**Aesculap Resorbable Pin**

**Intended use**
The Aesculap Resorbable Pin is intended for use in the fixation of non-load bearing bones, osteotomies, arthrodeses, meniscal tissue repair, and osteochondral repair.

Once the pin has fulfilled its task, it disintegrates into its molecular components, which are metabolized in the body.

The Aesculap Resorbable Pin is sterilized through gamma radiation. It is supplied inserted in an application aid, see Fig. 1.

**Materials**
The Aesculap Resorbable Pin consists of a mixture of various absorbable polyesters, based on polylactide (70 % L-lactide and 30 % D,L-lactide). The Aesculap Resorbable Pin is degraded completely.

The degradation occurs through hydrolytic cleavage of the macromolecules down to its break-up into its basic components, L and D lactic acid (2-hydroxypropionic acid).

These components are easily metabolized in the body. The Aesculap Resorbable Pin material is rich in monomers, resulting in a short absorption time.

The control label enclosed with each Aesculap Resorbable Pin pack allows tracing back the production process and quality control performed by the manufacturer. The control label is intended to be put into the patient file or operation report.

**Indications**
The Aesculap Resorbable Pin is intended for use in the fixation of non-load bearing bones, osteotomies, arthrodeses, meniscal tissue repair, and osteochondral repair.

The operating surgeon is responsible for establishing the above indications, taking into account the specific clinical, biological and biomechanical situation.

**Contraindications**
The Aesculap Resorbable Pin must not be used in the fixation of large-pored or wide-meshed carrier materials. Carrier materials with a mesh width/pore size ≥ 1 mm can not be fixated, except for carrier materials that can reach the required mesh width/pore size through a deep porosity. For polyphase carrier materials, the mesh width/pore width condition needs to be met by only one layer. The pore size/mesh width must be guaranteed to be stable through the required fixation period of 4 weeks.

Additionally, the application of the pin is contraindicated for patients with:

- foreign body sensitivity to the implant materials
- allergies against a pin material component or its degradation products
- acute or chronic infections in or close to the joint
- secondary conditions that could affect the functionality of the joint implant
- severe damage to bone structures that could preclude the possibility of a stable implantation
- arthrotfibrosis

- metabolic arthropaties
- lack of willingness to follow the doctor’s instructions

**Side-effects and adverse interactions**
Immune reactions cannot be excluded with absolute certainty. In the course of the degradation of the Aesculap Resorbable Pin, acid valences are released that can cause local inflammatory reactions.

There are no known interactions with other medicines. The general risks in connection with the treatment of joint cartilage defects apply in addition to the following risks of:

- incorrect positioning of the implants and possible consequent injuries to the corresponding joint surface, see Contraindications
- migration of the Aesculap Resorbable Pin
- fracture/chipping of the Aesculap Resorbable Pin
- infections

**Safety notes**
- It is the operating surgeon’s responsibility to ensure that the surgical procedure is performed properly.
- General risk factors associated with surgical procedures are not described in the present instructions for use.
- The operating surgeon must have a thorough command of both the hands-on and conceptual aspects of the established operating techniques.
- The operating surgeon must be thoroughly familiar with anatomy, including the pathways of nerves, blood vessels, muscles and tendons.
- Aesculap is not responsible for any complications arising from incorrect diagnosis, incorrect transplant selection and inappropriate surgical techniques, the limitations of treatment methods, or inadequate asepsis.
- The instructions for use of the individual Aesculap implant components must be observed.
- Implants that have been used before must not be reused.

Further information can be obtained from the manufacturer at any time.
Sterility
The Aesculap Resorbable Pin is supplied protected against humidity in sterile double packaging. Sterilization is carried by gamma irradiation with 25 kGy to max. 40 kGy.

The Aesculap Resorbable Pin has to be kept in its original packaging until immediately prior to its application. Prior to using the pin, check the use-by date and the temperature indicator and inspect the sterile packaging for any damage.

WARNING
Risk due to change of material properties!
• Do not resterilize.

If the temperature indicator point shows a black color, the Aesculap Resorbable Pin has been exposed to excessive heat. In this case the Aesculap Resorbable Pin must not be used anymore, because the excessive heat may have changed the material properties of the pin.

Sterile procedures must be observed when taking the product out of its packaging.

Storage
The Aesculap Resorbable Pin has to be stored in dry and cool conditions. The storage temperature must not exceed 38 °C (102°F).

Application
Prior to the operation, the surgeon must ensure that highly aseptic operating conditions are in place, the implantation instruments are complete and in working condition, all information materials are ready to hand and known to the surgeon and the operating team.

The Aesculap Resorbable Pin is supplied in an application aid, see Fig. 1, which allows easy and safe transfer form the packaging to the respective instruments.

The Aesculap Resorbable Pin is inserted into the bone through a channel drilled beforehand. If no channel was drilled, or if such channel is missed when the pin is applied, excessive force can result in breakage of the Aesculap Resorbable Pin. In such case the pin fragments must be removed from the joint.

WARNING
Risk of material breakage during implantation!
• Use the Aesculap Resorbable Pin instruments.
• Manipulate the instruments correctly.

Distributed in the U.S. by:
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