

June 1, 2016

Urgent Field Safety Notice

DAC UNIVERSAL MKIII

Device verification to design requirements

Dear Partner,

It has come to our attention that a few repairs have been made to the DAC Universal MKIII with an incorrect length screw placed in the lid holder of the autoclave. The incorrect screws were of the type M6x12mm and used for DAC UNIVERSAL MKII which had three pulling rods.

The DAC UNIVERSAL MKIII requires minimum M6x16mm screws to keep the lid securely in place during the hygienic cycle and some repairs were made with M6x12mm screws.

DAC UNIVERSAL MKIII potentially involved carries the following range of serial numbers:

14000-99999

104000-199999

202000-999999

B14000-B99999

B104000-B199999

B202000-B999999



Risk

If M6x12mm screws are installed in the lid holder of a DAC UNIVERSAL MKIII there is a risk that the lid may be released from the DAC UNIVERSAL MKIII during operation. Since the lid is under pressure and the chamber contains hot steam the release of the lid could cause severe injuries to the user or other persons.

Field Safety Corrective Action

Verifying lid holder screws in DAC UNIVERSAL MKIII

DAC UNIVERSAL MKIIIs suspected of having had screws shorter than 16 mm installed in the lid holder must not be used.

Please urgently use one of the contact options below to provide feedback whether or not you have reason to suspect that screws shorter than 16 mm might mistakenly have been installed in the lid holder of DAC UNIVERSAL MKIIIs within your customer base by your service technicians:

- Web form:



www.surveymonkey.com/r/verifying

Alternatively feedback must be provided by Email / FAX / Telephone:

Please use the form in Annex 1 attached to this letter.

- Email:
Contact.hygiene@sirona.com
- FAX:
+45 87 43 90 61
- Telephone:
Call +49 (0) 62 51/16 16 70 and then press "4" for hygiene products.

In order to comply with our legal obligations Dentsply Sirona requests this feedback.

New screws

In order to be able to distinguish between the round-headed M6x12mm and M6x16mm screws a new cylinder head M6x20mm screw has been introduced for the lid holder of all DAC UNIVERSAL versions. When installing the cylinder head M6x20mm screws make sure to:

1. Clean the thread inside the pulling rods for Loctite 243 residues, using a M6x20mm cylinder head screw; Insert the screw, without the lid holder installed and remove it again. Repeat if necessary.
2. Clean the M6x20mm cylinder head screw with a damp cloth
3. Realign the pulling rods
4. Apply a few drops of Loctite 243 to the inside thread of the pulling rods
5. Install the lid holder and tighten the new M6x20mm Cylinder head screws with 5 Nm.



Cylinder head screw M6x20mm

The round-headed M6x16mm screw will be discontinued immediately.

As a courtesy we have included 50 new cylinder head M6x20mm screws with this letter. Should you require more screws please order them by below reference number at the same price as the M6x16mm:

6594431/720322 Cylinder head screw M6x20mm (10x).

Informing clinics

If you do have reason to suspect that screws shorter than 16 mm might be installed in the lid holder of DAC UNIVERSAL MKIIIs within your customer base we kindly request you to:

- Immediately get in contact with your customers suspected of operating a DAC UNIVERSAL with screws shorter than 16 mm installed in the lid holder. Please inform the customers that their DAC UNIVERSAL MKIIIs must not be operated until the screws and pulling rods of the DAC UNIVERSAL MKIIIs are exchanged, since the internal threads of the installed pulling rods will have been subjected to stress and forces higher than they were designed for.
- Dispose all 6078898/720311 Round-head screws M6x12mm or M6x16mm you might find in your inventory.
- Provide feedback as requested in the chapter Verifying lid holder screws in DAC UNIVERSAL MKIII. (see above)
- Follow the steps in the chapter Exchanging lid holder screws in DAC UNIVERSAL MKIII to verify and repair DAC UNIVERSAL MKIIIs with screws shorter than 16 mm installed in the lid holder. (see below)

If you do not have reason to suspect that screws shorter than 16 mm might be installed in the lid holder of DAC UNIVERSAL MKIIIs within your customer base we kindly request you to:

- Dispose all 6078898/720311 Round-head screws M6x12mm/M6x16mm you might find in your inventory.
- Provide feedback as requested in the chapter Verifying lid holder screws in DAC UNIVERSAL MKIII. (see above)



Exchanging lid holder screws in DAC UNIVERSAL MKIII

When verifying the type of screws installed in the lid holder of a DAC UNIVERSAL MKIII these actions must be carried out:

- If finding M6x12mm screws installed the pulling rods must be exchanged as well as the screws with new original M6x20mm screws delivered with this letter as explained in the chapter New screws.
The reference numbers for the pulling rods are:
6308469/720145 Pulling rod right, complete WR
6308527/720175 Pulling rod left, complete WR
- If finding M6x16mm screws installed the screws must be exchanged with new original M6x20mm screws delivered with this letter as explained in the chapter New Screws.

In order to comply with our legal obligations Dentsply Sirona requests feedback on which DAC UNIVERSAL MKIIIs have been inspected & repaired.

When verifying DAC UNIVERSAL MKIIIs please make sure to get the serial numbers of all machines you verify - the ones with the incorrect M6x12mm as well as the ones with the correct M6x16mm screws.

Please urgently use one of the contact options below to provide the serial numbers and details whenever a DAC UNIVERSAL MKIII within your customer base has been inspected/repaired:

- Web form:



www.surveymonkey.com/r/exchanging

Alternatively feedback must be provided by
Email / FAX / Telephone:

Please use the form in Annex 2 attached to this letter and copy the amount you need.

- Email:
Contact.hygiene@sirona.com
- FAX:
+45 87 43 90 61
- Telephone:
Call +49 (0) 62 51/16 16 70 and then press "4" for hygiene products.

This notice must be passed on to all those who need to be aware within your organisation or to any organisation to which the potentially affected devices have been transferred.

If you have questions please contact the Dentsply Sirona hotline at:

<http://www.sirona.com/en/contact/requests/> or call +49 (0) 62 51/16 16 70 and then press "4" for hygiene products.

I am sure that you agree with us that safety should always be a first priority in all our business and we are looking forward to receiving your feedback.



Claus Bisgaard

Annex 1

Details

1. Please enter your contact information

Name	
Company*	
Address*	
Address 2	
City/Town*	
State/Province	
ZIP/Postal Code	
County*	
Email Address*	
Phone Number*	

*required field

2. Do you have any reason to suspect that anyone within your company might have installed incorrect M6x12mm screws in the lid holder of a DAC UNIVERSAL MKIII?

- ☐ Yes
- ☐ No (please specify why not below)

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3. Please confirm that you have searched for and disposed of all 6078898/720311 Round-head screws M6x12mm/M6x16mm within your inventory

- ☐ I confirm
- ☐ Other (please specify)

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Annex 2

Details

1. Please enter your contact information

Name	
Company*	
Address*	
Address 2	
City/Town*	
State/Province	
ZIP/Postal Code	
County*	
Email Address*	
Phone Number*	

*required field

Registration

Please enter the details of the DAC UNIVERSAL MKIII tested and repaired.

2. Please specify the serial number

3. Which type of screws were previously installed before dismounting the lid holder?

- ☐ 6078898/720311 Round-head screw M6x12mm
- ☐ 6078898/720311 Round-head screw M6x16mm
- ☐ Other (please specify)

4. Did you exchange the pulling rods?

- ☐ Yes
- ☐ No



5. Which screws did you install when remounting the lid holder?

- ☐ 6594431/720322 Cylinder head screw M6x20mm
- ☐ Other (please specify)

