TRIADYME®-C
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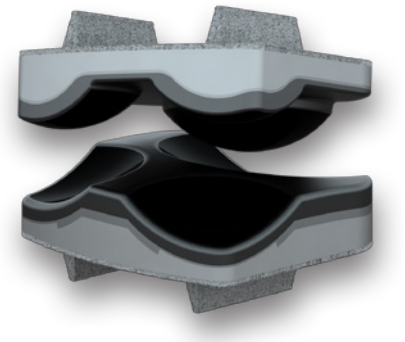
Triadyme®-C Cervical Total Disc Replacement Instrument Set



Cleaning and Sterilization Instructions

Important Information Regarding the Triadyme®-C Instrument Set

This instruction manual describes methods of care, cleaning, sterilization, and storage for the Triadyme®-C Cervical Total Disc Replacement Instrument Set. The recommended surgical procedure, including the proper use of the instrument set, is described in the Triadyme®-C Surgical Technique Guide.

For Triadyme®-C indications, contraindications, warnings and precautions, and other important medical information, please refer to the Triadyme®-C Instructions for Use and the Triadyme®-C Surgical Technique Guide.

Intended Use

Triadyme®-C Cervical Disc instruments are intended for use in Triadyme®-C implant procedures. The Triadyme®-C Instrument Set consists of reusable surgical instruments contained within a sterilization case.

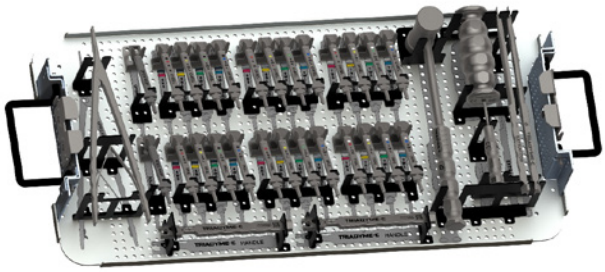
Triadyme®-C Instrument Set use is determined by the user's experience, training in the Triadyme®-C surgical procedure, and as outlined in the Triadyme®-C Surgical Technique Guide.

Triadyme®-C Instrument Set Contents

Catalog #	Description
CS-Tr-5A	5 Narrow Short Trial
CS-Tr-5B	5 Narrow Long Trial
CS-Tr-5C	5 Wide Short Trial
CS-Tr-5D	5 Wide Long Trial
CS-Tr-6A	6 Narrow Short Trial
CS-Tr-6B	6 Narrow Long Trial
CS-Tr-6C	6 Wide Short Trial
CS-Tr-6D	6 Wide Long Trial
CS-Tr-7A	7 Narrow Short Trial
CS-Tr-7B	7 Narrow Long Trial
CS-Tr-7C	7 Wide Short Trial
CS-Tr-7D	7 Wide Long Trial
CS-Ch-5A	5 Narrow Short Chisel
CS-Ch-5B	5 Narrow Long Chisel
CS-Ch-5C	5 Wide Short Chisel
CS-Ch-5D	5 Wide Long Chisel
CS-Ch-6A	6 Narrow Short Chisel

Catalog #	Description
CS-Ch-6B	6 Narrow Long Chisel
CS-Ch-6C	6 Wide Short Chisel
CS-Ch-6D	6 Wide Long Chisel
CS-Ch-7A	7 Narrow Short Chisel
CS-Ch-7B	7 Narrow Long Chisel
CS-Ch-7C	7 Wide Short Chisel
CS-Ch-7D	7 Wide Long Chisel
CS-Ex	Extractor
CS-ED	Extractor Pin Driver
CS-Mt	Mallet
CS-SH	Slide Hammer
CS-RH	Quick Release Handle (X2)
CS-Rp-1	Rasp (Solid)
CS-Rp-2	Rasp (Open)
CS-Sr	Spreader
CS-CA	Instrument Case

The Triadyme®-C instruments are manufactured from stainless steel, with color anodized aluminum used for color coding of the Trials and Chisels for ease of identification. The Instrument Case is manufactured from anodized aluminum, stainless steel, nylon, silicone, and Radel® polyphenylsulfone materials.



Disclaimer

The Triadyme®-C Instrument Set case is intended to protect the instruments and facilitate the sterilization process by allowing steam penetration and drying. Laboratory testing has verified that the instrument case is suitable for the specific sterilization methods and cycles for which it has been tested, as described herein. Health care facilities bear the ultimate responsibility for ensuring cleanliness and sterility and for ensuring that any packaging method or material, including a reusable rigid container system, is suitable for use in sterilization processing and sterility maintenance in a particular health care facility. Testing should be conducted in the health care facility to ensure that conditions essential to sterilization can be achieved. Dymicron® does not accept responsibility or liability arising from a lack of cleanliness or sterility of any medical devices supplied by Dymicron® that should have been properly cleaned and sterilized by the end user prior to use.

Recommendations

- The instruments and Instrument Case should be cleaned and sterilized as soon as possible after surgery.

(continued)

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Recommendations *(continued)*

- The instruments should be cleaned and sterilized only by trained personnel and according to the instructions in these cleaning and sterilization instructions.
- Appropriate personal protective equipment should be used when handling contaminated instruments.

Warnings and Precautions

- Surgical Instruments are precision devices, and careful handling is important for accurate and reliable functioning. Improper handling or treatment (dropping, bending, use for application other than those indicated, etc.) can cause product malfunction and impact the service-life of the instruments.
- The blades on the Chisel instruments are sharp. Care should be taken during handling to avoid injury.
- Before each use carefully inspect the Triadyme®-C Instrument Set to ensure all necessary instruments are in the set and in good working order. Do not use an instrument that is severely corroded, marred or worn, or has dull cutting surfaces.
- A nonwrapped instrument case does not maintain sterility.

Cleaning Prior to Use

The instrument set is NOT provided sterile. All instruments must be cleaned, sterilized, and inspected prior to use in surgery. Instruments must be removed from the case for manual or automated cleaning according to the instructions in this manual. The Instrument Case must be cleaned separately from the instruments. They must be thoroughly cleaned until visibly clean prior to sterilization. If the Instrument Case is not visibly clean, then repeat the cleaning process until it is visibly clean of all contamination prior to sterilization.

Initial Treatment at Point of Use

It is recommended that the instruments and case be cleaned promptly after use. It is advised to keep the instruments and case moist after point of use (i.e., soak in water or cover with damp towels) until the cleaning process is initiated.

Manual Cleaning Process

1. Prior to cleaning, ensure that the extractor pins are removed from the extractor and that the spring levers are removed from the Quick Release Handles as shown below.

a. Use the Extractor Pin Driver to remove the Extractor Pins from the Extractor halves.

b. The spring lever should be removed from the Quick Release Handle. Use an appropriately shaped tool (such as the Extractor Pin Driver) to gently pull the loop of the spring lever out from the slot in the Quick Release Handle. Pull the spring lever toward the rear of the Quick Release Handle to remove the spring lever from the slot. Avoid excessive bending of the spring lever during removal.

2. Rinse the instruments under ambient temperature (19°- 30°C) running utility (tap) water for at least 30 seconds to remove gross soil. Use a syringe to flush lumens and difficult-to-reach areas. A wire guide, pipe cleaner, or similar means may be used to aid in cleaning lumens and other difficult-to-reach areas. Actuate any joints while performing this process.

3. Prepare an enzymatic detergent bath (such as Enzol® Enzymatic Detergent) per the manufacturer's instructions in ambient temperature utility (tap) water.

4. Fully immerse instruments in the prepared solution and allow to soak for 5 minutes.

5. After the soak but while still immersed, use a soft-bristled nylon brush (Spectrum M-16 brush or equivalent) to gently scrub the instruments until all visible soil has been removed. Particular attention must be given to crevices, lumens, and other difficult-to-clean areas. Lumens should be cleaned with a long, narrow soft-bristled cannula brush. Actuate any joints while performing this process.

6. Remove the instruments from the cleaning solution and rinse in ambient temperature utility (tap) water for a minimum of 30 seconds. Thoroughly and aggressively flush lumens and other difficult-to-reach areas until all visual signs of detergent residue have been removed. Actuate any joints while performing this process.

7. Prepare an enzymatic detergent bath (such as Enzol® Enzymatic Detergent) per the manufacturer's instructions in a sonication unit using ambient temperature utility (tap) water. Completely submerge instruments in the detergent bath and sonicate for a minimum of 2 minutes.

8. Following sonication, rinse instruments in ambient temperature utility (tap) water for at least 3 minutes. Thoroughly and aggressively flush lumens and other difficult to reach areas. Actuate any joints while performing this process.

9. Remove excess moisture from the instruments with a clean, absorbent, lint-free cloth. Pressurized air may be used to assist in drying lumens or other difficult-to-reach areas.

10. Visually inspect each instrument for cleanliness. If they are not visibly clean, repeat the entire cleaning process.

11. Reassemble the spring lever into the Quick Release Handle according to the illustrations on page 3.

Triadyme®-C Cervical Total Disc Replacement Instrument Set

Cleaning and Sterilization Instructions

Insert release lever into slot in Quick Release Handle and slide forward.

Spring lever assembled in proper position in the Quick Release Handle.

12. Place all instruments securely into their respective positions in the instrument case. Do not place the Extractor Pins into the Extractor but place them in their respective slots in the instrument case below the Extractor halves.

Automated Cleaning Process

1. Prior to cleaning, ensure that the extractor pins are removed from the extractor and that the spring levers are removed from the Quick Release Handles as shown below.

a. Use the Extractor Pin Driver to remove the Extractor Pins from the Extractor halves.

b. The spring lever should be removed from the Quick Release Handle. Use an appropriately shaped tool (such as the Extractor Pin Driver) to gently pull the loop of the spring lever out from the slot in the Quick Release Handle. Pull the spring lever toward the rear of the Quick Release Handle to remove the spring lever from the slot. Avoid excessive bending of the spring lever during removal.

2. Rinse the instruments under running ambient temperature (19°- 30°C) tap water to remove gross soil. Use a syringe to flush lumens and difficult-to-reach areas. A wire guide, pipe cleaner, or similar means may be used to aid in cleaning lumens and other difficult-to-reach areas. Actuate any joints while performing this process.

3. Prepare a detergent bath, such as neodisher® MediClean forte, per the manufacturer's instructions in ambient temperature utility (tap) water.

4. Fully immerse instruments in the prepared solution and allow to soak for 5 minutes.

5. After the soak but while still immersed, use a soft-bristled nylon brush (Spectrum M-16 brush or equivalent) to gently scrub the instruments until all visible soil has been removed. Particular attention must be given to crevices, lumens, and other difficult-to-clean areas. Lumens should be cleaned with a long, narrow soft-bristled cannula brush. Actuate any joints while performing this process.

6. Remove the instruments from the cleaning solution and rinse in ambient temperature utility (tap) water for a minimum of 30 seconds. Thoroughly and aggressively flush lumens and other difficult-to-reach areas until all visual signs of detergent residue have been removed. Actuate any joints while performing this process.

7. Place the instruments into the washer-disinfector for processing.

8. Run the validated cycle parameters below.

Phase	Recirculation Time	Water/Temperature	Detergent Type and Concentration
Pre-wash	2 min	Cold tap	N/A
Wash	5 min	Heated (140°F/60°C)	neodisher® MediClean forte (5mL/L)
Rinse	3 min	Heated tap (140°F/60°C)	N/A
Thermal Disinfection	5 min	Heated DI (194°F/90°C)	N/A
Dry	15 min	210°F/99°C	N/A

Notes: The above automated cleaning cycle was validated using neodisher MediClean forte. Some alkaline cleaning agents may require a neutralization step. Refer to manufacturer's instructions to determine if neutralization is required.

Due to the many variables involved with washer-disinfectors, each healthcare facility should properly install, calibrate, and verify the process (e.g., temperatures, times) used for their equipment. Washer-disinfector manufacturer recommendations should always be followed. When cleaning multiple devices in one cleaning cycle, ensure the manufacturer's maximum load is not exceeded.

9. Remove the instruments from the washer-disinfector following the cycle.

10. Visually inspect each instrument for cleanliness. If the instruments are not visibly clean, repeat the entire cleaning process.

11. Reassemble the spring lever into the Quick Release Handle according to the illustrations below.

Spring lever assembled in proper position in the Quick Release Handle.

Insert release lever into slot in Quick Release Handle and slide forward.

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12. Place all instruments securely into their respective positions in the instrument case. Do not place the Extractor Pins into the Extractor but place them in their respective slots in the instrument case below the Extractor halves.

Sterilization Process

Since Dymicron is not familiar with individual hospital handling procedures, cleaning methods, bioburden levels, and other conditions, Dymicron assumes no responsibility for the sterilization of product by a hospital even if the specified guidelines are followed.

When sterilizing multiple instruments in an autoclave cycle, ensure that the sterilizer's maximum load is not exceeded. Do not stack another instrument case on top of the Triadyme®-C Instrument Case during the sterilization process.

The following sterilization cycle parameters were validated under laboratory conditions; however, these cycles must be re-validated by the end user to ensure that sterility can be achieved on site.

1. Ensure all instruments are reassembled and securely placed in their designated locations in the instrument case according to the cleaning instructions above.

2. Place the lid on the Triadyme®-C Instrument Case and secure the lid with the latches.

3. Wrap the Triadyme®-C Surgical Instrument Tray in two layers of FDA-cleared sterilization wrap (such as Halyard Health H400).

4. Perform sterilization with validated steam-sterilization equipment, using one of the following validated sterilization process schedules:

Cycle	Temperature	Exposure Time	Dry Time	Cool Time
Prevacuum/ Pulsating Vacuum	134° C (273° F)	3 min.	30 min.	10 min. (outside chamber on wire rack)
Cycle	**Temperature**	**Exposure Time**	**Dry Time**	**Cool Time**
Prevacuum/ Pulsating Vacuum	132° C (270° F)	4 min.	30 min.	10 min. (outside chamber on wire rack)

Notes: Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in this table. AAMI/AORN steam sterilization cycles with longer times than those listed are also acceptable. Validated using two applications of 1-ply polypropylene sterilization wraps (Halyard Health H400).

Storage

Instrument Cases that have been processed and wrapped to maintain sterility should be stored in a manner to avoid extremes in temperature and moisture. Care should be taken in the handling of wrapped cases to prevent damage to the sterile barrier. The health care facility should establish a shelf life for wrapped instrument cases based upon the type of sterile wrap used and the recommendations of the sterile wrap manufacturer. The user must be aware that maintenance of sterility is event related. Handling over time increases the probability of a contamination event.

Limitations on Reprocessing

Repeated reprocessing has a minimal effect on instruments. The service-life of instruments is normally determined by wear and/or damage sustained during use. Carefully inspect all instruments before use. Do not use an instrument if it has become severely corroded or worn, or if cutting edges have become dull.

Maintenance/Repair

To ensure the proper function of Triadyme®-C instruments, all repairs should be conducted by Dymicron or an authorized service agency. Regardless of age, return any damaged, broken, worn, corroded, or dull instruments to Dymicron for replacement or repair. All instruments must be cleaned and sterilized prior to shipping.

Note: Any conflict between these instructions and the policies and procedures of your facility should be brought to the attention of the responsible persons at your facility before attempting to clean and/or sterilize Dymicron® instruments.

Product Complaints

Any health care professional (e.g., customer or user of this system), who has complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness, and/or performance, should notify Dymicron®. Further, if the device (implant or instruments) ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended) or may have caused or contributed to the death or serious injury of a patient, Dymicron® should be notified immediately by telephone or written correspondence. When filing a complaint, please provide the device name and catalog number, lot number, your name and address, and the nature of the complaint.

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