Medistim Capital Markets Day

Hotel Continental, Oslo, Norway

March 8th 2013

Agenda

10:00	**Surgical market trends and opportunities**	Kari E. Krogstad *President & CEO, Medistim ASA*
10:20	**US market adoption**	Howie Milstein, *President Medistim USA*
10:40	**User experience with intraoperative ultrasound imaging**	Dr. Daniel Dohle, *Cardiac Surgeon,* *West Deutsche Heart Center, Essen, Germany*
11:00	**Outlook for blood flow measurement (TTFM)**	Dr. Ian Wilson, *Cardiac Surgeon,* *Queen Elisabeth Hospital, Birmingham*, UK
11:20	**New product development**	Erik Swensen, *Vice President R&D, Medistim ASA*
11:40	**Lunch & minglig**	
12:30	**Close**	

Surgical Market Trends and Opportunities

Kari E. Krogstad
President and CEO

Disclaimer

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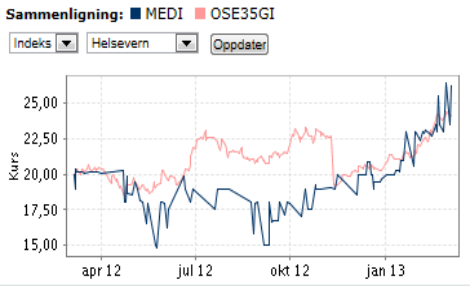
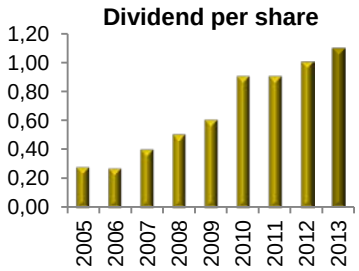
1. Medistim snapshot

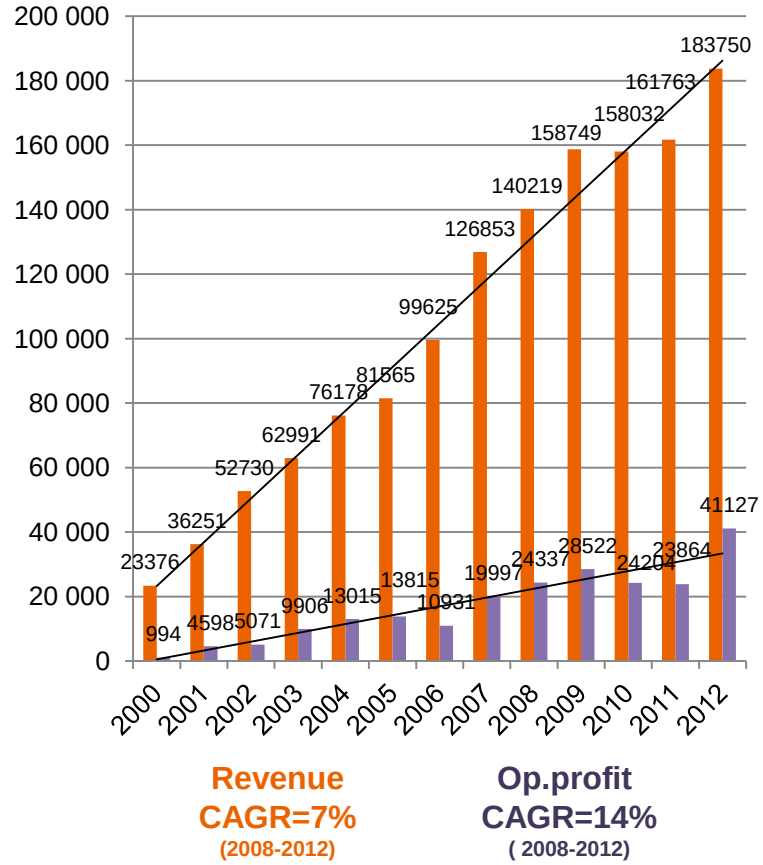
Medistim today

- Innovator and market leader within intra-operative transit time flow measurement (TTFM) and ultrasound imaging
- 78 employees in total, 54 in Norway
- Headquarter in Oslo, manufacturing in Horten
- Sales offices in USA, Germany, Denmark and UK
- Global representation with >50 distributors
- Listed OSE 2004





Revenue and operating profit growth (NOK)



Revenue CAGR=7% (2008-2012)

Op.profit CAGR=14% (2008-2012)

2. Technology and medical need

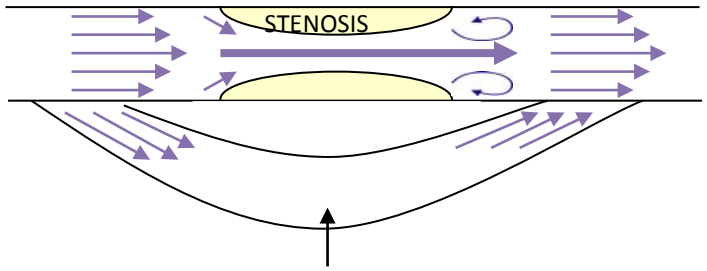
MEDICAL NEED

Our largest target indication is CABG what is coronary artery bypass grafting?

- **Problem**
  Plaque (atherosclerosis) builds up inside arteries due to deposits of fat, cholesterol, calcium

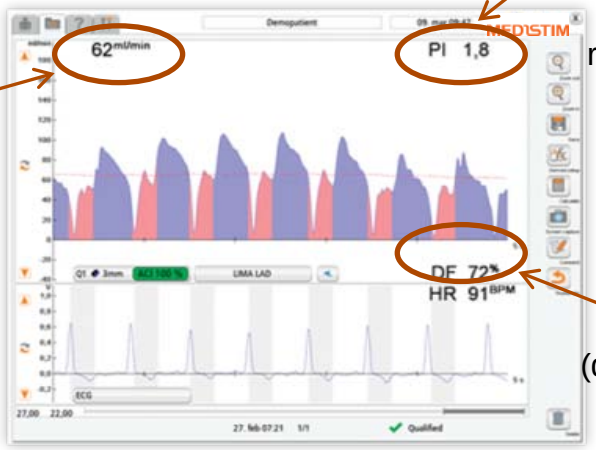
- **Symptoms**
  Reduced blood flow to the heart muscle may lead to chest pain (angina pectoris), heart attack (myocardial infarction), arrhythmias, cardiac arrest

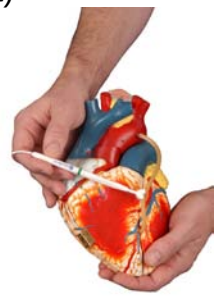
- **Solution**
  During bypass grafting (CABG), a diseased artery is bypassed by a new, harvested vessel (graft)
- CABG is the treatment of choice when a stenosis occludes > 60% of the vessel lumen



PI [≤5]
(pulsatility index)
an indicator of vascular resistance

Mean flow [>15]
(ml/min)





DF% [>50]
(diastolic filling %)

PRODUCTS

VeriQ and VeriQ C for intra-operative quality assessment in cardiac, vascular and transplant surgery

VeriQ™

Transit time flow measurement (TTFM) system

- Designed for intraoperative TTFM during cardiac, vascular and transplant surgery
- Fast, accurate and reproducible method for graft patency verification
- Easy-to-interpret data to assist the surgeon
- Blood flow is measured with sterile probes and a real-time flow curve is displayed together with Mean Flow in ml/min, Pulsatility Index [PI] and Diastolic Filling percentage [DF%]

VeriQ C™

Ultrasound imaging system

- Combines ultrasound imaging and proven TTFM in a single system specifically designed for cardiovascular surgery
- Combines quantitative, functional data [TTFM] with qualitative, morphological data [intra-operative ultrasound imaging]
- Imaging technology improves the quality assessment obtained from TTFM alone

PRODUCTS

Probes are sold as consumables

TTFM probes

- Together with the VeriQ and VeriQ C systems, the probes provide fast, accurate and reproducible measurements of blood volume flow intra-operatively
- Compatible with a range of cleaning and sterilization methods

Doppler probe

- The doppler X-plore probe is used on the surface of the heart/vessel to search for intramural coronary arteries or to locate and quantify the degree of a stenosis
- The X-plore stabiliser makes the velocity measurement on the beating heart easier

High-frequency ultrasound imaging probe

- Used with the VeriQ C system
- Specifically designed for cardiovascular surgery
- High-frequency probe providing excellent resolution in the near-field
- Unique in being approved for direct contact with cardiac tissue

MEDISTIM

MEDICAL NEED

Why verify graft patency in CABG?

- Early postoperative graft failure following CABG is associated with high morbidity and mortality
  - Postoperative major adverse cardiac events (MACE) 5-10%
  - Perioperative (30 days) mortality 2-3%
  - Perioperative stroke 1-5%
  - 12 months re-interventions >5%

- Graft patency verification with TTFM is predictive of outcomes

TTFM { Pulsatility index (PI) ≤ 5 / Flow volume > 15ml/min / Diastolic filling > 50% } ⇨ Patent grafts ⇨ Improved outcomes

- Quality of life for the patients

- ROI for the hospital and reduced health care spending

- Documentation and evidence of surgical performance

3. Market trends and opportunity in CABG

TRENDS

Medical device industry trends and drivers

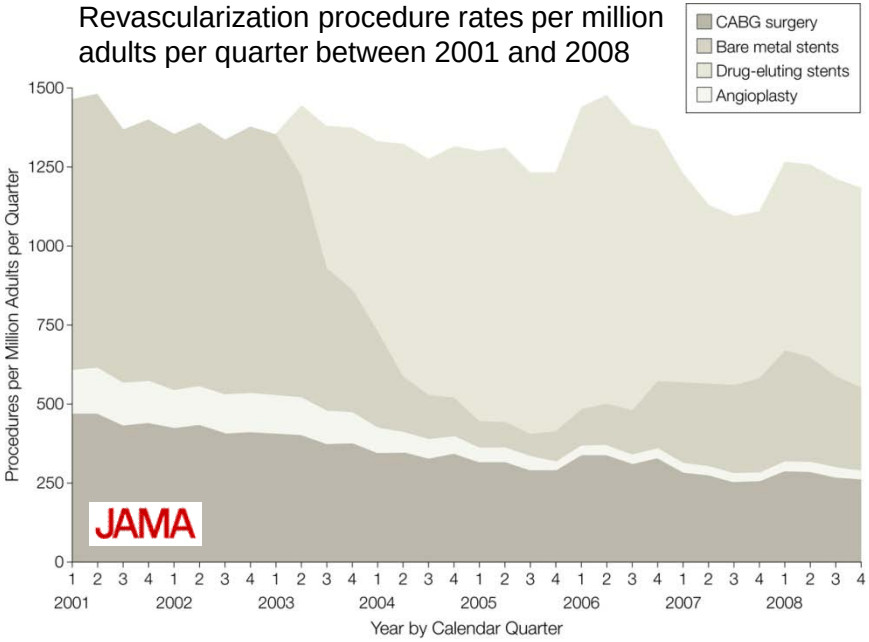
- Even healthcare is sensitive to economic recession
- Health care reforms in many countries
- Purchasing influence and power shift from surgeons to value analysis committees
- Demographics; high growth in population >65 years
- Socio-economic factors in emerging markets (lifestyle, prevalence of heart disease, growing middle class)
- Global harmonization of standards and regulatory requirements continues

TRENDS

CABG market trends

- In the Western world, CABG has seen a downward trend with stenting (PCI) taking share

Revascularization procedure rates per million adults per quarter between 2001 and 2008



Epstein, A. J. et al. JAMA 2011;305:1769-1776

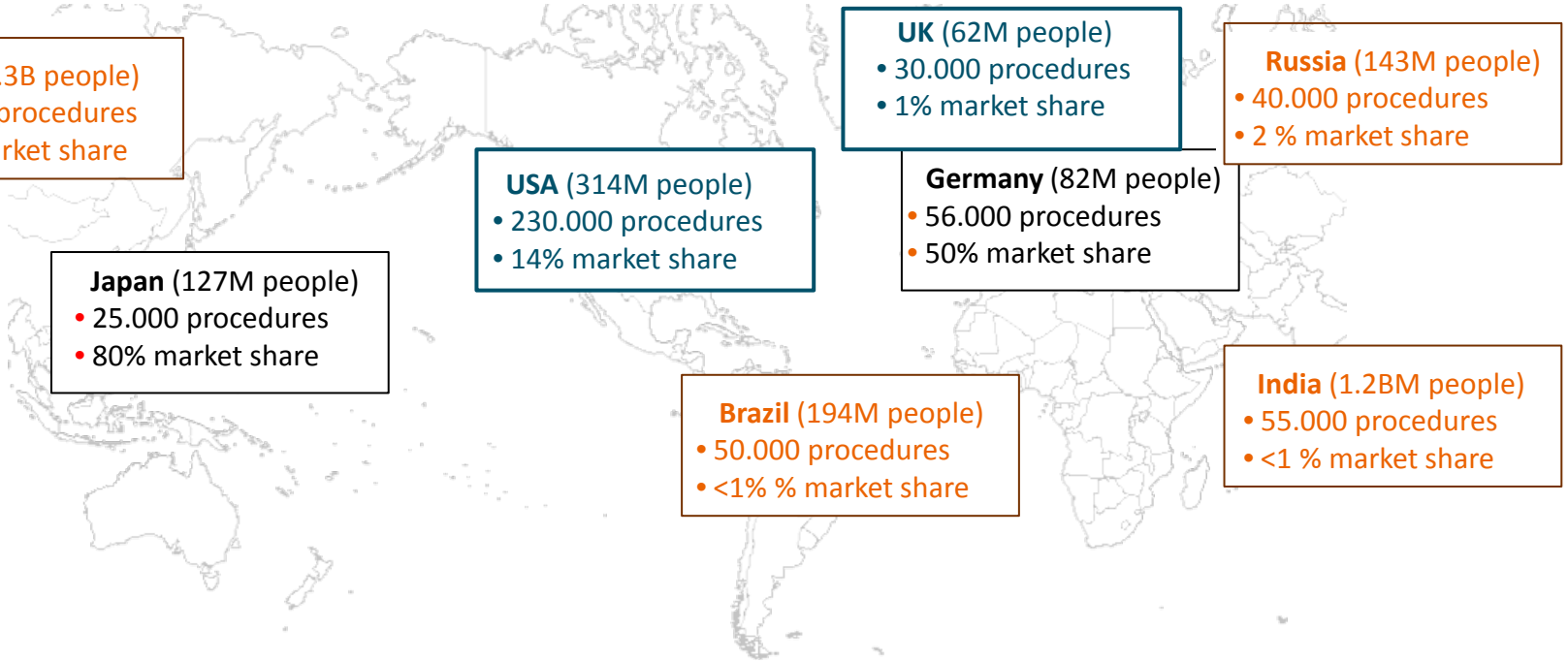
- Turning the trend:
  - Favourable long-term clinical evidence vs PCI
  - High population growth >65 years
- Emerging, high growth geographies
  - BRIC countries

Estimates suggests a growing CABG world market

PCI = Percutaneous coronary intervention
CABG = Coronary artery bypass grafting

OPPORTUNITY

The global CABG market size



GLOBAL MARKET SIZE

- > 700,000 CABG procedures per year (of about 1.5 million open heart surgeries, of which 80% is on-pump)
- Medistim has about 20% global market share
- Market value (TTFM only); NOK 1 Billion
- **Market value (Imaging & TTFM); NOK 2 Billion**

EXECUTING THE STRATEGY

Significant endorsements provide leap towards *standard-of-care*

- 2010: The **European guidelines** on myocardial re-vascularization recommends TTFM during CABG
  - Joint recommendations from the cardiac surgeons (EACTS) and the cardiologists (ESC)
- 2011: UK's National Institute for Health and Clinical Excellence (**NICE**) recommends routine use of VeriQ during CABG within the National Health System
  - *"The VeriQ system is associated with an estimated cost saving of £115 per patient compared with clinical assessment alone, when it is used routinely for assessing coronary artery bypass grafts during surgery."*
- 2011: The **American associations ACCF and AHA** recommended the routine use of epiaortic ultrasound imaging as a reasonable intervention to reduce stroke rate

4. New markets and applications

NEW TARGET MARKETS

Vascular and transplant – and all open heart surgeries

Vascular surgery

- Global peripheral vascular market is estimated to be **> 600 000 vascular procedures** annually, or **> 1 Billion NOK**
- Vascular applications include
  - ✓ Carotid endarterectomies
  - ✓ Femoral bypass surgery
  - ✓ Vascular access for hemodialysis (AV fistulae)
  - ✓ Neurosurgery
  - ✓ Plastic and reconstructive surgery (microvascular flaps)

Transplant surgery

- Adequate graft perfusion is crucial for the success of a liver or kidney transplant
- Liver transplantation is a costly, high-risk procedure with expressed need for quality assessment of the revascularization surgery

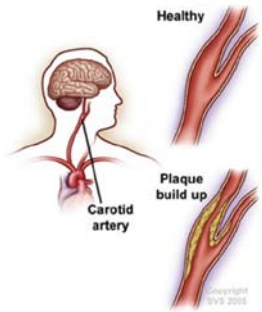
All on-pump open heart surgeries

- In addition to the CABG market, another **640 000 open heart procedures** are done on-pump
- All procedures requiring the use of a CPB machine and connecting it with the aorta, is a target for aorta scanning with VeriQ C
- **Market opportunity ≈ 1 B NOK**

PRODUCT DEVELOPMENT NEEDS

How to win in new application areas?

CAROTID SURGERY



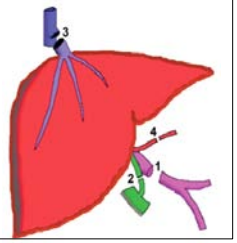
- Evaluate flow pattern after end-arterectomy and detect technical imperfections with imaging
- Unfulfilled needs:
  - Improved probes for a minimal invasive surgery
  - Adapted system user interface

SHUNT SURGERY

- Evaluate quality of anastomosis and monitor flow during creation of AV fistula for dialysis
- German guidelines: "…flow has to be measured intraop…"
- Unfulfilled needs:
  - The ability to measure flow on shunts
  - Adapted system user interface

LIVER TRANSPLANT SURGERY

- "Insufficient perfusion may harm the transplanted liver and even result in a rejection of the organ – evaluation of every graft with TTFM, reduce risk. " (Case Report 2004, Ghent)
- Unfulfilled needs:
  - Ability to detect and visualize deep laying vessels
  - Adapted system user interface

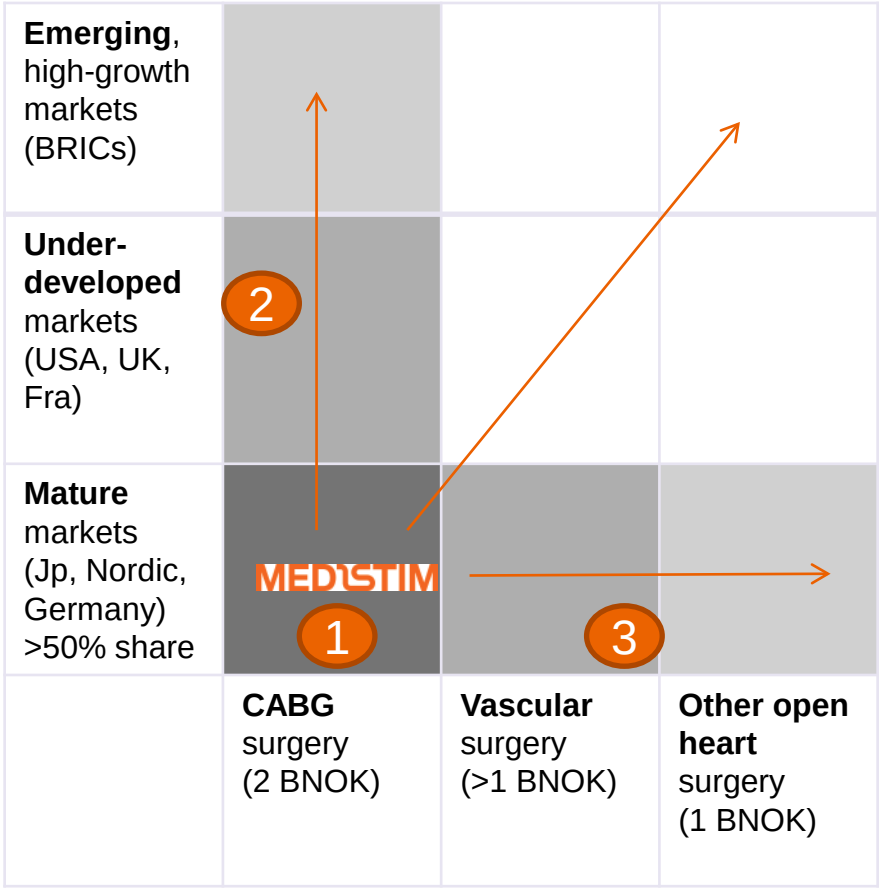


MICROVASCULAR SURGERY – FLAP TRANSFER

- "Operative decisions were modified on the basis of TTFM in 19 out of 52 cases (36.5%) in reconstructive surgery", Dr. Selber, MD Anderson, 2012.
- Unfulfilled needs:
  - Smaller probes

EXPANDING OUR STRATEGY

Strategic directions and priorities



1. Within mature markets for CABG; convert our large installed base of flowmeters to our latest innovation the VeriQ C™

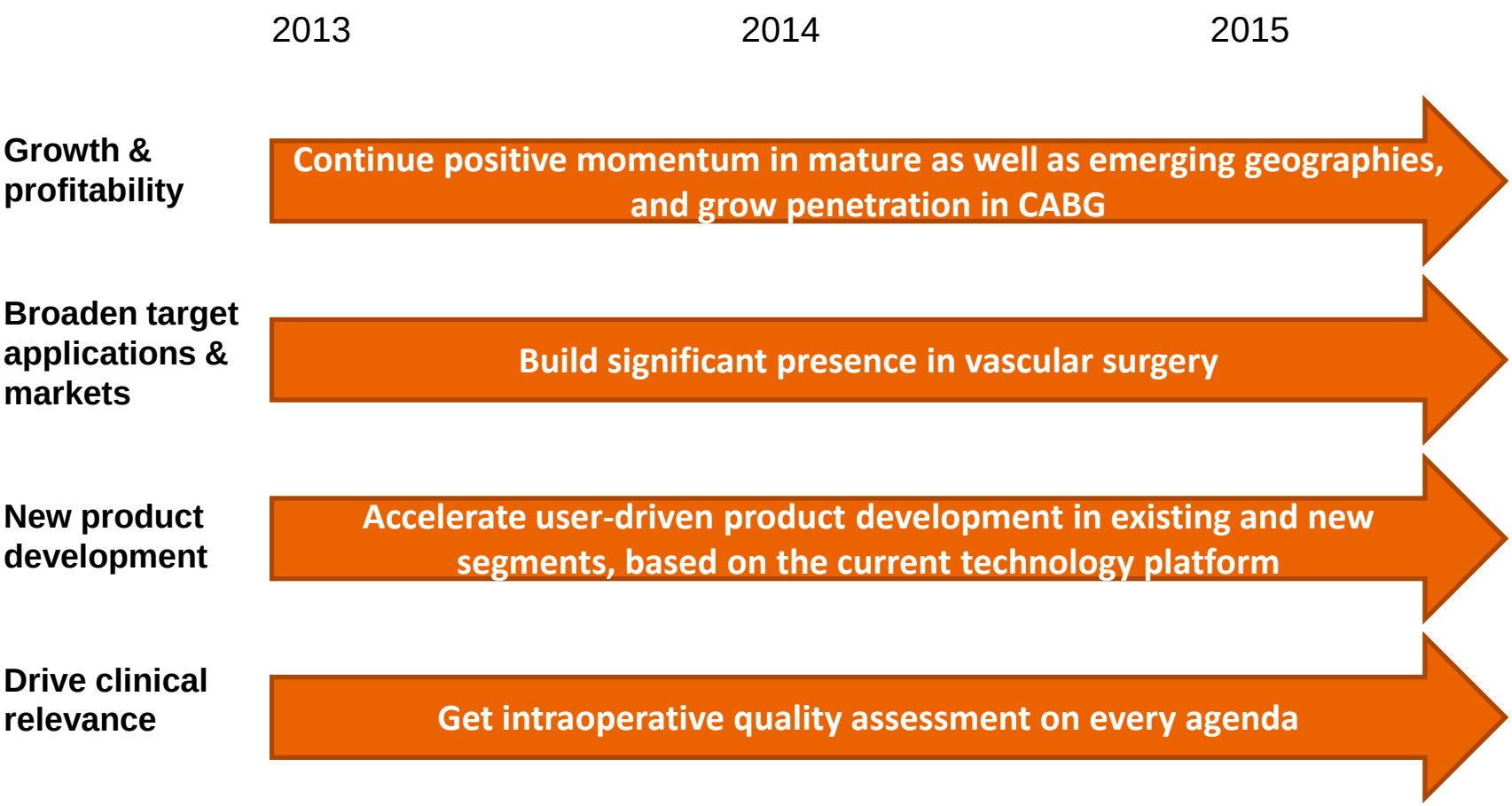
2. Through marketing and **product development**, offer differentiated products and solutions to win new, high- growth geographies for CABG

3. Through **product and applications innovation**, target new segments in vascular surgery and open heart surgery

Doubling market potential

5. Outlook

Outlook – what to expect from us?



Appendix

List of Shareholders

Shareholder	Number of shares	Shares in %	Nationality
FLØTEMARKEN AS	3 810 000	20,78 %	NOR
ZENITH MEDICAL AS	3 364 975	18,35 %	NOR
CHR SALVESEN & CHR T	1 862 500	10,16 %	NOR
SKAGEN VEKST	1 513 625	8,25 %	NOR
BUANES ASBJØRN JOHN	1 303 900	7,11 %	NOR
FOLLUM CAPITAL AS	1 000 000	5,45 %	NOR
SKANDINAVISKA ENSKIL A/C CLIENTS ACCOUN NOM	768 230	4,19 %	SWE
HOLMEN SPESIALFOND	550 000	3,00 %	NOR
STOREBRAND VEKST JPMORGAN EUROPE LTD,	521 454	2,84 %	NOR
ROSLAND BRIGT	271 000	1,48 %	NOR
FONDSFINANS SPAR	250 000	1,36 %	NOR
MEDI-STIM AS	236 000	1,29 %	NOR
NIPPON BXI INC.	226 411	1,23 %	JPN
KRISTOFFERSEN KJELL	203 500	1,11 %	NOR
RBC Investor Service S/A LUX-NON-RESIDENT NOM	200 000	1,09 %	LUX
BLIX RIGMOR HELEN	180 000	0,98 %	NOR
MP PENSJON PK	174 500	0,95 %	NOR
RETIRO AS	150 000	0,82 %	NOR
FONDSFINANS FARMASI-	127 000	0,69 %	NOR
CLIPPER TRADING AS	90 995	0,50 %	NOR
Total 20 largest shareholders	**16 804 090**	**91,64 %**	
Total number of shares outstanding	**18 337 336**		

About Medistim

Launch of 1st generation flowmeter *CardioMed™*

Launch of 2nd generation flowmeter *Butterfly™*

Launch of 3rd generation flowmeter *VeriQ™*

Launch of new paradigm Flowmetry & Imaging *VeriQ C™*

1984 1991 1994 1997 1999 2001 2003 2004 2006 2007 2009 2010 2011

3rd party distribution in Norway

Medi-stim AS founded

Arne Grip starts development of the first flowmeter

510(k) clearance from US FDA

Medtronic distributor in the USA

Listed on Oslo Stock Exchange

Acquiring Kir-Op AS

Direct sales operations in the USA

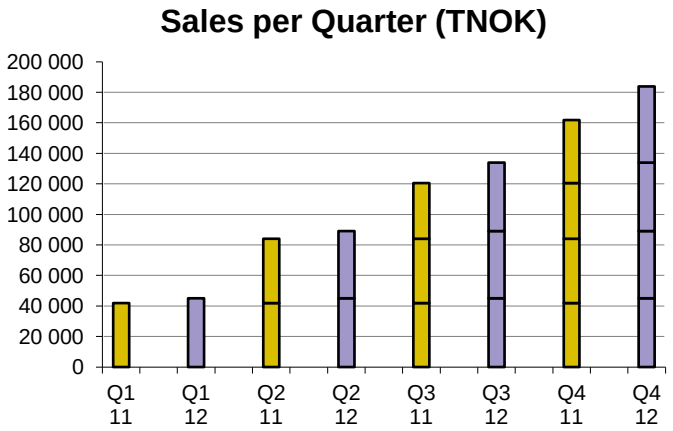
EU Guideline endorsement

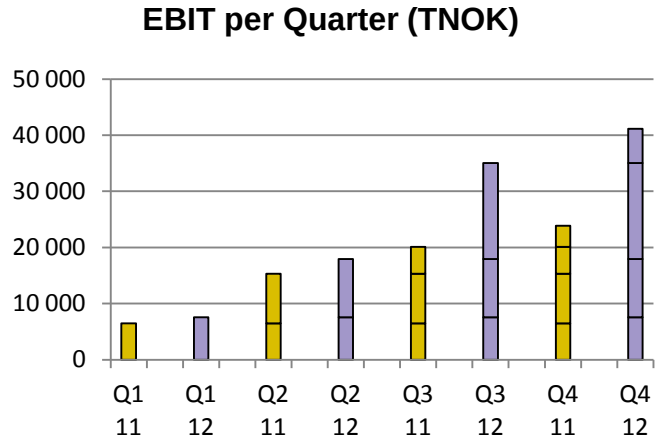
UK NICE endorsement

FINANCIAL RESULTS 2012

Profit and Loss Q4 and 2012

(MNOK)	Q4 2012	Q4 2011	Δ	2012	2011	Δ
Sales	**49.7**	**41.3**	**20.3%**	**183.8**	**161.8**	**13.6%**
GM %	*72.5 %*	*70.9 %*	*1.6 %*	*73.1 %*	*73.9 %*	*-0.8%*
EBIT	**6.1**	**3.7**	**63.4 %**	**41.1** [2)]	**23.9**	**72.3 %**
EBIT%	*12.2 %*	*9.0 %*	*3.2%*	*22.4 %*	*14.8 %*	*7.6 %*
Result	**1.6** [1)]	**2.1**	**-24.5 %**	**30.2**	**15.5**	**95.3 %**



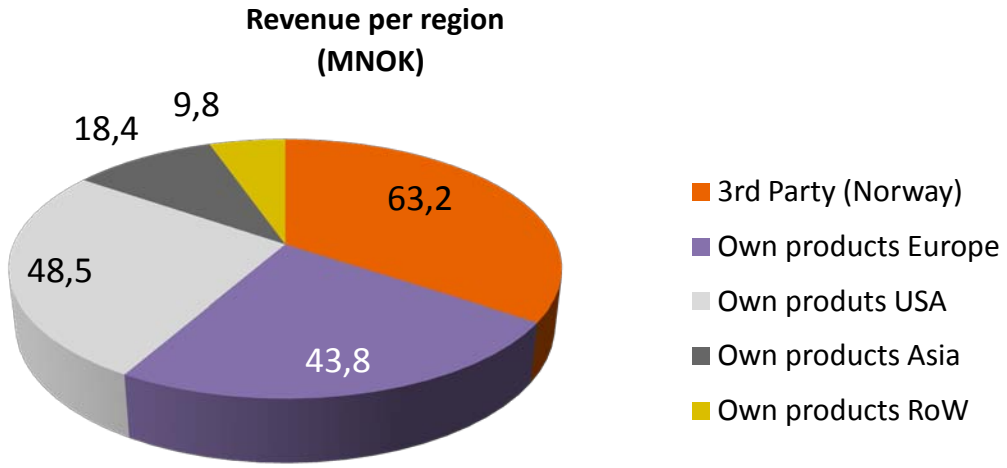


1) *The Q4 result is negatively affected by final tax calculations, compensating for too low tax accruals in previous quarters.*
2) *One-time effect of termination of defined benefit pension plan, resulting in the actuarial pension liabilities ceasing. The liability is recorded as a MNOK 9.3 reduction in salary and social expenses in Q3.*

GEOGRAPHICAL OVERVIEW

USA - the largest market for own products

Total revenue 2012
MNOK 183.8



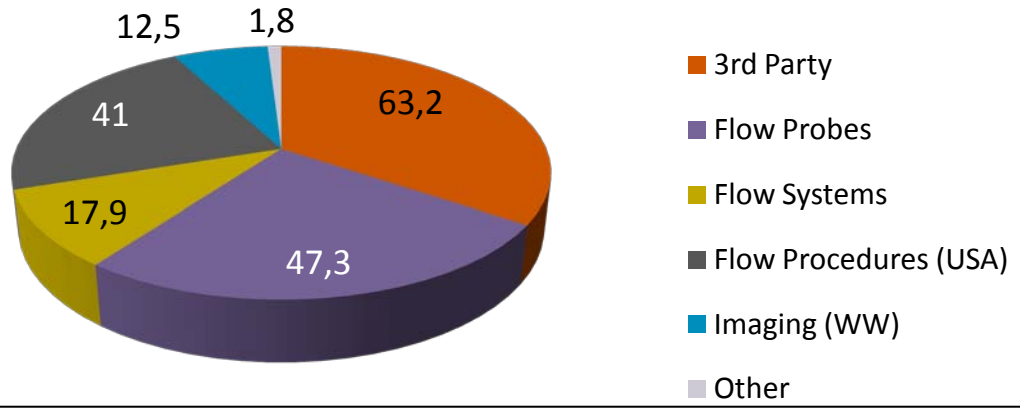
Geographical split of own product sales			
	2010	2012	Change
Europe	43%	36%	- 7 %
USA	37%	40%	+ 3%
Asia	12%	15%	+ 3%
RoW	8%	8%	

PRODUCT SEGMENT OVERVIEW

Imaging make up 10% of own product sales

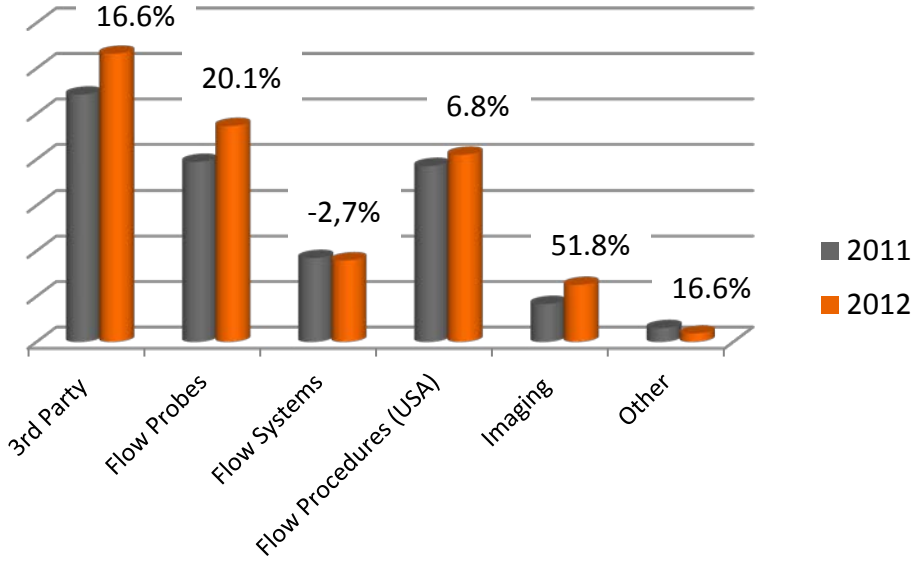
Revenue (NOK) per segment:

Total revenue 2012
MNOK 183.7



Growth (NOK) per segment:

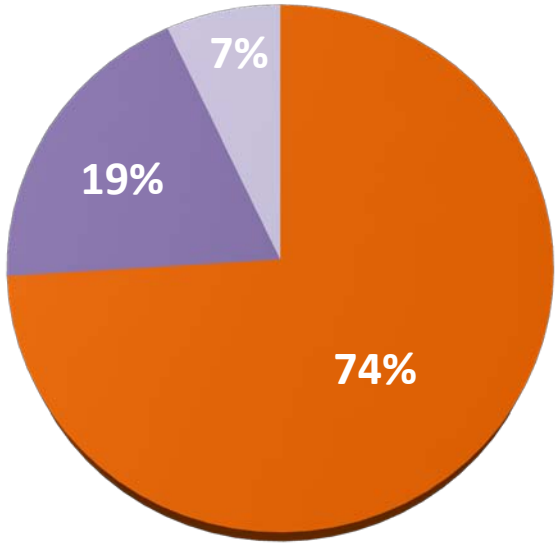
Total growth 2012
13.7%



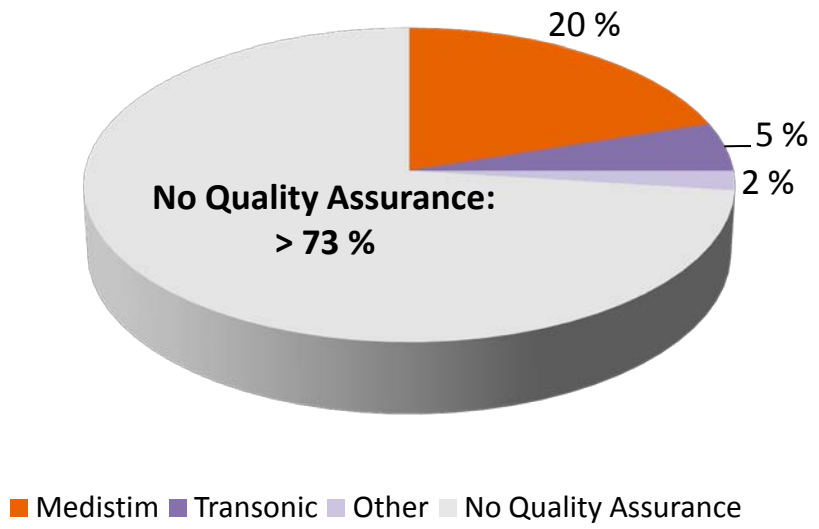
OPPORTUNITY

Main competition in CABG remains to be the surgeon's finger palpation

SHARE OF THE PENETRATED MARKET

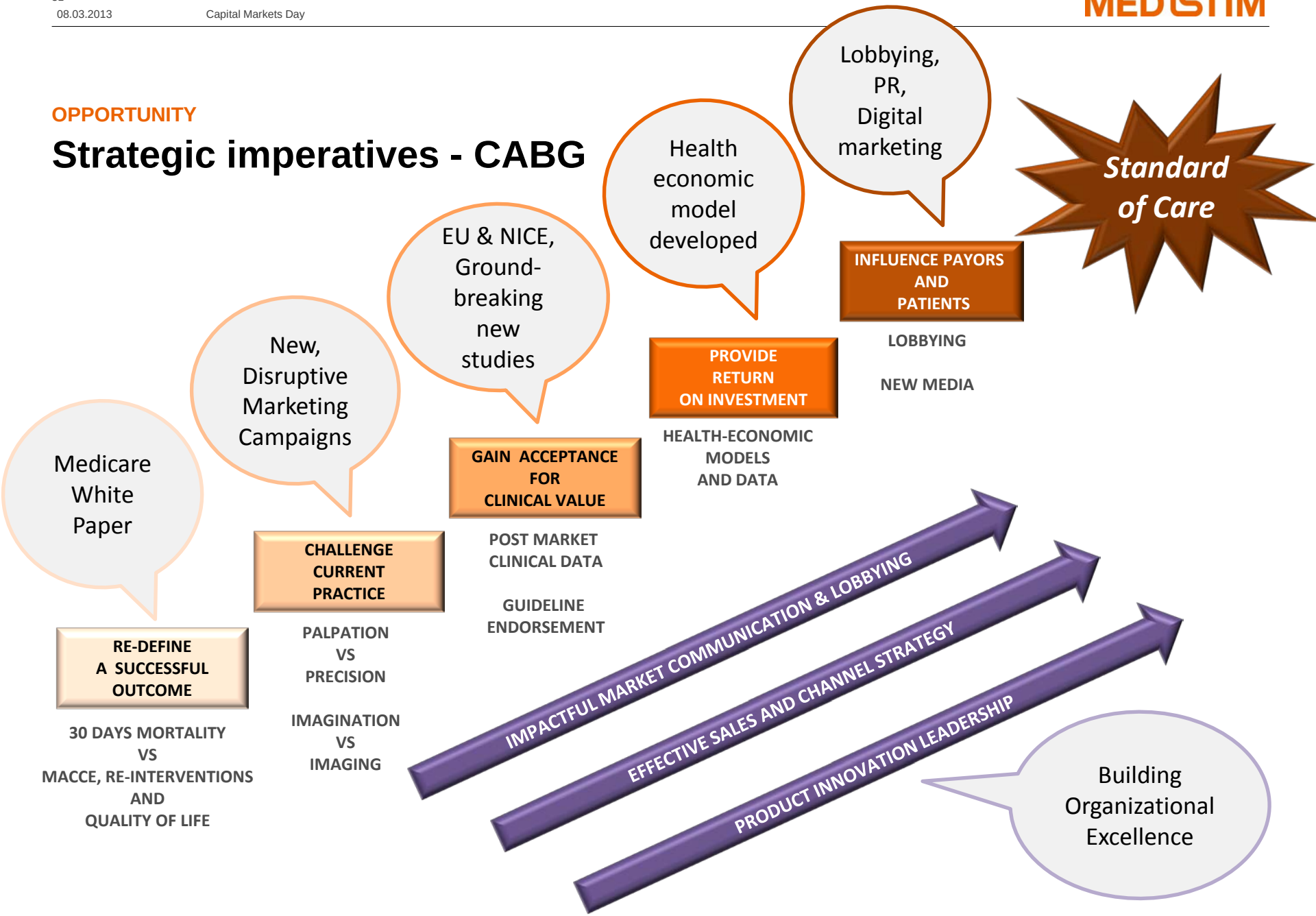


MARKET PENETRATION



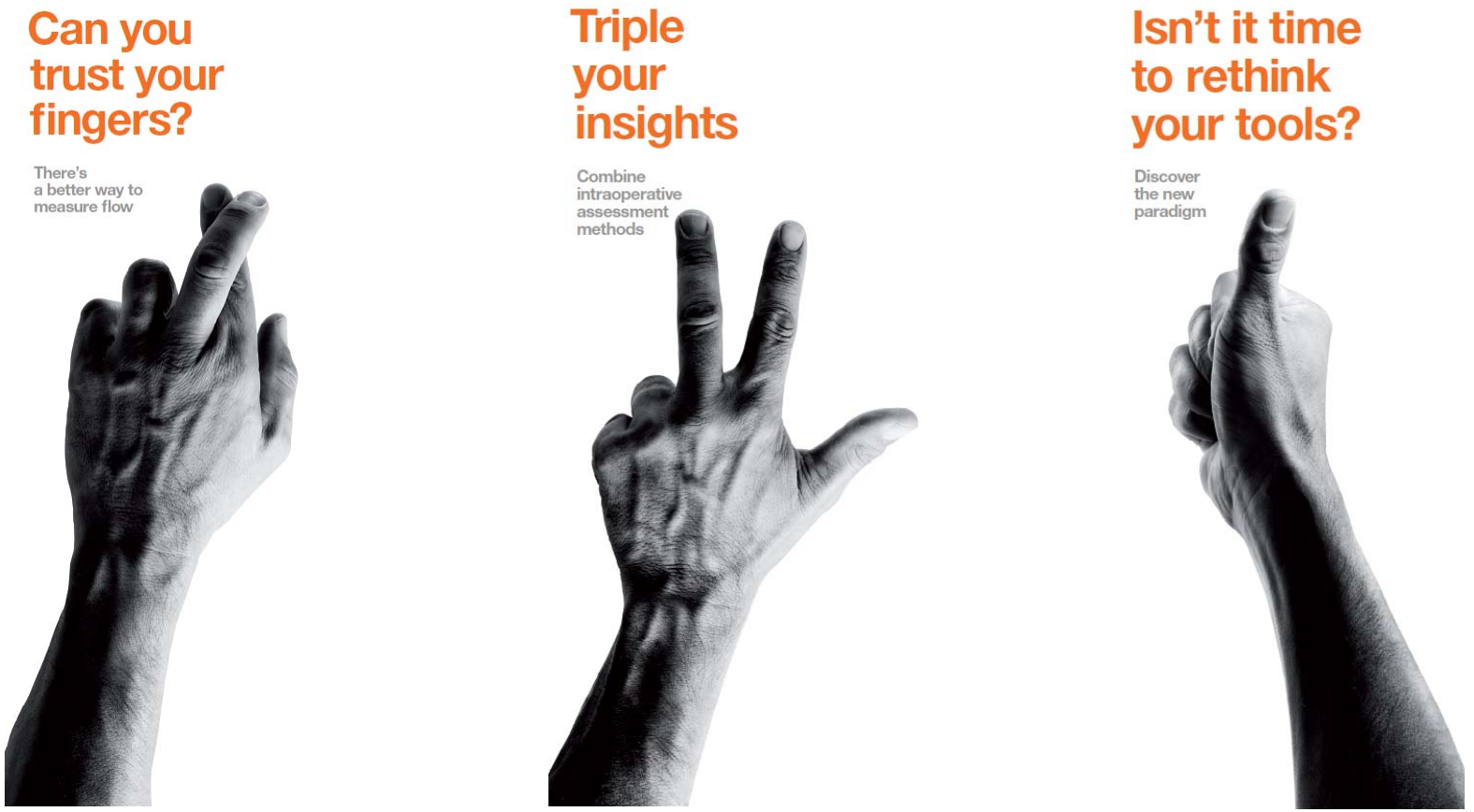
OPPORTUNITY

Strategic imperatives - CABG



EXECUTING THE STRATEGY

Challenging the current practice with new marketing messaging



Seeing is believing

Capital Markets: United States Market

Howie Milstein, President, Medistim USA

March 8, 2013

Market Overview

- U.S. economic considerations
- Influence of healthcare on overall economy
- Affordable Care Act (Obamacare)
- Medistim’s market
- Prognosis for Medistim in the U.S.

U.S. Economy

- Projected budget deficits (by the CBO, Congressional Budget Office)
  - 2013: $845 billion
  - 2014: $646 billion
  - 2015: $459 billion
  - Projected to rise again as Baby Boomers retire and claim Medicare and Social Security benefits
- Debt is currently > $16 trillion
- Healthcare costs cited as single greatest contributor to the rising debt and deficit spending

- Conclusion – Managing healthcare will most profoundly control the deficit and debt

Affordable Care Act

- Signed into law March 23, 2101, upheld by Supreme Court June 28, 2012
- Aimed at decreasing the number of uninsured Americans and reducing overall costs of healthcare
- Comprised of numerous mandates, subsidies and tax credits designed to increase the coverage rate
    - E.g., a 2.3% excise tax on medical device companies to support government healthcare programs.

Future of Healthcare Model

- Currently “Fee-for-Service”
  - Providers conduct a service (treatment, surgery, office visit), and gets paid by private insurance or Medicare
- Moving toward “Pay-for-Performance”
  - Providers get paid for long-term, effective disease management, incentivized by improving outcomes
  - Intention is to increase quality
- National Commission on Physician Payment Reform:
  - “Our nation cannot control runaway medical spending without fundamentally changing how physicians are paid, including the inherent incentives built into the current fee-for-service pay system.”
- The evolution of this model will be very slow, and some cite a goal for payment reform of the end of this decade

U.S. CABG Market

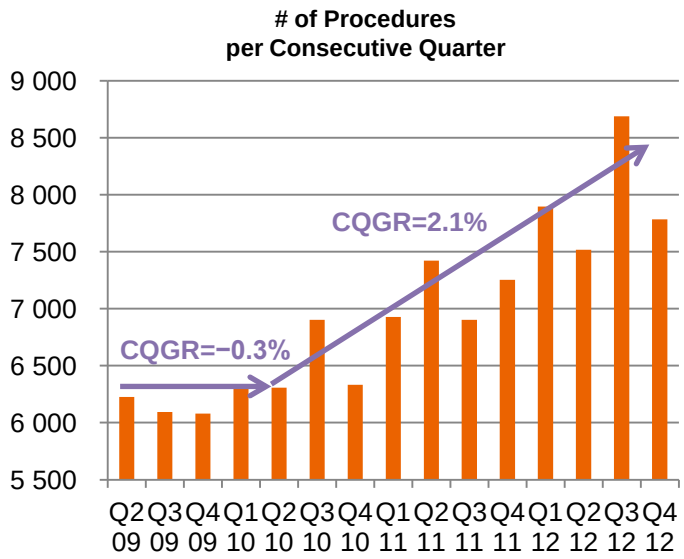
- Now looking more attractive
  - Baby Boomers are hitting 65 years of age
- CABG procedures had been declining 4-5% per year, for the past 8-10 years
  - Seeing some stabilization
    - Not necessarily due to demographics
    - SYNTAX study has compelling evidence favoring CABG over PCI (stenting), at least as interpreted by the cardiac surgery community
    - 5-year results recently published, showing MACCE (major adverse complications) are lower with CABG than PCI
- http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(13)60141-5/abstract

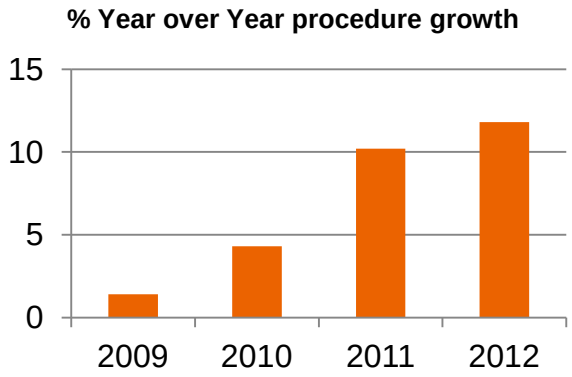
Medistim Growth in U.S.

- Accelerated growth rates in 2011, 2012
- Business model has been stable since leaving Medtronic in January, 2007
- No unintentional sales rep turnover in 6+ years
  - Allows for the development of deeper market awareness, more functional relationships with surgeons
- Market share has grown 40% since going direct (<10% to 14%)

Trend shift in the US market

Trend shift in procedure growth





CQGR=Compound Quarterly Growth Rate

Achieving Standard of Care Within CABG

Leveraging VeriQC

1. VeriQC strategy to add incremental clinical benefits
   - Reduced cerebral emboli (stroke)
   - Assess CABG graft and anastomosis quality
   - Find embedded targets (coronary arteries) in the heart
2. VeriQC strategy to access prospective customers
   - Surgeons curious about our unique delivery system of ultrasonic imaging modality
   - Opportunity to promote TTFM benefits during imaging surgical evaluations

Exploring Parallel Market Opportunities

- Sizable vascular market
  - A-V Access for hemodialysis
    - Type 2 diabetes continues to have explosive growth
  - Carotid endarterectomy
- Reconstructive Microsurgery
  - Subspecialty of plastic surgery
  - Reconstructions procedures due to cancer, trauma
  - “Flap” techniques requiring guidance and blood flow assesment
  - Current collaboration with MD Anderson (Houston) – largest cancer center in the U.S.
    - Very favorable pilot study involving Medistim TTFM
    - Looking at another study protocol, using TTFM

Medistim USA Knows its Customers

- Complicated hospital culture, compromised access to surgeons and other key stakeholders/decision-makers
- Value Analysis process is now virtually standard, often requiring approval prior to starting evaluations
  - Surgeons still critical in the decision-making process, but they lack the autonomy to make unilateral decisions
  - CFO, administration, materials management are powerful
  - Balancing quality and economy is a challenge, priorities are more often financial
- U.S. sales force has acquired specialized Action Selling skills, working to develop disruptive sales techniques to inspire new thinking in the customer base
- Provocative marketing to support sales process

Consultative Selling Process

- No longer “feature and benefit” selling

Patience

- Selling cycle typically runs 6 to 24 months
  - Key is to have a large pipeline
  - U.S. currently has >100 projects in the pipeline
  - 35 new customers in 2012 including VA hospitals

KOL Development

- More surgeons are well versed on telling the Medistim story
- AATS symposium in Minneapolis, May 6, 2013
  - Moderator: Dr. Joseph Sabik, Dept. Chair, Cardiovascular & Thoracic Sugery, Cleveland Clinic

U.S. Based Research

- Needed to help support society (e.g.) endorsement
  - Current discussing with Cleveland Clinic the development of a reference study on CABG outcomes using TTFM

Competition

- Conservative attitudes and the basic human nature to resist change are still greatest obstacles
- Transonic has a strong presence in the vascular market
  - When clinical efficacy is deeply scrutinized, Medistim is first choice
  - Still penetrates CABG market when cost is the primary consideration

U.S. Sales and Marketing Mission

- Challenge the beliefs of stakeholders who do not understand flow and imaging quality assesment
- New marketing campaign: Sweet CABG Dreams
    - (Last year’s was Nightmare on CABG Street)

west-german heart center essen

Epiaortic Imaging rationale and case reports

D.-S. Dohle, K. Tsagakis, W. Wiese, H. Jakob

Dept. of Thoracic- and Cardiovascular Surgery
West-German Heart Center, University Hospital Essen

University Hospital Essen

Structure

- West German Heart Center
- VeriQc rationale and application
- Case report 1: intramural leasion
- Case report 2: floating structure
- Case report 3: ulcerous plaque
- Further applications for intraoperative ultrasound
- TTFM in Essen

West-German Heart Center, University Hospital Essen

West-German Heart Center, Cardiac Surgery Team

H. Jakob, MD, PhD

Head of the Department of Thoracic and Cardiovascular Surger

~ 1500 On Pump operations / year

Conventional Surgery :

CABG (on-, off pump), Heart valves, etc

Essen versus Stroke

In cardiac surgery is the risk for Stroke still present

- CABG 1,6 % *(Tarakji et al, JAMA 2011)*
- CABG 1,2 % *(R.A. Baker, AnnThorac Surg 2005)*
- CABG 2-5 % *(Bucerius et al, Ann Thorac Surg 2003)*
- CABG vs. PCI 2,2% vs. 0.6 % *(Serruys et al, NEJM 2009)*
- Valve /Double valve 4-10% *(Bucerius et al, Ann Thorac Surg 2003)*

Stroke Prevention
Risk Factors Evaluation

- TEE : limited to the proximal ascending aorta

  (distal ascending aorta + arch = not visible)

- Aortic palpation:

  Limitation: < 50% correlation to ultrasonic findings

  (Bolotin et al, Chest 2006)

- CT : limited

  aortic calcification = yes

  soft plaques = no

  floating plaques = no

Stroke Prevention
Additional Tool

VeriQc:

- Epicardial ultrasound system for evaluation of the aorta intraoperatively by the surgeon

Stroke Prevention
Additional Tool

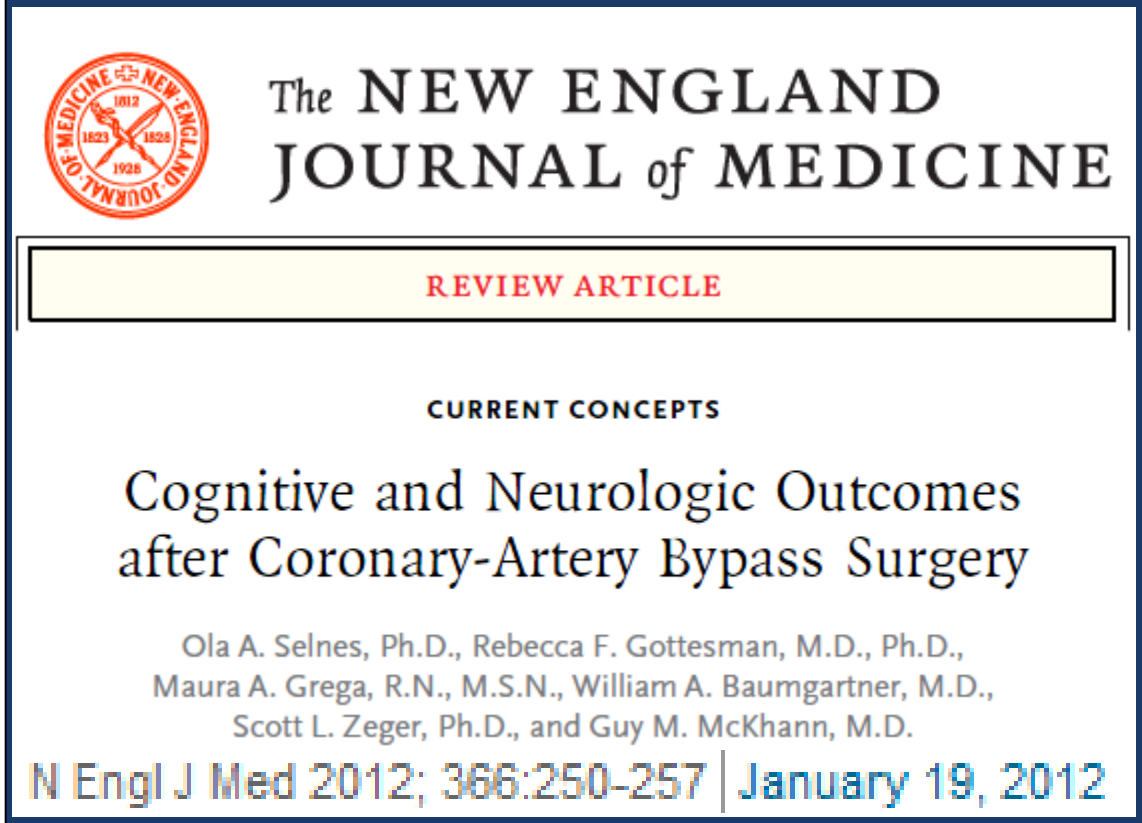
Epiaortic sonography enables visualisation of:

- palpable and not palpable plaques
- Intramural / intraluminal lesions
- Ulcerous lesions
- Floating structures

➢ Decesion making to prevent stroke, according to:

- Site of arterial cannulation
- Level of cross/tangential aortic clamp
- Avoidance of clamp (OPCAB, beating heart)
- Concomitant aortic replacement

Stroke Prevention
latest recommendation



The NEW ENGLAND JOURNAL of MEDICINE

REVIEW ARTICLE

CURRENT CONCEPTS

Cognitive and Neurologic Outcomes after Coronary-Artery Bypass Surgery

Ola A. Selnes, Ph.D., Rebecca F. Gottesman, M.D., Ph.D., Maura A. Grega, R.N., M.S.N., William A. Baumgartner, M.D., Scott L. Zeger, Ph.D., and Guy M. McKhann, M.D.

N Engl J Med 2012; 366:250-257 | January 19, 2012

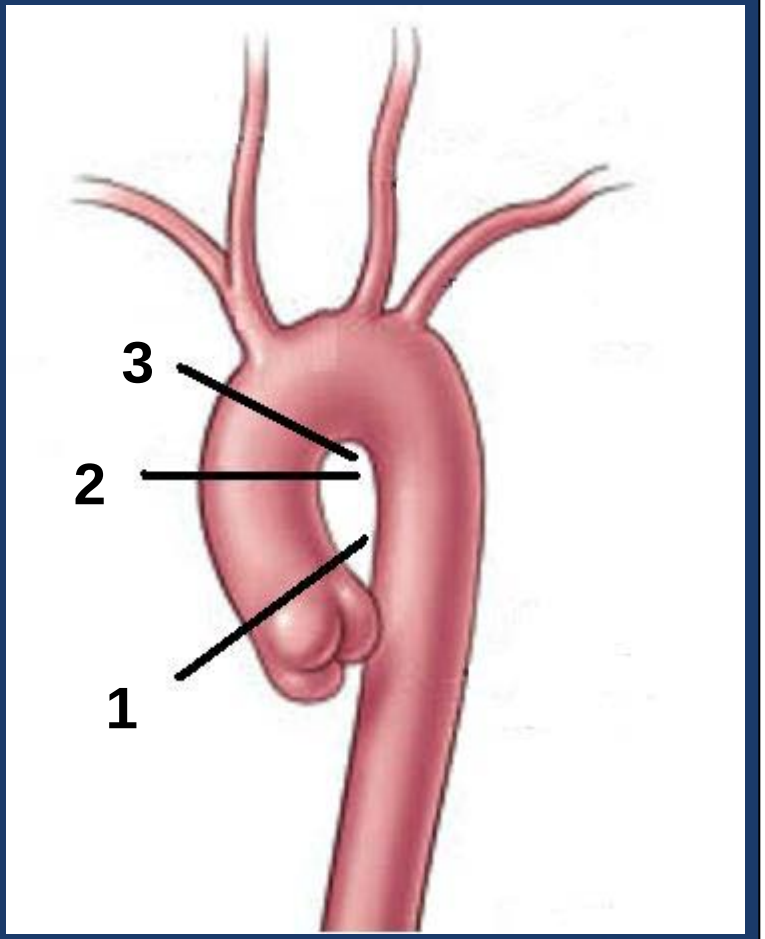
" … Data from randomized trials are not yet available, but observational studies have shown reduced stroke rates when the surgical decision making was guided by the results of epiaortic scanning… "

Intraopaerative Epiaortic Ultrasonography to guide the Surgical Approach.

9 standardized measuring points:

each area is scanned ventral, left and right

1. Proximal Ao. ascendens
   - central anastomoses
2. Distal Ao. Ascendens
   - Cannulation
   - x-clamp
3. Proximal Ao. Arch
   - Cannulation
   - Perfusion



Case Report 1: floating structure
Patient

characteristics:

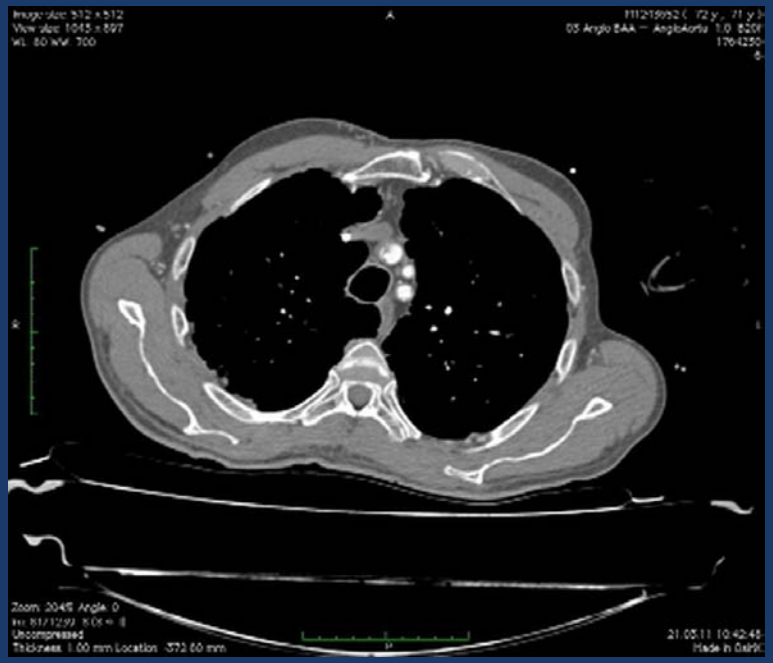
- male, 72 years
- 2 vessel CAD
- STEMI with CPR
- AI I°
- PAD
- Tr. Coeliacus stenosis
- COPD
- Renal insufficiency

planned procedures:

- 2 x CABG

Case Report 1: floating structure preoperative imaging additional to TEE

CT: malignoma exclusion



MRT: LV aneurysm exclusion

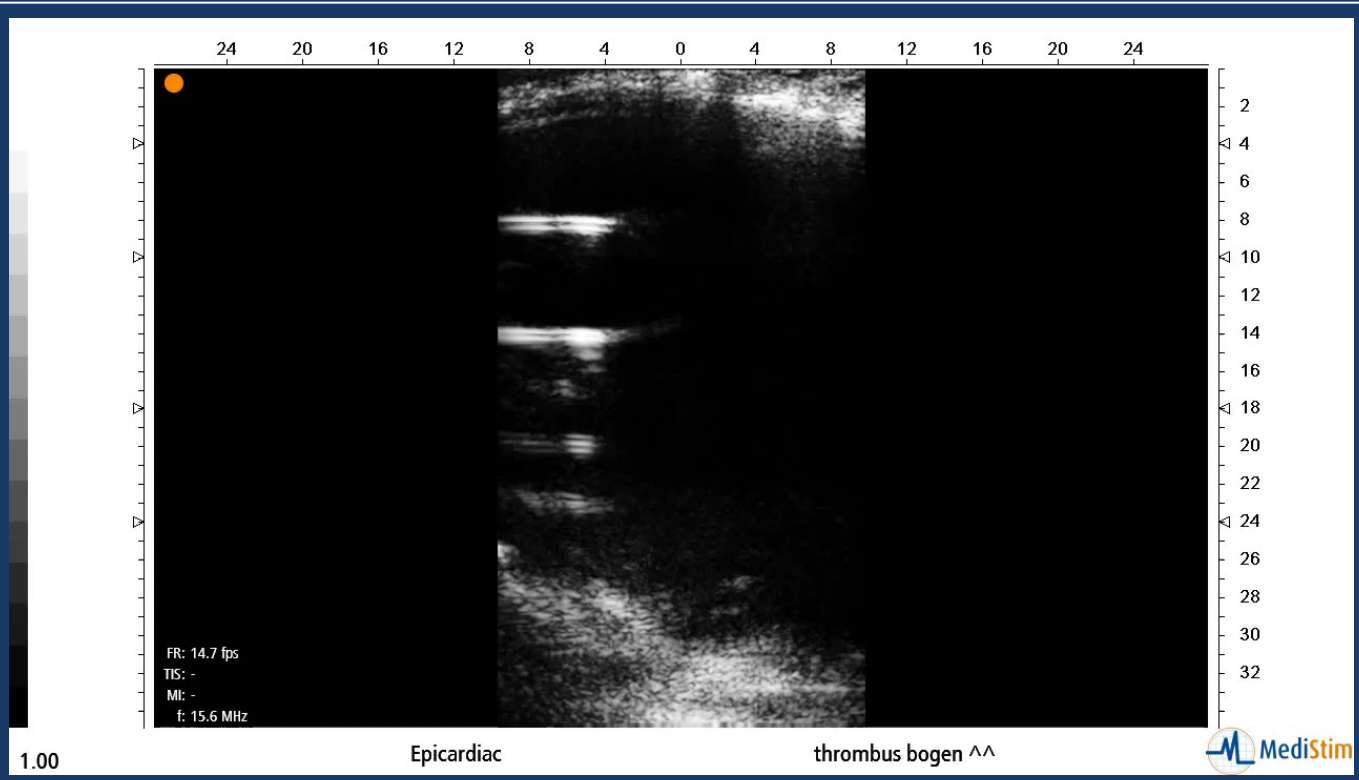
Case Report 1: floating structure
New Findings by Epiaortic Ultrasound

- Aortic palpation = no findings
- epiaortic scanning = floating structures in ascending aorta

Case Report 1: floating structure
Change of Operative Strategy

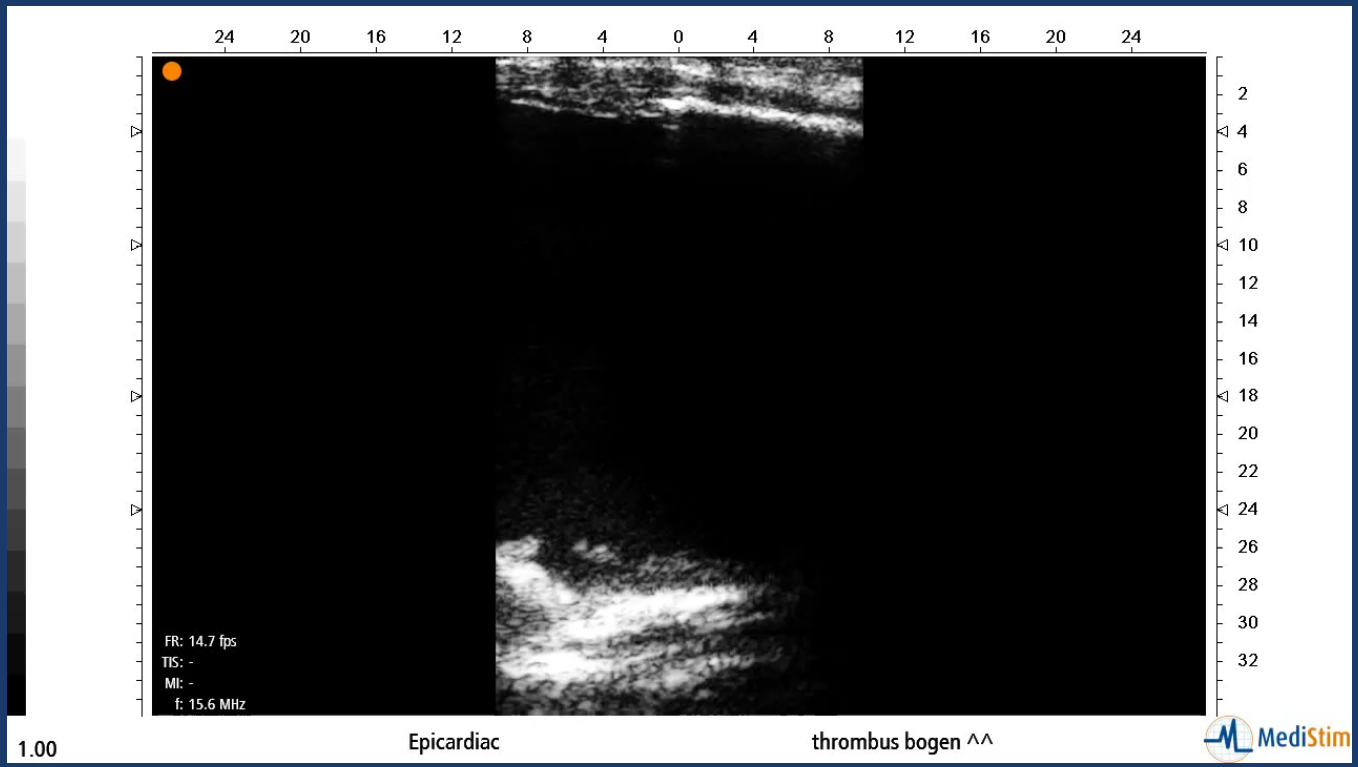
New strategy regarding multi-morbidity:

- Cannulation in the arch distal to the floating structure



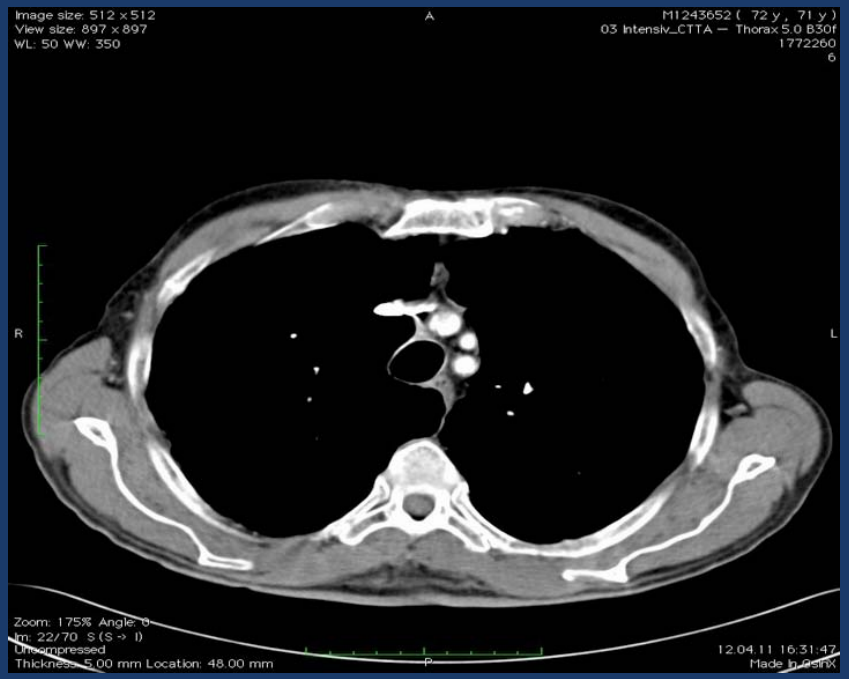
Case Report 1: floating structure
Change of Operative Strategy

Control after bypass

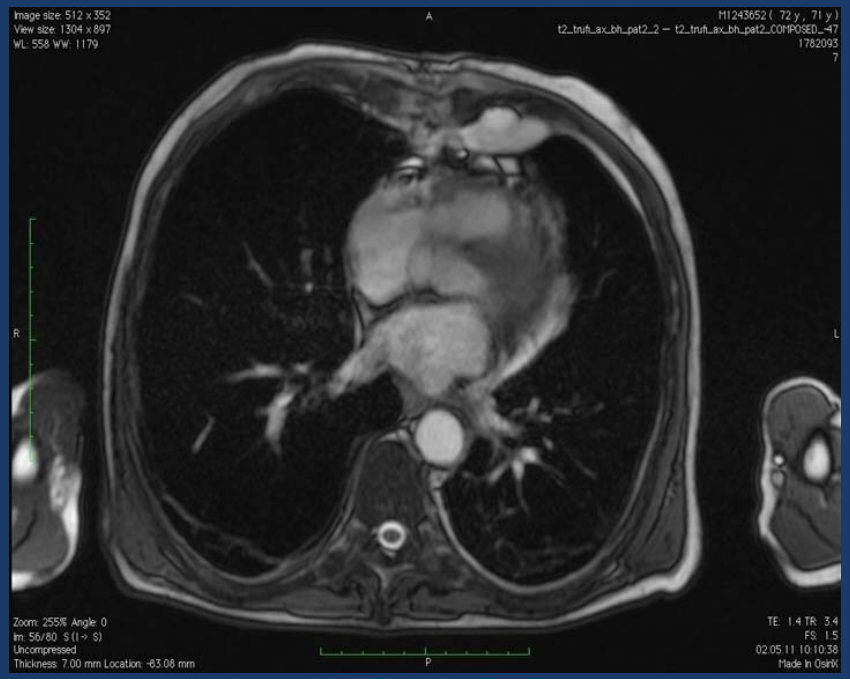


Case Report 1: floating structure postoperative imaging

CT:



MRT:



No floating structures detectable

Case Report 2: ulcerous plaque Patient

characteristics:

- male, 76 years
- 2 vessel CAD
- chronic AF
- 80% ACI stenosis

planned procedures:

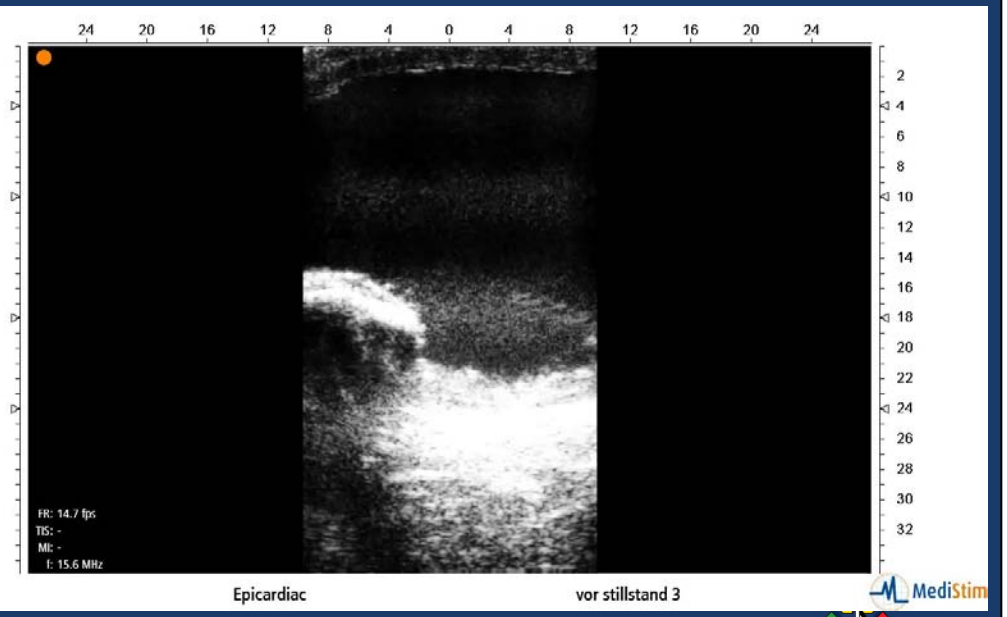
- 2 x CABG
- Maze procedure

Case Report 2: ulcerous plaque
New Findings by Epiaortic Ultrashound

- Aortic palpation = no findings
- epiaortic scanning = floating plaque and ulcerous lesion

floating plaque

ulcerous lesion



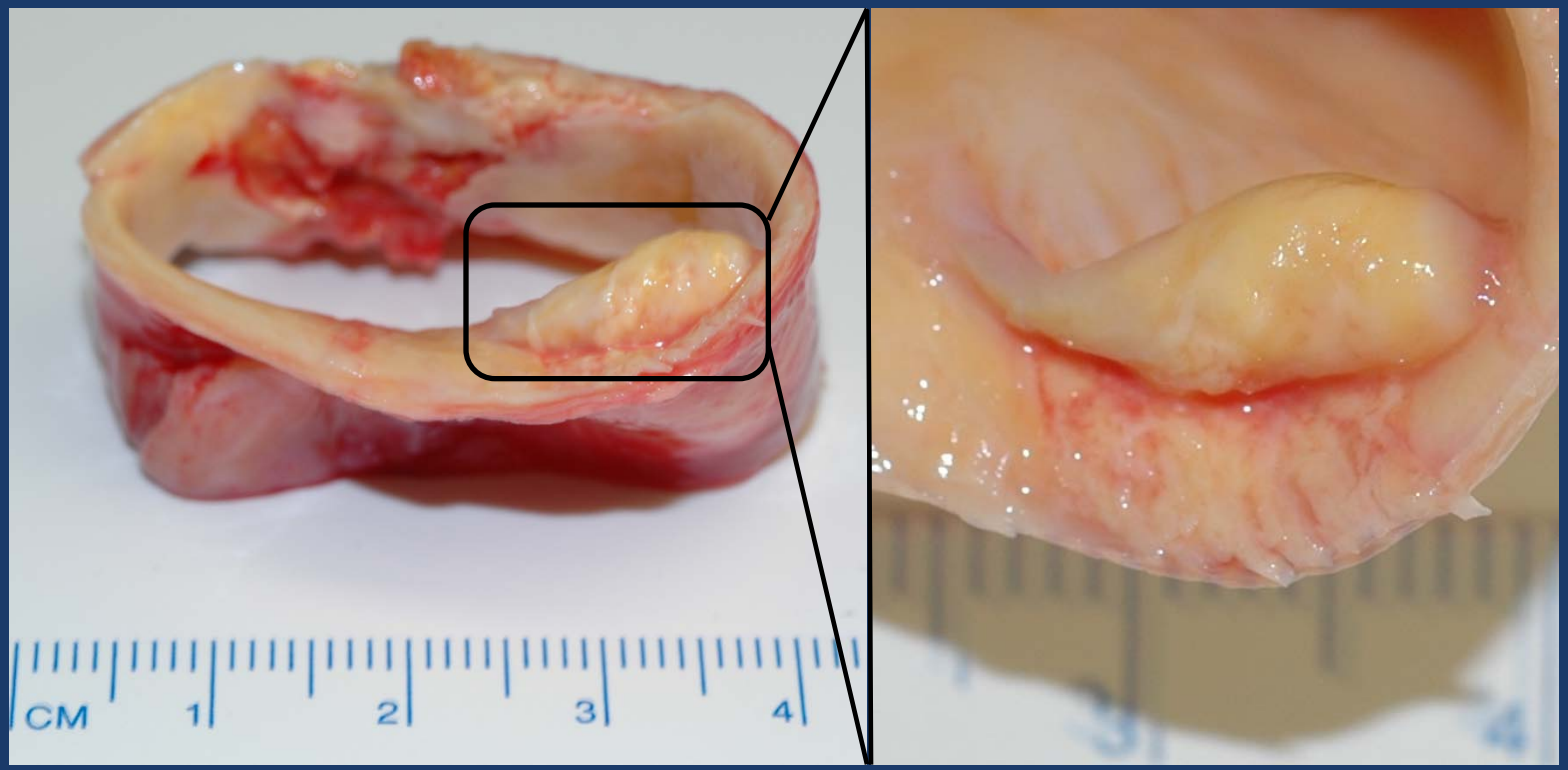
Case Report 2: ulcerous plaque
Change of Operative Strategy

New strategy:

- Cannulation right subclavian artery
- No clamp
- Cooling to 28° C, HCA
- Ascending replacement with open anastomosis distally
- CABG
- Maze (Epicor)

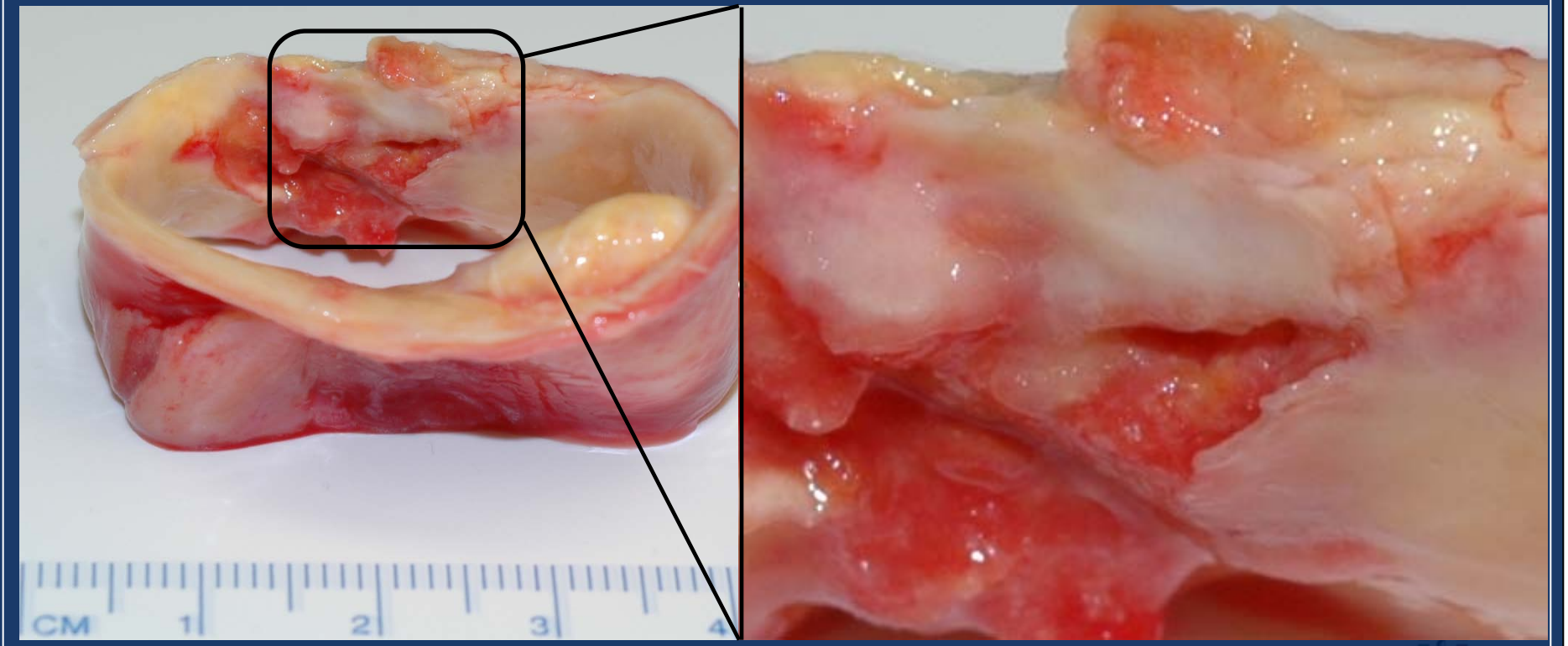
Case Report 2: ulcerous plaque
Macroscopic findings equal to VeriQ^{c}

1. Floating structure in X-clamp position:



Case Report 2: ulcerous plaque macroscopic findings equal to VeriQ^{c}

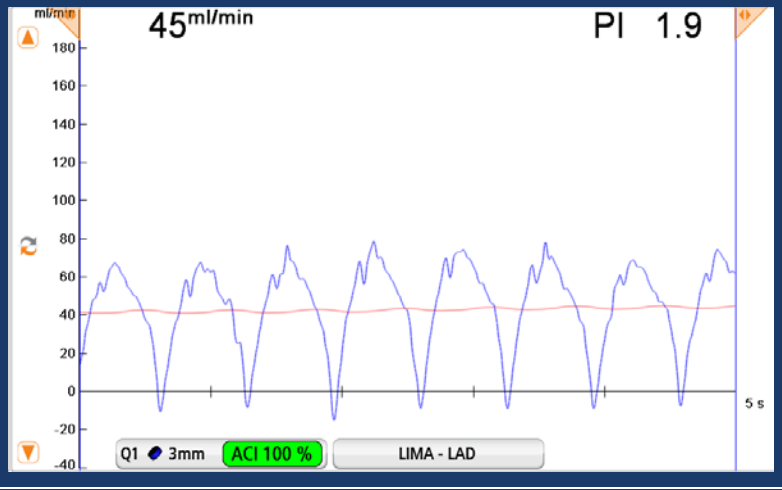
2. ulcerous plaque:



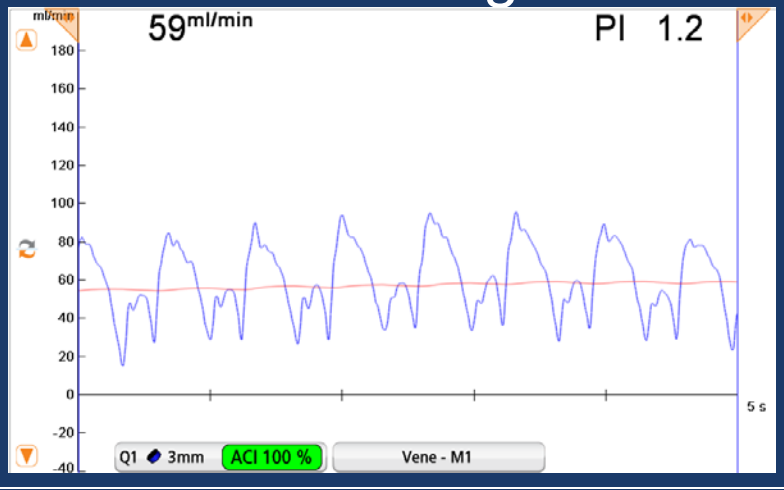
Case Report 2: ulcerous plaque
Flow Measurement

2 x CABG finished with flow measurement:

LITA – LAD



ACVB – Mg



- no complications during operation
- Postoperative course uneventful

Further applications for VeriQc

- Graft detection in Redo's
- Detailed examination of valves
- Scan of peripheral vessels
- Anastomoses check in case of bad TTFM

TTFM + VeriQc in Essen: no procedure without

General spreading slowly… WHY?

- Old generation of surgeons ?
- No need for demonstrable quality ?
- Fear of graft injury or truth ?

Summary

- VeriQ^{c} enables direct evaluation of the aortic wall from surgeon intraoperatively
- Allows decision making in order to avoid embolism
- VeriQ^{c} combined with TTFM enables safe and demonstrable high quality CABG surgery

west-german heart center essen

University Hospital Essen

Outlook for Blood Flow Measurement (TTFM)

Ian Wilson – Birmingham/UK

Outlook for Blood Flow Measurement (TTFM)

A Cardiac Surgical View Point

Ian Wilson – Birmingham/UK

Outlook for Blood Flow Measurement (TTFM)

A Cardiac Surgical View Point

From a Small Island

Ian Wilson – Birmingham/UK

NHS

- Population of 60 Million
- Limited Finances
  - 2.5 Million CAD
- Potential for Non-Uniform Distribution of Services
  - 40,000 Surgical Revascularisation Procedures / Year

Guidelines

- Should Guidelines be Mandatory?
- What Autonomy of Clinical Practice is Reasonable?

Society for
Cardiothoracic Surgery
in Great Britain and Ireland

Annual Meeting
Programme

The Brighton Centre

17th March 2013
SCTS University

18th - 19th March 2013
Annual Meeting

www.scts.org

Contemporary Coronary Artery Revascularisation: An Evolving Multidisciplinary Field

Sun, March 17, 2013
Auditorium: 09:00 - 10:15

Guidelines in Coronary Artery Revascularisation

Moderation: D. Jenkins[1], S. Kendall[2], D. Hildick-Smith[3], M. Norell[4]
[1]Cambridge/UK, [2]Middlesbrough/UK, [3]Brighton/UK,
[4]Wolverhampton/UK

09:00 - 09:15
Should Guidelines be Mandatory? A View from NICE
Sir Michael Rawlins; Chairman of NICE, London/UK

09:15 - 09:30
Should Guidelines be Mandatory? A View from the Commissioners
K. Caston; Head of Specialised Commissioning, London/UK

09:30 - 09:35
Discussion
Panel

09:35 - 09:55
ESC / EACTS Guidelines in Coronary Artery Revascularisation 2010 Implementation in to Clinical Practice
P. Kolh; Liege/BE

NHS
Delivery of Care

- Defined Annual Budget

- Define Standards of Care

NHS
Delivery of Care

- Defined Annual Budget

- Define Standards of Care

Commissioners

Defined Annual Budget

- Paymasters for the Institutions
- Fee for Item of Service
- Restructuring

Commissioners

Defined Annual Budget

- Paymasters for the Institutions
- Fee for Item of Service
- Restructuring
- April 2013

Commissioners

Defined Annual Budget

- National Commissioning Board
- Clinical Reference Groups

Delivery of Care

- Defined Annual Budget

- Define Standards of Care

NICE

National Institute for Health and Clinical Excellence

Mission Statement

NICE

National Institute for Health and Clinical Excellence

Provide:

Guidance

to Ensure

Quality and Value for Money

NICE

National Institute for Health and Clinical Excellence

Guidance:

Independent, Authoritative and Evidence Based

on the Most Effective Ways

to Prevent, Diagnose and Treat

Disease


Evidence Base
Cost Analyses
NICE
Evidence Based Guidelines
Standards for High Quality Care
Medical Technologies Evaluation Programme
National Commissioning Board

NICE

National Institute for Health and Clinical Excellence

Guidance:

Independent, Authoritative and Evidence Based Guidance

on the Most Effective Ways

to Prevent, Diagnose and Treat Disease

Goal:

Reducing Inequalities and Variation

NICE

National Institute for Health and Clinical Excellence

Benefits at the Coal Face

- Empowers Institutions to Invest in Technological Developments
- Maintains a Momentum for Iterative Change

Quality Assurance in Cardiac Surgery

- Dynamic Specialty
- Technological Advances
- Improved Survival Rates
- Increasing Scrutiny of Results

Quality Assurance in Cardiac Surgery

- Dynamic Specialty
- Technological Advances
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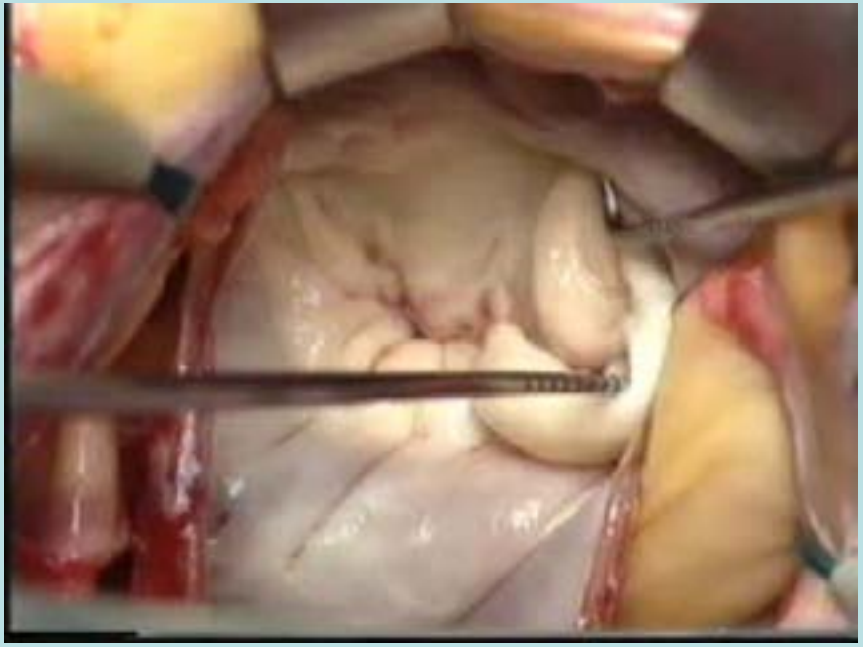
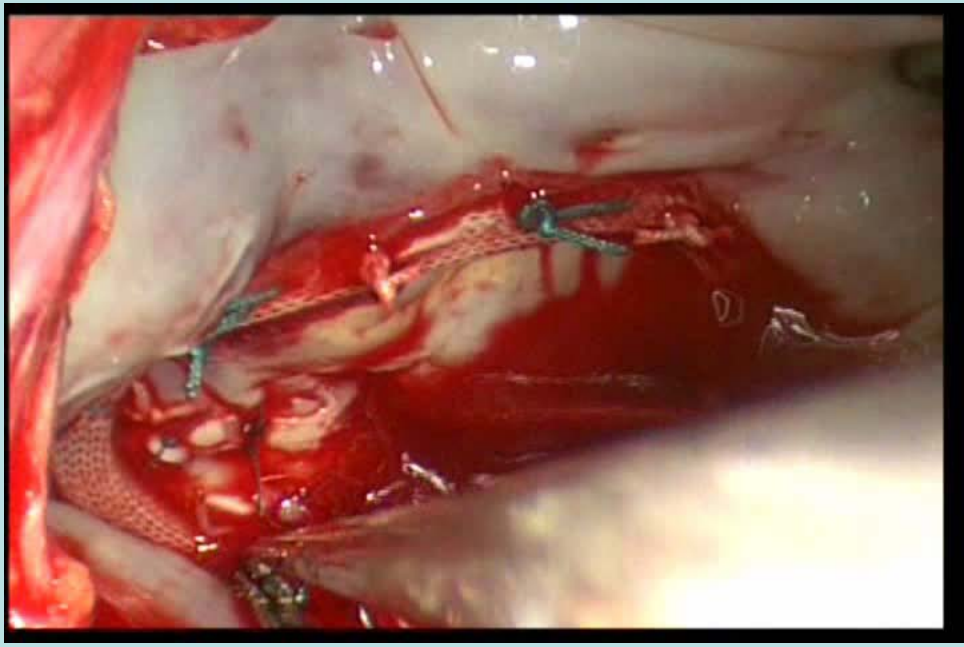
Mitral Valve Surgery



Post Op Mitral Surgery Q&A



Post Op Mitral Surgery Q&A

Levels of Evidence
Classes of Recommendation

- **Mitral Valve Repair Surgery**

- Class A Recommendation /

  Level I Evidence - TOE

Quality Assurance in Coronary Artery Surgery

- ESC / EACTS Guidelines 2010
  - Recommendation for Evaluation of Graft Flow

Table 32 Technical recommendations for coronary artery bypass grafting

	Class[a]	Level[b]	Ref.[c]
Procedures should be performed in a hospital structure and by a team specialized in cardiac surgery, using written protocols.	I	B	192, 196
Arterial grafting to the LAD system is indicated.	I	A	194
Complete revascularization with arterial grafting to non-LAD coronary systems is indicated in patients with reasonable life expectancy.	I	A	49, 194, 196, 197, 199
Minimization of aortic manipulation is recommended.	I	C	—
Graft evaluation is recommended before leaving the operating theatre.	I	C	—

[a]Class of recommendation.
[b]Level of evidence.
[c]References.
LAD = left anterior descending.

Class I Recommendation: Conditions for which there is evidence and/or general agreement that this procedure is useful and effective

Level of Evidence C: Expert consensus

MediStim Presents to NICE

- 2011

- NICE – Medical Technologies Evaluation Programme

The Question

TTFM Evaluation of Graft Flow:

An Important Adjunct or Unnecessary Expense?

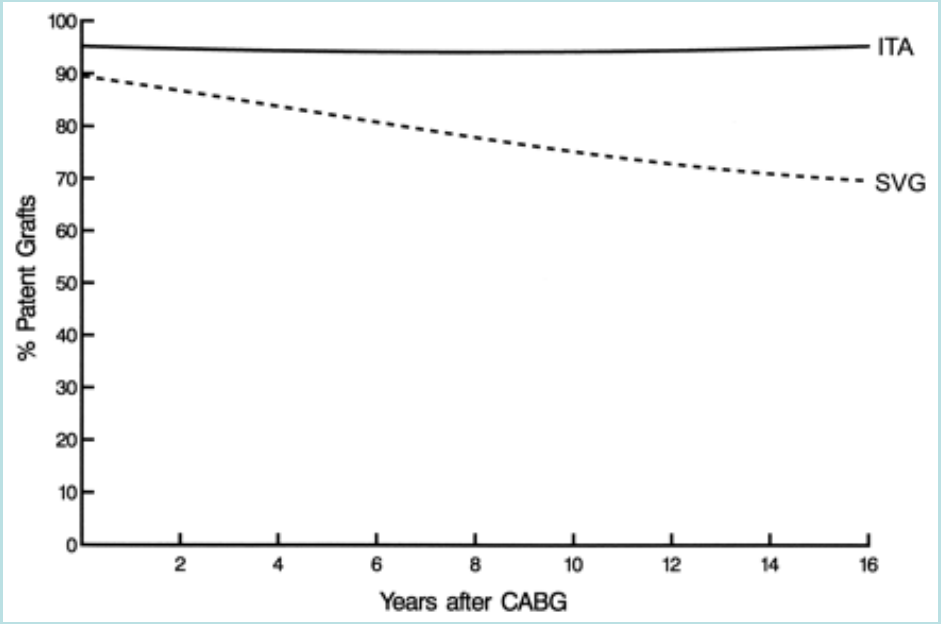
NICE Questions

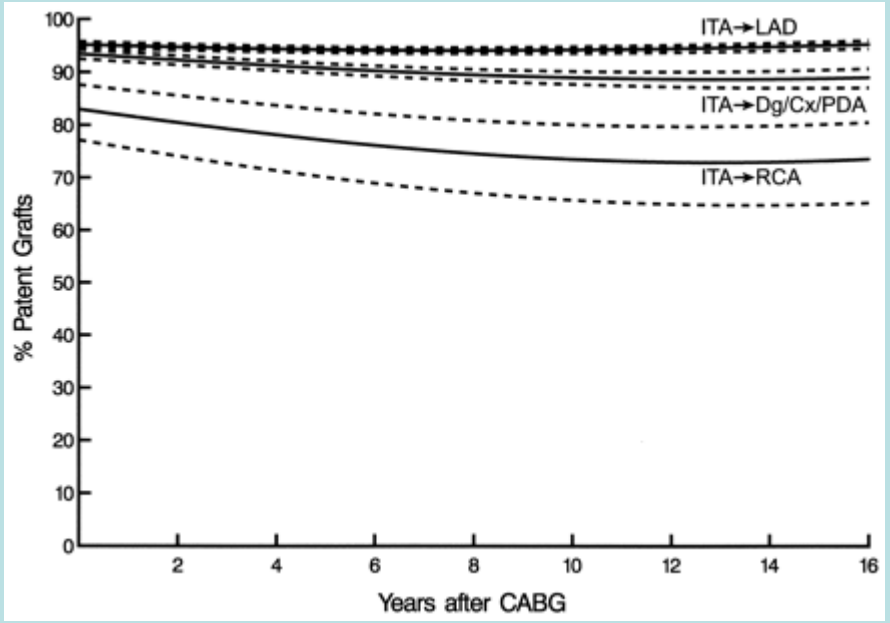
Clarification

- Time to Graft Failure
- Incidence of Graft Failure
- Consequences of Graft Failure
  - » Early
  - » Late
- Can TTFM Influence the Consequence of Graft Failure

CABG Graft Failure

- Early
- Mid-term
- Late





Early Graft Failure

Technical Failures

- Immediate Failure
- One month Failure
- One Year failure

Early Post Operative Graft Failure

Immediate

- 0.6 - 3.2% Grafts
- 1.8 - 8.1% Patients

Consequence of Immediate Post Operative Graft Failure

2 - 8% Patients

- **Myocardial Infarction**
  - Troponin Rises
    - Highly Sensitive Troponin
  - New Q waves 2.5 - 5%

Clinical Significance of MI Post CABG

- Minor Consequence
- Left Ventricular Dysfunction
- Ventricular Arrhythmia
- Haemodynamic Catastrophe

} Extended ITU Stay

Consequence of Immediate Post Operative Graft Failure

2 – 8% Patients

Myocardial Infarction 2.5 - 5 %

Patient /Institutional Impact:

- **Prolonged LOS**

- **Supplementary Interventions**
  - IABP
  - Early Repeat Surgery 1.0 - 1.5 %
  - Repeat Angiography 2.0 - 3.0 %

Consequences of Later Graft Failure

- Myocardial Infarction
- Recurrent Symptoms
- Repeat Interventions
  - » PCI
  - » CABG

QEHB Experience

PATS Database 1997-2011

Isolated CABG

Postoperatively

Patients Require Reoperation for:

- Bleeding / Tamponade
- Graft Problems
- Cardiac Arrest

Postoperatively

Patients Require Reoperation for:

- Bleeding / Tamponade
- Graft Problems
- Cardiac Arrest

	No Re-exploration for Graft Problem		Re-exploration for Graft Problem	
Number in Group	7536		62	**0.82%**

	No Re-exploration for Graft Problem		Re-exploration for Graft Problem	
Number in Group	7536		62	**0.82%**
	#	%	#	%
IABP	360	**4.8**	36	**58.1**

12x

	No Re-exploration for Graft Problem		Re-exploration for Graft Problem	
Number in Group	7536		62	**0.82%**
	#	%	#	%
IABP	360	**4.8**	36	**58.1**
Deep Sternal Wound Infection		**0.8**		**1.6**

2x

	No Re-exploration for Graft Problem		Re-exploration for Graft Problem	
Number in Group	7536		62	**0.82%**
	#	%	#	%
IABP	360	**4.8**	36	**58.1**
Deep Sternal Wound Infection		**0.8**		**1.6**
Transient Stroke		**0.5**		**3.2**
Permanent Stroke		**0.7**		**1.6**

2x

3x

	No Re-exploration for Graft Problem		Re-exploration for Graft Problem	
Number in Group	7536		62	**0.82%**
	#	%	#	%
IABP	360	**4.8**	36	**58.1**
Deep Sternal Wound Infection		**0.8**		**1.6**
Transient Stroke		**0.5**		**3.2**
Permanent Stroke		**0.7**		**1.6**
Moderate Renal Impairment		**4.2**		**12.9**
Dialysis		**1.6**		**8.1**

3x

5x

	No Re-exploration for Graft Problem		Re-exploration for Graft Problem	
Number in Group	7536		62	**0.82%**
	#	%	#	%
IABP	360	**4.8**	36	**58.1**
Deep Sternal Wound Infection		**0.8**		**1.6**
Transient Stroke		**0.5**		**3.2**
Permanent Stroke		**0.7**		**1.6**
Moderate Renal Impairment		**4.2**		**12.9**
Dialysis		**1.6**		**8.1**
In-hospital Mortality		**2.0**		**37.1**

19x

	No Re-exploration for Graft Problem		Re-exploration for Graft Problem	
Number in Group	7536		62	**0.82%**
	#	%	#	%
IABP	360	**4.8**	36	**58.1**
Deep Sternal Wound Infection		**0.8**		**1.6**
Transient Stroke		**0.5**		**3.2**
Permanent Stroke		**0.7**		**1.6**
Moderate Renal Impairment		**4.2**		**12.9**
Dialysis		**1.6**		**8.1**
In-hospital Mortality		**2.0**		**37.1**
	Median		**Median**	Mean
Ventilation - hrs	**12**		**48**	95.3

4x (7x)

	No Re-exploration for Graft Problem		Re-exploration for Graft Problem	
Number in Group	7536		62	**0.82%**
	#	%	#	%
IABP	360	**4.8**	36	**58.1**
Deep Sternal Wound Infection		**0.8**		**1.6**
Transient Stroke		**0.5**		**3.2**
Permanent Stroke		**0.7**		**1.6**
Moderate Renal Impairment		**4.2**		**12.9**
Dialysis		**1.6**		**8.1**
In-hospital Mortality		**2.0**		**37.1**
	Median		**Median**	Mean
Ventilation - hrs	**12**		**48**	95.3
ITU LOS - days	**2**		**5**	6.7

2.5x

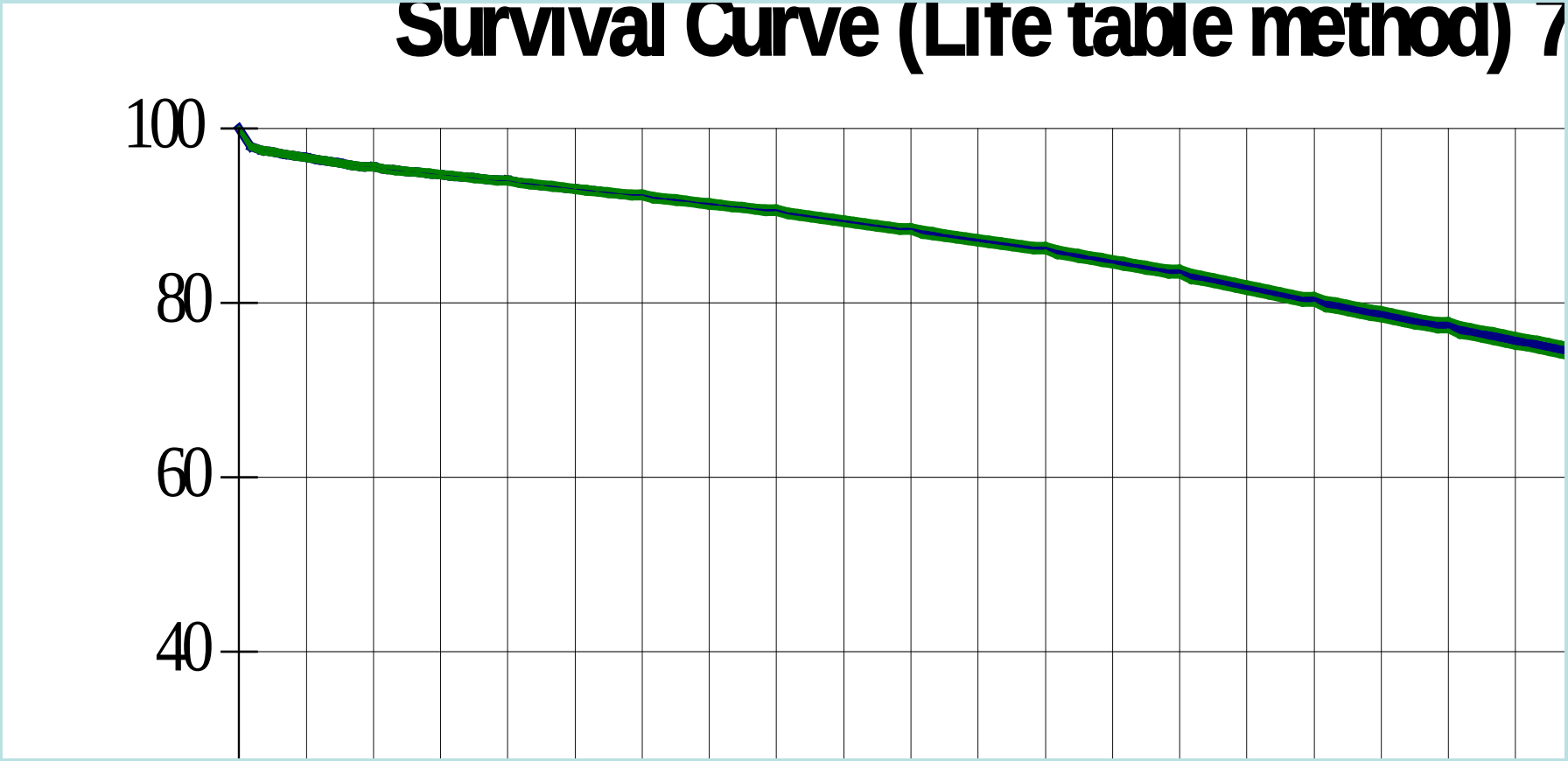
	No Re-exploration for Graft Problem		Re-exploration for Graft Problem	
Number in Group	7536		62	**0.82%**
	#	%	#	%
IABP	360	**4.8**	36	**58.1**
Deep Sternal Wound Infection		**0.8**		**1.6**
Transient Stroke		**0.5**		**3.2**
Permanent Stroke		**0.7**		**1.6**
Moderate Renal Impairment		**4.2**		**12.9**
Dialysis		**1.6**		**8.1**
In-hospital Mortality		**2.0**		**37.1**
	Median		**Median**	Mean
Ventilation - hrs	**12**		**48**	95.3
ITU LOS - days	**2**		**5**	6.7
Post-op LOS	**7**		**10**	14.5

	No Re-exploration for Graft Problem		Re-exploration for Graft Problem	
Number in Group	7536		62	**0.82%**
	#	%	#	%
IABP	360	**4.8**	36	**58.1**
Deep Sternal Wound Infection		**0.8**		**1.6**
Transient Stroke		**0.5**		**3.2**
Permanent Stroke		**0.7**		**1.6**
Moderate Renal Impairment		**4.2**		**12.9**
Dialysis		**1.6**		**8.1**
In-hospital Mortality		**2.0**		**37.1**
	Median		**Median**	Mean
Ventilation - hrs	**12**		**48**	95.3
ITU LOS - days	**2**		**5**	6.7
Post-op LOS	7		10	14.5
Post-op LOS - Survivors	**7**		**15**	17.7

	No Re-exploration for Graft Problem		Re-exploration for Graft Problem		Fold Increase
Number in Group	7536		62	**0.82%**	
	#	%	#	%	
IABP	360	**4.8**	36	**58.1**	**12**
Deep Sternal Wound Infection		**0.8**		**1.6**	**2**
Transient Stroke		**0.5**		**3.2**	**6**
Permanent Stroke		**0.7**		**1.6**	**2**
Moderate Renal Impairment		**4.2**		**12.9**	**3**
Dialysis		**1.6**		**8.1**	**5**
In-hospital Mortality		**2.0**		**37.1**	**19**
	Median		**Median**	Mean	**TIME**
Ventilation - hrs	**12**		**48**	95.3	**1.5 days**
ITU LOS - days	**2**		**5**	6.7	**3 days**
Post-op LOS	**7**		**10**	14.5	**3 days**
Post-op LOS - Survivors	**7**		**15**	17.7	**8 Days**

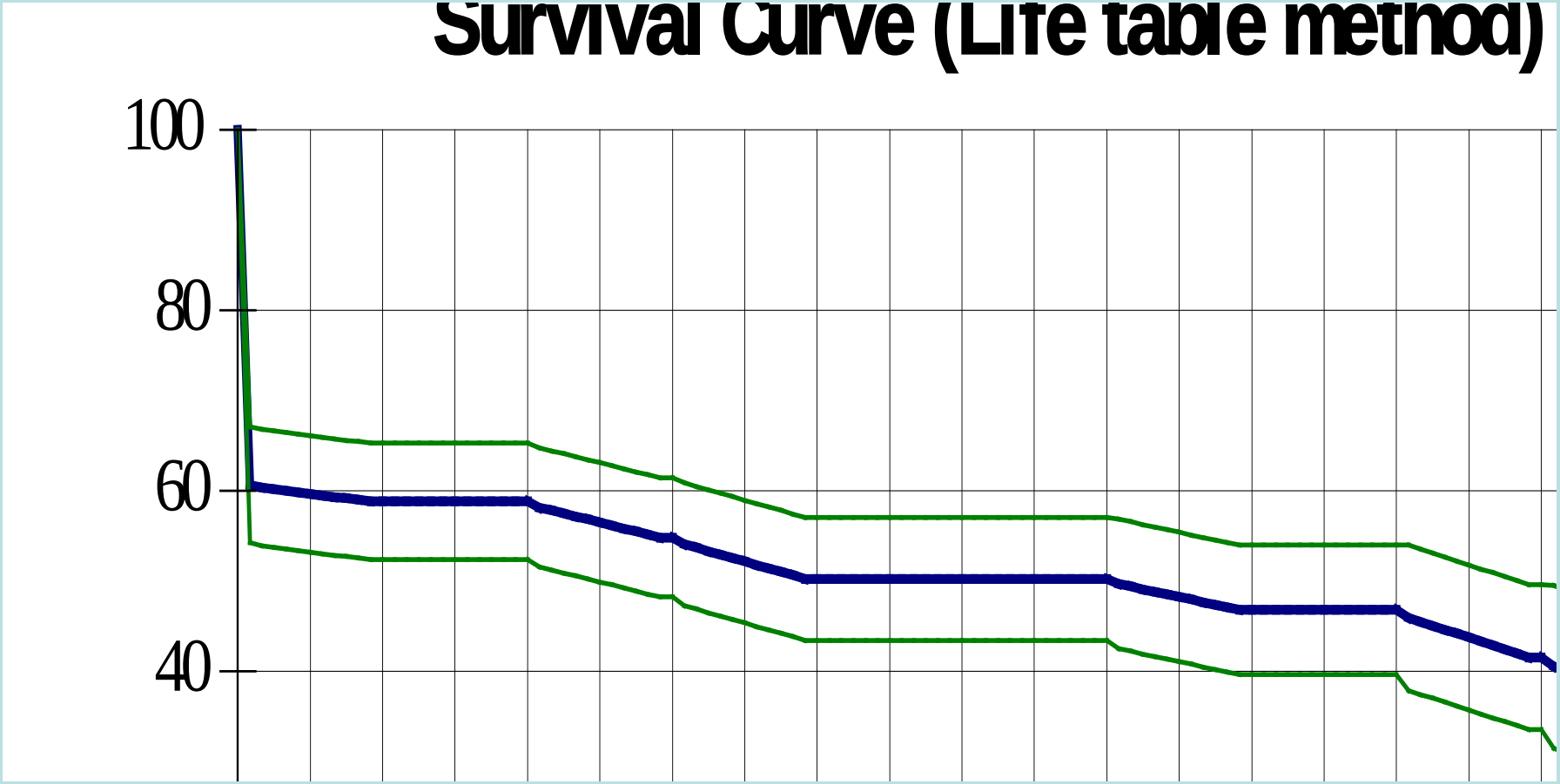
Late Survival

No Re-Exploration for CA / GP

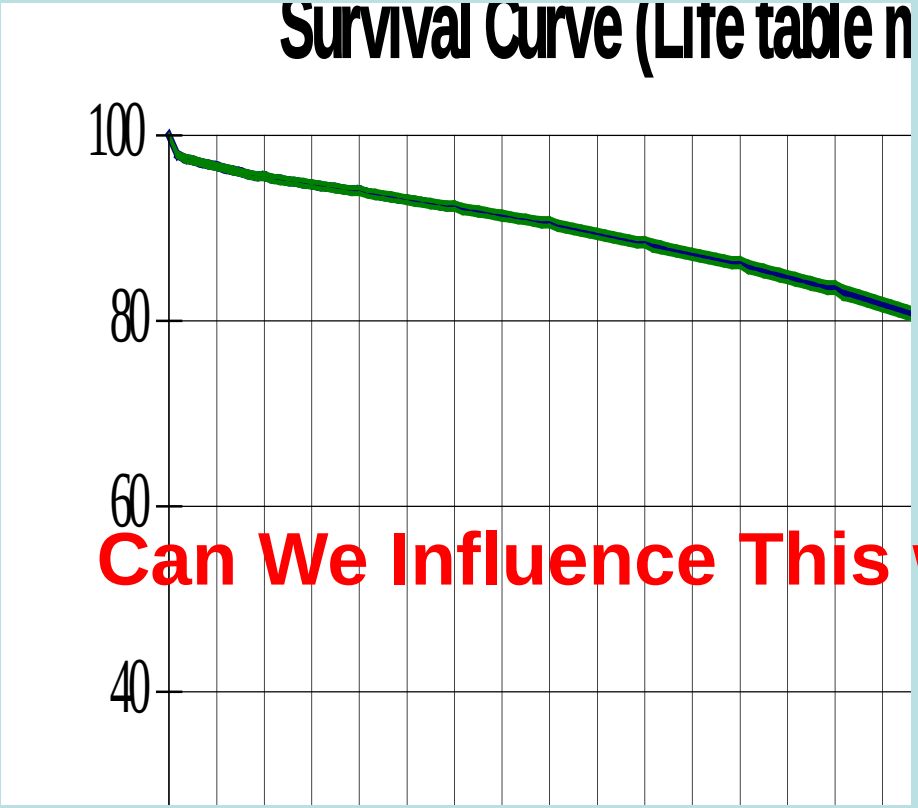


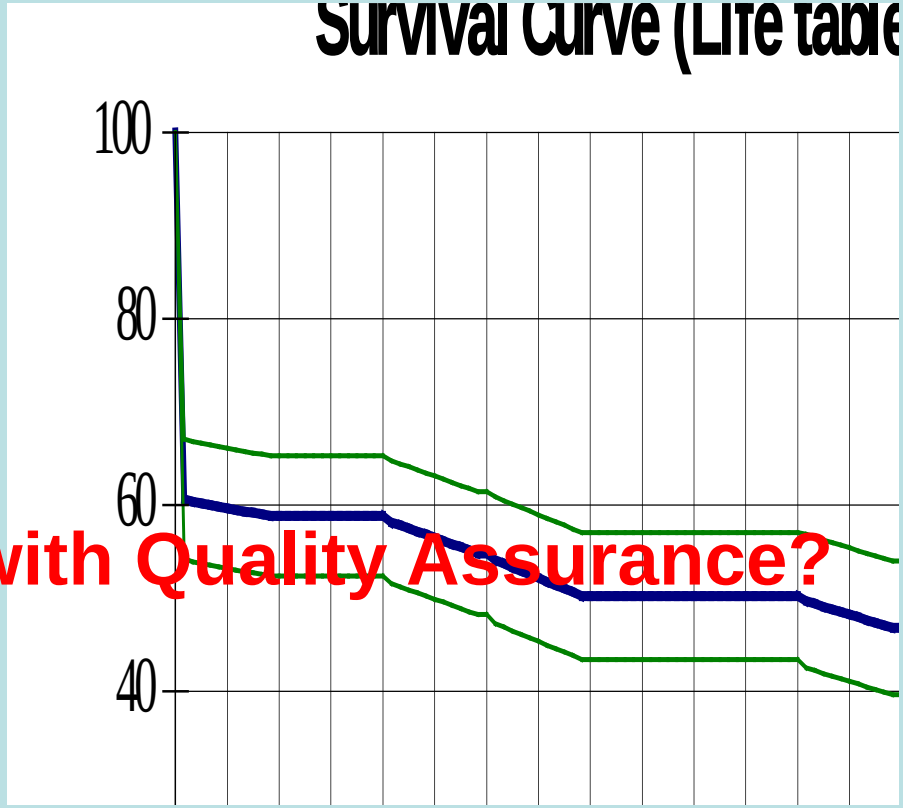
Late Survival

Re-Exploration for CA / GP



Comparative Late Survival





Can We Influence This with Quality Assurance?

Survival halved by 12 years

Reduction in absolute survival 33%

Consequences of TTFM

- Frequency of Graft Revision
- Impact of Graft Revision

Experience with TTFM in Bern 2000-2010

Professor Thierry Carrel

• Isolated CABG	≈ 6100
• Combined CABG +	≈ 2700
• Overall	≈ 8900
• Pathologic flow characteristics	≈ 254 (2.8%)
• Revision of anastomosis	in 95%
• Surgeon found technical problem	in 90%
• Normalized Flow / PI after revision	> 95%

Comparative Study

Small Patient cohort
TTFM vs MRI

TTFM Median Flow 58 ml/min (IQR: 41 – 80 ml/min)

MRI Median Flow 60 ml/min (IQR: 37.5 –78.5 ml/min)

Good agreement between TTFM and postoperative MRI flow measurements with (mean difference 1.02 ml/min)

Linear regression analysis of pooled data revealed a highly significant correlation

Clinical Implications

Graft failure is a major determinant of CABG morbidity / mortality

Early intraoperative recognition is essential for immediate corrective surgery

NICE Analysis

Quality and Cost

- Quality Adjusted Life Year
  - 20,000 - 30,000 per QALY

NICE Analysis

Quality and Cost

- Recognised the Cost Benefit of TTFM
- Recognised the Quality Benefits of TTFM
- Published Guidelines Approving use in CABG

SUMMARY

The Outlook for Transit-Time Fl

Received Endorsement by NICE and ESC/E

The Quality Agenda Grows in all Aspects of H

Spread of the Knowledge of the Technology

Increased Uptake will be Reinforced by Posit

Establish this Technology as a “Standard of Care” in CABG Surgery

SCTS Lunch Box Sessions

Intraoperative Imaging In CABG Surgery: Important Adjuncts or Unnecessary Expense

Sun, March 17, 2013
Syndicate 1 & 2: 12:15 - 13:45

Moderation: A. Ritchie[1], J. Dunning[2], F. De Robertis[3]
[1]Basildon/UK, [2]Middlesbrough/UK, [3]London/UK

12:15 - 12:27
The Role of Graft Evaluation Quality Assurance in CABG Surgery
D. Taggart; Oxford/UK

12:27 - 12:39
Anastomotic Probing Allows Adequate Evaluation of Graft Patency
S. Westaby; Oxford/UK

12:39 - 12:51
Evaluation of Graft Patency:
Understanding the Results and When to Re-graft
R. Haaverstad; Bergen/NO

12:51 - 12:56
Discussion
Panel

12:56 - 13:08
Recognising Potential Intraoperative Pitfalls:
Epiaortic Interrogation of the Ascending Aorta during CABG Surgery
R. Haaverstad; Bergen/NO

13:08 - 13:20
Intraoperative Palpation of the Aorta Yields Adequate Information
S. Westaby; Oxford/UK

13:20 - 13:32
Ascending Aortic Atheroma at CABG Surgery:
How Aggressive Should Surgical Strategies be?

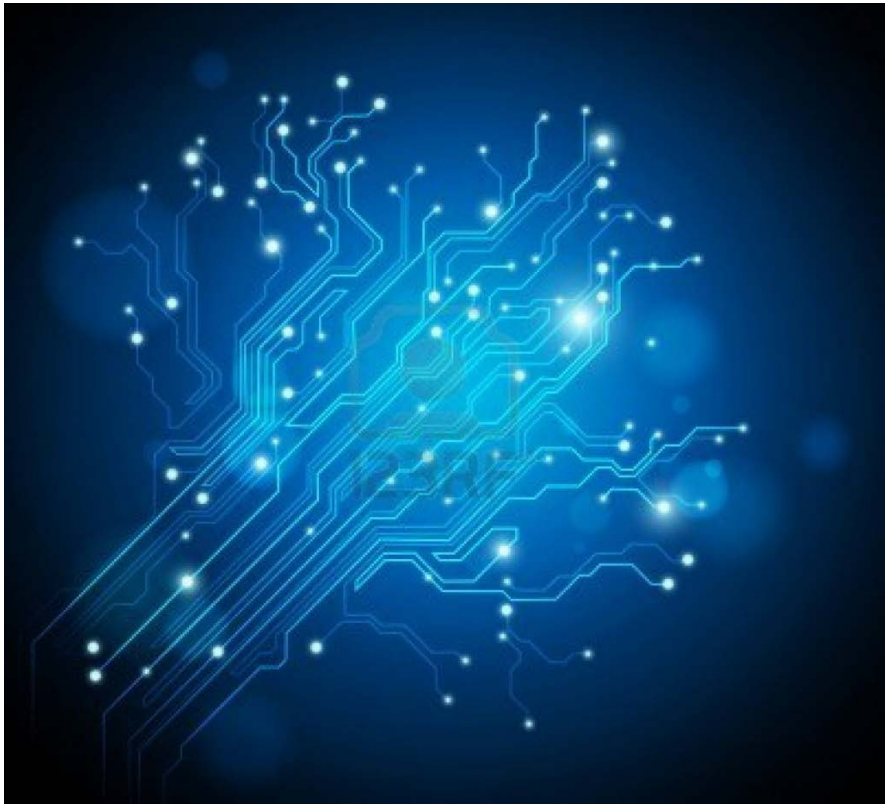
- 27 consecutive patients undergoing isolated CABG
- age 65.7 years, range 46 to 88 years
- 84 coronary bypasses 45 internal thoracic arteries, 39 saphenous vein-grafts
- bypass flow measured 10 minutes after MECC (mean value of 3 recordings)
- MRI scans were performed within one week post surgery (median 7 days, range 5 to 7 days)

New product development

Capital Markets Day
March 8th , 2013
Erik Swensen, VP R&D

Agenda

- Product development for a global market - the Medistim way
- VeriQ C : 3 years of evolution
- Trends and demands
- Next generation system platform



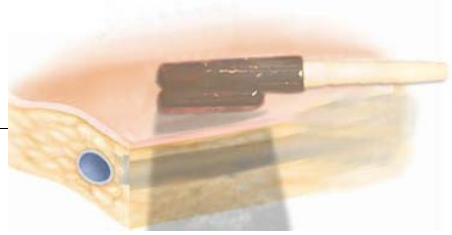
The Medistim way

- A successful collaboration model

- Strong Medistim core-team covering all relevant disciplines
  - Medical software development
  - Industrial design / Mechanics / manufacturing technology
  - Ultrasound / acoustics / image processing
  - Electronics
  - Medical product regulations, approval processes
- Carefully selected technology partners – national and international
- Close relations to surgeons and other clinical personnel
- Long term research involvement with strong scientific institutions
  - University hospitals
  - NTNU / MI-Lab

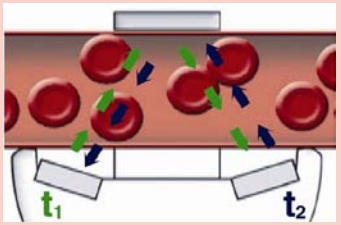
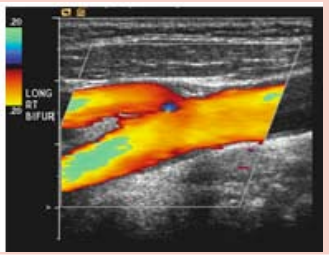
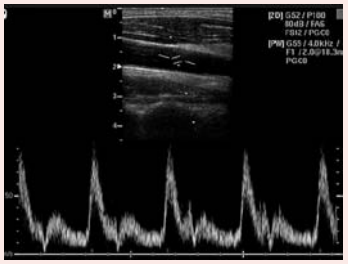
Key advantages

- **A lean organization capable of developing the company's core technology**
- **Utilization of our network of close partners to fill in the needed resources and competence for larger projects**



MEDISTIM

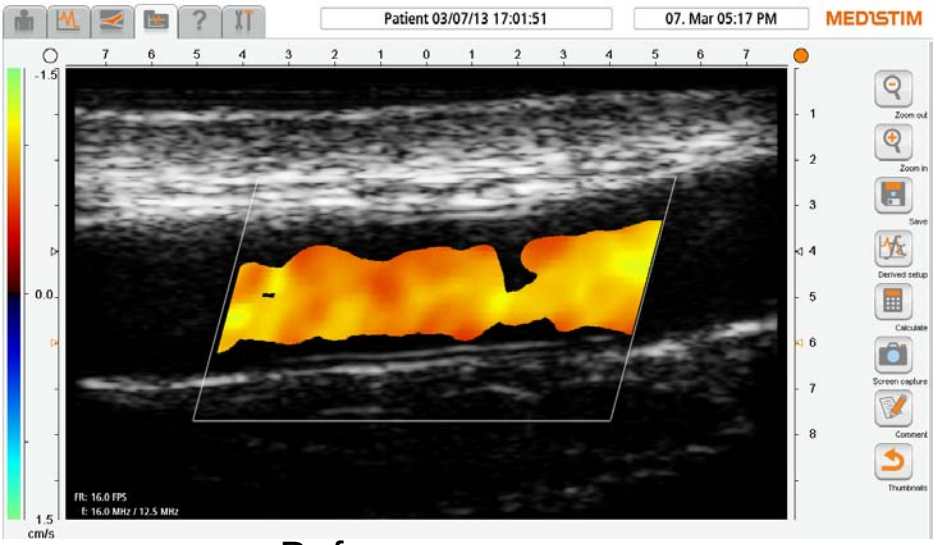
Modalities of medical ultrasound

Modality	Description	VeriQ	VeriQ C	Typical image
TTFM	Accurate quantitative blood flow measurement (VeriQ and VQC)	Yes	Yes	
B-mode	Cross-section greyscale image of the tissue (VQC)		Yes	
Color flow (CFM)	Qualitative view of flow velocities in a region (VQC)		Yes	
Spectral Doppler (PW-Doppler)	Quantitative blood velocity in a specific region		Yes	

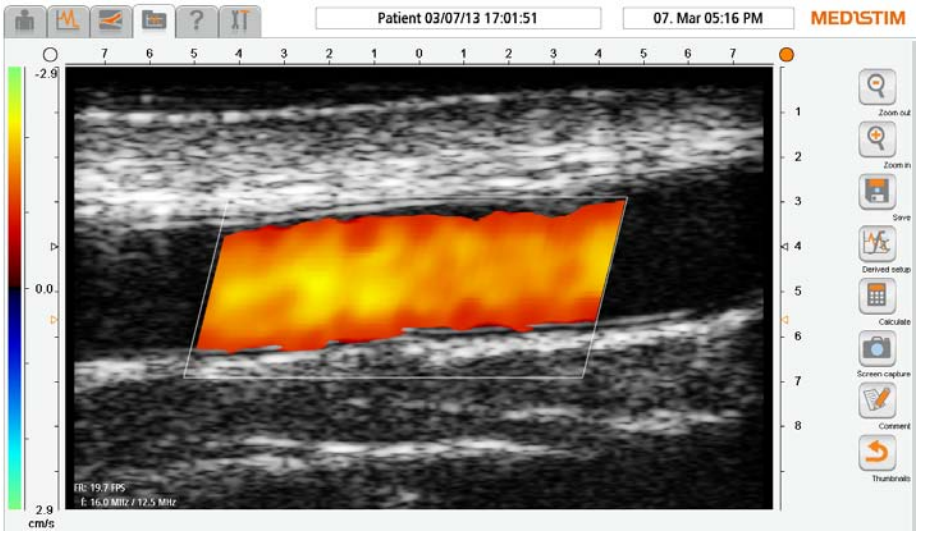
VeriQ C: 3 years of evolution

- VeriQ C at launch in 2009
  - Dedicated imaging technology adapted to an inexperienced user group – most surgeons were not familiar with ultrasound
  - Focused on B-mode image quality
  - 1st generation probe

- VeriQ C today
  - Significantly improved imaging quality
    - Improved color flow (CFM)
    - Improved image resolution with new probe
  - 3rd generation imaging probe
    - Improved ergonomics
  - System interconnectivity - DICOM



Before



Now

Trends and demands

- The customers demand **application specific probes**
  - Imaging probes
  - Flow probes
- Demand for effective hospital routines require focus on **usability and handling of probes**
- Increased competition from the general ultrasound market creates **enhanced customer expectations**
- The new information society drive demand for **system interconnectivity** due to higher demand for patient data-integrity, -security and -exchange
- New OR designs expects vendors to support tighter **systems integration** to help unifying the surgeons information flow in the OR

System platform evolution

1994

1997

2002

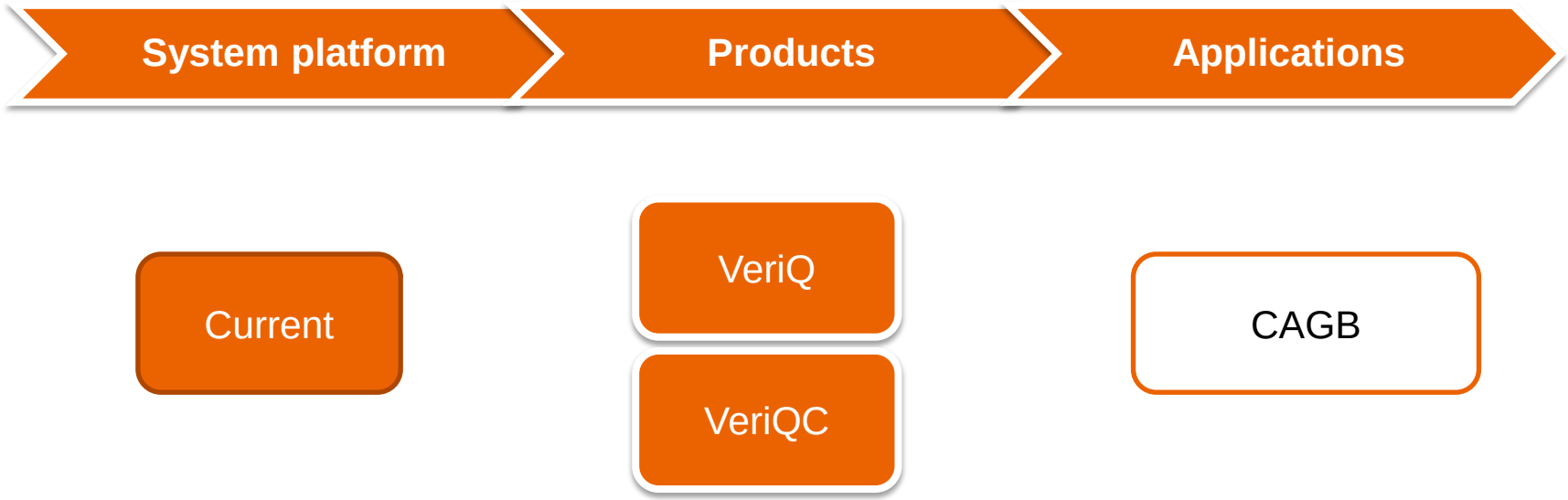
2009

2014

The next generation system platform

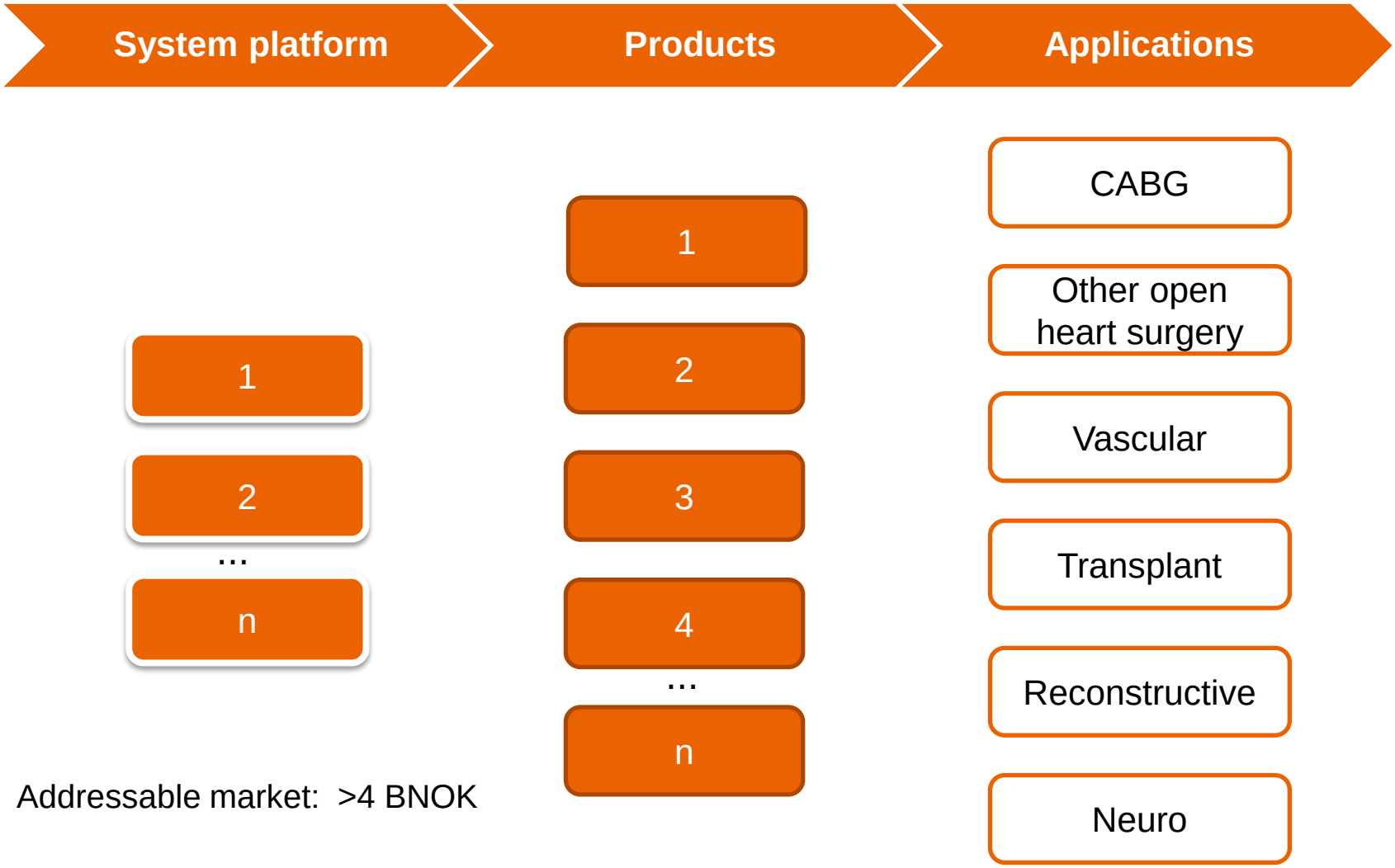
- On March 1st, 2013, Medistim initiated a new product development project in order to develop the next generation system platform
- A flexible system platform addressing new clinical applications and markets and maintaining leadership in existing applications
- The new system platform will be designed for future options and coming generations of systems
- The first products are planned for launch in 2014 / 2015

Today's system platform



Addressable market: 2 BNOK

The next system platform



Addressable market: >4 BNOK

Efficient development & low risk

Areas of focus for the R&D department:

Platform commons

Software
- Operating system
- Communication protocols
- Patient data security
- User interface engine
- Data processing

Hardware
- Mechanical base structure
- Electrical
- Main board
- Acquisition front-ends
- Safety

Application Specific

Software
- User interface
- Workflow
- Guidance
- Calculations and indices
- Reporting

Hardware
- Monitor/size
- Printer
- Mechanical adaptions
- Ergonomics

Probes
- Imaging
- Flow