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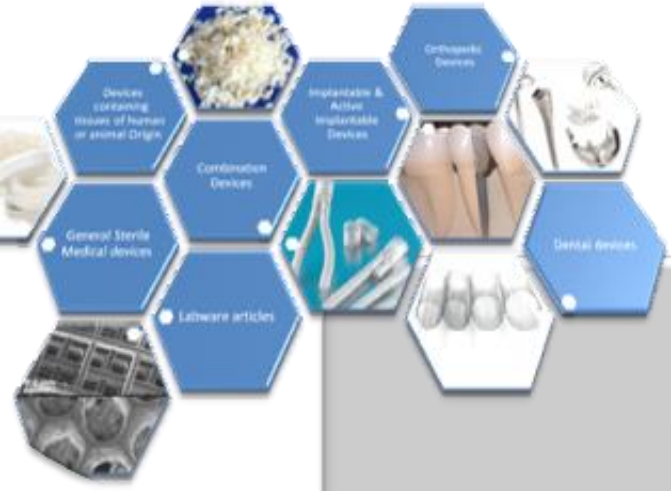
1st International Conference on Applications of Radiation Science and Technology



RADIATION STERILIZATION OF DEVICES AND SCAFFOLDS FOR TISSUE ENGINEERING

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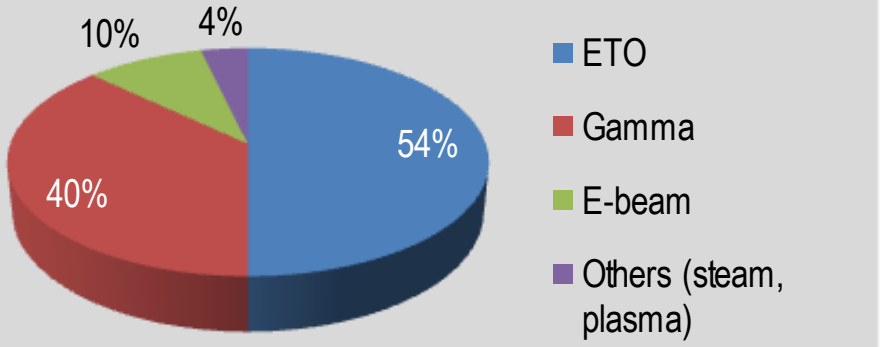
The selected method for sterilization of scaffolds and medical devices should :

- Effectively sterilize
- Maintain structural and biochemical properties, and
- Ensure that those product will fulfill their intended purposes post-sterilization

Sterilization techniques available for scaffold and medical devices:

Method		Advantages	Disadvantages
Heat	Steam	Simple, fast, effective, high penetration ability, no toxic residues	High temperature, wet process, affect the structural properties of biodegradable polymers
Irradiation	Gamma	High penetration ability, low temperature, effective, easy to control, no residue, dry	Induce structural properties changes, dose rate is lower than electron beams, long time
	E-beam	Low temperature, easy to control, no residue, fast, dry	Induce structural properties changes, electron accelerator needed, low penetration ability
	UV	Fast, low temperature, low cost, no toxic residues	Not effective, induce structural and biochemical properties changes under long exposure duration
Plasma	Plasma	Low temperature, improved cell interaction, increasing wettability on surface of biodegradable polymers, fast	May cause changes in chemical and mechanical properties of polymers, leave reactive species
Chemical Treatment	EtO	Effective, low temperature	Induce structural property change, leave toxic residue, flammable, explosive, carcinogenic

(X. Cao et.al.)



Source: Supply chain management Procurement sourcing medical device industry (2015)

The sterilization techniques should be precisely controlled and evaluated case by case

Multi-compounds products: tissue based products, medical devices, scaffolds

Strategies to improve the sterilization process

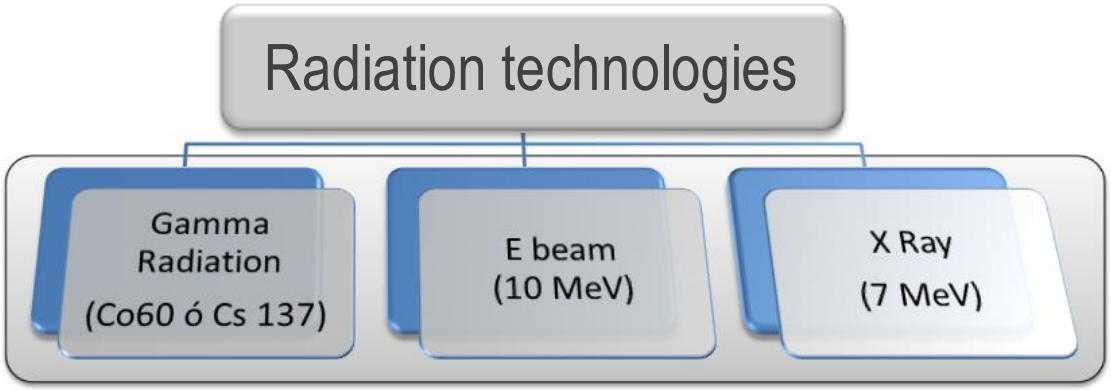
PROCESS Apply a validated radiation sterilization process, and using updated methodologies for dose setting

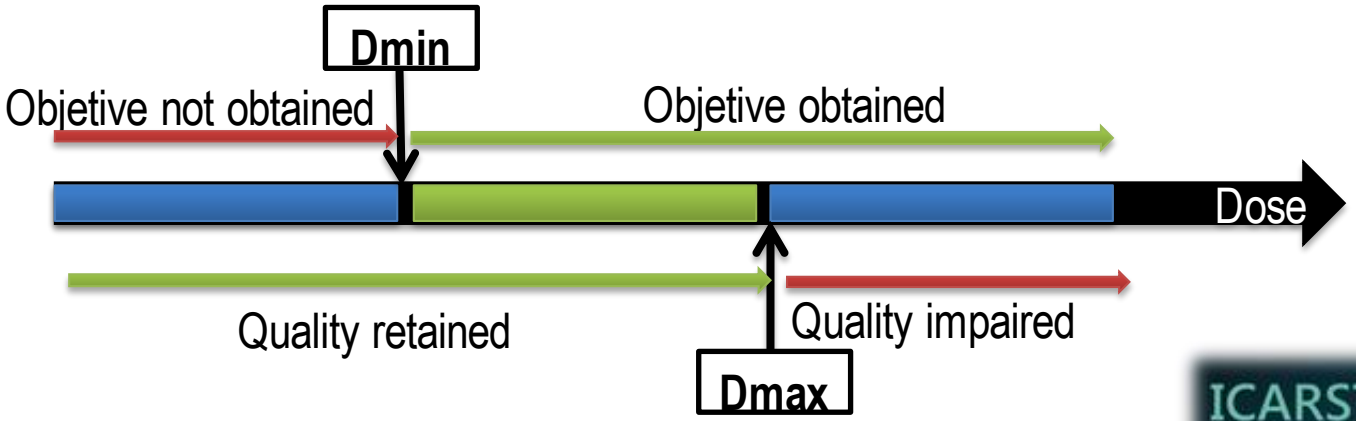
RISK Implement a risk management assessment for scaffold and devices manufacturing

SAL Select a different Sterility Assurance Level, to lower the radiation sterilization dose

PROCESS

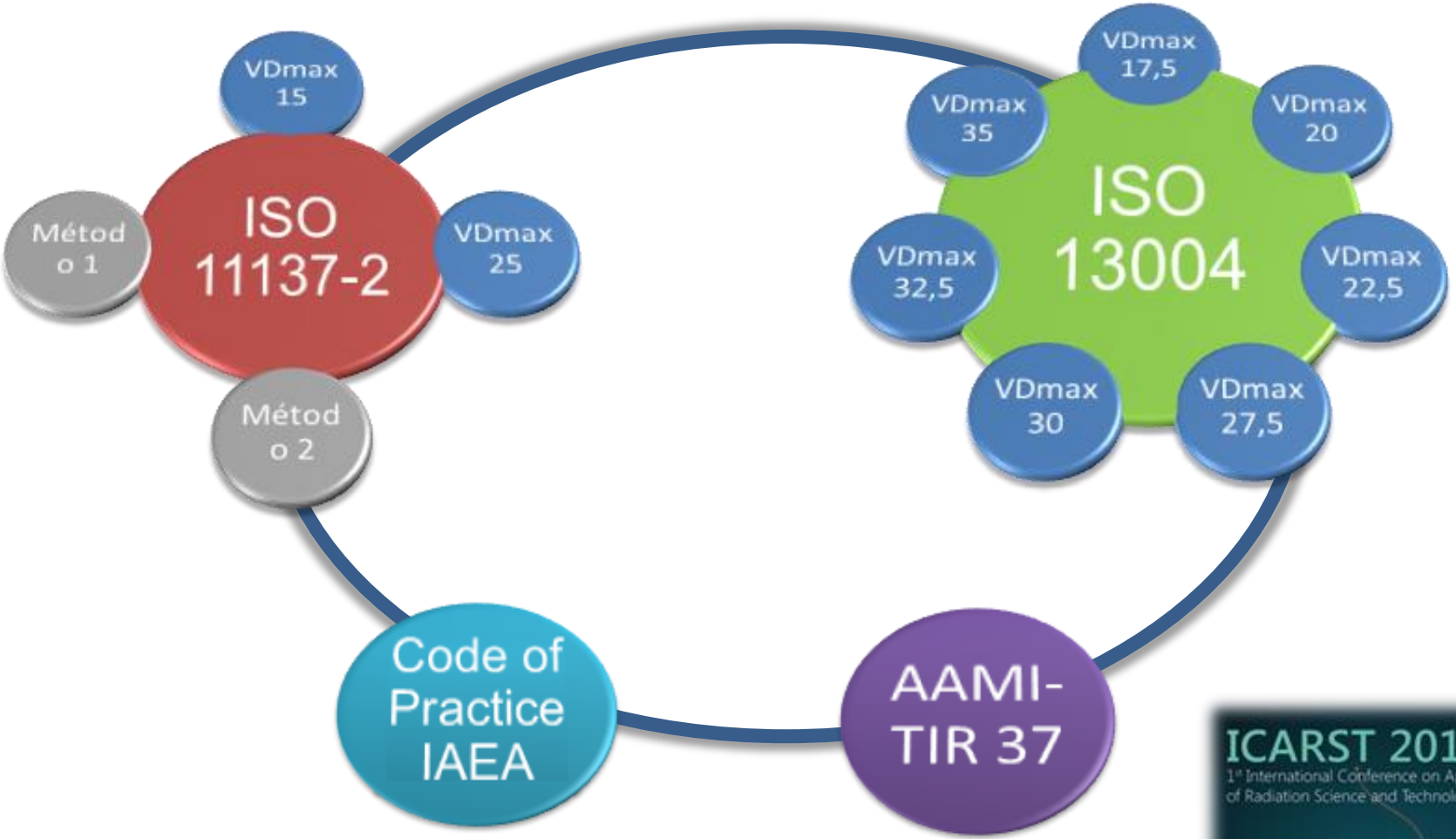
Apply a validated radiation sterilization process, and using updated methodologies for dose setting





PROCESS

Apply a validated radiation sterilization process, and using updated methodologies for dose setting



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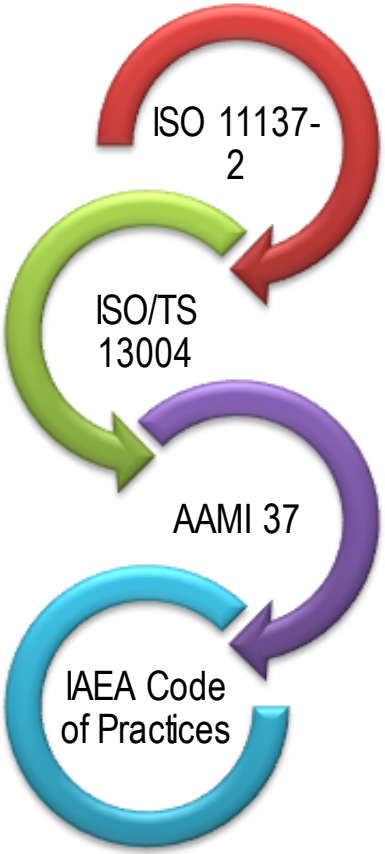
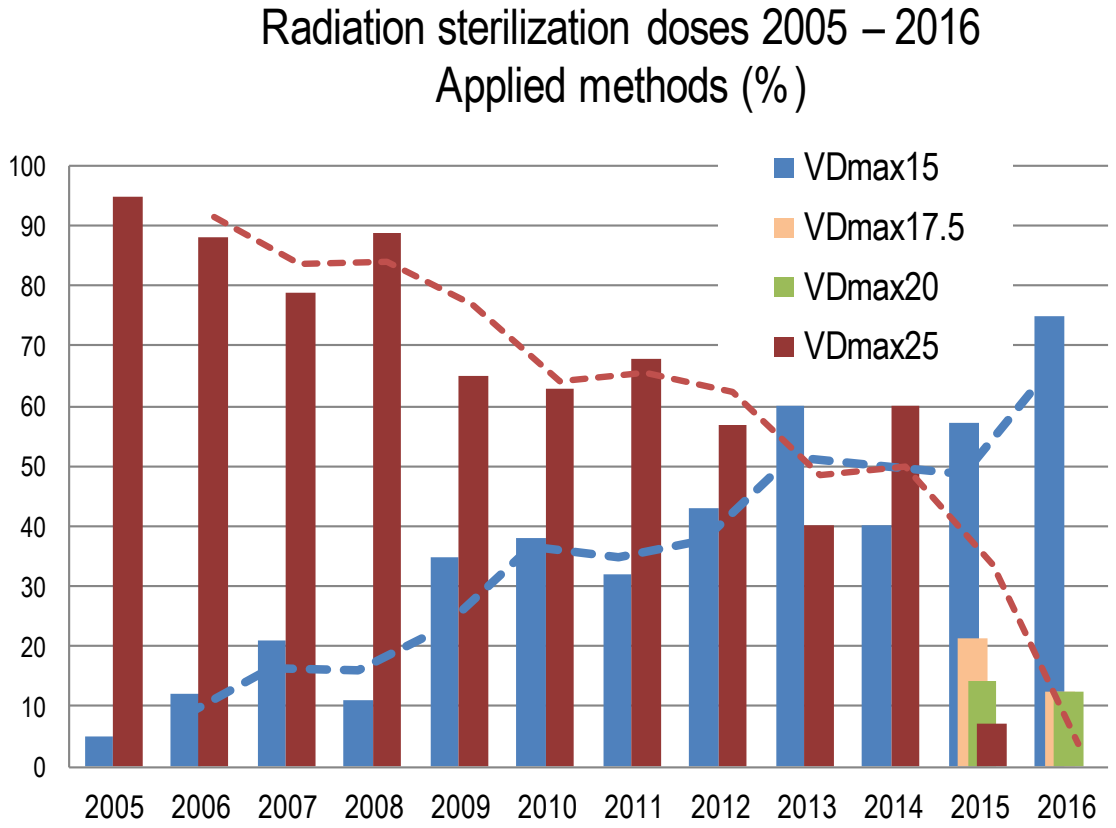
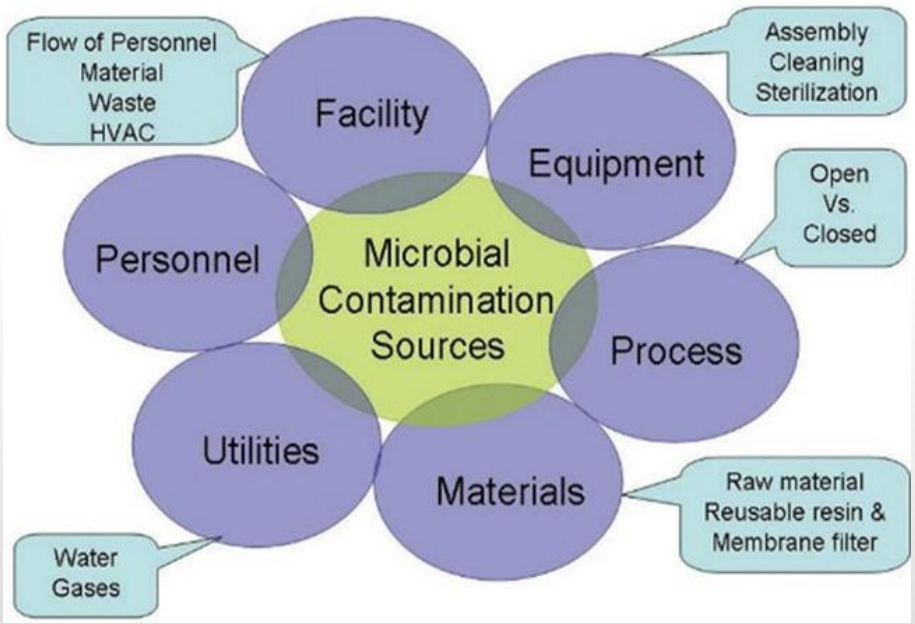


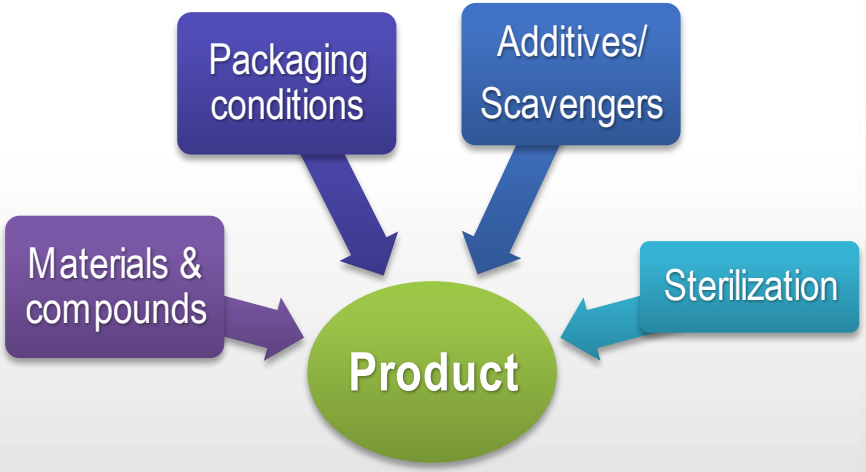


RISK

Implement a risk management assessment for scaffold and devices manufacturing



Improve the cleanness of the manufacturing process



Improve the manufacturing process

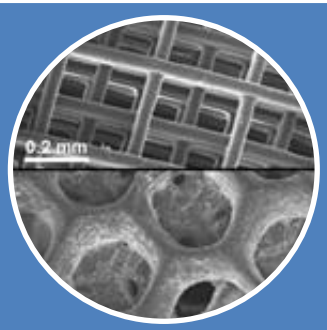
RISK

Implement a risk management assessment for scaffold and devices manufacturing

NATURAL POLYMERS

PROTEINS (collagen, gelatin, fibrinogen, elastin, keratin, actin, myosin)

POLYSACCHARIDES (cellulose, amylose, dextran, chitin, and glycosaminoglycans

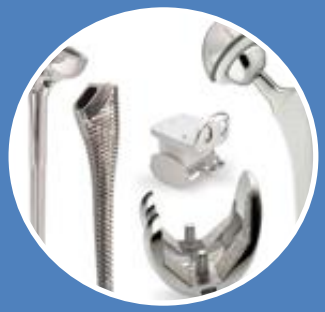


SYNTHETIC BIODEGRADABLE POLYMERS

(PLA, PGA, PLGA copolymers, PCL,)

SYNTHETIC NON-BIODEGRADABLE POLYMERS

(Bioactive ceramics: HAP, TCP, silicate and phosphate glasses)



METALIC MEDICAL DEVICES

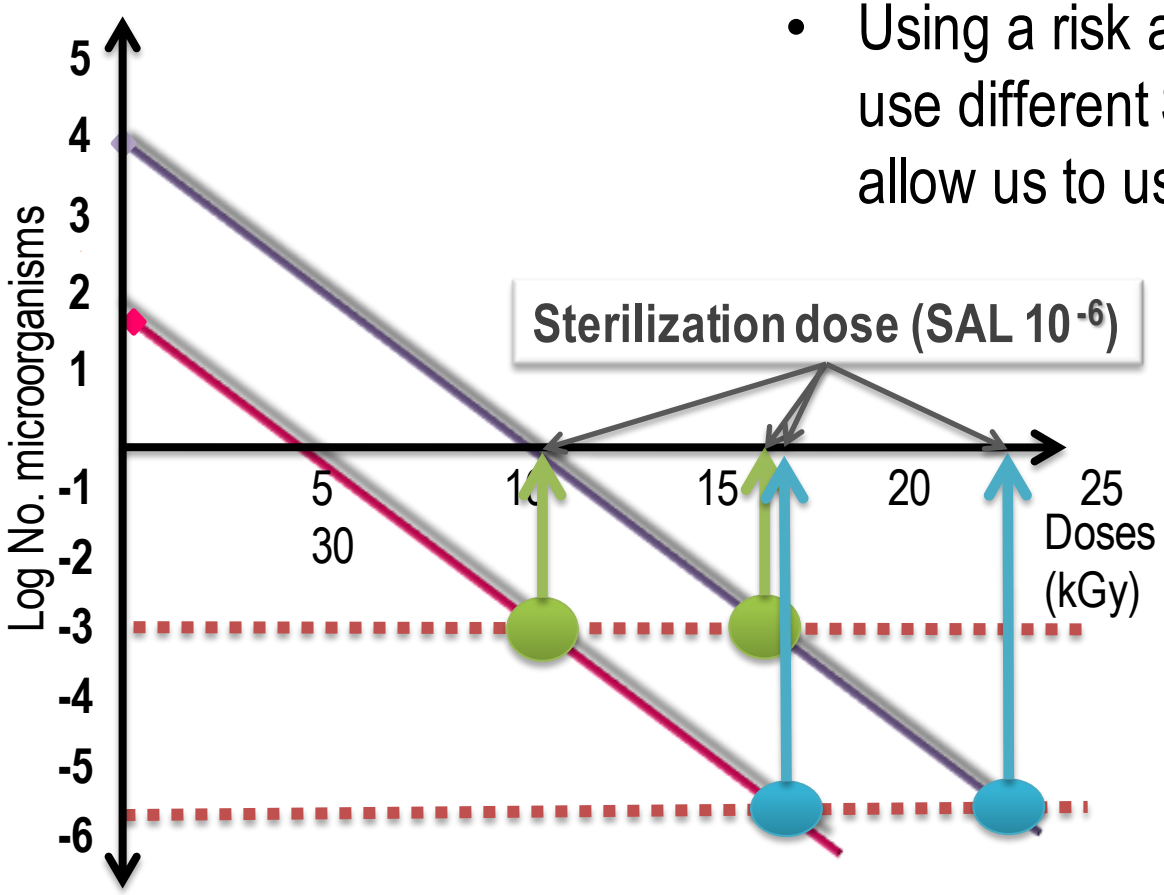
Steel, Titanium

SAL

Select a different Sterility Assurance Level, to lower the radiation sterilization dose

- Regulatory bodies recognize the sterility assurance level (SAL) of 10^{-6} for a device to be labeled “sterile”

- Using a risk assessment system, we can use different SAL´s, such us 10^{-3}. This allow us to use lower sterilization dose



- The **Medical devices** must be sterile, biocompatible and stable under physiological conditions during the time it would be implanted.

- An **scaffold** should act as a temporary matrix for cell proliferation and extracellular matrix deposition, with subsequent ingrowth until the tissues are totally restored or regenerated.

Conclusions

- Radiation sterilization fulfill most of the requirements mentioned before:

PROCESS

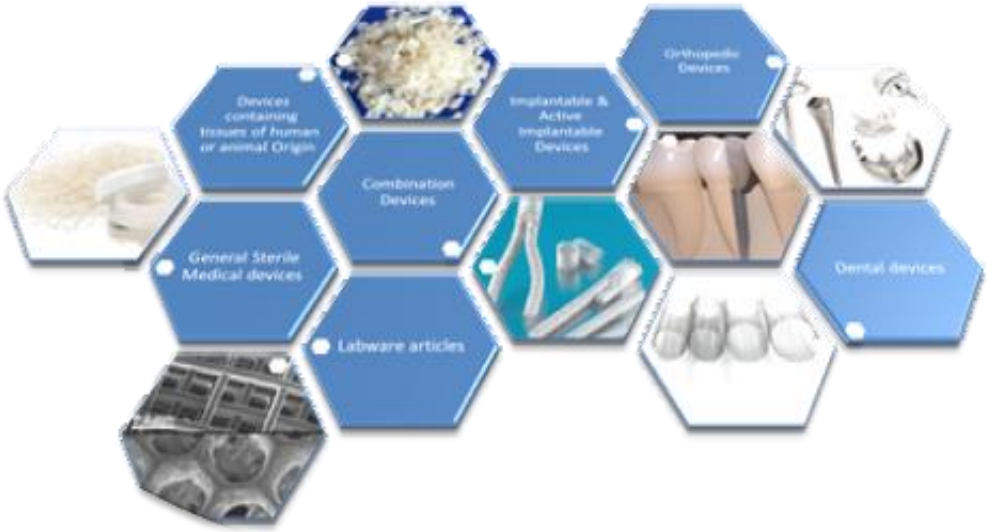
We can have a controlled process, and using the most properly sterilization dose. The present standards allow doses as low as 11 kGy to reach SAL 10-6

RISK

Risk is the KEY. A very well implemented risk assessment management will show to the manufacturers the better step to apply the methodology

SAL

When we need to reduce the dose even more, we should find the SAL that fit with my product/process



THANK YOU FOR YOUR ATTENTION!