NOTE: This portion of the document should not appear on produced Labels or IFUs. Stryker Instruments (269) 323-7700 (800) 253-3210	**Dimensions:** 8.5 inch x 11 inch Booklet Folded to 4.25 inch x 2.75 inch	**Color/Material/Finish:** Black Graphics on White Background 20# Bond or 45# Opaque	**Label Stock:** N/A	
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SilverGlide® Non-Stick Bipolar Electrosurgical Forceps

REF 6710-XXX-XXX 6725-XXX-XXX
6715-XXX-XXX 6740-XXX-XXX
6720-XXX-XXX 6750-XXX-XXX

Instructions For Use

R_x ONLY

NON STERILE

Manufactured for:
Stryker Instruments
4100 E. Milham
Kalamazoo, Michigan
(USA) 49001
1-269-323-7700
1-800-253-3210

Introduction

This instructions for use manual contains information intended to ensure the safe, effective, and compliant use of your product. 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.

For additional information, including safety information, in-service training, or current literature, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

Indications For Use

Stryker SilverGlide Non-stick Bipolar Electrosurgical Forceps are intended to facilitate grasping and manipulation of soft tissue and provide electrocautery in surgical procedures.

Contraindications

None known.

User/Patient Safety

WARNINGS:

- Before using this equipment, or any component compatible with this equipment, read and understand the instructions for use. Pay particular attention to safety information. Become familiar with the equipment before use.
- Only healthcare professionals trained and experienced in the use of this medical device should operate 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.
- DO NOT use this equipment in areas in which flammable anesthetics or flammable agents are mixed with air, oxygen, or nitrous oxide.
- Upon initial receipt and before each use, inspect each component for damage. DO NOT use any equipment if damage is apparent or the inspection criteria are not met. See the *Inspection and Testing* section for inspection criteria.
- Upon initial receipt and before each use, clean and sterilize the equipment as indicated. See the *Processing Instructions* section for care information.

Definitions

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

SYMBOL	DEFINITION	SYMBOL	DEFINITION
⚠	General warning sign	TIP	Tip

Accessories

WARNINGS:

- Use only Stryker-approved equipment, unless otherwise specified.
- SilverGlide Tip Guards are intended for a single use only. DO NOT reuse, reprocess, or repackage SilverGlide Tip Guards. Failure to comply may lead to infection or cross infection and result in patient and/or healthcare staff injury.

NOTE:

- Forceps fit standard two-pin US bipolar electrosurgical accessory cables.
- For a complete list of accessories, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

The following Stryker-approved accessories are sold separately:

DESCRIPTION	REF
ProClean Instrument Detergent®	3000-00X-000 series
Blu62™ Pretreatment Foam	3000-00X-000 series
SilverGlide Tip Guards (QTY 100)	6700-000-001
SilverGlide Polishing Cloth (QTY 10)	6700-000-002
SilverGlide Sterilization Trays	6700-002-000, 6700-005-000, 6700-010-000
SilverGlide Reusable Bipolar Forceps Cable	6701-000-000
SilverGlide Disposable Bipolar Forceps Cable	6702-000-000

Instructions

WARNINGS:

- Forceps must only be used with a standard electrosurgical generator with footswitching bipolar output.
- The forceps with smaller tip dimensions may be sharp and should be handled with care to prevent patient and health care staff injury.
- DO NOT bend or pull apart the tips of the forceps. Distortion or modification of forceps may cause patient and/or healthcare staff injury.
- DO NOT drop or mishandle the forceps. Damage such as nicks in the insulation or tip coating will compromise performance that may cause patient and/or healthcare staff injury.
- Use proper aseptic technique while handling forceps.

CAUTIONS:

- Inspect forceps prior to each use. Look for bent, misaligned, or damaged tips, tines, or guide stop. Inspect for cracks or voids in the protective insulation, cracks in the connector plug, and bent, broken, or loose connector pins. DO NOT use forceps if any component damage is apparent.
- DO NOT twist connectors while connecting or disconnecting forceps to the accessory cable.
- DO NOT use excessive force to connect forceps to the accessory cable.
- Forceps fit most standard bipolar electrocautery cables. It is important to check the instrument integrity and connection with the accessory cable to ensure fit and compatibility.

NOTES:

- Wearing protective surgical gloves while using the forceps is required.
- Fluid flow has a cooling effect on the tips of irrigating forceps, therefore, a reduction in fluid flow or a longer application may be required to achieve the desired effect.

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To Connect and Disconnect the Forceps

WARNINGS:

- Improper cable connection and use may result in injury to the patient and/or healthcare staff by unintentional contact at the forceps-cable connection. Keep active devices away from the patient when not in use.
- The forceps connector plug must fit securely into the active accessory cable connector. DO NOT use forceps if the connector plug does not insert fully in to the accessory cable connector.

1. To use the forceps, refer to the instructions supplied with the electrosurgical generator for the procedure to properly connect active devices to the generator.
2. Before connecting or disconnecting forceps from the accessory cable, turn off the electrosurgical generator or place the generator in the standby mode.
3. Hold the forceps by the blade and insert the forceps connector plug into the accessory cable connector until the forceps connector plug is fully engaged.

To Operate the Forceps

WARNINGS:

- The electrosurgical generator must be in the coagulation-mode only. DO NOT use forceps while the electrosurgical generator is in bipolar-cut mode.
- Use the lowest power or voltage that achieves the desired effect.
- The tips of the forceps may become hot during prolonged use. Use care to avoid unintended contact with the tips to prevent patient and healthcare staff injury.
- ALWAYS operate the equipment within the specified environmental condition values. See the *Specifications* section.

NOTE: During surgery, use a gauze sponge moistened with saline to gently remove eschar from the tips of the forceps.

Processing Instructions

Processing equipment, operators, detergents, and procedures all contribute to the efficacy of medical device processing. The healthcare facility should make sure that the combination used results in a medical device that is safe for use. Alternative methods of processing may be equally suitable.

Repeated processing has a minimal effect on this equipment. See the *Inspection and Testing* section for additional guidance on evaluating device functionality.

WARNINGS:

- Before processing this equipment, read and understand the care instructions. Pay particular attention to safety information.
- Only individuals trained and experienced in the processing of reusable medical devices should process this equipment.
- ALWAYS provide personal protective equipment (PPE) for processing personnel according to the instructions and safety data sheets (SDS) supplied with the detergent. Wear PPE at all times during processing.
- 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 or fragmentation during use.
  - 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.

Point of Use (Post-Surgery)

CAUTIONS:

- DO NOT use saline to wet or soak the equipment before transport to the decontamination processing area.
- If transport to the decontamination processing area is delayed, cover the equipment with a damp cloth or spray the equipment with a pretreatment foam as often as necessary to maintain moisture. The pretreatment foam will minimize the drying of soil and facilitate later decontamination processing. DO NOT allow pretreatment foam to dry on the equipment.

1. Separate reusable equipment from disposable waste.
2. Discard waste into an appropriate container; use a puncture-resistant container for sharps. See the *Disposal/Recycle* section.
3. Use absorbent wipes to remove gross soil from the equipment.

Transport to Decontamination Processing Area

WARNING: During transport, pay particular attention to sharp, cutting edges to avoid injury.

CAUTION: Avoid mechanical damage during transport. DO NOT mix heavy devices with delicate devices.

Clean the equipment as soon as practical, typically within two hours, to preclude extended or repeat cleaning procedures.

Preparation for Cleaning

Recommended Equipment

- PPE as recommended by the detergent manufacturer
- Warm, filtered or deionized water (See the *Water* section.)
- Prepared, specially formulated detergents (See the *Detergents* section.)
- Absorbent wipes
- Soft, lint-free cloth
- Syringe
- Non-abrasive, soft, flexible, synthetic bristle brushes
- Washer-disinfector
- Detergents and rinsing agents as required by the washer-disinfector
- Medical-grade compressed air, < 140 kPa [< 20 psi]
- Oven
- Sterilization wrap, grade 500 or higher
- Chemical indicators
- Sterilizer

Detergents

WARNINGS:

- To clean the equipment, use specifically formulated detergents only.
- Read, understand, and follow the indications, instructions, and safety information supplied with the detergent for correct handling and use of the product.
- ALWAYS prepare the detergent solution according to the manufacturer's recommendations. Pay particular attention to the concentration used and the total dispersion.

CAUTIONS:

- To clean the equipment, a mild alkaline detergent (neutral up to pH 12) is preferred. If a washer-disinfector is used, see the instructions for use supplied with the washer-disinfector machine to select the recommended detergent.
- ALWAYS use a detergent that is suitable for use on plastic, stainless steel, nylon, and silver surfaces.

NOTE: Stryker recommends the specified validated detergent (if available) for manual cleaning; however, other products may perform equally or better. Alternative detergents must be verified by referencing the information provided by the product supplier and/or physical testing.

Stryker used the following detergents to validate the manual and automated (washer-disinfector) cleaning processes described in these instructions:

Supplier	Product	Suitability	Process
Stryker	ProClean Instrument Detergent	All materials	Manual Cleaning
Steris	Prolystica 2x Concentrate Enzymatic	Aluminum, stainless steel, soft metals, and plastics	Automated Cleaning
	Prolystica 2x Concentrate Neutral		

Prepare the detergent solution according to the manufacturer's recommendations.

Water

WARNING: Use filtered water for diluting detergents and for rinsing the equipment. Mineral residues from hard water can stain the equipment and/or prevent effective cleaning and decontamination.

CAUTION: Poor water quality can adversely affect the life of medical devices. ALWAYS follow the water quality requirements per Association for the Advancement of Medical Instrumentation (AAMI) TIR 34.

Warm water with an optimum temperature range of 27 to 44 ˚C [80 to 110 ˚F] is recommended for manual cleaning. The water should not exceed 60 ˚C [140 ˚F] and should be warm to the touch.

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Cleaning

WARNINGS:

- Clean the equipment as indicated before first and every use. Use the cleaning methods as indicated in these instructions. Other cleaning methods may prevent proper sterilization of the equipment.
- Prior to cleaning, disconnect the forceps from the accessory cable.
- Use PPE at all times during cleaning.

CAUTIONS:

- ALWAYS handle the equipment with care. DO NOT drop the equipment.
- DO NOT use solvents, lubricants, or other chemicals, unless otherwise specified.
- DO NOT use disinfectants, such as Cidex, or other corrosive agents.
- DO NOT use ultrasonic cleaning equipment.
- Use a high pressure washer only if forceps are secured in a rack to prevent contact with other instruments.
- DO NOT use sandpaper, scraping devices, or abrasive cleaners.
- DO NOT bend connector pins during cleaning.
- ALWAYS make sure the detergent solution is completely rinsed from the interior and exterior of the equipment before drying the equipment.
- Use of compressed air is only recommended for drying of equipment.

NOTES:

- Two methods of cleaning are described, a manual cleaning method and an automated cleaning method. Manual removal of all gross soil is required for both cleaning methods.
- For maximum device life, manual cleaning is recommended.

Manual Cleaning

1. Remove all gross soil from the equipment using absorbent wipes or a soft, lint-free cloth moistened with the prepared detergent solution. Devices may be placed briefly under running water or flushed with a water-filled syringe to assist in the removal of gross soil.
2. Thoroughly clean the equipment.
   - Use suitable brushes and detergent solution to clean all surfaces. Pay particular attention to rough surfaces, crevices, and difficult-to-reach areas where soil may be shielded from brushing, such as details around a guide stop or connector.
   - Use a soft 0.5 mm brush or the supplied cleaning wire to clean the entire length of each lumen.
   - Use a syringe filled with detergent solution to flush difficult-to-reach areas.
   - Actuate all moving parts to clean hidden surfaces.
3. Optional: Soak the equipment in fresh detergent solution per the manufacturer's recommendations.
4. Thoroughly rinse the equipment with warm, running water until all traces of detergent solution are removed. Pay particular attention to rough surfaces and joints between mating parts. Actuate all moving parts to rinse hidden surfaces.

NOTE: A final rinse of the equipment using deionized or filtered water is recommended.

5. Visually inspect the equipment for any remaining soil or detergent solution. If soil or detergent solution remains, repeat the cleaning procedure using fresh detergent solution.
6. Allow the equipment to drain on absorbent wipes. If possible, orient the equipment vertically to assist in drainage.
7. Dry the equipment with a soft, lint-free cloth or medical-grade compressed air.
8. Optional: To protect the tips from damage, place new SilverGlide Tip Guards on the tips. See the *Accessories* section.
9. After manual cleaning, inspect the equipment immediately (see the *Inspection and Testing* section), or perform the steps in the *Automated Cleaning* section.

Automated Cleaning

1. Perform all manual cleaning steps. See the *Manual Cleaning* section.

NOTE: The drying step after manual cleaning may be skipped.

WARNING: ALWAYS load the equipment carefully to prevent movement that may inhibit proper cleaning during the automated washer-disinfector cycle.

2. Load the equipment into the washer-disinfector in an appropriate sterilization tray base, or secure the equipment in a wire basket. Avoid contact between components.

CAUTION: DO NOT use any type of lubricant in the automated washer-disinfector. Lubrication is not required and may leave residue on the equipment after cleaning.

3. Operate the washer-disinfector. Use the following validated phase parameters as required:

Phase	Time	Water Temperature	Cleaning Agent
Pre-rinse	2 to 4 minutes	< 21 ˚C [< 70 ˚F]	Prepared detergent (optional)
Enzyme Wash	2 to 4 minutes	43 to 66 ˚C [110 to 150 ˚F]	Prepared enzymatic detergent
Wash	2 to 4 minutes	60 to 82 ˚C [140 to 180 ˚F]	Prepared detergent
Rinse	2 to 4 minutes	43 to 82 ˚C [110 to 180 ˚F]	–
Dry	15 minutes	–	–

4. Unload the washer-disinfector and visually inspect the equipment for remaining soil or detergent solution. If soil or detergent solution remains, repeat the cleaning procedure using fresh detergent solution.
5. Dry the equipment with a soft, lint-free cloth or medical-grade compressed air, or by heating the equipment in an oven below 110 ˚C [230 ˚F].
6. Optional: To protect the tips from damage, place SilverGlide Tip Guards on the tips. See the *Accessories* section.
7. After automated cleaning, inspect the equipment immediately (see the *Inspection and Testing* section).

Inspection and Testing

WARNINGS:

- Only individuals trained and experienced in the maintenance of this reusable medical device should inspect and test this equipment.
- DO NOT sterilize any equipment if damage is apparent or the inspection criteria are not met.
- DO NOT disassemble, modify, or service this equipment without the authorization of the manufacturer. If the tips of the forceps must be realigned, return the forceps to Stryker for evaluation and repair.
- Maximum forceps life is 20 surgeries.

NOTES:

- If the equipment fails to meet the inspection and testing criteria, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.
- The useful life of this equipment is dependent upon many factors including, but not limited to, the method and duration of each use, and the handling of the equipment between uses.
- Routine and careful inspection and functional testing are the best methods for determining the serviceable life span of the equipment.

Visual and Functional Inspection

Visually inspect and test all equipment before sterilization. Pay particular attention to the following:

- Locations where soil may become trapped, such as mating surfaces
- Recessed features, such as holes
- Features where soil may be pressed into contact with the equipment

INTERVAL	ACTIVITY	CRITERIA
Upon initial receipt and before each use	Inspect the equipment	No visible soil, damage, signs of wear, and/or corrosion
		No bent, misaligned, or damaged tips, tines, or guide stop
		No cracks or voids in the protective insulation
		No cracks in the connector plug
		No bent, broken, or loose connector pins

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Polishing the Tips

After multiple reuse and sterilization cycles, some oxidation may form on the tips of the forceps. This oxidation may be removed by polishing the tips with the green side of a SilverGlide Polishing Cloth before sterilization. See the *Accessories* section.

Preparation for Sterilization

WARNINGS:

- ALWAYS use a chemical indicator within every sterilization load to make sure the proper sterilization conditions of time, temperature, and saturated steam are achieved.
- Prior to sterilization, separate all detachable components.

CAUTION: ALWAYS make sure the equipment is clean and completely dry before sterilization.

1. Load the equipment into an appropriate sterilization tray. See the *Accessories* section.
2. Place a chemical indicator in a corner of the insert tray.

Packaging

WARNING: ALWAYS use new sterilization wrap to enclose the equipment. Do not reuse sterilization wrap.

1. Enclose the equipment using a sterilization wrap that is suitable for the equipment, such as a grade 500 or higher, before sterile processing.
2. Follow the AAMI and the Association of periOperative Registered Nurses (AORN) recommended guidelines for appropriate wrapping configurations.

NOTE: The packaging material will maintain the sterility of the equipment after exposure.

Stacking and Constraints

WARNINGS:

- DO NOT stack multiple sterilization cases during sterile processing. Stacking multiple cases may damage the sterile barrier provided by the sterilization wrap.
- ALWAYS stack non-sterile cases in a safe and secure manner.
- DO NOT stack wrapped or unwrapped cases during transport.

Sterilization

WARNINGS:

- Sterilize the equipment as indicated before first and every use.
- Use the sterilization methods as indicated in these instructions. Using other sterilization methods may prevent proper sterilization of the equipment and/or damage the equipment.
- DO NOT use Sterrad, irradiation, or ETO sterilizers.
- Follow the recommended dry times to prevent moisture from accumulating inside the equipment. Moisture may prevent proper sterilization and/or damage the equipment.
- After sterilization, allow the equipment to cool to room temperature prior to use. Failure to comply may result in a burn injury and/or damage to the equipment.

CAUTION: High sterilization temperatures and/or long sterilization exposure times may shorten the life of the equipment.

NOTES:

- Stryker has validated several sterilization cycles for the sterilization of this equipment. However, sterilizer design and performance can affect the efficacy of the process. Healthcare facilities should verify the process they use, employing the actual equipment and operators that routinely process the equipment.
- The final responsibility for verification of sterilization techniques lies directly with the hospital. To ensure the efficacy of hospital processing, all cycles and methods should be verified for different sterilization chambers, wrapping methods, and/or various loading configurations.
- If wet trays or equipment are discovered after sterilization, a change in the product load configuration or a longer dry time may be necessary.
- Validation is based on the AAMI protocol.
- International sterilization parameters are per the following standards:
  - Australia/New Zealand per AS/NZS 4187
  - Netherlands per Field Standard for Loaner Instruments, Revision 03.02, April 2008
  - Europe and the United Kingdom per EN ISO 17664
  - Canada per CSA ISO 17664

Steam Sterilization

Perform one of the following validated steam sterilization cycles:

Wrapping Method	Cycle	Sterilization Temperature	Minimum Exposure Time	Minimum Dry Time
Double Wrapped	Dynamic Air Removal (Pre-vacuum)	132 °C [270 °F]	4 minutes	30 minutes
		134 °C[1] [273 °F]	3 minutes[2]	30 minutes
	Gravity	132 °C [270 °F]	15 minutes	15-30 minutes
		121 °C [250 °F]	30 minutes	15-30 minutes

[1] Minimum exposure time may be extended to 18 minutes.
[2] Maximum sterilization temperature may be extended to 137 °C.

Immediate-Use Steam Sterilization

WARNINGS:

- DO NOT place equipment into an insert tray, sterilization case, or sterilization container for immediate-use steam sterilization.
- After cooling to room temperature, ALWAYS immediately use equipment sterilized by immediate-use steam sterilization. Sterility assurance cannot be maintained for unwrapped equipment.

CAUTION: Stryker does not recommend immediate-use steam sterilization for routine sterilization of medical devices. Immediate-use steam sterilization should only be used when individual devices require immediate sterilization and use.

Perform one of the following validated steam sterilization cycles:

Wrapping Method	Cycle	Sterilization Temperature	Minimum Exposure Time	Minimum Dry Time
Unwrapped	Dynamic Air Removal (Pre-vacuum)	132 °C [270 °F]	4 minutes	No dry time
		134 °C [273 °F]	3 minutes	No dry time
	Gravity	132 °C [270 °F]	10 minutes	No dry time

Storage and Handling

Sterile Equipment

WARNINGS:

- ALWAYS transport wrapped equipment with care to prevent damaging the sterile barrier.
- ALWAYS store wrapped, processed equipment in a controlled environment and avoid extremes in temperature and moisture. Storing the forceps in a humid environment for extended periods may cause corrosion or degradation of the device or packaging.
- Excessive handling of wrapped equipment will increase the likelihood of damaging the sterile barrier and may lead to contamination.

NOTE: See the instructions for use supplied with the sterilization wrap for maximum shelf-life information.

Non-sterile Equipment

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

Disposal/Recycle

WARNING: ALWAYS follow the current local recommendations and/or regulations governing environmental protection and the risks associated with recycling or disposing of the equipment at the end of its useful life.

To comply with European Community Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU, this device should be collected separately for recycling. Do not dispose of as unsorted municipal waste. Contact local distributor for disposal information. Ensure infected equipment is decontaminated prior to recycling.

Specifications

Environmental Conditions:	Operation	Storage and Transportation
Temperature Limitation:	10 °C – 40 °C	-20 °C – 40 °C
Humidity Limitation:	30 % – 75 %	10 % – 75 %
Atmospheric Pressure Limitation:	70 *kPa* – 106 *kPa*	50 *kPa* – 106 *kPa*

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

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