

Date: March 27, 2019

Urgent Field Safety Notice 19/01

Adapter for handpiece, guided

<u>To:</u>	Distributors and dealers
<u>FSCA Identification:</u>	19/01
<u>Report Type:</u>	Initial Report
<u>Date:</u>	March 27, 2019
<u>Detailed description of the affected product:</u>	
Article number:	3.04.090
Lot number:	17415
Description:	Adapter for handpiece, guided, reusable, for guide sleeve Ø 4.8 mm

Description of the problem:

Thommen Medical AG has found parts in a production batch of the above-mentioned medical device whose hardness does not conform to specifications. The dental coupling of the adapter can become deformed when being inserted into the implant. The deformation of the dental coupling may make it difficult to remove the adapter from its counterpart (e.g. the handpiece).

It is also possible for the insertion aid to become tilted so that it can no longer be removed from the adapter.

Only adapters with lot number 17415 are affected; other lot number conform to our specifications.

Risk assessment:

A short-term or long-term impairment to the patient's health is not expected. A brief delay during treatment is possible.

Measures taken:

Addition to user manual THM61144 "Guided Surgery" (Pages 5 and 9):

The following text is inserted: "The one-piece adapter for the handpiece engages directly with the internal hexagon of the implant. It can be used after initially positioning the implant in the bone after the insertion aid has been removed."

User manual THM61144 is additionally supplemented with the article numbers of the instruments.

You will receive an electronic copy of the amended user manual THM61144. Please forward this copy to your customers.

Please confirm that you have forwarded it in the attached confirmation form.



SWISS CRAFTSMANSHIP FOR DENTAL PROFESSIONALS

Replacement of the shipped adapters for handpiece:

According to our documents, you have received adapter for handpiece, guided with article number 3.04.090 and batch number 17415 from us.

Please check your internal warehouse first and put any of these adapters there into quarantine.

Please retrieve any adapters for handpiece from lot number 17415 which have already been delivered to your customers. Send all of the adapters received this way back to us. You will receive a credit voucher for doing so.

We have enough 3.04.090 adapters in stock for you to reorder them immediately.

Please fill out the attached confirmation form and return it to us together with the adapters on hand.

Should you have any questions please contact:

Oscar Banz

Telephone: +41 61 965 90 36

E-mail: oscar.banz@thommenmedical.com

Competent authorities have been informed about this Urgent Field Safety Notice.

We apologize for the inconvenience caused by this recall and thank you for your cooperation.

Best regards,



Oscar Banz
Head QM & RA



SWISS CRAFTSMANSHIP FOR DENTAL PROFESSIONALS

Confirmation form

Urgent Field Safety Notice 19/01

Please fill out the form and send it, together with the retrieved adapters for handpiece to:

Thommen Medical AG
Oscar Banz
FSCA 19/01
Neckarsulmstrasse 28
2540 Grenchen
Switzerland

I confirm that I have received the electronic copy of user manual THM 61144 and forwarded it to all customers affected.

Please fill in the appropriate numbers:

We have procured	<input type="text"/>	units of adapters for handpiece, article no. 3.04.090, lot number 17415
<input type="text"/>		units of adapters for handpiece are in our warehouse
<input type="text"/>		units of adapters for handpiece were shipped to our customers.
<input type="text"/>		units of adapters for handpiece were successfully retrieved from our customers
<input type="text"/>		units of adapters for handpiece can be returned to Thommen Medical AG

Name and location/country of the distributor/dealer

Responsible person (Name in printed letters)

Signature of responsible person

Date



SWISS CRAFTSMANSHIP FOR DENTAL PROFESSIONALS