

Will new technologies make important differences?

CGCI from Magnetecs

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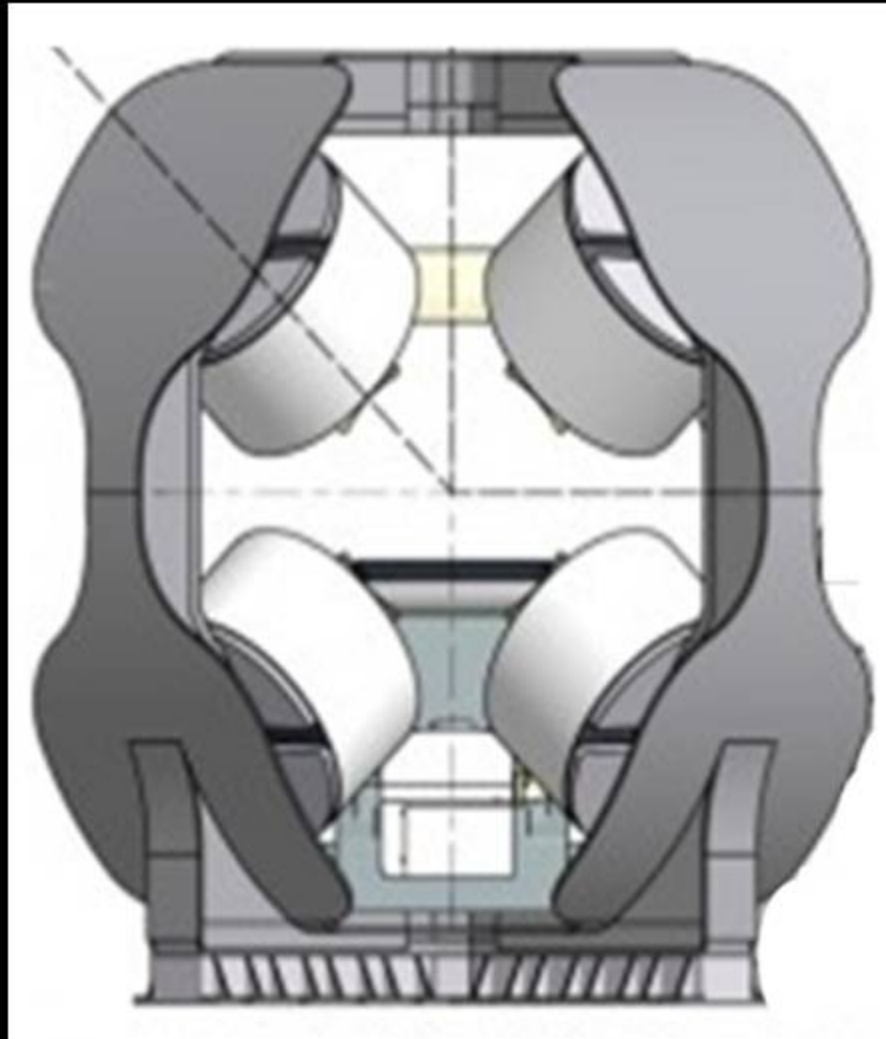
Madrid

Disclosure

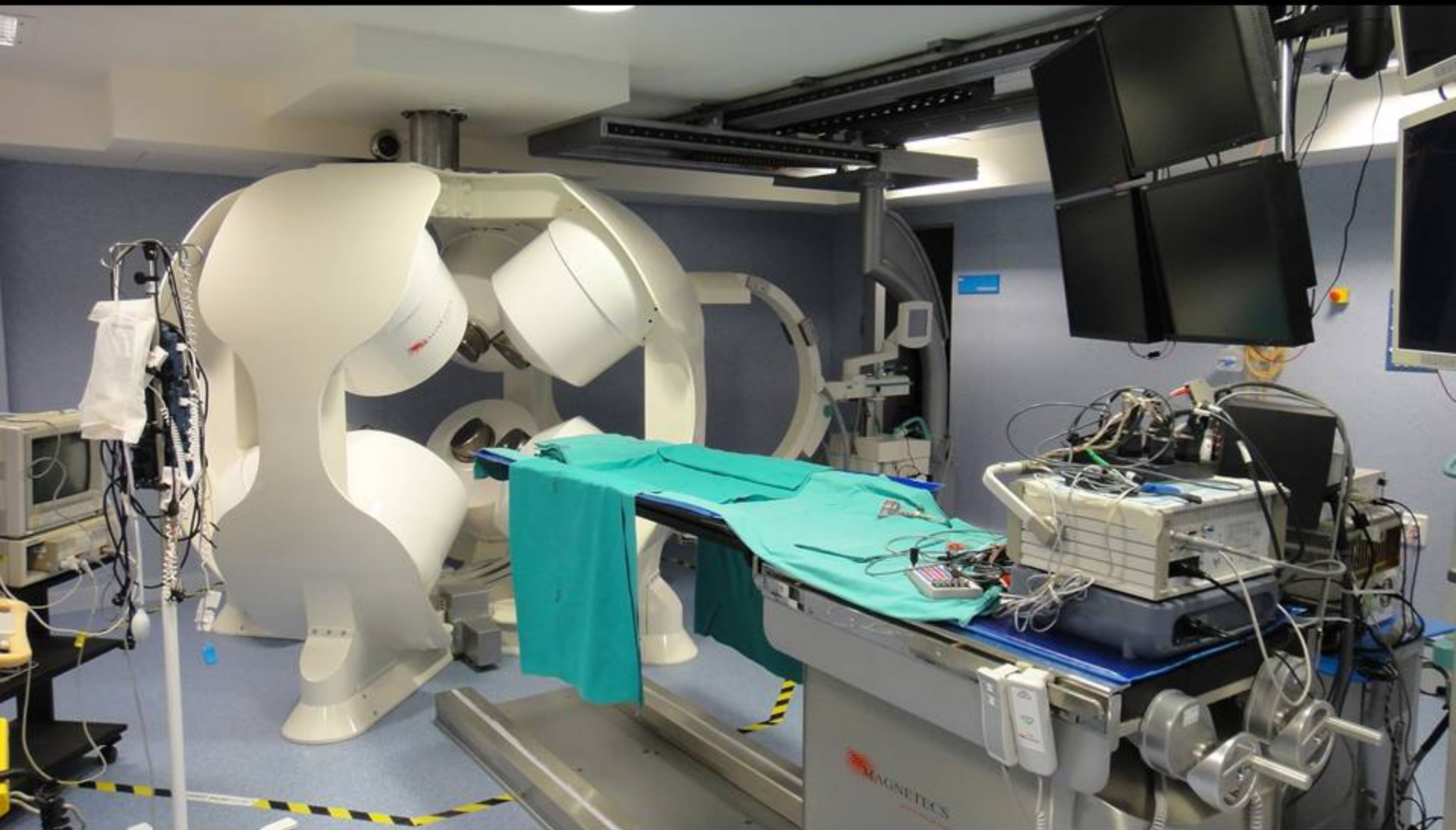
Conflict of interest

- **Advisory board: Magnetecs, Merck, Sanofi-Aventis**
- **Research grants: Medtronic, Boston Scientific, Sorin Group**
- **Educational contracts: St Jude Medical**

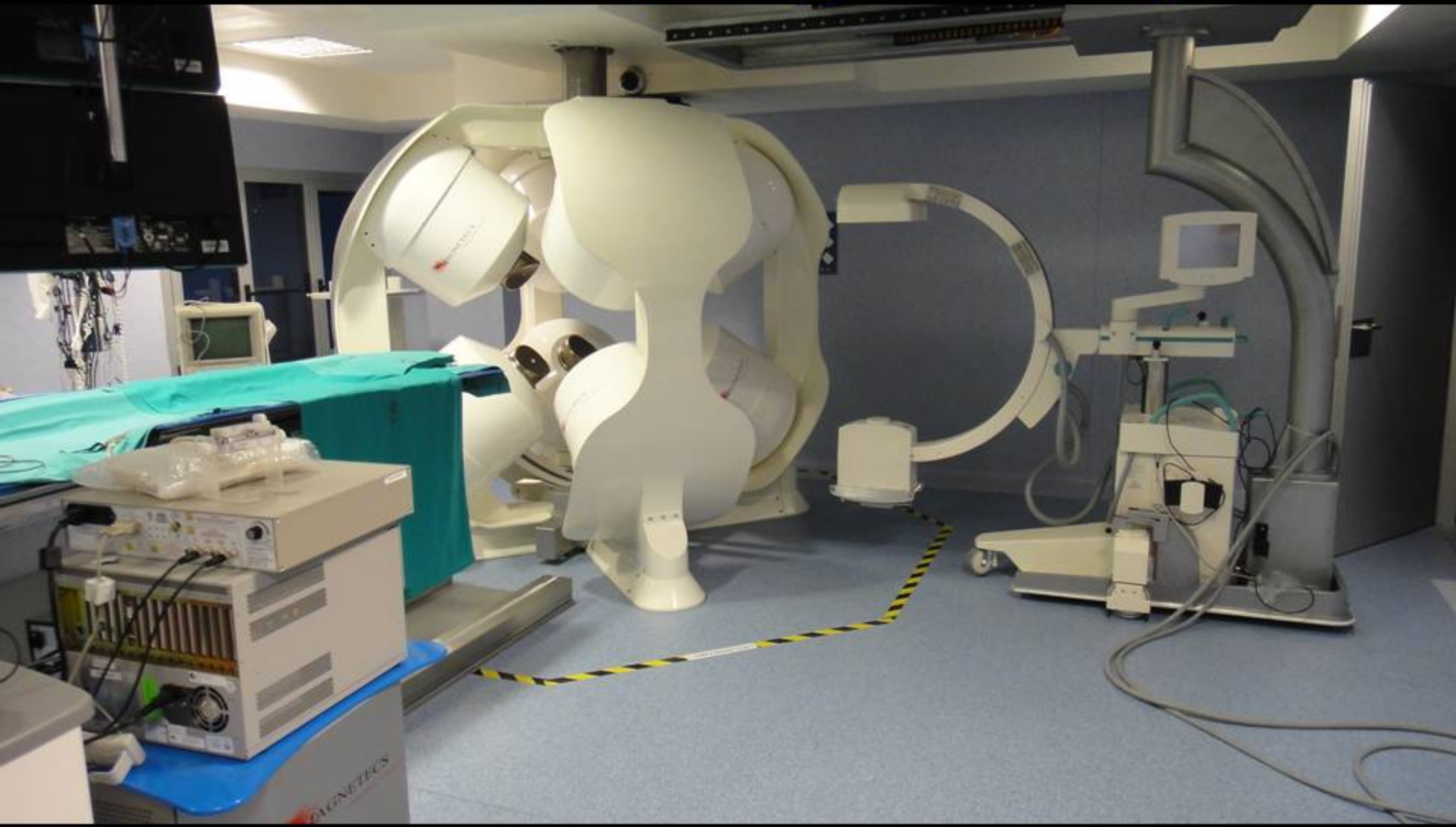
CGCI™ (Magnetecs)

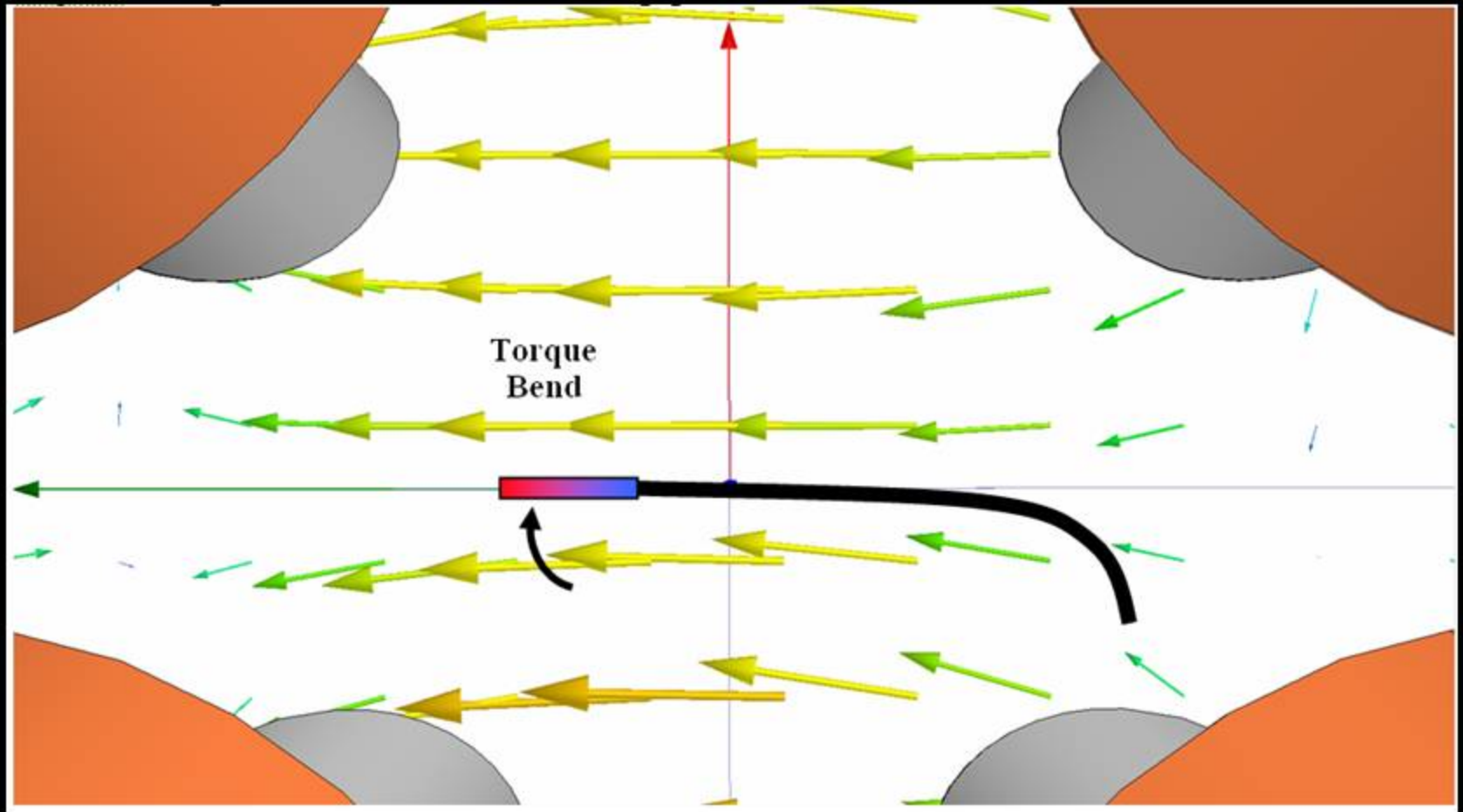


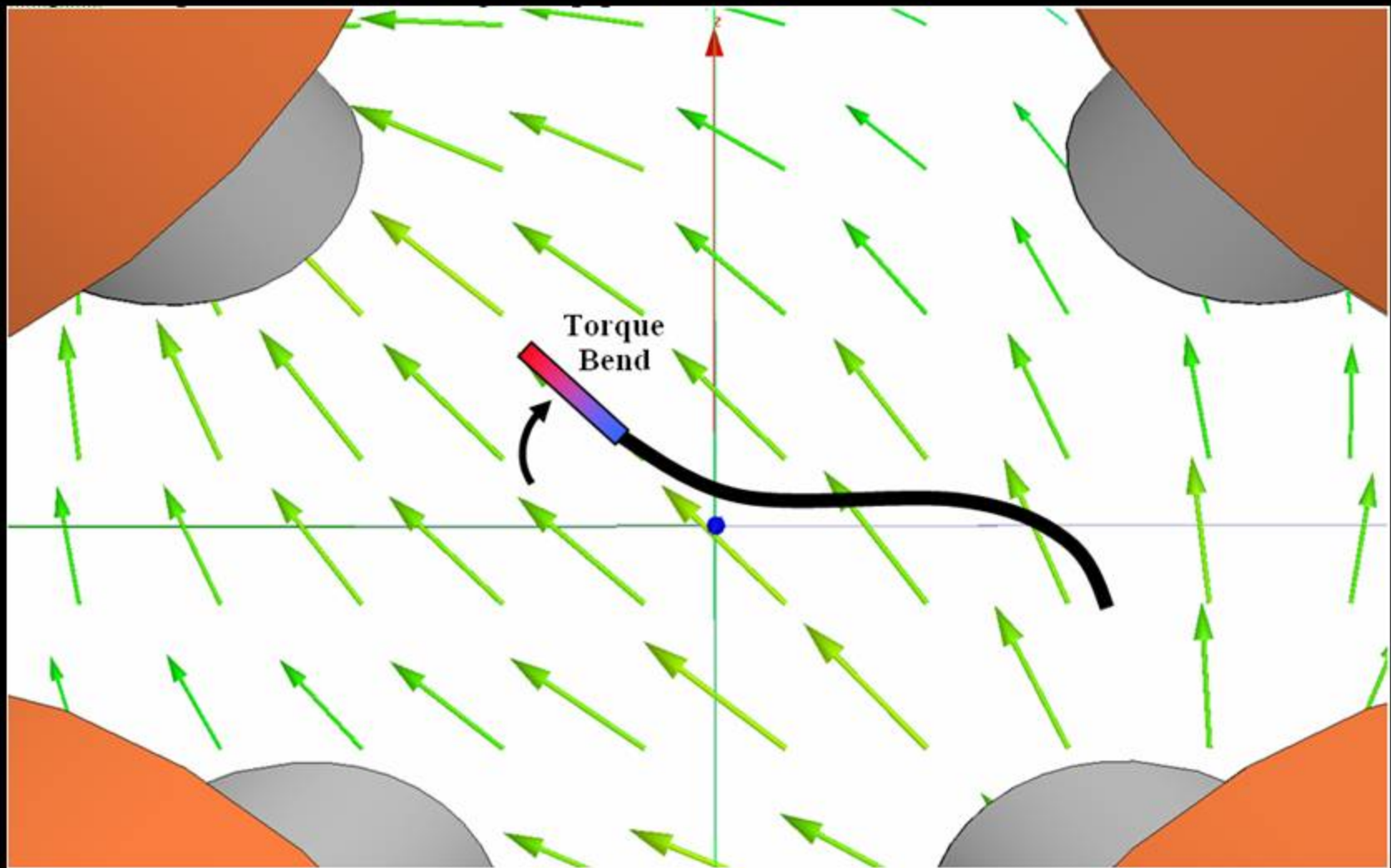
CGCI™ (Magnetecs)

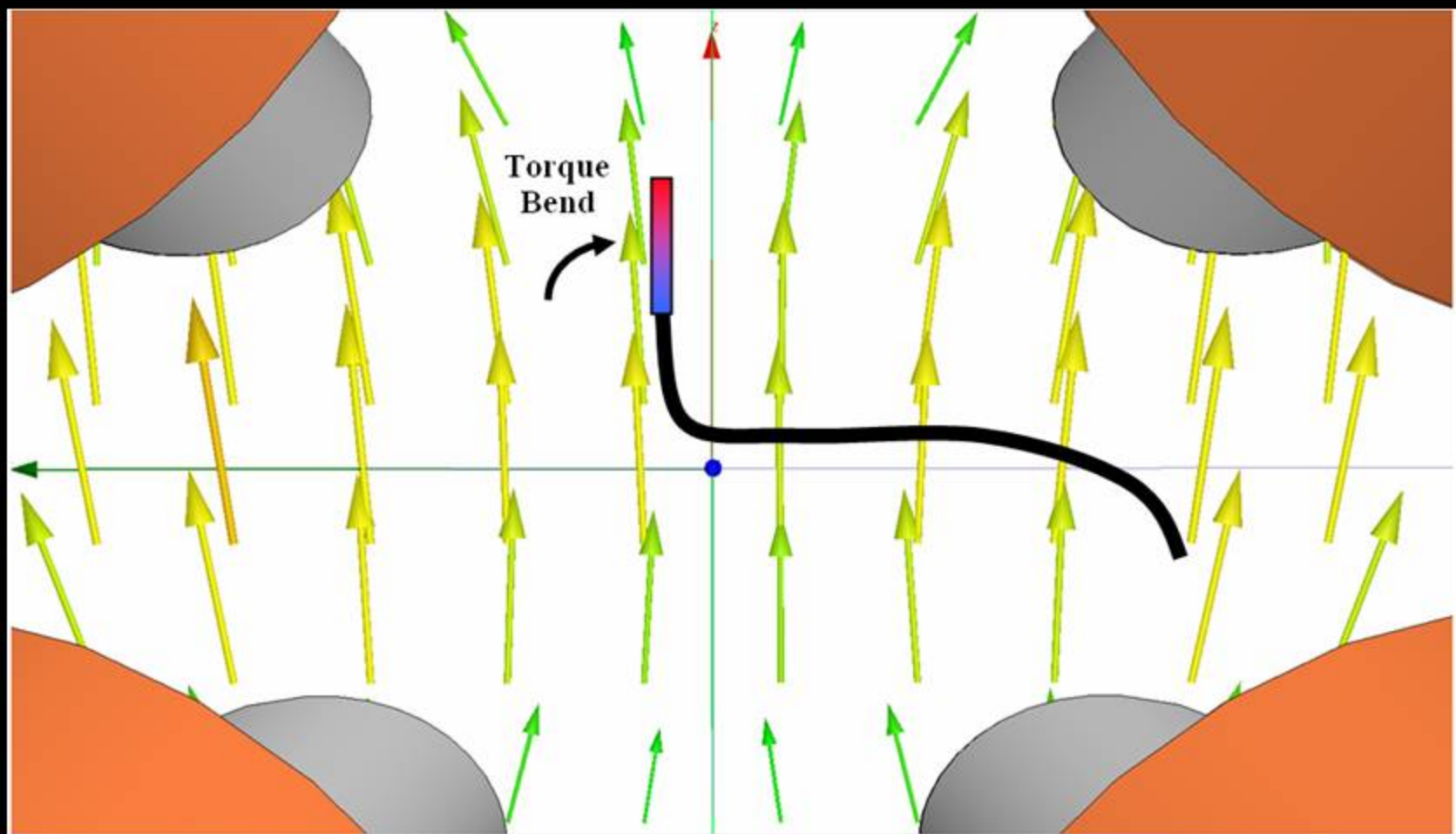


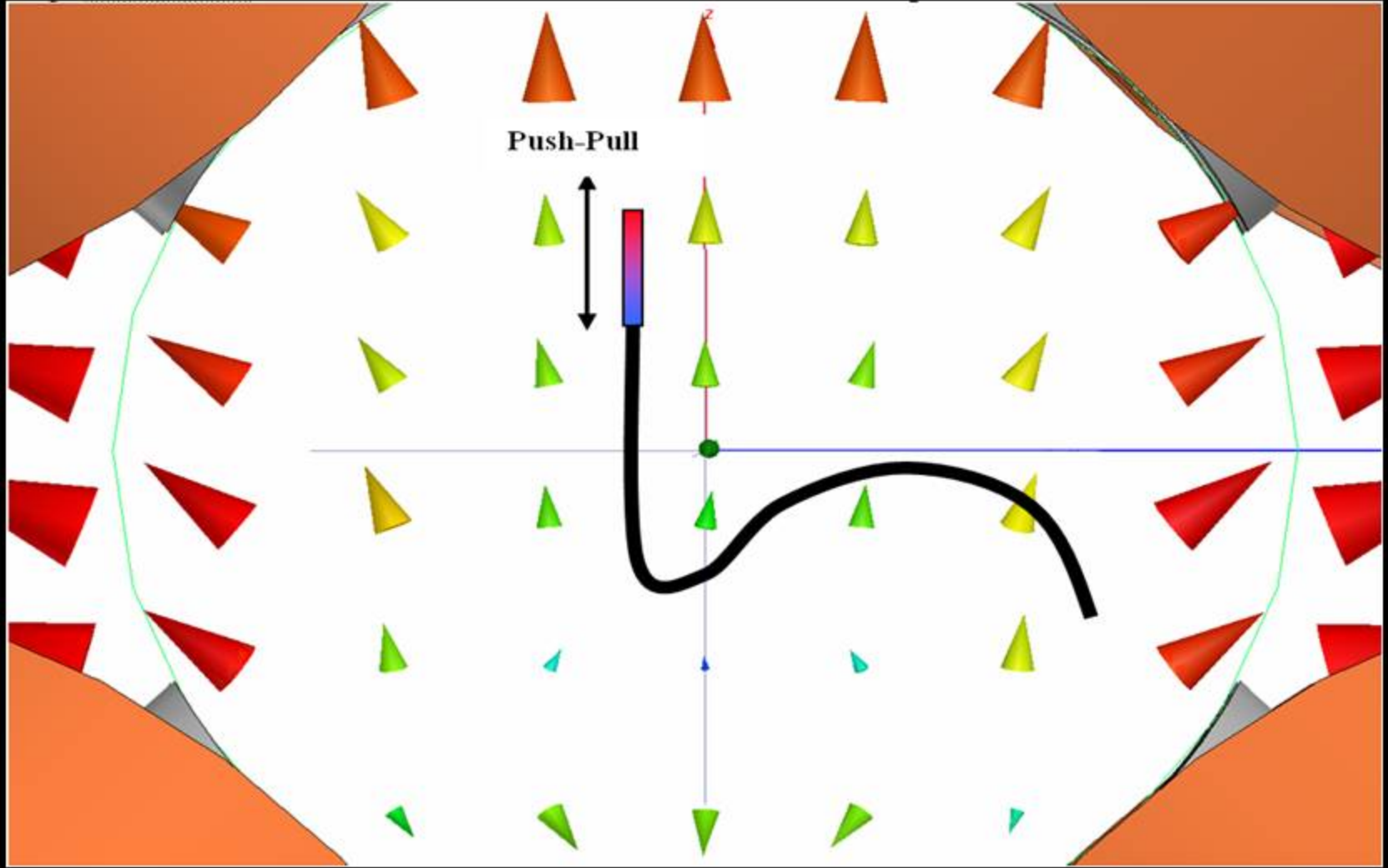
CGCI™ (Magnetecs)











CGCI

- **8 Electromagnets**
- **Catheter pushing and pulling device (CISD)**
- **Console:**
 - ◆ **3D electroanatomical system**
 - ◆ **2 Joysticks**
- **Disposables:**
 - ◆ **Magnetic catheter**
 - ◆ **Electrode sheath**

CGCI

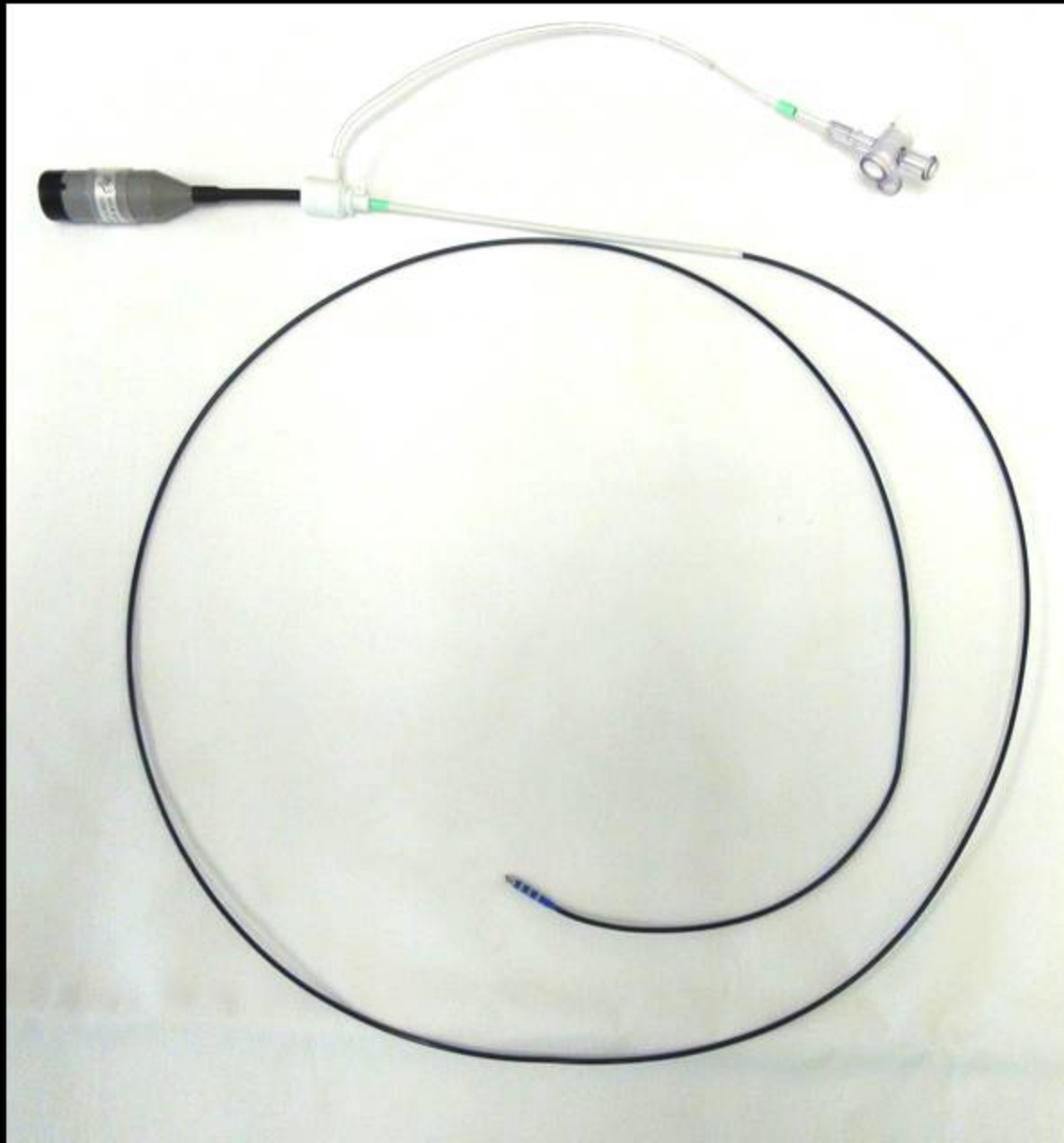
- 0.14 Tesla
- Magnetic shielding and lenses:
Focused magnetic field
 - ◆ 15 cm³
 - ◆ 25 g force
 - ◆ <25 gauss at 60 cm

- ◆ Room shielding not needed

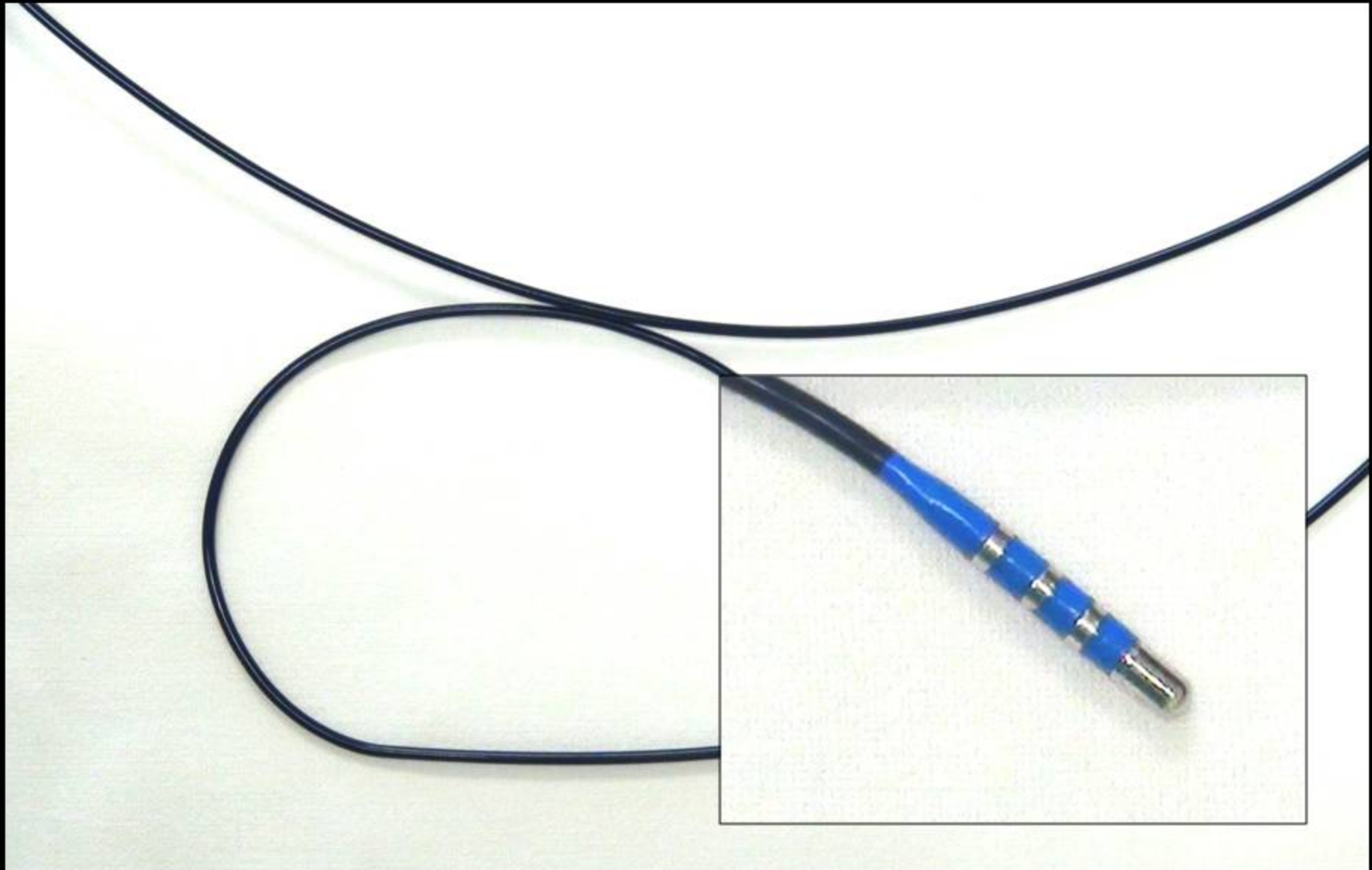
CGCI Disposables

- Agilis ES sheath (3 electrodes)
- Maxwell catheter
 - ◆ 7 F
 - ◆ Very soft
 - ◆ Magnetic pellet at its tip

Maxwell™ catheter



Maxwell™ catheter



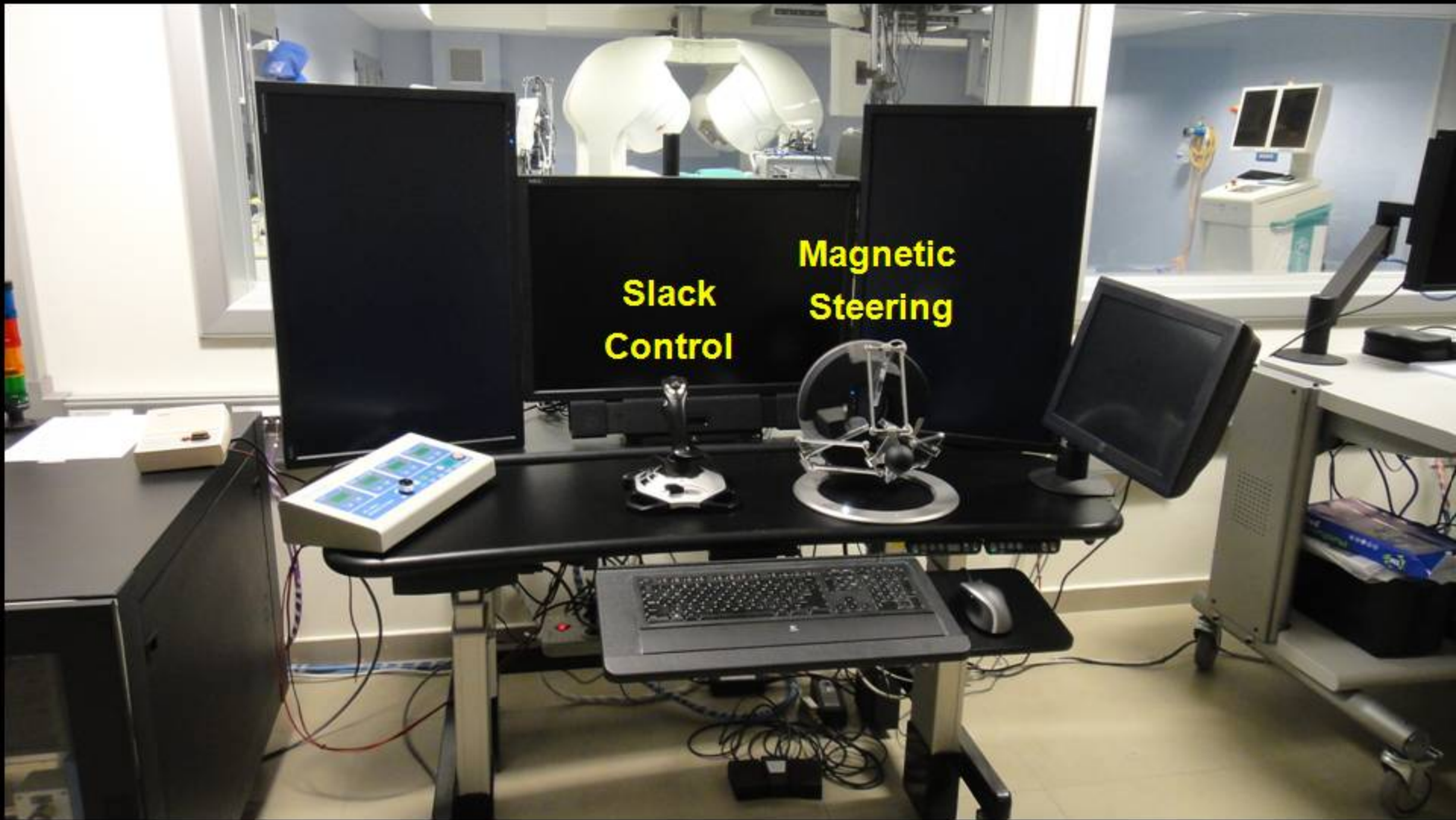




CGCI Console



CGCI Console



CGCI Console

- 3D electroanatomical system (Ensite-NavX) with embebed CGCI
- EP recording system (EP-Med)
- Fluroscopy (Ziehm)
- ICE
- Auxiliary equipment:
 - ◆ Stimulator
 - ◆ RF generator

gE20 Controller
Manual Magnetic Locks
Auto Mapping

None
Selected Target

43.0 Zone 3
Time to Target (sec) Priority

15.1
Distance to Target (cm)

Monitor Off
Mode Integrate

93.5 Off
CSD (sec) Jet/Soft Test

Off Off
CSD Regulator

1.00 0.19
File Rate Progress Ratio



ECD Connect Levels

Monitor ICE X RAY

Power On



CGCI Control Modes

Automatic Point and Click

3D CGCI Controller

Manual Magnetic Joystick

Auto Mapping

.1

Selected Target

12.0

Zone 3

Time to Target (sec)

Proximity

5.1

Distance to Target (mm)

Proximity

Off

Mode

Retrograde

0.5

CISD (mm)

Off

JoyStick Hold

On

CISD

On

Regulator

1.00

Filter Ratio

0.24

Progress Ratio

AVNRT

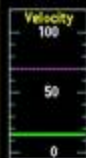
4 segments recorded.

Color Overlay NR 39:45

Mode: Realtime Review

File Signals Views PIU Tools HotKeys Help

AP LAO RAO View1 View2 View3



Coupling Wave
Electrode spacing | Distal | D-2 | 2-3
Nominal (mm) | 4.0 | 2.0 | 2.0
Measured (mm) | -200 | 1.8 | 2.5
-300%

NavX

Utilities Optimize Enguide

NavX Validation: Validate NavX

surface

NVA

EnGuide: Disabled Single Multi

14:31:41

Annotate & Click Complete ...

Amplifiers Enabled

RG:1.20

JSR

LCK

FTN

ADI

SS

NAV

MAG

ECG

EP1

EP2

CTR

Fri 11-19-2010 14:31:40



ECI Contact Levels



Patient



Mapping



ECG



Monitor



ICE



Interface



System



XRAY



CGCI Control Modes

Automatic Point and Click

3D CGCI Controller

Manual Magnetic Joystick

Auto Mapping

None

Selected Target

43.0

Time to Target (sec)

Zone 2

Proximity

3.1

Distance to Target (mm)

Monitor

Mode

Off

Retrograde

9.9

CISD (mm)

Off

JoyStick Hold

Off

CISD

Off

Regulator

0.20

Filter Ratio

-0.54

Progress Ratio

WPW 7 segments recorded. CGCI Overlay NR Mode: Realtime Review

File Signals Views PIU Tools HotKeys

Distal Color High -3.000 Color Low -1.000 Save... AP LAO RAO View1 View2 View3 Help

Velocity 150
100
50
0

Respiration 300
200
100
0
-100
-200
-300

CouplingWave 182.06 183.00

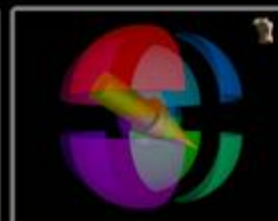
Electrode spacing	Distal	D-2	2-3	3-4
Nominal (mm)	4.0	2.0	5.0	2.0
Measured (mm)		2.5	4.0	2.5

Proximity to EnSite surface: -8.4 mm (Avg: -7) 13:22:59:1058

Save Event... Record Annotation: INICIO ANATOMIA Disk Space: 1:11:53 Trigger On NA EnGuide: Disabled Single Multi

System Ready EnSite Connect Offline 13:23:07

3D Controller RG:1.20 JSR LCK FTN ADJ SS NAV MAG ECG EP1 EP2 CTR



ECI Contact Levels 4000 300 200 100 0 145 Inactive

Patient Mapping ECG Monitor Monitor ICE XRAY

Power On 90% Interface XRay



Mon 11-22-2010 13:23:06

CGCI Control Modes

Automatic Point and Click

3D CGCI Controller

Manual Magnetic Joystick

Auto Mapping

None

Selected Target

0.0

Time to Target (sec)

Start

Proximity

0.0

Distance to Target (mm)

Ready

Mode

Off

Retrograde

21.6

CISD (mm)

Off

JoyStick Hold

Off

CISD

Off

Regulator

1.00

Filter Ratio

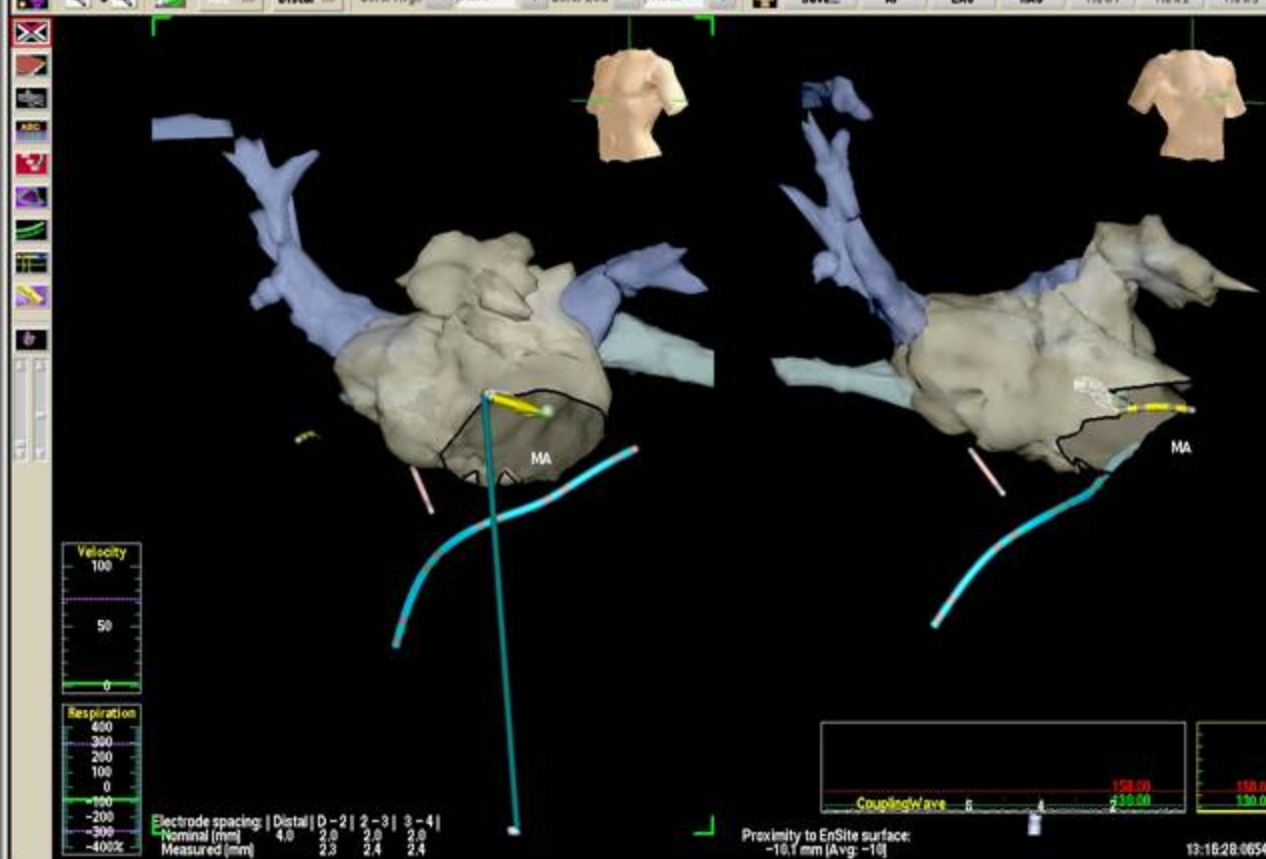
0.86

Progress Ratio

AVNRT 5 segments recorded. CISEI Overlay NR 30:44 Mode: Realtime Review

File Signals Views PIU Tools HotKeys Help

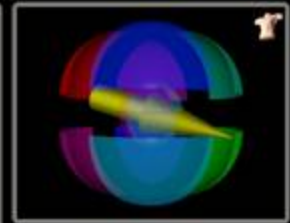
Distal Color High - 0.000 + Color Low - 1.000 Save... AP LAO RAO View1 View2 View3



Save Event... Complete Annotation: LA Disk Space: 4424 Trigger On N/A EnGuide: Disabled Single Multi

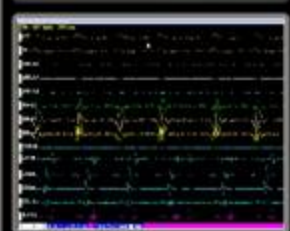
Annotate & Click Complete ... EnSite Connect Offline 13:16:37

RG-1.20 JSR LCK FTN ADJ SS NAV MAG ECG EPs EPs CTR



Power On 90%

System XRay



Wed 11-10-2010 13:16:36

CGCI Control Modes

Automatic Point and Click

3D CGCI Controller

Manual Magnetic Joystick

Auto Mapping

.1 (Last)

Selected Target

13.4

Time to Target (sec)

Zone 3

Proximity

5.2

Distance to Target (mm)

Proximity

Mode

Off

Retrograde

0.0

CISD (mm)

On

JoyStick Hold

Off

CISD

Off

Regulator

1.00

Filter Ratio

0.24

Progress Ratio

AVNRT

4 segments recorded.

CGCI Overlay NR

39:45

Mode: Realtime Review

Help

File Signals Views PIU Tools HotKeys

Distal Color High - 0.000 Color Low - 1.000 Save... AP LAO RAO View1 View2 View3



Coupling/avg

Electrode spacing: Distal	D - 2	2 - 3	3 - 4
Nominal (mm)	4.0	2.0	2.0
Measured (mm)	2.5	2.8	2.3

Proximity to EnSite surface:
-3.3 mm (Avg: -3)

14:29:50.0654

Save Event...

 Complete

Annotation: [CGCI PROTOCOL]

Disk Space: 53:31

 Trigger On

NA

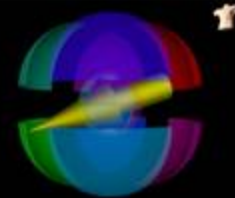
EnGuide: Disabled Single Multi

Annotate & Click Complete ...

EnSite Connect Offline

 14:30:00

3D Controller



ECI Contact Levels



145 Inactive

Patient



Mapping



ECG



Monitor



ICE



X RAY



Power On



90%



System



XRay



Fri 11-19-2010 14:29:59

RG-1.20

JSR

LCK

FTN

ADJ

SS

NAV

MAG

ECG

EP₁EP₂

CTR

Study 1 of 1 for search of: magnetecs

[← Previous Study](#) [Return to Search Results](#) [Next Study →](#)

[Full Text View](#)

[Tabular View](#)

[No Study Results Posted](#)

[Related Studies](#)

Accuracy and Safety Study of the Magnetecs CGCI System for Intracardiac Mapping (RICTAM)

This study is currently recruiting participants.

Verified by Magnetecs Corporation, October 2010

First Received: October 14, 2010 Last Updated: October 15, 2010 [History of Changes](#)

Sponsor:	Magnetecs Corporation
Information provided by:	Magnetecs Corporation
ClinicalTrials.gov Identifier:	NCT01222156

RICTAM Trial

- **Pts to enroll: 40**
- **Primary objective: Mapping accuracy**
 - ◆ Manual mode
 - ◆ Automatic mode
- **Primary safety objective: no SAE**
- **Inclusion criteria:**
 - ◆ SVT & VT for ablation
 - ◆ No AF or Ischemic VT

RICTAM Trial

Preliminary results

- N = 19 pts
- Chambers mapped:
 - ◆ RA (9 sites) = 9 pts
 - ◆ RV (9 sites) = 6 pts
 - ◆ LA (5 sites) = 5 pts
 - ◆ LV (5 sites) = 2 pts

RICTAM Trial

Preliminary results

- **Geometrical reconstruction**
 - ◆ **Better than conventional:**
more degrees of freedom, no stretching
- **Manual mode site acquisition: 100%**
- **Automatic mode site acquisition: 95%**
 - ◆ **Time to target: 16.5 ± 7.3 sec**
 - ◆ **Accuracy: 2.1 ± 1.5 mm**
- **No SAE**

Conclusions

- **Focused Magnetic Field & powerful magnetic catheter**
- **Electromagnets**
 - ◆ **Fast response**
 - ◆ **Servo loop control**
- **Integrated console for full control of all EP systems**
- **Preliminary results: promising**

CGCI Control Modes

Automatic Point and Click

3D CGCI Controller

Manual Magnetic Joystick

Auto Mapping

.9 (Last)

Selected Target

16.3

Zone 1

Time to Target (sec)

Proximity

2.0

Distance to Target (mm)

Monitor

Off

Mode

Retrograde

0.0

CISD (mm)

Off

JoyStick Hold

Off

CISD

Off

Regulator

0.20

Filter Ratio

-0.18

Progress Ratio

AVNRT

4 segments recorded.

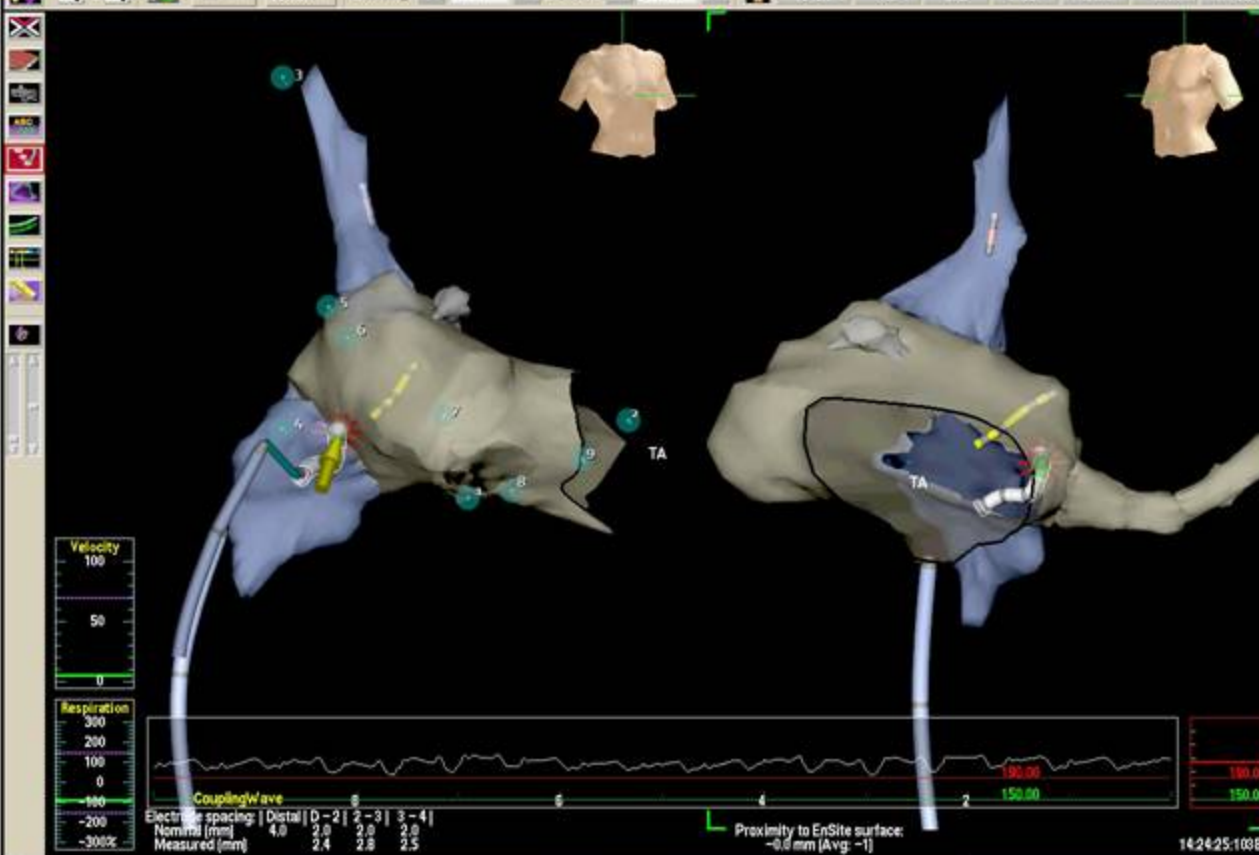
CGCI Overlay NR

39:45

Mode: Realtime Review

File Signals Views PIU Tools HotKeys Help

Distal Color High 1.000 Color Low 1.000 Save... AP LAO RAO View1 View2 View3



Save Event...

Complete

Annotation: CGCI PROTOCOL

Disk Space: 53:31

Trigger On

NA

EnGuide: Disabled Single Multi

Annotate & Click Complete ...

EnSite Connect Offline

14:24:36

3D Controller

Amplifiers Enabled

RG-1.20

JSR

LCK

FTN

ADI

SS

NAV

MAG

ECG

EP₁EP₂ CTR

Fri 11-19-2010 14:24:34