



Datum

Dnr

WG 12 Information for reprocessing of resterilizable devices.
20140922-23 London

22/9

Our new convener Wayne Spencer welcomes all and opened the meeting.
Following countries where representing: UK, US, DE, A, AU, CA, NL and
SE.

We all approved report from meeting held in Sydney.

We have received 459 comments and convener started to say that we will
not be able to go through, we need a second meeting. We all agreed.
We had a very long discussion on "single use". The problem is not single
but the word use.

One group with the UK in the lead means if you have opened the
packaging or the packaging is out of date it has been used.

The other group with AU in the lead means that if the manufacture has
given information how to reprocess the medical device then it is ok to
reprocess so long as the medical device has not been decontaminated.

We were not able to come to any conclusion. My concern is this: how will
I know how the manufacture has interpreted single use. If the manufacture
delivery non sterile screw meant to be sterilized on the hospital and I do
so. Then the screw was open by mistake, the information about process is
because the screw comes non sterile. I can't remember to have seen in any
manual saying that if I have open the packaging by mistake I can sterilized
the screw again. If this text is not there, doesn't this means I'm the
manufacture?

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At 5 pm we stopped on comments 107.

23/9

We continued with the comments. Once again we stopped at single use. I ask my question and we all agree to that the manufacture (we take the screw as example) has to give instruction to cleaning and sterilized when it come non sterile to the hospital. And if the manufacture can give me a validated method in cleaning and sterilization concerning open but not used or out of date then it would be ok to resterilize. But then it is not single use?

Next meeting will be in Washington, Arlington 22-24/4. We need three full days. This date is also chosen that WG 13 has the meeting 20-21/4 in the same place. Question was raised to have one meeting between now and April. We all agree to this will not be possible.

Wayne thank us for our work and hoped to see us i April.

Birte Oskarsson