What are Activa™ implants?  
They are orthopaedic implants made of bioabsorbable materials. In the early stages of bone healing, bioabsorbable implants preserve fixation. With time, the implant gradually absorbs and the stresses are gradually transferred to the healing tissue. The implant absorbs in vivo by hydrolysis into biocompatible absorption products, which are metabolized in the body.

Why to use Activa™ implants?  
Bioabsorbable Activa™ 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.

Do Bioretec's Activa™ implants offer advantages for the patient?  
Yes. In several cases, traditional metallic 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 osteolysis. As bioabsorbable implants absorb, 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 requires a second surgery, a removal procedure.

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.

What properties make a bioabsorbable 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 behaviour, 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. If the modulus is too low, the implant does not support enough the healing tissue and if it is too high, there’s a high risk of stress shielding (delayed healing and/or bone weakening).

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 happens simultaneously with the increase of strength and modulus of the healing tissue (bone).

e. Controlled Absorption in vivo
Tailored processing methods and rigorously adjusted processing and material parameters guarantee optimal and controlled absorption of Activa™ implants. The complete absorption of the Activa™ implants lasts approximately 2 years.

What happens to the Activa™ implant as it absorbs?
The implants absorb by hydrolysis forming lactic acid and glycolic acid as intermediate products, which are finally metabolized into carbon dioxide and water by human cells, which are then exhaled and excreted.

What materials are Bioretec Activa™ implants constructed of?
The Bioretec Activa™ implants are made of poly-L-lactide-co-glycolide polymer. The monomers, the construction units of PLGA are L-lactic acid and glycolic acid, which are part of the normal metabolic chemistry of mammalian cells.

Why was this material selected?
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 and also the absorption products 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 too rapid degradation of PGA material and too slow degradation of PLLA material by utilizing a combination of the degradation properties of both polymers.

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.

What is the difference between PLLA and PLGA bioabsorbable implants?
The manufacturing method of bioabsorbable implants has a remarkable effect on the strength, toughness and the hydrolytic absorption of the material. The advanced manufacturing technology employed to create Bioretec Activa™ implants delivers high strength, toughness and predictable, controlled strength to the absorption properties. Bioretec implants are made of PLGA. They maintain their mechanical strength at least up to 8 weeks and absorb within approximately 2 years. PLLA implants are reported to lose mechanical strength in 4 to 6 months. Absorption crystalline remnants of weak PLLA have been found in tissue 4 to 5 years after implantation.