# Medical devices SIG

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Medtronic

# Agenda

- Definition
- Main characteristics
- Challenges
- Discussion

# Definition

## Directive 93/42/EEC concerning medical devices amended by 2007/47/EC

‘medical device’ means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

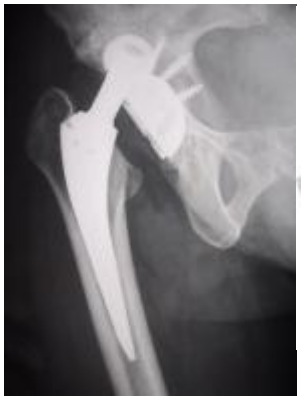
- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

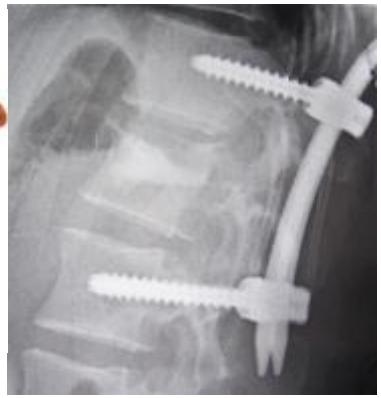
# A simplified definition

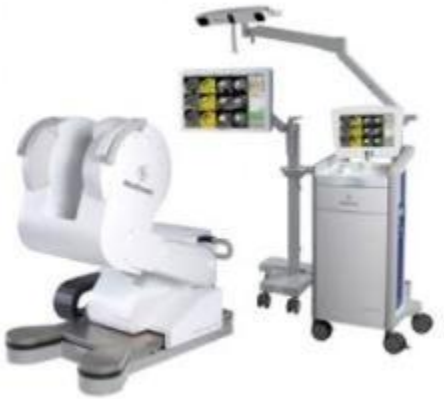
Medical Device can be defined as

any healthcare product that does not achieve its principal intended purposes by chemical action or by being metabolized.

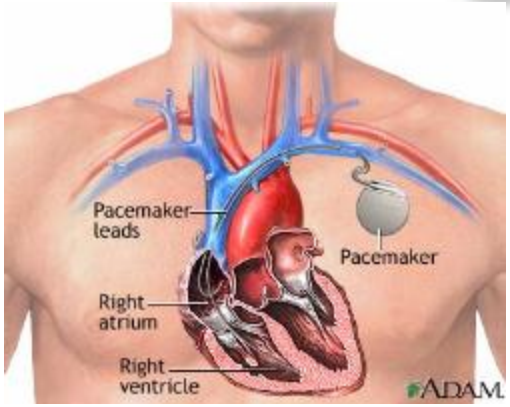
# Examples



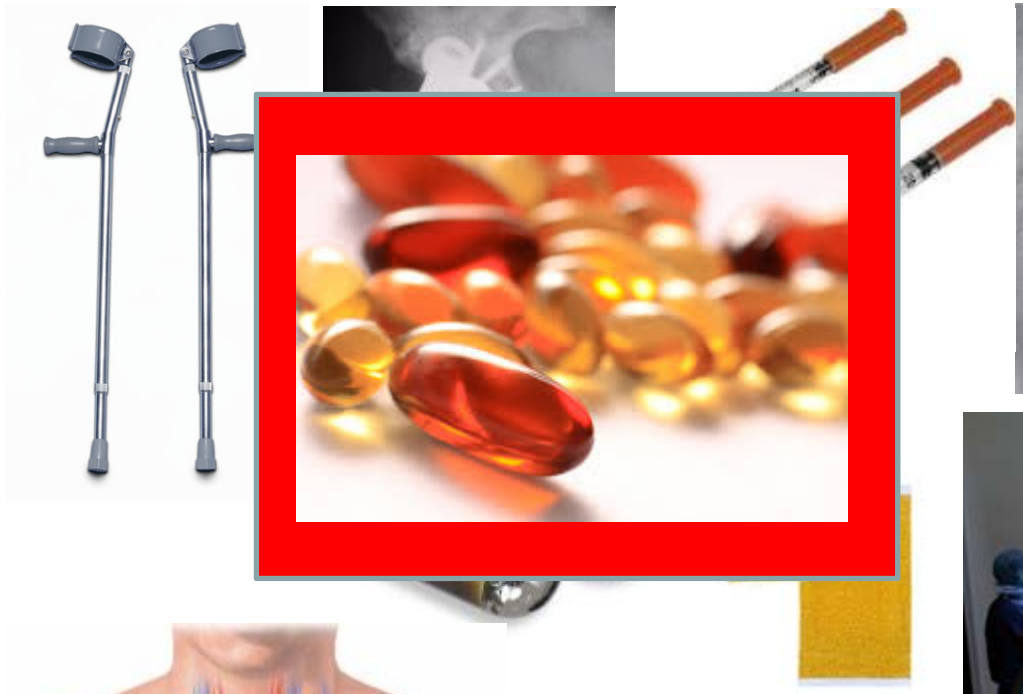


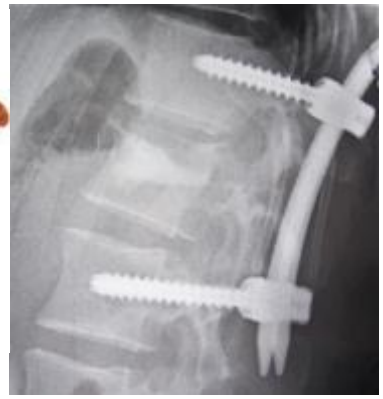


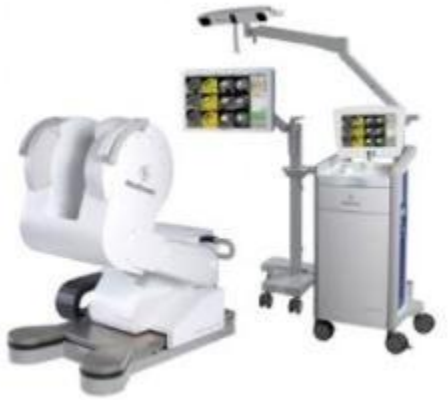

Pillcam
Pillcam

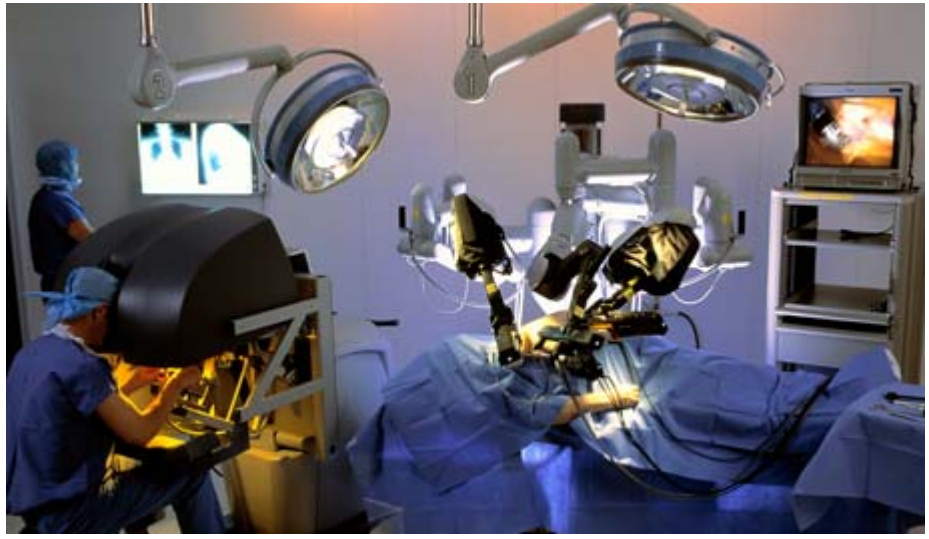

Pacemaker leads
Pacemaker
Right atrium
Right ventricle
ADAM.

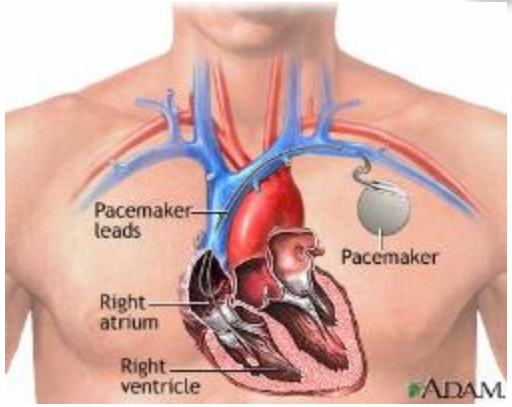
# Examples







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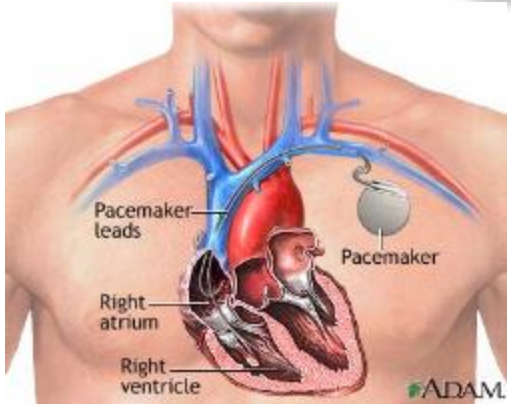
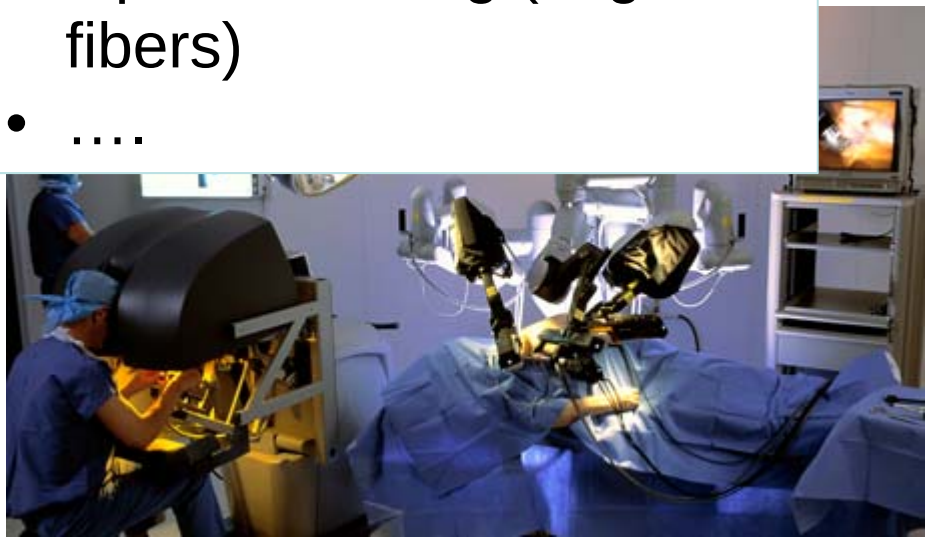
# Examples



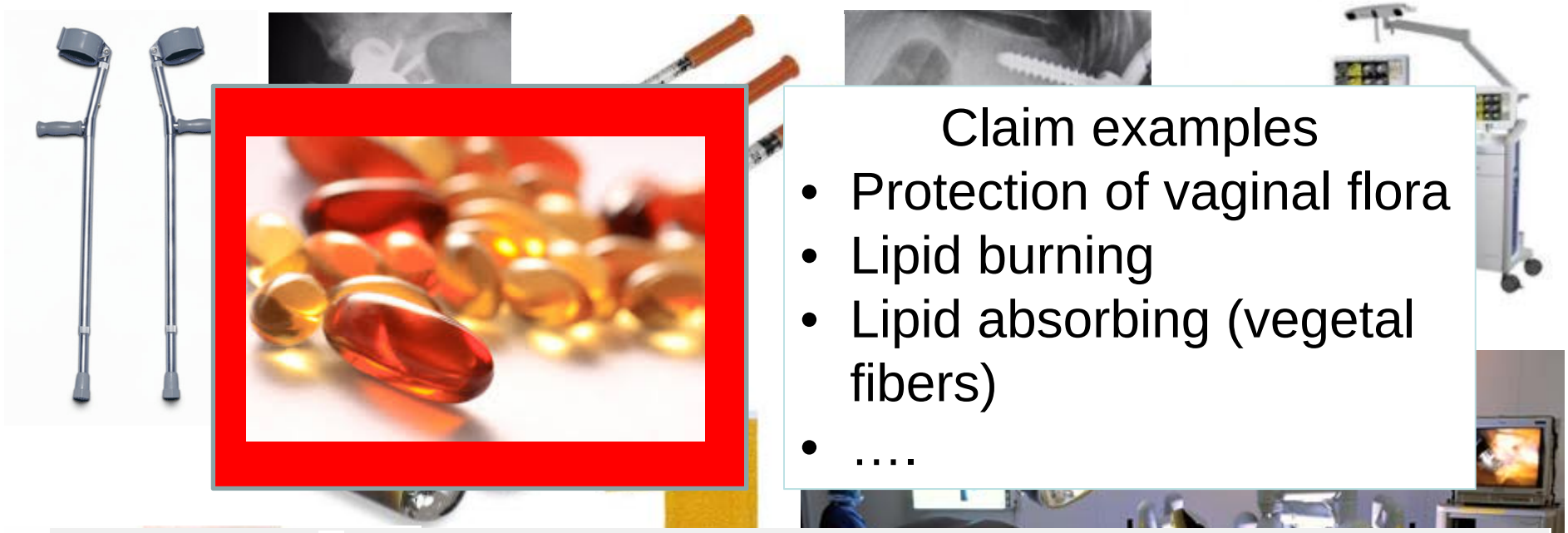
Claim examples

- Protection of vaginal flora
- Lipid burning
- Lipid absorbing (vegetal fibers)
- ….



# Examples



Claim examples

- Protection of vaginal flora
- Lipid burning
- Lipid absorbing (vegetal fibers)
- ….

Le principe actif contenu dans réduit l'activité de l'enzyme α-amylase responsable de la dégradation de l'amidon en molécules de sucres utilisables par le corps. Ceci réduit l'absorption de glucides et conduit ainsi à une réduction de l'apport calorique d'un repas riche en féculents (p. ex. pâtes, pain ou pommes de terre).

Est-ce que est un médicament?

Non. En raison de son action mécanique, est considéré comme un dispositif médical.

# Neuromodulation Therapies

Chronic Pain

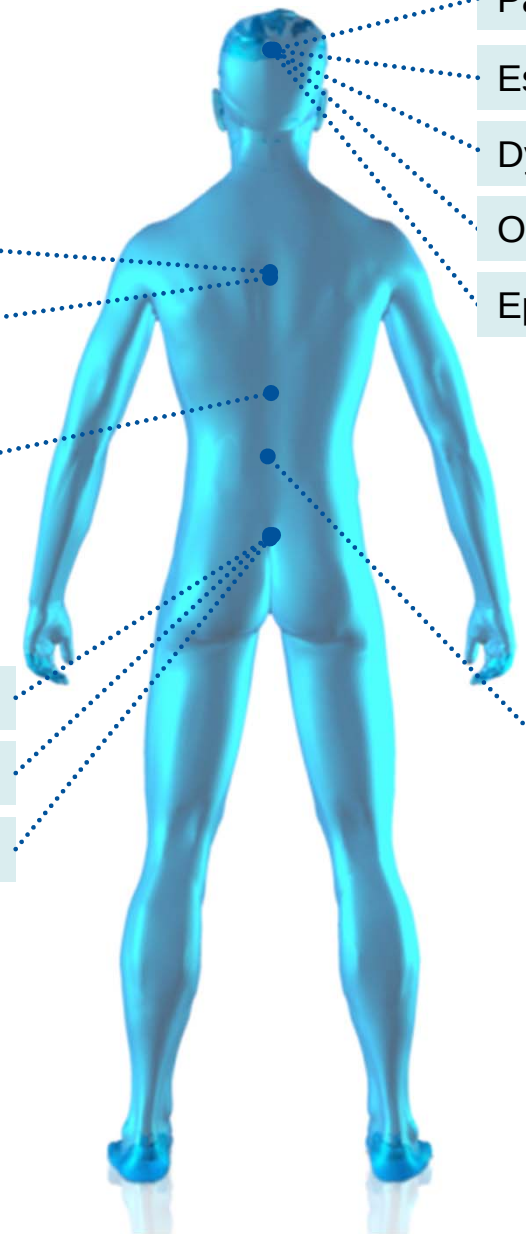
Severe Spasticity

Chronic Pain

Urinary Incontinence

Fecal Incontinence

Constipation



Parkinson's Disease

Essential Tremor

Dystonia

OCD

Epilepsy

Medtronic

Gastroparesis

# Main characteristics

Very high diversity of products

- Protheses
- Active devices

  - Internal
  - External

- Diagnosis devices
- Instruments, materials
- Robots
- ….

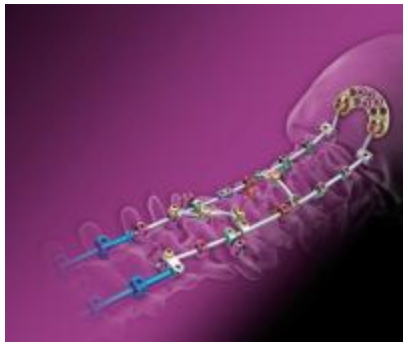
⇒ Very high diversity of modes of action

⇒ Very high diversity of expected effects

# Main characteristics

- Safety is always expected from a device
- Efficacy is not always expected
  and not always assessable

Is the screw efficace by itself?



- Medical device is one element of a therapy
  (if therapy)

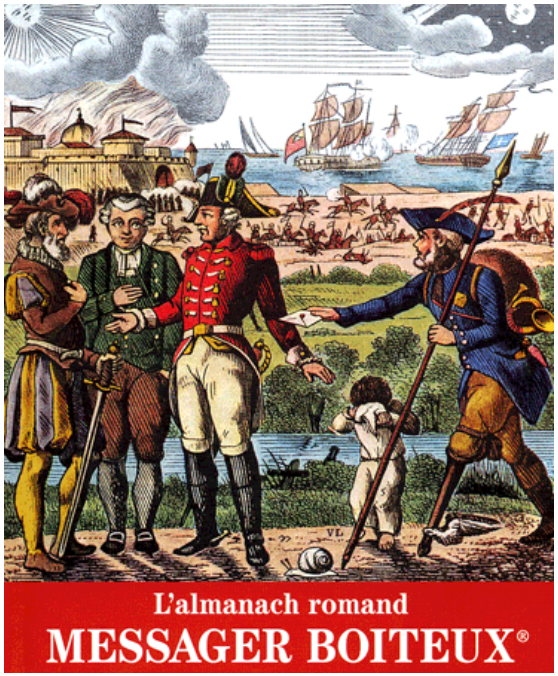
# Main characteristics

## Efficacy / Efficiency / Effectiveness

The operator can make the difference

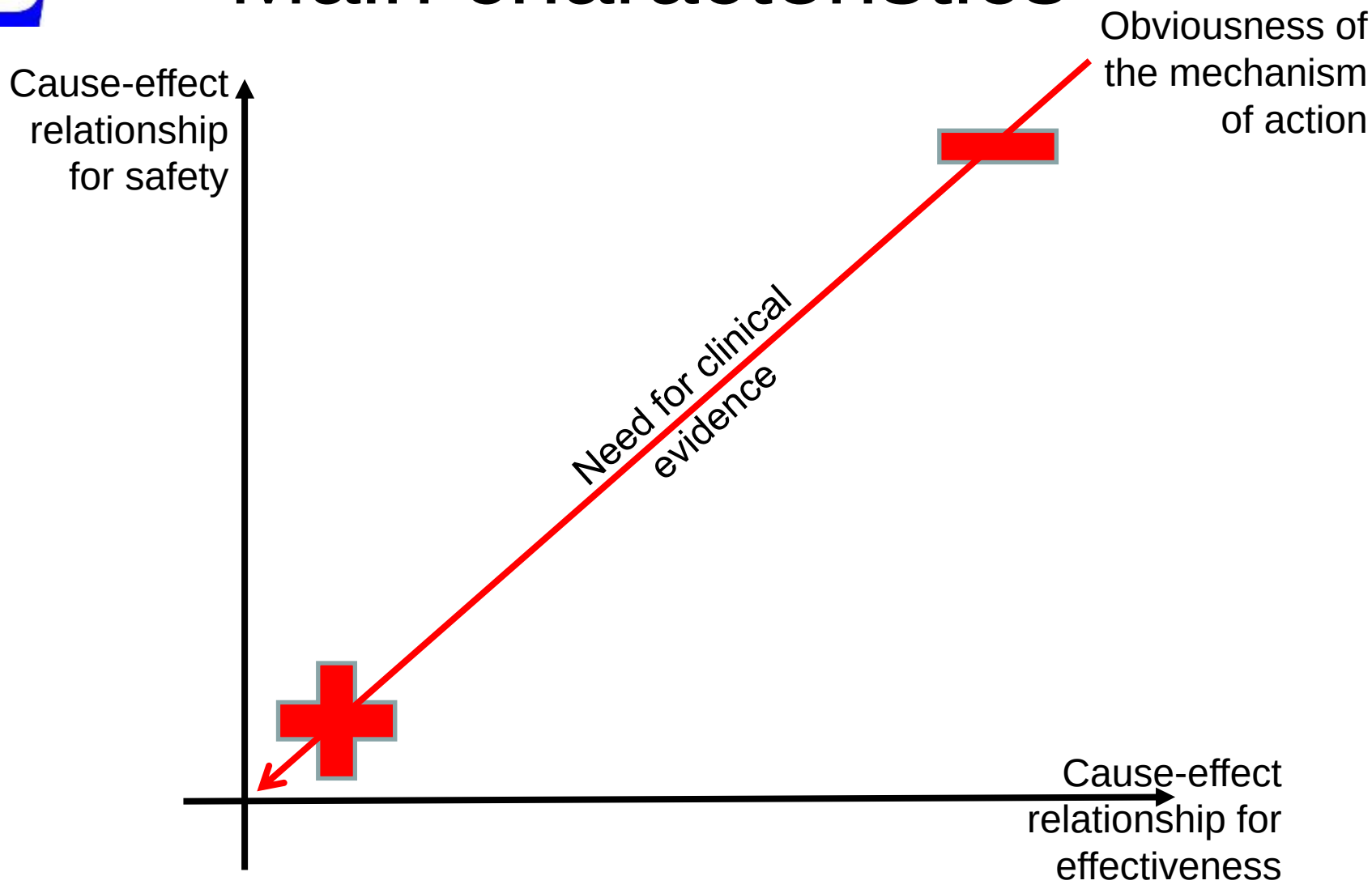
# Main characteristics

- Regulation issued from the “wood leg model”
- Effect directly observable => no need for clinical studies for efficacy
- “Immediate” safety assessment




- Actual regulation refers to Performance

# Main characteristics



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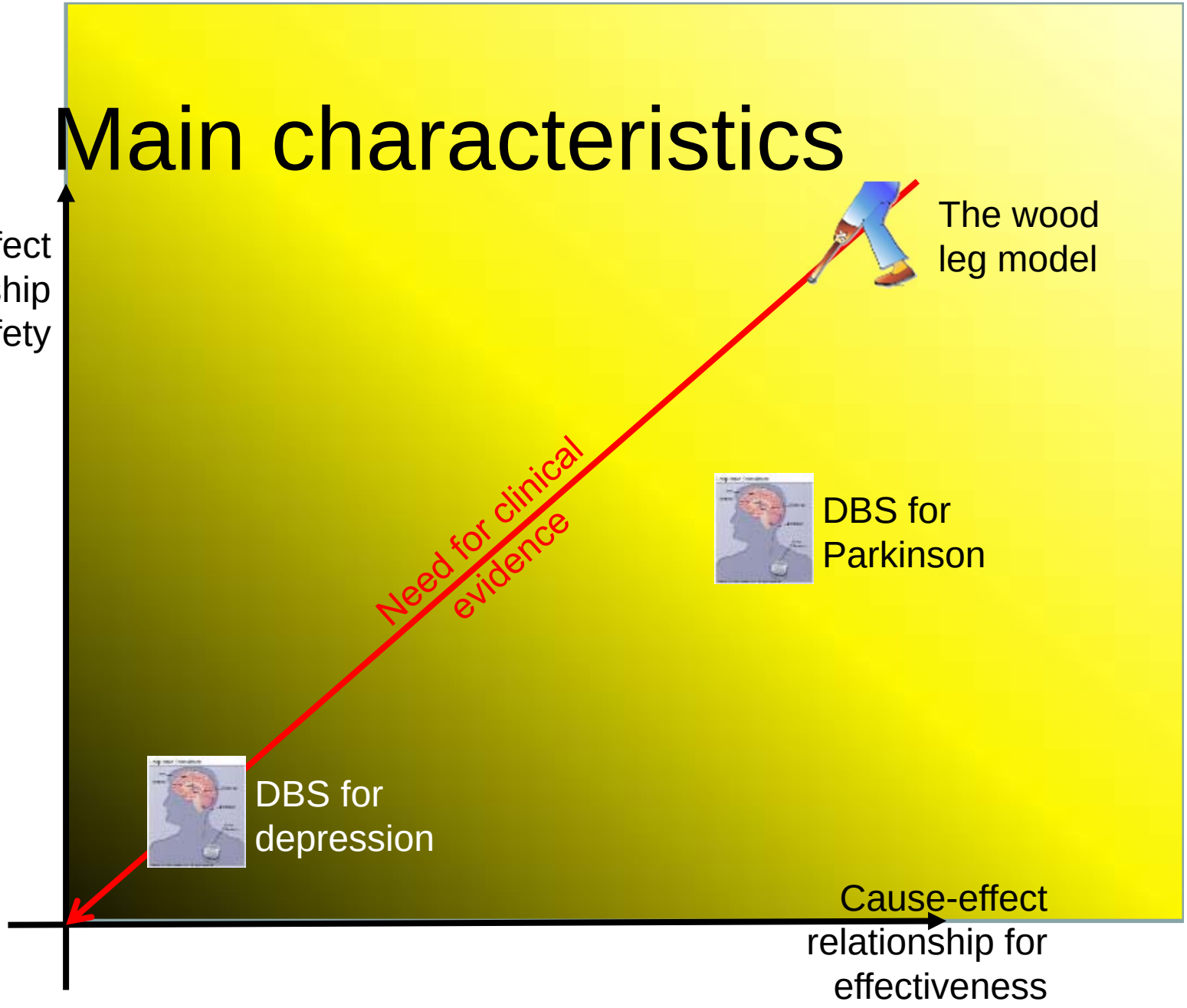

# Main characteristics

Regulation framework

- 3 directives:
  - 93/42/EEC Medical Devices (MDD)
  - 98/79/EC In Vitro Diagnostic Medical Devices (IVDD)
  - 90/385/EEC Active Implantable Medical Devices (AIMDD)
- CE mark
- 4 MD classes according to the level of risk (a very bad summary):
  - Class I: low — non-invasive (and not trt blood)
  - Class IIa: low-medium — invasive short-term devices
  - Class IIb: medium-high — invasive long-term devices
  - Class III: high — invasive active devices

# Main characteristics

Regulation framework

- Non centralized
- Delegated to Notified Bodies (TüV, LNE…)

  almost 75 for MD in Europe:
  http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=13
- ISO 14155:Clinical investigation of medical devices for human subjects
- ICH largely ignored and not always applicable
- National authorities and reimbursement bodies

# Challenges

- Ethics
  - When start testing on/in patients?
  - Comparison
  - Investigators = customers (not only prescribers)
- Methodology
  - Investigators not “trained” for clinical research
  - Comparison / randomization / blind
  - Trials complexity
- No clinical development model
- Industrial cycle of products against duration of clinical trials

# Challenges

- Scrutiny induced by different scandals
- National agencies / reimbursement bodies are more and more challenging the lack of evidence… but have no clear process
- Recast of the MD regulation
  - Proposal from the EU commission
  - EU parliament report
- Clinical evidence still not a fundament for market authorization
- Definition of MD classes doesn't match with the need for clinical evidences

# Discussion

- Why EFSPI ?
- SIG projects:
  - Deliver opinion on the draft report issued by the EU parliament
  - Guidelines applicable to Industry and Academic clinical research
  - Map the MD products
- Expectations from EFSPI