the User/Hospital	For Endoscope OEMs	For Medical Device Distributors, Endoscopy Repair Service & Resale
<p style="text-align: center;"><b>Improve the Process</b></p> <ul style="list-style-type: none"> <li>• Less work, less time to reprocess endoscopes</li> <li>• Easier to do leak test</li> <li>• Process consistency for leak testing</li> </ul>	<p style="text-align: center;"><b>Build Product Portfolio &amp; Value-Added Services</b></p> <ul style="list-style-type: none"> <li>• Upsell opportunity for Endoscopy product line</li> <li>• Expand Endoscopy product portfolio</li> <li>• Knight can supply the volume and quality of product they need (ISO-13485)</li> <li>• World class product support</li> <li>• Build service, replacement, repair programs</li> <li>• Private labeling for branding</li> <li>• Engineering collaboration for custom solution</li> </ul>	<p style="text-align: center;"><b>New Source of Equipment Revenue</b></p> <ul style="list-style-type: none"> <li>• Easy to sell, there is existing market and demand</li> <li>• Minimum 43% profit</li> <li>• Expand Endoscopy product portfolio</li> <li>• Knight can supply the volume and quality of product they need (ISO-13485)</li> <li>• World class product support</li> <li>• Build service, replacement, repair programs</li> <li>• Private labeling for branding</li> </ul>

## EndoFlate GI Channel Revenue Opportunity

<b>North America USD</b>	<b>1</b>	<b>10</b>	<b>25</b>	<b>50</b>	<b>100</b>
EndoFlate GI Market Price	\$850	\$8,500	\$21,250	\$42,500	\$85,000
EndoFlate GI Channel Price	\$483	\$4,832	\$12,080	\$24,161	\$48,321
<b>Profit 43% or more</b>	<b>\$367</b>	<b>\$3,668</b>	<b>\$9,170</b>	<b>\$18,340</b>	<b>\$36,679</b>

<b>Canada CAD</b>	<b>1</b>	<b>10</b>	<b>25</b>	<b>50</b>	<b>100</b>
EndoFlate GI Market Price	\$949	\$9,492	\$23,731	\$47,461	\$94,922
EndoFlate GI Channel Price	\$544	\$5,436	\$13,591	\$27,182	\$54,364
<b>Profit 43% or more</b>	<b>\$406</b>	<b>\$4,056</b>	<b>\$10,140</b>	<b>\$20,279</b>	<b>\$40,558</b>






  

<b>Europe EUROS</b>	<b>1</b>	<b>10</b>	<b>25</b>	<b>50</b>	<b>100</b>
EndoFlate GI Market Price	€ 667	€ 6,673	€ 16,683	€ 33,365	€ 66,730
EndoFlate GI Channel Price	€ 381	€ 3,805	€ 9,513	€ 19,026	€ 38,052
<b>Profit 43% or more</b>	<b>€ 287</b>	<b>€ 2,868</b>	<b>€ 7,170</b>	<b>€ 14,339</b>	<b>€ 28,678</b>

<b>Asia YUAN</b>	<b>1</b>	<b>10</b>	<b>25</b>	<b>50</b>	<b>100</b>
EndoFlate GI Market Price	¥5,196	¥51,965	¥129,912	¥259,824	¥519,648
EndoFlate GI Channel Price	¥2,956	¥29,556	¥73,889	¥147,778	¥295,556
<b>Profit 43% or more</b>	<b>¥2,241</b>	<b>¥22,409</b>	<b>¥56,023</b>	<b>¥112,046</b>	<b>¥224,092</b>

## EndoFlate GI Product and Feature Comparison

Leak Test Using Water Immersion Bubble Method					
					
<b>Manufacturer</b>	Hand-Held Leak Tester	Zutron Automatic Leak Tester	Olympus MU-1	Zutron Endo-Leak Tester	Knight EndoFlate GI
<b>Price USD</b>	\$150 - \$300	\$800	\$1000	\$1000	\$850
<b>Inflation Type</b>	Bulb Hand Pump	Automated	Automated	Automated	Automated
<b>Inflation Pressure Indicator</b>	Mechanical gauge that's hard to see, subject to incorrect readings	None	None	Digital	Digital
<b>Programmable Inflation Pressure</b>	None. Depends on technician	None	None	Not known	Inflation pressure can be set to meet scope manufacture's IFU.

## EndoFlate GI Competitive Positioning

### Manual Bulb Leak Tester VS Knight EndoFlate GI

<ul style="list-style-type: none"> <li>▪ Hand motion to inflate the scope liner</li> <li>• Higher risk for fluid ingress if the scope has a leak</li> <li>• Repetitive hand motion causes carpal tunnel syndrome</li> <li>• Inconsistency in the leak detection process</li> <li>• Hard to see pressure needle movement</li> <li>• Devices often break (cheap plastic) or get lost</li> <li>• The manual bulb pumping requires the user's full attention</li> <li>• Need a separate timer</li> </ul>	<ul style="list-style-type: none"> <li>▪ Automated inflation pump</li> <li>▪ System keeps scope inflated when there is a leak so tech can clean scope without risk of fluid ingress</li> <li>▪ Minimizes repetitive hand motion</li> <li>▪ Built-in timer to monitor inflation duration</li> <li>▪ Inflation is rapid and precise. Minimizes damage to the liner due to technician error</li> </ul>
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### Zutron/Olympus VS Knight EndoFlate GI

<ul style="list-style-type: none"> <li>▪ Zutron does not engineer or make their leak test systems</li> <li>▪ Zutron customers take on risks with product support as they are not a professional engineering organization</li> <li>▪ Zutron's <b>Automatic Leak Tester</b> and Olympus's <b>Mu-1</b> provide simple inflation, no feedback</li> <li>▪ Zutron and Olympus units don't show inflation pressure.</li> <li>▪ Requires tech to visually observe the liner, inflation</li> </ul>	<ul style="list-style-type: none"> <li>▪ Private labeling for branding</li> <li>▪ Professional engineering/support</li> <li>▪ ISO-13485 Quality System</li> <li>▪ Smarter inflation system with pressure sensor</li> <li>▪ Built-in timer</li> </ul>
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Bulb Type Inflation	Zutron Automatic Leak Tester	Olympus MU-1	Zutron Endo-Leak Tester	Knight EndoFlate GI
	No pressure reading	No pressure reading		

## Endoscope Channel Flushing



Inadequate rinsing/flushing may allow chemical or bio residue to remain on the internal and external surfaces of the endoscope. Any residue remaining after manual cleaning will interfere with the action of the HLD or sterilant, compromising the results of sterilization. Copious flushing of all endoscope channels is recommended.

FlushTech GI is an automated flushing system with 2 flush ports including a main flush and an auxiliary flush port. The auxiliary port is used to flush the elevator wire channel of a duodenscope, auxiliary water channel, or when dual port flushing is desired. FlushTech can track and report flushing events, flushing volume, cleaning productivity, scope

flushed by serial number, and flushing conditions to document compliance with industry recommended reprocessing protocols and endoscope manufacturer's IFU.

### FlushTech GI Target Customers

- Target customers of: Pure Processing Flexipump, Zutron ENDOFLUSH, Medivator Scope Buddy, Olympus OFP-2, PCI Endo-Flush
- Target endoscope repair service, medical device distributors, endoscopy OEM's



### FlushTech GI Benefits

For the User/Hospital	For Endoscope OEMs	For Medical Device Distributors, Endoscopy Repair Service & Resale
<p><b>Improve the Process</b></p> <ul style="list-style-type: none"> <li>• Less work, less time to reprocess endoscopes</li> <li>• Easier to flush/rinse scope channels</li> <li>• Process consistency for flushing/rinsing</li> <li>• Reports for documenting compliance with cleaning procedures</li> <li>• Flush multiple channels/multiple scopes at the same time</li> <li>• Better cleaning results</li> <li>• Flow meter alarms when</li> </ul>	<p><b>Build Product Portfolio &amp; Value-Added Services</b></p> <ul style="list-style-type: none"> <li>• Upselling opportunity for their Endoscopy product line</li> <li>• Expands Endoscopy product portfolio</li> <li>• Knight can supply the volume and quality of product they need (ISO-13485)</li> <li>• World class product support</li> <li>• Service, replacement, repair programs</li> <li>• Private labeling for branding</li> <li>• Engineering collaboration on custom solution</li> </ul>	<p><b>New Source of Equipment Revenue</b></p> <ul style="list-style-type: none"> <li>• Easy to sell, there is existing market and demand</li> <li>• Minimum 43% profit</li> <li>• Expands Endoscopy product portfolio</li> <li>• Knight can supply the volume and quality of product they need (ISO-13485)</li> <li>• World class product support</li> <li>• Service, replacement, repair programs</li> <li>• Private labeling for branding</li> </ul>

## FlushTech GI Channel Revenue Opportunity

<b>North America USD</b>	<b>1</b>	<b>10</b>	<b>25</b>	<b>50</b>	<b>100</b>
FlushTech GI Market Price	\$1,600	\$16,000	\$40,000	\$80,000	\$160,000
FlushTech GI Channel Price	\$919	\$9,185	\$22,964	\$45,927	\$91,854
<b>Profit</b>	<b>\$681</b>	<b>\$6,815</b>	<b>\$17,037</b>	<b>\$34,073</b>	<b>\$68,146</b>
<b>Canada CAD</b>	<b>1</b>	<b>10</b>	<b>25</b>	<b>50</b>	<b>100</b>
FlushTech GI Market Price	\$1,794	\$17,943	\$44,859	\$89,717	\$179,434
FlushTech GI Channel Price	\$1,026	\$10,262	\$25,655	\$51,309	\$102,618
<b>Profit</b>	<b>\$768</b>	<b>\$7,682</b>	<b>\$19,204</b>	<b>\$38,408</b>	<b>\$76,816</b>
<b>Europe EUROS</b>	<b>1</b>	<b>10</b>	<b>25</b>	<b>50</b>	<b>100</b>
FlushTech GI Market Price	€ 1,266	€ 12,655	€ 31,639	€ 63,277	€ 126,554
FlushTech GI Channel Price	€ 721	€ 7,212	€ 18,031	€ 36,061	€ 72,122
<b>Profit</b>	<b>€ 544</b>	<b>€ 5,443</b>	<b>€ 13,608</b>	<b>€ 27,216</b>	<b>€ 54,432</b>
<b>Asia YUAN</b>	<b>1</b>	<b>10</b>	<b>25</b>	<b>50</b>	<b>100</b>
FlushTech GI Market Price	¥9,778	¥97,776	¥244,440	¥488,880	¥977,760
FlushTech GI Channel Price	¥5,615	¥56,155	¥140,387	¥280,775	¥561,549
<b>Profit</b>	<b>¥4,162</b>	<b>¥41,621</b>	<b>¥104,053</b>	<b>¥208,106</b>	<b>¥416,211</b>

## FlushTech GI Competitive Positioning

### Syringe Flushing VS Knight FlushTech GI

<ul style="list-style-type: none"> <li>▪ Hand motion to flush</li> <li>▪ Slow tedious process</li> <li>• Repetitive hand motion causes carpal tunnel syndrome</li> <li>• Inconsistency flushing/rinsing results</li> <li>• Manual process requires the user's full attention</li> </ul>	<ul style="list-style-type: none"> <li>▪ Automated flushing</li> <li>▪ Minimizes repetitive hand motion</li> <li>▪ Pulsating flush technology get better results</li> <li>▪ Flow meter can validate flush volume</li> <li>▪ Flush all channels for one scope or process 2 scopes at the same time</li> <li>▪ Reports to document compliance with cleaning protocols</li> </ul>
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### Pure Processing, Zutron, Medivator VS Knight FlushTech GI

<ul style="list-style-type: none"> <li>▪ Simple, single port flushing</li> <li>▪ No report capabilities</li> <li>▪ Zutron and Medivator systems have no fluid volume validation</li> <li>▪ No flow meter</li> </ul>	<ul style="list-style-type: none"> <li>▪ Pulsating flush technology get better results</li> <li>▪ Flow meter can validate flush volume</li> <li>▪ Flush all channels for one scope or process 2 scopes at the same time</li> <li>▪ Reports to document compliance with cleaning protocols</li> <li>▪ Private labeling for branding</li> <li>▪ Engineering collaboration on custom solution</li> <li>▪ ISO-13485 Compliant</li> <li>▪ Smarter flushing system</li> </ul>
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### PCI Endo-Flush VS Knight FlushTech GI

<ul style="list-style-type: none"> <li>▪ No report capabilities</li> <li>▪ No fluid volume validation</li> <li>▪ Does not have pulsating flush technology</li> </ul>	<ul style="list-style-type: none"> <li>▪ Pulsating flush technology get better results</li> <li>▪ Flow meter can validate flush volume</li> <li>▪ Reports to document compliance with cleaning protocols</li> <li>▪ Private labeling for branding</li> <li>▪ Engineering collaboration on custom solution</li> <li>▪ ISO-13485 Compliant</li> <li>▪ Smarter flushing system</li> </ul>
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## FlushTech GI™ Product and Feature Comparison

	Manual Flush	Automated Flushing Systems				
						
<b>Mfg</b>	Syringe Pump	Pure Processing FlexiPump	Zutron ENDOFLUSH	Medivator Scope Buddy	PCI Endo-Flush EFP-500	<b>Knight FlushTech GI</b>
<b>Price USD</b>	<b>\$10</b>	<b>\$750</b>	<b>\$1500</b>	<b>\$1600</b>	<b>\$1200</b>	<b>\$1600</b>
<b>Footprint</b>		Don't know	5.60"L x 7.30"W x 10.50"H	9.5"H x 6"W x 8"D	Don't know	7"H x 8"W x 8"D
<b>Programmable Flush Time</b>	No				No	
<b>Main &amp; Aux Flush Ports</b>	No	No	No	No		
<b>Multi-Speed Pulsating Flush Technology</b>	No	No	No	No	No	
<b>Track Endoscope Flushing by Serial #</b>	No	No	No	No	No	
<b>Flushing Validation Reports</b>	No	No	No	No	No	
<b>Pump and Flushing Tube Step-Through Decontamination Procedure</b>	No	No	No	No	No	
<b>Flushing Flow Rate at Distal Tip</b>	60mL/min	100mL/min	800mL/min	800mL/min	900mL/min	1600mL/min