1. What is a bioabsorbable implant?

It is an implant made of resorbable material. In the early stages of bone healing, bioabsorbable implants preserve fixation. With the passage of time, the implant gradually decomposes and the stresses are gradually transferred to the healing tissue. The implant degrades \textit{in vivo} by hydrolysis into biocompatible degradation products, which are metabolized by the body.

2. Why are bioabsorbable implants used?

Bioabsorbable implants offer temporary support for the body to allow healing of damaged tissue and disappear after the fixation task is completed, leaving tissue without any foreign material present. The main benefit is that the tissue has a temporary help but it gets its original task and challenge back and thus the original function and anatomy of human skeleton is respected. Bioretec Activa™ implants include these traditional advantages, but also offer advantages to surgeons when compared to traditional bioabsorbable and metallic implants.

3. Do Bioretec Activa™ implants offer advantages for the patient?

Yes. In a certain number of cases, metal implants have to be removed due to e.g. movement limitation, pain, irritation, palpability, patient sensitivity or imaging interference. Bioabsorbable implants overcome these issues. Stress shielding associated with metallic implants may result in bone atrophy and osteoporosis. As bioabsorbable implants resorb, they gradually transfer loads to the healing bone, assisting in the healing process. Due to the implant absorption, the risks of implant-related long term complications are eliminated. If given a choice, patients often prefer a biodegradable implant to the one that permanently remains in their body or alternatively requires a second surgery, a removal procedure.

4. Do Bioretec Activa™ implants offer advantages for the surgeon?

Yes. Due to their mechanical properties and mechanical activity Bioretec Activa™ implants feature beneficial properties which are not available with metallic implants. The implants show a Self-Locking™ property due to diameter expansion of the implant. The Auto-Compression™ means longitudinal contraction of the implants with a controlled force. This feature helps in maintaining sufficient compression in the healing tissue throughout the healing. The bending modulus of Activa™ implants is closer to that of bone than bending modulus of metallic implants. Due to this modulus match with bone the fixation does not cause stress shielding, which could have a negative impact to the quality of the bone in the fixation area.
5. What properties make absorbable implant safe to use?

Material for a particular Activa™ product is chosen respecting the surgical target (indication), physical forces in the targeted area and the rate of the healing process in the related area. The selection of the material, however, is only one of the several parameters affecting the implant function and safety. The properties like strength, fracture behavior, degradation time and mechanical activity are defined in in-house developed manufacturing processes.

The common demands for a bioabsorbable implant are:

a. High Initial Strength

The implant must resist mechanical stresses during surgical procedures and it must carry external and physiological loads during the early stages of healing when the healing tissue/bone is still weak.

b. Appropriate Initial Modulus

The material must not be too stiff or too flexible for the special purpose it is used for. Modulus of the fixation material should be close to the modulus of the material (bone) under repair for the best biomechanical performance.

c. High Initial Toughness

The practical value of an implant material is rated during the surgery. Brittle materials are difficult to work with because they crack without a warning. Materials of Activa™ implants are tough meaning a benefit of feeling the deformation of the material, thus offering safe insertion and good handling properties.

d. Controlled Strength Retention in vivo

Optimally the loss of strength and modulus in vivo is in conformity with the increase of strength and modulus of the healing tissue (bone).

e. Controlled Absorption in vivo

In addition to thorough sterility, Gamma Radiation also reduces molecular weight of oriented Activa™ implants. This is advantageous for controlled bioabsorption of Activa™ implants completing within approximately 2 years in vivo.

6. What happens to the implant as it resorbs?

The implants degrade by hydrolysis forming lactic acid and glycolic acid as intermediate products and finally are metabolized into carbon dioxide and water, which are then exhaled and excreted.
7. What materials are Bioretec Activa™ implants constructed of?

The Bioretec Activa™ implants are made of poly-L-lactide-co-glycolide. The monomers of PLGA are L-lactic acid and glycolic acid, which are part of the normal chemistry of mammalian cells.

8. Why was this material selected?

From a chemical point of view, the medical grade poly L-lactide-co-glycolide copolymer (PLGA) used in the Bioretec Activa™ product line does not contain components which could negatively affect the biocompatibility of the product. The monomers of PLGA are L-lactic acid and glycolic acid, which are part of the normal chemistry of mammalian cells. PLGA copolymers overcome historical problems related to the rapid degradation of PGA material and the slow degradation of PLLA material by utilizing a combination of the degradation properties of both polymers.

9. Is there clinical proof that this material is safe?

Yes. The PLGA material used in the manufacturing of Bioretec Activa™ implants has a long history of safe clinical use, and has been shown to be biocompatible in both animal and clinical evaluations.

10. What is the difference between PGA, PLLA and PLGA bioabsorbable implants?

PGA implants are reported to lose mechanical strength in 4 to 6 weeks in vivo, while PLLA implants are reported to lose mechanical strength in 4 to 6 months. Bioabsorption of PGA material takes place within approximately 1 year, whereas crystalline remnants of PLLA have been found in tissue 4 to 5 years after implantation. By copolymerizing the PGA and PLLA the material properties can be tailored to fit the desired indication. Bioretec implants are made of PLGA. They maintain their mechanical strength at least up to 8 weeks and bioabsorb within approximately 2 years. In addition to the material composition, the manufacturing method of bioabsorbable implants has a remarkable effect on strength, toughness and hydrolytic degradation of the material. The advanced manufacturing technology employed to create Bioretec Activa™ implants delivers high strength, toughness and predictable, controlled strength to resorption properties.