Dot Compliance | CASE STUDY

Endospan Expands Quality Process Coverage with Dot Compliance

ENDOSPAN

Employees
40

Industry
Medical Device

Location
Israel

The Challenge

Endospan, a pioneer in off-the-shelf endovascular repair of aortic arch disease, was using Dot Compliance for Document Control, and wanted to expand additional processes. The company was manually handling change control – signing, printing, and scanning change control forms; DHR forms, QC inspection forms, purchase orders, etc.).

Due to COVID-19, with so many employees working remotely, the company faced additional challenges. The forms needed to be checked and approved via email. There were problems with having them signed by all parties and making sure that they were printed and scanned of good quality.

The Solution

Endospan expanded the use of Dot Compliance ready to use QMS solutions with Change Control module, templates for electronic forms, and training management to streamline training effectiveness.

Next Steps

Endospan plans on deploying additional Dot Compliance modules in 2021: Quality Event management, CAPA management, Deviation management, Complaint management, Audit management, Supplier management, Maintenance and Equipment management, Binders (for DHF & Technical File), Controlled copies, etc.

About

The NEXUS® Aortic Arch Stent Graft System by Endospan is the only CE-approved off-the-shelf branched endovascular aortic arch system. Indicated for wide range of aortic pathologies, including arch aneurysms, thoracic dissections, and PAU, NEXUS® is designed to overcome the specific challenges of the aortic arch anatomy. The NEXUS® "Dock and Lock" modular system provides stable and secured anatomical anchoring and atraumatic sealing in a wide range of anatomies.

"Dot Compliance has proven to be invaluable this year and a great asset to the company in assisting us to comply with DEKRA and FDA regulations".

- Sharon Katherine Haviv | Quality Records Manager