

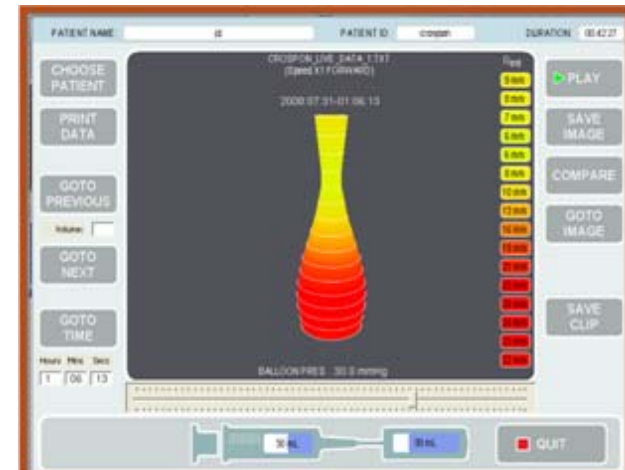
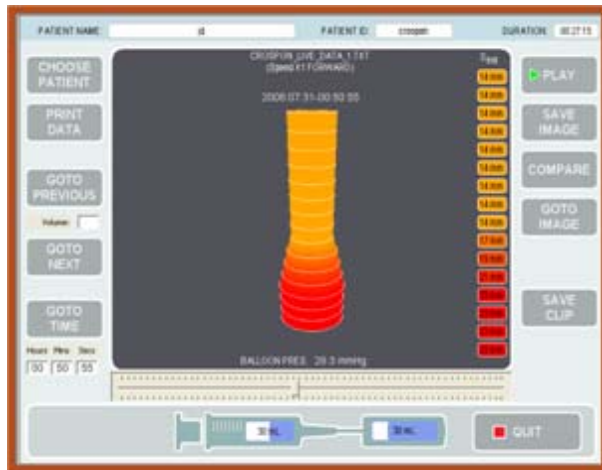
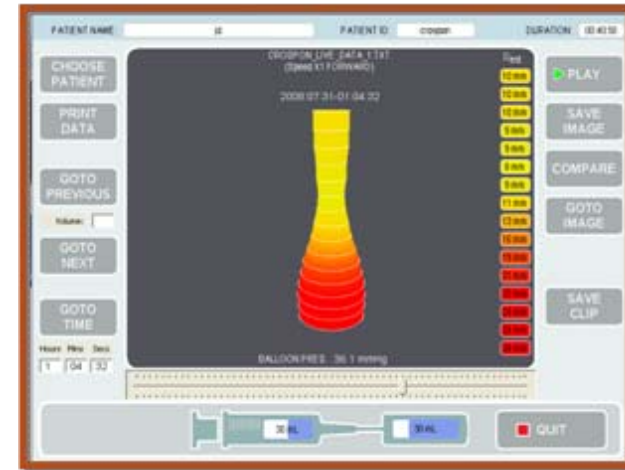
Introducing a new gastrodiagnostic tool, EndoFLIP

**John O'Dea PhD
CEO
Crospon Ltd**

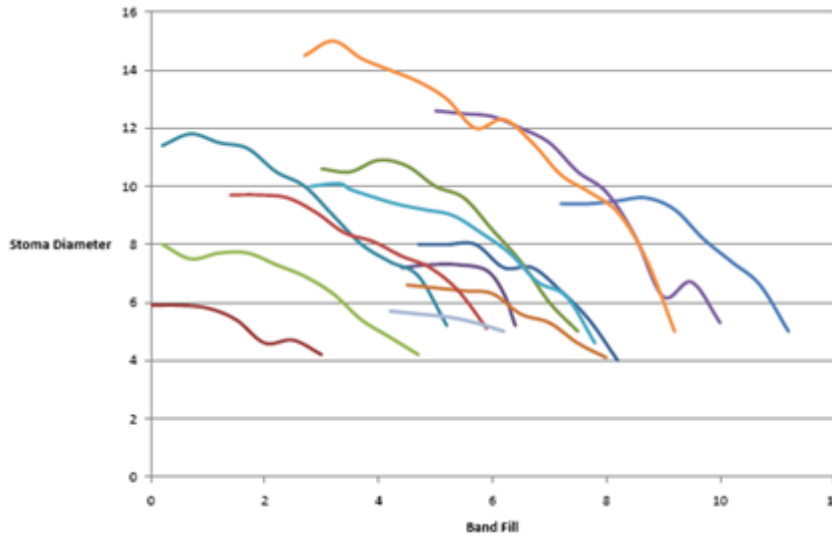
CROSPON

- **Medical Device Company**
- **Founded Nov 2006/ Based in Galway**
- **Gastroenterology/Surgery Focus**
- **Initial IFU**
 - **CE Marked Jan 2009**
 - **FDA 510K approved Dec 2009**
- **Diversifying into other measurement applications**

INTRA-OPERATIVE ASSESSMENT - Nissen



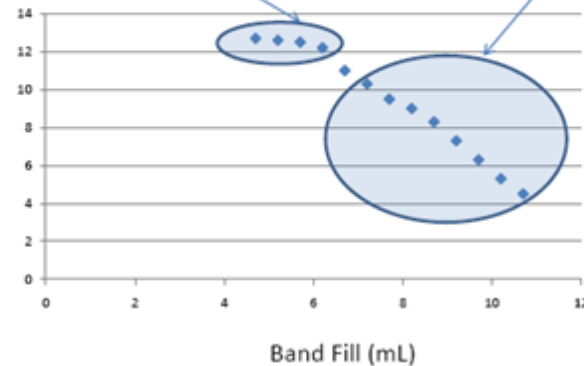
LapBand Adjustment



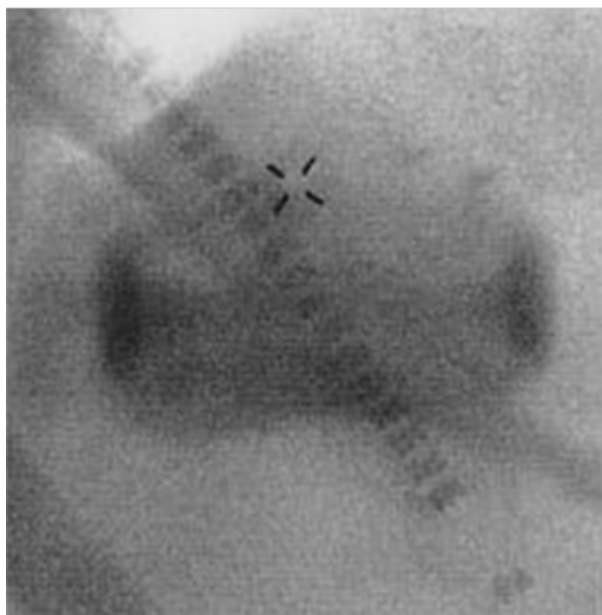
Stoma Diameter (mm)

Band loose –
Band fills here achieve nothing

Band snug –
good adjustment zone



LapBand Adjustment



Name – See Label
Date of Surgery – See Label
APS/APL (Circle)
Male/Female (Circle)
Weight <u>269</u> lb
Height <u>5</u> ft <u>4</u> inches
BMI <u>45.5</u>
Age – See Label

Table A Patient Demographics

EndoFLIP Diameter	Lap Band Fill Volume (ml)
5mm	<u>3.9 cc</u>
6mm	<u>3</u>
7mm	<u>2.8</u>
8mm	<u>1.9</u>
9mm	<u>1.6</u>
10mm	<u>∅</u>
11mm	

Table B Patient Band Adjustment Data

Post Surgery Adjustment Number	Date (yy/mm/dd)	Stoma Diameter (mm)	Lap Band Fill Volume (ml)	BMI	%EWL	Weight (lb)
	Surgery	7	2.8			
1	<u>12/14/09</u>	7	2.8	<u>40.3</u>	<u>24.31%</u>	<u>236</u>
2						
3						

Interim 01/2010: 4.5% improvement in %EWL versus historic controls after 1 month having used EndoFLIP during surgery

Challenges of implementing new technology

- CE mark just gets you on the playing pitch
- Clinical Evidence
- Reimbursement

Clinical Evidence

- Can demonstrate accuracy of measurement
- Why do the measurement ?
- No direct competitor to benchmark
- Trials process for low risk devices
- What is a clinical trial ?

Clinical Evidence – ISO14155

- **Definition**

Clinical investigation

A “systematic investigation in or on one or more human subjects, undertaken to assess the safety and/or performance of a medical device

- **Where does Customer Preference Testing fit ?**
- **New MDD places far greater emphasis on clinical evidence**

Reimbursement

- Clinical evidence is key
 - Can be part of the approval process
 - If not, it needs to be done anyway
 - PMA versus 510k in U.S. ?
- Does the product do a better job for the same price or does it do the same job for lower price or does the product
- Bundle to support another procedure ?

Reimbursement

- **Hard to get serious market traction without reimbursement**
- **Can take up to 2 years**
- **Be careful of conflict in approval and re-imbursement processes**
 - **Equivalence claims**
 - **Predicate code**
 - **Non-inferiority trials v's superiority**
 - **Economic end-points**

