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ORTHOPEDIC TECHNOLOGIES

MDD / MDR Phthalate Statement

Date:

4/13/2022

Scope:

- EU MDD and MDR Phthalate Statement (ER #7.5)
- EU MDR Phthalate Statement (GSPR #10.4)

Project Information

Technical File Affected:

TF-001, OGmend® Implant Enhancement System

Device Description:

The OGmend® Implant Enhancement System is a sleeve composed of polyethylene terephthalate (PET), which provides an interface for screw engagement with the surrounding bone by the principles of interference fit. Once implanted, the OGmend® Implant Enhancement System provides increased mechanical stability between the screw and bone; the threads of the screw cause the woven surface of the OGmend® Implant Enhancement System to engage with bone, thereby increasing the stability of the bone/screw interface.

Intended Use / Indications for Use:

The OGmend® Implant Enhancement System is for the use with screws as part of a fracture fixation plate system in long bones in rescue scenarios where the screw has lost purchase due to screw loosening, back out, or breakage and the stability of the plate construct is at risk. The OGmend® Implant Enhancement System is for use in skeletally mature patients.

Material Description:

- The SRT Implant System (OGmend®) consists of a braided PET Sleeve implant that is measured and cut to length by the user and positioned using an Inserter Instrument. The implant is a permanently implanted,

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braided Sleeve that provides enhanced fixation of bone screws in compromised screw engagement scenarios.

- The sole instrument used with the SRT Implant System is the Inserter, which is used to insert the Sleeve into the hole. The SRT Inserter is a 304 stainless steel rod with beveled ends. It has a diameter of 0.080" (2.032mm) and a length of 8" (203 mm). It can be used to insert up to 6 Sleeves in a single operative procedure. It is provided sterile as a disposable, single-use device. It is compatible with sterilization by gamma radiation.

Conclusions:

As detailed above, the sleeve implant is 100% manufactured from PET. Phthalates (i.e., phthalate ester plasticizers or orthophthalates) are not used in PET, nor is PET a phthalate.

As also specified, the inserter instrument is manufactured 100% from 304 stainless steel. Phthalates (i.e., phthalate ester plasticizers or orthophthalates) are not used in stainless steel, nor is stainless steel a phthalate.

Woven hereby certifies that these materials contain no phthalates and, therefore, are in compliance with MDD and MDR requirements relative to 'substances'. Furthermore, Woven certifies that the manufacturing process is entirely mechanical; no additional chemical processes are utilized which might introduce phthalate containing substances.

Approvals

Quality / Regulatory (Print Name and Title):
Stephen Page, QA / RA

Quality / Regulatory (Sign and Date):
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Engineering (Print Name and Title):
Rick LaPorte, Director of Operations & Process Development

Engineering (Sign and Date):
Richard LaPorte 04/13/2022