

# Mala Soccalingame

## SpyGlass DS

### Direct Visualization system



# Boston Scientific



**24 MILLION**  
PATIENTS TREATED  
EACH YEAR

100  
COUNTRIES



**100+ COUNTRIES**  
WITH COMMERCIAL  
REPRESENTATION

**\$8.4**

**BILLION**  
IN OPERATIONAL SALES

**R&D**

**\$920 MILLION**  
INVESTED IN R&D

## Our Mission

**Boston Scientific is dedicated to transforming lives through innovative medical solutions that improve the health of patients around the world.**

CARDIOVASCULAR

- Interventional Cardiology
- Peripheral Interventions

RHYTHM  
MANAGEMENT

- Cardiac Rhythm Management
- Electrophysiology

MEDSURG

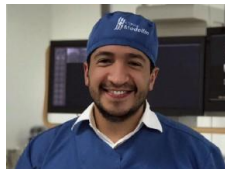
- Endoscopy
- Urology and Pelvic Health
- Neuromodulation

**40**

OFFICES AROUND  
THE WORLD

**27**

THOUSAND  
EMPLOYEES



# SpyGlass™ DS

Direct Visualization System

**Boston  
Scientific**  
Advancing science for life™

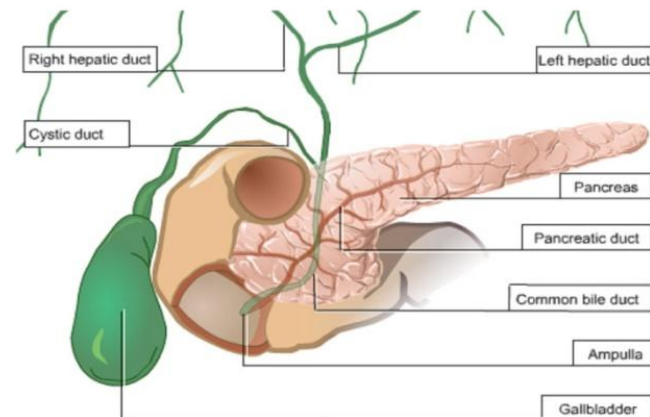
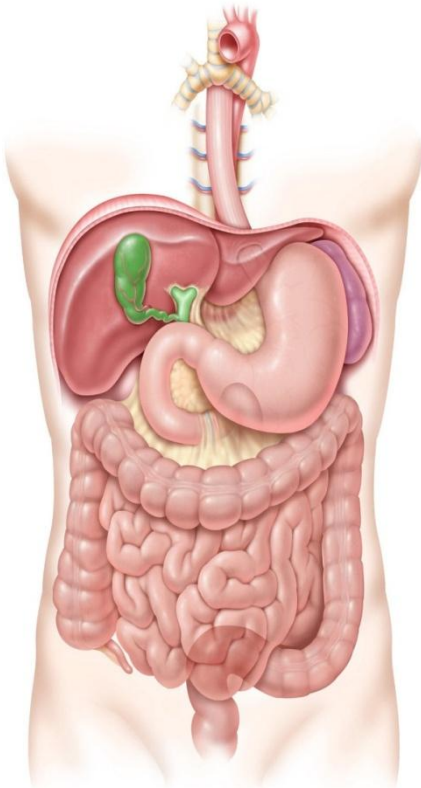
- Biliary system
- Diseases, Diagnostic & Treatments
- History and Development
- SpyGlass animation
- SpyGlass DS Applications
- Literature review

*You're going to  
want to see this.™*



# Biliary system

- Includes the gallbladder, as well the liver and pancreas, to form part of the body's digestive system which is responsible for nutrient absorption and waste disposal.
- Drains waste products from the liver into the duodenum and helps digestion through the controlled release of bile.



# Main diseases of the Biliary System

## □ Gallstones



- When the bile hardens and forms into small pebbles or stones, due, for example, to too much cholesterol.
- They can cause blockages in the [biliary tract](#), leading to inflammation and infection in the gallbladder, the bile ducts, or the liver itself. They can cause painful biliary colic, [obstructive jaundice](#) or [acute pancreatitis](#).

## □ Strictures

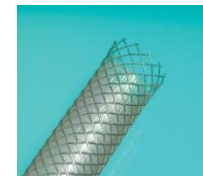
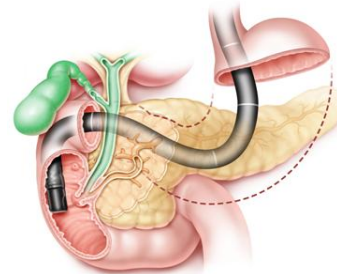


- Cancers of the bile duct and gallbladder are rare and account for ~2% of all cancers. In the UK, 2.4 cases per 100,000.
- 70-80% of strictures are malignant

# Diagnosis and Treatments

## ■ Diagnosis

- Blood tests
- Imaging techniques: Ultrasound, MRCP, CT, Endoscopic UltraSound (EUS)
- Endoscopic Retrograde Cholangiopancreatography (ERCP)
  - Combination of Endoscopy and Fluoroscopy
  - ERCP diagnosis rate for a stricture is low: brushing (45 %), intraductal biopsy (48.1 %) or a combination of both (59.4 %)\*
  - UK: 100,000 ERCP/year



## ■ Treatments

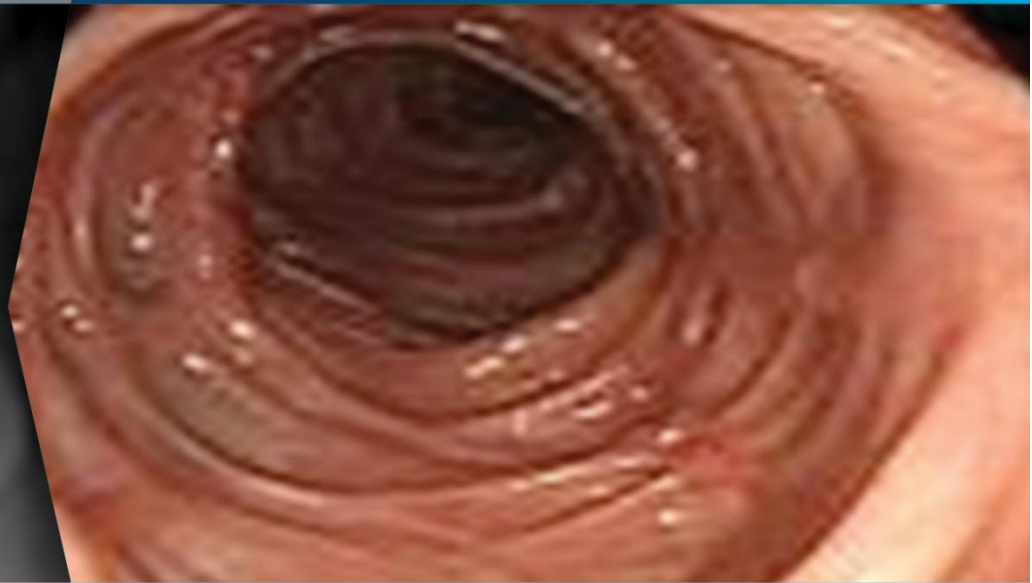
- ERCP
  - 10-15% of the stone cases are considered complex and require repeat ERCP
- Chemo, radiation for cancer
- Surgery

# History and now

BARIUM ENEMA



COLONOSCOPY

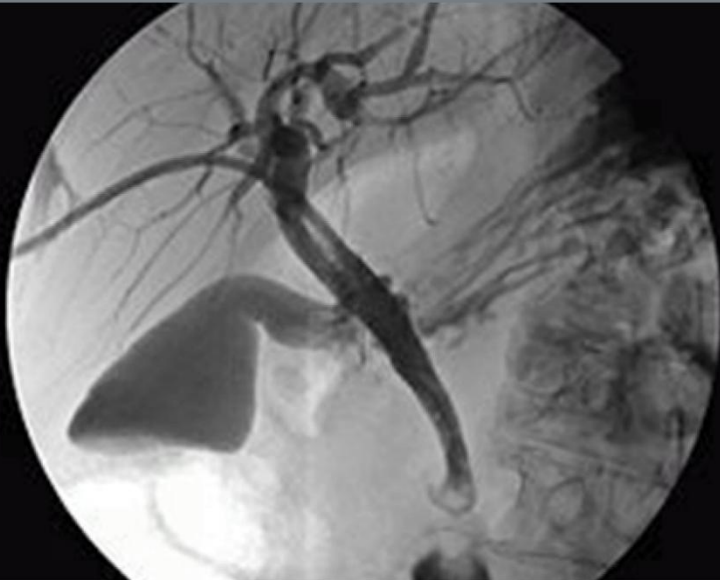


## Colonoscopy BENEFITS OVER Barium Enema:

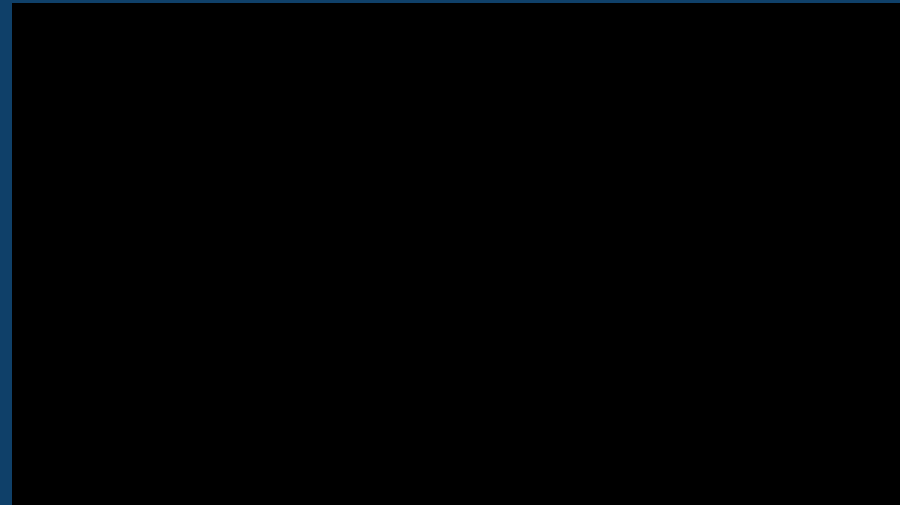
- Increased rates of early diagnosis
- Colon cancer screening protocols developed
- Improves population health management
- Lowers overall patient care costs
- Established GI as a contributor in the hospital

# Now and the future

## CHOLANGIOGRAM



## CHOLANGIOPANCREATOSCOPY WITH **SPYGLASS™ DS SYSTEM**



## Cholangiopancreatography with SpyGlass DS System **BENEFITS OVER Cholangiogram**

- For cancer and complex pancreaticobiliary disease management
- May provide earlier diagnosis for patients
- May reduce “Care Variation” and “Avoidable Care” by reducing number of ERCPs
- Supports population health management
- Potential to lower overall patient care costs

# SpyGlass DS

## Direct Visualization System

- SpyGlass video: product presentation with intraductal animation 3:24mn

# A History of Innovation in Cholangioscopy



1. Yang Chen, MD, et al, GIE, Vol. 74, 2011

Since its launch in 2015, the SpyGlass DS System has impacted more than 50,000 patient lives, and has been used in more than 2,200 hospitals across more than 55 countries.

# SpyScope™ DS II Catheter



SpyScope™ DS II Catheter  
NOT CE MARKED, NOT  
YET COMMERCIALY  
AVAILABLE



# Providing new tools for Cholangioscopy



SpyScope™ with EHL



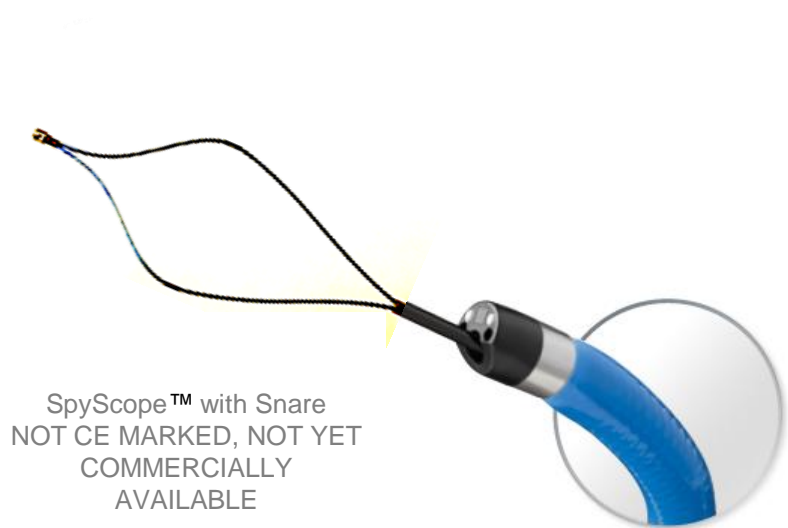
SpyScope™ with Laser



SpyScope™ with SpyBite™



SpyScope™ with Basket  
NOT CE MARKED, NOT YET  
COMMERCIALY AVAILABLE



SpyScope™ with Snare  
NOT CE MARKED, NOT YET  
COMMERCIALY  
AVAILABLE

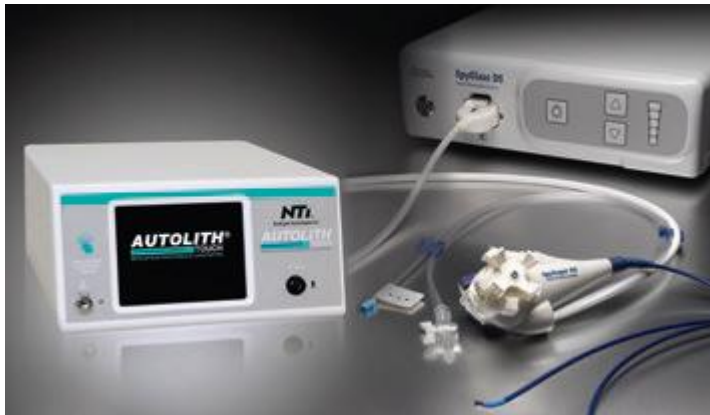
# Literature review

Author	Study	Complete complex stone clearance rate	Accuracy of POC visual diagnosis	Accuracy of histological diagnosis	Adverse event rate
Deprez et al, 2017	The economic impact of SpyGlass: Health economic model applied to stone clearance and diagnosis accuracy results from Laleman 2017 (n=200, 2 hospitals in Belgium)	Using SPyGlass for complex stones decreases the number of procedures -27% and costs -€73 000 or -11% when compared with ERCP	Using SPyGlass for indeterminate biliary strictures decreases the number of procedures -31% and costs -€13 000 or - 5% when compared with ERCP	NA	Deprez et al, 2017
Laleman et al, 2016	1. Single-center prospective cohort study (n=84) 2. Aggregated review of 15 studies (n=851)	1. <b>82,1%</b> with Northgate Autolith iEHL (n=39) 2. <b>88,3%</b> (n=205)	1. <b>82,9%</b> 2. <b>90,8%</b>	1. <b>95,7%</b> 2. <b>84%</b>	1. 21,4% 2. 9,4%
Korrapati et al, 2016	Meta-analysis of 49 studies on POC until December 2014	<b>88%</b> , SOC demonstrating higher technical success rates (P<0.01)	<b>89%</b>	<b>79%</b>	7%
Kurihara et al, 2016	Prospective multicenter study in Japan (n=148)	EHL or LL Biliary <b>74.2%</b> (n=23/31) Pancreatic <b>42.9%</b> (n=3/7)	<b>87.5%</b> (14/16) for IMPN	<b>70.7%</b> (53/75).	5,4%
Navaneethan et al, 2016	Multicenter, observational study of 105 consecutive patients, <b>Digital SOC</b>	<b>97%</b> (n=35/36) <b>86.1%</b> in one session (n=31/36)	Se <b>90%</b> Sp <b>98%</b>	Se <b>85%</b> Sp <b>100%</b>	2,9%*
NICE advice, 2015	9 prospective cohort studies involving a total of 629 people	Chen, 2011: <b>71%</b> (n=297) Draganov, 2011: <b>92.3%</b> (n=24/26)	88% (4 studies)	94% (4 studies)	4.8% to 13.5%, comparable to ERCP for complex procedures

# ExpertCare Service offer

## Boston Scientific Offers You Peace of Mind

- Repair by exchange of defective equipment with ExpertCare contracts
- EverCare includes any new software updrages and yearly checks
- Mediacapture USB-200 video recording devices need a free update to solve a date issue, please contact us.



### SpyGlass™ DS Direct Visualization System

SERVICE PLAN	EVERCARE	ESSENTIALCARE
Unlimited technical support calls	●	●
24/7 access to technical support	●	●
48h delivery of exchange machine	●	●
Unlimited in-house service repair and parts coverage	●	●
Electrical safety check and functional test	●	
Software updates and upgrades during the contract period	●	

### Autolith™ Touch EHL System

SERVICE PLAN	ESSENTIALCARE
Unlimited technical support calls	●
24/7 access to technical support	●
48h delivery of exchange machine	●
Unlimited in-house service repair and parts coverage	●

*"Action without vision  
is only passing time,  
vision without action  
is merely day dreaming,  
but vision with action  
can change the world."*

- Nelson Mandela



Thank you

Questions?

- All images owned by Boston Scientific.
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