Annex IV

Conditions to the marketing authorisation

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Tisseel / Tissucol and associated names

The Marketing Authorisation Holder (MAH) shall submit to the national competent authority, within one month of the European Commission decision on this procedure (EMEA/H/A-31/1337), an EU risk management plan for the products according to the EU Good Vigilance Practices which includes the safety concern of gas embolism.

The MAH shall ensure that, within 10 months of the European Commission decision for this procedure (EMEA/H/C/A31/1337), all users of the spray application of this product are provided with educational material and within 4 months of the European Commission decision for this procedure (EMEA/H/C/A31/1337) all internal personnel are provided with educational material.
This material shall inform about the

- risk of life-threatening gas embolism if the product is sprayed incorrectly
- correct pressure and distance from tissue depending on kind of surgery (open or laparoscopic)
- for laparoscopic surgery restriction to only use if the minimum spray distance of 2cm (recommended range 2-5cm) can be accurately judged and with CO_2 only
- requirement to dry the wound using standard techniques (e.g. intermittent application of compresses, swabs, use of suction devices) prior to using the product
- requirement to closely monitor blood pressure, pulse rate, oxygen saturation and end tidal CO_2 when spraying the product, for the occurrence of gas embolism.
- which regulator(s) should be used, in line with manufacturer recommendations and the SmPC instructions for use

The material shall include the latest Summary of Product Characteristics and the section titled "The following information is intended for medical or healthcare professionals only" of the latest package leaflet.

The MAH shall offer an educational program to all users of the spray application of this product. The program shall teach the content of the mentioned educational material.

The Marketing Authorisation Holder shall agree the exact content and format of the educational material and educational program with the national competent authority.

The MAH shall ensure that, within three months of the European Commission decision on this procedure (EMEA/H/C/A31/1337), all users of the spray application of this product are provided with

- labels for the pressure regulator with a symbol that informs about the correct pressures and distances in open and laparoscopic procedures

The MAH should ensure within two years, that the product is used in accordance with the SmPC, with a pressure regulator device that delivers a maximum pressure of no more than 2.0 bar (28.5 psi) in open wound surgery.

The MAH should ensure within two years, that the product is used in accordance with the SmPC, with a pressure regulator device that delivers a maximum pressure of no more than 1.5 bar (22 psi) in minimally invasive/laparoscopic procedures.

Artiss and associated names

The Marketing Authorisation Holder (MAH) shall submit to the national competent authority, within one month of the European Commission decision on this procedure (EMEA/H/A-31/1337), an EU risk management plan for the product according to the EU Good Vigilance Practices which includes the safety concern of gas embolism.

The MAH shall ensure that, within 10 months of the European Commission decision for this procedure (EMEA/H/C/A31/1337), all users of the spray application of this product are provided with educational material and within 4 months of the European Commission decision for this procedure (EMEA/H/C/A31/1337) all internal personnel are provided with educational material.
This material shall inform about the

- risk of life-threatening gas embolism if the product is sprayed incorrectly
- correct pressure and distance from tissue depending on kind of surgery (open or laparoscopic)
- requirement to dry the wound using standard techniques (e.g. intermittent application of compresses, swabs, use of suction devices) prior to using the product
- requirement to closely monitor blood pressure, pulse rate, oxygen saturation and end tidal CO_2 when spraying the product, for the occurrence of gas embolism.
- which regulator should be used, in line with manufacturer recommendations and the SmPC instructions for use
- restriction to open wound subcutaneous surgery only

The material shall include the latest Summary of Product Characteristics and the section titled "The following information is intended for medical or healthcare professionals only" of the latest package leaflet.

The MAH shall offer an educational program to all users of the spray application of this product. The program shall teach the content of the mentioned educational material.

The Marketing Authorisation Holder shall agree the exact content and format of the educational material and educational program with the national competent authority.

The MAH shall ensure that, within three months of the European Commission decision on this procedure (EMEA/H/C/A31/1337), all users of the spray application of this product are provided with

- labels for the pressure regulator with a symbol that informs about the correct pressures and distances in open and laparoscopic procedures

The MAH should ensure within two years, that the product is used in accordance with the SmPC, with a pressure regulator device that delivers a maximum pressure of no more than 2.0 bar (28.5 psi).