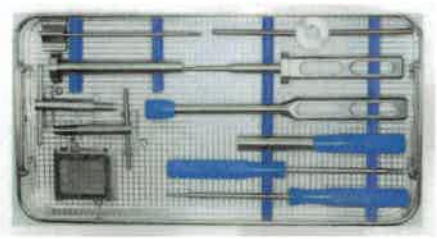
# Appendix 1

## Surgical Instrument Set: OTNI 13BS 'Osseointegration Step 1 + 2'

| UDI GS1 (GTIN) | REF | Product trade name | OFP surgery | OIP surgery | DM | Risk Class (MDD) | Risk Class (MDR) |
|---|---|---|---|---|---|---|---|
| **(01) 0 8719992774944 (21) XXXX** | **OTNI 13BS** | **Osseointegration Step 1+2** | **YES** | **YES** | **YES** | **I** | **Ir** |
| Contents of this kit: | | | | | | | |
| (01) 0 8719992774333 (21) XXXX | OTNI 1306 | M6 Femur installer | YES | YES | YES | I | Ir |
| (01) 0 8719992774340 (21) XXXX | OTNI 1307 | Taper Installer | YES | YES | YES | I | Ir |
| (01) 0 8719992774364 (21) XXXX | OTNI 1308 | Hexa 4.0 screw driver | YES | YES | YES | I | Ir |
| (01) 0 8719992774357 (21) XXXX | OTNI 1309 | Femur Tip Aiming device | YES | YES | YES | I | Ir |
| (01) 0 8719992774371 (21) XXXX | OTNI 1310 | Corer | YES | YES | YES | I | Ir |
| (01) 0 8719992774395 (21) XXXX | OTNI 1311 | Double Cone Punch | YES | YES | YES | I | Ir |
| (01) 0 8719992774301 (21) XXXX | OTNI 1312 | Retainer | YES | YES | YES | I | Ir |
| (01) 0 8719992774318 (21) XXXX | OTNI 1313 | Double Cone Remover M14x2 | YES | YES | YES | I | Ir |
| (01) 0 8719992774325 (21) XXXX | OTNI 1314 | Removal Cylinders 10 mm (5pcs) | YES | YES | YES | I | Ir |
| (01) 0 8719992774386 (21) XXXX | OTNI 1326 | Double Cone Remover M12x2 | YES | YES | YES | I | Ir |
| (01) 0 8719992774593 (21) XXXX | OTNI 1324 | Hexa 3.5 screw driver | YES | YES | YES | I | Ir |



# Appendix 2

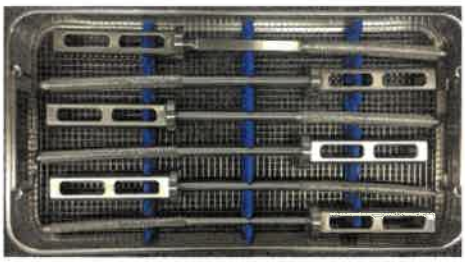
## Surgical Instrument Set: OTNI 13TR 'Tip Rasp Set'

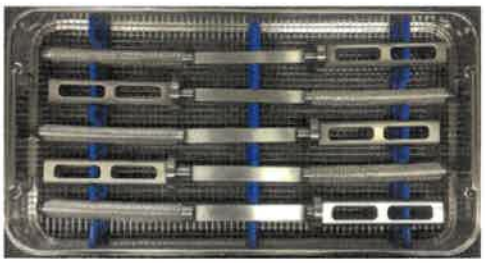
| UDI GS1 (GTIN) | REF | Product trade name | OFP surgery | OIP surgery | DM | Risk Class MDD | Risk Class MDR |
|---|---|---|---|---|---|---|---|
| **(01) 0 8719325796 (21) XXXX** | **OTNI 13TR** | **Tip Rasp Set** | **YES** | **YES** | **YES** | **I** | **Ir** |
| Contents of this kit: | | | | | | | |
| (01) 0 8719992774326 (21) XXXX | OTNI 1301 | Tip Rasp ø13 | YES | YES | YES | I | Ir |
| (01) 0 8719992774548 (21) XXXX | OTNI 1302 | Tip Rasp ø15 | YES | YES | YES | I | Ir |
| (01) 0 8719992774555 (21) XXXX | OTNI 1303 | Tip Rasp ø17 | YES | YES | YES | I | Ir |
| (01) 0 8719992774562 (21) XXXX | OTNI 1304 | Tip Rasp ø19 | YES | YES | YES | I | Ir |
| (01) 0 8719992774579 (21) XXXX | OTNI 1305 | Tip Rasp ø21 | YES | YES | YES | I | Ir |

# Appendix 3

## Surgical Instrument Set: OTNI CR01 'Curved Rasp Set 1'

| UDI GS1 (GTIN) | REF | Product trade name | OFP surgery | OIP surgery | DM | Risk Class MDD | Risk Class MDR |
|---|---|---|---|---|---|---|---|
| **(01) 0 8719992774913(21) XXXX** | **OTNI CR01** | **Curved Rasp Set 1** | **YES** | **NO** | **YES** | **I** | **Ir** |
| Contents of this kit: | | | | | | | |
| (01) 0 8719992774876 (21) XXXX | OTNI 1327 | Curved Rasp ø12 mm | YES | NO | YES | I | Ir |
| (01) 0 8719992774883 (21) XXXX | OTNI 1328 | Curved Rasp ø13 mm | YES | NO | YES | I | Ir |
| (01) 0 8719992774890 (21) XXXX | OTNI 1329 | Curved Rasp ø14 mm | YES | NO | YES | I | Ir |
| (01) 0 8719992774609 (21) XXXX | OTNI 1315 | Curved Rasp ø15 mm | YES | NO | YES | I | Ir |
| (01) 0 8719992774616 (21) XXXX | OTNI 1316 | Curved Rasp ø16 mm | YES | NO | YES | I | Ir |
| (01) 0 8719992774623 (21) XXXX | OTNI 1317 | Curved Rasp ø17 mm | YES | NO | YES | I | Ir |





# Appendix 4

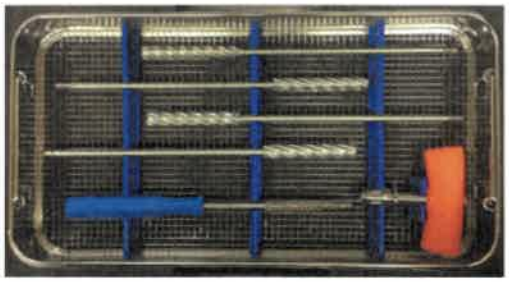
## Surgical Instrument Set: OTNI CR02 'Curved Rasp Set 2'

| UDI GS1 (GTIN) | REF | Product trade name | OFP surgery | OIP surgery | DM | Risk Class MDD | Risk Class MDR |
|---|---|---|---|---|---|---|---|
| **(01) 0 8719325796070(21) XXXX** | **OTNI CR02** | **Curved Rasp Set 2** | **YES** | **NO** | **YES** | **I** | **Ir** |
| Contents of this kit: | | | | | | | |
| (01) 0 8719992774876 (21) XXXX | OTNI 1318 | Curved Rasp ø18 mm | YES | NO | YES | I | Ir |
| (01) 0 8719992774883 (21) XXXX | OTNI 1319 | Curved Rasp ø19 mm | YES | NO | YES | I | Ir |
| (01) 0 8719992774890 (21) XXXX | OTNI 1320 | Curved Rasp ø20 mm | YES | NO | YES | I | Ir |
| (01) 0 8719992774609 (21) XXXX | OTNI 1321 | Curved Rasp ø21 mm | YES | NO | YES | I | Ir |
| (01) 0 8719992774616 (21) XXXX | OTNI 1322 | Curved Rasp ø22 mm | YES | NO | YES | I | Ir |

# Appendix 5

## Surgical Instrument Set: OTNI RR01 'Rigid Surgery 01'

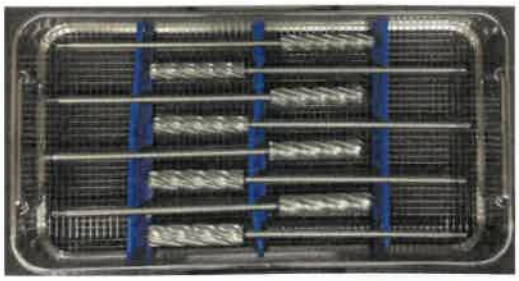
| UDI GS1 (GTIN) | REF | Product trade name | OFP surgery | OIP surgery | DM | Risk Class MDD | Risk Class MDR |
|---|---|---|---|---|---|---|---|
| **(01) 0 8719992774852(21) XXXX** | **OTNI RR01** | **Rigid Surgery 01** | **NO** | **YES** | **YES** | **I** | **Ir** |
| Contents of this kit: | | | | | | | |
| (01) 0 8719992774906 (21) XXXX | OTNI 1330 | Tibia Drop Rasp | NO | YES | YES | I | Ir |
| REF 42230023 LOT xxxxxABxx | OTNI 1331 | T-Handle Zimmer-Jakob | NO | YES | YES | I | Ir |
| REF 42203112 LOT xxxxxABxx | OTNI RR12 | Rigid reamer ø12 | NO | YES | YES | I | Ir |
| REF 42203113 LOT xxxxxABxx | OTNI RR13 | Rigid reamer ø13 | NO | YES | YES | I | Ir |
| REF 42203114 LOT xxxxxABxx | OTNI RR14 | Rigid reamer ø14 | NO | YES | YES | I | Ir |
| REF 42203115 LOT xxxxxABxx | OTNI RR15 | Rigid reamer ø15 | NO | YES | YES | I | Ir |



# Appendix 6

## Surgical Instrument Set: OTNI RR02 'Rigid Surgery 02'

| UDI GS1 (GTIN) | REF | Product trade name | OFP surgery | OIP surgery | DM | Risk Class MDD | Risk Class MDR |
|---|---|---|---|---|---|---|---|
| **(01) 0 8719325796087(21) XXXX** | **OTNI RR02** | **Rigid Surgery 02** | **NO** | **YES** | **YES** | **I** | **Ir** |
| Contents of this kit: | | | | | | | |
| REF 42203116 LOT xxxxxABxx | OTNI RR16 | Rigid reamer ø16 | NO | YES | YES | I | Ir |
| REF 42203117 LOT xxxxxABxx | OTNI RR17 | Rigid reamer ø17 | NO | YES | YES | I | Ir |
| REF 42203118 LOT xxxxxABxx | OTNI RR18 | Rigid reamer ø18 | NO | YES | YES | I | Ir |
| REF 42203119 LOT xxxxxABxx | OTNI RR19 | Rigid reamer ø19 | NO | YES | YES | I | Ir |
| REF 42203120 LOT xxxxxABxx | OTNI RR20 | Rigid reamer ø20 | NO | YES | YES | I | Ir |
| REF 42203121 LOT xxxxxABxx | OTNI RR21 | Rigid reamer ø21 | NO | YES | YES | I | Ir |
| REF 42203122 LOT xxxxxABxx | OTNI RR22 | Rigid reamer ø22 | NO | YES | YES | I | Ir |
| REF 42203123 LOT xxxxxABxx | OTNI RR23 | Rigid reamer ø23 | NO | YES | YES | I | Ir |



# Appendix 7

## Surgical Instrument Set: OTNI RR03 'Rigid Surgery 03'

| UDI GS1 (GTIN) | REF | Product trade name | OFP surgery | OIP surgery | DM | Risk Class MDD | Risk Class MDR |
|---|---|---|---|---|---|---|---|
| **(01) 0 8719325796094(21) XXXX** | **OTNI RR03** | **Rigid Surgery 03** | **NO** | **YES** | **YES** | **I** | **Ir** |
| Contents of this kit: | | | | | | | |
| REF 42203124 LOT xxxxxABxx | OTNI RR24 | Rigid reamer ø24 | NO | YES | YES | I | Ir |
| REF 42203125 LOT xxxxxABxx | OTNI RR25 | Rigid reamer ø25 | NO | YES | YES | I | Ir |
| REF 42203126 LOT xxxxxABxx | OTNI RR26 | Rigid reamer ø26 | NO | YES | YES | I | Ir |
| REF 42203127 LOT xxxxxABxx | OTNI RR27 | Rigid reamer ø27 | NO | YES | YES | I | Ir |
| REF 42203128 LOT xxxxxABxx | OTNI RR28 | Rigid reamer ø28 | NO | YES | YES | I | Ir |
| REF 42203129 LOT xxxxxABxx | OTNI RR29 | Rigid reamer ø29 | NO | YES | YES | I | Ir |
| REF 42203130 LOT xxxxxABxx | OTNI RR30 | Rigid reamer ø30 | NO | YES | YES | I | Ir |

# Appendix 8 - Description of the principles of operation

### Description of the principles of operation Principle of operation

OTNI 13 Reusable Surgical Instrument Sets for Osseointegration surgery consists of 7 surgical sets. Reusable surgical instrument means that the instrument are intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by to be reused after appropriate procedures such as cleaning, disinfection and sterilisation have been carried out.

### Mode of action

The sets are used for the press fit application of OTN Implants osseointegration implants in persons with extremity amputation. Osseointegration implants are used for stable skeletal fixation of artificial limbs. Bone anchoring of artificial limbs are usually applied in two step surgery. In surgery step 1 the non-cemented osseointegration implant is press fit fixated in the bone. Surgery step 2 is required to create an opening in the skin, the so-called 'stoma' and to install a transcutaneous component through the skin in the osseointegration implant. The exact surgical procedure is documented in two surgical technique session files. Surgical technique OIP Rev02.pages described the procedure for OIP surgery and 16013BR160801 OTNI OFP Surgical Technique rev7 describes the procedure for OFP surgery.

OTN Implants

### Scientifically

OTNI Reusable Surgical Instrument Sets for Osseointegration surgery do not have predecessors. There are no scientific studies performed that have specifically evaluated risk and performance of the product. The product has been used for the evaluation of the risks and performance of OTN Implants osseointegration implants in a prospective clinical study (PLOS One 2019).

### Rationale for the qualification of the product as a device

OTNI Reusable Surgical Instrument Sets for Osseointegration surgery is a medical device since the product is used for human application in medical / clinical environment by medical doctors.