INTEGRA
LIMIT UNCERTAINTY

**To the attention of Medical Device Vigilance responsible / Central Pharmacy**

Saint Priest, 07/12/2015

Subject: **URGENT - FIELD SAFETY NOTICE**

Medical devices:
***Instrumentation Set Forefoot I.5***
Reference:
***109900***
Legal manufacturer:
*NEWDEAL SAS, Immeuble Séquoïa 2 - 97 allée Alexandre Borodine - Parc Technologique de la Porte des Alpes - 69800 Saint Priest – France.*
Concerned batches:
***all batches***

Dear Valued Customer,

This letter is to inform you that NEWDEAL SAS, a company within Integra LifeSciences Group, is initiating a Field Safety Action on all batches of the instrumentation set Forefoot I.5 reference 109900. This field safety action defines additional steps to be taken to ensure the effective steam sterilization of the five (5) following devices that are in the Forefoot 1.5 set:

- The spreading forceps Uni-Clip® reference : 119311,
- The Bold® clamp reference : 119105,
- The drilling guide Uni-Clip® reference : 119301,
- The staple holder & impactor SOLUS 90° and 26° references: 119401; 119403.

Only the instrumentation set Forefoot I.5 is impacted by this Field Safety Action. The devices mentioned above which are included and sterilized in other sets are not concerned by this Field Safety Action.

**Problem description:**
Through an internal study, Newdeal has determined that the steam sterilization cycle recommended in the reprocessing instruction for the instrumentation set Forefoot I.5 would not provide a Sterility Assurance Level of $10^{-6}$ recommended by the standards EN556-1, for the five (5) devices that are in the instrumentation sets Forefoot I.5.

**Potential Risk:**
To date, there have been no reports of a patient injury or other adverse consequence related to this concern for the affected instruments. An incorrectly sterilized instrument has the potential to contribute to the transmission of a non-infectious or an infectious contaminate. However, the health hazard evaluation completed by Newdeal SAS has identified this potential consequence as to not be likely when taking into account patient and user standard-of-care factors such as patient prophylactic antibiotic regimens.

**Requested actions:**
Before the steam sterilizing of the instrumentation set Forefoot I.5, the five (5) affected devices mentioned must be OPENED, UNSCREWED, AND MOVED ACCORDING TO THE ATTACHED INSTRUCTIONS.

Additionally, a component needs to be added to the spreading forceps Uni-Clip® reference: 119311 in the instrumentation sets Forefoot I.5. This component is a metallic ring (reference: 119311**R**) that slides onto the handles of the forceps to keep the jaws in an open position during sterilization.



Integra LifeSciences Services (France)
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Société par Actions Simplifiée au capital de 37.000 € ▪ NAF 4646Z ▪ 492 534 466 RCS Lyon
Deutsche Bank AG Paris FR76 1778 9000 0110 5107 2400 081 DEUTFRPP ▪ No TVA Intracommunautaire / I.V.A.T. : FR 82 492 534 466

These cautions of use have been verified as effective with a pre-vacuum autoclave, to assure $10^{-6}$ sterility assurance level for the following sterilization parameters:

| | Temperature | Exposure time | Drying |
|---|---|---|---|
| French Cycle | 134°C | 18 minutes | 20 minutes |
| UK Cycle | 134°C | 3 minutes | 20 minutes |

We are notifying you of the Field Safety Notice as our records indicate that you have been supplied with one or several instrumentation sets Forefoot I.5.

**We ask you to take the following actions:**

1. **Identify the instrumentation set(s) Forefoot I.5 from your inventory according to the attached instruction.**
2. **Complete, sign and return the "Field Safety Notice Acknowledgment and Return Form" enclosed, by which you confirm that you have received this field safety notification and you intend to fully comply with. With this form, you will also confirm the quantity of instrumentation sets Forefoot I.5 in your inventory.**

   **After receipt of this form, Integra Customer Service will send to you the quantity of metallic ring(s) 119311R you will need for sterilizing the forceps Uni-Clip.**
3. **Until you receive the rings, isolate in quarantine and do not use the instrumentation set Forefoot I.5.**
4. **Apply the instruction « Identification of the concerned devices and cautions for the steam sterilization» which will also be attached to the shipment of the metallic ring.**

The receipt of this form ensures that Integra has achieved a level of effectiveness in communicating this information.

We also recommend that you keep a copy of this notification and a signed copy of the acknowledgement form for your records.

National Competent Authorities may perform audits of field actions of this nature to verify that our customers have been notified and understand the nature of the field action being taken.

The National Competent Authority of your country has been alerted of this Field Safety Corrective Action.

Please feel free to contact me for any additional questions. Your cooperation is appreciated, and we thank you for your continued collaboration.

Yours Sincerely,

**Angélique AUBERT**
Compliance coordinator
Europe, Middle-East & Africa

**Enclosed:** Recall Acknowledgment and Return Form (1 page)
Instruction "Identification of concerned devices and cautions for steam sterilization". (4 pages)



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## ACKNOWLEDGMENT AND RETURN FORM

Medical devices:
***Instrumentation Set Forefoot I.5***
Reference:
***109900***
Legal manufacturer:
*NEWDEAL SAS, Immeuble Séquoïa 2 - 97 allée Alexandre Borodine - Parc Technologique de la Porte des Alpes - 69800 Saint Priest – France.*
Concerned batches:
***all batches***

***November 2015***

**Please send the form back to :**

By fax/telecopy: +33 (0)4 37 47 59 30
Or by e-mail: *emea-fsca-recon@integralife.com*
With this form, I confirm that:

I have received, read and understood the information provided in the Integra Field Safety Notice notification regarding the cautions for the steam sterilization for the instrumentation set Forefoot I.5.

I ensure that all the affected products are being quarantined until the reception of the rings

My inventory has been reviewed and the results are as follow (*please tick the appropriate answer*):

☐ **Yes**, I do have affected product(s) in my inventory.

*Please indicate quantity in the table below:*

| Description of affected product | Reference | Quantity |
|---|---|---|
| **Complete set Forefoot I.5 including the inferior base and the superior base.** | 109900 including 109901 and 109902 | |

☐ **No**, I do not have the affected product in my inventory.

Distributor / Healthcare facility name

Contact Name

Street Address

City, Country, Postal Code

Telephone

Email

Signature



FSN-HHE-117-261115

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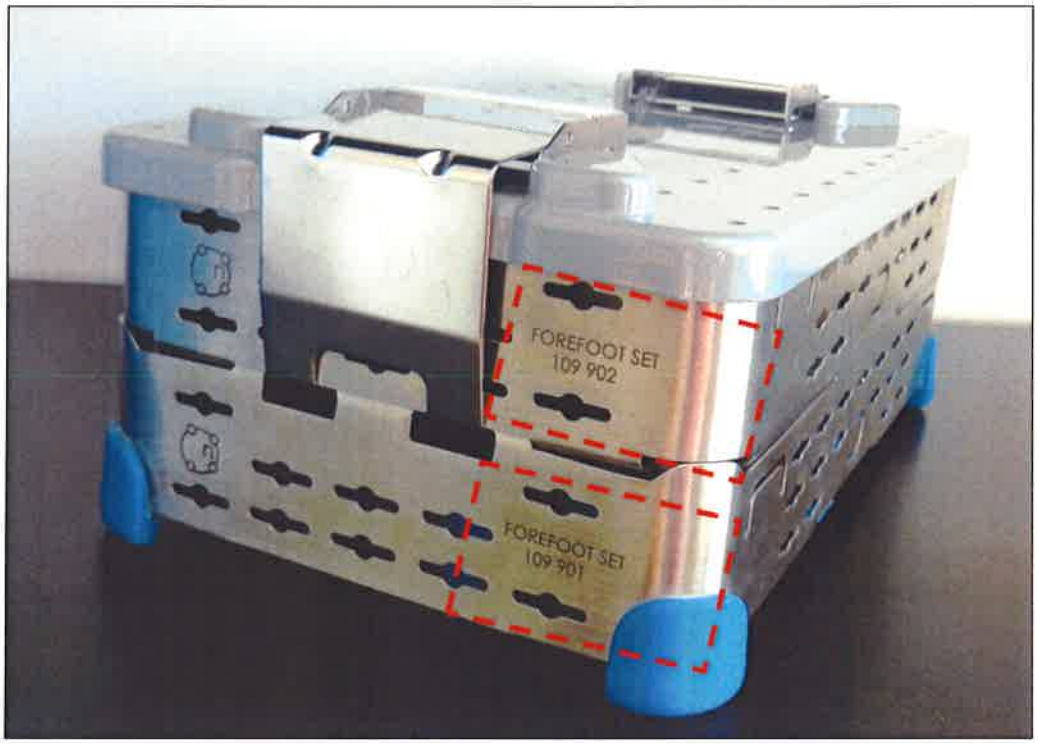
## URGENT - FIELD SAFETY NOTICE

# Instruction

## Identification of the concerned devices and Cautions for steam sterilization

| Product code | Product designations |
|---|---|
| **109900** | **Complete FOREFOOT I.5 set.** |
| 109901 | Inferior Base / Instrumentation Set FOREFOOT 1.5 |
| 109902 | Superior Base / Instrumentation Set FOREFOOT 1.5 |
| 119311 | Spreading forceps Uni-Clip® |
| 119311R | Metallic ring |
| 119105 | Bold® clamp |
| 119311 | Drilling guide Uni-Clip® |
| 119401 | SOLUS staple holder and impactor 90° |
| 119403 | SOLUS staple holder and impactor 26° |

1. Identify your FOREFOOT 1.5 instrumentation sets: this is the sets from FOREFOOT including basis in stainless steel reference 109901 and 109902. The part numbers are on the side of the trays (see picture below).





FSN-HHE-117-261115

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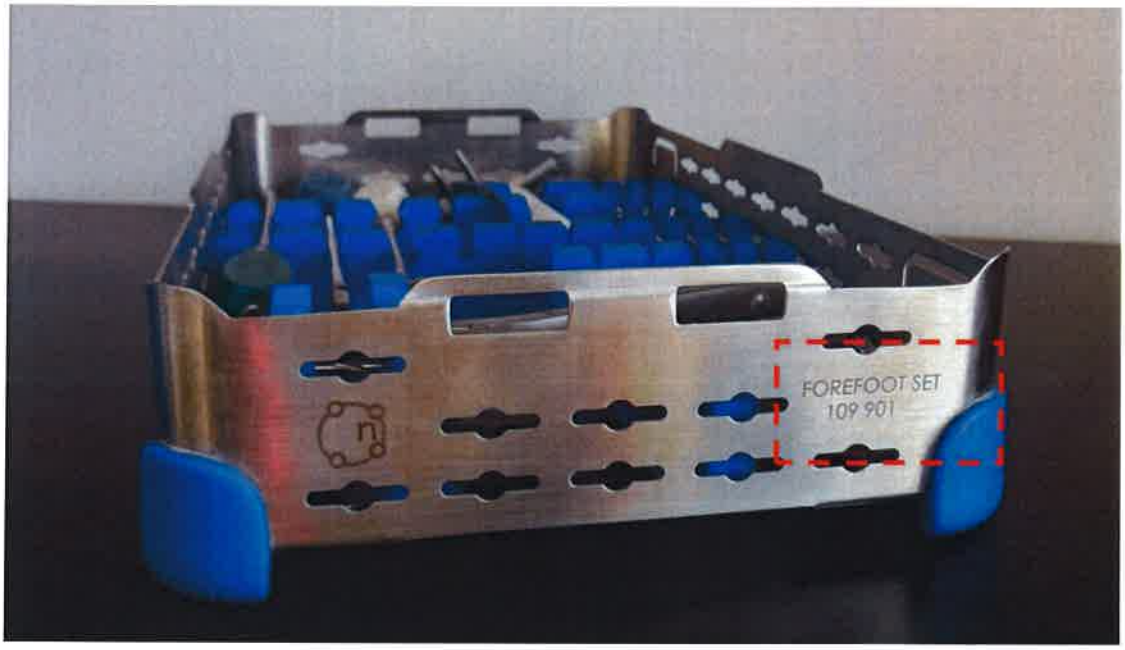
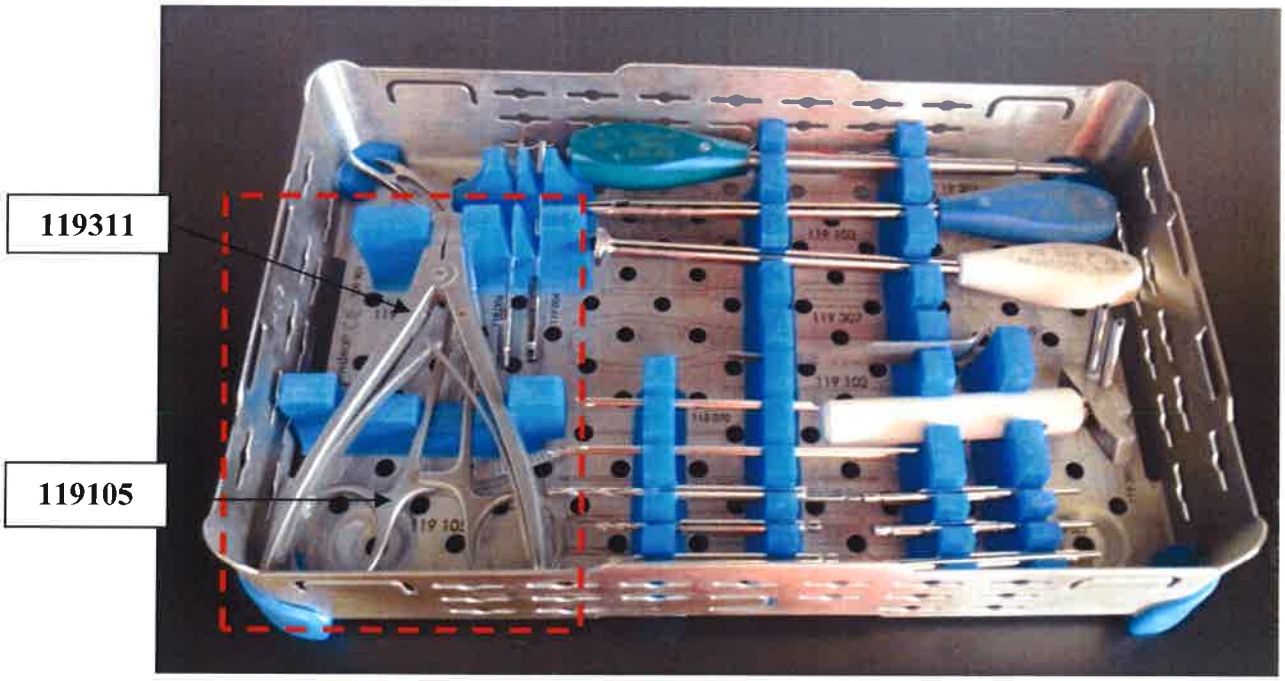
2. Take out the lid and take the inferior basis part number 109901.




3. Take out the spreading forceps Uni-Clip® part number 119311 and Bold® clamp part number 119105: they are located on the left part of the basis part number 109901.





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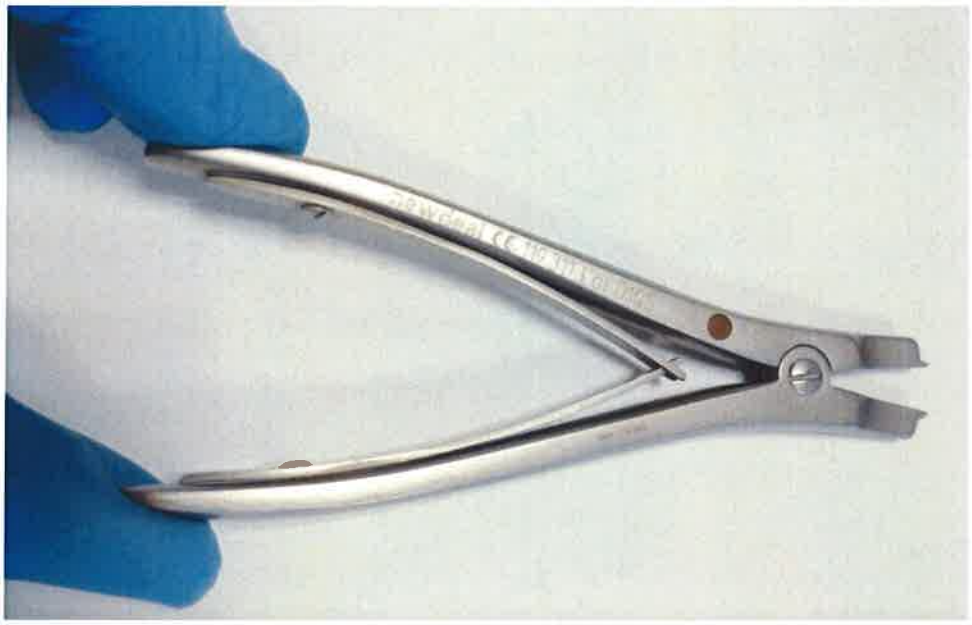
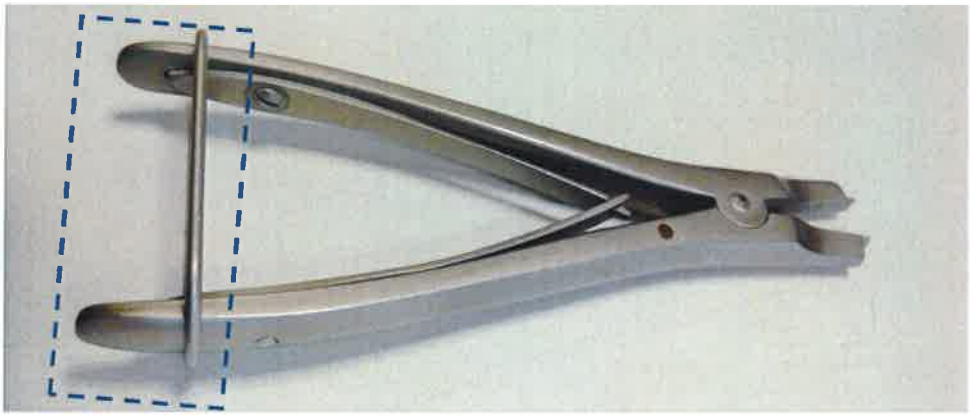
4. Take the spreading forceps Uni-Clip® part number 119311. Maintain the spreader in opening position:



5. Position the metallic ring part number 119311R at the level of the distal tips of the spreader (area underlined below).

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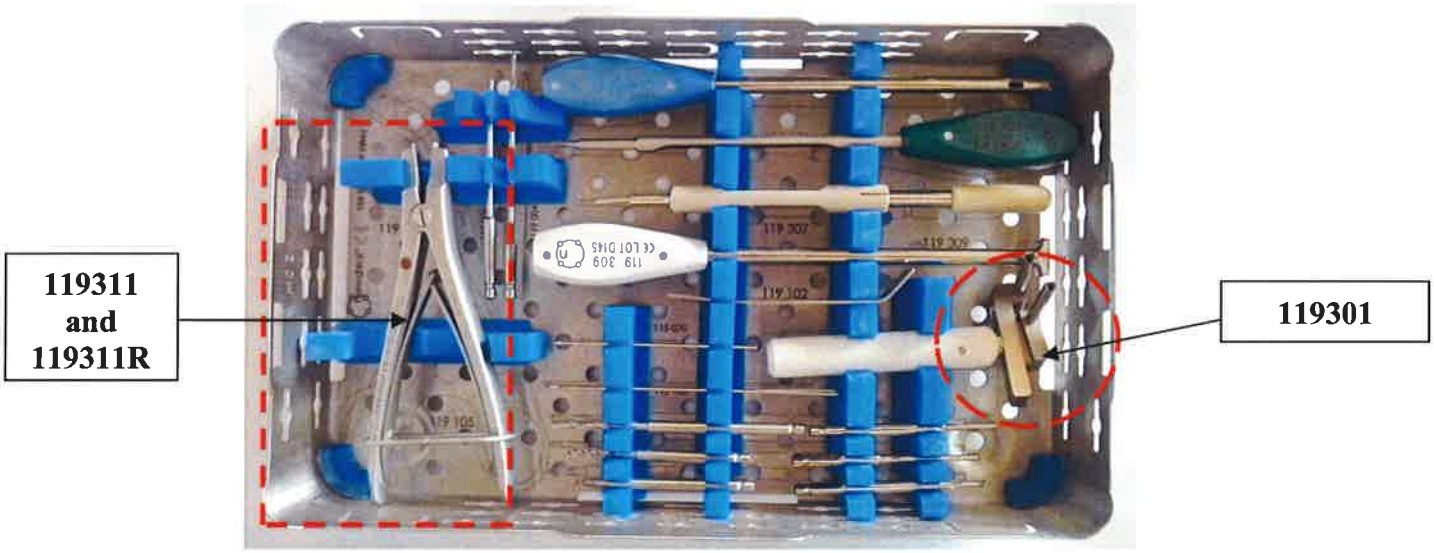
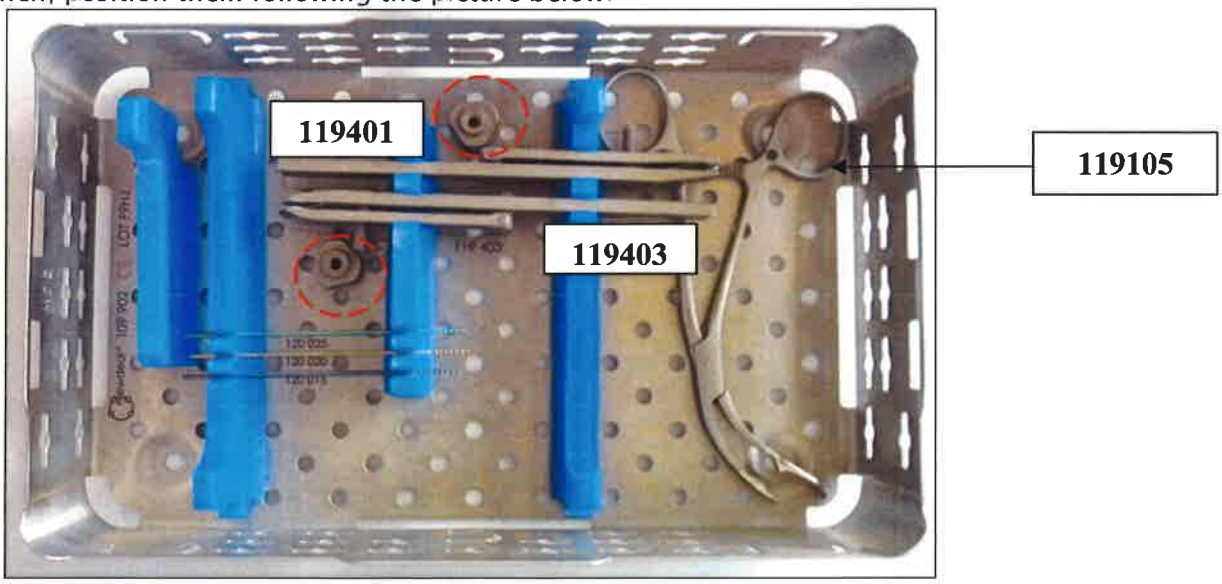
6. Insert the spreading forceps Uni-Clip® part number 119311 inside the silicones of the set by respecting the following position (see picture below)
Then, take drilling guide Uni-Clip® part number 119301 and unscrew the handle to obtain a significant gap between the metallic parts and the handle. Position the device inside the silicones.




7. Take the superior basis part number 109902 and Bold® clamp part number 119105.
Position Bold® clamp in opening position as indicated in the picture below.

Finally, unscrew the wheels on the SOLUS staple holder and impactors part number 119401 and 119403. Then, position them following the picture below.




8. After use keep the metallic ring part number 119311R and these instructions in the FOREFOOT 1.5 set and use during the next sterilization.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