Biocompatible, Pre-coloured and Sustainable ABS Optimised for Laser-marking to Support Medical UDI Identification along with Sustainability Targets

The EU's Medical Device Regulation (MDR) and US' Code of Federal Regulations Title 21, with regard to the labelling for medical devices (21 CFR 801 Subpart B), require a Unique Device Identification system (UDI) on each medical device, in addition to the creation of a central UDI database.

Several key public health targets are meant to be covered through UDI, such as anti-counterfeiting, safety communication promotion, reduction of inappropriate use of the device as well as the management of adverse events, incident reporting and efficient device recalls.

Laser-marking is a valid alternative to get the unique identifier permanently attached to the medical device and offers a series of additional advantages compared to alternative technologies like labelling, pad printing or hot stamping. Digital information can be created and stored in a digital database, facilitating traceability tasks and regulatory requirements, while digital data manipulation enables high flexibility to fit laser-marking according to the required size of the device, the available surface, and geometry. Adhesives or glues used in labelling or dyes /solvents needed in conventional printing processes are not required, avoiding contamination issues and the environmental impact related to the use of such substances.

There are some materials that can be more readily laser-marked than others, while some will give very poor results; indeed, that`s because it is very important to select the correct material to be laser-marked, besides choosing the correct laser-marking machine settings. In addition to the material, special attention should be given to its colour, in particular to the formulation of the colour that gets combined with the material and it' s needed when creating certain laser-marking effects or contrasting colours.

In the case of reusable medical devices, frequent cleaning, disinfection, or sterilisation procedures need to be also carried out to allow their safe reuse. The long-term readability of HRI (Human Readable Interpretation of the data characters) and AIDC (Automatic Identification and Data Capture through bar codes, smart cards, biometrics, and RFID) falling within the expected device lifetime is a challenging task. For this reason, it becomes even more important to maximise the contrast and resolution of the laser-marked text and make it indelible. Therefore, specific medical materials optimised for laser-marking have been developed.

Considering that ABS polymers are widely used in the production of external enclosures, covers, or shells for reusable medical devices to achieve a high level of aesthetic, functionality, and medical regulatory compliance, it's important to bear in mind that ABS is in itself a laser-markable material. Correct laser settings allow good laser-marking results to be achieved, nevertheless, there are special ABS formulations that have been optimised for laser-marking and can be used for boosting the contrast and resolution and attain the desired colour and contrasting effect on the surface of a medical device.

Special ABS formulations are particularly valuable when other relevant properties of the material come into play and must be maintained alongside the laser-marking optimisation, like for example the biocompatibility requirement according to ISO 10993.

Biocompatible medical ABS-optimised formulations for laser-marking that capture the laser energy more efficiently have been developed, enhancing the laser-marking effect whilst guaranteeing medical compliance.

Since ABS and its colour are both important factors in obtaining the required laser-marking effect, creating a selection in the database of available pigments with the highest performance assessed under different laser systems is one of the critical elements to look at with regard to this type of development. Several combinations of material-colour samples must be prepared and pass the scrutiny of a laser processing qualification process. Previously, another essential aspect is obtaining the optimal compound out of the selected colour pigments in the colour formulation of the ABS material formulation. The mix of colour masterbatches with ABS material in natural colour during the injection moulding process cannot guarantee the same level of colour homogeneity as pre-coloured ABS. The reason resides in a better dispersion of pigment powders in the ABS matrix during the compounding extrusion process required to produce pre-coloured ABS. Instead, in

a masterbatch, the colour pigments have been previously dispersed in a carrier, an additional material in granules 100% compatible with the material to be coloured (e.g. SAN or ABS in the case of ABS), being only afterwards dispersed into the ABS material through an injection moulding machine, which has, in addition, less mixing power efficiency than a specialised compounding extrusion machine. For the same reasons, colour stability and consistency show higher quality levels in pre-coloured ABS than in natural ABS previously combined with a colour masterbatch.

In the case of medical devices requiring biocompatibility, among the available pigments that optimise laser-marking contrast only the ones with biocompatibility properties and staying within the legal admissible concentrations can be selected, to guarantee the required medical regulation compliance. A key support is provided for this task by the ELIX Product Stewardship department, which adds value through the constant surveillance of admitted substances and concentrations and by guaranteeing that the complete formulation, including the colour formulation, stays within legal limits. The re-combinations of the validated pigments result in new colour formulations for medical ABS, in which the laser-marking contrast is enhanced while guaranteeing the same material colour target.

In addition to regulatory compliance, biocompatibility, long-term UDI conformity and optimised colours and marking contrast, the medical industry is also looking for more sustainable ABS materials for medical devices.

High concern is given to CO_2 emissions, which are strictly related to their environmental impact such as global warming, but also other sustainability priorities are considered, for example the introduction of circular products that can avoid incineration, landfills (or dispersion into the environment in the worst-case scenario) at the end of life of the product.

Due to biocompatibility risks associated with recycled medical devices, it is not possible to directly apply circularity and reintroduce in the same medical application recycled ABS materials coming from medical devices. At least not a mechanically recycled ABS, that may include contaminants and does not imply a significant change in the chemical structure of the material. Instead, such a type of circularity would be possible if a chemical transformation takes place. The resulting pyrolysis oil obtained from waste can be used to feed the petrochemical crackers, as an alternative to NAFTA oil, and useful basic molecules can be obtained by chemical reactions and be reintroduced into the supply chain of ABS plastics production.

In this sense, ISCC+ certified chemical recycling and also bio-attributed certified feedstocks have such a great potential to create circularity, complementing and overcoming mechanical recycling limitations when it comes to the need for materials free of contaminants for medical applications.

Chemically recycled and bio-attributed materials have the same chemical composition and properties of a virgin medical resin. As a consequence, they fulfil the same medical applications and meet the stringent medical regulation requirements. All the colours and optimised medical formulations that are available as virgin medical ABS can also be used in their circular and bio-circular versions, guaranteeing not only regulatory compliance but also the availability of bright and intense colours and optimised colour formulations for laser-marking in chemically recycled and/or bio-attributed ABS formulations. These types of ABS medical formulations cannot be achieved with mechanical recycled content. In the near future we are likely to witness a redefinition of waste as a raw material even for stringent medical applications. The mission is to offer top-quality, sustainable solutions, pushing the value chain towards a circular economic model.

Conclusions

The medical device industry is looking for compliant materials that fulfil several strict regulatory requirements, like biocompatibility and Unique Device Identification, but are also oriented towards a lower environmental impact and CO_2 emissions reductions. ABS materials are widely used to produce external enclosure components of medical devices due to their mechanical properties, colour appearance and post-processing versatility such as laser markability. Laser-marking represents a valuable technology for the Unique Device Identification of medical devices, supporting the traceability implementation and other related benefits. Further to recent ABS material developments of leading manufacturers, special pre-coloured circular and bio-circular ABS formulations with reduced CO_2 emissions have been made available, in conformity with the stringent requirements of the medical industry. By doing so, regulatory compliance, biocompatibility, material properties, colour stability, waste or bio-based certified content and even laser-marking optimisation can be ensured at the same time.

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