

Zwanenburg, August 19, 2020

## FIELD SAFETY LETTER

Concerns: Incorrect temperature range on the inner box of all Willocell devices

Our reference: CAPA-2020-1701-NL

Dear Distributor,

Our company always strives to provide high quality medical devices to our patients, and we wish to inform you that we recently detected the following mistake on the (inner or primary packaging) box of our Willocell devices: the storage temperature indicates a range from 5 to 25° C. instead of 15 to 25° C.

### Which devices are affected?

The list of affected devices is provided in Annex 1.

### Is there any potential risk to the performance of Willocell?

No, there is no risk as Willocell was tested for extreme transport conditions which included temperatures between 5 and 15° C., and successfully passed these tests.

The device was also tested for stability during its shelf live (3 years) with a storage temperature between 15 to 25° C. and successfully passed these tests as well.

This means that the stability / performance of the devices is guaranteed when the devices are stored between 15 and 25° C., and also during extreme transport conditions (between -35 and 55° C.).

As the mistake appears only on the inner box (primary packaging) and not on the pouch (unit sterile packaging), neither on the instruction for use (IFU); and as such devices are generally stored at ambient temperature, there is no risk for the performance of the devices.

### What do you have to do?

Nothing, except making sure that your stock is stored in a temperature-controlled area which ranges from 15 and 25° C as indicated on the Willocell pouches and the IFU.

### Can you continue to sell your current stock of Willocell devices?

Yes, but we suggest that you add a copy of this field safety letter to each shipment of concerned devices to your customers.

### Are my customers allowed to use the concerned Willocell devices?

Yes, if they were stored in areas with temperatures between 15 to 25° C.

### When can you expect to receive Willocell devices with correct labels?

With your next order, you will receive Willocell devices with correct labels.

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Whom can you contact for further questions, if needed?

Should you have any question, please feel free to contact our Quality manager for the medical devices: Myriam DESMET: [myriam.desmet@willpharma.com](mailto:myriam.desmet@willpharma.com).

What else do you need to do?

We would appreciate if you acknowledge the receipt of this field safety letter by replying by e-mail to [Rianne.veen@willpharma.com](mailto:Rianne.veen@willpharma.com).

Once again, we would like to certify that we are making all efforts to ensure the best quality of our devices,

Yours sincerely, 



Head of Medical Devices Unit



Filip KUHN  
Head RA & QA

### Annex 1: List of affected devices

| Device name                       | Item number | Batch number | Expiration date |
|-----------------------------------|-------------|--------------|-----------------|
| Willocell Standard 1.25X5 cm (12) | 25016NL-12  | 2016132      | 2019-04-01      |
|                                   |             | 2016367      | 2019-11-01      |
|                                   |             | 2017070      | 2019-11-01      |
|                                   |             | OR2019546    | 2023-01-28      |
|                                   |             | OR2020225    | 2023-04-29      |
| Willocell Standard 5X7.5 cm (12)  | 25018NL-12  | OR2020077    | 2023-02-28      |
|                                   |             | OR2020195    | 2023-04-29      |
|                                   |             | OR2020219    | 2023-04-29      |
| Willocell Standard 5X35 cm (12)   | 25019NL-12  | 2016134      | 2019-05-01      |
|                                   |             | 2017072      | 2020-02-01      |
|                                   |             | OR2020005    | 2023-01-28      |
|                                   |             | OR2020194    | 2023-04-29      |
| Willocell Standard 10X20 cm (12)  | 25020NL-12  | OR2020001    | 2023-01-28      |
|                                   |             | OR2020056    | 2023-02-28      |
|                                   |             | OR2020058    | 2023-02-28      |
|                                   |             | OR2020059    | 2023-02-28      |
|                                   |             | OR2020060    | 2023-02-28      |
|                                   |             | OR2020067    | 2023-02-28      |
|                                   |             | OR2020069    | 2023-02-07      |
|                                   |             | OR2020072    | 2023-02-28      |
|                                   |             | OR2020074    | 2023-02-28      |
|                                   |             | OR2020076    | 2023-02-28      |
|                                   |             | OR2020079    | 2023-02-28      |
|                                   |             | OR2020083    | 2023-02-28      |
|                                   |             | OR2020092    | 2023-02-28      |
| OR2020198                         | 2023-04-29  |              |                 |
| Willocell Knit 2.6X2.6 cm (10)    | 25021NL-10  | OR2020197    | 2023-04-29      |
|                                   |             | OR2020362    | 2023-06-30      |
| Willocell Knit 7.6X10.2 cm (12)   | 25022NL-12  | OR2020196    | 2023-04-29      |
|                                   |             | OR2020214    | 2023-04-29      |
|                                   |             | OR2020249    | 2023-06-30      |
| Willocell Knit 15.2X22.9 cm (10)  | 25023NL-10  | OR2020357    | 2023-06-30      |
|                                   |             | OR2020186    | 2023-04-29      |
|                                   |             | OR2020187    | 2023-04-29      |
|                                   |             | OR2020356    | 2023-06-30      |
|                                   |             | OR2020359    | 2023-06-30      |
|                                   |             | OR2020361    | 2023-06-30      |

| Device name                                | Item number | Batch number | Expiration date |
|--|-------------|--------------|-----------------|
| Willocell Knit 5.1X10.2 cm (10)            | 25024NL-10  | OR2019510    | 2023-04-29      |
|  |             | OR2020216    | 2023-04-29      |
|  |             | OR2020363    | 2023-06-30      |
| Willocell Fibril Special 2.6X5.1 cm (10)   | 25030NL-10  | 2017166      | 2020-04-01      |
|  |             | 2017394      | 2020-09-01      |
|  |             | OR2019539    | 2023-01-28      |
|  |             | OR2020053    | 2023-02-07      |
|  |             | OR2020110    | 2023-04-29      |
|  |             | OR2020167    | 2023-04-29      |
|  |             | OR2020173    | 2023-04-29      |
|  |             | OR2020175    | 2023-04-29      |
|  |             | OR2020177    | 2023-04-29      |
|  |             | OR2020179    | 2023-04-29      |
|  |             | OR2020183    | 2023-04-29      |
|  |             | OR2020222    | 2023-04-29      |
|  |             | OR2020233    | 2023-05-30      |
|  |             | OR2020311    | 2023-06-30      |
| OR2020353                                  | 2023-06-30  |              |                 |
| Willocell Fibril Special 5.1X10.2 cm (10)  | 25031NL-10  | 2017395      | 2020-09-01      |
|  |             | OR2019538    | 2023-01-28      |
|  |             | OR2020036    | 2023-06-30      |
|  |             | OR2020052    | 2023-02-07      |
|  |             | OR2020109    | 2023-04-29      |
|  |             | OR2020166    | 2023-04-29      |
|  |             | OR2020170    | 2023-04-29      |
|  |             | OR2020172    | 2023-04-29      |
|  |             | OR2020227    | 2023-04-29      |
|  |             | OR2020310    | 2023-06-10      |
| Willocell Fibril Special 10.2X10.2 cm (10) | 25032NL-10  | 2016250      | 2019-06-01      |
|  |             | 2017168      | 2020-04-01      |
|  |             | 2017396      | 2020-09-01      |
|  |             | OR2019540    | 2023-01-28      |
|  |             | OR2020051    | 2023-02-07      |
|  |             | OR2020174    | 2023-04-29      |
|  |             | OR2020176    | 2023-04-29      |
|  |             | OR2020178    | 2023-04-29      |
|  |             | OR2020182    | 2023-04-29      |
|  |             | OR2020221    | 2023-04-29      |
| OR2020355                                  | 2023-06-30  |              |                 |