

Carrières sur Seine, 2014-03-24

**Urgent recall of Temena USB and USC needles,  
article number: USB050-22 and USC050-22**

Dear Ladies and Gentlemen,

We got feedback from the market that some of our USB and USC needles were leaking at the hub. We cannot exclude that the some devices of the batches you received might be affected. Temena SAS therefore decided to recall the concerned medical devices voluntarily.

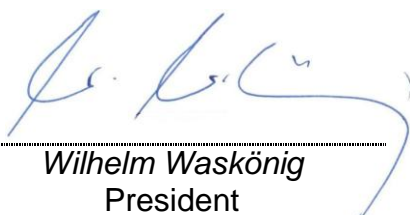
Following products/batches are affected:

Product designation	Manufacturer	Article number	Batch number	Expiry date
Ultra sound needle 22G (0.7 mm) x 50 mm	Temena SAS, Carrières sur Seine, France	USC050-22	B3170005	2018-05-31
Ultra sound needle, 30° bevel		USB050-22	B3070012	2018-02-28
Ultra sound needle, 30° bevel		USB050-22	B3250001	2018-06-30
Ultra sound needle, 30° bevel		USB050-22	B3250026	2018-06-30

**IMPORTANT INSTRUCTIONS:**

- Ensure that the devices questions will not be applied to humans.
- Opened packages shall not be used any more.
- Please send us back the request of products (including opened packages)
- Inform your distribution partners / further resellers about this recall to achieve a 100% recall of all unused products.
- Please add a copy of our invoice / respectively of our delivery notes, to carry out a cost reimbursement or receive compensation delivery or a credit note.
- Please use attached form to answer Temena SAS.

We sincerely apologize for the inconvenience this may have caused by this product recall we thank you in advance for your support.



.....  
**Wilhelm Waskönig**  
President



.....  
**Dr. Bernhard Kusian**  
vigilance manager

## Response Product Recall

Please reply to Fax Nr. +33 (0)1.30.86.05.31  
via email: [info@temena.fr](mailto:info@temena.fr)

**Re: Urgent recall of Temena USB (REF USB050-22) and  
USC needles (REF USC050-22)**

### Affected products:

Product designation	Manufacturer	Article number	Batch number	Expiry date
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### Customer:

Company: .....

Street: .....

ZIP / Town: .....

<input type="checkbox"/>	We have used all devices of the concerned LOTs. No defects have been observed so far.		
<input type="checkbox"/>	We still have following qualities of the concerned LOTs in our stock:		
<input type="checkbox"/>	REF:	LOT:	Amount:
<input type="checkbox"/>	REF:	LOT:	Amount:
<input type="checkbox"/>	REF:	LOT:	Amount:
<input type="checkbox"/>	REF:	LOT:	Amount:
<input type="checkbox"/>	We will return our remaining products from these LOTs, including opened cardboxes.		
<input type="checkbox"/>			
<input type="checkbox"/>			

Please check where appropriate.

Please send us  
a credit note , a cost reimbursement , a product exchange .

Further comments:

You will reach me as signatory under the following phone number.

.....  
.....  
Town, Date Name, signature