WoCoVA
7th World Congress on Vascular Access

16-18 OCTOBER 2022 MEGARON ATHENS GREECE

Impact in France of the European “Medical Device Regulation” on the availability of some specific devices : parenteral nutrition catheters …

Eric Desruennes

Pediatric Anesthesia Clinic

Jeanne de Flandre Hospital, Lille

GIFAV, France

EU MDR

- **EU Medical Device Regulation (MDR)** is a regulation of the European Union on the sale of medical devices for human use.
- Main objectives : establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health.
- This regulation was published on April 2017 but originally approved medical devices will have a transition time of three years (until May 2021) to meet new requirements.

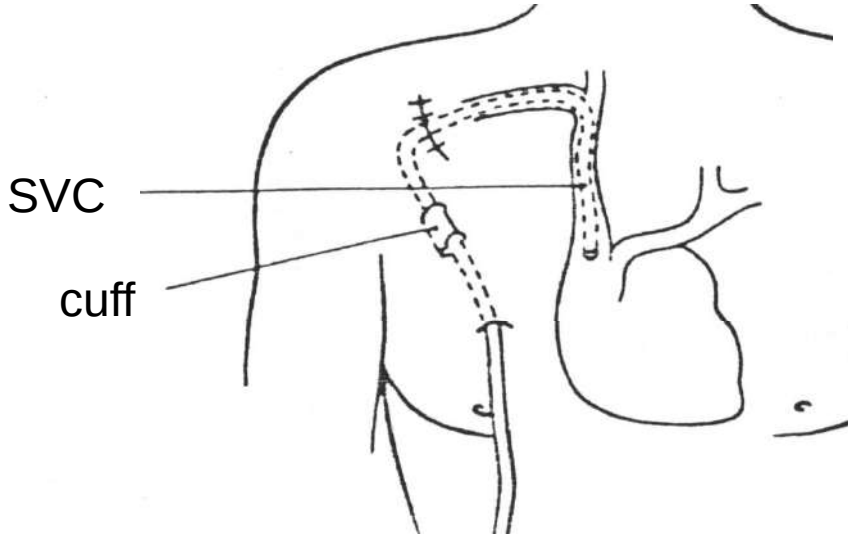
EU MDR : update in 2022

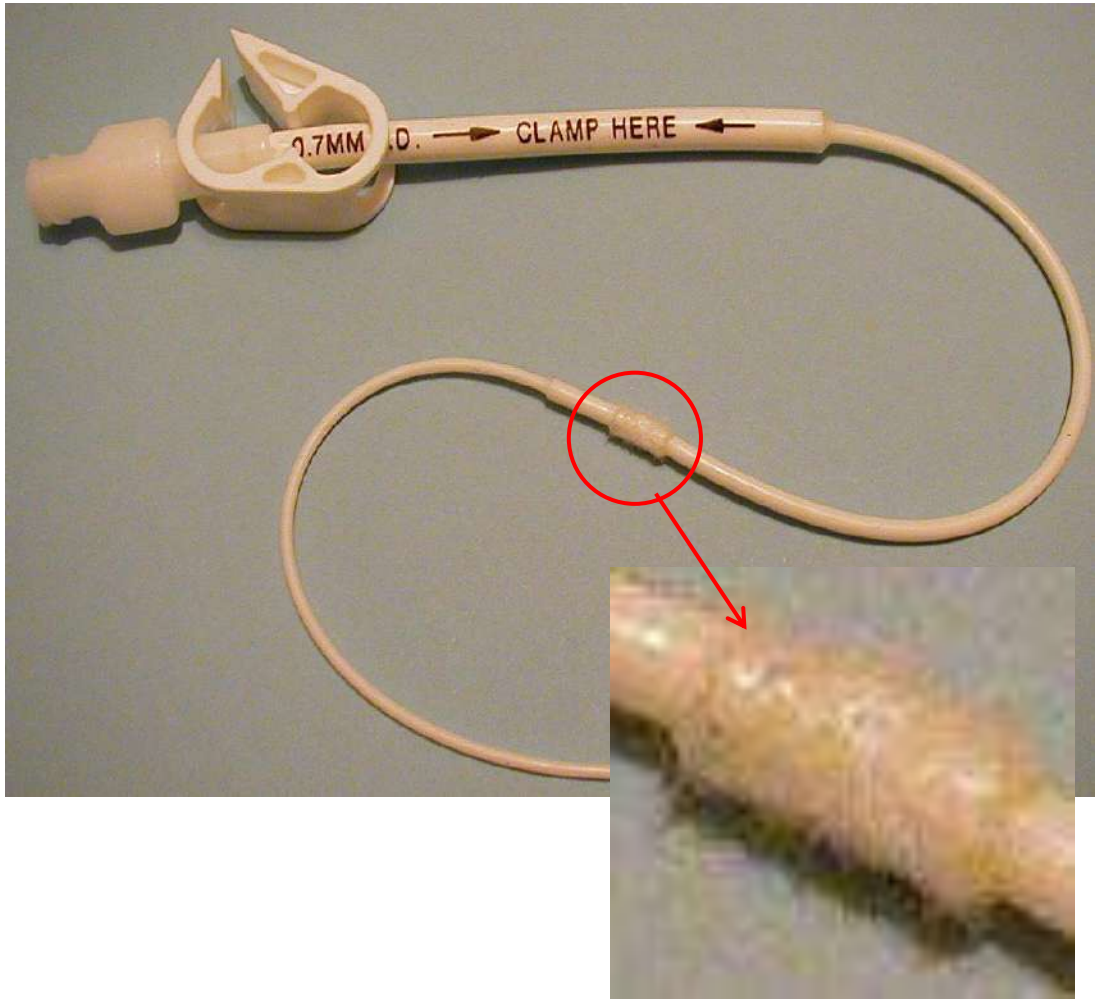
- 90% of currently valid certificates will expire in 2023-2024
- 25,000 files awaiting certification … but only 30 notified bodies for examination !!
- Moreover : in april 2022 more than 50% of the submitted applications submitted were rejected because they were incomplete …
- Some devices are no longer available due to the delay in certification, for example **Hickman-Broviac catheters**

Hickman-Broviac catheters

= long-term silicone catheters with a subcutaneous cuff :

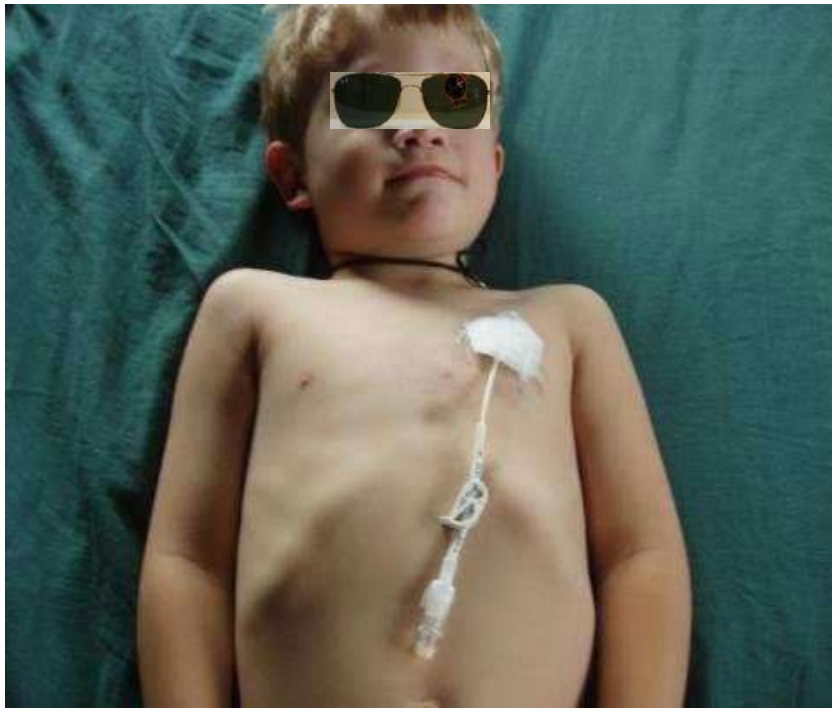
- 2.7 to 6.6 Fr in pediatrics
- inserted 1 to 2 cm from the skin emergence of the catheter
- fibrosis around the cuff in 2 to 4 weeks ⇒





Hickman-Broviac catheters

- Best indications : long-term parenteral nutrition, hematology
- +++ in pediatrics, as there are no easy alternatives for newborns and infants :
  - *short bowel syndrome, congenital enteropathies, chronic intestinal pseudo-obstruction syndrome, Hirschsprung's disease, Crohn's disease ...*
- difficult to use picclines or ports in newborns, infants and small children …
- = niche market, needs of 500 Broviac per year in pediatrics ?



Broviac : the situation mid-2022

- 3 manufacturers : Cook™ (USA), Bard™ (USA) and Vygon™ (France) :
  - Cook has stopped distribution in Europe
  - Bard has difficulties to supply due to increased demand and lack of certain basic ingredients
  - Vygon's certificate has expired and can no longer manufacture
- By mid-2022 **the situation is alarming** : no more percutaneous 4.2 and 6.6 Fr Broviac (placed by anesthesiologists), no more 4.2 Fr Broviac cutdown (placed by surgeons) !

Actions

- Warning message to scientific societies of gastroenterology, home parenteral nutrition, and patient associations
- Meetings in presential and by video-conference
- Contacts with manufacturers and with the French Health Authority (National Drug Safety Agency)
- In the same time an alert message was addressed to the Health Authority by the French Academy of Medicine

Results

- Vygon asked and obtained an exceptional extension of its certificate for 6 months (*article 59 of the MDR= derogation only if the use of the device concerned is in the interest of public health, patient safety or patient health*).
- Vygon have been engaged to accelerate the certification process in 2023
- Bard should be able to deliver all references again at the end of October 2022

Conclusion : if everything works out (and we hope it will), we have the impression that we have been useful in federating scientific societies, vascular access specialists, manufacturers and patient associations !

Thanks for your attention !

WoCoVA
7th World Congress on Vascular Access