

To the attention of medical device vigilance  
responsible / Central Pharmacy

Indirect Distributor

Saint-Priest, November 25<sup>th</sup> 2016

**URGENT - FIELD SAFETY NOTICE - Cautions for steam sterilization**

Medical devices: Instrumentation Set Forefoot 1.5

Reference: **109900**

Concerned batches: **all batches**

Legal Manufacturer: NEWDEAL SAS, Immeuble Séquoia 2 - 97 allée Alexandre Borodine -  
Parc Technologique de la Porte des Alpes - 69800 Saint Priest - France.

This safety action follows the safety action initiated by Newdeal S.A.S on November 26<sup>th</sup> 2015, defining 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 and 119403.

These additional steps required, before steam sterilization of the Forefoot 1.5 set:

- To add a component (metallic ring - reference: 119311R) to the spreading forceps Uni-Clip® reference: 119311 in order to keep the jaws in an open position during sterilization.
- To open, unscrew, move the five (5) devices impacted according to the instruction provided.

By the herewith notice, Newdeal S.A.S informs you that the Forefoot 1.5 set has been re-designed in order to ensure the effectiveness of the sterilization and avoid some of the handlings mentioned above.

The update consists on the replacement of two silicone brackets of the inferior base of the Forefoot 1.5 set reference 109901 according to the rework instruction for the silicone brackets attached.

In order to perform this modification Newdeal will supply a kit of silicone for replacement per set Forefoot 1.5.

The update of the two silicone brackets allows the open position of:

- the spreading forceps Uni-Clip® reference : 119311,
- the Bold® clamp reference : 119105,

In order to facilitate the traceability of this change, the new silicone brackets are in green color instead of blue currently.

This update of the silicone bracket exempts of the addition of the metallic ring reference 119311R used before, in order to open the forceps Uni-Clip® reference: 119311.

However, the unscrew step of:

- The drilling guide Uni-Clip®: reference: 119301
- The staple holder & impactor SOLUS 90° and 26°: references: 119401; 119403

is still required as mentioned in the Newdeal Instructions for reprocessing, attached.

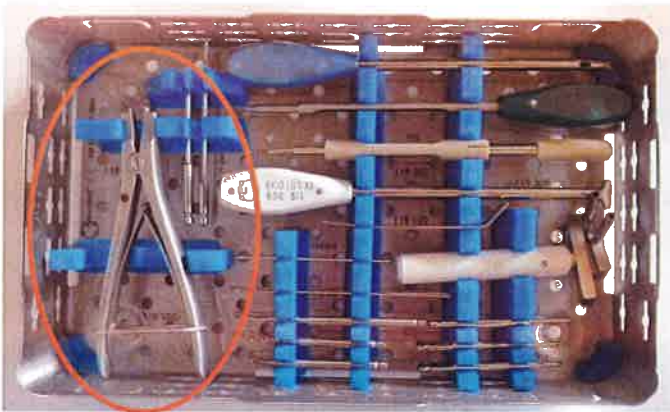
Newdeal

Siège Social : Immeuble Séquoia 2 • 97 allée Alexandre Borodine • Parc Technologique de la Porte des Alpes •  
69800 Saint Priest • France

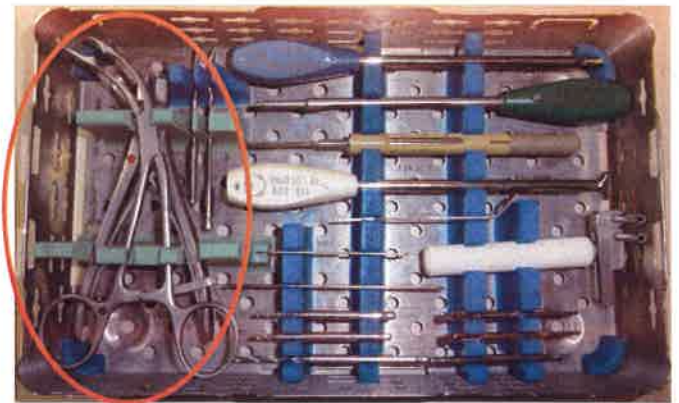
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Layout n°1: Forefoot 1.5 with metallic ring: **blue silicone brackets**



Layout n°2: Forefoot 1.5 updated: **green silicone brackets**



The new design of the Forefoot 1.5 set has been verified as effective to assure  $10^{-6}$  sterility assurance level for the following sterilization parameters in a pre-vacuum autoclave:

Temperature	Exposure time	Drying
134°C	18 minutes	20 minutes
134°C	3 minutes	20 minutes

Please complete, sign and return the return form attached to the Rework Instruction for the silicone brackets, by which you confirm that you have reworked all your Forefoot 1.5 sets.




Finally, if required by the national medical device regulation of your distribution area, please ensure this Field Safety Corrective Action is notified to the national competent authorities

**Marilyse Latour**  
**Quality Assurance & Regulatory Affairs Manager**  
**NEWDEAL SAS**

Copy: - Competent authority

In attached file:- Rework Instruction for the silicone brackets and return form  
(ND-02295-01-16)

- Instructions for reprocessing.

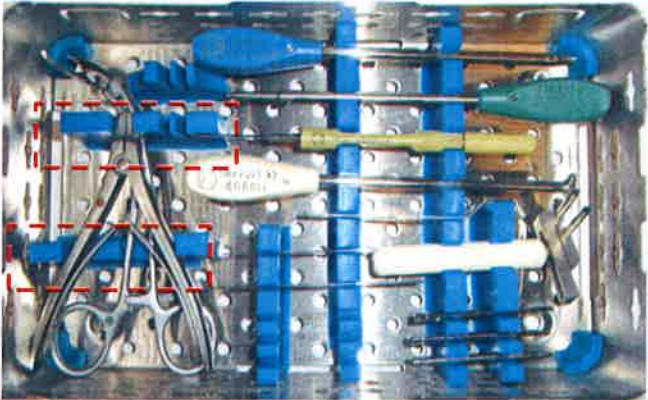
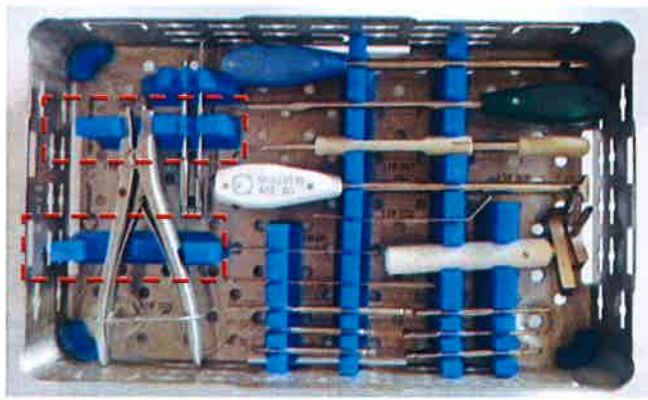
WRITING	CHECK	APPROVAL
Product Development Engineer	Quality Product Associate	Warehouse Operations supervisor
Name : Flavien PUGET	Name : Ibrahima PAYE	Name : Gregory LEETE
Date : 16 Novembre 2016	Date : 16 Novembre 2016	Date : 16/11/2016
Signature : 	Signature : 	Signature : 

**1. PURPOSE AND FIELD OF APPLICATION**

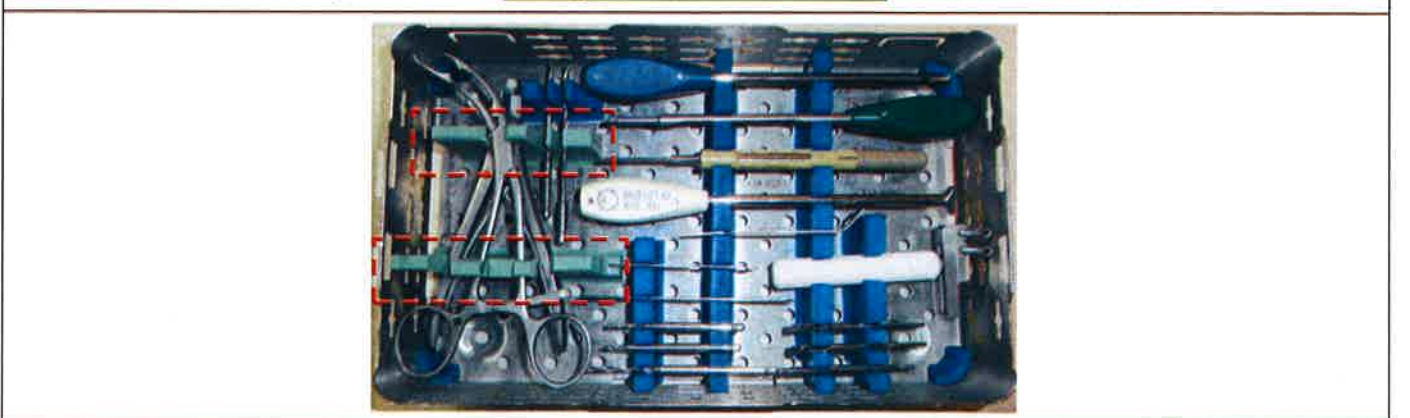
This instruction is linked with **FSN-HHE-117-141116**, concerning the effective steam sterilization of FOREFOOT 1.5 instrumentation sets.

It describes the needed materials and the rework procedure to replace some of the silicone brackets within the FOREFOOT 1.5 instrumentation sets (P/N 109 900, including basis P/N 109 901 and 109 902). It also describes the process to record the rework operation.



**Configurations before the rework**

Configuration 1 (original layout)	Configuration 2 (layout according to FSN-HHE-117-261115)
	

**Configuration after the rework**



Silicone brackets P/Ns 109 901 05 and 109 901 06 must be replaced by P/Ns 109 901B 01 and 109 901B 02 into the inferior basis (P/N 109 901) of the set.

Silicone brackets P/Ns 109 901 06 and 109 901 05 to be removed	New Silicone brackets P/Ns 109 901B 02 and 109 901B 01 to be mounted
	

Once the rework is completed:

- A copy of the latest instructions for reprocessing (document F-AL03-60) must be communicated to the end-user. The English version is available in Appendix 1. Other languages are also available ( French, German, Portuguese, Dutch, Italian and Danish)
- The additional ring (P/N 119 311R) must no longer be used and must be discarded, along with the former silicone brackets (109 901 05 and 109 901 06).
- The FOREFOOT 1.5 instrumentation set rework Form (available in Appendix 2) must be filled and sent back to Integra.

**2. NEEDED MATERIALS**

The needed material to perform the rework of a FOREFOOT 1.5 instrumentation set is defined below:

- 1x Silicone Kit for Forefoot 1.5 set rework P/N 109901B (including the 2 new silicone brackets and additional screws/washers)



- 1x Pozidriv PZ2 screwdriver  (an electrical screwdriver with the appropriate Pozidriv PZ2 tip can also be used)

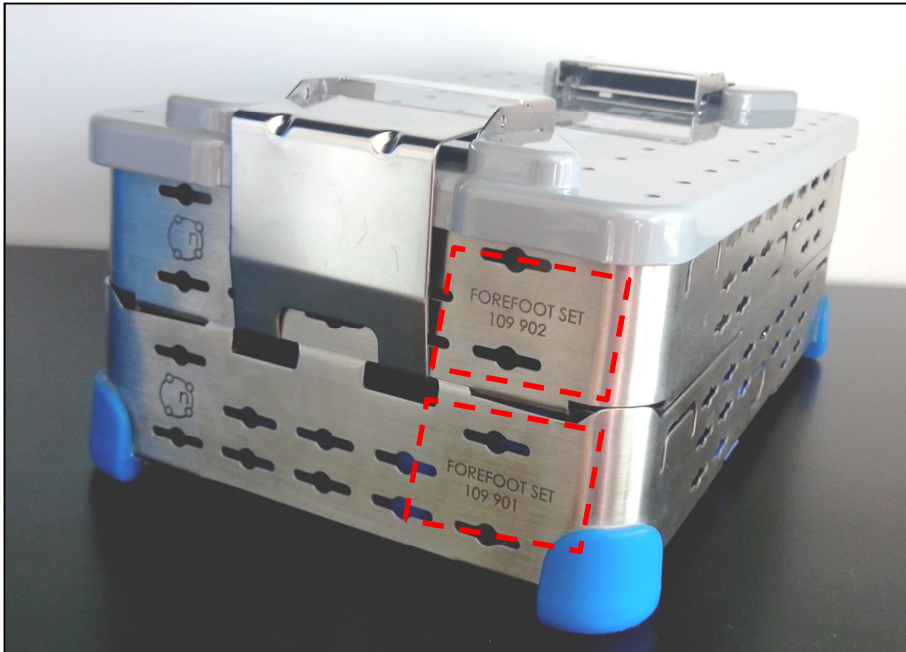
Important:

- The screwdriver is not a component of the instrumentation set and must be kept to perform other reworks
- During the rework operation, it is requested to wear gloves

### 3. REWORK PROCEDURE

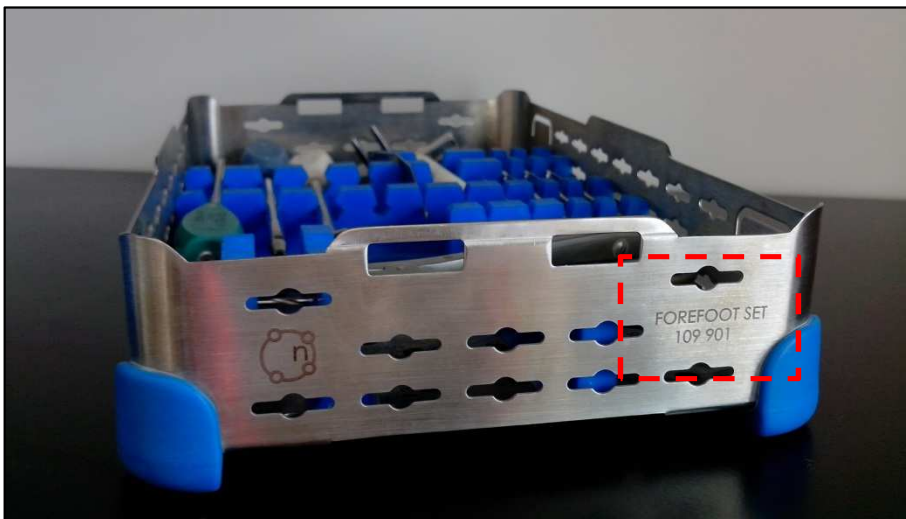
**Step1:**

Identify the FOREFOOT 1.5 instrumentation set to be reworked.  
The set is made with 2 trays in stainless steel reference 109901 and 109902.  
The part numbers are on the side of the trays (see picture below).



**Step2:**

Remove the lid and isolate the inferior tray part number 109901.



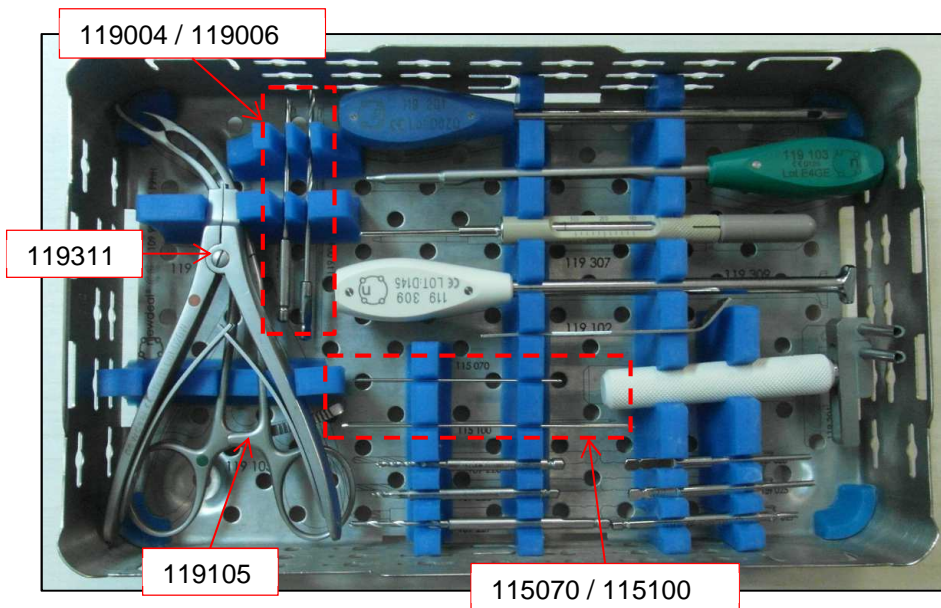
**Step3:**

Remove from the tray, at minimum, the following devices:

- Spreading forceps Uni-Clip® part number 119311
- Bold® clamp part number 119105
- Drills part numbers 119004 and 119006
- K-wires part numbers 115070 and 115100
- Metallic ring part number 119311R (if implemented)

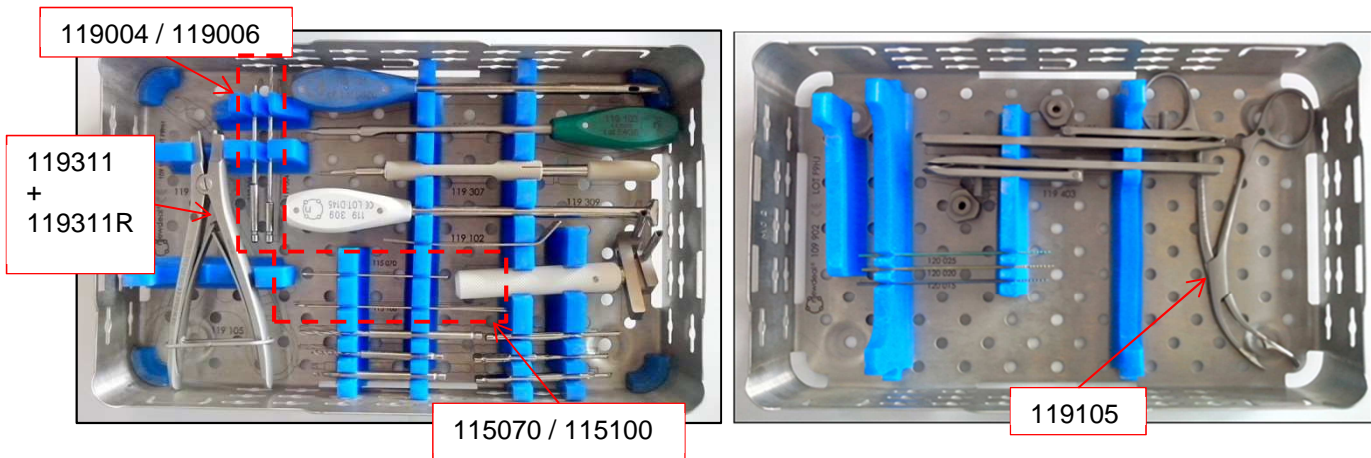
At this point, the set can be found loaded in 2 different ways, depending whether the metallic ring 119311R has been implemented or not

Original loading of the instrumentation set (without the ring 119311R):  
(All devices are located in the left side of the tray)



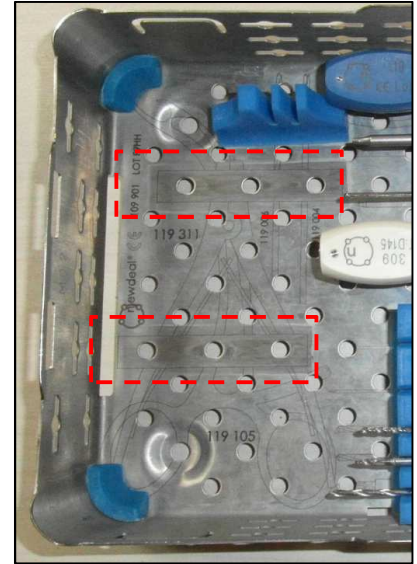
Modified loading of the instrumentation set with the ring (119311R)

(All devices are located in the left side of the tray, except clamp 119105 that is relocated into the upper tray)



**Step4:**

Place the tray upside-down and remove the 6 fixation screws holding the brackets to be replaced, using the appropriate screwdriver.



**Step5:**

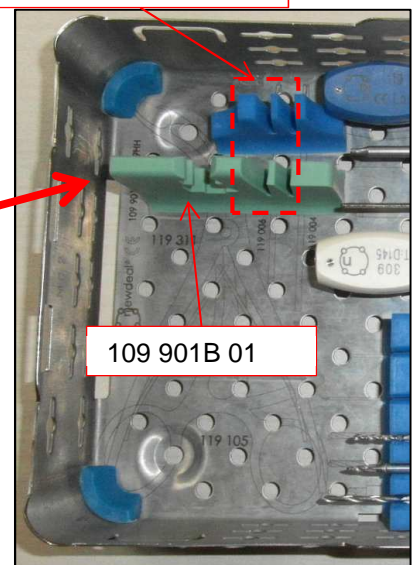
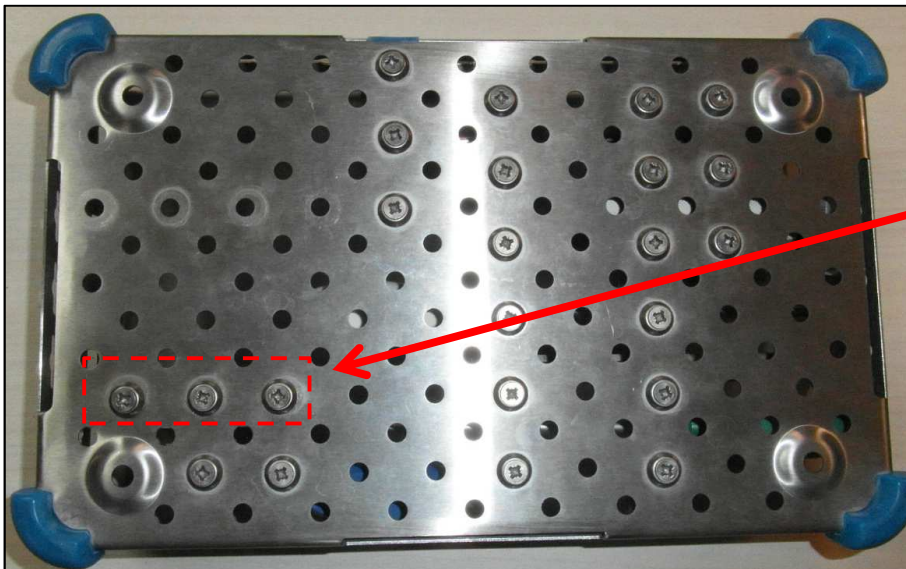
Fit the new silicone bracket 109 901B 01.

The correct orientation of the silicone bracket can be verified by checking the 2 drills grooves are aligned

Holes are pre-drilled below the brackets to ease the assembly and ensure a correct positioning.

Securely tight the 3 fixation screws (New screws and washers are available into the rework kit if needed)

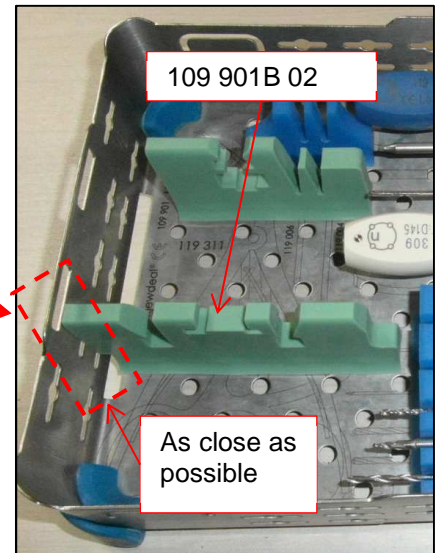
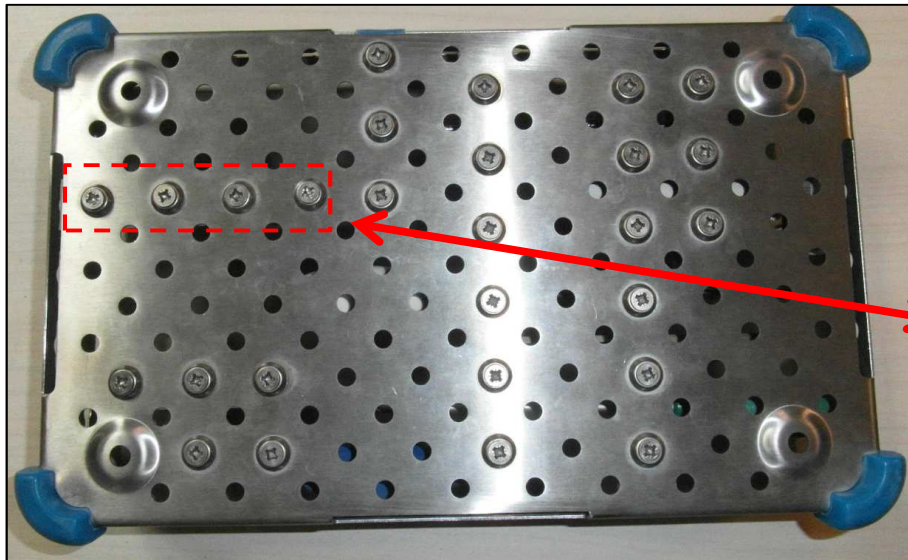
Drills grooves aligned



109 901B 01

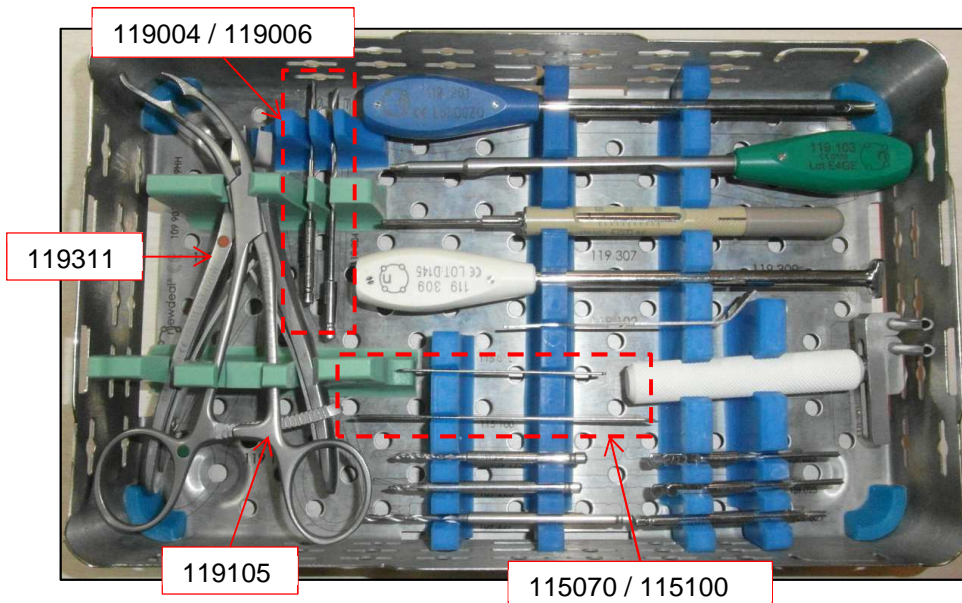
**Step6:**

Fit the new silicone bracket 109 901B 02, making sure its orientation is correct. Make sure the left end of the bracket is placed as close as possible to the side wall of the basis. Holes are pre-drilled below the brackets to ease the assembly and ensure a correct positioning. Securely tight the 4 fixation screws (Additional screws and washers are available into the rework kit)



**Step7:**

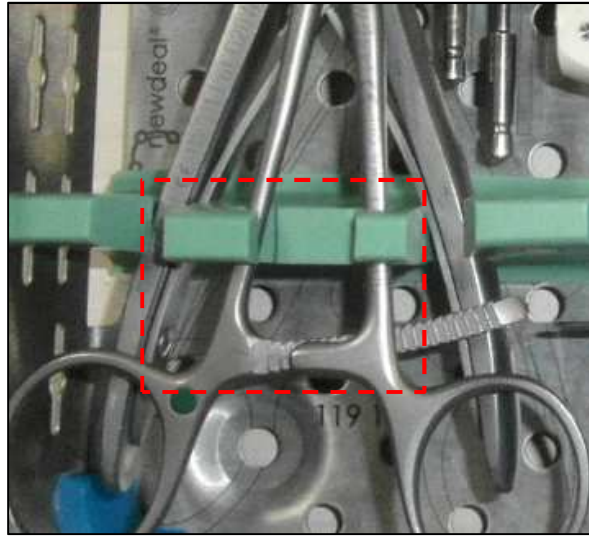
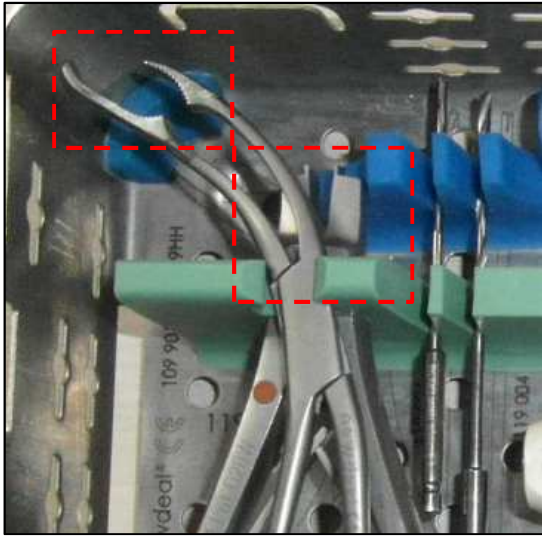
Re-load instruments, according to new layout



Note that:

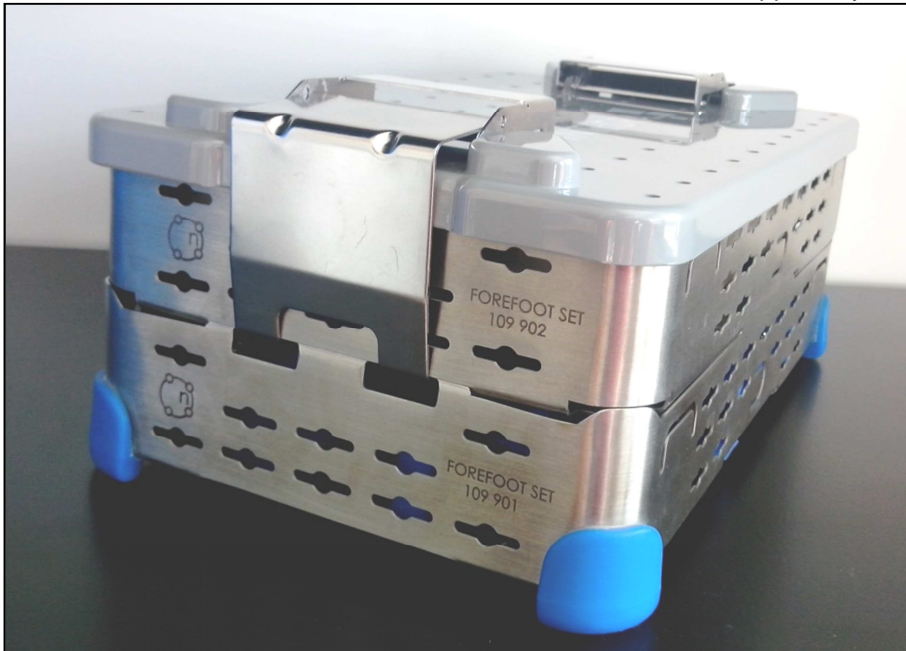
- The Spreading forceps Uni-Clip® should be in the open position with the new silicone brackets installed.
- The Bold® clamp must be slightly opened to fit into its intended location





**Step8:**

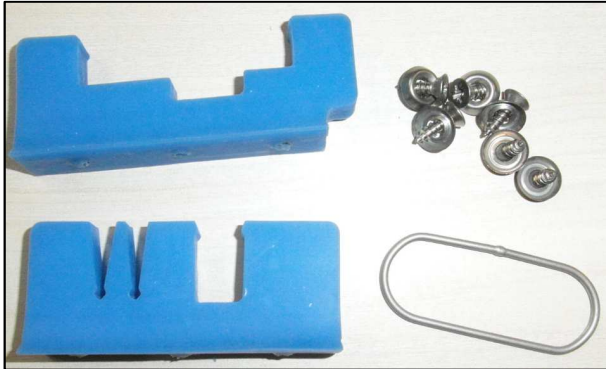
Re-assemble the FOREFOOT 1.5 Instrumentation set with the upper tray and close the lid



**Step9:**

Discard the obsolete components

- The former blue silicone brackets 109 901 05 and 109 901 06
- The remaining screws and washers
- The metallic ring 119 311R



**Important:**

The screwdriver must not be discarded or left with the FOREFOOT 1.5 Instrument set.

**Step10:**

Communicate to the customer a copy of the latest instructions for reprocessing (document F-AL03-60). The English version of the document is available in Appendix 1.

Other languages are also available (French, German, Portuguese, Dutch, Italian and Danish) if needed.

**4. TRACEABILITY OF THE REWORK**

Once the rework is completed, it must be recorded in the dedicated form provided in Appendix 2.

The form must be filled with all requested information, and signed by the person that has executed the rework activity.

It is not allowed to use the same form for several customers, for processing reason.

The form must be returned to Integra to ensure the traceability of the activity.

**5. HISTORY OF MODIFICATIONS**

MODIFICATIONS				
Version	Date	Origin	Section	Nature of modifications
01	15 Nov 2016	DM 2016-006	All	New instruction

## **Appendix 1**

F-AL03-60 Instructions for reprocessing EN ind 5

**Manufacturer : NEWDEAL**

**Device(s) : All reusable surgical instruments supplied by NEWDEAL**

<b>WARNINGS :</b>	<p>This product is sold non sterile.          Check the integrity of the packaging and labelling before opening the packing.          Remove excess soil with disposable paper wipe.          All products should be cleaned, decontaminated, and sterilized before use. It is recommended that instruments are reprocessed as soon as is reasonably practical following use.          In case these instructions are in conflict with local requirements for cleaning and sterilization, the latter shall prevail on the recommendations of Newdeal.</p>
<b>Limitations on reprocessing</b>	<p>Newdeal does not define a maximum number of uses for reusable medical devices. Repeated processing has minimal effect on these instruments. A thorough inspection and functional control are the best method to determine the lifetime of the device.</p>

## CLEANING INSTRUCTIONS

<b>Preparation for cleaning</b>	<p><u>Equipment:</u> Aldehyde-free detergent (neutral or alkaline), soft brush, tap water          Remove excess soil with disposable paper wipe.          To avoid drying stains on the DM, carry out an immediate pre-disinfection by soaking in detergent for a minimum 15 minutes.          Disassemble the device whenever possible.</p>
<b>Manual Cleaning</b>	<p><u>Equipment :</u> Ultrasonic bath, aldehyde free detergent (alkaline or neutral), soft brush, tap water  <u>Method :</u></p> <ul style="list-style-type: none"> <li>- Rinse excess soil from instrument with tap water for a minimum of 2 minutes,</li> <li>- Immerse devices in an ultrasonic bath containing detergent for 15 minutes,</li> <li>- With a soft brush, brush the components insisting on irregular surfaces and making sure that hinged instruments are cleaned in their open and closed positions,</li> <li>- With a syringe, introduce the decontaminating solution inside the cannulas.</li> <li>- Rinse thoroughly with distilled water until all traces of cleaning solution disappear. Ensure that water flows through the cannulas and that blind holes are filled and emptied several times.</li> <li>- If necessary, dry the devices with compressed air.</li> </ul>
<b>Automated Cleaning</b>	<p><u>Equipment :</u> Ultrasonic bath, washer/disinfector, alkaline or neutral detergent, tap water          Washer disinfectors must be properly installed and qualified in accordance with ISO 15883.  <u>Ultrasonic Cleaning:</u></p> <ul style="list-style-type: none"> <li>- Rinse excess soil from instrument with tap water for a minimum of 2 minutes,</li> <li>- Immerse devices in an ultrasonic bath containing detergent for 15 minutes,</li> </ul> <p><u>Cleaning in a washer-disinfector:</u></p> <ul style="list-style-type: none"> <li>- Load instruments such that hinges are opened and cannulations and holes can drain and tilt the hollow tip down</li> <li>- Run cycle, minimum 1 min wash and 10 min rinse,</li> <li>- The thermal disinfection phase can be done at 95°C for 10 min, (at a minimum temperature of 90°C for 1 minute),</li> <li>- The drying phase should be done between 70 and 95°C, for 20 minutes,</li> <li>- When unloading, visually inspect each device to ensure it remains free from dirt, or wet. If necessary, repeat cycle or use manual cleaning.</li> </ul> <p>(If necessary, dry the devices with compressed air).  <u>Note: Containers and racks should be cleaned in a washer-disinfector.</u></p>
<b>Inactivation</b>	<p>This stage occurs after cleaning and is not necessary if the detergent used for cleaning allows a total inactivation of the unconventional transmissible agents according to the protocol SPP (Standard Protocol Prion) and Instruction No. DGS/RI3/2011 / 449 of December 1, 2011.</p>
<b>Maintenance, inspection and Function Testing</b>	<p>All instruments: visual inspection of damage and wear. Cutting edges should be free of nicks and present a continuous edge. Never use instruments with obvious signs of excessive wear, damage, incomplete or otherwise unfunctional.          Hinged instruments: check for smooth movement of hinge without excessive "gap". Locking mechanisms should be checked.          Functional checks should be performed whenever possible:</p> <ul style="list-style-type: none"> <li>- Check instruments with long slender features for distortion.</li> </ul> <p>When instruments are parts of a larger assembly, check assembly with mating components : operate the moving parts, check the rotary instruments ....</p>
<b>Packaging :</b>	<p>Medical devices must be stored in the trays provided and designed for this purpose.</p> <ul style="list-style-type: none"> <li>- Trays / containers must be packed in Newdeal appropriate packaging for the sterilization of medical devices (refer to standards ISO11607, EN 868)</li> </ul>

## STERILIZATION INSTRUCTIONS

The steam sterilization is recommended. Cycles validated by Newdeal allow obtaining sterile medical devices; however the design and performance of the autoclave may compromise the effectiveness of the process. Health facilities have the responsibility to validate the sterilization process they use with the equipment used (including consideration of the maximum load of the autoclave).

**The process parameters are validated for steam sterilization :**

**Sterilization tray ADVANSYS® HINDFOOT :**

Cycle : Pre-vacuum - Minimum temperature: 132 ° C - Exposure time: 4min. – Vacuum Drying: 40 minutes  
 Cycle : Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 18 min. – Vacuum Drying: 20 minutes  
 Cycle : Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 3 min. – Vacuum Drying: 20 minutes

**Sterilization tray ADVANSYS® MIDFOOT :**

Cycle : Pre-vacuum - Minimum temperature: 132 ° C - Exposure time: 4min. – Vacuum Drying: 40 minutes  
 Cycle : Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 18 min. – Vacuum Drying: 20 minutes  
 Cycle : Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 3 min. – Vacuum Drying: 20 minutes – The two parts of the depth gauge, reference 219335, must be separated and installed one above the other in the container

**Sterilization trays B-BOP® Lock, B-BOP® :**

Cycle : Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 3 min. – Vacuum Drying: 20 minutes  
 Cycle : Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 18 min. – Vacuum Drying: 20 minutes

**Sterilization tray Calcanea :**

Cycle : Pre-vacuum - Minimum temperature : 134°C – Exposure time : 3 min. - Vacuum drying : 20 minutes  
 Cycle : Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 3 min. – Vacuum Drying: 20 minutes

**Sterilization tray DPR System Minimal Invasive :**

Cycle : Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 3 min. – Vacuum Drying: 20 minutes  
 Cycle : Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 18 min. – Vacuum Drying: 20 minutes

**Sterilization tray FOREFOOT I:**

Cycle: Pre-vacuum - Minimum temperature: 132 ° C - Exposure time: 9 min. - Vacuum Drying: 20 minutes  
 Cycle : Pre-vacuum - Minimum temperature : 134°C - Exposure time : 3 min. - Vacuum drying : 20 minutes  
 Cycle: *Pre-vacuum* - Minimum temperature: 134 ° C - Exposure time: 18 min. - Vacuum Drying: 20 minutes

⚠ For the container Forefoot I, in the pre-vacuum cycle, the user must disassemble the locking nuts for devices references 119401 and 119403 and place them in the base of the container prior to sterilization. Devices 119401: 90° Solustaple® Holder & Impactor and 119403: 26° Solustaple® Holder & Impactor are located at the intermediate level of the sterilization tray.

**Sterilization tray FOREFOOT I.5:**

*Cycle : Pre-vacuum - Minimum temperature : 134°C - Exposure time : 3 min. - Vacuum drying : 20 minutes  
 Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 18 min. - Vacuum Drying: 20 minutes*

⚠ *For the container FOREFOOT I.5, the user MUST:*  
 - *Disassemble the locking nuts for devices references 119401 and 119403 and place them in the base of the container prior to sterilization. Devices 119401: 90° Solustaple® Holder & Impactor and 119403: 26° Solustaple® Holder & Impactor are located at the superior level of the sterilization tray.*  
 - *Unscrew the handle of the drilling guide reference: 119301, the drilling guide 119301 is located at the inferior level of the sterilization tray.*

**Sterilization tray FOREFOOT II:**

Cycle: Pre-vacuum - Minimum temperature: 132 ° C - Exposure time: 4 min. – Vacuum Drying: 30 minutes  
 Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 3 min – Vacuum Drying: 10 minutes  
 Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 18 min. – Vacuum Drying: 10 minutes

⚠ The Forefoot II container for generic Instruments II (ref 229956) is a module designed to gather generic instruments for the surgeon during the surgery. This module can be sterilized without any ancillary. Using this set as sterilization container of generic tools has not been validated by Newdeal ; so it is under the responsibility of the user.

**Sterilization tray HALLU®-FIX :**

Cycle: Pre-vacuum - Minimum temperature: 132 ° C - Exposure time: 4 min. - Vacuum Drying: 20 minutes  
 Cycle : Pre-vacuum - Minimum temperature : 134°C - Exposure time : 3 min. - Vacuum drying : 20 minutes  
 Cycle: Gravity Displacement - Minimum temperature: 134 ° C - Exposure time: 18 min. – Vacuum Drying: 20 minutes

**Sterilization tray HALLU®-LOCK :**

Cycle: Pre-vacuum - Minimum temperature: 132 ° C - Exposure time: 4 min. – Vacuum Drying: 60 minutes  
 Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 3 min – Vacuum Drying: 20 minutes  
 Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 18 min. – Vacuum Drying: 20 minutes

**Sterilization tray HALLU®-Ream :**

Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 3 min – Vacuum Drying: 20 minutes  
 Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 18 min. – Vacuum Drying: 20 minutes

**Sterilization trays I.CO.S® XL, I.CO.S® 4.0, I.CO.S® Ablation:**

Cycle : Pre-vacuum - Minimum temperature : 134°C - Exposure time : 3 min. - Vacuum drying : 20 minutes  
 Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 18 min. – Vacuum Drying: 20 minutes

**Sterilization trays I.CO.S® 6.5:**

*Cycle : Pre-vacuum - Minimum temperature : 132°C - Exposure time : 4 min. - Vacuum drying : 60 minutes  
 Cycle : Pre-vacuum - Minimum temperature : 134°C - Exposure time : 3 min. - Vacuum drying : 20 minutes  
 Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 18 min. – Vacuum Drying: 20 minutes*

**Sterilization tray IPP-ON®:**

Cycle: Pre-vacuum - Minimum temperature: 132 ° C - Exposure time: 4 min. – Vacuum Drying: 30 minutes

Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 3 min – Vacuum Drying: 36 minutes

Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 18 min. – Vacuum Drying: 36 minutes

The user must open the forceps Ref. 239 500 and place it in the appropriate slot in the silicone in the base of the container prior to sterilization.

**Sterilization tray PEDIATRICS:**

Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 3 min – Vacuum Drying: 20 minutes

Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 18 min. – Vacuum Drying: 20 minutes

**Sterilization tray Large QWIX®:**

Cycle: Pre-vacuum - Minimum temperature: 132 ° C - Exposure time: 4min – Vacuum Drying: 20 minutes

Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 3 min – Vacuum Drying: 20 minutes

Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 18 min. – Vacuum Drying: 20 minutes

**Sterilization tray Large UNI-CLIP®:**

*Cycle: Pre-vacuum - Minimum temperature: 132 ° C - Exposure time: 4min – Vacuum Drying: 60 minutes*

Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 3 min – Vacuum Drying: 20 minutes

Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 18 min. – Vacuum Drying: 20 minutes

**Sterilization tray METIS®:**

Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 18 min. – Vacuum Drying: 20 minutes

**Sterilization tray OSTEOTOMY:**

Cycle: Pre-vacuum - Minimum temperature: 132 ° C - Exposure time: 4min – Vacuum Drying: 40 minutes

Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 18 min. – Vacuum Drying: 20 minutes

**Sterilization tray PANTA®:**

Cycle: Pre-vacuum - Minimum temperature: 132 ° C - Exposure time: 4 min. - Vacuum Drying: 40 minutes followed by a 20 minutes "cracked" phase (the sterilizer door is opened approximately 6 inches – 15 cm – while the tray remains inside).

Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 3 min – Vacuum Drying: 20 minutes

Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 18 min – Vacuum Drying: 20 minutes

**Sterilization tray PANTA®XL:**

Cycle: Pre-vacuum - Minimum temperature: 132 ° C - Exposure time: 4 min. - Vacuum Drying: 40 minutes followed by a 20 minutes "cracked" phase (the sterilizer door is opened approximately 6 inches – 15 cm – while the tray remains inside).

Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 18 min – Vacuum Drying: 20 minutes

**Sterilization tray PANTA® Removal:**

Cycle: Pre-vacuum - Minimum temperature: 132 ° C - Exposure time: 4min – Vacuum Drying: 40 minutes

Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 3 min – Vacuum Drying: 20 minutes

Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 18 min – Vacuum Drying: 20 minutes

**Sterilization tray QWIX® dia.3mm and 4.3mm:**

Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 3 min – Vacuum Drying: 20 minutes

Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 18 min. – Vacuum Drying: 20 minutes

**Sterilization tray TIBIAXYS®:**

Cycle: Pre-vacuum - Minimum temperature: 132 ° C - Exposure time: 4 min – Vacuum Drying: 20 minutes

Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 3 min – Vacuum Drying: 20 minutes

Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 18 min. – Vacuum Drying: 20 minutes

Containers Instruments, Reference 159990, and Trial Implants, reference 159970, must first be separated into two sets individually packaged.

**Sterilization tray TRAUMATOLOGY:**

Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 3 min – Vacuum Drying: 20 minutes

Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 18 min – Vacuum Drying: 20 minutes

**Sterilization trays TRAUMAX®, WIFIX®:**

Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 3 min – Vacuum Drying: 20 minutes

Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 18 min – Vacuum Drying: 20 minutes

**Sterilization tray UNI-CP®:**

Cycle: Pre-vacuum - Minimum temperature: 132 ° C - Exposure time: 4 min. – Vacuum Drying: 30 minutes - This cycle has been validated without "U" plates

Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 3 min – Vacuum Drying: 10 minutes

Cycle: Pre-vacuum - Minimum temperature: 134 ° C - Exposure time: 18 min. – Vacuum Drying: 10 minutes

**Storage :**

The shelf life before use depends on the used sterile barrier, storage conditions and handling. A maximum storage time before use sterilized medical devices must be defined by each health facility.

**Manufacturer Contact :**

NEWDEAL SAS  
Immeuble Séquoia 2 - 97 allée Alexandre Borodine  
Parc Technologique de la Porte des Alpes  
69800 Saint Priest - France  
[newdeal.contact@integralife.com](mailto:newdeal.contact@integralife.com)

The instructions provided above have been validated by NEWDEAL as being capable of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel in the processing facility achieve the desired result. This requires validation and routine monitoring of the process.

Date issued : Thursday, 10 November 2016

## Appendix 2

### FOREFOOT 1.5 instrumentation set rework Form

**Thank you for completing and sending back this form to Integra.  
We appreciate your cooperation in completing this form, and returning it to  
Integra**

To:  
**INTEGRA LIFESCIENCES SAS,**  
 Immeuble Séquoia 2 -97, allée Alexandre Borodine  
 Parc Technologique de la Porte des Alpes  
 69800 Saint-Priest - France  
 Attention to: Angélique Aubert  
 Or  
 By fax to: + 33 (0)4 37 47 59 30  
 By email: [emea-fsca-recon@integralife.com](mailto:emea-fsca-recon@integralife.com)

**With this form,**

- ⇒ I ensure that all affected product(s) bought or in consignment have been reworked according to the rework instruction ND 02295 01 16
- ⇒ I ensure that I've communicated the latest instructions for reprocessing (F-AL03-60) to the end-user.

**Name and address of the clinic/hospital (or stamp) \*:**  
 (\* Not applicable for distributor)

**Quantity of sets available:**

Date	Quantity of sets reworked	Ring discarded	Comments

**Other comments:**

Name: \_\_\_\_\_

Function / Department: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_