

Moray[®] micro forceps



A recent multi-center, prospective study of 114 patients with pancreatic cystic lesions (PCLs) showed a **significantly higher tissue acquisition yield** with the Moray micro forceps than with FNA (83.3% vs 37.7%) respectively and a **surgical concordance rate of 100%.¹**

¹ D. Yang, A. Trindade, P. Yachimski, P. Benias, J. Nieto, A. Manavar, S. Ho, A. Esnakula, A. Gamboa, A. Sethi, A. Gupta, H. Khara, D. Diehl, A. Chafic, J. Shah, C. Forsmark, P. Draganov. "Histologic Analysis of Endoscopic Ultrasound-Guided Through the Needle Microforceps Biopsies Accurately Identifies Mucinous Pancreas Cysts." Clinical Gastroenterology and Hepatology. 2019. 17 (8): 1587-1596.

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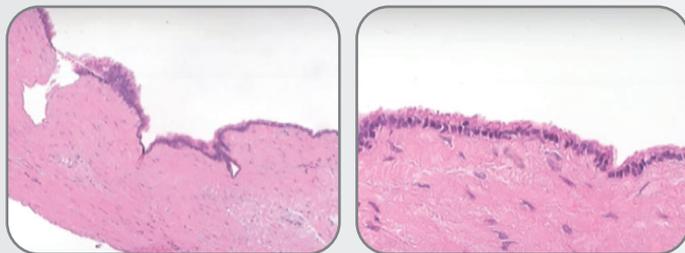
Clinically proven to support the diagnosis of pancreatic cysts...

The Moray micro forceps is designed to acquire reliable tissue samples from pancreatic cysts through an FNA needle, helping lead to a more definitive diagnosis and targeted therapy.

The single-use Moray micro forceps features...

- » Serrated jaws that effectively grab tissue
- » Spring sheath allowing for use in tortuous positions
- » A 0.8 sheath diameter to fit through most 19 gauge FNA needles

61 PCLs were determined to be mucinous through histologic analysis from the **Moray micro forceps** (53.5%) versus 11 through cyst fluid cytologic analysis with EUS-FNA (9.6%)¹



Photomicrograph of samples collected using the Moray micro forceps.²



For more information on the Moray micro forceps, contact STERIS Endoscopy today.

product number	description	sheath diameter (mm)	jaw diameter (mm)	jaw opening width (mm)	working length (cm)	units/box
BX00711889	Moray micro forceps	0.80	0.76	4.3	230	3

made in the USA This product is manufactured in the U.S.A.

¹ D. Yang, A. Trindade, P. Yachimski, P. Benias, J. Nieto, A. Manavar, S. Ho, A. Esnakula, A. Gamboa, A. Sethi, A. Gupte, H. Khara, D. Diehl, A. Chafic, J. Shah, C. Forsmark, P. Draganov. "Histologic Analysis of Endoscopic Ultrasound-Guided Through the Needle Microforceps Biopsies Accurately Identifies Mucinous Pancreas Cysts." *Clinical Gastroenterology and Hepatology*. 2019. 17 (8): 1587-1596.

² A. Larghi. Case Report: Moray micro forceps. On file at US Endoscopy

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Moray® micro forceps Case Report Series • Report 5

Dr. Stephen Kim | Clinical Instructor of Medicine | Division of Digestive Diseases | David Geffen School of Medicine at UCLA | Los Angeles, California



Procedure:

Endoscopic Ultrasound (EUS) with fine needle aspiration and tissue acquisition using the Moray micro forceps.

Indications:

A 54-year-old man had an incidental finding of a pancreatic cyst in the tail of the pancreas on a CT scan. Subsequent Magnetic resonance cholangiopancreatography (MRCP) revealed a 2.5cm cystic lesion in the tail of the pancreas with mural enhancement of the walls. EUS was performed for further evaluation.

Treatment:

A 2.6 x 2.4cm anechoic, well-demarcated cyst with a few septations was seen in the tail of the pancreas. The cyst wall was unusually thickened measuring up to 2.8mm in maximum thickness. The main pancreatic duct was non-dilated, and there was no clear communication seen between the cyst and main pancreatic duct. The cyst underwent fine needle aspiration with a 19-gauge FNA needle with about 5cc of thin, slightly pink colored, clear fluid. The cyst fluid was sent for carcinoembryonic antigen (CEA), amylase, and cytology. After injection of 5cc of normal saline back into the cyst, the Moray micro forceps was passed through the FNA needle and two biopsies of the thickened cyst wall were performed.

The cyst fluid analysis showed a CEA of 1.6ng/mL and amylase of 74U/L. Cytology was paucicellular and non-diagnostic. The microscopic results from the cell wall biopsies showed clusters of monotonous cells with round nuclei and smooth nuclear contours which stained positive for chromogranin. The findings were consistent with a neuroendocrine tumor.

Conclusion:

"I could not have made the diagnosis in this patient without the ability to biopsy the cell wall of the pancreatic cyst using the Moray [micro forceps]."

- DR. STEPHEN KIM

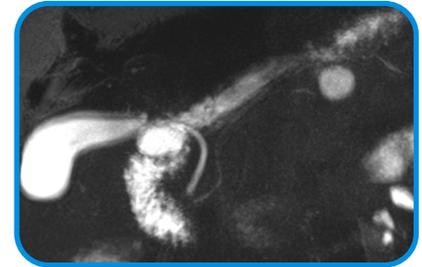


Figure 1:
MRCP image of the pancreatic cyst in the tail of the pancreas

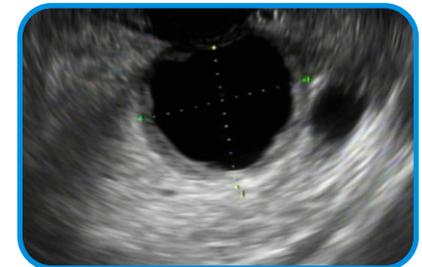


Figure 2:
EUS image of the pancreatic cyst



Figure 3:
EUS image of the Moray micro forceps obtaining a biopsy of the cell wall

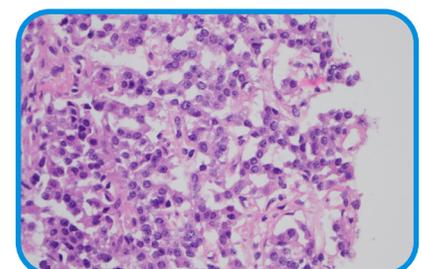


Figure 4:
Microscopic view of the cyst wall

ERCP Sampling Devices



“Several studies have shown that the use of multiple ERCP tissue sampling techniques in combination can improve the cancer detection rate.”¹

¹Korc, P. and Sherman, S. “ERCP tissue sampling.”
GIE Journal 2016; 84 (4)L 557-571.

An ideal pair, the new **Histoguide® wire-guided forceps** joins the clinically proven **Infinity® ERCP sampling device**. Pairing the two novel devices for a two-tiered, multi-modality sampling approach may help improve diagnostic capabilities and lead to increased sensitivity during ERCP procedures.¹

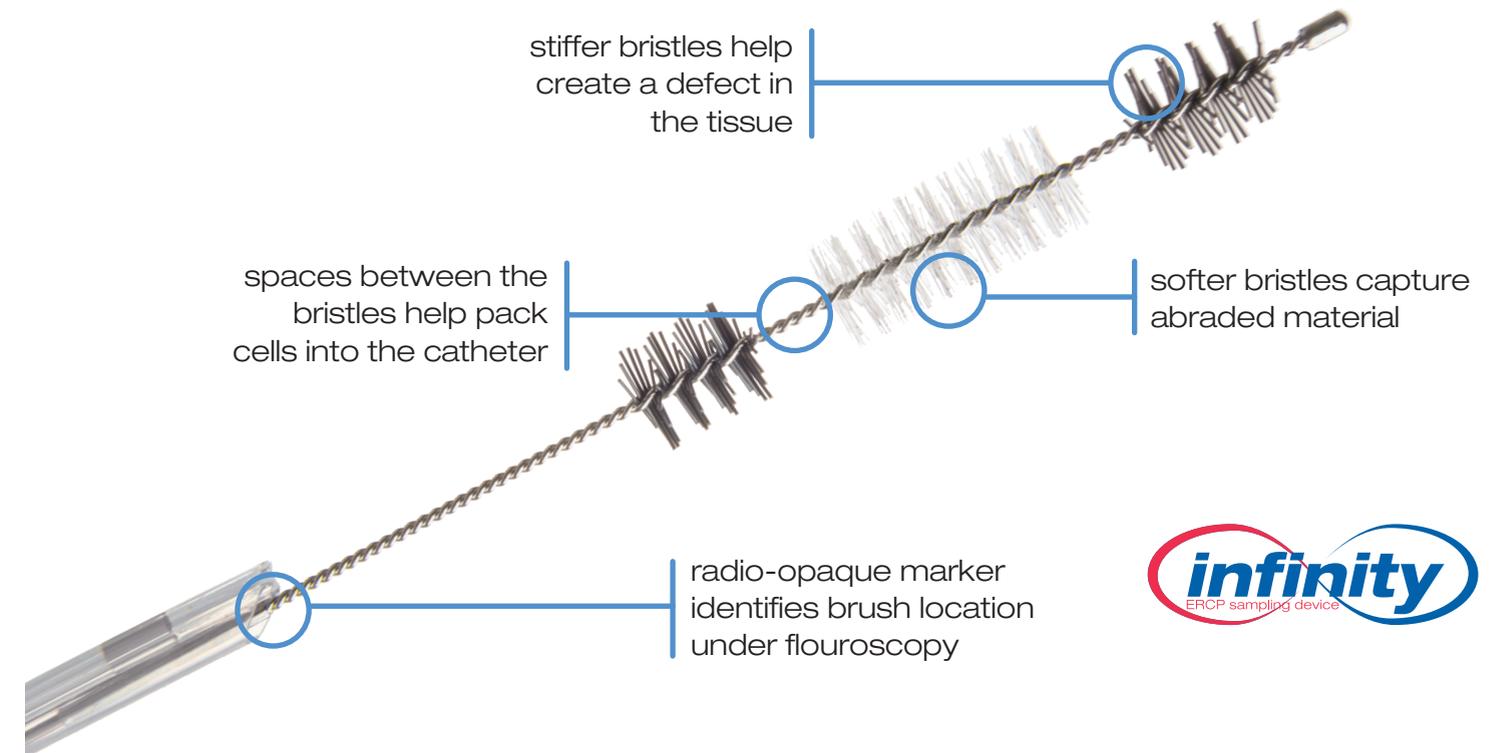
The Histoguide wire-guided forceps...

offers safe and effective placement of forceps into the biliary ductal system along a guidewire to facilitate stricture diagnosis.



The Infinity ERCP sampling device...

is proven to be an extremely effective biliary cytology brush delivering a diagnostic sensitivity of up to 85%.²



For more information on our ERCP portfolio, visit www.steris.com.

¹Korc, P. and Sherman, S. "ERCP tissue sampling." GIE Journal 2016; 84 (4)L 557-571.

²T. Barrioz, M. Wangermes, P. Levillain, M. Beauchant. The Infinity® brush improves the results of brush cytology for malignant biliary strictures. Societe Nationale Francaise de Gastro-Enterologie (SNFGE). <http://www.snfge.org/jfhod2013/7407.html> [25-4-2013 10:13:01]

Histoguide® wire-guided forceps

product number	description	catheter diameter (mm)	wire-guided diameter (mm)	minimum channel (mm)	jaw opening width (mm)	jaw diameter (mm)	length (cm)	units/box
BX00711660	Histoguide wire-guided forceps*	2.1	3.5	4.2	8.0	2.2	230	5

*Compatible with a .035" guidewire.

Infinity® ERCP sampling device

product number	description	sheath diameter (mm)	length (cm)	sterile	units/box
BX00711652	Infinity ERCP sampling device*	3 / 9FR	200	yes	5
BX00711653	Infinity ERCP sampling device*	2.5 / 7.5FR	200	yes	5

*Compatible with long and short guidewires.

ERCP accessories

product number	description	height (cm)	width (cm)	length (cm)	units/box
BX00711654	Boost® head positioner	9.5	19	23	5
product number	description	dimensions		pouch dimensions	units/box
BX00711750	Mio® medical device organizer	~86cm x ~76cm		~25cm x ~28cm	20



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Clinical Literature Summary for the:

**Infinity[®] ERCP
sampling device**



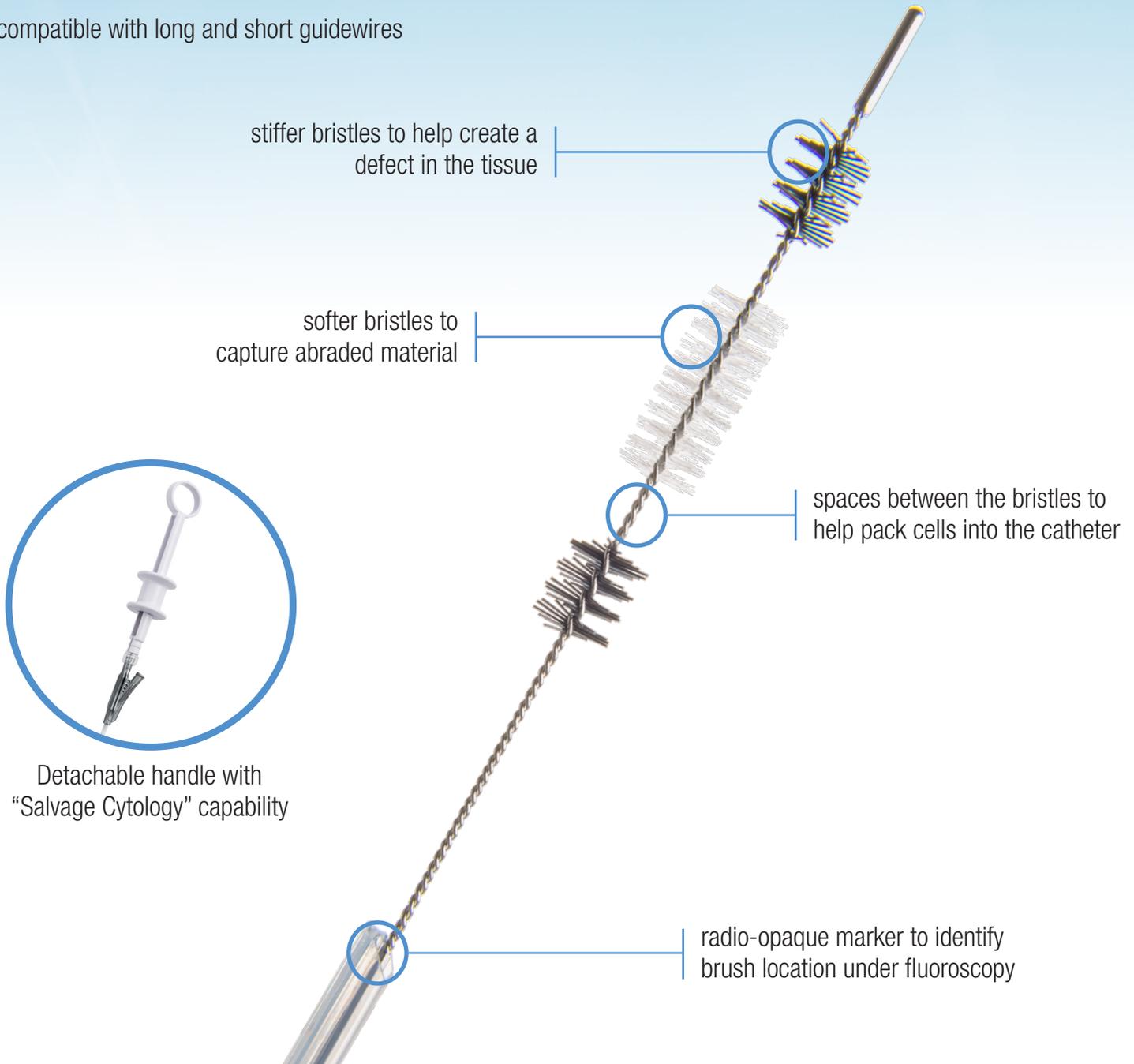
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Infinity ERCP sampling device - Collecting Quality Samples During ERCP

The Infinity ERCP sampling device is purpose built for collecting substantial and quality samples from strictures in the biliary duct.

The Infinity device features...

compatible with long and short guidewires



Indications for Use:

The Infinity ERCP sampling device is intended to be used to retrieve cytological cell samples in the gastrointestinal tract.

Agreement Between Endoscopic Ultrasound-Guided Fine-Needle Aspiration and Endobiliary Brush Cytology in Suspected Pancreaticobiliary Malignancies

Matthew J. Sullivan, Hope Kincaid, Shashin Shah, Hiral N. Shah, 2017²

Device	Patients	Sample Adequacy	Sensitivity
Infinity ERCP sampling device	n=41	97.6%	84.0%
EUS-FNA*	n=41	80.5%	80.8%

Study Details

- **Purpose:** Investigate whether Infinity ERCP sampling device's brush design would provide more adequate samples and have high agreement with EUS-FNA in patients who underwent both procedures.
- **Background:** A retrospective chart review was conducted of all patients who underwent both EUS-FNA and endobiliary brush cytology for suspicion of pancreaticobiliary malignancy from January 2013 to May 2015.
- **Method (Brushing Technique):**
 - » Strictures were brushed using a minimum of seven up-and-down motions before removing the brush and catheter.
 - » Obtained cells were collected in cytology solution along with the brush head.
 - » The catheter was then flushed into the same solution and submitted for interpretation by a group of in-house multidisciplinary pathologists with gastroenterology experience.
- **Results:**

	Infinity ERCP sampling device		EUS-FNA	
	Atypical Negative	Atypical Positive	Atypical Negative	Atypical Positive
Sensitivity, % (95 %CI)	60.0 (38.7 - 78.9)	84.0 (63.9 - 95.5)	69.2 (48.2 - 85.7)	80.8 (90.7 - 93.5)
Specificity, % (95 %CI)	93.3 (68.1 - 99.8)	66.7 (38.4 - 88.2)	100 (71.5 - 100)	81.8 (48.2 - 97.7)
PPV, % (95 %CI)	93.8 (69.8 - 99.8)	80.8 (60.7 - 93.5)	100 (81.5 - 100)	91.3 (72.0 - 98.9)
NPV, % (95 %CI)	58.3 (36.6 - 77.9)	71.4 (41.9 - 91.6)	57.9 (33.5 - 79.8)	64.3 (35.1 - 87.2)
Cancer detection rate	57.7%	80.8%	69.2%	80.8%

PPV, positive predictive value; NPV, negative predictive value; CI, confidence interval. **There was one inadequate brush cytology sample and four inadequate EUS-FNA samples. Therefore, calculations were performed using 40 samples for brush cytology and 37 for EUS-FNA.**

- » There was only a moderate level of agreement between EUS-FNA and biliary cytology samples (Cohen's Kappa; $k = 0.42$, $P = 0.0001$).
- » In three cases – two pancreatic adenocarcinomas and one cholangiocarcinoma – **the Infinity device diagnosed malignancy and EUS-FNA was either negative for malignancy or provided atypical cellularity.**
- » **If brush cytology was not performed, these malignancies may have been missed or additional diagnostic procedures at increased cost and risk of morbidity would have been required.**

Conclusion

*"In conclusion, we found that the **Infinity ERCP sampling device resulted in increased sample adequacy** compared with historical rates of brush cytology; this correlates with previous studies of this brush."*

"If the Infinity ERCP sampling device truly increases sample adequacy it could potentially provide results comparable to EUS-FNA at a lower cost."

* FNA samples were obtained using a 22 or 25 gauge of the following needles: EchoTip FNA needle, EchoTip ProCore FNB system (Cook Medical), or SharkCore FNB system (Medtronic).

Improved Endoscopic Retrograde Cholangiopancreatography Brush Increases Diagnostic Yield of Malignant Biliary Strictures

Frederick K Shieh, Adelina Luong-Player, Harshit S Khara, Haiyan Liu, Fan Lin, Matthew J Shellenberger, Amitpal S Johal, David L Diehl, 2014³

Device	Patients	Sample Adequacy	Sensitivity
Infinity ERCP sampling device	n=32	n/a	78.1%
Standard wire-guided brush	n=46	n/a	37.0%

Study Details

- **Purpose:** To determine if a new brush design could improve the diagnostic yield of biliary stricture brushings.
- **Background:**
 - » Retrospective chart review was performed of all endoscopic retrograde cholangiopancreatography procedures with malignant biliary stricture brushing between January 2008 and October 2012.
 - » A standard wire-guided cytology brush was used prior to protocol implementation in July 2011, after which, a new Infinity ERCP sampling device (9FR) was used for all cases.
- **Method:**

Historical Control:

 - » Cytology brushing was performed with a standard 8FR wire-guided brush (Cook Medical's Cytomax or Boston Scientific's RX Brush).
 - » 2 passes across the stricture were done.
 - » Smear on slides were prepared, the brush head was then cut off and sent in the cytology transport medium (RPML).

New Standardized Protocol:

 - » All cases were done with Infinity ERCP sampling device and 2 passes were always made of the stricture.
 - » 2 smears were prepared on the first pass (one air dried and one fixed), and the brush agitated in RPML to dislodge cells. The brush was rinsed with water. On the second pass, the brush was cut off into the RPML.
 - » Salvage cytology was also done by injecting 5mL of RPML through the brush catheter after brushing was completed. The 2 slides and the tube of the RPML were submitted, and a cell block made.
- **Results:**
 - » All specimens were reviewed by blinded pathologists who determined whether the sample was positive or negative for malignancy.

	Infinity ERCP sampling device	Standard Wire-Guided Brush
Pancreatic adenocarcinoma	17/23 (73.9%)	6/20 (30.0%)
Cholangiocarcinoma	7/7 (100%)	8/22 (36.4%)
Other malignancies	1/2 (50.0%) 2 Gallbladder	3/4 (75.0%) 2 Gallbladder, 1 Colorectal, 1 Unknown Primary

Conclusion

There was an increased diagnostic yield of brush cytology of these malignant biliary strictures in the new protocol group as compared to the historical controls ($P = 0.0003$).

*"The use of a **new brush design for brush cytology of biliary strictures shows increased diagnostic accuracy**, likely due to improved cellular yield, as evidenced by an increase in number of cellular clusters obtained."*

The Infinity Brush Improves the Results of Brush Cytology of Malignant Biliary Strictures

Thierry Barrioz, M. Wangermez, P. Levillain, M. Beauchant, 2014 ¹

Device	Patients	Sample Adequacy	Sensitivity
Infinity ERCP sampling device	n=20	n/a	85.0%
Standard wire-guided brush	n=20	n/a	30.0%

Study Details

- **Purpose:** Evaluate, in a prospective randomized controlled study, the efficacy of the Infinity ERCP sampling device.
 - **Background & Methods:**
 - » From May to July 2012, patients with suspected malignant biliary stenosis underwent endoscopic retrograde cholangiography with brushing.
 - » Brushing was performed with either an Infinity brush or a Standard wire-guided brush.
 - » 2 passes were made each device.
- Sample Processing Technique:
- » A smear was prepared from the sample.
 - » The brush was then placed into a tube of formalin and subjected to centrifugation.
 - » The resulting pellet was immersed in paraffin wax.
 - » The smear and cell block were then submitted to the pathology lab.
 - » The confirmation of the malignant nature of the stenosis and histological types that were collected by brushing were confirmed either by EUS punctures or biopsies per cholangioscopy.

- **Results:**

	Infinity ERCP sampling device	Standard Wire-Guided Brush
Location of stricture		
Proximal bile duct	10	9
Distal bile duct	8	9
Left hepatic duct	1	2
Secondary branch IHD	1	0
Suggested Diagnosis		
Cholangiocarcinoma CBD	13	11
Pancreatic cephalic cancer	7	9
Positive Diagnosis	85.0%	30.0%

Conclusion

*“The new Infinity brush significantly **improves the results of brush cytology of biliary strictures**. The quality of the sample not only confirmed malignancy but in most cases the type of histology of the lesion as well.”*

References:

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