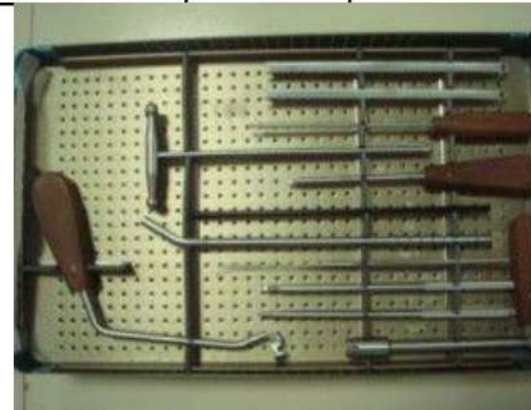


## JINLU MEDICAL RSS-III spinal system



| NO | P/N       | Product Name                 | Picture                                                                              | Size          | Unit | Material |
|----|-----------|------------------------------|--------------------------------------------------------------------------------------|---------------|------|----------|
| 1  | T080-T120 | Rod                          |    | 6.0*80-120mm  | PC   | Ti6Al4V  |
| 2  | T140-T200 |                              |                                                                                      | 6.0*140-200mm | PC   | Ti6Al4V  |
| 3  | T220-T280 |                              |                                                                                      | 6.0*220-280mm | PC   | Ti6Al4V  |
| 4  | T300-T360 |                              |                                                                                      | 6.0*300-360mm | PC   | Ti6Al4V  |
| 5  | T380-T400 |                              |                                                                                      | 6.0*380-400mm | PC   | Ti6Al4V  |
| 6  | T001-T004 | Mono Axis Screws             |    | Φ4.5*25-40mm  | PC   | Ti6Al4V  |
| 7  | T005-T010 |                              |                                                                                      | Φ5.5*30-50mm  | PC   | Ti6Al4V  |
| 8  | T010-T015 |                              |                                                                                      | Φ6.5*40-60mm  | PC   | Ti6Al4V  |
| 9  | T015-T020 |                              |                                                                                      | Φ7.5*40-60mm  | PC   | Ti6Al4V  |
| 10 | T021-T025 | Break-off Mono Axis Screws   |    | Φ4.5*25-40mm  | PC   | Ti6Al4V  |
| 11 | T026-T031 |                              |                                                                                      | Φ5.5*30-50mm  | PC   | Ti6Al4V  |
| 12 | T032-T037 |                              |                                                                                      | Φ6.5*40-60mm  | PC   | Ti6Al4V  |
| 13 | T038-T043 |                              |                                                                                      | Φ7.5*40-60mm  | PC   | Ti6Al4V  |
| 14 | T044-T048 | Multi-axial Screws           |   | Φ4.5*25-40mm  | PC   | Ti6Al4V  |
| 15 | T049-T054 |                              |                                                                                      | Φ5.5*30-50mm  | PC   | Ti6Al4V  |
| 16 | T055-T060 |                              |                                                                                      | Φ6.5*40-60mm  | PC   | Ti6Al4V  |
| 17 | T061-T066 |                              |                                                                                      | Φ7.5*40-60mm  | PC   | Ti6Al4V  |
| 18 | T067-T071 | Break-off Multi-axial Screws |  | Φ4.5*25-40mm  | PC   | Ti6Al4V  |
| 19 | T072-T077 |                              |                                                                                      | Φ5.5*30-50mm  | PC   | Ti6Al4V  |
| 20 | T078-T083 |                              |                                                                                      | Φ6.5*40-60mm  | PC   | Ti6Al4V  |
| 21 | T084-T089 |                              |                                                                                      | Φ7.5*40-60mm  | PC   | Ti6Al4V  |

|    |      |                         |                                                                                    |          |     |         |
|----|------|-------------------------|------------------------------------------------------------------------------------|----------|-----|---------|
| 22 | T041 | Crosslink connector     |  | 30-100mm | PC  | Ti6Al4V |
| 23 | T042 | Crosslink connector     |  | 30-75mm  | PC  | Ti6Al4V |
| 24 |      | RSS III instruments set |                                                                                    | 3 trays  | set | SS      |



\* All Ti implants are Type II anodized for biocompatibility and improved fatigue strength.  
Color anodizing Type III available upon request.  
Custom sizes available upon request.

# ORTOFIX

## Societatea cu Raspundere Limitata

Republica Moldova, Chisinau, bd. Stefan cel Mare 182.  
Tel. (373) 60-808-605 email: [ortofix.moldova@gmail.com](mailto:ortofix.moldova@gmail.com)  
Tel/fax (373) 22-295-845  
Cod fiscal 1014600000772  
BC "Eximbank – Gruppo Veneto Banca"  
MD36EX0000002251656584MD

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21.05.2021

### Către grupul de lucru pentru achiziționarea dispozitivelor medicale din cadrul Centrului Pentru Achiziții Publice Centralizate în Sănătate

#### Declarație

Prin prezenta, cu referire la licitația publică nr. ocds-b3wdp1-MD-1620980778807, privind Implanturi spinale conform necesităților IMSP Institutul de Medicină urgentă și IMSP Institutul Mamei și Copilului pentru anul 2021, **Ortofix SRL** declară ca:

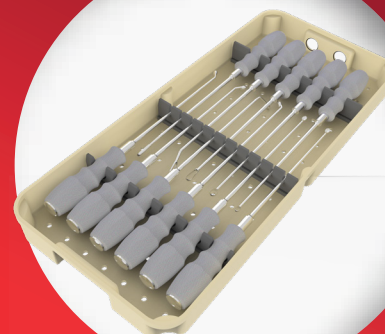
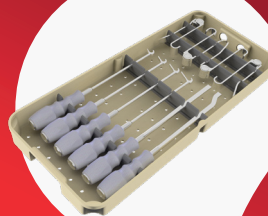
- Pentru produsele noi sau necunoscute pentru medici, vor fi prezentate mostre în termen de 5 zile de la solicitare.
- Termenul de valabilitate restant (la momentul livrării) va constitui 80% din termenul total al produsului, dar nu mai mic de 12 luni

**Cu respect,  
Director**

**Roman Bolocan**

# Osteotomy instrument set

thoracolumbar

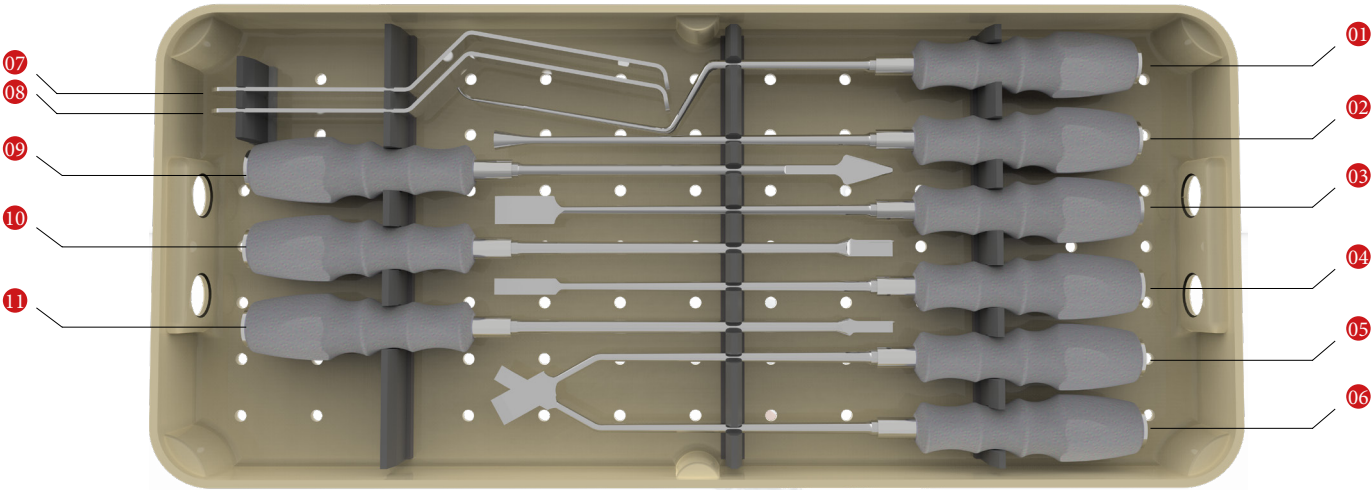


- Provide effective and simple use
- Include a wide selection of specialized instrumentation
- A truly complete set with dedicated instruments for corrective osteotomies
- Accommodate surgical preferences and anatomical variations
- Soft Tissue Retraction and Protection

## OSTEOTOMY INSTRUMENT SET

| Catalogue No. | Instrument Name                            | Quantity |
|---------------|--------------------------------------------|----------|
| NOS001        | SMALL RING CURETTE                         | 1        |
| NOS002        | LARGE RING CURETTE                         | 1        |
| NOS003        | CURETTE, STRAIGHT                          | 1        |
| NOS004        | CURETTE, LEFT                              | 1        |
| NOS005        | CURETTE, RIGHT                             | 1        |
| NOS006        | CUP CURETTE, STRAIGHT                      | 1        |
| NOS007        | CUP CURETTE, STRAIGHT THREADED             | 1        |
| NOS008        | CUP CURETTE 45 ANGLED                      | 1        |
| NOS009        | CUP CURETTE, OFFSET                        | 1        |
| NOS010        | CUP CURETTE, RIGHT                         | 1        |
| NOS011        | CUP CURETTE, LEFT                          | 1        |
| NOS012        | SMALL OSTEOTOMY, ANGLED                    | 1        |
| NOS013        | LARGE OSTEOTOMY, ANGLED                    | 1        |
| NOS014        | SMALL OSTEOTOMY, STRAIGHT                  | 1        |
| NOS015        | LARGE OSTEOTOMY, STRAIGHT                  | 1        |
| NOS016        | BELL CURETTE                               | 1        |
| NOS017        | NERVE ROOT RETRACTOR                       | 1        |
| NOS018        | VERTEBRAL BODY OSTEOTOMY 6mm x 8mm         | 1        |
| NOS019        | VERTEBRAL BODY OSTEOTOMY 8mm x 6mm         | 1        |
| NOS020        | TRIANGLE SHAVER, 30                        | 1        |
| NOS021        | BAYONET NERVE ROOT RETRACTOR, 12 mm        | 1        |
| NOS022        | BAYONET NERVE ROOT RETRACTOR, 14 mm        | 1        |
| NOS023        | VERTEBRAL BODY PUNCH, 15 mm                | 1        |
| NOS024        | VERTEBRAL BODY PUNCH, 20 mm                | 1        |
| NOS025        | VERTEBRAL BODY PUNCH, 25 mm                | 1        |
| NOS026        | VERTEBRAL BODY PUNCH, 30 mm                | 1        |
| NOS027        | STRAIGHT BONE IMPACTOR                     | 1        |
| NOS028        | OFFSET BONE IMPACTOR                       | 1        |
| NOS029        | ADJUSTABLE VERTEBRAL BODY RETRACTOR, 15 mm | 2        |
| NOS030        | ADJUSTABLE VERTEBRAL BODY RETRACTOR, 30 mm | 2        |

Osteotomy Instrument Set - Tray 1



| Instruments | Set No | Catalogue No. | Descrption |
|-------------|--------|---------------|------------|
|-------------|--------|---------------|------------|



01

NOS017

Nerve Root  
Retractor



02

NOS016

Bell Curette



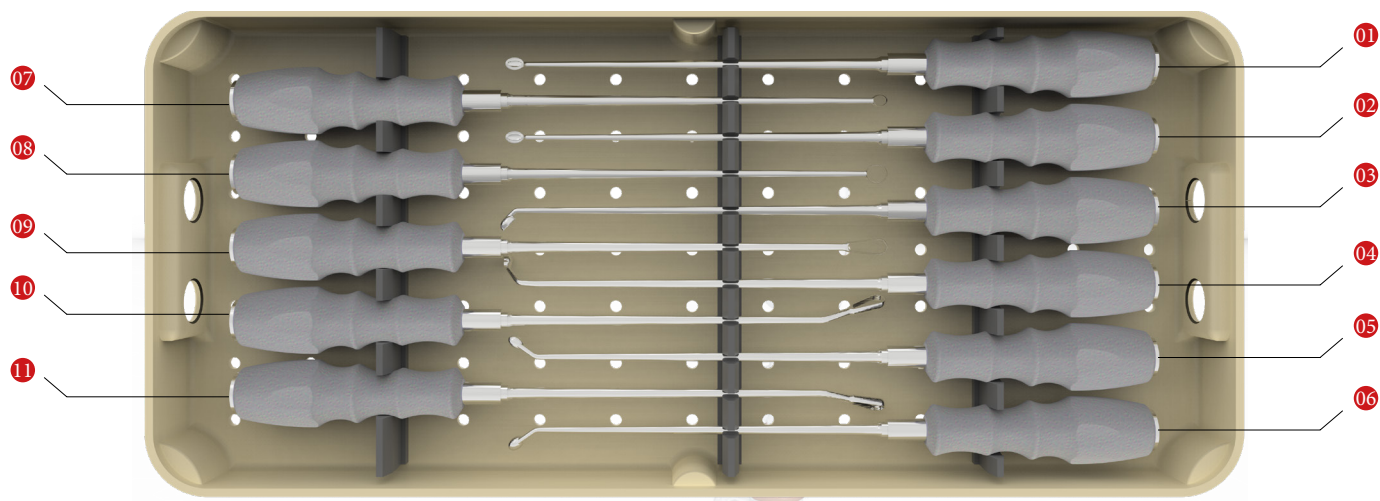
03

NOS015

Large  
Osteotomy, Straight

| Instruments                                                                         | Set No | Catalogue No. | Descprition                         |
|-------------------------------------------------------------------------------------|--------|---------------|-------------------------------------|
|    | 04     | NOS014        | Small Osteotomy, Straight           |
|    | 05     | NOS013        | Large Osteotomy, Angled             |
|    | 06     | NOS012        | Small Osteotomy, Angled             |
|    | 07     | NOS021        | Bayonet Nerve Root Retractor, 12 mm |
|                                                                                     | 08     | NOS022        | Bayonet Nerve Root Retractor, 14 mm |
|  | 09     | NOS020        | Triangle Shaver, 30                 |
|  | 10     | NOS018        | Vertebral Body Osteotomy 6mm X 8mm  |
|  | 11     | NOS019        | Vertebral Body Osteotomy 8mm X 6mm  |

Osteotomy Instrument Set - Tray 2



| Instruments | Set No | Catalogue No. | Description |
|-------------|--------|---------------|-------------|
|-------------|--------|---------------|-------------|



01

NOS006

Cup Curette,  
Straight



02

NOS007

Cup Curette, Straight  
Threaded



03

NOS008

Cup Curette 45  
Angled



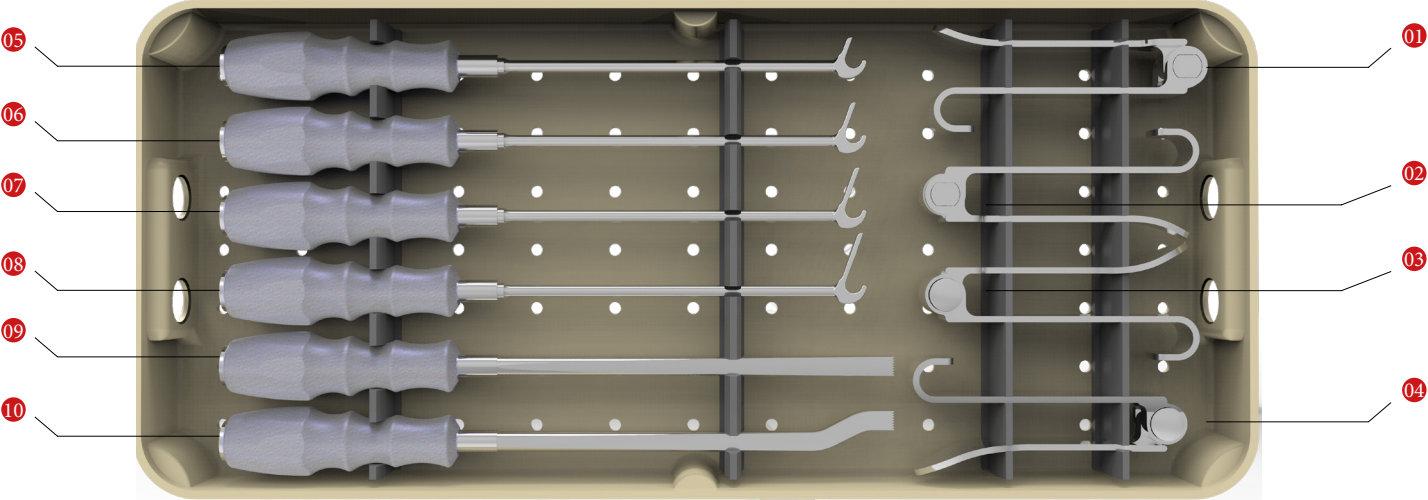
04

NOS009

Cup Curette,  
Offset

| Instruments                                                                         | Set No | Catalogue No. | Descrption         |
|-------------------------------------------------------------------------------------|--------|---------------|--------------------|
|    | 05     | NOS010        | Cup Curette, Right |
|    | 06     | NOS011        | Cup Curette, Left  |
|    | 07     | NOS001        | Small Ring Curette |
|    | 08     | NOS002        | Large Ring Curette |
|  | 09     | NOS003        | Curette, Straight  |
|  | 10     | NOS004        | Curette, Left      |
|  | 11     | NOS005        | Curette, Right     |

Osteotomy Instrument Set - Tray 3



| Instruments | Set No | Catalogue No. | Descprition |
|-------------|--------|---------------|-------------|
|-------------|--------|---------------|-------------|



01

NOS029

Adjustable Vertebral Body  
Retractor, 15 mm



02

NOS029

Adjustable Vertebral Body  
Retractor, 15 mm



03

NOS030

Adjustable Vertebral Body  
Retractor, 30 mm

| Instruments                                                                         | Set No | Catalogue No. | Descrption                                 |
|-------------------------------------------------------------------------------------|--------|---------------|--------------------------------------------|
|    | 04     | NOS030        | Adjustable Vertebral Body Retractor, 30 mm |
|    | 05     | NOS023        | Vertebral Body Punch 15 mm                 |
|    | 06     | NOS024        | Vertebral Body Punch 20 mm                 |
|    | 07     | NOS025        | Vertebral Body Punch 25 mm                 |
|  | 08     | NOS026        | Vertebral Body Punch 30 mm                 |
|  | 09     | NOS027        | Straight Bone Impactor                     |
|  | 10     | NOS028        | Offset Bone Impactor                       |

**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60124981 0001

**Report No.:** 15096167 001

**Manufacturer:** Jiangsu Jinlu Group Medical Device  
Co., Ltd.  
Jinfeng Town  
Zhangjiagang City  
215625 Jiangsu  
China

**Products:**

- Metal Bone Plates & Screw Systems
- Metallic Cannulated Bone Screws
- Metallic Interlocking Intramedullary Nails
- Spinal Fixation Devices
- External Fixation Devices with Needles
- Suture Wires

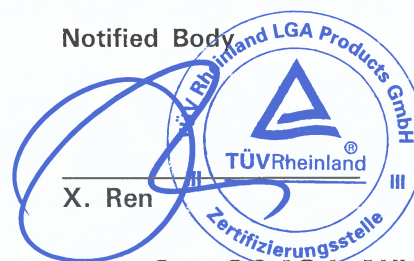
**Expiry Date:** 2022-06-30

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2017-12-11

**Date:** 2017-12-11

Notified Body



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Jiangsu Jinlu Group Medical Device  
Co., Ltd.  
Jinfeng Town  
Zhangjiagang City  
215625 Jiangsu  
China**

has established and applies a quality management system for medical devices  
for the following scope:

**Design and Development, Manufacture and Distribution of  
Medical Devices  
(see attachment for products included)**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**

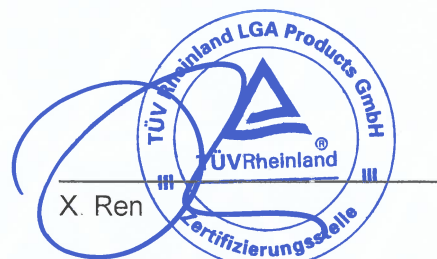
are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2017-12-11  
Certificate Registration No.: SX 60124982 0001  
An audit was performed. Report No.: 15096167 001  
This Certificate is valid until: 2020-06-30

Certification Body



Date 2017-12-11



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/1, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** SX 60124982 0001  
**Report No.:** 15096167 001

**Organization:** Jiangsu Jinlu Group Medical Device  
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Jinfeng Town  
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215625 Jiangsu  
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**Scope:**

**Products:**

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- External Fixation Devices with Needles
- Suture Wires

**Certification Body**



**Date:** 2017-12-11

