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## Important information

(with Cleaning and Sterilization Instructions)

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# Important information

## 2 Basic Instructions on the Use of Synthes Implants and Instruments for Orthopedics and Osteosynthesis

### Product Description

Surgical implants offer orthopedic surgeons a means of precise bone fixation. They also play a generally supportive role in treatment, healing of fractures, and reconstructive surgery (osteosynthesis and correction of degenerative diseases). However, implants are not suitable to replace normal body structures or bear the body's weight (see product-specific instructions).

### Selecting an Implant/Indications

Consider the following points when treating traumatic and/or degenerative skeletal changes:

**1. Selecting the implant.** It is of paramount importance to select the proper implant. The potential for success is increased by selecting the proper implant size and shape. The characteristics of human bone and soft tissue pose restrictions on the size and strength of implants. No partial weight-bearing or non-weight-bearing product can be expected to withstand the full, unsupported weight of the body. If a strong bone union is to be achieved, the patient needs adequate external assistance. Likewise, the patient must restrict physical activities that would place stress upon the implant or allow movement at the fracture site and thus delay healing.

**2. Patient-related factors.** A series of patient-related factors have a strong influence on the success of surgery:

**a** Weight. An overweight or obese patient can place so much stress on the product that it will fail, perhaps even reversing the effects of surgery.

**b** Occupation or activity. Professional occupations pose a risk when external forces subject the body to substantial physical loads. This can cause the product to fail and even undo the achievements of surgery.

**c** Senility, mental illness, or alcoholism. These conditions may cause the patient to ignore certain necessary limitations and precautions, leading to the failure of the product or other complications.

**d** Certain degenerative diseases and smoking. In some cases, a degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the implant. In such cases, the products serve only as a means to delay or temporarily relieve the disease.

**e** Sensitivity to foreign bodies. Where hypersensitivity to a material is suspected, appropriate tests should be undertaken prior to selecting or implanting the material.

**3. Correct handling.** Correct handling of the implant is extremely important. If the shape of the implant must be altered, the device should not be bent sharply, bent backwards, notched, or scratched. Such manipulations, in addition to all other improper handling or use, can produce surface defects and/or concentrate stress in the core of the implant. This in turn may eventually cause the product to fail.

**4. Postoperative care is essential.** Physicians should inform their patients about the implant's load restrictions and offer a plan for postoperative behavior and increasing physical loads. Failure to do this can generate malalignment, delayed bone healing, implant failure, infections, thrombophlebitis, and/or wound hematomas.

**5. Removal of the osteosynthetic product.** While the physician makes the final decision on when to remove the implant, it is advisable – if possible and appropriate for the individual patient – to remove fixation products after the healing process is complete. This holds true particularly for young and active patients.

**6. Compatibility.** Synthes guarantees the compatibility of its different original implants and/or instruments. The product-specific instructions for use as described by Synthes must be followed. It is not advisable to mix Synthes products with those of different manufacturers, since designs, materials, mechanics, and construction are not harmonized. Synthes assumes no liability for any complications arising from mixing components or from using foreign instruments.

If not otherwise mentioned it is not recommended to mix different implant metals.

Mixing of metals may lead to galvanic corrosion and a release of ions. This may cause inflammatory response, metal sensitivity reactions, and/or long term detrimental systemic effects. In addition, the corrosion process can reduce the mechanical strength of the implant.

**7. Information and qualification.** Surgeons should be fully aware of the intended use of the products and the applicable surgical techniques, and they should be qualified by appropriate training (for example, by the Association for the Study of Internal Fixation, AO).

### 8. Potential Risks:

- Implant failure from selecting the wrong implant and/or overloading the osteosynthesis
- Allergic reactions from material incompatibility
- Delayed healing from vascular disturbances
- Pain triggered by the implant

### 9. MRI – Magnetic Resonance Imaging

When a device has been evaluated for use in the MR environment, MRI information will be found in the instructions for use and/or corresponding surgical technique at <http://www.depuysynthes.com/ifu>.

### Single-Use Products

Products intended for single use must not be re-used (see product-specific instructions and "Interpretation of symbols").

Re-use or clinical processing (e.g. cleaning and re-sterilization) may compromise the structural integrity of the device and/or lead to device failure. This may result in patient injury, illness or death. Furthermore, re-use or clinical processing of single use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Do not reprocess soiled implants. Any Synthes implant that has been soiled by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

### Sterile Products

Products supplied in a sterile condition are labeled "STERILE" (see "Interpretation of symbols"). Remove products from the package in an aseptic manner. The manufacturer cannot guarantee sterility if the package seal is broken or if the package is improperly opened, and assumes no liability in such instances.

### Non-Sterile Products

Synthes products supplied in a non-sterile condition must be cleaned and steam sterilized prior to surgical use. Prior to cleaning, remove and dispose all original disposable packaging (e.g. silicone rubber guards, tip guards, protection caps, blisters, pouches, bags, packaging foam, card board etc.). Clean products before first and every use, and before returning for maintenance and repair. Prior to steam sterilization, place the product in an approved wrap or container.

The first and most important step in decontaminating all re-usable instruments is thorough (manual and/or mechanical) cleaning and rinsing. Thorough cleaning is a complex process whose success depends on various interrelated factors: Water quality, quantity and type of cleaning agent, cleaning method (manual, ultrasonic bath, washer/disinfector), thorough rinsing and drying, proper product preparation, time, temperature, and thoroughness of the individual responsible for cleaning.

Residual organic matter and/or a large number of microorganisms may reduce the effectiveness of the sterilization process.

### Locating of the instrument or fragments of instruments

Synthes instruments are designed and manufactured to perform safely within the scope of their intended use.

However if a metallic instrument (e.g. steel; aluminium; titanium and its alloy etc.) breaks during use, a medical imaging device (e.g. CT, Radiation Devices etc.) can aid in locating fragments and/or components of the instrument.

## 4 Reprocessing Synthes Reusable Devices – Instruments, Instrument Trays and Cases

These recommendations are for processing Synthes reusable devices. Synthes reusable devices include certain surgical instruments, instrument trays and cases. The information provided does not apply to Synthes implants. These recommendations are to be followed unless otherwise noted on specific product inserts.

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| <p><b>Cautions</b></p>               | <ul style="list-style-type: none"> <li>– Do not use steel wool or abrasive cleaners.</li> <li>– Avoid solutions containing iodine or high chlorine content.</li> <li>– Only place Synthes devices with items of similar metallic composition together in an ultrasonic cleaner.</li> <li>– Soiled or used Synthes devices should not be loaded into a case for cleaning in a mechanical washer. Soiled Synthes devices must be processed separate from trays and cases. Synthes cases are designed to be an organizational tool for the steam sterilization process, a storage tool for all medical devices and an organizational tool for surgery.</li> <li>– Long, narrow cannulations, blind holes and intricate parts require particular attention during cleaning.</li> <li>– All devices must be thoroughly cleaned.</li> <li>– Synthes instruments must be terminally sterilized prior to use.</li> <li>– The sterilization parameters are only valid for devices that are adequately cleaned.</li> <li>– The parameters listed are only valid for properly installed, maintained, calibrated and compliant reprocessing equipment in accordance with ISO 15883 and ISO 17665.</li> <li>– Cleaning agents with a pH between 7–9.5 are recommended. Cleaning agents with a pH-value up to 11 and higher than 11 respectively should only be used considering the data regarding material compatibility according to its data sheet. Refer to Material Compatibility of Synthes Instruments and Implants in Clinical Reprocessing, see below.</li> <li>– Clinical processing of Power Tool hand pieces and attachments should not be immersed in water or cleaning solution. Do not clean power equipment ultrasonically. Refer to product-specific literature for Power Tools.</li> <li>– Surgical patients identified as at-risk for Creutzfeldt-Jakob disease (CJD) and related infections should be treated with single-use instruments. Dispose of instruments used or suspected of use on a patient with CJD after surgery and/or follow current national recommendations.</li> <li>– Consult national regulations and guidelines for additional information. Compliance is additionally required with internal hospital policies and procedures and recommendations of manufacturers of detergents, disinfectants, and any clinical processing equipment.</li> </ul> |
| <p><b>Limits on reprocessing</b></p> | <ul style="list-style-type: none"> <li>– Repeated processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on Synthes surgical instrumentation.</li> <li>– End of life of a device is normally determined by wear and damage due to use. Evidence of damage and wear on a device may include but is not limited to corrosion (i.e. rust, pitting), discoloration, excessive scratches, flaking, wear and cracks. Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and excessively worn devices should not be used.</li> </ul>   |

### Clinical Reprocessing Instructions

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| <p><b>Point of Use Care</b></p> | <p>Wipe blood and/or debris from device throughout surgical procedure to prevent it from drying onto the surface.</p> <ul style="list-style-type: none"> <li>– Flush cannulated devices with sterile or purified water to prevent the drying of soil and/or debris to the inside.</li> <li>– Soiled devices should be separated from non-contaminated devices to avoid contamination of personnel or surroundings,</li> <li>– Devices should be covered with a towel dampened with sterile or purified water to prevent blood and/or debris from drying.</li> </ul> |
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| <b>Containment and Transportation</b>                             | <ul style="list-style-type: none"> <li>– Soiled devices should be transported separate from non-contaminated devices to avoid contamination.</li> </ul>   |
| <b>Preparation for Decontamination (for all cleaning methods)</b> | <ul style="list-style-type: none"> <li>– It is recommended that devices should be reprocessed as soon as is reasonably practical following use.</li> <li>– Disassemble device, if device is able to be disassembled, prior to reprocessing.</li> <li>– Further detailed instrument Dismantling instructions are available from your local sales representative or for download at <a href="http://emea.depuyssynthes.com/hcp/reprocessing-care-maintenance">http://emea.depuyssynthes.com/hcp/reprocessing-care-maintenance</a>.</li> <li>– Open devices with ratchets, box locks or hinges.</li> <li>– Remove sharp devices for manual cleaning or place into a separate tray.</li> <li>– Lumens/cannula of devices should be manually processed prior to cleaning. Lumens/cannula should first be cleared of debris. Lumens/cannula should be brushed thoroughly using appropriately sized soft-bristled brushes and twisting action. Brushes should be tight-fitting. Brush size should be approximately the same diameter of the lumen/cannulation to be cleaned. Using a brush that is too big or too small for the diameter of the lumen/cannulation may not effectively clean the surface of a lumen/cannulation.</li> <li>– Soak and/or rinse heavily soiled devices or cannulated devices prior to cleaning to loosen any dried soil or debris. Use an enzymatic cleaner or detergent solution. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration. Use cold tap water to rinse devices.</li> <li>– Synthes devices must be cleaned separately from Synthes instrument trays and Synthes cases. Lids should be removed from cases for the cleaning process, if applicable.</li> </ul>   |
| <b>Cleaning and disinfection – Manual Method with Ultrasonic</b>  | <p>Equipment: ultrasonic cleaner, various sized soft-bristled brushes, lint-free cloths, syringes, pipettes and/or water jet, enzymatic cleaner or detergent solution</p> <p>Pre-clean method (Pre-clean method must be performed prior to ultrasonic mechanical method listed below.)</p> <ol style="list-style-type: none"> <li>1. Rinse soiled device under running cold tap water for a minimum of two minutes. Use a soft-bristled brush to assist in the removal of gross soil and debris.</li> <li>2. Soak device in an enzymatic cleaner or detergent solution for a minimum of ten minutes. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration.</li> <li>3. Rinse device with cold water for a minimum of two minutes. Use a syringe, pipette, or water jet to flush lumens, channels and other hard to reach areas.</li> <li>4. Manually clean device for a minimum of five minutes in a freshly prepared enzymatic cleaner or detergent solution. Use a soft-bristled brush to remove soil and debris. Actuate joints, handles and other movable device features to expose all areas to the detergent solution, if applicable. Clean device under water to prevent aerosolization of contaminants. <i>Note: fresh solution is a newly-made, clean solution.</i></li> <li>5. Rinse device thoroughly using cold or warm tap water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens and channels. Actuate joints, handles and other moveable device features in order to rinse thoroughly under running water, if applicable.</li> <li>6. Visually inspect device. Repeat steps 2–6 until no visible soil remains on device.</li> </ol> <p>Ultrasonic process: (Pre-cleaning steps 1–6 should occur prior to this step.)</p> <ol style="list-style-type: none"> <li>7. Prepare a fresh detergent solution using an enzymatic cleaner or detergent solution. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration. <i>Note: fresh solution is a newly-made, clean solution.</i></li> <li>8. Clean Synthes device ultrasonically for a minimum of 15 minutes, using a minimum frequency of 40 KHz.</li> <li>9. Rinse device thoroughly with deionized (DI) or purified (PURW) water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens and channels. Actuate joints, handles and other moveable device features in order to rinse thoroughly under running water, if applicable.</li> <li>10. Visually inspect device. Repeat steps 2–10 until no visible soil remains on device,</li> <li>11. Perform a final rinse on device using DI or PURW water for a minimum of 15 seconds.</li> <li>12. Dry device using a clean, soft, lint-free single-use cloth or medical grade compressed air.</li> </ol> |

| <p><b>Cleaning – Automated/Mechanical washer Method</b></p> | <p>Equipment: Ultrasonic cleaner, washer/disinfector, various sized soft-bristled brushes, lint-free cloths, syringes, pipettes and/or water jet, enzymatic cleaner or detergent solution</p> <p>Pre-clean method (Pre-clean method must be performed prior to mechanical washer method listed below.)</p> <ol style="list-style-type: none"> <li>1. Rinse soiled device under running cold tap water for a minimum of one minute. Remove gross soil using a soft-bristled brush or soft, lint-free cloth.</li> <li>2. Manually clean device for a minimum of two minutes in a freshly prepared enzymatic cleaner or detergent solution. Follow the enzymatic cleaner or detergent manufacturer's instructions for the correct dilution, temperature, water quality and exposure time. Use a soft-bristled brush to remove soil and debris. Actuate joints, handles and other movable device features to expose all areas to detergent solution, if applicable. Clean device under water to prevent aerosolization of contaminants, <i>Note: fresh solution is a newly-made, clean solution.</i></li> <li>3. Rinse device using cold to lukewarm running tap water for a minimum of one minute. Use a syringe, pipette or water jet to flush lumens and channels. Actuate joints, handles and other moveable device features in order to rinse thoroughly under running water, if applicable.</li> <li>4. Prepare a fresh detergent solution using enzymatic cleaner or detergent. Follow the enzymatic cleaner or detergent manufacturer's instructions for the correct dilution, temperature, water quality and exposure time. <i>Note: fresh solution is a newly-made, clean solution.</i></li> <li>5. Clean Synthes devices ultrasonically for a minimum of 15 minutes, using a minimum frequency of 40 KHz.</li> <li>6. Rinse device using DI or PURW water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens and channels. DI or PURW water must be used for final rinse.</li> <li>7. Visually inspect device. Repeat steps 2–7 until no visible soil remains on device.</li> </ol> <p>Mechanical Washer process: (Pre-cleaning steps 1–7 should occur prior to this step.) <i>Note: The washer/disinfector should fulfill requirements specified in ISO 15883. Use MIS injector unit to process lumens and cannulations.</i></p> <p>8. Process device using the following cycle parameters:</p> <table border="1" data-bbox="314 963 1025 1219"> <thead> <tr> <th>Cycle</th> <th>Minimum Time (minutes)</th> <th>Minimum Temperature/Water</th> <th>Type of Detergent</th> </tr> </thead> <tbody> <tr> <td>Pre-wash</td> <td>2</td> <td>Cold tap water</td> <td>N/A</td> </tr> <tr> <td>Wash I</td> <td>2</td> <td>Cold tap water (&lt; 40 °C)</td> <td>Cleaning agent*</td> </tr> <tr> <td>Wash II</td> <td>5</td> <td>Warm tap water (&gt; 40 °C)</td> <td>Cleaning agent*</td> </tr> <tr> <td>Rinse</td> <td>2</td> <td>Warm DI or PURW (&gt; 40 °C)</td> <td>N/A</td> </tr> <tr> <td>Thermal Disinfection</td> <td>5</td> <td>&gt; 93 °C</td> <td>N/A</td> </tr> <tr> <td>Dry</td> <td>40</td> <td>&gt; 90 °C</td> <td>N/A</td> </tr> </tbody> </table> <p>* see Additional Information</p> | Cycle                     | Minimum Time (minutes) | Minimum Temperature/Water | Type of Detergent | Pre-wash | 2 | Cold tap water | N/A | Wash I | 2 | Cold tap water (< 40 °C) | Cleaning agent* | Wash II | 5 | Warm tap water (> 40 °C) | Cleaning agent* | Rinse | 2 | Warm DI or PURW (> 40 °C) | N/A | Thermal Disinfection | 5 | > 93 °C | N/A | Dry | 40 | > 90 °C | N/A |
|---|--|---------------------------|------------------------|---------------------------|-------------------|----------|---|----------------|-----|--------|---|--------------------------|-----------------|---------|---|--------------------------|-----------------|-------|---|---------------------------|-----|----------------------|---|---------|-----|-----|----|---------|-----|
| Cycle   | Minimum Time (minutes)   | Minimum Temperature/Water | Type of Detergent      |                           |                   |          |   |                |     |        |   |                          |                 |         |   |                          |                 |       |   |                           |     |                      |   |         |     |     |    |         |     |
| Pre-wash  | 2  | Cold tap water            | N/A                    |                           |                   |          |   |                |     |        |   |                          |                 |         |   |                          |                 |       |   |                           |     |                      |   |         |     |     |    |         |     |
| Wash I  | 2  | Cold tap water (< 40 °C)  | Cleaning agent*        |                           |                   |          |   |                |     |        |   |                          |                 |         |   |                          |                 |       |   |                           |     |                      |   |         |     |     |    |         |     |
| Wash II   | 5  | Warm tap water (> 40 °C)  | Cleaning agent*        |                           |                   |          |   |                |     |        |   |                          |                 |         |   |                          |                 |       |   |                           |     |                      |   |         |     |     |    |         |     |
| Rinse   | 2  | Warm DI or PURW (> 40 °C) | N/A                    |                           |                   |          |   |                |     |        |   |                          |                 |         |   |                          |                 |       |   |                           |     |                      |   |         |     |     |    |         |     |
| Thermal Disinfection  | 5  | > 93 °C                   | N/A                    |                           |                   |          |   |                |     |        |   |                          |                 |         |   |                          |                 |       |   |                           |     |                      |   |         |     |     |    |         |     |
| Dry   | 40   | > 90 °C                   | N/A                    |                           |                   |          |   |                |     |        |   |                          |                 |         |   |                          |                 |       |   |                           |     |                      |   |         |     |     |    |         |     |
| <p><b>Thermal disinfection</b></p>                          | <p>For automated/mechanical washer cleaning, thermally disinfect at a minimum of 93 °C for a minimum of 5 minutes. For devices with cannulations or lumens, orient the part such that the lumen or cannulation is in a vertical position. If this is not possible due to space limitations within the automated/mechanical washer, use an irrigating rack/load carrier with connections designed to ensure an adequate flow of process fluids to the lumen or cannulation of the device if necessary.</p>  |                           |                        |                           |                   |          |   |                |     |        |   |                          |                 |         |   |                          |                 |       |   |                           |     |                      |   |         |     |     |    |         |     |

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| <b>Drying</b>     | <p>If a dry cycle is not included in the mechanical washer:</p> <ul style="list-style-type: none"> <li>– Dry each device thoroughly inside and out to prevent rusting and malfunction.</li> <li>– Use a clean, soft, lint-free single-use cloth to avoid damage to the surface.</li> </ul> <p>Pay special attention to threads, ratchets and hinges or areas where fluid can accumulate. Open and close devices so that all areas are reached. Dry hollow parts (lumens, cannulations) using the air jet with medical grade compressed air.</p>   |
| <b>Inspection</b> | <p>Synthes instruments should be inspected after processing, prior to sterilization, for:</p> <ul style="list-style-type: none"> <li>– Cleanliness</li> <li>– Damage, including but not limited to, corrosion (rust, pitting), discoloration, excessive scratches, flaking, cracks and wear</li> <li>– Proper function, including but not limited to, sharpness of cutting tools, bending of flexible devices, movement of hinges/joints/box locks and moveable features such as handles, ratcheting and couplings</li> <li>– Missing or removed (buffed off) part numbers, and wear</li> <li>– Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and worn devices should not be used.</li> </ul> <p>Check instruments for sound surfaces, and correct adjustment and function. Do not use severely damaged instruments, instruments with unrecognizable markings, corrosion, or blunt cutting surfaces. Further detailed function control instructions are available from your local sales representative or for download at <a href="http://emea.depuyssynthes.com/hcp/reprocessing-care-maintenance">http://emea.depuyssynthes.com/hcp/reprocessing-care-maintenance</a>.</p> <p>Lubricate instruments with moving parts, such as hinges and joints, spring-loaded ball bearings, and threaded parts. It is recommended to lubricate and maintain Synthes instruments with Synthes special oil only.</p> <p>Disassembled devices should be reassembled prior to sterilization unless otherwise noted or the case is not configured for the assembled device. Further detailed instrument dismantling instructions are available from your local sales representative or for download at <a href="http://emea.depuyssynthes.com/hcp/reprocessing-care-maintenance">http://emea.depuyssynthes.com/hcp/reprocessing-care-maintenance</a>.</p> |
| <b>Packaging</b>  | <p>Put cleaned, dry devices into the proper location in the Synthes case. Additionally, use an appropriate sterilization wrap or re-usable rigid container system for sterilization, such as a sterile barrier system according to ISO 11607. Care should be taken to protect implants, and pointed and sharp instruments from contact with other objects that may damage the surface.</p>  |

| <p><b>Sterilization</b></p>   | <p>The following are the recommendations for the sterilization of Synthes devices:</p>  |  |   |  |                   |           |   |        |            |   |   |        |
|---|---|--|---|--|-------------------|-----------|---|--------|------------|---|---|--------|
|   | <table border="1"> <thead> <tr> <th data-bbox="309 217 434 240">Cycle Type</th> <th data-bbox="461 217 658 261">Minimum Sterilization Exposure Time (minutes)</th> <th data-bbox="698 217 878 261">Minimum Sterilization Exposure Temperature</th> <th data-bbox="922 217 1031 261">Minimum Dry Time*</th> </tr> </thead> <tbody> <tr> <td data-bbox="309 272 463 296">Prevacuum</td> <td data-bbox="551 272 564 296">4</td> <td data-bbox="757 272 819 296">132 °C</td> <td data-bbox="945 272 1020 296">20 minutes</td> </tr> <tr> <td data-bbox="309 296 463 386"><i>Saturated steam-forced air removal (pre-vacuum) (minimum three pulses)</i></td> <td data-bbox="551 320 564 344">3</td> <td data-bbox="757 320 819 344">134 °C</td> <td data-bbox="945 320 1020 344">20 minutes</td> </tr> </tbody> </table>   | Cycle Type                                 | Minimum Sterilization Exposure Time (minutes) | Minimum Sterilization Exposure Temperature | Minimum Dry Time* | Prevacuum | 4 | 132 °C | 20 minutes | <i>Saturated steam-forced air removal (pre-vacuum) (minimum three pulses)</i> | 3 | 134 °C |
| Cycle Type  | Minimum Sterilization Exposure Time (minutes)   | Minimum Sterilization Exposure Temperature | Minimum Dry Time*                             |  |                   |           |   |        |            |   |   |        |
| Prevacuum   | 4   | 132 °C                                     | 20 minutes                                    |  |                   |           |   |        |            |   |   |        |
| <i>Saturated steam-forced air removal (pre-vacuum) (minimum three pulses)</i> | 3   | 134 °C                                     | 20 minutes                                    |  |                   |           |   |        |            |   |   |        |
| <p><b>Storage</b></p>   | <p>Packaged products should be stored in a dry, clean environment, protected from direct sunlight, pests, and extremes of temperature and humidity.</p>   |  |   |  |                   |           |   |        |            |   |   |        |
| <p><b>Additional Information</b></p>  | <p>Synthes used the following supplies during validation of these reprocessing recommendations. These supplies are not listed in preference to other available supplies which may perform satisfactorily. Cleaning Agent Information: deconex TWIN PH10, deconex POWER ZYME, and deconex TWIN ZYME. Lint-free cloth: Berkshire Durx 670.</p> <p>The cleaning and sterilization information is provided in accordance with ANSI/AAMIST81, ISO 17664, AAMI TIR 12, ISO 17665-1 and AAMI ST77.</p> <p>The recommendations provided above have been validated by the medical device manufacturer as being capable of preparing a non-sterile Synthes medical device. It remains the responsibility of the processor to ensure that the processing is actually performed using equipment, materials and personnel in the reprocessing facility, and achieves the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the recommendations provided should be properly evaluated for effectiveness and potential adverse consequences.</p> |  |   |  |                   |           |   |        |            |   |   |        |
| <p><b>Manufacturer Contact</b></p>  | <p>For further information, contact your local Synthes sales representative.</p>  |  |   |  |                   |           |   |        |            |   |   |        |

## Processing Non-sterile Synthes Implants

These recommendations are for processing non-sterile Synthes implants. The information provided applies to unused and unsoiled Synthes implants only. Explanted Synthes implants must never be reprocessed and should be handled according to hospital protocol upon removal. Any implant that has not been used, but has become soiled, should be handled according to hospital protocol. Do not reprocess soiled implants. These recommendations are to be followed unless otherwise noted on specific product inserts.

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|--------------------------------------|---|
| <p><b>Cautions</b></p>               | <ul style="list-style-type: none"> <li>– Any implant that has not been used, but has become soiled with blood, tissue and/or bodily fluids/matter, should be handled according to hospital protocol. Synthes does not recommend the reprocessing of soiled implants.</li> <li>– Synthes implants should not be lubricated.</li> <li>– Do not use a Synthes implant if the surface has been damaged.</li> <li>– Do not use steel wool or abrasive cleaners on Synthes implants.</li> <li>– Synthes implants should not be processed or transported with any type of soiled or contaminated materials.</li> <li>– Synthes implants are critical devices and must be terminally sterilized prior to use.</li> <li>– The sterilization parameters are only valid for devices that are adequately cleaned.</li> <li>– Only rigid sterilization containers approved for moist heat sterilization may be used with Synthes devices and loaded cases (a case with all or part of its assigned contents).</li> <li>– The parameters listed are only valid for properly installed, maintained, calibrated and compliant reprocessing equipment in accordance with ISO 15883 and ISO 17665.</li> <li>– Cleaning agents with a pH 7–9.5 are recommended. Cleaning agents with a pH-value up to 11 and higher than 11 respectively should only be used considering the data regarding material compatibility according to its data sheet. Refer to Material Compatibility of Synthes Instruments and Implants in Clinical Reprocessing.</li> <li>– The options in using rigid sterilization containers with Synthes devices and loaded cases are as follows:             <ul style="list-style-type: none"> <li>– No more than one (1) fully loaded case can be placed directly into a rigid sterilization container.</li> <li>– Instrument trays from no more than one (1) loaded case can be placed in the rigid sterilization container.</li> <li>– Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.</li> </ul> </li> <li>– Rigid sterilization container must have a maximum volume to vent ratio of no greater than 322 cm<sup>3</sup>/cm<sup>2</sup>.</li> <li>– Only rigid sterilization containers approved for pre-vacuum steam sterilization can be used with Synthes devices and loaded cases.</li> <li>– The following parameters are only valid for properly installed, maintained, calibrated and compliant reprocessing equipment.</li> <li>– Consult national regulations and guidelines for additional information. Compliance is additionally required with internal hospital policies and procedures and recommendations of manufacturers of detergents, disinfectants, and any clinical processing equipment.</li> </ul> |
| <p><b>Limits on reprocessing</b></p> | <ul style="list-style-type: none"> <li>– Repeated processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on Synthes implants.</li> <li>– Synthes implants should be inspected for corrosion, damage such as scratches and notches, debris, discoloration or residue.</li> <li>– A discoloration has no adverse effect on titanium or titanium alloy implants. The protective oxide layer is fully maintained.</li> <li>– Any implant with corrosion, scratches, notches, residue or debris should be discarded.</li> </ul>  |

10 Processing Instructions

| <p><b>Point of Use Care</b></p>   | <ul style="list-style-type: none"> <li>– Implants should remain covered until needed to avoid becoming soiled or contaminated. Only those to be implanted should be handled.</li> <li>– Minimal handling of implants is necessary to prevent damage to the surface.</li> </ul>  |                           |                        |                           |                   |          |   |                |     |        |   |                          |                 |         |   |                          |                 |       |   |                           |     |                      |   |         |     |     |    |         |     |
|---|---|---------------------------|------------------------|---------------------------|-------------------|----------|---|----------------|-----|--------|---|--------------------------|-----------------|---------|---|--------------------------|-----------------|-------|---|---------------------------|-----|----------------------|---|---------|-----|-----|----|---------|-----|
| <p><b>Containment and Transportation</b></p>                            | <ul style="list-style-type: none"> <li>– Implants should not come in contact with soiled devices and/or equipment.</li> <li>– Avoid cross contamination of implants with soiled instruments during transport.</li> </ul>  |                           |                        |                           |                   |          |   |                |     |        |   |                          |                 |         |   |                          |                 |       |   |                           |     |                      |   |         |     |     |    |         |     |
| <p><b>Preparation for Processing</b></p>                                | <ul style="list-style-type: none"> <li>– Synthes does not recommend the reprocessing of soiled implants.</li> </ul>   |                           |                        |                           |                   |          |   |                |     |        |   |                          |                 |         |   |                          |                 |       |   |                           |     |                      |   |         |     |     |    |         |     |
| <p><b>Cleaning and disinfection – Manual Method with ultrasonic</b></p> | <p>Equipment: ultrasonic cleaner, enzymatic cleaner or detergent solution, clean soft lint-free cloths.</p> <ol style="list-style-type: none"> <li>1. Prepare a fresh detergent solution using enzymatic cleaner or detergent solution. Follow the enzymatic cleaner or detergent manufacturer's instructions for the correct dilution, temperature, water quality and exposure time.<br/><i>Note: a fresh solution is a newly-made, clean solution.</i></li> <li>2. Clean Synthes implant ultrasonically for a minimum of 15 minutes.</li> <li>3. Rinse implant using DI or PURW water for a minimum of two minutes. DI or PURW water must be used for final rinse.</li> <li>4. Dry implant using a clean, soft, lint-free single-use cloth or medical grade compressed air.</li> </ol>  |                           |                        |                           |                   |          |   |                |     |        |   |                          |                 |         |   |                          |                 |       |   |                           |     |                      |   |         |     |     |    |         |     |
| <p><b>Cleaning – Automated/ Mechanical washer Method</b></p>            | <p>Equipment: washer/disinfector, enzymatic cleaner or detergent solution<br/>Use the following cycle parameters:</p> <table border="1" data-bbox="314 794 1020 1054"> <thead> <tr> <th>Cycle</th> <th>Minimum Time (minutes)</th> <th>Minimum Temperature/Water</th> <th>Type of Detergent</th> </tr> </thead> <tbody> <tr> <td>Pre-wash</td> <td>2</td> <td>Cold tap water</td> <td>N/A</td> </tr> <tr> <td>Wash I</td> <td>2</td> <td>Cold tap water (&lt; 40 °C)</td> <td>Cleaning agent*</td> </tr> <tr> <td>Wash II</td> <td>5</td> <td>Warm tap water (&gt; 40 °C)</td> <td>Cleaning agent*</td> </tr> <tr> <td>Rinse</td> <td>2</td> <td>Warm DI or PURW (&gt; 40 °C)</td> <td>N/A</td> </tr> <tr> <td>Thermal Disinfection</td> <td>5</td> <td>&gt; 93 °C</td> <td>N/A</td> </tr> <tr> <td>Dry</td> <td>40</td> <td>&gt; 90 °C</td> <td>N/A</td> </tr> </tbody> </table> <p>* see Additional Information</p> | Cycle                     | Minimum Time (minutes) | Minimum Temperature/Water | Type of Detergent | Pre-wash | 2 | Cold tap water | N/A | Wash I | 2 | Cold tap water (< 40 °C) | Cleaning agent* | Wash II | 5 | Warm tap water (> 40 °C) | Cleaning agent* | Rinse | 2 | Warm DI or PURW (> 40 °C) | N/A | Thermal Disinfection | 5 | > 93 °C | N/A | Dry | 40 | > 90 °C | N/A |
| Cycle   | Minimum Time (minutes)  | Minimum Temperature/Water | Type of Detergent      |                           |                   |          |   |                |     |        |   |                          |                 |         |   |                          |                 |       |   |                           |     |                      |   |         |     |     |    |         |     |
| Pre-wash  | 2   | Cold tap water            | N/A                    |                           |                   |          |   |                |     |        |   |                          |                 |         |   |                          |                 |       |   |                           |     |                      |   |         |     |     |    |         |     |
| Wash I  | 2   | Cold tap water (< 40 °C)  | Cleaning agent*        |                           |                   |          |   |                |     |        |   |                          |                 |         |   |                          |                 |       |   |                           |     |                      |   |         |     |     |    |         |     |
| Wash II   | 5   | Warm tap water (> 40 °C)  | Cleaning agent*        |                           |                   |          |   |                |     |        |   |                          |                 |         |   |                          |                 |       |   |                           |     |                      |   |         |     |     |    |         |     |
| Rinse   | 2   | Warm DI or PURW (> 40 °C) | N/A                    |                           |                   |          |   |                |     |        |   |                          |                 |         |   |                          |                 |       |   |                           |     |                      |   |         |     |     |    |         |     |
| Thermal Disinfection  | 5   | > 93 °C                   | N/A                    |                           |                   |          |   |                |     |        |   |                          |                 |         |   |                          |                 |       |   |                           |     |                      |   |         |     |     |    |         |     |
| Dry   | 40  | > 90 °C                   | N/A                    |                           |                   |          |   |                |     |        |   |                          |                 |         |   |                          |                 |       |   |                           |     |                      |   |         |     |     |    |         |     |
| <p><b>Thermal disinfection</b></p>                                      | <ul style="list-style-type: none"> <li>– For automated/mechanical washer cleaning, thermally disinfect at a minimum of 93 °C for a minimum of 5 minutes.</li> </ul>   |                           |                        |                           |                   |          |   |                |     |        |   |                          |                 |         |   |                          |                 |       |   |                           |     |                      |   |         |     |     |    |         |     |
| <p><b>Inspection</b></p>  | <ul style="list-style-type: none"> <li>– Synthes implants should be inspected after processing, prior to sterilization.</li> <li>– Any implant with corrosion, scratches, flaws, residue or debris should be discarded.</li> </ul>  |                           |                        |                           |                   |          |   |                |     |        |   |                          |                 |         |   |                          |                 |       |   |                           |     |                      |   |         |     |     |    |         |     |
| <p><b>Packaging</b></p>   | <ul style="list-style-type: none"> <li>– Put cleaned, dry implants into the proper location in the Synthes case. Additionally, use an appropriate sterilization wrap or re-usable rigid container system for sterilization, such as a sterile barrier system according to ISO 11607. Care should be taken to protect implants, and pointed and sharp instruments from contact with other objects that may damage the surface.</li> </ul>  |                           |                        |                           |                   |          |   |                |     |        |   |                          |                 |         |   |                          |                 |       |   |                           |     |                      |   |         |     |     |    |         |     |

|                      | The following are the recommendations for the sterilization of Synthes implants:  |   |  |                   |
|----------------------|---|---|--|-------------------|
|                      | Cycle Type  | Minimum Sterilization Exposure Time (minutes) | Minimum Sterilization Exposure Temperature | Minimum Dry Time* |
|                      | Prevacuum   | 4   | 132 °C                                     | 20 minutes        |
|                      | <i>Saturated steam-forced air removal (pre-vacuum) (minimum three pulses)</i>   | 3   | 134 °C                                     | 20 minutes        |
| <b>Sterilization</b> | <p>* When applying dry times to Synthes cases and their accessories, dry times outside the standard healthcare prevacuum parameters may be required. This is especially important for polymer-based (plastic) cases/trays used in conjunction with heavy duty nonwoven sterilization wraps. The current recommended dry times for Synthes cases can range from a standard 20 minutes to an extended time of 60 minutes. The dry time is most often influenced by the presence of polymer based (plastic) materials; therefore, changes such as elimination of silicone mats and/or change in sterile barrier system (e.g. heavy grade to light grade wrap or the use of rigid sterilization containers) can reduce the necessary dry time. Dry times may be highly variable due to differences in packaging materials (e.g. nonwoven wraps), environmental conditions, steam quality, implant materials, total mass, sterilizer performance and varying cool down time. The user should employ verifiable methods (e.g. visual inspections) to confirm adequate drying.</p> <ul style="list-style-type: none"> <li>– The autoclave manufacturer’s operating instructions and recommended guidelines for maximum sterilization load should be followed. The autoclave must be properly installed, maintained, and calibrated. Only legally marketed, sterilization barriers (e.g. wraps, pouches or containers) should be used by the enduser for packaging terminally sterilized devices.</li> <li>– For product sold sterile, refer to device-specific insert for regarding resterilization.</li> <li>– Rigid Sterilization Container Use Instructions and Considerations<br/>In order to ensure proper sterilization of Synthes implants when using a rigid sterilization container, the following must be taken into consideration: <ul style="list-style-type: none"> <li>– The rigid sterilization container manufacturer’s instructions for use are to be followed. If questions arise regarding the use of the rigid sterilization container, Synthes recommends contacting the manufacturer of that specific container for guidance.</li> <li>– The options in using rigid sterilization containers with Synthes devices and loaded cases are as follows: <ul style="list-style-type: none"> <li>– No more than one (1) fully loaded case can be placed directly into a rigid sterilization container.</li> <li>– Instrument trays from no more than one (1) loaded case can be placed in the rigid sterilization container.</li> <li>– Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.</li> </ul> </li> <li>– When selecting a rigid sterilization container for Synthes devices and loaded cases, the rigid sterilization container must have a maximum volume to vent ratio of no greater than 322 cm<sup>3</sup>/cm<sup>2</sup>. For any questions related to the volume to vent ratio, please contact the container manufacturer.</li> <li>– Only rigid sterilization containers approved for pre-vacuum steam sterilization can be used with Synthes devices and loaded cases following the parameters provided in the table above.</li> </ul> </li> </ul> |   |  |                   |

12

|                               |   |
|-------------------------------|---|
| <b>Additional Information</b> | <ul style="list-style-type: none"> <li>– Synthes used the following supplies during validation of these reprocessing recommendations. These supplies are not listed in preference to other available supplies which may perform satisfactorily. Cleaning Agent Information: deconex TWIN PH10, deconex POWER ZYME, and deconex TWIN ZYME. Lint-free cloth: Berkshire Durx 670.</li> <li>– The cleaning and sterilization information is provided in accordance with ANSI/ AAMIST81, ISO 17664, AAMI TIR 12, ISO 17665-1 and AAMI ST77.</li> <li>– The recommendations provided above have been validated by the medical device manufacturer as being capable of cleaning and sterilizing a non-sterile Synthes medical device implants prior to surgical use. It remains the responsibility of the processor to ensure that the processing is actually performed using equipment, materials and personnel in the reprocessing facility, and achieves the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the recommendations provided should be properly evaluated for effectiveness and potential adverse consequences.</li> </ul> |
| <b>Manufacturer Contact</b>   | For further information, contact your local Synthes sales representative.   |

## Material Compatibility of Synthes Instruments and Implants in Clinical Processing

### Synthes Instrument Materials

Knowledge of the materials used and their properties is essential for ensuring that instruments are proficiently processed and maintained.

#### Stainless steels

Synthes instruments are made predominantly from corrosion-resistant steels, recognizable by their shiny or dull metallic color. As a result of their high chromium and nickel content, corrosion-resistant steels form a protective chromium oxide layer, known as a passive layer, on the metal surface. This passive layer protects the instrument against corrosion and rust. Incorrect or careless handling (e.g. damage to the surface) and attacks of a chemical, electrochemical or physical nature, can adversely affect the corrosion resistance.

Two types of stainless steels are used, differentiated based on their composition and properties:

- Martensitic steels, which are corrosion resistant and whose high hardness can be influenced and adjusted by heat treatment, possess high wear resistance and high cutting edge retention. These steels are used for cutting and sharp-pointed instruments, e.g. drill bits, reamer heads, awl, burrs or cutting edges of pliers.
- Austenitic steels, which cannot be hardened by heat treatment, possess high corrosion resistance, elasticity and toughness, and are generally non-magnetic. These steels are used for non-cutting instruments, e.g. drill guides, gauges and aiming devices.
- Synthes recommends disinfectants, cleaners or detergents with pH 7–11 for all stainless steels.

#### Aluminum, titanium and its alloys

Since aluminum is a lightweight material it is used, for example, for the graphic cases, instrument handles and certain other instrument parts. An electrochemical surface treatment (anodizing, "Ematal" or hard anodizing) produces a resistant oxide layer on the aluminum, which can be dyed.

Titanium and titanium alloys are widely used as implant materials. On instruments titanium is used for only a few applications, mainly color coding of instruments. The surface of titanium alloys is also treated electrochemically (anodizing), producing a resistant oxide layer. Various color shades can be applied using this layer.

Although anodized aluminum, titanium and its alloys have good corrosion resistance, contact with strong alkaline detergents or disinfectants and solutions containing iodine or certain metal salts can lead to chemical attack and dissolution of the surface depending on the specific composition of the detergent.

Consequently, Synthes recommends disinfectants, cleaners or detergents with pH 6–9.5. Products with a higher pH value, especially higher than pH 11, should only be used subject to the material compatibility requirements stated on the data sheet and other information from the manufacturer of the detergent.

#### Plastics

Various plastics are used for certain instrument parts, e.g. handles, radiolucent parts. In addition to pure plastics composite materials are also used in some cases, e.g. wood-looking phenolic resin reinforced with fabric for handles of screwdrivers, raspatories, chisels, etc, or carbon-fiber reinforced plastics for aiming arms.

All used plastics are able to withstand correct processing. Some of the plastics can become soft during steam sterilization, but do not undergo permanent deformation at normal sterilization temperatures below 140°C. The material can, however, be damaged, for example by repeated immersion in disinfectants outside the pH range of 4–9.5 and by overstraining. Also, some rinsing aids can lead to discoloration or embrittlement of plastics and composites by repeated use.

#### Recommended temperatures and pH levels

| Material        | Temperature* | pH    |
|-----------------|--------------|-------|
| Stainless steel | up to 149°C  | 7–11  |
| Aluminum        | up to 150°C  | 6–9.5 |
| Titanium alloys | up to 150°C  | 6–9.5 |
| Plastics        | up to 140°C  | 4–9.5 |
| Nitinol         | up to 149°C  | 6–9.5 |

\* The recommended processing temperatures take into account material properties and internally validated parameters for processing.

## 14 Causes of Corrosion and Surface Change or Damage

The surface of the instruments can be attacked and damaged by incorrect handling or contact with various substances. Awareness of the following possible causes of corrosion and material damage can help to avoid their occurrence.

### **Blood, pus, secretions etc.**

Most human body fluids and residues contain chlorine ions, which can lead to corrosion if left to adhere to, or dry on, the instrument for prolonged periods. Instruments should therefore be cleaned and dried immediately after every use.

### **Saline solutions, iodine tinctures, water**

The chlorine and iodine ions in these solutions cause pitting corrosion. Keep any contact with these ions to a minimum. Rinse instruments thoroughly with distilled water\* to remove all residues.

Normal tap water often also contains chlorides, as well as high concentrations of other minerals, which can form marks with sharply defined edges on the instrument surface. These can usually be removed with distilled water\* and non-abrasive stainless steel cleaners. Never leave wet instruments lying around; always dry them immediately. Condensation moisture produced during sterilization can be avoided by prolonging the drying phase.

### **Detergents, disinfectants, rinsing aids and other additives**

Excessive concentrations of these products or strongly acidic or alkaline detergents can attack the protective oxide layer of stainless steel, titanium and aluminum and lead to corrosion, discoloration or other changes of the materials, properties and surface conditions. When using such products, always follow the manufacturer's recommendations in respect of concentrations, contact times, temperatures and material compatibility. Products with pH levels between 7 and 9.5 are recommended. During repeated and prolonged use some rinsing aids can attack certain plastics and lead to discoloration or embrittlement. If the instruments are cleaned in an automated washer-disinfector, follow the directions of the manufacturers of the washer-disinfector, detergents, rinsing aids and other additives.

### **Steel wool, steel brushes, files and other abrasive cleaning tools**

Never use extra fine or normal steel wool, steel brushes, files or other cleaning tools with abrasive effect on metals to clean surgical instruments, as this will result in mechanical damage to the passive layer, leading to corrosion and malfunction.

### **Contact between instruments made from different metals**

If stainless steel instruments are left in contact for long periods with surface-damaged instruments and are simultaneously moistened with an electrolyte, rust can form at the points of contact. Steam, water, ultrasonic cleaning solutions or other liquids and solutions can act as electrolytes. Such phenomena are occasionally observed during automated cleaning. Corrosion products that have already formed can also be transferred to other instruments by electrolytes, thereby producing surface rust. If possible, instruments made from differing materials should be cleaned and sterilized separately. Consequently, instruments with corrosion or rust spots must always be excluded and exchanged for unblemished ones. Instruments should be cleaned in their opened and dismantled state in order to avoid not only insufficient cleaning but also crevice and fretting corrosion. The passive layer in crevices or joint gaps can be damaged by chemical or mechanical action, leading to corrosion.

### **Inadequate lubrication**

Moving instrument parts, e.g. joints, sliding parts, dismantable threaded connections etc. must be regularly lubricated. Constant metallic abrasion increases the damage to the passive layer and thus greatly increases the risk of corrosion.

### **Detergent residues in packing cloths**

Cloths used to pack the devices must be free of detergent or other residues. Such residues can be transferred to the device surface via steam and can interact with the surface.

### **Overstressing of instruments**

Instruments are designed only for a specific purpose and must be used accordingly. Inappropriate use can lead to mechanical overstressing, malfunction and permanent instrument damage, and this in turn increases their susceptibility to corrosion.

### **Note on latex**

Because Synthes instruments do not contain any latex, they can safely be used for patients with a latex allergy.

### **Note on Synthes Special Oil**

Synthes Special Oil is a synthetic oil and non-toxic. It is recommended to lubricate and maintain Synthes instruments only with Synthes special oil.

\* A conductivity of < 0.5 µS is recommended for distilled water.

## **Repair of Synthes instruments and ordering of spare parts**

Defective instruments can be sent to your local Synthes customer service for repair. Customer service will assess whether the instrument can be repaired. Make sure that you enclose a delivery note with the defective instrument containing the following information:

- Hospital address, contact person and telephone number
- Article number of the defective instrument being returned
- Description of the problem

If you send in power tools for repair, loan machines can be made available (if in stock), allowing you to continue performing operations. Consult your local customer service for information on the availability of loan machines.

Your local customer service can deliver spare parts for defective or missing components of simple, multi-part instruments (e.g. depth gauges, drill sleeves). Consult your local customer service for information on the availability of spare parts.

# Interpretation of symbols

16



Reference number



Lot or batch number



Serial number



Manufacturer



Authorized representative



2008-12  
Manufacturing date



2008-12  
Expiration date



Non-sterile



Sterile



Sterilized using irradiation



Sterilized using ethylene oxide



Do not re-use



Do not re-sterilize



Do not use if packaging is damaged



Contains or presence of natural rubber latex

**SSt**

Material

Stainless steel

**TiCP**

Pure titanium

**TAN**  
**(Ti6Al7Nb)**

Material Titanium-aluminium-niobium alloy

**TAV**  
**(Ti6Al4V)**

Titanium-aluminium-vanadium alloy



European Conformity



Notified body



Caution, see instructions for use



Consult instruction for use



Temperature indicator



Sterilization indicator



Temperature limitation



Upper limit of temperature



Lower limit of temperature



Keep dry



Keep away from sunlight



MR Conditional





