| | | | | |
|---|---|---|---|---|
| *Note: This portion of the document should not appear on produced Labels or IFUs.*<br><br>Stryker Instruments<br>(269) 323-7700<br>(800) 253-3210 | **Dimensions:**<br>6 inch (width) x 6 inch Booklet | **Color/Material/Finish:**<br>Color Graphics on White Background 20# Bond or Equivalent | **Label Stock:**<br>N/A<br>**Description/Type:**<br>Instructions For Use<br>**Part Number:**<br>7206-001-700 | **Rev.**<br>D |

stryker

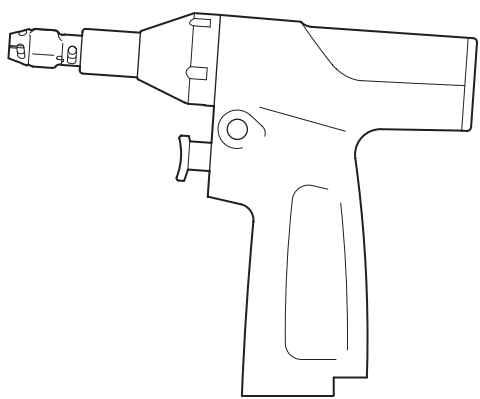
# System 7
# Reciprocating Saw

REF 7206-000-000

**Instructions For Use**

**$R_x$ ONLY**

CE 0197



ENGLISH (EN)

## Introduction

This *Instructions For Use* manual is the most comprehensive source of information for the safe and effective use of your product. This manual may be used by in-service trainers, physicians, nurses, surgical technologists, and biomedical equipment technicians. Keep and consult this reference manual during the life of the product.

The following conventions are used in this manual:

- A **WARNING** highlights a safety-related issue. ALWAYS comply with this information to prevent patient and/or healthcare staff injury.
- A **CAUTION** highlights a product reliability issue. ALWAYS comply with this information to prevent product damage.
- A **NOTE** supplements and/or clarifies procedural information.

If additional information or in-service training is required, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

## Indications For Use

The Stryker System 7 Battery Powered Heavy Duty System is intended for use in the cutting, drilling, decorticating, and smoothing of bone and other bone related tissue in a variety of surgical procedures. It is also usable in the placement of screws, wires, pins, and other fixation devices.

**NOTE:** The Stryker System 7 Reciprocating Saw (handpiece) is a component of the Stryker System 7 Battery Powered Heavy Duty System.

## Contraindications

None known.

## User/Patient Safety

**WARNINGS:**

- Before using any system component, or any component compatible with this system, read and understand the instructions. Pay particular attention to WARNING information. Become familiar with the system components prior to use.
- Only trained and experienced healthcare professionals should use this equipment.
- The healthcare professional performing any procedure is responsible for determining the appropriateness of this equipment and the specific technique used for each patient. Stryker, as a manufacturer, does not recommend surgical procedure or technique.
- Upon initial receipt and before each use, clean and sterilize the equipment as indicated. See the *Heavy Duty Care Instructions* manual for processing instructions.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- Upon initial receipt and before each use, operate the equipment and inspect each component for damage. DO NOT use any equipment if damage is apparent. See the *Heavy Duty Care Instructions* manual for inspection criteria.
- DO NOT use this equipment in areas in which flammable anesthetics or flammable agents are mixed with air, oxygen, or nitrous oxide.
- Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment. Place this equipment into service according to the EMC information contained in this manual. Portable and mobile radio frequency (RF) communications equipment can affect the function of this equipment.

## Accessories

**WARNINGS:**

- Use only Stryker-approved system components and accessories, unless otherwise specified. DO NOT modify any system component or accessory.
- Using other electronic components and accessories may result in increased electromagnetic emissions or decreased electromagnetic immunity of the system.
- DO NOT reuse, reprocess, or repackage a device that is intended for single use only.
  - A single use device may not withstand chemical, chemical vapor, or high temperature sterilization reprocessing.
  - Design features may make cleaning difficult.
  - Reuse may create a contamination risk and compromise structural integrity resulting in operational failure.
  - Critical product information may be lost during repackaging.

  Failure to comply may lead to infection or cross infection and result in patient and/or healthcare staff injury.
- When using one of the following blades, be alert for blade whip when operating the handpiece below the maximum speed:
  - REF 0277-096-251
  - REF 0277-096-275
  - REF 0277-096-276
  - REF 0277-096-277
  - REF 0277-096-325

  Blade whip increases the chance of blade fracture and may result in patient and/or healthcare staff injury.

**NOTE:** For a complete list of accessories, contact your Stryker sales representative. Outside the US, contact your nearest Stryker subsidiary.


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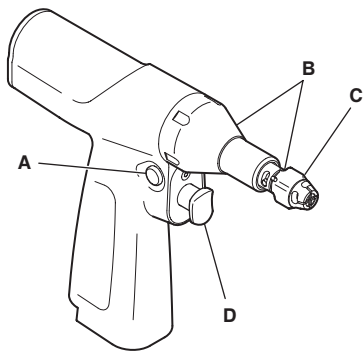
## Accessories (continued)

The following Stryker-approved accessories are sold separately:

| DESCRIPTION | REF |
|---|---|
| Blades | 0277-096-XXX series |
| System 6 Battery Pack, Large | 6215-000-000 |
| System 6 Aseptic Battery Kit, Large | 6126-000-000 |
| System 6 Aseptic Battery Kit, Small | 6127-000-000 |
| Stryker SmartLife™ Battery Pack, Small | 7212-000-000 |
| Stryker SmartLife Battery Pack, Large | 7215-000-000 |
| Stryker SmartLife Non-sterile Battery, Large | 7126-110-000 |
| Stryker SmartLife Aseptic Housing, Large | 7126-120-000 |
| Stryker SmartLife Transfer Shield, Large | 7126-130-000 |
| Stryker SmartLife Non-sterile Battery, Small | 7222-110-000 |
| Stryker SmartLife Aseptic Housing, Small | 7222-120-000 |
| Stryker SmartLife Transfer Shield, Small | 7222-130-000 |

## Features

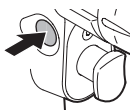
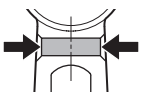
### Handpiece




| | |
|---|---|
| **A** | **Function Switch** – Sets the speed or locks the trigger. |
| **B** | **Applied Part** – The distal end of the handpiece (as defined by the standards listed in the *Specifications* section under *Product Safety Certification*). |
| **C** | **Blade Collar** – Retains the blade in the handpiece. |
| **D** | **Trigger** – Controls the variable speed operation of the handpiece. |

# Features (continued)

## Function Switch

| | |
|---|---|
|  | **Fast Mode** – The handpiece will operate at high speed when the trigger is depressed. |
|  | **Standard Mode** – The handpiece will operate at standard speed when the trigger is depressed. |
|  | **Safe Mode** – The trigger is locked to prevent inadvertent operation of the handpiece. |

# Definitions

The symbols located on the equipment and/or labeling are defined in this section or in the *Symbol Definition Chart*. See the *Symbol Definition Chart* supplied with the equipment.

| SYMBOL | DEFINITION |
|---|---|
|  | **Fast Mode** |
|  | **Standard Mode** |
| 1 min / 4 min x 5 | **Duty Cycle** – See the *Specifications* section. |
|  | General warning sign |
|  | To comply with European Community Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU, ALWAYS collect this product separately for recycling. DO NOT dispose of this product as unsorted municipal waste. Contact your local distributor for disposal information. |
|  | Direct current |

# Instructions

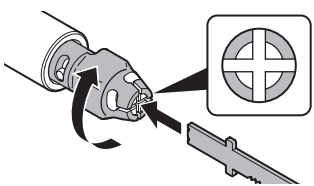
## To Install the Blade

**WARNINGS:**

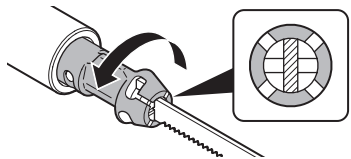
- ALWAYS slide the function switch to the safe mode position before installing the blade.
- ALWAYS make sure the blade collar springs back to its original position and the blade is securely locked in the blade collar after installation.

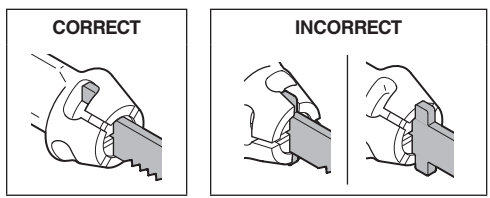
**NOTE:** The blade may be installed in any of four orientations.

1. Rotate the spring-loaded blade collar to align the slots in the distal end of the collar, and then fully insert the blade into the blade collar.



2. Release the blade collar. Make sure the blade collar springs back to its original position and the blade is securely locked in the blade collar.





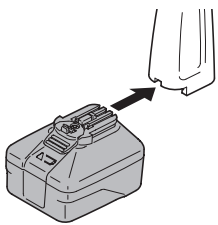

3. Gently tug the blade to make sure the blade is securely locked in the blade collar.

## To Install the Battery Pack

**WARNING:** ALWAYS slide the function switch to the safe mode position before installing the battery pack.

**NOTE:** See the instructions for use supplied with the battery pack and/or battery charger for charging instructions and specifications.

1. Slide a fully charged battery pack into the handpiece until the battery pack snaps into place.



2. Gently tug the battery pack to make sure the battery pack is securely locked in the handpiece.
3. Test the operation of the handpiece by sliding the function switch to the fast or standard mode position, and then depressing the trigger.

## To Operate the Handpiece

**WARNINGS:**

- ALWAYS slide the function switch to the safe mode position when the handpiece is idle or when passing the handpiece to another person.
- DO NOT change the position of the function switch while the handpiece is operating.
- Before operating the handpiece, ALWAYS gently tug the blade to make sure the blade is securely locked in the blade collar.
- ALWAYS operate the equipment within the specified environmental condition values. See the *Specifications* section.
- ALWAYS follow the recommended duty cycle to prevent the equipment from overheating. See the *Specifications* section.
- DO NOT apply excessive pressure, such as bending or prying, with the blade. Excessive pressure may bend or fracture the blade and result in tissue damage, loss of tactile control, and/or the ejection of blade fragments at a high velocity.

## To Operate the Handpiece (continued)

**CAUTIONS:**

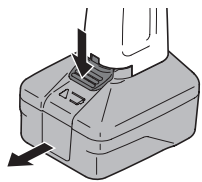
- When operating the handpiece, let the blade do the cutting. DO NOT apply excessive pressure with the blade. Excessive pressure may bend the blade and reduce the cutting quality.
- DO NOT stall the handpiece. Failure to comply may damage the electric motor and/or battery pack. If the handpiece jams, release the trigger immediately. Remove any obstructions before continuing to operate the handpiece.
- If any power loss is experienced while using the handpiece, ALWAYS replace the battery pack with a fully charged battery pack. Failure to comply may result in a drained or damaged battery pack with a shortened life.

1. Slide the function switch to the fast or standard position.
2. Depress the pressure-sensitive trigger for variable speed operation.

## To Remove the Battery Pack

**WARNING:** ALWAYS slide the function switch to the safe mode position before removing the battery pack.

Depress the battery latch and slide the battery pack out of the handpiece.



## To Remove the Blade

**WARNING:** ALWAYS slide the function switch to the safe mode position before removing the blade.

Rotate the blade collar to align the slots in the distal end of the collar, and then remove the blade from the handpiece.

# Care Instructions

For processing instructions and disposal/recycle information, see the care instructions manual supplied with the equipment.

# Troubleshooting

**WARNING:** DO NOT disassemble or service this equipment.

**NOTE:** For service, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

| PROBLEM | CAUSE | ACTION |
|---|---|---|
| The handpiece does not operate or operates at a reduced speed. | The battery pack is discharged. | Use a Stryker battery charger to recharge the battery pack. |
| | The function switch is in the standard position. | Set the function switch to the fast position. |
| | The battery pack is expended. | Replace the battery pack. |
| | The function switch is in the safe mode position. | Set the function switch to the fast or standard position. |
| | The drivetrain is malfunctioning. | Return the handpiece to Stryker for repair. |
| The handpiece operates but the blade does not move. | The drivetrain is malfunctioning. | Return the handpiece to Stryker for repair. |
| The handpiece continues to operate after the trigger is released. | The trigger is malfunctioning. | Depress the battery latch and slide the battery pack out of the handpiece. Return the handpiece to Stryker for repair. |
| The battery pack becomes unusually hot during use. | The circuitry is malfunctioning. | Use a Stryker battery charger to check the integrity of the battery pack. Replace the battery pack as required. |

## Troubleshooting (continued)

| PROBLEM | CAUSE | ACTION |
|---|---|---|
| The blade will not fit or cannot be secured in the blade collar. | The blade collar contains debris. | Use a small brush to clean the blade collar. |
| | The blade is not a Stryker product. | Use a Stryker blade. |
| | The blade collar is damaged. | Return the handpiece to Stryker for repair. |
| The blade collar does not spring back to its original position to securely lock the blade in the blade collar. | The blade collar contains debris. | Use a small brush to clean the blade collar. Actuate the collar several times to obtain smooth operation. |
| The handpiece is noisy and/or vibrates. | The drivetrain is malfunctioning. | Return the handpiece to Stryker for repair. |
| The handpiece experiences sporadic electrical interference. | Electrical noise is present. | Turn off all electrical equipment not in use in the operating room. |
| | | Relocate electrical equipment and/or increase spatial distance between electrical equipment. |
| | | Plug operating room equipment into different operating room outlets. |

# Specifications

**WARNING:** ALWAYS check any documentation that accompanies attachments, burs, pins, and/or blades for special duty cycle and usage instructions.

**CAUTION:** ALWAYS store the equipment within the specified environmental condition values throughout its useful life.

**NOTE:** Specifications are approximate and may vary between devices or as a result of power supply fluctuations.

| | |
|---|---|
| **Model:** | System 7 Reciprocating Saw (REF 7206-000-000) |
| **Dimensions:** | 168 mm [6.6 inch] height<br>38 mm [1.5 inch] width<br>191 mm [7.5 inch] length |
| **Mass:** | 0.94 kg [2.07 lb] |
| **Speed:** | 13,000 cpm (fast)<br>10,000 cpm (standard) |
| **Excursion:** | 3.9 mm [0.154 inch] |
| **Mode of Operation:** | Non-continuous Operation |
| Duty Cycle: | 1 minute on/4 minutes off, 5 times |
| Rest Between Cycles: | 3 hours |
| **Maximum Temperature of Applied Part:** | Less than 51 °C [124 °F] (Maximum surface temperature as tested to the standards listed under *Product Safety Certification*.) |
| **Power Supply:** | Internally Powered<br>Refer to battery housing for voltage rating. |
| **Ingress Protection:** | IPX0 Ordinary Equipment |
| **Equipment Type:** |  Type BF Applied Part |

# Specifications (continued)

**Product Safety Certification:**  CSA International

**Canadian Standards Association (CSA)**

CAN/CSA-C22.2 No. 60601-1:14, *Medical Electrical Equipment — Part 1: General Requirements for Basic Safety and Essential Performance;* (IEC 60601-1:2005+A1:2012, MOD)

**American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI)**

ANSI/AAMI ES60601-1:2005/(R) 2012, *Medical Electrical Equipment — Part 1: General Requirements for Basic Safety and Essential Performance;* Consolidated Reprint (2009/(R) 2012); Amendment 2 (2010/(R) 2012); Amendment 1 (2012)

**Product Safety Compliance:**

**International Electrotechnical Commission (IEC)**

IEC 60601-1:2005, Ed: 3.1, *Medical Electrical Equipment — Part 1: General Requirements for Basic Safety and Essential Performance;* Corrigendum 1 (2006); Corrigendum 2 (2007); Amendment 1 (2012)

**European Committee for Electrotechnical Standardization (CENELEC)**

EN 60601-1:2006+A12:2014, Ed: 3.1, *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance;* IEC Corrigendum 1 (2006); IEC Corrigendum 2 (2007); CENELEC Corrigendum (2010); CENELEC Amendment A11 (2011); IEC Amendment 1 (2013); IEC Corrigendum 3 (2014); CENELEC Amendment A12 (2014)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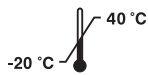
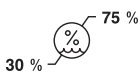
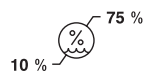
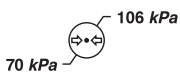
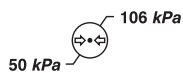
# Specifications (continued)

| Environmental Conditions: | Operation | Storage and Transportation |
|---|---|---|
| Temperature Limitation: |  |  |
| Humidity Limitation: |  |  |
| Atmospheric Pressure Limitation: |  |  |

# Specifications (continued)

| Guidance and manufacturer's declaration - electromagnetic emissions | | |
|---|---|---|
| The System 7 Reciprocating Saw (REF 7206-000-000) is intended for use in the electromagnetic environment specified below. The customer or the user of the System 7 Reciprocating Saw (REF 7206-000-000) should assure that it is used in such an environment. | | |
| **Emissions test** | **Compliance** | **Electromagnetic environment - guidance** |
| RF emissions<br>CISPR 11 | Group 1 | The System 7 Reciprocating Saw (REF 7206-000-000) uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions<br>CISPR 11 | Class B | The System 7 Reciprocating Saw (REF 7206-000-000) is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions<br>IEC 61000-3-2 | N/A | |
| Voltage fluctuations/flicker emissions<br>IEC 61000-3-3 | N/A | |

# Specifications (continued)

| Guidance and manufacturer's declaration - electromagnetic immunity | | | |
|---|---|---|---|
| The System 7 Reciprocating Saw (REF 7206-000-000) is intended for use in the electromagnetic environment specified below. The customer or the user of the System 7 Reciprocating Saw (REF 7206-000-000) should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment - guidance** |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | ±6 kV contact<br>±8 kV air | ±6 kV contact<br>±8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/ burst<br>IEC 61000-4-4 | ±2 kV for power supply lines<br>±1 kV for input/output lines | N/A<br>N/A | N/A |
| Surge<br>IEC 61000-4-5 | ±1 kV line(s) to line(s)<br>±2 kV line(s) to earth | N/A<br>N/A | N/A |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11 | <5% $U_T$ (>95% dip in $U_T$) for 0,5 cycle<br>40% $U_T$ (60% dip in $U_T$) for 5 cycles<br>70% $U_T$ (30% dip in $U_T$) for 25 cycles<br><5% $U_T$ (>95% dip in $U_T$) for 5 seconds | N/A<br>N/A<br>N/A<br>N/A | N/A |
| Power frequency (50/ 60 Hz) magnetic field<br>IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment. |

NOTE: $U_T$ is the alternating current mains voltage prior to application of the test level.

# Specifications (continued)

| Guidance and manufacturer's declaration - electromagnetic immunity | | | |
|---|---|---|---|
| The System 7 Reciprocating Saw (REF 7206-000-000) is intended for use in the electromagnetic environment specified below. The customer or the user of the System 7 Reciprocating Saw (REF 7206-000-000) should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment - guidance** |
| Conducted RF<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz | N/A | Portable and mobile RF communications equipment should be used no closer to any part of the System 7 Reciprocating Saw (REF 7206-000-000), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance:<br>$d=1.2\sqrt{P}$ 80 MHz to 800 MHz<br>$d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz<br>Where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:<br>  (Non-ionizing electromagnetic radiation) |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80 MHz to 2.5 GHz | 3 V/m | |

NOTE 1: At 80 MHz and 800MHz the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the System 7 Reciprocating Saw (REF 7206-000-000) is used exceeds the applicable RF compliance level above, the System 7 Reciprocating Saw (REF 7206-000-000) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating System 7 Reciprocating Saw (REF 7206-000-000).

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

# Specifications (continued)

| Recommended separation distances between portable and mobile RF communications equipment and the System 7 Reciprocating Saw (REF 7206-000-000) | | | |
|---|---|---|---|
| The System 7 Reciprocating Saw (REF 7206-000-000) is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System 7 Reciprocating Saw (REF 7206-000-000) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System 7 Reciprocating Saw (REF 7206-000-000) as recommended below, according to the maximum output power of the communications equipment. | | | |
| **Rated maximum output power of transmitter W** | **Separation distance according to frequency of transmitter m** | | |
| | **150 kHz to 80 MHz** N/A | **80 MHz to 800 MHz** $d=1.2\sqrt{P}$ | **800 MHz to 2.5 GHz** $d=2.3\sqrt{P}$ |
| 0.01 | N/A | 0.12 | 0.23 |
| 0.1 | N/A | 0.38 | 0.73 |
| 1 | N/A | 1.2 | 2.3 |
| 10 | N/A | 3.8 | 7.3 |
| 100 | N/A | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1: At 80 MHz and 800MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.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| | |
|---|---|
| *ES/DE/FR/IT/NL* | *7206-001-710* |
| *JA/ZH/KO* | *7206-001-720* |
| *SV/DA/FI/PT/NO* | *7206-001-730* |
| *PL/EL* | *7206-001-750* |

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1-800-253-3210

stryker®

# Signature History Report

| Version | Signature | Role | Event Date | Vote |
|---|---|---|---|---|
| D | Dickey Douglas | CA_Owner | 2017-10-12 13:55:18 EDT | Continue |
| D | Morgan, Carianne | CA_Product Safety | 2017-10-13 08:43:23 EDT | Approve |
| D | Bernardi Adam | CA_Tech Pubs-Tech Writer | 2017-10-13 11:42:44 EDT | Approve |
| D | Modi Karan | CA_Regulatory Affairs | 2017-10-16 09:44:32 EDT | Approve |
| D | Vayeda Ankur | CA_Product Design Engineer | 2017-10-19 10:19:59 EDT | Approve |
| D | VanderGenugten, Rachel | CA_Marketing Manager | 2017-11-15 08:53:32 EST | Approve |
| D | Joseph, Kaylee | CA_Quality Engineer | 2017-11-15 14:20:28 EST | Approve |
| D | holly.honeck@stryker.com | Editor | 2017-11-16 10:01:56 EST | Continue |

NOTE: IF THIS REPORT IS BLANK, PLEASE SEE WINDCHILL ECN FOR SIGNATURES.

# Related Information

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|---|---|
| CR Number | CR0321480 |
| CR Class | DMR-Commercially Released |
| Originating Entity | INST: Kalamazoo |
| Origin | Other |
| Initial CR Approval Date | 09/07/2017 17:20:05 |
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| CA Number | CA216591 |
| NPD Disposition Plan | |