Instructions for Use
Torque Limiting Instruments

This instruction for use is not intended for distribution in the USA.

Not all products are currently available in all markets.

Manuals are subject to change;
the most current version of each
manual is always available online.
Printed on: Jul 23, 2021

DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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SE_827954 AA 10/2020

Instructions for Use

Torque Limiting Instruments

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Torque Limiters (Power Driven)
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Introduction
Torque Limiting Instruments are small devices to attach to a surgical power tool or a manual surgical instrument to define the torque of that tool allowing the surgeon to apply the correct torque, when tightening an orthopedic screw during surgery.

Torque Limiting Instruments are available in various shapes, sizes and torque ranges, and they include a built-in clutch mechanism. The devices provide an indication to the surgeons when the pre-set torque level is reached with an audible click and release rotational traction. Torque Limiting Instruments are reusable devices and are offered non-sterile packed.

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Intended Use
Torque Limiting Instruments are intended to limit the tightening torque of the screws/nuts during orthopedic surgery.

Indications
Synthes manufactures surgical instruments intended to prepare the site and aid in implantation of Synthes implants. The indications/contraindications are based upon the implant devices rather than the instruments. Specific indications/contraindications for the implants can be found in the respective Synthes implant instructions for use.

Contraindications
Synthes manufactures surgical instruments intended to prepare the site and aid in implantation of Synthes implants. The indications/contraindications are based upon the implant devices rather than the instruments. Specific indications/contraindications for the implants can be found in the respective Synthes implant instructions for use.

Patient Target Group
Synthes manufactures surgical instruments intended to prepare the site and aid in implantation of Synthes implants. The patient target group is based upon the implant devices rather than the instruments. Specific patient target group for the implants can be found in the respective Synthes implant instructions for use.

Intended User
This IFU alone does not provide sufficient background for direct use of the Device or System. Instruction by a surgeon experienced in handling these devices is highly recommended.

This device is intended to be used by qualified health care professionals e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device. All personnel handling the device should be fully aware of the IFU, the surgical procedures, if applicable, and /or the Synthes `Important Information` brochure as appropriate.

Expected Clinical Benefits
Synthes manufactures surgical instruments intended to prepare the site and aid in implantation of Synthes implants. The clinical benefits for the instruments are based upon the implant devices rather than the instruments. Specific clinical benefits for the implants can be found in the respective Synthes implant instructions for use.

Performance Characteristics of the Device
Synthes has established the performance and safety of Torque Limiting Instruments and that they represent state of the art medical devices for allowing the surgeon to apply the correct torque for tightening an orthopedic screw during surgery when used according to their instructions for use and labeling.

Potential Adverse Events, Undesirable Side Effects and Residual Risks
Synthes manufactures surgical instruments intended to prepare the site and aid in implantation of Synthes implants. The adverse events/side effects are based upon the implant devices rather than the instruments. Specific adverse events/side effects for the implants can be found in the respective Synthes implant instructions for use.

Combination of Medical Devices
Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Treatment before Device is Used

Non-Sterile Device:
Synthes products supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the Synthes brochure "Important Information".

Troubleshooting
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Clinical Processing of the Device
Detailed instructions for processing of implants and reprocessing of reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling multipart instruments" are available on the website.

Reprocessing instructions for Torque Limiters deviate from the general reprocessing instructions and are listed below.

511.773, 03.110.002, 511.774, 511.776, 511.777, 511.115 and 03.140.023

Specific cautions for Torque Limiters
- For general cautions please refer to Synthes brochure "Important Information".
- Torque limiters should not be immersed in water or cleaning solution.
- Do not clean torque limiters ultrasonically.
- 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 in Important Information" at www.e-ifu.com.
- The following maximum values may not be exceeded: 143 °C over a maximum of 22 minutes. Higher values can damage the sterilized products.
- Do not accelerate the cooling process.
- Hot air, ethylene oxide, plasma and formaldehyde sterilization are not recommended.

Limits on reprocessing
- Frequent reprocessing does not have a great effect on the life of the Torque Limiters. 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.
- Torque Limiters are frequently exposed to high mechanical loads and shocks during use and should not be expected to last indefinitely. Proper handling and maintenance help extend the useful life of surgical instruments.

– Synthes recommends annual servicing and inspection by the original manufacturer or its exclusive sales outlets. The manufacturer assumes no warranty for damages arising from improper use or unauthorized servicing.

Clinical Reprocessing Instructions
Point of Use Care
– Wipe blood and/or debris from device throughout surgical procedure to prevent it from drying onto the surface.
– Flush cannulated devices with sterile or purified water to prevent the drying of soil and/or debris to the inside.
– Soiled devices should be separated from non-contaminated devices to avoid contamination of personnel or surroundings.
– Devices should be covered with a towel dampened with sterile or purified water to prevent blood and/or debris from drying.

Containment and transportation
– Soiled devices should be transported separate from non-contaminated devices to avoid contamination.

Preparation for decontamination (for all cleaning methods)
– It is recommended that devices be reprocessed as soon as is reasonably practical following use.
– Lumens/cannula of Torque Limiters 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 have 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.
– Rinse Torque Limiters 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.
– 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.

Cleaning – Manual method
Equipment: various sized soft-bristled brushes, lint-free cloths, syringes, pipettes and/or water jet, enzymatic cleaner or detergent solution.

Step	Duration (Minimum)	Cleaning Instructions
1	3 minutes	Rinse device under running cold tap water. Use a sponge, soft lintfree cloth and/or soft-bristled brush to assist in the removal of gross soil and debris. Clean all cannulations with a cleaning brush. Manipulate the moving coupling portion of the handle (collar) under running cold tap water to loosen and remove gross debris. **Note:** Do not use pointed objects for cleaning.
2	3 minutes	Spray and wipe device using an enzymatic cleaner or detergent solution or foam spray. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct temperature, water quality and concentration/dilution.
3	2 minutes	Rinse device with cold tap water. Use a syringe, pipette or water jet to flush lumens, channels and other hard-to-reach areas.
4	5 minutes	Clean device manually under running water using an enzymatic cleaner or detergent. Manipulate all moving parts under running water. Use a soft- bristled brush and/or soft lint-free cloth to remove all visible soil and debris. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct temperature, water quality and concentration/dilution.
5	2 minutes	Rinse device thoroughly using running cool to lukewarm water. Use a syringe, pipette or water jet to flush lumens and channels. Actuate the moving coupling portion of the handle (collar) in order to rinse thoroughly under running water.
6	Visually inspect device. Inspect the cannulations, coupling sleeves, etc. for visible soil. Repeat steps 1–5 until no visible soil remains.	
7	2 minutes	Final rinse with de-ionized or purified water.
8	Dry device using a soft lint-free cloth or clean compressed air.	

Cleaning – Automated/Mechanical washer method
Equipment: washer/disinfector, various sized soft-bristled brushes, lint-free cloths, syringes, pipettes and/or water jet, enzymatic cleaner or detergent solution.
Pre-clean method (Pre-clean method must be performed prior to mechanical washer method listed below.)

Note: Manual pre-cleaning prior to mechanical/automated cleaning and disinfection is important to ensure cannulations and other difficult-to-access areas are clean. Manual pre-cleaning as described below must be followed by the mechanical/automated cleaning procedure.

Step	Duration (Minimum)	Cleaning Instructions
1	2 minutes	Rinse device under running cold tap water. Use a sponge, soft lintfree cloth and/or soft-bristled brush to assist in the removal of gross soil and debris. Clean all cannulations with a cleaning brush. Manipulate the moving coupling portion of the handle (collar) under running cold tap water to loosen and remove gross debris. **Note:** Do not use pointed objects for cleaning.
2	2 minutes	Spray and wipe device using an enzymatic cleaner or detergent solution or foam spray. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct temperature, water quality and concentration/dilution.
3	5 minutes	Clean device manually under running water using an enzymatic cleaner or detergent. Manipulate all moving parts under running water. Use a soft-bristled brush and/or soft lint-free cloth to remove all visible soil and debris. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct temperature, water quality and concentration/dilution.
4	2 minutes	Rinse device thoroughly using running cool to lukewarm water. Use a syringe, pipette or water jet to flush lumens and channels. Actuate the moving coupling portion of the handle (collar) in order to rinse thoroughly under running water.
5	Visually inspect device. Repeat steps 1–5 until no visible soil remains.	
6	Load washing basket*. Ensure that all cannulations, if applicable, are positioned vertically, i.e., in an upright position.	

Mechanical Washer process: (Pre-cleaning steps 1–6 should occur prior to this step.)
Note: The washer/disinfector should fulfill requirements specified in ISO 15883. Use MIS injector unit to process lumens and cannulations.

7 Process device using the following cycle parameters:

Step	Duration (Minimum)	Cleaning Instructions	Type of Detergent
Rinse	2 minutes	Cold tap water	N/A
Pre-wash	1 minute	Warm water (≥ 40 °C)	Cleaning agent*
Cleaning	2 minutes	Warm water (≥ 45 °C)	Cleaning agent*
Rinse	5 minutes	Rinse with de-ionized (DI) or purified (PURW) water	N/A
Thermal disinfection	5 minutes	Hot DI water, ≥ 93 °C	N/A
Dry	40 minutes	≥ 90 °C	N/A

* see additional information

Thermal disinfection
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 so 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.

Drying
If a dry cycle is not included in the mechanical washer:
– Dry each device thoroughly inside and out to prevent rusting and malfunction.
– Use a clean, soft lint-free single-use cloth to avoid damage to the surface.
– 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.

Inspection
Synthes instruments should be inspected after processing, prior to sterilization, for:
– Cleanliness
– Cleanliness of cannulation
– Moving coupling portion (collar) and fix coupling portion for visible soil
– Damage, including but not limited to, corrosion (rust, pitting), discoloration, excessive scratches, flaking, cracks and wear
– Missing or removed (buffed off) part numbers and wear
– Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and worn devices should not be used.

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 www.e-ifu.com.

Lubricate Torque Limiters. It is recommended to lubricate and maintain Synthes instruments with Synthes special oil (519.970) only.
Note: Mechanical cleaning/disinfection is an additional stress for the Torque Limiter, especially for seals. Therefore, systems must be properly lubricated and regularly sent to be serviced.

Packaging
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.

Sterilization
The following are the recommendations for the sterilization of Synthes devices:

Cycle type	Minimum sterilization exposure time (minutes)	Sterilization exposure temperature	Dry time
Saturated steam-forced air removal (pre-vacuum) (minimum three pulses)	4	Minimum 132 °C Maximum 138 °C	20–60 minutes
	3	Minimum 132 °C Maximum 138 °C	20–60 minutes

When applying dry times to Synthes cases and their accessories, dry times outside the standard healthcare pre-vacuum 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 (i.e. heavy grade to light grade wrap) 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, device materials, total mass, sterilizer performance and varying cool-down time. The user should employ verifiable methods (e.g. visual inspections) to confirm adequate drying. Dry times generally range from 20 to 60 minutes due to differences in packaging materials (sterile barrier system, e.g. wraps or re-usable rigid container systems), steam quality, device materials, total mass, sterilizer performance, and varying cool-down time.

The autoclave manufacturer's operating instructions and recommended guidelines for maximum sterilization load should be followed. The autoclave must be properly installed, maintained, validated and calibrated.

Storage
Packaged products should be stored in a dry, clean environment, protected from direct sunlight, pests, and extremes of temperature and humidity.

Additional information
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, deconex TWIN ZYME, and Johnson & Johnson Enzol. Lint-free cloth: Berkshire Durx 670. Washing basket Synthes 68.001.606.

The cleaning and sterilization information is provided in accordance with ANSI/AAMIST81, ISO 17664, AAMI TIR 12, ISO 17665-1 and AAMI ST77.

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 in monitoring the process. Likewise, any deviation by the processor from the recommendations provided should be properly evaluated for effectiveness and potential adverse consequences.

Reprocessing instructions for the below Torque Limiting Instrument deviate from the general reprocessing instructions and are listed below.
03.127.016

General Information
Torque limiting devices are frequently exposed to high mechanical loads and shocks during use and should not be expected to last indefinitely. Proper handling and maintenance help extend the useful life of surgical instruments.
Frequent reprocessing does not have a great effect on the life of the unit and attachments. Gentle care and maintenance with proper lubrication can substantially increase the reliability and life of the system components.

Synthes recommends annual servicing and inspection by the original manufacturer or its exclusive sales outlets. The manufacturer assumes no warranty for damages arising from improper use or unauthorized servicing.

Caution
– Reprocessing must be performed immediately after each use.
– Cannulations, unlocking sleeves and other narrow sites require special attention during cleaning.
– Cleaners with a pH 7–9.5 are recommended. The use of cleaners with higher pH values can – depending on the cleaner – cause a dissolution of the surface of aluminum and its alloys, plastics or compound materials; they should only be used considering the data regarding material compatibility according to its data sheet. At pH values higher than 11 also the surfaces of stainless steel can be affected. For detailed information about material compatibility, see "Material Compatibility of Synthes Instruments in Important Information" at www.e-ifu.com.

Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct dilution concentration, temperature, exposure time, and water quality. If temperature and time are not provided, follow Synthes recommendations. Devices should be cleaned in a fresh, newly made solution.
– Alternative cleaning/disinfection procedures other than in the procedure described below (including manual pre-cleaning) have not been validated by Synthes.

Unusual Transmissible Pathogens
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.

Important
The clinical processing instructions provided have been validated by Synthes for preparing a nonsterile Synthes medical device; this instruction is provided in accordance with ISO 17664:2004 and ANSI/AAMI ST81:2004.
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. It remains the responsibility of the processor to ensure that the processing performed achieves the desired result using the appropriate properly installed, maintained, and validated equipment, materials, and personnel in the processing unit. Any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

Cleaning and Sterilization Instruction
Torque Limiting Handle 03.127.016 may be processed using
a) manual cleaning or
b) automated cleaning with manual pre-cleaning

Preparation prior to cleaning
Remove the screwdriver shaft from the Torque Limiting Handle prior to treatment. Do not disassemble the handle itself. Further detailed instrument dismantling instructions are available for download at www.e-ifu.com.

Cleaning – Manual method

Step	Duration (Minimum)	Cleaning Instructions
1	3 minutes	Rinse device under running cold tap water. Use a sponge, soft lintfree cloth and/or soft-bristled brush to assist in the removal of gross soil and debris. Clean all cannulations with a cleaning brush. Manipulate the moving coupling portion of the handle (collar) under running cold tap water to loosen and remove gross debris. **Note:** Do not use pointed objects for cleaning.
2	3 minutes	Spray and wipe device using an enzymatic cleaner or detergent solution or foam spray. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct temperature, water quality and concentrations/dilution.
3	2 minutes	Rinse device with cold tap water. Use a syringe, pipette or water jet to flush lumens, channels and other hard-to-reach areas.
4	5 minutes	Clean device manually under running water using an enzymatic cleaner or detergent. Manipulate all moving parts under running water. Use a soft- bristled brush and/or soft lint-free cloth to remove all visible soil and debris. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct temperature, water quality and concentrations/dilution.
5	2 minutes	Rinse device thoroughly using running cool to lukewarm water. Use a syringe, pipette or water jet to flush lumens and channels. Actuate the moving coupling portion of the handle (collar) in order to rinse thoroughly under running water.
6	Visually inspect device. Inspect the cannulations, coupling sleeves, etc. for visible soil. Repeat Steps 1–6 until no visible soil remains.	
7	2 minutes	Final rinse with de-ionized or purified water.
8	Dry device using a soft lint-free cloth or clean compressed air.	

Cleaning – Automated/Mechanical washer method
Manual pre-cleaning
Note: Manual pre-cleaning prior to mechanical/automated cleaning and disinfection is important to ensure cannulations and other difficult-to-access areas are clean. Manual pre-cleaning as described below must be followed by the mechanical/automated cleaning procedure.

Step	Duration (Minimum)	Cleaning Instructions
1	2 minutes	Rinse device under running cold tap water. Use a sponge, soft lint free cloth and/or soft-bristled brush to assist in the removal of gross soil and debris. Clean all cannulations with a cleaning brush. Manipulate the moving coupling portion of the handle (collar) under running cold tap water to loosen and remove gross debris. **Note:** Do not use pointed objects for cleaning.
2	2 minutes	Spray and wipe device using an enzymatic cleaner or detergent solution or foam spay. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct temperature, water quality and concentrations/dilution.
3	5 minutes	Clean device manually under running water using an enzymatic cleaner or detergent. Manipulate all moving parts under running water. Use a soft-bristled brush and/or soft lint-free cloth to remove all visible soil and debris. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct temperature, water quality and concentrations/dilution.
4	2 minutes	Rinse device thoroughly using running cool to lukewarm water. Use a syringe, pipette or water jet to flush lumens and channels. Actuate the moving coupling portion of the handle (collar) in order to rinse thoroughly under running water.
Visually inspect device. Repeat Steps 1– 5 until no visible soil remains.		
6	Load washing basket. Ensure that all cannulations, if applicable, are positioned vertically, i.e., in an upright position as shown.	
Note: The washer/disinfector should fulfill requirements specified in ISO 15883. Whenever possible, use MIS injector unit to process lumens and cannulations.		

Step	Duration (Minimum)	Cleaning Instructions
Rinse	2 minutes	Cold tap water
Pre-wash	1 minute	Warm water (≥ 40 °C); use detergent
Cleaning	2 minutes	Warm water (≥ 45 °C); use detergent
Rinse	5 minutes	Rinse with de-ionized (DI) or purified water (PURW)
Thermal disinfection	5 minutes	Hot DI water, ≥ 93 °C
Dry	40 minutes	≥ 90 °C

Inspection
Remove all devices from washing basket. Inspect the cannulation, the moving coupling portion of the handle (collar) and the fix coupling portion for visible soil. If necessary, repeat the manual precleaning/automated cleaning cycle. Mechanical cleaning/disinfection is an additional stress for the Torque Limiting Handle, especially for seals. Therefore, systems must be properly lubricated and regularly sent to be serviced.

Lubrication
Torque Limiting Handle
After every use, apply 1 drop of Synthes Special Oil (519.970) between the moving coupling portion (collar) and the fix coupling portion. Distribute the oil by moving the collar several times and wipe off any surplus oil with a cloth.

Function Control
Assemble a screwdriver shaft with the Torque Limiting Handle to check the coupling function.

Packaging
Put cleaned, dry devices into the proper places in the Synthes case or washing basket. 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 or the sterile barrier system.

Sterilization
Synthes Torque Limiting Handles may be re-sterilized using validated steam sterilization methods (ISO 17665 or national standards). Synthes recommendations for packed devices and cases are as follows.

Cycle type	Minimum sterilization exposure time (minutes)	Sterilization exposure temperature	Dry time
Saturated steam-forced air removal (pre-vacuum) (minimum three pulses)	Minimum 4 minutes	Minimum 132 °C Maximum 138 °C	20–60 minutes
	Minimum 3 minutes	Minimum 134 °C Maximum 138 °C	20–60 minutes

Dry times generally range from 20 to 60 minutes due to differences in packaging materials (sterile barrier system, e.g., wraps or re-usable rigid container systems), steam quality, device materials, total mass, sterilizer performance, and varying cool-down time.

Caution
- The following maximum values may not be exceeded: 143 °C over a maximum of 22 minutes.
- Higher values can damage the sterilized products.
- Do not accelerate the cooling process.
- Hot air, ethylene oxide, plasma and formaldehyde sterilization are not recommended.

Storage
Storage conditions for products labeled "STERILE" are printed on the packaging label.
Packaged and sterilized products should be stored in a dry, clean environment, protected from direct sunlight, pests, and extremes of temperature and humidity. Use products in the order in which they are received ("first-in, first-out principle"), taking note of any expiration date on the label.

Disposal
Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

Special Operating Instructions

314.163 and 324.052
Calibration:
The Torque Limiting Screwdriver needs to be calibrated annually.

324.305
Important:
Hold the entire handle of the torque wrench in your hand when tightening.

Product life:
This instrument has a product life of 4 years. After this period, the instrument must be replaced. Consult your sales representative at this time.

03.127.016
Recalibrating the Torque Limiting Handle:
The Torque Limiting Handle has to be sent to your Synthes service center annually for maintenance and calibration. Please refer to the inspection report for information on when the next service is due or when the device was last calibrated. The user accepts the responsibility for this annual calibration.

03.231.018 and 03.231.013
Recalibration of the Torque Limiting Handles:
DePuy Synthes recommends 6 months servicing and inspection by the original manufacturer. The Torque Limiting Handle has to be sent to your DePuy Synthes repair center annually for calibration. The user accepts the responsibility for this annual calibration.

03.312.851
Milk Bath:
After hand washing, and prior to sterilization, clean the 10 Nm Torque Wrench according to the recommendations outlined in Synthes Important Information.

This instrument requires immersion in a milk bath. After cleaning and rinsing, fully immerse the 10 Nm Torque Wrench hand piece in instrument milk (non-silicone based medical lubricant) prepared according to the lubricant manufacturer at room temperature in a suitable container and agitate for 30-45 seconds.

Calibration:
Every six months the 10 Nm Torque Wrench must be returned to the Service Department for re-calibration.

03.140.023
Additional device-specific information:
The TL can be attached to handles and power tools. Locking must be performed solely by hand with a manual handle while turning clockwise and never directly with the power tool. After one, audible, click the optimal torque is achieved. While used counterclockwise the TL must not be exposed to torques higher than 15Nm, otherwise the device may be damaged.

DePuy Synthes recommends that the TL be sent for a torque control once per year or if it is suspected that the TL is out of calibration. Torque control is handled through normal sales channels of the subsidiary in the respective country. The user accepts the responsibility for this annual check.

The device must be replaced when 300 cleaning/sterilization cycles are reached. The manufacturer assumes no warranty for damages arising from improper use or unauthorized servicing.

511.773, 03.110.002, 511.774, 511.776, 511.777 and 511.115
Important:
This system requires regular maintenance service, at least once a year, in order to maintain its functionality. This service has to be performed by the original manufacturer or an authorized sit. The manufacturer assumes no responsibility for damage resulting from neglected or unauthorized maintenance.

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