

# doc+box<sup>®</sup>

## Standardization of Surgical Trays - Oral Implantology -

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## Intended purpose

Importable and user-applicable integrated surgical trays (risk class critical B) used in medical device reprocessing, batch documentation, inventory management and implant documentation.

The drills, instruments, and accessories contained in the trays are processed and used according to the manufacturer's instructions. The user documents their use, including the type and duration of application. doc+box® fully meets these high quality assurance standards as described under the current laws in the EU (e.g. MDR, MPBetreiberV/Medical Devices Operator Ordinance).

## Terms

- **JSON**  
Javascript Object Notation-Format
- **ZIP**  
Compression format, contains the tray definition file and possibly images and all other media as within defined

## Contents of the ZIP-File

Filename *XXXXXXXXXX.ZIP, freely selectable*

JSON *TRAYDEF.JSON*

Media *{...}, all supported file types in the same ZIP directory, e.g. SVG, PNG, JPG, BMP, PDF, MP4*

## Tray-Definition File

Filename *TRAYDEF.JSON*

Key	Definition/Example
<b>uuid</b>	Text, Unique Identifier, e.g. „company.tray.1“
<b>manufacturer_name</b>	Text, e.g. „Implant Company“
<b>manufacturer_url</b>	Text, e.g. „www.implantcompany.com“
<b>manufacturer_logo</b>	Text, name to local image file
<b>tray_type</b>	Text, <b>oi_tray</b>
<b>tray_name</b>	Text, e.g. „Modular Tray“
<b>tray_manual</b>	Text, name to local PDF file
<b>tray_link</b>	Text, URL regarding this tray
<b>tray_image</b>	Text, local Image file for tray background, JPG, PNG, SVG
<b>md_class</b>	Number, Medical Device Risk-Class 0 = <i>uncritical</i> 1 = <i>semi-critical A</i> 2 = <i>semi-critical B</i> 3 = <i>critical A</i> 4 = <i>critical B</i> 5 = <i>critical C</i>
<b>md_certificates</b>	Array of Object, Certificates for different countries

	<p>or jurisdictions, e.g. within EU = CE, within US = UL/ETL  nr = <i>Number of certificate</i>  cc = <i>ISO-CC two letter Country code</i>  type = <i>Type of certificate</i>  ca = <i>Notified Bodies/Testing laboratories</i></p> <p>[ { „nr“: „0123“, „cc“: „EU“, „ctype“: „CE“, „ca“: „xxxx“ }, ... ]</p>
<b>maxcycle</b>	Number, Maximum number of lifetime machine processing cycles for the entire tray
<b>maxusage</b>	Number, Maximum number of lifetime tray uses
<b>packtype</b>	Number, Type of sterile packaging 0 = <i>Sterile barrier</i> 1 = <i>Packaging system (including protective packaging)</i> 2 = <i>unpacked</i> 9 = <i>undefined</i>
<b>storage</b>	Number, Storage method 0 = <i>open shelves</i> 1 = <i>closed cabinets or drawers</i> 9 = <i>undefined</i>
<b>processing</b>	Object, definition of processing parameters for the whole tray md = <i>manual disinfection</i> md_agents = <i>disinfection agents</i> md_duration = <i>disinfection duration [min]</i> td = <i>thermal/mechanical disinfection</i> st = <i>sterilization</i>  { „md“: true/false, „td“: true/false }
<b>systems</b>	Array of Object for supported systems
<b>content</b>	Array of Object for Tray content

## Tray Systems

Array of supported systems.

Key	Definition/Example
<b>id</b>	Number, Unique
<b>title</b>	Text, Name of system
<b>icon</b>	Text, Local image filename
<b>url</b>	Text, URL Link
<b>manual</b>	Text, Local filename for PDF
<b>rpm</b>	Number, insertion rotation [min <sup>-1</sup> ]
<b>torque</b>	Number, insertion torque [Ncm]

# Tray Content

Array of instruments, drills, tools and consumables within the surgical tray.

Key	Definition/Example
<b>ctype</b>	Number, Content type 0 = Ball milling cutter 1 = Milling drill 2 = Trepan drill 3 = Mucosal punch 4 = Pilot drill 5 = Face milling cutter 6 = Cortical drill 7 = Profile drill 8 = Screw tap drill 9 = Lindemann drill 10 = Adaptor 11 = Drill bit 12 = Screw-in tool 13 = Fixation screw 14 = Fixation pin 15 = Positioning aid 16 = Ratchet
<b>title</b>	Text, Name of instrument
<b>pcn</b>	Text, Reference number/Product code
<b>icon</b>	Text, local image filename (PNG/JPG/SVG)
<b>color</b>	Text, Color in HTML-Notation, e.g. #DC143C
<b>posx</b>	Number, Position X within Tray-Image
<b>posy</b>	Number, Position Y within Tray-Image
<b>width</b>	Number, Width from X/Y Coordinates
<b>height</b>	Number, Height from X/Y Coordinates
<b>guided</b>	Boolean, True/False for guided content
<b>diameter</b>	Number, Instrument diameter [mm]
<b>diameter_system</b>	Number, System diameter [mm]
<b>length</b>	Number, Instrument length [mm]
<b>maxusage</b>	Number, Maximum number of uses
<b>torque</b>	Number, Maximum / Recommended torque [Ncm]
<b>rpm</b>	Number, Maximum rotation [ $\text{min}^{-1}$ ]
<b>systems</b>	Text, comma-separated system IDs
<b>usage_calc_nn [ d1 .. d4 ]</b>	Automatic usage calculation regarding bone density nn (D1 .. D4) per instrument, default = 1

## Example

```
{
  "uuid": "implant.company.tray1",
  "manufacturer_name": "The Implant Company",
  "manufacturer_url": "www.implantcompany.com",
  "manufacturer_logo": "companylogo.jpg",
  "tray_type": "oi_tray",
  "tray_name": "Implant Tray #1",
  "tray_manual": "manual_en.pdf",
  "tray_link": "www.implantcompany.com/trays/tray1",
  "tray_image": "tray_background.jpg",
  "md_class": 4,
  "md_certificates": [
    {
      "nr": "1234",
      "cc": "DE",
      "ctype": "CE",
      "ca": "Laboratory A, 01234, City, Street"
    }
  ],
  "maxcycle": 999,
  "maxusage": 999,
  "packtype": 0,
  "storage": 1,
  "processing": {
    "md": false,
    "td": true,
    "st": true,
    "md_agents": "Agent Solution A, 10%",
    "md_duration": 20
  },
  "systems": [
    {
      "id": 1,
      "title": "Implant System A",
      "icon": "impa.png",
      "url": "www.implantcompany.com/impa",
      "manual": "imps_systema.pdf",
      "rpm": 20,
      "torque": 35
    },
    {
      "id": 2,
      "title": "Implant System B",
      "icon": "impb.png",
      "url": "www.implantcompany.com/impb",
      "manual": "imps_systemb.pdf",
      "rpm": 20,
      "torque": 45
    }
  ],
  "content": [
    {
      "ctype": 4,
      "title": "Pilot Drill™ short",
      "pcn": "011.020001",
      "icon": "pd01.png",
    }
  ]
}
```

```
"color": "#DC143C",
"guided": false,
"diameter": 2.2,
"length": 16,
"diameter_system": 2.2,
"maxusage": 10,
"torque": 45,
"rpm": 1100,
"systems": "1,2",
"usage_calc_d1": 2,
"usage_calc_d2": 2,
"usage_calc_d3": 1,
"usage_calc_d4": 1
},
{
  "ctype": 3,
  "title": "Punch 3.5",
  "pcn": "011.000023",
  "icon": "punch.png",
  "color": "black",
  "guided": true,
  "diameter": 3.3,
  "diameter_system": 3.0,
  "length": 0,
  "maxusage": 50,
  "torque": 99,
  "rpm": 45,
  "systems": "1,2",
  "usage_calc_d1": 2,
  "usage_calc_d2": 2,
  "usage_calc_d3": 1,
  "usage_calc_d4": 1
}
]
}
```

# Remarks

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