

Urgent Field Safety Notice

FSN number: TQFSN21001
 Commercial name of the affected product: Trial spacer
 FSCA-identifier) TQFSCA21001
 Type of action: return the medical device to supplier and device modification.

Date: 7th April 2021

Attention: Notified body number:1984/ Distributors / Competent Authority: AEMPS/

Details on affected devices:

Reusable surgical instruments: Trial spacers small-medium and large.



Model	Description	Involved Batch	units
TGUI0122062	Large Size Test Spacer	26134	15
TGUI0122058	Medium Size Test Spacer	26133	15
TGUI0122054	Small Size Test Spacer	26132	15

Our records indicate that you may have received the affected devices on December 2018.

Description of the problem:

Tequir is conducting a medical device Field Safety corrective Action (return and device modification) for only one manufactured batch number corresponding to each model of reusable surgical trial spacer. The affected device did not pass steam sterilization process validation testing. To date there are no adverse event reported which could be linked to this issue. The affected device is going to be modified eliminating the blind hole in a through hole.

Risks		
<i>Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.</i>	<i>Most probable</i>	<i>Highest Severity</i>
	<i>None</i>	<i>None</i>
<i>Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue</i>	<i>Most probable</i>	<i>Highest Severity</i>
	<i>None</i>	<i>Infection leading to medical surgical intervention</i>

Surgeries can continue running without using the trial spacer. This issue does not affect the surgical procedure, performance or safety of the implant with the advice to plan previously the needed soft tissue to close the stump.

Advise on action to be taken by the user:

Hospital Recommendations:

1. Review this Field Safety Notice and ensure that affected personnel are aware of the contents.
2. If you have any affected products at your facility, assist your Tequir sales representative and quarantine all affected products.
3. Complete Attachment 1_REPLY FORM and send to info@tequir.com. this form must be returned even if you do not have affected products from your facility.
4. Retain a copy of the reply form with your field action records in the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this field safety notice, please contact your Tequir sales representative.

Surgeon Responsibilities:

1. Review this field Safety notice for awareness of the contents.
2. There are no specific patient monitoring instructions related to this Field Safety Notice that are recommended beyond your existing follow-up schedule.
3. Complete Attachment 1_REPLY FORM and send to info@tequir.com. this form must be returned even if you do not have affected products from your facility
4. Retain a copy of the reply form with your field action records in the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this field safety notice, please contact your Tequir sales representative.

Other information:

This medical device Safety Notice was reported to all relevant competent authorities and the related notified body as required under the applicable regulations for Medical Devices as per MEDDEV2.12-1 in Europe.



Please, keep Tequir informed of any adverse event associated with this affected device or any other product by emailing to info@tequir.com or your local sales representative.

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (If appropriate)

Please, be aware that the names of user facilities notified are routinely provided to the competent authorities for audit purposes.

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

Contact reference person:

MAGDA BRESÓ / TEQUIR, Polígono industrial el Oliveral 46190 Ribarroja del Turia, Valencia Spain.
Pone: +34 96 166 87 95
info@tequir.com

We would like to thank you for your cooperation in advance and regret any inconveniences caused by this Field Safety Corrective actions.

Sincerely,