

TECHNICAL BULLETIN

From: Marketing CoE Chasseneuil

To: All affiliates

B. Braun Access Port Systems Celsite®

Question: Can DMSO and Taxol® be used with Celsite® ports and catheters?

To remind you what these are?

– Paclitaxel (Taxol®) is an intra venous chemotherapy agent indicated in ovarian cancer, breast cancer, lung cancer and Kaposi syndrome.

Paclitaxel may be infused over 3 to 24 hours (infusion concentration must be 0,3 to 1,2mg/l) The solvent contains alcohol and castor oil.

- DMSO (Dimethyl sulfoxide) at 10% concentration is used as a preservative for cells which have been harvested for stem cell therapy, used in haemotology.

The test method, performed in usual (real) conditions of use, consisted of infusing the catheter with a concentration of

- 10% for DMSO over 4,5 hours (corresponding to 1 transplantation).
- 20% for Paclitaxel up to 24 hours x 10 infusion treatments.

Tests were performed in order to measure and evaluate the possible modifications, caused by the two drugs to the:

- A) mechanical properties of the Celsite® catheter (silicone, PUR and Anthron®)
- B) **chemical properties** of the Celsite® catheter (silicone, PUR and Anthron®)

The measurements demonstrate that:

With regards to DMSO

- Silicone catheters show no alteration to their properties, under usual conditions.



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- Polyurethane and Anthron® catheters show no alteration of their properties under usual conditions

With regards to Paclitaxel (Taxol®)

- **Silicone** catheters show no alteration to their properties, regardless of concentration and duration of contact
- Polyurethane and Anthron® catheters show a reduction in their mechanical properties (due to a small absorption of the alcohol solvent present in the drug) but still conform to our requirements including of ISO 10555-1 "Sterile, single use intravascular catheters-part 1: General requirements ". The chemical properties had not show any modification or release of components of the materiel into the liquid which it was in contact.

CONCLUSION

Answer: Celsite® ports with silicone catheters or with polyurethane-Anthron® catheters can be used with Taxol® and DMSO under usual conditions of use.

Bibliography

• Use of totally implantable central venous access ports for high-dose chemotherapy and peripheral blood stem cell transplantation: results of a monocentre series of 376 patients

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Double lumen port access in patients receiving allogenieic blood stem cell transplantation

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• **Standard ISO 10555–1**" Sterile, single use intravascular catheters-part 1: General requirements ".