Biocompatible cables & assemblies FOR MEDICAL DEVICES

AXON' CABLE designs and manufactures biocompatible sterilisable cables and assemblies which meet the requirements of the medical market. AXON' engineers support their customers in their risk management in accordance with the European directives (directives 93/42/CEE and 2007/47/CE).

RESEARCH & DESIGN

From the cable to the connectors, ranging from moulded or overmoulded parts and mechanical parts, AXON' engineers are involved in the design of medical equipment.
Interconnect systems are designed with the help of the Autodesk Inventor software which is compatible with most of the engineering software via .step and .iges files.
All products are designed in accordance with the CEI60601-I standard.

STERILISATION & SEALABILITY

AXON' medical assemblies are insulated with PVC, PU, TPE and other plastics which are easy to clean and chosen according to the sterilisation method required from the customer :
- Disinfecting,
- Plasma sterilisation,
- Ethylenoxyde,
- Gamma sterilisation, etc.

AXON' assemblies insulated with silicone or thermoplastic elastomers are able to be autoclaved like most of surgical devices. AXON' is able to offer assemblies which are sealed accurately in the connecting area for a safer use and a guaranteed life time.

FLEXIBILITY & AESTHETICS

For applications such as endoscopy, ambulatory equipment, patient monitoring and diagnostics, assemblies have to be flexible and withstand handling from the medical staff and patients.
AXON' offer biocompatible materials (ISO 10993, USP class VI) coloured with FDA approved pigments which are developed in accordance with the customers' requirements. Its expertise in moulded and overmoulded parts enables AXON' to offer cords which meet not only the technical but also the aesthetic requirements of the customers.

ELECTRICAL & MECHANICAL RELIABILITY

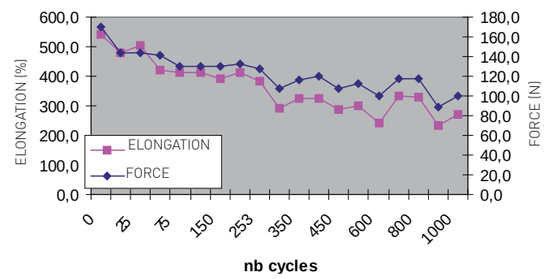
AXON' also has a long expertise in the manufacture of coaxial cables, microwave cables and PTFE tubes. This allows the group to offer hybrid hydro-electrical assemblies able to transmit signals, power and fluids (liquid or gas).
Electromagnetic protection is an important stake for medical applications too. AXON' has two types of test equipment to evaluate the protection of the assembly :
a transfer impedance test bench to measure the shielding efficiency of the cable and a mode stirred chamber to measure the shielding efficiency of the assembly.
AXON' integrate the test method and equipment from the design stage in order to guarantee electrical performance of assemblies and special sensors.

NOSO-FREE®, ANTIBACTERIAL ASSEMBLIES

AXON' CABLE has developed a new range of anti-bacterial medical assemblies which helps reduce cross-contamination.
AXON' adds silver ions, known for their antimicrobial and anti-fungus properties, into the polymers used for the jacketing and the overmoulding of assemblies. Bacteria then stop multiplying and die within a few hours.

NOSO FREE

Evolution of mechanical properties of silicone (ASCI60ME2) after autoclave sterilisation at 134°C



BIOCOMPATIBILITY TESTS

We decided to test on ISO10993 Chapter 5 and 10, according to the chapter 1 guiding the biocompatibility test selection regarding applications, duration of exposure and type of exposed tissues. The standard advised therefore to test cytotoxicity, sensitization and irritation. We selected the most common application type among our range of products: surface contact devices which can be mainly for the skin, and more rarely mucosa or injured surface.

MATERIAL	PVC						TPU			TPE			SILICONE									PE	FLUORINATED POLYMERS	
Axon' Ref.	PVCMED475RL				PVCFDACE		TPUL93AISO.A	TPUL85AUSP	PTUE85SME	ASC2MED79	CETHAX MED7	CETHAX 970	ASCI60ME1			ASCI60ME2			SIMED 42FDA	SIMED20BIOCT	SIMED20BIOLT	LDPEMED66USP	PTFE	FEP
Colour	Fog white	Black	Grey RAL7035	Black+ nosofree	White	Black	Clear	Clear	Clear	Black	Clear	Clear	Grey RAL7035	Grey RAL7037	Black	Grey RAL7035	Grey RAL7037	Black	Clear	Clear	Clear	Clear	Clear	Clear
ISO 10993 Chap. 5 Cytotoxicity	●	●	●	●		●	○		○ ○	●	○		●	●	●	●	●	●		○ ○	○ ○			
ISO 10993 Chap. 10 Irritation intracutaneous	●	●	●	●	●	●	◇		○ ○	●			●	●	●	●		●		○ ○	○ ○			
ISO 10993 Chap. 10 Sensitization	●	●	●	●	●	●	◇		○ ○	●			●	●	●	●	●	●		○ ○	○ ○			
USP Class VI								○		○	○	○							FDA approved	○ ○	○ ○	○	○	○
Possible Process	Jacketing / Overmoulding						Jacketing / Overmoulding			Jacketing / Overmoulding			Jacketing / Overmoulding			Jacketing			Overmoulding			Jacketing	Insulation (tubes and wires only)	Insulation / Jacketing
Sterilisation Compatibility	EtO STERRAD, STERRIS, STERRAD NX Cold disinfection (alcohol wipes...)						EtO Cold disinfection (alcohol wipes...)			Autoclave 121°C (134°C for MED 7) EtO STERRAD, STERRIS, STERRAD NX Cold disinfection (alcohol wipes...) Gamma			Autoclave 134°C 2 bar EtO STERRAD, STERRIS, STERRAD NX Cold disinfection									EtO STERRAD, STERRIS, STERRAD NX Cold disinfection (alcohol wipes...)	Autoclave 134°C 2 bar EtO STERRAD, STERRIS, STERRAD NX Cold disinfection (alcohol wipes...)	
Common use	Equipment worn on the patient / Skin contact / Medical Healthcare Application												Surgery room equipment									Medical healthcare application		

Short term implantable

Long term implantatable

Clear polymers tested as biocompatible are usually used with FDA compliant pigments. The low concentration of pigment should allow this coloured mix to remain biocompatible.

● Tested on an jacket extruded in AXON' in 2015 /2016. Samples cleaned with alcohol wipes only, standard production conditions.
○ Tested by the material supplier.
◇ Representative sample of the same familly (same monomers in different ratio) have been tested in accordance with ISO10993 §4/6/10/11 after EtO.
○ ○ According to previous recorded test data, should pass the test, must be confirmed by specific lab test/.

The upper information are subjected to changes without prior notice.

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