

Methodology for evaluating Augmented Intervention in Medicine

Clinical Investigation Centre - Innovative Technology

Dr A. Moreau-Gaudry
Pr P. Cinquin

DMIS / IN3S CHU de Grenoble
BP 217, 38043 Grenoble Cedex 09
☎ : +33 (0)4 76 76 92 60

email : cic-it@imag.fr
website : <http://www.maxithec.com>

Outline

1. Introduction
2. Background
3. Examples
4. Missions

Computer Assisted Medical Intervention

Augmented surgery in Grenoble:
a serie of premieres

Prostate Biopsy 3D
reconstruction
Dr Mozer, Pr Richard



Compact motorized scope holder for
advanced laparoscopic surgery
J-L Descotes, J-J Rambeaud, C Létoublon,
F Richard, P Mozer



MRI/sonography fusion for prostate
curietherapy
Pr Solla, Dr Fournier, J.Y. Giraud,
Pr Descotes

Robotized TeleEchography
G. Ferretti, I. Bricault, J-J Benhachem



Navigation of Total Knee Prothesis
Pr D. Saragaglia



Navigation of vertebral pedicular screws
Pr Ph Merlot



Navigation of Knee Ligamentoplasty
Dr. R. Jullard

1995

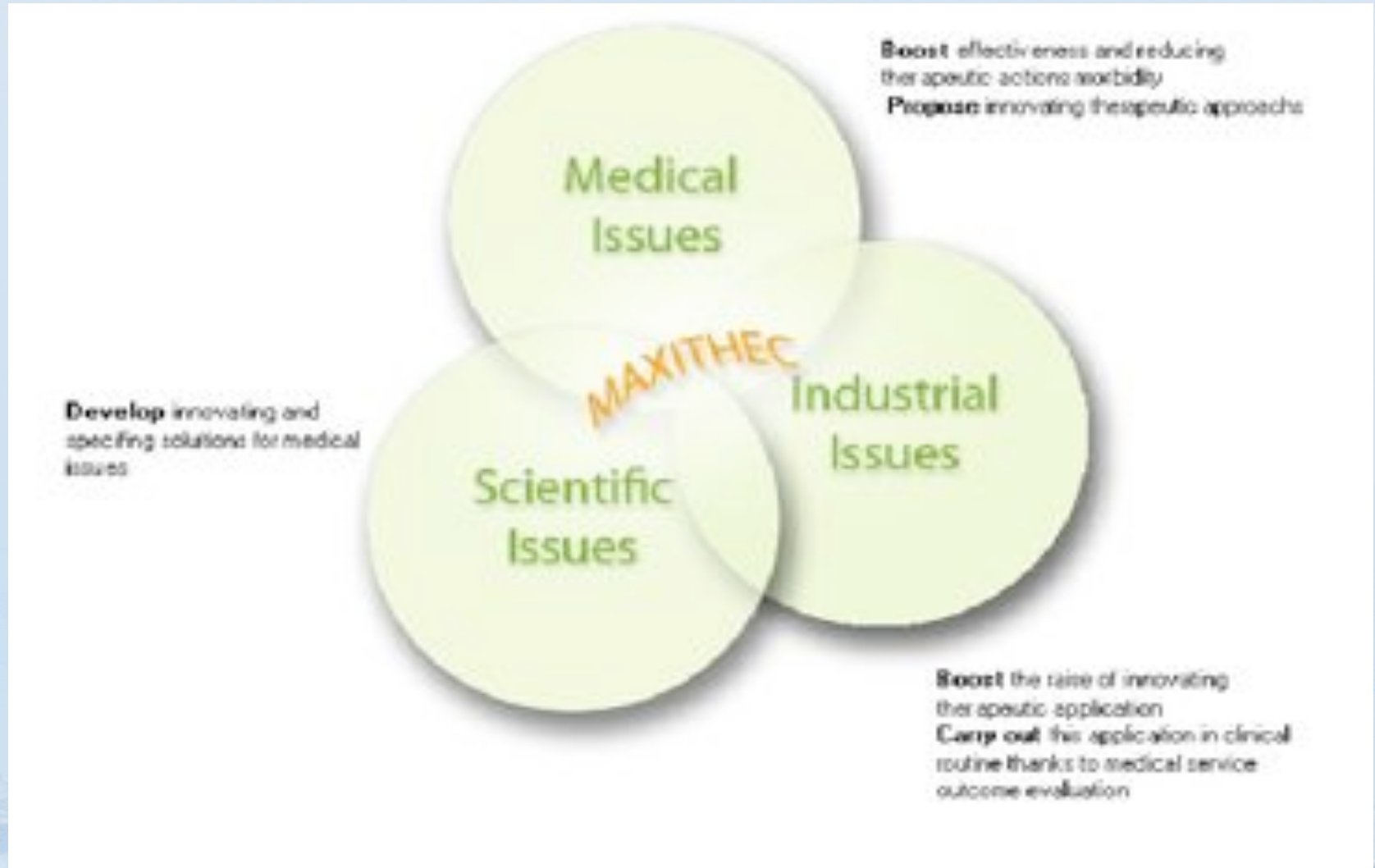


Navigation of Orthognatic surgery
Pr. B. Raphael

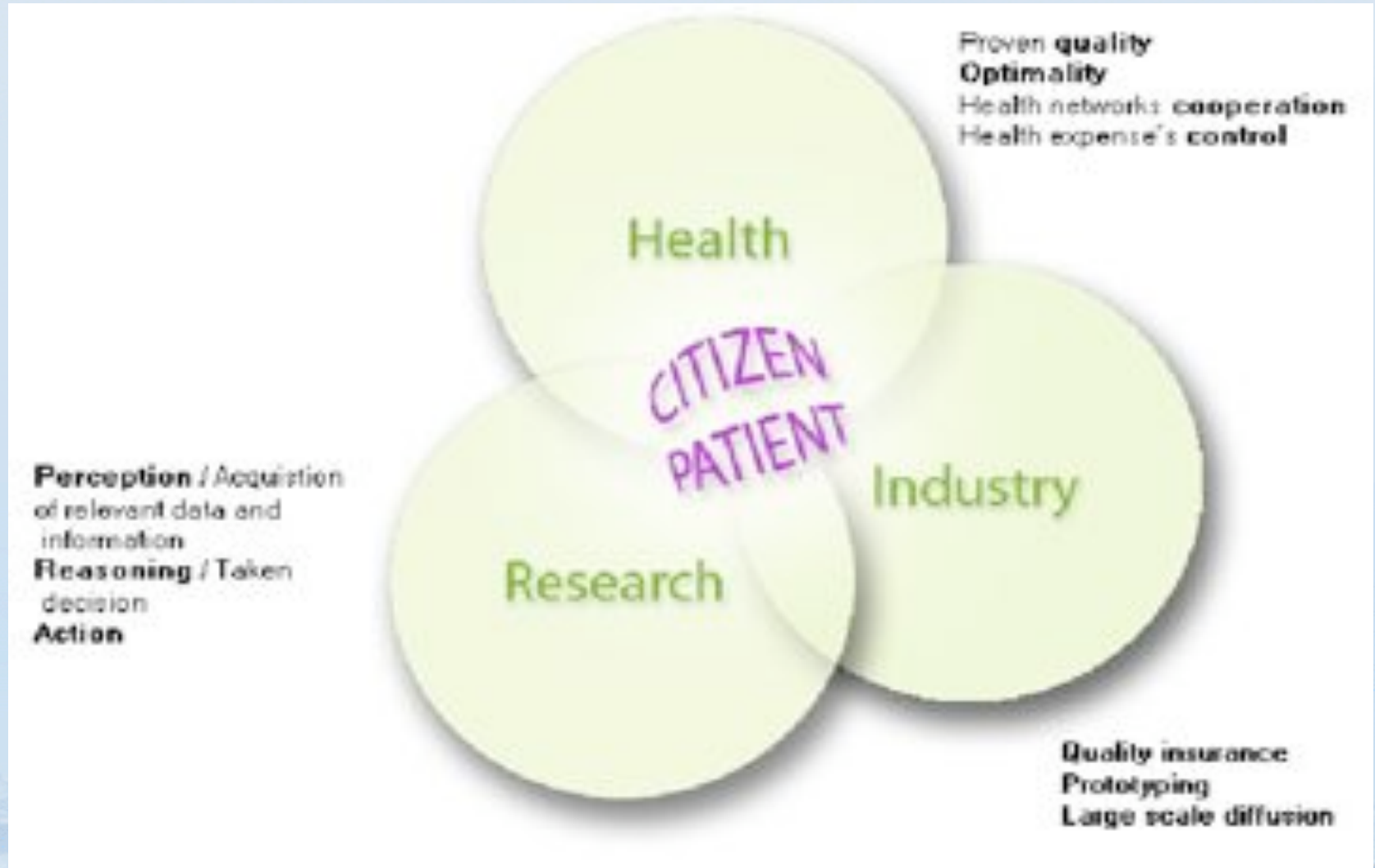


Robotized Brain Stereotaxic Surgery
S. Lavalée, Pr. A.L. Benabid

A structure at a crossroads of the different issues...



... with the patient at the heart of the challenge.



MAXITHEC

MAXImizing the effects of expert targeted therapies

- **Therapeutic action ...**

surgery, interventional radiology, radiothérapie, endoscopic surgery, immunotherapy, monitoring, ...

- **... that needs a model coming from the expertise of the operator ...**

mathematical model, informatic model, biomécanical model, anatomo-physiological model, ...

- **... guided towards an target to optimize the benefit/risk ratio by tools built from previous model.**

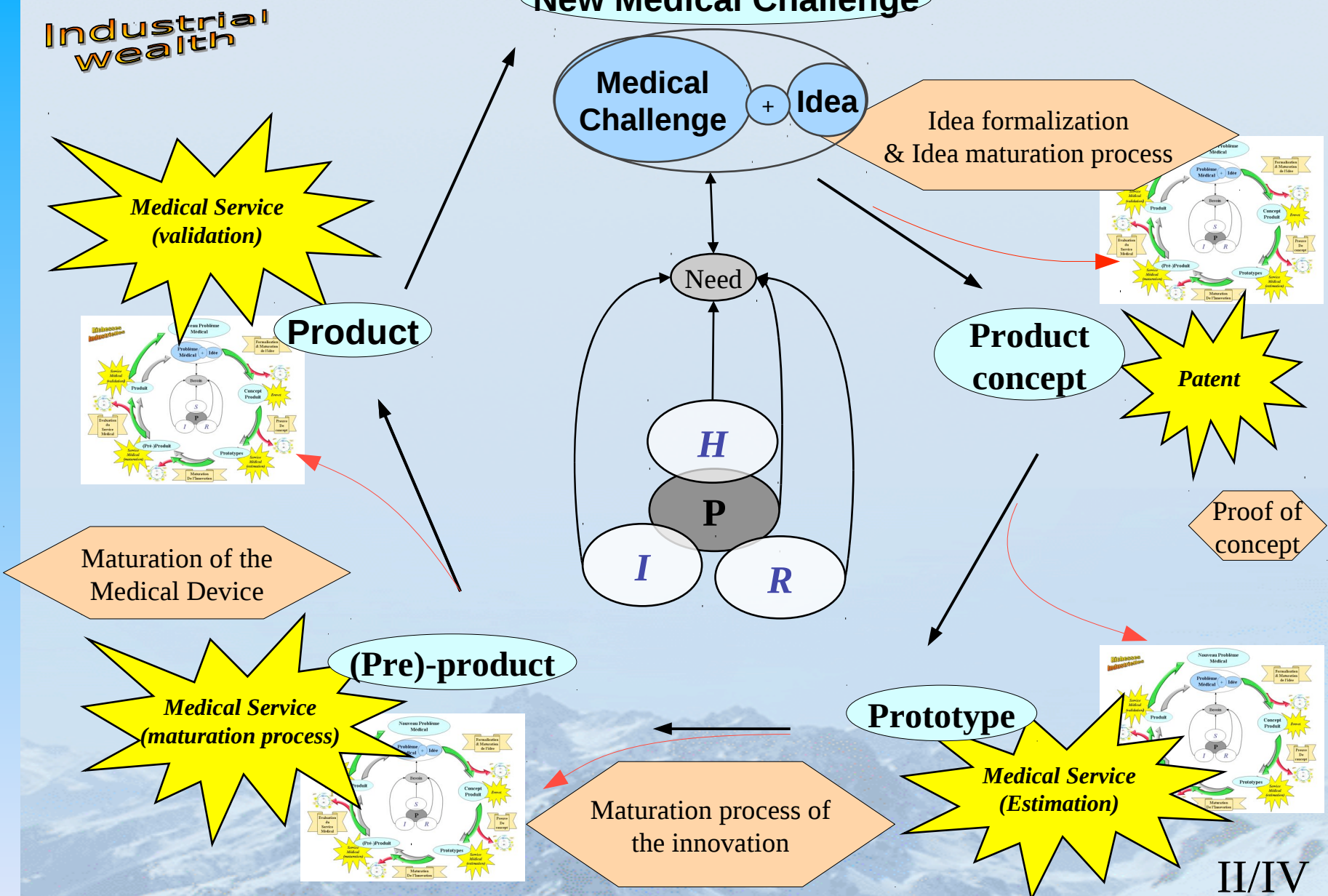
CREPS Cycle

- **Concept**
- **Research**
- **Experiment**
- **Product**
- **Safe Care**

Développement d'une Innovation
Technologique en Santé :
le cycle CREPS – Concept –
Recherche - Essais – Produit – Soins

Numéro spécial CIC-IT
ITBM-RBM
31(1)2010 pp12-21

New Medical Challenge



Organization & the maturation process of Innovation

CIC-IT GRENOBLE
 Centre d'Investigation Clinique - Innovation Technologique

MAXITHEC trials illustrate the innovation DMS evaluation processus : proof of concept, maturation, validation

Presentation

- Background
- Issues
- The citizen patient

Founding members and partners

- Summary
- Health
- Research
- Industry

Trials

- Summary
- Proof of concept step
- Maturation step
- Validation step

Search

- DMS evaluation

Press

- Press

The CIC in France

- CIC-IT France map
- CIC France map

Proof of concept step trials

Planned trials	Trials in progress	Completed trials
Ligament balance Prostate Assigned endoscopy Optical imagery	PRIOD SSLEP HEMOCARD EMG-MMG	VEQU TMAT

Maturation step trials

Planned trials	Trials in progress	Completed trials
	TER2 CT-NAV	

Validation step trials

Planned trials	Trials in progress	Completed trials
	REL	NavPerOp

Stage : « Proof of concept »

- **HEMOCARD**



Stage : « Proof of concept »

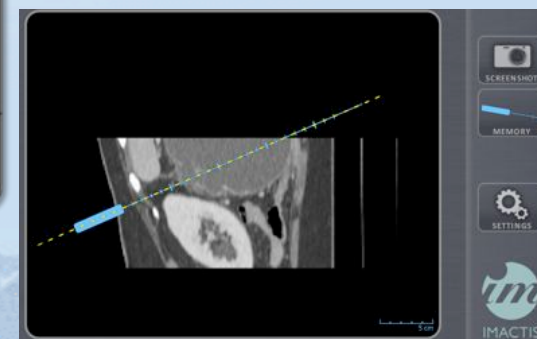
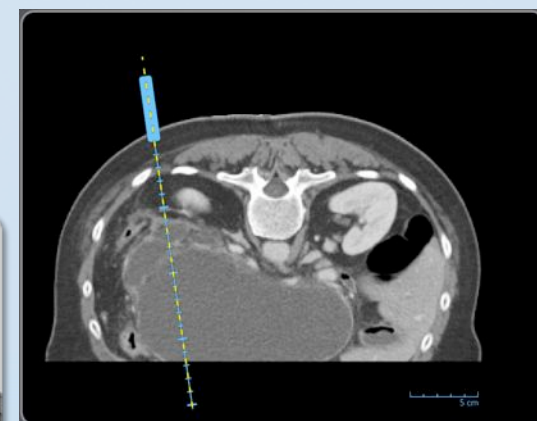
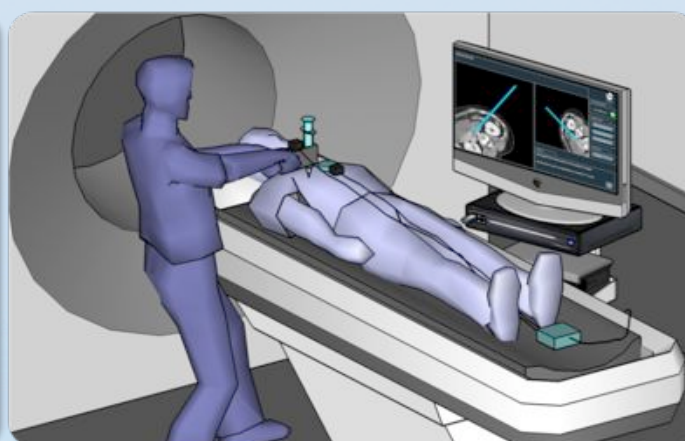
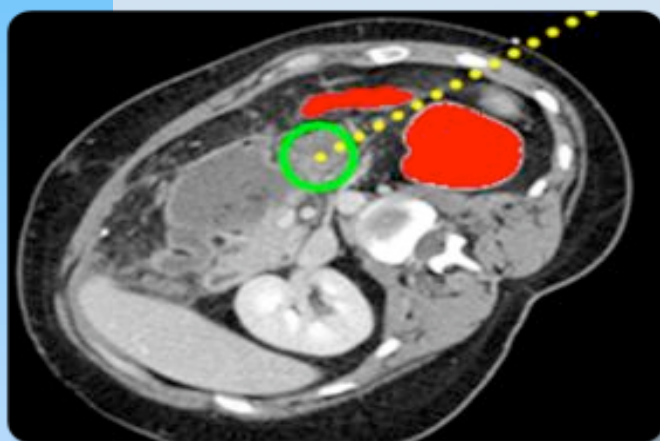
- **HEMOCARD**

- Innovative Medical Device
- Class III / Not CE Marked
- Biomedical Research Protocol
 - Risk Analysis, CPP, AFSSAPS
- First results
 - 2 / 30
 - EJCTS
 - Startup « *Hemosquid* »



Stage : « Maturation »

- CT-Nav
 - Startup IMACTIS®



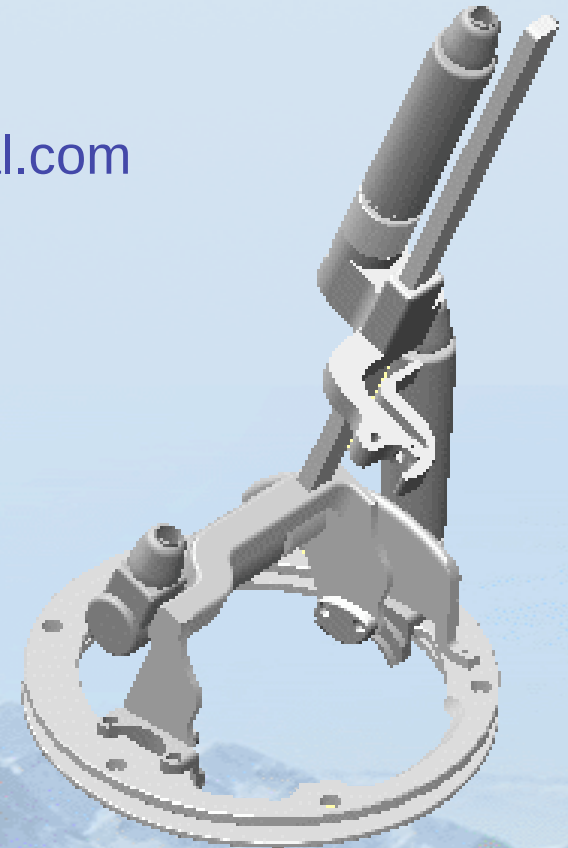
Stage : « Maturation »

- **CT-Nav**
 - Startup IMACTIS®
 - <http://www.imactis-grenoble.fr>
 - Innovative Medical Device
 - Class I / Not CE Marked
 - Biomedical Research Protocol
 - Risk Analysis, CPP, AFSSAPS
 - First results
 - 30/120
 - first analysis 03/2011

Stage : « Validation »

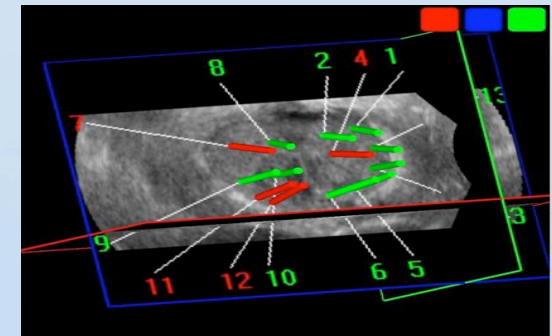
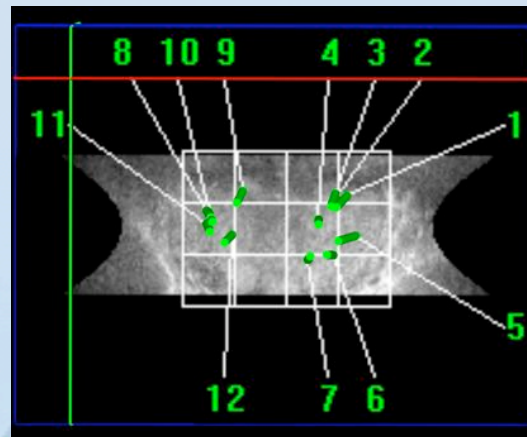
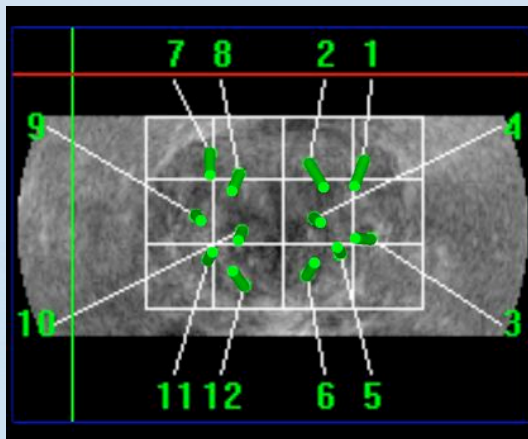
- **REL**

- Startup ENDOCONTROL®
 - <http://www.endocontrol-medical.com>
- Innovative Medical Device
- Class I / CE Marked
- Biomedical Research Protocol
 - CPP, AFSSAPS
- First results
 - 76/102
 - Final analysis 03/2011



Stage : « Validation »

- **Urostation®**
 - Startup **KOELIS®**



Stage : « Validation »

- **Urostation®**
 - Startup KOELIS®
 - <http://www.koelis.com>
 - Innovative Medical Device
 - Class I / CE Marked
 - PHRC-INCA
 - Medical evaluation
 - Medico-economic evaluation

CIC-Innovative Technology

- Part of the national network of the CIC-IT (<http://www.cic-it.fr>)
- Strategic partner in specialized domain
- often at the interface between actors from
 - the health field,
 - research field
 - industrial field
- Short circuit between concerned actors

CIC-Innovative Technology

- **To make faster :**
 - the *revelation* of the need
 - the *definitions* of functional specification and operational specification
- **Know-how in the biomedical research field**
 - Acquire objective proves
- **At term**
 - to decrease the *duration* of the maturation process of an Innovative Technology
 - To demonstrate the Medical Benefit of the Innovative Technology

CIC-Innovative Technology

Thank you for your attention